

Maine Peer Team Review Summary (October 29, 2007- November 2, 2007)

Submitted to: Paul Anderson, Director Maine Sea Grant

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Date submitted: November 29, 2007

This is a summary report of a peer review of part of the Maine Department of Marine Resources (DMR) Shellfish Sanitation Program, conducted between October and November of 2007 in response to a request from Maine state officials. A more thorough discussion of specific findings, conclusions and recommendations follows this summary.

The review was conducted by Joe Migliore, Rhode Island Shellfish Program; Lori Romick, formerly of the Connecticut Shellfish Program; and, Tom Herrington, retired Food and Drug Administration (FDA) shellfish specialist; under a Maine state contract. The team was contracted to consider; 1) whether the Maine DMR exceeded the minimum requirements of the National Shellfish Sanitation Program (NSSP), 2) if sampling protocols are appropriate, 3) if standard operating procedures are appropriate, and 4) whether facilities and the program are adequate and appropriate. The review consisted of meetings and interviews with industry and various state officials, field site visits, and a review of various state reports. Specific industry concerns were addressed. The Review Team conclusions and findings were in agreement with FDA's previous findings.

Substantial paper review was conducted the week before the team visit to Maine and during the week following the field visits. Initial meetings, first with industry, and then with Maine DMR personnel were held in DMR's Boothbay Harbor Lab on October 29, 2007, giving opportunity for both parties to convey information and concerns. Under the field visit itinerary, site reviews were made along Maine's coastline of the following shellfish growing areas: Haraseeket River, George River, and Machias Bay. The team further requested a brief field review of a relaying area within the Weskeag River and Timber Cove in Whiting Bay (Cobscook Bay) in Lubec. A final meeting was held with both industry and Maine DMR personnel on November 2, 2007.

Maine's shellfish program and industry offer many unique opportunities and challenges. It was concluded that:

- Several of industry's specific concerns regarding DMR's use of salinity, data information, and pollution source sampling were a matter of misunderstanding and much of that concern was ameliorated or mitigated with the meetings that were held.
- There was apparent mistrust and some hostility between industry and Maine DMR that can only be addressed through openness and honesty.
- Growing area classification boundaries are not all necessarily made in coordination with marine patrol authorities.
- Sampling protocols and standard operating procedures (SOPs) can be improved.
- Specific legislative actions may be required to protect Maine's shellfish resources from future impairment.

- Maine DMR does not exceed the minimum requirements of the NSSP requirements and additional sampling does not necessarily mean there will be any additional openings.

Final Peer Review Team recommendations:

1. Additional Staff is required in order for the Maine Shellfish Growing Area Program to be able to comply with the NSSP-Model Ordinance requirements. Additional staffing will allow for: timely assessment of data, additional sample collection and studies, and timely preparation of reports.
2. Biannual meetings should be held between industry and DMR representatives, the structure of which should be initial presentations followed by discussion. An independent moderator should also be considered. The meetings should also be staged to coincide with the biennial Interstate Shellfish Sanitation Conference (ISSC) to enable joint DMR/shellfish industry request for change to the NSSP Model Ordinance prior to the ISSC.
3. A Shellfish Advisory Council should be established to act as mediator for DMR and industry.
4. The Standard Operating Procedures (SOPs) should be finalized.
5. Sampling protocol should continue to be standardized and should address subsurface sampling when the sampler is at a minimum knee deep water depth, and the sample is collected up-current, and away from floating objects such as seaweed. Samplers should be further evaluated to ensure that sediments are not disturbed in the collection area.
6. Water samples should not be collected at periods of “no water,” in rivulets or stagnant pools.
7. Sampling should be scheduled using the Systematic Random Sampling (SRS) method but should be timed during the day with respect to tidal conditions that allow for sample collection at the minimum water depth of 18”.

**** The FDA has concerns with recommendation #7 as written without further clarification. The Authority may not schedule sample runs to target a particular tide unless they have determined scientifically through data analysis which tide concentrates fecal coliform in the growing areas. [Chapter IV@.02.F.1]**

The FDA has concerns with establishing a minimum depth for shoreside sampling which is an absolute. Minimum depths should be a range based on substrate found at the individual sample location. The precaution is not to stir the sediment while collecting a sample. There is no expectation of significant stirring at a station with a sandy or rock-like bottom. Therefore and sufficient minimum depth could be 12 inches without compromising the sample. Proper sample collection should be taught and certification provided. The minimum 18 inch water depth is unlikely to work in all areas of Maine’s growing areas due to tidal variation. Any water depth application should be based on individual growing areas and not made a state wide directive. **

8. Samples should be collected during various tidal conditions especially in areas where times of tidal impacts have not yet been adequately determined. Collection during both ebb and flood tides is acceptable.
9. DMR should continue to collect salinity data.
10. Pollution source sampling should continue.
11. DMR should utilize volunteer industry or shellfish warden boats where possible for growing area classification sampling.
12. A simplified version of the NSSP statistical information should be presented for the local community.
13. Additional sample stations should be added further out in bays and across growing areas that may be used to more specifically define classification lines such as in the Timber Cove area.
14. The boundary line separating the conditional from the approved classification in growing area ER may be moved, thereby opening an additional harvest beach without compromising public health. (Station 8.0 to Station 45.0). This should be further reviewed by DMR.
15. DMR should consider the viability of remote area classifications.

**** Remote area classification does not currently exist within the NSSP Model Ordinance. Remote area status does exist, however, the definition states: *a designation applied to a shellfish growing area that has no human habitation and is not impacted by any actual or potential pollution sources. The FDA is currently unaware of any coastline in Maine which meets this definition.* ****

16. A river gauge should be added below the confluence of the Kennebec and Androscoggin Rivers so DMR can more accurately assess impacts of river stage on those affected growing areas.

17. “No Discharge Zones” should be established in critical shellfish growing areas.

**** The FDA fully supports this concept. ****

18. Specific legislation should be enacted prohibiting overboard discharge into critical shellfish habitat.

**** The FDA fully supports this concept. ****

19. Dye dilution studies should continue to be conducted by trained parties but may be made a local requirement of WPCFs and NPDES permittees and at their expense.

**** The FDA fully supports this concept. Other shellfish producing states have made this a requirement. The DMR should also have routine access to a staff engineer to assist with developing, performing, reviewing and completing all aspects of hydrographic reviews. ****

We wish to thank all who made our visit possible and accompanied us, and the hospitality displayed by all parties throughout this evaluation.

Lori Romick, Joe Migliore, and Tom Herrington

Maine Peer Review Report of Findings

Date of Review Site Visit: October 29, 2007- November 2, 2007

Review Team Members:

Joe Migliore, State of Rhode Island Growing Area Specialist

Tom Herrington, Retired FDA Shellfish Specialist

Lori Romick, Retired State of CT Shellfish Specialist

Introduction: The Maine Shellfish Industry campaigned for assistance from the Maine State Legislature requesting a review of the State Shellfish Program as administered by the Maine Department of Marine Resources (DMR). Maine Sea Grant advertised for shellfish growing area experts and developed a review process and plan for program component evaluations. A contract was developed and awarded to the chosen contractors by DMR requesting a review of the following:

A. Specifications of Work to be Performed

Contract item 1. Review DMR Public Health Division operations to determine if Maine exceeds the United States Food and Drug Administration Northeast Region minimum requirements for its Shellfish Sanitation Program. This is primarily in the context of how other state programs in the region are complying with the NSSP. If the review determines that the State does exceed these requirements then it should make specific recommendations for any areas where it feels the State is unnecessarily impacting the shellfish industry.

