

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 131**

[OW-2004-0010; FRL-7785-6]

RIN 2040-AE63

Water Quality Standards for Coastal and Great Lakes Recreation Waters**AGENCY:** Environmental Protection Agency.**ACTION:** Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to establish water quality criteria for bacteria for coastal recreation waters in specific States and Territories. The States and Territories covered by this proposed rule do not have water quality standards for bacteria that comply with the requirements of section 303(i) of the Clean Water Act. Under these circumstances, the Act requires EPA to promptly propose such standards. The criteria proposed today apply to coastal and Great Lakes waters that specific States and Territories have designated for swimming, bathing, surfing, or similar water contact activities and for which the State or Territory does not have in place EPA-approved bacteria criteria that are as protective of human health as EPA's 1986 recommended bacteria criteria. If this proposal is promulgated, the Federally designated water quality criteria will be added to the States' and Territories' water quality criteria applicable to coastal recreation waters. If a State or Territory subsequently adopts and EPA approves water quality standards that meet the requirements of section 303(i), EPA will withdraw the Federal standards for that State's or Territory's coastal recreation waters.

DATES: EPA will accept public comments on this proposed rule until August 9, 2004.

ADDRESSES: Submit your comments, identified by Docket ID No. OW-2004-0010, by one of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the online instructions for submitting comments.
- Agency Web site: <http://www.epa.gov/edocket>. EDOCKET, EPA's electronic public docket and comment system, is EPA's preferred method for receiving comments. Follow the online instructions for submitting comments.
- E-mail: wilcut.lars@epa.gov.
- Fax: (202) 566-0409.
- Mail: Water Quality Standards for Coastal and Great Lakes Recreation Waters, Environmental Protection Agency, Mailcode: 4305 T, 1200

Pennsylvania Ave., NW., Washington, DC 20460. Please include a total of three copies.

- Hand Delivery: EPA Docket Center Public Reading Room, EPA/DC, EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC 20460. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information. Please include a total of three copies.

Instructions: Direct your comments to Docket ID No. OW-2004-0010. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at <http://www.epa.gov/edocket>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through EDOCKET, regulations.gov, or e-mail. The EPA EDOCKET and the Federal regulations.gov Web sites are "anonymous access" systems, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through EDOCKET or regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit EDOCKET on-line or see the May 21, 2002 **Federal Register** (67 FR 38102). For additional instructions on submitting comments, go to section I.B. of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket>. Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material,

is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Water Quality Standards for Coastal and Great Lakes Recreation Waters Docket, EPA/DC, EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the Water Quality Standards for Coastal and Great Lakes Recreation Waters Docket is (202) 566-2422.

FOR FURTHER INFORMATION CONTACT: Lars Wilcut, Standards and Health Protection Division, Office of Science and Technology (4305 T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 566-0447; fax number: (202) 566-0409; e-mail address: wilcut.lars@epa.gov.

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I. General Information

A. Does This Action Apply to Me?

State and Territorial agencies responsible for adopting and implementing water quality standards in the States and Territories identified in 40 CFR 131.41 are the only entities directly affected by the proposed rule. People concerned with water quality in Coastal and Great Lakes States may be interested in this proposed rule. Facilities discharging pollutants to certain waters of the United States in Coastal and Great Lakes States could be indirectly affected by this proposed rule since water quality standards are used in determining water quality-based National Pollutant Discharge Elimination System (NPDES) permit limits. In addition, beach managers and businesses in beach areas could also be indirectly affected by this proposed rule since water quality standards are used in making decisions regarding beach advisories and closures. Categories and entities that may indirectly be affected include:

Category	Examples of potentially affected entities
Industry	Industries discharging pollutants to the waters of the States and Territories identified in § 131.41.
Municipalities	Publicly-owned treatment works discharging pollutants to the waters of the States and Territories identified in § 131.41.
Other	Beach owners and managers, beach goers

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. This table lists the types of entities that EPA is now aware could potentially be affected by this action. Other types of entities not listed in the table could also be affected. To determine whether your facility may be affected by this action, you should carefully examine the language in § 131.41 of today's proposed rule. If you have questions regarding the

applicability of this action to a particular entity, consult one of the persons listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit information claimed as CBI to EPA through EDOCKET, regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for Preparing Your Comments.* When submitting comments, remember to:

- i. Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).
- ii. Follow directions—The agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- iv. Describe any assumptions and provide any technical information and/or data that you used.
- v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- vi. Provide specific examples to illustrate your concerns, and suggest alternatives.
- vii. Explain your views as clearly as possible.
- viii. Make sure to submit your comments by the comment period deadline identified.

3. *Docket Copying Costs.* The first 266 pages are free. Additional copying incurs a \$25 administrative fee and each additional page is \$0.15.

II. Background

A. Statutory and Regulatory Background

1. Clean Water Act

Section 303 (33 U.S.C. 1313) of the Clean Water Act (CWA) directs States,

Territories, and authorized Tribes, 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, Territories, and authorized Tribes are to develop water quality standards for navigable waters of the United States within the State, Territory, or authorized Tribe. Section 303(c) provides that water quality standards shall include the designated use or uses to be made of the water and water quality criteria necessary to protect those uses. The designated uses to be considered by States, Territories, and authorized Tribes in establishing water quality standards are specified in the CWA: Public water supplies, propagation of fish and wildlife, recreation, agricultural uses, industrial uses and navigation. States, Territories, and authorized Tribes are to review their water quality standards at least once every three years and, if appropriate, revise or adopt new standards. The results of this triennial review must be submitted to EPA, and EPA must approve or disapprove any new or revised standards.

Section 303(c) of the CWA authorizes the EPA Administrator to promulgate water quality standards to supersede State, Territorial, or authorized Tribal standards that have been disapproved or in any case where the Administrator determines that a new or revised standard is needed to meet the CWA's requirements. EPA regulations implementing CWA section 303(c) are published at 40 CFR part 131. Under these rules, the minimum elements that must be included in a State's, Territory's, or authorized Tribe's water quality standards include: Use designations for all water bodies in the State, Territory, or authorized Tribe, water quality criteria sufficient to protect those use designations, and an antidegradation policy (see 40 CFR 131.6).

2. The BEACH Act of 2000

The Beaches Environmental Assessment and Coastal Health (BEACH) Act of 2000 amended the CWA in part by adding section 303(i). Section 303(i)(1)(A) requires that not later than April 10, 2004, "each State having coastal recreation waters shall adopt and submit to the Administrator water quality criteria and standards for the coastal recreation waters of the State for those pathogens and pathogen indicators for which the Administrator has published criteria under section 304(a)." EPA's *Ambient Water Quality Criteria for Bacteria—1986* (EPA 440/5–

84-002) is the relevant criteria document published by the Administrator under CWA section 304(a).

Section 303(i)(2)(A) requires that, “[i]f a State fails to adopt water quality criteria and standards in accordance with [section 303(i)(1)(A)] that are as protective of human health as the criteria for pathogens and pathogen indicators for coastal recreation waters published by the Administrator, the Administrator shall promptly propose regulations for the State setting forth revised or new water quality standards for pathogens and pathogen indicators described in [section 303(i)(1)(A)] for coastal recreation waters of the State.”

The BEACH Act also added section 502(21) to the CWA, which defines “coastal recreation waters” as “(i) the Great Lakes; and (ii) marine coastal waters (including coastal estuaries) that are designated under section 303(c) by a State for use for swimming, bathing, surfing, or similar water contact activities.” Section 502(21) explicitly excludes from the definition of coastal recreation waters “inland waters; or waters upstream of the mouth of a river or stream having an unimpaired natural connection with the open sea.”

B. 1986 Ambient Water Quality Criteria for Bacteria

In 1986, EPA published *Ambient Water Quality Criteria for Bacteria—1986*. This document contains EPA’s current recommended water quality criteria for bacteria to protect people from gastrointestinal illness in recreational waters, *i.e.*, waters designated for primary contact recreation or similar full body contact uses. Primary contact recreation is typically defined by States and Territories to encompass activities that could be expected to result in the ingestion of, or immersion in, water, such as swimming, water skiing, surfing, kayaking, or any other activity where immersion in the water is likely. The main route of exposure to illness-causing organisms in recreational waters is through accidental ingestion of fecally-contaminated water while engaging in these activities.

EPA’s water quality criteria for bacteria are based on levels of indicator bacteria, namely *Escherichia coli* (*E. coli*) and enterococci, that demonstrate the presence of fecal pollution. Indicator organisms such as these have long been used to protect people from illnesses that may be contracted from engaging in recreational activities in surface waters contaminated by fecal pollution. These organisms generally do not cause illness directly, but have demonstrated

characteristics that make them good indicators of fecal contamination and thus the potential presence of pathogens capable of causing human illnesses such as gastroenteritis. Gastroenteritis is a term for a variety of diseases that affect the gastrointestinal tract and are rarely life-threatening. Symptoms of the illness include nausea, vomiting, stomachache, diarrhea, headache, and fever. Prior to its publication of the 1986 bacteria criteria document, EPA recommended the use of fecal coliforms as an indicator organism to protect people from gastrointestinal illness in recreational waters. However, EPA conducted epidemiological studies and evaluated the use of several organisms as indicators, including fecal coliforms, *E. coli*, and enterococci. EPA subsequently recommended the use of *E. coli* or enterococci for fresh recreational waters and enterococci for marine recreational waters, because levels of these organisms were more accurate predictors of acute gastrointestinal illness than levels of fecal coliforms.

In EPA’s epidemiological studies, *E. coli* and enterococci exhibited the strongest correlation to swimming-associated gastroenteritis, the former in fresh waters only and the latter in both fresh and marine waters (*Ambient Water Quality Criteria for Bacteria—1986*, January, 1986, EPA 440/5-84-002; *Health Effects Criteria for Fresh Recreational Waters*, August, 1984, EPA 600/1-84-004; *Health Effects Criteria for Marine Recreational Waters*, August, 1983, EPA 600/1-80-031). In marine waters, the stronger correlation may be due to enterococci’s ability to survive longer than coliforms, similar to the pathogens of concern. In addition, fecal coliforms are sometimes detected where fecal contamination is absent, possibly resulting in inaccurate assessments of recreational safety. For example, *Klebsiella* spp., a bacterial organism that is part of the fecal coliform group but which is generally not harmful to humans, is often present in pulp and paper and textile mill effluents (Archibald, F., *Water Qual. Res. J. Canada* 35(1):1-22, 2000; Dufour, *Journal WPCF*, 48:872-879).

Table 1 contains the water quality criteria values for the protection of primary contact recreation that EPA recommended in the 1986 bacteria criteria document (*Ambient Water Quality Criteria for Bacteria—1986*). These values were developed based on the concentrations of *E. coli* and enterococci from EPA-sponsored epidemiological studies that roughly correlated to the estimated illness rate associated with EPA’s previously recommended fecal coliform criterion.

This illness rate was estimated to be approximately 0.8% of swimmers exposed in freshwater and 1.9% of swimmers exposed in marine waters. EPA’s 1986 bacteria criteria document indicates the illness rates are “only approximate” and that the 1986 values that appear in Table 1 were based on these approximations. The 1986 bacteria criteria document provides geometric mean densities (represented as average densities over the swimming season) as well as single sample maximum (SSM) values (representing an unacceptably high value for a single sample).

A geometric mean represents the central tendency of a series of data points. Using a geometric, as opposed to an arithmetic, mean helps to minimize the effect of measurements that might otherwise be considered outliers. The best way to interpret a series of bacterial measurements taken over a period of time is in comparison to the geometric mean. With a large number of measurements, the calculated geometric mean is expected to be “close” to the “true” mean of bacterial concentrations in the waterbody. In contrast, a single sample with a high value does not necessarily indicate that the waterbody as a whole has high bacterial levels. The SSM values in the 1986 bacteria criteria document correspond to probabilities of getting a particular single sample result when the true mean meets the criterion. A 75% confidence level value corresponds to the level above which individual sample values would occur only 25% of the time if the mean level in the waterbody still meets the standard. Statisticians say that a single sample reading at this level indicates, with 75% confidence, that the standard is not being met. The best way to interpret any single measurement (or small number of measurements) is in comparison to the SSM. Selecting a lower SSM (*e.g.*, 75%) for comparison to single measurements will result in a more conservative estimate of whether the standard is being met. That is, it will set a relatively low bar (75% confidence) for a determination that the standard has been exceeded. This will be protective of public health but may result in a greater number of determinations that the standard was violated. In contrast, selecting a higher SSM (*e.g.*, 95%) for comparison to single measurements will result in a less cautious (*i.e.*, less protective) decision rule but greater certainty that a reading above the SSM really does indicate that bacteria levels in the waterbody as a whole exceed the standard.

The 1986 bacteria criteria document includes a table of four SSM values for each geometric mean based on beach

usage, which in turn are based on different confidence levels. In general, where there is a greater potential for exposure in a given area, a higher degree of protectiveness (*i.e.*, a lower bar for determining an exceedance) is warranted. The 1986 bacteria criteria document categorizes the four SSMs as follows: “designated bathing beach” for the 75 percent (most protective) confidence level, “moderate use for

bathing” for the 82 percent confidence level, “light use for bathing” for the 90 percent confidence level, and “infrequent use for bathing” for the 95 percent confidence level. The lowest SSM was assigned to designated bathing beach areas because a high degree of caution should be used to evaluate the statistical significance of a measured single value above the criteria for these areas. The 1986 bacteria criteria

document stated that bathing beach areas are “frequently lifeguard protected, provide parking and other public access and are heavily used by the public.” The document does not specifically describe in greater detail the potential use frequency differences of the 82 percent, 90 percent, and 95 percent confidence levels.

TABLE 1.—CRITERIA FOR INDICATORS FOR BACTERIOLOGICAL DENSITIES

Acceptable swimming associated gastroenteritis rate per 1000 swimmers	Steady state geometric mean indicator density	Single sample maximum allowable density			
		Designated beach area (upper 75% C.L.)	Moderate full body contact recreation (upper 82% C.L.)	Lightly used full body contact recreation (upper 82% C.L.)	Infrequently used full body contact recreation (upper 95% C.L.)
Freshwater:					
Enterococci—8	33/100 ml ¹	61	78	107	151
<i>E. coli</i> —8	126/100 ml ²	235	298	409	575
Marine Water:					
Enterococci—19	35/100 ml ³	104	158	276	501

NOTES:

¹ Calculated to nearest whole number using equation: (mean enterococci density) = antilog₁₀ ((illness rate/1000 people + 6.28)/9.40).

² Calculated to nearest whole number using equation: (mean *E. coli* density) = antilog₁₀ ((illness rate/1000 people + 11.74)/9.40).

³ Calculated to nearest whole number using equation: (mean enterococci density) = antilog₁₀ ((illness rate/1000 people - 0.20)/12.17).

⁴ Single sample limit = antilog₁₀ (log₁₀ indicator geometric mean density/100 ml + (factor determined from areas under the Normal probability curve for the assumed level of probability * log₁₀ standard deviation)). The appropriate factors for the indicated one sided confidence levels are: 75% C.L.—.675; 82% C.L.—.935; 90% C.L.—1.28; 95% C.L.—1.65.

