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Implementation Guidance for *Ambient Water Quality Criteria for Bacteria* -- 1986

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Executive Summary

This guidance was developed to assist States, Territories, and authorized Tribes implement EPA's recommended water quality criteria for bacteria. EPA recommended *E. coli* or enterococci for freshwaters and enterococci for marine waters in its *Ambient Water Quality Criteria for Bacteria*–1986. Despite these recommendations, many States, Territories, and authorized Tribes continue to use fecal or total coliforms to protect human health from the risk of gastrointestinal illness in primary contact recreation designated waterbodies.

States, Territories, and authorized Tribes have identified several issues that are impeding their adoption of *E. coli* and/or enterococci as water quality criteria for bacteria. Many of these issues are addressed in this guidance, including a reaffirmation of the scientific validity of EPA's 1986 water quality criteria for bacteria, recommendations for how States, Territories, and authorized Tribes may make the transition from fecal coliforms to *E. coli*/enterococci, application of EPA's recommended water quality criteria to waterbodies contaminated by non-human sources, application of EPA's recommended water quality criteria in tropical environments and recommendations of appropriate water quality criteria for bacteria for waterbodies that are designated for non-primary contact uses.

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1.0 Background and Introduction

Water quality criteria for bacteria are concentrations of indicator organisms that should not be exceeded in order to protect human health from pathogen-caused illness. These indicator organisms often do not cause illness directly, but have demonstrated characteristics that make them good predictors of harmful pathogens in waterbodies. Pathogens are disease-causing microorganisms that include viruses, protozoa, and bacteria.

Many of these pathogens can not be measured directly. In addition, waterbodies may contain many different pathogens, making measurement and enumeration impractical, even if techniques were available to detect all pathogens of concern. Therefore, indicator organisms are used to predict the health risks from pathogens residing in waterbodies. The U. S. Environmental Protection Agency (EPA) conducted studies [1,2] demonstrating that for fresh water, *Escherichia coli* (*E. Coli*) and enterococci are best suited for predicting the presence of gastrointestinal illness-causing pathogens in freshwater and for marine waters, enterococci is best suited. EPA published its recommendations in *Ambient Water Quality Criteria for Bacteria*–1986.[3]

1.1 What is the purpose of this guidance?

This guidance provides recommendations to help States, Territories, and authorized Tribes[*] implement EPA's recommended water quality criteria for bacteria. EPA strongly encourages States[**] that have not already done so, to adopt the recommendations set forth in *Ambient Water Quality Criteria for Bacteria* – 1986 or other water quality criteria for bacteria based on scientifically defensible methods into their water quality standards to replace water quality criteria for total or fecal coliforms. EPA's 1986 water quality criteria for bacteria recommend the use of enterococci for marine waters and *E. coli* or enterococci for fresh waters. As indicated in EPA's Office of Water *Guidance to States, Tribes, and Regions on Priorities for the Water Quality Standards Program for FY 2000-2002*, the transition to *E. coli* and enterococci bacterial indicators is an Agency priority for the triennial review of water quality standards occurring in FY2000-2002. EPA encourages States to take these steps during their upcoming triennial reviews. If a State, Territory, or authorized Tribe does not adopt EPA's recommended 1986 bacteria water quality criteria during this period, EPA intends to act under section 303(c)(4)(B) of the Clean Water Act (CWA) to promulgate federal water quality standards, with the goal of assuring that EPA's recommended 1986 bacteria water quality criteria apply in all States, Territories, and authorized Tribes, as appropriate, by 2003.

[*]Pursuant to section 518(e) of the CWA, EPA is authorized to treat an Indian Tribe in the same manner as a State for the purposes of administering a water quality standards program. 40 CFR 131.8 establishes the criteria by which the Agency makes such a determination. At this time, 21 tribes have requested and been granted authorization for treatment as a State, and 14 Tribes have adopted water quality standards pursuant to section 303(c) of the Act, and the implementing federal regulations at 40 CFR 131.

[**]Note: The term "States" will be used to denote States, Territories, and authorized Tribes.

1.2 Why is EPA publishing this guidance?

Despite EPA's and other studies (see section 2.0) demonstrating better correlation between swimming-associated illnesses and *E. coli* and enterococci counts, many States continue to use either fecal or total coliform water quality criteria to protect and maintain designated uses. As of April 1999, only 16 States, two Territories, and two Tribes had adopted EPA's recommended water quality criteria for *E. coli* and/or enterococci to protect designated recreational waters. EPA recognizes there has been some uncertainty among States with regard to how EPA's recommended 1986 bacteria water quality criteria should be implemented and how the transition should be made from fecal coliforms to *E. coli* and enterococci. This guidance addresses those issues identified by States as impeding their progress toward adopting and implementing EPA's current recommended water quality criteria for bacteria.

In March 1999, EPA released its *Action Plan for Beaches and Recreational Waters* (Beach Action Plan). In the Beach Action Plan, the Agency acknowledges the need to move to *E. coli* and enterococci and commits EPA's Office of Water to developing a policy to facilitate State adoption of the recommended water quality criteria. This guidance carries out that commitment and continues to strongly encourage States to adopt the 1986 water quality criteria for bacteria during their next triennial reviews. To assist States in the adoption and implementation of EPA's recommended water quality criteria for bacteria, this document addresses the following:

- A reaffirmation of the scientific validity of the *Ambient Water Quality Criteria for Bacteria* -- 1986 through a review of relevant peer-reviewed studies conducted since EPA's 1984 epidemiological studies;

- Explanation of the relationship between water quality standards and beach monitoring and advisory programs;

- Recommendations for making the transition from fecal coliforms to EPA's recommended water quality criteria, including the use of multiple indicators during a transition period;

- Implementation of EPA's recommended water quality criteria in water quality regulatory programs;

- Application of EPA's recommended water quality criteria to waters contaminated by non-human sources;

- Appropriate approaches for monitoring the safety of recreational waters in those tropical climates where *E. coli* and enterococci may exist naturally in the soil environment, possibly complicating the use of those organisms as indicators;

- Appropriate approaches for managing risk in non-primary contact recreational waters, including the use of alternate illness rates and site-specific water quality criteria;

- Current and future activities: projected schedule for proposed promulgation of methods

into 40 *CFR* 136, announcement of a training video, drafts of the *National Guidance for Recreational Beach Managers* and the *Implementation of the Water Quality-Based Provisions in the CSO Control Policy*, and the schedule for the release of the *Assessment Methodology Guidance*.

1.3 Who should use this guidance?

This guidance should be used by State, Territory, and authorized Tribal environmental agencies administering a water quality standards program.

1.4 What is the basis for EPA's 1986 water quality criteria for bacteria?

In 1986, EPA published *Ambient Water Quality for Bacteria* –1986. The water quality criteria recommend bacterial geometric mean densities not to be exceeded in marine and fresh recreational waters and provide a scientific rationale for developing water quality standards to maintain the safety of waters used as recreational resources. The data supporting the water quality criteria were obtained from a series of research studies conducted by EPA examining the relationship between swimming-associated illness and the microbiological quality of the waters used by recreational bathers.[1,2]

The results of those studies demonstrated that fecal coliforms, the indicator originally recommended in 1968 by the Federal Water Pollution Control Administration of the Department of the Interior, showed less correlation to swimming-associated gastroenteritis than some other indicator organisms. Two indicator organisms, *E. coli* and enterococci, showed a strong correlation, the former in fresh waters only and the latter in both fresh and marine waters. The strong correlation may be a result of the survivability of the indicator organisms in the environment being similar to the survivability of the pathogens of concern. Regrowth of fecal coliforms under certain environmental conditions has been problematic; the conditions necessary for *E. coli* and enterococci to experience regrowth are within much narrower ranges than the conditions suitable for the regrowth of fecal coliforms. Another factor favoring enterococci as an indicator organism is its resistance to environmental factors, particularly saline environments, enhancing its ability as a suitable indicator for marine waters.

Consequently, EPA's *Ambient Water Quality Criteria for Bacteria* - 1986 recommended the use of *E. coli* and enterococci rather than fecal coliforms. The recommended steady-state geometric mean values of these water quality criteria for bacteria are 33 enterococci per 100 milliliters (ml) and 126 *E. coli* per 100 ml for fresh waters; and a geometric mean of 35 enterococci per 100 ml for marine waters. These values are based on specific levels of risk of acute gastrointestinal illness. The levels of risk used by EPA correlating to these values are no more than eight illnesses per 1,000 swimmers for fresh waters, and no more than 19 illnesses per 1,000 swimmers for marine waters. The illness rates are EPA's best estimates of the accepted illness rates for areas that had previously applied the fecal coliform criterion. EPA has determined that when implemented in a conservative manner, these water quality criteria are protective of gastrointestinal illness resulting from primary contact recreation.

2.0 Reaffirmation of EPA's recommended water quality criteria

2.1 Does EPA still support its *Ambient Water Quality Criteria for Bacteria* – 1986?

EPA reviewed the original studies supporting its recommended 1986 water quality criteria for bacteria and the literature on epidemiological studies conducted after EPA performed its marine and freshwater studies of swimming-associated health effects. As a result of these reviews, EPA continues to believe that when applied and implemented conservatively, EPA's recommended water quality criteria for bacteria are more protective of human health for gastrointestinal illness than fecal coliforms.

