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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 7
IMPLEMENTATION REALITIES

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EPA requests that experts consider implementation realities when providing input to all specific and general questions throughout this document.

The Implementation Realities workgroup members were charged with providing input to EPA and the experts participating on the other six workgroups concerning the practical implications of incorporating any proposed changes to the recreational bacteria criteria into State Water Quality Standards (WQS) and subsequent impacts on existing water quality management programs. To this end, the workgroup members met frequently with and actively participated in the deliberations of the other workgroups over the course of the workshop. Implementation issues and concerns are therefore incorporated into the individual workgroup chapters throughout these proceedings. This chapter provides a summary of the major areas of concern identified by the Implementation Realities workgroup during the deliberations resulting from the workgroup's internal discussions as well as discussions with other workshop participants.

At the most basic level, the success of implementing any new initiative depends on providing resources and guidance that are adequate to accomplish the stated objectives. Where additional effort is needed, either additional resources must be obtained or existing resources must be diverted from other activities. Workgroup members attempted to evaluate resource needs as a critical component of implementing new bacteria criteria across a broad spectrum of programmatic responsibilities from conducting necessary research to educating stakeholders and gaining acceptance of the public and regulated entities of program changes, to actual impact on the day-to-day implementation of water quality management programs.

The results of the discussions are presented in three sections. First, an evaluation of the four principal program areas where recreational bacteria criteria are currently employed: (1) water quality beach notification and advisory programs; (2) National Pollutant Discharge Elimination System (NPDES) permitting, including regulation of wastewater treatment facilities, urban stormwater, and combined sewer overflow and sanitary sewer overflow (CSO/SSO) discharges; (3) monitoring and assessment programs required for compliance with Clean Water Act (CWA) §303(d) and §305(b) purposes; and (4) development of total maximum daily loads (TMDLs) for waters identified as not meeting State WQS. The second section provides an evaluation of the implementation concerns that must be addressed that relate specifically to three potential approaches for the development of new or revised recreational water quality criteria. The third and final section identifies the specific areas of research that workgroup members considered to be most critical to facilitating implementation efforts.

7.1 Application to Specific Program Areas

7.1.1 Beach Monitoring and Water Quality Notification Programs

The objective of this program is to provide accurate and timely information to the public regarding the health risks associated with participating in recreational activities at marine and freshwater beaches. Significant concerns have been expressed regarding both the accuracy and timeliness of the information currently provided.

The most pressing need for regulatory authorities who conduct beach monitoring programs is to get better information to the public as quickly as possible regarding the safety of the recreational water. There is currently a minimum 24 hour delay between the time when a water sample is collected, tested, and when the results of the test are available. Thus, decision makers only know what the quality of the bathing water was like yesterday.

"Rapid Tests"

Research in the past few years has resulted in the development of molecular-based tests that can provide results in just a few hours following the initiation of the test compared to 24 hours for the currently used culture-based tests.

Rapid tests have several benefits. They shorten the time from when an unsafe water condition occurs (an "exceedance") to when the test reveals the existence of an exceedance. This provides a capability to shorten the time it takes to post an advisory or to close the beach during unsafe conditions. The reduced test period thereby reduces the public health risk. The shorter test period also shortens the time it would take to remove the advisory and/or reopen the beach when water quality returns to a safe condition. Thus, the period of "loss of beneficial use" is also reduced. Because test results can be obtained in a shorter period, it is possible that they could be used to aid fecal pollution source identification efforts such as in identifying a problem in a specific location by enabling more samples to be analyzed in a shorter period of time.

Although there is a desire to use the new, rapid tests in beach monitoring programs, several issues related to their use must first be resolved. First and foremost, it must be shown that these new "molecular" methods provide a level of human health protection equal to or above that provided by the currently used tests. States need to know that there is a beneficial reduction in illness to justify the costs of adopting and implementing a new test methodology.

While rapid tests are sometimes referred to as "real-time" tests, they are not in fact real-time tests as there is still a delay of several hours between water sampling and test results. The public may still be exposed to potentially unsafe water for some period of time, albeit likely a shorter time period compared to current culture-based methods used to measure indicator organism levels. The rapid tests will not shorten the time required to collect water samples and deliver them to the test laboratory (typically 4 to 5 hours or longer), nor will they shorten the time required to convey test results to the appropriate authorities and the public (1 to 2 hours or more).

Many States only have the resources to sample periodically (e.g., weekly, monthly) as opposed to daily. The new tests are not likely to provide authorities with resource savings sufficient to analyze water quality more frequently. However, the ability to obtain test results faster may raise the expectation of the public or regulatory mangers that, since the tests are faster, additional samples can or should be collected and tested—even when this may not be possible due to resource constraints. Taking full advantage of the benefits associated with more rapid tests will likely require additional resources for increased monitoring.

Before any new test can be used broadly, the EPA will have to adopt and validate a standardized method for its use. State and local public health officials use the results of monitoring to make health-based decisions to close or open a beach, or to issue or lift a beach advisory. These officials need to know that the analytical method they use provides reliable results; therefore, they only endorse methods that have already been validated by EPA.

