

Development of Health Outcome Based Measures Drinking Water Program Activities

Overview and Charge

April 2, 2008

Briefing for the SAB



Outline of Presentation

- **Background**
- **Measure Development Process and Consultations**
- **Model-Based Measures**
 - **Bladder cancer**
 - *Cryptosporidiosis*
- **Charge Questions**
- **Summary**

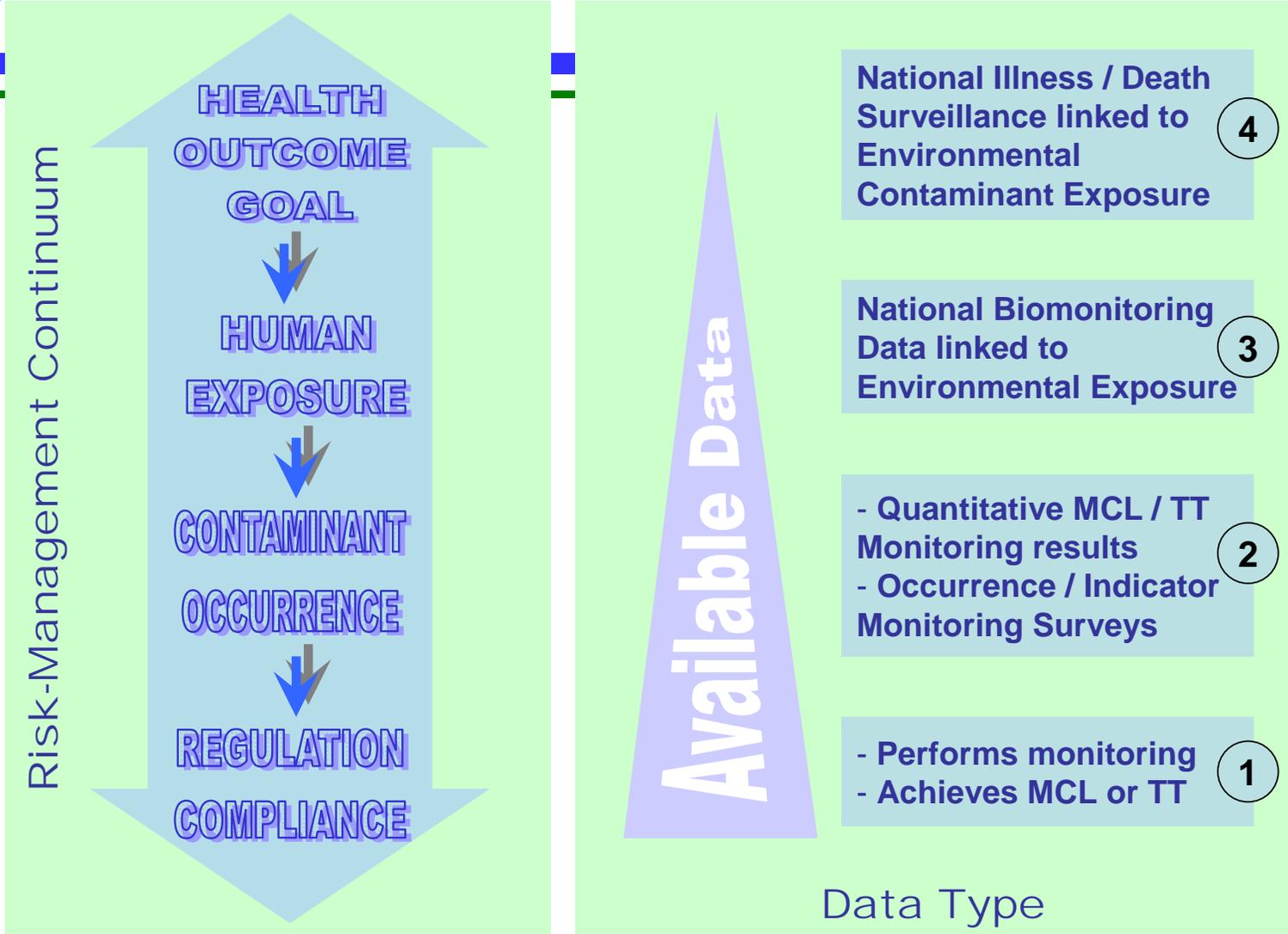


Background

- **Current program measure based on compliance with DW standards**
 - *Subobjective 2.1.1 Percentage of population served by community water systems that receive drinking water that meets all applicable health-based drinking water standards through effective treatment and source water protection.*

- **Develop a health outcome-based program measure to demonstrate the performance of the drinking water program**
 - **Improve the data available to support using this measure in future Agency Strategic Plans**

- **Goal: By May 2008 develop two health-outcome based measure for inclusion into the 2009-2014 strategic plan**
 - **Develop Measure language, baseline metric and out-year target metric**





Measure Development Process and Consultations

- **EPA developed a framework to develop two new health-outcome based measures**
 - **Microbial Measure**
 - **Chemical Measure**

- **Framework identified several issues and potential approaches to include in the 2009-2014 Strategic Plan**
 - **Bladder Cancer associated with DBP exposure**
 - **Cryptosporidiosis**
 - **Bladder cancer and other cancers associated with Arsenic**
 - **National Waterborne Disease Estimate**
 - **Data needs for measure evaluation**



Measure Development Process and Consultations- NDWAC

- **NDWAC Drinking Water Measures & Indicators Subgroup**
 - Formed to provide input to Agency on developing program measures
- **EPA received Subgroup review of concepts and approaches proposed in framework**
 - Subgroup reviewed an EPA-developed White Paper that refined our measure approach: Fall of 2007
 - Subgroup report to Full NDWAC with recommendations from review - November 2007
 - Full NDWAC approval in January 2008
- **NDWAC recommends:**
 - Including prototype strategic targets in 2009-2014 Strategic plan for:
 - 1) Chemical (Bladder cancer associated with DBPs)
 - 2) Microbial (Crypto)
 - Work with others, including NDWAC, in developing and implementing measures methodologies and to collect data