EPA believes that these water quality criteria must be applied and implemented conservatively for several reasons. Alternative statistical models applied to the original studies on which the water quality criteria are based suggest higher estimated illness rates for the same recommended geometric means. In addition to the results of the statistical analyses, several other factors also argue for the conservative application of water quality criteria for bacteria. New pathogens and strains of antibiotic resistant bacteria capable of causing gastrointestinal illness have evolved since EPA's studies were conducted. In addition, EPA's recommended water quality criteria for bacteria are only intended to protect against gastrointestinal illness-causing pathogens. Other pathogens may be present in a waterbody capable of causing eye, ear, nose, and throat infections as well as skin rashes and respiratory illness. Also, as stated in *Ambient Water Quality Criteria for Bacteria*–1986:

> "...the major limitations of the criteria are that the observed relationship may not be valid if the size of the population contributing the fecal wastes becomes too small or if epidemic conditions are present in a community. In both cases the pathogen to indicator ratio, which is approximately constant in a large population becomes unpredictable and therefore, the criteria may not be reliable under these circumstances."

To assure water quality criteria for bacteria are generally protective for gastrointestinal illness, EPA recommends frequent monitoring of known bathing areas to establish a more complete database upon which to determine if the waterbody is attaining the water quality criteria; conservative use of mixing zones for bacteria where mixing zones are authorized; prohibiting mixing zones from impacting known primary contact recreation areas; using the appropriate single sample maximum in the assessment of primary contact recreation waterbodies; and conducting a sanitary survey when higher than normal levels of bacteria are measured. A sanitary survey is an examination of a watershed to determine if unauthorized sanitary discharges are occurring from sources such as failed septic tank leach fields or cesspools, sewage leakage from broken pipes, sanitary sewer overflows from hydraulically overloaded sewers, or overflows from storm sewers that may contain illegal sanitary sewer connections. The survey should use available public health and public works departments' records to identify where such septic tanks and sewer lines exist so that observations are focused in the right places. A sanitary survey might also use dyes or other tracers in both dry and wet weather to see if unauthorized discharges are occurring from septic tanks and sewers. In addition, EPA recommends that sanitary surveys identify other possible sources, including confined animal areas, wildlife watering points, and

recreational spots, such as dog running/walking areas, since these are also sources of fecal pollution. EPA also reiterates that States may adopt more stringent water quality criteria to address these concerns.

In addition to its review of the original studies, EPA reviewed the literature on epidemiological studies conducted after EPA performed its marine and freshwater studies of swimming-associated health effects. The review examined recent data to determine if EPA's findings were supported or if different indicator bacteria were consistently shown to have quantitatively better predictive abilities. EPA's Office of Research and Development (ORD) reviewed 11 separate peer-reviewed studies. This detailed review is contained in the following paragraphs. Upon this review, ORD concluded:

> The epidemiological studies conducted since 1984, which examined the relationships between water quality and swimming-associated health effects, have not established any new or unique principles that might significantly affect the current guidance EPA recommends for maintaining the microbiological safety of marine and freshwater bathing beaches. Many of the studies have, in fact, confirmed and validated the findings of the U.S. EPA studies. There would appear to be no good reason for modifying the Agency's current guidance for recreational waters at this time.

As a result of this examination, EPA believes its 1986 water quality criteria for bacteria continue to represent the best available science and serve as a defensible foundation for protecting public health in recreational waters. EPA finds no reason to undertake a revision of the water quality criteria at this time. EPA continues to believe that when applied and implemented conservatively, EPA's recommended *Ambient Water Quality Criteria for Bacteria*–1986 are fully protective of human health for gastrointestinal illness.

2.2 What was the design of the studies used to develop EPA's recommended water quality criteria?

In 1986, EPA published its recommended ambient water quality criteria for bacteria for marine and fresh recreational waters. The water quality criteria provide a scientific rationale for States, Territories, and authorized Tribes to use as guidance in adopting water quality standards to maintain the safety of waters used as recreational resources. The data supporting the water quality criteria were obtained from a series of research studies[1,2] conducted by EPA examining the relationships between swimming-associated illness and the microbiological quality of waters used by recreational bathers. Some of the salient features of the design of the research studies are described below and will be referred to in later parts of the review. The EPA design for beach studies has been used in many subsequent studies of swimming-associated health effects and water quality in other countries.

The EPA studies were unique at the time they were initiated because they attempted to relate swimmer illness to water quality at the time of swimming. This was done by approaching individuals as they were leaving the beach and asking if they would volunteer to be a part of the bathing beach studies. Individuals that had been swimming in the previous week were not made

part of the study. After seven to 10 days, the volunteers were contacted by telephone to determine their health status since the swimming event. Control non-swimmers, usually a member of the volunteer's family, were questioned in a similar manner. The water quality was measured on the day the volunteers swam. Multiple potential indicators were measured in each beach water sample. Multiple indicators were measured because it was unknown which one would best correlate to swimmer illness. The swimming-associated illness parameter was obtained by subtracting the non-swimmer illness rate from the swimmer illness rate using data collected over a summer trial. In those studies reported here using this design, it will state that the EPA design was used rather than describing it in detail each time.

2.3 What epidemiological studies on swimming-associated health effects and the quality of recreation water have been conducted since EPA published its recommended 1986 water quality criteria for bacteria?

A recent review by Pruss[4] of all studies since 1953 that examined the relationship between swimming-associated gastroenteritis and water quality, pointed out that nine separate marine studies and at least two fresh water studies had been conducted since the EPA studies were completed in 1984. In this review, each of those studies is summarized with regard to the size of the study, the study design, the water quality indicator bacteria measured, and the results of the study with respect to gastrointestinal illness. Some of the studies looked only at whether an association existed between swimming and illness at a polluted beach or a non-polluted beach, while other studies attempted to determine the relationship between increasing levels of poor water quality and the levels of gastrointestinal illness associated with those increases. This review does not address studies that examined non-enteric illnesses or infections unrelated to gastrointestinal disease. The intent of the review is to carefully examine all of the studies conducted subsequent to the EPA studies and to determine if they have a significant impact on the current water quality criteria for bacteria recommended by the Agency.

Marine Studies

In 1987, Fattal *et al*[5] reported on a study of health and swimming conducted at beaches near Tel-Aviv, Israel. The study design was the same as the one used by EPA. Beach water quality was measured using fecal coliforms, enterococci, and *E. coli*. Three beaches with different water qualities were studied. Symptoms among bathers were analyzed according to high and low categories of bacterial indicator densities in the seawater. The high and low categories for fecal coliforms were above and below 50 colony forming units (cfu) per 100 ml. The limits for enterococci and *E. coli* were 24 cfu per 100 ml. Excess illness was observed only in swimmers 0-4 years old at low categories of the indicators. Significant differences in illness rates between swimmers and non-swimmers occurred only at high indicator densities. Enterococci were the most predictive indicator for enteric disease symptoms.

In 1990, Cheung and his co-workers[6] reported on a health effects study related to beach water pollution in Hong Kong. The basic EPA design was used in conducting this investigation. Nine microbial indicators were examined as potentially useful measures of water quality. They included fecal coliforms, *E. coli, Klebsiella* spp, fecal streptococci, enterococci, staphylococci,

Pseudomonas aeruginosa, Candida albicans, and total fungi. The study was carried out at nine beaches that were polluted either by human sewage discharged from a submarine outfall or carried by storm water drains running into the beaches. Two of the beaches were contaminated mainly by livestock wastes. Approximately nineteen thousand usable responses were obtained, of which about 77% were from swimmers. The enterococci densities at the beaches ranged from 31 to 248 cfu per 100 ml. The range for *E. coli* was from 69 to 1714 cfu per 100 ml. The overall gastrointestinal illness rates were significantly higher in swimmers than in non-swimmers. Children under 10 years old were more likely to exhibit gastrointestinal illness (GI) and highly credible gastrointestinal illness (HCGI) symptoms than individuals older than 10 years. The best relationship between a microbial indicator density and swimming-associated health effects was between *E. coli* and HCGI.

Health risks associated with bathing in sea water in the United Kingdom were described by Balarajan *et al.*[7] in 1991. This study used the EPA design for these trials. The reported study was conducted at one beach where 1,883 individuals participated, 1,044 bathers and 839 non-bathers. The methods used to measure water quality were not given. Ratios of illness in swimmers to non-swimmers were developed. The rate of gastrointestinal illness was found to be significantly greater in bathers than in non-bathers. The risk of illness increased with the degree of exposure, rising from 1.25 in waders, 1.31 in swimmers, and 1.81 in surfers or divers. The authors concluded that the increase was indicative of a dose-response relationship.

Von Schirnding and co-workers[8] conducted a study to determine the relationship between swimming-associated illness and the quality of bathing beach waters. A series of discrete, prospective trials was carried out at a relatively clean and a moderately polluted beach following the methodology used in the EPA studies. The beaches were situated on the Atlantic coast of South Africa. The moderately polluted beach was affected by septic tank overflows, storm water run-off, and feces-contaminated river water. A number of potential indicator organisms were measured including enterococci, fecal coliforms, coliphages, staphylococci, and F-male-specific bacteriophages. A total of 1,024 people were contacted, of whom 733 comprised the final study population. The moderately polluted beach was characterized by fecal coliforms and enterococci. The median fecal coliform density was 77 cfu per 100 ml and the median enterococci density was 52 cfu per 100 ml. The median fecal coliform and enterococci densities at the relatively clean beach were 8 and 2 cfu per 100 ml, respectively. The rates for gastrointestinal symptoms were appreciably higher for swimmers than non-swimmers at the more polluted beach than at the less polluted beach, but the differences were not statistically significant, either for children less than ten years of age or for adults. The lack of statistical significance may have been due in part to the uncertain sources of fecal contamination.

