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**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460**

**OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD**

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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). 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 data sources used to estimate baseline total coliform and *E. coli* occurrence, public water system profiles, 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 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

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1 analyses. These additional analyses, together with the work already performed, would provide a
2 basis for adequate predictions and descriptions of total coliform (TC) and *E. coli* (EC)
3 occurrence and violation rates.
4

5 The Committee agreed that the Agency's characterization of the types of corrective
6 actions that systems would implement was reasonable and complete. The Committee
7 recommends that the Agency explain how it compiled this list of corrective actions. The
8 Committee notes that the rTCR should ideally be designed so that a larger percentage of small
9 systems would take corrective actions that result in long-term benefits. The central estimate of
10 10% represents only a modest benefit from the rule. Therefore the Committee recommends that
11 the sensitivity analysis use a wider range of corrective action implementation including
12 corrective actions up to around 50%, especially after a Level 2 assessment. In contrast, just
13 because a corrective action has been taken and a sanitary defect corrected, this does not mean the
14 public water systems (PWS) will be free of TC positive results for a period of time. Specifically
15 the Committee questions whether the benefits of flushing will result in reduced risks for multiple
16 years as used in the model.
17

18 The framework and methodology of the Economic Analysis (EA) appear to be in keeping
19 with a properly conducted EA based on the USEPA Guidelines for Economic Analysis
20 (2000). The Committee recommends that an analysis and discussion in the EA would better
21 inform policy makers by identifying and summarizing all the variables with known distributions.
22 It should also be noted that the EA model is developed as a reference baseline and has yet to be
23 validated as a predictive tool.
24

25 The Agency will need a database that is far more robust than the six-year data review
26 database used in the EA and the long list of assumptions needs to be addressed via better data
27 collection. Also, it is not clear that the proposed reduced monitoring strategy offers significant
28 savings in the annual national costs for the assays that are not offset by an increased risk of
29 waterborne disease outbreaks. A quarterly or annual sampling plan is highly unlikely to detect a
30 TC or EC event lasting only one week. Therefore, once a public water system is placed in the
31 reduced monitoring regimen, it is highly unlikely, unless the sanitary defect is egregious, to be
32 triggered into more frequent sampling. Overall, the Alternative Analysis (AA) appears to
33 address public health protection sooner in time than the AIP proposed implementation.
34

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

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1 integrity, have been recently considered in a report by the National Research Council and may
2 provide valuable supplemental information on health risk of distributed.
3

4 The SAB appreciates the opportunity to provide EPA with advice on this important
5 subject. We look forward to receiving the Agency's response.
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10 Sincerely,
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13
14 Dr. Deborah L. Swackhamer, Chair
15 EPA Science Advisory Board
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18 Dr. Joan Rose, Chair
19 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***

CHAIR

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Dr. Lauren Zeise, Chief, Reproductive and Cancer Hazard Assessment Branch, Office of

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1 Environmental Health Hazard Assessment, California Environmental Protection Agency,
2 Oakland, CA
3

4 **The following DWC member provided written comments but did not attend the face-to-**
5 **face meeting:**

6
7 **Dr. Mark Borchardt**, Director, Public Health Microbiology Laboratory, National Farm
8 Medicine Center, Marshfield Clinic Research Foundation, Marshfield, WI
9

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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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1 EXECUTIVE SUMMARY

2

3 EPA's Office of Water (OW) requested that the Science Advisory Board (SAB) Drinking
4 Water Committee (DWC) review its draft supporting analysis in preparation for revising the
5 Total Coliform Rule (TCR). As the Agency embarked on revising the TCR, it expended a great
6 amount of time and effort to include stakeholder input meeting with state regulators, water
7 utilities, local governments, environmental advocates, public health professionals, consumer
8 advocates, Indian tribes, and others. As a result of these discussions, an Agreement in Principle
9 (AIP) was developed that is being used as the foundation for the proposed Revised Total
10 Coliform rule (rTCR). The Agency has proposed a new, more proactive approach for
11 identifying sanitary defects and incorrect monitoring practices.

12

13 The DWC of the EPA Science Advisory Board met in June 2009 to deliberate on four
14 charge questions raised by OW. These questions focused on: (1) the data sources used to
15 estimate baseline total coliform and *E. coli* occurrence, public water system profile, and sensitive
16 subpopulations in the United States, (2) the occurrence analysis used to inform the benefits
17 analysis, (3) the qualitative analysis used to assess the reduction in risk due to implementation of
18 the rule requirements, and (4) analysis of the engineering costs and costs to States resulting from
19 implementation of the revisions. Since the text of the rTCR was not available to the committee,
20 the members relied solely on the text of the AIP to inform this task and their evaluation. This
21 Executive Summary highlights the outcome of the Committee's deliberations.

22

23 The Committee found that the Agency's statistical analysis of the TCR monitoring data
24 used to inform the prediction of the underlying baseline total coliform and *E. coli* occurrence and
25 violation rates is reasonable but would benefit from some refinements and further explanation.
26 The Agency is commended for the development and application of a statistical approach to a
27 large, complex dataset, thereby enabling the analysis of a difficult and diverse problem. The
28 Committee had considered recommending various improvements on the analytical work done,
29 but noted that the proposed changes were unlikely to show a substantially different result and

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1 would involve a significant effort over a protracted period. Instead, the Committee suggested
2 that some of the key issues should be further explored through limited sensitivity analyses. The
3 Committee ultimately found that these additional analyses, together with the work already
4 performed, would provide a sufficient basis for adequate predictions and descriptions of total
5 coliform and *E. coli* occurrence and violation rates.

6
7 The Committee noted, however, that while the analysis was well done, there was
8 insufficient background explanation of the assumptions and methods used in the analysis needs
9 improvement. The Committee was unable to ascertain whether the analysis was reasonable
10 solely by reading the materials provided. For example, the Data Quality Report which was
11 referenced through the document was not available to the Committee. Several assumptions were
12 not stated or were not clearly explained. The approach was not completely described, and the
13 analysis and critical assumptions needed further justification.

