

March 31, 2008

The Honorable Stephen Johnson  
Administrator  
U.S. Environmental Protection Agency  
Ariel Rios Building  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460

Dear Administrator Johnson:

Enclosed for your consideration is the Report of the Small Business Advocacy Review Panel (SBAR Panel or Panel) convened for EPA's planned proposed rulemaking entitled "Revisions to the Total Coliform Monitoring and Analytical Requirements and Consideration of Distribution System Issues." Possible revisions to the Total Coliform Rule (TCR) are being developed by the U.S. Environmental Protection Agency (EPA) under the Safe Drinking Water Act (SDWA).

The TCR was promulgated on June 29, 1989 and became effective on December 31, 1990. 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 includes maximum contaminant levels (MCLs) for total coliforms (TC) and fecal coliforms (FC), and has requirements for public notification (PN) when MCL violations occur. The TCR also includes requirements for reporting and recordkeeping and periodic sanitary survey inspections of the water system.

The SDWA requires EPA to review existing national primary drinking water regulations every six years. In 2003, EPA completed its Six-Year Review of the TCR and 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. The SDWA requires that public health protection be maintained or improved any time EPA revises a drinking water regulation.

In conjunction with its consideration of TCR revisions, EPA is also considering if and how risks associated with drinking water distribution systems should be addressed. This evaluation is being conducted to address the recommendations of the Stage 2 Microbial/

Disinfection Byproducts Federal Advisory Committee (M/DBP FAC) “Agreement in Principle” that was completed in 2000. That Advisory Committee was formed to make recommendations concerning two other drinking water rules, the Long-Term 2 Enhanced Surface Water Treatment Rule and the Stage 2 Disinfection Byproducts Rule. In its Agreement in Principle, the M/DBP FAC recommended that EPA review and evaluate available data and research on those aspects of distribution systems that may create or pose risks to public health. 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 other distribution systems issues related to significant health risks. EPA is conducting the distribution system data and research review and the stakeholder participation process in conjunction with the consideration of the TCR revisions.

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 SBAR Panel will inform the TCRDSAC of the findings in this report before the TCRDSAC completes its final analysis and recommendations.

On January 31, 2008, EPA’s Small Business Advocacy Chairperson convened this Panel under section 609(b) of the Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA). In addition to its chairperson, the Panel consists of the Director of the Standards and Risk Management Division within EPA’s 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). It is important to note that the Panel’s findings and discussion are based on the information available at the time this report was drafted. EPA is continuing to conduct analyses relevant to the proposed rule, and additional information may be developed or obtained during this process as well as from public comment on the proposed rule. The options the Panel identified for reducing the rule’s economic impact on small entities will require further analysis and/or data collection to ensure that the options are practicable, enforceable, protective of public health, environmentally sound and consistent with the SDWA.

## **SUMMARY OF SMALL ENTITY OUTREACH**

EPA is involving stakeholders very early in the rule revision process to ensure the quality of information on affected entities, identify and understand potential implementation and compliance issues, and explore regulatory alternatives. In the process, EPA received direct input from small PWSs (those that serve less than 10,000 persons per day) and their industry representatives about the possible impacts of the planned proposed rule revisions.

Prior to convening the Panel, EPA conducted outreach with small entities that will potentially be affected by these regulations. In November 2007, EPA invited SBA, OMB, and 23 potentially affected small PWSs and industry representatives to a conference call and solicited comments from them on preliminary information sent to them. EPA shared the small entities' written comments with the Panel as part of the Panel convening document.

After the SBAR Panel was convened, the Panel distributed additional information to the small entity representatives (SERs) on January 31, 2008, for their review and comment and in preparation for another outreach meeting. On February 25, 2008, the Panel met with the SERs to hear their comments on the information distributed in these mailings. The SERs were asked to provide written feedback on ideas under consideration for the proposed rulemaking and responses to questions regarding their experience with the existing TCR requirements. The Panel received written comments from the SERs in response to the discussions at this meeting and the outreach materials. See Section 8 of the Panel Report for a complete discussion of SER comments. Their full written comments are also attached. In light of these comments, the Panel considered the regulatory flexibility issues specified by RFA/SBREFA and developed the findings and discussion summarized below.

## **PANEL FINDINGS AND DISCUSSION**

Under section 609(b) of the RFA, the Panel is to report its findings related to these four items:

- 1) A description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply.
- 2) A description of the projected reporting, recordkeeping and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record.
- 3) Identification, to the extent practicable, of all relevant federal rules which may duplicate, overlap or conflict with the proposed rule.
- 4) A description of any significant alternatives to the planned proposed rule which would minimize any significant economic impact of the proposed rule on small entities consistent with the stated objectives of the authorizing statute.

The Panel's most significant findings and discussion with respect to each of these items are summarized below. To read the full discussion of the Panel findings and recommendations, see Section 9 of the Panel Report.

### **A. 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 of the Report. The total number of small systems possibly affected by the rule revisions is estimated at 153,868. The types of small systems affected could be Community Water Systems (public water systems which serve at least 15 service connections used by year-round residents or regularly serves at least 25 year-round residents) or Non-Community Water Systems, such as restaurants, parks, schools or factories with their own water system. Small Entity Representatives (SERs) noted the large number of small systems possibly impacted and suggested that different requirements might be advisable for different classes of 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 in water systems. Additional recommendations regarding how requirements can be tailored to different system types and sizes are indicated in the following sections.

### **B. 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.

### **C. Related Federal Rules**

The Panel is aware that numerous drinking water regulations are related to the TCR, including the Surface Water Treatment Rule, three enhanced surface water treatment rules (Interim, Long Term 1 and Long Term 2 Enhanced Surface Water Treatment), the Total Trihalomethanes, Stage 1 and Stage 2 Disinfectants and Disinfection Byproducts Rules, and the Ground Water Rule. The Panel is aware of how the requirements of these

rules might relate to possible revised TCR requirements, and the relationships were discussed with the SERs at the outreach meetings. For a detailed description of these related rules, see section 2.3 of the Report. 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.

## **D. Regulatory Flexibility Alternatives**

### **1. MCLs, Corrective Action and Public Notification**

As described in Section 2.2 of the report, 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 are total coliform positive (TC (+)). 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 believes 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/or 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 immediately 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.

## **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

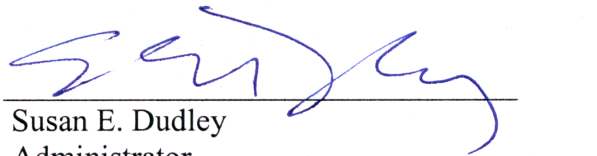
commenced in as timely a manner as possible. EPA should also consider whether there is analytic value in receiving a colony count, as well as a presence/absence result, and tailor analytic requirements accordingly.

Sincerely,




---

Alexander Cristofaro  
Small Business Advocacy Chair  
Office of Policy, Economics and Innovation  
U.S. Environmental Protection Agency




---

Susan E. Dudley  
Administrator  
Office of Information and Regulatory Affairs  
U.S. Office of Management and Budget



---

Thomas M. Sullivan  
Chief Counsel  
Office of Advocacy  
U.S. Small Business Administration



---

Pamela Barr  
Director  
Standards and Risk Management Division  
Office of Ground Water and Drinking Water  
U.S. Environmental Protection Agency

Enclosure