In 1993, Corbett *et al.*[9] conducted a study to determine the health risks of swimming at ocean beaches in Sydney, Australia. The study used a design slightly modified from the EPA approach. First, no one under the age of 15 was recruited for the study and, second, multiple samples were taken at the time of swimming activity. The inclusion of families and social groups was minimized. Water quality was measured using fecal coliforms and fecal streptococci. A total of 2,869 individuals participated in the study. Of this group, 32.2% reported that they did not swim. In general, gastrointestinal symptoms in swimmers did not increase with increasing counts of fecal bacteria. However, fecal streptococci were worse predictors of swimming-

associated illness than fecal coliforms. Although no relationship was observed between the measured indicators and gastrointestinal illness, swimmers who swam for more than 30 minutes were 4.6 times more likely to develop gastrointestinal symptoms than were those that swam for less than 30 minutes. The lack of a relationship between increasing fecal coliform densities and gastrointestinal symptoms was similar to results noted in the EPA marine and freshwater studies where increasing illness rates were not associated with increasing fecal coliform densities.

In 1994, Kay *et al.*[10] conducted a series of four trials at bathing beaches in the United Kingdom to examine the relationship between swimming-associated illness and water quality. The design of this study differed from previous studies in that the study population was selected prior to each trial. On the trial date, half of the participants were randomly assigned to be swimmers, with the remaining participants being non-swimmers. Each swimmer swam in a designated area that was monitored by taking a sample every 30 minutes. Samples were analyzed for total and fecal coliforms, fecal streptococci, *Pseudomonas aeruginosa,* and total staphylococci. The total number of participants in the study was 1,112, of which 46% were selected as swimmers. All of the study volunteers were older than 18 years of age. Analysis of the data indicated that the rates of gastroenteritis were significantly higher in the swimming group than in the non-swimming group. Only fecal streptococci showed a significant dose-response relationship with gastroenteritis. The analysis suggested that the risk of gastroenteritis did not increase until bathers were exposed to about 40 streptococci per 100 ml.

In 1995, Kueh *et al*[11] reported a second study conducted at Hong Kong beaches. Only two beaches were examined in the second study, rather than the nine beaches examined in the 1990 Hong Kong study. The study design for collecting health data was similar to that followed in the EPA studies. The ages of study participants ranged from 10 to 49 years of age. Unlike the EPA studies, follow-up telephone calls were made two days after the swimming event rather than seven to 10 days. Another aspect of the Hong Kong study differing from the EPA studies was the collection of clinical specimens from ill participants with their consent. Stool specimens were analyzed for Rotavirus, *Salmonella* spp, *Shigella* spp, *Vibrio* spp, and *Aeromonas* spp. Throat swabs were examined for Influenza A and B; Parainfluenza virus types 1, 2 and 3; Respiratory Syncytial Virus and Adenovirus. Water samples were examined for *E. coli*, fecal coliforms, staphylococci, *Aeromonas* spp, *Clostridium perfringens, Vibrio cholera, Vibrio parahemolyticus, Vibrio vulnificus, Salmonella* spp, and *Shigella* spp. A total of 18,122 individuals participated in the study. Although the levels of indicator densities were not reported for the beaches, the gastrointestinal illness rates were significantly higher at the more polluted beach. This study did not find a relationship between *E. coli* and swimming-associated illness as had been found in the original Hong Kong study. This may have been, as pointed out by the authors, due to the fact that only two beaches were examined rather than nine. The cause of the infections could not be ascertained from the clinical specimens obtained from ill individuals.

In 1998, McBride *et al*[12] reported prospective epidemiological studies on the possible health effects from sea bathing at seven New Zealand beaches. A total of 1,577 and 2,307 non-swimmers participated in the studies. Although the EPA study design was used, it was slightly modified in that follow-up interviews were conducted three to five days after the swimming event rather than the seven to 10 days used in the U.S. studies. Fecal coliforms, *E. coli*, and enterococci were used to measure water quality. The results of the study showed that enterococci

were most strongly and consistently associated with illness risk for the exposed groups. Risk differences between swimmers and non-swimmers were significantly increased if swimmers stayed in the water for more than 30 minutes as compared to those in the water less than 30 minutes. The risk differences were slightly greater for paddlers than for swimmers.

The most recent study of possible adverse health effects associated with swimming in marine waters was conducted at beaches on Santa Monica Bay, California, by Haile and co-workers.[13] The objective of this study was to determine if excess swimming-associated illness could be observed in swimmers exposed to waters receiving discharges from a storm drain. The study design was patterned after the U.S. EPA studies. Water samples were taken at ankle depth and collected from sites at the storm drain, 100 yards up-coast, and 100 yards down-coast. Samples were also collected 400 yards up-coast or down-coast of the storm drain, depending on which location would be used as a control area. The samples were analyzed for total coliforms, fecal coliforms, enterococci, and *E. coli*. One sample was collected each Friday, Saturday, and Sunday of the study at the mouth of the storm drain and analyzed for enteric viruses. Subjects of all ages participated in the study. A total of 11,686 subjects volunteered to take part in the study. The results of the study with regard to associations between bacterial indicators and health outcomes were presented in terms of thresholds of bacterial densities, which were somewhat arbitrarily chosen. No positive associations, as measured by risk ratios, were observed for *E. coli* at bacterial density thresholds of 35 and 70 cfu per 100 ml. A less arbitrary analysis using a continuous model showed more positive associations, especially for enterococci. The model for enterococci indicated positive associations with fever, skin rash, nausea, diarrhea, stomach pain, coughing, runny nose and highly credible gastrointestinal illness. The associations of symptoms with indicators were very weak in the case of *E. coli* and fecal coliforms. The authors also found that the total coliform to fecal coliform ratio was very informative. Using a ratio of 5.0 as a threshold, diarrhea and highly credible gastrointestinal illness were associated with a lower total coliform to fecal coliform ratio regardless of the absolute level of fecal coliforms. When their analysis was restricted to subjects where the total coliforms exceeded 5000 cfu per 100 ml, significantly higher risks were detected for most outcomes. One of the general conclusions of the study was that excess gastrointestinal illness is associated with swimming in feces-polluted bathing water.

Fresh Water Studies

In 1985, Seyfried *et al.*[14] reported on a prospective epidemiological study of swimming-associated illness in Canada. These investigations used the EPA methodology in carrying out the study. Water quality was measured with the following bacterial indicators of swimming water quality: fecal coliforms, fecal streptococci, heterotrophic bacteria, *Pseudomonas aeruginosa* and total staphylococci. A total of 4,537 individuals participated in the study, of which 2,743 were swimmers and 1,794 were non-swimmers. Swimmers were found to have significantly higher gastrointestinal illness rates than non-swimmers, and swimmers under the age of 16 had substantially higher rates than swimmers 16 and older. Logistic regression analysis was performed to determine the best relationship between water quality indicators and swimming-associated illness. A small degree of correlation was observed between fecal streptococci and gastrointestinal illness. The best correlation was between gastrointestinal illness and

staphylococcus densities.

In 1989, Ferley *et al*[15] described an epidemiological study conducted in France that examined health effects associated with swimming in a freshwater river. A total of 5,737 individuals participated in the study. The quality of the water was measured by assaying for fecal coliforms, fecal streptococci, and *Pseudomonas aeruginosa*. The study design for collecting health data was unique. The maximum latency period for the illness category groups examined in this study was three days. Illnesses occurring during the course of the study were assigned to the nearest day within the latency period on which a sample was taken. A weighted linear regression was performed to relate gastrointestinal morbidity incidence rates to different levels of exposure to indicator bacteria. Significant excess gastrointestinal illness was observed in swimmers. Furthermore, regression of gastrointestinal illness incidence to the concentration of indicator organisms showed a good relationship between swimming-associated illness, and both fecal coliforms and fecal streptococci. The strongest correlation with incidence rates of acute gastrointestinal disease was to fecal streptococci densities. The authors indicate that what they defined as fecal streptococci essentially included what the U.S. EPA studies call enterococci.

2.4 Have subsequent studies affected EPA's recommended water quality criteria for bacteria?

No. None of the studies examined by EPA in its review presented evidence that necessitate revising the 1986 water quality criteria for bacteria recommended by EPA. Most of the studies used a survey plan similar to that used by EPA in the Agency's studies during the 1970's and 1980's. The study sites chosen by most, if not all, of the investigators also were similar to those studied by EPA. One site was usually a beach, with some fecal contamination, and the other site was usually a relatively unpolluted beach. Most of the pollution sources to the polluted beaches came from known point sources. The results from these studies were similar to those found in the EPA studies, *i.e.*, swimming in fecal contaminated water is associated with a higher rate of gastrointestinal illnesses in swimmers when compared to non-swimmers. This outcome was not observed in one or two of the studies. The reason for a negative finding is unclear, but it could be related to factors such as the short length of time between the swimming event and the follow-up contact, the lack of children in the study groups, or the selection of a study site where the pollution source was poorly defined.

Only a limited number of studies attempted to show a dose-response relationship between swimming water quality and gastrointestinal illness. Six of the studies [6,10,12,14,15] showed that as the level of pollution increased, there was also an increase in swimming-associated illness. Only two studies that looked for a relationship between swimming-associated illness and the level of water quality failed to find such a relationship.[9,11] It is possible that these findings were related to the indicator organisms measured, fecal coliforms and fecal streptococci, or to the methodology used to detect the indicators. In general, the result of these studies was similar to the results found in the EPA studies, *i.e.*, the swimming-associated illness rate increased with the water pollution levels.