14
15 The Committee agreed that the Agency's characterization of the types of corrective
16 actions that systems would implement was reasonable and complete. Corrective actions are
17 closely aligned with the assessments that must follow positive TC/EC test results during routine
18 system monitoring. The Committee recommends the Agency explain how it compiled this list of
19 corrective actions, and where the information came from (i.e., from expert discussions in the
20 Technical Workgroup of the TCRDSAC, and from information provided by utilities). In
21 addition, the Committee recommends that the sensitivity analysis use a wider range of corrective
22 action implementation including corrective actions up to and including 50%, especially after a
23 Level 2 assessment. Disinfection seemed to be the main corrective action considered. If this is
24 correct, then, this fact should be stated, and if it is not, then the other corrective action options,
25 their costs, and the sensitivity analysis results should be clearly discussed. The Committee also
26 questioned whether the benefits of flushing would result in reduced risks for as long as several
27 years as used in the model. Such assumptions should have justification.

28
29 The framework and methodology of the Economic Analysis (EA) appear to be consistent
30 with a properly conducted EA based on the USEPA Guidelines for Economic Analysis

1 (2000). The USEPA guideline should be referenced so that readers understand where the
2 framework for this EA originates and better understand the reasoning behind the rTCR EA
3 structure. The Committee recommends that an analysis and discussion in the EA would better
4 inform policy makers by identifying and summarizing all the variables with known distributions.
5 Further, it should also be clearly noted that the EA model is developed as a reference baseline
6 and has yet to be validated as a predictive tool.

7
8 The Agency will need a database that is far more robust than the six-year data review
9 database used in the EA to improve the vigor of the model. The long list of assumptions needs to
10 be reduced via better more focused data collection. Further, it is not clear from the analysis that
11 the savings in the annual national costs accomplished by the reduced monitoring strategy are not
12 offset by an increased risk of waterborne disease outbreaks or endemic waterborne disease.
13 Overall, the Alternative Analysis (AA) appears to address and protect public health sooner in
14 time than the AIP proposed implementation.

15
16 The Committee struggled in trying to determine whether there are measurable health-
17 related benefits attributable to the revised Total Coliform Rule. If the goal is to protect public
18 health, the Committee felt that measuring reductions in total coliforms (TC) and *E. coli* (EC)
19 occurrences are **not** effective **sole** endpoints for informing benefits because of the difficulties in
20 linking these indicators to adverse human health outcomes. A decrease in the number of acute
21 violations is expected with the assumption that assessment and the implementation of appropriate
22 corrective action will provide a concomitant decrease in waterborne disease and occurrence of
23 acute violations. The Agency's proposal to use TC as part of an overall treatment technique,
24 where TC-positive sampling results would trigger an assessment to identify sanitary defects
25 instead of having an MCLG/MCL for TC, is seen as a positive step forward. However, several
26 other indicators could be considered, as TC, in itself, is not an adequate measure of health risk.
27 Even though *E.coli* is viewed as more appropriate measure of risk, of enteric disease, it does not
28 capture the health risks from *Legionella*. Other measures, including structural and hydraulic
29 integrity, have been recently considered in a report by the National Research Council and may
30 provide valuable supplemental information on health risks from distributed water.

1 BACKGROUND ON THE REVISIONS TO THE TOTAL COLIFORM RULE 2 (TCR) 3

4 The Total Coliform Rule (TCR), established in 1989, is one of the primary national
5 regulations governing the microbiological quality of treated drinking water in the US. As such,
6 it is an important element for protecting against waterborne disease. Each standard is mandated
7 by law to be reviewed and revised, if appropriate, every six years as part of the existing drinking
8 water regulations requiring revisions to improve/maintain public health protection, including the
9 TCR. As part of the review and in order to revise the TCR, the Agency and its advisory
10 committees conducted a substantial amount of work, which included the evaluation of available
11 data and research on aspects of distribution systems that may create risk to public health. The
12 Agency also began working with stakeholders to address controls for cross connections and
13 requirements for backflow prevention in distribution systems, as these are known to be
14 associated with significant risks, but in some cases, may be out of the water system's direct line
15 of control. (C. Rodgers-Jenkins, USEPA, Office of Water, SAB teleconference presentation,
16 5/20/09).

17
18 The Agency began the review of the 1989 TCR in 2003. Based on stakeholder comments,
19 the Agency prepared a series of white papers on the TCR and distribution system issues (2003-
20 07). In July, 2007, the Agency established the Total Coliform Rule/Distribution System
21 Advisory Committee (TCRDSAC). The TCRDSAC consisted of fifteen members representing
22 the Agency and state regulators, water utilities, local governments, environmental advocates,
23 public health professionals, consumer advocates, and Indian tribes. The Agency charged the
24 TCRDSAC with two major tasks; 1) provide the Agency with recommendations on how best to
25 revise the TCR, and 2) develop information and research needs to improve the understanding of
26 the risks posed by distribution system issues. TCRDSAC then formed a technical work group
27 (TWG) to provide data analysis and information to contribute to the discussion of the Committee.
28 An Agreement in Principle (AIP) was developed as a result of these discussions, and the AIP is
29 being used as the foundation for the proposed Revised Total Coliform rule (rTCR). TCRDSAC

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1 met thirteen times between 2007 and 2008. Each representative on the TCRDSAC agreed to
2 support the proposed rTCR components that reflect the elements of the AIP.

