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REPORT OF THE EXPERTS SCIENTIFIC WORKSHOP ON CRITICAL RESEARCH NEEDS FOR THE DEVELOPMENT OF NEW OR REVISED RECREATIONAL WATER QUALITY CRITERIA

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CHAPTER 1
APPROACHES TO CRITERIA DEVELOPMENT

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1.1 Benchmarks for Criteria Development

The workgroup was charged with answering 21 questions and providing a range of alternatives for the development of new or revised national recreational ambient water quality criteria (AWQC; see Section 1.5 for summary response). The following six potential approaches that could be used or adapted for an approach to develop new or revised criteria were initially discussed: (1) EPA's 1986 approach, (2) World Health Organization (WHO), (3) European Union (EU), (4) Hazard Analysis and Critical Point Analysis (HAACP), (5) Heal the Bay's Beach Report Card, and (6) EPA's Air Quality Index. The workgroup members concentrated the discussions on the three approaches that were deemed most appropriate for consideration in the context of Clean Water Act (CWA) Section 304(a) ambient water quality criteria (AWQC), namely, the WHO approach (with possible modifications), the EU approach (adopted 2006), and a modified version of EPA's 1986 criteria. Before the workgroup defined the approaches and determined the potential application of the three alternative approaches, workgroup members agreed that it was critical to identify desirable attributes or benchmarks for the criteria. The benchmarks or attributes that were identified are summarized below.

1. The criteria are health-based. The workgroup demonstrated a preference that the criteria be as directly as possible anchored to health effects demonstrated in epidemiology studies.
2. The criteria should demonstrate utility for and be compatible with all of the CWA §304(a) criteria (as amended by the Beaches Environmental Assessment and Coastal Health Act of 2000 [BEACH Act]) needs, including water quality assessment for public notification at beaches in a timely manner, assessment for impaired waters listings, development of total maximum daily load (TMDL) development and implementation, and development of National Pollution Discharge Elimination System (NPDES) permits.
3. The criteria should be scientifically defensible for application in a wide variety of geographical locations (climatic conditions), including fresh and marine waters, and temperate, subtropical, and tropical waters.
4. The criteria be sufficiently robust and flexible so that they can be configured to protect the public health of those exposed to recreational water impacted by sewage effluent, concentrated animal feed operation (CAFO) contaminated runoff, non-point sources (e.g., agriculture [non-CAFO], urban runoff) and waters not impacted by anthropogenic sources.
5. The criteria should be sufficiently robust and flexible so that they can be configured to provide regulators the ability to protect susceptible (sensitive) subpopulations such as children and immunocompromised individuals. Commonality was found among workgroup members that protecting the health of children was of paramount concern.
6. The criteria are associated (linked) with analytical methods that are reliable, robust, and provide reproducible results.
7. The criteria should protect primary contact recreation in freshwaters, marine waters, temperate, subtropical, and tropical waters equally. Similarly, the criteria should provide equal protection those exposed to effluent, urban runoff, and/or non-point source runoff impacted waters via primary contact recreation.

The workgroup members agreed that all seven of the above attributes are critical considerations for criteria development. In assessing the potential application of each of the proposed alternatives, it is important to keep in mind that criteria applied to these alternatives are assumed to be consistent with all of the above attributes (or at least most of them) before the final frameworks and criteria are developed. The likelihood that some of these attributes will not be met in the near-term seems to make the WHO or EU approaches more suitable for implementation.

The workgroup expressed the opinion that EPA should release the new or revised criteria and implementation guidance concurrently to provide clarity to States on how the criteria should be used for regulatory and public notification needs.

1.2 Integration of Workshop Components

A summary of the interactions between the various subject areas addressed in this workshop is presented in Figure 3. In Figure 3 shaded boxes correspond to the seven workgroups. The alternatives boxes in Figure 3 refer to various possible indicators that a toolbox approach could provide for each of the CWA applications. Briefly, the Pathogen/Pathogen Indicator workgroup proposes indicators that may have utility for criteria development (see Chapter 2). In doing so, they consulted with the Methods Development workgroup members (see Chapter 3) to assure that validated methods are or could be available and usable for the implementation of the proposed parameter. Different methods have different specificities for identifying whether the source of fecal contamination is human- or animal-based. The Comparing Risks workgroup provided information on the relative risks to human health from different sources of fecal contamination (Chapter 4). Once identified, the pathogen/pathogen indicator and the associated method are used during the criteria development process. Another critical component in the criteria development process is the identification of a risk level. Information from the Acceptable Risk workgroup (see Chapter 5) on how to develop "acceptable risk" thresholds is used in this context during the criteria development process. The Modeling workgroup discussed how predictive modeling can be used to inform criteria approaches and to provide information on water quality notification (Chapter 6). Once these pieces were integrated, an initial check was conducted against the suggestions and concerns of the Implementation Realities workgroup (see Chapter 7) members to help ensure that the potential for criteria development does not conflict with actual "on the ground" implementation.

As discussed in the Introduction to these proceedings, recreational AWQC are used for a number of purposes. First, these criteria are used to make assessment determinations under CWA §305(b) and §303(d).[2] Within this regard and depending on the framework, a number of alternate indicators or methods may be used to assist in making the determination as to the overall quality of a waterbody and the compliance with the underlying criteria. Second, these criteria are used to determine permit limits for NPDES permit holders and for TMDL purposes. Finally, these criteria are used to determine the acceptability of the water for direct primary contact recreation. Conceptually, alternative indicators, including models, could also be used for these purposes.