Measure Development Process and Consultations

- **OMB Consultations**
 - **Measure Development & Implementation Plan (MDIP) for Microbial Drinking Water Regulations to OMB in Sept. 2004**
 - **OW submitted “OMB Report on Drinking Water Performance Measures” on 02/22/07**
 - **Briefed OMB March 17, 2008**

- **EPA has developed a Final Measures Document based on the Framework and NDWAC input for SAB review**
 - **Measures Language**
 - **Model, Inputs & Uncertainty**
 - **Measures Baseline Metrics (shown as range)**
 - **Measures Out-year Targets (shown as range)**
 - **Methodology for populating Out-Year Metrics**

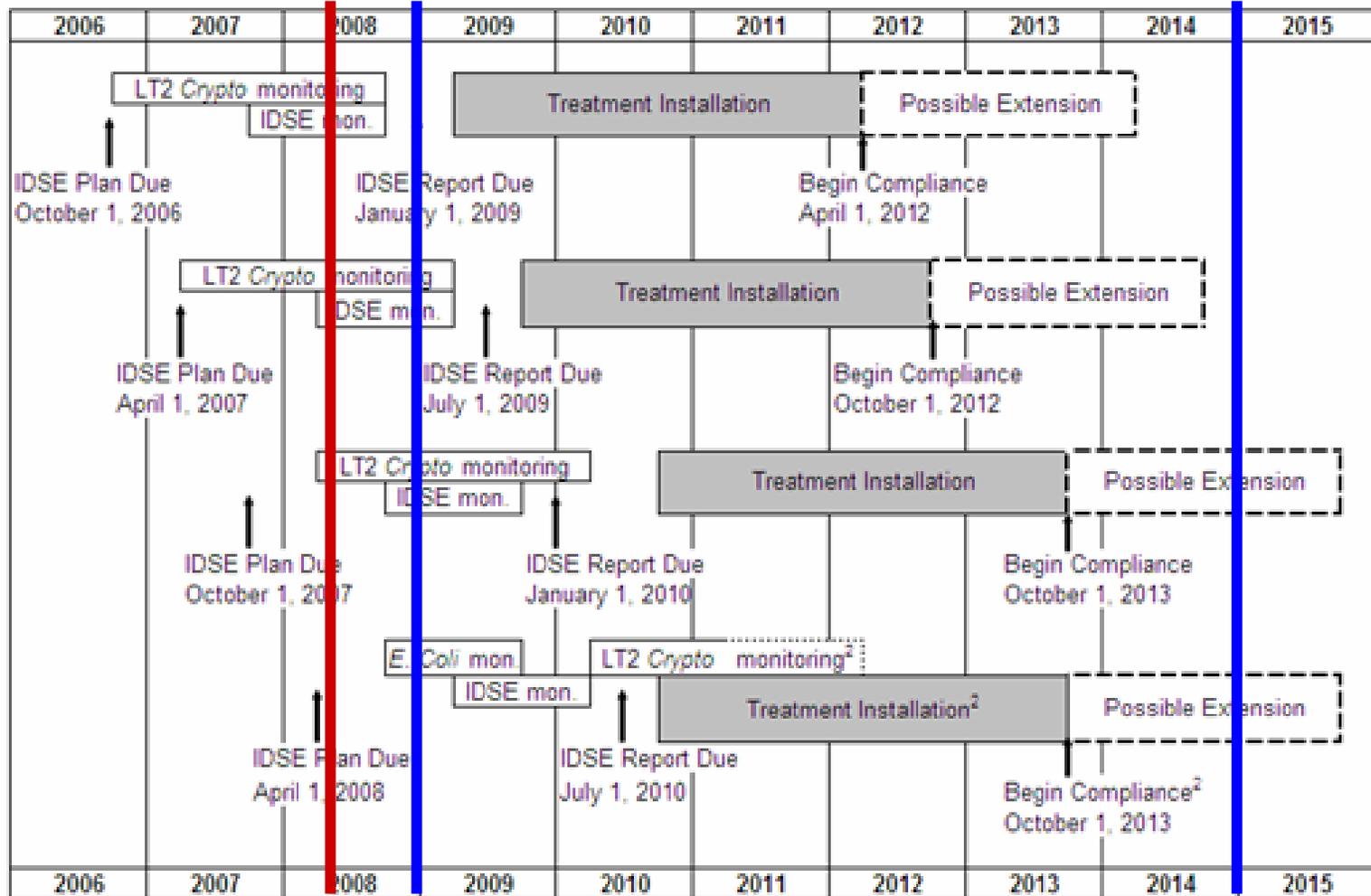


Bladder Cancer Measure Overview – Stage 1 & 2 DBP Rules

- **Stage 1 Disinfectants/Disinfection Byproducts (DBP) Rule**
 - Purpose- Reduce potential cancer from disinfection byproducts (DBPs) in drinking water
 - Requires systems that disinfect to meet MCLs as a system-wide running annual average for total trihalomethanes (TTHM) and five haloacetic acids (HAA5)
- **Stage 2 DBP Rule**
 - Purpose- Reduce potential cancer and reproductive and developmental health risks from disinfection byproducts (DBPs) in drinking water
 - Builds on Stage 1 DBP Rule by requiring systems that disinfect to meet MCLs as an average at each compliance monitoring location for TTHM and HAA5
 - **Initial Distribution System Evaluation (IDSE) requirement**
 - one-time studies to identify distribution system locations with high TTHMs and HAAs
 - IDSE results and Stage 1 DBPR compliance monitoring data will be used to select compliance monitoring locations for Stage 2 DBPR



Compliance Schedule for Stage 2 and LT2



¹ Includes systems that are part of a combined distribution system in which the largest system serves this population.