- **Review Team findings:**

- The classification line in Growing Area ER may be able to be reevaluated and moved if coordination is agreed with the shellfish warden and additional acceptable sample results.
- There were no inefficient exceedences with staff and time in sampling, except for the collection of samples at low tide when timing for sampling may be expended without the ability to collect a sample due to insufficient water depth. Determining the dates for sampling as required when using Systematic Random Sampling (SRS) and subsequently identifying the time of sampling for those dates with regards to tides would be more effective instead of predetermining a timeframe with no regard to tidal stage.

**** Each growing area must be assessed prior to any sampling which would target a particular tide. An extensive review of every growing area is needed to ensure that sample stations are located in most appropriate place to find any pollution. Sample stations shall be located in sufficient number to adequately and effectively evaluate all pollution sources. [Chapter IV@.02.B] ****

- The addition of offshore stations as sentinel samples with collection at various tidal stages is recommended in order to adequately monitor the entire growing area.

- Boat sampling would be more efficient in some cases, if boats were made available by towns (when available) or assistance by governmental or agency professionals for sampling.
- The State needs to supply necessary/additional staffing and equipment to improve efficiency and effectiveness. This would allow for refining of the growing area classification. One example as observed during the field trips would be in Timber Cove. Additional sampling could possibly allow for a more timely management of the openings of that area. Additional staffing of the laboratories, especially the Lamoine Lab, would ease the burden with regards to collection times and possibly expand the number of days during the week for sample analyses. Currently there is only one full-time laboratory Staff member assisted by three full-time growing area specialists, who primarily conduct field work and assist with lab sample preparation, and one part-time seasonal summer hire.

Contract item 2. Review DMR Public Health Division Standard Operating Procedure (SOP) for Water Quality Sampling and specifically review all protocols related to following and make specific recommendations for any changes it feels are needed in either the SOP or to sampling site locations, including:

- review sampling stations locations as related to harvest/growing areas, fresh water inputs, access points and tide-related issues
 - **Review Team findings:** A lack of additional stations offshore and across the growing areas may impact future FDA Program Element Evaluation Report (PEER) negatively. Additional stations may also allow for reclassifications.
- review appropriate depths for water sample collection
 - **Review Team findings:** The current Standard Operating Procedure (SOP) revision requires samplers to carefully wade out to knee deep water and collect the water sample by plunging the Whirl-Pak bag 8”-10” below the surface, opening it and drawing in water up current. The review team observed samples being collected in the western area after the collector had physically moved seaweeds and at another station after significantly disturbing sediments. The current SOP requirements for sample collection are considered to be adequate by the review team, however more quality control and standardized training is needed. The collection of samples should be done as uniformly as possible as this is a procedure that may produce great variability in the data.
- review whether (and how) salinity should be a factor in determining the utility of a water sample for growing area classification
 - **Review Team findings:** Salinity is not used to determine classifications but may be utilized as additional data and may be used to assess and track potential pollution transport into a growing area. DMR data indicates no significant differences in fecal results on either side of the tide. This information is very important with regards to environmental conditions for Vibrio species and should continue to be collected.

- review timing of sample in relationship to tidal stages
 - **Review Team findings:** The DMR should continue to add data in order to predetermine if and which tidal stages affect the growing area(s). The DMR uses Systematic Random Sampling (SRS) and currently predetermines dates and times of sampling for staff without considering the tidal stages during those times. It would be a more efficient use of time to determine sampling times for the SRS dates after reviewing the tidal conditions. The review team observed collectors having to go back to stations a second time during the day in order for there to be sufficient water depth to collect the samples. This is more time consuming than a predetermined time for samples when it is known that sufficient water will be available.

**** FDA concurs that additional tidal data is needed prior to altering any systematic random sampling schedule to account for tide. ****

- review mode of sampling (land-based vs. boat)
 - **Review Team findings:** It would be more efficient to utilize boats when available and in partnership with the industry and/or local enforcement agencies. The development of partnerships between local municipalities and/or industry representatives for boat transportation to collect samples has the additional value of community outreach and involvement. Land-based sampling is extremely time-consuming due to the overall logistics of driving the coastline, the distance a sampler has to walk out to collect a sample, and the general terrain. The weather is the main restricting force for boat sampling. The review team suggests that the DMR maintain land stations and add stations away from shore, striving to collect all, yet realizing that each type of sampling has its own set of constraints.
 - **Note:** Additional samples will burden the existing laboratory staff. The review team understands that the current laboratories capacity is adequate at this time for additional sampling but not the current level of staffing.

- review appropriate time frame for utilizing historical water sampling data and potential for expediting review and possibly the reclassification of existing areas.

- **Review Team findings:** The review of the DMR reports and the FDA PEER is consistent with other states operation and a function of staffing limitations. Reclassifications are currently being done with the Triennial Reevaluations. Again, additional staffing may provide for real-time review and expedited reclassifications.

**** FDA concurs with the audit that additional staff is needed to complete shoreline surveys, required reports, various sampling projects and pollution abatement in a more timely fashion. ****

- review the role of hydrographic studies in determination of sampling locations and in growing area classification.

- **Review Team findings:** The review team has read the presented materials with regards to dye-dilution studies and has taken all concerns into consideration. The studies have

been thoroughly reviewed by past FDA shellfish personnel and it has been determined that sampling locations are adequately located, except for the addition of some stations in the middle of the growing areas, overlying shellfish waters.

Contract item 3. Review of the DMR Public Health Division should consider standard operating procedures from other states in the region to determine if there are other approaches that nearby states are using that would be appropriate for use in Maine and whether Maine's industry has been placed at a competitive disadvantage by any of the current procedures.

- **Review Team findings:** The two state reviewers feel that the Maine program is very similar to the procedures and management that is currently conducted in other nearby New England states. Again, the FDA PEERs have not identified any major significant procedural inconsistencies with regards to the National Shellfish Sanitation Program – Model Ordinance (NSSP-MO) and progress of the program areas has been made since the 2000 reports.

**** The FDA concurs with the findings of the Audit as we also are unaware of any potential competitive disadvantage that can be attributed to the manner in which DMR administers the state's shellfish safety program requirements. ****

Contract item 4. Review DMR Public Health Division operations to determine whether the facilities and the program are both staffed and equipped adequately and appropriately to address the current and future needs of the shellfish industry and the general public. The reviewers will evaluate laboratory and field personnel workloads, laboratory space and capacity, and the role of non-DMR personnel (volunteers) in the program. If the review determines that deficiencies exist then it should make specific recommendations for any changes it feels are needed.

- **Review Team findings:**
 - The DMR is understaffed with regards to the growing area portion of the program. Additional staff is needed in order to conduct surveys and collect water samples in accordance with the frequencies specified by the NSSP-MO.

