UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

DATE

EPA-SAB-09-0XX

The Honorable Lisa P. Jackson
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Subject: Review of EPA's Revised Total Coliform Rule.

Dear Administrator Jackson:

In response to a request from EPA's Office of Water (OW), the Science Advisory Board (SAB) convened the Drinking Water Committee with additional experts from the Board to conduct a review of EPA's draft supporting analysis in preparation for the proposed revision of the Total Coliform Rule (TCR). The Total Coliform Rule (TCR) was established in 1989 and is one of the primary national regulations governing the microbiological quality of treated drinking water in the US. The Total coliform rule addresses the monitoring of coliform bacteria and *E.coli*, and is an important element in the protection against waterborne disease via demonstration of appropriate disinfection and groundwater protection. This rule is mandated by law to be reviewed every six years as part of the existing drinking water regulations requiring revisions to improve/maintain public health protection.

The SAB was asked to comment on (1) the underlying statistical analysis of the TCR monitoring data used to inform the prediction of the underlying baseline total coliform and *E. coli* occurrence and violation rates (2) the characterization of the types of corrective actions that systems will implement and the percentages of systems that will implement certain corrective actions (3) the methodology and assumptions used to predict the net impacts in total coliform-positive (TC+) samples, *E. coli*-positive (EC+) samples, acute violations, assessments, and corrective actions between the current TCR (with and without the effects of the Ground Water Rule), the AIP, and the Alternative Analysis (4) the use of reduction in *E. coli* and TC occurrence and acute violations as endpoints for informing benefits.. The Committee commends the Agency for all the work and analyses undertaken. They took on a sensitivity analysis which greatly increases confidence in the assessment. There was also only a limited amount of data from the Safe Drinking Water Information System – Federal Version (SDWIS/FED) and six-year review databases used in the EA deemed useful for the rTCR analyses and the Agency did a good deal of work and put a significant amount of thought and effort into addressing those segments of the database that would be useful. The work of the Agency in engaging with

stakeholders and developing the Agreement in Principal which addresses goals for improvement and research needs was laudable.

The SAB Committee's report contains a number of recommendations that are aimed at making the rTCR more transparent and improving the scientific basis for the proposed revisions presented. While a more detailed description of the technical recommendations is contained in the body of the report, the key points and recommendations are highlighted below:

The Committee found that the Agency's statistical analysis of the TCR monitoring data used to inform the prediction of the underlying baseline total coliform and *E. coli* occurrence and violation rates is reasonable but would benefit from some refinements and further explanation. The Agency is commended for the development and application of a statistical approach to a large, complex dataset enabling the analysis of a difficult and diverse problem. The Committee suggested that some of the key issues should be further explored through limited sensitivity analyses. These additional analyses, together with the work already performed, would provide a basis for adequate predictions and descriptions of total coliform (TC) and *E. coli* (EC) occurrence and violation rates.

The Committee agreed that the Agency's characterization of the types of corrective actions that systems would implement was reasonable and complete. The Committee recommends that the Agency explain how it compiled this list of corrective actions. The Committee notes that the rTCR should ideally be designed so that a larger percentage of small systems would take corrective actions that result in long-term benefits. In working with states, the Agency found that 10% or less of the utilities were able to find the cause of the coliform or *E.coli* occurrence and as a result take corrective actions. Thus there is a central estimate that 10% of the small systems will take corrective action which represents only a modest benefit from the current rule. This is without the impact of the *Ground Water Rule*. However, some corrective actions may be undertaken without knowing the exact cause, such as implementation of a flushing program. Therefore, the Committee recommends that the sensitivity analysis use a wider range of corrective action implementation including corrective actions up to around 50%, especially after a Level 2 assessment. In contrast, just because a corrective action has been taken and a sanitary defect corrected, this does not mean the public water systems (PWS) will be free of TC positive results for a period of time. Specifically the Committee questions whether the benefits of flushing will result in reduced risks for multiple years as used in the model.

The framework and methodology of the Economic Analysis (EA) appear to be in keeping with a properly conducted EA based on the USEPA Guidelines for Economic Analysis (2000). The Committee recommends that an analysis and discussion in the EA would better inform policy makers by identifying and summarizing all the variables with known distributions. It should also be noted that the EA model is developed as a reference baseline and has yet to be validated as a predictive tool.

The Agency will need a database that is far more robust than the six-year data review database used in the EA and the long list of assumptions needs to be addressed via better data collection. Also, it is not clear that the proposed reduced monitoring strategy offers significant savings in the annual national costs for the assays that are not offset by an increased risk of waterborne disease outbreaks. A quarterly or annual sampling plan is highly unlikely to detect a TC or EC event lasting only one week. Therefore, once a public water system is placed in the reduced monitoring regimen, it is highly unlikely, unless the sanitary defect is egregious, to be

triggered into more frequent sampling. Overall, the Alternative Analysis (AA) appears to address public health protection sooner in time than the AIP proposed implementation.

In trying to determine whether there are measurable health-related benefits attributable to the revised Total Coliform Rule, the Committee felt that measuring reductions in total coliforms (TC) and *E. coli* (EC) occurrences are **not** effective **sole** endpoints for informing benefits because of the difficulties in linking these indicators to human health outcomes. The Agency's recommendations of using TC as part of an overall treatment technique where TC-positive sampling results would trigger an assessment to identify sanitary defects instead of having an MCLG/MCL for TC, is seen as a positive step forward. However, there are a number of other indicators that need to be considered, as the TC is not an adequate measure of health risk. Even though *E.coli* is viewed as a more appropriate measure of risk of enteric disease, it does not capture the health risks from *Legionella*. Other measures, including structural and hydraulic integrity, have been recently considered in a report by the National Research Council and may provide valuable supplemental information on health risk of distributed.

The SAB appreciates the opportunity to provide EPA with advice on this important subject. We look forward to receiving the Agency's response.

Sincerely,

Dr. Deborah L. Swackhamer, Chair
EPA Science Advisory Board

Dr. Joan Rose, Chair
SAB Drinking Water Committee

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U.S. Environmental Protection Agency
Science Advisory Board
Drinking Water Committee Augmented for EPA's Revised Total Coliform Rule*

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Dr. Richard Sakaji, Manager, Planning and Analysis for Water Quality, East Bay Municipal Utility District, Oakland, CA

Dr. Gary Sayler, Beaman Distinguished Professor of Microbiology, and Ecology and Evolutionary Biology, Director of the Joint Institute for Biological Sciences and Director of the Center for Environmental Biotechnology, Oak Ridge National Laboratory, University of Tennessee

Dr. Gina Solomon, Senior Scientist, Health and Environment Program, Natural Resources Defense Council, San Francisco, CA

Ms. Susan Teefy, Principal Engineer, Water Quality and Treatment Solutions, Inc., Canoga Park, CA

Dr. Lauren Zeise, Chief, Reproductive and Cancer Hazard Assessment Branch, Office of Environmental Health Hazard Assessment, California Environmental Protection Agency, Oakland, CA

* provided written comments but did not attend the face-to-face meeting

SCIENCE ADVISORY BOARD STAFF

Dr. Sue Shallal, Designated Federal Officer, 1200 Pennsylvania Avenue, Washington, DC, Phone: 202-343-9977, Fax: 202-233-0643, (shallal.suhair@epa.gov)

ACRONYMS

AA	Alternative Analysis
AIP	Agreement in Principle
CWS	Community Water System
DWC	Drinking Water Committee
EA	Economic Assessment
EC	Escherichia coli (E. Coli)
EPA	Environmental Protection Agency
GW	Ground Water
GWDR	Ground Water Disinfection Rule
MCL	Maximum Contaminant Level
MCLG	Maximum Contaminant Level Goal
PWS	Public Water System
rTCR	revised Total Coliform Rule
SAB	Science Advisory Board
SDWIS/FED	Safe Drinking Water Information System /Federal Version
SW	Surface Water
SWTR	Surface Water Treatment Rule
TC	Total Coliform
TCR	Total Coliform Rule
TCRDSAC	Total Coliform Rule / Distribution System Advisory Committee
TT	Treatment Technique
TWG	Technical Working Group
UA	Uncertainty Analysis

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EXECUTIVE SUMMARY

EPA's Office of Water (OW) requested that the Science Advisory Board (SAB) Drinking Water Committee (DWC) review its draft supporting analysis in preparation for revising the Total Coliform Rule (TCR). The Total Coliform Rule (TCR) was established in 1989 and is one of the primary national regulations governing the microbiological quality of treated drinking water in the US. The Total coliform rule addresses the monitoring of coliform bacteria and *E.coli*, and is an important element in the protection against waterborne disease via demonstration of appropriate disinfection and groundwater protection. As the Agency embarked on revising the TCR, it expended a great amount of time and effort to include stakeholder input meeting with state regulators, water utilities, local governments, environmental advocates, public health professionals, consumer advocates, Indian tribes, and others through a FACA process. As a result of these discussions, an Agreement in Principle (AIP) was developed that is being used as the foundation for the proposed Revised Total Coliform rule (rTCR). The Agency has proposed a new, more proactive approach for identifying sanitary defects and incorrect monitoring practices.

