REPORT OF THE SMALL BUSINESS ADVOCACY REVIEW PANEL

ON

EPA'S PLANNED PROPOSAL OF THE NATIONAL PRIMARY DRINKING WATER REGULATION FOR ARSENIC

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1. INTRODUCTION

This report is presented by the Small Business Advocacy Review Panel convened for the proposed rulemaking on the National Primary Drinking Water Regulation for Arsenic that the Environmental Protection Agency (EPA) is currently developing. On March 30, 1999, 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 of 1996 (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, and the Chief Counsel for Advocacy of the Small Business Administration.

This report provides background information on the proposed arsenic in drinking water rule being developed and the types of small entities that would be subject to the proposed rule; a summary of OGWDW's and the Panel's outreach activities; and the comments and recommendations of the small entity representatives (SERs). In addition, Section 609(b) of the RFA directs the review panel to report on the comments of SERs and make findings as to issues related to identified elements of an initial regulatory flexibility analysis (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;
- A description of 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 relevant Federal rules which may duplicate, overlap, or conflict with the proposed rule; and
- A description of 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.

Once completed, the Panel report is provided to the agency issuing the proposed rule and included in the rulemaking record. In light of the Panel report, the agency is to make changes, where

appropriate, to the draft proposed rule, 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 this report was drafted. EPA is continuing to conduct analyses relevant to the proposed rule. The Agency expects additional information will be developed or obtained during the remainder of the rule development process. It is important to note that the Panel makes its report at an early stage in the rule development process when SER comments and insights can inform the Agency's thinking about fundamental issues of rule design and scope, and can be taken into account in a meaningful way. Early involvement ensures that small entity perspectives are considered as the Agency develops the supporting analyses for the rule. However, this early opportunity means that less information and analysis regarding possible regulatory options is available than would be the case at a later stage in the process when the Agency focuses in on a relatively narrow set of regulatory options.

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, protective of public health and consistent with the statute authorizing the proposed rule.

2. BACKGROUND

Arsenic (As) is a natural element found in the human body and present in food, water, soil, and air. In water the primary arsenic species (As^{V+} and As^{III+}) are inorganic. Present data indicates that the inorganic forms are usually more toxic than organic forms, however more data are needed.

Exposure of humans to high levels of arsenic has been associated with skin and various internal cancers. Specifically, various studies have associated arsenic ingestion with cancers of the human kidney, bladder, liver, lung, and other organs. Unfortunately, at the present time, there is no reliable animal model for studying the development of arsenic-induced cancers. Accordingly, work on its potential mode(s) of action are limited. Its noncarcinogenic (non-cancer) effects are also potentially serious depending on the levels of ingestion and include dermal (lesions), cardiovascular, neurological, hematological and gastroenterological effects and diabetes. EPA is in the process of quantifying the non-cancer effects of arsenic in order to compare the exposures to arsenic that are associated with carcinogenic and noncarcinogenic effects.

EPA currently regulates arsenic in drinking water at 50 parts per billion (ppb; micrograms per liter [µg/L] is frequently used as an equivalent unit of measurement for ppb), which was set as a National Interim Primary Drinking Water Regulation in 1975 and converted to a National Primary Drinking Water Regulation (NPDWR) in 1986, subject to revision by 1989. When EPA failed to meet the statutory deadline, a citizens' group filed suit and the Agency entered into a consent decree to issue the regulation. EPA held internal workgroup meetings throughout 1994, addressing risk assessment,

treatment, analytical methods, arsenic occurrence, exposure, costs, implementation issues, and regulatory options before deciding in early 1995 to defer the regulation in order to conduct additional research to better characterize health effects and treatment costs.

Congress amended the Safe Drinking Water Act (SDWA) in 1996, requiring EPA to propose a NPDWR for arsenic by January 1, 2000, and issue a final regulation by January 1, 2001. In addition, EPA must review the new regulation by 2007 at the latest, and revise it, if appropriate, based on new data and information. With the new statutory deadlines for the arsenic regulation, the litigation for arsenic was dismissed in November, 1996. The 1996 SDWA amendments also directed EPA to "develop a comprehensive plan for study in support of drinking water rulemaking to reduce the uncertainty in assessing health risks associated with exposure to low levels of arsenic," by February 1997. Congress specified that EPA consult with the National Academy of Sciences, and other interested entities in conducting the research. EPA provided the draft Arsenic Research Plan for peer review in early 1997, and the final report responded to the peer review comments. The plan serves as the framework for directing research that will contribute to the regulation, both for the statutory deadline and for future reviews. It identifies the health risks and control technology research EPA is involved in and the essential projects that the Agency has not funded, which may be funded by other groups. In addition, as part of its efforts to develop the new regulation, EPA asked the subcommittee on Arsenic in Drinking Water of the Committee on Toxicology of the National Research Council (NRC) in the National Academy of Sciences (NAS) to review EPA's risk assessment of arsenic. NRC submitted its report in March 1999.

EPA has estimated human exposure to arsenic in drinking water, food, and air based on various surveys analyzing the occurrence of arsenic in public water supplies, dietary foods, and ambient air. Using the Food and Drug Administration's (FDA) Total Diet Study, recent dietary analyses indicate that the average adult's total arsenic intake is about 50 Fg/day. However, the FDA analytical methodology does not differentiate between organic and inorganic forms of arsenic. Since the inorganic forms are considered to be more toxic, it is important to estimate the amount of inorganic arsenic in the diet. EPA used the FDA data along with a separate study that characterized arsenic species in foods, and this characterization indicated that about 10 to 20 percent of the daily intake of dietary arsenic may be in the inorganic form. Likewise, the NRC report provided data assuming that A10% of the arsenic in seafood is inorganic and that 100% of arsenic in the rest of the food is inorganic. The estimates are high but nevertheless set an upper bound." The NRC report gave the example that an adult male would ingest almost 10 µg of inorganic arsenic per day. EPA's national air sampling data bases indicate very low concentrations of arsenic in both urban and non-urban locations, at levels typically ranging from about 0.003-0.03 Fg/m^3. Therefore, air is an insignificant source of arsenic intake, representing typically less than one percent of overall exposure.

3. OVERVIEW OF POTENTIAL REQUIREMENTS AND GUIDELINES OF THE PROPOSAL

EPA has not yet developed a revised maximum contaminant level (MCL) or compliance requirements for the rule. As part of the development of these requirements, EPA would like to involve States and other stakeholders, including SERs, in the process. To obtain input from SERs, the following briefly describes the two main categories of potential compliance requirements: treatment and monitoring.

3.1 Treatment for Arsenic in Drinking Water

Treatment technologies are available for small systems to treat arsenic contaminated water. Centralized treatment technologies include ion exchange, activated alumina and membrane technologies. In addition, point-of-use and point-of-entry devices may also be a viable option for the smaller systems. Several other technologies, such as greensand filtration, require further investigation, but may also be applicable for small system treatment. Non-treatment alternatives also deserve consideration, especially if the source water is of poor quality. One option would be to purchase water from a nearby utility. Another option may be to find another water source (*e.g.*, by relocating a well). However, since arsenic is a naturally occurring contaminant, it may be ubiquitous at a particular site, so drilling another well may not improve the situation.

Compliance Technologies

Since small water systems often have difficulties raising the revenue to install and operate water treatment technologies, they favor low-cost treatment options. Section 1412(b)(4)(E) of the 1996 SDWA Amendments requires EPA to issue a list of technologies that achieve compliance with MCLs established under the Act that are affordable and applicable to typical small drinking water systems, if such technology exists. (If not, small systems may receive a variance under certain conditions - see detailed discussion below) These small public water system categories are listed below:

- Population of more than 25 but less than 500;
- Population of more than 500, but less than 3,300; and
- Population of more than 3,300, but less than 10,000.

Owners and operators may choose any technology or technique that best suits their conditions, as long as the MCL is met.

Treatment Technology Issues

EPA is presently studying the arsenic removal technologies listed in Table 1. Also listed in this table are some of the major issues associated with each technology. A short description of these issues follows.

Table 1: Arsenic treatment technologies and issues

Treatment Technology	Issues
Ion exchange	Competition issues. Recommended for low sulfate and total dissolved solids (TDS). Possibly polishing step after filtration. Produces highly concentrated waste stream. Possible to recycle brine to reduce waste stream.
Activated alumina	Effective with high TDS. Chemical handling issues. Competition for adsorption sites. Produces highly concentrated waste streams.
Reverse osmosis, nanofiltration and electrodialysis reversal (EDR)	Corrosion control for low-level options. Dilute waste stream uses more water. EDR may have higher costs and lower process efficiency.
Alternative technologies: iron oxide coated sand, granular ferric hydroxide, iron filings, sulfur-modified iron, greensand filtration, iron addition with microfiltration, conventional iron/manganese removal	Most are emerging, tested at bench-scale and require more full-scale testing. Some have higher costs.
Coagulation/Filtration and Lime Softening	Primarily for large systems. May be useful in package plant form, however, installation solely for arsenic not likely.

Ion Exchange

In using ion exchange, the column bed's regeneration frequency is a key factor in calculating costs. Sulfate, TDS, selenium, fluoride and nitrate compete with arsenic and can affect the run length. Systems with high levels of these contaminants may require pretreatment. This technology is recommended primarily for small, ground water systems with low sulfate and TDS. Recent research indicates that ion exchange may be useful up to approximately 120 mg/L of sulfate. Ion exchange produces a highly concentrated waste by-product stream, and the disposal of this brine must be considered. Brine recycling might reduce the impact somewhat.

Activated Alumina

Activated alumina may be appropriate when treating water with high TDS. The usage of corrosive and caustic chemicals associated with this technology may make it inappropriate for small systems. For instance, most ground waters will require addition of an acid to lower the pH into the optimal range and then require a pH increase to avoid corrosion. Also, sulfuric acid and sodium

hydroxide are required in the regeneration process. Regenerating the media off-site or disposing of spent media is a possibility. While this may be affordable at a MCL of 50 ppb, it may not be at lower MCLs. Another issue is competition with adsorption sites from selenium, fluoride, chloride, sulfate and silica. The media experiences incomplete regeneration. Activated Alumina may not be efficient in the long term, as it seems to lose significant adsorptive capacity (on the order of 5-10%) with each regeneration cycle. Activated alumina produces highly concentrated waste streams (approximately 30,000 mg/L TDS content), making it necessary to investigate disposal of the brine.

Membrane Technologies: Reverse Osmosis, Nanofiltration, Electrodialysis Reversal

Membrane technologies may also be appropriate for small systems. However, for low MCLs the ability to blend would be limited and all of the stream may have to be treated. This, in turn, would remove most of the alkalinity and hardness from the water. In that case, to avoid corrosion problems and to restore minerals to the water, post-treatment corrosion control may be necessary. Nanofiltration is of interest because it can be operated at lower pressures which translate into lower operation and maintenance costs. However, when nanofiltration is operated at realistic recoveries, the removal efficiency appears to be low. Water rejection, of approximately 20-25%, may be an issue in water-scarce regions. If used by small systems in the western U.S., water recovery will likely need to be optimized due to the scarcity of water resources. The increased water recovery can lead to increased costs for arsenic removal. Electrodialysis reversal, although easier to operate, may not be competitive with respect to costs and process efficiency when compared to reverse osmosis and nanofiltration.