⁵ Based on the observed log standard deviations during the EPA studies: 0.4 for freshwater *E. coli* and enterococci; and 0.7 for marine water enterococci. Each jurisdiction should establish its own standard deviation for its conditions which would then vary the single sample limit.

III. Proposed Criteria for Pathogen Indicators in Coastal Recreation Waters

A. Scope of Proposed Rule

The requirements of the BEACH Act are limited to “coastal recreation waters,” which are defined in CWA section 502(21) as the Great Lakes and marine coastal recreation waters (including coastal estuaries) that are designated under CWA section 303(c) by a State for use for swimming, bathing, surfing, or similar water contact activities. The definition explicitly excludes “inland waters or waters upstream of the mouth of a river or stream having an unimpaired natural connection with the open sea.” EPA interprets CWA section 502(21) to apply only to those Great Lakes waters that are designated for swimming, bathing, surfing, or similar water contact activities, consistent with the purpose of the BEACH Act to protect the public from the health risks associated with swimming in polluted water. Therefore, today’s proposal applies only to those Great Lakes and marine waters designated by a State or Territory for swimming, bathing, surfing, or similar water contact activities.

The BEACH Act clearly envisioned and intended that States, Territories, and authorized Tribes with coastal

recreation waters adopt into their water quality standards bacteria criteria as protective of human health as EPA’s 1986 ambient water quality criteria for bacteria. Under EPA’s water quality standards regulations at 40 CFR part 131, States, Territories, and authorized Tribes have broad discretion to designate specific uses to specific waters. They are not required to designate all waters for swimming, bathing, surfing, or similar water contact activities (*i.e.*, primary contact recreation), as long as they have conducted a use attainability analysis that supports the decision that full attainment of CWA section 101(a) uses (“fishable/swimmable”) is not feasible for those waters (40 CFR 131.10(g)). For example, Ohio has designated all of its portion of Lake Erie as “bathing waters.” In contrast, Pennsylvania has designated a portion of Lake Erie as incidental, or secondary, contact recreation. As explained in the preceding paragraph, today’s proposal applies only to those waters designated by a State or Territory for swimming, bathing, surfing, or similar water contact activities, not to waters designated for uses that only involve incidental contact. However, States, Territories, and authorized Tribes are to continue to work towards the goal of achieving full

attainment of CWA section 101(a) uses (“fishable/swimmable”) in waters that do not currently attain such uses. Further, any waters with designated uses that do not include the uses specified in CWA section 101(a)(2) must be re-examined every three years to determine if any new information has become available (40 CFR 131.20(a)). If such new information indicates that the uses specified in CWA section 101(a)(2) are attainable, the State, Territory, or authorized Tribe is required to revise its water quality standards accordingly. EPA expects States, Territories, and authorized Tribes to continue this process and revise their water quality standards where appropriate. States, Territories, and authorized Tribes may remove a designated use that is not an existing use if it conducts a use attainability analysis to demonstrate that the designated use is not attainable (40 CFR 131.10(g)).

B. Proposed Criteria for Pathogen Indicators

EPA’s *Ambient Water Quality Criteria for Bacteria—1986* were developed to protect primary contact recreation uses in ambient waters. The criteria have two components: a geometric mean, which has the most direct relationship to risk over the course of a recreation season,

and a single sample maximum (SSM) which is the best value against which to compare individual measurements. A geometric mean represents the central tendency of a series of measurements: in this case, measurements of bacteria levels. This helps to minimize the effect

of measurements that might otherwise be considered outliers. EPA is proposing a geometric mean of 126/100 ml for *E. coli* in fresh waters and four different SSMs, which vary for coastal recreation fresh waters based on intensity of use. EPA is proposing a geometric mean of

35/100 ml for enterococci in marine waters and four different SSMs, which vary for coastal recreation marine waters based on intensity of use. These are the same values as in the 1986 bacteria criteria document.

TABLE 2.—PROPOSED AMBIENT FRESH WATER QUALITY CRITERIA FOR BACTERIA

A indicator	B geometric mean	C single sample maximum (per 100 ml)			
		C1 designated bathing beach (75% con- fidence level)	C2 moderate use coastal recre- ation waters (82% con- fidence level)	C3 light use coastal recre- ation waters (90% con- fidence level)	C4 infrequent use coastal recre- ation waters (95% con- fidence level)
<i>E. coli</i>	126/100 ml ^a	235 ^b	298 ^b	409 ^b	575 ^b

Footnotes to table in paragraph (c)(1):

^a This value is for use with analytical methods 1106.1 or 1600 or any equivalent viable method.

^b Calculated using the following: single sample maximum = geometric mean * 10^(confidence level factor * log standard deviation), where the confidence level factor is: 75%: 0.68; 82%: 0.94; 90%: 1.28; 95%: 1.65. The log standard deviation from EPA's epidemiological studies is 0.4.

TABLE 3.—PROPOSED AMBIENT MARINE WATER QUALITY CRITERIA FOR BACTERIA

A indicator	B geometric mean	C single sample maximum (per 100 ml)			
		C1 designated bathing beach (75% con- fidence level)	C2 moderate use coastal recre- ation waters (82% con- fidence level)	C3 light use coastal recre- ation waters (90% con- fidence level)	C4 infrequent use coastal recre- ation waters (95% con- fidence level)
Enterococci	35/100 ml ^a	104 ^b	158 ^b	276 ^b	501 ^b

Footnotes to table in paragraph (c)(2):

^a This value is for use with analytical methods 1103.1, 1603, or 1604 or any equivalent viable method.

^b Calculated using the following: single sample maximum = geometric mean * 10^(confidence level factor * log standard deviation), where the confidence level factor is: 75%: 0.68; 82%: 0.94; 90%: 1.28; 95%: 1.65. The log standard deviation from EPA's epidemiological studies is 0.7.

With respect to identifying an acceptable risk level, *Ambient Water Quality Criteria for Bacteria—1986* includes an estimate of the historically accepted illness rate associated with the previously recommended geometric mean value for the fecal coliform criterion. Based on ratios of *E. coli* and enterococci to fecal coliform densities, the historically accepted risk levels for gastrointestinal symptoms were estimated to be 0.8% of swimmers at fresh water beaches and 1.9% of swimmers at marine beaches. However, the analysis upon which these estimates is based is inherently uncertain because there was little correlation between illness rate and fecal coliform density. These estimated risk levels were used to calculate the specific bacteria density values presented in tabular form in the 1986 bacteria criteria document. These estimated illness rates are described in the 1986 bacteria criteria document as approximate and as EPA's best estimates at the time. Moreover, it is clear that there is uncertainty both in estimating the actual historically-accepted risk

levels and in translating these values into corresponding concentration criteria for *E. coli* and enterococci in fresh and marine waters. It is also clear that because the 1986 bacteria criteria document was published before the BEACH Act added section 303(i) to the CWA, the specific values presented in tabular form in the 1986 bacteria criteria document were only recommendations representing one acceptable choice of risk level to apply to the criterion. At the time the 1986 bacteria criteria document was published, EPA did not expect that the specific geometric mean and SSM values would necessarily be used for establishing uniform Federal water quality criteria for coastal recreation waters in multiple States, or establish a fixed benchmark for assessing the protectiveness of State/Territorial water quality standards for bacteria. There is no a priori reason to establish a higher level of protection for fresh waters than for marine waters. The difference in acceptable risk levels in the 1986 bacteria criteria document (8

illnesses per 1000 swimmers in fresh waters v. 19 per 1000 in marine waters) was based solely on the calculated risk levels for the previously recommended criterion of 200 fecal coliforms per 100 ml, which were different in marine and fresh waters. If the science supported a reliable correlation between bacteria concentrations and illness rates, the EPA could, in judging whether a fresh water criterion is "as protective of human health as" EPA's 1986 bacteria criteria, consider fresh water criteria associated with risk levels up to 1.9% of swimmers to be sufficient. However, EPA cannot determine, based on the available data that relate *E. coli* and enterococci levels to illness rates, what bacteria concentration would correlate with risk levels over 1.0% in freshwater. Therefore, the data that relate risk levels to bacteria concentrations in freshwater are not reliable beyond 1.0% risk to swimmers. Recent peer review of EPA's analysis of the study data relating illness rates to bacteria concentrations supports the conclusion that the existing data do not support the

relationship between rates beyond the level of 1.0% of swimmers and their correlating bacteria concentrations (External Peer Review of EPA Analysis of Epidemiological Data from EPA Bacteriological Studies, February 2004). The peer reviewers said that EPA should not extrapolate beyond the 1.0% risk level, based on the observed data. Based on that peer-reviewed information, EPA does not believe, at this juncture, that it can justify a criterion for fresh water based on any geometric mean or SSM higher than the levels associated with an illness rate of 1.0% of swimmers as being as protective of human health as EPA's 1986 bacteria criteria. However, EPA is considering adopting a geometric mean and SSM values for fresh water that correspond to an illness rate of 1.0% of swimmers, which would be slightly higher than the criteria in this proposed rule, which correspond to an illness rate of 0.8% of swimmers. The *E. coli* criteria corresponding to an illness rate of 1.0% of swimmers would be a geometric mean of 206/100 ml and SSM values of 385/100 ml, 489/100 ml, 668/100 ml, and 940/100 ml, corresponding to the 75, 82, 90, and 95 percent confidence levels. EPA solicits comment on its choice of illness rate for calculating the criteria.

1. Use of the Single Sample Maximum

EPA is proposing all four SSMs included in the 1986 bacteria criteria document for each geometric mean. The SSM values allow decision makers to quantitatively determine, based on a single sample, when water quality at a particular site may not be associated with long-term protective conditions (*i.e.*, when overall bacteria concentrations are likely to exceed the protective central tendency). This is especially important for beaches that are infrequently monitored or prone to short term spikes in bacteria concentrations (*e.g.*, waters that may be affected by a combined sewer overflow outfall). The 1986 bacteria criteria document does not interpret the meaning of the term "single sample maximum". One interpretation is that it is a single value never to be exceeded. EPA is soliciting comment on this interpretation.

An alternative option would be to allow for exceedance of the SSM when making attainment decisions because bacterial measurements are inherently variable, due to a number of factors that may not necessarily reflect underlying water quality. Under this option, an unacceptably high value for any given individual sample may be used to trigger a beach advisory or closing or additional monitoring, or it might be

evaluated with other sample results, but would not necessarily be used alone to determine nonattainment of the water quality standards.

EPA recognizes that the 1986 bacteria criteria document discusses SSMs solely in the context of beach closures. SSMs are particularly important in this context because States and Territories generally use one or two samples to make beach opening or closure decisions. EPA could thus interpret the 1986 bacteria criteria document as recommending the use of SSMs only for decisions related to public health at beaches. Under this interpretation, the SSMs would be part of the water quality criteria, but only used for making beach closure and opening decisions. States and Territories could use only the geometric mean for other CWA purposes, such as NPDES permitting, TMDLs, and waterbody assessments. EPA solicits comment on each of the above interpretations of the term "single sample maximum." Based on its consideration of these comments, EPA may decide to include an explicit interpretation or definition of this term in the final regulatory text.

The 1986 bacteria criteria document describes the analysis used to calculate the criteria. EPA conducted a series of epidemiological studies in coastal and Great Lakes waters. At each water studied, EPA calculated the geometric mean of the summer bacterial density, and correlated this with the summer average gastrointestinal illness rate. EPA used this correlation as the basis of the geometric mean criterion. Thus, the geometric mean has the most direct relationship to the illness rate. With this in mind, EPA could interpret the phrase "as protective of human health as" the 1986 bacteria criteria document to apply only to the geometric mean. Under this interpretation, EPA would promulgate only the geometric mean in the final rule. The SSMs would be available for use as an implementation tool for making beach opening and closure decisions but would not be part of the applicable water quality standards. States and Territories would have the flexibility to use the SSMs in this or any other application of the water quality standards as they deem appropriate. EPA is soliciting comment on this interpretation.

2. Categories of Coastal Recreation Waters

Only one SSM would apply to each category of coastal recreation water: designated bathing beach waters, moderate use coastal recreation waters, light use coastal recreation waters, and infrequent use coastal recreation waters.

In the 1986 bacteria criteria document, EPA associated these categories (corresponding to decreasing exposure potential) with increasing confidence level thresholds on which an exceedance determination would be based. EPA is proposing the following definitions for each category of waterbody:

- *Designated bathing beach waters* are those coastal recreation waters that, during the recreation season, are heavily-used and may have: a lifeguard, bathhouse facilities, or public parking for beach access. States may include any other waters in this category even if the waters do not meet these criteria.

- *Moderate use coastal recreation waters* are those coastal recreation waters that are not designated bathing beach waters but typically, during the recreation season, are used by at least half of the number of people as at typical designated bathing beach waters within the State. States may also include light use or infrequent use coastal recreation waters in this category.

- *Light use coastal recreation waters* are those coastal recreation waters that are not designated bathing beach waters but typically, during the recreation season, are used by less than half of the number of people as at typical designated bathing beach waters within the State, but are more than infrequently used. States may also include infrequent use coastal recreation waters in this category.

- *Infrequent use coastal recreation waters* are those coastal recreation waters that are rarely or occasionally used.

Examples of infrequent use coastal recreation waters might include waters that are at remote locations, difficult to access, or infrequently used for primary contact recreation due to commerce or navigation. States and Territories could, at their discretion, place waters in more protective categories. For example, States and Territories could choose to provide "light use" protection to waters that might otherwise be considered "infrequent use" waters. EPA is soliciting comment on the proposed definitions of the four categories, and describes the basis for deriving the definitions in the following paragraph.

The 1986 bacteria criteria document describes designated bathing beach waters as those that are frequently lifeguard protected, provide parking and other public access, and are heavily used by the public. EPA conducted its epidemiological studies using these types of waters. The 1986 bacteria criteria document does not define or otherwise describe the other usage

categories. EPA recognizes that in order for the public and beach authorities to understand which SSMs apply to which waters, the terms in the 1986 bacteria criteria document (designated bathing beach, moderate use for bathing, light use for bathing, and infrequent use for bathing) need to be defined. EPA reviewed Web sites in various fields of study (e.g., meteorology, human health risk characterization, and urban planning) that use such terminology to differentiate intensities. EPA observed that moderate rainfall is considered to be about 40% of heavy rainfall, that moderate alcohol consumption is about 50% of heavy consumption, and that moderate traffic is about 50% of heavy traffic (“The Effects of Moderate Alcohol Consumption on Mortality After Heart Attack,” [www.coloradohealthsite.org/CHNReports/alcohol_heart\(1\).html](http://www.coloradohealthsite.org/CHNReports/alcohol_heart(1).html); “What Constitutes Moderate, Significant, and Major Events?,” www.wxrisk.com/Pages/glossary_geography.htm; “The Beaufort Wind Scale,” www.crh.noaa.gov/lot/webpage/beaufort). Therefore, EPA proposes that moderate use coastal recreation waters be defined as waters that are about 50% less intensely used than are designated bathing beach waters. EPA also observed that a light breeze is considered to be about half that of a moderate breeze, which led to EPA’s proposal that light use coastal recreation waters have less use than moderate use coastal recreation waters.

a. State Identification of Coastal Recreation Waters by Category. EPA intends in today’s proposal to objectively define the four categories so that the public can clearly identify to which category each coastal recreation water belongs based on its intensity of use for primary contact recreation. EPA does not have sufficient information regarding frequency of use of each specific coastal recreation water covered by this proposal to list all those waters in the rule according to the four categories defined in 40 CFR 131.41(b). Therefore, EPA is proposing not to list individual coastal recreation waters by intensity of use category. EPA recommends that States and Territories evaluate existing use information and identify which individual coastal recreation waters belong to each category and make this information publicly available (e.g., on a State’s or Territory’s Web site). Even in the absence of such a listing, EPA believes the proposed definitions can be objectively applied when CWA actions are taken based on the proposed rule. A State or Territory would be required to

use the 75 percent confidence level SSM when developing TMDLs for, or issuing permits to facilities discharging into, coastal recreation waters that meet the definition of designated bathing beach waters. Similarly, a State or Territory would be required to use an SSM that is no less stringent than the 95 percent confidence level when developing TMDLs for, or issuing permits to facilities discharging into, coastal recreation waters that meet the definition of infrequent use coastal recreation waters. As States and Territories developed TMDLs and issued permits consistent with the SSMs, the public would have the opportunity to review and comment upon the application of SSMs as part of the TMDL and permitting processes. EPA would use its oversight authority under CWA section 402(d) to ensure that States and Territories apply the appropriate SSMs when conducting these types of activities.