It has been shown that some organisms are superior to others for predicting gastrointestinal illness in swimmers based on the density of the indicator organism in bathing waters. In the EPA studies, *E. coli* and enterococci showed the strongest relationships to swimming-associated gastrointestinal illness. Some of the studies reviewed describe other microbes showing strong relationships to swimming-associated gastrointestinal illness, such as staphylococci,[14] *Clostridium perfringens*,[11] and *Aeromonas* spp.[11] Most of the studies, however, had findings similar to those of the EPA studies where enterococci were shown to be the most efficient indicator for measuring marine water quality. One of the two fresh water studies indicated that *E. coli* and enterococci showed very strong relationships to swimming-associated gastrointestinal illness. In general, the best indicator organisms for measuring water quality in the reviewed studies were similar to those observed in the EPA studies (*e.g.*, *E. coli* and enterococci).

The EPA and other studies reviewed here mainly examine the relationships between densities of indicator bacteria and gastrointestinal illness. EPA's recommended water quality criteria for bacteria are for protection from gastrointestinal illness. Pathogens are also capable of causing other health effects, including skin, eye, ear, nose, and throat infections, as well as skin rashes and respiratory illness. As part of EPA's Beach Action Plan, EPA intends to investigate the development of water quality criteria for other pathogens capable of causing other adverse health effects.

The epidemiological studies conducted since 1984, examining the relationships between water quality and swimming-associated gastrointestinal illness, have not established any new or unique principles that might significantly affect the current water quality criteria EPA recommends for protecting and maintaining recreation uses of marine and fresh waters. Many of the studies have, in fact, confirmed and validated the findings of EPA's studies. Thus, EPA has no new scientific information or data justifying a revision of the Agency's recommended 1986 water quality criteria for bacteria at this time.

Summary of Research Conducted since 1984

Researcher	Year	Location	Type of Water	Microorganisms Evaluated	Relevant Findings
Fattal *et al.*[5]	1987	Israel	Marine	Fecal coliforms Enterococci *E. coli*	• Enterococci were the most predictive indicator for enteric disease symptoms
Cheung *et al.*[6]	1990	Hong Kong	Marine	Fecal coliforms *E. coli* *Klebsiella* spp Enterococci Fecal streptococci Staphylococci *Pseudomonas aeruginosa* *Candida albicans* Total fungi	• Best relationship between a microbial indicator density and swimming-associated health effects was between *E. coli* and highly credible gastrointestinal illness.
Balarajan *et al.*[7]	1991	United Kingdom	Marine	Unknown	• Risk of illness increased with degree of exposure. If the non-exposed population risk ranked at 1, risk increased to 1.25 for waders, 1.31 for swimmers, and 1.81 in surfers or divers.
Von Schirnding *et al.*[8]		South Africa (Atlantic coast)	Marine	Enterococci Fecal coliforms Coliphages Staphylococci F-male-specific bacteriophages	• Uncertainty in sources of fecal contamination may explain lack of statistically significant rates of illness between swimmers and non-swimmers.
Corbett *et al.*[9]	1993	Sydney, Australia	Marine	Fecal coliforms Fecal steptococci	• Gastrointestinal symptoms in swimmers did not increase with increasing counts of fecal bacteria. • Counts of fecal streptococci were worse predictors of swimming-associated illness than fecal coliforms.
Kay *et al.*[10]	1994	United Kingdom	Marine	Total coliforms Fecal coliforms Fecal streptococci *Pseudomonas aeruginosa* Total staphylococci	• Only fecal streptococci were associated with increased rates of gastroenteritis. • Risk of gastroenteritis did not increase until bathers were exposed to about 40 fecal streptococci per 100 ml.

Summary of Research Conducted since 1984

Researcher	Year	Location	Type of Water	Microorganisms Evaluated	Relevant Findings
Kueh *et al.*[11]	1995	Hong Kong	Marine	*E. coli* Fecal coliforms Staphylococci *Aeromonas* spp *Clostridium perfringens* *Vibrio cholera* *Vibrio parahemotylicus* *Salmonella* spp *Shigella* spp	• Also analyzed stool specimens for rotavirus, *Salmonella* spp, *Shigella* spp, *Vibrio* spp, and *Aeromonas* spp; throat swabs for Influenza A and B; Parainfluenza Virus types 1, 2, and 3; and Respiratory Syncytial Virus, and Adenovirus. • Did not find a relationship between *E. coli* and swimming-associated illness [possibly due to low number of beaches sampled (only two)].
McBride *et al.*[12]	1998	New Zealand	Marine	Fecal coliforms *E. coli* enterococci	• Enterococci were most strongly and consistently associated with illness risk for the exposed groups. • Risk differences significantly greater between swimmers and non-swimmers if swimmers remained in water for more than 30 minutes.
Haile *et al.*[13]	1996	California, USA	Marine	Total coliforms Fecal coliforms Enterococci *E. coli*	• Results for enterococci indicate positive associations with fever, skin rash, nausea, diarrhea, stomach pain, coughing, runny nose, and highly credible gastrointestinal illness. • Association of symptoms with both *E. coli* and fecal coliforms were very weak. • Total coliform to fecal coliform ratio very informative — below the cutpoint of 5.0, diarrhea and highly credible gastrointestinal illness were associated with a lower ratio regardless of the absolute level of fecal coliforms.
Seyfried *et al.*[14]	1985	Canada	Fresh	Fecal coliforms Fecal streptococci Heterotrophic bacteria *Pseudomonas aeruginosa* Total staphylococci	• Small degree of correlation observed between fecal streptococci and gastrointestinal illness. • Best correlation was between gastrointestinal illness and staphylococcus densities.

Summary of Research Conducted since 1984					
Researcher	**Year**	**Location**	**Type of Water**	**Microorganisms Evaluated**	**Relevant Findings**
Ferley *et al.*[15]	1989	France	Fresh	Fecal coliforms Fecal streptococci *Pseudomonas aeruginosa*	• In this study, the definition of fecal streptococci is essentially the same as the U.S. definition of enterococci. • Good relationship between swimming associated illness and fecal coliform and fecal streptococci concentrations. • Strongest relationship was between gastrointestinal disease and fecal streptococci densities.

3.0 Relationship between water quality standards and beach monitoring and advisory programs

Section 303 of the Clean Water Act (CWA or "the Act") directs States, with oversight by EPA, to adopt water quality standards to protect the public health and welfare, enhance the quality of water and serve the purposes of the CWA. Under section 303, States are required to develop water quality standards for waters of the United States within the State. Section 303(c) provides that water quality standards shall include the designated use or uses to be made of the water, taking into account the water's use and water quality criteria necessary to protect those uses. Water quality criteria must be based on sound scientific rationale and must contain sufficient parameters to protect designated uses. EPA's implementing regulations at 40 *CFR* 131.11 require States, Territories and authorized Tribes to adopt water quality criteria based on EPA's recommended 304(a) water quality criteria or other scientifically defensible methods. Within the context of this guidance, States, Territories and authorized Tribes would adopt EPA's recommended water quality criteria for bacteria, or other water quality criteria for bacteria based on scientifically defensible methods, to protect those waterbodies designated for primary contact recreation. Waterbodies designated for primary contact recreation may vary from small, locally known swimming holes to large well-known bathing beaches.

EPA's current 304(a) criteria are used as the basis for Agency decisions, both regulatory and nonregulatory, until EPA revises and reissues chemical-specific 304(a) criteria. For example, 304(a) criteria are used in the following ways: (1) as guidance to States and Tribes for use in establishing water quality standards; (2) as the basis for EPA promulgation of water quality standards; (3) in establishing NPDES water quality-based permit limits, where the criteria have been adopted by a State or Tribe or promulgated by EPA; and (4) for all other purposes of Section 304(a) criteria under the Act. It is important to emphasize again two distinct purposes which are served by the 304(a)criteria. The first is as **guidance** to States, Territories, and authorized Tribes in the development and adoption of water quality criteria which will protect designated uses, and the second is as the basis for **promulgation** of a superseding Federal rule when such action is necessary. EPA's recommended 304(a) water quality criteria for bacteria are based on a geometric mean calculated from samples taken over a 30-day period with no samples exceeding a specified "single sample maximum."

In addition to the uses for EPA's recommended water quality criteria listed above, some beach monitoring and advisory programs have used EPA's recommended water quality criteria for bacteria to issue beach advisories and make opening and closure decisions for designated bathing areas. While EPA encourages coordination between State water quality standards programs and beach monitoring and advisory programs, States have considerable flexibility when implementing EPA's water quality criteria as part of beach monitoring and advisory programs. EPA understands that the authority for administering these programs varies from State to State and may rest with State, local, or municipal government. When the governmental body with the responsibility and authority for a beach monitoring and advisory program differs from a State's water quality standards program, EPA encourages coordination of these programs to ensure the greatest efficiency and consistency in monitoring and data collection.

Currently, there are two pending pieces of legislation in Congress which would support

both EPA water quality criteria for recreational uses and beach monitoring and public notification programs. As currently drafted, H.R. 999 and S. 522 would require States to adopt EPA's recommended 1986 water quality criteria for bacteria for their coastal recreation waters and require EPA to promulgate federal water quality standards for these waters if the States fail to do so. The bills would also establish a national beach program involving monitoring and public notification.