Alternative Technologies

There are several emerging technologies that may be applicable for small system treatment; however, these require more testing for arsenic removal. Iron oxide coated sand removes arsenic using adsorption, and the sand also doubles as a filtration media. The technology has only been tested at the bench-scale level and may have a high cost associated with it. Granular ferric hydroxide also employs an adsorption process. Full scale-tests are currently in progress in Germany. Costs may be a problem with this technology as well. Iron filings are essentially a filter technology, initially developed for arsenic remediation. Though quite effective at remediation, this technology may have limited use as a drinking water treatment technology; the technology performs well when treating high influent arsenic levels typical of remediation, but needs to be proven in treating lower influent levels expected in raw drinking water to finished levels below MCL options. Sulfur-modified iron appears to remove total organic carbon (TOC) and disinfection byproducts (DBPs) as well as arsenic. However, it has only been tested at the bench scale. Greensand filtration has an advantage in that there is not as much competition with other ions. However, the process has not been used very much for arsenic removal. In addition, similar to activated alumina, greensand filtration may require pH adjustment to optimize removal, which may be difficult for small systems. Conventional iron and manganese removal is a process that has been around for a long time, but needs further study as far as arsenic removal is concerned. As the iron and manganese is removed, the arsenic is also removed. If the naturally occurring amount of iron and

manganese is not enough to get the desired arsenic removal, more iron may be added. Iron addition with microfiltration is another process presently being studied; it essentially involves precipitating the arsenic with iron, and then filtering it.

Coagulation/Filtration and Lime Softening

Coagulation/Filtration and Lime Softening are technologies primarily for large systems. Package plants may make it more affordable for small systems to employ these technologies. Package plants are pre-engineered, meaning that the process engineering for the package plants has been done by the manufacturer. What remains for the water system's engineer to design is the specifics of the on-site application of the equipment. However, these technologies still require well-trained operators. If it is not possible to keep a trained operator at the plant, an off-site contract operator may be able to monitor the process with a telemetry device. Disposal of the sludge may also be a concern. Due to these complexities, these technologies are not likely to be installed solely for arsenic removal. However, if they are already in place, modification of these two technologies to achieve higher arsenic removal efficiencies is a viable option.

Preoxidation

The technologies under review perform most effectively when treating arsenic in the form of As(V). As (III) may be converted through pre-oxidation to As(V). Data on oxidants indicate that chlorine, ferric chloride, and potassium permanganate are effective in oxidizing As(III) to As(V). Pre-oxidation with chlorine may create undesirable concentrations of disinfection by-products. Ozone and hydrogen peroxide should oxidize As(III) to As(V), but no data is available on performance. For POU/POE devices, central chlorination may be required for oxidation.

Point of Use/Point of Entry (POU/POE)

The SDWA stipulates that POU/POE treatment systems "shall be owned, controlled and maintained by the public water system, or by a person under contract with the public water system to ensure proper operation and compliance with the MCL or treatment technique and equipped with mechanical warnings to ensure that customers are automatically notified of operational problems." Since centralized treatment is not always a feasible option, POU/POE devices can be effective and affordable compliance options for small systems to meet a new arsenic MCL. Allowing the use of POU devices as compliance technologies is one of the new elements of the SDWA Amendments. These devices are especially applicable for systems that have a large flow and only a minor part of that flow directed for potable use. Non-transient, non-community systems may be able to take advantage of these devices. POE/POU options include reverse osmosis, activated alumina, and ion exchange processes. POU systems are easily installed and can be easily operated and maintained. In addition, these systems generally offer lower capital costs and may reduce engineering, legal, and other fees associated with centralized treatment options.

Using POU/POE devices introduces some new issues. Adopting a POU/POE treatment system in a small community requires more record-keeping to monitor individual devices than does central treatment. POU/POE systems may require special regulations, such as increased monitoring to ensure that the treatment units are operating properly, regarding customer responsibilities and water utility responsibilities.

Water systems with high influent arsenic concentrations (*i.e.*, greater than 1 mg/L) may have difficulty meeting MCLs much lower than the 10 to 20 ppb level when POU/POE devices are used. As a result, influent arsenic concentration and other source water characteristics must be considered when evaluating POU/POE devices for arsenic removal.

Home water treatment can consist of either whole-house or single faucet treatment. Whole-house, or POE treatment, is necessary when exposure to the contaminant by modes other than consumption is a concern. However, EPA estimates that POE treatment is more expensive than centralized treatment when more than 20 to 30 units are in place. POU treatment, which usually involves single-tap treatment, is preferred when treated water is needed only for drinking and cooking purposes, as would be the case for arsenic.

Variances and Exemptions

The 1996 SDWA identifies two classes of technologies for small systems: compliance technologies and variance technologies. A compliance technology is one that achieves compliance with the MCL or treatment technique requirement. Under new provisions in the 1996 amendments, EPA must list affordable compliance technologies for three size categories of small systems: those serving 3,301 to 10,000 people, those serving 501 to 3,300 people, and those serving 25 to 500 people. If EPA cannot identify an affordable compliance technology for a particular category of system, it must then list a variance technology instead. Only if EPA lists such a variance technology can small systems apply for a small system variance. Variance technologies are only specified for those system size/source water quality combinations for which there are no listed affordable compliance technologies. **While these variance technologies may not meet the MCL, they must achieve the maximum reduction that is affordable, considering the size of the system and the quality of the source water. In addition, these variance technologies must be protective of public health.**

The criteria used to make the affordable technology determinations are referred to as "national-level affordability criteria". The primary function of the national-level affordability criteria is to determine whether affordable compliance technologies are available for all size categories of small systems, or, alternatively, whether EPA should list a variance technology and thus grant flexibility to states to make affordability determinations for variance purposes on a case-by-case basis. Affordability determinations to prioritize systems for assistance from the Drinking Water State Revolving Fund are not affected by the variance technology listing. Once a variance technology is

listed, a small system can receive a variance if the state determines, with appropriate public input, that the system cannot afford to comply with the standard.

The options potentially available for compliance are to install a technology to comply with the MCL or treatment technique; obtain an alternate source of supply that meets drinking water standards; restructure, which could include interconnection with another water system; and receive an exemption, which gives the system time to install a technology to comply with the MCL or treatment technique. Systems are not required to install a compliance technology identified by EPA. Other technologies can be installed as long as the MCL or treatment technique requirements are met.

When no nationally affordable compliance technologies are listed, systems can proceed down the variance pathway. States must first evaluate, for each system applying for a variance, whether treatment, alternate source, or restructuring are affordable options for that system to comply with the standard. If none of these options are affordable, then a variance technology listed by EPA can be installed to obtain a small system variance. The system must then install the (less expensive) variance technology, in accordance with conditions specified by the state to ensure that it is operated in a way that is protective of public health. Households served by a system under a small system variance will still incur treatment cost increases to their annual water bills. These increases will be lower in magnitude than if they had installed a compliance technology.

Issues associated with EPA's development and revision of its national affordability criteria and the possibility of allowing small system variances for arsenic are discussed extensively in Section 9 of the report.

'General' variances, for systems with such poor source water that even after installing best available technology they cannot comply with the standard, are still possible for systems of any size - that has not changed. Thus, if there is no alternate source, and as long as there is no unreasonable risk to health, a system can still apply for a general variance if it agrees to install a specified 'best available technology'(i.e., one of the listed compliance technologies).

An exemption is intended to allow a system with compelling circumstances an extension of time before the system must comply with a MCL or treatment technique. An exemption is limited to three years after the otherwise applicable compliance date, although extensions up to a total of six additional years may be available to small systems under certain conditions. Under an exemption, a schedule is established for achieving compliance with the MCL or treatment technique within the exemption period. If the system is not taking all practical steps in meeting the milestones established in the schedule, then enforcement action may be taken. As of December 1997, there were 17 exemptions and 1 general variance for arsenic.

Treatment Technology Costs

Table 2 contains 1995 preliminary estimates of total annual costs, total capital costs, and annual household costs. These estimates were based on 1992 occurrence estimates and 1994 cost curves. They assume that systems out of compliance would treat all the water produced by a system, rather than blend the water to lower the arsenic level to the MCL. In some cases, this assumption may have led to an overestimate of treatment costs. EPA will revise these estimates in 1999 to reflect updated technology cost curves and assumptions including the use of POU devices as compliance technologies, which could tend to lower treatment costs. EPA will also update occurrence estimates which are presently in the process of redevelopment. In addition, the system size categories used by the Agency have changed. The system sizes in Table 2 refer to the old categories (*i.e.*, small = 25-3300, medium = 3301-10,000 and large = more than 10,000). The system size categories that would now be classified as small systems are shaded in Table 2 (see Appendix D for preliminary cost estimates for multiple treatment technology options, which was provided to SERs as attachment C in a April 13, 1999 mailing).

Table 2: Pre-1996 Preliminary Cost Estimates Based on Previous Treatment and Occurrence Data

	System size	**MCL option (ppb)**				
		2	**5**	**10**	**20**	**50**
Total Annual Cost ($ million)	Small	762	295	124	40	13
	Medium	261	96	40	12	4
	Large	1115	295	130	34	10
Total Capital Cost ($ million)	Small	3195	1218	502	160	51
	Medium	729	255	106	33	9
	Large	2897	700	301	74	25
Annual Household Cost	25-100	1234	1202	1188	1160	1126
	101-500	670	654	655	645	638
	501-3300	365	362	373	378	369
	3301-10K	237	236	254	266	281
	10K-100K	168	170	191	212	243
	100K +	63	26	31	1	N/A

3.2 Monitoring for Arsenic in Drinking Water

To determine compliance with the regulation, EPA currently requires only CWSs to monitor for arsenic, although some States may require their NTNCWSs to monitor as well. The new regulation for arsenic may also apply to NTNCWSs with ground water and surface water supplies.

To reliably monitor for drinking water contaminants, EPA evaluates and approves analytical methods to measure for drinking water contaminants. These methods are selected and approved based on the following criteria:

- The specificity or the selectivity of the drinking water method to detect arsenic in the presence of interfering compounds.
- The reliability of methods to detect and measure arsenic over a wide range of concentrations including the proposed MCL.
- The availability of equipment, facilities and trained personnel to perform the analysis.
- The rapidity of the method to measure arsenic in drinking water. Analytical methods that can be performed in a short period of time provide important feedback to water utilities and allow for corrective actions to be taken more quickly when problems arise. This is less of a concern with chronic contaminants such as arsenic however.
- The cost of the analysis to water utility. The Agency estimates the cost of the method on a per sample basis to determine the economic burden to the water utility. Currently, the cost of the analysis using approved analytical techniques can range from approximately $10 to $ 50 per sample.[1]

EPA has identified and updated several analytical methods that meet the selection criteria stated above (40 CFR 141.23). The analytical techniques used to measure arsenic in drinking water include:

- Inductively Coupled Plasma - Atomic Emission Spectroscopy (ICP-AES)
- Inductively Coupled Plasm - Mass Spectrometry (ICP-MS)
- Graphite Furnace Atomic Absorption (GFAA)
- Stabilized Temperature Platform - Graphite Furnace Atomic Absorption (STP-GFAA)
- Gaseous Hydride Atomic Absorption (GHAA)

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[1] EPA contacted seven laboratories that perform environmental analysis of drinking water to determine the approximate cost per sample analysis. The two laboratories that used ICP-AES cited a cost of $15 to $25 per sample. The laboratory that performed ICP-MS charged $10 per sample. Four of the laboratories performed GFAA and charged $15 to $50 per analysis.

The approved methods can measure arsenic levels as low as 0.5 ppb to 2 ppb. Modifications to some of these methods also allow arsenic levels as low as 0.1 ppb to be detected. Whereas some of the approved analytical methods measure only arsenic, other techniques can measure several other inorganic contaminants at the same time. The ability to measure other drinking water contaminants at the same time as arsenic provides greater savings in the cost of the analysis. Some of the approved analytical techniques have been in use for many years for compliance monitoring with the current 50 ppb arsenic standard and, therefore, are widely available at certified laboratories. The Agency has found these methods to be technically and economically feasible for compliance monitoring.

