

June 9, 1998

Ms. Carol M. Browner
Administrator
United States Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Dear Administrator Browner:

Enclosed for your consideration is the Report of the Small Business Advocacy Review Panel convened for EPA's rulemaking on the Ground Water Rule (GWR). The Agency's goal in developing the GWR is to reduce the risk of illness caused by microbial contamination in public water systems relying on ground water. To achieve this goal, EPA is considering a multi-barrier approach that could include source water assessment and protection, identification and correction of system defects, proper maintenance of the well and distribution system, appropriate use of disinfection where necessary, and monitoring.

On April 10, 1998, EPA's Small Business Advocacy Chairperson (Thomas E. Kelly) convened this Panel under section 609(b) of the Regulatory Flexibility Act 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 of the Office of Ground Water and Drinking Water within EPA's Office of Water, the Administrator of the Office of Information and Regulatory Affairs within the Office of Management and Budget, and the Chief Counsel for Advocacy of the Small Business Administration.

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 the remainder of the rule development process and from public comment on the proposed rule. Any options the Panel identifies 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.

Stakeholder Meetings and Small Entity Outreach

The rule being considered could potentially affect all public water supplies that use ground water as a source of drinking water. A public water system provides water for human consumption through pipes and other constructed conveyances. There are 158,000 public water systems that use

ground water. The term “public water systems” applies not only to water utilities, but also to a wide range of privately or publicly owned businesses and entities that provide drinking water (e.g., campgrounds, factories, restaurants, and schools).

The Office of Ground Water and Drinking Water (OGWDW) plans to develop a proposed rule in March of 1999 and a final rule by November of 2000. To facilitate regulation development, EPA has actively involved stakeholders in the development of the proposed rule. As part of this effort, EPA is sponsoring public meetings across the country. The purpose of these meetings is to provide stakeholders with summaries of the data that support rule development; engage stakeholders in analysis and discussion of the implications of the data; solicit additional data; discuss EPA’s next steps for rule development, data analysis, and stakeholder involvement; and identify additional parties who may be interested in future meetings. OGWDW is planning two additional stakeholder meetings to collect additional information regarding the potential impact the GWR may have on regulated systems.

OGWDW believes that input from small entities is particularly important in the rulemaking process because so many systems are small. EPA consulted with twenty two small entity representatives (SERs) for the GWR SBREFA process which represent a broad range of the entities potentially affected by the rule including small water utilities and businesses providing drinking water ancillary to their primary business, such as, restaurants, mobile home parks, hotel/motels, factories, and campgrounds, representatives from home-owner associations, investor-owned systems, purchased water systems, small local governments, and churches. The SERs were provided with background information on the Safe Drinking Water Act and the GWR at a meeting on March 4, 1998 at EPA Headquarters. The SERs also received *Information for Small Entity Representatives Regarding the Ground Water Rule* that described possible components of a GWR. All 22 SERs provided comments on these materials. The SBAR Panel convened on April 10, 1998. The SERs were provided with additional information on possible regulatory approaches for the GWR and a discussion of the occurrence data prior to a teleconference with the Panel on May 18, 1998. Three SERs provided additional written comment following the teleconference. A summary of the comments during a teleconference and written comments received by both OGWDW and the Panel are included in the report. OGWDW will consider the comments received at the public meetings along with the Panel’s recommendations when developing the proposed rule.

Panel Findings and Discussion

Under the RFA, the Panel is to consider four regulatory flexibility issues related to the potential impact of the rule on small entities: (1) the type and number of small entities to which the rule will apply; (2) record keeping, reporting and other compliance requirements applicable to small entities; (3) the rule’s interaction with other Federal rules; and (4) regulatory alternatives that would minimize the impact on small entities consistent with the stated objectives of the statute authorizing the rule. The Panel’s most significant findings and discussion with respect to each of these issues are summarized below. In addition, the Panel discussed several issues related to the general approach currently being considered

by EPA for the proposed rule.

Major Topics of Panel Discussion

Panel members have not been able to agree upon the degree to which currently available viral and bacterial occurrence data for public ground water systems are representative of national conditions. The range in the occurrence rate is reflective of the different testing methods used in the different studies and the sensitivity of particular methods. In addition, the studies underlying those numbers were conducted at different times and for different purposes. Some emphasized high-risk wells, and some examined a variety of wells, including many that were not expected to present high risk. Therefore, the 600 wells included in these studies do not represent a statistically random sample of ground water wells. EPA has not presented the data to represent a nationally applicable occurrence rate for fecal contamination.

With regard to national data on Total Coliform Rule (TCR) violations, EPA is concerned that fecal coliform data are not necessarily a good indicator of national microbial pathogen occurrence, both because of a low frequency of sampling for many systems and because neither fecal nor coliform tests can identify the presence or absence of virus. However, these data are clearly relevant to the rule development process and will be included with the other information that EPA considers with stakeholders in developing the GWR proposal.