**** The FDA concurs with the finding that the Growing Area portion of the Maine Shellfish Sanitation Program is understaffed. ****

- The review team commends the DMR for the work that is being accomplished and the difficulties due to the uniqueness of your coastline and environment is appreciated. Additional water sampling will impose additional burden to the already overworked and understaffed laboratories. It was stated to the team that the current laboratory space and equipment was sufficient.
- Due to the lack of DMR boats, sample collection using the assistance of municipal employees or industry to provide boat transportation would also promote stewardship and improve communication and trust between the DMR and industry. The review team does not recommend the use of industry for the actual collection of the water samples due to conflict of interest. The industry can volunteer transportation to the growing areas for the sample collectors.

- The use of municipal or local enforcement volunteers may provide the additional staffing needed, but this also requires a great deal of communication, quality control and program coordination.

Contract item 5. Review of the DMR Public Health Division will likely involve at least 5 days in Maine with some time dedicated to visiting at least 3 shellfish growing areas. These areas will be selected by the DMR staff and industry to represent a variety of water bodies that will provide the reviewers the opportunity to see the situation from the field. The balance of time will be spent on file review in the two DMR laboratories in Boothbay Harbor and Lamoine, and also in interviews with Industry and DMR staff.

- **Review Team findings:** Monday, October 29, 2007 through Friday, November 2, 2007 were scheduled for the team visit, with Monday and Friday scheduled as meetings days before and after the three scheduled field days during the middle of the week.

B. Review Process:

A large volume of related materials including growing area reports, water quality data, maps, FDA evaluations, and a historical summary of program information were sent to the review team two weeks before the planned visit. A total of five days were scheduled for the review team to allow for meetings with all parties and for specific coastal site visits as related to the issues of concern. Days one and five were meeting days scheduled to allow for the exchange of information and question and answer sessions. The review team was in the field for three days in between, and escorted by representatives from the industry, DMR and the state legislature. Additional industry, enforcement and DMR representatives met the team at various locations to expand upon information, address specific growing area concerns, and point out site specific efforts. The team observed commercial shellfishing activities, gathered information on the growing areas, pollution sources, and sampling locations. DMR representatives collected water samples and discussed pollution sources and surveys. Industry representatives relayed information of resource utilization and classification concerns. Local enforcement officials provided specific information with regards to activities of the areas and the local residents.

Discussions, questions and observations were recorded during the entire review. Additional informational material that was presented was reviewed by the team at the end of each day. The review team applied findings to the NSSP-MO requirements as well as discussed differences and similarities between the State of Maine Shellfish Program and other states. The team assessed the importance of observations and reported information and determined the need for change, if any.

C. Review Team Site Visit Summary:

Industry Concerns

What follows is a list of the areas that Industry would like the reviewers to evaluate and comment on. Suggestions should be made primarily in the context of how other state programs in the region are complying with the NSSP:

1. Location of growing area classification (GAC) stations as related to harvest/growing areas, fresh water inputs, access points and tide-related issues.

- **Review Team findings:** The review team suggests that the DMR continue to finalize the SOPs implementing sample collection at a minimum water depth of “knee-deep,” or approximately 18” with the sample collected 8”-10” below the surface. Sampling routine growing area stations from stagnant or minimal water is not recommended as it creates unacceptable variability in the dataset and is not representative of the overlying waters with regards to the shellfish. The DMR SOP clearly states that water samples should not be collected from streams crossing a mud flat or from stagnant pools of water. Pollution source sampling may and should continue to be collected during low tide stages. The NSSP-MO requires sampling during tidal stages that, through data assessment, have shown to negatively impact the area(s).

**** The FDA believes that a prescribed minimum depth of 18 inches will not offer the flexibility that the DMR will need to collect samples throughout the vast coastline of Maine. Samples should be collected when the water accurately represents the water impacting the shellfish. ****

2. Distinction between GAC stations vs. pollution monitoring stations.

- **Review Team findings:** The pollution source samples may be collected during the routine sampling runs for the growing areas as a means of being more efficient as logistically returning to the same areas a day or two later for just the pollution source samples would waste a great deal of time. The data however is stored in separate databases. Collection of pollution source samples is required but a statistical review of a representative number of pollution source samples may allow for the deactivation of such stations and allow for better time management.

3. Random Sampling method versus Adverse Sampling method for different types of areas.

- **Review Team findings:** A validation of data indicating acceptable fecal levels is required to determine predictability with regards to automatic reopenings. First the trigger for closure must be identified. Then the recovery period has to be defined. This is done by storm tracking and intensive sampling. A large database of sample results collected continuously daily after non-point pollution events would be utilized to verify the time for growing waters to return to acceptable levels of fecal coliforms. Once the recovery period is defined and is consistent and predictable, a management plan can be written. Such verification studies are extremely time-consuming and labor intensive. The NSSP-MO requires that the areas must meet the “Approved” area classification criteria when open and defines the requirements for the operation of “Conditionally Approved” growing areas.

**** The FDA wishes to point out that any automatic reopening must consider shellstock meat quality in accordance with MO Chapter IV@.03.C.2.c.iii. The study must determine the amount of time needed before a conditional area is reopened. This requires knowledge of how the shellstock in the area is affected and how quickly the shellstock return to pre-closure bacteriological levels. ****

4. Rainfall conditional areas: their role in ME's Growing Area Classification Program; Guidelines on how to manage them.

- **Review Team findings:** A shellfish resource study should be performed in areas that sampling results and shoreline survey reports indicate there is a good chance of being managed as a conditionally approved area. If the resource appears to be productive and abundant it should be prioritized as a candidate for conditionally approved management. If and when the DMR obtains additional resources they may be able to include this in their work plan.

**** The FDA concurs that additional conditionally managed growing areas should not be created without additional resources provided to the DMR so they may properly monitor the conditions which adversely affect the growing area. ****

5. Standard Operating Procedure (SOP) for Water Quality Sampling: Depth for water sample collection, and distance from GAC station at which samples may be collected.

- **Review Team findings:** Most other states rely on boats sampling for the vast majority of their growing area stations. The review team also notes that Maine has a very extreme environment as compared to most other states making the utilization of boats possible. Most states follow the EPA guidance for the collection of bathing beach waters having a minimum of 36” of water depth and plunging the collection bottle rapidly below the surface to an approximate depth of 12”-18”. The Review team suggests that the DMR continue to finalize the SOPs implementing sample collection at a minimum water depth of “knee-deep,” or approximately 18” with the sample collected 8”-10” below the surface.

**** The FDA believes that the current Maine DMR SOP provides accurate direction as to under what conditions a sample should be collected along the coastline of Maine. ****

- **Review Team findings:** Evaluating a distance of 300’ may be difficult. Noting that the sample may have been collected away from the GPS location on the collection form is important. If the stations are significantly greater than 300’ from each other then 300’ feet of “leeway” would be acceptable.

**** The FDA believes that the 300’ leeway is not acceptable under all circumstances and that collecting a sample away from its original location is problematic. Sample stations collected on a routine basis should be located in areas where there is accessible water at most times. Depending on the water body itself and in what part of the coast of Maine you are located, 300’ could significantly change the water quality results for better or worse. ****

6. Role of salinity to determine the utility of a sample for GAC.

- **Review Team findings:** The Review team was repeatedly told by the DMR that salinities are not used to determine growing area classifications. No collected data should be discarded. Salinity data collected at pollution source sampling location is kept in a separate database from the growing area data. Salinity data is a valuable tool and the usefulness was thoroughly discussed during the final meeting day of 11/02/07.

