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Water Quality Standards for Coastal and Great Lakes Recreation Waters; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 131

[OW–2004–0010; FRL–7837–5]

RIN 2040–AE63

Water Quality Standards for Coastal and Great Lakes Recreation Waters

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is promulgating water quality criteria for bacteria for coastal recreation waters in specific States and Territories. The States and Territories covered by this promulgation do not have water quality standards for bacteria that comply with the requirements of section 303(i)(1)(A) of the Clean Water Act. Under these circumstances, the Act requires EPA to promptly propose such standards and to promulgate such standards not later than 90 days after proposal. The criteria promulgated 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. Through this promulgation, the Federally designated water quality criteria will be added to the States' and Territories' water quality criteria applicable to coastal recreation waters.

DATES: This final rule is effective December 16, 2004.

ADDRESSES: EPA has established a docket for this action under DOCKET ID No. OW–2004–0010. 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.*, Confidential Business Information (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 20460. 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 Water Docket is (202) 566–2422.

FOR FURTHER INFORMATION CONTACT: For information concerning today's rulemaking, 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 entities most directly affected by today's rule. People concerned with water quality in coastal and Great Lakes States may be interested in this rulemaking. Facilities discharging pollutants to certain waters of the United States in coastal and Great Lakes States could be affected by this rulemaking because water quality standards are used in determining water quality-based National Pollutant Discharge Elimination System permit limits. In addition, beach managers and businesses in beach areas could also be indirectly affected by this rulemaking because water quality standards are used in making decisions regarding beach advisories and closures. Categories and entities that may be affected include:

Category	Examples of potentially affected entities
Industry	Industries discharging pollutants to the waters of the States and Territories identified in 40 CFR 131.41.
Municipalities	Publicly-owned treatment works or municipal wet weather discharges (such as combined sewer overflows) that discharge pollutants to the waters of the States and Territories identified in 40 CFR 131.41.
Other	Beach owners and managers, beach goers. States identified in 40 CFR 131.41.

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 40 CFR 131.41 of today's final rule. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

B. How Can I Get Copies of This Document and Other Related Information?

1. Docket. EPA has established an official public docket for this action under Docket ID No. OW–2004–0010. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information the disclosure of which is restricted by statute. The official public docket is the collection of materials that is available for public viewing 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. Docket copying costs are as follows: the first 266 pages are free, additional copying incurs a $25 administrative fee, and each additional page is $0.15.

2. Electronic Access. You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at *http://www.epa.gov/fedrgstr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EDOCKET. You may use EDOCKET at *http://www.epa.gov/edocket/* to view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Section I.B. Once in the system, select "search," then key in the appropriate docket identification number.

II. Background

A. Statutory and Regulatory Background

1. Clean Water Act

Section 303 (33 U.S.C. 1313) of the Clean Water Act 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 Clean Water Act. 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 for the waters and water quality criteria necessary to protect those uses. Section 303(c)(2)(A) of the Clean Water Act specifies the uses that States, Territories, and authorized Tribes should consider in establishing new or revised water quality standards. These uses are public water supplies, propagation of fish and wildlife, recreational purposes, agricultural, industrial, and other purposes, and navigation. States, Territories, and authorized Tribes must review their water quality standards at least once every three years and, if appropriate, revise or adopt new standards. States, Territories, and authorized Tribes must submit the results of this triennial review to EPA, and EPA must approve or disapprove any new or revised standards.

Section 303(c) of the Clean Water Act 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 Clean Water Act's requirements. EPA regulations implementing Clean Water Act section 303(c) are published at 40 CFR Part 131. Under these rules, the minimum elements that States, Territories, or authorized Tribes must incorporate in their 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). Section 303(c)(4) requires the EPA Administrator to promulgate any new or revised water quality standard not later than 90 days after publishing a proposed Federal standard unless prior to this deadline, the State, Territory or authorized Tribe has adopted a water quality standard that the Administrator determines to be in accordance with the Clean Water Act.

2. The BEACH Act of 2000

The Beaches Environmental Assessment and Coastal Health (BEACH) Act of 2000 amended the Clean Water Act 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, January 1986) (the 1986 bacteria criteria document) is the relevant criteria document published by the Administrator under Clean Water Act 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)(A) to the Clean Water Act, 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)(B) 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. States and Territories typically define primary contact recreation to encompass recreational activities that could be expected to result in the ingestion of, or immersion in, water, such as swimming, water skiing, surfing, kayaking, or any other recreational activity where ingestion of, or immersion in, the water is likely. The main route of exposure to illness-causing organisms during recreation in water is through accidental ingestion of fecally contaminated water while engaging in these activities.

