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OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

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EPA-SAB-DWC-LTR-00-005

Honorable Carol M. Browner
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Subject: Science Advisory Board Letter Report on EPA's Draft Proposal for the Groundwater Rule

Dear Ms. Browner:

The Drinking Water Committee (DWC) of EPA's Science Advisory Board (SAB) met on March 13-14, 2000 to review the Agency's draft proposal for its Ground Water Rule. This rule addresses the use of disinfection in ground water and other components of ground water systems to assure public health protection.

The Committee conducted this review in fulfillment of its responsibilities under Section 1412(e) of the Safe Drinking Water Act (SDWA as amended in August 1996) which state:

> *The Administrator shall request comments from the Science Advisory Board (established under the Environmental Research, Development, and Demonstration Act of 1978) prior to proposal of a maximum contaminant level goal and national primary drinking water regulation. The Board shall respond, as it deems appropriate, within the time period applicable for promulgation of the national primary drinking water standard concerned. This subsection shall, under no circumstances, be used to delay final promulgation of any national primary drinking water standard.*

This review was conducted in a public meeting in Washington, DC. EPA's draft proposal was reviewed by the Committee while it was still under review by the Office of Management and Budget (OMB) and prior to being released for publication in the Federal Register as a proposed rule. As such, the DWC members recognized that specific elements were subject to change during the OMB review.

The Committee reached closure on its conclusions during the March meeting. It was the view of the Committee that: 1) both bacterial and viral indicators should be employed in ground water source monitoring plans; 2) either *E. coli* or enterococci will serve as the bacterial indicator and coliphage should be used as the viral indicator; 3) to save on costs of monitoring, the Agency should develop and validate the use of a common host to simultaneously detect both male-specific and somatic coliphage; 4) the Agency should depend upon monitoring and wellhead protection programs to insure ground water sources are not subject to microbial contamination; and 5) source monitoring should include all ground water systems and some less frequent repeat monitoring that goes beyond the intensive monitoring proposed for the first year. These points are discussed in detail later in this letter.

A general issue raised by members during the discussion concerned the need for detailed technical information on the science that supports the rules which EPA requests SAB comments upon pursuant to SDWA 1412(e). Not having specific technical information available on the issues discussed in the rule can impede the effective evaluation of important issues by the Board. In this review, the Committee discussed the adequacy of a number of monitoring technologies that were referred to in the proposed rule. However, the technical descriptions of the methods were not provided to the Committee by EPA. In this case, several of the members were familiar with the methods thus the Committee was able to carry its discussion through to completion. However, the discussion would have been more efficient and effective if all members had been provided technical information on the methods prior to the meeting. Committee members noted that for future reviews, it will be important to identify, and obtain for all members, the relevant technical support documents that underpin critical elements in the Agency's proposed drinking water rules.

1. BACKGROUND

1.1 Statutory Context

The Safe Drinking Water Act (SDWA, 1996a) requires that EPA "publish a maximum contaminant level goal [MCLG] for contaminants: 1) that may have an adverse effect on the health of persons; 2) that are known to occur or there is a substantial likelihood that will occur in public water systems with a frequency and at levels of public health concern; and 3) for which a regulation presents a meaningful opportunity for health risk reduction for persons served by public water systems." MCLGs are to be "set at the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety"(SDWA, 1996b). Further, EPA must also publish a National Primary Drinking Water Regulation (NPDWR) that specifies a maximum contaminant level (MCL) for such contaminants "which is as close to the [MCLG] as is feasible" (SDWA, 1996c) or specify "the use of a treatment technique in lieu of establishing an [MCL]," if EPA finds "that it is not economically or technologically feasible to ascertain the level of the contaminant" (SDWA, 1996d) in water. "The term 'feasible' means feasible with the use of the best technology, treatment techniques, and other means [found by examination under] field conditions...are available (taking cost into consideration)" (SDWA, 1996e)

In addition, SDWA requires that when EPA "proposes a [NPDWR]...the Administrator shall: 1) "publish a determination as to whether the benefits of the [MCL] justify, or do not justify, the costs based on..." (SDWA, 1996f) a "Health Risk Reduction and Cost Analysis" [HRRCA]; 2) "use – i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data)" (SDWA, 1996g); and 3) "ensure that the presentation of information on public health effects is comprehensive, informative, and understandable." This information is to be contained in a publicly available document that specifies, "to the extent practicable – i) each population addressed by any estimate of public health effects; ii) the expected risk or central estimate of risk for the specific populations; iii) each appropriate upper-bound or lower-bound estimate of risk; iv) each significant uncertainty identified in the process of the assessment of public health effects and studies that would assist in resolving the uncertainty; and v) peer-reviewed studies known to the Administrator that support, are directly relevant to, or fail to support any estimate of public health effects and the methodology used to reconcile inconsistencies in the scientific data" (SDWA, 1996h).