7. Access to GAC stations: Land vs. boat, AND

8. Use of municipal resources and volunteers: Role of DMR-trained personnel, municipal boats and vehicles etc.

For items 7 and 8:

- **Review Team findings:**
 - Most other states rely on boat sampling for the vast majority of their growing area stations. The review team notes that Maine has a very extreme environment, as compared to most other states, making the full year-round utilization of boats impossible.
 - Due to the lack of DMR boats, sample collection using the assistance of municipal employees or industry to provide boat transportation would also promote stewardship and improve communication and trust between the DMR and industry. The review team does not recommend the use of industry for the actual collection of the water samples as the interest may be conflicting. The industry can volunteer transportation to the growing areas for the sample collectors.
 - The use of municipal or local enforcement volunteers may provide the additional staffing needed, but this also requires a great deal of communication, quality control and program coordination. The use or expansion of a volunteer program does have its own inherent concerns with regards to quality control and dependability.

9. Threshold for initiating a state-wide flood closure.

- **Review Team findings:** It is up to the DMR to determine, via extensive post-rainfall sampling, the conditions that areas become impacted under and subsequently “clean-up” to acceptable levels of fecal coliforms. Most states do initiate state-wide closure at between 2.0”-3.0” and the areas remain closed for a minimum of two weeks. The DMR SOP initiates flood sampling on or after day three. DMR also conducts subset sampling to determine lingering impacts prior to reopening.

**** The FDA has informed the DMR in the past that sampling flood closures immediately after a rain event is an ineffective use of existing resources. Furthermore the FDA has disagreed with the DMR decision to suspend required sampling in order to collect sporadic flood sampling to open growing areas impacted by floods. The suspending of sampling runs during flood sampling has led to a gap in the data at rainfall amounts greater than 2 inches. This gap in the data will keep the rainfall closure threshold where it is as the DMR does not have the data to fully assess the rainfall impact on the growing areas.****

10. Method for establishing boundary lines between open and closed areas.

- **Review Team findings:** Logistically, the distances between samples are a direct condition of the expansive linear miles of coastline. In order for the reclassification and

upgrading of areas, there must be representative sampling station locations to create a classification delineation line. The current level of DMR staff is insufficient to accomplish additional sampling or area reclassifications.

**** The FDA concurs that the DMR are insufficiently staffed to perform any additional sampling which would fine tune any existing closure lines. It is critical to note that sample station placement is more a function of pollution source location than linear miles of coastline. ****

11. Accelerated sampling for expediting review and possibly the reclassification of existing growing areas. Role of independent laboratories in ME's Program.

- **Review Team findings:** State programs that have regulatory duties are often cautious to allow for analyses to be conducted outside of their control. Strict regulatory criteria and minimal variability directly affect the areas available for market harvest. The DMR laboratory staff expressed concerns with regards to a loss of quality control if the utilization of commercial laboratories is allowed. Additional laboratories will also cause an increased workload on the Laboratory Evaluation Officer (LEO) as conducting additional quality control verifications and inspections at each approved laboratory. A more reasonable request may be for additional DMR laboratory staff.

12. Real-time closing and opening of growing areas based on P90 calculations.

- **Review Team findings:**
 - This issue was not addressed in the most recent FDA PEER. The DMR has stated that it normally reclassifies areas based on the Triennial Evaluations. This concern is a legitimate one as areas that may be impacted by fecal coliforms need to be closed. However, it is "normal" for states to reclassify during annual data assessments as one elevated result may not be just cause for the reclassification of an area. Elevated results must be addressed and both temporary closures and/or additional sample collection may be useful in identifying the predictability of the impacts.
 - Additional DMR staff would be extremely useful in this area as statistically sound assessments may be able to be conducted routinely in a more time-critical manner.

**** The FDA has noted during annual evaluations that the DMR reclassify shellfish growing areas on an annual basis. The FDA has noted that when time permits the water quality staff will alert a town when elevated scores are noted. This provides the town with some time to review the affected area and look for possible pollution sources.**

The Shellfish program is based on water quality trends. The water quality program is based on the presence of persistent elevated bacteria found when reviewing the past 30 pieces of sampling data. The bacterial concerns are different than that of the biotoxin program. The biotoxin program is designed to work in a real-time fashion. The water quality program looking for bacteria does not work in real-time using P90 calculations. The P90 scores are used to facilitate the trend review.

The NSSP-MO places the utmost importance on proper classification. The shoreline survey is the most critical step in completing a proper classification of any shellfish growing area. Pollution source identification and abatement is the cornerstone of this program. The water sampling portion (routine sampling sites) of the program is simply the monitoring aspect which verifies the classification and fine-tunes the closure lines where necessary. These monitoring sites only need to be sampled six (6) times per year. **

13. Hydrographic studies: their role in determination of sampling locations and in growing area classification.

- **Review Team findings:** The review team has read the presented materials with regards to dye-dilution studies and has taken all concerns into consideration. The studies have been thoroughly reviewed by past FDA shellfish personnel and it has been determined that sampling locations are adequately located, except for the addition of some sampling stations in the middle of the growing areas, overlying shellfish waters. The studies were conducted by trained recognized agencies even though there may have been differences in the methods or presentation. Utilizing local or state study requirements by outside contractors may be useful in the future especially with the permitting of wastewater treatment facilities, their renovations, and or pre-treated industrial discharges. The financial burden is then placed on the facility discharging instead of the state or municipality.

14. Cross-check method(s) for ensuring that only samples collected under the Random protocol get used for growing area P90 calculations.

- **Review Team findings:** The DMR has addressed this issue through its' SOPs and there have been evident improvements in the way that data is entered, checked, queried and analyzed. The review team advises DMR to continue with their quality control (Q/C) checks and improvements with their databases. Also note that additional Q/C of data involved additional staff time.

Industry Advisory Panel/ Review Team Meeting October 29, 2007, Boothbay, 9:30 am

Summary of Industry Meeting Discussions:

The industry was assisted by State Representative David Webster. Representatives from the industry included commercial diggers, clambers, aquaculturists, shellfish commissions, the Maine Seafood Alliance, Maine Clam Association and local law enforcement officers. Valy Steverlynck, a shellfish grower from the Town of Freeport was the organizer and a spokesperson. (See attached list of participants.)

The meeting began with a review of the Interstate Shellfish Sanitation Conference (ISSC) and the National Shellfish Sanitation Program (NSSP) as voiced by Team Specialist Tom Herrington.

The discussion progressed to a review of the shellfish industry including types of shellfish (species) and harvesting methods and gear types. Much of the shoreline is hand dug by

commercial diggers for soft-shelled clams during periods of low tide when the extensive flats are exposed. The soft-shell clam resource is extremely important to the industry across the coastal towns. The mahogany clam fishery is primarily located offshore in deeper waters and is primarily affected by phytoplankton blooms that may cause paralytic shellfish poisoning. *Mercenaria* (hard clam) and surf clams (*Spisula*) are harvested to a lesser degree both intertidally. Mussels are often cultured, hand picked, and harvested by dredges dragged over the bottom. Oysters are extensively cultured with almost no natural setting. Maine also has a limited scallop and razor clam fishery.