Further, to be able to bring a faster test into routine use, issues related to test equipment, training, laboratory capacity, and certification of laboratories will need to be resolved. The initial capital cost and any ongoing operation and maintenance costs need to be calculated and compared to that of the currently used tests. Regardless of how "good" the more rapid tests are, if they are too expensive, regulatory authorities may not be able to afford them.

In addition, because the test endpoints of molecular-based tests are different than culture-based tests, a new regulatory scheme may need to be adopted to accommodate the new water quality criteria. See the discussion in Section 7.1.2 for further information on this topic.

For the public and local authorities, a period of time may be required to gain "acceptance" of the new indicator.

In general, any change in current monitoring practices (e.g., sampling type, frequency, location) necessitated by a change in recreational water quality criteria will need to be carefully considered relative to benefits offered because it will involve resource issues and many implementation concerns.

Predictive Modeling

Changes in microbial indicator counts in recreational waters are typically controlled to a large extent by a variety of meteorological and water quality factors. Data for many of these factors (e.g., wind, rainfall, etc.) can be obtained in real or near-real time. By monitoring and identifying which of these factors control indicator count changes, it is possible to create "predictive models" (see Chapter 6). Such models are essentially mathematical equations that have the "controlling" meteorological and/or water quality parameters as components. A "robust" model that is validated by comparison of predicted indicator concentrations to a sufficient number of actual concentrations is able to successfully predict, within a stated degree of precision, when unsafe water conditions will exist more accurately than the currently used culture-based assays are able to do.

Predictive modeling offers great promise because it estimates when there may be a problem *prior* to the bather exposure. The use of predictive models may also reduce the need for rapid testing. Furthermore, they can be employed daily, providing information beyond that available from periodic microbial monitoring. However, it is important to note that predictive models are not themselves criteria. Predictive models are tools that can be used to evaluate compliance with criteria.

Models are only as good as the data used in their construction. If critical data are not available, a valid model cannot be developed until those data are obtained. As discussed in Chapter 6, the amount of data, especially microbial monitoring data, required to develop a predictive model within a stated confidence level may be significant. In general, model development may require significant time and resources depending primarily on the availability of data on indicator densities and associated predictive variables (e.g., antecedent rainfall, wind direction, wave height, etc.).

Currently developed predictive models appear to be site-specific. A predictive model developed for one beach or location is not likely to be usable at other beaches or locations because the effect of a predictive variable such as wind direction on indicator densities will be different at each beach. Therefore, for each "problem" beach or location, a separate model (i.e., set of predictive equations) is likely to be required.

Competing financial resources may make modeling a low priority. For example, limited funds may have to be used for higher priority tasks such as improving impaired waters (e.g., fecal source identification).

Any proposed use of modeling results for compliance purposes is likely to present implementation difficulties. Model results may not be always accepted as "proof" of a water quality standards violation because of the inherent uncertainty associated with model results. That is, regulators are likely to require actual monitoring data rather than modeling output for compliance purposes, particularly if non-compliance may lead to legal enforcement action. Regulators as well as members of the public often perceive monitoring as accurate and modeling as estimates.

Statistical models are currently used in some States to assess compliance with their water quality standards for purposes other than beach monitoring. If there is a change in the criteria (as would occur if a new indicator is adopted) then corresponding model would have to be modified, which would require additional resources.

It is important to note that modeling should not supplant routine water quality monitoring, which will always be needed to detect unanticipated events such as a sewer line break. Thus, regular monitoring provides an ongoing, direct measure of microbial water quality. Monitoring also provides data to help improve the precision of model predictions.

General Considerations

Workgroup members felt that any new or revised recreational water quality criteria need to allow for a binary (pass/fail) decision (e.g., close or not close a beach), must be a numeric, and must be based on a health risk determination for water quality notification/closure purposes. The criteria for reopening a closed beach or removing an advisory should be the same as that used for the initial closure or advisory. New or revised criteria must be expressed in a way that the authorities using the criteria are able to fully explain the criteria and their health risk basis, in a readily understandable way to the public.

New or revised criteria should have some "flexibility"; for example, there may be State-specific circumstances and the criteria will need to be able to be used in all such circumstances. At the same time, the new or revised criteria need consistency so that the public has confidence that their health is being protected.

Any new or revised criteria should be tied to a specific method unless "equivalency" of the new method to a previously used (and validated) method can be demonstrated to facilitate implementation (see Chapter 3 for further information).

The development of guidance to implement new or revised criteria should occur simultaneously with the development of the criteria. The implementing authorities will need assurance that the new criteria will be effective in ensuring that public health goals are met.

Finally, the successful implementation of new or revised criteria will very likely result in the need for increased funding for microbial source tracking (see also Chapters 2 and 3) and for beach management programs.

7.1.2 NPDES Permitting Programs

The purpose of the NPDES permitting program is to insure that point source discharges of pollutants to waters of the United States achieve the statutory required level of treatment and do not cause waters to exceed State WQS after discharge. This is accomplished by imposition of the more stringent of either technology-based or water quality-based limits on discharge quality and mandating discharge monitoring at a frequency adequate to insure compliance with permit limits and conditions.