SDWA requires EPA to develop regulations specifying the use of disinfectants for ground water systems as necessary. Under the provision, EPA must develop a ground water rule which specifies the appropriate use of disinfection, and, in addition, addresses other components of ground water systems to assure public health protection (SDWA, 1996i). Other rules applying to ground water systems include: the Total Coliform Rule (EPA, 1989a), the Surface Water Treatment Rule (EPA, 1989b), Interim Enhanced Surface Water Treatment Rule (EPA, 1998a), the Information Collection Rule (EPA, 1996), and the Stage 1 Disinfectants/Disinfection Byproducts Rule (EPA, 1998b). In addition programs for Underground Injection Control, Wellhead Protection, and the Source Water Assessment and Protection are also intended to address issues that are protective of ground water.

1.2 Provisions of the Proposal Reviewed by the Drinking Water Committee

The draft proposed rule requires states to conduct <u>sanitary surveys</u> on all ground water systems and surface water systems adding ground water directly to the distribution system without treatment (every 3 years for community systems and 5 years for non-community systems) (EPA, 2000a, EPA, 2000b). Significant deficiencies are to be identified. All ground water systems not achieving the equivalent of a 4-log reduction in concentration of viruses found in source water (commonly referred to as 4-log virus inactivation or removal, i.e., a 99.99% decrease in the viruses found in the source water) must do a one-time <u>hydrogeologic sensitivity assessment</u> to determine if the system is in a sensitive aquifer (within 6 to 8 years of the final rule). Monthly source water monitoring will be required for those systems determined to be hydrogeologically sensitive. Triggered (one-time) source water sampling will be required if a positive total coliform positive sample is found in the distribution system. Finally, if sampling shows significant deficiencies or positive microbial samples that indicate fecal contamination, the problem must be corrected by the system. Finally, systems notified of "...significant deficiencies by the state, or notified of a [positive] source water sample,...must... correct the contamination problem (by eliminating the contamination source), correct the significant deficiencies, provide an alternative source water or install a treatment process which reliably achieves 4-log removal or inactivation of viruses" (EPA, 2000a)."

2. CHARGE

The Charge provided to the Drinking Water Committee by EPA requested that the Committee evaluate the premise that "...more than one fecal indicator may increase the likelihood of detecting fecal contamination than a single indicator" (EPA, 2000c) in two areas:

a) Given the available data upon incidence, fate, and transport of virus and bacteria through the soil/aquifer matrix, is it appropriate to monitor for both bacterial and viral indicators to determine the presence of fecal contamination?

b) Based upon the available data, can each of the four candidate indicators (*E. coli*, enterococci, somatic coliphage, male-specific coliphage) be justified as a monitoring tool for determining the presence of fecal contamination in ground water?

3. SPECIFIC COMMENTS

Key points raised by the Committee are summarized below, to indicate the nature of their concerns. Section 3.1 responds to specific charge questions from the Agency. Sections 3.2 and 3.3 address issues which were raised as questions within the draft proposal reviewed by the Committee.

3.1 Fecal Indicators

3.1.1 *Given the available data upon incidence, fate and transport of virus and bacteria through the soil/aquifer matrix, is it appropriate to monitor for both bacterial and viral indicators to determine the presence of fecal contamination?*

The Committee recommends that the Agency propose monitoring for both bacterial and viral indicators for both routine and triggered monitoring. Specifically, the Committee recommends that the Agency propose the use of *E. coli* or enterococci and coliphages.

The Committee noted that occurrence studies that measure groundwater quality using several microbial indicator organisms show that no single indicator adequately reflects the presence of fecal contamination under all conditions. The draft proposed rule presents data from 13 studies (EPA, 2000b, pages 61-80). Different results were obtained for various bacterial and viral indicators in a wide variety of groundwater sources. It is difficult to compare these studies side-by-side because different methods and sample volumes were used. However, it is evident that no *single* indicator organism was consistently detected in all the contaminated groundwater sources that were examined. The use of both bacteria and coliphage indicators will provide better ability to detect fecal contamination and protect human health.

For water samples collected close to the source of contamination, it is more likely that several microbial indicators will be detected. For water samples collected distant from the source of contamination, it is critical to use indicators that model the transport and survival characteristics of viral pathogens because viruses are known to have prolonged survival in the environment and can be transported long distances. *The scientific literature documents significant differences between transport and survival characteristics of enteric bacteria and enteric viruses.* Field studies that have spiked septic tanks with known quantities of virus have shown that viruses and bacteria have different survival and transport characteristics in soil (Curry, 1999, Cogger et al., 1988, Vaughn et al., 1983, Yates et al., 1986). Tracer studies where primary sewage effluent was applied to a rapid infiltration site indicated that enteric viruses penetrated deeper into the ground than bacteria (Keswick, 1984). Gerba and Bitton (1984) present a thorough review of the survival and transport of microorganisms in groundwater.