EPA’s *National Beach Guidance and Required Performance Criteria for Grants* (June, 2002, EPA–823–B–02–004) outlined elements that States and Territories with BEACH Act implementation grants are to consider in developing tiered monitoring plans. States with BEACH Act implementation grants are required to tier their beaches according to potential risk to human health and beach use. The monitoring frequency and methodology would likely differ depending on how a beach is tiered. Because most coastal States and Territories are recipients of BEACH Act implementation grants, States and Territories could use their existing beach tiering process as a source of information for determining frequency in categorizing a coastal recreation water for purposes of determining the applicable SSM. EPA is soliciting comment on this approach.

b. *Alternative Options for Categorization of Coastal Recreation Waters.* EPA recognizes that some States and Territories may not have enough data regarding the intensity of the use of their coastal recreation waters to easily and quickly categorize them according to the four categories specified in the proposed rule. For example, some States have designated bathing beach waters, but do not further categorize the remainder of their coastal recreation waters as to intensity of use. Therefore, EPA is considering another approach by which the final rule would include only two SSMs for coastal recreation waters: the 75 percent confidence level for all designated bathing beaches and a single other confidence level (the 82 percent, 90 percent, or 95 percent confidence level SSM) for all other coastal

recreation waters. If EPA promulgates this approach in the final rulemaking, the rule would include two columns for SSMs, one column for designated bathing beach waters and the other column for all other coastal recreation waters. EPA would select the specific percent confidence levels from the 1986 bacteria criteria document based on comments received during the public comment period. In addition, the final rule would not include the definitions for moderate, light, and infrequent use coastal recreation waters. The final rule would continue to include a definition of designated bathing beach waters where the SSM corresponding to a 75 percent confidence level would apply. In all waters that are not designated bathing beach waters the other SSM would apply. As in the proposed option, in implementing SSMs, States and Territories would apply the designated bathing beach SSM consistent with the proposed definition of designated bathing beach waters in 40 CFR 131.41(b). EPA expects that a State or Territory would use the 75 percent confidence level SSM when developing TMDLs for, or issuing permits to facilities discharging into, coastal recreation waters that meet the definition of designated bathing beach waters, and would use the other SSM when conducting these activities for other coastal recreation waters. As States and Territories develop TMDLs and issue permits consistent with the SSMs, the public would have the opportunity to review and comment upon the application of SSMs as part of the TMDL and permitting processes. EPA would use its oversight authority under CWA section 402(d) to ensure that States and Territories appropriately apply the SSMs. EPA is soliciting comment on this approach.

EPA is also considering promulgating only the 75 percent confidence level SSM that would apply to all coastal recreation waters of the States and Territories included in the final rulemaking. This approach applies the most stringent SSM to all coastal recreation waters and is thus more protective than the 1986 bacteria criteria. However, it also simplifies the application of the standards by eliminating the need to delineate which SSM applies to specific coastal recreation waters. Seven States have already adopted the 1986 bacteria criteria for some or all of their coastal recreation waters using this approach. However, the 1986 bacteria criteria document clearly recognized that “one size does not fit all,” and that it is reasonable to have different SSMs

depending on use intensity. EPA is soliciting comment on this approach.

EPA is also requesting comment on an approach under which an SSM would be identified only for designated bathing beach waters. Since these are the types of waters in which the epidemiological studies on which the criteria are based were conducted, and since the primary focus of the 1986 bacteria criteria document is protecting users of these types of waters, EPA could interpret the phrase "as protective of human health as" the 1986 criteria to require an SSM only for designated bathing beach waters, with attainment decisions and other CWA actions in other coastal recreation waters relying on the geometric mean only. EPA is also considering an approach where the SSM is not part of the criterion, but rather part of the water quality standards implementation process (see Section III.A.1.). If EPA selects this approach in the final rule, EPA would not need the proposed definitions of designated bathing beach waters, moderate use coastal recreation waters, light use coastal recreation waters, or infrequent use coastal recreation waters in the final rule because these definitions would only be needed in applying an SSM.

c. Intrastate vs. Interstate Determinations of Use Intensity. EPA's proposed SSMs apply to categories based on definitions of intensity, and EPA is proposing that they be interpreted on an intrastate basis (*i.e.*, the comparison of frequency of use would be made relative to only the waters within that State). Using this approach, a State or Territory would categorize its most frequently used coastal recreation waters as designated bathing beach waters and all others in comparison to those. An alternative option that EPA is considering is for States and Territories to apply these categories to particular waters using interstate comparisons. For example, the number of people at beaches in a State with a cooler climate (*e.g.*, Washington) may be considerably less than the number of people at beaches in a State with a much warmer climate (*e.g.*, Florida). As a result, the number of people at what a cooler State would designate as a "moderate use coastal recreation water" may be more characteristic of the number of people at an "infrequent use coastal recreation water" for a warmer State. States and Territories could apply these definitions so as to achieve a consistent level of protection at beaches in the same category nationally. However, to do so, States and Territories would need national beach use information to be able to categorize their coastal

recreation waters. EPA is not aware that this information is available. EPA is soliciting comment on whether these definitions should be applied using either an intrastate or interstate (national) comparison of frequency of use or whether it should give States and Territories the option to choose the basis for comparison. EPA also solicits comment on where information on beach usage may be found and whether it is appropriate for use in applying the definitions. EPA is also seeking comment on the potential consequences of a nationally-based comparison in States with cooler climates.

d. State Calculation of Site-specific SSMs. EPA is proposing SSMs based on the 75, 82, 90, and 95 percent confidence levels and is proposing to include in the rule the equation to calculate site-specific SSMs. Bacteria measurements are typically highly variable from day to day. As the SSMs are derived based on a distribution around a central tendency, the standard deviation of measurements plays an important role in the width of that distribution. The standard deviations observed in EPA's epidemiological studies may not be the same as that for a particular waterbody. Therefore, EPA encourages States and Territories to collect enough data to calculate site-specific standard deviations. EPA recognizes that States and Territories might not have the data to calculate their own standard deviation; in such a case, those States and Territories would be required to use EPA's calculated SSMs.

EPA is proposing to require that the data set needed to provide a site-specific standard deviation used for calculating a revised SSM contain at least thirty samples for a single recreation season (see 40 CFR 131.41(c)(3)). EPA recognizes that the 1986 bacteria criteria document contemplates use of a site-specific log standard deviation, but notes that the document does not provide any information to guide States and Territories in developing a site-specific log standard deviation. The 1986 bacteria criteria document references the log standard deviations observed in EPA epidemiological studies, but does not specify the number of values used to compute the log standard deviations. EPA recognizes that the number of values has an effect on the confidence one places on the standard deviation. For example, in the *Technical Support Document for Water Quality-based Toxics Control* (EPA/505/2-90-001, March 1991, revised June 1992) EPA displays the effect of the number of values on the precision of the calculated coefficient of variation

(standard deviation divided by the mean). This display shows that for one coefficient of variation, the 90 percent confidence interval around the standard deviation is $\pm 62\%$ for five values, $\pm 42\%$ for 10 values, $\pm 30\%$ for 20 values, and $\pm 25\%$ for 30 values, with the confidence intervals not changing much for more than 30 values. (See *Technical Support Document for Water Quality-based Toxics Control*, page 55.)

EPA believes that when a State or Territory calculates an SSM using a site-specific log standard deviation, the State or Territory should use a site-specific standard deviation that is based on a large enough sample size. Ideally, the sample size is large enough that the "Central Limit Theorem" holds. The central limit theorem demonstrates that in large enough samples, the distribution of a sample mean approximates a normal curve regardless of the shape of the distribution from which it is sampled. The larger the sample size, the better the approximation to the normal distribution. A sample size of thirty is generally accepted by statisticians as the smallest sample size where the sample standard deviation will approximate the true standard deviation in a statistically meaningful way (Walpole, R.E., *Probability and Statistics for Engineers and Scientists*, 1989). Therefore, EPA believes that States and Territories should use at least thirty samples to compute the site-specific log standard deviation. EPA recognizes that a data set of 30 samples represents a significant amount of data for States and Territories to collect. EPA also recognizes that it recommended in the *Technical Support Document for Water Quality-based Toxics Control* that permit writers use at least 10 data points for calculating site-specific coefficients of variations for effluents when developing permit limits. EPA solicits comments on what constitutes an adequate data set for calculating site-specific SSMs and whether EPA should specify a minimum data requirement in the final rule.

3. Choice of Pathogen Indicator for Fresh Coastal Recreation Waters

EPA's 1986 bacteria criteria document shows that either enterococci or *E. coli* is an acceptable indicator in fresh waters. EPA is proposing *E. coli* for all Great Lakes States with coastal recreation waters because it is consistent with the 1986 bacteria criteria and because all Great Lakes States have either adopted or are in the process of adopting *E. coli* as a criterion into their water quality standards. Should a Great Lakes State express a preference for enterococci rather than *E.*

coli before EPA promulgates the final rule, EPA would promulgate the equivalent enterococci values for that State's fresh coastal recreation waters. EPA is also soliciting comment on whether it would be more appropriate to promulgate both *E. coli* and enterococci criteria for Great Lakes States and allow each State to choose which indicator to apply to its coastal recreation waters at the time of implementation.

C. Applicability of the Proposed Rule

1. Applies in Addition to any State/Territory Criteria

Today's proposed Federal criteria do not replace existing bacteria criteria for coastal recreation waters already adopted by States and Territories (and for those adopted after May 30, 2000, approved by EPA). Rather, today's proposed criteria apply in addition to any other existing CWA-effective criteria for coastal recreation waters already adopted (and for those adopted after May 30, 2000, approved by EPA). For states and territories included in today's proposal, permitting under the National Pollutant Discharge Elimination System (NPDES), as well as monitoring and assessment based on applicable CWA water quality standards, would need to be based on the applicable standards for bacteria in the final rule, in addition to any other applicable standards for bacteria previously adopted by the State or Territory to protect uses other than primary contact recreation. This will ensure that, where commercial shellfishing and primary contact recreation occur in the same coastal recreation waters, both uses will be adequately protected by existing State and Territorial standards (which generally still use fecal coliform) and the new standards for either *E. coli* or enterococci. States and Territories may also continue to use existing criteria for fecal coliform to supplement the new indicators for the purposes of water body assessment and other purposes where ambient data are needed. The dual sets of bacteria criteria also will enable regulatory decisions and actions to continue while collecting data for the newly adopted *E. coli* or enterococci criteria. For States and Territories included in today's proposal, EPA expects that States and Territories 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., NPDES, CWA section 305(b), and CWA section 303(d) programs. As they accomplish this, States and Territories may phase out

their use of fecal coliform as a supplemental indicator to protect primary contact recreation, provided this does not result in less protective determinations. While EPA cannot remove or revise existing State or Territorial standards, EPA believes that it would not be an efficient use of resources for States and Territories to base CWA actions related to protection of primary contact recreation on both fecal coliform and the new, preferred indicators if the fecal coliform criteria do not provide any additional protection. States and Territories are also encouraged to expeditiously revise their water quality standards to remove fecal coliform criteria that have been replaced by the new indicators in their implementation of the CWA. EPA solicits comment on this approach to transitioning from existing standards to the new standards in this proposed rule.

EPA recognizes that some States and Territories are in the process of adopting water quality standards to be as protective of human health as EPA's 1986 bacteria criteria. Once a State or Territory submits the adopted standards to EPA, the Agency will use CWA sections 303(c) and 303(i) to guide its review of the standards. Water quality standards do not become effective for Clean Water Act purposes until EPA approves them (40 CFR 131.21). Once EPA approved a State's or Territory's standards as being as protective of human health as EPA's 1986 bacteria criteria, EPA would remove that State or Territory from 40 CFR 131.41. However, there will be some indefinite period of time between EPA's approval and EPA removing the State or Territory from 40 CFR 131.41. As a result, EPA is proposing rule language which would make the EPA-approved bacteria criteria in State or Territorial water quality standards effective for CWA purposes upon their approval such that EPA's promulgated criteria would no longer apply. See 40 CFR 131.41(d)(1). EPA would still plan to remove the State or Territory from 40 CFR 131.41 but any delay in that process would not delay the approved State criteria in becoming the sole applicable criteria. EPA solicits comment on this approach of making the approved State or Territorial criteria the applicable criteria without first undertaking APA rulemaking to withdraw the Federal rule for that State or Territory.

2. Role of State/Territorial General Rules of Applicability

Section 131.41(d)(2) provides that the Federal criteria in today's rule would be subject to States' general rules of applicability in the same way and to the

same extent as are other Federally-adopted or State-adopted numeric criteria for coastal recreation waters. For example, if State or Territorial regulations would authorize mixing zones in deriving effluent limitations for discharges of bacteria to coastal recreation waters, such regulations would apply to permit limitations implementing the criteria in today's rule. As another example, some State's or Territory's regulations specify the dilution equations used to develop TMDLs or calculate permit limits; such regulations would apply using the criteria proposed in today's rule. EPA is requesting comment on this approach.

IV. EPA Review of State and Territorial Standards

A. How Did EPA Decide Which States and Territories To Include in Today's Proposed Rule?

As required by CWA section 303(i)(1)(A), EPA evaluated the water quality standards for bacteria for all 35 coastal States and Territories using five considerations to determine whether the water quality standards are as protective of human health as the *Ambient Water Quality Criteria for Bacteria—1986*. If a State's or Territory's water quality standards for bacteria for coastal recreation waters are as protective of human health as the 1986 bacteria criteria as of the signature date of the proposed rule, EPA is not including the State or Territory in the proposed rule. If a State or Territory included in the proposed rule adopts criteria satisfying CWA section 303(i), and EPA approves them, prior to promulgation of the final rule, EPA will not include that State or Territory in the final rule. EPA encourages States and Territories that are in the process of adopting such criteria to expeditiously complete this process. EPA believes it is preferable for a State or Territory to adopt its own such standards than for EPA to promulgate Federal standards for that State or Territory. The following paragraphs describe the five considerations.

