

US EPA ARCHIVE DOCUMENT

EPA's Timeline for Development of New or Revised Recreational Water Quality Criteria

Lisa Christ
Office of Science and
Technology
USEPA



EPA's 1986 Bacteria Criteria

- EPA's 1986 recommended water quality criteria are for indicator organisms
 - Indicators are not generally pathogenic themselves
- Pathogens are disease-causing microorganisms that include viruses, protozoa, and bacteria
- Monitoring for the many illness-causing pathogens is difficult and costly
- *E. coli* and Enterococci are EPA's current indicators

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EPA's 1986 Bacteria Criteria

Risk Level (% of swimmers)	Geometric Mean Density (per 100 mL)	Single Sample Maximum Allowable Density (per 100 mL)			
		75 th percentile	82 nd percentile	90 th percentile	95 th percentile
Enterococci for Marine Water					
1.9	35	104	158	276	501
E. Coli for Freshwater*					
0.8	126	236	299	409	576

*EPA also has recommended enterococci for freshwater. Although few states have adopted those values and allows criteria values up to a 1% risk level in freshwater

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The Use of EPA's Recommended Criteria

- The criteria are used in two different, yet related ways:
 - Protection of public health in water bodies designated for swimming and similar water contact activities in state and tribal WQS
 - Used to derive permit limits, make listing decisions, and develop TMDLs
 - Beach monitoring and notification programs
 - Protect public health at monitored beaches
 - Aid in determining when to issue advisories or close beaches

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The BEACH Act 2000

- Beaches Environmental & Coastal Health (BEACH) Act was signed into law October 2000
- The Act amended the Clean Water Act by adding sections:
 - 303(i): Water Quality Standards
 - 104(v): Studies
 - 304(a)(9): New Criteria
 - 406: Grants

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The BEACH Act 2000

- Required states to adopt water quality criteria for *E. coli* and Enterococci by April 10, 2004.
 - EPA promulgated regulations for 21 remaining states in November 2004
- Required EPA to conduct certain studies
 - Assess potential risks from pathogen exposure
 - Develop appropriate indicators of pathogens presence in a timely manner
 - Develop 304(a) criteria/guidance
- Required EPA to publish new or revised criteria based on these studies and review every 5 years.

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Lawsuit Filed Against EPA

- EPA was sued in 2006 by NRDC, NACWA, and the Los Angeles County and LA County Flood Control District for not meeting deadlines to complete studies and publish new or revised recreational water quality criteria.

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Experts Scientific Workshop

- **Preparation:**
 - Oct 2006: Nomination of experts by stakeholders
 - Dec 2006: Workshop to develop charge to experts
- **Workshop:**
 - March 2007 at Arlie House
 - 43 U.S. and international experts
 - Assess state of the science and identify critical path research and science needs for next 2-3 years to develop scientific foundation for new or revised criteria
- **Report:**
 - June 2007
 - Identified the following critical path research areas as high priority:
 - Human health effects from different sources of fecal contamination
 - Measurement issues – climatic, geographic and temporal variability
 - Determining risk level and subpopulation of concern
 - Indicators and methods for measuring fecal contamination
- Experts Scientific Workshop report (June 2007) available at:
<http://www.epa.gov/waterscience/criteria/recreation/experts/index.html>

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Critical Path Science Plan (CPSP)

- Based on input from experts
- Describes critical research and science to be conducted by EPA to establish the scientific foundation for new or revised criteria
 - Includes over 30 studies/projects
 - Released August 2007
- Key research questions:
 - What is the risk to human health from swimming in water contaminated with human fecal matter as compared to swimming in water contaminated with non-human fecal matter?
 - How well do culture and molecular methods for various indicators (singly or in combination) correlate with swimming-related illness?
 - Are there indicators, methods and models suitable for use in different types of waters and for different CWA programs?

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Stakeholder Meeting

- Held February 20, 2008, Washington, DC
- Update stakeholders on activities since the December 2006 meeting
- Share EPA's Critical Path Science Plan and report on progress
- Obtain stakeholder input on:
 - research directions for inland waters;
 - desired attributes of new criteria; and
 - how best to engage stakeholders during Critical Path Science Plan implementation and criteria development through 2012

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Settlement of Lawsuit

- August 2008
 - Consent Decree
 - Settlement Agreement

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Studies & Activities EPA is Obligated to Complete - Consent Decree

- Requires EPA to publish new or revised Section 304(a)(9) water quality criteria recommendations by October 15, 2012.
- Requires EPA to complete the following studies by December 15, 2010
 - (a) an epidemiological study in marine waters impacted by urban runoff in a temperate region, and
 - (b) an epidemiological study in a tropical region

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Studies & Activities EPA is Obligated to Complete – Settlement Agreement

EPA agrees to complete the following studies by December 15, 2010:

- Rhode Island and Alabama epi studies (P1, P2)
- Support SCCWRP in Avalon study (P3)
- Conduct Ag animal QMRA (freshwater) (P4)
- Performance of QPCR signal (fate & transport) (P8)
- Design & evaluate monitoring approach (P12)
- Evaluate multiple indicator/method combos to develop quantifiable relationships (P15)
- Sample holding time/preservation (P16)
- Develop, refine, validate, publish one or more new ambient test methods (P17a)
- Develop, refine, validate, publish one or more new wastewater test methods, provided results of P8 and P18 indicate need (P17b)
- Evaluate the suitability of individual combos of indicators and methods for different CWA purposes (P18)

