 **EPA Disinfection Byproducts and
Surface Water Treatment: A
EPA Science Advisory Board
Review of Certain Elements
of the Stage 2 Regulatory
Proposals**

**A Review by the Drinking Water
Committee of the EPA Science
Advisory Board Executive
Committee**

May 21, 2003

EPA-SAB-DWC-03-005
Honorable Christine Todd Whitman
Administrator
U. S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Subject: Disinfection Byproducts and Surface Water Treatment: A EPA Science Advisory Board Review of Certain Elements of the Stage 2 Regulatory Proposals

Dear Governor Whitman:

This review was conducted by a panel convened in response to a request by the Office of Ground Water and Drinking Water (OGWDW) that the EPA Science Advisory Board (SAB) review several parts of two rules¹ that are being proposed together:

1. The Long Term 2 Enhanced Surface Water Treatment (LT2ESWT) rule.
2. The Stage 2 Disinfectant/Disinfection Byproducts (S2DBP) rule.

The panel consisted of the twelve members of the SAB Drinking Water Committee (DWC) and six consultants.

During September, 2000, a Federal Stakeholder Advisory Committee (Stage 2 Microbial Disinfectants and Disinfection Byproducts Advisory Committee) reached an Agreement in Principle on recommendations for both these "Stage 2" rules after nearly two years of fact finding, deliberation, negotiation, and consensus building. The Stage 1 rules promulgated in 1998, had also been developed after a series of formal negotiations with stakeholders. This report presents the results of the SAB Drinking Water Committee (DWC) review of information provided by Agency on the Stage 2 rules. The LT2ESWT rule is intended to increase protection of public water systems against microbial pathogens, with specific focus on *Cryptosporidium*. The S2DBP rule is intended to increase protection of public water systems from disinfection

¹ Only partial drafts of the two rules were provided; see Sections 3.3, 4.1 for listing of review materials.

byproducts (DBPs), specifically variability in exposure. OGWDW intends to propose and finalize the LT2ESWT and S2DBP rules simultaneously so that systems maintain adequate microbial protection while reducing risk from disinfection byproducts.

The Agency's charges with the Panel's comments follow in abbreviated form:

LT2ESWT Rule:

Charge: The SAB was asked to comment on 1) the analysis of the occurrence (measured, modeled) of a disease-inducing protozoan (*Cryptosporidium*) in drinking water systems, 2) the validity of a risk assessment both before and after applying the proposed treatment methods in the LT2ESWTR to those drinking water distribution systems and 3) the proposed treatment credits (effectiveness in reducing protozoan contamination) by four methods including off-stream water storage, pre-sedimentation, lime softening and reducing filtered water turbidity (referred to as microbial toolbox options).

Findings:

1. The Panel commends the Agency on its groundbreaking work addressing the impact of the proposed regulation on endemic disease and agrees that the regulation should address this issue. On the other hand, neither the design of the regulation nor the form of the economic analysis directly addresses waterborne outbreaks. Historically waterborne outbreaks are the primary stimulus for the regulation and they are the arena where intervention through improved water treatment has demonstrated its greatest effectiveness. Failure to consider the impact of the proposed regulation on reducing waterborne disease outbreaks underestimates the benefit of this regulation on public health.
2. There is a large amount of uncertainty in the modeling of the occurrence of *Cryptosporidium* and of the incidence of the disease cryptosporidiosis and the current benefits analysis does not give this uncertainty sufficient visibility.
3. The modeling of *Cryptosporidium* occurrence appears to be plausible and well done. On the other hand:
 - a) The economic analysis is necessarily complex and a greater effort is required for effective communication.
 - b) Some statistical issues need to be addressed, and
 - c) Understanding the transmission of cryptosporidiosis should be explored more thoroughly.
4. The Panel also commends the Agency, as well as the stakeholder process, for developing the bin classification framework² as it adds great flexibility to the rule.

² Determination of regulatory action using a simple classification of water sources based on observed cryptosporidium densities ("bins").

Recommendations:

1. Reducing the likelihood of waterborne outbreaks should continue to be one of the most important goals of Agency regulations in water treatment. The Panel recommends the Agency conduct a systematic review of the design of the LT2ESWT Rule, assessing its effectiveness in addressing outbreaks. Changes should be considered if necessary.
2. The magnitude of the uncertainty in estimating the occurrence of *Cryptosporidium* oocysts and estimating the risk of *Cryptosporidium* infection and the potential significance of these uncertainties to the over- or under-estimation of benefits should have high visibility in any final documents.
3. With regard to the modeling of the occurrence of cryptosporidiosis, the Agency should:
 - a) Include better graphics in the documentation to help the reader understand the analytical process.
 - b) Conduct and document sensitivity analyses to the prior distributions³ and demonstrate the absence of seasonal effects on annual average *Cryptosporidium* concentrations.
 - c) Clarify and justify the selection of the dose-response function, assumptions about oocyst infectivity, assumptions of host susceptibility, and estimates of water consumption.
 - d) Provide more information on evidence of endemic disease; discuss the significance of secondary transmission; discuss the role asymptomatic infections play in disease transmission and address the effect of age on host susceptibility to the disease.
 - e) Compare the quantitative microbial risk assessment approach used by the Agency to previous quantitative risk assessments for *Cryptosporidium* described in the scientific literature.
4. For the bin Classifications the Agency asked the Panel to review, our recommended credits are as follows: a) for off-stream and pre-sedimentation - no credits, b) for two stage lime softening - 0.5 credits, but only if all the water is treated in both stages; and c) for plants that meet special requirements in each filter - 0.5 credits.

S2DBP Rule:

Charge: The Agency asked the SAB to comment on: 1) whether the locational running annual average (LRAA) (a new method of estimating concentrations of DBPs) of total trihalomethanes (TTHM)⁴ and haloacetic acids (HAA5), in conjunction with the initial distribution system evaluation (IDSE) (recommendations to utilities for identifying appropriate monitoring sites) of

³ Previous probability assessments of existing data used to estimate occurrence under new conditions.

⁴ These terms refer to by-products of the chlorination process. The Panel believes that the terminology, TTHMs (total trihalomethanes), to represent the four regulated bromine- and chlorine-containing THMs is not adequate since they do not represent the full spectrum of trihalomethanes in drinking water. For example, for some time researchers have also been reporting iodinated THMs in finished drinking water. To avoid confusion regulations that pertain to only the four bromine- and chlorine-containing THMs should refer to these as THM4. A precedent for this form of nomenclature already exists, e.g. HAA5, HAA6, HAA9. For the sake of clarity this report has attempted to employ that nomenclature throughout.

the proposed rule more effectively achieves public health protection than the running annual average (RAA) (current method of estimating concentrations of DBPs) of the Stage 1 DBP rule and 2) if the IDSE is capable of identifying new compliance monitoring points that target high TTHM³ and HAA5 levels and if it is the most appropriate tool available to achieve this objective.

Findings:

1. The Panel believes that the proposed DBP2 rules will result in a reduction in the health risk to drinking water consumers.
 - a) The principal outcome of these rules will be increased assurance that each consumer will be exposed to regulated DBP levels that are at or below the MCLs specified.
 - b) A second, important outcome will be a reduction in the average level of the regulated DBPs in many systems.
2. The Panel does not believe that the current draft of the benefits document does an adequate job of reflecting the uncertainties associated with estimating the reduction in the health risk to drinking water consumers:
 - a) The Source Water Analytical Tool (SWAT) is used to estimate DBP concentrations in distribution systems before and after the rule, but the Agency's own work demonstrates that SWAT does not do a good job of this.
 - b) The rule seeks to reduce short term exposure to high DBP levels, but the IDSE is used to identify monitoring points with high DBP levels and it does not consider diurnal short-term variations.
 - c) Benefits are estimated by assuming that the incidence of DBP-related bladder tumors will decrease in proportion to the reduction in the nine regulated DBPs, but it is not evident that this will occur because it has not been adequately demonstrated that bladder cancer is associated with any of the regulated DBPs.
3. The Panel believes that substantial further research will be required before the benefits of DBP reduction can be adequately quantified.

Recommendations:

1. The Panel recommends that the Agency promulgate the proposed rule without delay, pursuing the IDSE and LRAA as more effective means of controlling exposure to DBPs in drinking water than present practice.
 - a) The Agency should give high visibility to the fact that this rule will increase the assurance that each consumer will receive water that meets the DBP MCLs.
 - b) The Agency should also give high visibility to the fact that this rule can be expected to reduce the average level of regulated DBPs in most systems.

2. The Panel recommends that the Agency do a more straightforward job of describing the uncertainties in the benefits analysis:
 - a) Either the portion of the benefits analysis which used the SWAT should be abandoned or the presentation should be revised to reflect the true uncertainties associated with the use of this model.
 - b) The Agency should acknowledge that the IDSE does not consider short term (diurnal) variations.
 - c) The Agency should be more candid about the limitations it faces in estimating improvements in health risk reduction due to the implementation of the new rule rather than assuming that bladder cancers will be reduced in proportion to reductions in THM4 and HAA5.
3. For the future, so that it can address the limitations inherent in the use of the surrogates (THM4, HAA5) to represent the full spectrum of DBPs present in drinking water, the Panel recommends that the Agency:
 - a) Focus its future research program upon identifying causal agents for bladder cancer and other adverse health effects (other risks of cancer, impairment of male and female reproduction, effects on developing organisms) associated with chlorinated drinking water in epidemiological studies.
 - b) Link future control strategies for DBPs more directly to the reduction of these causal agents.

Thank you for the opportunity to review these proposals. We would be happy to continue to engage with the Agency as it pursues this action. We look forward to your response to this report.

Sincerely,

/s/

Dr. William Glaze, Chair
EPA Science Advisory Board

/s/

Dr. R. Rhodes Trussell, Chair
Drinking Water Committee
EPA Science Advisory Board

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1. EXECUTIVE SUMMARY

The Drinking Water Committee (DWC) of EPA's Science Advisory Board (SAB) met to consider several support documents that are a part of the Agency's Long Term 2 Enhanced Surface Water Treatment (LT2ESWT) rule and the Stage 2 Disinfectant/Disinfection Byproducts (S2DBP) rule, both of which are under development by the Agency. During September, 2000, a Federal Stakeholder Advisory Committee reached an Agreement in Principle on recommendations for both these Stage 2 rules after nearly two years of fact finding, deliberation, negotiation, and consensus building. The Stage 1 rule promulgated in 1998, had also been developed after a series of formal negotiations with stakeholders. This report presents the results of the SAB Drinking Water Committee (DWC) review of information provided by the Agency on the Stage 2 rules.

The 1996 Amendments to the Safe Drinking Water Act (SDWA) require the Agency to develop National Primary Drinking Water Regulations (NPDWRs) for contaminants which have an adverse effect on the health of persons and where regulation provides a meaningful opportunity for public health protection. The Agency is developing a LT2ESWT rule to provide increased protection for public water systems against microbial pathogens, with a specific focus on *Cryptosporidium*. The proposed rule is intended to supplement existing surface water treatment rules by establishing targeted treatment requirements for systems with greater vulnerability to *Cryptosporidium*. Such systems include those with high concentrations of *Cryptosporidium* in their source water and those that do not provide filtration. In addition, the 1996 SDWA Amendments require the Agency to develop a S2DBP rule. The intent of the proposed S2DBP rule is to reduce the variability of exposure to disinfection byproducts (DBPs) for people served at different points in the distribution systems of public water supplies. The Agency has suggested that this decreased exposure will result in reduced risks from potential reproductive and developmental health effects and cancer. To be consistent with the SDWA requirements for risk balancing, the Agency intends to propose and finalize the LT2ESWT and the S2DBP rules simultaneously. This coordinated approach is designed to ensure that systems maintain adequate microbial protection while reducing risk from disinfection byproducts.

The Panel believes that the terminology, TTHMs (total trihalomethanes), to represent the four regulated bromine- and chlorine-containing THMs is not adequate since they do not represent the full spectrum of trihalomethanes present in drinking water. For example, for some time researchers have also been reporting iodinated THMs in finished drinking water. To avoid confusion, regulations that pertain to only the four bromine- and chlorine-containing THMs should refer to these as THM4. A precedent for this form of nomenclature already exists, e.g. HAA5, HAA6, HAA9. For the sake of clarity this report has attempted to employ that nomenclature throughout.

This report has two major parts reflecting the structure of the Agency Charge. The charge to the SAB Panel for the Long Term-2 Enhanced Surface Water Treatment rule asked the SAB to comment on: a) the analysis of *Cryptosporidium* occurrence; b) the pre- and post-LT2ESWTR *Cryptosporidium* risk assessment; and c) the proposed treatment credits for four

microbial toolbox options. For the S2DBP rule, the Agency asked the SAB to comment on: a) whether the locational running annual average (LRAA) for total trihalomethanes (TTHM) and haloacetic acids (HAA5), in conjunction with the initial distribution system evaluation (IDSE), of the proposed rule more effectively achieves public health protection than the running annual average (RAA) of the Stage 1 DBP rule and b) if the IDSE is capable of identifying new compliance monitoring points that target high TTHM and HAA5 levels and if it is the most appropriate tool available to achieve this objective.

For the **LT2ESWTR**, because the risk assessment is quite complex, the Panel recommends that the document include graphics that show how the different elements were derived and how they relate to each other. For clarity, comments and recommendations are presented separately for the three charge questions related to the risk assessment.

First, the Panel concludes that the occurrence modeling appears to be both plausible and well-done. However, the Panel believes that a number of issues need to be addressed, either by supplementing the current documents and/or modifying the model.

The Panel recommends that the Agency:

- a) Conduct and document sensitivity analyses to the prior distributions and,
- b) Demonstrate the absence of seasonal effects on the annual average *Cryptosporidium* concentration.

Secondly, for the microbiological risk assessment review, each of the basic elements was examined in order: hazard identification, dose-response assessment, and exposure assessment. Then the outcome of the risk assessment was evaluated. Two criteria were considered in the Panel evaluation: a) whether the Agency assumptions were transparent, and b) whether scientific evidence exists to support the assumptions. *Cryptosporidium parvum* has been responsible for significant waterborne disease outbreaks, and it is likely that the organism is responsible for reports of significant endemic disease as well. Both of these outcomes are important. The current Agency analysis (The Cadmus Group, Inc., 2001b) for the LT2ESWTR does an excellent job of addressing the impact of drinking water quality on the incidence of non-reportable endemic disease and the health risk reduction that will result from the reduction of endemic disease as a result of the proposed regulation. The Agency is to be congratulated for this ground-breaking work. On the other hand, in the present draft, neither the design of the regulation nor the contents of the Agency analysis directly address reportable waterborne outbreaks. These outbreaks are the primary stimulus for the regulation and reducing their occurrence should be one of the most important potential outcomes from the regulation as well. The Panel recommends that the Agency conduct a systematic review of the design of the LT2ESWTR regulation keeping its effectiveness in addressing waterborne outbreaks in mind.