² Subpart H systems serving fewer than 10,000 that must conduct Crypto monitoring have an additional 12 months to comply with Stage 2 DBPR MCLs.



Measures Overview – Bladder Cancer

- **Health-Based Measure: *Avoided bladder cancer cases attributable to the national reduction of average concentration of TTHMs observed resulting from the implementation of the Stage 1 and Stage 2 Disinfectant and Disinfection Byproduct (DBP) Rules***

- **Three basic steps to this health based measure**
 - **1) Establish a pre-Stage 1 baseline estimate of the number of bladder cancer cases attributable to drinking water***

 - **2) Estimate a target estimate of annual cancer cases to be avoided due to implementation of the Stage 1 and Stage 2 rules***

 - **3) In 2014, evaluate estimate**

***Steps 1 & 2 use methodologies in the Stage 2 Economic Analysis**



1) Pre-Stage 1 Estimate

- **Baseline Assumptions: TTHM Concentrations (from Stage 2 EA)**
 - Population-weighted national TTHM average for Pre-Stage 1 was ~ 38 ug/L

- **Baseline Assumptions: Attributable Annual Bladder Cancers**
 - Baseline number of annual cases of bladder cancer from all causes was estimated to be 56,500 for 2003.

 - The population attributable risk for DBPs from Villanueva et al. (2003) was 15.7%.

 - Applying this population attributable risk to the 56,500 cases from all causes results in an estimate of ~ 8,900 annual bladder cancer cases attributable to DBPs.



2) Target Estimate of Avoided Cases

- **Changes in Attributable Bladder Cancer Cases with Changes in TTHM Average as used in the EA**
 - **Use a simple linear relationship between changes in the national average TTHM concentrations and changes in the annual cases of bladder cancer attributable to DBPs.**
 - **For example: 10% reduction in TTHM concentration implies a 10% reduction in bladder cancer cases attributable to DBPs**
 - **Consider cessation lag in developing a predicted range of attributable bladder cancer cases that are avoided (as done in Stage 2 EA)**
 - **The 2014 target estimate of annual avoided bladder cancer cases attributable to DBPs range from 1,380 to 2,480, with a 95% CI of 460 to 4,460**



3) 2014 Measure - Evaluation of Estimate

➤ Performance Measure Data Needs

- EPA will need to work with states to obtain access to the monitoring data collected by the states during the period up to ~2012 to use for the 2014 performance measure
- Will use occurrence data and compare to target estimate (Step 2) of avoided cases attributable to national reduction of average TTHM concentrations
 - Consideration of IDSE and compliance schedule

➤ Presentation of Uncertainty in Performance Measure Estimates

- EPA will include an uncertainty range for both the target estimated in 2008 and the final performance measure in 2014 and will describe the components of uncertainty.



4) Additional Measure Analyses

➤ Cumulative Bladder Cancer Cases Avoided

- In addition to evaluating the target estimate focused on bladder cancer cases avoided in 2014 specifically, EPA will also develop two sets of estimates addressing cumulative bladder cancer cases avoided.
 - Cumulative estimate of bladder cancer cases avoided from the promulgation of the Stage 1 Rule through the year 2014.
 - Cumulative cases avoided through the year 2025, reflecting a 20-year implementation period from the promulgation of the Stage 2 Rule.
- These cumulative estimates will also account for the effect of cessation lag and will include consideration of other contributions to uncertainty
- Estimate through 2014 = 8,500 to 17,300 (95% CI: 2,800 to 31,200)
- Estimate through 2025 = 28,200 to 47,400 (95% CI: 9,300 to 85,200)