The DWC of the EPA Science Advisory Board met in June 2009 to deliberate on four charge questions raised by OW. These questions focused on: (1) the underlying statistical analysis of the TCR monitoring data used to inform the prediction of the underlying baseline total coliform and *E. coli* occurrence and violation rates (2) the characterization of the types of corrective actions that systems will implement and the percentages of systems that will implement certain corrective actions (3) the methodology and assumptions used to predict the net impacts in total coliform-positive (TC+) samples, *E. coli*-positive (EC+) samples, acute violations, assessments, and corrective actions between the current TCR (with and without the effects of the Ground Water Rule), the AIP, and the Alternative Analysis (4) the use of reduction in *E. coli* and TC occurrence and acute violations as endpoints for informing benefits.

Since the text of the rTCR was not available to the committee, the members relied solely on the text of the AIP to inform this task and their evaluation. This Executive Summary highlights the outcome of the Committee's deliberations.

The Committee commends the Agency for all the work and analyses undertaken. They took on a sensitivity analysis which greatly increases confidence in the assessment. There was also only a limited amount of data from the Safe Drinking Water Information System – Federal Version (SDWIS/FED) and six-year review databases used in the EA deemed useful for the rTCR analyses and the Agency did a good deal of work and put a significant amount of thought and effort into addressing those segments of the database that would be useful. The work of the Agency in engaging with stakeholders and developing the Agreement in Principal which addresses goals for improvement and research needs was laudable.

The Committee found that the Agency's statistical analysis of the TCR monitoring data used to inform the prediction of the underlying baseline total coliform and *E. coli* occurrence and violation rates is reasonable but would benefit from some refinements and further explanation. The Agency is commended for the development and application of a statistical approach to a large, complex dataset, thereby enabling the analysis of a difficult and diverse problem. The Committee had considered recommending various improvements on the analytical work done, but noted that the proposed changes were unlikely to show a substantially different result and would involve a significant effort over a protracted period. Instead, the Committee suggested that some of the key issues should be further explored through limited sensitivity analyses. The Committee ultimately found that these additional analyses, together with the work already performed, would provide a sufficient basis for adequate predictions and descriptions of total coliform and *E. coli* occurrence and violation rates.

The Committee noted, however, that while the analysis was well done, there was insufficient background explanation of the assumptions and methods used in the analysis needs improvement. The Committee was unable to ascertain whether the analysis was reasonable solely by reading the materials provided. For example, the Data Quality Report which was referenced through the document was not available to the Committee. Several assumptions were not stated or were not clearly explained. The approach was not completely described, and the analysis and critical assumptions are in need of further justification.

The Committee agreed that the Agency's characterization of the types of corrective actions that systems would implement was reasonable and complete. Corrective actions are closely aligned with the assessments that must follow positive TC/EC test results during routine system monitoring. The Committee recommends the Agency explain how it compiled this list of corrective actions, and where the information came from (i.e., from expert discussions in the Technical Workgroup of the TCRDSAC, and from information provided by utilities). In working with states, the Agency found that 10% or less of the utilities were able to find the cause of the coliform or *E.coli* occurrence and as a result take corrective actions. Thus there is a central estimate that 10% of the small systems will take corrective action which represents only a modest benefit from the current rule. This is without the impact of the *Ground Water Rule*. However, some corrective actions may be undertaken without knowing the exact cause, such as implementation of a flushing program. Therefore, the Committee recommends that the sensitivity analysis use a wider range of corrective action implementation including corrective actions up to and including 50%, especially after a Level 2 assessment. Disinfection seemed to be the main corrective action considered. If this is correct, then, this fact should be stated, and if it is not, then the other corrective action options, their costs, and the sensitivity analysis results should be clearly discussed. The Committee also questioned whether the benefits of flushing would result in reduced risks for as long as several years as used in the model unless this is a routine flushing program and this should be clarified. Such assumptions should also have justification.

The framework and methodology of the Economic Analysis (EA) appear to be consistent with a properly conducted EA based on the USEPA Guidelines for Economic Analysis (2000). The USEPA guideline should be referenced so that readers understand where the framework for this EA originates and better understand the reasoning behind the rTCR EA structure. The Committee recommends that an analysis and discussion in the EA would better inform policy makers by identifying and summarizing all the variables with known distributions. Further, it should also be clearly noted that the EA model is developed as a reference baseline and has yet to be validated as a predictive tool.

The Agency will need a database that is far more robust than the six-year data review database used in the EA to improve the vigor of the model. The long list of assumptions needs to be reduced via better more focused data collection. Further, it is not clear from the analysis that the savings in the annual national costs accomplished by the reduced monitoring strategy are not offset by an increased risk of waterborne disease outbreaks or endemic waterborne disease. Overall, the Alternative Analysis (AA) appears to address and protect public health sooner in time than the AIP proposed implementation.

The Committee struggled in trying to determine whether there are measurable health-related benefits attributable to the revised Total Coliform Rule. If the goal is to protect public health, the Committee felt that measuring reductions in total coliforms (TC) and *E. coli* (EC) occurrences are **not** effective **sole** endpoints for informing benefits because of the difficulties in linking these indicators to adverse human health outcomes. A decrease in the number of acute violations is expected with the assumption that assessment and the implementation of appropriate corrective action will provide a concomitant decrease in waterborne disease and occurrence of acute violations. The Agency's proposal to use TC as part of an overall treatment technique, where TC-positive sampling results would trigger an assessment to identify sanitary defects instead of having an MCLG/MCL for TC, is seen as a positive step forward. However, several other indicators could be considered, as TC, in itself, is not an adequate measure of health risk. Even though *E.coli* is viewed as more appropriate measure of risk, of enteric disease, it does not capture the health risks from *Legionella*. Other measures, including structural and hydraulic integrity, have been recently considered in a report by the National Research Council and may provide valuable supplemental information on health risks from distributed water.

BACKGROUND ON THE REVISIONS TO THE TOTAL COLIFORM RULE (TCR)

The Total Coliform Rule (TCR), established in 1989, is one of the primary national regulations governing the microbiological quality of treated drinking water in the US. As such, it is an important element for protecting against waterborne disease. Each standard is mandated by law to be reviewed and revised, if appropriate, every six years as part of the existing drinking water regulations requiring revisions to improve/maintain public health protection, including the TCR. As part of the review and in order to revise the TCR, the Agency and its advisory committees conducted a substantial amount of work, which included the evaluation of available data and research on aspects of distribution systems that may create risk to public health. The Agency also began working with stakeholders to address controls for cross connections and requirements for backflow prevention in distribution systems, as these are known to be associated with significant risks, but in some cases, may be out of the water system's direct line of control. (C. Rodgers-Jenkins, USEPA, Office of Water, SAB teleconference presentation, 5/20/09).

The Agency began the review of the 1989 TCR in 2003. Based on stakeholder comments, the Agency prepared a series of white papers on the TCR and distribution system issues (2003-07). In July, 2007, the Agency established the Total Coliform Rule/Distribution System Advisory Committee (TCRDSAC). The TCRDSAC consisted of fifteen members representing the Agency and state regulators, water utilities, local governments, environmental advocates, public health professionals, consumer advocates, and Indian tribes. The Agency charged the TCRDSAC with two major tasks; 1) provide the Agency with recommendations on how best to revise the TCR, and 2) develop information and research needs to improve the understanding of the risks posed by distribution system issues. TCRDSAC then formed a technical work group (TWG) to provide data analysis and information to contribute to the discussion of the Committee. An Agreement in Principle (AIP) was developed as a result of these discussions, and the AIP is being used as the foundation for the proposed Revised Total Coliform rule (rTCR). TCRDSAC met thirteen times between 2007 and 2008. Each representative on the TCRDSAC agreed to support the proposed rTCR components that reflect the elements of the AIP.