Tiered Approach

Water quality criteria might be expressed in a tiered approach; that is, that the criteria include multiple attributes, each of which apply for a specific purpose. With respect to NPDES permits, the tiered approach should be workable as long as one attribute of the criteria is specifically developed for NPDES requirements. This would necessitate choice of a pathogen indicator that achieves NPDES needs (see more below).

In addition, NPDES effluent limits are developed with an implicit exceedence rate. NPDES permitting guidance for water quality-based effluent development is based on a wasteload allocation that is calculated based on an exposure condition that represents the upper 99^{th} percentile of conditions (e.g., conditions occurring under rare low flows such as the 7Q10 [the lowest streamflow for 7 consecutive days that occurs on average once every 10 years]) when point source discharges have the greatest impact on water quality conditions. As a result, it is important that water quality criteria include an allowable exceedance frequency to facilitate permit limit derivation. This is particularly important for deriving permit limits for pathogen indicators in wet weather conditions because the flow conditions at the time of discharge can be extreme and represent rarely occurring situations.

Pathogen Indicators

Changes in pathogen indicators from the current ones (*E. coli* and enterococci) will significantly affect implementation, especially if the change results in a different indicator being used for TMDL modeling than for permitting or uses an indicator that cannot reflect the efficacy of wastewater (sewage) treatment practices (disinfection). At a minimum, the indicator used for

NPDES permitting needs to be sensitive to disinfection so that the permitting authority can determine that the NPDES regulated facility is adequately disinfecting its discharge. If the indicator cannot do so, then there will be a need for different indicators for ensuring the discharge achieves water quality standards and the wastewater is properly disinfected. Another way to accomplish this is to develop an approach that translates between the various indicators.

Analytical Methods

There is concern that molecular-based methods may not adequately verify that wastewater disinfection has been effective. This concern is based on research that shows the qPCR (quantitative polymerase chain reaction) signal does not decrease post-chlorination. Many State public health codes require disinfection of human waste and the analytical method used for NPDES permitting needs to be able to measure disinfection. As a result, a molecular-based method may not be suitable to fulfill all NPDES needs.

It is also important for implementation that the analytical methods be tested in a wastewater matrix and approved for use in wastewater. NPDES regulations require that effluent monitoring be conducted using either an EPA-approved analytical method or an analytical method specified in the permit. In the latter situation, the permit documentation needs to defend the use of the method. However, many States do not have the technical experience to defend analytical methods or have legal restrictions on the use of alternative methods and thus must rely solely on use of EPA-approved methods.

Resources

Many NPDES regulated dischargers conduct analysis of their wastewater on-site. The existing laboratory expertise of these dischargers may not be sufficient to conduct analyses for new pathogen indicators (e.g., molecular-based methods). The start up cost of purchasing equipment for conducting the new analyses and additional training for staff poses a resource drain for both the dischargers and the regulatory authority that must provide oversight. Should the dischargers choose to contract out their laboratory analysis, they will need to pay to ship the samples to the contract laboratories, which is also a resource drain.

Finally, many states require that laboratories be certified for analysis with certification being specific to the parameter being analyzed. Therefore, States will need to amend their laboratory certification program to include the new pathogen indicators. This is also a resource drain on States.

7.1.3 Monitoring and Assessment for CWA §303(d) and §305(b)

The purpose of this program is to provide an accounting of the condition of the Nation's waters, identify those that do not meet current State WQS for focused mitigating action, and to track progress in improving the overall quality of the Nation's water resources.

Assessment and listing based on the current ambient water quality criteria (AWQC) have disproportionately focused State resources on what are often perceived as minimal to nonexistent public health issues. States have expressed frustration at being effectively handcuffed by strict application of the criteria and the inability to adjust assessment findings based on other data indicating the health risk is significantly lower than implied by the criteria exceedance. Such factors include evidence that elevated indicator levels are not due to human sources of fecal contamination and hydrologic factors that preclude recreational exposure, such as during or immediately after high rainfall events. Areas where improvements can be made in the new or revised criteria and implementation guidance associated with the criteria includes monitoring, criteria, guidance, and (inland) flowing waters.

Monitoring

Workgroup members felt that new or revised recreational AWQC must include a clear discussion regarding linkages between an advisory/closure decision at a beach and assessment of use attainment. Beach advisories/closure decisions may, but need not necessarily, be linked to such assessments. There may be instances where beach advisories or notifications are made based on models, or special circumstances (such as sewer line breaks) that should not be counted as non-attainment for assessment purposes. In a similar vein, if the beach advisory regulations are more stringent than State WQS, the advisory in and of itself should not constitute non-attainment unless the State chooses to list that beach as impaired on that basis.

Ambient Water Quality Criteria

Alternative AWQC or methodologies that more precisely define health risk would be highly useful in improving assessments—in particular indicators of human versus nonhuman pathogens. The criteria and implementation guidance need to recognize the potentially lower risk of pathogens from nonhuman sources and provide a way for addressing and discounting pathogen and indicator data not associated with anthropogenic sources of fecal contamination.