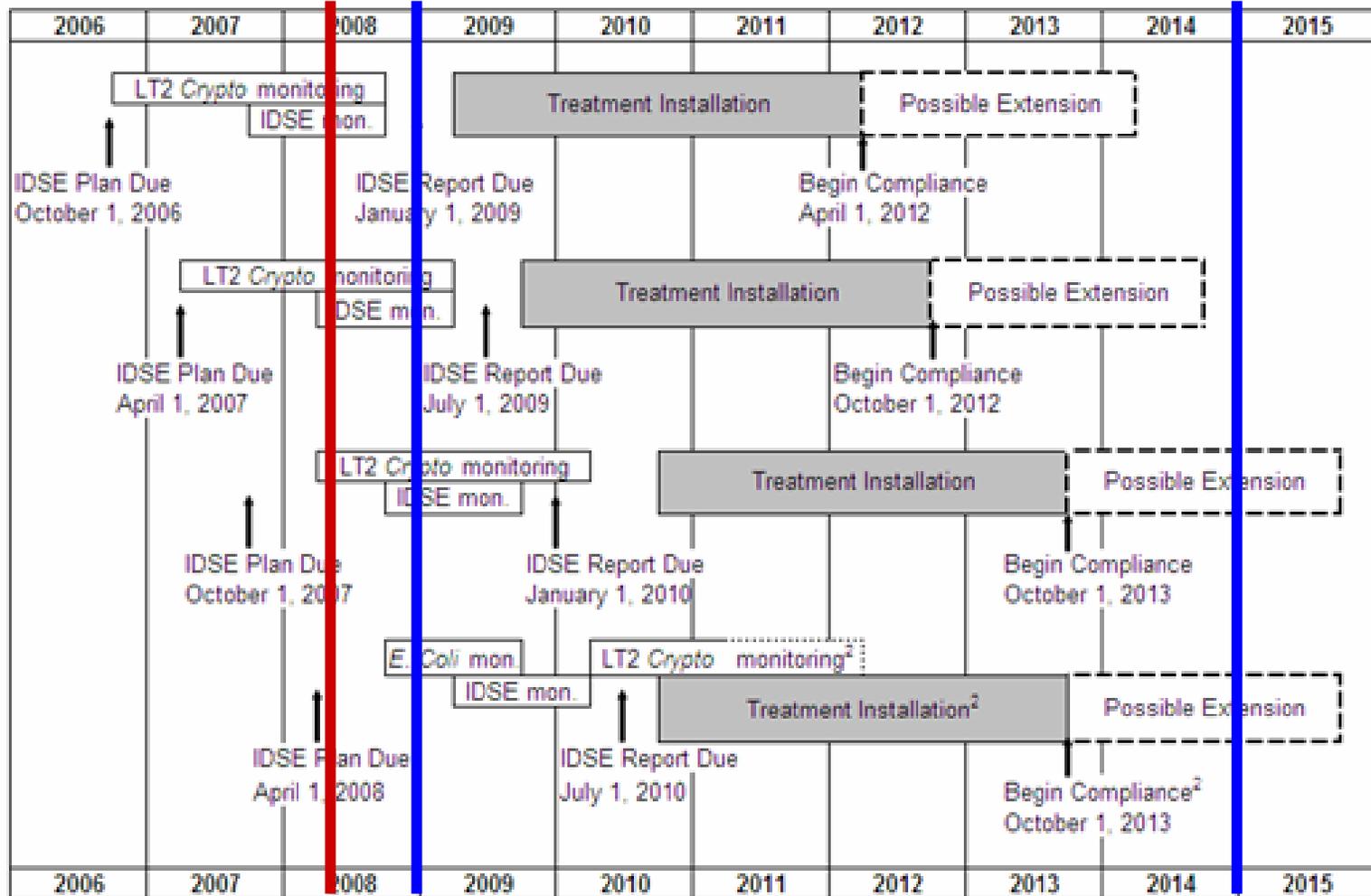


Cryptosporidiosis Measure Overview – LT2 ESWTR

- **Long Term 2 Enhanced Surface Water Treatment Rule (LT2)**
 - **Purpose-- Improve public health protection through control of microbial contaminants, focusing on PWSs with elevated *Cryptosporidium* levels**
 - **Requires systems to:**
 - **Monitor source water**
 - **Calculate an average *Cryptosporidium* concentration**
 - **Use *Crypto* results to determine source vulnerability (Bin classification)**
 - **Additional treatment may be required based on Bin classification**
 - **Cover finished water storage facilities**
 - **Second round of source water monitoring in six years**



Compliance Schedule for Stage 2 and LT2



¹ Includes systems that are part of a combined distribution system in which the largest system serves this population.

² Subpart H systems serving fewer than 10,000 that must conduct Crypto monitoring have an additional 12 months to comply with Stage 2 DBPR MCLs.



Measures Overview – Crypto

- **Health-Based Measure: *Annual cases avoided nationally of endemic Cryptosporidiosis illnesses attributable to implementation of the Long Term 2 Enhanced Surface Water Treatment Rule***
- **Three basic steps to this health based measure**
 - **1) Estimate pre-LT2 cryptosporidium cases from exposures using the concepts from the LT 2 Rule Economic Analysis (EA)**
 - **2) Estimate a target number of cases avoided based on available monitoring and LT2 EA data**
 - **3) In 2014, using additional monitoring data and the LT2 EA analysis, Evaluate how well the rules are achieving this estimate**



LT2 EA Model

- **National Source Water Cryptosporidium Occurrence = 3 Baselines**
 - Information Collection Rule (ICR) data
 - ICR Supplemental Survey (ICRSS) data – Large Systems
 - ICRSS data – Medium Systems

- **Occurrence of *Cryptosporidium* in source water for individual plants can vary from one year to the next, and the national distribution of the annual average across all plants will also vary over time**

- **Potential to add a fourth occurrence baseline from available LT2 source water compliance monitoring data**
 - EPA is in the process of analyzing the fourth baseline



LT2 EA Model (cont'd)

- **Pre-LT2 Treatment In-Place**
- **LT2 Bin Classifications Based on Source Water Occurrence**
- **Post-LT2 Treatment and Cryptosporidium Reductions**
- **Finished Water Cryptosporidium Occurrence**
- **Dose-Response Model – Quantified Annual Avoided Illnesses**
 - same assumptions used in the LT2 EA: *Cryptosporidium* oocyst viability, infectivity, morbidity and secondary spread



1) Pre-LT2 Baseline *Cryptosporidiosis* Cases

➤ **Baseline Assumptions**

- **Occurrence: see slide 18**
- **Pre-LT 2 Treatment Effectiveness**
 - **Unfiltered Systems: No removal of Crypto**
 - **Filtered Systems:**
 - **Small: 2 to 4 log-- most likely 3- log removal**
 - **Large: 2 to 5 log--- most likely 3.25-log removal**

➤ **Baseline Cases:**

- **294,000 to 993,000* (95% CI of 45,000 to 2.4 M*)**

*Combined across the three EA occurrence baselines (will be shown in a table instead with each baseline as a separate row)



2) Estimate 2014 Target Cases Avoided

- **LT2 Treatment Changes → Finished Water Occurrence**
 - **Depends on Monitoring Results and Bin Classification**
 - **Unfiltered systems- 2 log or 3 log removal depending upon their source water monitoring results and the rule requirements.**
 - **Filtered systems- some systems add treatment to achieve an additional 1 log to 2.5 log removal**



2) Estimate 2014 Target Cases Avoided (cont'd)