- a) The Panel agrees with the basic information on *Cryptosporidium* health effects in the Hazard Identification section but recommends that the following be included in the analysis: a) evidence of current prevalence of endemic disease; b) information on secondary transmission of cryptosporidiosis; and c) host age and frequency of asymptomatic infections.

- b) For the Dose-Response Assessment, the Panel recommends clarification and justification of: a) the basis for the selection of the dose response function that was used and whether other models were considered; b) the term “infectivity” as it is used in the Agency analyses; c) the assumptions about infectivity of oocysts used in human dosing experiments, infectivity of oocysts found in environmental samples and of the significance of *Cryptosporidium* genotype when evaluating infectivity for humans; and, d) assumptions about variability in host susceptibility, both due to possible immunity resulting from previous infections and due to other susceptibility factors such as age and health.
- c) For Exposure Assessment, the estimates of consumption require clarification.
- d) For the Risk Assessment, the Panel notes that quantitative microbial risk assessment is a rapidly developing field. The Agency should a) identify other approaches to microbial risk assessment, especially risk assessments for *Cryptosporidium*, that are reported in the literature and consider how they compare to their own assessment; b) include a discussion of uncertainties and variability; and c) discuss assumptions which may lead to underestimates or overestimates of risk and benefits.

Finally, for the treatment credits for the four microbial toolbox options, the Panel commends the Agency, as well as the stakeholder process used, for developing the bin classification framework for identifying the treatment requirements for drinking water and the microbial toolbox containing possible treatment options to guide systems having treatment needs. These alternatives add great flexibility for meeting varying water quality and treatment options and should result in safe drinking water for the people of the United States. The Agency charged the Panel with evaluating Agency information on four of the toolbox options: a) off stream raw water storage; b) pre-sedimentation, c) lime softening and d) lower finished water turbidity. Specifically, the Agency asked the Panel to comment on the credits that have been proposed for specific toolbox options for *Cryptosporidium* removal. In summary, the Panel recommends that no presumptive credits be given for off-stream storage and pre-sedimentation. It does agree with giving 0.5 log credit for two-stage lime softening if all the water is treated with both stages, and 0.5 log credit for plants that demonstrate a turbidity level in each individual filter effluent less than or equal to 0.15 NTU in at least 95 percent of the measurements taken each month. Details about these recommendations are found in the report.

For the **Stage 2 DBP rule**, the Panel believes that the proposed Initial Distribution System Evaluation is capable of identifying new compliance monitoring points that target higher THM and HAA levels than are currently measured in the existing THM Rule and Stage 1 DBP Rule compliance monitoring programs. However, the IDSE does not consider short-term, temporal variations that occur at different sites in the distribution system due to varying water demands and distribution system architecture and operation. This temporal variability needs to be acknowledged in the IDSE documentation. The Panel further believes that the proposed standard monitoring program (SMP) for sub-part H systems serving more than 10, 000 people is reasonable. The Panel, however, does make some recommendations concerning the proposed

sampling requirements. The switch from the running annual average (RAA) approach to the locational running annual average (LRAA) approach provides a measure of equity not previously reflected in the standards for disinfection by-products. The LRAA allows one to state that a larger segment of the consumers will be provided with drinking water within a particular water system which will meet the MCL than would be the case using the RAA approach. The Panel also agrees that these changes are likely to result in a reduction in health risk due to DBP exposure, but the Agency has not demonstrated that this reduction in health risk will be in direct proportion to the reduction in the THM and HAA5 concentrations.

The Committee recommends that in proposing its Stage 2 DBP rule, the Agency:

- a) Continue to pursue the concept of locational running annual averages (LRAAs) as a more effective means of controlling exposure to harmful compounds in the drinking water than system-wide running annual averages (RAAs).
- b) Identify temporal limitations in the IDSE documentation and require periodic reevaluation of selected sites;
- c) Reallocate sampling locations so that, for both free chlorine and chloramines, sampling takes into account potential high THM and HAA sites;
- d) Require the measurement and reporting of residual chlorine and individual THM and HAA species;
- e) Provide more guidance to utilities to identify sampling sites with highest HAA concentrations;
- f) Improve the proposed system specific studies (SSS) approach (Chapter 6);
- g) Reconsider the use of the SWAT (Surface Water Analytical Tool) model and ICR (Information Collection Rule) data in economic analyses or risk reduction calculations;
- h) Focus their research program upon identifying causal agents for bladder cancer and other potential adverse health effects associated with chlorinated drinking water; and,
- i) Link control strategies for DBPs to reduction of causal factors of health effects.

2. INTRODUCTION AND CHARGE

2.1 Introduction

The 1996 Amendments to the Safe Drinking Water Act (SDWA) require the Agency to develop National Primary Drinking Water Regulations (NPDWRs) for contaminants which have an adverse effect on the health of persons and where regulation provides a meaningful opportunity for public health protection. The Agency is developing a Long Term 2 Enhanced Surface Water Treatment (LT2ESWT) rule to provide increased protection for public water systems against microbial pathogens, with a specific focus on *Cryptosporidium*. The proposed rule is intended to supplement existing surface water treatment rules by establishing targeted treatment requirements for systems with greater vulnerability to *Cryptosporidium*. Such systems include those with high concentrations of *Cryptosporidium* in their source water and those that do not provide filtration.

In addition, the 1996 SDWA Amendments require the Agency to develop a Stage 2 Disinfectant/Disinfection Byproducts (S2DBP) rule. The intent of the proposed S2DBP rule is to reduce the variability of exposure to disinfection byproducts for people served at different points in the distribution systems of public water supplies. The Agency has suggested that this decreased exposure will result in reduced risks from potential reproductive and developmental health effects and cancer.

To be consistent with the SDWA requirements for risk balancing, the Agency intends to propose and finalize the LT2ESWT and the S2DBP rules simultaneously. This coordinated approach is designed to ensure that systems maintain adequate microbial protection while reducing risk from disinfection byproducts. During September, 2000, a Federal Stakeholder Advisory Committee reached an Agreement in Principle on recommendations for both these rules after nearly two years of fact finding, deliberation, negotiation, and consensus building. Prior to that, the Stage 1 rules for DBPs and surface water treatment also reflected periods of formal regulatory negotiations and stakeholder discussions over a period of years stretching from the early to mid-1990s.

The Panel believes that the terminology, TTHMs (total trihalomethanes), to represent the four bromine- and chlorine-containing THMs is not adequate since they do not represent the full spectrum of trihalomethanes in drinking water. For example, for some time researchers have also been reporting iodinated THMs in finished drinking water. To avoid confusion regulations that pertain to only the four bromine- and chlorine-containing THMs should refer to these as THM4. A precedent for this form of nomenclature already exists, e.g. HAA5, HAA6, HAA9. For the sake of clarity this report has attempted to employ that nomenclature throughout

The EPA Office of Ground Water and Drinking Water (OGWDW) representatives requested that the EPA Science Advisory Board (SAB) review several parts of the LT2ESWT and the S2DBP rule proposals and certain support documents and provide advice in response to a

number of charge questions. This report presents the results of the SAB Drinking Water Committee (DWC) review of these issues.

2.2 The Charge

The Agency charge to the SAB Panel for the Long Term-2 Enhanced Surface Water Treatment rule asked the SAB to comment on: a) the analysis of *Cryptosporidium* occurrence; b) the pre- and post-LT2ESWTR *Cryptosporidium* risk assessment; and c) the proposed treatment credits for four microbial toolbox options.

For the Stage 2 DBP rule, the Agency asked the SAB to comment on: a) whether the locational running annual average (LRAA) for total trihalomethanes (TTHM) and haloacetic acids (HAA5), in conjunction with the initial distribution system evaluation (IDSE), of the proposed rule more effectively achieves public health protection than the running annual average (RAA) of the Stage 1 DBP rule and b) if the IDSE is capable of identifying new compliance monitoring points that target high TTHM and HAA5 levels and if it is the most appropriate tool available to achieve this objective.

3. LONG TERM 2 ENHANCED SURFACE WATER TREATMENT RULE

3.1 Introduction

The Agency convened a group of stakeholders, including EPA itself, to hold formal negotiations on issues related to the LT2ESWT and Stage 2 DBP rules from 1999 to 2000. Their Agreement in Principle, which contains recommendations for the proposed LT2ESWT and Stage 2 DBP rules, was published in the Federal Register on December 29, 2000 (US EPA, 2000).

In general, because the risk assessment is quite complex, the Panel recommends that the document include more graphics to illustrate how the different elements of the model were derived and how they relate to each other. Exhibit 5.2 (The Cadmus Group, Inc., 2001b) is helpful but does not provide sufficient detail. Additional figures are needed to show what elements were in the pre-regulation risk assessment versus the post-regulation risk assessment and how the reduction in risk from the proposed regulation was calculated. Figures 3.1 through 3.4 of this report are examples displaying the Panel's understanding based on its reading of the documents provided by the Agency and its discussions with EPA personnel and discussed below.

3.2 Charge Question 1: Analysis of *Cryptosporidium* occurrence

*The Agency requested SAB comments on the EPA analysis of *Cryptosporidium* occurrence.*

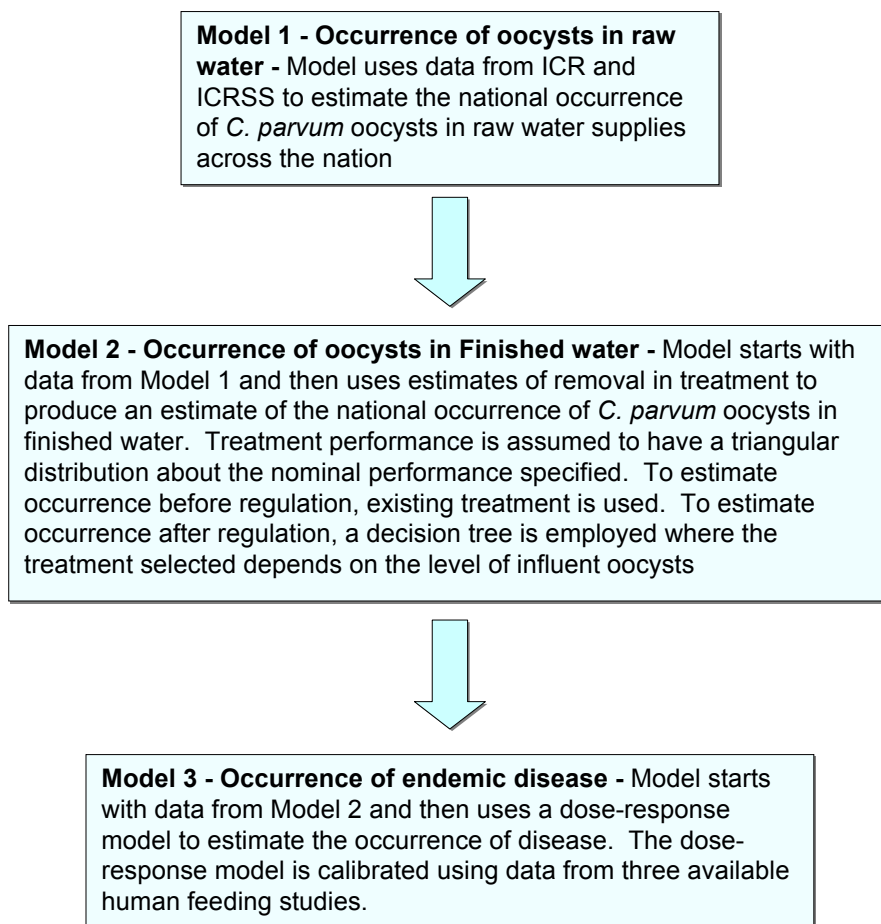
The Agency provided the Panel with a draft document entitled *Occurrence and Exposure Assessment for the Long Term 2 Enhanced Surface Water Treatment Rule*. (The Cadmus Group, 2001a) that discusses how the Agency estimated the occurrence distribution of *Cryptosporidium* in the source and finished water of public water systems prior to implementation of a new LT2ESWT rule. Sections of the document considered to be of particular importance discussed the data sources used to estimate *Cryptosporidium* occurrence in source water, along with analytical methods, data quality issues, and the statistical techniques used to model occurrence distributions; information on observed and modeled results from the source water occurrence surveys; information from studies of the physical removal of *Cryptosporidium* by treatment processes; finished water occurrence data resulting from the Information Collection Rule (ICR); a description of how the Agency estimated finished water *Cryptosporidium* levels prior to implementation of the LT2ESWTR; and technical information on the statistical models used to analyze source water occurrence data.