3
4 Highlights of TCRDSAC recommendations are: 1) There will no longer be an
5 MCL/MCLG for total coliforms (TC); 2) TC- and *E. coli* (EC) positive sampling results will
6 trigger investigation (assessment), leading water managers to find the problem and fix it; 3)
7 Monitoring on a quarterly and annual basis may be allowed for some small ground water
8 systems; 4) Distribution system research and information collection need to be a priority; 5)
9 There will be an overall shift in focus from monitoring results that lead to public notification to
10 monitoring results that trigger an assessment and corrective action. Benefits from this
11 recommendation are that a more proactive approach to public health protection can be instituted
12 which should reduce confusion associated with the actions needed for TC violations. The
13 Agency stated that it was committed to proposing a rule consistent with TCRDSAC
14 recommendations. The initial rule will be proposed in 2011. The final rule will be proposed in
15 2012, and compliance with the final rule is expected in 2015.

16
17 The Agency's recommendations in the rTCR are to use TC as part of an overall treatment
18 technique, where there is no MCLG/MCL for TC, but where TC-positive sampling results would
19 trigger an assessment to identify sanitary defects. A sanitary defect finding would then trigger
20 corrective action. A treatment technique (TT) violation would be assessed if the investigation or
21 corrective action was not completed. The Agency would retain an MCLG = 0 for *E. coli* and the
22 current MCL associated with presence of TC/EC. The Agency would not use fecal coliforms as
23 a water quality indicator in this Rule, and there would be public notification for TT or acute
24 MCL violations.

25
26 For systems serving $\leq 1,000$ people, there are new criteria for both increased and reduced
27 monitoring, a transition from the existing monitoring frequency unless primacy agency
28 determines otherwise and a decrease in the number of additional routine monitoring and repeat
29 monitoring samples. For systems serving $> 1,000$ people, there are no changes in routine

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1 monitoring but a decrease in repeat samples and the elimination of additional routine monitoring
2 for systems serving $\leq 4,100$ people.

3

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

14

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

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1 INTRODUCTION

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

12
13 The SAB DWC was asked to comment on the scientific soundness of the supporting
14 analysis for the rTCR, not on specific provisions of the rTCR itself. The Committee deliberated
15 on the charge questions during their June 9-10, 2009 face-to-face meeting. The responses that
16 follow represent the views of the Committee.

17
18 The specific charge questions given to The Committee are included on the following page:

21 ***Charge Questions to the Science Advisory Board, Drinking Water Committee***

22
23 The Agency requests that the SAB Drinking Water Committee review the materials provided and
24 provide recommendations in the areas specified in the charge questions. As the Committee
25 considers the specific charge questions that follow, it is asked to consider whether the overall
26 approach that the Agency has taken to assess the impacts of rTCR is appropriate, given the
27 availability of the information, and, if it is not, whether there are alternatives that might be
28 considered.

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11. Is the underlying statistical analysis of the TCR monitoring data used to inform the prediction of
2 the underlying baseline total coliform and *E. coli* occurrence and violation rates reasonable? If
3 not, what changes or refinements might be appropriate?
42. Is the characterization of the types of corrective actions that systems will implement and the
5 percentages of systems that will implement certain corrective actions reasonable? If not, what
6 else might be considered?
73. Are the methodology and assumptions used to predict the net impacts in total coliform-positive
8 (TC+) samples, *E. coli*-positive (EC+) samples, acute violations, assessments, and corrective
9 actions between the current TCR (with and without the effects of the Ground Water Rule), the
10 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
12 informing benefits? Do they appropriately capture the added value of the proposed revisions? If
13 not, what other analyses or endpoints might be considered?

14 **The following attachments were included to facilitate the SAB discussions:**

- 15 • Draft Supporting Analyses
- 16 • Baseline Conditions
- 17 • Occurrence and Predictive Model
- 18 • Benefits Analysis
- 19 • Cost Analysis
- 20 • Draft Technology and Cost Document
- 21 • Agreement in Principle
- 22 • Background on Current TCR and Rule Revisions Development (presentation)
- 23 • Comparison of Current TCR Requirements with the AIP and Alternative Analysis (table)

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1 **RESPONSE TO THE CHARGE**

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

3
4 The DWC evaluated the five TCRDSAC recommendations and found them to be mostly
5 appropriate. First, the total coliform (TC) has little relationship to fecal pollution and public
6 health risk, and thus it is appropriate that there is no longer an MCL/MCLG for total coliforms
7 (TC). The second recommendation, that TC- and *E. coli*- positive sampling results will trigger
8 investigation (assessment) that is intended to lead water managers to find the problem and fix it.
9 This should place an emphasis on investigating and correcting the deficiencies, rather than on
10 just reporting them. The third recommendation, that monitoring on a quarterly and annual basis
11 may be allowed for some small ground water systems, is appropriate as long as these systems
12 have demonstrated the ability to maintain microbiological water quality and groundwater
13 protection, particularly during the rainy seasons. The fourth recommendation, that distribution
14 system research and information collection need to be a priority, is also appropriate. The fifth
15 recommendation, of an overall shift in focus from monitoring results that only result in public
16 notification to monitoring results that trigger an assessment and corrective action, is a significant
17 advancement if it is properly executed. It places the emphasis where it should be, on corrective
18 action. The DWC agrees that benefits from this more proactive approach to public health
19 protection should reduce confusion associated with what follow-up actions are necessary and
20 taken for TC violations. However the DWC notes that the EPA analysis appears to contradict
21 the stated goals of the rTCR by assuming only rare (10% of cases) corrective actions.