➤ Estimating Annual Endemic Illnesses Avoided

- same dose-response models and assumptions as used in the LT2 EA: *Cryptosporidium* oocyst viability, infectivity, morbidity and secondary spread
- Estimates of the range of cases avoided will be made separately for the four occurrence baselines.
- The 2014 target estimate of annual avoided endemic cases of Cryptosporidiosis range from 231,000 to 964,000*, with a 95% confidence interval of 37,000 to 2.3 M* *Combined across the three EA occurrence baselines (will be shown in a table instead with each baseline as a separate row)



3) 2014 - Evaluation of Target Estimate

- **Presentation of Performance Measure for 2014**
 - Because of the expected year-to-year variability in source water occurrence, we will continue to use the four occurrence estimates.
 - Use only compliance monitoring data for bin classification/treatment changes

- **Presentation of Uncertainty in Performance Measure Estimates**
 - EPA will include an uncertainty range for both the 2014 target estimated in 2008, and the actual measure in 2014 and will describe the components of uncertainty



4) Additional Measure Analyses

➤ Cumulative Cases of Cryptosporidiosis Avoided

- In addition to evaluating the target estimate focused on Cryptosporidiosis cases avoided in 2014 specifically, EPA will also develop two sets of estimates addressing cumulative cases avoided.
 - Cumulative estimates of endemic cases of Cryptosporidiosis avoided from the promulgation of the LT2 Rule through the year 2014
 - Cumulative cases avoided through the year 2025, reflecting a 20-year implementation period from the promulgation of the LT2 Rule
- These cumulative estimates will also include the four occurrence data sets and other contributions to uncertainty
- Estimate range through 2014 = 0.9 M to 3.8 M* (95%CI 0.1 M to 9 M*)
- Estimate range through 2025 = 3.4 M to 14.4 M* (95%CI 0.6 M to 34 M*)
 - *Combined across the three EA occurrence baselines (will be shown in a table instead)



Charge Questions

- 1. Does the discussion provide the reader with a balanced understanding of the measure's value in assessing program results?**
- 2. Please Identify other data sources besides state compliance data that EPA can draw on for the 2014 analysis**
- 3. Cumulative vs. annual measure: Please comment on which of these metrics might serve as a better indicator of public health outcomes and include the basis for the section**

Please identify issues for further research that could support development of other measure approaches, as well as any future program measures that the Agency should consider developing



Summary – Next Steps

- **Incorporate SAB comments into the Measures Document (April 2008)**
- **Final Measures Document (by mid-May 2008)**
- **Beyond May 2008**
 - Further data gathering efforts
 - In 2014, did we meet our target?
 - Future metrics