3.2.1 Panel Response to LT2ESWTR Charge Question 1--Analysis of *Cryptosporidium* occurrence

3.2.1.1 Background. The model developed by the Agency can be thought of in three parts (Figure 3-1). The first part is designed to address an important limitation of the data collected in the ICR and ICR Supplemental Survey (ICRSS), namely information on the national occurrence of *Cryptosporidium parvum* oocysts at levels below the detection limits (DLs) of the

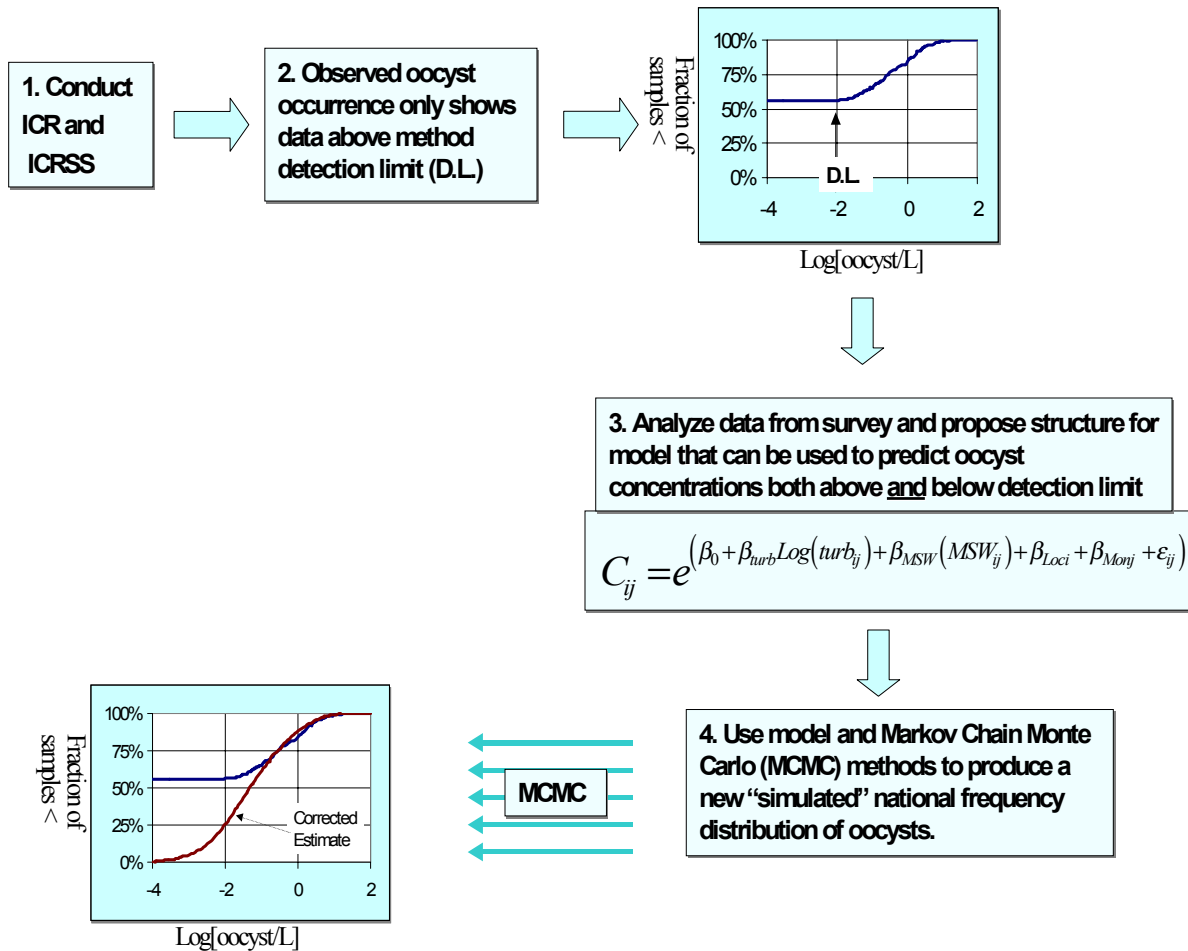
methods used in those surveys. Thus, the first part simulates national distributions of the concentration of *C. parvum* oocysts in the source water. Using ICR and ICRSS data, the model is designed to produce an estimate of the national occurrence of oocysts in untreated surface waters, above and below the ICR and ICRSS DL⁴s. Bayesian hierarchical models and Markov chain Monte Carlo (MCMC) methods are used to accomplish this (Figure 3-2). These models accommodate the many complex features seen in the data used by the Agency to develop its national occurrence estimates, including low recovery probabilities, the presence of false positives, and the presence of true *Cryptosporidium*-free source waters.

Figure 3-1. The model developed by the EPA contains three components. The first uses data from the ICR and ICRSS to produce a national distribution of *C. parvum* oocysts in untreated surface water. The second uses that national distribution and a model of treatment performance to produce a simulation of the national distribution of *C. parvum* oocysts in finished water. The third component uses a dose-response model calibrated via human exposure studies, data on water consumption, and finished water oocyst levels to predict the level of endemic disease.



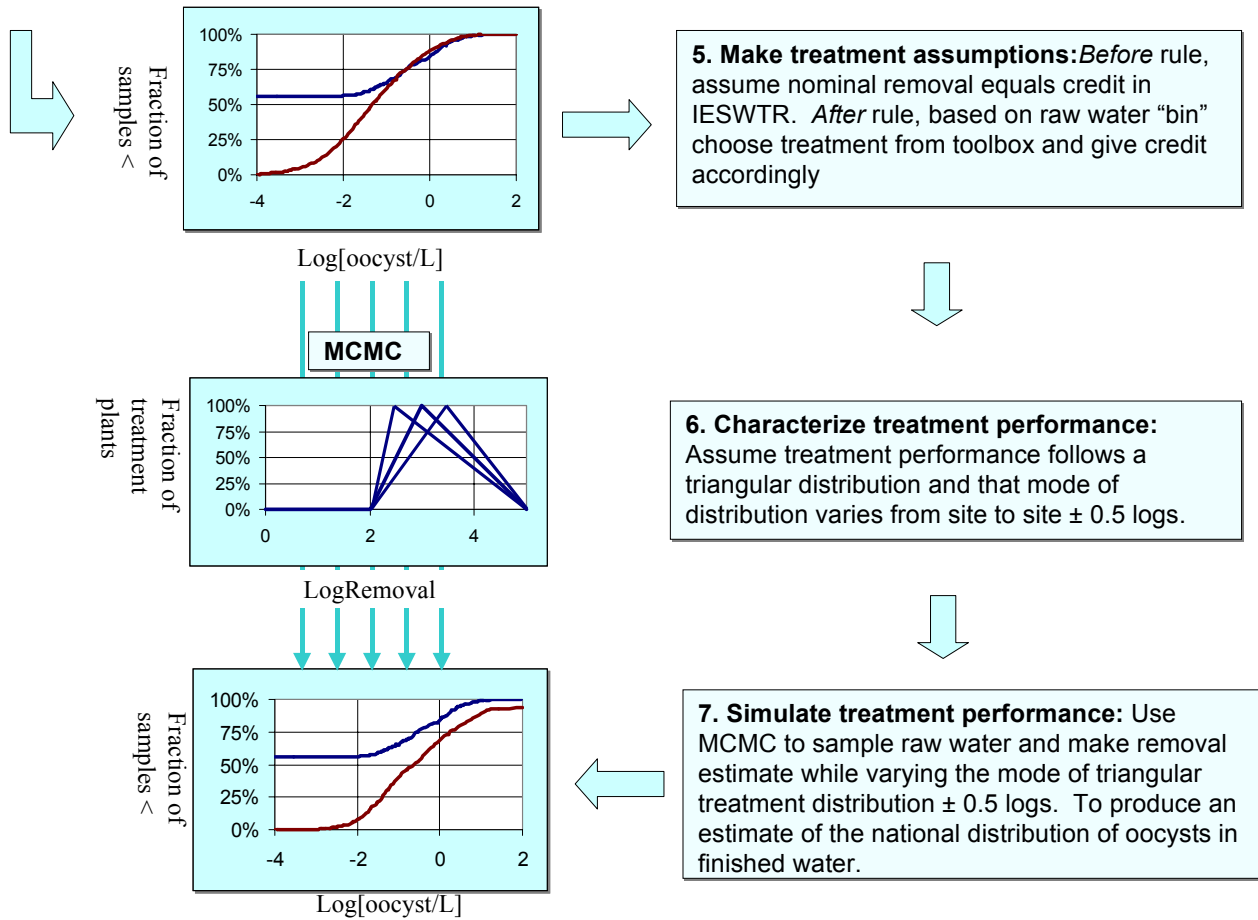
⁴ Responses are modeled above the detection limit as a function of turbidity, location, etc., and the model uses this in addition to information about the number below the detection limit to ‘impute’ values below the limit. The MCMC approach also integrates over the uncertainty of the values below the detection limit (as opposed to ‘imputing’ a single value). In terms of validation, there is no way to validate ‘values’ below the DL as they were not observed, but we can determine how well the model fits for values above the limit and determine whether the proportion predicted by the model for the number below the limit is consistent with the observed data.

Figure 3-2. Model 1: Occurrence of oocysts in raw water - Bayesian hierarchical models and MCMC Methods were used to estimate the national occurrence of *C. parvum* oocysts in raw water.



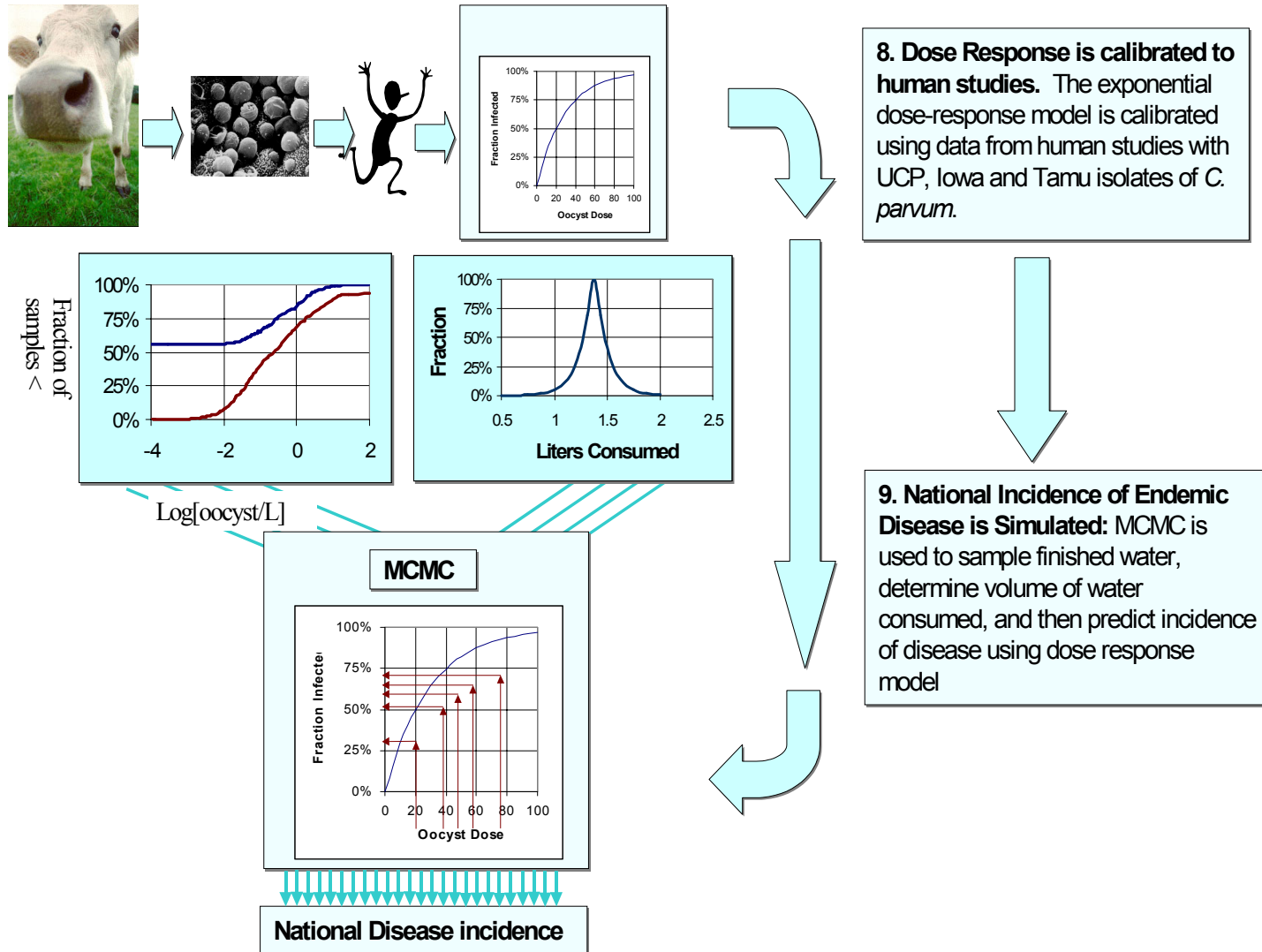
The second part of the model takes the national occurrence in untreated water from the first part and uses treatment assumptions to produce an estimate of the national occurrence of *C. parvum* oocysts in treated water (Figure 3-3). To estimate occurrence before regulation, treatment credits in the existing Interim Enhanced Surface Water Treatment Rule (IEWSTR) are used. The proposed regulation assigns water systems into various bins depending on the level of oocysts in their untreated water. A higher degree of removal is required for systems with untreated water falling into bins that correspond to higher oocyst concentrations. To estimate occurrence after regulation, treatment is assumed to meet the requirements that correspond to the bin selected for each supply. For the analysis in this second part, the Agency assumed that treatment effectiveness is independent of concentration and, based on expert opinion, treatment effectiveness across the nation is assumed to follow a simple triangular distribution with the mode at the performance specified by the rule.

Figure 3-3. Model 2 - Occurrence of oocysts in Finished water - Treatment performance is assumed to have a triangular distribution. Before regulation, existing treatment is assumed to meet the IESWTR. After regulation, a decision tree is employed where the treatment selected depends on the level of influent oocysts (the bin).



The third part of the model estimates the national occurrence of disease. The model uses the national occurrence of *C. parvum* oocysts in finished water and combines it with data on water consumption and on dose-response to produce an estimate of disease. The model considers the distribution of infection (and disease) conditional on the concentration of viable oocysts in the drinking water through the use of an exponential dose-response model. The parameters of the dose-response model were estimated using data from three human dosing studies. A Bayesian hierarchical model is also used here to model the distribution of infectivity across *Cryptosporidium* strains. To predict the occurrence of disease, Monte Carlo methods are used to sample oocyst concentrations in finished water and volumes of water consumed and estimate disease using the dose-response model (Figure 3-4).

Figure 3-4. Model 3 - Occurrence of endemic disease - Human feeding studies are used to calibrate the dose-response model and then MCMC methods are used to sample from finished water, determine the liters consumed and estimate the national incidence of endemic disease.



Monte Carlo integration is used throughout the model, and, for the first and third parts of the model, MCMC methods were used to sample from posterior distributions which are used to both estimate parameters in the model and to address the uncertainty associated with these parameters. In complex Bayesian models, MCMC is the appropriate way to do this. Both parts two and three of the model must be re-run each time different regulations or different treatment conditions must be considered.

Immediately below, is a discussion of some specific issues regarding the first piece of the model, the national occurrence distribution of *Cryptosporidium*.

3.2.1.2 Panel Conclusions. First, the Panel concludes that the occurrence modeling appears to be both plausible and well-done. However, the Panel believes that a number of issues need to be addressed, either by supplementing the current documents and/or modifying the model.