[2] http://www.epa.gov/owow/tmdl/tmdl0103/

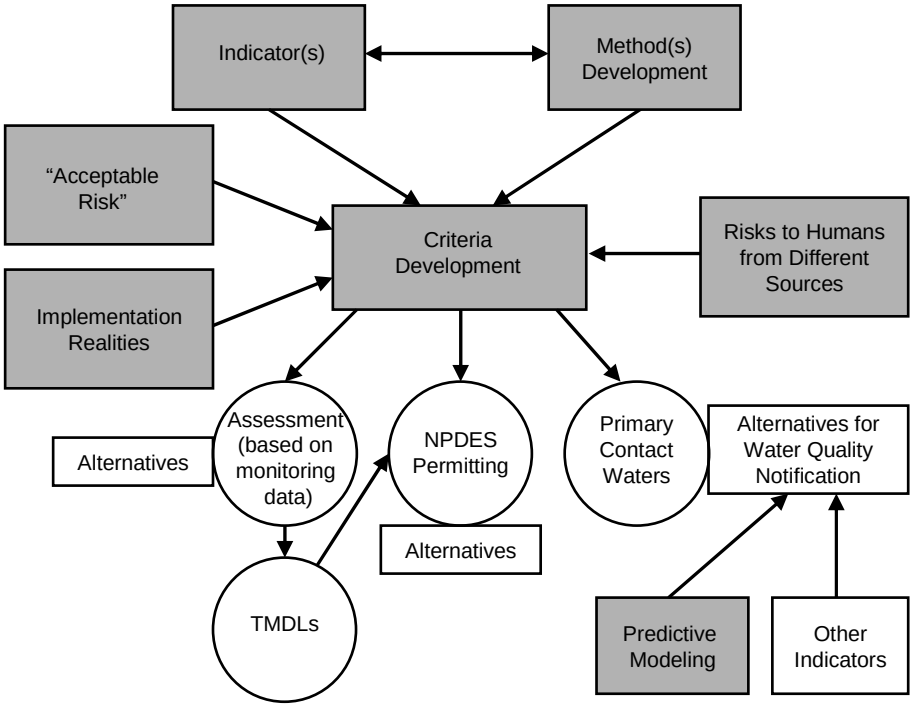

Figure 3. Flow Diagram of How the Workgroup Topics Contribute to the Development and Implementation of New or Revised Recreational Water Quality Criteria.

1.3 Summary of Currently Available Water Quality Criteria Setting Approaches

The three alternatives that were identified by the workgroup were a modified WHO approach, the EU approach, and a modified version of the EPA 1986 approach because all of these approaches are largely based on peer reviewed epidemiology studies and some version of each of these frameworks are in use currently in at least one country.

Workgroup members generally agreed that all three criteria development approaches are feasible providing the criteria meet the becnhmarl/attributes listed above. Although the workgroup briefly discussed other approaches such as the EPA's Air Quality Index, HAACP, and Heal the Bay's Beach Report Card approaches, none of these approaches were deemed to be appropriate for the desired purposes for a variety of reasons, including lack of applicability for criteria development.

1.3.1 WHO Approach for Water Quality Criteria Setting

The WHO has been concerned with health issues associated with recreational water environments for many years and has published several influential reports that represent a well accepted view among international experts (Prüss, 1998). The WHO approach provides a basis

for standard setting in light of local and regional circumstances, such as the nature and seriousness of local endemic illness, exposure patterns, and competing health risks that are not associated with recreational water exposure.

The WHO approach is based on the perspective that recreational water quality and protection of public health are best described by a combination of sanitary inspection and microbial water quality assessments (the WHO [2003] Guidelines use enterococci as the fecal indicator of choice; see Table 1). This approach considers possible sources of pollution in a recreational water ("sanitary inspection category" in Table 1), as well as observed levels of fecal pollution ("microbial water quality assessment category" in Table 1), and combines them into a five-level classification scheme for recreational water environments. To date, the classification system has been used primarily to "grade" recreational waters and to provide an assessment for regulatory compliance purposes. This approach however, also could be adapted for other CWA §304(a) applications such as NPDES permitting and TMDL development.

The microbial water quality assessment criteria are based on a banded system, where the band divisions are equivalent to a risk of acquiring gastrointestinal (GI) illness for (A) <1 case in 100 exposures, (B) <1 case in 20 exposures, (C) <1 case in 10 exposures, and (D) >1 case in 10 exposures. The 95th percentile value was selected as an appropriate descriptor of the microbial probability density function because it is easily understood to be the probability of encountering

Table 1. WHO Classification Matrix for Integrating Microbial Water Quality as Measured by Enterococci Density with Sanitary Inspection Category.

		Microbial Water Quality Assessment Category (95th percentile intestinal enterococci/100 ml)				
		A ≤40	**B** 41–200	**C** 201–500	**D** >500	**Exceptional circumstances**
Sanitary Inspection Category (susceptibility to faecal influence)	**Very low**	Very good	Very good	Follow up[1]	Follow up[1]	Action
	Low	Very good	Good	Fair	Follow up[1]	
	Moderate	Good[2]	Good	Fair	Poor	
	High	Good[2]	Fair[2]	Poor	Very poor	
	Very high	Follow up[2]	Fair[2]	Poor	Very poor	
	Exceptional circumstances	Action				

Notes:

[1] implies non-sewage sources of faecal indicators (e.g., livestock), and this should be verified (section 4.6.2).

[2] indicates possible discontinuous/sporadic contamination (often driven by events such as rainfall). This is most commonly associated with Combined Sewer Overflow (CSO) presence. These results should be investigated further and initial follow-up should include verification of sanitary inspection category and ensuring samples recorded include "event" periods. Confirm analytical results. Review possible analytical errors (see section 4.6.2).

[3] In certain circumstances, there may be a risk of transmission of pathogens associated with more severe health effects through recreational water use. The human health risk depends greatly upon specific (often local) circumstances. Public health authorities should be engaged in the identification and interpretation of such conditions (section 4.6.5).

[4] Exceptional circumstances (see section 4.6.5) relate to known periods of higher risk, such as during an outbreak with a pathogen that may be waterborne, sewer rupture in the recreational water catchment, etc. Under such circumstances, the classification matrix may not fairly represent risk/safety.

SOURCE: WHO, 2003.

polluted water and focuses on water quality that is likely to cause illness (i.e., greater probability of illness associated with increasing density of human sources of fecal pollution). The WHO levels of risk for the bands described above were selected based on a series of science policy decisions in consultations with numerous international experts and were intended to be reasonable for both the developed and developing world. The expectation in the United States is that the "acceptable risk" (see Chapter 5) levels would be similar or more protective than the risk levels adopted by other developed countries. The methodology used to derive the 2003 WHO Guideline values is summarized in Appendix C.

The sanitary inspection category is intended to classify the risk of illness caused by fecal pollution in a recreational waterbody, although human fecal pollution will tend to drive the overall sanitary inspection category derived for an area. WHO experts believe that the three most important sources of human fecal contamination of recreational water environments for public health purposes are typically sewage, riverine discharges, and direct contamination from bathers. Sanitary inspections are required to address those sources as well as others, and inspections should take on a tiered approach, dependent on the level of perceived risk and its uncertainty. For example, if human and domestic fecal pollution is considered low based on land uses, but fecal indicator counts are relatively high, further exploration of the source(s) and their relative risks would be recommended. This higher level of examination (tier) may utilize more expensive methods and approaches and further cycles (tiers) of investigation as necessary. Based on the results of the sanitary inspections, recreational waters are ranked (from very low to very high) with respect to evidence for the degree of influence of fecal material.