22
23 The Agency's recommendations of using TC as part of an overall treatment technique,
24 where TC-positive sampling results would trigger an assessment to identify sanitary defects
25 instead of having an MCLG/MCL for TC, is seen as a positive step forward in principle. The
26 fact that a sanitary defect finding would trigger corrective action is also very good and
27 appropriately places more emphasis on remedial action. The DWC agrees that a treatment
28 technique (TT) violation should be assessed if an investigation or corrective action was not
29 completed. The DWC also agrees that the Agency should retain an MCLG = 0 for *E. coli*, as
30 well as the current MCL-associated with the absence of TC/EC, and not use fecal coliforms as

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

3
4 For systems serving $\leq 1,000$ people, there are new criteria for increased and reduced
5 monitoring, a transition with existing monitoring frequency unless primacy agency determines
6 otherwise and a decrease in number of additional routine monitoring and repeat monitoring
7 samples. For systems serving $> 1,000$ people, there are no changes in routine monitoring but a
8 decrease repeat samples and elimination of additional routine monitoring for systems serving \leq
9 4,100 people. The DWC is skeptical that the monitoring frequencies for small systems ($< 1,000$
10 people) will provide a change to the TCR that improves public health protection. The DWC is
11 not generally supportive of decreased monitoring. Given the highest percentage of TCR
12 violations occurs in the smaller systems, it appears as though small systems are more vulnerable
13 and are more likely to experience a waterborne outbreak. Thus, this vulnerability may be better
14 captured with improved comprehensive assessments. The problems in the sanitation of these
15 small water systems, which do not have substantial capital and personnel to monitor their
16 systems comprehensively, may only be best controlled through a required monitoring scheme.

17
18 The DWC agrees that in this new rTCR scenario, the PWS should be responsible for
19 assessment, and this should strengthen their capacity to ensure barriers are in place and effective.
20 DWC also agrees that there should be two levels of assessment, based on the severity of the
21 trigger, Level 1 and Level 2, and that the systems should correct all sanitary defects found in the
22 assessments. A TT violation would consist of failure to perform a Level 1 and/or 2 assessment
23 when triggered, failure to correct all sanitary defects identified in the assessment, and failure to
24 correct sanitary defects according to an agreed upon schedule. The public notification continues
25 to be important and should include not only a description of the violation but also the necessary
26 follow-up remedial actions. This would assist in alleviating public concerns that the PWS is not
27 attending to the problems. The four types of violations that need public notification are: 1) an *E.*
28 *coli* MCL violation (Tier 1) which may be of immediate public health concern; 2) a treatment
29 technique violation (Tier 2); 3) routine monitoring violation (Tier 3); and 4) a reporting violation
30 (Tier 4). DWC agrees with these revisions to the TCR.

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

12

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

17

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

24

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

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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.

1 The Committee does recognize that the analysis performed is complex and somewhat
2 difficult to explain, and that it may take extra effort than may typically be the case to make the
3 chapter clear and understandable. It may help to have a number of technically facile, non-expert
4 readers review the revised chapter to see whether they understand the analysis, whether they
5 could explain it to someone else based on what was written, and whether they find the analysis
6 including assumptions adequately justified. Specific comments, suggestions and
7 recommendations are given below.
8

9 **Assumptions to Justify and Explain**

10

11 Some examples of assumptions and procedures are provided below that would benefit
12 from better explanation. These are given only as examples, and we leave it to the Agency staff
13 to work through the chapters to make sure that all major assumptions are clearly articulated and
14 adequately explained. Again, the Committee is recommending that the key assumptions be
15 presented early, and that other minor ones are explained as they occur in the description of the
16 analysis and results.
17

- 18 • It is not clearly stated that a main goal of the model fitting exercise is to get a
19 characteristic distribution of probability of positive hits for each water system class, and
20 that the distribution is representing how systems within the class vary from one another in
21 that probability. The reader is left to guess what the distribution is supposed to represent.
22
- 23 • There needs to be an explanation of basic model structure. Exhibit 5.2 appears to be an
24 attempt at showing how different parameters in the beta distribution are related to one
25 another for different systems within a water system class. The title is very general, and
26 the exhibit has no legend. Subscripts are used to indicate the different water systems
27 within the class; however, the subscripts are not used anywhere else in the chapter. What
28 would be a difficult concept to convey with full annotation is totally incomprehensible.
29 The reader is left to guess what the subscripts in the figure mean and how they relate to

1 the analysis. The figure also needs a more explanatory title. If the figure is retained, it
2 needs to be explained in a figure legend and in the text. The Committee also recommends
3 the addition of another illustration to show data inputs and model outputs, with full
4 accompanying annotation and description.

- 5
- 6 • The reason for assuming that seasonality does not impact the analysis should be
7 discussed and justified, perhaps through a sensitivity analysis.
- 8
- 9 • There is a hierarchy to the analysis that is left unexplained. Each water system class has
10 its own characteristic beta distribution. Yet, alpha and beta in the figure and text are not
11 subscripted. In the text, the probability parameters, number of samples (binomial “N”s),
12 positive samples (binomial “K”s), all have no subscript. In the figure, for example,
13 subscripts were left out of equations (such as on p 5-7). This made it unclear that they
14 were relevant to each individual system. While the use of subscripts can be avoided, the
15 underlying assumptions need to be clear, e.g., be clearer about the fact that independent
16 analyses (probability distributions) of the routine and repeat samples were performed.
- 17

18 **Explaining and Disentangling Uncertainty and Variability**

19

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

29

1 Chapter 5 could, for example, include a figure plotting positive occurrence rates for some
2 different prototypical classes of systems. This would provide the reader a visual representation
3 for how systems can differ within a class. Chapter 5 could also provide plots of the maximum
4 likelihood estimate for mean positive occurrence for a system class and display the uncertainty in
5 that estimate. Agency staff has developed some plots like this that could be annotated and
6 included with proper explanation in the document. Plots that disentangle uncertainty from
7 variability would be helpful. On the basis of the discussion with Agency staff, the Committee
8 believes that these plots have been done and that the analysis is fine in this regard, but the
9 presentation is somewhat lacking.

10
11 The Committee recognizes that there are data gaps and that assumptions based on best
12 professional judgment were made. Therefore, the Committee is not recommending a full Monte
13 Carlo analysis of uncertainty; rather, we suggest the issue be explored in a limited way in a
14 sensitivity analysis. The analysis can be qualitative or semi-quantitative and should explain how
15 uncertainty in the beta distribution for classes, where uncertainties are relatively large, may
16 affect the ultimate result. The Agency stated that uncertainties are greatest for classes with few
17 observations, and that this is due to the fact that the actual number of systems in the class is small.
18 However, while this may be a reasonable rationale, it might also be due to one or two outliers
19 that skew the distribution. The Committee suggests that some simple calculations should
20 adequately illustrate that the overall result is robust and the rationale has been tested rather than
21 assumed.