Although some drinking water utilities have an on-site laboratory to perform the necessary analysis, many utilities send their samples to an environmental laboratory that is certified for drinking water analysis. Sampling protocols are specified within the approved methods. Critical elements for chemical analyses are also detailed in EPA *Manual for the Certification of Laboratories Analyzing Drinking Water* (USEPA, 1997).

Under current monitoring requirements, surface water systems must sample for arsenic once every year and ground water systems must sample once every three years at each entry point to the distribution system [40 CFR section 141.23 (l)-(q)]. If the result of the analysis exceeds the MCL, then the system is in violation and is required to report to the State within seven days and to sample three additional times at the same sampling point within one month. When the average of the four analyses exceeds the MCL, the system must notify the State and give notice to the public. Monitoring after public notification shall continue as directed by the State until a minimum of two successive samples are less than the MCL. Then the system may return to the regular monitoring frequency.

For the upcoming proposed rule, EPA plans to revise the arsenic monitoring requirement to be consistent with the consolidated monitoring requirements for other regulated inorganic chemicals (IOC) [40 CFR section 141.23 (c)]. These consolidated monitoring requirements are frequently referred to as the Standardized Monitoring Framework (SMF). The goal of SMF was to streamline the drinking water monitoring requirements and to standardize the monitoring requirements within contaminant groups, *e.g.*, IOCs, volatile organic compounds, and synthetic organic compounds. The chemicals included in IOC contaminant group are antimony, barium, beryllium, cadmium, chromium, cyanide, fluoride, mercury, nickel, selenium, and thallium. Arsenic was excluded from the SMF for IOCs when it was finalized in 1992, because revision of the arsenic rule was thought to be imminent.

If arsenic is added to the SMF for IOCs, monitoring for arsenic would continue once every year for surface water systems and once every three years for ground water systems at each entry point to the distribution system. If one sample exceeds the MCL, the system would have an MCL violation unless the State directs a confirmation sample. In this case, the determination of an MCL violation would be based on the average of the initial and State-directed confirmation samples. As a result of the exceedance, the system would sample quarterly until the State determines that the system is reliably and

consistently below the MCL. Then the system would return to the regular monitoring schedule. States may grant monitoring waivers if a sampling point has at least three samples[2] and all results are less than the MCL. In addition, the State would consider the following: all previous monitoring data, variation of results, the proximity of results to MCL, and other factors which may affect contaminant concentrations such as changes in ground water pumping rates, system's configuration, operating procedures, and stream flows (for surface water). Under the waiver, a system would monitor a minimum of once every nine years.

4. APPLICABLE SMALL ENTITY DEFINITION

EPA's authority under SDWA extends to all "public water systems." The law applies the term "public water system" to water utilities and a wide range of businesses (*e.g.*, campgrounds, factories, and schools). For purposes of RFA analyses for SDWA rulemakings, the Agency has defined small entities as systems serving 10,000 or fewer customers. EPA has selected systems serving 10,000 or fewer persons as the criterion for small water systems for the definition of small entity because this is the system size category specified in SDWA for small system flexibility.

5. DESCRIPTION AND ESTIMATE OF SMALL ENTITIES TO WHICH THE PROPOSED RULE WILL APPLY

For the purpose of regulating contaminants in drinking water, EPA divides public water systems into two main types: community water systems (CWSs) and non-community water systems. The Agency further divides non-community water systems into non-transient non-community water systems (NTNCWSs) and transient non-community water systems (TNCWSs).

Currently, the arsenic standard only applies to CWSs with ground water and surface water supplies. The new standard for arsenic may also apply to NTNCWSs with ground water and surface water supplies. Based on information in EPA's Safe Drinking Water Information System (SDWIS), there are approximately 54,000 community water systems and 20,000 non-transient, non-community water systems in the United States (USEPA, 1998). These CWSs serve approximately 249 million people, and NTNCWSs serve

Community Water Systems (CWS) *provides drinking water to at least 15 service connections used by year-round residents or regularly serves at least 25 year-round residents (e.g., homes, apartments, condominiums).*
Non-Transient, Non-Community Water Systems (NTNCWS) *regularly serves at least 25 of the same persons more than 6 months per year (e.g., schools, office buildings).*
Transient, Non-Community Water Systems (TNCWS) *serve at least 25 people daily but do not serve the same individuals for more than six*

[2]For the three samples, surface water systems must have monitored annually for at least three years and ground water systems have conducted a minimum of three rounds of monitoring.

approximately 6 million people. Ninety-three percent of the CWSs and ninety-nine percent of NTNCWSs serve less than 10,000 people. The rule would not apply to TNCWSs since the duration of exposure is considered to be occasional and infrequent and would pose a minimal health risk to the public.

CWSs and NTNCWSs potentially affected by the arsenic rule can be divided into a number of size categories, that are defined by the number of people they serve. For the purposes of the SBREFA analysis, all systems that serve fewer than 10,000 people qualify as "small entities." There are approximately 42,300 ground water CWS and 7,700 surface water CWS that serve fewer than 10,000 people. These systems are estimated to serve a total population of approximately 33 million and 17 million people, respectively (USEPA, 1998).

6. SUMMARY OF SMALL ENTITY OUTREACH

To facilitate regulation development, EPA has actively involved interested parties in the development of the proposed rule. As part of these efforts, EPA has provided many opportunities for input since the 1996 SDWA Amendments, including many public stakeholder meetings on arsenic, an environmental justice stakeholder meeting, consultations with Tribes, and small entity representatives conference calls. In addition, EPA has held meetings with and given presentations to a number of organizations that have small public water systems among their membership, such as the Rural Community Action Program, Association of California Water Agencies (ACWA), and American Water Works Association.

6.1 Stakeholder Meetings

EPA conducted three stakeholder meetings, open to the public, to discuss the arsenic regulatory development process. These meetings were held in Washington, D.C. on September 11-12, 1997, in San Antonio, Texas on February 25, 1998, and in Monterey, California on May 5, 1998. The stakeholder meetings provided information and solicited input on a broad range of issues including: (1) regulatory process, including risk management decisions; (2) arsenic risk assessment (exposure, health assessment, national occurrence); (3) key technical assessments (treatment technologies, treatment residuals, cost, analytical methods, co-occurrence of contaminants); (4) small system concerns; and (5) future stakeholder involvement.

The Washington, D.C. stakeholder meeting had over 65 participants, with an additional 25 participants on the conference phone. There were over 40 people that attended, with an additional 15 on the conference phone, at the Texas stakeholder meeting. Participants included representatives from water districts and utilities, water utility associations, State regulatory departments, consulting engineering firms, environmental groups, mining companies, research institutions, EPA, and other federal agencies. The California stakeholder meeting was held prior to the biannual ACWA meeting, which facilitated the participation of water systems in California and other States in the western region

of the United States. More than 50 people participated in person, with an additional 15 participants on the conference phone lines.

EPA will be holding two additional stakeholders meetings; the first meeting is a day-and-a-half meeting in Washington, DC on June 2-3, 1999 and the second is a half-day conference call on June 3, 1999. The purpose of these meetings is to present an update on EPA's work to develop the proposed arsenic rule and to solicit additional input on the major technical and implementation issues.

6.2 Environmental Justice Stakeholder Meeting

On March 12, 1998, the EPA/Office of Ground Water and Drinking Water (OGWDW) held a stakeholder meeting to address environmental justice in minority populations and low-income populations in regard to implementing the SDWA Amendments of 1996. The meeting occurred simultaneously in eleven cities via video conference. The meeting was held in the following cities: Boston, New York, Edison, Philadelphia, Atlanta, Chicago, Kansas City, Dallas, Denver, San Francisco, and Washington, D.C. The purposes of the meeting were to identify issues and solicit input from stakeholders and the public at large on environmental justice related considerations of several proposed drinking water regulations. Specifically, EPA addressed efforts to develop new regulations for radon, arsenic, ground water disinfection, enhanced surface water treatment, disinfection byproducts, and filter backwash recycling. The stakeholder meeting attendance included 169 people: 61 EPA employees and 108 individuals from other organizations. The stakeholders included participants from environmental organizations, church groups, Tribes, public health organizations, professors, industry, and interested citizens.

6.3 Tribal Consultations

In order to address Executive Order 13084 (Consultation and Coordination with Indian Tribal Governments), OGWDW gave presentations to and requested input regarding new drinking water regulations, including arsenic, from Native Americans attending the National Indian Health Board's (NIHB) 16th Annual Conference in Anchorage, Alaska. The conference was held in October, 1998. At this consultation, contact was made with the Inter Tribal Council of Arizona (ITCA) and EPA's Tribal Operations Committee (TOC). OGWDW also held a Tribal consultation in Las Vegas, Nevada, in February 1999, which was hosted by ITCA and attended by TOC members, along with other Tribal representatives. A total of 21 people from 19 Tribes attended. The tribal representatives hold various positions in Indian Country, ranging from water utility operators to directors of tribal Environmental Protection Offices.

A meeting summary was created from feedback and input received at the consultation. Following the consultation, the National Tribal Environmental Council (NTEC) sent a mailing to all 565 federally recognized Tribes, which included the meeting summary and background documents explaining requirements of SDWA and OGWDW regulations and requesting feedback and input from

all federally recognized Tribes. The consultation and follow-up specifically requested input on the following regulations currently under development: Radon, Arsenic, Filter Backwash Rule, Long Term1 Enhanced Surface Water Treatment Rule, and Stage 2 Disinfection By-Product Rule.

6.4 American Water Works Association Technical Work Group on Arsenic

The American Water Works Association (AWWA) convened a Work Group to discuss technical issues related to the development of the arsenic rule. The Work Group held meetings on December 10-11, 1998 and February 18-19, 1999, in Washington, D.C. A diverse group of people attended from State public health and environmental departments, drinking water districts, consulting engineering firms, an environmental group, university academicians, the Association of State Drinking Water Administrators, the U.S. Geological Survey (USGS), and EPA staff. Although the invited participants did not include small entities, the Work Group addressed a number of small water system treatment issues.

6.5 Small Entity Representatives Conference Calls

On December 3, 1998, EPA distributed background information and materials to SERs to review. On December 18, 1998, EPA held a SER conference call from Washington, D.C. to provide a forum for SER input on key issues related to the planned proposal of the arsenic in drinking water rule. 15 SERs from small water systems in Alabama, Arizona, California, Georgia, Massachusetts, Montana, Nebraska, New Hampshire, New Jersey, Utah, Virginia, Washington, and Wisconsin participated in the call. Appendix A is the summary of the conference call. Following the conference call, EPA sent on January 6, 1999, a number of documents in response to questions and requests for additional information from the SERs. The list of these documents is included as Appendix B.

The SBAR Panel for arsenic in drinking water was convened on March 30, 1999. On April 13, 1999, the SBAR Panel distributed additional information to the SERs for their review. The materials included: fact sheets on and the executive summary of the National Research Council of the National Academy of Sciences' (NRC/NAS) report on arsenic in drinking water; list of questions for the SERs on treatment technologies; information on POU and POE treatment; preliminary estimates of treatment costs; and information on variances and exemptions. The SERs were asked to review the new materials and to provide any additional comments to the Panel at a follow-up conference call and in writing after the call. The conference call was held on April 21, 1999 and included participation by 11 SERs. The SERs were asked to comment on the costs and viability of various treatment options under consideration by EPA. A summary of the meeting and a list of documents distributed to the SERs is included as Appendix C.

7. SMALL ENTITY REPRESENTATIVES

EPA, in consultation with the SBA, invited the following 22 SERs to participate in its SBREFA consultation process. 17 SERs participated in at least one of the conference calls sponsored by OGWDW and the Panel. Nine SERs provided written comments to OGWDW or the Panel (Note: OMB and SBA participated in the OGWDW-sponsored conference call and all comments received by OGWDW were provided to all Panel members.)