1.3.2 EU Approach for Water Quality Criteria Setting

The EU broadly adopted the 2003 WHO Guidelines in formulating the 2006 Bathing Water Directive. A summary of the European Commission Directive is provided in Appendix D. The approach incorporates the following fundamental elements:

- The EU starts with the WHO risk assessment framework, but does not include the sanitary inspection category information for the purposes of recreational water classification. Instead, it uses only the microbial water quality assessment information to characterize the probability of exposure to human pathogens.
- The EU approach used the WHO microbiological criteria for marine waters and applied the same risk assessment framework to new epidemiological data to derive standards for fresh recreational waters.
- The EU approach allows sample discounting. Under discounting, numeric excursions above the water quality standards that are predicted and/or measured do not count against the waterbody for compliance determination (i.e., such values are discounted from the data set prior to calculation of the 95^{th} percentile, but only 15% of scheduled samples can be so discounted). Sample discounting is allowed when a predictive model, source reduction plan, and communication management system are in place to inform the public about short-term pollution events derived during predictable conditions (e.g., rainfall).

The EU Bathing Water Directive (7/EU/EEC; dated February 15, 2006) is currently being translated by Member States for implementation (EP/CEU, 2006). The Directive establishes

separate numerical microbiological criteria for fresh (inland) and marine (coastal and transitional) bathing waters for the 24 EU Member States (Table 2). The numerical values are based on epidemiological studies reported by Kay et al. (1994) and Wiedenmann et al. (2006)—the former was used by WHO in formulating their Guidelines (Kay et al., 2004; WHO, 2003).

Table 2. Numerical Microbiological Water Quality Assessment Classification for Fresh (Inland) and Marine (Coastal and Transitional) Bathing Waters for the 24 EU Member States.

Inland (Fresh) Waters			
Indicator	Excellent	Good	Sufficient
(Intestinal) enterococci (cfu/100 mL)	200*	400*	360**
E. coli (cfu/100 mL)	500*	1,000*	900**
Coastal and Transitional (Marine) Waters			
Indicator	Excellent	Good	Sufficient
(Intestinal) enterococci (cfu/100 mL)	100*	200*	200**
E. coli (cfu/100 mL)	250*	500*	500**

Notes: * = Based on a 95th percentile evaluation; ** = Based on a 90th percentile evaluation to reduce the risk of statistical anomalies when using a small data set, which also allows lower limit values for enterococci and *E. coli* densities in inland waters to be classified as sufficient versus good microbiological water quality.
Source: Adapted from EP/CEU (2006).

1.3.3 EPA 1986 Water Quality Criteria Setting

In the late 1970s and early 1980s, EPA conducted public health studies evaluating several organisms as possible indicators, including total and fecal coliforms, *E. coli*, and enterococci. The studies showed that enterococci and *E. coli* are the best predictors of GI illness (gastroenteritis) in sewage effluent-impacted freshwaters, while enterococci were the best predictor in sewage-impacted marine waters. Gastroenteritis describes a variety of diseases that affect the GI tract and are rarely life-threatening; self-limiting symptoms include nausea, vomiting, stomachache, diarrhea, headache, and fever. Based on these studies, EPA published a criteria document, *Ambient Water Quality Criteria for Bacteria – 1986*, recommending the use of these bacterial indicators in ambient water quality criteria values for the protection of primary contact recreation (US EPA, 1986). Table 3 summarizes the *Water Quality Standards for Coastal and Great Lakes Recreation Waters Rule* (US EPA, 2004) that requires States and Tribes to adopt the 1986 AWQC for Bacteria.

States and Tribes generally define their designated use of "primary contact recreation" to encompass recreational activities that could be expected to result in the ingestion of, or immersion in, water, such as swimming, water skiing, surfing, or any other recreational activity where ingestion of, or immersion in, the water is likely.

EPA derived standards that implied an acceptable excess illness probability of 0.8% in swimmers exposed in freshwater and 1.9% in swimmers exposed in marine waters. EPA's 1986 bacteria criteria document indicates the illness rates are "only approximate" and that the Agency based the 1986 values that appear in Table 3 on these approximations.

Table 3. Summary of EPA's 1986 Recommended Water Quality Criteria for Bacteria and 2004 Rule

Indicator	Swimming-Associated Gastroenteritis Rate per 1,000 Swimmers	Geometric Mean	Single Sample Maximum Allowable Density			
		Steady State Geometric Mean Indicator Density	Designated Beach Area	Moderate: Full Body Contact Recreation	Lightly Used: Full Body Contact Recreation	Infrequently Used: Full Body Contact Recreation
Freshwater						
Enterococci	8	33	61	78	107	151
E. coli	8	126	235	298	409	575
Marine Water						
Enterococci	19	35	104	158	276	501

Source: US EPA (2004).

EPA's 1986 bacteria AWQC document provides geometric mean densities as well as four different single sample maximum values (representing values below which an increasing percentage of single values are expected to fall if the geometric mean of samples from the waterbody is equal to the geometric mean criteria). The 1986 bacteria AWQC document categorizes the single sample maximum values based levels of beach usage as follows: "designated bathing beach" for the 75% (most conservative) confidence level, "moderate use for bathing" for the 82% confidence level, "light use for bathing" for the 90% confidence level, and "infrequent use for bathing" for the 95% confidence level. The lowest confidence level corresponds to the highest level of protection.

In the 1986 AWQC context, single sample maximum criteria are water quality assessment tools that provide a sense of when the water quality in a waterbody is not consistent with the AWQC. Insights based on single observations are very difficult because of the expected variability of fecal indicators. For instance, if the long-term geometric mean concentration of enterococci in the water at a marine beach is 35/100 mL and the log standard deviation is 0.4, then there is an 18% chance that the concentration of enterococci in a single sample would be over 158/100 mL. The higher the single sample maximum, the lower the probability that a single sample exceeding that value would occur as part of the normal random variability of samples (US EPA, 2006).