EPA based its 1986 water quality criteria for bacteria on levels of indicator bacteria, namely *Escherichia coli* (*E. coli*) and enterococci, which demonstrate the presence of pathogens in fecal pollution that can cause acute gastrointestinal illness. Public health agencies have long used indicator organisms such as these to protect people from illnesses that they may contract 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 describes 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. The previously recommended numeric criteria for fecal coliform were a geometric mean of 200/100 ml, with no more than 10% of the total samples taken during any 30-day period exceeding 400/100 ml. 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 more accurately predict acute gastrointestinal illness than levels of fecal coliforms. On page 5, EPA's 1986 bacteria criteria document states: "[E]nterococci showed the strongest relationship to gastroenteritis. *E. coli* was a very poor second and all of the other indicators, including total coliforms and fecal coliforms showed very weak correlations to gastroenteritis."

In EPA's epidemiological studies, *E. coli* and enterococci exhibited the strongest correlation to swimming-associated gastroenteritis, the former in freshwaters only and the latter in both fresh and marine waters (1986 bacteria criteria document; *Health Effects Criteria for Fresh Recreational Waters*, EPA 600/1–84–004, August 1984; *Health Effects Criteria for Marine Recreational Waters*, EPA 600/1–80–031, August 1983). 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 and does not occur with fecal contamination, 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, 1976).

Table 1 contains the water quality criteria values for the protection of primary contact recreation that EPA recommended in the 1986 bacteria criteria document. EPA developed these values 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 criteria. EPA estimated this illness rate 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 Agency based the 1986 values that appear in Table 1 on these approximations. The 1986 bacteria criteria document provides geometric mean densities as well as four different single sample maximum values (representing values below which an increasing percentage of single values are expected to fall if the mean (average) of all samples equals the geometric mean criterion). The higher the single sample maximum, the lower the probability that a single sample exceeding that value would occur as part of the normal random variability of samples around the geometric mean. Single sample maximums are water quality assessment tools that provide a sense of when a single value that comes from a waterbody may be part of a bacterial density with a geometric mean concentration higher than that specified by the water quality criteria. For instance, if the geometric mean concentration in the water at a marine beach is 35/100 ml, then there is an 18% probability that the concentration of enterococci in a single sample would be over 158/100 ml. One could thus consider a single sample with this value to be indicative of bacterial densities with a geometric mean above 35/100 ml, but there would be a non-trivial chance of being wrong in this determination. Statisticians say this conclusion can be drawn "with 82% confidence."

The 1986 bacteria criteria document includes, for each geometric mean, a table of four single sample maximum values that are appropriate for different levels of beach usage. In general, where a given area has a greater potential for more people to be exposed, that area may warrant a higher degree of protectiveness (*i.e.*, a lower single sample maximum). The 1986 bacteria criteria document categorizes the levels of beach usage corresponding to the four single sample maximums as follows: "designated bathing beach" for the 75%

(most protective) confidence level, "moderate use for bathing" for the 82% confidence level, "light use for bathing" for the 90% confidence level, and "infrequent use for bathing" for the 95% confidence level. Note that the lowest confidence level corresponds to the highest level of protection because it leads to a more precautionary judgment to treat the waterbody as exceeding the mean criterion, even though there is less statistical confidence that this is the case. EPA assigned the lowest single sample maximum to designated bathing beach areas because a high degree of caution should be used to evaluate the status of such areas, giving greater weight to a measured single value above the geometric mean, even though the statistical significance of this single measurement may be weak. EPA believes this is appropriate because more people are likely to become ill at heavily used areas if they exceed the criteria. The 1986 bacteria criteria document described bathing beach areas as those areas that 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 "moderate," "lightly used," and "infrequently used" full body contact recreation waters.

TABLE 1.—1986 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 [4 5]			
			Designated beach area (upper 75% C.L.)	Moderate full body contact recreation (upper 82% C.L.)	Lightly used full body contact recreation (upper 90% C.L.)	Infrequently used full body contact recreation (upper 95% C.L.)
Freshwater						
Enterococci	8	33/100 ml [1]	61	78	107	151
E. coli	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) = antilog$_{10}$ ((illness rate/1000 people + 6.28)/9.40).
[2] Calculated to nearest whole number using equation: (mean *E. coli* density) = antilog$_{10}$ ((illness rate/1000 people + 11.74)/9.40).
[3] Calculated to nearest whole number using equation: (mean enterococci density) = antilog$_{10}$ ((illness rate/1000 people − 0.20)/12.17).
[4] Single sample limit = antilog$_{10}$ (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 may establish its own standard deviation for its conditions which would then vary the single sample limit.