4.0 Implementation of EPA's *Ambient Water Quality Criteria for Bacteria* – 1986

4.1 What is EPA's recommended approach for States making the transition from fecal coliforms to *E. coli* and/or enterococci?

EPA recognizes that States that have yet to adopt EPA's recommended 1986 water quality criteria for bacteria may be concerned about how to ensure consistency and continuity within their regulatory programs. In addition, some States may lack an adequate database sufficient to support certain regulatory actions. One approach States may use to address this situation is to include both fecal coliforms and *E. coli*/enteroocci in their water quality standards for a limited period of time in order to establish an adequate database for *E. coli* and/or enterococci. For States choosing this approach, EPA expects that during this limited period of time, States will be actively collecting data on *E. coli* and/or enterococci and working to incorporate *E. coli* and/or enterococci water quality criteria into their water quality programs, *e.g.*, National Pollutant Discharge Elimination System (NPDES), 305(b), and 303(d) programs.

EPA notes that a State's lack of data for *E. coli* and/or enterococci is not sufficient cause for delaying adoption of the 1986 water quality criteria for bacteria into water quality standards or, once adopted, for not serving as the basis for 303(d) listing decisions. Further, current Agency guidance and policy explicitly reject the notion that States can avoid listing waters in anticipation of a change to a State's water quality standards.[16,17] For waterbodies previously listed under section 303(d) for not attaining water quality standards for fecal coliforms, EPA recommends that the waterbody continue to be included in the State's 303(d) list for pathogens until sufficient data have been collected on *E. coli*/enterococci to either develop a Total Daily Maximum Load (TMDL) or to support a de-listing decision. However, a State should not delay developing a TMDL where there is an immediate threat to public health or where a waterbody has been listed under 303(d) on the basis of fecal coliform exceedances, and such waterbody is a priority due to court order or state statute or regulations. In these situations, the State should develop the TMDL using the fecal coliform criterion, and monitor progress toward meeting all bacterial water quality standards. The TMDL may need to be revised if later data show a continuing problem under the *E. coli*/enterococci criterion. (Note: EPA proposed in August 1999 to change its TMDL regulation to require that listed waters stay on the 303(d) list until such time that the water quality achieves water quality standards. See 64 Fed. Reg. 46012, 46049 (Aug. 23, 1999). If this proposed change is promulgated, then the above recommendation is modified accordingly.)

4.2 How should EPA's recommended water quality criteria be implemented in State, Territory, and Tribal water quality programs?

EPA's recommended water quality criteria for bacteria have several roles in State water quality programs. To enable the various water quality programs to fully implement the water quality criteria for bacteria, States should adopt both a single sample maximum (based on the expected frequency of use) and a geometric mean into their water quality standards. As recommended in the water quality criteria, the single sample maximum for designated bathing areas should be used for those areas. In applying the other recommended values for single

sample maxima for less frequently used recreational waters, States should use their best judgment, considering the activities taking place or that may take place on the waterbodies within the State. EPA encourages States to utilize the single sample maxima recommended in the 1986 water quality criteria for bacteria, unless, as outlined in the water quality criteria, data are collected to tailor the single sample maximum values to site-specific conditions.

The following discussion regarding the implementation of EPA's 1986 water quality criteria for bacteria are based on EPA's recommendations for adopting geometric mean values and single sample maxima. In addition to using the water quality criteria for bacteria within water quality regulatory programs, States are encouraged to incorporate the water quality criteria within their beach monitoring and advisory programs. Separate guidance will be prepared by EPA's Beaches Environmental Assessment, Closure, and Health (BEACH) program in consultation with States, Territories, Tribes, other federal agencies, and the general public recommending where and how to monitor to decide if beach advisories or closures are necessary. (See section 3.0 and section 6.3 for further information.)

How should the primary contact recreation use be assessed and attainment determined?

The *Guidelines for Preparation of the Comprehensive State Water Quality Assessments (305(b) Reports) and Electronic Updates*[18] requires 1) the geometric mean of the samples taken to not exceed the criterion **and** 2) the single sample maximum to be met for a waterbody to be fully supporting its primary contact recreation use. The recommendations for preparation of 305(b) reports contained in the above document represent EPA's most recent guidance on assessing and determining attainment of designated uses.

In some situations, there has been a misconception regarding the first required element for assessing the status of the primary contact recreation use. Some States have mistakenly interpreted the water quality criteria as requiring a minimum number of samples in order to determine the attainment of the numeric water quality criteria. The confusion may have arisen because the water quality criteria recommend a geometric mean based on five samples taken over a 30-day period. The minimum number of samples used in the 1986 water quality criteria for bacteria is for accuracy purposes only; clearly, more frequent sampling yields more accurate results when determining the geometric mean. It is the geometric mean of the *samples collected* in conjunction with a single sample maximum that determines attainment of the numeric water quality criteria [*e.g.*, CWA §303(d) listing for fresh and marine waters], regardless of the number collected. This interpretation encourages the collection and use of data and is what has always been intended. EPA notes that this interpretation was used by the Agency when promulgating water quality standards for the Colville Confederated Tribes (40 *CFR* 131.35).

EPA recommends that recreation waters should be continuously monitored throughout the swimming season, particularly waters that are designated bathing areas, to ensure human health is adequately protected. However, there may be some waterbodies that merit less frequent monitoring. For waterbodies that are designated for primary contact recreation but are infrequently used by the public for recreation, it may not be possible to monitor frequently due to resources or other constraints. For situations such as these, EPA intends to explore more fully how data collected under these circumstances may be applied in making designated use support

decisions and attainment determinations as it develops the forthcoming *Assessment Methodology Guidance*. For designated bathing areas, additional monitoring guidance will be contained in the *National Guidance for Recreational Beach Managers*. (See section 6.0 for additional information about these future documents.) Regardless of the frequency of use, when monitoring indicates higher than normal levels of indicator bacteria, sanitary surveys should be conducted to determine and control the source. (See section 2.1 for recommendations on conducting sanitary surveys.)

How should permit limits be established for EPA's recommended water quality criteria for bacteria?

Attainment of water quality criteria for bacteria is a critical component of ensuring attainment of primary contact recreation uses. Once adopted as water quality standards by States, Territories, authorized Tribes, or EPA, these water quality criteria form the basis for water quality program actions, both regulatory and non-regulatory. For example, water quality criteria are used in establishing National Pollutant Discharge Elimination System (NPDES) water quality-based effluent limitations (WQBELs), are used as the basis for listing impaired waters under section 303(d), and may be used for beach monitoring and advisory programs. Under the Clean Water Act and the implementing federal regulations, States have flexibility in how they translate water quality standards into NPDES permit limits to ensure attainment of designated uses.

Many States have raised concerns regarding how EPA's 1986 water quality criteria for bacteria should be implemented through NPDES permits. The Agency is aware that States have taken different approaches in deriving NPDES permit limits for pathogens to ensure the ambient water quality criteria are met. For example, many States apply the ambient water quality criteria for bacteria directly to the discharge with no allowance for in-stream mixing (this is often referred to as "criteria end-of-pipe"). Alternatively, some States provide mixing zones for bacteria, and derive permit limits that account for in-stream dilution. EPA has also stated that for certain types of regulated discharges [*e.g.*, municipal separate storm sewer systems (MS4s), concentrated animal feeding operations (CAFOs)], the most appropriate permit requirements may be non-numeric controls such as best management practices (BMPs). The underlying principle, however, is that whichever approach the permitting authority uses, the permitting authority must determine that permit limits and requirements derive from and comply with applicable water quality standards.

With respect to determining whether WQBELs for pathogens are needed for a specific discharge, the Agency expects permitting authorities to use the same approach that applies to other pollutants. Thus, the permitting authority must include a WQBEL in the NPDES permit for any discharger if it determines that a pollutant (including all pathogenic pollutants) is or may be discharged at a level which will cause, have reasonable potential to cause, or contribute to an exceedance of any State water quality standard. See 40 CFR 122.44(d)(1)(i). When a State adopts new water quality criteria for *E. coli* and/or enterococci, it must immediately begin implementing these criteria through its NPDES permitting program. Additionally, if the State chooses to retain an existing water quality criterion for fecal coliforms, the State must continue to

implement this criterion in the form of a WQBEL as well.

Following adoption of water quality criteria for *E. coli* and/or enterococci, the Agency does not believe that permitting authorities will typically need to reopen existing permits prior to their expiration dates to incorporate WQBELs based on the newly adopted water quality criteria. Instead the Agency expects that existing WQBELs for fecal coliforms will continue to be enforced through the existing permit's term, and that permitting authorities will incorporate WQBELs based on newly adopted water quality criteria (as needed) at the time of permit issuance.

States that eliminate their water quality criterion for fecal coliforms when they adopt water quality criteria for *E. coli* and/or enterococci should also be aware of NPDES "antibacksliding" provisions. The CWA and implementing NPDES federal regulations contain specific restrictions on when an existing WQBEL may be removed or replaced with a less stringent effluent limitation in a reissued NPDES permit. See CWA section 402(o). It is the Agency's position that when a State replaces a fecal coliform criterion with water quality criteria for *E. coli* and/or enterococci, that the replacement will not generally result in less stringent effluent limits in the permit. In other words, if all other factors are unchanged, the WQBEL(s) based on the newly adopted water quality criteria (for *E. coli* and/or enterococci) will not be less stringent than the previous WQBEL (for fecal coliform) and the backsliding prohibitions in section 402 of the CWA and its implementing regulations do not apply.