The criteria must also be sufficiently flexible for assigning attainment of use based on limited data sets, particularly for inland waters. Often, States only collect data on a monthly, bi-monthly, or annual basis and compare these data to previously collected data to assess trends. The problem will be exacerbated for assessment purposes if new or revised criteria are adopted. It could take years to develop a statistically significant data set.

If the format of the new or revised criteria requires a specific number of samples to be collected in a set timeframe, States will be challenged as they are with the current criteria (e.g., 5 samples over a 30-day period). Criteria that allow assessment samples collected at any frequency to be statistically manipulated to the appropriate exposure frequency would allow States to maintain their current monitoring approaches while appropriately applying the criteria.

Also, for ease of State implementation, new or revised criteria need to allow for some reasonable excursion frequency. Criteria expressed as a percentile value (e.g., cannot exceed criteria more than x% of time) would provide an incentive to conduct additional sampling so as to not have the assessment rely on one or two samples and would facilitate implementation for assessment purposes.

If the European Union (EU; EP/CEU, 2006) or World Health Organization (WHO, 2003) approach for criteria development is followed, there needs to be a clear distinction between the criteria that is needed to protect human health and what is considered to be supplemental guidance. For instance, is it possible to have a "good" beach or a "very good" beach and still be considered non-impaired? Apparently, "good" meets the criteria while "very good" is a desired higher level of microbial water quality. Such discussion should be in supplemental guidance rather than in the criteria.

If a rapid method is selected as the indicator, the speed of a rapid method offers no additional benefit relative to assessment, unless the rapid method provides more precision/better protection to benefit public health. Therefore, a rapid method may offer the benefit of more rapid water quality notification, but has little positive effect on the overall assessment process that is conducted on data collected over a 2 year period.

Workgroup members expressed concerns with establishing a new or revised recreational water quality criteria linked to a sanitary investigation. If a WHO-type criteria model is chosen that includes use of a sanitary investigation to modify the criteria and allow for nonhuman sources of fecal contamination, the frequency of performing that investigation would need to be identified in assessment guidance. There was a strong preference among workgroup members that the frequency be longer than the two year assessment cycle for State's issuance of assessment information pursuant to §303(d) and §305(b) of the federal CWA. The available information for the sanitary investigation did not specify the frequency for repeating such investigations.

Lastly, for assessment purposes, there needs to be some way to translate between previously used indicators and any new indicator(s) so information from past monitoring is not lost. If a "translator" is not available, it might take several years to build up enough information to conduct a statistically valid assessment for pathogen indicators.

Guidance

If new criteria indicator/methodology combinations are adopted, issuance of guidance for implementation will be imperative. With the likelihood of rapid molecular-based test methods, sanitary investigations, and so on, guidance will need to accompany the criteria to help States understand how to apply the new or revised criteria and thus achieve State acceptance.

Flowing Waters

Flowing freshwaters (e.g., streams, rivers) present some unique challenges that have not been addressed with previous epidemiological studies of recreational waters. Therefore, if new or revised criteria include application to flowing freshwaters, consideration needs to be given to an allowance for different values/applications of the criteria to reflect the differences in hydrologic regime (e.g., extreme high flows) through one of the following:

- higher criteria that applies in extreme events; or

- changes to the use/criteria when the use is not taking place (e.g., when recreation is unlikely to occur such as during winter months or during or immediately after heavy rainfall).

Lastly, an indicator applicable to flowing freshwaters needs to be identified. As stated elsewhere in these proceedings, *E. coli* appears to be a more appropriate freshwater indicator of fecal contamination than enterococci. *E. coli* are a subset of fecal coliform bacteria while enterococci bacteria are a separate group of enteric bacteria. More recent water quality data generated using *E. coli* can be more easily compared to earlier water quality data generated using fecal coliform bacteria than can more recent water quality data generated using enterococci bacteria.

7.1.4 Total Maximum Daily Load Program

The purpose of this program is to establish the maximum pollutant load that a specific waterbody can assimilate and apportion that load among sources of that pollutant to the waterbody, leading to the development of a management plan that when fully implemented will result in reducing those loads to the extent that State WQS are achieved and maintained.

TMDLs for bacteria designed to achieve consistency with the current (US EPA, 1986) criteria are typically difficult to develop and explain to stakeholders because expressing pollutant loadings of bacteria or pathogens in terms of mass is nonsensical. Pathogens or pathogen indicators are not measured as mass but rather as cell counts (e.g., colony forming units [cfu]). Developing wasteload allocations for point sources and load allocations for non-point sources in mass units does not make sense to the vast majority of TMDL practioners and those responsible for implementing bacteria TMDLs. For this reason, alternative means of expressing loading reductions (e.g., "percent reduction," "load duration curve-based," "reference watershed" methods) have been used by many States. TMDL development for waters impaired by excessive indicator bacteria densities is further complicated in that the necessary load reductions are typically strongly linked to hydrologic factors and intermittent sources such as stormwater runoff. Establishing a static steady-state design condition, as is frequently done for other types of pollutant impairments, is not possible for bacteria due to the significant wet weather event-driven characteristics of many bacteria-impaired waters.

