

**Comment Response Document**  
**Regarding the Draft Total Maximum Daily Loads of Fecal Coliform for Restricted Shellfish Harvesting Areas in St. Clements Bay in St. Mary's County, Maryland**

**Introduction**

The Maryland Department of the Environment (MDE) has conducted a public review of the proposed Total Maximum Daily Loads (TMDLs) of fecal coliform for restricted shellfish harvesting areas in St. Clements Bay. The public comment period was open from August 11, 2004 through September 9, 2004. MDE received five sets of written comments.

Below is a list of commentors, their affiliation, the date comments were submitted, and the numbered references to the comments submitted. In the pages that follow, comments are summarized and listed with MDE's response.

**List of Commentors**

<b>Author</b>	<b>Affiliation</b>	<b>Date</b>	<b>Comment Number</b>
Kenneth C. Rossignol	<i>St. Mary's Today</i> newspaper	August 18, 2004	1
Richard Pelz	Circle-C Oyster Ranchers Association	August 23, 2004	2
Jennifer Murphy, Staff Attorney and Robert Albanese, Intern	Mid-Atlantic Environmental Law Center	September 8, 2004	3
Richard Pelz	Circle-C Oyster Ranchers Association	September 9, 2004	4 through 19
Jennifer Schaafsma	Maryland Department of Agriculture	September 10, 2004	20 through 22

**Comments and Responses**

1. The commentor stated that decisions involving regulations proposed by MDE regarding fecal coliform TMDLs for restricted shellfish harvesting should only be formulated after seeking input from the people such actions affect and after having public hearings in St. Mary's County.

**Response:** MDE is not proposing regulations. Instead, the Department is proposing to establish TMDLs of fecal coliform for restricted shellfish harvesting areas. The development of TMDLs is required under Section 303(d) of the federal Clean Water Act for waters that do not meet water quality standards and are identified on Maryland's 303(d) list. The restricted shellfish harvesting areas, for which draft TMDLs have been developed, are listed as impaired due to levels of bacteria exceeding Maryland's water quality standards for fecal coliform and, as such, are closed to shellfish harvesting. It is important to note that the TMDLs do not propose the closure of these waters to harvesting - they are already closed to harvesting. The goal of the TMDLs is to identify sources and allocate loading limits such

that the designated uses for these areas will be met, meaning that these areas could be opened to shellfish harvesting.

The Department has solicited input from the public. All TMDLs undergo 30-day public comment periods, which are announced on MDE's website and in newspapers in the area of the proposed TMDLs. The draft documents are made available on MDE's website and in libraries in the area of the proposed TMDLs. Additionally, the documents are mailed directly to known stakeholders at the local, county and State level. These same people were notified of our intent to develop the fecal coliform TMDLs in early 2004 and were encouraged to contact the TMDL outreach staff with questions. Finally, all comments received during the comment period are included in formal Comment Response Documents like this one.

Comments received by the Department have been considered in preparing the draft final TMDL document to be submitted to the U.S. Environmental Protection Agency (EPA). The Department welcomes the opportunity to meet for the purpose of discussing the issues of concern to the commentor. The Department received only three requests (two from the same individual) for a public hearing regarding the St. Clement Bay TMDLs, which do not constitute sufficient public interest to warrant holding a public hearing.

2. The commentor requested a public hearing.

**Response:** Please see the last paragraph of the Department's response to Comment 1. Because the Department met with the commentor to discuss his individual concerns more fully, the Department has concluded that a hearing is not warranted.

3. The draft TMDL does not contain an adequate Margin of Safety (MOS) that appropriately account[s] for uncertainty related to the TMDL, including uncertainties associated with pollutant loads, modeling water quality, and monitoring water quality as required by the Code of Federal Regulations. Specifically, the decay rate of 1.6 per day used in the TMDL calculation does not constitute a "conservative estimate" of the decay rate for the purposes of incorporating an implicit MOS in the TMDL, because it is essentially the average decay rate of fecal coliform in salt water (which ranges from 0.4 to 3.0 per day). The commentor suggested that the slowest decay rate of 0.4 per day should be used.