22 23 **Criterion for Significance and Combining Data Sets**

24
25 In a number of places, the chapter asserts that systems do not significantly differ in the
26 probability that they will test positive for total coliform. That finding is used to justify
27 combining data sets for different types of systems. The criterion for testing significance and for
28 deciding to combine or not combine different data sets should be more explicitly stated and
29 perhaps more rigorously done, including a statistical power test. Figure 5.3 is the only attempt to
30 explain this combining, and both the figure itself and the explanation of for combining data sets

1 are weak.

2

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

15

16

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

20

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

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1 distribution system, or reservoirs such as biofilms and stagnant and aged waters within the
2 system itself (these are not sanitary defects as they are not pathways into the system that can
3 result in intrusion nor are they ineffective treatment or loss of a barrier; they are a result of poor
4 operation and maintenance practices).

5

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

9

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

19

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

26

- 27 1) Flushing
- 28 2) Sampler Training
- 29 3) Replacement and Repair
- 30 4) Pressure Maintenance

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- 1 5) Hydraulic Residence Time Maintenance
- 2 6) Storage Facility Maintenance
- 3 7) Booster Disinfection
- 4 8) Cross Connection and Backflow Prevention
- 5 9) On-line Monitoring and Control
- 6 10) General Security Measures
- 7 11) Standard Operation Procedure Training and Implementation

8

9 The Committee recommends that the Agency explain how it compiled this list of

10 corrective actions, and where the information came from (i.e., from expert discussions in the

11 Technical Workgroup of the TCRDSAC, and from information provided by utilities). It is

12 important for the Agency to acknowledge that this is not a definitive list of all actions that could

13 be taken and that it is possible that even if all these actions were implemented in a system, that

14 all total coliform positive observations may not be eliminated. Coliform-positive samples may

15 be the result of numerous factors in a water system, including cross connections, construction,

16 sampling, etc. It is also noted that a Level 2 assessment mandates that a “certified” operator

17 must respond to violations. Certification is rather ill defined and is a responsibility of the

18 individual State. The expertise of the “certified” operator will be very important in determining

19 the efficacy of the investigations, and the percentage of systems taking corrective action after

20 Level 2 assessments.

21

22 The list of corrective actions appears somewhat dismissive of investments in analytical

23 methods and monitoring, source water analysis, water quality databases and analysis resulting

24 from the Level 1 and 2 assessments. Real time microbial monitoring, ultimately capable of

25 | targeting specific pathogens of direct public health significance, is on the horizon and real time

26 residual chlorine monitoring is only a limited surrogate approach.

27

28 **Analysis of Percentage of Systems Implementing Corrective Action**

29

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

15
16 Based primarily on the results of a limited survey of current TCR requirements, the
17 Agency estimates that corrective actions will on average be implemented only 10% of the time
18 (section 6.2.7 and associated footnote 1 on page 6-8). It is surprising that such a relatively small
19 percentage of systems are projected to take some kind of corrective action – at least by flushing
20 their systems - after a Level 1 or Level 2 event. We expect that flushing would (and should) be a
21 more common practice. Therefore, we think it would be justifiable for the Agency to use a
22 greater than 10% likelihood of taking corrective action. In addition, after a Level 2 event, a
23 serious assessment, done by a certified operator, should find some type of corrective action that
24 can be taken in most small systems, especially if the menu of corrective actions includes a switch
25 to disinfection.

26
27 This entire discussion appears overly weighted on the influence of the ground water rule
28 (GWR) and instituting disinfection processes for GW. Does implementation of disinfection in
29 ground water (GW) systems bias the presumed 10% of corrective action? The sensitivity
30 analysis uses a range of 5-20% of corrective action implementation. We suggest a broader range

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

5
6 Assessment and corrective actions are well described. However, the discussion of
7 corrective action appears to rely on an overt fallback position that emphasizes flushing in
8 response to a positive monitoring result. While offering immediate public health protection,
9 flushing alone may not provide solutions to the underlying problem causing the positive TC/EC
10 monitoring result. Therefore, the Committee questions whether the benefits of flushing will
11 result in decreased risks for several years, as the Agency currently estimates in the model. The
12 Committee recognizes that from a utility perspective, flushing and disinfection is a cost effective
13 solution, if the origins of the TC/EC cannot not be adequately documented, thus avoiding
14 potential costly repair and replacement corrective actions that may not ultimately be warranted.
15 It makes sense to switch some proportion of GW systems to long-term disinfection in the model,
16 and thus change their attributed rates accordingly after a positive finding.

17
18 Overall, the challenge laid down to the Agency by the TCRDSAC was to come up with a
19 revised TCR that will foster continuous improvement in the industry by encouraging assessments
20 and corrective actions. It is discouraging to see that the Agency's projections do not fully realize
21 that vision. The rule should be designed so that a larger percentage of small systems would take
22 corrective actions that result in long-term benefits. The central estimate of 10%, although
23 perhaps realistic, represents only a modest benefit from the rule, although it may be better than
24 the *status quo* for small systems. It would be useful for the Agency to run the model with a
25 significantly higher percentage of corrective actions (i.e., 50%), to determine whether the
26 benefits would increase substantially if the rule can be designed such as to achieve these higher
27 rates.