The Panel recommends that sensitivity analyses of the modeling effort (specifications of prior distributions) be conducted and documented. A key component in Bayesian hierarchical models is the specification of prior distributions, which *a priori*, characterize the state of knowledge about the parameters at the higher levels of the model. Little information is contained about such priors in the current documentation and it is not evident that the sensitivity of the occurrence distribution and the infectivity parameter, k , to these priors has been assessed. Sensitivity analyses should be conducted and documented. Particular concerns arise when the data are used to assess the model and direct the selection of prior distributions. While such practices are sometimes needed in difficult problems, they can result in underestimation of uncertainty due to the double use of the data. The analysts need to be clear about whether or not such methods were used, and if so, how the final uncertainties may be impacted. Much of the concern can be ameliorated through complete sensitivity analysis.

The Panel also recommends that seasonal effects be more carefully addressed. In the Panel's opinion, the absence of seasonal effects on the annual average *Cryptosporidium* concentration has not been demonstrated. The Agency should address and clarify its computation of the average *Cryptosporidium* concentration for plants in a system over the 18-month period for which the data were collected in the Information Collection Rule (ICR). Averaging concentrations equally over the 18 months to obtain an annual average will only give an unbiased estimate of the true annual average if there are no seasonal effects. But the absence of seasonal effects has not been demonstrated. The current approach effectively counts six months twice in the averaging⁵. During discussions at the DWC meeting in December 2001, Agency representatives stated that parameters characterizing seasonality were included in the model (in the form of the turbidity term). This problem might be solved by averaging the data by month, and then to using the mean of the resulting twelve monthly averages as the annual average.

The Panel believes that a number of other improvements would also strengthen the Agency's LT2ESWTR documentation. Additional model checking should be conducted. The current Agency report includes some model-checking using the estimated distributions of true concentrations, but the Panel recommends additional model checking, specifically, an additional internal check and an external check. The internal check could use the current output from the MCMC sampler to sample from the distribution of predicted oocyst counts ("Y") (from the posterior predictive distribution of "Y"). To assess how consistent predictions from the model

⁵ Averaging is desired for 12 months for an annual average so the data are averaged by month first (6 months of averaging two values and six months of just one value) and then averaging across months.

are with the observed data, about twenty sample distributions can be plotted versus the observed distribution of counts. The observed distribution ideally should lie within these 20 and should look similar. For an external check, the current model could be fit to the first 12 months of the 18 month ICR data, then months 13-18 could be predicted by the model and finally these predictions could be compared to the observed data.

There are some additional features that could be included in the documentation to improve the clarity of the Agency's analyses. A map of the sites for both the ICR and Information Rule Supplemental Survey (ICRSS) data would be helpful to see how similar the spatial distribution of sites was across the surveys and to also look for spatial similarity in concentrations for sites close together and/or in the same regions of the country. In addition, the Panel recommends that a short paragraph be added documenting the convergence and mixing checks on the MCMC sampler. An additional issue of moderate importance is that several parameters that were included in the modeling of oocyst levels in filtered water are excluded in the discussion of the model for the unfiltered plants (e.g., turbidity). Justification for this would improve the clarity of the Agency's analysis.

The Panel notes that the Agency approach to concisely summarize the occurrence distribution functions using parametric models, in particular the log normal function, was done to simplify computations for the individuals conducting the risk analysis. Documentation could be made available to confirm that the realizations of the cumulative distribution functions (CDFs) from the MCMC sampler were well approximated by log-normal cumulative distribution functions (CDFs). Second, several *ad hoc* simplifications were done to sample the CDF for the risk analysis (see bottom of p. 5-15 of the economic analysis document, The Cadmus Group, Inc. 2001b). The Panel recommends that these be examined carefully for their plausibility and the conclusions documented.

The Panel concluded that there is a large amount of uncertainty in the modeling of the occurrence of *Cryptosporidium*. For example, the occurrence distributions are estimated based on only one year of data. This will be fine if these distributions are stable over years. However, the current data does not allow determination if the particular year in which the data were collected were aberrant (for example, due to weather patterns) or if there is some sort of trend in occurrence over time. In addition, for the infectivity modeling, the distribution of infectivity across strains is estimated based on only three *Cryptosporidium* strains which may or may not be a random sample of strains. The only way this distribution can be estimated is to make a strong assumption about its form (here it is assumed to be log-normal). The ultimate accuracy of the predicted decrease in disease from these stochastic models relies on both the representativeness and applicability of the observed data and the numerous modeling assumptions that were made in the course of the three pieces of the model discussed at the beginning of this section. This qualification should be noted in the document.

3.3 Charge Question 2: Pre- and post-LT2ESWTR *Cryptosporidium* risk assessment

Agency requested SAB comments on the pre- and post-LT2ESWTR Cryptosporidium risk assessment.

The Agency provided the Panel with partial drafts of documents entitled: 1) *Economic Analysis for the Long Term 2 Enhanced Surface Water Treatment Rule* (The Cadmus Group, Inc., 2001b) and 2) *Appendices to the Economic Analysis for the Long Term 2 Enhanced Surface Water Treatment Rule* (The Cadmus Group, Inc., 2001c). These documents show how the Agency estimated the incidence of endemic cryptosporidiosis attributable to drinking water both prior to and following implementation of the LT2ESWTR. Information in the documents considered by the Agency to be of particular relevance included:

- a) a summary of the LT2ESWTR to be proposed, based on the Stage 2 —DBP Advisory Committee Agreement in Principle;
- b) baseline information used to conduct the risk assessment;
- c) descriptions of how the Agency modeled pre- and post-LT2ESWTR risk of cryptosporidiosis;
- d) a summary of how the Agency predicted the technologies that filtered and unfiltered systems would select to comply with the LT2ESWTR;
- e) descriptions of how the Agency estimated the percentage of plants expected to receive 0.5 and 1.0 log additional *Cryptosporidium* treatment credit under the LT2ESWTR;
- f) details on estimates of the percent of systems that would be assigned to different bins as a result of source water monitoring under the LT2ESWTR;
- g) distributions of risk of illness;
- h) unit costs for treatment technologies;
- i) descriptions of the methodology used to forecast the percentage of plants assigned to a given bin that would select a particular technology;
- j) results of the technology selection forecast;
- k) total treatment costs for different system categories associated with different regulatory alternatives and assumptions about technology availability.

3.3.1 Panel Response to LT2ESWTR Charge Question 2. This SAB review panel included experts in statistical modeling, in public health microbiology and engineering, but it did not include specialists in quantitative microbiological risk analysis, a relatively new field. For the review, each of the basic elements of microbial risk assessment was examined in order: hazard identification, dose-response assessment, and exposure assessment. Then the outcome of the risk assessment was evaluated. Two criteria were considered in the Panel evaluation: a) whether the Agency assumptions were transparent, and b) whether scientific evidence exists to support the conclusions.

Cryptosporidium parvum has been responsible for significant waterborne disease outbreaks, and it is likely that the organism is responsible for significant endemic disease as well. Both of these outcomes are important. The current form of the Agency's analysis (The

Cadmus Group, Inc., 2001b) for the LT2ESWTR does an excellent job of addressing the impact of drinking water quality on the incidence of endemic disease and the health risk reduction that will result from the reduction of endemic disease as a result of the proposed regulation. The Agency is to be congratulated for this ground-breaking work.

On the other hand, in the present draft, neither the design of the regulation nor the contents of the Agency analysis directly address waterborne outbreaks. These outbreaks are the primary stimulus for the regulation and reducing their occurrence should be one of the most important potential outcomes from the regulation as well.

The Panel recommends that the Agency conduct a systematic review of the design of the LT2ESWTR regulation and evaluate its effectiveness in addressing waterborne outbreaks. This review should include an examination of the causes of past outbreaks and how the proposed regulatory framework will address those causes. The Agency should then consider if any changes in the framework must be made. Additional consultation with specialists in quantitative microbial risk assessment could be of benefit to the Agency as it completes its consideration of *Cryptosporidium* risks.

3.3.1.1 Hazard Identification. The Panel agreed with the basic information on *Cryptosporidium* health effects that were presented in this section. See pages 5-7 - 5-8 of the *Economic Analysis for the Long Term 2 Enhanced Surface Water Treatment Rule* (US EPA 2001b). There are a few additional areas that should also be included in the analysis:

- a) **Evidence of current prevalence of endemic disease.** The Agency's analysis is based on reduction of endemic disease. Some direct evidence of endemic disease levels would greatly strengthen the case. Perhaps the results of serological studies could be used to indicate about the prevalence of *Cryptosporidium* exposure/infection in the US.
- b) **Information on secondary transmission of cryptosporidiosis.** The current analysis does not consider secondary transmission of the disease. This decision should have stronger support in the documentation or should be reconsidered. Haas et al. (1999) present data on prevalence of secondary cases of cryptosporidiosis from two outbreak investigations that range from 4 - 33%. Other data in the published research literature, and perhaps data from the Centers for Disease Control may provide the basis for estimating the magnitude of secondary transmission [e.g., household via child (e.g., Newman et al., 1994), household via adult (MacKenzie et al., 1995), child care centers, swimming pools (Puech et al., 2001; Sorvillo et al., 2001); Millard, et al., 1994]. Asymptomatic infections may play an important role in secondary transmission of infection. Failure to consider secondary transmission will likely underestimate the impact of the LT2ESWTR on reducing the risks of cryptosporidiosis.
- c) **Age Effects.** Information on the prevalence of asymptomatic *Cryptosporidium* infections by age should be included in the hazard identification. The rationale

for including age effects is that, in general, different age groups are more or less prone to asymptomatic infections. Thus there may be a high prevalence of Cryptosporidiosis in some age groups that may not be detected if only symptomatic cases are evaluated.

3.2.1.2 Dose-Response Assessment. For the dose-response component of the risk assessment, the Panel comments on four areas of the assessment: a) selection of a dose-response function, b) use of the term infectivity, c) the morbidity rate, and d) the mortality rate.

a) Clarify the Basis for Selection of a Dose Response Function. The general exponential model was used to characterize the dose-response relationship based on the data from three human challenge studies. Modeling this relationship is important for estimating the risk of infection at low doses because it is not economical to conduct large human challenge studies to directly measure infection rates. The choice of the exponential dose-response model is reasonable and has been used in previous cryptosporidiosis risk assessments (Haas et al., 1996, 1999). But it is not clear if other models were considered and fit to the data from the human challenge studies. The Panel recommends that the Agency document the models that were considered and the reasons for selecting this particular one.

b) Clarify the Use of the Term Infectivity in the Agency Analysis. A number of aspects of infectivity that are described in the Agency's analysis (pages 5-10) deserve further discussion. Among these things are: I) the use of the proportion of the total oocysts from the occurrence estimates that have internal structures to determine the fraction of oocysts considered infectious, ii) the fraction of the oocysts from the three strains of *C. parvum* used in the human challenge studies (IOWA, TAMU and UCP) which were considered infectious and iii) the relationship between the two, namely the fraction of oocysts that were infectious in the human studies versus the fraction of the oocysts that were infectious in environmental samples (i.e., the parameter "v" in the equation below).

Infectivity of oocysts in the environment: The assumptions about the proportion of infectious oocysts in the environment determine the variable "v" used in the Agency equation for estimating morbidity:

$$P_M = M\{1 - [e^{-(CvI/k)}]^n\}$$

Where:

M = fraction of infections resulting in morbidity
C = concentration of oocysts in water (oocysts/L)
v = fraction of oocysts that are infectious
I = volume of water ingested each day (L)
k = infectivity parameter
n = number of days of exposure
P_M = probability of disease

In the occurrence data, the Agency assumed that only a proportion of oocysts detected in the environment are infectious and that proportion was determined by use of data from microscopic examination of the oocysts. The proportion of *Cryptosporidium* oocysts in the environment that are infectious was estimated from the ICR and ICRSS data based on morphological appearance of oocysts and the proportion of oocysts with internal structures. These measures are more frequently used as a measure of viability than infectivity. Viability, usually evaluated by evidence of dye uptake, excystation or the presence of RNA, is a measure of the organism's ability to continue to survive as a living organism. Infectivity is usually defined as invasion and replication in a host cell, mouse model or human volunteers (analogous to infection). The set of organisms that are infectious is a subset of the set of organisms that are viable. Infectivity, not viability, is the relevant issue where the parameter is concerned.

The Agency analysis also used data on infectivity from a study by LeChevallier (2000). The data were expressed as a distribution with a range of 30 - 50%, mode = 40% (page 5-17). There is some evidence that polymerase chain reaction (PCR) detection of *Cryptosporidium* DNA in cell culture will give false positives because some oocysts may not be infectious but it is still possible to detect their DNA. Thus, direct detection of DNA by PCR may also pick up noninfectious oocysts that stick to the cell monolayer even if they have not infected the cells (Rochelle et al., 2001; De Leon and Rochelle, 2000). The Panel recommends that a careful analysis of these issues be conducted and their impact on the risk reduction estimates be evaluated.

Infectivity of oocysts in the dose in the human challenge studies: The analysis of the human dose-response data assumes that 100% of the oocysts in the dose were infectious. However, it is likely that not all of the oocysts in the dose are "infectious". During its deliberations, the Panel discussed new data on cell culture infectivity and mouse infectivity that shows that approximately 5% of freshly excreted oocysts from a cow are "infectious" (see Upton et al. 1994; Rochelle et al. 2001; Rochelle et al. 2002). It is important to clarify how the viability and/or infectivity of the oocysts used in the dose was evaluated. Was this based on excystation rate or on the morphological appearance of intact oocysts? It would also be helpful to verify the time between oocyst excretion and dosing volunteers (<2 weeks?) because this may affect the proportion of infectious oocysts in the various doses. The Panel recommends that the Agency clarify these details on the conduct of the original study and include this clarification in its own documentation.

Use of human infectivity and cell infectivity data for the analysis: The Agency risk analysis incorporates viability determinations (a much weaker technique) and direct PCR-cell culture technique (which gives false positives). It is important that the Agency clearly indicate that human challenge data are currently limited to three strains necessitating the use of several major assumptions in the analysis. However, several strains have been studied in cell culture and in mouse infectivity assays. Since it is unclear whether these strains will ever be tested in human volunteers, it would be of value to compare the data between human, animal and cell culture lines. It would be useful for the Agency to consult with a number of researchers who have conducted infectivity studies on *Cryptosporidium* to gain a deeper understanding of how animal and cell infectivity data might supplement the data on infectivity from human challenge

studies. Further, it will be important to make broader use of statistical analysis as the Agency seeks to compare these differing types of infectivity data. The Panel recommends using the PCR-cell culture data as a supplement to the human infectivity data and clarify with the investigators the strengths, limitations and use of these data.