There is considerable evidence in the literature to support the use of coliphage as surrogates for enteric animal viruses. Havelaar et al. (1993) examined virus and coliphage survival in a wide variety of fresh water environments and concluded that, overall, coliphage were better indicators of culturable enteroviruses than were bacterial indicators. Field Studies and soil column studies have shown that coliphage are good predictors of the movement of enteric viruses in soils (Nasser et al., 1989; Sobsey et al., 1995, DeBorde et al., 1999). Several occurrence studies have shown a strong correlation between coliphage detection and viral and/or fecal contamination of groundwater (Lieberman et al., 1999). Phase II of the EPA/AWWA study conducted monthly testing of seven wells known to have viral contamination. Somatic coliphages were detected more frequently in these wells (71% of specimens were positive) compared to *E. coli* (50% of specimens were positive) or enterococci (55% of specimens were positive) (Lieberman et al., 1999). Twenty of 21 transient non-community groundwater systems in migrant worker camps in Wisconsin were found to be positive for male-specific coliphage over a six month period, but *E. coli* was never detected in any of these wells EPA 1998c). A study of fecal contamination in groundwater wells 500 feet down gradient of a water recharge infiltration basin in California detected coliphage in all 23 wells at least once and repeatedly in 20 of the 23 wells. *E. coli* were not detected in any of the 23 wells (Yanko et al., 1999). Preliminary results of another study in California also indicate that coliphage are detected more frequently than fecal streptococci in groundwater with viral contamination (Yates, 1999). Taken together, the data in the body of literature strongly suggest that it is necessary to include coliphage as indicators of viral contamination.

Data from waterborne disease outbreaks indicate that there is significant risk of illness associated with groundwater - both "treated" and untreated groundwater systems. In the draft proposed rule, the Agency cites CDC data that between 1971 and 1996 there were 371 outbreaks of waterborne disease associated with groundwater sources. This represents 58% of all the reported waterborne disease outbreaks during this period (EPA 2000b, page 55). It is likely that much more epidemic and endemic waterborne disease is associated with groundwater sources. Because of the many small groundwater systems, it is probable that the majority of waterborne disease outbreaks associated with these small systems are never recognized and reported. Of the 371 outbreaks in groundwater systems from 1971 - 1996, 34 (9%) of the outbreaks were attributed to viral pathogens. For the majority of these waterborne disease outbreaks (63%) the etiology was never determined. However, it is likely that most of these outbreaks were due to viral agents because of the characteristics of the outbreaks (symptoms, incubation period, duration) and the fact that viral agents are less likely to be detected in infected persons because of inadequate diagnostic techniques.

The major target of the Groundwater Rule is viral disease. The treatment recommendation is expressed in terms of 4-logs of virus inactivation or removal. Therefore, it is logical that the target of groundwater monitoring should be viral indicators such as coliphage. Further, the use of both a bacterial indicator and coliphage was also recommended by a panel of experts at the February 1999 "Workshop on Fecal Indicators for Ground Water Sampling Under the Groundwater Rule" (ISSI, 1999).

3.1.2 ***Charge. Based upon the available data, can each of the four candidate indicators (E. coli, enterococci, somatic coliphage, male-specific coliphage) be justified as a monitoring tool for determining the presence of fecal contamination in ground water?***

The Committee noted that both *E. coli* and enterococci are effective bacterial indicators and that the States or water systems could chose either indicator. *E. coli* methods may be more familiar to many laboratories which may make this indicator a more likely choice and provide data which will be comparable to already existing data. However, the enterococci may be somewhat hardier in terms of environmental persistence. The media for enterococci is more selective and less subject to non-target bacterial growth. Laboratories that are already testing for enterococci should not be required to change to *E. coli* if they are comfortable with the enterococci methods. The Committee recommends that the Agency define the term "enterococci" because different media and methods may detect different sets or sub-sets of organisms, and there is some confusion about this term in the international scientific literature (LeClerc et al., 1996).