Mr. James Bailey, Superintendent
Warner Village Water District
Warner, NH

Mr. Greg Bouc, Utility Superintendent
Village of Valpariso, NE

Mr. Doug Evans, Mayor
Salt Lake County Service #3
Snowbird, UT

Ms. Shirley Glynn, Clerk
Bates Township
Iron River, MI

Mr. JD Hightower, City Planner
City of Escalon
Escalon, CA

Ms. Kaye Kiker
Sumter County Water Authority
York, AL

Mr. David Monie
GPM Associates, Inc.
Cherry Hill, NJ

Mr. Ronald Payne
Payne Utilities, Inc.
Conroe, TX

Mr. Jim Sheldon
Cedar Knox Rural Water Project
Hardington, NE

Mr. Bob Beaver, Principal
Adams Friendships Schools
Adams, WI

Mr. Bob Campbell
Wilson School, Teton County School District
Jackson Hole, WY

Mr. Paul Gardner
Queen Creek Water Co.
Queen Creek, AZ

Mr. Lynton Godwin
City of Plains
Plains, GA

Mr. Jon Hirst
Southeastern Rural Community Assistance Project, Roanoke, VA

Mr. Michael Knox, Superintendent
Cherry Valley and Rochdale Water District
Rochdale, MA

Paul Noran
Consumer Water Company
Portland, ME

Mr. Al Ricksecker, Secretary Treasurer
Brooklyn Tapline Co., Inc.
Monroe, UT

Rafael A. Terrero
Florida Water Services Corporation
Apopka, FL

Mr. Paul Torok
Seeley Lake-Missoula County Water District
Seeley Lake, MT

Mr. Dale Tyler
New Utsalady Water System
Camano Island, WA

Mr. Gary Walter
Tuolumne Utilities District
Tuolumne, CA

Ms. Nancy Woodruff
Clarkston United Methodist Church
Clarkston, MI

8. SUMMARY OF WRITTEN COMMENTS FROM SERs

OGWDW received 14 sets of written comments from SERs. Exhibit 2 provides a record of the comments, and is followed by a summary of the main issues raised by the SERs in their written submittals. The complete written comments are provided in Appendix D.

Exhibit 2: List of SER Written Comments

Name	Organization	Date Received	Number of Pages
Paul Noran	Consumers Water Company	12/10/98	1
Paul Noran	Consumers Water Company	1/12/99	½
Jim Bailey	Warner Village Water District	1/14/99	2
Doug Evans	Salt Lake County Service Area #3	1/14/99	2
Dale Tyler*	New Utsalady Water District	1/14/99	1
Al Ricksecker	Brooklyn Tapline Company, Inc.	1/15/99	1
Gary Walter	Tuolumne Utilities District	1/29/99	4
Dale Tyler	New Utsalady Water System	2/25/99	2
David Monie	GPM Associates (SB Water Company)	4/22/99	2
James Bailey	Warner Village Water District	4/25/99	2
Greg Bouc	Village of Valparaiso	4/29/99	2
Al Ricksecker	Brooklyn Tapline Company, Inc.	4/29/99	2
J.D. Hightower	City of Escalon	5/14/99	2

Name	Organization	Date Received	Number of Pages
Dale Tyler	New Utsalady Water System	5/15/99	3

*Note: To supplement his written comments, Mr. Tyler invited Mr. Lawrence Baum , a non-SER, to submit comments. Therefore, Mr. Baum's comments will be considered as comments from Mr. Tyler.

8.1 Number and Type of Small Entities Impacted

One SER indicated that he believed arsenic would prove to be more pervasive in small ground water system than EPA's preliminary figures suggest, if the standard is set as low as 5 or 10 ppb.

8.2 Potential Reporting, Record Keeping and Compliance Requirements

TREATMENT TECHNOLOGIES

Coagulation/Filtration and Lime Softening

Only one SER addressed the merits of this technology. The SER stated that conventional coagulation filtration and lime softening work at high pH, but that they can be operator-intensive and generate large amounts of sludge. The SER indicated that at very low levels, this technology does not work well.

Ion Exchange

The same SER commented that ion exchange poses serious waste problems.

Activated Alumina

This SER also conveyed his concern that activated alumina is difficult to find and involves high costs. Another SER commented that with a staff of two full-time employees, it would not be possible to conduct regeneration on-site or handle corrosive chemicals. He also indicated that pH adjustment is an issue for small systems and may create its own health concerns.

Reverse Osmosis/Nano-filtration

One SER commented that these technologies work with pre-oxidation and remove arsenic well at low levels. However, he believes these technologies are the most expensive. A SER also expressed concern about the amount of water which is wasted through these processes, a serious issue for the western U.S.

Oxidation Filtration

One SER stated that oxidation filtration is the simplest method used to treat for metals and has been utilized by PWSs for years, in the form of green-sand related technologies. Presently, a type of oxidation filtration is being pilot tested by the SER's system to treat for antimony, which has so far presented a difficult compliance problem. The SER is concerned that arsenic is chemically similar to antimony, though easier to treat. He also pointed out that a recognized shortcoming of oxidation filtration is its inability to remove arsenic at levels below 25 ppb. This remains true even with the addition of iron salts and ozone as an oxidant, and with some pH adjustment.

POU/POE

A number of SERs commented on the use of POU/POE technologies. One SER supported POE treatment, but suggested that POU should only be permitted with specific health agency approval. Another SER did not support POU/POE as a treatment alternative or BAT for arsenic (or any other SDWA-regulated substance), except for drinking water systems serving 25 people or less [note: systems serving fewer than 25 people are not regulated under SDWA and would not be subject to the proposed rule] While the SER believes that POU/POE involve less of a capital cost investment, as compared to whole system treatment technologies, he stated that operation and maintenance costs would outweigh the investment costs. He pointed out the impracticability of larger systems choosing these technologies because the water supplier would become responsible for all of the installed POU/POE devices which would translate into costs from a variety of sources including: POU/POE service checks at customer homes; removal/replacement of canisters with accumulated arsenic; and disposal of these canisters. The SER was concerned that visiting customers' homes may have to be scheduled after business hours or on weekends, which would cause an increase in the salary budget for scheduled overtime work or hiring new personnel. He further added that POU/POE treatment would require either a yearly budget to purchase the devices, replacement parts and canisters or the actual stockpiling of them.

One SER, whose system serves 150 households and 53 other customers (industry, commercial, schools, etc), indicated that his system would need to increase its staff from two to three full-time employees to operate POU treatment, with possible part-time employees added as needed. He was also concerned about the system's potential liability for use by customers of non-treated faucets and thought that POE, when compared to POU, would greatly reduce the need to police the use of such faucets. Another SER indicated that the POU's cost effectiveness breakpoint of around 72 households or 180 people seems reasonable. However, he expressed concern that extending the system's responsibility beyond the meter could expose it to civil claims and that the system cannot control the customers' use of the POU devices.

COSTS

Treatment Costs and Funding

Most of the SERs submitting written comments and participating in the conference calls expressed concern regarding treatment costs. One SER stated that treatment costs would rise exponentially the lower the MCL for arsenic is set. Another stated that all five of the treatment technologies identified would be expensive for small systems. Another SER was concerned that treatment for arsenic at low levels is expensive and predicted that it likely would not be cost effective, thereby resulting in having to take groundwater wells off-line. The SER estimated that treatment costs for his system would be $198,000 per well, for 28 wells. This translates into a total cost of $5.5 million for the water system, and an increase of $55 per customer per year. Another indicated that the annual household cost estimates provided by EPA ranging from $236 to $1234 would not be affordable for his customers, whose current water bills average $250 per year. [The Panel notes that these are preliminary cost estimates from 1995 which will likely change–see section 3.1] He believed that with the added costs of treatment, he customers would "abandon" the system and revert to using private wells. Another SER estimated that it would cost his system $500.00 to dispose of a 55-gallon drum of hazardous waste. In addition, he estimated that it would cost $100 per foot for regionalization, which would translate to $10,000,000 to hook up 200 customers to the nearest alternate source, which is 20 miles away. This would not be a feasible alternative for his system. Another SER noted that, faced with very high compliance costs, many small communities would probably choose to subsidize drinking water out of general funds, which would adversely impact other programs such as recreation, tree planting, bicycle lanes and street renovations.

One SER commented that small systems have great difficulty securing long term capital for water system improvements. He believed that Drinking Water State Revolving Fund could be of assistance, however large systems and small systems owned by large holding companies are more capable of obtaining the loans because they have better expertise in applying for them. He suggested that both EPA and SBA might be more helpful to small systems in obtaining such loans. Another SER commented that the impact of the arsenic rule would be primarily financial and believed that loans were not just compensation. The sentiment was echoed by another SER who objected to low interest loans as "government handouts" that should not be required to comply with regulations that have "not been totally reviewed through accurate science."

One SER indicated his belief that the cost data provided by EPA was inaccurate, and offer suggestions on elements that should be considered in estimating small systems cost impacts, including analyzing smaller classes of small water systems and estimating the costs for treatment technology design, engineering, construction/installation, testing, waste disposal, operator training, and annual operation. The SER believes that it is very important for EPA to provide accurate, valid, and reliable cost data so small systems can choose the most effective treatment option.

Several SERs also expressed concern with the cumulative impact of multiple regulations on small system costs.

Waste Disposal Costs

A number of SERs commented on difficulties and/or potentially high costs associated with disposal of sludge, wastewater, or spent medium from the various technologies under consideration. One noted the particular concern in his State (California) with hazardous waste, necessitating substantial effort and cost for disposal. Another SER expressed the concern that there would be factors, such as total dissolved solids from ion exchange process, which could cause sewer plants not to accept the wastewater from arsenic treatment. He suggested that EPA encourage States to assist small systems in convincing sewer plants to accept such wastes. This same SER was initially concerned about treatment plants refusing to accept the discharge from reverse osmosis POU devices, but withdrew this concern once he understood that such devices would be treating only 1% of household flow and would not increase the total arsenic contained in the wastewater.

Administrative Costs

Only one SER specifically addressed administrative costs. He commented on the added burden to small water systems of handling concentrated hazardous waste material, that is, the concentrated brine water or sludge resulting from treatment processes. He was concerned about complying with his State and local government's environmental requirements. He recommended that EPA take into account costs from State regulatory compliance, public hearings, and hazardous waste management requirements for the handling storage, and disposal of the waste. This SER also expressed concern about the growing trend of State and local agencies to require water purveyors to pay the costs of agency monitoring and oversight.

SAMPLING AND MONITORING

One SER suggested that analytical methods should be developed which are capable of measuring both organic and inorganic arsenic as separate parameters. The SER suggested that there may be a number of drinking water systems with elevated levels of organic arsenic, which would cause them to exceed the MCL. Although organic arsenic is generally considered to be non-toxic, the SER indicated that EPA should acquire data corroborating or contradicting this generalization and determine whether organic arsenic needs to be regulated.

Another SER suggested the provision of waivers and/or the selection of a few index wells for monitoring in an aquifer region as a method of decreasing the amount of resources utilized addressing non-problem regions. He stated that his system, as well as many other small ground water systems, may be able to predict that their ground water is in the low risk/no risk category for contamination with arsenic, based of many years of testing and analytical records. The SER suggested that by decreasing agency monitoring and oversight, genuinely worrisome regions could receive greater attention.

8.3 Related Federal Rules

A number of SERs submitted comments regarding the possible relevance of other Federal rules, in the context of treatment and cost. One SER remarked that antimony and arsenic are chemically similar and may have similar treatment technologies. Both are difficult to treat effectively at low levels, although arsenic is more responsive to treatment. The SER stated his belief that the MCL for antimony (0.006 mg/L) was set at a level at which it is extremely difficult to treat affordably. Two SERs asked if EPA has considered the effect arsenic treatment will have on other treatment processes currently in use, particularly corrosion control for lead and copper. One of these SERs gave the example of arsenic treatment with activated alumina which requires lowering the pH to a range of 5.5 to 6.0. However to treat corrosiveness to comply with the lead and copper rule, the pH needs to be raised to 8.

