United States
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EPA INFORMATION COLLECTION RULE: *KEY ISSUES*

Issue #1: Strategy for Collecting and Using Protozoa Data

One of the major causes of delay between the proposal of the Information Collection Rule in February 1994 and its promulgation in May 1996 was the need to assess the adequacy of the analytical method to be used to collect data on *Giardia* and *Cryptosporidium*. Early testing indicated there were significant questions about the ability of the analytical method (Immunofluorescent Assay) to produce meaningful data. Nonetheless, negotiators were hopeful that subsequent evaluation would enable the method to be included in the rule.

EPA conducted extensive testing of the method. Based on that testing, EPA recognizes that the method is difficult to run, has poor recovery, and does not have a high level of precision. Because of the method's limitations, EPA will restrict analysis of samples to laboratories which meet stringent approval criteria. EPA will also limit the use of the data to developing a national occurrence data base and national cost impacts of regulatory options. These and other steps EPA has taken to improve the method and ensure data quality are described more fully below.

➤ ***Consultation with Outside Experts***

In 1994 and 1995, EPA held public meetings to discuss the method, possible modifications, and results of performance studies. Important recommendations on improving the method emerged from these meetings and were implemented to the extent possible.

➤ ***Testing***

Two full rounds of performance studies (method analysis using a single source water) were conducted in 1995, as well as a field spiking study to show the performance of the method with representative source waters.

➤ ***Statistical Analysis***

After the testing was completed, EPA performed an extensive statistical analysis to determine minimum percentage recoveries and precision to meet the objectives for the data. The objectives at the time of proposal were to provide EPA with a national occurrence data base and cost estimates for regulatory options for controlling microbes and disinfection byproducts, and to provide public water systems with site specific information they could use to comply with any future rules.

➤ ***Narrowed Scope of Objectives***

Based on EPA's statistical analysis, EPA no longer believes the last objective (site-specific information) can be met with the current protozoa method. EPA believes that the objectives of meaningful national occurrence data and regulatory impact analyses can be derived if laboratories achieve, on average, greater than an 8% recovery for protozoan cysts. EPA simulation studies indicate that this level of laboratory performance should detect protozoa in at least two of eighteen monthly samples in at least 60% of the sites where protozoa are actually present. This level of occurrence, with use of a statistically-derived adjustment factor for estimating true protozoan concentrations from measured values, would enable EPA to estimate the number of systems nationally that require different levels of treatment to achieve a desired finished water concentration, as might be prescribed in the Enhanced Surface Water Treatment Rule.

➤ ***Tighten Lab Approval Criteria***

EPA recognizes that, to meet the data quality objective of 8% recovery for protozoan cysts, protozoa laboratories will have to meet stringent approval criteria to qualify for performing ICR analyses. These criteria include performance evaluation studies, an on-site inspection, employment of at least one principal analyst with extensive experience using this method, and a comprehensive inventory to ensure the adequacy of equipment and personnel.

➤ ***Narrow Coverage of Rule***

In order to ensure sufficient laboratory capacity to perform the testing, EPA has limited the number of water systems required to conduct microbial testing from the 10,000 persons and above contained in the proposed rule to 100,000 and above in the final rule.

➤ ***Supplemental Surveys***

EPA will augment the data collected under the rule with three surveys. The first is a survey of 50 utilities serving 100,000 people or more to measure *Cryptosporidium* under even more tightly controlled laboratory conditions than can be imposed on laboratories analyzing data under the ICR. The second is a survey of 50 utilities serving between 10,000 and 100,000 people to ensure that data developed on large systems can be extrapolated to medium size systems. The third is a survey of systems serving fewer than 10,000 persons to understand differences affecting smaller systems. The first and second of these surveys are to be conducted in 1997; the third would occur the following year. Only data from the rule which meet the data quality objectives, with the EPA survey data, will be used in EPA's analysis.