III. EPA's Proposed Rule and Solicitation of Comment

A. July 2004 Proposed Rule

On July 9, 2004, EPA published a proposal entitled "Water Quality Standards for Coastal and Great Lakes Recreation Waters" (see 69 FR 41720). At that time, EPA proposed to promulgate *E. coli* and enterococci standards for coastal recreation waters in States that had not adopted water quality standards for those waters that are as protective of human health as EPA's 1986 bacteria criteria.

EPA proposed a geometric mean of 126/100 ml for *E. coli* in fresh coastal recreation waters and a geometric mean of 35/100 ml for enterococci in marine coastal recreation waters. EPA also proposed four different single sample maximums in both fresh and marine coastal recreation waters. Each single sample maximum was assigned to a category of coastal recreation water based on intensity of use. EPA proposed to interpret the single sample maximums as maximum values that would not be allowed to be exceeded, but requested comment on various other interpretations. EPA did not propose particular waters to which a specific single sample maximum would apply; rather, EPA proposed that States and Territories would determine which single sample maximum would apply to each of its coastal recreation waters. The criteria values for fresh and marine coastal recreation waters are the same values that are found in the 1986 bacteria criteria document.

EPA did not include coastal or Great Lakes States and Territories in the proposed rule if their current standards met each of five criteria: the standards are based on EPA's 1986 recommended pathogen indicators; the standards are derived from a scientifically-defensible methodology linked quantitatively to an acceptable risk level under Clean Water Act section 303(i); the standards include appropriate single sample maximums; the standards do not address fecal contamination from non-human sources in a way inconsistent with the 1986 bacteria criteria; and EPA approved the standards. If a State or Territory met all five criteria, EPA proposed to not include that State or Territory in the rule.[1]

B. Public Comments

The comment period for this rule closed on August 9, 2004. EPA received 55 comments on the proposed rule from a variety of sources, including academic associations, environmental groups, municipal wastewater associations, industry, State agencies, local governments, and private citizens. Most of the comments focused on the following issues: choice of pathogen indicator, promulgation of a geometric mean and four single sample maximums for the indicators, use of the single sample maximum, intensity of use categories of coastal recreation waters, intrastate vs. interstate determinations of use intensity, State calculation of site-specific single sample maximums, and addressing non-human sources of bacteria. This preamble includes a general summary of public comments in

[1] In the case of Washington State, EPA has determined that a fecal coliform standard of 14/100 ml for marine waters is "as protective as" EPA's 1986 bacteria criteria. (*See* section V.A.1 of this preamble.)

the discussions of the various issues addressed here. EPA has prepared a "Comment Response Document" that includes responses to comments submitted on the proposed rule, which is in the docket for today's rule.

IV. Criteria That EPA Is Promulgating Today

A. Scope of the Rule

EPA is promulgating the rule to apply, as proposed, to Great Lakes and marine coastal recreation waters (including coastal estuaries) designated by a State or Territory under Clean Water Act 303(c) for swimming, bathing, surfing, or similar water contact activities. As explained in the preamble to the proposed rule (69 FR 41723), the requirements of the BEACH Act are limited to "coastal recreation waters," which are defined in Clean Water Act section 502(21) as the Great Lakes and marine coastal recreation waters (including coastal estuaries) that are designated under Clean Water Act 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 Clean Water Act 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.

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 bacteria criteria. 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 complied with the requirements of the Clean Water Act and EPA's implementing regulations for designating uses. Today's rule 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 Clean Water Act 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 Clean Water Act 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 Clean Water Act 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)).

EPA received few comments on the scope of the rule. One commenter suggested that the rule should not apply to State waters outside of the areas where swimming normally occurs, citing as an example Hawaii's water quality standards, which are consistent with EPA's 1986 bacteria criteria but apply only to those swimming waters within 300 meters of shore. This commenter also suggested that the criteria should only have to apply at depths of less than 150 feet. EPA does not find these comments persuasive in light of the clear language of Clean Water Act sections 303(i) and 502(21), which together require the adoption of criteria for all of the coastal or Great Lakes waters designated by the State for use for swimming, bathing, surfing, or similar water contact activities even if, as a factual matter, the waters designated for swimming are not frequently or typically used for swimming.