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Studies & Activities EPA is Obligated to Complete – Settlement Agreement

EPA agrees to complete the following studies by December 15, 2010:

- Re-analyze archived NEEAR samples using molecular methods for other indicators, provided samples have not degraded per outcome of P16 (P22)
- Pilot test Virtual Beach (P23)
- Refine and validate existing models for freshwater beaches (P24)
- Refine and validate other existing models for marine beaches (P25)
- Develop technical protocol for site-specific application of predictive models (P26)
- Compare 1986 recommendations to NEEAR studies, provided we can obtain raw data used to develop 1986 criteria (P27)
- Evaluate applicability of NEEAR Great Lakes data to inland waters (P28)
- Conduct statistical analysis of children data from epi studies (P29)

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Important Definitions from Settlement Agreement

- **Complete or Completed** – when modifying any form of the word “study” means EPA has (a) concluded its work related to the project identified in the Settlement Agreement including, as deemed necessary by EPA, internal and/or external peer review and addressing comments from such peer reviews and (b) provided written notice to the Plaintiff and Intervenor
- **External Peer Review** – either peer review conducted by EPA using independent, external peer reviewers, or peer review conducted by a professional journal.
- **Rapid Test Method** – a method for testing the water quality of coastal recreation waters for which results are available as soon as practicable after a water quality sample is received by the testing facility. NRDC believes “as soon as practicable” to be 2 hours and EPA believes it to be no more than 6 hours.

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CPSP Projects NOT in Consent Decree or Settlement Agreement

- Contingency POTW impacted beach epi study (P6)
- Data components for QMRA (P7)
- Prep for ag animal QMRA (P9)
- Expand data collection at epi study locations to support modeling and QMRA (P10)
- Prep for urban runoff epi study (P11)
- Develop quantitative sanitary investigation protocol (P13)
- Pilot sanitary survey in Great Lakes (complete) (P14)
- Human and bovine genetic markers (P19, 20, 21)
- Literature reviews (complete) (P30-32)

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Other Agreements in Settlement Agreement

EPA epi studies

- EPA will use a suite of indicators and methods that EPA determines to be the most promising for the development of new or revised criteria.

Epidemiological Studies by Other Entities

- If an epidemiological study proposed by SCCWRP for Doheny Beach is initiated no later than December 2009, EPA will provide technical assistance on study design and analysis.
- EPA will review epidemiological studies conducted by others and consider them in developing the criteria if results are made available by December 2010.

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Other Agreements in Settlement Agreement (cont.)

Method Validation

- Validate and publish a rapid test method for the new or revised criteria by October 15, 2012.
 - Note: "Publication" does not include promulgation of an EPA-approved method in the CFR.

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Other Agreements in Settlement Agreement (cont.)

Avian Research

- Continue to conduct research currently underway to identify genetic sequences that could form the basis of chicken and seagull specific source assays, and if EPA is able to develop those assays, EPA would also evaluate them for specificity and sensitivity.
- Convene an Experts Scientific Workshop no later than December 15, 2011 on what future science and research might be conducted to further improve the understanding of potential human health risks from exposure to fecal contamination from avian wildlife and other wildlife in coastal recreation waters.

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Other Agreements in Settlement Agreement (cont.)

Providing Data

- Provide access to data from the studies conducted under the SA and the CD after QA/QC and, as deemed necessary by EPA, internal or external peer review, including addressing comments of such review.
- By June 15, 2009, provide data from epidemiology studies previously conducted by EPA (e.g., Great Lakes NEEAR studies).

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Other Agreements in Settlement Agreement (cont.)

Stakeholder Meetings

- Hold Stakeholder Workshops in 2009, 2010, and 2011.
 - 2009 and 2010 workshops will focus on updating stakeholders on progress and framing issues associated with criteria development and to obtain comments on EPA's update.
 - 2011 workshop will focus on providing opportunity to stakeholders to comment on EPA's evaluation, synthesis, summarization and statistical analysis of studies and development of options for overall structure and content of the new/revised criteria.

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Inland Waters Experts Workshop

- February 18-20, 2009, Dallas/Ft. Worth, TX
- Workshop organized by WERF and supported by EPA
- 28 scientific experts from academia, government, private sector and NGOs invited
- Experts charge:
 - assess current state of knowledge similarities/differences between inland and Great Lakes and coastal waters with regard to pathogens
 - Identify knowledge gaps and research priorities for development of recreational WQ criteria
- Workshop report available at: www.werf.org

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Research Forum

- April 23, 2009 meeting to provide an opportunity for EPA and external researchers to meet face-to-face.
- Intended to initiate a dialogue among scientists conducting research on topics related to beach water quality and associated bather health risks.
- Break out sessions in the topic areas of:
 - Sampling and analysis methods (e.g., pathogens, indicators and MST)
 - Source to receptor modeling and relationships (e.g., QMRA modeling)
 - Compliance monitoring and predictive modeling
 - Characterizing risks (e.g., epidemiology)

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Next Steps: 2010 to 2012

- Hold Stakeholder Meeting in 2010
- Complete all research in CD and SA by December 15, 2010
- Hold Stakeholder Meeting in 2011

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Next Steps: 2010 to 2012

- Target date for Proposed Criteria – Early 2012
 - Publish in the Federal Register
 - Public comment period
- Address/respond to public comments
- Revise criteria accordingly
- Sign for publication final criteria recommendation – October 15, 2012

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Questions ?

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