Highlights of TCRDSAC recommendations are: 1) There will no longer be an MCL/MCLG for total coliforms (TC); 2) TC- and *E. coli* (EC) positive sampling results will trigger investigation (assessment), leading water managers to find the problem and fix it; 3) Monitoring on a quarterly and annual basis may be allowed for some small ground water systems; 4) Distribution system research and information collection need to be a priority; 5) There will be an overall shift in focus from monitoring results that lead to public notification to monitoring results that trigger an assessment and corrective action. Benefits from this recommendation are that a more proactive approach to public health protection can be instituted which should reduce confusion associated with the actions needed for TC violations. The Agency stated that it was committed to proposing a rule consistent with TCRDSAC recommendations. The initial rule will be proposed in 2011. The final rule will be proposed in 2012, and compliance with the final rule is expected in 2015.

The Agency's recommendations in the rTCR are to use TC as part of an overall treatment technique, where there is no MCLG/MCL for TC, but where TC-positive sampling results would trigger an assessment to identify sanitary defects. A sanitary defect finding would then trigger corrective action. A treatment technique (TT) violation would be assessed if the investigation or corrective action was not completed. The Agency would retain an MCLG = 0 for *E. coli* and the current MCL associated with presence of TC/EC. The Agency would not use fecal coliforms as a water quality indicator in this Rule, and there would be public notification for TT or acute MCL violations.

For systems serving ≤ 1,000 people, there are new criteria for both increased and reduced monitoring, a transition from the existing monitoring frequency unless the primacy agency determines otherwise and a decrease in the number of additional routine monitoring and repeat monitoring samples. For systems serving > 1,000 people, there are no changes in routine monitoring but a decrease in repeat samples and the elimination of additional routine monitoring for systems serving ≤ 4,100 people.

As a principle of the assessments, the rTCR would pro-actively enhance public health by identifying sanitary defects and incorrect monitoring practices. In this new scenario, the public water system (PWS) is responsible for the investigation which should ensure barriers are in place and effective. Two levels of assessment would be created based on the severity of the trigger, Level 1 and Level 2. The systems would be required to correct all sanitary defects found in the assessments. A TT violation would consist of: 1) failure to perform a Level 1 or 2 assessment when triggered, 2) failure to correct all sanitary defects identified in the assessment, and 3) failure to correct sanitary defects according to an agreed upon schedule. Four types of violations that need public notification are: 1) an *E. coli* MCL violation (Tier 1); 2) a treatment technique violation (Tier 2); 3) a routine monitoring violation (Tier 3); and 4) a reporting violation (Tier 4).

It should be noted that the data analysis to support the revisions to the TCR are based on current and historical water quality data and practices in the United States. The SAB DWC comments are tailored specifically to those water quality data and practices. Revisions to the TCR should not be extrapolated to other situations without due consideration of the historical water quality data and water treatment/distribution practices in those regions. Rules governing the microbiological quality of water distributed for drinking water in other regions should not be revised or modified based on solely on this analysis and critical review without considering the context in which these comments are made.

INTRODUCTION

This report was prepared by the Science Advisory Board (SAB) Drinking Water Committee (DWC) (the "Committee") in response to a request by the Agency's Office of Water (OW) to review their draft supporting analysis for the proposed Revised Total Coliform Rule (rTCR). The Committee was asked to focus on information regarding (1) the data sources used to estimate baseline total coliform and *E. coli* occurrence, public water system profile, and sensitive subpopulations in the United States, (2) the occurrence analysis used to inform benefits analysis, (3) the qualitative analysis used to assess the reduction in risk due to implementation of the rule requirements and (4) analysis of the engineering costs and costs to States resulting from implementation of the revisions.

The SAB DWC was asked to comment on the scientific soundness of the supporting analysis for the rTCR, not on specific provisions of the rTCR itself. The Committee deliberated on the charge questions during their June 9-10, 2009 face-to-face meeting. The responses that follow represent the views of the Committee.

The specific charge questions given to The Committee are included on the following page:

Charge Questions to the Science Advisory Board, Drinking Water Committee

The Agency requests that the SAB Drinking Water Committee review the materials provided and provide recommendations in the areas specified in the charge questions. As the Committee considers the specific charge questions that follow, it is asked to consider whether the overall approach that the Agency has taken to assess the impacts of rTCR is appropriate, given the availability of the information, and, if it is not, whether there are alternatives that might be considered.

11. Is the underlying statistical analysis of the TCR monitoring data used to inform the prediction of the underlying baseline total coliform and *E. coli* occurrence and violation rates reasonable? If not, what changes or refinements might be appropriate?

42. Is the characterization of the types of corrective actions that systems will implement and the percentages of systems that will implement certain corrective actions reasonable? If not, what else might be considered?

73. Are the methodology and assumptions used to predict the net impacts in total coliform-positive (TC+) samples, *E. coli*-positive (EC+) samples, acute violations, assessments, and corrective actions between the current TCR (with and without the effects of the Ground Water Rule), the AIP, and the Alternative Analysis reasonable? If not, what alternatives might be considered?

114. Are reduction in *E. coli* and TC occurrence and acute violations appropriate endpoints for informing benefits? Do they appropriately capture the added value of the proposed revisions? If not, what other analyses or endpoints might be considered?

The following attachments were included to facilitate the SAB discussions:

- Draft Supporting Analyses
- Baseline Conditions
- Occurrence and Predictive Model
- Benefits Analysis
- Cost Analysis
- Draft Technology and Cost Document
- Agreement in Principle
- Background on Current TCR and Rule Revisions Development (presentation)
- Comparison of Current TCR Requirements with the AIP and Alternative Analysis (table)

RESPONSE TO THE CHARGE

DWC's Overall Critique of Revisions to the Total Coliform Rule (TCR)

The DWC evaluated the five TCRDSAC recommendations and found them to be mostly appropriate. First, the total coliform (TC) has little relationship to fecal pollution and public health risk, and thus it is appropriate that there is no longer an MCL/MCLG for total coliforms (TC). The second recommendation, that TC- and *E. coli*- positive sampling results will trigger investigation (assessment) that is intended to lead water managers to find the problem and fix it. This should place an emphasis on investigating and correcting the deficiencies, rather than on just reporting them. The third recommendation, that monitoring on a quarterly and annual basis may be allowed for some small ground water systems, is appropriate as long as these systems have demonstrated the ability to maintain microbiological water quality and groundwater protection, particularly during the rainy seasons. The fourth recommendation, that distribution system research and information collection need to be a priority, is also appropriate. The fifth recommendation, of an overall shift in focus from monitoring results that only result in public notification to monitoring results that trigger an assessment and corrective action, is a significant advancement if it is properly executed. It places the emphasis where it should be, on corrective action. The DWC agrees that benefits from this more proactive approach to public health protection should reduce confusion associated with what follow-up actions are necessary and taken for TC violations. However the DWC notes that the EPA analysis appears to contradict the stated goals of the rTCR by assuming only rare (10% of cases) corrective actions.

The Agency's recommendations of using TC as part of an overall treatment technique, where TC-positive sampling results would trigger an assessment to identify sanitary defects instead of having an MCLG/MCL for TC, is seen as a positive step forward in principle. The fact that a sanitary defect finding would trigger corrective action is also very good and appropriately places more emphasis on remedial action. The DWC agrees that a treatment technique (TT) violation should be assessed if an investigation or corrective action was not completed. The DWC also agrees that the Agency should retain an MCLG = 0 for *E. coli*, as well as the current MCL-associated with the absence of TC/*EC*, and not use fecal coliforms as

indicators of water quality in this Rule. There should be public notification for any TT or acute MCL violations.

For systems serving ≤ 1,000 people, there are new criteria for increased and reduced monitoring, a transition with existing monitoring frequency unless primacy agency determines otherwise and a decrease in number of additional routine monitoring and repeat monitoring samples. For systems serving > 1,000 people, there are no changes in routine monitoring but a decrease repeat samples and elimination of additional routine monitoring for systems serving ≤ 4,100 people. The DWC is skeptical that the monitoring frequencies for small systems (< 1,000 people) will provide a change to the TCR that improves public health protection. The DWC is not generally supportive of decreased monitoring. Given the highest percentage of TCR violations occurs in the smaller systems, it appears as though small systems are more vulnerable and are more likely to experience a waterborne outbreak. Thus, this vulnerability may be better captured with improved comprehensive assessments. The problems in the sanitation of these small water systems, which do not have substantial capital and personnel to monitor their systems comprehensively, may only be best controlled through a required monitoring scheme.