1. Are the Standards Based on EPA's Recommended Indicators?

EPA interprets CWA section 303(i)(1)(A) to require that States and Territories must adopt and submit water quality criteria for enterococci in marine waters and either enterococci or *E. coli* in fresh waters. Section 303(i)(1)(A) requires that States and Territories submit criteria “* * * for the pathogens and pathogen indicators for which the Administrator has published criteria under section 304(a).” EPA's *Ambient*

Water Quality Criteria for Bacteria—1986 is the CWA section 304(a) criteria referred to in CWA section 303(i)(1)(A). The *Ambient Water Quality Criteria for Bacteria—1986* recommended the use of *E. coli* and enterococci as pathogen indicators for fresh waters and enterococci for marine waters. This represented a major shift, as fecal coliform had historically been the preferred indicator of fecal matter in coastal waters. As described in *Ambient Water Quality Criteria for Bacteria—1986*, EPA does not believe that fecal coliform is a reliable indicator of human illness risk from full body contact recreation in coastal recreation waters. Therefore, EPA believes that any State or Territory with fecal coliform as the only bacteria criterion for some or all of its coastal recreation waters is not fully compliant with the BEACH Act and has thus included it in today's proposal. EPA solicits comment on its interpretation of 303(i). If the commenter disagrees that States and Territories must adopt criteria for *E. coli* or enterococci, EPA requests that the commenter address what type and amount of information should be sufficient for EPA to determine that fecal coliform (or any other pathogen indicator) is as protective of human health as the 1986 bacteria criteria. EPA also solicits comment on its assessment of each State's and Territory's standards.

2. Are the Standards for *E. coli* and Enterococci Derived From a Scientifically-Defensible Methodology That Links Them Quantitatively to an Acceptable Risk Level Under CWA Section 303(i)?

States and Territories have the flexibility to determine an acceptable risk level within the context of the statutory requirement in CWA section 303(i) that their water quality standards be "as protective of human health as" the 1986 bacteria criteria. That flexibility is constrained by the bounds of acceptable risk articulated by EPA in *Ambient Water Quality Criteria for Bacteria—1986*. However, as discussed in the legislative history of the BEACH Act, a State's criteria may be as protective of human health as the 1986 bacteria criteria document "without being numerically equivalent" but the criteria would have to be scientifically defensible. (S. Rep. No. 106–366, at 4 (2000)).

Section III.B. of the preamble explains that the risk levels in the 1986 bacteria criteria document for gastrointestinal symptoms were 0.8% of swimmers at fresh water beaches and 1.9% of swimmers at marine beaches. These estimated illness rates are described in

the 1986 bacteria criteria document as approximate and as EPA's best estimates at the time. Section III.B. of the preamble explains why EPA believes that fresh water criteria corresponding to risk levels up to 1.0% of swimmers would satisfy the protectiveness requirement of CWA section 303(i), and also why EPA cannot determine, based on the available data that relate *E. coli* and enterococci levels to illness rates, what bacteria concentration would correlate with risk levels over 1.0% in freshwater. EPA solicits comment on its acceptance of criteria associated with risk levels up to 1.0% in freshwater.

3. Do the Standards Include Appropriate SSMs?

In the 1986 bacteria criteria document, EPA recommended that States and Territories adopt appropriate SSM values that correspond to specific use intensity categories of coastal recreation waters (e.g., 75 percent confidence level SSM for designated bathing beaches, 82 percent confidence level SSM for moderate use coastal recreation waters, etc.). Tables 2 and 3 in Section III.B include qualitative descriptors of beach usage categories associated with different confidence levels.

EPA's *Ambient Water Quality Criteria for Bacteria—1986* also recommends that States and Territories use a site-specific log standard deviation in calculating the SSM in recognition of the possibility that States and Territories may observe significant differences in the log standard deviation of bacterial measurements. The 1986 bacteria criteria document explicitly recommends that States and Territories base the SSM values on a site-specific log standard deviation or, if site data are insufficient, to use the values EPA observed in its studies. EPA believes that States and Territories should not be required to rely on frequency distributions observed in EPA's epidemiological studies when sufficient site-specific data are available. In determining whether State and Territory bacteria criteria are as protective of human health as EPA's 1986 bacteria criteria, EPA evaluates whether the data set is robust enough to adequately characterize the distribution. If a State or Territory chooses not to collect adequate data and not calculate site-specific SSM values, the State/Territory would need to use the standard deviations from EPA's studies in *Ambient Water Quality Criteria for Bacteria—1986*.

EPA reviewed State and Territorial submissions of CWA section 303(i) standards for coastal recreation waters

for the adoption of both a geometric mean and an SSM value. Because the criteria are used for several purposes under the CWA, adoption of both a geometric mean and an SSM value gives States and Territories the necessary components to implement bacteria criteria when developing water quality-based effluent limits, determining whether a waterbody is attaining its water quality standards, and issuing beach notifications and advisories. For example, the SSM value gives States and Territories a practical tool for making daily decisions to open or close beaches. In contrast, a geometric mean gives States and Territories a practical tool for assuring the appropriate level of treatment at NPDES-regulated facilities to protect human health over the long term.

EPA proposes to consider water quality standards for bacteria for coastal recreation waters to be as protective of human health as *Ambient Water Quality Criteria for Bacteria—1986* if they include at least one SSM and if designated bathing areas have an SSM based on at least the 75 percent confidence level. EPA reviewed State and Territorial standards for SSM values, and found that many States and Territories used "designated beach area" as a designation for a subset of their primary contact recreation waters and assigned the 75 percent confidence level to those water bodies, while assigning the 95 percent confidence level to all other water bodies. Other States and Territories had three categories, while other States and Territories only had one. EPA solicits comments on this approach for evaluating State and Territory SSM values in relation to the requirements of the BEACH Act.

4. Do the Standards Exempt Fecal Contamination From Non-Human Sources?

The *Ambient Water Quality Criteria for Bacteria—1986* included a background discussion of non-human sources under the heading "Limitations and Extrapolations of Criteria." The text of the 1986 bacteria criteria document recommends that States and Territories apply the *E. coli* and enterococci criteria to all full body contact recreation waters unless (1) sanitary and epidemiological studies show the sources of the indicator bacteria to be non-human, and (2) the indicator densities are not indicative of a health risk to those swimming in such waters. CWA section 303(i) provides that if a State or Territory fails to adopt standards "that are as protective of human health as the criteria for pathogens and pathogen

indicators for coastal recreation waters published by the Administrator," EPA must promptly propose water quality standards for pathogens and pathogen indicators. In reviewing State or Territorial water quality standards to determine whether the bacteria criteria are "as protective of human health as" EPA's 1986 bacteria criteria document, EPA examined whether the State or Territorial bacteria criteria exempted non-human sources. If a State's or Territory's water quality standards included such an exemption, EPA looked to see whether that exemption has the same basis as that presented in the 1986 bacteria criteria document, namely, that sanitary and epidemiological studies show the sources are non-human and that the bacterial densities are not indicative of a health risk to those swimming in such waters. EPA is including in today's proposal those States and Territories where the criteria include exemptions for non-human sources that are inconsistent with the plain language of EPA's 1986 bacteria criteria document, as described above.

EPA's approach in developing this proposed rule has been to rely as much as possible on the actual language in the 1986 bacteria criteria document. EPA has taken this approach because CWA section 303(i)(2)(A) requires EPA to promptly propose criteria for States and Territories that are "as protective of human health as" EPA's 1986 bacteria criteria in cases where a State or Territory has failed to do so. However, EPA's scientific understanding of pathogens and pathogen indicators has evolved since 1986. As a result, EPA has, over the course of the last 18 years, applied its new scientific understanding to the formulation of policy in the area of how non-human sources are addressed in water quality standards. For example, in EPA's 1994 *Water Quality Standards Handbook*, EPA articulated a policy that States and Territories may apply water quality criteria for bacteria to waterbodies designated for recreation with the rebuttable presumption that the indicators show the presence of human fecal contamination. This 1994 policy stated:

States may apply bacteriological criteria sufficient to support primary contact recreation with a rebuttable presumption that the indicators show the presence of human fecal pollution. Rebuttal of this presumption, however, must be based on a sanitary survey that demonstrates a lack of contamination from human sources. The basis for this option is the absence of data demonstrating a relationship between high densities of bacteriological water quality indicators and

increased risk of swimming-associated illness in animal-contaminated waters.

In short, under this policy, a State or Territory could justify a decision not to apply the criteria to a particular waterbody when bacterial indicators were found to be of animal origin. EPA is soliciting comment on a second approach that uses the rebuttable presumption approach articulated in the 1994 Handbook to be "as protective of human health as" EPA's 1986 bacteria criteria. This approach would require States and Territories to presume that the source of *E. coli* or enterococci is of human origin unless a sanitary survey demonstrates a lack of contamination from human sources. This approach would effectively allow for the exclusion of any animal sources if a State or Territory can demonstrate that the source of contamination is not human waste.

Some recent studies suggest there may be some risk posed to humans as a result of exposure to non-human fecal contamination, particularly those animal sources with which humans regularly come into contact, *i.e.*, livestock and other domestic animals. Livestock, domestic pets, and wildlife are carriers of human pathogens and can transmit these pathogens to surface waters as well as contribute significant numbers of indicator bacteria to waterbodies (Centers for Disease Control and Prevention *Morbidity and Mortality Report Surveillance for Waterborne Disease Outbreaks*, 1993, 1996, 1998, 2000; *Waterborne Pathogens in Agricultural Watersheds*, USDA, June 2000).

Outbreaks of enterohemorrhagic *E. coli* O157:H7, *Salmonella*, *Giardia*, and *Cryptosporidium* are frequently of animal origin. Incidents where these pathogens have been spread to humans through water have been documented in recent years. In the case of *E. coli* O157:H7, several cases have been cited in which fecal contamination from animals was the probable source of the pathogen. The most prominent examples include contamination of water supplies, including an outbreak in Alpine, Wyoming, in June, 1998, affecting 157 people, and a major outbreak in Walkerton, Ontario, in May and June of 2000 causing more than 2,300 people to become ill and causing seven deaths (Olsen, S.J., CDC Emerging Infectious Diseases, Vol. 8, No. 4, April 2002; CDC Morbidity and Mortality Weekly Report, 2000; Ontario's Ministry of the Attorney General, 2000). In the Alpine, Wyoming case, contamination by wildlife of the community water supply is the suspected source, and in

Walkerton, Ontario, heavy rains causing agricultural runoff to leak into city wells is suspected. The 1993 Milwaukee *Cryptosporidium* outbreak is a well-known example of water supply contamination that resulted in 403,000 illnesses and approximately 100 deaths. The source of the oocysts was not identified, but suspected sources include agricultural runoff from dairies in the region, wastewater from a slaughterhouse and meat packing plant, and municipal wastewater treatment plant effluent (Casman, E.A., Interstate Commission on the Potomac River Basin Report No. 96-6, 1996; USDA National Animal Health Monitoring System Report: *Cryptosporidium parvum* Outbreak, 1993). In addition, *Cryptosporidium* was the known cause of 15 other outbreaks associated with drinking and recreational water affecting 5,040 individuals in the U.S. between 1991 and 1994 (Gibson, C.J., *Parasitology* 117 (Supp.): S205-S212, 1998). While many of the reported outbreaks have occurred through the consumption of contaminated drinking water, other incidences of *E. coli* O157:H7 infection from exposure to surface waters have been documented (CDC Morbidity and Mortality Weekly Report, 2000, 2002). While non-human sources are capable of transmitting pathogens that can cause the specific kinds of gastrointestinal illness identified in EPA's original epidemiological studies, the specific risk from these sources has not been fully determined.

The risk presented by fecal contamination of waters by non-human sources is possibly less significant than the risk presented by fecal contamination of waters by human sources. However, the increasing number of cases such as those described above, in which animals are suspected as being the likely cause of the contamination and resulting illness, present a case for not exempting these sources where human contact or consumption are likely to occur. In addition, because the presence of bacterial indicators provides evidence of fecal pollution, high levels of these indicator organisms originating from animal sources may also indicate the presence of pathogens capable of causing other human illnesses in addition to acute gastroenteritis.

Animals are more likely to carry or be infected with human pathogens when those animals are in close proximity to humans and their waste. The closer the association between animals and humans, the more likely it is that human pathogens will pass back and forth between humans and animals. The

more crowded an animal herd, the more likely it is that human pathogens will be shared between animals of the herd. These pathogens are transmitted to others in the herd because of the direct contact between animals and their fecal matter. Fecal contamination from these infected herds, unless sufficiently treated or contained, can find its way into surface or ground waters and present a potential exposure route for people using the contaminated waters for recreation or drinking. This scenario potentially applies not only to animal feeding operations but also to herds of wildlife (e.g., deer). However, the threat from livestock herds is likely to be greater given the larger typical herd size and the resultant greater quantity of fecal wastes. Wild herds are typically more dispersed and smaller and therefore likely represent a smaller risk to watersheds. In addition, wildlife are not typically in routine daily contact with humans, as may be the case for livestock and other domestic animals. Therefore, EPA is considering a third approach for addressing non-human sources of fecal contamination in establishing water quality standards that apply the criteria only to bacteria from human and non-wildlife animal sources.

In summary, the preceding paragraphs describe three possible approaches in reviewing exemptions for non-human sources of fecal contamination:

- (1) Require sanitary and epidemiological studies before excluding non-human sources;
- (2) Require only sanitary surveys before excluding non-human sources; or
- (3) Exclude only wildlife sources.

EPA is soliciting comment on all of the above approaches. Should EPA revise its approach in the final rule addressing non-human sources of *E. coli* and enterococci, States and Territories that exempt non-human sources and are included in today's proposal may not be included in the final rule.

5. Has EPA Approved the Standards?

Under section 303(i)(2)(A) of the CWA, EPA must determine whether a State or Territory has failed to adopt water quality standards as protective of human health as EPA's 1986 bacteria criteria. Moreover, under 40 CFR 131.21, EPA must approve State or Territorial water quality standards that are adopted after May 30, 2000, in order for those standards to be in effect for CWA purposes. Therefore, EPA must have approved State and Territorial standards for enterococci or *E. coli* that are consistent with CWA section 303(i) for the State or Territory to be excluded from the proposed rule if the standards were adopted after May 30, 2000. State

and Territorial standards adopted prior to May 30, 2000 that are consistent with CWA section 303(i) are in effect for CWA purposes even without explicit EPA approval.

