

# **FINAL REPORT**

**Small Business Advocacy Review Panel on  
EPA Planned Revisions to  
Public Water System Requirements:**

**Revisions to the Total Coliform Monitoring and Analytical  
Requirements and Consideration of Distribution System Issues**

**March 31, 2008**

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Appendix A: List of Materials the SBAR Panel Shared with Small Entity Representatives

Appendix B: Written Comments Submitted by Small Entity Representatives

## 1. INTRODUCTION

This final report is presented by the Small Business Advocacy Review Panel (SBAR Panel or Panel) convened to consider the planned proposed rulemaking on Revisions to the Total Coliform Monitoring and Analytical Requirements and Consideration of Distribution System Issues. Possible revisions are currently being developed by the U.S. Environmental Protection Agency (EPA or the Agency). Under section 609(b) of the Regulatory Flexibility Act (RFA) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), a Panel must be convened prior to publication of the initial regulatory flexibility analysis (IRFA) that an Agency may be required to prepare under the RFA. In addition to EPA's Small Business Advocacy Chairperson, the Panel members are the Director of the Standards and Risk Management Division of the EPA Office of Ground Water and Drinking Water, the Administrator of the Office of Information and Regulatory Affairs within the Office of Management and Budget (OMB), and the Chief Counsel for Advocacy of the Small Business Administration (SBA).

This report includes the following:

- Background information on the proposed rule being developed;
- Information on the types of small entities that would be subject to the proposed rule;
- A description of efforts made to obtain the advice and recommendations of representatives of those small entities; and
- A summary of the comments that have been received to date from those representatives.

Section 609(b) of the RFA directs the Panel to report on the comments of Small Entity Representatives (SERs) and make findings on issues related to certain elements of an IRFA under section 603 of the RFA. Those elements of an IRFA are:

- A description of, and where feasible, an estimate of the number of small entities to which the proposed rule will apply;
- Projected reporting, record keeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirements and the type of professional skills necessary for preparation of the report or record;
- An identification, to the extent practicable, of all other relevant Federal rules which may duplicate, overlap, or conflict with the proposed rule; and
- Any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities

The Panel's final report is provided to the EPA and is to be included in the rulemaking record. The Agency is to consider the Panel's findings when developing the proposed rule. In light of the Panel report, and where appropriate, the Agency is also to consider whether changes are needed to the IRFA for the proposed rule or the decision on whether an IRFA is required.

The Panel's findings and discussion are based on the information available at the time the final Panel report was drafted. EPA will continue to conduct analyses relevant to the proposed rule, and additional information may be developed or obtained during the remainder of the rule development process. The Panel makes this final report at a preliminary stage of rule development and the Agency should consider the report in that light. At the same time, the report provides the Panel and the Agency with an opportunity to identify and explore potential ways of shaping the proposed rule to minimize the burden of the rule on small entities while achieving the rule's purposes.

Any options identified by the Panel for reducing the rule's regulatory impact on small entities may require further analysis and/or data collection to ensure that the options are practicable, enforceable, environmentally sound, and consistent with the Safe Drinking Water Act and its amendments.

## **2. BACKGROUND**

### **2.1 Regulatory History of the Total Coliform Rule (TCR)**

The TCR was promulgated on June 29, 1989 and became effective on December 31, 1990. The purposes of the TCR, as stated in the 1987 proposed rule, are to:

- Evaluate the effectiveness of treatment
- Determine the integrity of the distribution system
- Signal the possible presence of fecal contamination

In 2000, as part of its recommendations concerning the Long-Term 2 Enhanced Surface Water Treatment Rule and the Stage 2 Disinfection Byproducts Rule, the Stage 2 Microbial/Disinfection Byproducts Federal Advisory Committee (M/DBP FAC) recognized the following points in its Agreement in Principle:

- "Finished water storage and distribution systems may have an impact on water quality and may pose risks to public health."
- "Cross-connections and backflow in distribution systems represent a significant public health risk."
- "Water quality problems can be related to infrastructure problems and aging of distribution systems may increase risks of infrastructure problems."
- "Distribution systems are highly complex and there is a significant need for additional information and analysis on the nature and magnitude of risk associated with them."

The M/DBP FAC concluded that EPA should review and evaluate available data and research on those aspects of distribution systems that may create or pose risks to public health as a part of the Six-Year Review of the TCR. The M/DBP FAC also concluded that EPA should initiate a process with stakeholder participation for addressing requirements for cross-connection control and backflow prevention, and distribution systems issues related to significant health risks.

In 2003, EPA completed its Six-Year Review of the TCR (EPA is required to review existing national primary drinking water regulations every six years). The purpose of the review was to identify current health risk assessments, changes in technology, and other factors that would provide a health or technological basis to support a regulatory revision that will maintain or improve public health protection. In the 2003 announcement of the completion of the Six-Year Review, EPA provided public notice of its intent to revise the Total Coliform Rule. As part of the planned TCR revisions, EPA intends to assess the effectiveness of the current TCR and determine whether technically supportable alternative/additional monitoring strategies are available that would decrease economic burden while maintaining or improving public health protection. In response to recommendations from the M/DBP FAC, the Agency also intends to consider if and how risks associated with distribution systems should be addressed.

In July 2007 EPA convened a Total Coliform Rule/Distribution System Federal Advisory Committee (TCRDSAC) charged with evaluating how well the objectives of the TCR are met and possible revisions to the rule. The TCRDSAC is scheduled to complete its analysis and recommendations by the summer of 2008. The Panel will inform the TCRDSAC of the findings in this report before the TCRDSAC completes its final analysis and recommendations.

## **2.2 Description and Scope of the Existing TCR**

The TCR establishes a health goal (Maximum Contaminant Level Goal, or MCLG) of zero for total coliform bacteria (including fecal coliforms and *E. coli*), and a legal limit (Maximum Contaminant Level, or MCL) based on the percentage of positive samples collected during each monthly compliance period. The TCR requires all Public Water Systems (PWSs) to monitor for the presence of total coliforms in the drinking water distribution system. Total coliforms are a group of closely related bacteria that are (with few exceptions) not harmful to humans. Because total coliforms are common inhabitants of ambient water, and because they may be injured by environmental stresses and water treatment in a manner similar to most bacterial pathogens and many viral enteric pathogens, EPA has considered them a useful indicator of these pathogens.

