Protozoan Method Development Stakeholder Meeting

EXECUTIVE SUMMARY

December 16, 1997

EPA held a public meeting on December 16, 1997, in Washington, D.C., to discuss drinking water protozoan analytical methods. The objectives of the meeting were to present EPA's regulatory and programmatic needs for improved protozoan analytical methods, share and discuss information from the Protozoan Method Development Workshop held in Arlington, Virginia on October 20-22, 1997, describe a possible approach for defining method performance goals, present the status on the development of an improved, near-term protozoan analytical method (Method 1622), discuss possible methods that may be available for the Long Term Stage 2 Enhanced Surface Water Treatment Rule (LT2ESWTR), receive feedback from stakeholders concerning the information presented, obtain new information and data from stakeholders regarding methodologies that may offer promise but were not presented, and determine possible ways the Agency could proceed to evaluate performance of new methodologies.

Background

Cryptosporidium oocysts and *Giardia* cysts are ubiquitous in the environment. The standard method for detecting these protozoa in water samples is the indirect fluorescent antibody (IFA) procedure as specified by the Information Collection Rule (ICR). The ICR method has been heavily scrutinized by scientists which led them to conclude that the method has low capture and recovery efficiencies; the results are widely variable both within and among laboratories; it is difficult to perform and requires a skilled microscopist; and it can determine neither viability nor speciation of oocysts and cysts.

As part of the Long Term Stage 2 Enhanced Surface Water Treatment Rule (LT2ESWTR), to be promulgated in May 2002, EPA is considering requiring systems to monitor their source water for *Giardia* and *Cryptosporidium* to determine appropriate levels of treatment. The three rule options currently being considered to determine appropriate treatment levels are: 1) fixed treatment approach (i.e., all systems would be required to provide at least the same level of treatment); 2) proportional treatment approach (i.e., level of treatment required to achieve a desired risk level would be based on the density of *Giardia* cysts and *Cryptosporidium* oocysts in source water during the reasonably worst case occurrence period); and 3) watershed-based approach (i.e., systems would be required to monitor the source water and provide a level of treatment based on a combination of factors that indicate the level of vulnerability of the source water to pathogen contamination.

To determine the appropriate treatment level, it is essential to be able to reliably measure the occurrence of the organisms in the source water. An improved analytical method that meets certain acceptability goals (e.g., acceptable recovery efficiencies, precision, and accuracy) is a precondition for implementation of the proportional treatment approach or the watershed-based approach. For the above reasons, EPA plans to have data on one or more new complete methods which have undergone preliminary validation procedures prior to LT2ESWTR Regulatory Negotiation (Reg-Neg) Committee discussions scheduled for mid-1999.

Summary

EPA presented an overview of how ongoing EPA drinking water activities and the Protozoan Method Development meetings, in particular, relate to the 1996 Amendments to the Safe Drinking Water Act. Depending upon which rule options are selected for the LT2ESWTR, water utilities may have to monitor their source water to determine protozoa occurrence. As mentioned earlier, the ICR method has a number of limitations (i.e., low recovery efficiencies, precision, accuracy and wide intra- and inter-

laboratory variability) and is therefore not believed to be an adequate method to determine necessary treatment levels.

EPA also presented an overview of the Agency's approach to developing a protozoan analytical method. Over the past year, EPA has been developing and validating a new analytical method, Method 1622, to detect and enumerate *Cryptosporidium* and *Giardia* in source water. Method 1622 will be used to collect protozoa occurrence data for the ICR Supplemental Surveys. Method 1622 is expected to have higher recovery and lower detection limits that the ICR method due to enhanced features such as optimized filtration procedures and immunomagnetic separation. Depending upon overall method performance, Method 1622 may be a potential analytical method candidate for consideration in the LT2ESWTR.

EPA explained that the choice of the method that the Agency may consider for the LT2ESWTR will depend upon two fundamental areas: 1) technical considerations, and 2) programmatic goals. Technical considerations, or method performance goals, include: recovery efficiencies, analyzable volume, precision, and feasibility of laboratories to adopt method. Programmatic goals include: cost per sample, sample analysis time, simplicity, availability of a method/method component from principal investigators, and when method will be commercially available.

EPA further mentioned that to evaluate the effectiveness of different protozoa methods, method performance goals need to be established. Under a proportional rule structure, one goal is to minimize the number of plants that would misclassify their source water protozoa concentrations. The risks are: 1) if monitoring misclassifies on the high side, than plants will treat more than needed thus incurring unnecessary costs), and 2) if monitoring misclassifies on the low side, than plants may not provide adequate treatment. Misclassification depends on several factors: 1) level and variability of protozoa occurrence at a specific site, 2) method percent recovery, volume analyzed, accuracy, and 3) monitoring frequency and duration. Factors which affect the significance of misclassification are: 1) national distribution of level of treatment in place (ICR data and research will provide data), 2) national distribution of oocysts/cysts occurrence and other water quality factors (e.g., bromide levels affect feasibility for using ozone to control for *Cryptosporidium* because of concurrent bromate standards that would also have to be met), 3) source water concentration levels and corresponding levels of treatment based on total, viable, or infectious counts, and 4) EPA's definition of an acceptable risk level. EPA also presented a misclassification rate simulation analysis.

After EPA's presentation on the need to establish method performance goals and a possible approach for doing so, the Agency posed two questions to stakeholders. Question #1: Is the above misclassification simulation protocol appropriate for estimating desired protozoa method performance goals? Question #2: Are the source water classification goals in the right ball park?

To give a report on available analytical methods and methodologies that are being developed, EPA presented an overview of the ICR protozoa method, indirect fluorescent assay (IFA), and gave a status report on Method 1622. Procedurally, Method 1622, like most complete analytical methods, is similar to the ICR method because it consists of several sequential steps: 1) concentration, 2) purification/clarification, 3) assay procedure, and 4) microscope examination. EPA also presented a summary of the October 1997 workshop which briefly described the ongoing research that was presented by experts at the workshop and conveyed the various issues that were discussed at the workshop related to the research presented. In addition to EPA's report, a representative from a state laboratory gave a presentation on the status of viability/infectivity research.

During the final session, titled "Where are we? vs. Where we need to go?", EPA presented how the Agency may proceed with evaluating possible analytical method candidates for the LT2ESWTR. EPA presented a draft plan of how the Agency is considering to proceed to evaluate methods. Following are the components of the plan: 1) refine existing laboratory guidelines, 2) develop goals/process for selecting candidate methods, 3) peer review of candidate methods, 4) identification of best candidate methods, 5) select process for best candidate method, 5) revise method and establish criteria for scoring, and 6) round robin evaluation. The method evaluation process (as drafted) was scheduled to last through

mid-1999. A plan that was suggested which stakeholders believed is a more plausible approach was to ship water samples and spiked performance evaluation (PE) samples to any interested method developer to allow them to test their method and submit their results to EPA for analysis. This approach will provide the Agency with preliminary data and allow EPA to determine if the analytical method should be considered for further evaluation.

A few issues that were raised at the meeting were that: 1) EPA should not only look into methodologies that can be used to monitor protozoa concentrations in source water but also methodologies that can be used to monitor finished water protozoa concentrations; 2) more statisticians should review EPA's method performance goals; 3) the Agency should consider prescribing different methods for different matrix effects (i.e., high vs. low turbidity water).

Next Steps

- Proceedings from the October 1997 workshop will be available in March 1998.
- EPA will revise the draft method evaluation plan to reflect the comments and suggestions made by stakeholders.
- EPA also plans to collaborate with other organizations (i.e., American Water Works Association) to convene a subsequent method development meeting in Fall 1998.