Since publication of the 1986 criteria, many States have expressed concern that the current fecal indicator/illness rate relationships identified in the epidemiology studies leading up to the 1986 criteria are not appropriate or representative of all U.S. waters. For example, States have concern that the most appropriate indicator in tropical waters may be different than in temperate waters, and that appropriate levels of indicators may be different in waters where human fecal waste predominates animal waste. Other identified issues are as follows:

- lack of clear, timely, and flexibile guidance regarding use of the single sample maximum values and differing risk levels;
- no EPA-approved analytical methods for use in wastewater for the indicator bacteria;

- lack of data to correctly assess the applicability of the 1986 bacteria criteria to flowing waters; and
- lack of data to quantify the risk associated with contributions from nonhuman sources of fecal contamination as well as lack of flexibility to adjust the criteria for water bodies that do not receive human sources of fecal contamination.

1.3.4 Summary of Proposed Criteria Development Approaches

Workgroup members developed a summary of the three proposed criteria development approaches, including strengths and limitations (Tables 4a and 4b).

Table 4a. Summary of Proposed Criteria Development Approaches: Strengths and Limitations

Criteria Approach	Science Supporting Approach	Strengths	Limitations
World Health Organization (WHO, 2003)	Fleisher et al., 1996 Kay et al., 1994, 2004 WHO, 1999 Wyer et al., 1999	• Flexible • Most comprehensive of available methods • Adopted by other countries • Incentives for beaches to upgrade • Allows more site appropriate protection of health	• Sanitary inspection component is qualitative; not quantitative • Greatest data needs • Would need to adapt potentially complex system to wide range of conditions in U.S. • Potential implementation issues
European Union (EP/CEU, 2006)	Fleisher et al., 1996 Kay et al., 1994, 2004 Wiedenmann et al., 2006 WHO, 1999, 2003	• Flexible • Relatively straightforward • Incentives for beaches to upgrade • Adopted by other EU Member States	• Discounting system has no direct precedent in the U.S. • Would need to devise robust and acceptable discounting scheme • Potential implementation issues
Current U.S. Criteria (US EPA, 1986)	US EPA, 1983, 1984	• Relatively straightforward • Currently in place in most states, new implementation issues less likely • Fewest data requirements	• Allows less flexibility • Single sample max (75^{th} percentile) has been criticized from implementation perspective • Credibility concerns in many parts of the U.S.

Table 4b. Summary of Three Proposed Criteria Development Approaches: Benchmarks

Criteria Approach	Criteria Attribute	Approach Compatible with Attribute
World Health Organization (WHO, 2003)	Health-based	Yes
	CWA §304(a) applications	Most challenging – unclear how different grades for beaches would be interpreted with respect to impaired waters; for example, TMDLs would need to be considered.
	Geographic variability	Not with current indicator, ongoing research could fill gaps
	Point vs. non-point	No, epidemiological data would be needed
	Multiple subpopulations	Could be, but in current configuration children not analyzed separately
	Uniform risk across waterbody types	Yes
	Linked to method that is validated	Yes currently, but will also depend on future indicators
European Union (EP/CEU, 2006)	Health-based	Yes, but differential risks from different sources of fecal contamination is not included, thus, this approach is less health-based than WHO approach
	CWA §304(a) applications	Yes, but challenging for same reasons as WHO approach
	Geographic variability	Not with current indicator, ongoing research could fill gaps
	Point vs. non-point	No
	Multiple subpopulations	Could be, but in current configuration children not analyzed separately
	Uniform risk across waterbody types	Yes
	Linked to method that is validated	Yes currently, but will also depend on future indicators
Current U.S. Criteria (US EPA, 1986)	Health-based	Yes, but concern about single sample standard, also concerns that differential risks from different sources of fecal contamination are not included
	CWA §304(a) applications	Yes
	Geographic variability	No
	Point vs. non-point	No
	Multiple subpopulations	No
	Uniform risk across waterbody types	No, fresh and marine recreational waters have different “acceptable risks”; this could be addressed in new or revised criteria
	Linked to method that is validated	Yes currently, but will also depend on future indicators

1.3.5 Other Approaches Considered

As noted previously, the workgroup considered a number of other frameworks and approaches that might be applicable to criteria development, including the following:

- Hazard Analysis and Critical Control Point Principles (HACCP);
- Heal the Bay Beach Report Card; and
- EPA Air Quality Index.

The EU, EPA (1986) criteria, and the WHO approaches are already being used for the intended purpose, either in the United States or other countries. The other possible approaches listed above have not been applied in a regulatory framework for proposed water regulation and would need to be thoroughly assessed to determine their utility or applicability to derive recreational water quality criteria. The workgroup members felt that it was beyond their ability to conduct such an assessment at this time. One workgroup member noted that the Heal the Bay approach was never intended for use in all regulatory purposes and would not be recommended for such.

1.4 Summary of Critical Issues to be Resolved in Applying Available Water Quality Criteria Approaches

No matter which recreational water quality criteria development approach is selected, a number of research needs have to be met before criteria development can reach completion. Additional epidemiological studies that take into account marine waters, subtropical and tropical waters, urban runoff, and non-point sources of contamination will need to be completed in the next 2 to 3 years to provide the health effects data necessary if nationally applicable are to be developed. Further testing of quantitative polymerase chain reaction (qPCR) methods to detect enterococci and/or any additional proposed indicators under the conditions listed above also is critical. The epidemiological studies should also include (1) culture-based methods in addition to molecular methods for enterococci; (2) culture and molecular-based methods for *E. coli* in fresh water studies because national freshwater criteria and numerous States currently use *E. coli* in recreational criteria and including *E. coli* would maintain a level of consistency with the existing CWA §304(a) guidance; and (3) sensitive subpopulations to the extent feasible, including children at a minimum.

Other research gaps that can be filled in the next few years include, but are not limited to, fate and transport of molecular-based indicator organisms in wastewater treatment plants and in the ambient aquatic environment. Workgroup members expressed a significant concern about the issue of conservation of measurable genetic material throughout the treatment process because of the regulatory ramifications in the NPDES, water quality assessment, and TMDL programs of moving to molecular-based criteria.

Another research need is for effective predictive models for beach water quality forecasting to notify the public of the potential health risks of recreational water contact. The current use of single sample assessments using culture-based methods has proven to be largely ineffective for public notification of beaches purposes because of the time required for sample processing (i.e., sample transportation to a laboratory, 18 to 24 hour incubation time, and time required for results

to reach and be evaluated by a decision maker). In addition to their development, the models need to be adequately field verified and calibrated. Ideally, regional models can be developed, but if predictive models can only be developed on a site specific basis over the next 3 years, the data needed to develop, field verify, and calibrate the models should not be cost prohibitive to collect. At a minimum, recreational beach managers should consider a simple, predictive rainfall model to more effectively protect public health.