The TCR specifies the frequency and type of testing that water systems must complete. The number of samples that PWSs must collect in a month is proportional to the number of people served. The rule also requires PWSs to establish a sample siting plan and to sample from locations representative of the distribution system, but does not specify criteria for how to determine which locations are representative. If any sample tests positive for total coliforms (TC), the system must perform the following additional tests:

- Further test the positive culture for the presence of either fecal coliforms (FC) or *E. coli* (EC);
- Take one set of 3-4 repeat samples within 24 hours. At least one of the repeat samples must be collected at the original sample tap, at least one within 5 service connections upstream, and at least one within 5 service connections downstream; and
- Take at least 5 routine samples the next month of operation.

However, the rule also provides States with some flexibility to allow exceptions to the repeat and next month sampling requirements.

Two types of MCL violations are possible under the TCR: monthly violations and acute violations. Under the TCR, a monthly (non-acute) MCL violation has occurred if more than 5.0 percent of distribution system samples collected in any month contain TC bacteria. For PWSs serving 33,000 or fewer people, this means that no more than 1 sample per month may be TC (+), because these PWSs collect fewer than 40 samples per month. When the number of TC (+) samples exceeds these limits a monthly MCL violation has occurred, and the PWS must notify the State by the end of the next business day after the PWS learns of the violation, and must notify the public within 30 days. An acute MCL violation has occurred if a repeat sample is FC/EC (+), or a repeat sample is TC (+) following a FC/EC (+) routine sample. For an acute violation, the PWS must notify the State by the end of the day the PWS is notified of the result, and must notify the public within 24 hours.

The existing TCR includes provisions that provide regulatory relief for small systems, including:

- Fewer samples per month for smaller systems if a sanitary survey has been conducted and shows no sanitary defects
- Non-community water systems (NCWSs) can provide public notice via postings
- Sample frequency may be reduced by the State
- Repeat samples may be waived by the State
- Systems with one tap can take one large-volume repeat sample, rather than taking 3-4 individual repeat samples.

The TCR allows States to reduce monitoring requirements for a small community water system serving 25 – 1,000 people if it has no history of TC contamination and a sanitary survey shows that it is supplied solely by a protected groundwater source and is free from sanitary defects. The rule does not include minimum requirements for the sanitary survey, however, requirements and recommendations for conducting sanitary surveys have been provided by subsequent rules and guidance.

### **2.3 Related Federal Rules**

This section provides a brief description of the regulatory history and requirements of rules related to the TCR by common objectives and of those rules which have objectives that must be balanced with the objectives of the TCR.

#### **Surface Water Treatment Rule**

The Surface Water Treatment Rule (SWTR), like the TCR, was promulgated in 1989. The SWTR applies to all PWSs using surface water or ground water under the influence of surface water. It includes treatment technique requirements for filtered and unfiltered systems that are designed to protect against microbial pathogens, specifically viruses, Legionella, and *Giardia lamblia*. To assure adequate microbial protection in the distribution system, the SWTR also

requires water systems to provide continuous disinfection of the drinking water entering the distribution system and to maintain a detectable disinfectant level within the distribution system. The SWTR requires that the residual disinfectant concentration must be measured at least at the same points and same time as TC samples are collected to comply with the TCR.

### **Interim, Long Term 1 and Long Term 2 Enhanced Surface Water Treatment Rules**

The three enhanced surface water treatment rules amended the existing SWTR to strengthen microbial protection and include provisions specifically intended to address removal or inactivation of *Cryptosporidium* that may be present in source waters. The rules also include disinfection profiling and benchmarking provisions to ensure that systems maintain microbial protection as they take steps to reduce the formation of disinfection byproducts. Collectively, the rules also reduce risk of contamination in the distribution system by requiring covers on new finished water reservoirs and treatment or covering for existing uncovered finished water reservoirs. The Interim Enhanced rule also required sanitary surveys, conducted by States, for all surface water systems regardless of size.

### **Total Trihalomethanes and Stage 1 and Stage 2 Disinfectants and Disinfection Byproducts Rules**

These rules establish MCLs for byproducts of commonly used drinking water disinfectants where these byproducts have been shown to be harmful to public health over long-term exposure. The rules also specify monitoring frequencies and locations. The use of disinfection treatment to reduce risks from microbial pathogens must be balanced with the possible development of disinfection byproducts. For that reason, as noted above, the enhanced surface water treatment rules include disinfection profiling and benchmarking provisions to ensure that systems maintain microbial protection as they take steps to reduce the formation of disinfection byproducts to maintain compliance with the disinfection byproducts rules. These requirements apply only to disinfecting Community Water Systems (CWSs) and Non-Transient Non-community Water Systems (NTNCWSs).

### **Ground Water Rule**

EPA published the Ground Water Rule on November 8, 2006 (71 FR 65573). The purpose of the rule is to provide for increased protection against microbial pathogens in PWSs that use ground water sources, especially in ground water systems that are susceptible to fecal contamination and hence disease-causing pathogens. The GWR applies to PWSs that serve ground water and to any system that mixes surface and ground water if the ground water is added directly to the distribution system and provided to consumers without treatment.

The targeted, risk-based strategy addresses risks through an approach that includes:

- Periodic sanitary surveys of systems that require the evaluation of eight critical elements of a public water system and the identification of significant deficiencies (e.g., a well located near a leaking septic system);

- Triggered source water monitoring when a system identifies a positive sample during its TCR monitoring;
- Assessment monitoring targeted at high-risk systems (at the option of the state);
- Required corrective action (possibly including disinfection) for any system with a significant deficiency or source water fecal contamination; and
- Compliance monitoring of treatment processes.

### **3. OVERVIEW OF POSSIBLE TCR REVISIONS AND DISTRIBUTION SYSTEM ISSUES UNDER CONSIDERATION**

EPA has been working with stakeholders through the TCRDSAC to develop rule options. On November 28, 2007, the TCRDSAC circulated among its participants a compilation of initial ideas for possible revisions to the TCR. This compilation was provided to the SERs identified for this rule. The compilation was designed to stimulate discussion but is not a complete list of possible revisions. The TCRDSAC is discussing a range of possible approaches and it will be working over the next three months to narrow the options that it will recommend to the Agency. This section contains several regulatory options that EPA is evaluating, and may use in combination to develop a proposed TCR revision that is more effective and efficient than the current TCR and that maintains or improves public health protection.