One of the points that EPA emphasized in its fact sheet distributed to SERs on Microbial Occurrence is the question of how all these data should be interpreted and used in developing the GWR. EPA believes these data raise an important concern that current microbial monitoring approaches may significantly understate the occurrence of ground water contamination from fecal viruses and fecal bacteria. This information indicates that both viral and bacterial contamination can and do occur in underground sources of drinking water, though the degree and extent of this contamination is not fully known.

EPA believes that most ground water supplies are safe. However, EPA has a statutory obligation to protect public health by regulating contaminants of concern for which there is a meaningful opportunity for health risk reduction. Taking into account all the data currently available to the Agency, EPA believes that fecal contamination of ground water warrants such regulation.

OMB and SBA shared the concern of some commenters that the study data presented by EPA may significantly overstate the extent of ground water fecal contamination nationally. OMB and SBA thus recommend that in evaluating the usefulness of these data for estimating national occurrence rates, the agency give careful consideration to the well selection criteria and methodologies used in the individual studies. Studies in which wells were selected because of a known risk of contamination would not be appropriate for estimating national occurrence. EPA should also be alert to inadvertent sources of bias in the occurrence rate estimates produced by these studies. For example, if all of the

wells in a study are currently disinfecting, this may be an indication that many of them previously detected contamination and are therefore more likely to be high risk. Conversely, if well operators volunteered for participation in a study, there may have been a natural self selection process in which those most likely to have contamination problems would be least likely to volunteer. Finally, if a study included a mix of targeted high risk wells along with a more representative sample, occurrence rate estimates should only be based on the subset of wells considered to be representative.

EPA recognizes and understands the concern that available study data may overstate the extent of ground water contamination. OGWDW notes, however, that it has received input from a number of virologists and microbiologists suggesting that available information may also possibly understate the extent of ground water contamination for several reasons. Much of the current occurrence data is based on single grab samples; the analytical methods used are sensitive only to a subset of virus families associated with water-borne diseases; and, as noted above, there may have been significant self-selection among system operators volunteering to participate in these studies. In light of these different perspectives, EPA continues to stress that a central issue facing all participants and stakeholders in this rulemaking is how to interpret available information. EPA agrees that the Ground Water Rule must be based on the best available data, good science, and sound analysis. OGWDW will continue to evaluate existing information, gather new information from studies not yet complete, and consult with all stakeholders on the nature and scope of the problem. As noted above, the studies EPA has under examination were conducted at different times and for different reasons; each requires careful analysis to ensure its proper use and to avoid misuse.

Types and Number of Potentially Affected Small Entities

The Panel notes that the number of potentially impacted small systems is significant (about 157,000) and suggests EPA focus the compliance requirements upon only those systems which are at risk of fecal contamination. In this regard, the Panel suggests that EPA continue to evaluate whether it may be appropriate to establish different ground water requirements for a particular system based upon system type, size, or location. This can also be accomplished by giving maximum flexibility to primacy states, consistent with ensuring an appropriate minimum level of public health protection nationally, to tailor specific requirements to individual system needs and resources.

Record Keeping, Reporting and Other Compliance Requirements

The Panel notes the concern of many SERs that small systems often have a single, part-time operator with many other responsibilities and suggests EPA keep reporting and record keeping requirements to the minimum necessary to ensure adequate protection of public health. The Panel further suggests EPA focus the record keeping, reporting and other compliance requirements upon the ground water systems which face the greatest risk of contamination. Minimal requirements should be imposed upon systems which demonstrate they are at a low risk of contamination.

The Panel recommends development of cost effective approaches for evaluating the risk of contamination that minimizes the need for system operators to produce records that are not readily available. Risk evaluation approaches should focus upon techniques which are inexpensive and effective. EPA, after consultation with the SERs, stakeholders and SBAR Panel has determined that it will not use factors such as: (1) lack of adequate well records, (2) lack of a cross-connection control program, or (3) intermittent pressure fluctuations as automatic triggers to indicate a potential risk of contamination, although these factors may be considered along with other evidence which more definitively demonstrates risk (e.g. uncorrected significant defects noted in past sanitary surveys) in evaluating whether corrective action is needed and what that action should be. The Panel supports this determination.

The Panel notes the SERs' concerns regarding the impact additional monitoring would have upon small systems, particularly if expensive viral indicator methods are required. The Panel believes that in determining whether and under what circumstances to require monitoring for viral indicators, EPA should consider the value of the information obtained from such monitoring in comparison to the cost of obtaining that information. EPA should only require monitoring for additional indicators if it determines that such monitoring can cost-effectively provide significant additional information on the presence of fecal contamination in ground water. Furthermore, the Panel is concerned about the practicability of requiring viral monitoring for small systems unless there is a significant decline in the cost (which currently ranges from several hundred to a thousand dollars per sample). Therefore, the Panel recommends continuing to support, as a high priority, efforts to develop cost effective viral indicator methods (such as a \$50 coliphage test). In addition, the Panel notes that EPA is currently supporting research intended to develop an approach by which states can identify those systems with the highest risk of viral contamination and strongly endorses this effort. If a reliable and workable method for identifying high risk systems is developed and some viral monitoring is required, the Panel believes that EPA should consider requiring viral monitoring only for these high risk systems.