Appendices

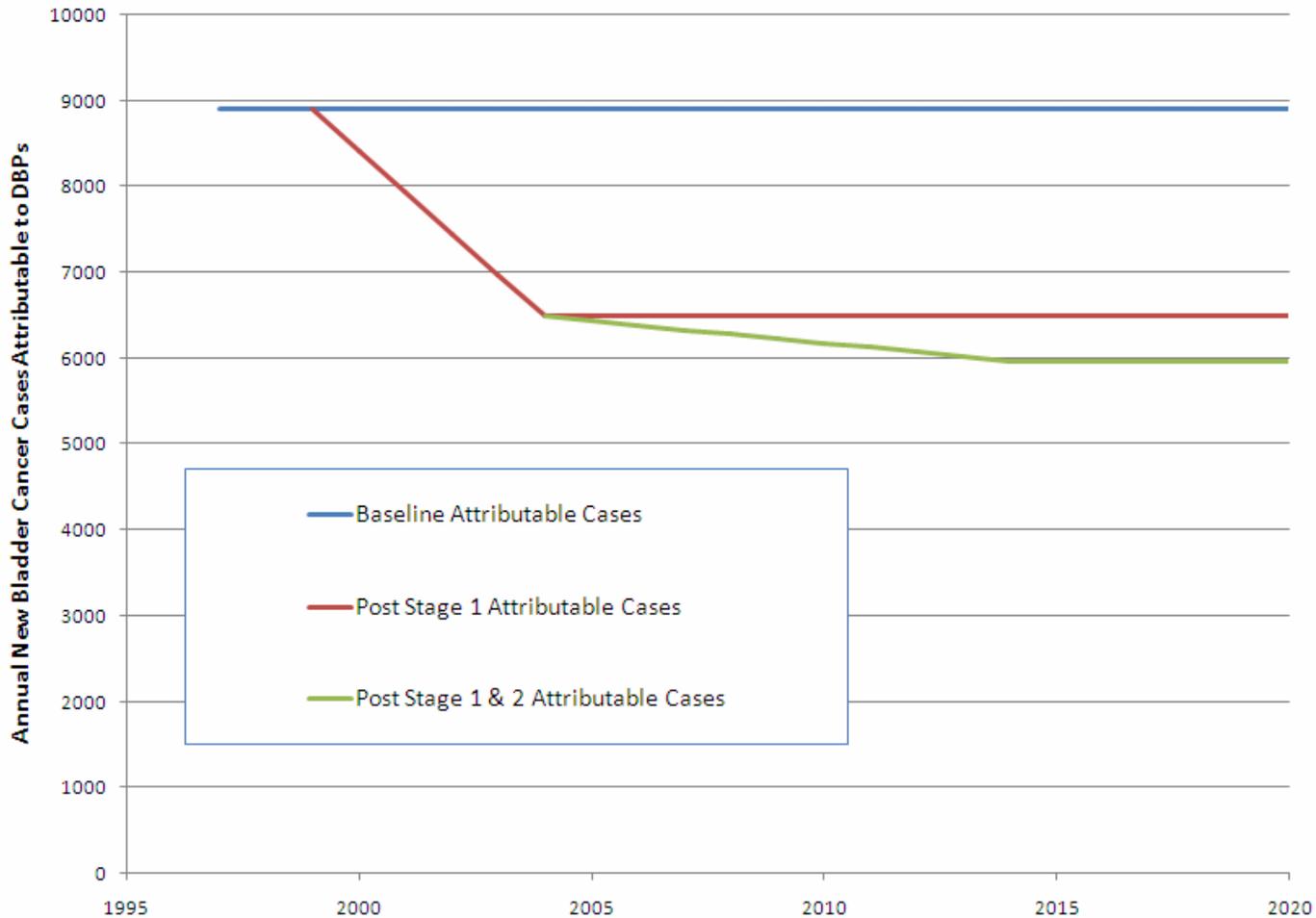


Appendix – DBP Measure

- **The main components where uncertainty are discussed in the Stage 2 EA that will be included in the DBP Measure are in:**
 - **The PAR value**
 - **The reduction in national average TTHM concentrations (reflecting uncertainty in both the Pre-Stage 1 average and the Post-Stage 2 average)**
 - **The consideration of cessation lag**
 - **Incomplete information regarding treatment changes in progress**