Workgroup members viewed criteria expressed in numerical terms as a practical necessity to implementing any revised recreational use criteria in TMDL programs due to the need to quantify loadings. Implementation realities dictate that the criteria be expressed in terms that facilitate calculation of an acceptable daily loading under a range of hydrological conditions. The criteria has to be a number (as opposed to a category/classification) to make implementation in TMDL programs feasible. The workgroup experts expressed a diversity of opinions over the benefits of a geometric mean or other statistic versus single sample maximum criteria with specified exceedance frequency for water quality assessment and TMDL purposes. Some prefer use of single sample maximum (SSM) while others prefer geometric mean largely reflecting current practice in their particular State. If the new or revised criteria are expressed as a single value, the benefits of allowing for that value to be exceeded at some stated frequency for TMDL and assessment purposes cannot be overstated. EPA should expect intense resistance from Sstates if future criteria guidance proposes criteria expressed as a "never to be exceeded" value.

An acceptable exceedance frequency is critical to facilitate design of treatment requirements and best management practices (BMPs) to implement the TMDL as well as accounting for rare extreme event-driven conditions not practical to mitigate. Providing States (and other stakeholders) with evidence that the criteria incorporate flexibility to accommodate the variability inherent in bacterial densities in natural systems would greatly facilitate acceptance and subsequent implementation efforts.

Criteria that distinguish between human and nonhuman sources of fecal contamination would also make TMDL development significantly easier. The ability to make allocation decisions would be enhanced and public acceptance of the TMDL implementation requirements would be achieved much more readily if additional confidence could be provided in estimates of source category loading. Further, the ability to adjust TMDLs based on more accurate source separation and to make allowances that "discount" the contribution of certain lower risk sources (e.g., non-anthropogenic) or sources from which the contributed risk may be lower (e.g., wildlife) would encourage States to move forward to adopt the criteria into their WQS. If the criteria or implementation protocol includes a sanitary investigation there should be guidance provided to encourage consistency in sanitary investigation methodologies among States. This guidance might be a combination of minimum expectations and general framework for what constitutes an acceptable sanitary investigation. A mandate to provide confirmation of investigation results through alternative means (e.g., microbial source tracking, use of more human-specific indicators) may also be acceptable provided the cost and technical difficulty are not prohibitive or use of this additional step is only required in selected instances where the results of the investigation are not conclusive.

7.1.5 Important Differences Between Workgroup Members as to Views/Observations

Workgroup members had a diversity of opinions over the benefits of a geometric mean-based as opposed to AWQC based on SSM for certain water quality assessment and TMDL purposes. Some preferred the use of a SSM-based standard, while others preferred the use of a geometric mean-based standard. One of the times of potential concern is when an individual sample result may be over the SSM but the data set does not exceed the geometric mean. The concern is that some event may have occurred during that time and the public could potentially be at risk; however, it is also possible that the result is a one-time occurrence and the public is not at a greater risk than at other locations that meet the geometric mean-based criteria.

7.2 Evaluation of Alternative Approaches for Criteria Development

This section describes the implementation considerations for each of the three alternative approaches for the development of new or revised recreational water quality criteria that were proposed and discussed at the workshop (see Chapter 1). Some of the concerns regarding implementation that are common to all three approaches include the following:

- level of discriminatory power/sensitivity of a method;
- if rapid method is used, difficulty in implementation in some places (e.g., holding time); and

- if site-specific epidemiological studies are needed, most States will be unlikely to fund these studies.

Many of the above concerns, as well as the concerns described in the following sections, would be eliminated if the following statements were true:

- epidemiological studies demonstrate that indicator organisms are sufficiently correlated to human health risk;
- studies provide a scientific basis for discounting risk to human health from wildlife sources of fecal contamination;
- criteria included flexibility to account for the reduced exposure (and thus, lower risk) of use at extreme conditions (e.g., high flow);
- relationships between advisories and impairments were more clearly defined in EPA guidance;
- level of disinfection necessary to provide adequate pathogen reduction/inactivation in human sewage was determined; and
- criteria applied for NPDES purposes included flexibility to account for wet weather conditions.

7.2.1 WHO Approach

The WHO approach provides a range of risk levels and accounts for differences in relative risk resulting from site-specific considerations of sources of indicator organisms based on the results of a sanitary inspection performed prior to the assessment of monitoring results. The following implementation concerns are not specific to any specific application of the WHO model, but rather reflect the general use of this approach.