Discussion continued regarding the growing areas and classifications. The industry indicated that the Maine DMR was working on a Standard Operating Procedures Manual (SOP) and that much progress has already started but that the industry wished for this to continue until completed. There had been recent area closures and the industry feels that Maine's sampling restrictions are tougher than those in other states.

The industry was concerned about the techniques used to collect samples and the standardization between different collectors. There were concerns raised with regards to samples being collected during low tide which along most of the shoreline meant no water. The DMR collects samples using Systematic Random Sampling (SRS) methodology instead of Adverse Pollution Collection (APC).

The industry was concerned with regards to the samples being collected with no water present. Such samples would not be representative of condition shellfish are being exposed. Some growing areas only have water for six (6) hours, two times per day. Tides can change substantially from 12 feet to up 30 feet along the coast. The industry also raised concerns about testing in streams and not necessarily over the shellfish growing area. There were concerns raised of past samples that were collected on foot from land of water in stagnant depressions.

The NSSP MO requires that sampling be collected during conditions that may negatively impact the growing areas, or the waters that the shellfish are subject to. A lengthy discussion took place regarding the location of stations vs. changes in pollution sources since the original station location. Questions regarding the distance between stations and the classification lines were debated. The industry wanted to know how the DMR determined the pollution sources and the classifications. Questions regarding pollution sampling vs. routine growing area sampling were raised.

The industry stated that there are only three growing areas that area classified as "Conditionally Approved" and closed based on specified rainfall amounts. The Industry wanted more "Conditionally Approved" areas. The flood closure conditions including the statewide 3.0" closure trigger were also discussed.

The industry felt that more labs are needed to analyze the samples. Questions regarding the collections of samples during ice conditions were also addressed.

The timing of reclassifications was a concern as the industry felt that too much time passes before reclassifications are made.

Overall the industry expressed a genuine desire and need to improve communication and build trust with DMR.

A letter was presented regarding competency and uniformity concerns with hydrographic studies and their significance. The response was that FDA is fully qualified and considered as experts. Each of the review team members have worked with the FDA groups, support them and consider them fully competent in these studies and their formal training.

Question regarding the need for diggers to have a dealers permit and to have a refrigerated vehicle or whether they can sell shellfish at their home was discussed, if they do not have a reefer truck they cannot sell to retail directly.

Summary of Discussions: DMR Meeting, October 29, 2007

Maine DMR representatives:

Amy Fitzpatrick, DMR Public Health Director
Mercuria Cumbo, DMR Water Quality Laboratory
Jan Barter, DMR Boothbay Lab
Robert Goodwin, DMR Lamoine Lab

Industry Representatives:

Valy Steverlynck
Dan Devereaux

Note: DMR was not present during the industry meeting earlier that morning but industry was present during the DMR meeting.

Amy Fitzpatrick presented a PowerPoint slide show. In summary, there are more than 5,300 miles of coastline with 800-1,200 miles assigned per growing area staff person, totaling six. These people also help with the lab. There are 14 seasonal program people and 86 volunteers covering 33,000 sq miles of growing areas, including more than 60,000 acres of mud flats. There are two labs that analyze samples from 1,463 stations a minimum of five (5) runs per week with 20-25 samples per run three days a week annually. The Laboratory also analyzes dealer well water samples. The work load for the PSP program is great. Volunteers will have to sign an agreement regarding sampling protocols as part of the revised SOP and attend an annual standardized retraining.

DMR uses SRS and has three (3) rainfall “Conditionally Approved” areas. The DMR has not adequately determined all tidal impacts to the sampling stations yet. Closure is initiated in areas after more than 2.0” of rain and statewide closures are enacted after ≥ 3.0 ” of rain. Subsets of runs are sampled after heavy rain conditions to assess lingering impacts prior to reopening. The DMR has both routine growing area classification sampling stations and pollution source monitoring stations. River stage was also addressed. The cost of press releases was discussed.

The vast majority of samples are collected by land due to several factors; pollution sources are from the land, the subtidal areas are extensive, the drop in tide is extreme and can leave vessels stranded, times of sample with sufficient water depth is short, and travel time by boat or with a trailer is restricted due to distances and weather (ice, waves, wind, fog). Sampling by boat requires two people while only one is required by car. All stations have global positioning system (GPS) coordinates.

Pollution source samples, such as pipes or ditches, in growing areas not open are not used for growing area classification. The DMR collects both routine samples that are used to classify

growing areas and pollution source monitoring stations at the same time as a means of efficiently monitoring both. Pollution source monitoring is an important tool in determining the level of bacterial contamination entering a growing area and the predictability. A chronically, extremely elevated station (pipe, culvert, ditch) is one that must be studied further and abated. A source that occasionally is flowing with elevated bacterial levels will not impact the shellfish growing areas constantly.

Sampling procedures (SOPs) have been redefined to allow for land sample to be collected with water depths of 18” and a plunge depth of 8”-10”.

DMR has reclassified areas with downgrades from 2003-2007. The majority of upgraded classifications were from “Prohibited” to “Restricted-Relay.”

Salinity data is collected but DMR does not use salinity for any area classifications. The salinity data is used to determine if there is a freshwater pollution source for traceback and follow-up action and for use with temperature data to monitor environmental conditions with regards to *Vibrio* species.

Field Site Visit: October 30, 2007 Harraseeket River Area (Shellfish Growing Area J)

Macquoit Bay, Whistler’s Cove (low) and Sandy Beach were visited and included pollution source sampling and growing area classification station discussions. The review team was accompanied by DMR (Amy Fitzpatrick and Laura Livingston), Dan Devereaux for the industry, Tom Kay a local enforcement officer and Legislator David Webster.

The team discussed land sampling, station locations and sampling techniques. The team observed samples being collected with little or no water after moving seaweeds and after disturbance of sediments. Samples were attempted to be collected at preset times irregardless of tides. The team felt that this was a waste of time especially when attempts are later made to collect the sample again at a later tide.

**** Many sample stations within a growing area are located at different elevations with respect to the tide. Some sample stations are located next to known pollution sources at the head of bays and coves. These stations only have water at the higher of tides. If the sampling run is completed based on all stations having water then all stations are collected at a higher tide which is in direct violation of the NSSP-MO unless the Authority (DMR) has determined that the higher tide presents the worst (most adverse) condition affecting the growing area.**

The FDA welcomes any specific guidance the audit review team will provide on how to address the concern of “wasting time” when sampling versus the requirement of sampling each station on all tidal stages unless determined through data analysis. **

The team observed maps with no closure lines for areas with undetermined water quality. It was noted that the river gauging station on the Kennebec River was not located at the confluence of the Kennebec and the Androscoggin Rivers and should be moved or an additional river stage monitoring station should be installed.

**** The FDA noted in a 2000 report that the Kennebec River is affected by river flow. We would not concur with moving an existing river gauging station but would agree that a second gauging station would most likely provide additional needed data. ****

**Field Site Visit: October 31, 2007
Saint George's River Area (Shellfish Growing Areas U and V)**

Participants: DMR (Amy Fitzpatrick and Fran Pierce), Dan Devereaux for industry, Neil Pollis representing local enforcement and Butch Taylor from the Saint Georges River Shellfish Committee.