The statistical analysis supporting the data quality objectives has been peer reviewed within EPA and by two outside reviewers. The outside reviewers found no significant problems which would prevent the analysis from being used to support the data quality objectives established by EPA. EPA recognizes that much more dialogue and peer review is needed for stakeholders to understand the analysis and assess their support of it. EPA is committed to conducting that dialogue during 1996. EPA is initiating a series of meetings with stakeholders to discuss issues such as this one and to keep stakeholders informed while the Information Collection Rule and the research program are underway.

EPA also recognizes that the ultimate usefulness of the data will depend upon: 1) the ability of laboratories to meet the data quality objectives, and 2) the comparability of the data generated under the rule and the surveys to data generated by whichever method is adopted in the Enhanced Surface Water Treatment Rule.

EPA believes the protozoa method should be included in the Information Collection Rule because:

- There is a good likelihood it will provide useful data
- The more experience laboratories have with the method, the better their performance should be
- Through subsequent testing, an adjustment factor may be generated to improve the utility of rule-generated protozoan data
- There is a public perception that protozoa occurrence is a significant health issue; whatever data can be gathered will help address this concern
- The total cost of including it is less than $5 million of the $130 million estimated for the entire rule, with less than $1 million attributed to the incremental inclusion of *Cryptosporidium* over *Giardia*.

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Issue #2: Implementation Schedule

The schedule for implementation of the Information Collection Rule is as follows:

June 1996:	EPA mails notice of applicability to utilities expected to be subject to the rule
August 1996:	Utilities initiate TOC monitoring and begin to prepare their sampling plans
November 1996:	Utilities submit sampling plans
December 1996:	EPA issues sampling plan decisions
February 1997:	Sampling begins

This schedule is ambitious. While some slippage is possible, EPA is hopeful that most utilities will begin testing by March so that data are collected during the 1997 spring runoff--a period of expected high microbial contamination and natural organic content.

Utilities will report data to EPA on a monthly basis and will have four months from the time of sampling to conduct the analyses and submit the data. EPA will then validate the data and they will become publicly available.

Negotiators envisioned that eight months of data would be sufficient to initiate analysis and identify appropriate regulatory options for the Enhanced Surface Water Treatment Rule. EPA plans to issue a Notice of Availability containing its analysis and choice of regulatory option for the Enhanced Surface Water Treatment Rule in late 1998. EPA would receive and process comments on that notice and then begin preparation of the final rule. The rule would only be promulgated after the full 18 months of data were received, analyzed, and found to corroborate the analysis of the first eight months. These steps would probably not be completed until the year 2000. (The Enhanced Surface Water Treatment Rule proposed in July 1994 applied only to systems serving 10,000 or more people. An Enhanced Surface Water Treatment Rule covering smaller size systems, and possible modifications applicable to large systems, would be proposed later.)

Similarly, EPA would analyze all the data (disinfection byproduct and microbial monitoring and treatment technology effectiveness) collected under the rule, as well as the results of research conducted to date. EPA would then publish the results of its analysis in a Notice of Availability. That notice would likely be published in early 2000. Discussions regarding the Stage II DBP rule could begin shortly thereafter.

Issue #3: Implementation of the Research Plan

Negotiators recognized that two activities were needed to select the appropriate regulatory option for the Enhanced Surface Water Treatment Rule and to enable meaningful discussion of the Stage II DBP rule: 1) the Information Collection Rule and 2) the five year, $50 million research program. The research program was to be funded jointly by EPA and other research organizations. Utilities are concerned that they should not be required to spend funds to generate data under the Information Collection Rule until EPA had initiated its share of the research effort.

Since the negotiation, EPA has drafted a research plan to better identify research needs. EPA has made a significant commitment to funding the research on health effects, risk assessment, exposure, and treatment research that will be used in conjunction with the Information Collection Rule data to develop the Enhanced Surface Water Treatment Rule and the Stage II DBP rule. This topic is among EPA's top research priorities as described in the Strategic Plan for EPA's Office of Research and Development. EPA has reprogrammed research monies from other planned projects and has requested additional money to conduct necessary research. By the end of FY 96 EPA will have funded greater than $10 million of the estimated $50 million research effort.

For More Information Contact the Safe Drinking Water Hotline at 1-800-426-4791