The DWC agrees that in this new rTCR scenario, the PWS should be responsible for assessment, and this should strengthen their capacity to ensure barriers are in place and effective. DWC also agrees that there should be two levels of assessment, based on the severity of the trigger, Level 1 and Level 2, and that the systems should correct all sanitary defects found in the assessments. A TT violation would consist of failure to perform a Level 1 and/or 2 assessment when triggered, failure to correct all sanitary defects identified in the assessment, and failure to correct sanitary defects according to an agreed upon schedule. The public notification continues to be important and should include not only a description of the violation but also the necessary follow-up remedial actions. This would assist in alleviating public concerns that the PWS is not attending to the problems. The four types of violations that need public notification are: 1) an *E. coli* MCL violation (Tier 1) which may be of immediate public health concern; 2) a treatment technique violation (Tier 2); 3) routine monitoring violation (Tier 3); and 4) a reporting violation (Tier 4). DWC agrees with these revisions to the TCR.

It appears from the table provided to the DWC, entitled, "Comparison of Current TCR Requirements with the AIP and Alternative Analysis," that the PWS can still do its own assessment (left to the discretion of the primacy agency; but the person doing the assessment is required to have specific qualifications, unlike a Level 1 Assessment), even if the PWS's lack of action results in frequent Level 1 triggers that then lead to a Level 2 assessment. This could result in a public health risk that may be unaddressed in a timely fashion. (if the issue is raised to a Level 2 Assessment the primacy agency should be deeply involved.) The Drinking Water Committee (DWC) generally agrees that the assessment concept will orient the PWS toward action and that this will likely improve the microbiological quality of the drinking water delivered.

Charge Question 1. **Is the underlying statistical analysis of the TCR monitoring data used to inform the prediction of the underlying baseline total coliform and *E. coli* occurrence and violation rates reasonable? If not, what changes or refinements might be appropriate?**

The data analysis is reasonable, and the Agency is commended for its systematic and thoughtful analysis of such a large dataset. The documentation of the analysis in Chapter 5, however, should be improved, which will address transparency and clarity. The Committee recommends that Chapter 5 be revised with details which allow the reader to understand what was done, and all key assumptions should be clearly stated and justified. The Committee also suggests that further sensitivity analyses be undertaken.

The Agency did a good job analyzing a difficult and diverse problem. This involved developing and applying a statistical approach to a large, complex dataset. Positive samples for different classes of water systems were characterized and used for prediction. Water systems within a class were allowed to vary in their characteristics. The approach was reasonable and appears well executed. A significant amount of thought went into structuring the problem and the analysis.

The Committee had considered recommending various improvements on the analytical work done, but noted that the proposed changes were unlikely to show a substantially different result and would involve a significant effort over a protracted period with little added benefit. Instead, the Committee suggests that some of the key issues be further explored through a limited sensitivity analyses. The Committee ultimately finds that these additional analyses, together with the work already performed (with a few refinements discussed below), will provide a basis for adequate predictions and descriptions of total coliform and *E. coli* occurrence and violation rates.

In making these findings, the Committee notes, however, that the explanation of the analysis is deficient. The Committee was unable to ascertain whether the analysis was reasonable solely by reading the materials provided, including Chapter 5, where the analysis is laid out. Several assumptions are not stated or are not clearly explained. The approach is not completely described, and the analysis and critical assumptions need further justification.

The Committee was only able to understand what was done as a result of the discussion during the meeting. The Committee members had to ask a number of clarifying questions to understand the analyses performed. EPA staff explained what was done and why. After hearing these explanations, the Committee was satisfied that the analyses performed were reasonable and, with a few minor refinements noted below, adequate and, in fact, commendable.

The Committee recommends that Chapter 5 be revised to describe the analysis in sufficient detail so that the reader can understand the basics of what was done. Assumptions should be stated clearly and justified. The key assumptions that affect the entire analysis should be stated early in the chapter, and better justified. Implicit assumptions should be stated and explained. The basic elements of the analysis should be clearly described. As the chapter currently stands, the reader is left to use his or her judgment as to whether the assumptions are justified and what was done.

The Committee does recognize that the analysis performed is complex and somewhat difficult to explain, and that it may take extra effort than may typically be the case to make the chapter clear and understandable. It may help to have a number of technically facile, non-expert readers review the revised chapter to see whether they understand the analysis, whether they could explain it to someone else based on what was written, and whether they find the analysis including assumptions adequately justified. Specific comments, suggestions and recommendations are given below.

Assumptions to Justify and Explain

Some examples of assumptions and procedures are provided below that would benefit from better explanation. These are given only as examples, and we leave it to the Agency staff to work through the chapters to make sure that all major assumptions are clearly articulated and adequately explained. Again, the Committee is recommending that the key assumptions be presented early, and that other minor ones are explained as they occur in the description of the analysis and results.

- It is not clearly stated that a main goal of the model fitting exercise is to get a characteristic distribution of probability of positive hits for each water system class, and that the distribution is representing how systems within the class vary from one another in that probability. The reader is left to guess what the distribution is supposed to represent.

- There needs to be an explanation of basic model structure. Exhibit 5.2 appears to be an attempt at showing how different parameters in the beta distribution are related to one another for different systems within a water system class. The title is very general, and the exhibit has no legend. Subscripts are used to indicate the different water systems within the class; however, the subscripts are not used anywhere else in the chapter. What would be a difficult concept to convey with full annotation is totally incomprehensible. The reader is left to guess what the subscripts in the figure mean and how they relate to the analysis. The figure also needs a more explanatory title. If the figure is retained, it

needs to be explained in a figure legend and in the text. The Committee also recommends the addition of another illustration to show data inputs and model outputs, with full accompanying annotation and description.

- The reason for assuming that seasonality does not impact the analysis should be discussed and justified, perhaps through a sensitivity analysis.

- There is a hierarchy to the analysis that is left unexplained. Each water system class has its own characteristic beta distribution. Yet, alpha and beta in the figure and text are not subscripted. In the text, the probability parameters, number of samples (binomial "N"s), positive samples (binomial "K"s), all have no subscript. In the figure, for example, subscripts were left out of equations (such as on p 5-7). This made it unclear that they were relevant to each individual system. While the use of subscripts can be avoided, the underlying assumptions need to be clear, e.g., be clearer about the fact that independent analyses (probability distributions) of the routine and repeat samples were performed.

Explaining and Disentangling Uncertainty and Variability

Within a given system classification, water systems can vary considerably in terms of whether they will test positive and in terms of their violation rates because some of the causes for TC positives are not under the control of the PWS. For some classes of systems, there may be a large number of systems within the class and the certainty regarding how much they vary from one another and the difference in their average characteristics may be high. For other classes, there may be far fewer observations which may contribute to less certainty. Thus, both uncertainty and variability are an issue in the analysis. The Committee found that the document needed to be clearer in how these issues were handled and suggests that Chapter 5 and the analysis address the issue through a sensitivity analysis and in graphical presentations.

Chapter 5 could, for example, include a figure plotting positive occurrence rates for some different prototypical classes of systems. This would provide the reader a visual representation

for how systems can differ within a class. Chapter 5 could also provide plots of the maximum likelihood estimate for mean positive occurrence for a system class and display the uncertainty in that estimate. Agency staff has developed some plots like this that could be annotated and included with proper explanation in the document. Plots that disentangle uncertainty from variability would be helpful. On the basis of the discussion with Agency staff, the Committee believes that these plots have been done and that the analysis is fine in this regard, but the presentation is somewhat lacking.

The Committee recognizes that there are data gaps and that assumptions based on best professional judgment were made. Therefore, the Committee is not recommending a full Monte Carlo analysis of uncertainty; rather, we suggest the issue be explored in a limited way in a sensitivity analysis. The analysis can be qualitative or semi-quantitative and should explain how uncertainty in the beta distribution for classes, where uncertainties are relatively large, may affect the ultimate result. The Agency stated that uncertainties are greatest for classes with few observations, and that this is due to the fact that the actual number of systems in the class is small. However, while this may be a reasonable rationale, it might also be due to one or two outliers that skew the distribution. The Committee suggests that some simple calculations should adequately illustrate that the overall result is robust and the rationale has been tested rather than assumed.

Criterion for Significance and Combining Data Sets

In a number of places, the chapter asserts that systems do not significantly differ in the probability that they will test positive for total coliform. That finding is used to justify combining data sets for different types of systems. The criterion for testing significance and for deciding to combine or not combine different data sets should be more explicitly stated and perhaps more rigorously done, including a statistical power test. Figure 5.3 is the only attempt to explain this combining, and both the figure itself and the explanation of for combining data sets are weak.

