UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

July 28, 1994

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

EPA-SAB-DWC-LTR-94-010

Honorable Carol M. Browner
Administrator
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

Subject: Science Advisory Board (SAB) Review of Information Collection Rule (Monitoring Requirements for Public Drinking Water Supplies)

Dear Ms. Browner:

On April 27, 1994, the Drinking Water Committee of the Science Advisory Board reviewed the Agency's proposed "Monitoring Requirements for Public Drinking Water Supplies" (59 FR 6332, February 10, 1994) or the "Information Collection Rule (ICR)." This letter summarizes the Committee's views of the proposed rule, following the outline of the Charge to the Committee (see enclosures).

General comments

Under the proposed rule, the Agency will require that many public water systems gather data for 18 months to support the development of a regulatory strategy for reducing the potential risks of both microbial and chemically-induced diseases arising from drinking water. The information collected under the rule "will be used to consider possible changes to the current Surface Water Treatment Rule (SWTR) and to develop drinking water regulations for disinfectants and disinfection by-products."

The committee generally supports the development and implementation of this rule but is concerned that the Agency has not articulated an overall research plan to guide the collection and analysis of the data in a meaningful way. A clear research plan is critically needed to define the questions that the data are intended to answer, as well as the methods that will be used to analyze the collected data. Without such a plan, the rule may result in

the collection of data that may not be necessary or usable, and thus may fail to adequately support the development of an enhanced SWTR or regulations for disinfectants and their by-products.

The Committee recommends that the Agency develop an overall research plan to underpin the ICR effort, with more clearly defined scientific objectives and methodology. The plan should explicitly define a specific set of questions or scientific hypotheses that the data collected under the rule would serve to answer, as well as the methods that will be used to analyze the data.

Finally, the collection of occurrence data for microbial agents and disinfectants and their by-products is not capable of resolving the health risk issues involved without parallel research quantifying the chemical and microbial risks that are associated with those occurrences. While a full discussion of this issue is beyond the scope of this report, it is important to emphasize that there is a strong need for the Agency and others to continue to conduct and stimulate substantial research in these areas. The Drinking Water Committee has addressed this issue in numerous reports in the past.

Archiving of Microbiological Samples

The ICR proposes to archive a percentage of the water concentrates collected for enteric viruses and certain protozoan parasites in a central repository maintained by the EPA. These samples would in theory be used in the future by researchers to study correlations between indicators of harmful contamination of drinking water, and also to study viral pathogens for which adequate detection methods do not yet exist (e.g., Norwalk virus).

The logistics of archiving virus samples are achievable. Most enteric viruses are very stable at ultra-cold (-70°C) temperatures for many years and some virus testing laboratories already archive samples. These samples may later be tested for viruses using new and highly sensitive molecular techniques for important human pathogens such as hepatitis A or Norwalk viruses, for which no testing under the ICR is proposed. The archived samples could also be used to determine the suitability of molecular detection methods currently under development.

The Committee cautioned, however, that archiving virus samples can provide future benefits only if the samples are collected according to a clear research plan supported by sufficient allocation of resources. Without such a plan and commitment of resources the Committee does not recommend that virus samples be archived, because it is unlikely that they would be put to a profitable use.

The case for archiving for parasites and its objectives are less clear. The integrity, quality, and viability of the protozoan cysts and oocysts which would be the focus of such sampling do not appear to be stable under long-term storage, regardless of the storage option (formalin/refrigeration or freezing). Because of the uncertainties about viability of cyst and oocyst samples, it is unlikely that scientifically valid inferences can be drawn from later analysis of archived samples. Also, the proposed rule does not contain a clear definition of the scientific questions that would be answered through the collection, storage and archiving of the cyst and oocyst samples, or a specific plan to guide their collection and analysis.

Particle size count data

EPA is considering the collection and use of particle size distribution data in lieu of, or in addition to, monitoring of finished water for *Giardia* cysts and *Cryptosporidium* oocysts. If a precise relationship between these variables can be established, it could eliminate or reduce the need for technically-complex monitoring for these microbes.

The technology and methods for particle counting are more sensitive and more precise than those for monitoring for *Giardia* cysts and *Cryptosporidium* oocysts, but they are not well standardized in the waterworks industry. Also, particle size counts during the treatment process are useful in optimizing and determining the effectiveness of treatment processes, but no direct relationships between changes in particle counts and the removal of protozoan parasites has been established.