Proper statistical treatment of human challenge data from multiple isolates: As discussed above, there are some major concerns with the models for infectivity across strains. There are data from only three strains available to estimate the distribution of infectivity across strains. As a result, the distribution of infectivity derived from fitting the model relies heavily on both the assumed class of distributions (log normal) used and the assumed prior distribution for the standard deviation parameter σ , which characterizes the variability of infectivity across strains. The Panel believes that the Agency could use a mixture of two distributions for infectivity to help characterize this uncertainty. The first component of the mixture will be a log normal distribution (with probability = λ) and the second component will be a log-t distribution with three degrees of freedom (with probability = $1 - \lambda$). The latter provides heavier tails and considers more extreme values for k to be more likely. Sensitivity analyses regarding the impact of the prior on σ should also be performed.

The importance of genotype: It is correctly recognized that there are anthroponotic and zoonotic strains of *Cryptosporidium parvum*. One limitation of the infectivity data from human challenge studies is that currently only zoonotic strains (genotype 2) have been tested to date. However, most of the recognized *Cryptosporidium* outbreaks (foodborne and waterborne) have involved human genotypes. A human challenge study with a human genotype strain (genotype 1) is currently in progress and will provide valuable data for future risk assessments. The Panel recommends that when this data becomes available, the Agency reevaluate this risk assessment and the dose response model.

Variability in host susceptibility and the effect of previous infections: Variability in host susceptibility was not considered in the analyses of infectivity and morbidity. For example, the Agency dose-response model takes the number of oocysts as the dose surrogate. Thus the same approach is used to evaluate risk for infants and adults. The Panel recommends that the risk assessment consider explicitly the risk to susceptible populations (e.g., elderly, young, immunocompromised, etc.). These groups may be at greater risk of infection and/or disease due to greater water consumption per unit body weight, less effective immune systems, etc. Data from outbreak investigations may provide evidence of the consequences of infection for these populations.

Also, the analysis assumed that the exposed population had no previous immunity to *Cryptosporidium*. It is likely that the volunteers in the human challenge study are a mix of naive and previously exposed individuals, and that differences in host susceptibility and previous immunity had an effect on the estimates of the dose-response parameter. The Panel recommends that the Agency compare its approach to this issue with the approach taken in other studies. Differences in host susceptibility and previous immunity will have an effect on the estimates of the infectivity parameter " k ".

c) Morbidity Rate (pg 5-13). The morbidity rate was defined as the probability of illness given infection and was estimated using a triangular distribution based on a range from Haas et al 1996. This rate may not be accurately estimated if asymptomatic infections were not detected in the human challenge studies. The greater the rate of asymptomatic infections, the more the probability of illness given infection will be underestimated.

In addition, the probability of illness given infection may be underestimated because these data are based on challenge studies in healthy adult volunteers. In the general population, there may be a greater probability of developing illness given infection because the whole population includes sensitive sub-populations that are more likely to develop symptomatic illness given infection.

Individuals with existing antibodies to *Cryptosporidium* may have a lower morbidity rate, although, data from Okhuysen et al., (1998) does not seem to support this. The Okhuysen, et al., experiment was conducted at relatively high doses, and there are no data on the morbidity rate at low doses in a population with previous *Cryptosporidium* infection. The high doses employed may have overwhelmed any immune response in a way that low doses would not. If a significant fraction of the population carries antibodies, the incidence of disease might be significantly reduced.

The mortality rate in AIDS patients that was used in the economic analysis is based on old data from the 1993 Milwaukee outbreak. Current therapy has markedly reduced cryptosporidiosis mortality in AIDS cases. As a result, the mortality rate in this analysis is probably overestimated. At the same time, the mortality rate derived from Milwaukee may be too low for populations with a greater proportion of immunocompromised individuals.

The Panel recommends that these questions of morbidity rate, and their potential impact on the analysis of risk reduction, be more thoroughly analyzed and discussed in the document.

3.3.1.3 Exposure Assessment (pgs 5-14 - 5-24). Exposure assessment in the Agency's analysis included estimation of: a) the distribution of total and infectious *Cryptosporidium* oocysts in finished water - derived from source water levels and estimated removal/inactivation from treatment; b) the population served by systems potentially affected by the LT2ESWTR, and c) the distribution of individual daily average drinking water consumption. The Panel has a number of comments on this assessment.

a) Estimates of Consumption (pg 5-22) require clarification. There are a number of questions that arise in a review of the water consumption estimates used in the analysis. These questions should be more effectively addressed in the documentation. They include:

- 1) Why were two distributions of consumption used? What is the difference between them?
- 2) Why are the median values (1.045, 0.71) lower than previous estimates of daily water consumption?

- 3) Why was Distribution 1 used for the main analysis and Distribution 2 used in the analysis in the appendix?

Finally, it is not clear how the daily estimated consumption was extrapolated to annual exposure in Exhibit 5.8 (pg 5-23). Is individual consumption split between Community Water Systems and Non-Transient Non-Community Water Systems based on the estimated proportion of their time spent at home and at work or school or are individuals counted in both categories - i.e., total consumption counted twice. This estimate could be refined by age group. The Agency should examine water consumption patterns of the very young and very old because these are the most vulnerable age groups.

3.3.1.4 Results of the Risk Assessment.

The estimates of risk require clarification as to the general approach to quantitative microbial risk assessment, discussions of uncertainty and significance of assumptions made..

Quantitative microbial risk assessment is a rapidly developing field. Previous work includes risk assessments by Casman et al., (2000), Haas et al., (1999)(see in NRC 2000), Perz, et al., (1998), and Teunis, et al., (1999) and an outbreak model done by Eisenberg, et al., (1998). The Panel recommends that a review of these and other preceding studies (including the sources of data, assumptions and statistical methods) be added to the document preamble. To the extent the approaches by these predecessors differ from the approach used by the Agency, the significance of the differences should be discussed and the reasoning behind the choices provided.

In regard to discussions of uncertainty, the document should include a summary discussion of uncertainty and variability that is more detailed than that currently presented on pg 5-26. This discussion should include the following:

- a) Identifying sources of uncertainty (already included on pg 5-26)
- b) Magnitude of uncertainty
- c) Effect of uncertainty on the estimate of risk
- d) Sensitivity analysis of which sources of uncertainty have the greatest impact on the estimate and the implications of this for future research efforts. It appears that uncertainty in estimates of risk and uncertainty in costs have different drivers. Uncertainty in estimates of risk was driven by dose-response data. Uncertainty in cost was driven by occurrence data (how the systems are classified into bins where action is necessary). Hence, it may turn out that uncertainty is much greater in cost than in estimates of risk or vice versa.
- v) Identifying sources of variability (already included on pg 5-26). Sources of oocysts may be different for different communities (watersheds) animal sources vs human sources
 - 1) Magnitude of variability
 - 2) Effect of variability on the estimate of risk

3) Sensitivity analysis of what sources of variability have the greatest impact on the estimate

In regard to the significance of assumptions, the document should also include a discussion of which assumptions may lead to an underestimate or overestimate of the risk and the benefits of the proposed regulation. For example, because the analysis only considered morbidity and mortality as outcomes, it is possible that the benefit is underestimated because the benefit of avoided infection was not considered. Avoiding infection in the community will reduce the potential for secondary transmission and additional cases and deaths. From a public health perspective, infection is the key outcome.

3.4 Charge 3: Treatment credits for four microbial toolbox options

The Agency requested SAB comments on the treatment credits for four specific technologies included among its microbial toolbox options.

The Agency provided the Panel with drafts of portions of the preamble to the LT2ESWTR, including: a) a Microbial toolbox overview (US EPA 2001a), b) Off-stream raw water storage (US EPA, 2001b), c) Pre-sedimentation (US EPA 2001c), d) Lime softening (US EPA, 2001d), and e) Lower finished water turbidity (US EPA 2001e).

These draft documents were intended to provide the Panel with an understanding of the role and context of toolbox options in the LT2ESWTR and specific information on each of the four toolbox options that the Agency asked the Panel to comment upon.

3.4.1 Panel Response to LT2ESWTR Charge Question 3

a) Comments on the Four Options. The Panel commends the Agency, as well as the stakeholder process used, for developing the bin classification framework for identifying the treatment requirements for drinking water and the microbial toolbox containing possible treatment options to guide systems having treatment needs. These alternatives add great flexibility for meeting varying water quality and treatment options and should result in safer drinking water for the people of the United States.

The Agency charged the Panel with evaluating Agency information on four of the toolbox options: 1) off stream raw water storage; 2) pre-sedimentation, 3) lime softening and 4) lower finished water turbidity. Specifically, the Agency asked the Panel to comment on the credits that have been proposed for specific toolbox options for *Cryptosporidium* removal. The proposal requires that utilities monitor the oocyst densities in their raw water supplies. It then classifies each supply into one of several bins depending on the oocyst densities observed, each bin having different treatment removal requirements. The proposal then identifies a “toolbox” of several actions that utilities can take in order to get credit for removal. Removal credits are generally expressed as the logarithm of the reduction required. For example, a 1 log credit would correspond to 90% removal.

In summary, the Panel recommends that no presumptive credits be given for off-stream storage and pre-sedimentation. It does agree with giving 0.5 log credit for two-stage lime softening if all the water is treated with both stages, and 0.5 log credit for plants that demonstrate a turbidity level in each individual filter effluent less than or equal to 0.15 NTU in at least 95 percent of the measurements taken each month. Details about these recommendations follow.

Off-Stream Storage: The data utilized by the Agency in determining the appropriate credit for off-stream storage were derived from experiences in the United States as well as peer-reviewed literature from elsewhere in the world. The data show that there is variability in the removal of active oocysts in different reservoirs, due primarily to sedimentation, but also due to inactivation within the environment, both of which are governed to some degree by temperature and by residence time in the facility. After reviewing the supporting documentation, the Panel does not feel there are adequate data to demonstrate the proposed credits for off-stream storage and therefore recommends that no presumptive credits be given for this toolbox option. However, the Panel agrees that a particular utility should be able to take advantage of any removal achieved by this option by sampling after the off-stream storage facility for appropriate bin placement.

Pre-sedimentation: With regard to pre-sedimentation, many water treatment plants located on surface waters having large variations in water quality utilize pre-sedimentation as a treatment technique to remove large quantities of suspended material prior to input to an existing conventional treatment plant or lime softening operation. The real purpose of pre-sedimentation is to provide for more consistent water quality prior to the conventional or lime softening treatment. In reviewing the literature provided by the Agency, not only on *Cryptosporidium*, but also on spore removal with both pilot as well as full-scale plants, it seems that the data are insufficient to support a 0.5 log presumptive credit for pre-sedimentation. As a result, the Panel feels that no credit should be given for pre-sedimentation. Additionally, the Panel feels performance criteria other than overflow rate need to be included if credit is to be given for pre-sedimentation. As with off-stream storage, the Panel does agree that a utility should be able to take advantage of this removal by sampling after the pre-sedimentation treatment process for appropriate bin placement.

Lime-softening: The Agency proposes a 0.5 log credit toward *Cryptosporidium* treatment with lime softening plants that utilize two-stage softening. Based on the data provided, it appears that a 0.5 log of additional *Cryptosporidium* removal is an average number for a two-stage lime softening plant. Based on the data, single stage as well as two-stage lime softening generally outperforms conventional treatment due primarily to the heavy precipitation that occurs in lime softening reactors particularly when magnesium precipitation occurs. By treating water through a second precipitation reactor, additional removal should occur. However, depending on how the second reactor is utilized and the chemical feeds to the second reactor, the removal efficiencies vary significantly as presented in the literature. Therefore, the Panel supports an additional 0.5 log removal for two stage lime softening only if all the water passes through both stages. If a portion of the water bypasses the first stage, the Panel feels there should be no additional removal credit given.

Lower Finished-Water Turbidity: Finally, the additional credits for lower finished water turbidity seem to be consistent with what is known in both pilot and full-scale operational experiences for *Cryptosporidium* removal. As was contained in the Enhanced Surface Water Treatment Rule, lowering effluent turbidity in the treated water results in lower concentrations of *Cryptosporidium*. Therefore, it would be consistent to assume that even further lowering of turbidity would result in further reductions in *Cryptosporidium* in the effluent from filtration processes. It is also logical to assume that individual filter effluent turbidity meeting a specific criterion will provide for better water quality than for combined filter effluent meeting the same requirement. However, limited data were presented to show the exact removal that can be achieved using these two operational benchmarks. Based on the data provided, the Panel recommends that a 0.5 log credit be given to plants that demonstrate a turbidity level in each individual filter effluent less than or equal to 0.15 NTU in at least 95 percent of the measurements taken each month. No additional credit should be given to plants that demonstrate a combined filter effluent turbidity of 0.15 NTU or less.

b) Other Issues. The Panel's understanding of the approach used in developing the microbial toolbox is as follows. The additional log removals in the table of bin requirements are based in part on the assumption that conventional filtration plants in compliance with the Interim Enhanced Surface Water Treatment Rule (IESWTR) achieve an average of 3 logs removal of *Cryptosporidium*. The Panel also understands that this assumption indicates that all conventional treatment plants can be expected to remove a minimum of 2 logs of *Cryptosporidium*. Furthermore, it is the Panel's understanding that an objective of the rule is to achieve an average oocyst concentration in treated surface waters of 10^{-4} oocysts/l or lower. Given the oocyst concentrations in bins 2, 3, and 4, and considering an average removal of 3 logs for conventional treatment, the additional removal requirements in bins 2, 3, and 4 are expected to provide an average treated water oocyst concentration of 10^{-4} oocyst/l or lower.

This approach differs from past regulatory approaches to *Giardia* and *Cryptosporidium* treatment credits and from present regulatory approaches to *Giardia* control. Current regulations for *Giardia* control provide 2.5 logs of removal credit when conventional treatment is used. It is the understanding of the Panel that this removal credit for *Giardia* is based on the minimum removal (not the average removal) achieved by these plants.

These differences between the IESWTR and LT2ESWTR regulations in the bases for assuming removal credits for *Giardia* and *Cryptosporidium* are not readily apparent and should be clarified and supported in the new regulations. Appropriate guidance will be needed for consistent implementation of these two regulations.

4. STAGE 2 DISINFECTION BYPRODUCTS RULE

4.1 Charge 1: Initial Distribution System Evaluation (IDSE):

The Agency requests SAB comment on whether the IDSE is capable of identifying new compliance monitoring points that target high TTHM and HAA5 levels and whether it is the most appropriate tool available to achieve this objective.