How should EPA's recommended water quality criteria be applied to non-human sources of fecal contamination?

Today, EPA is changing its policy to recommend that States, Territories, and authorized Tribes apply the 1986 water quality criteria for bacteria or other water quality criteria for bacteria based on scientifically defensible methods to all waterbodies designated with primary contact recreation in order to ensure protection of human health from gastrointestinal illness. The relative health risk from waters contaminated by human sources versus non-human sources has been the subject of recent debate, particularly related to the application and implementation of EPA's recommended water quality criteria. Livestock, wildlife (especially waterfowl and deer), and domestic pets can contribute significant numbers of indicator bacteria to waterbodies. In the 1994 *Water Quality Standards Handbook*[19] EPA established a policy that States may apply water quality criteria for bacteria with the rebuttable presumption that the indicators show the presence of human fecal contamination. This policy was based on the absence of data correlating non-human sources of fecal contamination and human illness and on the belief that pathogens originating from non-human sources present an insignificant risk of gastrointestinal illness in humans.

Recent evidence indicates that warm-blooded animals other than humans may be responsible for transmitting pathogens capable of causing illness in humans. Examples include outbreaks of enterohemorrhagic *E. coli* O157:H7, *Giardia*, and *Cryptosporidium*, all of which are frequently of animal origin. These pathogens can cause significant gastrointestinal illness, although direct measurement of these organisms is not readily quantified by current conventional

microbial methods. In addition, while such non-human sources may be less significant in the transmission of the kinds of gastrointestinal illnesses identified in EPA's original epidemiological studies, the bacterial indicators contributed by non-human sources may also indicate risks of other human illnesses.

EPA recognizes that a study was conducted by Calderon *et al*[20] to determine if the human health risk from animal sources could be quantified. The study was conducted on a small 3-acre pond in a semi-rural community in central Connecticut and examined the relationship between water quality degraded by dispersed, unidentified sources of animal fecal contamination and swimmer illness. It found that although large numbers of indicator organisms were contributed to the waterbody by animals, the resulting health risk was insignificant to swimmers. This study concluded that EPA's currently recommended bacterial indicators are ineffective for predicting potential health effects associated with water contaminated by non-point, *i.e.*, animal sources, of fecal pollution.

EPA believes that this one study does not provide an adequate basis to conclude that non-human sources of fecal contamination have no potential to cause gastrointestinal illness in humans. For this reason, EPA believes it is not appropriate for the application of bacteria water quality criteria to distinguish between human and non-human sources. Until the time that a relationship between non-human sources of fecal contamination and human illness rates is established, EPA will continue to recommend the application of its water quality criteria for bacteria or other water quality criteria for bacteria based on scientifically defensible methods to all waterbodies designated with primary contact recreation in order to ensure protection of human health from gastrointestinal illness. Therefore, EPA is changing its policy regarding non-human sources of fecal contamination from what was previously contained in the *Water Quality Standards Handbook* on this issue.

While EPA believes a change in this policy is necessary to ensure protection of human health, EPA acknowledges such a change may present States with difficulties where the ambient water quality criterion is routinely exceeded due to non-anthropogenic sources of pollution, such as wildlife. Anthropogenic sources include sources related to man's activities, such as animal production agriculture, which may be controlled by effluent limitations or best management practices. Examples of non-anthropogenic and potentially uncontrollable sources are wildlife refuges or lakes frequented by waterfowl. For waterbodies such as these, where the source of fecal contamination is shown to be solely from uncontrollable natural sources and a State demonstrates the water quality criteria for bacteria or the primary contact recreation designated use is not attainable, EPA offers two options.

Under the first option, a State, Territory, or authorized Tribe may adopt a site-specific water quality criterion for such waterbodies. Such a criterion must ensure protection of the designated uses of the waterbody and be scientifically defensible. It is EPA's policy that when reviewing such a change, EPA will evaluate if a State has demonstrated that the source of fecal contamination is from a natural source and uncontrollable by either effluent limitations or best management practices. This can be done through a sanitary survey or other monitoring that adequately demonstrates the sources affecting the waterbody are from uncontrollable natural sources. (See section 2.1 for recommendations on conducting sanitary surveys.) The State

should also collect data to show what ambient concentrations of indicator bacteria are occurring, and provide its rationale supporting a site-specific criterion protective of the designated uses of that waterbody. EPA notes that in the development of a site-specific criterion, the data should be analyzed using the EPA formulas in *Ambient Water Quality Criteria for Bacteria*–1986 to calculate the log standard deviations and single sample limits of appropriate stringency.

The second option available to States is to change the designated use of the waterbody. This would require a use attainability analysis (UAA), consistent with 40 *CFR* 131.10, demonstrating that the current designated use is not an existing use and justifying that the use is not attainable. Under 40 *CFR* 131.10(j), States are required to conduct a use attainability analysis whenever the State designates uses that do not include the uses specified in section 101(a)(2) of the CWA, when the State wishes to remove a designated use that is specified in section 101(a)(2) of the Act, or adopt subcategories of uses that require less stringent water quality criteria. Existing uses are defined in 40 *CFR* 131.3 as any use which has occurred since November 28, 1975. In addition, designated uses are considered by EPA to be attainable, at a minimum, if the use can be achieved (1) through effluent limitations under section CWA §301(b)(1)(A) and (B) and §306, and (2) through cost effective and reasonable best management practices. The federal regulation at 40 *CFR* 131.10 establishes the basis for finding that attaining the designated use is not feasible, as long as the designated use is not an existing use. EPA also emphasizes that when adopting uses and appropriate criteria, States, Territories, and authorized Tribes must ensure that such standards provide for the attainment and maintenance of downstream water quality standards. See 40 *CFR* 131.10(b).

In some instances, demonstrating that a source is an uncontrollable natural source under the first option may be difficult. For example, waterfowl may be the only source of contamination for a waterbody running through a golf course. As stated above, a State must demonstrate that the contamination is solely from a natural source and is uncontrollable. With geese as the source of fecal pollution, it qualifies as a natural source. However, in this case it is human activity, *i.e.*, the golf course, that has attracted the waterfowl and thus would be considered an anthropogenic source. Such anthropogenic sources would be subject to best management practices prior to determining the water quality criteria were not attainable. If, after implementation of best management practices, the water quality criteria are determined to be unattainable, it may be desirable to set a site-specific criterion. Implementation of best management practices will establish how much of the fecal pollution is controllable. Upon the implementation of best management practices, a State may then choose to develop site-specific criteria based on the best attainable water quality.

The second option to remove the primary contact recreation use may be particularly applicable in cases such as wildlife refuges, where the presence of the identified source of contamination, wildlife, is desirable. Due to physical barriers and restrictions, primary contact recreation may not be an existing use. Controlling the source of pollution would not be appropriate by effluent limitations or best management practices, and thus the use can be demonstrated to be not attainable. If the primary contact recreation is not an existing use and is not attainable, the State may justify removing the primary contact recreation use.

With both options, an extensive sanitary survey would be necessary to identify all sources

of fecal contamination and eliminate any possible source of human or controllable non-human sources. Also, for the first option establishing site-specific criteria, the State, Territory or authorized Tribe would need to submit information detailing the existing ambient water quality. For the second option, documentation must be submitted to EPA demonstrating that the primary contact recreation use is not an existing use as defined in 40 *CFR* 131.3. For both of these options, EPA emphasizes the importance of public participation.

4.3 How should EPA's recommended water quality criteria be applied for recreational waters in tropical climates?

Recent research suggests that EPA's recommended indicator bacteria, *E. coli* and enterococci, may not be appropriate indicators for assessing the risk of gastrointestinal illness in tropical recreational waters. *E. coli* and enterococci have been found in soils and waterbodies where site surveys have indicated that it is unlikely that the source of these bacteria has been human fecal contamination.[21,22,23] Some researchers have hypothesized that these bacteria originated from other animals residing in the area and have developed mechanisms to maintain viable cell populations for significant periods of time in the uniform tropical conditions.[21] Because of this, the Hawaii Department of Health proposed *Clostridium perfringens* as an alternate indicator of human fecal contamination.[24]

Does EPA recommend a different indicator for tropical climates?

At this time there are insufficient data and information to allow EPA to recommend a different microbial indicator specifically for tropical waters. EPA believes that other microbial indicators may be appropriate for tropical waters, given the potential for *E. coli* and enterococci to persist in this climate. However, no studies have been published to date demonstrating the scientific defensibility of using an alternate indicator. EPA developed its recommended 1986 water quality criteria for bacteria based on correlations of indicator organism concentrations with gastrointestinal illness. Because bacteriological indicator water quality criteria are intended to protect primary contact recreation uses, a State, Territory or authorized Tribe intending to develop water quality criteria using alternate indicators should apply a risk-based methodology in the water quality criteria development process. See 40 C.F.R. § 131.11(b)(1)(iii) (scientifically defensible methods). In addition to demonstrating a statistically significant relationship to gastrointestinal illness, an alternate indicator should be indicative of recent contamination and be detectable using acceptable peer-reviewed analytical methods.

Clostridium perfringens is one such organism that has been proposed by a State as a bacteriological indicator. Hawaii recently proposed its use; however, in correspondence with Hawaii, EPA expressed concern about the lack of demonstrated correlation between the indicator and the incidence of gastrointestinal illness. An acceptable peer-reviewed analytical method does not yet exist and, in addition, because *C. perfringens* forms spores that can survive for extended periods of time, EPA questioned the ability of *C. perfringens* to indicate recent fecal contamination.