#### Changes to the MCL

EPA is evaluating options that could result in changes to the MCL and to the use of TC, FC, and *E. coli* as regulatory indicators. The possible changes include replacing the MCL with a treatment technique and using TC as a trigger for follow-up monitoring and/or corrective action; and, basing the MCL on *E. coli* only. Other approaches that EPA is evaluating include changing the specific threshold associated with monthly/acute MCL violations, dropping FC as a follow-up indicator and relying on *E. coli* only, incorporating additional indicators such as disinfection residual into the rule requirements, and treating failure to perform required corrective action, including follow up monitoring, as a treatment technique violation.

#### Monitoring

EPA is evaluating options that may involve changes to the monitoring frequency. These include eliminating the current reduced monitoring provisions for routine monitoring; adding additional triggers and/or opportunities for reduced monitoring, such as maintenance of disinfection residual or compliance history; allowing reduced monitoring for systems serving populations of >1,000 where none is provided for now; and ensuring that all systems monitor at least monthly.

Some options under consideration address monitoring location. These include changing “representative” monitoring to monitoring of locations with greatest risk; requiring monitoring only at the entry point to the distribution system; requiring monitoring at the entry point and in the distribution system for undisinfecting groundwater systems; allowing greater flexibility in the

applicability and locations of repeat monitoring; and requiring State approval of monitoring locations.

### Corrective Action

The current TCR does not include corrective action requirements. EPA is evaluating options that could include mandatory corrective action in some circumstances and development by EPA of guidance or a “toolbox” of possible PWS responses to indicator positive monitoring results. EPA will consider requiring the PWS to notify the states of their investigation and response actions, for state review and possible action. Possible PWS responses that are being discussed include operational evaluations, cross-connection control programs, pressure maintenance, flushing, temporary/increased disinfection residual in distribution system, and consultation with the State.

### Public Notification

EPA is evaluating Public Notification (PN) requirements for possible revision. Options could include eliminating “Tier 2” PN for non-acute MCL violations, and strengthening “Tier 1” PN for acute violations by requiring reverse dialing of customers. Another option might be to establish a “Tier 2” treatment technique violation when the treatment technique requirement is triggered and follow up actions are not completed or sufficiently underway. EPA is also evaluating possible improvements to the required PN content to better communicate health risks, and considering alternate triggers for PN, such as *E coli* detection combined with loss of disinfection residual.

### Sanitary Surveys

Given that sanitary survey (SS) requirements are currently contained in several rules, EPA is evaluating options that could include consolidating all SS requirements in the TCR, or eliminating the SS requirements from the TCR. The TCR revisions might also provide greater specificity regarding SS elements related to distribution systems and regarding qualifications for sanitarians who conduct surveys.

### Other Possible TCR Revisions

EPA is considering options that might result in an adjustment in how systems are categorized, to better tailor the rule requirements that apply to each category. Differences in water system structure and operation could be considered to more appropriately categorize systems or system requirements based on whether the system is small or large, whether it has a surface or ground water source, whether it is disinfected or non-disinfected, or whether there is a distribution system or there is no significant distribution system. Options are also being evaluated to consider if and how the requirements for groundwater systems under the TCR can be better coordinated with requirements under the Ground Water Rule.

## Consideration of Distribution System Requirements

The TCRDSAC is considering the current state of knowledge regarding distribution system issues to help determine what, if any, distribution system requirements might be appropriate to include in the TCR revisions. Issues being reviewed include cross-connection control programs; return to service criteria for water main repairs, rehabilitation, installation and replacement; protection of water quality in storage tanks; water quality changes in the distribution system; and pressure maintenance. The TCRDSAC may recommend distribution system research and information collection activities to EPA as a result of its review. If no TCR revisions that explicitly address distribution system issues are included in the proposed rule, some of these issues might still be relevant to EPA consideration of the rule options described above; for example, toolbox options for corrective action may include cross-connection control or other distributions system management approaches.

### **4. APPLICABLE SMALL ENTITY DEFINITIONS**

The Regulatory Flexibility Act (RFA) defines small entities as including “small businesses,” “small governments,” and “small organizations” (5 USC 601) and references the Small Business Act for the definition of “small business.” The SBA regulations define small business by size standards using the North American Industry Classification System (NAICS) (13 CFR 121.201). The RFA also authorizes an Agency to adopt an alternative definition of “small business” “where appropriate to the activities of the Agency” after consultation with the SBA and opportunity for public comment. Pursuant to 5 USC 601(3), EPA has previously established an alternative small entity definition for traditional, stationary public water systems as “a public water system that serves 10,000 or fewer people.” (*See* EPA’s Consumer Confidence Reports regulation, 63 FR 44511, August 19, 1998). Therefore, for the purposes of this SBREFA Panel Report, a small water system is any system that serves fewer than or equal to 10,000 persons. This is consistent with the SBA Office of Advocacy agreement with the EPA alternative definition used for most drinking water regulations. Small water systems affected by the rule may include PWSs in the following categories:

- Community Water System (CWS) - a public water system which serves at least 15 service connections used by year-round residents or regularly serves at least 25 year-round residents
  - Ex: towns and cities or universities, with their own water systems for residents
- Non-community Water System (NCWS) - a public water system that is not a community water system. A non-community water system is either a “transient non-community water system” or a “non-transient non-community water system.”
  - Transient non-community water system (TNCWS) - a non-community water system that does not regularly serve at least 25 of the same persons over six months per year.
    - Ex: restaurants or parks, with their own water systems

- Non-Transient Non-community Water System (NTNCWS) - a public water system that is not a community water system and that regularly serves at least 25 of the same persons over six months per year.
  - Ex: schools or factories, with their own water systems

## 5. SMALL ENTITIES THAT MAY BE SUBJECT TO THE PROPOSED REGULATION

The sizes and types of small water systems that may be subject to the planned proposed regulation are summarized in the following table.