One SER commented that the costs from arsenic treatment and monitoring and radon monitoring will be extremely high, relative to the $250 per year that his customers are currently paying for water. This SER suggested that because of the impending total costs of compliance with the radon, ground water, uranium, and microbiological and disinfection byproducts rules, EPA should allow these rules to take effect before arsenic. In a follow-up letter, this SER further suggested that the costs from all of these rules should be added together in a package so that the total cost impacts can be reviewed. He also noted the importance of considering potential incompatibilities among treatment options for different contaminants. Another SER indicated that the proposed treatment for arsenic alone did not seem unreasonable, however, the costs from other rules that he had reviewed over the past year would pose a significant cost to water systems. He suggested that EPA examine the costs of all the rules that the SERs had reviewed and commented on during the last year (e.g., radon, ground water, long-term 1 enhanced surface water treatment) and develop a master compliance plan..

8.4 Regulatory Alternatives

One SER suggested that the MCL not be set below 25 ppb because, “like antimony, it just becomes impossible to treat effectively at very low levels.” Another SER commented on the likelihood that all of the elements on the periodic table are detrimental to health at some concentration. He advocated regulating metals that naturally co-occur as a group, rather than one at a time, as a method of conserving federal and local resources. He stated that this principle is widely utilized in geochemical exploration for mineral deposits because the chances are good, although admittedly not perfect, that if one element is measured low in an aquifer then its associates will be also.

Two SERs submitted comments which were supportive of EPA creating a waiver process for certain circumstances. One suggested that a waiver process should be implemented for wells that are used for supplemental or backup purposes, such as wells used less than 60 days per year. As reflected earlier, another SER suggested that EPA and the States provide waivers and/or the selection of a few index wells for monitoring in an aquifer region as a method of decreasing the amount of resources utilized addressing non-problem regions. He suggested that these alternatives would conserve resources such that additional attention could be devoted to problem regions.

Another SER suggested that POU/POE devices could be required for new construction or major renovations (this could be implemented through building permits), while a "grandfather clause" could exempt existing homes and businesses.

A SER also stated that provisions should be made for the blending of well water with surface water supplies before the product reaches the consumer. The SER indicated that although this process is costly in most cases, in certain situations it is the most feasible and efficient alternative. [The Panel notes that this is permitted under current regulations.]

One SER stated that an alternative to the proposed rule that would accomplish EPA's stated objectives while minimizing its impact on small systems would be for EPA to fully fund the cost of compliance.

Another SER commented on the national affordability criteria that EPA uses to determine whether or not to allow small system variances. He was concerned that many small systems serve communities with median incomes well below the $30,000 per year that EPA used to derive its criteria, and felt that 1.5% of income would be a more appropriate threshold than 2.5%. He indicated that the Drinking Water Division of the Washington State Department of Health uses the 1.5% figure as the acceptable percentage of income spent on water services.

8.5 Other Issues

Overall, there was consensus among the SERs that EPA should carefully consider the costs and benefits before lowering the standard for arsenic. Similarly, a number of SERs stated that EPA lacked sufficient evidence of adverse health effects from levels of arsenic below 50 ppb and should not tighten the standard until more evidence is available. In contrast, one SER stated that a lowering of the standard appeared to be warranted and that small systems should not be exempt from compliance with a lowered standard.

Two SERs commented on the inadequacy of relying on studies conducted in other countries for health effects evidence. One of the SERs noted that the measured levels of arsenic in Taiwan were higher than those measured in the U.S. and that different cultural and environmental factors unique to each region, such as diet, likely had some impact on the health effects measurements. The other SER stated that for the studies conducted in Taiwan, Chile, and Argentina, the people would have different life-styles and living habits. The two SERs suggested that health effects studies should be conducted in the U.S. and that EPA base the arsenic standard on U.S. data. Another SER expressed concern that scientific review of data on health effects associated with arsenic is being "rushed" to facilitate rule development, and that excessive consideration is being given to "simple correlational studies," which he believes to be one of the weakest forms of scientific proof. He stated that the article on the feasibility assessment of the Utah Mortality Study and the speaker's abstract on preliminary results were a good beginning to assessing the impact of arsenic on humans. However, based on these initial materials, the

SER felt that the Utah Mortality Study may still have uncertainties and ambiguities because the study did not establish an adequate "non-arsenic" control group and had some potential confounders. In a follow-up letter, this SER stated that further research is required to prove through sound science that there are health risks at lower arsenic levels.

Two SERs recommended that the MCL should not be lowered based on the NRC/NAS Report's findings and recommendations. They pointed to the NRC/NAS recommendations for further research on health effects as an indication that there is no conclusive evidence of arsenic being harmful to humans at levels below 50 ppb. One of these SERs also noted the compounding of conservative assumptions in the report, which tends to bias the results toward the "safe side" without regard for cost. This SER also noted that arsenic is a natural contaminant rather than a pollutant.

9. PANEL FINDINGS AND DISCUSSIONS

9.1 Number of Small Entities

The Panel notes that EPA maintains the national Safe Drinking Water Information System (SDWIS) database, which is the inventory of all public water systems in the United States. In addition, the Panel notes that EPA is revising the draft 1992 estimates by using arsenic compliance monitoring data from 23 States, with support of data from other studies, to establish a more accurate and scientifically defensible occurrence and exposure distribution. Therefore, the Panel believes that EPA will have very good information about the number and type of systems impacted by the arsenic rule.

9.2 Potential Reporting, Record Keeping, and Compliance Requirements

9.2.1 Treatment Technologies, Waste Disposal, and Cost Estimates

EPA provided to SERs, on April 13, 1999, preliminary cost estimates for three technologies that are applicable for treating arsenic at small ground water systems (see Appendix D for the preliminary cost estimates that were provided to the SERs). These technologies are reverse osmosis, activated alumina and ion exchange. Cost estimates were also provided for using these technologies in point-of-use (POU) and point-of-entry (POE) form. The tables showed several general trends that are to be expected. Costs per household per year decrease with less stringent MCL options, decrease as the size of the system increases, decrease as the influent sulfate level decreases (for ion exchange), and decrease as the influent arsenic decreases. The cost estimates are preliminary, and will be updated prior to proposal. For example, ion exchange costs will have some adjustments made to account for additional capital and O&M costs and are expected to be closer to, but not as high as those currently estimated for activated alumina.

Several SERs expressed concern, at the April 21, 1999 conference call, that waste disposal costs were not provided in the tables. SERs commented that waste disposal costs can be significant.

EPA, at the conference call, agreed to develop some preliminary cost estimates of waste disposal options. These were provided to the Panel and are presented below in Tables 3 and 4. As with the treatment cost estimates, these figures will be revised prior to proposal. For centralized reverse osmosis treatment, there are three applicable waste disposal options: direct discharge, sanitary sewer and chemical precipitation. For centralized ion exchange treatment there are three applicable disposal options: direct discharge, evaporation pond/non hazardous landfill, and sanitary sewer. The costs presented in Tables 3 and 4 do show that waste disposal costs can be significant. Total costs will vary from system to system, and will depend on the waste disposal options that are available.

Table 3. Reverse osmosis waste disposal costs

Population of System	Direct Discharge[3] ($/household/yr)	Sanitary Sewer ($/household/year)	Chemical Precipitation ($/household/year)
25-500	6	78	170
500-3.3K	<1	76	62
3.3K-10K	<1	28	23

Table 4. Ion Exchange waste disposal costs

Population of System	Direct Discharge[1] ($/household/yr)	Sanitary Sewer ($/household/year)	Evaporation Pond/ Non Hazardous Landfill ($/household/year)
25-500	6	13	293
500-3.3K	<1	9	232
3.3K-10K	<1	9	not affordable

Costs shown for direct discharges are incomplete, as they do not include administrative or treatment costs associated with obtaining National Pollution Discharge Elimination System (NPDES) permits, which are required for all direct discharges. The direct discharge estimates include the following capital costs: piping and fittings, trenching and land clearing. The operation and maintenance (O&M) components of these estimates are relatively small because these capital components require little oversight and maintenance. The estimates do not include monitoring costs or land costs and assume that no pretreatment or concentration of the waste stream is necessary prior to discharge.

[3]These estimates do not include costs for NPDES permit application, monitoring or land and assume that no pretreatment is necessary.

Sanitary sewer discharge costs could also be somewhat higher, depending upon local Pretreatment program requirements and sewer use ordinances of the Publicly or Privately Owned Treatment Works receiving the wastes. Whether or not this type of discharge will be permitted will depend on the local Publicly or Privately Owned Treatment Works. The capital components of the sanitary sewer estimates presented above include costs for piping and fittings, trenching and land clearing. The O&M components include labor and basic POTW charges. The estimates do not, however, include any fees that may be charged by the POTW for the initial connection and land costs, or any other costs for permitting or pretreatment that may be required by the POTW.

Chemical precipitation is a relatively expensive disposal option, and would significantly increase costs per household. The capital components of the chemical precipitation estimates presented above include costs for tanks, agitators, pumps, building, piping and instrumentation. The O&M components include costs for lime, electricity, labor, insurance, administration and water. The costs do not, however, include costs for sludge dewatering and disposal; these will be added when developing more accurate estimates.

Evaporation ponds are also relatively expensive disposal options. The capital components of the estimates presented above include costs for piping and fittings, pumps, land clearing, instrumentation, and the actual evaporation pond. The O&M component includes labor, insurance and administration. The estimates also include costs for solids removal from the pond and dewatered sludge disposal. Evaporation ponds become prohibitively expensive in the largest small system size category because of the cost of acquiring land.

The Panel appreciates the concern of the SERs regarding costs of treatment and waste disposal. The Panel therefore recommends that EPA further develop these preliminary treatment and waste disposal cost estimates, and fully consider these costs when proposing an MCL and identifying affordable compliance technologies for all system size categories. The Panel also recommends that EPA develop guidance for small systems to accompany the final rule, that would highlight the various waste disposal options and the necessary technical and procedural steps for small community water systems to follow in exploring these alternatives.

Some SERs also expressed concern, at the April 21, 1999 conference call, about the public perception of using POU devices. The Panel appreciates this concern, and notes that the EPA prohibition on using POU devices was only recently lifted (63 FR 31934: June 11, 1998). Therefore, it will likely be some time before customers are accustomed to the use of POU devices in their homes. One SER stated that his system has been using POU devices in some areas for 25-30 people over the last several years. He remarked that their usage has generally been a success. Another SER commented that POU ion exchange resins are capable of treating for a wide range of metals, and could therefore address several problems at once. The Panel recommends that EPA continue to promote the use of POU devices as alternative treatment options for very small systems where appropriate. EPA should do so in its upcoming update to the list of compliance technologies for small systems (projected

to be completed by December 1999). In evaluating the costs of POU/POE devices, however, it is important that all costs be fully accounted for, including costs that may not routinely be explicitly calculated, such as unanticipated repairs, educating customers in their proper use, and responding to customer concerns. The Panel also notes the concern, raised by several SERs, that POU/POE devices may raise liability issues for water systems and recommends that these issues also be considered as EPA evaluates their appropriateness as compliance technologies.

Some SERs also expressed concern about potential waste issues from using POU devices, such as the concern that spent cartridges from ion exchange and activated alumina devices may not be readily disposed, and the concern that the spent waste cartridges could accumulate and contaminate ground water supplies. One SER commented that the State of Washington has non-degradation limitations regarding the contamination of ground water and the SER indicated uncertainty as to whether this sort of disposal method would be allowed. Other SERs expressed concern that POU reverse osmosis units would discharge arsenic contaminated streams down the water drain.

