

**Comment Response Document
Regarding the Total Maximum Daily Loads of Fecal Coliform for Restricted Shellfish
Harvesting Areas in the Wicomico River Watershed Basin (Charleston Creek and
Chaptico Bay) in Charles and St. Mary's Counties, 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 Wicomico River. The public comment period was open from August 25, 2004 through September 23, 2004. MDE received three 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

Author	Affiliation	Date	Comment Number
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
Richard Pelz	Circle 'C' Oyster Ranchers	September 9, 2004	3 through 10

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 received requests from two individuals for a public hearing regarding the Wicomico River TMDLs. The Department welcomes the opportunity to meet for the purpose of discussing the issues of concern to commentors, and, in this case, met at length with Mr. Pelz to discuss his comments. In light of the limited number of individuals requesting a hearing and the fact that the Department has met with one of them, the Department has concluded that a hearing is not warranted.

2. The commentor requested a public hearing.

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

3. The commentor questioned the need to use the more protective 90th 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 90th 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.

4. 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.

5. 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 90th 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 90th 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 less than 49 (i.e., 90th percentile) applies.

6. 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. It is anticipated that bacteria source tracking will provide refined precision in the estimated source loads.

7. 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 the EPA document reported that more people 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

8. 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 because of 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.

9. 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.

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

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