**Response:** After further review of the literature, MDE agrees that a lower value of the decay rate should be used to more adequately reflect the margin of safety in the bacteria TMDLs for the restricted shellfish harvesting areas. MDE selected a new decay rate using the lower end of the range reported by Mancini (1978), and presented in Thomann and Mueller (1987), and then confirmed this value with ranges found in the literature (MDE, 2004).

The low end of the range is approximately 0.7 per day (0.36 per tidal cycle). This rate (0.7 per day) is now used in the revised calculations in all shellfish TMDL reports. There is a change in the assimilative capacity but minimal or sometimes no change in the required reduction to the watershed loads since the same decay rate is used in both the current condition and TMDL calculations. The document has been revised to reflect this modification.

- The commentor stated that, according to “the collected information”, there are no public sewer systems in the watershed. In fact, St. Clements Shores has had public sewer for over 15 years.

**Response:** This has been fixed in the revised reports. MDE staff also identified this oversight and made immediate corrections; however, the document had already been released for public comment. The document will be revised to note that there is a small portion of the watershed served by public sewer system. The accompanying table will read as follows:

	<b>RID</b>	<b>Area Name</b>	<b>Proportional Population</b>	<b>Proportional Septic Systems</b>	<b>Proportional Households</b>
Public review document	44A	St. Clements Bay	4,395	2,022	1,511
Revised document	44A	St. Clements Bay	4,395	1,561	1,511

These changes had no bearing on the TMDL or allocations presented during the public comment period.

- The commentor stated that the proposal assumes two people per septic system. In fact, the Chopticon High School, with a student population of 1,626 last year, is on a septic system that is known to be problematic.

**Response:** The source assessment is based on the available and most scientifically defensible information. When septic systems were estimated, US Census population (2000) and household information were used in conjunction with site specific Maryland Department of Planning Septic system coverage and master sewer plans. The population and households estimates are based on spatial ratios and are generally representative for watersheds in that region. Septic failure rates are estimated using results from MDE routine shellfish sanitary surveys.

For these study areas, most or all of the properties are using septic systems. Therefore, the averages per household are accurate. MDE recognizes that people are transient throughout the day and may be in different locations. Based on the currently available information, MDE supports the assumption that the source estimates predict the bacteria sources in the watershed on average.

- The commentor questioned how farmers can be expected to pay for implementation of these TMDLs, given that funding sources cited for farmers to draw from (e.g., Maryland’s Agricultural Cost Share Program and the Environmental Quality Incentives Program) are limited.

**Response:** The programs outlined in the assurance of implementation identify potential sources that can be used to provide funding for implementation. It is expected that during the implementation planning stage additional funding sources will be investigated and innovative approaches to solving these pollution problems will be developed. MDE continues to support the shellfish sanitary surveys for identification and mitigation of failing septic systems that impact shellfish harvesting areas and EPA is now requires allocations, in the form of loads or best management practices, for National Pollutant Discharge Elimination System (NPDES) permitted jurisdictions. Thus, the financial burden is not placed entirely on the farmer.

7. The commentor questioned why the Maryland Farm Bureau was not notified about “these new regulatory proposals”.

**Response:** The Department regrets that the Maryland Farm Bureau was not notified regarding the development of these TMDLs; however, the Department attempted to include the farming community by contacting the Maryland Department of Agriculture and the pertinent Soil Conservation Service offices were notified. The Maryland Farm Bureau will be notified regarding all future agriculture-related TMDLs. Please also see the first paragraph of the Department’s response to Comment 1.

8. The commentor questioned why St. Clements Bay and Canoe Neck Creek are closed to shellfish harvesting, given that the data table on page A6 shows that fecal coliform concentrations in these two areas are below the water quality criteria (14 MPN per 100 ml).