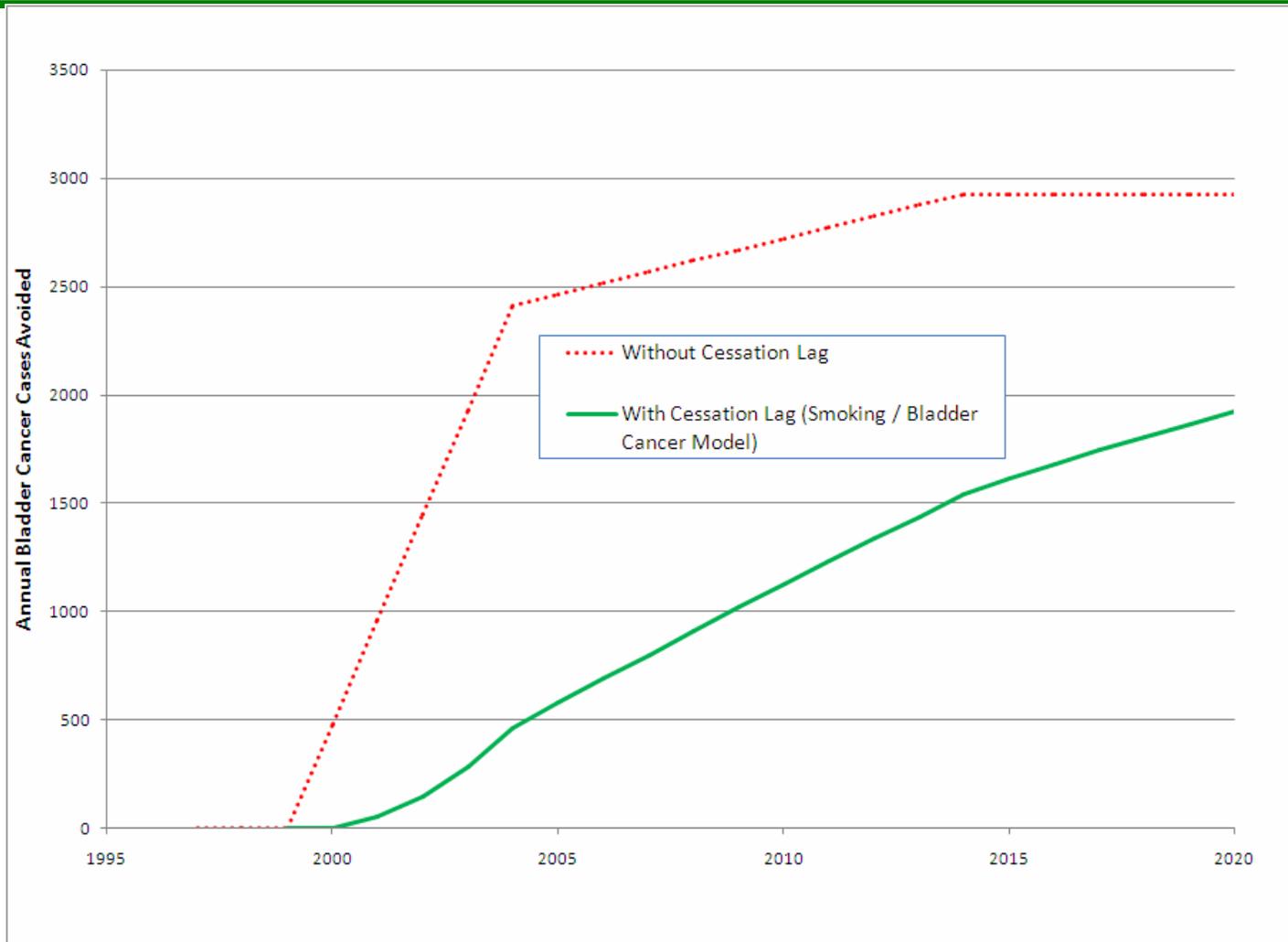


Changes in Attributable Bladder Cancer Cases with Changes in TTHM Average





Annual Bladder Cancer Cases Avoided - With & Without Cessation Lag Included



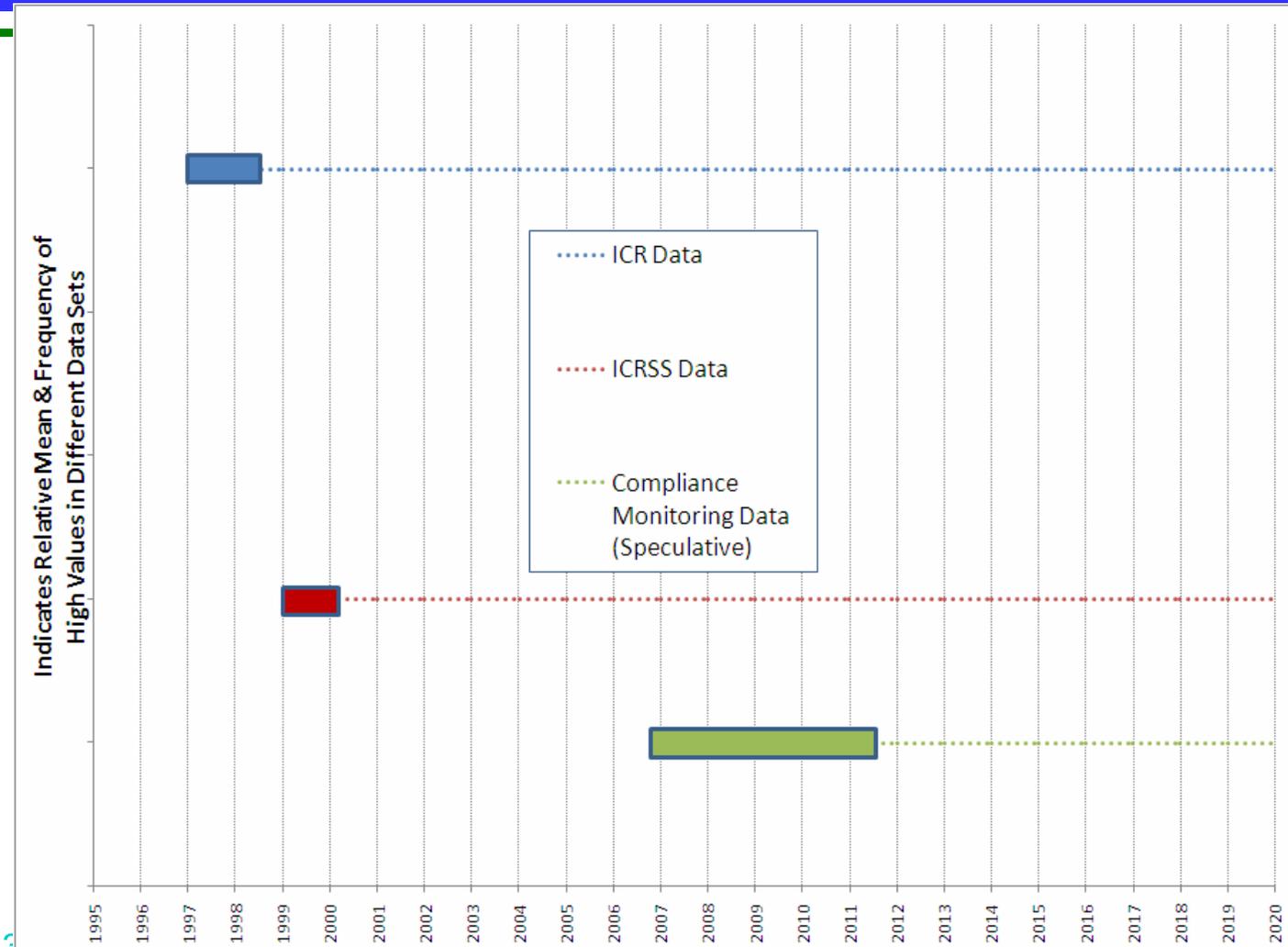


Appendix – Microbial Measure

- **The main components where uncertainty are discussed in the LT2 EA and will be included in the Measure are in:**
 - **The alternative source water occurrence data sets reflecting year to year variability (and therefore uncertainty with respect to a “typical” year).**
 - **Uncertainty factors used in the EA for the existing treatment effectiveness distributions and for the dose-response relationships.**
 - **Uncertainty related to incomplete information regarding treatment changes in progress and implemented as a result of bin classifications**