The Agency provided the Panel with two draft documents on the Initial Distribution System Evaluation that is to be proposed in the S2DBP rule. Information provided in support of Charge question 2 below in this section also bears some relevance to this question. The documents provided by the Agency include:

- a) “E. Initial distribution system evaluation (IDSE)” (US EPA, 2001f) a draft overview of the IDSE intended for the preamble of the rule; and
- b) Stage 2 Disinfectants and Disinfection Byproducts Rule Initial Distribution System Evaluation Guidance Manual (The Cadmus Group, Inc., 2001d) which provides recommendations for how utilities should proceed to determine monitoring sites to reflect the highest levels of TTHM and HAA5 occurrence within the distribution system.

4.1.1 Panel Response to S2DBP rule Charge Question 1.

4.1.1.1 Initial Distribution System Evaluation (IDSE) Effectiveness. The Panel believes that the proposed IDSE is capable of identifying new compliance monitoring points that target higher DBP levels than are currently monitored in the existing compliance monitoring programs for the THM Rule and Stage 1 DBP Rule. However, the IDSE may not identify the highest levels to which consumers in a given distribution system are exposed. The basis for the latter statement is that the IDSE does not consider short-term, temporal variations that occur at different sites in the distribution system due to varying (e.g. diurnal) water demands and distribution system architecture and operation. Distribution systems are, by their nature, highly dynamic. Varying water demand patterns (e.g. low density and high density residential water use, industrial and commercial water use, irrigation) and operating conditions (e.g. pumping patterns and storage tank operations) normally lead to appreciable temporal and spatial variations in hydraulic residence times (water age) and water quality throughout the system that are not captured by the proposed IDSE. Hence, it is unlikely that a single grab sample taken at any site at any time will yield a representative DBP concentration for that site, and that grab samples taken at a number of sites will identify sampling sites with the highest DBP concentrations.

Further, rates of disinfection byproduct formation and degradation are temperature-dependent and may change on a seasonal basis. Coupling this with the fact that water demand patterns, and therefore hydraulic residence times, also may change with season may mean that peak DBP levels migrate from the remote parts of the system during colder months to interior

portions of the system during warmer months. Furthermore, this behavior will probably not be consistent for all.

Therefore, the Panel believes that it is important that site selection be re-evaluated periodically. In rapidly growing utilities changes in the distribution system architecture and flow patterns are common. As a result, the sites with high DBP levels often change. Significant changes also occur in systems that are not rapidly growing as components fail and/or improvements are made. If sample locations are not updated with time to reflect these changes in distribution system behavior, then the sample locations may lose their relevance over time. Further, the IDSE is only a 12-month program, and utilities and primacy agencies have no assurances that the 12-month period over which the IDSE is performed will indeed be typical of normal system operations. The Panel recommends that temporal limitations be identified in the documentation and that periodic re-evaluation of selected sites be required so that changes in the system and/or its use will be addressed.

4.1.1.2 IDSE Appropriateness. The Agency also asked if the IDSE is the most appropriate tool to reach the objective of identifying new compliance monitoring points that target higher THM4 and HAA5 levels. The Panel believes that the proposed standard monitoring program (SMP) for sub-part H systems serving more than 10,000 people, in which 8 samples are collected at 2-month intervals, is reasonable. The Panel does recommend, however, that the 8 samples be re-allocated so that, for both free chlorine and chloramines, 3 samples be taken at potential high THM4 sites, 3 samples be taken at potential high HAA5 sites, and only 1 sample each be taken at an average site and at the point of entry to the system. If indeed the objective is to locate and monitor the sites with high THM4 and high HAA5 concentrations, more samples need to be allocated to this objective. One point of entry site is sufficient to gauge the initial concentration of DBPs entering the system, and only one “average” site should be sufficient to maintain connectivity to the existing compliance monitoring program. The Panel also believes that the “average” site for the IDSE should be one of the average locations in the existing Stage 1 DBP compliance monitoring program. This would mean that every 6 months (twice during the IDSE), utilities would only have to take 7 samples as part of the IDSE, with the eighth sample being one of the compliance monitoring samples.

The Panel also recommends that the IDSE should require the measurement and reporting of residual chlorine (free or combined) concentrations at the time of DBP sample collection, and that individual THM and HAA species be reported in addition to the aggregate concentrations. The Panel also suggests that the IDSE recommend that complementary pH, temperature, and heterotrophic plate count be measured and recorded concurrently with DBP measurements. Such information will prove to be valuable to the utilities, the primacy agencies, and the Agency in the future.

With respect to time of sample collection, there is no reason to believe that THM4 or HAA5 levels will be highest in the morning. In view of the dynamic and highly complex nature of water distribution systems, it is equally likely that THM4 or HAA5 levels at some locations will be highest in the evening. The Committee recommends that the reference to time of sample

collection be omitted from the Guidance Manual (e.g. p. 2.9 of Guidance Manual) and be left to the discretion of the utilities and their respective primacy agency.

The Panel also recommends that the Agency provide more guidance to the utilities with respect to identifying potential sampling sites with the highest HAA5 concentrations. The only reference in which some guidance is provided is on page 5-18, line 39 of the Guidance Manual, although that guidance is not especially clear. It might be expected that, at least in waters with temperatures supporting microbial activity, HAA5 levels may decrease when free chlorine residuals decrease below 0.2-0.3 mg/l or combined chlorine residuals decrease below 0.5 mg/l. This may not be the case in cold waters in which microbial activity is minimal; in such cases, high HAA5 sites may coincide with high THM4 sites. Distribution system dynamics, water age, chlorine residual data, and heterotrophic plate count data should be examined in selecting sample sites.

The Panel also recommends that the Agency require that the selection of monitoring sites be justified rather than simply recommending that they be justified (p. 1-4, line 14), and that the IDSE report provide justification for the selection of sites (p. 5-24, line 16) (The Cadmus Group, Inc., 2001d).

The Panel believes that the proposed system specific studies (SSS) approach described in Chapter 6 of the Guidance Manual needs improvement if sound guidance is to be provided to the utilities. Water consumption (demands) should be more accurately simulated in the network model, given the availability of such information. It is important to realize that different types of water users will consume water at different times and rates during the day. Water demands should be classified and allocated based on their water use type (domestic, industrial, commercial, etc.) and each type of water user should be assigned an individual water use pattern over a 24-hour (or other) period. Estimates of demand distributions could be obtained by using land use information or by using a water meter or assessor's parcel number location methodology (geocoded meter location). For example, the land use computation method consists of intersecting demand area polygons with land use polygons using water duty factors to create water demands for selected analysis nodes. The geocoded meter location method consists of grouping water billing data into demand areas around analysis nodes by using a spatial reference of water meters, yielding a credible demand distribution as demands are allocated per customer billing accounts (and automatically taking into account vacant parcels and large water users). Other spatial demand allocation methods include assigning geocoded customer meters to the nearest analysis node or to the nearest pipe and then split the demand among the bounding analysis nodes. Some care will be required to ensure that demands are accurately allocated according to actual spatial consumption.

4.1.1.3 Other Considerations. The Panel has a number of concerns that it considers to be of significance but which do not easily fit into the other two charge questions on the S2DBP Rule. These are discussed in the following paragraphs.

Clarification of Assumptions: A number of assumptions and policy decisions were made in the development of the form of the Stage 2 DBP Rule and the IDSE. These need to be stated at the outset and made clear throughout the documentation in support of the rule. These include:

- a) the decision to continue to regulate THM4s and HAA5s collectively as group parameters rather than as individual species;
- b) the decision to continue to regulate only five of the HAAs (HAA5) rather than all nine bromine- and chlorine-containing HAAs (HAA9);
- c) recognition of the fact that, for purposes of simplicity, the IDSE overlooks short-term temporal variability in the selection of sites for locating and monitoring maximum levels of THM4s and HAA5s;
- d) recognition of the fact that sampling and monitoring costs were key considerations in designing the requirements for the standard monitoring program for the IDSE;
- e) recognition of the fact that, although the Source Water Analytical Tool (SWAT) model was developed for modeling the effects of treatment on DBP formation and was not developed to model changes in individual or aggregate DBP concentrations in distribution systems, it was the only tool that the Agency had for purposes of the benefits analysis in support of the Stage 2 Rule.

Use of the SWAT Model: In the risk reduction analysis, the SWAT model is used to predict monthly DBP concentrations both under current conditions and under conditions where plant modifications have been made to meet the requirements of Stages 1 and 2 (sections 3.7.2 and 5.4.1.1) (The Cadmus Group, Inc., 2001e). This use of the SWAT model would be appropriate if it could be relied upon for valid predictions in such applications. Unfortunately, the Agency has not demonstrated that this is the case. Large discrepancies exist between SWAT predictions and ICR data, and these discrepancies raise serious questions regarding both the accuracy of the SWAT model and the adequacy of attempts to characterize DBP concentrations of dynamic systems with such a limited number of samples (four sites with four samples per year).

Two aspects of data presentation in the Stage 2 DBPR Economic Analysis serve to illustrate how the discrepancies are under-represented: a) the use of cumulative frequency distributions (pages 3-31 and A-18 through A20)(The Cadmus Group, Inc., 2001e), and b) miscalculation of “mean predicted errors” (page A-34 and Exhibit A.21). The problem with the use of cumulative frequency diagrams is that such plots have the same shape even when paired values have little agreement. Plants with low THM4 or HAA5 from the SWAT model are not necessarily the same plants with low THM4 or HAA5 plants from the ICR data. This discrepancy is totally lost when the data are presented as cumulative frequency curves. In the calculation of the “mean predicted error,” “the absolute value of the difference between “SWAT annual plant mean” and “ICR annual plant mean” should have been used instead of signed values, or an R^2 value should have been calculated. The way the calculation was done, positive deviations canceled out negative deviations thereby grossly underestimating “mean predicted errors.” The graphical results of pages A-23 to A33 convey a much greater sense of the discrepancies between the SWAT predictions and the ICR data. The magnitude of these

discrepancies diminishes the value of the subsequent use of either SWAT or ICR data in Economic Analyses or risk reduction calculations.

The limitations to the model's accuracy arise from the inherent limitations of the existing state of the art for predicting DBP concentrations from water quality data and/or the inherent limitations in the available database, and hence cannot be easily fixed. Under the circumstances, the contribution that the model can make to an evaluation of the risk reduction from the Stage 2 rule is marginal at best. The Panel recommends that either this portion of the analysis of the risk reduction be eliminated or that the presentation be altered to reflect the uncertainties associated with use of the model.

Monitoring Frequency Under the IDSE: Though this is a relatively minor point, it should be made clear, in all documents relevant to the Stage 2 Rule, that quarterly monitoring of DBPs means every 3 months. For example, Table 5.4 and page 192 (US EPA, 2001h) do not unequivocally indicate that the basis for the LRAA calculation is sampling at 3-month intervals rather than once each quarter as in the current THM Rule and Stage 1 Rule.

4.2 Charge 2: Public Health Protection of S2DBPR.

4.2.1 Panel Response to S2DBPR Charge Question 2.

The Agency requests SAB comment on whether the locational running annual average (LRAA) standards for total trihalomethanes (TTHMs) and haloacetic acids (HAA5), in conjunction with the Initial Distribution System Evaluation of the proposed S2DBP rule, more effectively achieves public health protection than the current running annual average (RAA) standards, given the existing knowledge of DBP occurrence and the available health effects data.

The Agency is concerned with reproductive, developmental, and carcinogenic effects which are associated with TTHMs and HAAs. The Agency intends to reduce the variability of exposure to DBPs for people at different points in the distribution system, and therefore reduce risks.

The Agency provided the Panel with documents that gives the Agency's case for why it believes there is a health concern for disinfection byproducts. Documents provided to the Panel in support of the Health concerns determination include:

- a) A draft of preamble section "III. Public Health Risk" (US EPA, 2001g) that briefly discusses reproductive and developmental epidemiology information received after the Stage 1 DBP rule;
- b) Quantification of Bladder Cancer Risk from Exposure to Chlorinated Surface Water (US EPA, 1998) which provides details on the population attributable risk concept used to quantify the estimated number of cancer cases that would be attributable to the consumption of chlorinated drinking water;

- c) Reproductive and Developmental Effects of Disinfection By-Products (Reif et al., 2000) which provides a critical review of the epidemiologic literature pertaining to reproductive and developmental effects of exposure to disinfection byproducts in drinking water;
- d) Review of Animal Studies for Reproductive and Developmental Toxicity Assessment of Drinking Water Contaminants: Disinfection By-Products (DBPs) (Tyl, 2000), which provides a review of the animal reproductive and developmental toxicity data on disinfection byproducts; and
- e) “*V. Discussion of Proposed Stage 2 DBPR Requirements*” (US EPA, 2001h) which explains how the chloroform MCLG was developed.

One document was provided to support evaluation of charge question 2 in the area of “Occurrence/Reduction of Peaks”:

- a) *Excerpts from the Economic Analysis for the Stage 2 Disinfectants and Disinfection Byproducts Rule* (The Cadmus Group, Inc., 2001e) which indicates the extent to which the Agency estimates that DBP peaks might be reduced by the proposed S2DBPR.

One document was provided to support evaluation of charge question 2 in the area of “Monitoring Requirements and Compliance Determination.”:

- a) *G. Monitoring requirements and compliance determination.* (US EPA, 2001i).

The Agency issued a Stage 1 DBP regulation that requires regulated water systems to meet a standard of 80 ug/l Total Trihalomethanes (THM4) and 60 ug/l for five Haloacetic Acids (HAA5) as well as other DBPs during 1998. Consistent with the original THM rule, the regulation requires that systems implement a Running Annual Average (RAA) approach to monitoring for these contaminants and that they be kept at or below these levels. In arriving at these standards, the Agency recognized, as does this Panel, that the regulated THM4 and HAA5, which are prominently identified in the rule, are not the only DBPs in these classes that could be in drinking water, nor are these classes the only possible DBPs in chlorinated or other drinking water systems. However, the Agency and a large group of stakeholders who were involved in an extensive series of negotiations, agreed that it was appropriate to focus on these DBPs in the policy embodied in the Stage I standard. They further agreed that it was reasonable to assume that the controls that would be implemented for reducing levels, and therefore risks, of those regulated DBPs, would also reduce risks from other DBPs that are, as yet, to be identified and/or studied for health effects.