**Response:** Use II- Shellfish Harvesting Waters (Code of Maryland Regulations (COMAR) 26.08.02.08M) water quality standards are described in COMAR Section 26.08.02.03-3C. As noted in Section 2.3 of the TMDL report, these waters require that the median fecal coliform most probable number (MPN), of at least 30 water sample results taken over a three year period to incorporate inter-annual variability, shall not exceed 14 per 100 milliliters, and in areas not affected by point source discharges, the 90<sup>th</sup> percentile of water sample results shall not exceed an MPN of 43 per 100 ml for a five-tube decimal dilution test or 49 MPN per 100 ml for a three-tube decimal dilution test. Maryland uses the three-tube decimal dilution test. Since both criteria must be met, and both St. Clements Bay and Canoe Creek exceed the 90<sup>th</sup> percentile criterion, these areas are classified as restricted and are closed to shellfish harvesting.

9. The commentor requested a clarification regarding the risks to human health from fecal coliform sources other than human waste, and whether or not the risk factors from all fecal coliform sources are equal.

**Response:** From EPA’s Draft Implementation Guidance for Ambient Water Quality Criteria for Bacteria (2002), EPA no longer supports that pathogens originating from animal sources present an insignificant risk of acute gastrointestinal illness in humans. EPA now states that available data suggest that there is some risk posed to humans as a result of exposure to microorganisms resulting from non-human fecal contamination. At this time no adjustment to the load calculation will be made to the bacteria levels based on animal sources. Source

load allocations are estimated and are included in the TMDL document to assist in calculating source reductions to achieve water quality standards. Maryland's water quality standard and the analysis for bacteria do not distinguish any potential differences in risk factors due to human or non-human sources.

10. The commentor requested a clarification regarding the process for selecting the shellfish water quality monitoring stations within the main stem of St. Clements Bay, particularly the station located approximately one mile from the commentor's aquaculture operation.

**Response:** Shellfish monitoring stations are placed to best represent the characteristics of the shellfish growing area and are placed with regard to actual or potential pollution sources that impact shellfish water quality. In Maryland, shellfish harvesting waters include areas where oysters and clams are harvested. In addition, stations are placed to mark the boundary between approved and restricted waters. Waters that require a TMDL are found on Maryland's 303(d) list of impaired waters. Subsequent to the listing of St. Clements Bay, the restricted area increased and the section of St. Clements Bay, including the aquaculture site in question, were classified as restricted in June 2004 using data from a station located adjacent to the aquaculture site. Stations located in approved waters at the time the area was listed were not included in this draft. The draft TMDL for Restricted Shellfish Harvesting Areas in St. Clements Bay was based on the most recent 303 (d) list and the data used for it included the period through December 2003.

11. The commentor questioned the level of protectiveness of a TMDL that does not take into account the quantity of treated sewer sludge trucked into the watershed from the Baltimore-Washington metropolitan area for application on farms or disposal in gravel pits. Of greatest concern is the possibility that the sludge, though treated to kill fecal coliform, may contain a variety of contagious diseases associated with the consumption of raw shellfish.

**Response:** The St. Clements Bay TMDL is designed to calculate the bacteria loading to the waterbody that would meet the water quality standard for bacteria. The TMDL is linked to the Food and Drug Administration (FDA) standard which determines whether the water is meeting its designated use; the standard does consider human health. Maryland's Shellfish Program has been successful in reducing public health risk to consumers of shellfish for over 50 years and the TMDL process does not alter this important responsibility. In the 30+ years that MDE has been monitoring bacteriological water quality in shellfish waters, there has never been a link between elevated levels of bacteria in the water and sewage sludge applied to land. In addition, there has never been a reported illness linked to the application of sludge to land and the consumption of shellfish in Maryland. Therefore, evidence of a potential risk of this pathway does not appear to be significant.

12. The commentor questioned the need to use the more protective 90<sup>th</sup> percentile criteria, given that a margin of safety based upon the decay rate is included in the calculation.

**Response:** The margin of safety is used to account for modeling uncertainties in estimation of the loading caps and is independent of the water quality criterion. Shellfish harvesting areas must meet both the median and 90<sup>th</sup> percentile criterion to meet water quality standards.

Because there are two criteria that must be attained, the more stringent was selected to estimate the reduction required.

13. The commentor stated that the use of both standard and metric units of measure throughout the document is confusing.

**Response:** MDE has checked the calculations in these documents but will consider using all metric units in future shellfish TMDL reports.