### Small Water Systems that may be subject to the Proposed TCR Revisions (2005 SDWIS)

Type	Source	<500		501 – 3,300		3,301 – 10,000		Total	
		# PWSs	Population	# PWSs	Population	# PWSs	Population	# PWSs	Population
CWS	Unknown	9	1,652	3	4,377	0	0	12	6,029
	GW	26,282	4,234,070	10,209	13,929,151	2,658	15,134,120	39,149	33,297,341
	SW	3,372	690,026	3,911	6,119,272	2,090	12,380,594	9,373	19,189,892
	Subtotal	29,663	4,925,748	14,123	20,052,800	4,748	27,514,714	48,534	52,493,262
NTNCWS	Unknown	3	141	0	0	0	0	3	141
	GW	15,917	2,207,480	2,548	2,508,977	85	449,898	18,550	5,166,355
	SW	428	75,007	157	198,234	17	107,844	602	381,085
	Subtotal	16,348	2,282,628	2,705	2,707,211	102	557,742	19,155	5,547,581
TNCWS	Unknown	19	973	2	3,000	0	0	21	3,973
	GW	81,631	7,127,312	2,584	2,486,784	86	459,247	84,301	10,073,343
	SW	1,700	169,919	132	170,345	25	139,259	1,857	479,523
	Subtotal	83,350	7,298,204	2,718	2,660,129	111	598,506	86,179	10,556,839
Total		129,361	14,506,580	19,546	25,420,140	4,961	28,670,962	153,868	68,597,682

## 6. SUMMARY OF SMALL ENTITY OUTREACH

EPA has conducted outreach to the entire stakeholder community, including small systems, since January 2000. EPA completed numerous TCR and Distribution System status and issue presentations at drinking water industry (stakeholder) conferences between 2002 and 2007. EPA also conducted expert workshops, in 2002, 2003, and 2007. Topics for the presentations and workshops included background information on the TCR, drivers for revisions to the rule, an update on EPA review of TCR and distribution system issues, EPA perspective on cross-connection control, potential outreach strategy (information gathering, expert review, and stakeholder outreach), activities to date, and the 2006 National Academy of Sciences report on critical distribution system issues.

In addition, EPA is maintaining a web page for stakeholders and the general public to document the progress of the rule revisions. The web page contains information about the TCR Revisions, including the background papers, information about the TCRDSAC, and information about the current TCR. The web page is accessible at

[http://www.epa.gov/safewater/disinfection/tcr/regulation\\_revisions.html](http://www.epa.gov/safewater/disinfection/tcr/regulation_revisions.html).

To assist interested parties in understanding the issues that are being evaluated in the development of a revised TCR and during the consideration of distribution system issues, EPA completed nine Distribution System White Papers and 11 Total Coliform Rule Issue Papers. These papers are available on the TCR revisions web page and are listed below.

#### Distribution System White Papers

1. The Potential for Health Risks from Intrusion of Contaminants into the Distribution System from Pressure Transients
2. Potential Contamination Due to Cross-Connections and Backflow and the Associated Health Risks
3. Deteriorating Buried Infrastructure
4. Permeation and Leaching
5. Nitrification
6. Health Risks From Microbial Growth and Biofilms in Drinking Water Distribution Systems
7. Finished Water Storage Facilities
8. Effects of Water Age on Distribution System Water Quality
9. New or Repaired Water Mains

#### Total Coliform Rule Issue Papers

1. Total Coliform Rule and Distribution System Issue Papers Overview
2. Distribution System Indicators of Water Quality
3. The Effectiveness of Disinfectant Residuals in the Distribution System
4. Invalidation of Total Coliform Positive Samples
5. Analysis of Compliance and Characterization of Violations of the Total Coliform Rule
6. Evaluating HACCP Strategies for Distribution System Monitoring, Hazard Assessment and Control
7. Inorganic Contaminant Accumulation in Distribution Systems
8. Distribution System Inventory, Integrity and Water Quality
9. A Review of Distribution System Monitoring Strategies under the Total Coliform Rule
10. Effect of Treatment on Nutrient Availability
11. Causes of Total Coliform Positive Samples and Contamination Events in Distribution Systems

## 6.1 EPA's Outreach to Potential Small Entity Representatives

In July 2007, EPA began an informal outreach process to potential SERs as part of the pre-Panel planning process. EPA Headquarters contacted EPA Regional offices, States, and organizations known to represent small systems or deal with small system issues, including the SBA, to ask them to submit the names of potential SERs. EPA sought representatives from all different types of small systems (CWS, TNCWS, NTNCWS), in different ownership categories (public, private, coop), with different types of source water (GW, SW), well distributed throughout the US. EPA also looked for a range of experience including management or operation of a single system, experience assisting systems that do not have operators, and experience with a broad range of small system types and issues.

The organizations contacted included the following:

- National Rural Water Association
- The American Water Works Association
- Rural Community Assistance Program and the Midwest Assistance Program (water capacity related organizations who work closely with small systems, providing training and assistance on day to day operational problems)
- The Manufactured Housing Institute
- The American Camp Association
- The USDA Forest Service (involved with managing operations at transient non-community water systems (generally parks) in different parts of the US)

EPA also contacted potential SERs from contact lists compiled for other small system outreach/survey efforts and individuals or organizations who had volunteered in the past to participate on a SBAR Panel. Those who had previously been on a Panel and declined to participate were asked to recommend someone else from a small system in the same geographic area.

On November 1, 2007 EPA held a pre-Panel outreach meeting and teleconference with the potential SERs and invited representatives from the Office of Advocacy of SBA and the Office of Information and Regulatory Affairs within OMB to the meeting. To help SERs prepare for the meeting, EPA sent materials to each of the potential SERs via email on October 18, 2007. A list of the materials shared with the potential SERs during the pre-Panel outreach meeting is contained in Appendix A. A total of 14 potential SERs participated in the meeting. EPA presented an overview of the SBREFA process, an explanation of the planned rulemaking, and technical background regarding the 1989 TCR. This included:

- The regulatory history of the TCR and a description of related rulemakings
- Applicable small entity definitions for public water systems and numbers of the various small entities potentially subject to the planned revised rule
- Drivers for the TCR revisions, including the EPA process for reviewing drinking water regulations every 6 years and the recommendations of a prior Federal Advisory Committee

- Key activities to date, including web posting of background information and the formation of the TCRDSAC
- Available data sources under review, including historic monitoring and violation data for the existing TCR
- Small system regulatory relief that is already provided in the existing TCR
- Potential ideas for revising the TCR
- The list of potential SERs

## 6.2 SBAR Panel's Outreach to Small Entity Representatives

Thirteen of the 14 potential SERs who participated in the pre-Panel outreach activities in the fall of 2007 were invited to participate as SERs for the official Panel process. On February 25, 2008, the SBAR Panel held an outreach meeting/teleconference with the SERs. In addition to the materials that the SERs received for the pre-Panel outreach, the SERs were provided with the following background information to help them prepare for the meeting/ teleconference and prepare their comments on a proposed TCR and distribution system issues.