B. Which States and Territories Are Included in Today's Proposed Rule?

EPA researched the status of water quality standards for bacteria for each State and Territory with coastal recreation waters. On April 20, 2004, EPA sent letters to the Commissioners of every coastal and Great Lakes State and Territory to inform them of this impending proposed rule and of EPA's understanding at that time of their water quality standards. These letters stated that EPA would propose to include in this rule all States and Territories with coastal recreation waters (i.e., those coastal and Great Lakes waters designated for swimming, bathing, surfing and similar water contact activities) that do not have CWA-effective water quality standards for pathogen indicators as protective of human health as EPA's 1986 bacteria criteria. In preparing these letters, EPA conducted a preliminary review of the water quality standards of the thirty-five States and Territories with coastal recreation waters. In some cases, EPA has received additional or updated information since sending the letters. EPA's current understanding of each State's and Territory's water quality standards is reflected in the discussion in this section. EPA solicits comment to confirm whether EPA has accurately characterized the current status of water quality standards for coastal recreation waters, and seeks information on the progress of States' and Territories' adoption of the *E. coli* and enterococci criteria.

Alabama

On April 20, 2004, Alabama adopted criteria for all of its coastal recreation waters consistent with EPA's 1986 bacteria criteria, and EPA approved these on June 25, 2004. The criteria are for enterococci and have a geometric mean of 35/100 ml and an SSM of 104 for coastal waters designated by Alabama as "Outstanding Alabama Waters", "Swimming", and "Shellfish Harvesting". Waters designated by Alabama as "Public Water Supply" and "Fish and Wildlife" include water contact sports as a use only from June through September. The enterococci criteria for those months have a geometric mean of 35/100 ml and an SSM of 158/100 ml. From October through May, Public Water Supply and Fish and Wildlife waters are not designated for recreation. EPA considers

these criteria to be as protective of human health as EPA's 1986 bacteria criteria and Alabama is therefore not included in this proposal.

Alaska

Alaska has not adopted criteria as protective of human health as EPA's 1986 bacteria criteria. Therefore, EPA is including Alaska in today's proposal. Alaska has notified EPA of the State's intention to initiate rulemaking to adopt criteria consistent with EPA's 1986 bacteria criteria by taking public comment in Summer 2004. The State anticipates adoption of the criteria into State water quality standards by December, 2004.

American Samoa

On November 16, 1999, American Samoa adopted criteria for all of its coastal recreation waters consistent with EPA's 1986 bacteria criteria, and EPA approved these on May 2, 2001. The criteria are for enterococci with a geometric mean of 35/100 ml and an SSM value of 104/100 ml for Pago Pago Harbor, Fagatele Bay, and Pala Lagoon; the criteria have a geometric mean of 35/100 ml and an SSM value of 124/100 ml for open coastal waters; and the criteria have a geometric mean of 35/100 ml and an SSM value of 276/100 ml for those ocean waters beyond the 600-foot depth contour seaward. EPA considers these criteria to be as protective of human health as EPA's 1986 bacteria criteria, and American Samoa is therefore not included in this proposal.

California

California has adopted criteria consistent with EPA's 1986 bacteria criteria for some but not all of its coastal recreation waters. The Los Angeles Regional Board (RB4) adopted criteria on July 18, 2002, and EPA approved them on September 25, 2002. The RB4 criteria are for enterococci and have a geometric mean of 35/100 ml and an SSM of 104/100 ml. The other Regional Boards with coastal recreation waters have not yet adopted bacteria criteria as protective of human health as EPA's 1986 bacteria criteria. The California Ocean Plan, which was adopted on March 22, 1990, applies enterococcus monitoring requirements to nearshore ocean waters; however, it does not establish State water quality criteria. State Health Regulations adopted by the State pursuant to Assembly Bill 411 apply enterococcus requirements to all coastal waters; however, these regulations are separate from State water quality standards. Therefore, EPA is including California in today's proposal,

except for waters covered by RB4's approved standards.

Commonwealth of Northern Mariana Islands

The Commonwealth adopted a geometric mean criterion for enterococci on January 20, 1997, and EPA approved it on February 3, 1997. However, the Commonwealth has not adopted SSM values. Therefore, EPA is including the Commonwealth in today's proposal but only with respect to the SSM portion of the rule. EPA could remove the Commonwealth from the final rule depending on which SSM option EPA chooses in the final rule. The Commonwealth has initiated the rule-making process to adopt SSM values. The Commonwealth published the amendment to the standards in the Commonwealth Register on April 23, 2004, and the amendment is scheduled to be adopted before September, 2004.

Connecticut

On November 7, 2001, Connecticut adopted criteria for all of its coastal recreation waters consistent with EPA's 1986 bacteria criteria, and EPA approved these on December 17, 2002. Connecticut's enterococci criteria include a geometric mean of 35/100 ml and an SSM of 104/100 ml for "Designated Swimming" waters, which include areas designated by state or local authorities as bathing areas, and a geometric mean of 35/100 ml and an SSM of 500/100 ml for "All Other Recreational Uses", which are applied to other coastal waters (see Connecticut Water Quality Standards, Appendix B). The Connecticut water quality standards include General Standards 8 and 25, which include special additional provisions regarding application of Connecticut standards. Standard 8 provides that water quality criteria do not apply to conditions brought about by natural causes which may include normal land uses. Standard 25 provides that exceedance of bacteria criteria should be investigated by means of a sanitary survey or other appropriate means to determine sources of elevated indicator bacteria levels. In practice, Connecticut uses the numeric criteria established for enterococci in Appendix B of the Connecticut WQS regardless of source in coastal recreation waters for CWA purposes. For example, Connecticut's 2002 CWA section 303(d) list includes waters that are impaired due to bacteria from nonpoint sources and waterfowl. EPA considers these criteria to be as protective of human health as EPA's 1986 bacteria criteria, and Connecticut is therefore not included in this proposal.

Delaware

Delaware adopted enterococci criteria on July 15, 1999, and EPA approved these on December 2, 1999. Delaware's CWA-effective standards include criteria for enterococci with a geometric mean of 10/100 ml but no corresponding SSM. In addition, the Delaware standards apply only to human sources of fecal contamination. Therefore, EPA is including Delaware in today's proposal. EPA could remove Delaware from the final rule depending on which SSM option and which nonhuman source option EPA chooses in the final rule. Delaware is in the process of adopting and submitting to EPA revised standards for bacteria.

Florida

Florida has not yet adopted criteria consistent with EPA's 1986 bacteria criteria. Therefore, EPA is including Florida in today's proposal. Florida has initiated internal discussions and the State plans to initiate adoption of criteria consistent with EPA's 1986 bacteria criteria this year.

Georgia

Georgia has not yet adopted criteria consistent with EPA's criteria, nor has it initiated any regulatory process to adopt water quality standards consistent with EPA's bacteria criteria. Therefore, EPA is including Georgia in today's proposal.

Guam

On June 18, 2002, Guam adopted criteria for all of its coastal recreation waters consistent with EPA's 1986 bacteria criteria, and EPA approved these on July 24, 2002. The criteria are for enterococci and have a geometric mean of 35/100 ml for all marine waters. The SSM is 104/100 ml for whole body contact recreation waters and is 276/100 ml for limited body contact recreation. EPA considers these criteria to be as protective of human health as EPA's 1986 bacteria criteria and Guam is therefore not included in this proposal.

Hawaii

Hawaii has adopted criteria consistent with EPA's 1986 bacteria criteria for some but not all of its coastal recreation waters. Hawaii has adopted, and EPA has approved, a geometric mean criterion of 7 for enterococci in non-estuarine marine recreational waters within 300 meters (1,000 feet) of the shoreline. Hawaii is in the process of adopting an SSM criterion for non-estuarine marine waters within 300 meters of shore and both components of the enterococci criteria for coastal estuaries, consistent with EPA's 1986 bacteria criteria. Hawaii has no numeric

criteria protecting State waters beyond 300 meters from shore, although these waters are designated for recreation in the State's water quality standards. Therefore, EPA is including Hawaii in this proposal.

Illinois

Illinois has not yet adopted criteria consistent with EPA's 1986 bacteria criteria. Therefore, EPA is including Illinois in today's proposal. Illinois has informed EPA that it will initiate the rulemaking process to adopt revised standards for bacteria by September 30, 2004.

Indiana

On December 13, 1989, Indiana adopted criteria for all of its coastal recreation waters consistent with EPA's 1986 bacteria criteria, and EPA approved these on May 7, 1990. The criteria are for *E. coli* and include a geometric mean of 125/100 ml and an SSM of 235/100 ml. EPA considers these criteria to be as protective of human health as EPA's 1986 bacteria criteria, and therefore Indiana is not included in this proposal.

Louisiana

Louisiana has not yet adopted criteria consistent with EPA's 1986 bacteria criteria, nor has the State initiated any regulatory process to meet BEACH Act requirements. Therefore, EPA is including Louisiana in today's proposal.

Maine

Maine made effective enterococci criteria for its coastal recreation waters classified as "SB" and "SC", and EPA approved these criteria on July 16, 1986. The enterococci criteria include a geometric mean of 8/100 ml and a single sample maximum of 54/100 ml in the State's waters classified as "SB." Class "SB" waters are those that are "suitable for the designated uses of recreation in and on the water" as well as other uses. (ME. REV. STAT. ANN. tit. 38 § 465-B (2003)). Additionally, the enterococci criteria include a geometric mean of 14/100 ml and an SSM of 94/100 ml for the State's waters classified as "SC." Class "SC" waters are also those that are "of such quality that they are suitable for recreation in and on the water" as well as other uses. (ME. REV. STAT. ANN. tit. 38 § 465-B (2003)). Although Maine's criteria numbers are lower than EPA's, Maine's criteria pertain only to enterococci of human origin. Based on the non-human source discussion in Section IV.A.4. of this preamble, EPA does not believe that Maine's criteria would be as protective of human health as EPA's 1986 bacteria criteria in cases

where the enterococci are of non-human origin. The 1986 bacteria criteria document recommends that States and Territories apply the *E. coli* and enterococci criteria to all full body contact recreation waters unless both (1) sanitary and epidemiological studies show the sources of the indicator bacteria to be non-human, and (2) the indicator densities are not indicative of a health risk to those swimming in such waters. EPA recognizes that Maine's approach for addressing non-human pathogen sources is consistent with an option for addressing recreational uses that is included in EPA's 1994 Water Quality Standards Handbook, and Maine is cited in this document as an example of a State that has successfully implemented such an approach. When EPA approved the Maine pathogen standards in 1986, it did so using the requirements of 40 CFR 131.5 and 131.6, which requires water quality criteria be sufficient to protect the designated uses. However, the BEACH Act of 2000 added CWA section 303(i) which requires that the pathogen criteria be "as protective of human health as" EPA's 1986 bacteria criteria document. This is a different standard of review than articulated in 40 CFR 131.5 for other water quality standards. Based on the comparison of Maine's approach for nonhuman sources to that in EPA's 1986 bacteria criteria document, and using its proposed non-human source option, EPA does not find Maine's approach to be "as protective of human health as" EPA's bacteria criteria document. Therefore, EPA is proposing to include Maine in today's rule for limited purposes. EPA could remove Maine's SB and SC waters from the final rule depending on which nonhuman source option EPA chooses in the final rule. EPA is aware that independent of this proposed rule, it is Maine's intent to revise the applicability of its bacteria criteria to include enterococci from domestic animals as well as enterococci of human origin. This revision is expected during Maine's next legislative session in January 2005.

EPA's proposed criteria would not apply to Maine's SB and SC waters if the enterococci bacteria are of human origin. In these cases, Maine's criteria would apply. Should EPA receive information during the public comment period showing that there are only human sources of fecal contamination in Maine Class SB and SC coastal recreation waters, EPA would remove Maine from the promulgation of the final rule for Class SB and SC waters because Maine's criteria would apply to

all sources of enterococci to coastal recreation waters.

Maine also has as its most protective class, "SA" waters. Class SA "shall be the highest classification and shall be applied to waters which are outstanding natural resources" and "shall be of such quality that they are suitable for designated uses of recreation in and on the waters" as well as other uses. (ME. REV. STAT. ANN. tit. 38 § 465-B (2003). The bacteria content of Class SA waters "shall be as naturally occurs." EPA believes that this narrative criterion for bacteria—"as naturally occurs"—is consistent with the objective of the CWA at Section 101(a) to "restore and maintain the chemical, physical, and biological integrity of the Nation's waters." Naturally occurring bacteria levels should not present more risk than the 19 illnesses per 1000 swimmers accepted in the 1986 bacteria criteria document. Although storm water discharges to Class SA waters are allowed, EPA understands Maine's standards to not authorize storm water discharges that exceed bacteria levels that would otherwise occur naturally in the receiving water absent the storm water discharges. For these reasons, EPA is not including Maine's Class SA waters in today's proposal.

Maryland

Maryland has not yet adopted criteria consistent with EPA's 1986 bacteria criteria. Therefore, EPA is including Maryland in today's proposal. Maryland is completing its rulemaking process and expects to submit newly adopted criteria to EPA in the near future. Maryland has been working with EPA to assure the development of state water quality standards that are consistent with EPA's 1986 bacteria criteria.

Massachusetts

Massachusetts has not yet adopted criteria consistent with EPA's 1986 bacteria criteria. Therefore, EPA is including Massachusetts in today's proposal. Massachusetts has initiated the rulemaking process and expects to adopt criteria consistent with EPA's 1986 bacteria criteria by December 31, 2004.

Michigan

On May 20, 1994, Michigan adopted criteria for all of its coastal recreation waters consistent with EPA's 1986 bacteria criteria, and EPA approved these on August 11, 1994. The State standards include *E. coli* with a geometric mean of 130/100 ml and an SSM value of 300/100 ml for total body contact recreation and an SSM of 1000/100 ml for partial body contact

recreation. Michigan's criteria are considered to be within the acceptable risk level range of 0.8% to 1.0%. (This range was described in Section IV.A.2.). Therefore, EPA interpreted Michigan's *E. coli* geometric mean of 130/100 ml to be as protective of human health as EPA's 1986 bacteria criteria, which recommended a geometric mean of 126/100 ml. EPA considers these criteria to be as protective of human health as EPA's 1986 bacteria criteria, and Michigan is therefore not included in this proposal.

Minnesota

Minnesota has not yet adopted criteria consistent with EPA's 1986 bacteria criteria. Therefore, EPA is including Minnesota in today's proposal. Minnesota has initiated the rulemaking process and expects to adopt criteria consistent with EPA's 1986 bacteria criteria by July 2005.

Mississippi

Mississippi has not yet adopted criteria consistent with EPA's 1986 bacteria criteria. Therefore, EPA is including Mississippi in today's proposal. Mississippi has initiated internal discussions and expects to adopt a geometric mean criterion by August 2004. The State will be conducting beach user studies in the summer of 2004 to determine the appropriate SSM based on usage of certain areas and expects to adopt SSM criteria by August 2005.

New Hampshire

On July 2, 1991, New Hampshire adopted EPA's 1986 bacteria criteria for all of its coastal recreation waters and the criteria became effective for CWA purposes on August 31, 1991. The standards include enterococci and have a geometric mean of 35/100 ml and an SSM of 104/100 ml for all coastal recreation waters. EPA considers these criteria to be as protective of human health as EPA's 1986 bacteria criteria, and New Hampshire is therefore not included in this proposal.