28
29 The AIP recognizes the evolution of analytical capabilities (section 3.2) for TC and EC.
30 As part of Assessment and Corrective Action, best available methods are appropriate. As an

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1 active area of research, future relevant analytical methodologies should be embraced as they
2 become available, and the rTCR should not be constrained to current best available technology.
3 It is important to note that while various methods may report TC, not all the TC's mean the same
4 thing. There is an ongoing study comparing the methods and the AIP contains a component that
5 addresses it. The Committee also suggests that the Agency consider moving to alternative
6 measures other than TC which they believe is not a reliable indicator from a public health
7 perspective.
8

9 Monitoring needs are also identified. As part of research and information needs (4.2.c),
10 Tier 1 should include molecular microbial methods, stable isotope ratio techniques, and mass
11 spectroscopic analytical methods for source and contaminant identification which need to be
12 developed to assist in focused corrective action, rather than corrective action in immediate
13 response to a rTCR monitoring violation. Tier 2 needs emphasis on human and animal pathogen
14 detection and real time monitoring.
15

16 **Charge Question 3. Are the methodology and assumptions used to predict the net**
17 **impacts in total coliform positive (TC+) samples, *E. coli*-positive (EC+) samples, acute**
18 **violations, assessments, and corrective actions between the current TCR (with and without**
19 **the effects of the Ground Water Rule), the AIP, and the Alternative Analysis reasonable? If**
20 **not, what alternatives might be considered?**
21

22 The framework and methodology of the Economic Analysis (EA) appear to be consistent
23 with a properly conducted EA based on the USEPA Guidelines for Economic Analysis
24 (2000). The USEPA guideline should be referenced so readers understand where the framework
25 for this EA originates and better understand the reasoning behind the revised total coliform rule
26 (rTCR) EA structure. Using this framework, the Agency should guide the reader through the EA
27 clearly pointing out elements that were completed, where assumptions were made, and where
28 steps were omitted (along with justification for omitting them).
29

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

10
11 Unlike the sensitivity analysis, the uncertainty analysis examines the inherent variability
12 in the data and its subsequent impact on the distribution of the output. Some variability is
13 inherent and a portion may be associated with the measurements used to characterize the
14 population. The Agency should identify the sources of uncertainty and determine the level of
15 confidence that should be placed in the final results.

16
17 In reviewing the EA guideline, it is apparent that one deficiency in the rTCR uncertainty
18 analysis originates from the guideline itself and is not a deficiency introduced by the rTCR EA.
19 While the EA guideline does admit the approach outlined may be different than what other
20 disciplines consider a complete uncertainty analysis, the USEPA EA Guideline appears to
21 discuss conducting an Uncertainty Analysis (UA) only. The Agency should identify that the UA
22 is comprised of a single part, the sensitivity analysis. Since the Agency’s EA guideline is not a
23 regulation or legislated requirement, its structure and content are not so rigid as to preclude
24 interpretation and improvement, when and if the application warrants it. In this case, the Agency
25 should point out that the UA in the EA is only comprised of a sensitivity analysis, which does
26 not include an actual evaluation of uncertainty associated with the output. The analysis and
27 discussion in the EA would better inform policy makers by identifying and summarizing all the
28 variables with known distributions, and those without, to aid risk managers with the
29 interpretation of the results.

30

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

9
10 When evaluating the baseline condition, the admission that data are missing from 15
11 states, including states with large populations (California, Florida, and Pennsylvania), there is
12 very little discussion on what impact this data gap might have on the final result. In addition, the
13 number of states submitting TC and EC data in each tier (1 – 4) is not described. Again, there is
14 no discussion of how the missing data may have biased the baseline estimate.

15
16 In addition, the Committee recommends that in regard to the effectiveness of the
17 corrective actions to reduce future TC- and EC-positive samples, the Agency should repeat the
18 analysis with values for the percentage of communities that will actually implement corrective
19 actions from 1% for the less effective corrective actions to 50% for the most effective. In
20 addition, it is not clear that the reduced monitoring strategy offers significant savings in the
21 annual national costs for the assays that are not offset by an increased risk of waterborne disease
22 outbreaks. Overall, the Alternative Analysis (AA) appears to provide public health protection in
23 a more timely fashion than the AIP .

24
25 The Drinking Water Committee (DWC) of the Science Advisory Board (SAB), while
26 providing comments on the methodology and assumptions used to predict the net impacts of the
27 rTCR under the current TCR, AIP, and Alternative Analysis (AA), cannot provide an adequate
28 assessment which could serve as a substitute for an Uncertainty Analysis. In this EA, one can
29 argue the Uncertainty Analysis is not complete, because of the undefined or ill-defined

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

3

4 **Safe Drinking Water Information System (SDWIS)/Federal Version (FED) and 6-** 5 **year Review Databases**

6

7 The Total Coliform Rule is the drinking water rule that applies to all public water
8 systems regardless of size, source or treatment. Utilities across the United States have invested
9 billions of dollars in monitoring to meet the requirements of this rule. Unfortunately, data
10 management for these data has been challenging. There was only a limited amount of data from
11 the Safe Drinking Water Information System – Federal Version (SDWIS/FED) and six-year
12 review databases used in the EA deemed useful for the rTCR analyses. Given this limited data,
13 there was still a good deal of work, along with a significant amount of thought and effort,
14 expended on identifying those segments of the database that would be useful. A large amount of
15 data has been gathered and screened by the USEPA when the States voluntarily submitted
16 electronic monitoring data reflecting records from 1998-2005.

17

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

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

3
4 Further, it should be noted that the EA model was developed to produce a reference
5 baseline and has yet to be validated as a predictive tool. The EA uses the SDWIS/FED database
6 of violations as the reference for their model. The data for the model came from the six-year
7 data review data set, which contained all sample results (with the stated limitations). The model
8 output was compared to the SDWIS/FED data as the means of validating it. The violations in the
9 SDWIS/FED database should reflect the sampling results in the six-year data review for those
10 same periods of time, since the sampling results determine PWS compliance. However, this
11 should not be considered a “validation” of the model as a predictive tool. A model should only
12 be considered validated as a predictive tool if it can be shown that it accurately forecasts events
13 that have not yet taken place. The EA model should be considered as being validated for
14 establishing a reference baseline, but no more until additional data are available to confirm
15 model output. The Agency will need a database that is far more robust than the 1 year of data
16 from the six-year data review database used in the EA to validate the model and decrease the
17 long list of assumptions used in the current EA (see comments in next section).