The Panel appreciates these concerns and recognizes the importance of fully considering disposal issues in evaluating treatment technologies, including POU/POE devices. However, the Panel notes that spent activated alumina and ion exchange cartridges are not likely to be heavily contaminated if they are replaced frequently, as would probably be required to ensure compliance with a revised standard. Also, EPA envisions that POU reverse osmosis units would only be treating drinking and cooking water, or about 1% of the total household water. Further, the total amount of arsenic leaving the household would be unchanged by the installation of such devices, though the pattern of arsenic discharge could be altered. Nonetheless, it is possible that use of such devices may be constrained by state and local regulation of their wastes, as some SERs suggested. The Panel recommends that EPA further investigate this issue and address it thoroughly when proposing a revised arsenic in drinking water regulation. The Panel further recommends that EPA provide specific recommendations and technical information relative to the use of POU devices to treat arsenic in drinking water in the small systems compliance guidance manual to accompany the final rulemaking, and that EPA provide guidance to state and local authorities on waste disposal issues relative to the use of these devices.

9.2.2 Small Systems Variance Technologies

Prior to the April 21, 1999 meeting, the SERs were provided with background material on small system variances. Attachment D of the Background Information and Questions Regarding Treatment Technologies for Arsenic discussed the new provisions that exist in the 1996 SDWA amendments for States to grant variances to small water systems (i.e., systems having fewer than 10,000 customers) from complying with an MCL if EPA determines that there are no nationally affordable compliance technologies for that system size/water quality combination. The system must then install an EPA listed variance treatment technology that makes progress toward the MCL, if not necessarily reaching it. For such variances to be allowed, three “hurdles” must be passed: 1) EPA must make a determination on a national level that there are no compliance technologies that are affordable

for the given small system size category/source water quality combination; 2) If there is not a nationally affordable compliance technology, then EPA must identify a variance technology that will aid small systems in making progress toward the MCL, without necessarily reaching the MCL - this technology must be listed as a small systems variance technology by EPA; and 3) EPA must make a finding on a national level, that the use of the variance technology would be protective of public health. Primacy States must then make a site-specific determination for each system as to whether or not the system can afford to meet the MCL based on State-developed affordability criteria. If the State determines that compliance is not affordable for the system, it may grant a variance, but it must establish terms and conditions as necessary to ensure that the variance is adequately protective of human health.

In the Agency's draft national-level affordability criteria, published in the August 6, 1998 Federal Register, EPA discussed the affordable treatment technology determinations for the contaminants regulated before 1996. The national-level affordability criteria were derived as follows. First an "affordability threshold" (i.e., the total annual water bill that would be considered affordable) was calculated. The 1998 draft criteria used 2.5% of median household income, or about $750, for the affordability threshold. The median water bill for households in each small system category was then subtracted from this threshold to determine the affordable level of household expenditures for new treatment. This difference is called the available expenditure margin. Based on EPA's 1995 Community Water System Survey, median water bills were about $250 per year for small system customers. Thus, an average available expenditure margin of up to $500 per year was considered affordable for the contaminants regulated before 1996. EPA identified treatment technologies for all pre-1996 contaminants with average per household costs below $500 per year, and so did not list any small system variance technologies. EPA recognizes that individual water systems may have higher than average treatment costs, fewer than average households to absorb these costs, or lower than average incomes, but believes that the affordability criteria should be based on characteristics of typical systems and should not address situations where costs might be extremely high or low or excessively burdensome. EPA believes that there are other mechanisms that may address these situations to a certain extent.

EPA expects the available expenditure margin to be lower than $500 per household per year for the arsenic rule because water rates are currently increasing faster than median household income and the baseline for annual water bills will rise as treatment is installed for compliance with regulations promulgated after 1996 and before arsenic. Lower available expenditure margins increase the likelihood of small system variance technologies being listed for the revised arsenic standard.

Two SERs indicated that the national median household income values for each size category did not accurately reflect the median household income of the households served by their water system, thus arsenic treatment was more likely to be unaffordable in their view. Another SER commented that EPA should compile income data to more accurately reflect the varying income levels of small public water systems. Another SER commented that he did not support variances because not being in compliance with the standard would concern his customers. The Panel notes, however, that no system

would ever be required to obtain a variance and that a variance could only be granted if the State determined that the system (and its customers) could not afford to comply with the standard.

The Panel met on April 27, 1999 to discuss the SERs' comments. The Panel discussed other aspects of the small system variance process and the national-level affordability criteria. Two Panel members were concerned that EPA's current approach for determining national affordability does not account for the variability of treatment costs across systems, the variability of current water bills, and the variability of incomes among communities served by small systems. In particular, they were concerned that an approach based on national medians would not allow states to use small system variances to address situations where the impact of installing new treatment on an individual community was severe, because the community already had especially high water costs, was composed primarily of low-income households or needed to install treatment to deal with multiple rules. They also noted that, based on information provided by EPA in Appendix F of its 1998 Information for States on Developing Affordability Criteria for Drinking Water, the affordability threshold of 2.5% of median income appears to be higher than that used by various States, and by other agencies and organizations (including the Department of Housing and Urban Development, National Consumer Law Center, and earlier guidance from EPA itself), to assess household affordability of drinking water costs for various purposes. EPA notes that the State affordability criteria in Appendix F are intended for use in prioritizing systems for assistance from the Drinking Water Sate Revolving Fund and are not necessarily the same criteria that the State would use to make small system variance determinations. The two Panel members are concerned that use of such a high threshold, which has so far resulted in no variance technologies being listed for any contaminants, may be counter to Congress' intent that States be permitted to grant variances on a case-by-case basis to small systems that truly cannot afford to comply with a particular drinking water standard, as long as the system provides as much treatment as it can afford and maintains adequate protection of public health. These Panel members suggested that the affordability criteria used for determining whether to list a small system variance technology be less restrictive, thereby allowing more opportunity for States to make affordability determinations for individual systems by applying State-wide criteria on a case-by-case basis.

EPA would be concerned about an approach involving the use of what it considered to be an inappropriately low national level affordability criteria since it would not, in EPA's view, be supported by its analysis of comparable household expenditures for other goods and services. EPA considered the percentage of median household income spent by an average household on such items as housing (28%), transportation (16%), food (12%), energy and fuels (3.3%), telephone (1.9%), water and other public services (0.7%), entertainment (4.4%) and alcohol and tobacco (1.5%) in identifying an initial range of options for the affordability threshold (this analysis did not consider comparable expenditures by low-income households). One of the key factors that EPA used to select an affordability threshold of 2.5% of median household income were cost comparisons with other risk reduction activities for drinking water. Section 1412(b)(4)(E)(ii) of the SDWA identifies both Point-of-Entry and Point-of-Use devices as options for compliance technologies. EPA examined the projected costs of these options. EPA also investigated the costs associated with supplying bottled water for drinking and

cooking purposes. The median income percentages that were associated with these risk reduction activities were: Point-Of-Entry (> 2.5%), Point-of-Use (2%) and bottled water (> 2.5%). The complete rationale for EPA's selection of 2.5% as the affordability threshold is described in Variance Technology Findings for Contaminants Regulated Before 1996. EPA is concerned that a less restrictive set of criteria could have the net result of a national level finding that this and many future drinking water rulemakings were unaffordable for small systems -- thus creating, in effect, a two-tiered approach to national rulemakings and public health protection. A two-tiered approach could be created because large systems would be complying with the MCL while some small systems might be operating at a level above the MCL, though it would still need to be protective of public health. These systems could only receive a small system variance if the State determined that there was no affordable technology and that alternate sources or restructuring were unaffordable. However, EPA is concerned that States might find it difficult, in practice, to determine that compliance was affordable if EPA itself had not listed a nationally affordable compliance technology for a particular small system size category.

Two Panel members noted, however, that EPA could list technologies that were affordable for most systems in a size category but indicate that it is not officially classifying them as "nationally affordable," in order to allow States to grant variances to the small number of systems for whom such technologies are truly not affordable. EPA would be concerned about an approach to national level affordability determinations in which it found some technologies to be affordable for most systems in a size category but did *not* list them as such due to a small number of systems that would find such technologies unaffordable. States would then be left the responsibility for making all such affordability decisions on a case-by-case basis -- after a "nationally affordable" technology had not been identified at the national level. Such an approach would involve making "national affordability" decisions based on the most disadvantaged systems, in EPA's judgment. As noted elsewhere in this report, EPA believes that there are other mechanisms (loans, grants, special utility rate structures, etc.) that are designed to help address these situations. While EPA certainly recognizes that the statute provides for a State role in making local level affordability decisions, it also believes that the statute requires a meaningful national level affordability screen to be applied. In addition, if a variance technology is installed, the goal is to achieve the maximum contaminant reduction that is affordable considering the size of the system and the quality of the source water rather than to comply with the MCL. Systems receiving a small system variance would likely exceed the MCL and, while still protecting public health, would not have the same level of health protection as systems complying with the MCL. EPA believes that one goal of the SDWA is to provide the same high quality drinking water for all customers of public water systems. At the same time, EPA recognizes that Congress was concerned about the high costs of treatment to small systems and provided small system variances as a means of addressing that concern.

Two Panel members were also concerned about EPA's plans to cumulatively account for the effect of various rulemakings on the national-level affordability criteria. EPA indicated that the treatment costs associated with other rules promulgated between 1996 and the arsenic rule would be incorporated into revised national-level affordability criteria. The national median annual household

water bills for each size category will be adjusted by averaging the total national costs for the size category over all of the systems within the size category. In other words, the costs incurred by these rules at the affected water systems will be averaged over all of the systems in that size category regardless of whether they are affected by the rules or not. A revised available expenditure margin will be calculated by subtracting the new baseline from the affordability threshold. The affordable technology determinations will be made by comparing the projected costs of treatment against the lower available expenditure margin. If the projected costs of all treatment technologies for a given system size/source water quality exceed the revised available expenditure margin, then variance technologies may be identified for those systems. Two Panel members were concerned that this approach does not address the systems that need to treat for multiple contaminants such as arsenic and radon.

To understand this concern, consider the following example. There are approximately 29,500 CWSs in the 25-500 size category, of which 8500, or about 29%, would exceed a radon standard set at 500 pCi/L. The average cost for such systems to come into compliance with such a standard would be about $250 per household per year. By EPA's methodology, however, this cost would be distributed over the entire 29,500 systems and decrease the available expenditure margin by only about $80 per household per year. (Note this example is hypothetical. EPA has not yet proposed a standard for radon.) Thus EPA would calculate a remaining expenditure margin of over $400 for all of the systems in this size category, even though a third of them are spending on average an additional $250 per household per year to comply with the radon standard. Even more troubling, for the several thousand private systems serving less than 100 people, the average cost for radon compliance would actually be $420 per household per year, but EPA would still calculate the same $400+ expenditure margin for their compliance with the arsenic and other future standards.

While EPA understands the concerns expressed by the two Panel members about its approach to the upward adjustment of the baseline in increments as each new drinking water regulation is promulgated, it believes there are a number of mitigating circumstances that would not make this situation as difficult for a portion of the small systems as the above illustration would indicate. EPA's approach to establishing the national-level affordability criteria did *not* incorporate a baseline for in-place treatment technology. Assuming that systems would always need to install a new treatment technology to comply with a NPDWR may thus significantly overestimate the *actual* costs for these systems. EPA also believes there are various mechanisms in the SDWA to help address cost impacts on small systems (discussed elsewhere in this report).