The WHO (2003) approach to criteria development relies on identification of the potential for human sources of fecal contamination to impact a beach or other recreational water area. Many pathogens are host-adapted and so human fecal sources may contain many pathogens not found in feces from non-human animals (e.g., *Salmonella typhi*, *Vibrio cholerae*, *Cryptosporidium hominis*, *Entamoeba*, many viruses). Thus, it is essential to have available a reliable methodology to distinguish between human and natural sources (e.g., wildlife only) of pathogens for use of the WHO model. As part of this, the methodology should also be able to either quantify that the risk from natural sources is low or provide some way to characterize the risk from natural sources as being acceptable. It is important to characterize or quantify the risk from natural sources rather than to completely discount it because this risk needs to be included in beach advisory decisions. For example, if pathogens from sea lions pose a risk to humans, then it is important to post an advisory on a beach where sea lions reside. However, it would not be necessary to consider this risk in determining impairment because sea lions are a “natural” source and most environmental agencies would not view development of a plan to eliminate sea lions as consistent with their overall mission.

It is also important to be able to quantify the risk from domestic animals and livestock and include this risk if a WHO-based approach is pursued. Although these sources of fecal contamination are nonhuman in nature, these animals live in close proximity to humans and may carry human (zoonotic) pathogens in their feces(e.g., *E. coli* O157:H7, *Cryptosporidium parvum*; see also Strauch and Ballarini, 1994). Use of the WHO model will require including the likelihood of these sources impacting beaches and other recreational water areas. As a result, it becomes important to quantify risks of exposure to fecal material of these animals.

The WHO approach appears to be amenable for use with multiple pathogen indicators (e.g., the toolbox). If multiple pathogen indicators are used in application of the WHO model, then all the considerations related to use of both molecular and culture methods that were discussed for each CWA application above apply. In addition, if multiple WHO model tables are used, it may be advantageous to develop separate tables for lakes and flowing waters because exposure in these two situations are different.

There are several implementation issues that arise if the WHO model is applied using a qPCR analytical method. The first issue is the capacity of States and NPDES dischargers to adopt and use a qPCR method, as initially, there may be insufficient laboratory capacity to conduct the method. Specific concerns with respect to NPDES facilities are discussed in the preceding Section (7.12) on the NPDES permitting program. Additionally, it is reasonable to expect that the initial costs per sample will be substantially higher than for the currently used culture-based methods, which poses an additional cost to States and NPDES facilities.

The second implementation issue with respect to qPCR is its apparent inability to confirm that disinfection is being properly applied. As discussed previously, NPDES permits need to both assure that WQS are achieved and that State disinfection requirements are being met. If qPCR method is used to apply the WHO approach, then another indicator using culture-based methods will be needed in NPDES permits to demonstrate adequate disinfection.

Another implementation issue is the use of sanitary investigations based on the WHO approach. However, the protocols for a sanitary investigation should not be overly prescriptive to the point of making the investigation resource-prohibitive. There is a need to define the minimum elements of a sanitary investigation to ensure that it is reliable. Application of the criteria needs to invoke trust by the public. If there is too much variety in sanitary investigations, then the public will perceive that the investigations have no technical rigor and which will undermine use of the WHO model. In addition, States will need to develop the capacity to conduct sanitary investigations on every waterbody with recreational uses, which constitutes a resource burden. Finally, States need sufficient time to conduct sanitary investigations by the time the new or revised criteria are adopted into their WQS.

The WHO approach includes columns that characterize different risk (see Table 1, Chapter 1). Two of the columns include water characterizations of “very good” but are associated with different risk. The model should be applied with only one “acceptable risk” level. If there is more than one acceptable category of good, it implies there is more than one “acceptable risk” level. This makes it difficult to explain to the public, difficult to enforce, and difficult to make decisions on the lower risk level. Any further distinction between “good” and “very good” outcomes should be voluntary.

It is possible that States will issue advisories in situations that are not considered as CWA impairments. This can occur when a state public health agency wants to impose a higher degree of protection than the state environmental agency, or at beaches where there are wildlife sources that pose risk. It is uncertain how such a situation would work with the WHO model, and this would need to be developed.

The WHO model uses ranges of pathogen densities. This allows States to select which specific value to use, and thus result in inconsistencies on thresholds to close or open beaches between various states. It is much more preferable for the criteria to specify one threshold rather than a range. However, it was discussed that while the range may be difficult to implement in a regulatory fashion, it may more realistically describe the precision of epidemiological-based criteria applied to a wide range of waters coupled with the precision of indicator measurement.

Finally, it appears that empirical models of pathogen densities can be used with the WHO model, as long as one threshold is used rather than a range.

7.2.2 EU Approach

The EU approach provides defined criteria at a single risk level but allows for adjustment of the assessment result based on a sanitary investigation performed following review of monitoring results.

Like the WHO (2003) approach, the EU (EP/CEU, 2006) model uses sanitary inspections; however, unlike the WHO approach, the EU model uses the inspections to rationalize that monitoring results above the criteria levels do not indicate an elevated risk to human health. Thus, the rigor of any type of sanitary investigation that may be required for an approach based on the EU approach seems to be greater than for WHO-based approaches (i.e., requires a more detailed site assessment). A workgroup participant indicated that for some waters a desktop GIS-based methodology could constitute a sufficient sanitary survey for many bathing waters (Paul Hunter, University of East Anglia, U.K., personal communication, 2007).