14. The commentor questioned whether the data shown in the graphs of observed fecal coliform concentrations per 100 ml is based upon “the standard, five or three tube decimal dilution, or three tube decimal dilution 90<sup>th</sup> percentile”.

**Response:** Use II- Shellfish Harvesting Waters (Code of Maryland Regulations (COMAR) 26.08.02.08M) water quality standards are described in COMAR Section 26.08.02.03-3C. As noted in section 2.3 of the TMDL report, these waters require that the median fecal coliform MPN, of at least 30 water sample results taken over a three year period to incorporate inter-annual variability, shall not exceed 14 per 100 milliliters, and in areas in areas not affect by point source discharges, the 90<sup>th</sup> percentile of water sample results shall not exceed an MPN of 43 per 100 ml for a five tube decimal dilution test or 49 MPN per 100 ml for a three tube decimal dilution test. Both the five-tube and the three-tube test are included in Maryland regulation. However for decades the shellfish program has relied on and uses the three tube decimal dilution test. All data used to calculate shellfish TMDLs utilized ongoing routine monitoring of shellfish waters using the three-tube test and therefore, the criteria of <49 90<sup>th</sup> percentile applies.

15. The commentor stated that, in general, the charts showing fecal coliform source loads appear to be inaccurate.

**Response:** TMDLs for the restricted shellfish harvesting areas were developed using the best available data to estimate source contributions. MDE recognizes that there is uncertainty in estimating bacteria source loads and notes in the TMDL report the commitment to follow up with bacteria source tracking. MDE’s bacteria source tracking schedule is also available on our web site at: [http://www.mde.state.md.us/Programs/WaterPrograms/TMDL/home/tmdl\\_bacteria\\_monitoring.asp](http://www.mde.state.md.us/Programs/WaterPrograms/TMDL/home/tmdl_bacteria_monitoring.asp). It is anticipated that bacteria source tracking will provide refined precision in the estimated source loads.

16. The commentor questioned the State’s use of fecal coliform as a indicator species of salt water contamination and the subsequent development of fecal coliform TMDLs, given the findings of a national guidance document released by EPA in January 1986 stating that the use of fecal coliform as an indicator for unsafe saltwater does not protect the public from waterborne diseases. The commentor added that numerous scientific papers corroborating EPA’s findings have since been written, and cited the findings of several examples.

**Response:** As a member of the Interstate Shellfish Sanitation Conference (ISSC) (a voluntary, cooperative association of states, U.S. Food and Drug Administration (FDA), National Marine Fisheries Service (NMFS), Environmental Protection Agency (EPA) and shellfish industry), and to remain in compliance with the National Shellfish Sanitation Program (NSSP) Model Ordinance, Maryland must use fecal coliform to classify shellfish harvesting waters. The decision on whether or not to use fecal is not one that Maryland can make independently.

Other members of the ISSC include all coastal states in the U.S., Hawaii, other countries including, Canada, Chile, Republic of Korea, Mexico, and New Zealand. Members of the ISSC are permitted to ship raw molluscan product in interstate and international commerce. State and international responsibilities include adopting laws and regulations for the sanitary control of the shellfish industry, formulating comprehensive shellfish harvesting area surveys and adopting control measures to ensure that shellfish are grown, harvested and processed in a safe and sanitary manner. FDA reviews methods for classification and management of shellfish areas proposed by the ISSC, and incorporates those methods consistent with standard health practice into the NSSP Model Ordinance. FDA is also responsible for the annual on-site review of each state and international shellfish control program to determine conformity with the NSSP standards and guidelines. NMFS and EPA comment to the ISSC. Shellfish industry responsibilities include commenting to the ISSC, obtaining shellfish from safe sources, maintaining sanitary operating conditions and making records available that document location of harvest and sale of all shellfish. FDA, MDE and the shellfish industry fulfill their responsibilities to a high degree, thus ensuring shellfish harvested in Maryland are safe and wholesome.