EPA further believes that an alternative means of adjusting the baseline that would address the concerns of the two Panel members is problematic. For instance, a calculation that apportioned the expenditures of those systems impacted by the rule to all systems in the particular small system size category would very quickly and inappropriately utilize the available small system "budget." This would likely render all technologies for future rules as "unaffordable" from a national standpoint, setting up a situation in which all small systems could potentially receive variances, provided, of course, that the State determined compliance was not affordable on a site-specific basis. EPA does not feel that this is

consistent with Congressional intent. EPA believes that small system variances should be the exception and not the rule and is concerned about an approach that it believes could make small system variances the primary pathway for the majority of small systems.

In addition, EPA has separate projects to examine the treatment needs of systems with occurrence of multiple contaminants. EPA has examined raw water data to determine the co-occurrence of contaminants above various thresholds. EPA will use the co-occurrence data together with treatment cost data to determine the number of systems that could face high costs from both the radon and arsenic rules. The Panel recommends that EPA include a discussion of the co-occurrence of arsenic and radon in the proposed rule for arsenic and of the issues surrounding appropriate adjustment of its national affordability criteria to account for new regulatory requirements. The Panel also recommends that EPA provide guidance identifying cost-effective treatment trains for ground water systems that need to treat for both arsenic and radon in the proposed rule.

The two Panel members were also concerned that the cumulative approach is based on chronological order rather than risk. They were concerned that small systems might receive small system variances for high risk contaminants because the available expenditure margin had been used up on lower risk contaminants. EPA does not have much flexibility on the promulgation order for the upcoming drinking water rules because the SDWA contains specific deadlines for proposal and promulgation. Thus, the radon rule is required to be promulgated before the arsenic rule regardless of the relative risk. However, EPA does have the flexibility to adjust its national affordability criteria and the way they are applied to address this concern. For example, EPA might be able to base affordability determinations on projected compliance needs for several upcoming standards simultaneously. Several SERs indicated that affordability should not be considered one contaminant at a time, but rather looking over a longer time horizon. The Panel recommends that EPA consider revising its approach to national affordability criteria to address this concern, to the extent allowed by statutory and regulatory requirements. The Panel also notes that the regulatory promulgation order would have no effect on the availability of small system variances for microbial contaminants. Section 1415(e)(6)(B) of the SDWA expressly forbids small system variances for microbial contaminants or indicators of microbial contaminants.

EPA notes that high water costs are often associated with systems that have already installed treatment to comply with a NPDWR. Such treatment facilities may also facilitate compliance with future standards. As noted before, EPA's approach to establishing the national-level affordability criteria did not incorporate a baseline for in-place treatment technology. Assuming that systems with high baseline water costs would need to install a new treatment technology to comply with a NPDWR may thus overestimate the actual costs for some systems. To investigate this issue, EPA examined a group of five small surface water systems with annual water bills above $500 per household per year during the derivation of the national-level affordability criteria. All of these systems had installed disinfection and filtration technologies to comply with the surface water treatment rule. If these systems exceeded the revised arsenic standard, modification of the existing processes would be much more

cost-effective than adding a new technology to comply with the arsenic rule. These systems have already made the investment in treatment technology and that is reflected in the current annual household water bills. As previously noted in this report, some technologies can interfere with treatment in-place or require additional treatment to address side effects which will increase costs over the arsenic treatment technology base costs. (An example is corrosion control for lead and copper, which may need to be adjusted to accommodate other treatment) While EPA tries to account for such interference in its cost estimates for each new compliance technology, it is not possible to anticipate all the site specific issues which may arise. The Panel recommends that EPA examine the data in the 1995 Community Water Supply Survey to determine if in-place treatment baselines can be linked with the current annual water bill baseline in each of the size categories for the proposed rule.

EPA believes that there is another mechanism in the SDWA to address cost impacts on small systems composed primarily of low-income households. Systems that meet criteria established by the State could be classified as disadvantaged communities under Section 1452(d) of the SDWA. They can receive additional subsidization under the Drinking Water State Revolving Fund (DWSRF) program, including forgiveness of principal. Under DWSRF, States must provide a minimum of 15% of the available funds for loans to small communities and have the option of providing up to 30% of the grant to provide additional loan subsidies to the disadvantaged systems, as defined by the State. Two Panel members noted that there will be many communities competing for the limited funding available under the DWSRF and remained concerned that this funding may not be adequate to address the needs of all individual small systems that cannot afford to comply with drinking water standards. The Panel asked if EPA had a database listing the distribution of funds from the DWSRF based on size of system. In addition, the Panel noted one SER's concern that small systems have difficulty securing DWSRF loans. The SER stated that "big systems, along with small systems owned by big holding companies, get almost all the money since they have the expertise necessary to cut through the red tape needed to get these funds."

EPA does not have a database listing the distribution of funds from the DWSRF. EPA does have data from the Intended Use Plans that the States are required to develop before they receive the capitalization grant from EPA. The data from the Fiscal Year 1997 Intended Use Plans for the DWSRF indicate that small systems would receive over 50% of the loans and over 25% of the funds, or about $289 million total. In addition, States have the flexibility to take set-asides from their grants for program management purposes. One of these set-asides is the option to allocate up to 2% of the grant to provide technical assistance to systems serving 10,000 or fewer persons. This set-aside may include providing technical assistance and expertise to small systems on coming into compliance with current requirements, implementing new regulations, and applying for the DWSRF loan. Based on the Fiscal Year 1997 State Intended Use Plans, the States have set aside an average of 1.7% of the grants for small system technical assistance, or about $20 million total, with 39 States using the full 2% allowed. The Panel recommends that EPA encourage small systems to discuss their infrastructure needs for complying with the arsenic rule with their primacy agency to determine their eligibility for DWSRF loans, and if eligible, to ask for assistance in applying for the loans.

9.2.3 Monitoring

The Panel notes a SER's comment that small ground water systems may be able to predict that their ground water has no/low risk of being contaminated with arsenic, with support of many years of testing and analytical records. The SER supported providing waivers for systems with no/low risk of arsenic, in order to direct resources to the systems that have arsenic.

The Panel notes that EPA plans to revise the arsenic monitoring requirement to be consistent with the Standardized Monitoring Framework (SMF) for inorganic contaminants (IOCs), in which States may grant monitoring waivers to water systems if they find that the system is unlikely to violate the MCL during the term of the waiver. Under a waiver, the system would monitor a minimum of once every nine years. This determination would be based on a number of criteria, which are specified in Section 3.2 on monitoring (page 12). The Panel also understands that community water systems have been monitoring for arsenic for many years to comply with the 50 ppb MCL; once every three years for ground water systems and once a year for surface water systems. However, a number of analytical laboratories may not report arsenic levels to the lowest possible detection limits so that the lowest reported level of arsenic may be as high as 10 ppb. The Panel supports EPA's proposal to move arsenic into the SMF for IOCs, in order to allow waivers. The Panel further recommends that EPA consider allowing States to use recent compliance monitoring data, where they will meet analytical requirements and have reporting limits sufficiently below the revised MCL, to satisfy initial sampling requirements or to obtain a waiver.

Like the current monitoring regime for arsenic, the SMF requires monitoring at all entry points to the distribution system, including those served by backup or supplemental wells. A possible alternative for such wells, however, is discussed below in section 9.4.

9.2.4 Analyzing Arsenic Species

On the basis of the information provided, one SER commented that EPA's analytical methods should distinguish between organic and inorganic forms of arsenic. This SER noted that drinking water systems containing almost entirely organic forms of arsenic may analytically violate the MCL due to the presence of organic arsenic. In addition, the SER encouraged EPA to acquire data on the toxicity of organic arsenicals, if necessary, to support regulation of inorganic forms. The Panel notes that the organic arsenic form found in fish and shell fish [arsenobetaine] appears to be much less toxic than inorganic arsenic, although the currently approved test methods for arsenic measure total arsenic, including inorganic and organic species. Sources of information available to EPA prior to the NRC report indicated that drinking water contained primarily inorganic species of arsenic. However, the NRC's report on arsenic in drinking water provided new information. One study found that lake water can contain 1 - 59% organic methylarsenicals, averaging 24% of the total dissolved arsenic at the surface. However, the study showed that the total arsenic concentration varied with the season and organic arsenic concentrations can vary in the yearly cycle. EPA expects that systems using lake water

generally tend to withdraw water at deeper levels that would typically contain less organic arsenic. These systems also usually have filtration treatment in place, which can be optimized to remove arsenic. While EPA agrees with the SER that the available data indicate that organic arsenic forms appear to be much less toxic than inorganic arsenic, EPA believes that testing for total arsenic will rarely affect compliance costs. Other researchers in the NRC report continued to identify little or no concentrations of organic monomethylarsonic acid (MMA) and dimethylarsinic acid (DMA) (the most common organic forms) in ground water. Systems using ground water are expected to make up the overwhelming proportion of facilities potentially impacted by the proposed rule.

In addition to the prevalence of inorganic arsenic, EPA's rationale for measuring total arsenic for compliance with the MCL is based on analytical cost and availability of laboratory capacity. While some analytical methods can distinguish between organic and inorganic forms of arsenic, they require more analytical separations, consuming more time and increasing the number of measurements and equipment calibrations necessary. In cases where organic methylarsenicals like DMA are in drinking water, the total arsenic test methods will detect it and be protective. The Panel recommends that EPA continue to explore whether or not to make a regulatory distinction between organic and inorganic arsenic based on compliance costs and other considerations.

9.3 Relevance of Other Federal Rules

The Panel notes the valid substantial concern of a number of SERs about impending total costs of compliance with other upcoming rules, including the ground water, disinfection by-products, radon, and uranium rules. The Panel understands that some treatment technologies useful for uranium removal, such as ion exchange and activated alumina, would also remove arsenic. If a system will need to install disinfection treatment for the ground water rule (GWR) or radon rule, this technique may contribute to arsenic pre-oxidation from As (III) to As (V). Arsenic pre-oxidation will enhance the removal efficiencies of arsenic treatment technologies. In addition, systems may use membrane filtration for GWR, which will remove some arsenic depending on the size of the membrane. However, arsenic treatment may also interfere with existing or required future treatment. For example, some of the technologies under consideration for arsenic may lower pH (e.g., reverse osmosis), which could adversely affect corrosion control for lead and copper.

The Panel recommends that EPA encourage systems to be forward-looking and test for the multiple contaminants to determine if and how they would be affected by the upcoming rules. To the extent permitted by law, the Panel urges EPA to consider establishing standards and compliance periods over a period of time that permits systems to engage in long-range water treatment planning to avoid unnecessary replacement of water treatment systems to meet new requirements. Furthermore, the Panel recommends that EPA take possible interactions among treatments for different contaminants into account in costing compliance technologies and determining whether they are nationally affordable for small systems, and provide guidance to small systems, to accompany the final rule, to assist them in making treatment decisions to address multiple contaminants in the most cost-effective manner.

9.4 Regulatory Alternatives

The Panel finds that the preliminary costs figures cited elsewhere in this report, including the significant waste disposal costs, could place a very large burden on small systems, particularly those that serve less than 100-500 persons. The potentially high costs appear to be the most important concern to the majority of the SERs. In this light, it is important for the Agency to examine very carefully the science underlying the setting of the MCLG and the MCL and the uncertainties in the data and risk assessments in developing the proposal later this year. The Panel further observes that the NRC outlined a host of scientific issues that remain unresolved and recommended that EPA pursue these in the future. Such new evidence may be available in the next six-year review of the arsenic standard mandated by SDWA. Given these significant uncertainties and potentially large costs, and the applicable statutory provisions, EPA may choose to be more cautious in considering a stricter standard, while still meeting its statutory obligations to be protective of public health. If EPA later finds that it has lowered the standard unnecessarily it will be too late for the small systems which have installed new systems at great cost, or gone out of business. The Panel therefore recommends that in performing its obligations under SDWA, EPA take cognizance of the scientific findings, the large scientific uncertainties, the large potential costs, and the fact that this standard is scheduled for review in the future.