New Jersey

On July 14, 1989, New Jersey adopted criteria for all of its coastal recreation waters consistent with EPA's 1986 bacteria criteria, and EPA approved these on April 23, 1991. New Jersey's bacteria criteria include enterococci and have a geometric mean of 35/100 ml and an SSM of 104/100 ml for all coastal recreation waters. For the Delaware Bay, New Jersey incorporates by reference the water quality standards adopted by the Delaware River Basin Commission (DRBC) (N.J.A.C. 7:9B-1.13). The DRBC

adopted enterococci criteria with a geometric mean of 35/100 ml, but no SSM, for the Delaware Bay. However, New Jersey's standards include a provision that applies New Jersey water quality criteria to the Delaware Bay if the DRBC has not established criteria (N.J.A.C. 7:9B-1.14(d)). Therefore, New Jersey's water quality standards include an SSM that applies to the Delaware Bay in the absence of an SSM in the DRBC's standards, as explained in a May 19, 2004, letter from Brad Campbell, Commissioner of the New Jersey Department of Environmental Protection to Ben Grumbles, Acting Assistant Administrator for Water, U.S. EPA. EPA considers New Jersey's criteria to be as protective of human health as EPA's 1986 bacteria criteria, and New Jersey is therefore not included in this proposal.

New York

New York has not yet adopted criteria consistent with EPA's 1986 bacteria criteria. Therefore, EPA is including New York in today's proposal. New York has informed EPA that it will initiate its rulemaking process to adopt revised standards for bacteria shortly. The State anticipates final adoption of revised bacteria criteria in 2005.

North Carolina

North Carolina has not yet adopted criteria consistent with EPA's 1986 bacteria criteria. Therefore, EPA is including North Carolina in today's proposal. The State has started internal discussions and has exchanged draft language with EPA.

Ohio

Ohio has adopted a geometric mean consistent with EPA's 1986 bacteria criteria for all waters in Lake Erie in addition to fecal coliform standards. Ohio had previously adopted fecal coliform as its recreational water quality criteria. The standards for *E. coli* include a geometric mean of 126/100 ml for designated bathing waters and for designated primary contact waters. However, the Ohio water quality standards allow the use of either *E. coli* or fecal coliform and specify that compliance with the criteria can be demonstrated by attainment of either criterion. Because Ohio's standards allow the use of either indicator, and fecal coliform is not as protective of human health as EPA's 1986 bacteria criteria, EPA is including Ohio in today's proposal. In addition, EPA is including Ohio in today's proposal because the State does not have an SSM, as EPA interprets the term (see Section III.B.1). Instead, Ohio's standards include *E. coli* values not to be exceeded

in more than ten percent of the samples taken during any thirty-day period: 235/100 ml for designated bathing waters and 298/100 ml for designated primary contact waters. These values are identical to EPA's SSM values for the 75 and 82 percent confidence levels respectively, but they are not expressed as SSMs because they allow 10 percent of the samples to exceed the SSM.

Should EPA receive information during the public comment period showing that Ohio applies its *E. coli* criterion for all Clean Water Act implementation purposes in Lake Erie, and applies its upper bound values in a manner as stringent as the approach EPA takes for the SSM in the final rule, EPA would remove Ohio from the final rule.

Oregon

Oregon has not yet adopted criteria consistent with EPA's 1986 bacteria criteria, nor has the State initiated any regulatory process to meet the BEACH Act requirements. Therefore, EPA is including Oregon in today's proposal.

Pennsylvania

Pennsylvania has not yet adopted criteria consistent with EPA's 1986 bacteria criteria. Pennsylvania has initiated a modification to its Department of Health regulations relating to the bacteriological standards and monitoring of its Great Lake public bathing beaches but has not yet submitted any revision of its water quality standards to EPA. Therefore, EPA is including Pennsylvania in today's proposal.

Puerto Rico

The Commonwealth of Puerto Rico's water quality criteria for recreational waters applies to those Class SB (coastal) waters which are intensely used for primary contact recreation, like special bathing zones (beaches), and the Class SC waters for which EPA recently completed a rulemaking (40 CFR 131.40) to establish a designated use and applicable water quality criteria (including the 1986 bacteria criteria for enterococci) to protect primary contact recreation. The remaining Class SB waters, which are not designated bathing beaches but are coastal recreation waters, do not have bacteria criteria as protective of human health as EPA's 1986 bacteria criteria. Therefore, EPA is including Puerto Rico, except for coastal recreation waters intensely used for primary contact recreation and those covered by the recent EPA rule, in today's proposal. Puerto Rico has informed EPA of its intent to adopt criteria consistent with EPA's 1986

bacteria criteria for the remaining Class SB waters.

Rhode Island

Rhode Island has not yet adopted criteria consistent with EPA's 1986 bacteria criteria. Therefore, EPA is including Rhode Island in today's proposal. Rhode Island has informed EPA of its intent to adopt criteria consistent with EPA's 1986 bacteria criteria and has initiated the rulemaking process. Rhode Island plans to adopt EPA's criteria by the end of 2004.

South Carolina

South Carolina has not yet adopted criteria consistent with EPA's 1986 bacteria criteria. Therefore, EPA is including South Carolina in today's proposal. South Carolina has initiated the rulemaking process and expects to adopt EPA's criteria or submit them for EPA review by July 2004.

Texas

On July 26, 2000, Texas adopted criteria for all of its coastal recreation waters consistent with EPA's 1986 bacteria criteria, and EPA approved these on June 30, 2004. Texas' bacteria criteria include enterococci and have a geometric mean of 35/100 ml and an SSM of 89/100 ml for all coastal recreation waters. The water quality standards also include criteria for fecal coliform. Kathleen Hartnett White, Chair of the Texas Commission on Environmental Quality, sent two letters dated June 16 and June 29, 2004, explaining Texas' interpretation of the State's standards. Ms. White acknowledged that, under these revised standards, Texas has discretion to use fecal coliform as an alternative recreational indicator. At the time Texas adopted these standards, in 2000, it included this discretion for three reasons: (1) Texas wanted time to transition from monitoring for fecal coliform to enterococci for waters designated for contact recreation; (2) Texas was concerned about monitoring resources and laboratory equipment needed to sustain monitoring for both enterococci and fecal coliform in Oyster Waters, and (3) Texas wanted to allow for the possibility that additional data and evaluation of the two indicators would show that the Oyster Water criterion for fecal coliform would be a protective surrogate for enterococci. Ms. White also explained in her June 2004 letters that currently the State is monitoring for enterococci in all of its coastal recreation waters, including Oyster Waters. In addition, she expressly recognized that, at this time, the relationship between fecal coliform

and enterococci has not been demonstrated for Texas coastal waters. Finally, in the letter of June 29, 2004, Texas explicitly states that the enterococci criteria are in effect for all CWA purposes for all coastal recreation waters, including those designated as Oyster Waters. With this additional information, EPA considers enterococci to be the applicable criteria in all of Texas' coastal recreation waters for all CWA purposes. EPA considers these criteria to be as protective of human health as EPA's bacteria criteria, and Texas is therefore not included in this proposal.

United States Virgin Islands

The Virgin Islands have not yet adopted criteria consistent with EPA's 1986 bacteria criteria. Therefore, EPA is including the Virgin Islands in today's proposal. The Virgin Islands have initiated the rulemaking process and expect to adopt EPA's criteria by September 30, 2004.

Virginia

On February 12, 2002, Virginia adopted EPA's 1986 bacteria criteria for all of its coastal recreation waters, and EPA approved these on November 8, 2002. The standards include enterococci and have a geometric mean of 35/100 ml for all coastal waters and an SSM value of 104/100 ml. The standards also have fecal coliform for shellfish waters in addition to enterococci. EPA considers the enterococci criteria to be as protective of human health as EPA's 1986 bacteria criteria, and Virginia is therefore not included in this proposal.

Washington

Washington has not yet adopted criteria consistent with EPA's 1986 bacteria criteria. In a letter dated May 11, 2004, Washington explained its view that the State's data show that where the geometric mean of fecal coliform concentrations are at or below 14 counts/100 ml, the corresponding geometric mean of enterococci bacteria are at or below EPA's 1986 marine criterion of 35 counts/100 ml. EPA is reviewing this information and requests comment on it. The data submitted by Washington are available in the official public docket for this rulemaking. Because EPA has not yet determined that the data demonstrate that Washington's standards satisfy the requirements of section 303(i), EPA is including Washington in today's proposal.

Wisconsin

Wisconsin has not yet adopted criteria consistent with EPA's 1986 bacteria

criteria. Therefore, EPA is including Wisconsin in today's proposal. Wisconsin has initiated the rulemaking process and intends to adopt criteria consistent with EPA's bacteria criteria by winter 2005–2006.

Tribes

No Tribes are included in this proposal. EPA has determined there are about 40 Federally-recognized Tribes located next to either coastal or Great Lakes waters. As of the date of this proposal, none of these Tribes have coastal recreation waters (*i.e.*, coastal or Great Lakes waters designated for swimming, bathing, surfing or similar water contact activities). EPA is not including these Tribes in today's proposal because the requirements of CWA section 303(i) only apply to coastal recreation waters. EPA recognizes that the criteria in today's proposal will help inform Agency decisions related to its review of current and future Tribal water quality standards submissions to EPA. EPA has contacted those Tribes identified as having coastal or Great Lakes waters to inform them of the potential future impact this proposal could have on Tribal waters. EPA solicits comment on its interpretation of CWA section 303(i) as it applies to coastal Tribal waters that have not been designated for swimming, bathing, surfing, or similar water contact activities.

C. Under What Conditions Will States and Territories Be Removed From a Final Rule?

As discussed in Section II of this preamble, the water quality standards program has been established with an emphasis on State primacy. Although this proposed rule has been developed to promulgate Federal bacteria criteria for certain States and Territories, EPA prefers that States and Territories maintain primacy and revise their own standards to meet CWA sections 303(c) and 303(i) requirements. EPA is hopeful that today's proposed rulemaking will provide additional impetus for States and Territories to adopt the criteria for bacteria necessary to comply with CWA section 303(i).

For States and Territories that adopt criteria that EPA approves as meeting CWA section 303(i) requirements before publication of the final rulemaking, EPA will not include them in the final rulemaking. At any point in the process prior to final promulgation, a State or Territory can ensure that it will not be affected by this action by adopting the necessary criteria pursuant to State or Territorial law and receiving EPA approval. EPA will make every effort to

issue timely approval of revised criteria submitted before promulgation of the final rule.

Following a final promulgation of this rule, removal of Federal standards for a State or Territory will require rulemaking by EPA according to the requirements of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*). When a State or Territory adopts standards as protective of human health as EPA's 1986 bacteria criteria, EPA will undertake such a rulemaking to withdraw the Federal criteria. However, as discussed in Section III.C.1, EPA is proposing that State and Territorial standards for bacteria approved by EPA pursuant to CWA sections 303(c) and 303(i) will be in effect for CWA purposes, and the Federal criteria for this rule will no longer apply even before EPA withdraws the Federal criteria for that State or Territory.

V. Alternative Regulatory Approaches and Implementation Mechanisms

In developing a final rule, EPA will consider any data or information submitted to the Agency during the comment period. However, it is possible that relevant information for particular coastal recreation waters covered by this proposed rule may become available after completion of this rulemaking. If EPA ultimately promulgates a Federal *E. coli* and enterococci criteria for coastal recreation waters for some or all of the States and Territories covered by this proposal, there are several ways to ensure that the primary contact recreation use and its implementing mechanisms appropriately take into account such future information.

A. Designating Uses

States and Territories have considerable discretion in designating uses. A State or Territory may find that changes in use designations are warranted. EPA will review any new or revised use designations adopted by the States or Territories for coastal recreation waters covered by this proposed rule to determine if the standards meet the requirements of the CWA and implementing regulations. In adopting recreation uses, the States and Territories may wish to consider additional categories of recreation uses. If States and Territories change the designated use of a waterbody consistent with CWA section 303(c) and the regulations at 40 CFR 131, such that they are no longer designated for swimming, bathing, surfing, or similar water contact activities then the waterbody would not be covered by the BEACH Act definition of "coastal recreation waters".

EPA reminds the States and Territories that they must conduct use attainability analyses as required by 40 CFR 131.10(g) when adopting water quality standards with uses not specified in CWA section 101(a)(2) or with subcategories of designated uses specified in CWA section 101(a)(2) that require less stringent criteria (see 40 CFR 131.10(j)).

B. Compliance Schedules

A compliance schedule refers to an enforceable sequence of interim requirements in a permit leading to ultimate compliance with water quality-based effluent limitations (WQBELs) in accordance with the CWA. In an NPDES permit, WQBELs are the value determined by selecting the most stringent of the effluent limits calculated using all applicable water quality criteria for a specific point source to a specific receiving water for a given pollutant (See NPDES Permit Writers Manual, EPA-833-B-96-003, December, 1996).

Although many States and Territories have adopted regulations that are effective for CWA purposes authorizing compliance schedules for WQBELs, some have not done so. Therefore, EPA is proposing that where a State or Territory does not have a regulation that is in effect for CWA purposes authorizing compliance schedules for WQBELs, this proposed rule would authorize, but would not require, the permit issuing authority to include such compliance schedules in permits under appropriate circumstances. If a State or Territory does have a regulation that is in effect for CWA purposes authorizing compliance schedules, that compliance schedule regulation would continue to apply and would not be affected by today's proposed rule. It may be that a State or Territory that does not have a regulation authorizing compliance schedules has chosen that it does not want such a regulation. Thus, if a State or Territory notifies EPA in writing prior to promulgation that it does not want to authorize compliance schedules in permits implementing the bacteria criteria, then EPA would exclude that State or Territory from the compliance schedule provision contained in the final rule. Deferring to each State's or Territory's compliance schedule decisions would be consistent with the CWA's approach of giving the States and Territories the primary authority over water pollution control (CWA section 101(b)).

In States and Territories where this proposed rule's compliance schedule provision would apply, the permitting authority authorized to administer the

National Pollutant Discharge Elimination System (NPDES) program would exercise its discretion when deciding if a compliance schedule is justified because of the technical or financial (or other) infeasibility of immediate compliance. A provision authorizing compliance schedules is included in today's proposed rule because of the potential for existing dischargers to have new or more stringent effluent limitations for which immediate compliance would not be possible or practicable.

EPA supports the States and Territories in adopting statewide provisions independent of or as part of their effort to readopt statewide water quality control plans, or in adopting individual basin-wide compliance schedule provisions. The States and Territories have broad discretion to adopt such provisions, including discretion on reasonable lengths of time for final compliance with WQBELs. EPA recognizes that practical time frames within which to set interim goals may be necessary to achieve meaningful, long-term improvements in water quality.

New and Existing Pathogen Dischargers: The provision would allow compliance schedules only for an "existing pathogen discharger" which would be defined as any discharger which is not a "new pathogen discharger." EPA is proposing to define a "new pathogen discharger" as any building, structure, facility, or installation from which there is or may be a discharge of pathogens, the construction of which commenced after the effective date of the final rule. This definition is modeled after the definition of a new Great Lakes discharger at 40 CFR 132.2 which EPA created to implement the compliance schedule provision of 40 CFR Part 132 Appendix F, Procedure 9. The definition of "new pathogen discharger" only includes new sources if the new source commences construction after the effective date of the final rule. Other new sources that commence construction before the effective date of the final rule would be treated as "existing pathogen dischargers." EPA solicits comment on the utility of these definitions for implementing a compliance schedule for the proposed enterococci and *E. coli* criteria in 40 CFR 131.41.