If Maryland is found in non-compliance of the NSSP Model Ordinance, FDA could ban Maryland molluscan shellfish from interstate commerce. Just as the draft TMDL for restricted shellfish harvesting areas must use the current water quality criteria in Maryland regulation, so must Maryland comply with the current requirements in the NSSP to remain a member and continue in interstate commerce. In order to make changes to the NSSP Model Ordinance, a proposal must be submitted to the ISSC, and all the members must agree, with FDA having the final say on the matter.

In 1997, a proposal was submitted to the ISSC by the South Carolina Department of Health and Environmental Control for using enterococcus analysis as an acceptable method for classification of shellfish growing waters (Issue 97-123, 1997 ISSC). In the absence of specific research related to using enterococcus as an indicator for shellfish waters, no action was taken. The issue has not been formally raised at the ISSC since.

Maryland cannot change the indicators it uses until the federal agencies, in this case FDA, agree to the change. Before making such a change, FDA would need to undertake extensive, and expensive studies to justify such a change and quantify the *E. coli* and enterococcus numbers. Even if they are the same thresholds almost certainly would not apply to this different purpose (i.e., quantitatively). The FDA and ISSC position is supported by EPA. In EPA's May 2002 Draft Implementation Guidance for Ambient Water Quality Criteria for Bacteria (page 61) states: "The 1986 *E. coli* and enterococci criteria were developed to

protect against human health effects, namely acute gastroenteritis, that may be incurred due to incidental ingestion of water while recreating. These criteria do not account for exposure that may be incurred by the consumption of shellfish, and therefore, are not appropriate for waters designated for shellfish.” The same document also states that “data and information do not yet exist that would support the use of *E. coli* or enterococci as criteria to protect waters designated for shellfishing.”

Contacts for exploring changes in the FDA and ISSC standards are:

US Food & Drug Administration  
Al Ondis, Regional Shellfish Specialist  
600 Metro Drive Suite 101  
Baltimore, MD 21215  
Phone: 410-779-5102

Interstate Shellfish Sanitation Conference  
www.issc.org  
Ken Moore, Executive Director  
209-2 Dawson Drive  
Columbia, SC 29223  
Phone: 803-788-7559

17. The commentor stated that limiting or prohibiting shellfish production, especially in contaminated areas, increases the public’s exposure to disease-causing organisms because shellfish destroy pathogens.

**Response:** It’s important to distinguish between the presence of shellfish and shellfish produced for human consumption. Shellfish populations are valuable to the health of the Chesapeake Bay and Maryland’s economy; therefore, the Department would not suggest that shellfish production be limited or prohibited in the areas for which the fecal coliform TMDLs are being developed. However, in these areas, due to poor water quality, the shellfish should not be harvested for human consumption due to the potential risk from pathogens. The TMDLs have been developed for the purpose of identifying the sources of the high fecal coliform levels which have resulted in the waters being closed to shellfish harvesting and to propose load reductions from each of those sources. It is important to note that the TMDLs do not propose the closure of these waters to harvesting – these waters are already closed to harvesting to protect human health. The goal of the TMDLs is to reduce high fecal coliform concentrations to levels at which the designated uses for these areas will be met and that, perhaps, these areas could be opened to shellfish harvesting.

18. The commentor questioned why MDE’s primary focus is not the development a risk-based adjusted water quality assessment (an option stated in the “Assurance of Implementation” section of the document), given the commentor’s aforementioned statement regarding the problems associated with using fecal coliform as an indicator species.

**Response:** The statement in the report is "If the water quality standards are not being attained, then MDE would consider developing either a risk based adjusted water quality assessment or a Use Attainability Analysis (UAA) to reflect the presence of naturally high bacteria levels from uncontrollable sources."

The purpose of the sentence was to show that the Department is considering how to address issues of wildlife, especially in the areas identified as not meeting WQS until wildlife sources



are reduced. Risk-based adjustment would be assessing how likely public health will be affected by (in this case) fecal coliform from wildlife sources. The idea is to determine the amount of fecal coliform coming from wildlife (which may not affect human health) and adjust the "final" fecal coliform count of a water quality sample count and compare the adjusted number to the standard. Other state's are attempting this approach for recreational waters (not yet approved by EPA. A risk-based adjusted water quality assessment is another option to consider instead of a UAA. It is important to note that risk information for wildlife sources would require significant additional research before implementation.