It is difficult to chose between somatic and male-specific coliphage. Occurrence studies show that the somatic coliphage are more prevalent in septic tanks, but both somatic and male specific coliphages are detected with similar frequency in wastewater. Male-specific coliphages occur in higher densities so they may provide additional sensitivity. The Committee recommends that the Agency propose the use of both somatic and male-specific coliphage because this will detect a larger population of coliphage. For most monitoring purposes, it is not necessary to be able to distinguish between somatic and male-specific phage. Laboratory methods are available to detect both at the same time, using a single host such as *E. coli* C3000 (ATCC 15597), so that it would not be necessary to collect additional sample volume. The Agency is encouraged to initially propose testing for somatic and male-specific coliphage on separate hosts and conduct round-robin testing of coliphage detection using *E. coli* C3000 as the single host. Because the laboratory methods are the same whether using one or more bacterial host strains, the round-robin testing of coliphage detection on a single host should be relatively straightforward.

3.2. Hydrogeological Assessment

Hydrogeological assessment is being considered by the Agency as a basis for distinguishing between groundwater sources that are more vulnerable from those that are less vulnerable to fecal contamination. The Committee is concerned about the ability to accurately assess the sensitivity of specific groundwater sources.

The Committee questions whether hydrogeological assessment can be adequately conducted based solely on maps. The Committee recognizes that some aquifers are well characterized with an abundance of good hydrogeological information and well logging data, but other aquifers may have very little information and it may be more economical to monitor these aquifers than to conduct an extensive hydrogeological assessment. Furthermore, the Committee cited an example of a 2000 foot deep aquifer with a confining layer that would give the appearance of being a well-protected source, but in reality this source was contaminated due to infiltration through corroded casing of an existing well. This illustrates the necessity of source monitoring for all groundwater sources rather than relying on hydrogeological information to determine whether a source is likely to be contaminated.

The Committee is concerned that aquifers in sandy soils are not included in the list of sensitive sources (karst, fractured rock, gravel). Field studies of virus transport from septic tanks show that viruses rapidly move into groundwater in sandy soils (Cogger et al., 1988, Vaughn et al., 1983).

The Committee recommends that all groundwater sources be required to monitor for bacterial indicators and coliphage for at least one year - regardless of sensitivity determination.

3.3 Source Monitoring

The Committee is concerned about the possibility that many untreated groundwater systems will not be monitored at the source. CDC data on waterborne disease outbreaks indicate that 86% of the outbreaks in groundwater systems between 1971 and 1996 were due to contaminated source water (EPA, 2000b, page 55). As currently proposed, only groundwater systems in sensitive soils (karst, fractured rock or gravel) will be monitored monthly for 12 months. After this time, it is possible for the states to require less frequent or no source monitoring if all the source samples in the 12-month period are negative. The Committee is concerned that one year of monthly monitoring may not provide representative data (e.g., may not capture periods of heavy rainfall) or that new sources of fecal contamination (septic tanks, animal feeding operations) may occur after the monitoring period. The results of the occurrence studies indicate that 4 - 31% of groundwater sources had some evidence of viral contamination. This high prevalence of groundwater contamination makes it critical to promote regular source monitoring for untreated systems. It is possible that information from a hydrogeological assessment and a strong wellhead protection program could provide a legitimate basis for decisions on the frequency of source monitoring. The Committee recommends that all groundwater sources should be monitored for a year and that all untreated sources should continue to be monitored at some frequency that should be based on the size of the population served, hydrogeological assessment, well logging information, and well head protection programs. Source sampling of at least once per year should be required for all systems. Due to insufficient data and scientific knowledge of all factors that may make a well susceptible to fecal contamination, the Committee recommends a conservative approach of monitoring all wells at the source as part of the evaluation process.

If laboratory capacity for source monitoring is a concern, it would be possible for the monitoring requirement to be staged over a period of several years. Untreated systems serving the largest populations should be first priority for source monitoring because more people have the potential of being affected.

The Drinking Water Committee was pleased to conduct this review of the proposed rule. The Committee looks forward to the response from the Assistant Administrator for the Office of Water to the advice in this letter.

Sincerely,

/signed/

Dr. Mort Lippmann,
Interim Chair
Science Advisory Board

/signed/

Dr. Richard J. Bull, Chair
Drinking Water Committee
Science Advisory Board

ROSTER

U.S. Environmental Protection Agency
Science Advisory Board, Drinking Water Committee (DWC)
March 13-14, 2000 Meeting

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(1996a): Section 1412(b)(1)(A) General Authority.
(1996b): Section 1412(b)(4)(A) MCLGs
(1996c): Section 1412(b)(4)(B) MCLs
(1996d): Section 1412(b)(7)(A) Treatment Technology
(1996e): Section 1412(b)(4)(D) Feasible
(1996f): Section 1412(b)(4)(C) B-C Justification
(1996g): Section 1412(b)(3)(A) Best Science
(1996h): Section 1412(b)(3)(B) Public Information
(1996i): Section 1412(b)(8) Disinfection

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