



Use of Microbiological Testing and Microbiological Criteria by the U.S. Environmental Protection Agency

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Concerns About Microbiological Contamination of Surface Waters

- Water can be recipient of, or source of many different microbial contaminants
- Water contamination events may be minor or catastrophic in size.
- Contamination is often driven by meteorological events or breakdowns in pollution control
- Human exposure can arise from direct contact or consumption of microbial pathogens
- Many Pathogens of food are also concerns for water media

Clean Water Act (CWA) Goals for Protection of Human Health – A Major Focus in Water

- CWA requires waters of the U.S., when feasible, to be safe for designated purposes such as drinking, recreation, & fishing (shell & fin fish)
- EPA prepares human health (& ecological) protective criteria as guidance for the various uses based upon sound science
- States & tribes utilize the criteria to develop enforceable standards to protect the uses designated for their waters – EPA approval
- States & tribes monitor & report to EPA when the quality of a designated water use is impaired

Use of Microbiological Testing for Criteria

- Testing typically for fecal indicators, except known pathogen challenges, e.g., those causing serious disease or resistant to treatment and environmental influence (*Cryptosporidium*)
- Why not regularly test for pathogens in water:
 - Hundreds to monitor
 - Sporadic occurrence
 - Usually at very low levels requiring large samples and concentration
 - Often require sophisticated/expensive equipment and technical support

Use of Microbiological Testing for Criteria

(cont)

- Sampling approaches:
 - Grab samples; composite samples; timed samples; sample grids; event samples
- Statistical approaches to produce numerical criteria:
 - Geometric or arithmetic means; 95%tiles; quartiles, bins
- Exceedence of numeric standards is actionable:
 - resample; public notification; closing or restricting water's use; additional treatment/disinfection; upstream mitigation

Current Uses of CWA 304(a) Ambient Water Quality Criteria (AWQC) for Microorganisms

- Provide numerical limits of indicator organisms considered appropriate for water use – linked to an allowable level of infectious disease
- Allow numerical determination for whether a water body meets its intended use over the short term and over time (e.g. seasons)
- Provides listing of water bodies not meeting use
- Provides total maximum daily loads (TMDLs) for pollution sources contaminating water uses – allocate & reduce pollutant levels from sources

Basis of Current AWQC for microbial contamination of water uses

- Significant Focus on enteric infectious diseases & associated fecal contamination indicators in waters of U.S. – Risk Based
- Provide health protection against specific infectious disease endpoints, e.g., acute gastrointestinal illness (AGI) or specific diseases such as typhoid fever or cholera (shellfish)
- Requires water monitoring to determine if water use is protected – currently consider only one use or type of exposure to water.

Current Recreational AWQC - 1986

- Based on AGI & correlations with indicators: *E. coli* for fresh water or enterococcus (subgroup of fecal strep.)
- Fresh water Criteria - 126 *E. coli* or 33 enterococci/100ml sample
 - AGI risk is 8/1000 swimmers/day
- Marine Water Criteria - 35 enterococci/100ml sample
 - AGI risk is 19/1000 swimmers/day
- Recognize skin, URT, eye, ear infections, but no health criteria: correlation to sewage contributions is not definitive.
- Beach Rule in 2004 to get State compliance.

Current AWQC – Shellfish Harvesting Waters

- Established many decades ago to protect against typhoid fever & cholera “Outbreaks” from raw or partially cooked shellfish consumption
- Sample 100ml total (TC) or fecal (FC) coliforms by MPN to characterize acceptability of water overlying commercial shellfish beds for criteria
 - Criteria: Approved - 14 FC; 70 TC: <10% samples exceed
 - Conditionally Approved; Restricted; Conditionally Restricted – sanitary surveys, treatment plant performance, monitoring, can allow relaying or depuration for shellfish harvest
 - Prohibited waters– contamination too great for use other than shellfish seed stock