For "existing pathogen dischargers" whose permits are reissued or modified to contain new or more stringent limitations based upon certain water quality requirements, the permit could allow up to five years to comply with such limitations. The provision would

apply to new or more stringent effluent limitations based on the criteria in this proposed rule. EPA has included "increasing dischargers" within the category of "existing pathogen dischargers" for purposes of this rule since "increasing dischargers" are existing facilities with a change—an increase—in their discharge. Such facilities may include those with seasonal variations. "Increasing dischargers" will already have treatment systems in place for their current discharge, thus, they are constrained in the types of efficiencies they can gain from their existing treatment system processes. In contrast, a new discharger can design and build a new treatment system which most efficiently will meet the new water quality-based requirements. Allowing existing facilities with an increasing discharge a compliance schedule in appropriate circumstances would avoid placing the discharger at a competitive disadvantage vis-a-vis other existing dischargers who are eligible for compliance schedules.

Today's proposed rule would not prohibit the use of a short-term "shake down period" for new pathogen dischargers as is provided for new sources or new dischargers in 40 CFR 122.29(d)(4). These regulations would require that the owner or operator of (1) a new source; (2) a new discharger (as defined in 40 CFR 122.2) which commenced discharge after August 13, 1979; or (3) a recommencing discharger shall install and implement all pollution control equipment to meet the conditions of the permit before discharging. The facility would also be required to meet all permit conditions in the shortest feasible time (not to exceed 90 days). This shake-down period is not a compliance schedule, some types of facilities that are eligible for a "shake down period" may also be eligible for a compliance schedule if they are existing pathogen dischargers. This approach would be used to address violations which may occur during a new facility's start-up, especially where permit limits are water quality-based and biological treatment is involved.

The burden of proof to show the necessity of a compliance schedule would be on the discharger, and the discharger would be required to request approval from the permit issuing authority for a schedule of compliance. The discharger should submit a description of the minimum required actions or evaluations that must be undertaken in order to comply with the new or more restrictive discharge limits. Dates of completion for the required actions or evaluations should be included, and the proposed schedule

should reflect the shortest practicable time to complete all minimum required actions.

Duration of Compliance Schedules: Today's proposed rule would provide that compliance schedules may provide for up to five years from date of permit issuance, reissuance, or modification to meet new or more stringent effluent limitations in those circumstances where the permittee can demonstrate to the permit authority that an extended schedule is warranted. EPA's regulations at 40 CFR 122.47 require compliance with standards as soon as possible. This means that permit authorities should not allow compliance schedules where the permittee fails to demonstrate their necessity. This provision should not be considered a default compliance schedule duration for all existing facilities. In instances where dischargers find that their current level of disinfection or other treatment is not sufficient to achieve the *E. coli* or enterococci criterion, dischargers will need to increase their current level of disinfection or evaluate and install new treatment technology. EPA believes that five years is sufficient time within which to complete this process.

Under this proposed rule, where a schedule of compliance exceeds one year, interim requirements are to be specified and interim progress reports would be required to be submitted at least annually to the permit issuing authority.

The proposed rule would allow all compliance schedules to extend up to a maximum duration of five years. Under the proposal, an existing pathogen discharger may obtain a compliance schedule when the existing permit for that discharge is issued, reissued or modified to contain more stringent limits based on the water quality criteria in today's proposed rule. Such compliance schedules, however, would not be able to be extended indefinitely because the compliance schedule provision in this rule limits the length of a compliance schedule for any facility to a maximum of five years.

EPA recognizes that where a permit is modified during the permit term, and the permittee needs the full five years to comply, the five-year schedule may extend beyond the term of the modified permit. In such cases, the rule allows for the modified permit to contain a compliance schedule with an interim limit to be achieved by the end of the permit term. When the permit is reissued, the permit authority may extend the compliance schedule in the next permit, provided that, taking into account the amount of time allowed under the previous permit, the entire

compliance schedule contained in the permit shall not exceed five years. Final permit limits and compliance dates will be included in the record for the permit. Final compliance dates for any WQBEL must occur within five years from the date of permit issuance, reissuance, or modification.

Antibacksliding: EPA wishes to address the potential concern over antibacksliding where revised permit limits based on new information are the result of the completion of additional studies. The Agency's interpretation of the CWA is that the antibacksliding requirements of section 402(o) of the CWA do not apply to revisions to effluent limitations made before the scheduled date of compliance for those limitations.

EPA is requesting comment on the setting and use of compliance schedules to provide permitted dischargers time to meet their permit effluent limitations based on today's proposed bacteria criteria. Compliance schedules can be set as part of the water quality standard or as part of the implementing regulations; in this specific case, the standard is authorizing the use of compliance schedules in cases where the permitting authority determines it would be appropriate. EPA is interested in views concerning the duration of the schedule. Today's proposal limits compliance schedules to a period not to exceed five years. It also requires interim limits where the five year term exceeds the length of time remaining in the permit after modification and requires specific milestones and reporting on an annual basis. EPA is interested in whether the limitation of five years for compliance schedules is reasonable or should longer schedules be allowed for certain permit activities that require extensive studies and construction activities (e.g., long term control plans associated with combined sewer overflows).

VI. Economic Analysis

These water quality standards may serve as a basis for development of NPDES permit limits. Many of the affected jurisdictions (i.e., States and Territories) are the NPDES permitting authorities, which retain considerable discretion in implementing standards. EPA evaluated the potential costs to NPDES dischargers in affected jurisdictions associated with future State and Territorial implementation of EPA's Federal standards. This analysis is documented in "Economic Analysis for Proposed Water Quality Standards for Coastal Recreation Waters," which can be found in the record for this rulemaking.

Any NPDES-permitted facility that discharges to water bodies affected by this proposed rule could potentially incur costs to comply with the rule's provisions. The types of affected facilities may include industrial facilities and publicly owned treatment works (POTWs) discharging sanitary wastewater to surface waters (i.e., point sources). EPA addresses discharges of bacteria from municipal separate storm sewer systems, combined sewer overflows (CSOs), and sanitary sewer overflows (SSOs) to coastal waters in existing and anticipated regulations and policies, and has tallied potential control costs as part of analyses for these actions. Controls for these types of discharges, which are not based on numeric limits are not likely to be substantially affected by the revised indicators in the proposed rule, at least in the near future. Therefore, to avoid double counting, EPA did not estimate costs for such discharges for this rule. EPA did not evaluate concentrated animal feeding operations (CAFOs) because section 301(a) of the CWA prohibits point sources, including CAFOs, from discharging to surface waters without a permit (except in compliance with CWA section 402 and other specified sections of the CWA), and because NPDES permits for CAFOs in turn prohibit discharges except in unusual circumstances (i.e., very large storms) that are unlikely to be affected by the revised indicators. EPA does not have data to quantify the effects of the proposed rule on total maximum daily loads for pathogen-impaired waters. Finally, EPA did not evaluate the potential for costs to nonpoint sources, such as agricultural runoff, and did not attempt to quantify the potential benefits of the proposed rule.

EPA recognizes that a State or Territory may decide to require controls for nonpoint sources (e.g., agricultural runoff) or point source discharges (e.g., CSOs and SSOs) due to wet weather events. However, as a technical matter, these sources are difficult to model and evaluate with respect to potential costs impacts because they are intermittent, highly variable, and occur under different hydrologic or climatic conditions than continuous discharges from industrial and municipal facilities, which EPA evaluates under critical low flow or drought conditions. Also, data on instream and discharge levels of bacteria after States have implemented controls to meet current water quality standards based on fecal coliform are not available. Therefore, trying to determine which sources would not achieve standards based on *E. coli* or

enterococci after complying with existing regulations and policies may not be possible, or would be extremely time and resource intensive. Finally, it is likely that any controls needed to meet existing standards (*i.e.*, based on fecal coliform) would also address any water quality problems indicated by standards based on *E. coli* or enterococci.

A. Identifying Affected Facilities

EPA identified approximately 850 point source facilities from 28 States and Territories that may be affected by the proposed rule. Of these potentially

affected facilities, 362 are classified as major dischargers, and 488 are minor dischargers. EPA did not include general permit facilities in its analysis because data for such facilities are extremely limited, and flows are usually negligible. Furthermore, EPA could not determine if any of these facilities actually discharge to the affected water bodies because location information is not available in EPA's PCS database.

EPA assumed that only facilities located in jurisdictions included in the proposed rule that discharge within 2 miles of coastal waters or the Great Lakes may be affected. EPA identified

these facilities by relating facility information to the potentially affected waters using GIS software. EPA also assumed that only wastewater treatment plants or facilities with similar effluent characteristics (*i.e.*, facilities having the potential to discharge bacteria) would potentially be affected by the proposed rule. For those facilities for which latitude/longitude data are not included in PCS, EPA included only facilities for which the receiving water body name in PCS indicates a coastal water (*e.g.*, Pacific Ocean, Lake Erie). Table 4 summarizes these potentially affected facilities by type and category.

TABLE 4.—POTENTIALLY AFFECTED FACILITIES ¹

Category	Number of facilities			Total
	Major ²	Minor		
		Municipal	Other ³	
Coastal	298	283	108	689
Great Lakes	64	76	21	161
Total	362	359	129	850

¹ Facilities from States and Territories included in the proposed rule that discharge within two miles of coastal waters or the Great Lakes.

² No major industrial facilities are affected by the proposed rule. However, 6 other facilities (SIC codes 9711 and 9999) are included because their names indicate that they are wastewater treatment plants.

³ Includes the following SICs: Eating places (5812), drinking places (5813), operators of nonresidential buildings (6512), operators of apartment buildings (6513), operators of dwellings other than apartment buildings (6514), operators of residential mobile home sites (6515), hotels and motels (7011), recreational vehicle parks and campsites (7033), organization hotels and lodging houses (7041), physical fitness facilities (7991), amusement and recreation services (7999), skilled nursing care facilities (8051), general medical and surgical hospitals (8062), elementary and secondary schools (8211), colleges, universities, and professional schools (8221), civic, social, and fraternal associations (8641), private households (8811). Also includes the following SICs if the facility name suggests that they may discharge sanitary waste: Operative builders (1531), sanitary services, not elsewhere classified (4959), real estate agents and managers (6531), business associations (8611), religious organizations (8661), services not elsewhere classified (8999), air and water resource and solid waste management (9511), nonclassifiable establishments (9999).

B. Method for Estimating Potential Compliance Costs

To estimate costs, EPA evaluated the 15 major municipal facilities with design flows greater than 120 mgd, thus ensuring that the facilities with potential for the largest costs would be evaluated. For the remaining facilities, EPA evaluated a sample of facilities to represent discharger type and category.

The proposed standards are for the affected waters, and permitting authorities have flexibility in implementing the criteria. Facilities in some States that have adopted the 1986 criteria have effluent limits for *E. coli* or enterococci, and in other such States, facilities do not have bacteria limits. To be conservative (*i.e.*, err on the side of higher costs), EPA assumed that potentially affected facilities would be required to meet both the applicable geometric mean and SSM (although EPA's bacteria implementation guidance indicates that the intent of the SSM value is not for permitting).

PCS does not contain *E. coli* or enterococci effluent data for any of the sample facilities. Therefore, to evaluate

potential costs associated with the *E. coli* criteria, EPA assumed that 100% of the fecal coliform measured is *E. coli* because *E. coli* is a type of fecal coliform. EPA estimated that facilities with average monthly effluent levels, based on the last 3 years of data, exceeding a geometric mean of 126 fecal coliform/100 mL, or maximum daily levels exceeding 235 fecal colonies/100 mL, would need treatment controls to meet potential permit limits based on the proposed criteria.

Enterococci are fecal bacteria in the fecal streptococcus group, and their relationship to fecal coliform bacteria is uncertain. Therefore, for coastal facilities, EPA used data and information in the literature regarding the ratio of fecal coliform to enterococci in untreated sewage, and the inactivation of both of these bacteria at minimum disinfection levels, to identify the concentrations of fecal coliform that may indicate a need for controls. Data in the literature indicate that the ratio of fecal coliform to fecal streptococcus in untreated sewage ranges from about 4 to 28. EPA used the most conservative (*i.e.*,

erring on the side of overestimating costs) ratio of 4 (*i.e.*, fecal coliform levels are 4 times fecal streptococcus levels) to estimate the fecal coliform levels at which facilities would need treatment to comply with the proposed enterococci criteria. Again, EPA compared fecal coliform levels over the last three years to both the proposed geometric mean and SSM enterococci criteria values.

Experiences from facilities currently meeting the proposed *E. coli* and enterococci criteria, as well as the current fecal coliform criteria, suggest that chlorination processes can be upgraded or adjusted to produce the levels of bacteria necessary for compliance with the proposed rule. Therefore, EPA estimated that optimization of existing disinfection processes would enable the sample facilities to comply with the proposed rule. Process optimization usually involves process analysis and process modifications, and EPA's cost estimates include both capital and operating and maintenance costs.

C. Results

Based on the potential costs for the 15 facilities with flows greater than 120 mgd, and extrapolating costs for a sample of 60 facilities to the remaining 835 facilities potentially affected by the proposed rule, EPA estimated a total annual cost of approximately \$22 million (\$15 million for coastal facilities, and \$7 million for Great Lakes facilities). EPA estimates that approximately 110 major and 30 minor permittees could incur control costs as a result of modified permits to comply with the revised criteria. However, this estimate is considered conservative because it is based on assumptions regarding how States and Territorial will implement the proposed standards that may overstate the actual cost impacts and two States (Alabama and Texas) included in EPA's cost analysis are not part of today's proposed rule.

Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866, (58 FR 51735 (October 4, 1993)) the Agency must determine whether the regulatory action is "significant" and therefore subject to OMB review and the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may:

- (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;
- (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
- (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
- (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, it has been determined that this rule is a "significant regulatory action" because the rule raises novel policy issues arising out of the BEACH Act. As such, this action was submitted to OMB for review. Changes made in response to OMB suggestions or recommendations will be documented in the public record.

B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). It does not include any information collection, reporting, or record-keeping requirements.

Burden means the total time, effort or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 *et seq.*, generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations and small governmental jurisdictions.

For purposes of assessing the impacts of today's proposed rule on small entities, small entity is defined as: (1) A small business according to RFA default definitions for small business (based on SBA size standards); (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's proposed rule on

small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This proposed rule will not impose any requirements on small entities. The RFA requires analysis of the impacts of a rule on the small entities subject to the rule's requirements. See *United States Distribution Companies v. FERC*, 88 F.3d 1105, 1170 (DC Cir. 1996). Today's proposed rule establishes no requirements applicable to small entities, and so is not susceptible to regulatory flexibility analysis as prescribed by the RFA. ("[N]o [regulatory flexibility] analysis is necessary when an agency determines that the rule will not have a significant economic impact on a substantial number of small entities that are subject to the requirements of the rule," *United Distribution at 1170*, quoting *Mid-Tex Elec. Co-op v. FERC*, 773 F.2d 327, 342 (DC Cir. 1985) (emphasis added by *United Distribution* court).) We continue to be interested in the potential impacts of the proposed rule on small entities and welcome comments on issues related to such impacts.