In the Agency's analysis, the criterion for deciding whether there is a significant difference in probabilities is based solely on whether there is a difference in the mean probabilities of a positive test result for the two systems being compared. However, some system types can have the same mean, yet the systems may vary within that class. An analysis of a class of non-disinfected water systems may, for example, include a large number of systems on a pristine water source in a cold climate, and at the same time also include a large number of systems with a not so pristine source. The variance for this class can have a wide frequency distribution, but the mean may be the same as that for another class that is more homogeneous but relatively pristine. Violations may be more common in the first class than the second. Thus, in addition to the mean, the variance should also be considered. The beta distributions for these two classes will differ. Therefore, an alternative criterion for combining could be based on the hypothesis that both systems have the same beta distribution.

Charge Question 2. **Is the characterization of the types of corrective actions that systems will implement, and the percentages of systems that will implement certain corrective actions, reasonable? If not, what else might be considered?**

To answer charge question 2, the Committee reviewed Chapter 5, Appendix D, and the *Technology and Cost Document for the Revised Total Coliform Rule.* The Committee agrees that the Agency's characterization of the types of corrective actions that systems will implement is reasonable and complete. The types of corrective actions can be ascertained from current practices. Corrective actions are closely aligned with Level 1 and 2 assessments following positive TC/EC testing during routine system monitoring. Both assessments are intended to be part of a proactive approach to identify sanitary defects that may put public health at risk, due to the potential exposure to and consumption of contaminated potable water. Such contamination can arise from source water (not a sanitary defect; the lack of a barrier or ineffective treatment is the defect) and ineffective treatment, any practice or event that results in intrusion into the distribution system, or reservoirs such as biofilms and stagnant and aged waters within the system itself (these are not sanitary defects as they are not pathways into the system that can

result in intrusion nor are they ineffective treatment or loss of a barrier; they are a result of poor operation and maintenance practices).

The rTCR clearly recognizes these issues and uses an assessment process to initiate analysis of system variables that trigger corrective actions. Assessments are intended to aid in the following:

1) Identifying inadequacies in sampling sites and protocols, sample processing and presumably appropriateness and QA/QC of the TC/EC analytical methodology.
2) Identifying atypical events such as storm flows or construction breaks affecting or indicating impaired water quality.
3) Identifying changes in distribution system maintenance and operation that may affect water quality.
4) Identifying changes in source water quality and/or treatment resulting in the potential for impaired water quality.
5) Identifying inadequacies in the underlying WQ monitoring data itself.

These assessment elements and corrective actions are clearly identified in supporting documentation for the rTCR, specifically in the *Technology and Cost Document for the Revised Total Coliform Rule*. However, they could be more clearly listed in Chapter 5, so the reader does not have to delve into supporting reports to find the information. Cost estimates principally for salary and wages (including monitoring, reporting, and operations and analytical analysis) are also provided. The corrective actions are summarized as follows:

1) Flushing
2) Sampler Training
3) Replacement and Repair
4) Pressure Maintenance
5) Hydraulic Residence Time Maintenance
6) Storage Facility Maintenance

7) Booster Disinfection
8) Cross Connection and Backflow Prevention
9) On-line Monitoring and Control
10) General Security Measures
11) Standard Operation Procedure Training and Implementation

The Committee recommends that the Agency explain how it compiled this list of corrective actions, and where the information came from (i.e., from expert discussions in the Technical Workgroup of the TCRDSAC, and from information provided by utilities). It is important for the Agency to acknowledge that this is not a definitive list of all actions that could be taken and that it is possible that even if all these actions were implemented in a system, that all total coliform positive observations may not be eliminated. Coliform-positive samples may be the result of numerous factors in a water system, including cross connections, construction, sampling, etc. It is also noted that a Level 2 assessment mandates that a "certified" operator must respond to violations. Certification is rather ill defined and is a responsibility of the individual State. The expertise of the "certified" operator will be very important in determining the efficacy of the investigations, and the percentage of systems taking corrective action after Level 2 assessments.

The list of corrective actions appears somewhat dismissive of investments in analytical methods and monitoring, source water analysis, water quality databases and analysis resulting from the Level 1 and 2 assessments. Real time microbial monitoring, ultimately capable of targeting specific pathogens of direct public health significance, is on the horizon and real time residual chlorine monitoring is only a limited surrogate approach.

Analysis of Percentage of Systems Implementing Corrective Action

The percentages of systems that will implement corrective actions are un-knowable, so there is nothing the Agency or the DWC can do except to take a best guess. An estimate that is based on expert judgment is a reasonable approach to this situation. Two things need to be done when taking a best guess: (1) a careful justification of what expert information sources were relied upon, and (2) a sensitivity analysis. The Committee commends the Agency for doing the latter, which greatly increases confidence in the assessment. However, the Agency could do a much clearer job justifying and explaining how it arrived at these numbers. Specifically, there should be some text explaining the tables in Appendix D, and there should be reference to Appendix D and the list of corrective actions in Chapter 5. As the tables stand now, it appears that large surface water-community water systems (SW CWS) would do nothing in response to a TC positive; zero percent implementation is assigned for all Level 1 Corrective Actions for those system categories. Presumably, this is because large systems are assumed to already be doing assessments and corrective actions. The Agency should clearly document the logic for these assigned values.

Based primarily on the results of a limited survey of current TCR requirements, the Agency estimates that corrective actions will on average be implemented only 10% of the time (section 6.2.7 and associated footnote 1 on page 6-8). It is surprising that such a relatively small percentage of systems are projected to take some kind of corrective action – at least by flushing their systems - after a Level 1 or Level 2 event. We expect that flushing would (and should) be a more common practice. Therefore, we think it would be justifiable for the Agency to use a greater than 10% likelihood of taking corrective action. In addition, after a Level 2 event, a serious assessment, done by a certified operator, should find some type of corrective action that can be taken in most small systems, especially if the menu of corrective actions includes a switch to disinfection.

This entire discussion appears overly weighted on the influence of the ground water rule (GWR) and instituting disinfection processes for GW. Does implementation of disinfection in ground water (GW) systems bias the presumed 10% of corrective action? The sensitivity analysis uses a range of 5-20% of corrective action implementation. We suggest a broader range

for analysis, including corrective actions up to around 50%, especially after a Level 2 assessment. In addition, if disinfection is the main corrective action, this should be stated. If it is not, then the sensitivity analysis results should be clearly discussed for other corrective action alternatives and the costs associated with them.

Assessment and corrective actions are well described. However, the discussion of corrective action appears to rely on an overt fallback position that emphasizes flushing in response to a positive monitoring result. While offering immediate public health protection, flushing alone may not provide solutions to the underlying problem causing the positive TC/EC monitoring result. Therefore, the Committee questions whether the benefits of flushing will result in decreased risks for several years, as the Agency currently estimates in the model. The Committee recognizes that from a utility perspective, flushing and disinfection is a cost effective solution, if the origins of the TC/EC cannot not be adequately documented, thus avoiding potential costly repair and replacement corrective actions that may not ultimately be warranted. It makes sense to switch some proportion of GW systems to long-term disinfection in the model, and thus change their attributed rates accordingly after a positive finding.

Overall, the challenge laid down to the Agency by the TCRDSAC was to come up with a revised TCR that will foster continuous improvement in the industry by encouraging assessments and corrective actions. It is discouraging to see that the Agency's projections do not fully realize that vision. The rule should be designed so that a larger percentage of small systems would take corrective actions that result in long-term benefits. The central estimate of 10%, although perhaps realistic, represents only a modest benefit from the rule, although it may be better than the *status quo* for small systems. It would be useful for the Agency to run the model with a significantly higher percentage of corrective actions (i.e., 50%), to determine whether the benefits would increase substantially if the rule can be designed such as to achieve these higher rates.

The AIP recognizes the evolution of analytical capabilities (section 3.2) for TC and EC. As part of Assessment and Corrective Action, best available methods are appropriate. As an

active area of research, future relevant analytical methodologies should be embraced as they become available, and the rTCR should not be constrained to current best available technology. It is important to note that while various methods may report TC, not all the TC's mean the same thing. There is an ongoing study comparing the methods and the AIP contains a component that addresses it. The Committee also suggests that the Agency consider moving to alternative measures other than TC which they believe is not a reliable indicator from a public health perspective.

Monitoring needs are also identified. As part of research and information needs (4.2.c), Tier 1 should include molecular microbial methods, stable isotope ratio techniques, and mass spectroscopic analytical methods for source and contaminant identification which need to be developed to assist in focused corrective action, rather than corrective action in immediate response to a rTCR monitoring violation. Tier 2 needs emphasis on human and animal pathogen detection and real time monitoring.