A number of SERs indicated that they were not opposed to a modest increase to the minimum frequency of total coliform monitoring or to an increase in sampling locations to include the source water in the event of a positive TCR sample because this would be far less burdensome than a requirement for regular viral monitoring. The Panel urges EPA to evaluate continued use of the sampling methods required by the TCR as the central tool for detecting fecal contamination until cost effective alternative methods are developed.

The Panel notes that many SERs believe sanitary surveys are effective tools for identifying problems which may lead to fecal contamination. The Panel believes that States should also have the authority to require the correction of significant defects as a cost effective method of eliminating risks of contamination. The Panel recommends, however, allowing States the flexibility to distinguish among the defects those which are significant for public health protection and those which are not.

The Panel also notes concerns expressed by many SERs that EPA should not require disinfection for all public water systems regardless of the potential risk of contamination. The Panel agrees with EPA that fecal contamination of public drinking water is a public health threat that must be corrected. The Panel recommends, however, that States be provided with the flexibility to select the most appropriate corrective action from a list which includes, but is not limited to, disinfection. At the same time, States should also have the flexibility to mandate across-the-board disinfection for all or a subset of systems if they determine that this provides the most appropriate level of public health protection. In this context, however, the Panel notes the concern of several SERs that disinfection not be viewed as a substitute for good sanitary engineering.

Although disinfection may be necessary in some circumstances, the Panel is concerned about the potential cost burden to systems that may be required to disinfect as a result of the GWR. In developing requirements or guidance concerning the appropriate use of disinfection, EPA should consider (and include in its regulatory cost estimates) the complete burden and benefits associated with the rule.

EPA should also consider (and quantify to the extent possible) health risks and benefits that may result from the use of disinfectants, including those associated with elevated levels of other contaminants and with the storage and use of hazardous chemicals.

Interaction with Other Federal Rules

The Panel suggests using the Source Water Assessment Program's (SWAP) susceptibility determination as a component of the vulnerability assessment process. SWAP assessments could provide much of the data needed to evaluate the risk of fecal contamination. EPA should encourage States and systems to utilize SWAP data to the extent possible when assessing system vulnerability, in order to avoid duplicative data collection.

The Panel also recommends that any monitoring required under the GWR should complement TCR monitoring and rely as much as possible on the TCR's analytical methods as indicators of fecal contamination in ground water.

The Panel also notes that when developing regulations or guidance relating to disinfection, EPA should carefully consider the potential increase in other contaminants of concern (e.g., disinfection byproducts) and allow states and systems adequate flexibility to avoid or mitigate them in the most cost-effective manner. They should also be appropriately accounted for in the Regulatory Impact Analysis for the GWR.

Regulatory Alternatives

In general, SERs supported the multi-barrier approach, while at the same time commenting on

various aspects of it that might be burdensome or otherwise problematic for them. The Panel recommends that EPA consider tailoring compliance requirements to system size. For example, the burden upon the smallest systems (e.g. systems serving 500 or less) could be decreased by reducing the required monitoring frequency, or the minimum required frequency of sanitary surveys.

The Panel recommends that EPA consider combining the vulnerability assessment and sanitary survey into a single requirement. This requirement could be tiered, with a relatively low-effort screening assessment used to eliminate low-risk systems, followed by more data-intensive assessments for systems that might be at risk. Systems that find no contamination over a period of years may be considered low-risk.

The Panel also recommends EPA consider some variation on this approach as it could significantly reduce the record-gathering burden on small systems and the assessment burden on primary states. Another option might be to allow a streamlined, combined vulnerability assessment and sanitary survey for very small systems, which are least likely to have complete records, while requiring more comprehensive (and perhaps separate) vulnerability assessments and sanitary surveys for larger systems.

The Panel believes EPA should carefully consider all comments received during this outreach process on these and other issues of concern to small entities. A full discussion of the comments received and Panel recommendations are included in the final report.

Sincerely,

/S/

Thomas E. Kelly, Chair
Small Business Advocacy
Environmental Protection Agency

/S/

Don Arbuckle, Acting Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget

/S/

Jere W. Glover
Chief Counsel for Advocacy
U.S. Small Business Administration

/S/

William R. Diamond, Director
Standards and Risk Management Division
Office of Ground Water and Drinking Water
Office of Water
U.S. Environmental Protection Agency

Enclosure