The panel is generally supportive of the THM4 and HAA5 actions under consideration. Although the epidemiology data associating cancer with chlorinated drinking water has resulted in relatively small odds ratios, the observations have now been consistent across a broad number of studies with varying degrees of increasing sophistication, especially for bladder cancer. While the odds ratios are small, the numbers of attributable cases are large relative to other environmental issues of concern (Morris et al., 1992; Poole, 1997). Therefore, the epidemiology

data can be taken to indicate that there is a problem that needs to be taken seriously. The THM4 and HAA5 standards reviewed by the Panel are a constructive interim step towards addressing this problem.

The Panel also agrees that establishing an LRAA would be expected to reduce exposure to the nine compounds that are regulated. As detailed in section 4.1.1.1 of this document, which discusses the dynamics of water movement through the distribution system and on-going production and degradation of disinfection by-products, it is uncertain that the requirements of the IDSE will result in a sufficiently complete distribution system characterization to be confident that the locations with the highest exposure will be identified and therefore that all the households will gain the protection of the new standards. Nevertheless, the variability in exposure to regulated DBPs, from one point in the system to another, will be reduced, particularly at the extreme locations that the IDSE does identify, and the consumers at those locations will have lower levels of exposure to the measured DBPs.

The principle outcome of the LRAA/IDSE proposal will be increased assurance that each consumer will be exposed to THM4/HAA5 levels that are at or below the MCLs specified. The existing RAA allows locations with THM4/HAA5 levels above the MCL to be averaged with other locations in the system that do not. The LRAA identifies locations in the system with consistently high concentrations of the regulated DBPs and requires that they meet the MCL. Thus the new proposal substantially reduces the probability that a given consumer will be exposed to THM4/HAA5 levels above those specified in the regulation. The Panel recommends that the Agency give greater visibility to this benefit.

A second, but important outcome of the LRAA/RAA proposal will be reduced overall average level of the regulated DBPs in many systems. This will occur because, when systems use precursor removal as their strategy, THM4/HAA5 levels must be reduced throughout the system in order to bring sampling points with high THM4/HAA5 levels into compliance.

Assessments of health risk reduction from this rule have emphasized reductions in bladder cancer risk. It is important to address bladder cancer because epidemiological data consistently indicate that lifetime consumption of chlorinated surface water poses a bladder cancer risk (Cantor et al., 1998; Doyle et al., 1997; King and Marrett, 1996; McGeehin et al., 1993; Morris et al., 1992; Poole, 1997; Vilanueva et al., 2001; Vena et al., 1993). There are other serious putative health effects that have been identified from epidemiology studies or toxicological studies of individual disinfection byproducts (Cantor et al., 1999; Hildesheim et al., 1998; King et al., 2000; Reif et al., 2000; Tyl, 2000). These include risks of other cancers (brain, colon, rectal), impairment of male and female reproduction, and effects on developing organisms. Additionally, it should be noted that the brominated THM and HAAs might account for some of the colon cancer as they can produce colon cancer in rats. Collectively, the risks calculated from these toxicological studies are 1-2 orders of magnitude less than the bladder cancer risks indicated by the epidemiology studies. The bladder cancer may well be due to agents other than the THM4 and HAA5 species (Bull et al., 2001) While based on more limited evidence, reductions in reproductive health risks are considered to be a benefit of the rule; however the lack of data preclude quantification of this benefit.

On the other hand, the panel cautions that the Agency has not satisfactorily demonstrated that promulgating the S2DBP rule will result in the reduction in bladder cancer risk which has been projected. The following are the reasons for this statement:

- a) The disinfectant by-product mixture produced when water is chlorinated is extremely complex, and within a given system, varies considerably.
- b) The specific by-products resulting in increased bladder cancer have not been identified, but are unlikely to be accounted for by the aggregate THM4 or HAA5⁶ concentrations.
- c) It has not been demonstrated that actions taken to control the collective THM4 and HAA5 concentrations will also control other known and unknown by-products.
- d) Treatment technologies may emerge that target only the regulated by-products, without addressing the rest of the DBP mixture.
- e) Some technologies aimed at reducing the target DBPs might result in new DBPs of unknown significance⁷.

In summary, it is the Panel's opinion that cancer and reproductive health risks are likely to result from water chlorination. However, the Agency has not demonstrated that the health risk reductions that accrue from the proposed rule will be proportional to the reductions in the THM4 and HAA5 concentrations. Some health benefits in addition to those specifically attributable to these classes of DBPs could accrue, but only to the extent that the measures that water systems take to reduce these byproducts also reduce the concentrations of other byproducts. It should be remembered that changing treatment has some potential to change the by-product mixture produced and some of the new compounds generated could be more harmful. Nevertheless, the Panel believes that some risk reduction will occur and that speculation such as that discussed above should not delay the promulgation of the present rule.

⁶For example, the target DBPs being regulated may not be good surrogates for the compounds that produce the reproductive toxicities. The risks identified in the epidemiology studies are much greater than those suggested by the studies of these individual by-products in animals. It is important to note, that the target DBPs do not include the most potent reproductive toxicant among the DBPs examined to date, bromochloroacetic acid.

⁷The recent identification of N-nitroso-N-dimethylamine (NDMA) as a by-product of chloramination is an example. NDMA belongs to a class of chemical carcinogens which contains some members that are known to produce bladder cancer in rats. NDMA is between 3 and 4 orders of magnitude more potent as a carcinogen than the THM4 and HAA5 (U.S. EPA,1997). Perhaps the most common method used for controlling THM4 and HAA5 formation is to use chlorine combined with ammonia for residual control. Recent work has shown that this combined chlorine can result in increased NDMA formation (Najm and Trussell, 2002, Choi and Valentine, 2002, Mitch and Sedlak, 2002).

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ATTACHMENT A

ACRONYMS AND ABBREVIATIONS

| | |
|-----------------|---|
| BAT | Best Available Treatment |
| cdf | Cumulative Distribution Frequency |
| CWS | Community Water System |
| DBP | Disinfection Byproducts |
| DWC | Drinking Water Committee |
| EPA | U.S. Environmental Protection Agency |
| HAA5 | Haloacetic Acids |
| HAN | Haloacetonitriles |
| ICR | Information Collection Rule |
| ICRSS | Information Collection Rule Supplemental Survey |
| IDSE | Initial Distribution System Evaluation |
| IESWTR | Interim Enhanced Surface Water Treatment Rule |
| LRAA | Locational Running Annual Average |
| LS | Lime Softening |
| LT2ESWTR | Long Term 2 Enhanced Surface Water Treatment Rule |
| MCL | Maximum Contaminant Level |
| MCLG | Maximum Contaminant Level Goal |
| NTNCWS | Non-transient Non-community Water Systems |
| PCR | Polymerase Chain Reaction |
| POTW | Publically Owned Treatment Works |
| RAA | Running Annual Average |
| SAB | U.S. EPA Science Advisory Board |
| SDWA | Safe Drinking Water Act Amendments of 1996 |
| SWAT | Surface Water Analytical Tool |
| S2DBPR | Stage 2 Disinfection/Disinfectant Byproduct Rule |
| THM | Trihalomethanes |
| TTHM | Total Trihalomethanes |

ATTACHMENT B

SELECTED GLOSSARY OF TERMS

Bayesian hierarchical models - Statistical hierarchical models with Bayesian parameter estimation techniques which fit probability models to a set of data and summarizes the results with a probability distribution, to determine parameters of a hierarchical model to predict the occurrence distribution.

Bin classification framework - The LT2ESWTR incorporates specific treatment requirements for protection against *Cryptosporidium* involving assignment of systems into different categories (bins) based on the results of source water *Cryptosporidium* monitoring. *Additional treatment requirements* depend on the bin to which the system is assigned (see Microbial Toolbox Options).

Cryptosporidium - Microbial pathogen, *Cryptosporidium parvum*, associated with waterborne disease (i.e., cryptosporidiosis) and known to infect immunocompetent and immunocompromised humans.

Endemic disease - Disease levels that are natural or “on-going” in the “normal” population and do not usually reach the attention of medical observers as would an epidemic.

Information Collection Rule (ICR) - EPA rule promulgated in 1996 pursuant to SDWA requirements which required approximately 300 large public water systems to conduct 18 months of sampling for water quality and treatment related to DBP formation and the occurrence of microbial pathogens. Data on DBP formation in small systems was obtained through 1) a survey of approximately 120 treatment plants in systems serving fewer than 10,000 people and 2) information received from seven states on small systems.

ICR Supplemental Surveys (ICRSS) - EPA obtained additional pathogen occurrence data through ICRSS which involved 127 water treatment plants, including 40 small systems, and comprised one-year of bi-monthly sampling for *Cryptosporidium*, *Giardia*, and other water quality parameters (small systems did not measure protozoa).

Initial distribution system evaluation - Studies conducted by Community Water Systems which are intended to select new compliance monitoring sites that more accurately reflect sites representing high TTHM and HAA5 levels. The studies are based on either on system specific monitoring or other system specific data that provides equivalent or better information on site selection.

Locational running annual average (LRAA) - RAAs (see below) calculated for each sample location in the distribution system which must be below the compliance levels (MCLs) in each quarter of the year.

Log credits - The logarithmic range of credit given for water system treatment and management options employed, e.g., reducing pathogen loading into the plant, pretreatment processes, additional pathogen barriers, etc.

Log removal - The logarithm of the reduction in microbial density due to an action. For example 90% removal corresponds to 1 log removal.

Markov Chain Monte Carlo - A method to obtain a sample from the posterior distribution of the parameters in a Bayesian hierarchical model that involves both Monte Carlo integration, to handle high-dimensional, intractable integrals and construction of Markov chains to draw these samples. The posterior distribution is used to make inferences about parameters in the model and to do predictions.

Microbial tool box options - Water systems will choose technologies to comply with additional treatment requirements from a 'toolbox' of options, e.g., pretreatment of water or improved disinfection.

PCR (Polymerase chain reaction) - The process of rapidly amplifying a defined region of DNA by sequential steps of denaturation and replication.

Priors or Prior Distributions - Previous probability assessments of existing data used to estimate occurrence under new conditions.

Posterior Probabilities - Estimates of occurrence under new conditions produced using prior distributions.

Running annual average (RAA) - Quarterly measurements of various sampling points in a water distribution which are *averaged* over the year to provide a average which is compared against the Maximum Contaminant Levels (MCLs) for TTHM and HAA5.

Surface Water Analytical Tool - Model used in conjunction with the ICR data to predict the impact of potential new standards for DBPs and/or pathogens on shifts in treatment technologies among water systems and resulting DBP exposure profiles.

Waterborne Disease Outbreak- A waterborne disease outbreak occurs when two or more persons experience a similar illness after consumption or use of water intended for drinking and epidemiologic evidence implicates the water as the source of illness. This outbreak is reported by the authorities. Also, a single case of chemical poisoning constitutes an outbreak if laboratory studies indicate that the water has been contaminated by the chemical. Only outbreaks associated with water intended for drinking are included.

ATTACHMENT C

BIOSKETCHES OF THE DRINKING WATER COMMITTEE MEMBERS Science Advisory Board (SAB) U.S. Environmental Protection Agency

Dr. Mary E. Davis: Dr. Mary E. Davis is a Professor of Toxicology in the Department of Physiology and Pharmacology at West Virginia University Health Sciences Center. Her research interests are in the mechanisms of toxicity, focusing on renal and cardiovascular systems and liver and emphasizing agents of environmental and occupational interest, including halomethanes and disinfection by-products. She earned a doctorate in Pharmacology from Michigan State University in 1977.

Dr. Davis is a member of the Editorial Board of *Toxicology and Applied Pharmacology*, and has served on the Editorial Board of *Toxicology*. She served as Treasurer for the Society of Toxicology. Dr. Davis previously served on two NRC Subcommittees on the health effects of disinfectants and their by-products and use of physiologically-based pharmacokinetics in risk assessment. She served as an external reviewer of EPA's risk assessment of the WTI hazardous waste incinerator and of EPA's proposed guidelines for human health risk assessment protocol for hazardous waste incinerators. In addition to serving on the DWC, Dr. Davis has been the SAB Liaison to the National Drinking Water Advisory Council (NDWAC) and was a member of the SAB's Chloroform Review Panel.

Dr. Ricardo DeLeon: Dr. De Leon is the Laboratory Manager for the Microbiology Unit of the Water Quality Laboratory of Metropolitan Water District of Southern California. The Microbiology Unit consists of the Compliance, Development and Reservoir Management Teams. His area of expertise is water microbiology, methods development for detection of microorganisms in water, inactivation of pathogens by disinfection and removal by treatment technology. He is currently working primarily on drinking water but his expertise also includes water reuse and public health issues associated with water. He has been working in the area of water microbiology since 1983.

Dr. De Leon holds a Bachelor's of Science in Microbiology and a Ph.D. in Microbiology and Immunology from the University of Arizona and did post-doctoral training in the Department of Environmental Sciences and Engineering of the University of North Carolina. He was also a faculty member at the University of California, Irvine Campus prior to joining Metropolitan Water District. He has been the principal or co-principal investigator on 22 research grants on methods development, disinfection of microorganisms and microbial aspects of water treatment technology. He has published more than 29 journal articles and book chapters on pathogen detection in environmental samples. He is currently serving in the Drinking Water Committee of the Science Advisory Board to the U.S. Environmental Protection Agency and on the National Research Council Committee on Indicators of Pathogens in Water.

Dr. Barbara Harper: Dr. Harper is an independent consultant in the areas of toxicology, risk assessment, CERCLA oversight, tribal water quality, and environmental management. She is affiliated with AESE, Inc (www.aeseinc.com). AESE's clientele consists entirely of Tribes/Alaska Natives. She is also an adjunct faculty member of Oregon State University's Public Health Department. Dr. Harper is a board-certified toxicologist (Diplomate of the American Board of Toxicology, 1989). She received her B.A. degree cum laude with departmental honors in biology from Occidental College in 1970. She received her PhD in genetics from the University of Texas at Austin in 1974. She was on the faculty of the University of Texas Medical Branch (UTMB) at Galveston in the Department of Preventive Medicine and Community Health; Division of Genetic and Environmental Toxicology. She then took a position with the Commonwealth of Pennsylvania's Department of Environmental Resources, and developed and managed the Special Science and Resources Program. She taught risk assessment as an adjunct faculty member at Penn State Harrisburg during this time period as well. She was recruited by Battelle's Pacific Northwest National Lab as a program manager in risk assessment in 1993 (Hanford), where she started working on tribal risk issues. She joined the Yakama Nation ERWM Program in 1997 and developed methods for tribal risk assessment methods now in use at DOE and EPA, and continues to develop tribally-relevant methods for evaluating cumulative risks and impacts to tribal health and culture. Her research interests include contamination of fish and other tribal subsistence foods, the associated health effects, eco-cultural and human health risk method development, nutrition, anthro-toxicology, and tribal parameters for subsistence exposure assessment.