How should States, Territories, and authorized Tribes apply EPA's recommended 1986 water quality criteria for bacteria in tropical waters?

EPA strongly recommends conducting sanitary surveys in addition to microbial indicator testing, especially in areas where higher than normal microbial densities are observed during monitoring. This approach would be particularly applicable to tropical waters. (See section 2.1 for recommendations on conducting sanitary surveys.) Although a thorough sanitary survey process may eliminate human origin as the likely source of the indicator bacteria, care should be taken in concluding that there are no significant risks. Domestic pets and wildlife (especially waterfowl) can contribute significant numbers of indicator bacteria. While such non-human sources may be less significant in the transmission of the kinds of gastrointestinal illnesses identified in EPA's original epidemiological studies, the bacterial indicators may indicate risks of other illnesses. Recent outbreaks of enterohemorrhagic *E. coli* O157:H7, *Giardia* and *Cryptosporidium*, which are frequently of animal origin, cause significant illness.

As a general rule, the heavier the recreation population density, the more stringent the water quality criteria should be in order to protect public health. This is the philosophy followed by EPA in the *Ambient Water Quality Criteria for Bacteria* --1986, which allows a less stringent single sample limit at less heavily used swimming locations. Site-specific criteria may be developed following the process outlined in section 4.2 for non-human sources. EPA notes that in the development of a site-specific criterion, the data should be analyzed using the EPA formulas in *Ambient Water Quality Criteria for Bacteria*–1986 to calculate the log standard deviations and single sample limits of appropriate stringency.

In the case of Hawaii, which proposed the adoption of *C. perfringens* as a bacteriological indicator, EPA recommended the use of enterococci (expressed both as a geometric mean and single sample maximum) as the primary bacteriological indicator for marine and fresh waters, with *C. perfringens* as a secondary tracer of human fecal contamination if desired. This approach, in conjunction with site surveys, should be adequate to protect the primary contact recreational uses.

The above approaches are applicable, in general, to any tropical area with high background concentrations of indicator bacteria. EPA recommends determining the source of the bacteria by the application of the sanitary survey technique. If, based on a sanitary study, the State determines that contamination is unlikely to be caused by human sources and other factors have been evaluated, the State may then develop site-specific water quality criteria for bacteria as described in section 4.2. EPA recommends such water quality criteria for bacteria follow the EPA model of a geometric mean and single sample maximum.

4.4 Stream Flow (reserved)

4.5 Application of water quality criteria for bacteria in high flows (reserved)

4.6 Development and adoption of site-specific water quality criteria (reserved)

5.0 Appropriate Approaches for Managing Risk in Non-Primary Contact Recreational Waters

Recreation occurs in many forms throughout the U.S. and frequently centers around waterbodies and activities occurring in and on the water. To protect the public while recreating, States have adopted primary contact recreation uses and bacteriological criteria for the majority of the waterbodies. A primary contact recreation use should be adopted for any waterbody where people engage or are likely to engage in activities that could result in ingestion of the water or immersion. These activities include swimming, water skiing, kayaking, and others. The designation of this use should also take into account the behavior of children. Children are more likely to engage in activities where ingestion of water is likely, even in waterbodies where ingestion would not be likely for adults. Children will splash and swim in shallow waters that may otherwise be considered too shallow for full body immersion.

While most recreational waters are designated for primary contact recreation to protect people engaged in these activities, there are some waters where a recreation use with less stringent water quality criteria may be justified. States may justify a change to the primary contact recreation use for a waterbody through a use attainability analysis. See 40 *CFR* 131.10(g). These uses can include the designation of intermittent, secondary, or seasonal recreation uses. In some instances, recreation uses may be removed altogether. Subject to the provisions of 40 *CFR* 131.10, non-primary contact recreation uses may be applicable to waters that are, for example, irreversibly impacted by wet weather events, where meeting the primary contact recreation use at all times would result in substantial and widespread social and economic impact, or where the climate allows primary contact recreation to occur only on a seasonal basis.

Many States have adopted seasonal and secondary contact recreation uses for waterbodies. States with bacteriological water quality criteria based on fecal coliforms have generally adopted a secondary contact water quality criterion of 2000 cfu/100ml. This water quality criterion has been applied to secondary contact uses and to seasonal recreation uses during the months of the year not associated with primary recreation. The *Ambient Water Quality Criteria for Bacteria* -- 1986 recommending *E. coli* and enterococci as indicators did not recommend water quality criteria for recreation uses other than primary contact recreation. States have cited this as one reason why they have not adopted EPA's recommended water quality criteria.

5.1 Where should the primary contact recreation use and EPA's recommended water quality criteria apply?

EPA recommends States designate primary contact recreation and adopt water quality criteria to support primary contact recreation use wherever feasible to ensure protection of human health from gastrointestinal illness. Although conditions such as the location of a waterbody, high or low flows, safety concerns, or other physical conditions of the waterbody may make it unlikely that primary contact recreation would occur, EPA believes that people, particularly children, may swim or make other use of the waterbody such that ingestion may occur. Other populations, such as kayakers or surfers may actually seek out high flow or unsafe waters in

which to recreate. Further, EPA's recommended water quality criteria for bacteria are intended to provide protection against gastrointestinal illness-associated pathogens, and the infectious doses may vary depending on the individual and characteristics of the pathogen. In many instances, particularly for immuno-compromised individuals and children, this dose may be very low. This risk from pathogens differs markedly from the effects of other risk-based water quality criteria, such as carcinogens, which require chronic exposure to low doses of carcinogens before effects are evident.

5.2 When is it appropriate to designate recreation uses other than primary contact recreation?

EPA considers waters designated with primary contact recreation and waters designated with secondary contact recreation with bacteriological water quality criteria sufficient to support primary contact recreation to be consistent with the CWA §101(a) goal uses. States may designate subcategories of these recreation uses after demonstrating that primary contact recreation is not an existing use and the water quality necessary to support the use is not attainable based on chemical, physical, and biological analyses, as well as economic considerations. See 40 *CFR* 131.10(g). Any adoption of a subcategory of recreation uses with less stringent water quality criteria than required for primary contact recreation or the removal of recreation uses requires the State to submit appropriate justification for the change in designated use to EPA for review and approval. This includes instances where States adopt designated uses with associated water quality criteria that are less protective than EPA's recommended values or water quality criteria based on higher illness rates. (See section 5.4 for EPA's recommended water quality criteria for non-primary contact recreation uses.) In determining whether or not primary contact recreation is an existing or attainable use, States should take into account the fact that in certain circumstances, people will use whatever waterbodies are available for recreation, regardless of the physical conditions.

After considering whether a primary contact use and the water quality necessary to support the use is attainable, a State may wish to adopt subcategories of recreation uses. These can include the designation of intermittent, secondary, or seasonal recreation uses. Based upon an appropriate justification, recreation uses may be removed altogether. An **intermittent recreation use** may be appropriate when the water quality criteria associated with primary contact recreation are not attainable for all wet weather events, even with well-designed and operated systems. Meeting the water quality criteria associated with the primary contact recreation use may be suspended during defined periods of time, usually after a specified hydrologic or climatic event. EPA intends this designated use to be adopted for waterbodies in a limited number of circumstances, contingent upon a State, Territory, or authorized Tribe demonstrating that placing additional controls on sources of fecal contamination would result in substantial and widespread social and economic impact. Further guidance on refining water quality standards for combined sewer overflow receiving waterbodies will be contained in the *Implementation of the Water Quality-Based Provisions in the CSO Control Policy.* (See section 6.4 for more information.)

Where primary contact recreation is not an existing use, a **secondary contact recreation**

use with less stringent water quality criteria may be appropriate in some circumstances. For example, a discharger may not be able to meet the primary contact recreation use without causing substantial and widespread social and economic impact, but can meet the secondary contact recreation use. This would meet one of the six reasons contained in 40 CFR 131.10(g) justifying the removal of a designated use. The secondary contact recreation use may also be applicable to certain waterbodies where it can be demonstrated that flowing or pooled water is not present during the months when primary contact recreation is taking place, the waterbody is not in close proximity to residential areas, and that primary contact recreation is not an existing use. As discussed in section 4.2, designating a secondary contact recreation use may be appropriate where primary contact recreation is not an existing use and high levels of natural and uncontrollable fecal pollution exist.

A **seasonal recreation use** may be appropriate in those states where ambient air and water temperatures cool substantially during the winter months. For example, in many northern areas, primary contact recreation is possible only a few months out of the year. Several States have adopted, and EPA has approved, primary contact recreation uses and the associated microbiological water quality criteria, for those months when primary contact recreation occurs and have relied on less stringent secondary contact recreation water quality criteria to protect for incidental exposure in the "non-swimming" season.

5.3 What information should be contained in a use attainability analysis to adopt subcategories of a primary contact recreation use or to remove a primary contact recreation use?

States should consult EPA guidance[3,19] for general guidelines on conducting use attainability analyses (UAAs) for recreation uses. The likely components of a UAA for recreation uses may include:

- physical analyses considering the actual use, public access to the waterbody, facilities, proximity to residential areas, safety considerations, and substrate, depth, width, etc. of a waterbody;
- chemical analyses of existing water quality;
- potential for water quality improvements including an assessment of nutrients and bacteriological contaminants; and
- economic/affordability analyses.