Charge Question 3. **Are the methodology and assumptions used to predict the net impacts in total coliform positive (TC+) samples, *E. coli*-positive (EC+) samples, acute violations, assessments, and corrective actions between the current TCR (with and without the effects of the Ground Water Rule), the AIP, and the Alternative Analysis reasonable? If not, what alternatives might be considered?**

The framework and methodology of the Economic Analysis (EA) appear to be consistent with a properly conducted EA based on the USEPA Guidelines for Economic Analysis (2000). The USEPA guideline should be referenced so readers understand where the framework for this EA originates and better understand the reasoning behind the revised total coliform rule (rTCR) EA structure. Using this framework, the Agency should guide the reader through the EA clearly pointing out elements that were completed, where assumptions were made, and where steps were omitted (along with justification for omitting them).

The Council for Regulatory Environmental Modeling notes in their November, 2003, guidelines, both an uncertainty analysis and a sensitivity analysis should be conducted on any model developed and used as a basis for a regulatory decision. The term "uncertainty analysis" itself can lead to confusion, because an overall Uncertainty Analysis (UA) is composed of two separate components, sensitivity and uncertainty, one of which uses the same term as the overall analysis itself. Both components are necessary to complete the overall uncertainty analysis. The sensitivity analysis illustrates the degree of impact that one variable has on the outcome when all other values are held constant (possibly using a median or average value), such as the use of the lower and upper bound estimates used in the rTCR EA.

Unlike the sensitivity analysis, the uncertainty analysis examines the inherent variability in the data and its subsequent impact on the distribution of the output. Some variability is inherent and a portion may be associated with the measurements used to characterize the population. The Agency should identify the sources of uncertainty and determine the level of confidence that should be placed in the final results.

In reviewing the EA guideline, it is apparent that one deficiency in the rTCR uncertainty analysis originates from the guideline itself and is not a deficiency introduced by the rTCR EA. While the EA guideline does admit the approach outlined may be different than what other disciplines consider a complete uncertainty analysis, the USEPA EA Guideline appears to discuss conducting an Uncertainty Analysis (UA) only. The Agency should identify that the UA is comprised of a single part, the sensitivity analysis. Since the Agency's EA guideline is not a regulation or legislated requirement, its structure and content are not so rigid as to preclude interpretation and improvement, when and if the application warrants it. In this case, the Agency should point out that the UA in the EA is only comprised of a sensitivity analysis, which does not include an actual evaluation of uncertainty associated with the output. The analysis and discussion in the EA would better inform policy makers by identifying and summarizing all the variables with known distributions, and those without, to aid risk managers with the interpretation of the results.

The EA also seems to assume that the variables for which there are no data will not have a significant impact on the overall uncertainty. Until the EA can better characterize the error associated with the output, one should be cautious about inferring too much from the results. Statements, such as the one beginning on line 23 pg 5-31 (and others similar to it), should be made with consideration for the error or uncertainty surrounding the outcome, as the observed difference is probably not significant. The EA discusses some differences as if they are significant and other differences as if they are not, without a simultaneous discussion as to how the difference is judged to be significant in one case, but not in the other.

When evaluating the baseline condition, the admission that data are missing from 15 states, including states with large populations (California, Florida, and Pennsylvania), requires additional discussion on what impact this data gap might have on the final result. In addition, the number of states submitting TC and EC data in each tier (1 – 4) is not described. Again, there is no discussion of how the missing data may have biased the baseline estimate.

In addition, the Committee recommends that in regard to the effectiveness of the corrective actions to reduce future TC- and EC-positive samples, the Agency should repeat the analysis with values for the percentage of communities that will actually implement corrective actions from 1% for the less effective corrective actions to 50% for the most effective. In addition, it is not clear that the reduced monitoring strategy offers significant savings in the annual national costs for the assays that are not offset by an increased risk of waterborne disease outbreaks. Overall, the Alternative Analysis (AA) appears to provide public health protection in a more timely fashion than the AIP .

The Drinking Water Committee (DWC) of the Science Advisory Board (SAB), while providing comments on the methodology and assumptions used to predict the net impacts of the rTCR under the current TCR, AIP, and Alternative Analysis (AA), cannot provide an adequate assessment which could serve as a substitute for an Uncertainty Analysis. In this EA, one can argue the Uncertainty Analysis is not complete, because of the undefined or ill-defined

distributions associated with many of the input variables. Regardless, it appears that the EA represents the best possible analysis given the paucity of available data.

Safe Drinking Water Information System (SDWIS)/Federal Version (FED) and 6-year Review Databases

The Total Coliform Rule is the drinking water rule that applies to all public water systems regardless of size, source or treatment. Utilities across the United States have invested billions of dollars in monitoring to meet the requirements of this rule. Unfortunately, data management for these data has been challenging. There was only a limited amount of data from the Safe Drinking Water Information System – Federal Version (SDWIS/FED) and six-year review databases used in the EA deemed useful for the rTCR analyses. Given this limited data, there was still a good deal of work, along with a significant amount of thought and effort, expended on identifying those segments of the database that would be useful. A large amount of data has been gathered and screened by the USEPA when the States voluntarily submitted electronic monitoring data reflecting records from l998-2005.

In estimating the baseline in Chapter 4, there is one troubling assumption - basing the analysis solely on one year (2005) out of six years of total coliform (TC) and enteric coliforms (EC) occurrence data. The Agency states, "Using only a single year of data was beneficial in that it [*sic*] simplified the analysis…" (page 4-6, line 36). This assumption completely ignores potentially large inter-annual differences in TC and EC occurrence. Such differences could be driven, for example, by inter-annual variability in precipitation patterns, which the Agency acknowledges with the statement (line 39): "…changing environmental factors may be important." Even groundwater shows large year to year differences in the occurrence and quantity of human enteric viruses, as evidenced in studies of municipal wells. The baseline occurrence rate could shift up or down depending on which year of data is analyzed. It may be possible to evaluate the importance of TC and EC inter-annual variability using data from the states that submitted complete 6 year datasets. It may also be possible to clarify this issue by

expanding on the statement regarding the consistency of the TC-positive rates in the years outside the year selected for this analysis.

Further, it should be noted that the EA model was developed to produce a reference baseline and has yet to be validated as a predictive tool. The EA uses the SDWIS/FED database of violations as the reference for their model. The data for the model came from the six-year data review data set, which contained all sample results (with the stated limitations). The model output was compared to the SDWIS/FED data as the means of validating it. The violations in the SDWIS/FED database should reflect the sampling results in the six-year data review for those same periods of time, since the sampling results determine PWS compliance. However, this should not be considered a "validation" of the model as a predictive tool. A model should only be considered validated as a predictive tool if it can be shown that it accurately forecasts events that have not yet taken place. The EA model should be considered as being validated for establishing a reference baseline, but no more until additional data are available to confirm model output. The Agency will need a database that is far more robust than the 1 year of data from the six-year data review database used in the EA to validate the model and decrease the long list of assumptions used in the current EA (see comments in next section).

Given the scheduling of the revised total coliform rule (rTCR), the assumptions used to fill the data gaps identified in the six-year review database should be considered adequate for this EA. However, they indicate a deficiency in the data collection system that should be rectified prior to implementation of the rTCR. On page 4-7 one justification includes the line "...single year data allows for a single database." This implies that the databases were of such different structure that the years in the database prior to 2005 could not be combined into a single database. This points to a need to improve data management and collection practices. To address at least one of the items in Section 3.17 of the AIP, the Agency will need a database that is far more robust than the six-year data review database used in the EA.

To assess the long-term effectiveness of the rTCR (Section 3.17 of the AIP), the metrics will need to be established and the data collection systems put into place, before the rule is

promulgated. This will allow data collected, under the current TCR, to be used as a reference baseline against which future regulatory actions and their impacts can be compared. Failure to do so will result in the need to employ similarly weak assumptions in future regulatory documents and evaluations.

Corrective Actions

Filling data gaps by making assumptions is sometimes necessary, especially when the data needed are not available or have not been collected. Such is the case for the corrective actions in Exhibit 7.16. These data have never been collected, so the table was populated using the professional judgment of the TCRDSAC Technical Workgroup (TWG). However, the Agency should recognize that current data systems are not set up to collect this information as the rTCR moves forward. Until the data systems are set up to collect this information, future EAs and regulation assessments will be limited in their usefulness as quantitative assessments upon which risk managers can and should base their policy decisions.