- (1) The SBAR Panel Outreach PowerPoint Presentation "**Total Coliform Rule Revisions: Small Entity Outreach Meeting, February 25, 2008.**" The outreach presentation was the same as the pre-Panel outreach presentation except that there were three new questions for the SERs regarding cross-connection control programs.
- (2) The Small Business Advocacy Review (SBAR) Panel Memo summarizing the initial ideas of the TCRDSAC and the Compilation Matrix of the TCRDSAC "**Initial Ideas for Revisions to the Total Coliform Rule.**"
- (3) Presentations from the December 2007 meeting of the TCRDSAC: "**Analysis of Incidence of TCR Indicators;**" and "**Implementation Actions Being Taken in Response to a TC+**"
- (4) **Potential SER Comments and Summary of Potential SER Comments** from the November 1, 2007 EPA Pre-Panel Outreach Meeting.
- (5) **List of Small Entity Representatives**

The outreach meetings with SERs were held to solicit feedback on the information provided and their suggestions for the upcoming rulemaking. At the meetings, the SERs were asked to also provide written feedback on ideas under consideration for the proposed rulemaking and responses to questions regarding their experience with the existing TCR requirements. Comments made during the November 1, 2007 and February 25, 2008 outreach meetings and written comments submitted by the potential SERS are summarized in section 8 of this document. Written comments received are included in Appendix B.

## 7. LIST OF SMALL ENTITY REPRESENTATIVES (SERs)

Thirteen of the 14 potential SERs who participated in the pre-Panel outreach activities in the fall of 2007 were invited to participate as SERs for the Panel process. One potential SER indicated that he could not participate in the Panel process. The 13 SERs invited to participate in the SPAR Panel process are listed in the table below.

### SMALL ENTITY REPRESENTATIVES – TCR Revisions

Name (State)	PWS category and Size	Affiliation / position / experience
1. Bob Bozikowski (CT)	Small systems	Atlantic States Rural Water and Wastewater Association / Training specialist for small system operations
2. Mike Sienkiewicz (PA)	GW/ CWS / Private (140)	Lebanon Valley Manufactured Housing Community / Managing partner of property / Served on the PA DEP Technical Assistance Committee for Small Water Systems. Member PA DEP Operator Certification Advisory Board. Manufactured Housing Representative since inception (9 yrs)
3. Nathan Tice (VA)	SW/ CWS, TNCWS (500-1,500)	Prince William County Service Authority/ Environmental Health Specialist, County water and wastewater program / Authority operates 8 systems, including 2 small CWSs (Home and Property Owner Associations, Country Club) and 1 NTNCS (Public Training Center)
4. Satgur Klar (GA)	SW, GWUDI, GW / TNCWS /NTNC /Fed (25-300)	Atlanta Field Office - USDA Forest Service, Southern Region / 10 years Virginia Dept of Health drinking water program. 5 years Forest Service. Managing compliance and providing technical assistance to PWS./ Most are NTNC camp grounds, picnic areas, visitor centers, some are NTNC work centers administrative offices. Treatment - from none or disinfection (GW) to filtration and disinfection for SW and GWUDI.
5. Mike Boyd (NE)	SW, GW / CWS, NTNC, TNC (<10,000)	Midwest Assistance Program / Director of Training, 7 years / Trains operators and provides technical assistance to small rural community, transient and non-transient systems.
6. Charlie Abbe (OK)	SW and GW / CWS / member owned (10,000)	Southern Oklahoma Water Corporation / Manager / With the water district for 17 years, manager since 1997. A member of NRWA. PWS participated in the Information Collection Rule Supplemental Survey.
7. George Hanson (MD)	CWS / GW / not- for-profit cooperative (9,500)	General Manager\CEO\CFO Chesapeake Water Association. Has more than 35 years management and operations experience in water treatment and distribution. System uses gaseous chlorine disinfection.

Name (State)	PWS category and Size	Affiliation / position / experience
8. Chuck Van Der Kolk (MI)	Consecutive SW (6,000)	Water Supervisor, Zeeland Board of Public Works, 33 years, served as AWWA officer, at TCR workshop (March 2007), AWWA Water Utility Council
9. Kevin Coyle	GW / SW, CWS, NTNC, TNCWS / Fed	Coronado National Forest / Water & Wastewater Systems Coordinator / 97% of systems are NC. 90% of those are TNCWS. Mostly campgrounds, administrative centers,
10. Neal Fujita (CA)	SW, GW / 4 NCWSs / public (<1,000 & 1,000+)	Water Resources Manager, East Bay Regional Park District / Operator / several NCWSs in regional parks in the San Francisco Bay area
11. John Scheltens (SD)	CWS / GW / public + Small Systems Rep. (500 + 250)	City of Hot Springs, SD and AWWA / Former PWS system engineer (30 yrs), current AWWA Chairman, Small Systems Division. Also served on AWWA Board of Directors, Executive Committee, Water Utility Council, Technical & Education Council, Administrative & Policy Council, and as Representative to the Association of Boards of Certification. Six years on NDWAC.
12. Harvey Minnigh (PR)	CWS / GW / public + RCAP (25-3,300)	Representing RCAP on the TCRDS FAC. 30 yrs experience. Has owned, operated, administered, managed water and wastewater systems from 31 service connections to 5,000, including main installation/repair, operating plants and labs, writing software for billing, officering authority boards. Last 15 years, mainly consulting and research, working in the Northeast, PR, the Caribbean, Latin America.
13. John Sasur (MA)	CWS / GW / (3,100)	Water Superintendent, Three Rivers Water Dept Corrosion control (pH adj) treatment only. Sole operator for the past 30 yrs with extensive knowledge of TCR and the implications for small systems. Very active on the MA Water Works Assoc.'s legislative committee. Also national director representing MA with NRWA.