Workgroup members emphasized that a sanitary investigation[3] approach to characterize drainages to primary contact recreational waters would prove useful for at least the WHO criteria development framework. A simple to implement, quantitative-based sanitary investigation, in conjunction with the health risk data from the proposed additional epidemiology studies, may enable the development of source specific risk parameters for criteria development. To clarify expectations for these surveys, a standardized and relatively simple approach would need to be developed that includes fecal bacteria source characterization (publicly owned [wastewater] treatment works [POTWs], storm drain outfalls, CAFOs, on-site wastewater treatment systems ["septic systems"], agriculture, etc.) on a drainage-wide basis, distance of sources to primary contact recreational waters, flow, developed area in the drainage, and the frequently high variability in water quality from day to day. Additional sanitary investigation components such as source identification and source tracking[4] may not need to be implemented unless there is a need in the regulatory process to implement a TMDL or to protect the public health of swimmers at chronically polluted beaches.

The following summary assumes that all of the approaches encompass and achieve the benchmarks outlined in Section 1.1 to the extent feasible.

1.4.1 Summary of Application of WHO Approach for U.S. Criteria Setting

The general framework described by the WHO (2003) would be applicable to U.S. criteria setting in the near-term given that the following research is conducted and science policy decisions are made:

[3] This is similar to Canada's "Environmental Health and Safety Assessment" in Appendix A of *Guidelines for Canadian Recreational Water Quality* (MNHW, 1992). Although the WHO (2003) uses the term "sanitary inspection," some workgroup members expressed concern that use of that specific term or the related term "sanitary survey" might imply adoption of all the protocols for sanitary inspections/surveys from other contexts. Thus, the term "sanitary investigation" was selected for use in these proceedings to minimize preconceived assumptions regarding the nature of the sanitary investigation and is used to refer to a quantitative approach to gauge watershed susceptibility to fecal influence. However, "sanitary inspection" is used when the WHO approach is described.

[4] Although there is not universal acceptance of definitions for microbial source tracking and microbial source identification, the Methods workgroup discussions assumed the following working definitions: source identification is determination of the type of animal (sometimes human versus nonhuman, sometimes more specific) that produced the fecal contamination. It does not include determining where in the watershed that material came from, but it does suggest what to look for upstream. Source tracking is determination of the actual source of fecal matter, such as a leaking pipe, a septic system, or a cow pasture. It typically involves using some of the marker techniques associated with source identification, but not necessarily. Source tracking can also be achieved through extensive spatial sampling with existing indicators or (for example) through use of dye tablets in septic systems.

1. Analyze epidemiological data to determine the values of water quality that correspond to the identified levels of "acceptable risk" for the indicator of fecal contamination using the selected method(s).
2. Identify a suitable indicator of fecal contamination or suite of fecal indicators (particularly for subsequent tiers of investigation). This information needs to be epidemiologically based.
3. Identify "acceptable risk" levels. Choosing an "acceptable risk" level is a policy decision that is informed by science (e.g., epidemiology studies). See Chapter 5 for a discussion of the process through which an "acceptable risk" level could be chosen.
4. Derive a quantitative sanitary investigation category rather than a qualitative process; also, the sanitary investigation should be standardized nationwide.
5. Statistically validate the linkages between different indicator/method combinations for different CWA §304(a) purposes to facilitate translation between the various indicator/methods.
6. Consider and develop a recreational water quality reclassification scheme, if appropriate. If such a reclassification scheme is appropriate, a management system would be necessary to facilitate implementation of beach advisories and to ensure informed choice regarding beach use.
7. Develop a public information management system and a beach signage provision. The purpose of these programs would be to represent bathing water characteristics derived from a "bathing water profile" and historical water quality.
8. Institute a monitoring program to acquire bathing water quality data for numerical compliance assessment purposes.
9. Release CWA §304(a) criteria guidance and associated implementation guidance concurrently.

To apply the WHO (2003) approach for future criteria setting, the following issues will need to be considered in detail and expanded:

1. Develop a process to determine how waterbodies get listed as impaired.
2. Determine the appropriate number of categories for microbial and sanitary investigation categories.
3. Possibly change several qualitative determinations in the framework (i.e., very good, good, fair) to less descriptive terms (i.e., Category I, Category II, etc.).
4. Develop a process for categorization of NPDES dischargers (consideration for default to most restrictive category).
5. Determine how to use different indicator/method combinations for CWA §304(a) applications and translate to each other to ensure equivalent levels of protection.
6. Determine whether health risks from nonhuman fecal sources are substantially different than from human sources.
7. Determine what is the most appropriate metric for expressing the water quality criteria (geometric mean, upper percentile, a combination of those and/or other)

8. Determine how to make water quality public notification decisions (this is likely a function of the indicator/method combination[s] that are employed and the strength of a predictive model).
9. Develop a well described and vetted quantitative sanitary investigation guidance; here the workgroup members suggested a tiered approach that allows for varying levels of effort based on likely benefit from the assessment (high and low risk should be easier to assess [i.e., beaches downstream from POTWs or urban catchments would be high risk, and beaches downstream of catchments with 100% natural sources would be low risk]). Although completion of the sanitary investigation does not need to be required, surface waters would default to the most restrictive criteria until such time as a completed investigation provides justification for changing the applicable criteria.
10. Develop a well described and vetted recreational water quality reclassification scheme.

1.4.2 Summary of Application of EU Approach for U.S. Criteria Setting

The general framework described by the EU (EP/CEU, 2006) would be applicable to U.S. recreational water quality criteria setting given the same research and science policy decisions as described above for the WHO except (1) a classification scheme based on a quantitative sanitary investigation would not be necessary because the sanitary inspection category is not used to determine the beach classification, and (2) it would not be necessary to determine whether health risks from nonhuman sources of fecal contamination are substantially different than from human sources, because the beach classification is based on microbial densities only..

To apply the EU approach for future criteria setting the same issues described above will need to be considered in detail and expanded, with the following exceptions:

1. Reform the microbial categories to fit U.S. waters, do not include the “sufficient” category of EU Directive EEC/7/2006.
2. Determine if a discounting scheme is necessary and appropriate (e.g., elimination of monitoring data for compliance purposes), and if so, then there is a need to determine how to make it most protective of public health.

1.4.3 Summary of Application of EPA 1986 Approach for U.S. Criteria Setting

The current EPA (1986) framework described previously would be applicable to new or revised U.S. criteria development with the following modifications:

1. Develop additional indicators and analytical methods that would be applicable to tropical and temperate waters and also for use in wastewater.
    a. Base additional indicators and methods on health risks (i.e., occurrence would be correlated with rates of illness from epidemiological studies).
    b. Ensure that the revised criteria framework specifies the appropriate indicator/methods combination for the various waters.