The Committee does not recommend the use of particle size count data in lieu of monitoring Giardia and Cryptosporidium in finished water. Currently, there is no valid scientific basis for assuming that particle counts are predictive of either *Giardia* and/or *Cryptosporidium* occurrence and/or concentrations in raw water or their reductions by drinking water treatment processes. On the contrary, existing data indicate considerable variability in the relationships between particle counts and the protozoan parasites. However, utilities should be encouraged to obtain as much data as possible concerning these variables (particle counts and concentrations of protozoan parasites) in order to better establish if relationships between them exist.

Monitoring for other indicators

The Agency wishes to establish whether it is useful to require monitoring for *Clostridium perfringens* and coliphages in addition to the more traditional bacterial indicators (i.e., total coliforms and fecal coliforms in source and treated drinking waters). Numerous

studies have shown a lack of correlation between the occurrence of coliform and fecal coliform bacteria in raw and finished drinking water and the presence of pathogenic microorganisms. Development of new indicators which are easy, rapid, and can be detected at low cost are desirable.

C. perfringens is a common inhabitant in the human intestinal tract and forms endospores which are very resistant to most disinfectants. *C. perfringens* is always found in human feces at high density but there is controversy on its occurrence in the feces of other animals. Tests for sulfite-reducing Clostridium bacteria have been performed in European water systems as a supplementary test for some time. Recent work in Canada has demonstrated a correlation between removal of *C. perfringens* with removal of oocysts, cysts, and viruses during conventional drinking water treatment.

Coliphages, or the viruses of coliform bacteria, have been studied for many years as potential indicators of human enteric viruses in water. Studies done by investigators in The Netherlands have found correlations between the presence of male-specific coliphage and enteric viruses in fecally polluted river and lake water, but not raw sewage. A recent Canadian study found a correlation between somatic coliphage and enteric viruses and oocysts in filtered drinking water, but not river water. Enough information is not available to recommend either somatic or male specific coliphages at this time.

The analyses of both these microorganisms is affordable and easily performed by any microbiological laboratory. However, methods would still have to be standardized and determination of the host bacteria for the coliphage assay would have to be determined.

The ICR offers a unique opportunity to determine if these microorganisms could be useful indicators of enteric viruses and protozoan parasites. ***The Committee agrees with the Agency's proposal to require monitoring for these two contaminants.*** The incremental cost of monitoring for coliphages and *C. perfringens* is small and the methods relatively well developed, technically simple and reasonably reliable. A strong motivation for including them in monitoring in the ICR is the potential for these candidate indicators to be predictive of the occurrence and reductions during water treatment of enteric viruses and protozoan cysts and oocysts. If the validity of these candidate indicators can be established on a national basis, it offers the potential to incorporate them into the regulations of the drinking water program. Enough data from previous research endeavors have been obtained to identify them as good candidate indicators (references can be provided to the Agency on request). The best way to evaluate their potential as indicators for enteric viruses and parasites is to incorporate them into a nationwide study.

Treatment Plant Data

The Agency proposes to develop a database that includes the relevant characteristics of the water treatment plants covered by the ICR. This database will be used to refine models that predict the formation of disinfection by-products, characterize the performance of existing treatments in forming disinfection by-products and removing and/or inactivating pathogens. This information would be used to evaluate the consequences of future regulatory options.

A large number of data items concerning many variables would be required from many public water systems under the proposed rule. It is therefore critically important that the Agency carefully define the *scientific objectives* for its modeling effort and its planned approach for use of the database, prior to the start of the monitoring. It is also critical that the Agency establish *standardization and verification procedures* for data collection. ***A large, complex information system must be developed for this massive data collection process and the Committee strongly recommends that planning begin quickly and comprehensively.***

After defining the scientific objectives, the EPA should consider convening two coordinated panels of experts to assist in defining the critical design and operation data that will need to be collected from each treatment plant under the rule. One panel would focus on disinfection-by-products, the second on removal and disinfection of microorganisms. It would also be wise to review and pilot the structure of the database with selected candidate utilities to ensure that its structure is sufficiently robust to handle the wide variety of custom designs that will be found in domestic water treatment plants.

Finally, of the information to be collected under this portion of the rule, the Committee wishes to bring special attention to the need to locate and quantitatively assess the importance of point and non-point contamination of source waters. This is needed in order to adequately interpret and respond to the data that will be obtained on the occurrence of protozoan parasites and viruses in drinking water sources. It is essential that the sources of such microbial contamination in watersheds be clearly identified and quantified. While the original proposal specifies the performance of sanitary surveys to be done in connection with the ICR, possible revisions now under consideration suggest that the Agency is planning to substitute these surveys with data from existing databases within the Agency. It is critical that a validation of these databases be done in a representative number of locations to confirm that they can in fact be used with confidence for this purpose.