Acronyms

CWS:	Community Water System
NCWS:	Non-Community Water System
SW:	Surface Water
GW:	Ground Water
GWUDI:	Ground Water under the Direct Influence (of Surface Water)
NTNC:	Non-Transient Non-Community (Water System)
RCAP	Rural Community Assistance Partnership
RWA	Rural Water Association
TNCWS:	Transient Non-Community Water System
TCRDS FAC	Total Coliform Rule/Distribution System Federal Advisory Committee

## **8. SUMMARY OF COMMENTS FROM SMALL ENTITY REPRESENTATIVES**

As described in Sections 5 and 6 above, EPA and the SBAR Panel conducted outreach to SERs and Potential SERs by sending outreach packages to them and conducting outreach meetings (teleconferences) with them on November 1, 2007 and February 25, 2008. In addition to the comments that the SERs made during the outreach meetings, the Panel received 12 sets of written comments from a total of eight Potential SERs during the pre-Panel outreach, and five sets of additional written comments from four SERs during the formal Panel outreach process. The written comments received were distributed to all Panel members as they were received and are included in Appendix B. A summary of the comments follows.

### **8.1 Number and Types of Entities Affected**

Several SERs suggested that the rule requirements should be tailored based on system type and size to address the various types, configurations, operation, and ownership of water systems affected by the rule.

One SER suggested that EPA should consider differences between systems that have a distribution system and those that do not, given that systems that do not have a distribution system are generally simpler and the sampling and corrective action requirements should not be the same as the requirements for more complex systems. Another SER specified that TNCWS tend to be very different and may need different requirements and methods of implementing the TCR, the assumption being that most TNCWS have no significant distribution system and thus normally will have less exposure to breaches in the sanitary barriers.

Several SERs suggested that State focus, assistance, and oversight should be on all smaller systems to improve public health protection. Three SERs suggested that TCR revisions focus on NCWS requirements. One suggested that NCWSs should be the focus of the TCR, given that they are more frequently the systems that require attention. A second recommended that monitoring frequency should be the same for NCWSs and CWSs that serve the same number of people. A third SER recommended that the frequency of sanitary surveys should be higher at NCWSs than at CWSs, and that NCWSs need more attention than CWSs because CWSs are for the most part operating properly.

One SER suggested that the requirements for TNCWSs should be the same as those for NTNCWSs because they can expose the same number of people to potential health risks.

One SER recommended that the definition of a “small water system” should be revised downward to include only systems that serve 3,300 people or less. This SER believes that combining such uniquely small systems with other systems that serve up to 10,000 persons masks the problems that systems serving 3,300 or less have in complying with additional burdens. This SER also noted that systems serving less than 500 persons per day are very different from those serving 500-10,000 per day, so that cost calculations and rule requirements should be considered separately for these two groups.

One SER provided data tables, developed from SDWIS, showing that most NCWS have 2 or less service connections, while the vast majority of CWS have a much larger number of service connections. The data tables also show that a majority of systems in all categories serve 1,000 persons or less, and that about 90% of these serve 500 persons or less.

## **8.2 Potential Reporting, Recordkeeping, and Compliance Requirements**

### **8.2.1 Maximum Contaminant Levels (MCLs), MCL Violations, Indicator Organisms and Public Notification Requirements**

SERs made several recommendations regarding whether TC, FC or *E. coli* should be the basis of the MCL, and which should be used to identify violations and spur corrective action and public notification (PN).

Two SERs suggested that the MCL should be based on *E. coli* as the correct indicator for public health protection. However, one SER was concerned about using only *E. coli* as an indicator because it does not show if there are other potential pathogens in the water supply, whereas TC provides some indication of the probability of other contamination. One SER suggested that TC should be a Maximum Contaminant Level Goal of zero, rather than an MCL.

Many SERs suggested that PN based on TC (+) results, as is required by the current rule when there are monthly, non-acute violations, is inappropriate and unjustified. Several SERs questioned the effectiveness of this type of PN. Some suggested that PN in such circumstances unnecessarily diminishes the public confidence in the drinking water supply. One suggested that TC (+) results should only be reportable to the local public health agency for the purpose of requisitioning aid and guidance to identify the source of the TC. Another SER recommended that no water system should be required to conduct PN based on a single sampling event (positive results in a routine and follow-up sample) unless that system has a history of such results or has not complied with either monitoring or inspection requirements. One SER suggested that intangible costs must also be weighed when reviewing the public notice requirements of the TCR, including the costs of finding alternatives to tap water and the environmental cost of such alternatives. This SER also believes that the relative risks of alternatives and of potential sources of contamination must be evaluated and compared.

One SER recommended that the Tier 2 public notice should not be required for TC unless multiple sites have a colony count greater than one. This SER believes that the current required language is confusing, and that for TC it implies greater contamination than may be present. The SER also suggested that requiring a notice weeks after a violation only leads to negative perception of the drinking water supply.

One SER suggested more flexibility in the TCR for the acceptable PN delivery mechanisms to allow for modern technology, such as email delivery, web posting, or auto-dialing. Another SER recommended that there needs to be uniformity in State practice regarding PN requirements.

## **8.2.2 Investigative and Corrective Action**

Several SERs suggested that TC should be used only as an operational and diagnostic tool to determine when a system should evaluate and possibly adjust its operation. One SER suggested that TC monitoring should be required as a standard operating procedure quality control tool, and that water system operators should be allowed to test randomly and as often as they see fit to protect public health. Another suggested that operators should be allowed to use TC investigative sampling without fear of triggering a violation. One SER recommended that the planned rule create a sanitary survey process of troubleshooting taught to all surveyors and operators and conducted according to procedures established in a system specific, state-approved plan. One SER suggested that both monitoring and any triggered action should be scaled to system complexity.

One SER suggested that any rule revision should include appropriate follow-up requirements, but that if repeat samples are (-), no action should be triggered. This SER also recommended that violations in the same area the next month should trigger follow-up inspections.

In general, the SERs suggested a toolbox of appropriate follow-up actions that could include: additional sampling, backflow surveys and device testing, tank inspections, cleaning and disinfection, equipment checks, line flushing, chlorine residual adjustment, and source evaluations. Two SERs opined that negative pressures in the distribution system are the cause of many problems. One of these SERs mentioned the problem of competing priorities between fire protection and drinking water supply, and suggested that pressure maintenance should be regulatory.