The team reviewed land sampling in Prohibited, Conditionally Restricted, Restricted-Relay, and Conditionally Approved growing areas. The conditions and survey for the identification of pollution sources was discussed. The need for straight visible delineation lines for area classifications is important to law enforcement.

On 10/31/07, after the field work, a late afternoon meeting between the review team, DMR and industry representative Dan Devereaux took place at the Holiday Inn.

The concern regarding the use of salinity data had been discussed each day with several representatives and was clearly a point of contention. Mercuria Cumbo prepared and presented salinity data analyses. Results showed no significant difference of fecal levels between the different stages of tide. A general trend showed lower fecal levels at higher salinities. Since 2000, an effort has been made to collect samples under all tidal conditions. During dry weather conditions, fecal levels were higher in samples collected with lower salinities. Fecal levels were elevated significantly after rain and with lower salinities indicative of non-point pollution (runoff).

This meeting was scheduled on the agenda indicating "DMR" and industry to be present. Dan did voice objection, stating that Mercuria was not actually listed to speak. Dan was present for the entire meeting and suggested that Mercuria present the same information at the industry meeting scheduled for the last day of the visit.

**Eastern Maine Field Site Visit: November 1, 2007
Machias Bay, Buck's Harbor, and Timber Cove.**

Participants included: DMR (Amy Fitzpatrick and Rob Goodwin), and industry represented by Dan Devereaux, Ginny Olsen, Jeremy Wood (Machiasport Shellfish Commission), and Julie Keene from the Lubeic area.

Impacts from farm animals were observed. All samples were collected from land with no offshore sample locations designated.

One area was classified as "Conditionally Approved" based on Wastewater Pollution Control Facility (WPCF) performance, and combined sewer outflow (CSO) and pump station bypassing. The areas along the rivers had registered overboard discharges (OBDs) constituting a point source. These systems collect sewage waste from several area homes and are not inspected or evaluated for performance. Maine currently does not have a "No Discharge Zone."

This entire area is extremely important to independent diggers for soft-shelled clams. It was noted that the report for this area did not reflect the current classifications even though it was finalized after a reclassification of the area. An updated summary reclassification report and justifying data is needed.

The amount of current staff to adequately monitor this area is clearly insufficient.

A discussion regarding a classification delineation that may be moved between the Conditionally Approved and Approved area at a point from Station 8.0 to Station 45.0 to open the clam flat that is currently closed.

Additional stations offshore should be added to this area as there is resource that is harvested.

Misunderstandings were resolved regarding the interpretation by the industry of the statistics, specifically the 90th percentile (P90). DMR needs to develop a clearer explanation so that the industry can understand. A simplified version of the statistics may be helpful.

The team met with Julie Keene and her sister (soft-shell clammers) to review a Timber Cove site in Lubeic. There were concerns over a stream flowing from two ponds above surrounded by homes. The industry concern was for unnecessary closures due to lack of information. The DMR staff assigned to this area has been addressing this concern and conducting follow-up work with regards to shoreline survey working the entire area.

Summary of Discussions - Final Meeting Day with Industry and DMR: November 2, 2007

Mercuria Cumbo (Laboratory Supervisor) presented the salinity information. Sample data was statistically analyzed for trends in salinity and tides from 188 coastal stations located within 300 feet of a freshwater source and collected using Systematic Random Sampling. The fewest number of samples were collected at low tide representative of the lack of available water. Results showed no significant difference of fecal levels between the different stages of tide. General trend showed lower fecal levels at higher salinities. Since 2000, an effort has been made to collect samples under all tidal conditions. During dry weather conditions fecals levels were higher in samples collected with lower salinities. Fecal levels were elevated significantly after rain and with lower salinities indicative of non-point pollution (runoff).

It was made clear that salinity is an important tool for addressing impacts from freshwater sources with regards to follow-up remediation actions. Salinity is also an important data set with regards to monitoring environmental conditions with regards to *Vibrio* bacteria. This issue was answered satisfactorily to the industry and put to rest as a concern. The Maine DMR does not use salinity to classify growing areas. The DMR collects routine growing area classification stations as well as pollution source monitoring stations sometimes at the same time but maintains two separate databases for the sample results.

A review of the laboratories capabilities with regards to space and equipment currently allows for less than 350 samples per day for no more than three days a week between the two labs. They currently run up to 12,000 samples a year could be increased to 15,000 samples a year with a sampling coordinator.

The importance of sampling properly by opening the bag under water at depth and collecting the sample at the correct locations was thoroughly discussed. The current SOP requires walking out to knee-deep water and collected the sample at a depth of 8"-10" of depth. Although the SOP is not finished it is moving slowly toward completion. Annual retraining is being conducted as a means of standardizing sample collectors and volunteers will have to sign an agreement.

Emphasis was placed on the economic importance of the shellfish industry in eastern Maine and the industry's request for the DMR to continue to consider the hardship incurred with closures.

There is a need for industry involvement with local committees and commissions to plan for future area development and impacts. The need for a Shellfish Advisory Council was also addressed. Annual forums were suggested as a means of continuing communication with presentations and dialogue that is developed in an understandable way. The value of statistics, including the P90 (90th percentile) calculations was reviewed. Industry, DMR and FDA are a team that needs to utilize each others capabilities and experience.

It was suggested that DMR consider the possibility of remote area classifications.

Conclusions:

The NSSP through the ISSC is meant to be a cooperative program. All parties must be actively involved, familiar with the program and willing to learn from their involvement to achieve success. The ISSC is an avenue to propose change. Each entity has a primary charge that defines the areas of their concern. The DMR has the primary charge of protecting public health through regulation by remaining in compliance with the NSSP-MO. The industry has a responsibility to work with the DMR in assuring that a safe wholesome product is harvested and offered to the consumer while working to enhance and maintain production of the economic resource. The FDA provides reviews, oversight, interpretations and training.

The shellfish industry is not alone in being regulated. All food production in the United States is regulated to some degree. Shellfish are eaten raw, whole and alive and thus are a potentially hazardous food with a greater risk of illness than many other protein food items.

Maine is unique in the Northeast region as it has by far the most extensive coastline with more than 5,300 miles and more than 60,000 acres of mud flats. The staffing is evidently insufficient to adequately adhere to the requirements or to be able to take on any additional special studies. The location logistics are extreme in the amount of driving time to and from, and the time to walk out to the site to collect a sample. Sampling stations are located along the shore but not across the growing areas. DMR's concern for staff safety is legitimate.

**** The FDA concurs with the assessment that the staffing level is insufficient to adequately adhere to the requirements. ****

Daily weather and seasonal weather constraints reduce the numbers of days for sampling. Tidal extremes further reduce the sampling ability with some tides changing more than 30 feet. Daylight hours are reduced during much of the year. Although SRS is primarily used the DMR should evaluate for areas where SRS is not the best means of monitoring specific areas effectively.

During the discussions with both industry and DMR it was stated that improvements have been made. Volunteers are retrained and evaluated annually and SOPs are being drafted that will include signed agreements by the sampling volunteers agreeing to follow all sampling protocols and sample at the determined locations. Sampling has become more consistent. Sample locations are designated using a global positioning system (GPS).