The Panel also notes that although EPA is required to propose a standard for arsenic based on the new science and analysis, the statute is silent on whether the new standard need be more stringent than the current 50 ppb, provided that all of the applicable statutory, standard-related provisions are adhered to.

Perhaps the single most important regulatory alternative with the potential to significantly affect small entities is the choice of the MCL itself. In this regard, the Panel notes that the 1996 amendments to the SDWA require that the Agency identify and analyze a comprehensive set of costs and benefits associated with a proposed NPDWR, including consideration of non-quantifiable costs and benefits. In addition, the new statutory provisions allow the Administrator to select an alternative, less stringent MCL for chemical contaminants such as arsenic when the benefits of a proposed regulation do not justify the costs (SDWA Sections 1412(b)(4)(C) and 1412(b)(6)(A)). Executive Order 12866, which was issued on October 4, 1993, directs regulatory agencies, to the extent permitted by law and where applicable, to assess both the costs and benefits of any intended regulation, and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify the costs. The Panel recommends that EPA give full consideration to the provisions of the Executive Order and to the option of exercising the new statutory authority under SDWA Sections 1412(b)(4)(C) and 1412(b)(6)(A) in the development of a National Primary Drinking Water Regulation for arsenic. In doing so, EPA should take into account both quantifiable and non-quantifiable costs and benefits of the standard and the needs of sensitive sub-populations, and give due consideration to the impact of the rule upon small systems.

Another important rule development consideration with the potential for significant impacts on small entities is the scope of coverage of the rule, in terms of the types and numbers of facilities to which it will apply. The current arsenic regulation applies only to Community Water Systems, as is the case with other drinking water standards promulgated prior to 1986. The Panel understands that the proposed rule will apply, at a minimum, to Community Water Systems and may apply to Non-Transient Non Community Water Systems (e.g., schools, hospitals, etc.). The Panel recommends that the Agency carefully consider the appropriateness of extending the scope in this manner. In doing so, EPA should separately array and evaluate the incremental costs and benefits attributable to coverage of these categories of water systems. The Panel further understands that, in general, standards for chronic contaminants such as arsenic are not applied to Transient Non-Community Water Systems (e.g., campgrounds, rest stops, etc.) and agrees that this approach is reasonable for arsenic.

One important provision of the SDWA designed to provide regulatory relief from high compliance costs to small systems is the small system variance option that was added by the 1996 amendments. This alternative, and issues surrounding its applicability to the arsenic rule, are discussed extensively in Section 9.2.2. The Panel understands that, consistent with the SDWA, EPA may list a variance technology for any size category of small system for which it does not identify a nationally affordable compliance technology.

The Panel also notes that SERs suggested a number of specific regulatory alternatives to address unique situations related to particular categories of wells. One SER suggested that a waiver process should be implemented for wells that are used for supplemental or backup purposes, such as wells used for less than 60 days per year. Another SER suggested that EPA and the States provide waivers and/or select a few index wells for monitoring in an aquifer region as a method of decreasing regulatory burden and the amount of resources utilized in addressing non-problems regions. These SERs suggested that these alternative would conserve resources to enable additional attention to be devoted to problem regions. The Panel believes that these suggestions merit careful consideration by the Agency in the development of the rule.

9.5 Other Issues

9.5.1 Water Blending

One SER commented that provisions should be made for the blending of well water with surface water supplies before the product reaches the consumer. The Panel notes that EPA does not prohibit the blending of water from different sources to comply with a regulation. The Panel understands that EPA will not require a specific treatment technology for treating arsenic in drinking water, but will identify compliance technologies that are affordable and applicable to typical small water systems for meeting the MCL if such technologies exist. The water system may choose any treatment technique to best suit its conditions and capabilities, as long as the MCL is met. In addition to installing a treatment technology, options include finding another water source, purchasing water from a nearby

utility, or consolidating. Based on this information, the Panel recommends that EPA provides information to small water systems on possible options for complying with the MCL, in addition to installing any listed compliance technologies.

9.5.2 Arsenic Health Effects and the NRC/NAS Report on Arsenic in Drinking Water

In 1996, EPA asked the National Research Council (NRC) of the National Academy of Sciences (NAS) to review the current state of the science for estimating risks associated with arsenic in drinking water. The NRC's report, issued in March 1999, is based on a more complete database and research findings that have become available since the 1988 EPA risk assessment. The report recommends lowering the current drinking water standard of 50 ppb. The Panel notes that the NRC report stated "EPA did not request, nor did the subcommittee [on arsenic in drinking water] endeavor to provide, a formal risk assessment for arsenic in drinking water." (NRC, 1999) In particular, the Panel understands that the hazard identification and dose-response sections of the NRC report were performed in a manner consistent with EPA practice, but realizes that the report did not contain an exposure assessment. The NRC report is one of the elements that EPA will consider in preparing the Health Risk Reduction and Cost Analysis for arsenic required by SDWA. In addition, the Panel notes, as does NRC, that the NRC's recommendation was not based on the review of the costs of treatment, technical feasibility, or other factors that EPA legally must consider in the promulgation of a new MCL. The report outlines uncertainties and assumptions that are part of any risk assessment and EPA will consider them in its rulemaking to set new standards.

The NRC's recommendation is based primarily on their assessments of the risks of skin, lung, and bladder cancer from drinking water containing inorganic arsenic. The report also describes potential risks of cardiovascular effects. The NRC report provides an update to the science needed to support revising the risk characterization to develop the health-based non-enforceable goal for drinking water, known as the maximum contaminant level goal (MCLG). In addition to using the results of a revised risk characterization, the revised MCL for arsenic will be based on consideration of a number of factors including the availability of appropriate analytical methods; the efficiency of treatment technologies for all sizes of public water systems; the cost of treatment options; and the health benefits achieved by different arsenic levels in drinking water.

The subject of the health effects of arsenic in drinking water was of considerable interest to the SERs and was discussed at some length in some written comments and during the meetings on both December 18, 1998 and April 21, 1999. Several SERs urged the Agency not to use findings from studies from other countries based on arsenic levels atypical of the U.S. to develop a new, more stringent arsenic in drinking water standard. In particular, some SERs observed that the data used in the studies reviewed by the NRC are based upon arsenic exposures to individuals many times higher (e.g., greater than 300 ppb) than levels typically found in the U.S. (i.e., less than 50 ppb). These SERs noted

that the results from those studies were extrapolated to the range of interest (i.e., less than 50 ppb) as a part of the NRC's evaluations and recommendations to the Agency.

In this context, the shape of this "dose-response" curve for any such extrapolation is significant since a straight-line assumption about the shape of the curve would lead to a higher risk projection than a "sub-linear" curve. The NRC report states that all of the plausible modes of action for arsenic-induced carcinogenesis would produce sub-linear dose response curves. However, in the absence of evidence confirming non-linearity, the NRC used EPA's cancer risk assessment guidelines and applied a linear extrapolation from the does-response curve in its illustration of how the Agency could estimate the human health risks associated with arsenic in drinking water.

In light of these questions and uncertainties, several SERs felt it was inappropriate to contemplate a more stringent arsenic in drinking water standard until and unless there is compelling human health effects information from the U.S. in the range of interest (i.e., at and below 50 ppb). Several SERs pointed to the recommendations in the NRC report for additional research as a clear indication that significant data gaps in our understanding of arsenic health effects exist. These points, coupled with the SERs' concerns about the costs to small systems to comply with a new, more stringent standard for arsenic in drinking water, bolstered the recommendation of several SERs that EPA should refrain, in the near term, from promulgating a new, more stringent standard for arsenic in drinking water.

As of the time of the NRC report, NRC noted that there are no U.S. studies of sufficient scope or size to compare to the studies conducted in Taiwan, Chile, or Argentina. However, the Panel does note with interest the recent preliminary findings of the Utah Study conducted by EPA's Office of Research and Development that show a statistical difference between the study population and the general population with regard to certain health effects. The study population of about 4,000 people had been exposed to a range of levels of arsenic (14-166 ppb) in drinking water, the upper end of which is well above the average exposure of the general population. The study compared death rates within the study population from about 30 different causes to the general death rates from these causes within the State of Utah.

For males, there was a statistically significant increase in death from hypertensive heart disease, nephritis and nephrosis, and prostate cancer within the study group, and a statistically significant decrease in death from other cardiovascular causes, respiratory causes, and cancers of the digestive organs and peritoneum, large intestine, and respiratory system. For females, there was a statistically significant increase in death from hypertensive heart disease within the study group, and a significant decrease in death from ischemic heart disease, malignant neoplasms, and cancers of the digestive organs and peritoneum, pancreas, respiratory system and breast. The study suggests several explanations for the decreased death rates from some causes, including the healthy life style of the Mormons and genetic factors based on ethnic background.

It also discusses the possibility that the elevated death rates from some causes may have been due to arsenic exposure in drinking water. However, when the study population was divided into groups with high, medium, and low exposure, there generally was no clear relationship between level of exposure and elevated death rates. In particular, though increases in lung and bladder cancers were noted in the Argentina, Chile and Taiwan studies, the Utah study found decreases in digestive organs and respiratory system cancers among both males and females in the study population. However it should be noted that baseline risk levels in the Utah population are low (on the order of one per 1,000) and that it is thus difficult to discern statistically significant results in a study population of only 4,000 people. The Panel understands that there are number of factors which may contribute to the different findings between the Utah study and the other studies (e.g., different sample sizes, arsenic concentrations, scope and type of studies, etc.). However, based on the preliminary results discussed here, two Panel members believe that the Utah study does not provide strong evidence of a relationship between adverse health effects and arsenic exposure in the range studied in a U.S. population.

The Panel recommends EPA further evaluate the Utah study and its relationship to the studies on which the NRC report was based and give it appropriate weight in the risk assessment for the proposed arsenic standard. The Panel understands that the Agency frequently extrapolates from distinct and identifiable health effects linked to relatively high exposure to a contaminant to effects potentially associated with considerably lower exposures. This is consistent with the goals of the SDWA to be protective of human health. Previous drinking water standards with no known "zero risk" thresholds have typically been set at levels where effects are projected to occur only infrequently (e.g., 1 death in 10,000).

The Panel appreciates the concern of the SERs regarding the use of the NRC report in developing a new arsenic in drinking water standard and notes that additional work on the health effects of arsenic at low levels in the U.S. as well as other needed arsenic studies would be helpful and appropriate. The Panel therefore encourages EPA and other interested stakeholders to continue to pursue the kinds of research that will inform EPA's reevaluations of its National Primary Drinking Water Regulations (review required once every six years, at a minimum). However, the Panel recognizes that the statutory mandate of the 1996 amendments to the Safe Drinking Water Act directs the Agency to promulgate a new standard within the statutory deadlines (i.e., by January 1, 2001) based on the best currently available scientific information, while, at the same time, conducting and encouraging new research to help inform future decisions. The Panel also notes that the NRC report recommended that the Agency move expeditiously to develop a new drinking water standard for arsenic since its existing standard was judged by the NRC as not achieving EPA's goal for public health protection (although the NRC was not specific about what this goal is or should be).

The Panel recommends that the Agency thoroughly consider the SER concerns and that the NRC recommendations be examined in the light of the uncertainties associated with the report's recommendations (e.g., ethnic differences and relative source contribution differences among the various populations and the populations in the U.S.; extrapolation assumptions to determine arsenic

concentrations in the range of interest; groupings of wells which were used in the Taiwan study, and other pertinent factors), and any new data, such as the Utah Mortality study, that may not have been considered in the NRC report. The Panel also notes that the risk assessment of arsenic in drinking water is one component of the overall rulemaking effort and recommends that EPA fully consider all of the "risk management" components of its rulemaking effort to ensure that the financial and other impacts on small entities are factored into its decision-making processes.

10. REFERENCES

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