CWA section 303(i)(2)(A) requires that if a State or Territory fails to adopt water quality criteria and standards in accordance with paragraph (1)(A) that are as protective of human health as the criteria for pathogen indicators for coastal recreation waters published by the Administrator, the Administrator shall promptly propose regulations for the State or Territory setting forth revised or new water quality standards for pathogen indicators described in paragraph (1)(A) for coastal recreation waters of the State or Territory. These State standards (or EPA-promulgated standards) are implemented through various water quality control programs including the NPDES program, which limits discharges to navigable waters except in compliance with an NPDES permit. The CWA requires that all NPDES permits include any limits on discharges that are necessary to meet applicable water quality standards.

Thus, under the CWA, EPA's promulgation of water quality standards establishes standards that the State generally implements through the NPDES permit process. In this case, EPA Regional Offices are the NPDES permitting authority in five of the States and Territories subject to today's proposal. EPA Regions 1, 2, 9 and 10 are the permitting authorities for Massachusetts, Puerto Rico, the Commonwealth of the Northern Mariana Islands, for some permits in Hawaii, and Alaska, respectively. As such, EPA Regions 1, 2, 9, and 10 have discretion

in developing discharge limits as needed to meet the standards. While these Regions' implementation of Federally promulgated water quality standards may result in new or revised discharge limits being placed on small entities, the standards themselves do not apply to any discharger, including small entities.

Today's proposed rule, as explained earlier, does not itself establish any requirements that are applicable to small entities. As a result of this action, States, Territories, and EPA Regional offices will need to ensure that permits they issue include any limitations on discharges necessary to comply with the standards established in the final rule. In doing so, the States, Territories, and EPA Regions will have a number of choices associated with permit writing. While the implementation of the rule may ultimately result in some new or revised permit conditions for some dischargers, EPA's action today does not impose any of these as yet unknown requirements on small entities.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104-4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments and the private sector. The definition of "State" for the purposes of UMRA includes "a territory or possession of the United States." Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures to State, local, and Tribal governments, in the aggregate, or to the private sector, of \$100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation of why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including Tribal governments, it must have developed

under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

Today's proposed rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) that may result in expenditures to State, local and Tribal governments, or the private sector, in the aggregate of \$100 million or more in any one year. Therefore, this rule is not subject to the requirements of sections 202 and 205 of the UMRA.

EPA has determined that this proposed rule contains no regulatory requirements that might significantly or uniquely affect small governments. Thus, this proposed rule is not subject to the requirements of section 203 of the UMRA.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have Federalism implications." "Policies that have Federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

This proposed rule does not have Federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. EPA's authority and responsibility to promulgate Federal water quality standards when State standards do not meet the requirements of the CWA is well established and has been used on various occasions in the past. The proposed rule would not substantially affect the relationship of EPA and the States and Territories, or the distribution of power or responsibilities between EPA and the various levels of government. The proposed rule would not alter the States' or Territories'

considerable discretion in implementing these water quality standards. Further, this proposed rule would not preclude the States and Territories from adopting water quality standards that meet the requirements of the CWA, either before or after promulgation of the final rule, thus eliminating the need for Federal standards. Thus, Executive Order 13132 does not apply to this proposed rule.

Although Executive Order 13132 does not apply to this rule, EPA did consult with representatives of the States and Territories subject to CWA section 303(i) in developing this rule. Prior to this proposed rulemaking action, EPA had numerous phone calls, meetings and exchanges of written correspondence with the States to discuss EPA's concerns with the States' bacteria criteria, compliance with the BEACH Act, and the Federal rulemaking process. In June 2000 EPA and the Association of State and Interstate Water Pollution Control Administrators (ASIWPCA) established a State/EPA Work Group on Water Quality Standards, composed of selected senior State and EPA managers, to provide input to EPA on water quality standards issues. The group has met approximately three times per year since then, beginning with a meeting in September 2000. At every meeting the group has discussed the scientific, programmatic, and policy aspects of bacteria criteria for both coastal and non-coastal recreation waters, and has provided useful input to EPA on these topics. Members of this group, together with other interested State participants, have also served as an ad-hoc work group since 2001 to assist EPA in developing draft detailed scientific and policy guidance (*Implementation Guidance for Ambient Water Quality Criteria for Bacteria*, May 2002 Draft, EPA-823-B-02-003) concerning adoption and implementation of EPA's recommended criteria for bacteria. EPA will continue to work with the States and Territories before finalizing these water quality standards. In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicits comment on this proposed rule from State and local officials.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 6, 2000), requires EPA to develop an accountable process to ensure "meaningful and timely input by

tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive Order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.”

This proposed rule does not have tribal implications. It will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. There are four authorized Indian Tribes with coastal or Great Lakes waters; however, they have not yet adopted water quality standards, and therefore, have no designated coastal recreation waters within their jurisdiction. These tribes are therefore not subject to today’s proposed rule. Thus, Executive Order 13175 does not apply to this rule.

EPA has contacted those Tribes identified as having coastal or Great Lakes waters to inform them of the potential future impact this proposal could have on Tribal waters. EPA specifically solicits additional comment on this proposed rule from tribal officials.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045: “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997) applies to any rule that: (1) Is determined to be “economically significant” as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This proposed rule is not subject to the Executive Order because it is not economically significant as defined in Executive Order 12866.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This rule is not a “significant energy action” as defined in Executive Order 13211, “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355 (May 22, 2001)) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. EPA estimates that compliance with the proposed rule will create a negligible increase in nationwide energy consumption for point source facilities discharging to coastal recreation waters in affected States. In Section VI, EPA presented its estimated incremental costs to permitted facilities as a result of the proposed rule. Some of these costs include energy use associated with increased maintenance of disinfection tanks. EPA estimates that the increased energy use from these activities would be about 140,000 kilowatt hours. Net production by electric power generation facilities in the United States in 2002 was 3,858,452 million kilowatt hours (Energy Information Administration, Department of Energy, <http://www.eia.doe.gov/neic/quickfacts/quickelectric.htm>). EPA estimates that the additional energy requirements of EPA’s rule are insignificant (*i.e.*, 0.000004% of national energy generation).

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (“NTTAA”), Public Law 104–113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

While ambient water quality criteria may be considered technical standards EPA is not aware of any voluntary consensus standards relating to bacteria criteria to protect human health. Furthermore, even if there were such voluntary consensus standards the BEACH Act specifically directs EPA to promulgate Federal standards based on its own bacteria criteria, published in

accordance with CWA section 304(a), in cases where States fail to do so. Therefore, EPA is not considering the use of any voluntary consensus standards.

List of Subjects in 40 CFR Part 131

Environmental protection, Intergovernmental relations, Reporting and recordkeeping requirements, Water pollution control.

Dated: July 1, 2004.

Michael O. Leavitt,
Administrator.

For the reasons set out in the preamble, EPA proposes to amend 40 CFR part 131 as follows:

PART 131—WATER QUALITY STANDARDS

1. The authority citation for part 131 continues to read as follows:

Authority: 33 U.S.C. 1251 *et seq.*

Subpart D—[Amended]

2. Section 131.41 is added to read as follows:

§ 131.41 Bacteriological criteria for those states not complying with Clean Water Act section 303(i)(1)(A).

(a) *Scope.* This section is a promulgation of the Clean Water Act section 304(a) criteria for bacteria for coastal recreation waters in specific States. It is not a general promulgation of the Clean Water Act section 304(a) criteria for bacteria. This section also contains a compliance schedule provision.

(b) *Definitions*—(1) *Coastal Recreation Waters* are the Great Lakes and marine coastal waters (including coastal estuaries) that are designated under section 303(c) of the Clean Water Act for use for swimming, bathing, surfing, or similar water contact activities. Coastal recreation waters do not include inland waters or waters upstream from the mouth of a river or stream having an unimpaired natural connection with the open sea.

(2) *Designated bathing beach waters* are those coastal recreation waters that, during the recreation season, are heavily-used and may have: A lifeguard, bathhouse facilities, or public parking for beach access. States may include any other waters in this category even if the waters do not meet these criteria.

(3) *Moderate use coastal recreation waters* are those coastal recreation waters that are not designated bathing beach waters but typically, during the recreation season, are used by at least half of the number of people as at typical designated bathing beach waters

within the State. States may also include light use or infrequent use coastal recreation waters in this category.

(4) *Light use coastal recreation waters* are those coastal recreation waters that are not designated bathing beach waters but typically, during the recreation season, are used by less than half of the number of people as at typical designated bathing beach waters within

the State, but are more than infrequently used. States may also include infrequent use coastal recreation waters in this category.

(5) *Infrequent use coastal recreation waters* are those coastal recreation waters that are rarely or occasionally used.

(6) *New pathogen discharger* for the purposes of this rule means any building, structure, facility, or installation from which there is or may

be a discharge of pathogens, the construction of which commenced on or after [THE EFFECTIVE DATE OF THE RULE].

(7) *Existing pathogen discharger* for the purposes of this rule means any discharger that is not a new pathogen discharger.

(c) *EPA's section 304(a) ambient water quality criteria for bacteria.*

(1) Fresh waters:

A Indicator	B Geometric mean	C Single sample maximum (per 100 ml)			
		C1 Designated bathing beach (75% confidence level)	C2 Moderate use coastal recreation waters (82% confidence level)	C3 Light use coastal recreation waters (90% confidence level)	C4 Infrequent use coastal recreation waters (95% confidence level)
<i>E. coli</i>	126/100 ml ^a	235 ^b	298 ^b	409 ^b	575 ^b

Footnotes to table in paragraph (c)(1):

^a This value is for use with analytical methods 1106.1 or 1600 or any equivalent viable method.

^b Calculated using the following: single sample maximum = geometric mean * 10[^] (confidence level factor * log standard deviation), where the confidence level factor is: 75%: 0.68; 82%: 0.94; 90%: 1.28; 95%: 1.65. The log standard deviation from EPA's epidemiological studies is 0.4.

(2) Marine waters:

A Indicator	B Geometric mean	C Single sample maximum (per 100 ml)			
		C1 Designated bathing beach (75% confidence level)	C2 Moderate use coastal recreation waters (82% confidence level)	C3 Light use coastal recreation waters (90% confidence level)	C4 Infrequent use coastal recreation waters (95% confidence level)
Enterococci	35/100 ml ^a	104 ^b	158 ^b	276 ^b	501 ^b

Footnotes to table in paragraph (c)(2):

^a This value is for use with analytical methods 1103.1, 1603, or 1604 or any equivalent viable method.

^b Calculated using the following: single sample maximum = geometric mean * 10[^] (confidence level factor * log standard deviation), where the confidence level factor is: 75%: 0.68; 82%: 0.94; 90%: 1.28; 95%: 1.65. The log standard deviation from EPA's epidemiological studies is 0.7.

(3) As an alternative to the single sample maximum in paragraph (c)(1) or (c)(2) of this section, States may use a site-specific log standard deviation to calculate a single sample maximum for individual coastal recreation waters, but must use at least 30 samples from a single recreation season to do so.

(d) *Applicability.* (1) The criteria in paragraph (c) of this section apply to the coastal recreation waters of the States identified in paragraph (e) of this section and apply concurrently with any ambient recreational water criteria adopted by the State, except for those coastal recreation waters where State regulations contain criteria approved by EPA as meeting the requirements of Clean Water Act section 303(i), in which case the State's criteria for those coastal recreation waters will apply and not the criteria in paragraph (c) of this section.

(2) The criteria established in this section are subject to the State's general

rules of applicability in the same way and to the same extent as are other Federally-adopted and State-adopted numeric criteria when applied to the same use classifications.

(e) *Applicability to specific jurisdictions.* (1) The criteria in paragraph (c)(1) of this section apply to fresh coastal recreation waters of the following States: Illinois, Minnesota, New York, Ohio, Pennsylvania, Wisconsin.

(2) The criteria in paragraph (c)(2) of this section apply to marine coastal recreation waters of the following States: Alaska, California (except for coastal recreation waters within the jurisdiction of Regional Board 4), Delaware (except for waters with human sources of fecal contamination), Florida, Georgia, Hawaii (except for non-estuarine coastal recreation waters within 300 meters of the shoreline), Louisiana, Maine (except for SB and SC

waters with human sources of fecal contamination), Maryland, Massachusetts, Mississippi, New York, North Carolina, Oregon, Puerto Rico (except for waters classified by Puerto Rico as intensely used for primary contact recreation and for those waters included in 40 CFR 131.40), Rhode Island, South Carolina, United States Virgin Islands, Washington.

(3) The criteria in column C of paragraph (c)(2) of this section apply to marine coastal recreation waters of the following States: Commonwealth of the Northern Mariana Islands, Hawaii (for non-estuarine coastal recreation waters within 300 meters of shore).

(f) *Schedules of compliance.* (1) Subsection (f) applies to any State that does not have a regulation in effect for Clean Water Act purposes that authorizes compliance schedules subject to this paragraph, except for [LIST OF STATES AND TERRITORIES

THAT TELL EPA IN WRITING THAT THEY DO NOT WANT TO ALLOW A SCHEDULE OF COMPLIANCE]. All dischargers shall promptly comply with any new or more restrictive water quality-based effluent limitations based on the water quality criteria set forth in this section.

(2) When a permit issued on or after [THE EFFECTIVE DATE OF THE RULE] to a new pathogen discharger as defined in paragraph (b) of this section contains water quality-based effluent limitations based on water quality criteria set forth in paragraph (c) of this section, the permittee shall comply with such water quality-based effluent limitations upon the commencement of the discharge.

(3) Where an existing pathogen discharger reasonably believes that it will be infeasible to comply immediately with a new or more restrictive water quality-based effluent limitations based on the water quality criteria set forth in this section, the discharger may request approval from

the permit issuing authority for a schedule of compliance.

(4) A compliance schedule for an existing pathogen discharger shall require compliance with water quality-based effluent limitations based on water quality criteria set forth in paragraph (b) of this section as soon as possible, taking into account the dischargers' ability to achieve compliance with such water quality-based effluent limitations.

(5) If the schedule of compliance for an existing pathogen discharger exceeds one year from the date of permit issuance, reissuance or modification, the schedule shall set forth interim requirements and dates for their achievement. The period between dates of completion for each requirement may not exceed one year. If the time necessary for completion of any requirement is more than one year and the requirement is not readily divisible into stages for completion, the permit shall require, at a minimum, specified

dates for annual submission of progress reports on the status of interim requirements.

(6) In no event shall the permit issuing authority approve a schedule of compliance for an existing pathogen discharge which exceeds five years from the date of permit issuance, reissuance, or modification, whichever is sooner.

(7) If a schedule of compliance exceeds the term of a permit, interim permit limits effective during the permit shall be included in the permit and addressed in the permit's fact sheet or statement of basis. The administrative record for the permit shall reflect final permit limits and final compliance dates. Final compliance dates for final permit limits, which do not occur during the term of the permit, must occur within five years from the date of issuance, reissuance or modification of the permit which initiates the compliance schedule.

[FR Doc. 04-15614 Filed 7-8-04; 8:45 am]

BILLING CODE 6560-50-P