(See also Section 4.2 for changes to recreation uses for waterbodies impacted by non-human sources)

On the subject of physical analyses, EPA has previously stated that, "Physical factors, which are important in determining attainability of aquatic life uses, may not be used as the basis for not designating a recreational use consistent with the CWA section 101(a)(2) goal".[25] This policy was further refined in the Advance Notice of Proposed Rulemaking on the Water Quality Standards Regulation (63 *FR* 36741), which stated:

EPA's current thinking is that physical factors, alone would not be sufficient

> justification for removing or failing to designate a primary contact recreation use. EPA's suggested approach to the recreational use question has been for States and Tribes to look at a suite of factors such as, the actual use, existing water quality, water quality potential, access, recreational facilities, location, safety considerations, and physical conditions of the waterbody in making any use attainability decision. The guidance suggests that any one of these factors, alone, may not be sufficient to conclude that designation of the use is not warranted.[25]

EPA continues to believe that downgrading or removing recreational uses due only to physical conditions is inappropriate when it is *otherwise feasible to meet water quality standards.* However, when considered with other data collected for a UAA, there are a few instances where physical considerations may play an important role. This may include a waterbody where access is prevented by fencing or in an urban waterbody that also serves as a shipping port or has close proximity to shipping lanes. It may also include waterbodies where primary contact recreation is not an existing use, it can be demonstrated that flowing or pooled water is not present during the months when recreation is taking place, and that the waterbody is not in close proximity to residential areas. In instances such as these, the physical attributes help to ensure primary recreation does not and will not occur in these waterbodies.

EPA understands that substantial and widespread social and economic impacts are often determining factors in assessing whether or not the primary contact recreation use and water quality to support the use can be met. EPA has published guidance to assist States in considering economic impacts in adopting water quality standards.[26] The cost of placing additional control measures on sources of fecal contamination are often-cited causes of being unable to meet the primary contact recreation use and the associated water quality criteria in all waters at all times. The federal regulation at 40 CFR 131.10(g) lists these factors that may be taken into account when demonstrating a designated use cannot be met through a UAA, including substantial and widespread social and economic impact, natural conditions, and physical attributes. EPA reminds the reader that water quality criteria are derived solely on the basis of data and scientific judgments between pollution concentrations, environment, and human health effects. While the setting of designated uses may take into account social and economic considerations, water quality criteria do not reflect consideration of economic impacts or the technological feasibility of meeting the ambient criterion concentration in the waterbodies.

5.4 What water quality criteria should be applied to waters where primary contact recreation is not occurring?

Intermittent recreation uses may be appropriate for wet weather impacted waters. Such an intermittent use may only be adopted after a State demonstrates that the primary contact recreation use is not attainable through effluent limitations under section CWA §301(b)(1)(A) and (B) and §306, or through cost effective and reasonable best management practices. Determining the length of time the recreation use should be suspended and what water quality criteria will apply during these events should be determined on a case-by-case basis taking into account the proximity of outfalls to sensitive areas, the amount of rainfall, time of year, etc.

For waterbodies where a State demonstrates through a use attainability analysis that primary contact recreation will not occur, adoption of a recreation use and water quality criteria to protect secondary contact activities may be appropriate. EPA defines secondary contact activities as those activities where a very low percentage of participants would have very little direct contact with the water and where ingestion of water is unlikely, such as wading, canoeing, motor boating, fishing, etc. EPA's policy is that any secondary contact criterion adopted by a State should be developed commensurate with the anticipated use and not exceed a geometric mean five times EPA's recommended water quality criteria for primary contact recreation. Thus, applying a less stringent criterion to a waterbody where a State has demonstrated that only "secondary contact" activities are occurring should result in no greater risk of gastrointestinal illness than waterbodies designated with primary contact recreation.

A seasonal recreation use will generally apply the water quality criteria associated with the primary contact recreation use during the recreation season and apply less stringent water quality criteria during the months when the ambient air and water temperatures are too cold. During the times of year when people are not recreating in the water, a State may adopt less stringent water quality criteria based on EPA's recommendation for secondary contact waters to protect for incidental ingestion.

5.5 Will EPA publish risk-based water quality criteria to protect for "secondary contact" uses?

EPA's *Ambient Water Quality Criteria for Bacteria*– 1986 are designed to protect the public from gastrointestinal illnesses associated with accidental ingestion of water. EPA has not developed any water quality criteria for secondary contact recreation to protect for other human health-based risks. Such additional water quality criteria could conceivably be based on the effects of dermal contact and inhalation of the water, such as rashes or other minor skin irritations or infections. As part of EPA's Beach Action Plan, EPA intends to investigate the development of water quality criteria for transmission of organisms that cause skin, eye, ear, nose, respiratory illness, or throat infections. Some elements of such future water quality criteria may potentially be applicable to secondary contact uses.

While in the future, EPA may publish additional health-based water quality criteria to protect for health risks other than gastrointestinal illness, EPA's policy until that time is that States should designate primary contact uses to protect against secondary exposure, unless a State conducts a use attainability analysis to remove a primary contact recreation use or adopt a primary contact recreation use with a less stringent criterion. In the case where a less stringent criterion is being applied, such water quality criteria should not exceed five times EPA's recommended water quality criteria for bacteria.

6.0 Identification of Current and Future Activities

6.1 When will EPA propose and promulgate 24-hour methods?

The Beach Action Plan committed EPA to propose and promulgate the latest 24-hour methods for *E. coli* and enterococci into 40 *CFR* 136. One of the reasons cited by States for not making the transition to the 1986 water quality criteria for bacteria was that EPA's newly validated analytical methods for *E. coli* and enterococci had not been promulgated as methods under 40 *CFR* 136. EPA's National Pollutant Discharge Elimination System (NPDES) permit regulations allow the use of methods not included in 40 *CFR* 136; however without promulgation of the methods into 40 *CFR* 136, it is difficult for the permitting authority to require the use of the methods in permits. This proposal would make available a suite of multiple-tube and membrane filter test procedures for enumerating (determining organism density) *E. coli* and enteroccoci bacteria in water as part of State, Territory, Tribal, and local water quality monitoring programs. Thus, EPA intends to propose the methods for adoption into 40 *CFR* 136 by May 2000.

EPA has initiated this process, and it is undetermined at this time what methods other than those developed by EPA's Office of Research and Development will be included in the proposed rulemaking. However, EPA intends to propose all methods for which a suitable supporting database is available to demonstrate acceptable performance.

6.2 When will EPA develop a laboratory techniques video?

In 1986, EPA revised its bacteriological ambient water quality criteria recommendations to include new indicator bacteria, *E. coli* and enterococci, which provide a better correlation with swimming-associated gastrointestinal disease than the previous water quality criteria using fecal coliform bacteria. EPA's 1986 water quality criteria for bacteria recommended the use of two new media, modified mTEC agar for *E. coli* and mE agar for enterococci. A video of the test methods was made and demonstrations were given to interested parties in various Regions.

A new video, "Improved Enumeration Media for E. coli and Enterococci," demonstrates the four methods currently recommended by EPA, including the mE and the mEI agar methods for enterococci and the modified mTEC and mTEC agar methods for *E. coli*. The purpose of the video is to introduce and demonstrate the improved methods and help answer any questions regarding these methods. This video will supercede the earlier video demonstrating only the earlier laboratory methods: mEI agar method for enterococci and mTEC method for *E. coli*.

Accompanying the video is a laboratory manual, explaining all methods in a step-by-step format. The laboratory manual also contains color photographs of the target colonies on all media to aid in identification. The new video and methods manual are now available to State and private laboratories and can be obtained by e-mailing Latisha Parker at parker.latisha@epa.gov. If funds are available, EPA will also provide hands-on laboratory training for State and local laboratory personnel.

6.3 What will be addressed in the upcoming *National Guidance for Recreational Beach Managers* and when will it be published?

EPA's Office of Water is currently constructing the *National Guidance for Recreational Beach Managers* to assist beach managers with monitoring and public notification of recreational waters. This document will address recreational water quality monitoring, risk assessment, risk management, and risk communication and incorporate results of the EPA Office of Research and Devleopment's research, input from EPA's Office of Water programs, and technical input from State and local stakeholders. EPA expects to complete the first draft by the end of FY2000.

6.4 What will be addressed in the upcoming *Implementation of the Water Quality-based Provisions in the CSO Control Policy* and when will it be published?

EPA intends to publish a draft of the *Implementation of the Water Quality-Based Provisions of the CSO Control Policy* for public review and comment in April 2000. The draft guidance will lay a strong foundation for integrating the development and implementation of long-term combined sewer overflow (CSO) control plans with water quality standards reviews for CSO-receiving waters.

6.5 What will be addressed in the upcoming *Assessment Methodology Guidance* and when will it be published?

EPA intends to publish the *Assessment Methodology Guidance* in the fall of 2000 in conjunction with the final Water Quality Planning and Management Regulation. On August 23, 1999, EPA proposed revisions to the Water Quality Planning and Management Regulation, including revisions to the process by which waterbodies are listed as impaired under §303(d) of the CWA. The objective of the assessment methodology guidance is to help improve the scientific basis of decisions characterizing waters as attaining water quality standards and identifying threatened and impaired waters. It will provide guidance on data quality, data interpretation, acceptable error, while acknowledging variation in topography, geology, hydrology, and land use that may influence the way a State, Territory, or authorized Tribe interprets or applies the guidance.

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