New Microbiological 304(a) AWQC Efforts for Water Protection

- Need consistent approach to setting criteria – now developing Human Health Microbial AWQC Methodology as guideline for Criteria Setting
- Office of Water Strategy for Water Quality Stds & Criteria; also GPRA goal 2.1
 - Establish new/revised Recreational Criteria – BEACH Act of 2000
 - Establish Cryptosporidium Drinking Source Water Criteria
 - Establish improved Shellfish Growing water Criteria
 - Establish Integrated (across use) Criteria

New 304(a) AWQC Human Health Methodology (HHM) for Criteria Guidance

- Developing HHM jointly with comprehensive EPA Microbial Risk Assessment (MRA) protocol
- Focuses on exposure and human health components of EPA's draft MRA protocol
- Provides applications for single & multiple water use criteria development
- Considers unique aspects of microbial contaminants, environmental exposures, and human dose response
- Applies a number of features in common with current chemical HHM for AWQC

Features Being Incorporated into HHM

- Capable of application to age groups and sensitive subpopulations
- Can apply static and dynamic immunity models
- Can apply a number of dose response models
- Will allow partitioning of relative source contributions for water use applications
- Provides exposure assessment modeling
- Guidance for single and multiple water uses
- Will seek to harmonize within Agency & others

New Recreational AWQC Development Approach – BEACH Act of 2000 Requirements

- Evaluate rapid non-cultural methods for the fecal indicator enterococci - validate during water sampling in swimmer health studies
- Conduct human health epidemiology study – characterize AGI and other illnesses at multiple beaches
- Develop & apply multi-point grid sampling system to characterize water quality during epidemiology study
- Statistically evaluate data base on AGI incidence against enterococci levels in waters during exposures

New Proposed Recreational AWQC Features

- Provide capability for rapid (same day) determination of pollution level at beaches - <2hr of analysis for enterococci
- Establish multi-location or composite sampling protocol to characterize overall water quality
- Improve health risk estimations thru improved epidemiology protocol
- Potential additional features:
 - Criteria may focus on children risks, if excessive
 - Consider secondary infection multiplier for estimate of total risk
 - Target sampling for when & where exposure is likely

New Safe Drinking Water Act Regulation for Drinking Water - *Cryptosporidium* oocysts

- EPA plans to promulgate Long Term 2 Enhanced Surface Water Treatment rule by end of 2005
- Targets *Cryptosporidium* treatment to provide safe drinking water in distribution system
- Utilities will sample water at intakes over 24 mo. Period to determine ave. *Cryptosporidium* levels.
- *Cryptosporidium* at/or < 0.075 oocysts/L at intake can be effectively removed for health protection by conventional water treatment - "bin 1"
- Higher oocyst levels require additional treatment

AWQC for *Cryptosporidium* in Drinking Source Waters

- A follow-on to Long Term Two Enhanced Surface Water Treatment Rule for drinking water
 - Criteria will be for water treatment plant intakes
 - Health protection calculations would consider drinking water treatment capabilities
- States would monitor source water to insure long term quality – don't want new challenges to existing treatment capabilities – high costs for add-on treatment
- Water would only be sampled periodically because of high analysis costs for *Cryptosporidium*
 - typically can't sample pollution events for short term excursions – would need rapid, inexpensive indicators to implement this provision

AWQC for *Cryptosporidium* in Drinking Source Waters

- *Cryptosporidium* Risk Assessment in Progress:
 - Evaluate 6 *C. hominis* and *parvum* isolates dose response from human feeding studies
 - Evaluate different water consumption levels & periods.
- New Criteria will consider use of “bin” levels for *Cryptosporidium* as is applied for LT2ESWTR
- EPA Method 1623 will be used for Criteria setting – measures all oocysts (species and dead or alive) - a conservative measurement.

AWQC – Enhancements to Protection of Water for the Future

- Integrated multi-use criteria approaches
- Development of tool box of fecal indicators (NAS Study debunks single magic indicator) or use specific pathogen analysis – focus on molecular analysis techniques, e.g., micro-arrays
- Application of animal models for establishing dose response and human health implications
- Establish Drinking Source Water Criteria for *Giardia* and enteric viruses (targeted)
- Iterative improvements to HHM and risk assessment protocols