The biggest red flag (assumption) is the effectiveness of the corrective actions in reducing future TC- and EC-positive samples. The Agency should repeat the analysis with more extreme values for the percentage of communities that will actually implement corrective actions, e.g., 1% for the less effective corrective actions and 50% for the most effective. It is not clear how the current values in the analysis -10%, 5%, and 20% - were selected. The extreme values are justified, in our opinion, given the absence of any previous knowledge on how well these assessments will be performed or the true long-term effectiveness of the corrective actions.

The assumption that systems following a corrective action will be TC -free for a period of time should be reconsidered. As the EA implies, there are a number of causes for a TC-positive result. Each of the causes may or may not be linked to a corrective action. In addition, the causes should be viewed as independent events. Just because a corrective action has been taken and a sanitary defect corrected, does not mean the public water systems (PWS) will be free of TC-positive results for a period of time. Granted, some actions may result in long-term solutions,

such as rebuilding a problematic sampling station or modifying sampling habits. However, given the reports on the aging infrastructure of our water distribution systems in the U. S. and the fact that distribution systems are continually being exposed to disruptive external conditions (plumbing activities, excavation, pipe replacement), assuming a system will be coliform-free for a period of time following a corrective action is a poor assumption. Assuming that a corrective action will result in TC and EC compliance for three to five years assumes that once a sanitary defect is found and corrected, a similar incursion won't happen again for another three to five years. As there are a variety of events, separated by time and space, that could produce a TC or EC violation, there is no guarantee that one of these events would not produce a TC or EC violation immediately following remedial action in an entirely different part of the system.

Each column or corrective action in Exhibit 7.16 represents an action triggered by an independent event. These actions are not dependent on each other. Thus, the corrective actions should not be pooled or linked. The causes listed Exhibit 7.16 appear to be all inclusive as each line (for a given size system) seems to add to 100%. By summing to 100% for a given size category, it appears as though the corrective actions listed are the only ones that could mitigate a sanitary defect identified in a Level 1 or 2 triggered assessment.

The list of corrective actions focuses on actions associated with the distribution system to correct a TC or EC trigger. The list does not include remedial actions taken on other components of the multiple barriers (source and treatment) that may contribute to a TC or EC trigger. The discussion of corrective actions should acknowledge changes or modifications made in the maintenance or operation of the treatment process train, as the assessments may trigger changes in or the addition of treatment. While it is assumed that the actions taken on the treatment barriers would be an appropriate response under the Groundwater Disinfection Rule (GWDR) or Surface Water Treatment Rule (SWTR), these actions may be triggered by monitoring in the distribution system under the rTCR and identified by the assessment. The linkage between the rules and the subsequent impact on the EA needs to be fully and clearly explained so the reader knows which impacts are being included and which have been attributed to previous rules.

The rTCR allows for reduced monitoring, which opens up a policy and technical issue regarding the adequacy of sampling. 1) The public water systems given more options to qualify for reduced monitoring are the small systems. Unfortunately, these are the very same systems most likely to have water sanitary quality problems. This is evident in Exhibit 4.10 where the public water systems (Community Water Systems + Non-transient, non-community water systems + Transient Non-Community Water Systems) serving a population size less than 1,000 are responsible for 90% (7,822/8,734) of the TCR violations! The DWC believes that these small water systems simply do not have the capital investment to provide the necessary monitory and corrective actions to reduce this high level of violations. A possible solution is to encourage smaller water systems to combine with larger systems to reduce the number of TCR violations. 2) The TC and EC assays are the only routine, widely-available distribution system monitoring tool for assessing and ensuring the microbiological quality of drinking water delivered to the public. The TC and EC monitoring has its limitations, but why does that translate to requiring less rather than more monitoring? 3) The TC and EC assays are inexpensive. It is difficult to believe that a reduced monitoring strategy offers significant savings in the annual national costs for the assays that are not offset by an increased risk (and costs) of waterborne disease outbreaks. 4) Our experience with viral pathogens in groundwater and distribution systems shows that occurrence is amazingly variable in space and time. We have come to believe there is no such thing as steady-state fecal contamination. Granted, TC and EC are not 100% correlated with virus occurrence, but the bacterial indicators do provide some information, particularly if there is a positive test result. The only way to counter the variability and not miss an event is to perform more frequent sampling, not less. A quarterly or annual sampling plan is highly unlikely to detect a TC or EC event lasting only one week. Therefore, once a public water system is placed in this reduced monitoring regimen, it is highly unlikely, unless the sanitary defect is egregious, to be triggered into more frequent sampling.

Delaying rule implementation to improve the data sets on which this EA is based would not be protective of public health. From the discussion, it is clear that the Agency needs to improve the databases containing monitoring and compliance information. Without improvements, future EAs will be hampered by the issues discussed herein. As the TCRDS FAC

recognized, it is important to characterize the impacts of promulgated rules by identifying, establishing, and collecting the necessary metrics to do so. The long list of assumptions needed to cover data gaps in the EA reinforces the need for better data collection.

It is understood the analytical and labor costs listed represent national averages for routine sampling. However, a coliform-positive test will trigger additional sampling, assessments, or other actions that may not be accommodated within normal work schedules. As noted in the previous paragraph, other responsibilities may force TCR activities, especially non-routine activities, into overtime. Hence, some cost factor to account for these activities outside of the normal labor rates should be considered. After all, one would hope that repeat sampling and assessment activities are not routine, but that they are conducted by personnel trained and knowledgeable in these areas. (If assessments are conduced using outside contracts, the labor costs may actually be higher than the utility's pay scale, considering the level of expertise that might be required.). In addition, the projected labor costs include fringe benefits, but do not include overhead (an additional multiplier to cover administrative activities, utilities, office space, etc.).

Not including the state costs in the ratepayer cost table could skew the underlying cost distribution. Those states (CA and AL) that operate their regulatory programs on a cost recovery basis will have their fees passed along directly to the ratepayer (in 2005, the labor cost for an hour of a state engineer's time was $105). This raises a concern, because when the state costs and the utility costs (both of which are higher in CA than the national average) are combined, the cost to the CA ratepayer will be greater. If one considers the distribution of ratepayers, this will skew the ratepayer costs among the states, pushing the states with higher costs even further out (widening one end of the distribution).

The Drinking Water Committee believes the model output with respect to the relative impacts of the AIP and AA is satisfactory, given the limitations of the corrective actions input data. Since the frequency distributions for TC and EC monitoring results for the AIP and AA are the same, the only principle difference between the AIP and AA appears to be the initial

monitoring requirements (AIP allows for a transitional period, while AA does not). Since the AA requires more initial monitoring, not allowing for a transition period, the impacts of the rTCR under the AA will be observed sooner. However, the overall frequency of TC- or EC-positives remains essentially the same in both cases. From the standpoint of public health protection, the AA would be preferred because the endpoint improvements are achieved relatively sooner than the timeline in the AIP. In addition, getting such a program running at the small utility and state level would pose initial logistical and administrative challenges. The net cost for the AA is slightly higher than the AIP, but given the absence of underlying distributions, the significance of the net difference is not known. In fact, given all the assumptions made, the difference in the net cost between the AA and AIP is likely not significant, which an uncertainty analysis would probably verify.

Alternatives and Suggestions

The following is a summary of some of the changes that could be considered.

1. Consider revisions to the Federal data collection system to ensure the data collected are adequate to establish a baseline from which to measure the rTCR impact.
2. Rerun the EA using more extreme values for the proportion of water systems that implement corrective actions, e. g., 1% and 50%.
3. Revise the assumption that corrective actions will lead to extended periods of TC- and EC-negative results.
4. Revise cost estimates to compensate for the overtime needed for repeat sampling and analyses in response to TC- or EC positives samples or the additional costs for contracting out an assessment.
5. List, identify, and separate those actions and costs associated with TC- or EC-positives that would be mitigated by other rules, such as the surface water treatment rule or groundwater disinfection rule. This will more clearly identify those actions and impacts associated with the different rules and show how the rules are linked.

The Agency should continue its long-term research efforts to develop tests to identify specific disease-causing organisms, particularly pathogenic strains of *E. coli* and other pathogenic bacteria, to enable public water systems to eliminate these disease-causing organisms from their water systems. This would require a long-term research project(s) which should commence now with high priority. One could visualize first moving to pathogenic strains of *E. coli* by culture methods and biochemical methods, and later by PCR methodology, which is very rapid and very specific. The PCR detection of pathogens fits within the rubric of other recommendations made by the DWC to the EPA concerning the monitoring for, and the rapid detection of, pathogens. This is yet one more example of how moving along to this form of monitoring would be helpful and protective of public health. The DWC recognizes that this form of monitoring acts to address multiple threats to public health, and has the potential to provide timely and specific information. It is important to take advantage of the latest techniques in molecular biology, such as PCR, which have exquisite sensitivity and specificity, to advance the problem of identification of pathogenic bacteria in the water systems. This should be done carefully and with extensive validation of molecular biology methodology against classical culture and microbiology methodology to determine whether adoption of these methodologies would actually advance water sanitation. In addition, the Agency still has to balance maintaining a broad bacterial screen vs. moving to screens for specific pathogenic organisms.