19. The commentor reiterated his request for a public hearing.

**Response:** Please see the last paragraph of the Department's response to Comment 1.

20. The commentor questioned why the Department is developing fecal coliform TMDLs before the Bacteria Source Tracking (BST) study (a one-year effort MDE has undertaken for each restricted shellfish harvesting area to confirm the bacteria source allocations) is completed. The commentor stated that lack of certainty regarding sources is detrimental to the funding and development of watershed plans and remediation projects.

**Response:** All of the restricted shellfish harvesting areas for which TMDLs are being submitted exceed the current bacteria water quality criteria and, as a result, are not meeting their designated use. Reductions in fecal coliform loading are required for these waterbodies to attain their designated uses as shellfish harvesting areas. Because of the limited laboratory capacity required to complete the bacteria source tracking and the uncertainty of when that data would be available, MDE is being proactive by developing a TMDL with the best information currently available. The Department remains committed, however, to follow up with BST to refine the precision in the original source estimates. If the BST results do not require a change, it will be unnecessary to modify the reports. The link to the current BST schedule is provided in the report ([http://www.mde.state.md.us:8001/assets/document/BST\\_schedule.pdf](http://www.mde.state.md.us:8001/assets/document/BST_schedule.pdf)).

It is MDE's position that implementation beyond the current regulatory controls (i.e. nutrient management plans, sanitary survey, sludge application permits) will not be required for these watersheds until the BST becomes available. However, a voluntary effort to reduce identified, controllable bacteria sources (e.g., failing septic systems, animals in streams) would be recommended as a head start to the clean up efforts.

Comparison of the source allocations with and without the benefit of BST will also allow the Department to evaluate BST as a means of refining analyses and assist in determining whether BST should be used for TMDL analyses in other watersheds.

21. The commentor questioned whether the source categories following BST would be as broad as the current "wildlife" source category, and noted that the contribution of small mammals is missing.

**Response:** MDE is using the method of antibiotic resistance analysis to estimate the relative source contribution in water samples. An essential component of the BST projects are the scat collection and field study done to develop a BST library of known sources. It is expected that wildlife results will be grouped into one category given their similarity in resistance patterns. MDE plans to evaluate the level of categorization that is first, scientifically defensible and second, provides practical management based knowledge for the watershed planning.

22. The commentor stated that the St. Mary's Soil Conservation District conducted an inventory of farm animals for the subwatersheds at issue in this document, the results of which indicate changes from the data used for the preparation of these TMDLs. The commentor provided the more recent survey results.

**Response:** The source assessment was based on the available and most scientifically defensible information available at the time the assessment was performed. MDE determined the appropriate scale that could be used to represent different sources based on limitations of data (i.e., county estimates, privacy act, etc.). All livestock animal counts, except horses, were proportioned to 8-digit watersheds using the Maryland Agricultural Census Service State total estimates with information from (Brodie and Lawrence, 1996) at the 8-digit scale. Further proportioning to subwatersheds followed the procedure outlined in Appendix B, Figure B-4. Horses were proportioned using the County census data and proportioning based on farms identified in the State equine survey. This is similar to the procedure used in MDE's nutrient watershed modeling.

MDE attempted to obtain the best available information by notifying the Maryland Department of Agriculture and the Soil Conservation District of its intent to develop fecal coliform TMDLs at the beginning of TMDL development process. In addition, MDA was included in the interagency TMDL workgroup where the fecal coliform TMDL work was presented and was included in interagency review process. MDE recognizes that there may be differences in animal counts from more detailed information and would like to work more cooperatively with the SCD on future TMDLs.

## REFERENCES:

Mancini, J.L. (1978) Numerical Estimates of Coliform Mortality Rates Under Various Conditions. Journal WPCF, November, 2477-2484.

Maryland Department of the Environment (2004). Technical Memorandum: Literature Survey of Bacteria Decay Rates.

Thomann, R. V. and J. Mueller (1987). Principles of surface water quality modeling and control. Harper Collins Publishers.