Lab staffing to process the samples from the 1,463 stations was summarized. The staff receives no compensatory time but do have flexible work schedules.

A loss of trained qualified staff is a concern of the industry. The replacement of staff and refilling of positions must be given top priority by DMR. Additional staff would be required in order to adequately monitor areas and collect additional samples. Summer hires or interns could be encouraged to return with scholarships.

**** The FDA concurs that any new staff members must be properly educated in the relevant sciences to ensure quality work is produced for and by the DMR shellfish program. ****

The DMR closes shellfish growing areas after $\geq 2.0''-3.0''$ of rainfall, for a minimum of 14 days, with subset sampling runs to determine when full runs of samples should be collected to reopen. Some areas are resampled repeatedly. The DMR does not have enough staff to conduct sampling studies to determine automatic reopenings.

The overboard discharges (OBDs) in general, are not reliable and must be monitored. They must be considered as a potentially serious public health concern.

The industry indicated that cleaner water is a priority for them. In Connecticut the Nonpoint Education for Municipal Officials (NEMO) program and CT Sea Grant have both been instrumental in educating the local governments on the shellfishing issues.

**** The FDA concurs that the Maine Sea Grant should play a more involved role in educating the shellfish industry and the general public about shellfish issues, hazards and the national and state requirements. ****

The review team has reviewed and agrees with both the 2006 and 2007 Program Element Evaluation Report (PEER) completed by FDA Shellfish Specialist Peter Koufopoulos. The DMR continues to be understaffed and thus found unable to be in compliance with the requirements of the NSSP-MO.

The "Chronology of events" has indicated several improvements. A number of closures were made during the Fall of 2006. There was a lack of effective communication between the DMR and the industry. Several key questions were raised by the industry and as a result, DMR began to develop Standard Operating Procedures (SOPs). The SOPs include; adjustments to the minimum depth of sampling, improved communication, the utilization of local enforcement agencies for sampling assistance, the use of boat sampling when possible, and a reevaluation of the sampling station location and area classifications.

A lack of effective communication is a main reason for the lack of confidence by the industry with the DMR. Both parties must be active participants. The DMR are the Shellfish Authority; they are the public health experts. Meetings and workshops educating the industry would be beneficial. The finalization of the SOPs will provide for uniformity. Changes in policy and

reclassifications should be explained in writing with detailed justification for the decisions. It was noted that other states have more communication with their state Department of Environmental Protection (DEP), harbor management commissions, shellfish commissions, Sea Grant, and advisory councils. One question placed to the review team was to discuss whether the Maine Shellfish Advisory Council should communicate with DMR or to the legislature. The Shellfish Advisory Council may represent the industry voice to DMR but they should use Maine Sea Grant as their “sounding board.” Together the industry and DMR can develop proposals for ISSC.

Final Peer Review Team recommendations:

**** The FDA comments found under the Summary Recommendations at the beginning of this document are the same and should be applied below. ****

1. Additional Staff is required in order for the Maine Shellfish Growing Area Program to be able to comply with the NSSP-Model Ordinance requirements. Additional staffing will allow for: timely assessment of data, additional sample collection and studies, and timely preparation of reports.
2. Biannual meetings should be held between industry and DMR representatives, the structure of which should be initial presentations followed by discussion. An independent moderator should also be considered. The meetings should also be staged to coincide with the biennial Interstate Shellfish Sanitation Conference (ISSC) to enable joint DMR/shellfish industry request for change to the NSSP Model Ordinance prior to the ISSC.
3. A Shellfish Advisory Council should be established to act as mediator for DMR and industry.
4. The Standard Operating Procedures (SOPs) should be finalized.
5. Sampling protocol should continue to be standardized and should address subsurface sampling when the sampler is at a minimum knee deep water depth, and the sample is collected up-current, and away from floating objects such as seaweed. Samplers should be further evaluated to ensure that sediments are not disturbed in the collection area.
6. Water samples should not be collected at periods of “no water,” in rivulets or stagnant pools.
7. Sampling should be scheduled using the Systematic Random Sampling (SRS) method but should be timed during the day with respect to tidal conditions that allow for sample collection at the minimum water depth of 18”.
8. Samples should be collected during various tidal conditions especially in areas where times of tidal impacts have not yet been adequately determined. Collection during both ebb and flood tides is acceptable.
9. DMR should continue to collect salinity data.
10. Pollution source sampling should continue.
11. DMR should utilize volunteer industry or shellfish warden boats where possible for growing area classification sampling.
12. A simplified version of the NSSP statistical information should be presented for the local community.

13. Additional sample stations should be added further out in bays and across growing areas that may be used to more specifically define classification lines such as in the Timber Cove area.
14. The boundary line separating the conditional from the approved classification in growing area ER may be moved, thereby opening an additional harvest beach without compromising public health. (Station 8.0 to Station 45.0). This should be further reviewed by DMR.
15. DMR should consider the viability of remote area classifications.
16. A river gauge should be added below the confluence of the Kennebec and Androscoggin Rivers so DMR can more accurately assess impacts of river stage on those affected growing areas.
17. “No Discharge Zones” should be established in critical shellfish growing areas.
18. Specific legislation should be enacted prohibiting overboard discharge into critical shellfish habitat.
19. Dye dilution studies should continue to be conducted by trained parties but may be made a local requirement of WPCFs and NPDES permittees and at their expense.

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APPENDIX A: Industry Concerns and Perspectives

The following document was prepared by Valy Steverlynck on behalf of the Shellfish Industry in preparation for the review team meeting on Monday, October 29th. It represents industry's understanding of the issues and their perspective as organized into these 14 focus areas.

Industry Advisory Panel/ Review Team 10/29 Meeting Boothbay, 9:30 am

What follows is a list of the areas that Industry would like the reviewers to evaluate and comment on. Suggestions should be made primarily in the context of how other state programs in the region are complying with the NSSP:

- 1) Location of GAC stations as related to harvest/growing areas, fresh water inputs, access points and tide-related issues.*

Throughout the coast, there is a high percentage of GAC stations that have no water at low tide (e.g. run 6V-Freeport, Maquoit Bay, Kennebec River, etc). For samplers operating under the April 26, 2007 SOP, it is often impossible to collect low tide samples because there simply isn't any water present at that tidal stage- except for runoff streams and puddles of standing water. Does FDA require that stations be sampled specifically at low tide, or is "low water" data (collected on low-to-mid tide) acceptable for compliance with FDA's directive that random samples be collected at "all tidal stages"?

- 2) Distinction between GAC stations vs. pollution monitoring stations.*

ME DMR does not distinguish between GAC stations and pollution monitoring stations. From the Random sampling run station maps, it appears that stations located on streams and high on river banks are used for both purposes (e.g. WJ30 (Bunganuc Creek), WI53 (mouth of Cousin's River)). This leads to sample runs that have a great number of stations and thus require ample time and lab resources to sample.

Please comment on the effectiveness of this approach: Would random runs be more manageable if only stations monitoring overlying waters were sampled fro GAC? Keeping in mind that DMR has limited staff and resources and that on occasion runs don't have the minimum 6 samples/yr required by FDA, having fewer stations per run may make it easier for DMR to comply with FDA regulations.

Is it appropriate to use GAC stations for monitoring both pollution sources and overlying growing waters?