18
19 Given the scheduling of the revised total coliform rule (rTCR), the assumptions used to
20 fill the data gaps identified in the six-year review database should be considered adequate for this
21 EA. However, they indicate a deficiency in the data collection system that should be rectified
22 prior to implementation of the rTCR. On page 4-7 one justification includes the line “...single
23 year data allows for a single database.” This implies that the databases were of such different
24 structure that the years in the database prior to 2005 could not be combined into a single database.
25 This points to a need to improve data management and collection practices. To address at least
26 one of the items in Section 3.17 of the AIP, the Agency will need a database that is far more
27 robust than the six-year data review database used in the EA.

28
29 To assess the long-term effectiveness of the rTCR (Section 3.17 of the AIP), the metrics
30 will need to be established and the data collection systems put into place, before the rule is

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1 promulgated. This will allow data collected, under the current TCR, to be used as a reference
2 baseline against which future regulatory actions and their impacts can be compared. Failure to
3 do so will result in the need to employ similarly weak assumptions in future regulatory
4 documents and evaluations.
5

6 **Corrective Actions**

7

8 Filling data gaps by making assumptions is sometimes necessary, especially when the
9 data needed are not available or have not been collected. Such is the case for the corrective
10 actions in Exhibit 7.16. These data have never been collected, so the table was populated using
11 the professional judgment of the TCRDSAC Technical Workgroup (TWG). However, the
12 Agency should recognize that current data systems are not set up to collect this information as
13 the rTCR moves forward. Until the data systems are set up to collect this information, future
14 EAs and regulation assessments will be limited in their usefulness as quantitative assessments
15 upon which risk managers can and should base their policy decisions.
16

17 The biggest red flag (assumption) is the effectiveness of the corrective actions in
18 reducing future TC- and EC-positive samples. The Agency should repeat the analysis with more
19 extreme values for the percentage of communities that will actually implement corrective actions,
20 e.g., 1% for the less effective corrective actions and 50% for the most effective. It is not clear
21 how the current values in the analysis -10%, 5%, and 20% - were selected. The extreme values
22 are justified, in our opinion, given the absence of any previous knowledge on how well these
23 assessments will be performed or the true long-term effectiveness of the corrective actions.
24

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

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

11
12 Each column or corrective action in Exhibit 7.16 represents an action triggered by an
13 independent event. These actions are not dependent on each other. Thus, the corrective actions
14 should not be pooled or linked. The causes listed Exhibit 7.16 appear to be all inclusive as each
15 line (for a given size system) seems to add to 100%. By summing to 100% for a given size
16 category, it appears as though the corrective actions listed are the only ones that could mitigate a
17 sanitary defect identified in a Level 1 or 2 triggered assessment.

18
19 The list of corrective actions focuses on actions associated with the distribution system to
20 correct a TC or EC trigger. The list does not include remedial actions taken on other components
21 of the multiple barriers (source and treatment) that may contribute to a TC or EC trigger. The
22 discussion of corrective actions should acknowledge changes or modifications made in the
23 maintenance or operation of the treatment process train, as the assessments may trigger changes
24 in or the addition of treatment. While it is assumed that the actions taken on the treatment
25 barriers would be an appropriate response under the Groundwater Disinfection Rule (GWDR) or
26 Surface Water Treatment Rule (SWTR), these actions may be triggered by monitoring in the
27 distribution system under the rTCR and identified by the assessment. The linkage between the
28 rules and the subsequent impact on the EA needs to be fully and clearly explained so the reader
29 knows which impacts are being included and which have been attributed to previous rules.

30

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

26
27 Delaying rule implementation to improve the data sets on which this EA is based would
28 not be protective of public health. From the discussion, it is clear that the Agency needs to
29 improve the databases containing monitoring and compliance information. Without
30 improvements, future EAs will be hampered by the issues discussed herein. As the TCRDS FAC

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1 recognized, it is important to characterize the impacts of promulgated rules by identifying,
2 establishing, and collecting the necessary metrics to do so. The long list of assumptions needed
3 to cover data gaps in the EA reinforces the need for better data collection.
4

5 It is understood the analytical and labor costs listed represent national averages for
6 routine sampling. However, a coliform-positive test will trigger additional sampling,
7 assessments, or other actions that may not be accommodated within normal work schedules. As
8 noted in the previous paragraph, other responsibilities may force TCR activities, especially non-
9 routine activities, into overtime. Hence, some cost factor to account for these activities outside
10 of the normal labor rates should be considered. After all, one would hope that repeat sampling
11 and assessment activities are not routine, but that they are conducted by personnel trained and
12 knowledgeable in these areas. (If assessments are conducted using outside contracts, the labor
13 costs may actually be higher than the utility's pay scale, considering the level of expertise that
14 might be required.). In addition, the projected labor costs include fringe benefits, but do not
15 include overhead (an additional multiplier to cover administrative activities, utilities, office space,
16 etc.).
17

18 Not including the state costs in the ratepayer cost table could skew the underlying cost
19 distribution. Those states (CA and AL) that operate their regulatory programs on a cost recovery
20 basis will have their fees passed along directly to the ratepayer (in 2005, the labor cost for an
21 hour of a state engineer's time was \$105). This raises a concern, because when the state costs
22 and the utility costs (both of which are higher in CA than the national average) are combined, the
23 cost to the CA ratepayer will be greater. If one considers the distribution of ratepayers, this will
24 skew the ratepayer costs among the states, pushing the states with higher costs even further out
25 (widening one end of the distribution).
26

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

1 monitoring requirements (AIP allows for a transitional period, while AA does not). Since the
2 AA requires more initial monitoring, not allowing for a transition period, the impacts of the
3 rTCR under the AA will be observed sooner. However, the overall frequency of TC- or EC-
4 positives remains essentially the same in both cases. From the standpoint of public health
5 protection, the AA would be preferred because the endpoint improvements are achieved
6 relatively sooner than the timeline in the AIP. In addition, getting such a program running at the
7 small utility and state level would pose initial logistical and administrative challenges. The net
8 cost for the AA is slightly higher than the AIP, but given the absence of underlying distributions,
9 the significance of the net difference is not known. In fact, given all the assumptions made, the
10 difference in the net cost between the AA and AIP is likely not significant, which an uncertainty
11 analysis would probably verify.
12

13 **Alternatives and Suggestions**

14
15 The following is a summary of some of the changes that could be considered.