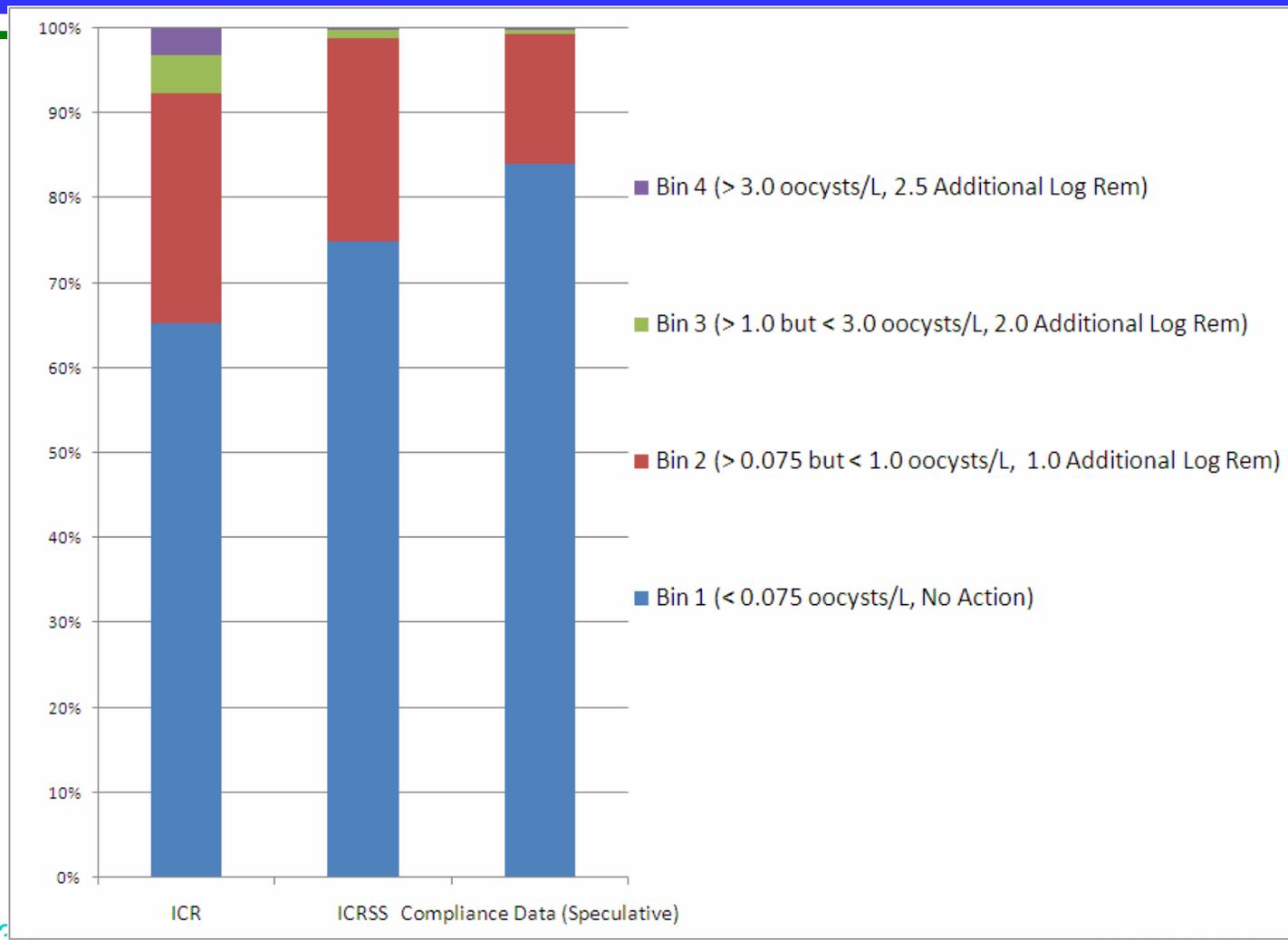


Key Inputs: *Cryptosporidium* Source Water Occurrence





LT2 Predicted “Binning” for Filtered Systems





Appendix - Collaboration with CDC & ORD

- **OGWDW collaboration with ORD and CDC to Improve Outbreak Surveillance**
 - **Goal: improve outbreak recognition, investigation and reporting**
 - **Convert from paper to electronic outbreak reporting system (2008)**
 - **EPA/CDC/Council of State & Territorial Epidemiologists (CSTE) Outbreak Workshops (2007)**
 - **EHS-Net Drinking Water Pilot – Goal is improved state surveillance capacity & investigation of outbreak environmental causes**
 - Began as foodborne outbreak program –now expanding to water
 - CDC funded 1st Drinking Water applicant site in 2006 (5 year program)
 - OGWDW 2nd Water pilot site beginning in 2006
 - Additional 3 sites received funding beginning in 2007
- **CDC Technical Advisor to NDWAC & TCR DS FAC**



Collaboration with CDC & ORD (continued)

- **EPA/CDC MOU on Environmental Public Health Tracking (EPHT)**
 - **OEI & ORD lead partners with CDC/NCEH**
 - OW participation in MOU meetings
 - **Emphasis on noninfectious disease data integration across health, human exposure and hazard IT systems**
 - **First round 5-Year Grants completed- Phase I to develop model systems linking data**
 - OW participation in NY State Grantee Advisory Panel
 - **Phase II began in – Built on work of on Phase I grants -**
 - **Various media content workgroups identified indicators to be tracked by EPHT grantees**
 - OGWDW participates on Water Content Workgroup
 - **Currently developing data standards and specifications for implementing National EPHT Networks for indicators**



ORD Collaborations

- **OGWDW Collaboration on ORD Microbial Risk and Indicator Research**
 - **Accountability Study-**
 - Drinking water community intervention study
 - Salivary antibody prevalence, reported GI illness & changes related to CWS Treatment Changes
 - **STAR 2003 Grants- Microbial Risk- 3 Epi Studies funded to generate data to indicate attributable risk in drinking water**
 - **EPA/CDC/CSTE Waterborne Disease Workshops-** to improve infrastructure for outbreak reporting
 - **National Estimate Research Summary Report-** summarizes research on microbial exposures in drinking water and health effects



National Estimate: SDWA Framework

- **SDWA 1458 (d) WATERBORNE DISEASE OCCURRENCE STUDY.-(1) SYSTEM.—The Director of the Centers for Disease Control and Prevention, and the Administrator shall jointly –**
 - (A) within 2 years after the date of enactment of this section, **conduct pilot waterborne disease occurrence studies** for at least 5 major United States communities or public water systems; and
 - (B) within 5 years after the date of enactment of this section, **prepare a report on the findings of the pilot studies, and a national estimate of waterborne disease occurrence.”**



EPA/CDC National Estimate Activities

- **EPA and CDC have been working collaboratively on the Studies and approaches to the National Estimate**
- **National Estimate Research Summary Report**
 - Published in *Journal of Water & Health* Supplement in July 2006
 - Summarizes research on microbial exposure in drinking water and effects
 - Includes OGWDW article on National Estimate analysis and approach



OGWDW National Estimate Analysis

- **Analysis presents approach and estimate of GI illness (AGI) attributable to drinking water for US CWSs**
- **OGWDW developed approach over two years**
 - Agency workgroup review Oct-Nov 2005
 - External Reviews: Peer Review & ORD Report Review
- **Analysis Results (Messner et al):**
 - Mean incidence of AGI due to drinking water:
0.06 cases per person/year (0.02, 0.12 95% CI)
 - Translation of estimate for 272.5 M persons served by CWSs
 - **16.4 million annual cases of AGI cases due to drinking water**
 - **196 million annual cases of AGI due to all causes**
- **Based on available data- considerable limitations in water quality data, AGI incidence, and data linking water quality, treatment and AGI data**