In summary, the Committee feels strongly that the ICR can only prove effective if it generates the data that are truly needed to effectively regulate chemical and microbiological

contaminants in drinking water. To accomplish this, there is an urgent need for the Agency to develop a research plan that defines precisely what data are needed and how they will be analyzed to answer the critical questions regarding these contaminants. The Committee would be pleased to help review such a plan.

The Committee was pleased to be able to review this important proposed rule and we look forward to your response.

Sincerely,

Genevieve M. Matanoski

Dr. Genevieve M. Matanoski, Chair
Executive Committee
Science Advisory Board

Verne A. Ray

Dr. Verne A. Ray, Chair
Drinking Water Committee
Science Advisory Board

Enclosures

To: SAB Drinking Water Committee

From: Stig Regli (4603)
D/DBP Regulation Manager
Regulation Branch, Standards Division
Office of Ground water and Drinking Water

Subject: Request for Review of Proposed Information Collection Rule (ICR)

The Office of Water would like your review of the proposed ICR which you should have received in mid March 1994. While we welcome your comments on any aspects of the ICR, we would like you to comment on whether the general objectives of the ICR are likely to be met and on a few particular issues described below. The particular issues are described by subject and page number and were highlighted for you in the previous mailing, the February 10, 1994, Federal Register Notice.

General

The information to be collected by utilities in the proposed ICR, in conjunction with complementary research, is intended to fill various large data gaps that would assist the Agency in developing criteria for the enhanced surface water treatment rule and Stage 2 DBP regulation.

Is the information requested under the ICR appropriate in scope and specificity to support the development of the ESWTR and Stage 2 DBP regulations?

Specific

Archiving of Microbiological Samples (page 6338)

EPA is considering whether to require systems to submit some percentage of their processed microbiological samples to the Agency for archiving. For Giardia/Cryptosporidium samples, systems/laboratories would collect a total volume of at least 140L and 1400L for raw and treated waters, respectively, and send approximately one-fourth of the sample concentrate (1/4 of the pellet), i.e., about 5 ml of sediment in 5 ml of formalin, to EPA for archiving under refrigeration. For viruses,

systems/laboratories would collect a total volume of at least 200L and 1400L for raw and treated waters, respectively, and ship a 100-ml filter eluant (pH neutralized) on dry ice to EPA for archiving at -70 C.

EPA solicits SAB comment on the feasibility of archiving samples, particularly the study of correlations between indicators and pathogens, among pathogens, and measurements of pathogens that not yet be adequately measured (e.g., Norwalk agent and as yet unrecognized pathogens. What precautions should EPA take to ensure that archiving is done properly?

Particle size count data (page 6338)

EPA is considering allowing systems the option of collecting particle size count data for each removal process within the treatment plant in lieu of finished water monitoring for Giardia and Cryptosporidium.

EPA solicits SAB comment on the following issues pertaining to monitoring of particle size counts: Under what circumstances, if any, should monitoring of particle size counts be allowed in lieu of monitoring finished water for Giardia and Cryptosporidium? What precautions should EPA take for ensuring that pertinent and reliable data is collected?

Monitoring for other indicators (page 6340)

EPA is considering whether to require systems to monitor for Clostridium perfringens (C. perfringens) and coliphage in addition to total coliforms, fecal coliforms/E.coli in source waters and treated waters.

EPA solicits SAB comment on the utility and feasibility of requiring systems to monitor for one or both of these supplemental parameters for the purpose of indicating source water pathogen densities and treatment effectiveness for pathogens? If coliphage is recommended for monitoring which type should be analyzed - somatic, male specific, and/or total coliphage?

Treatment Plant Data (pages 6346-6351)

The proposed ICR requires systems to submit treatment plant and unit processes information listed in Table III.6. This will be used to a) refine models that predict the formation of DBPs, and b) characterize treatment now in place for controlling DBPs and for removing and/or inactivating pathogens. The information in Table III.6, in conjunction with other occurrence data collected under the ICR, would help the Agency evaluate existing assumptions about treatment efficiency and the national impacts of future regulatory options.

EPA solicits SAB comment on the completeness of Table III.6. Is all the requested information essential? Should additional information be requested?