16 1. Consider revisions to the Federal data collection system to ensure the data collected
17 are adequate to establish a baseline from which to measure the rTCR impact.

18 2. Rerun the EA using more extreme values for the proportion of water systems that
19 implement corrective actions, e. g., 1% and 50%.

20 3. Revise the assumption that corrective actions will lead to extended periods of TC-
21 and EC-negative results.

22 4. Revise cost estimates to compensate for the overtime needed for repeat sampling and
23 analyses in response to TC- or EC positives samples or the additional costs for contracting out an
24 assessment.

25 5. List, identify, and separate those actions and costs associated with TC- or EC-
26 positives that would be mitigated by other rules, such as the surface water treatment rule or
27 groundwater disinfection rule. This will more clearly identify those actions and impacts
28 associated with the different rules and show how the rules are linked.
29

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

19

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

24

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

1 distribution system sanitation, i.e., The DWC recommends caution in making changes to the
2 TCR, and incorporating only those changes that have a high probability of making water systems
3 more sanitary as this is likely a means to lower frequencies of water-borne illnesses.
4

5 Where possible, please be concise in writing the rTCR, to make it clear and easy to
6 comply with for the convenience of the PWS. In addition, the DWC strongly recommends
7 placing all information related to aspects of the rTCR on one website and document, accessible
8 on the web, with links to supporting materials. The DWC believes that development of a similar
9 book embodying all the rules contained within the rTCR would be very valuable to the water
10 quality community.
11

12 **Charge Question 4. Are reductions in *E. coli* and TC occurrence and acute violations**
13 **appropriate endpoints for informing benefits? Do they appropriately capture the added**
14 **value of the proposed revisions? If not, what other analyses or endpoints might be**
15 **considered?**
16

17 The Committee struggled with its response to Charge Question 4 in trying to determine
18 whether there are measurable health-related benefits attributable to the revised Total Coliform
19 Rule. If the goal of the Rule is to protect public health, the Committee felt that measuring
20 reductions in total coliforms (TC) and *E. coli* (EC) occurrences are **not** effective **sole** endpoints
21 for informing benefits because of the difficulties (discussed below) in linking these indicators to
22 human health outcomes. It is expected that there will be a decrease in the number of acute
23 violations with the assumption that assessment, followed by corrective action will decrease the
24 occurrence. The Committee believes there is value in the TT-model. However, there are a
25 number of other indicators that need to be considered, as TC is not an adequate measure of health
26 risk. Even though *E. coli* is viewed as a more appropriate measure of risk of enteric illness, they
27 do not capture the health risks from *Legionella*. Other measures, including structural and
28 hydraulic integrity, have been recently considered in a report by the National Research Council
29 and may provide valuable supplemental information on health risks of distributed water.
30

1 **TC as an appropriate endpoint**

2

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

4

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

19

20 Despite these limitations, the Committee recognizes that:

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

29

30 With respect to *E. coli*, the Committee felt that it represents a more credible indicator of
31 public health risk. The utility of *E. coli* testing, however, is limited by the rarity of its detection.

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1 It is useful as a confirmatory, follow-up test, and the Committee felt it appropriate to retain it as
2 an MCL. The Committee notes that the Agency's modeling does not predict much effect on *E.*
3 *coli* occurrence, potentially limiting its usefulness as an indicator of improvement.
4

5 Reductions in acute violations as appropriate endpoints for informing benefits

6
7 It is expected that there will be a decrease in the number of acute violations and
8 associated Public Notifications following implementation of the rTCR. This expectation is
9 fueled by the assumption that many Level 1 and Level 2 assessments will be done, that
10 corrective actions will be taken, and that EC-positive occurrences will decrease. Because
11 information on the relationship between EC-positive occurrence rates and illness rates is not
12 available, we have to assume that a reduction in acute violations will lead to reduction in
13 waterborne illness, which is reasonable. This seems like a reasonable assumption but it is
14 currently not supported by data. Further, in the years since the implementation of the original
15 TCR, there has been a persistent level of acute violations among small water systems that has not
16 changed substantially. Generally, these small water systems lack sufficient resources to bring
17 their systems into compliance. It is assumed that the number of systems in this acute violation
18 category will be reduced by the new emphasis in the revised rule on assessments and repairing
19 defects. This is an appropriate and measurable endpoint.
20

21 Added value of the proposed revisions

22
23 The DWC agrees that there is value in moving from an MCL-model to a TT-model to
24 better address the nature of the issue. It is more logical to treat these microorganisms as
25 indicators of the possible presence of pathogens and to require corrective action than to employ a
26 fixed number (e.g. 5% of all samples) as a "bright line" indicator of a public health problem.
27 There is value in having a regulation that is more rational and closely aligned with the nature of
28 the contamination problems. This is discussed briefly at the end of Chapter 6. Increasing the
29 awareness and familiarity of the operators of small water systems with their specific issues and

1 focusing efforts on correcting deficiencies rather than meeting strict numerical targets is more
2 likely to decrease overall risk to the communities served.

3

4 **Other analyses or endpoints that might be considered**

5

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

12

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

24

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

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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.