Those small and large water systems that fail to comply with corrective action requirements should perhaps be tasked with more frequent monitoring and reporting requirements to encourage them to rapidly become compliant with the rTCR for long periods of time, at which point the requirements could be relaxed.

Overall, the Drinking Water Committee (DWC) advises USEPA to move forward deliberately to ensure any changes made in generating the rTCR actually result in a significant reduction in the frequency and severity of Total Coliform observations in our drinking water systems. DWC recommends substantial caution in developing the rTCR. To date, most U. S. water systems are maintained well, hence, DWC recommends being very careful in adopting new changes to the TCR, unless there is a very high probability they will improve water

distribution system sanitation, i.e., The DWC recommends caution in making changes to the TCR, and incorporating only those changes that have a high probability of making water systems more sanitary as this is likely a means to lower frequencies of water-borne illnesses.

Where possible, please be concise in writing the rTCR, to make it clear and easy to comply with for the convenience of the PWS. In addition, the DWC strongly recommends placing all information related to aspects of the rTCR on one website and document, accessible on the web, with links to supporting materials The DWC believes that development of a similar book embodying all the rules contained within the rTCR would be very valuable to the water quality community.

Charge Question 4. **Are reductions in *E. coli* and TC occurrence and acute violations appropriate endpoints for informing benefits? Do they appropriately capture the added value of the proposed revisions? If not, what other analyses or endpoints might be considered?**

The Committee struggled with its response to Charge Question 4 in trying to determine whether there are measurable health-related benefits attributable to the revised Total Coliform Rule. If the goal of the Rule is to protect public health, the Committee felt that measuring reductions in total coliforms (TC) and *E. coli* (EC) occurrences are **not** effective **sole** endpoints for informing benefits because of the difficulties (discussed below) in linking these indicators to human health outcomes. It is expected that there will be a decrease in the number of acute violations with the assumption that assessment, followed by corrective action will decrease the occurrence. The Committee believes there is value in the TT-model. However, there are a number of other indicators that need to be considered, as TC is not an adequate measure of health risk. Even though *E. coli* is viewed as a more appropriate measure of risk of enteric illness, they do not capture the health risks from *Legionella*. Other measures, including structural and hydraulic integrity, have been recently considered in a report by the National Research Council and may provide valuable supplemental information on health risks of distributed water.

TC as an appropriate endpoint

With respect to the use of TC, the Committee notes the following:

a. TC can be considered an indicator of treatment efficacy at the point of treatment. To that end, it may be judicious to encourage utilities to sample for TC at plant effluent. However, there is no evidence (of which we are aware) to suggest that the detection of TC in the distribution system indicates risk to human health. The Committee recognizes that there are many reasons why TC could be detected in the DS, *e.g.* release from biofilms, intrusion, regrowth, improper sampling, nitrification, and cross-connections. Therefore, the significance of TC detection is difficult to interpret and depends in part on context (such as temperature, season and climate).
b. For many systems, the number of samples that will be collected under the revised TCR is inadequate to measure statistically significant reductions in TC and EC occurrence.
c. There exist acknowledged problems with false negative and false positive results that further complicate the interpretation of results.
d. These indicators are not used by most other industrialized countries around the world as a measure of drinking water quality. We believe that they are used only by the US and Canada (and only under some circumstances).

Despite these limitations, the Committee recognizes that:

a. The use of TC represents a tool that is already in place, relatively inexpensive, and familiar to users. Specifically, there is already existing expertise and infrastructure with which to conduct these analyses in most water systems.
b. The presence of TC is indicative of gross contamination, a breach in treatment or distribution system failure.
c. The fact that there exist differences in occurrence between disinfected and non-disinfected water systems suggests that, at some level, there is a correlation with water quality improvement.

With respect to *E. coli*, the Committee felt that it represents a more credible indicator of public health risk. The utility of *E. coli* testing, however, is limited by the rarity of its detection. It is useful as a confirmatory, follow-up test, and the Committee felt it appropriate to retain it as

an MCL. The Committee notes that the Agency's modeling does not predict much effect on *E. coli* occurrence, potentially limiting its usefulness as an indicator of improvement.

Reductions in acute violations as appropriate endpoints for informing benefits

It is expected that there will be a decrease in the number of acute violations and associated Public Notifications following implementation of the rTCR. This expectation is fueled by the assumption that many Level 1 and Level 2 assessments will be done, that corrective actions will be taken, and that EC-positive occurrences will decrease. Because information on the relationship between EC-positive occurrence rates and illness rates is not available, we have to assume that a reduction in acute violations will lead to reduction in waterborne illness, which is reasonable. This seems like a reasonable assumption but it is currently not supported by data. Further, in the years since the implementation of the original TCR, there has been a persistent level of acute violations among small water systems that has not changed substantially. Generally, these small water systems lack sufficient resources to bring their systems into compliance. It is assumed that the number of systems in this acute violation category will be reduced by the new emphasis in the revised rule on assessments and repairing defects. This is an appropriate and measurable endpoint.

Added value of the proposed revisions

The DWC agrees that there is value in moving from an MCL-model to a TT-model to better address the nature of the issue. It is more logical to treat these microorganisms as indicators of the possible presence of pathogens and to require corrective action than to employ a fixed number (e.g. 5% of all samples) as a "bright line" indicator of a public health problem. There is value in having a regulation that is more rational and closely aligned with the nature of the contamination problems. This is discussed briefly at the end of Chapter 6. Increasing the awareness and familiarity of the operators of small water systems with their specific issues and focusing efforts on correcting deficiencies rather than meeting strict numerical targets is more likely to decrease overall risk to the communities served.

Other analyses or endpoints that might be considered

Given the limitations of TC and EC as endpoints (as measures of health benefit), the Committee questioned whether there may be value in adding additional endpoints, even though these additional endpoints may also have limitations. The question raised was whether several endpoints, in combination, may be more effective than the use of single indicators. It was not our intention to suggest these additional endpoints as replacements for TC and EC. Several possible additional indicators were discussed.

First, the Committee considered measures of improvement in public health, such as surveillance for waterborne disease outbreaks and/or measures of endemic gastrointestinal illnesses in communities. The Committee recognized that there are issues of sensitivity, timeliness and cost associated with any surveillance system. However, there may be circumstances when enhanced surveillance systems (such as monitoring nurse hotline calls, monitoring sales of anti-diarrheal medication, monitoring hospital emergency department visits for gastrointestinal illness) could be useful in areas where there is concern about water quality and/or vulnerable populations. For example, New York City used enhanced surveillance systems for gastrointestinal disease as part of their strategy to protect public health while avoiding water filtration (see *Watershed Management for Potable Water Supply: Assessing the New York City Strategy*, National Research Council, 2000).

In addition to considering health endpoints, the Committee also considered indicators of health risk and asked the following questions and looked to the NAS study for guidance. a) What factors are "known" to be associated with health risk? b) What factors can be measured by small systems?; by large systems? A recent study by the National Research Council entitled *Drinking Water Distribution Systems: Assessing and Reducing Risks* (2006) suggested the following measures as useful indicators of risk associated with drinking water distribution systems:

1. Measures of hydraulic integrity following the use of the indicators:

- Decreased frequency of pressure drops
- Areas of the distribution system with extreme water age

2 Measures of structural integrity and distribution system management

- Chlorine residual
- Heterotrophic Plate Count (HPC) bacteria
- Assessment of biofilms using snaking cameras
- Number of utilities with routine prophylactic flushing program
- Number of utilities with active leak detection program
- Number of utilities with active cross-connection detection program
- Number of utilities with active backflow prevention program (e.g. Increased number of utilities that adopt better management practices)

Some combination of these measures may serve as helpful endpoints when trying to assess the impact of the revised TCR.

Finally, the Committee also discussed concerns about health risks that are not adequately captured by these endpoints, in particular, risks due to *Legionella* that is associated with a significant number of waterborne disease outbreaks each year (Surveillance for Waterborne Disease and Outbreaks Associated with Drinking Water and Water not Intended for Drinking - United States, 2005–2006, *MMWR*, September 12, 2008 / Vol. 57 / No.SS-9). Thus, some of these pathogen-specific measures may need to be monitored if they are not captured by the fecal endpoints.