- 3) Random Sampling method versus Adverse Sampling method for different types of areas.*

Maine relies mostly on Random Sampling for GAC. It uses adverse sampling when monitoring pollution, but not for growing area classification. Industry recognizes the need for upfront

investment when using adverse sampling for GAC, yet where there are adversities clearly impacting an area it may be worth considering using this method.

How much data needs to be collected before an area can be on an “automatic” trigger? (by “automatic trigger” we mean that the area can be opened or closed when certain conditions are present without the need for testing). Maine does not have the resources to switch to Adverse sampling, but Industry is committed to helping gather data or help fund studies that will make it possible for key areas to be tested under the Adverse Sampling method and operate on “automatic” triggers.

4) *Rainfall conditional areas: their role in ME's Growing Area Classification Program; Guidelines on how to manage them.*

Despite the length of Maine’s coast, there are only three rainfall conditional areas in the whole state (Medomak River, St. George River and Atkins Bay, Kennebec). There are several areas that have enough data that point to the need for rain gauges, including the Cousin’s River in Freeport/Yarmouth.

Rainfall Conditional areas consume a large share of DMR’s resources: they require extensive testing (to re-open after rainfall events) and expensive notification (newspaper ads to close and re-open the areas). DMR has recently eliminated a number of rainfall conditional areas and is reluctant to instituting any additional ones.

While the financial burden of managing rainfall conditional areas is evident, the productivity of these areas must be taken into account as well. In order to maximize the state’s natural resources, Maine’s shellfish industry and municipalities are committed to doing whatever is necessary to help institute more conditional areas and manage them. Industry contributions would include, but not be limited to, funding studies that would help determine the “triggers” for such areas.

5) *Standard Operating Procedure (SOP) for Water Quality Sampling:*

- *Depth for water sample collection*

ME’s 2007 SOP requires that samplers wade 12-18” and that they plunge the bag 4-10” under the surface. How do these depths compare to those used by other states?

- *Distance from GAC station at which samples may be collected*

ME’s 2007 SOP allows samplers to walk up to 300’ from the GPS location of the GAC station. Is that distance appropriate and most importantly, is it applied consistently by all samplers?

6) *Role of salinity to determine the utility of a sample for GAC.*

Samples with extremely low salinity are routinely used for growing area classification purposes. Do such samples accurately represent the quality of the overlying waters? Are there ways to determine if/when a sample should be discarded?

7) *Access to GAC stations: Land vs. boat.*

8) *Use of municipal resources and volunteers: Role of DMR-trained personnel, municipal boats and vehicles etc.*

For 5) and 6):

Boat sampling is generally considered more accurate than sampling by land: it allows samplers to get to the stations without stirring the bottom and it ensures proper depth when drawing a sample. Nearby states make heavy use of boats when sampling GAC stations.

Sampling a run by boat takes on average ½ the time it takes to do the same run by land.

For safety reasons, ME DMR requires that there always be at least two people when operating a boat. DMR has very few boats and a limited budget. It is therefore unrealistic to expect that the Department will be able to sample by boat.

Many municipalities, however, have access to boats and DMR-trained personnel (wardens) available to aid DMR in collecting samples. In the case of Scarborough, Brunswick, Freeport, Bath and other towns, wardens already sample for DMR. They most often sample by boat (town boats).

Industry members have also offered to provide DMR staff with boat rides when collecting samples.

Could this “volunteer program” be expanded to help alleviate DMR’s lack of resources and available staff? There are many towns and wardens who have expressed an interest in helping out.

9) Threshold for initiating a state-wide flood closure.

The state is currently on a 2”-3”/24 hr rain closure: The flood-closure conversation at DMR starts between two and three inches: it may be initiated after two inches based on ground saturation, recent rainfall events, etc. Once rainfall reaches three inches/24 hrs., a state-wide closure goes immediately into effect.

For areas that are susceptible to rainfall but are not classified as rainfall conditional, it is beneficial to have a low trigger (2”). This prevents random samples from being taken when the area is polluted: these samples have a long-term impact on the area’s P90 and its long-term classification.

Since state-wide closures have a great impact on a business’s bottom line industry members working in areas that are not susceptible to rainfall events prefer a higher trigger (3”).

If productive areas that are prone to water quality deterioration after rainfall events (but clean otherwise) were classified “rainfall conditional” the state-wide closure could be initiated at 3”. Would this be a reasonable and effective approach?.

10) Method for establishing boundary lines between open and closed areas.

Boundary lines are established by ME DMR at the first station that meets the criteria for a different classification. In many cases stations are spread far apart, sometimes a mile or more (eg Scarborough). The area that lies between a “closed” and an “open” station is considered “closed.” Given that this “in-between” expanse is sometimes large and oftentimes productive, Industry would like to ask that the reviewers evaluate this approach and suggest alternative ways for establishing boundary lines, if appropriate.

Areas that are susceptible to rain but are classified using random sampling/P90s have their own set of issues when it comes to drawing boundary lines: In the case of the Cousin’s River, the area that is classified “open” is influenced by rainfall events and should not be permanently open (it is currently open based on P90 calculations). On the other hand, the area that is currently “closed” (restricted) is clean during dry periods and should not be permanently closed.

11) Accelerated sampling for expediting review and possibly the reclassification of existing growing areas. Role of independent laboratories in ME's Program.

ME DMR collects the minimum six samples/year required by FDA for each GAC station. Areas where pollution abatement plans have successfully eradicated the pollution source (eg a failing septic that has been repaired) are good candidates for accelerated sampling (FDA allows up to 24/samples/year). Currently, accelerated sampling is not conducted by ME DMR due to budgetary and staffing shortfalls. Industry would like to make accelerated sampling possible, either helping in data collection (through the use of trained wardens and municipal personnel or by providing boat rides to DMR staff), or by contracting independent laboratories to process the samples (to this date no independent lab has been certified by DMR to process GAC samples)-or both.

12) Real-time closing and opening of growing areas based on P90 calculations.

In Maine, areas are reclassified only at the time of their annual review. If a certain area shows signs of pollution it still remains open for the remainder of the year (Little River/Recompence, Freeport, 2006). Conversely, an area that has P90s that meet the criteria for re-classification to the open status can't be opened until the date of its annual review (Harpowell, 2007). Are there ways to make the closing and opening of areas more accurate and time-sensitive? What does Industry need to do to help DMR achieve the goal of real-time closing and opening?

13) Hydrographic studies: their role in determination of sampling locations and in growing area classification.

Dye studies are complicated and require in-depth knowledge and experience in dealing with hydrographic issues. DMR-generated studies have sometimes been challenged and questioned. Case in point: The Harraseeket River study. Please comment on the role of such studies and on the qualifications necessary to conduct them. Is there precedent in other states for contracting dye studies to third party experts?

14) Cross-check method(s) for ensuring that only samples collected under the Random protocol get used for growing area P90 calculations.

Adverse samples have been known to get mixed up with Random samples and used to generate P90s (e.g. Brunswick, Scarborough). Are there methods/programs available to eliminate these mistakes?

As far as calculating the P90s themselves, Massachusetts encourages its WQ staff to double-check computer generated P90 calculations by hand (apparently computer programs are sometimes not accurate)

Is this a real concern? Should Maine be doing likewise?