Dr. Irva Hertz-Picciotto: Irva Hertz-Picciotto, Ph.D., Professor. Dr. Hertz-Picciotto received her Master's of Arts in Biostatistics, a Ph.D. in Epidemiology and a Master's of Public Health from the University of California, Berkeley. She has held positions as Assistant, Associate and Full Professor at the University of North Carolina, Chapel Hill, and most recently joined the Department of Epidemiology and Preventive Medicine at the University of California, Davis. Dr. Hertz-Picciotto receives funding for research from the National Institutes of Health, the U.S. Environmental Protection Agency, the Medical Investigations of Neurodevelopmental Disorders (M.I.N.D.) Institute, State of California Office of Environmental Health Hazard Assessment, the Health Effects Institute, the Hawaii Heptachlor Research and Education Foundation, the International Life Sciences Institute, and the University of California, Berkeley.

Dr. Hertz-Picciotto serves on editorial boards for the two major journals in her field, namely Epidemiology and the American Journal of Epidemiology, as well as for Human and Ecological Risk Assessment. She served as Chair of the Institute of Medicine/National Academy of Science's Veterans and Agent Orange: Update 2000 committee, and is currently Chair of the IOM/NAS Update 2002 committee. Dr. Hertz-Picciotto is also a member of the Board of Scientific Counselors of the U.S. National Toxicology Program, the Food Safety in Europe Working Group sponsored by the International Life Sciences Institute, and the Carcinogen Identification Committee of the California Governor's Scientific Advisory Board. She is currently President of the International Society for Environmental Epidemiology, and was recently a delegate to the NIEHS-sponsored U.S.-Vietnam Scientific Conference on the

Environmental and Health Effects of the Vietnam War. She founded the Center on Environmental Health and Susceptibility at the University of North Carolina, Chapel Hill. For over ten years, she has taught methods for epidemiologic data analysis in Chapel Hill, and has taught courses on four continents. Dr. Hertz-Picciotto has published seminal papers on the use of epidemiology in quantitative risk assessment and is internationally renowned for her work in this field, as well as occupationally related cancer, environmental exposures, reproductive outcomes, and methods for epidemiologic research.

Dr. Joseph R. Landolph: Dr. Joseph R. Landolph is currently Associate Professor of Molecular Microbiology and Immunology and Pathology and a Member of the USC/Norris Comprehensive Cancer Center, in the Keck School of Medicine and Associate Professor of Molecular Pharmacology and Toxicology, in the School of Pharmacy, with tenure, at the University of Southern California (USC) in Los Angeles, California. Dr. Landolph received a B. S. degree in Chemistry from Drexel University in 1971 and a Ph. D. in Chemistry from the University of California at Berkeley in 1976, under the guidance of the late Professor Melvin Calvin, where he studied the metabolism of the chemical carcinogen, benzo(a)pyrene, and its ability to induce cytotoxicity in cultured mouse liver epithelial cells and morphological transformation in Balb/c 3T3 mouse fibroblasts. Dr. Landolph performed postdoctoral study in chemical carcinogenesis and chemically induced morphological and neoplastic cell transformation and mutagenesis at the USC/Norris Comprehensive Cancer Center at the University of Southern California under the late Professor Charles Heidelberger from 1977-1980. Dr. Landolph was appointed Assistant Professor of Pathology in 1980, and Associate Professor of Microbiology, Pathology, and Toxicology at USC in 1987. Dr. Landolph has served as a grant reviewer for the U. S. E. P. A. Health Effects Panel, for special RFAs for the N. I. E. H. S., and as an ad hoc member for the Chemical Pathology Study Section and the AI-Tox-4 Study Section of the N.I. H. Dr. Landolph has also been a member of the Carcinogen Identification Committee reporting to the Scientific Advisory Committee of the Office of Environmental Health Hazard Assessment of the California Environmental Protection Agency from 1994-2002. He is the recipient of numerous awards, including the Merck Award in Chemistry and the Superior Cadet Award in ROTC from Drexel University in 1971, the Edmundson Teaching Award in the Dept. of Pathology at USC in 1985, a Traveling Lectureship Award from the U. S. Society of Toxicology in 1990, and a competitive American Cancer Society Postdoctoral Fellowship from 1977-1979. Dr. Landolph receives funding from the Nickel Producers Environmental Research Association (NiPERA), from the National Cancer Institute, National Institutes of Health, from the National Institute of Allergy and Infectious Diseases, National Institutes of Health, and from the Office of Environmental Health Hazard Assessment of the Environmental Protection Agency of the State of California.

Dr. Landolph's research interests and activities include studies of the genetic toxicology and carcinogenicity of carcinogenic insoluble nickel compounds, carcinogenic chromium compounds, carcinogenic arsenic compounds, and carcinogenic polycyclic aromatic hydrocarbons. His laboratory is focused on studying the ability of these carcinogens to induce morphological and neoplastic transformation of C3H/10T1/2 mouse embryo cells and the cellular and molecular biology of the transformation process. His laboratory is currently studying the ability of carcinogenic nickel compounds to induce activation of expression of

oncogenes and inactivation of expression of tumor suppressor genes in cells transformed by insoluble carcinogenic nickel compounds, such as nickel subsulfide, crystalline nickel monosulfide, and green (high temperature) and black (low temperature) nickel oxides. His laboratory is also studying the molecular biology of chromium compound-induced cell transformation and the role of valence in cell transformation by various chromium-containing compounds. Dr. Landolph is an expert in chemically induced morphological and neoplastic transformation and chemically induced mutation in murine and human fibroblasts. He is the author of 32 peer-reviewed scientific publications, 21 book chapters/review articles, and has held peer-reviewed research grant support from the U. S. E. P. A., the U. S. National Cancer Institute, and the U. S. Institute of Environmental Health Sciences.

Dr. David L. Sedlak: Dr. David L. Sedlak is Associate Professor of Civil and Environmental Engineering at the University of California, Berkeley. Dr. Sedlak received his B.S. degree in Environmental Science from Cornell University in 1986. He received his Ph.D. degree in Water Chemistry from the University of Wisconsin in Madison in 1992 and served as a postdoctoral researcher at the Swiss Federal Institute for Environmental Science and Technology (EAWAG) from 1992 to 1994. He has received several notable awards including the NSF CAREER Award in 1997, the Hellman Family Faculty Award in 1996 and the American Chemical Society Graduate Student Award in 1991. His areas of research interest include analytical methods for measuring organic compounds in water, fate of chemical contaminants in water recycling systems, metal speciation and its effect on metal uptake and reaction, environmental photochemistry and ecological engineering. David Sedlak receives research funding from federal (i.e., National Science Foundation) and state (i.e., University of California Water Resources Program, University of California Toxic Substances Research and Teaching Program) programs. He also receives funding from a private foundation (i.e., National Water Research Institute) and several water industry sponsored foundations (i.e., American Water Works Association Research Foundation, Water Environment Research Foundation and WaterReuse Foundation)

Dr. Philip C. Singer: Dr. Philip C. Singer is the Dan Okun Professor of Environmental Engineering in the Department of Environmental Sciences and Engineering in the School of Public Health at the University of North Carolina at Chapel Hill. He directed the Water Resources Engineering Program at UNC for 19 years and currently directs UNC's Drinking Water Research Center. He has conducted research on chemical aspects of water and wastewater treatment and on aquatic chemistry for the past 35 years, and has published more than 160 papers and reports in these areas. For the past 27 years, Dr. Singer's research has focused on the formation and control of disinfection by-products in drinking water. In 1993, Dr. Singer was selected for the Freese Lecture by the American Society of Civil Engineers, in 1995 he was given the A.P. Black Research Award by the American Water Works Association, and in 1999 he received the Fuller Award from the North Carolina section of the American Water Works Association.

Dr. Singer has been active in the American Water Works Association, serving as a past Chair and Trustee of the Research Division, and has served on the Research Advisory Council of the American Water Works Association Research Foundation. He was on the editorial board of

Ozone Science and Engineering and is a past associate editor of Environmental Science and Technology. He was a member of the Water Science and Technology Board of the National Research Council, and served on the National Research Council's Committee on Drinking Water Contaminants. He is currently on the Board of Directors of the Water Environment Research Foundation and the U.S. Environmental Protection Agency Science Advisory Board's Drinking Water Committee. In 1995, Dr. Singer was inducted into the National Academy of Engineering.

Dr. Laura Steinberg: Dr. Steinberg is Associate Professor in the Civil and Environmental Engineering Department of Tulane University. She holds a B.S.E. in Civil and Urban Engineering from the University of Pennsylvania and an M.S. and Ph.D. in Environmental Engineering from Duke University. Her research currently focuses on water quality modeling and natural hazards management. She has recently completed modeling studies of arsenic concentrations in water distribution systems and transport processes in contaminated sediments, and is working on spatial statistical modeling of heavy metals and PCB's in contaminated sediments. During the last two years, she has spent several months in Turkey, investigating the impacts of the devastating earthquake of 1999 on industrial infrastructure and the environment, and evaluating the effectiveness of chemical risk management procedures. Dr. Steinberg is the incoming chair of the American Society of Civil Engineer's National Environmental Policy Committee, and a past member of the ASCE's National Water Policy Committee. She serves on the Water Environment Federation's Disinfection Committee, and is a fellow of the Institute of Civil Infrastructure Systems and a former member of the Chapel Hill, NC Planning Board. She has consulted to the USEPA's Science Advisory Board on technology diffusion, and the Department of Energy on risk assessment. Prior to her work in academia, Dr. Steinberg was Environmental Engineering Department Head at the planning and engineering firm of Louis Berger International, and Business Development Manager at Geraghty and Miller, an environmental engineering firm. She also had the distinct honor of serving as a US Congressional Page while attending high school.

Ms. Susan Teefy: Susan Teefy currently serves on the staff of the Water Quality and Treatment Solutions, Inc. Susan formerly served as the Operations Engineer for the Alameda County Water District in Fremont California. Since 1992, she has worked with this public water agency to ensure compliance with drinking water regulations, and analyze and optimize plant operations. She has held positions of increasing authority with the District, including Manager of the Water Production Division, which is responsible for the operation and maintenance of three water treatment plants and the distribution system. Ms. Teefy has also supervised ACWD's Environmental Engineering section, where she developed and implemented water quality monitoring programs and conducted plant optimization studies. Her particular interest is surface water treatment (particulate removal processes) and ozone disinfection. Prior to working with the Alameda County Water District, she worked at the East Bay Municipal Utility District in Oakland California, providing technical support for surface water treatment plant operations. Ms. Teefy also worked for the U.S. Environmental Protection Agency, Region 9, in San Francisco where she managed the drinking water program on Indian Lands in California.

Ms. Teefy has a bachelor's degree in civil engineering from the University of California at Berkeley, and a master's degree in environmental engineering from the University of North

Carolina at Chapel Hill. She is a registered civil engineer in the state of California, and a licensed water treatment plant operator (Grade 5, highest level). In 1985 she was awarded USEPA's Bronze Medal for outstanding service for significantly improving compliance with drinking water regulations on California Indian Lands. In 1989 she was the first recipient of the AWWA Larson Aquatic Research Support (LARS) Scholarship. In 1991 she received AWWA's Academic Achievement award for her Master's thesis. She has chaired AWWA's California Nevada Section Research Committee, and currently is a member of AWWA's national coagulation and filtration committee. Ms. Teefy has been a Project Advisory Committee member on several projects funded by the AWWA Research Foundation, and a peer-reviewer for the Journal of AWWA. She has served on AWWARF's Unsolicited Proposal Review Committee, as well as AWWARF and EPA-convened Expert Panels regarding water treatment issues. She has given numerous presentations at international AWWA and International Ozone Association conferences

Dr. Gary A. Toranzos: Gary A. Toranzos is a professor of microbiology in the Department of Biology, University of Puerto Rico, Rio Piedras Campus. He got his Ph.D. in 1985 at the University of Arizona in Tucson. His research interests are varied and include water microbiology, the ecology of enteric pathogens and the development of indicators of risk. He has published extensively on all the above subjects and is currently working on projects dealing with bacterial nitrification and denitrification in soils, as well as development of new indicators of biological contamination in waters. Dr. Gary A. Toranzos receives funding from NASA to study nitrifying and denitrifying microbial communities in tropical soils. He also has funding from the USGS (Water Resources Center, University of the U.S. Virgin Islands) to study the microbial water quality of bathing beaches in Puerto Rico and St. Thomas, U.S.V.I.

He is currently working at the National Science Foundation as a Program Director in the Division of Molecular and Cellular Biosciences.

He is an elected member of the American Academy of Microbiology, a Fellow of the American Association for the Advancement of Science and is serving a term as member of the Technical Advisory Board of the Water Environment Research Foundation

Dr. Rhodes Trussell: Dr. R. Rhodes Trussell is Director of the Water Knowledge Center and Senior Vice President at MWH, Inc. He has served in that Role since September 2001. For several years prior to that he served as the firm's Director of Corporate Development and as a member of the firm's Board of Directors. The bulk of Dr. Trussell's technical career has been spent advising municipal utilities, both in the US and abroad, concerning problems of drinking water quality and treatment. Dr. Trussell is active in American Water Works Association and in the International Water Association where he serves on the program committee, the Strategic Council and the editorial board for North America. He also serves on the Water Science and Technology Board for the National Resource Council where he has served on several specific Committees, most recently those on potable reuse, the CCL, and indicators for pathogens in water. Dr. Trussell serves on the Magazine Board for Environmental Science and Technology, as a member of the Industrial Advisory Board for Engineering program at UC Riverside and as Chair of the Industrial Advisory Board for the Department of Civil Engineering at UCLA. Dr.

Trussell received his B.S.(1966), M.S.(1967), and Ph.D.(1972) in Environmental Engineering from the University of California at Berkeley. He was elected to the National Academy of Engineering in 1995 and serves on the Peer Committee for Civil Engineering. He is currently the Chair of the SAB's Drinking Water Committee.

For the past 30+ years, Dr. Trussell has worked for MWH, Inc. and is solely funded by the corporation. During the past year he as worked directly on projects for the city of Portland Oregon, for the East Bay Municipal Water District, for Hong Kong, the City of San Diego, the City of Long Beach, the Metropolitan Water district of Southern California, and the Los Angeles Department of Water and Power.