As was the case for the WHO model, there are implementation concerns regarding the time and capacity for conducting sanitary investigations, and the ability to distinguish between risks from human and nonhuman sources of fecal contamination. Specifically, States will need to know how good are the techniques to distinguish between risks from human and nonhuman sources, and what is the degree of risk from nonhuman sources. Thus, the discussion of the WHO approach on these topics likewise applies to the EU approach.

As one way to implement the EU model, EPA could use a "pristine" watershed as a baseline. In this situation, EPA would look at pathogen indicator counts at baseline flows and use these values to determine how to adjust concentrations.

The EU model process presents opportunities to be more transparent to the public than the WHO approach. States could seek public involvement in determining how to conduct the sanitary investigation/discounting process.

One impediment to implementation of the EU approach is how domestic and agricultural animals are addressed. It appears that these sources can be excluded; however, these fecal contamination sources may have a potential risk to human health.

The EU model characterizes beaches using the 95th percentile of a set of microbial water quality data. This seems to prevent making short-term decisions for beach closure or reopening unless beach managers use some sort of predictive modeling. This is an implementation concern given the aforementioned (see Chapter 6) data needs of models. Not all recreational water sites can currently develop a model due to limited data. If there is no model, then decisions would likely be based on a data set over a period of time, rather than a specific data point, which would require interpretation for beach monitoring for closing or opening decisions.

Like the WHO approach, the EU approach includes columns that characterize different risk (see Table 2, Chapter 1). The model should be applied with only one "acceptable risk" level. If there is more than one acceptable category of good, it implies there is more than one "acceptable risk" level. This makes it difficult to explain to the public, difficult to enforce, and difficult to make decisions on the lower risk level. Any further distinction between "good" and "very good" outcomes will make implementation difficult in some jurisdictions.

7.2.3 Existing U.S. Model – 1986 Criteria

The existing model provides defined criteria at a single risk level but does not provide for adjustment based on other sources of information such as sanitary investigations or source identification.

The original basis for the (EPA) 1986 criteria were freshwater and marine water epidemiological studies conducted at a limited number of sites with restricted geographic extent and waterbody type (lake beaches and marine beaches). Therefore, a concern exits that single value criteria may not be applicable to all waters across the United States—for instance, inland flowing waters, tropical waters, or freshwaters under tidal influence. In the development of new or revised criteria, epidemiological data or quantitative microbiological risk assessment (QMRA) for as wide a variety of fresh and marine waters as is possible should be used.

If single value criteria are to be developed, as was the case for the 1986 criteria, it is vital to use as many indicators as necessary to best characterize the microbiological quality of the water. There is a variety of opinion as to the most appropriate indicators for fresh and marine waters. However, there is evidence that *E. coli* is the most suitable indicator for flowing freshwaters while enterococci, either by culture- or molecular-based methods, is most suitable for marine waters; however, the workgroup did not reach a common opinion on the evidence.

A major criticism of the 1986 criteria was the lack of approvable test methods for wastewater effluent. If new indicator organisms or test methods are identified for the new criteria, approved test methods must be developed for all potential needs such as NPDES permitting and ambient water quality monitoring.

The 1986 criteria provide minimal implementation guidance. Due to most States' interpretation of the criteria in their WQS, the criteria tend to be treated as requiring compliance at all times and in all waters. This interpretation has caused considerable problems in the assessment and TMDL arenas. Any new or revised criteria must include implementation guidance that allow for methods to address issues such as extreme flows and nonhuman sources of fecal contamination.

EPA needs to provide more scientific data and information to States for implementation of pathogen indicator criteria. States have concerns regarding the effectiveness of existing sewage treatment capabilities on new indicator organisms. In switching from enterococci or *E. coli* as an indicator, there is concern that disinfection designs may not meet permit limits based on the new indicator criteria. This issue needs to be addressed by EPA so that the State programs will have consistent, valid, and scientifically defensible responses when these concerns are raised during the implementation of new WQS.

7.2.4 Alternative Approaches

Two additional potential approaches to consider in the development of new or revised recreational water quality criteria include the following:

1. An alternative hybrid approach could blend the single value criteria with facets of the WHO (2003) and EU (EP/CEU, 2006) models to allow for demonstration of mitigating (or discounting) factors to be completed by a fixed date after criteria adoption. This has the advantage in preventing waters from being CWA §303(d)-listed based solely on excursions above a single value criteria. If the water was ultimately listed, it could be de-listed at a later date if it were demonstrated that mitigating factors prevented designated use attainment.
2. The largest implementation concern with the single value (EPA) 1986 criteria is regarding assessment. An alternative approach to developing new criteria could incorporate the existing 1986 criteria with the following implementation provisions:
   - a provision to discount non-compliance with the single value criteria after investigation of the contributing watershed to confirm the absence of nonhuman sources and lower risk than implied by the criteria exceedance;
   - criteria/use inapplicability during extreme high flow events; and
   - a process to exclude natural sources of fecal indicator organisms (i.e., indicators specific to human sources are not present), according to the corresponding risk to human health.