Two SERs suggested that determination of appropriate corrective action after a TC (+) should be left to the water system and local jurisdictions, because state prescribed actions might not be appropriate to all systems. One added that the State could be notified and provided the opportunity to comment on the corrective action chosen. One other SER suggested that positive results should be weighed in the light of the system's monitoring and inspection history, and in light of the owner or operator's commitment, where it is possible to make such a judgment.

## **8.2.3 Routine and Repeat Sampling Requirements**

SERs had numerous suggestions regarding routine, repeat, and next-month sampling requirements and regarding the circumstances under which sampling could be reduced or made more flexible.

One SER suggested that there should be a minimum of one sample per month for all systems to confirm the safety of the water. Others agreed, but when discussing options for allowing reduced monitoring there was disagreement among the SERs regarding the situations where reduced monitoring could be justified. Two SERs suggested reduced monitoring for systems with a history of non-occurrence in samples and compliance with maintenance of sanitary barriers, but one believed that the frequency of routine sampling should not be reduced for such circumstances because they do not guarantee protection from future contamination risks.

Several SERs made recommendations regarding the number of samples that should be required after a TC (+) result:

- One SER suggested that for small systems, routine monitoring should stay at one sample per month following a TC (+).
- One SER opined that small systems are punished financially with repeat sampling requirements that are illogical (three repeat samples for most systems, four repeat samples for others.)
- One SER suggested that no extra routine samples should be required in the month following a TC (+) routine if all of the repeat samples are negative.
- One SER suggested that the smallest systems that are required to take only one sample per month should not be required to take more than three repeat samples following a TC (+) result, and should not be required to take more than three routine samples in the month following a TC (+).
- One SER recommended that systems should be required to continue monitoring after a TC (+) until TC is non-detected.
- Several SERs suggested more flexibility in repeat, upstream and downstream sampling. One SER indicated that this would allow those with experience with the water system to generate more information about the system. One SER recommended more flexibility in repeat monitoring requirements to allow for issues with shipping distance, holidays, weekends and sample site access.
- One SER recommended that small systems without a distribution system should be required to take only one repeat sample if there are no upstream or downstream sites.

One SER suggested that there are better methods available now and that a method that allows simultaneous analysis for TC and *E. coli* should be required to reduce the time to obtain the *E. coli* results that suggest a public health issue.

### **8.3 Related Federal Rules**

The Ground Water Rule (GWR) requires source water monitoring for groundwater (GW) systems based on their TCR distribution system monitoring results. One SER recommended that for GW systems without a distribution system, the two rules should be coordinated to work together without confusion or duplication.

Several SERs made suggestions regarding the sanitary survey requirements in related rules as described in Section 2.3, Related Federal Rules. One SER suggested that the sanitary survey requirements could be more comprehensive. One SER suggested that distribution system

components of the sanitary survey provisions should be made more clear and concise, but that cross connection control requirements should not be added. One SER suggested that non-community systems should have more frequent sanitary surveys than community systems, instead of the other way around, as may happen under the current rules. Another SER indicated that sanitary surveys are not conducted frequently enough, they should be part of the compliance requirements, and there should be additional less rigorous inspections between sanitary surveys.

Several SERs recommended more sanitarian and operator training to improve expertise in conducting sanitary surveys and in water system operation, especially for NCWSs. One SER provided information regarding a State mentoring program that provides free technical assistance and support for operators of small systems.

#### **8.4 Regulatory Flexibility Alternatives**

The regulatory alternatives being evaluated are reflected in the SER comments above. These include:

- Replacing PN requirements for non-acute violations with investigation and corrective action requirements.
- Requirements tailored to system size and type, such as small vs. large, CWS vs. NTNCWS vs. TNCWS, and no distribution system vs. significant distribution system.
- Flexibility and criteria for reduced monitoring. Criteria that are being evaluated include compliance history and sanitary survey findings.

### **9. PANEL FINDINGS AND DISCUSSION**

Pursuant to section 609(b) of the RFA, the Panel's most significant findings and discussion with respect to the issues related to sections 603(b)(3), (4), (5) and 603(c) of the RFA are summarized below. The Panel's findings are based on the information available at the time this report was drafted. EPA is continuing to conduct analyses relevant to the planned proposed rule, and additional information may be developed or obtained during this process and from public comment on the proposed rule. Any options the Panel identifies for reducing the planned rule's regulatory impact on small systems may require further analysis and/or data collection to ensure that the options are practical, enforceable, protective of public health, and consistent with the Safe Drinking Water Act. For example, the SDWA requires that any revision of a National Primary Drinking Water Regulation must at least maintain, or provide for greater, protection of the health of persons.

#### **9.1 Number and Types of Entities Affected**

For a complete description and estimate of the small water systems to which the proposed revised rule will apply, see Section 5. At least one SER noted the large number of small systems possibly impacted (153,868) and suggested, as described in Section 8.1 above, that different requirements might be advisable for different classes of small systems based on system type,

size, and configuration. The Panel notes that the current TCR already establishes different requirements based on system size and type, but recommends that EPA continue to evaluate whether it is appropriate to further differentiate TCR requirements based on the differences among water systems.

## **9.2 Recordkeeping, Reporting, and Other Compliance Requirements**

For any drinking water program, EPA must have assurances that the drinking water provided to the public will meet the health-based drinking water MCLs and treatment requirements. Historically, EPA drinking water requirements, including the current TCR, have included requirements for public water system recordkeeping and reporting. The current TCR includes reporting and recordkeeping requirements for monitoring results, PN, and sanitary surveys. At the same time, the Paperwork Reduction Act (PRA) requires that all reporting and recordkeeping requirements have practical utility and appropriately balance the needs of government with the burden on the public. As EPA proceeds with any revisions to the requirements of the current TCR, EPA will also assess the need for revisions to reporting and recordkeeping requirements and will consider them in any estimation of the burden and benefits of the rule changes. EPA is committed to keeping paperwork requirements to the minimum necessary to fulfill its statutory obligations, as required by the PRA.