2. Consider more timely methods for beach monitoring and water quality notification. Currently, there is no scientific evidence supporting beach water quality determinations based on, at best, day-old (culture-based) data.
    a. If molecular-based methods are used, then fate and transport data for that indicator using that method would be needed.
    b. If molecular-based methods are limited to beach monitoring and water quality notification, then these methods must be linked somehow to the methods used for the other CWA purposes. Currently, very limited data are available for this purpose.
    c. If predictive modeling is used in water quality notification programs, the models need to be adequately field-verified and calibrated.
3. Risk threshold
    a. Any final recommendation for CWA §304(a) criteria must be health-based and derived from the available epidemiological data.
    b. If a single sample criteria is used, it should be of similar stringency to any other measure used (e.g., geometric mean) and the single sample criteria should account for the expected frequency of exceedance (e.g., if the single sample criteria is based on a 95^{th} percentile, a 5% exceedance should be allowed without invoking compliance ramifications).
    c. Consider risk to sensitive subpopulations (e.g., children) in the determination of the risk threshold.
    d. The risk of illness should be the same for swimmers in all types of waters (i.e., marine, fresh, temperate, tropical, etc.) exposed to all types of fecal contamination sources (e.g., point, non-point).
    e. Secondary contact recreation waters:
        i. Acquire data to show health risks associated with limited, but defined levels of contact and/or incidental exposure.
        ii. Data can be from epidemiological studies or estimated using quantitative microbial risk assessment (QMRA).
        iii. Develop a more accurate descriptor of what constitutes secondary contact.
4. CWA §304(a) AWQC recommendations and associated implementation guidance should be released concurrently.

1.5 Summary of Response to Workgroup Charge Questions

See Appendix A for the complete (original) charge questions.

1. ***What approaches exist currently for setting limits of pollutants that may be relevant for developing nationally recommended recreational water quality criteria? Consider approaches used for other kinds of pollutants in water, in other environmental media, and by other countries as well as approaches being implemented by States. What are the pros and cons of each of these approaches?***

- European Union Revised Bathing Water Directive 2006/7/EC

- Hazard Analysis and Critical Control Point Principles
- Heal the Bay Beach Report Card
- EPA Air Quality Index
- EPA *Ambient Water Quality Criteria for Bacteria – 1986*
- WHO *Guidelines for Safe Recreational Water Quality Environments. Volume 1 Coastal and Fresh Waters*

The EU (EP/CEU, 2006), (US EPA) 1986 criteria, and the WHO (2003) approaches are already being used for the intended purpose, either in the United States or other countries. The other possible approaches listed above have not been applied in a regulatory framework for proposed water regulation and would need to be assessed to determine their utility or applicability to derive new or revised recreational water quality criteria.

2. *Which of these approaches is most applicable and appropriate for developing nationally recommended recreational water quality criteria in the near-term? Why is this approach on balance considered the most applicable and appropriate?*

Workgroup members identified the following critical benchmarks for water quality criteria development:

- Be applicable to human health effects;
- Fulfill the needs of Clean Water Act (CWA) and meet the associated regulatory purposes (monitoring, permitting, total maximum daily loads [TMDLs], and §303(d));
- Address geographic variability (i.e., tropical, subtropical, and temperate regions);
- Address potential differences between point and non-point sources of fecal contamination and associated risk;
- Consider risks to susceptible subpopulations, primarily children; and
- Be based upon methods that are reliable and reproducible.

Based on these benchmarks, workgroup members further identified three approaches for further consideration—European Union Revised Bathing Water Directive 2006/7/EC (EP/CEU, 2006), EPA *Ambient Water Quality Criteria for Bacteria – 1986*, and the 2003 World Health Organization *Guidelines for Safe Recreational Water Quality Environments. Volume 1 Coastal and Fresh Waters.* Table 4a summarizes the advantages and disadvantages of each approach and is provided in Section 1.3.4.

3. *For those approaches identified as applicable and appropriate, what is the science that supports the approach? Is that science sufficient and of adequate quality?*

Epidemiological research identified to support the best selected approaches was:

- European Union Revised Bathing Water Directive (2006/7/EC; EP/CEU, 2006)
  - Fleisher et al. (1996)

  - Kay et al. (1994)
  - Weidenmann et al. (2006)
  - Wyer et al. (1999)
- EPA *Ambient Water Quality Criteria for Bacteria - 1986*
  - US EPA (1983)
  - US EPA (1984)
- World Health Organization 2003 *Guidelines for Safe Recreational Water Quality Environments. Volume 1 Coastal and Fresh Waters*
  - Fleisher et al. (1996)
  - Kay et al. (1994)

All members of the workgroup agreed that the research reports listed above support the respective approaches but some members questioned whether the research identified above was adequate to meet all of the identified benchmarks. They also agreed that additional epidemiological and modeling work needed to be performed in order to successfully implement any of the approaches above for future new or revised recreational water quality criteria development in the United States.

4. *Are there any critical research and science needs that should be addressed in developing or selecting an appropriate approach? Can this research be completed n time to be used in criteria development in the near term?*

The workgroup members identified the following research and science needs to support the suggested approaches.

- Information on the geographic applicability of fecal indicators for assessing health risks at tropical and subtropical fresh and marine recreational bathing areas impacted by point and non-point sources of fecal contamination (see Chapters 2, 3, and 4; research on sensitive subpopulations should also be incorporated into this need [see Chapter 5]);
- Ability to discriminate between human and nonhuman sources of fecal contamination;
- Information on sources of runoff (e.g., concentrated animal feeding operations [CAFOs]) from both marine and fresh recreational waters;
- How much water are bathers ingesting while swimming?; and
- Fate and transport of indicators (and pathogens) in the aquatic environment.

Workgroup members also identified the following possible long-term research needs:

- Comparison of prospective cohort and randomized control trial epidemiological studies;
- Identification of pathogens (viruses, bacteria, or parasites) responsible for GI illnesses at bathing beaches;

- Health impacts following exposures over multiple days;
- Significance of non-GI illnesses (dermal, aural, nasal); and
- Comparison of severity of illnesses related to exposure to human and animal (domestic and wildlife) fecal contamination (see Chapter 4).