7.3 Research Needs

Research is clearly needed to provide support for implementing any alternative approach to criteria development, expression, or application. A key concern is the role research results play in the ability of State and federal regulators to explain and gain public acceptance of changes in existing CWA programs. Opportunities to leverage the value of individual research programs by employing data collection designs that may be useful to answer multiple questions should be exploited.

7.3.1 Near-term (Next 1 to 3 Years)

Beach Monitoring

1. Provide a quantitative protocol to identify the types of nonhuman sources of fecal contamination. For example, other than molecular-based fecal source identification techniques, are there methods (e.g., sanitary investigations) to track nonhuman sources such as waterfowl, dogs, horses, and other anthropogenic sources? The WHO and EU approaches to criteria development provide for "discounting" exceedances if it can be determined they are of nonhuman origin through a sanitary inspection. If risks from nonhuman sources can be adequately quantified, sanitary inspections could be used to support decision making.
2. Determine the risk from different types of nonhuman sources of fecal contamination (e.g., domestic and indigenous wildlife). Although the new or revised criteria would need to address all potential risks, a delineation of the categories of risk made available to the public would improve water quality notification and informed consent aspects of implementation. Specifically, the perceived risk associated by the public with elevated concentrations of indicators derived from indigenous sources (e.g., deer, birds) may be more acceptable than sources of domestic origin (e.g., cattle, poultry). The public may wish to make an informed decision about usage relative to specific pathogens such as enterohemorrhagic *E. coli* (EHEC) that are potentially associated with agricultural land usage.
3. Determine under what conditions a sanitary investigation would be sufficient (as opposed to microbial source tracking). This research is most important if the WHO and EU approaches are being considered.
4. Identify minimum elements that a sanitary investigation should include. Again, the focus should be on the minimum elements necessary for a reliable sanitary investigation. If the requirements for a sanitary investigation are too onerous, they will become resource-prohibitive and of minimal value. Assess the reliability, accuracy, and validity (etc.) of the various types of sanitary investigations. Without some sort of standardized investigation criteria, inconsistencies will result in the implementation of the criteria and create potential variances in health risk levels at beaches.
5. Predictive modeling offers the prospect of benefits to beach management that are sufficiently significant such that it should be explored further. An identification of data needs is required for such models. For water quality notification purposes, models should be developed and calibrated to assure a minimum confidence level.

NPDES

1. Conduct studies to develop a methodology to compare the correlation of the culture-based methods and the qPCR (molecular-based) method. Identify how or where the same level of protection can be provided, even if implementation is different. Any requirement to use non culture-based methods may have significant impacts on NPDES permit monitoring programs. Non culture-based methods may not adequately assess treatment processes or determine permit compliance.

2. Develop an improved understanding of disinfection using the different indicators. Determine how well each indicator is in measuring disinfection effectiveness, including determination of the viability of the organisms (pathogens and indicators) following various disinfection processes (e.g., chlorination, UV light).
3. Determine risks of exposure from intermittent microbial pollution discharges, CSOs, urban runoff, and concentrated animal feeding operations (CAFOs).
4. Evaluate the effectiveness and cost of stormwater and agricultural BMPs as related to pathogens and microbial contaminants. This evaluation should be made in concert with epidemiological studies/QMRA analyses that will determine the risk from different types of sources (urban and agricultural runoff, indigenous and domestic animals, regrowth).
5. Evaluate the efficacy, costs, and benefits of disinfection for the purposes of supporting eventual promulgation of a disinfection rule. It is anticipated that disinfection could eventually be promulgated as a mandatory treatment technology nationwide as it already is in many States. Specifically, research is needed to support levels of disinfection necessary to provide adequate pathogen reduction/inactivation.

Use Attainment

1. Research to determine the risk from different types of nonhuman sources of fecal contamination (e.g., domestic and indigenous) is needed to better quantify the risk from nonhuman sources so that when implemented at recreational waters, those risks are better accounted for.
2. Develop criteria or methodologies that more precisely define the health risk associated with pathogen exposure in recreational waters.

Overall

1. Conduct research so that monitoring using indicators can help to distinguish human from nonhuman sources of fecal contamination.
2. Conduct epidemiological/QMRA studies on flowing recreational waters. Current (1986) criteria were based on epidemiological studies conducted in relatively static waterbodies. Additional studies are needed to assess risks in flowing waters. This has significant implications for criteria development for inland U.S. waterways.
3. Need to better understand the health-basis for allowable exceedance frequency. Additional explanation is needed to justify percentile criteria differences between WHO, EU, and EPA (1986) criteria development approaches (e.g., use of 95^{th} or 90^{th} percentile).
4. Conduct research to better understand how to measure the impact of regrowth and persistence in sediments of indicator bacteria on water quality. The source of some problems of high pathogen indicator levels may at times be due to regrowth rather than urban runoff, animals, birds, biofilms, ocean circulation, etc.

7.3.2 Long-term (Beyond 3 Years)

NPDES

- Develop a viability assay for the viral and protozoan portion of effluent.

Overall

- Develop methodologies that are pathogen-specific.

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