## **9.3 Related Federal Rules**

The Panel is aware of the Surface Water Treatment Rule, three enhanced surface water treatment rules (Interim, Long Term 1 and Long Term 2 Enhanced Surface Water Treatment); Total Trihalomethanes, Stage 1 and Stage 2 Disinfectants and Disinfection Byproducts and the Ground Water Rule, and is aware of how the requirements of these rules might relate to possible revised TCR requirements. The Panel notes that these rules have all been developed with careful attention to the interaction between each new rule addressing microbial and disinfection issues and the earlier rules addressing these issues. The Panel recommends that EPA continue to ensure that any revisions to the TCR be coordinated with, and do not either duplicate or conflict with, the requirements of these other rules. Specifically, the Panel recommends that EPA consider how best to conform the sanitary survey requirements that appear in the different rules.

## **9.4 Regulatory Flexibility Alternatives**

### **9.4.1 MCLs, Corrective Action and Public Notification Requirements**

As described in Section 2.2 above, under the current TCR, a monthly (non-acute) MCL violation has occurred if more than 5.0 percent of distribution system samples collected in any month contain TC bacteria. For PWSs serving 33,000 or fewer people, this means that no more than 1 sample per month may be TC (+), because these PWSs collect fewer than 40 samples per month. When the number of TC (+) samples exceeds these limits a monthly MCL violation has occurred, and the PWS must notify the State by the end of the next business day after the PWS learns of the violation, and must notify the public within 30 days. The SERs commented that this requirement is ineffective, confusing, and leads to unnecessary public distrust of the water

system, because total coliforms do not themselves represent a health risk and the notification usually comes well after the incident occurred and water quality has returned to normal.

SERs also suggested that TC (+) samples could serve a better purpose by triggering assessment or corrective action requirements appropriate to the water system type and complexity. SERs also emphasized the wide variability in system sources, configurations, and issues and indicated that any corrective action requirements should leave flexibility to the operator to respond to the detection in an appropriate manner, which might range from merely confirming that a TC (+) result was an isolated incident of short duration, to major rehabilitation of the system in cases where the detection turned out to be indicative of significant structural problems.

The Panel agrees that the TCR as revised should continue to meet the three objectives of the 1989 rulemaking: to ensure integrity of the distribution system, indicate effectiveness of treatment, and indicate possible fecal contamination. The Panel supports an approach which uses TC as a trigger for investigation and corrective action rather than as the basis for an MCL violation and notification to the public. With the appropriate monitoring, investigation, and corrective action elements, the Panel believes that such an approach can be structured to satisfy the SDWA requirement that any revised regulation at least maintain the level of public health protection of existing regulations. Under such an approach, TC (+) results would still require immediate follow up or concurrent testing for *E. coli*, and *E. coli* positive results would serve as the basis for an acute MCL violation and as a trigger for immediate public notification. The Panel further recommends that EPA develop a toolbox of appropriate enforceable investigative and corrective action responses. The Panel recognizes that in many cases system operators and primacy state regulatory authorities have considerable expertise in system operations, and encourages EPA to develop an approach that includes flexibility to rely on this expertise where appropriate.

#### **9.4.2 Monitoring**

The Panel notes that several SERs were concerned that the monitoring scheme in the current TCR allows States to reduce monitoring to quarterly or annually for some classes of systems (such as small non-community systems), and that such reduced monitoring schemes may not be sufficiently protective of public health. The Panel recommends that EPA develop options that would ensure that routine monitoring and any provisions for reduced monitoring appropriately balance risk and cost/burden and ensure protection of public health. This could include targeting more frequent monitoring for small community and/or non-community systems to high risk sites or systems. The Panel also recommends that, when considering criteria under which systems could reduce monitoring from the baseline, or would be required to increase monitoring back to the baseline after it has been reduced, EPA should consider public health protection and the resources required in tracking changes in monitoring frequency. Examples of criteria that may be appropriate for determining the frequency of monitoring include system size, sanitary survey results, compliance history, past monitoring results, system configuration (e.g. distribution system vs. no distribution system), source type, source water vulnerability, treatment in place (e.g. disinfection) and operator training.

SERs also commented that requirements should be different for water systems without a distribution system, especially TNCWSs, because the system is much simpler and less vulnerable to sanitary breaches. More generally, most SERs expressed concern with the current repeat and next-month routine sampling requirements following a TC (+) result. For example, it may not make sense to require multiple repeat samples for a system without a distribution system that has only one tap. Therefore, the Panel recommends that EPA specifically tailor small system repeat monitoring requirements to the characteristics and situations of different system types, where practicable. One approach may be to allow greater flexibility in the number and location of repeat samples, with appropriate State oversight.

The Panel also recommends that EPA continue to evaluate what parameters are most appropriate for routine monitoring and as potential triggers for investigative and corrective action. Specifically, EPA should assess the advantages and disadvantages of continuing to allow FC as an alternative indicator to *E. coli* and the appropriate role for monitoring disinfectant residual. The Panel also recommends that EPA continue to evaluate the possible use of methods that will provide a rapid result for both TC and *E. coli*, so that any additional monitoring, assessment, and corrective action can be commenced in as timely a manner as possible. EPA should also consider whether there is analytic value in receiving a colony count, as well as a presence/absence result, and tailor analytic requirements accordingly.

## **Appendix A**

### **List of Materials EPA shared with Potential Small Entity Representatives** (October 2007)

- The presentation prepared for the meeting/teleconference
- The URL for the TCR Revisions Web Page
- Distribution White Papers
- Total Coliform Rule Issue Papers
- Prior Presentations Regarding TCR Revisions
- List of Potential Small Entity Representatives
- TCR Six-Year Review Information

### **Additional Materials the SBAR Panel shared with Small Entity Representatives** (February 2008)

- The SBAR Panel Outreach PowerPoint Presentation "**Total Coliform Rule Revisions: Small Entity Outreach Meeting, February 25, 2008.**"
- The Small Business Advocacy Review (SBAR) Panel Memo summarizing the initial ideas of the TCRDSAC and the Compilation Matrix of the TCRDSAC "**Initial Ideas for Revisions to the Total Coliform Rule.**"
- Presentations from the December 2007 meeting of the TCRDSAC: "**Analysis of Incidence of TCR Indicators;**" and "**Implementation Actions Being Taken in Response to a TC+**"
- **Potential SER Comments and Summary of Potential SER Comments** from the November 1, 2007 EPA Pre-Panel Outreach Meeting.
- **List of SERs**

## **Appendix B**

### **Written Comments Submitted by Small Entity Representatives**

**(Comments were forwarded to the Panel as they were received)**