Although workgroup members identified these long-term research needs there were some differences of expert opinion on the essentiality of these needs. In conjunction with these research needs, workgroup members also noted the necessity to clarify the objectives of environmental health assessments (sanitary investigations) and microbial source tracking methods.

5. ***Is a "toolbox" approach appropriate for developing new or revised recreational criteria in the near-term? Why or why not?***

The Approaches to Criteria Development workgroup members interpreted the concept of a toolbox approach differently. Some members believed that shifting from the current (US EPA, 1986) criteria approach to either the WHO (2003) or EU (EP/CEU, 2006) model approach would constitute a type of toolbox approach. For example, the sanitary investigation as used within the WHO approach could be considered to be an additional tool in the implementation of the new or revised criteria. Others believed the toolbox approach meant the use of alternative or additional fecal indicators or pathogen methods. In either case, the implementation of the toolbox approach was dependent upon additional epidemiological studies being conducted that may or may not be possible within the near-term (2.5 to 3 years).

Predictive models could be an integral part of the toolbox. Models that have been both validated and calibrated are critical for accurately predicting recreational waters that exceed criteria. Improved notification via forecasting models is likely to protect public heath better then the use of single sample criteria based on current indicators measured by culture methods.

6. ***What are the pros and cons of selecting a "toolbox" approach?***

There was commonality of workgroup member opinions in regards to several of the pros and cons related to the use of a toolbox approach.

Most of the workgroup members believed that a toolbox approach would help address some of the issues with geographic variability. For example, the use of different fecal indicators that demonstrate improved indicator/illness rate relationships in subtropical or tropical waters would reduce the likelihood of these waters inappropriately being listed as impaired under the CWA. The use of some form of sanitary investigations, as within the WHO (2003) approach, would potentially allow for discounting those waters that were identified as having limited or no anthropogenic fecal loading, thereby avoiding those waters being listed as impaired inappropriately.

The cons associated with a toolbox approach were primarily related to the current lack of data on the fecal indicator/illness rate relationships for additional methods. There was also some concern expressed about the difficulty in incorporating the toolbox approach to account for the use of different indicators for different CWA §304(a) needs. There was also concern about the feasibility of establishing requisite and defensible linkages between the various indicator/method combinations that could comprise the toolbox.

7. ***What are the desired features or characteristics that would make a "toolbox" approach appropriate?***

Any additional fecal indicator or pathogen measure within the toolbox would need to have proven indicator/illness rate relationships, or at a minimum, have a linkage to another indicator that does. The characteristic of being interrelated (correlated) with each other would be of particular use, especially if one was going to be used to support one aspect of the CWA §304(a) needs and the other was being used to support another §304(a) need.

The toolbox approach should support more then just one aspect of the CWA §304(a) needs. Any of the tools within the toolbox should be validated, either by predictive modeling or by correlation to other tools within the toolbox. Additionally, if a management action is initiated on the results of a particular tool within the toolbox (e.g., a beach closure based on qPCR) the follow up action should also be based upon the same tool (beach opened based on qPCR), to the extent possible.

8. ***Would a "toolbox" approach achieve additional public health protection as compared to another approach? Why or why not?***

Yes, as mentioned above, the additional tools within the toolbox could potentially improve the assessment of waters (e.g., reduce the listing of tropical or subtropical waters as impaired due to the poor indicator/illness relationship for these waters) or the appropriateness of beach advisories or closures.

9. ***Criteria for secondary contact recreation could be part of a "toolbox." What approaches would be appropriate for developing criteria for secondary contact recreation?***

Workgroup members defined secondary contact as limited or incidental contact. As such, workgroup members believed that the same approach could be used for waters designated as secondary contact as used for primary contact, meaning that epidemiologically-based health data could be used to define acceptable exposure limits. QMRA could also be used for these purposes to supplement available epidemiological information.

10. ***What are critical research and science needs in developing or selecting an appropriate approach for secondary contact recreation?***

Additional epidemiological studies may be needed under secondary contact conditions. These epidemiological studies should address the same data needs as those proposed in support of the primary recreation criteria. Alternatively, QMRA could be used if exposure data are available.

Can this research be completed in time to be used in criteria development in the near-term?

It is possible, but unlikely given the current demands for additional epidemiological work in support of the primary contact designated use. However, a QMRA study could be conducted during this timeframe.

11. ***What are the implementation considerations of the different approaches for CWA purposes (1) beach monitoring and notification, (2) development of NPDES permits, (3) assessments to determine use attainment, and (4) development of TMDLs?***

All three approaches—the (EPA) 1986 criteria, EU (EP/CEU, 2006), and WHO (2003) approaches—would require additional epidemiological studies to implement. Given additional epidemiological data with additional indicators, it is possible that each approach could potentially be implemented and could support multiple CWA §304(a) needs. As noted above, using multiple indicators for different purposes is a cause of concern.

Are there practical considerations that could preclude, or greatly limit, the use of an approach in routine, regulatory implementation (e.g., field sampling issues, laboratory challenges, staff training, etc.)?

If future epidemiological studies do not identify additional indicator tools that would improve the indicator/illness relationship for a broader geographic range, the (EPA) 1986 model would be a much less desirable option than either the WHO (2003) or EU (EP/CEU, 2006) approach. Both the EU and WHO approaches apply a discounting scheme, so the failure of near-term epidemiological studies to identify more robust indicator tools does not preclude the implementation of these approaches for the development of new or revised recreational water quality criteria.

Geographic Applicability

1. Is a single criterion available that is appropriate for the diverse range of geographic conditions? Why or why not?

No. Different regions of the country have different potentials for regrowth, persistence, indicator/pathogen die off rates (UV exposure), and indicator/illness rate relationships. The literature supports the conclusion that additional indicators will be necessary to accurately identify those recreational waters that are at risk across all geographic regions of the country.

Workgroup members felt that future epidemiological studies should include additional indicators to improve the indicator/illness relationship across all geographic areas of the United States.

2. Is a toolbox approach appropriate for different geographical conditions? Why or why not?

Yes, for the reasons noted in the response to Question #1 above.

3. What would a "toolbox" that addresses geographical differences look like?

The toolbox might include alternative or additional indicators that better predict, either individually or in combination, the indicator/illness relationship. Alternatively, the toolbox might include environmental health and safety assessments (sanitary investigations) that allow for the discounting of waters that appear as impaired based upon the indicator results, but for which the impairment judgments are not supported by demonstrable impacts (elevated indicators from wildlife or sediment sources only). The toolbox approach also could be used to allow different indicators and be used for different CWA §304(a) purposes.

4. What are critical research and science needs in developing or selecting an approach that will appropriately factor-in diverse geographical conditions?

Additional epidemiological studies are needed that provide improved indicator/illness rate relationships for all regions of the United States. These additional epidemiological studies should focus on recreational waters that are under a variety of potential pathogen sources (e.g., sewage, urban runoff, non-point sources, non-anthropogenic sources). Where possible, the various potential sources of pathogens should be considered within a single epidemiological study rather than each being considered in separate studies. This might be possible by examining waters that have varying sources depending upon rainfall or climatic conditions. For example, California beaches that have urban runoff sources during wet weather but no known point or non-point sources during dry weather.

To pursue the 2003 WHO approach, a quantitative environmental health and safety assessment (i.e., sanitary investigation) tool would have to be developed in order to support the categorization of recreational waters as to their risk of potential fecal contamination. To have greater confidence in the WHO model, research is needed to determine if the notion that fecal contamination from non-anthropogenic sources is of lesser human health risk that anthropogenic sources.

Expression of Criteria

1. Given the diverse needs of the CWA programs and the overarching goal of protecting and restoring waters for swimming, what protection is provided by establishing a 30-day "average" value as the criteria?

There was some commonality of workgroup member opinion on this issue. Several members felt that the criteria would best be expressed as a geometric mean and/or a standard deviation or

95th percentile. Several members believed that these values would have to be site specific in order to be protective. If formatted correctly, an average value is as protective as any other single measure.

What additional protection (if any) is provided by a daily or instantaneous maximum value?

The added value provided by an instantaneous maximum value is dependent upon the indicator/illness rate association. Short-term variability associated with the current indicators limit the usefulness of single sample maximum values; however, using qPCR or other non culture-based methods may improve the utility of single sample values. Additional epidemiological data is needed to assist in making this determination. One problem is that the formulation of the current single sample maximum is such that it is more stringent than the geometric mean, and this has caused substantial confusion among States.

From a scientific standpoint, is one measure better scientifically than another for particular purposes (e.g., mean value for purposes of identifying waters and daily maximum for beach monitoring and notification purposes)? Why?

It depends on how the new or revised criteria are derived and the assumptions made about the variability in water quality. There is some scientific merit to the continued use of single sample maximum values for some CWA purposes. This is of particular interest with respect to public health protection; however, there was not agreement among the workgroup members on this point.

2. What are pros and cons of expressing the criteria differently for the various CWA program needs?

As currently used, single sample maximum values are not effective for beach monitoring purposes. This may change somewhat if the shift from culture-based methods to non culture-based methods improves the issues with variability and indicator/illness rate relationships.

There is potential to use single values, whether culture- or non-culture based, in predictive models for beach monitoring. The geometric mean, standard deviation, or 95th percentiles show promise for multiple CWA programs. So long as there is data from epidemiological studies that demonstrates the one expression of the criteria is equally as protective as another, there would be no problem with using different expressions of the criteria for different CWA purposes.

3. What are the implications of instantaneous or daily values for public health protection? If we don't currently have a good understanding of this, what are the critical research and science needs to answer the questions?

Currently there is very little data to support the use of instantaneous or daily values derived from culture-based methods from Day 1 to predict the need to post or close recreational waters on Day 2. There are recent epidemiological data (Wade et al., 2006) that indicates that qPCR (non culture)-based indicator methods may be effective for same day notification at some beaches.

Group members identified several critical research needs that would potential improve the utility of an instantaneous or daily value (see Chapter 1).

4. If EPA were to set criteria at a mean concentration over 30 days and not recommend a single sample maximum, do we understand the illnesses that could occur on a single day (where the level would still lead to compliance with the 30-day average)?

In general, workgroup members agreed that the probability of illness on any single day is not understood. Some reasons for this are as follows:

- the variance in water quality in any particular water body could be significantly different than the criteria from which it was derived;
- the variability of indicator could change between beaches and temporally; and
- if the exposure-response curve is based on a geometric mean, the interpretation of a single sample is difficult.

With research, a single sample maximum could be used to estimate the probability of illness on a particular day.

5. If the science is "not there," what are the critical research and science needs to answer this question?

Critical research and science needs centered on expanding epidemiological studies based on qPCR (and other indicators and methods) to other situations (e.g., example marine beaches or non-point pollution sources).

6. What are the implementation considerations for CWA purposes of failing to address (and addressing) differences geographically in the criteria and failing to include (and including) a single sample maximum value for (1) beach monitoring and notification, (2) development of NPDES permits, (3) assessments to determine use attainment, and (4) development of TMDLs? Are there practical considerations that could preclude, or greatly limit, the usage in routine, regulatory implementation (e.g., field sampling issues, laboratory challenges, staff training, etc.)?

To address this question it was separated into the following two components: (1) failing to address geographical differences, and (2) failing to include a single sample maximum for various purposes identified in the CWA.

(1) Failure to recognize that the current criteria may not be applicable to tropical and subtropical beaches could present an unacceptable risk to bathers in these recreational waters.

(2) Single sample maximum NPDES permits – compliance tools such as NPDES permits require single sample maximums and need to continue that approach.

Regarding States' designated use attainment, single sample maximum values are not necessarily required and in fact may not be necessary. These types of criteria could be useful for beach

monitoring and water quality notification. Regarding TMDLs, single sample maximum values do not seem applicable for TMDLs for indicator bacteria.

1.6 Concluding Remarks

The workgroup members did not specifically prefer one criteria approach over another primarily because it is believed that additional data that will become available from epidemiological studies within the next 2 to 3 years and how those data will inform the criteria development process is not yet known. For example, it is not known what new information will be available based on new indicators and/or methods and how that information might inform a sanitary investigation component of a WHO-based criteria approach.

Further, it was the opinion of workgroup members that there may be differences in the ability to implement each of the three approaches if all of the various criteria attributes are not met. For example, workgroup members felt that the 1986 EPA approach with a new or different indicator and/or method would not be satisfactory if most or all of the criteria attributes were not met. Workgroup members also felt that the same set of circumstances may not preclude the use of the WHO or EU approach. With respect to the use of a toolbox-based approach where different indicators are used for different CWA §304(a) applications, workgroup members expressed concern about the feasibility of developing health-based linkages (as described above) as would be required by either the WHO or EU approaches. Thus, at this time, no workgroup member was definitively able to recommend one approach over another; however, the workgroup members agreed that the choice of approaches must be deferred pending the outcome of ongoing and near-term research.

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