One commenter expressed concern that the rule could establish a binding precedent for EPA's review of pathogen criteria for inland waters that do not fall within the definition of a coastal recreation water. As discussed above, section 303(i) of the Clean Water Act does not apply to inland waters other than the Great Lakes because such waters are explicitly excluded from the definition of "coastal recreation waters" in section 502(21) of the Clean Water Act. For all other waters (*i.e.*, waters that are not coastal recreation waters), section 303(c) of the Clean Water Act and EPA's implementing regulations at 40 CFR part 131 require States, Territories, and authorized Tribes to adopt criteria that are scientifically defensible and sufficient to protect the designated uses of those waters. When EPA reviews a State's, Territory's or authorized Tribe's new or revised water quality standards, EPA applies its regulations at 40 CFR 131.5 and 131.6. EPA's decision on future State or Territorial submissions will be based on the information supporting those submissions. EPA's decisions in today's rule should not be considered as binding on States and Territories adopting bacteria criteria for inland waters other than the Great Lakes.

B. Criteria for Pathogen Indicators

1. Selection of Pathogen Indicator

For States and Territories covered by today's rule, EPA is promulgating water quality criteria using the pathogen indicators of enterococci for marine waters and both enterococci and *E. coli* for freshwaters. EPA interprets Clean Water Act section 303(i)(1)(A) to require States and Territories to adopt and submit water quality criteria for enterococci in marine waters and either enterococci or *E. coli* in fresh waters because it requires States and Territories to submit criteria "for the pathogens and pathogen indicators for which the Administrator has published criteria under section 304(a)." EPA's 1986 bacteria criteria document is the relevant Clean Water Act section 304(a) criteria referred to in Clean Water Act section 303(i)(1)(A). It recommends the use of enterococci in marine waters and *E coli* or enterococci in fresh waters for the protection of primary contact recreation. Clean Water Act section 303(i)(2)(A) requires EPA to promptly propose regulations for the State setting forth revised or new water quality standards for pathogens and pathogen indicators described in Clean Water Act section 303(i)(1)(A) for coastal recreation waters of the State for those States that fail to adopt criteria that are as protective of human health as the criteria referenced in section 303(i)(1)(A).

In the proposal (69 FR 41727), EPA proposed to adopt only *E. coli* for freshwaters because most of the States and Territories that had adopted or were in the process of adopting the 1986 bacteria criteria had chosen to use *E. coli* instead of enterococci. However, EPA also solicited comment on whether to promulgate criteria based on both indicators for freshwater and to allow States and Territories to choose which indicator to apply to its coastal recreation waters at the time of

implementation. EPA received comments from the New York Department of Environmental Conservation (DEC) and the Pennsylvania Department of Environmental Protection (DEP) requesting EPA to do so. Both of these State agencies have responsibility for promulgating State water quality standards. New York DEC explained that the New York Department of Health had recently adopted regulations adding both *E. coli* and enterococci as the criteria for its freshwater bathing beaches, and that the New York DEC was in the process of deciding which of the two indicators it would adopt for its water quality standards in the Great Lakes. Consequently, New York DEC requested that EPA's final rule include values for both indicators and allow the State to select either at the time of implementation. Pennsylvania DEP explained that the Pennsylvania Department of Health had adopted *E. coli* criteria for public bathing beaches, but also requested that EPA promulgate a final rule allowing Great Lakes States to choose either *E. coli* or enterococci criteria at the time of implementation. Pennsylvania DEP offered no reason for its request. None of the other States included in the proposal with fresh coastal recreation waters commented on this aspect of the proposal.

As requested by these States, EPA is promulgating criteria for both indicators and allowing New York and Pennsylvania determine which indicator to apply for each waterbody. EPA also determined that it is reasonable to extend this flexibility to all of the Great Lakes States covered by this rule. Accordingly, EPA has added the freshwater criteria values for enterococci to the table in 40 CFR 131.41(c)(1) as well as a footnote to the table explicitly recognizing that the State may decide which indicator, *E. coli* or enterococci, will be the applicable criterion for its freshwater coastal recreation water (*i.e.*, which criteria apply to the Great Lakes waters within the State's jurisdiction). Until a State makes that determination, *E. coli* will be the applicable indicator.

EPA is providing this flexibility to all Great Lakes States in the rule because the Great Lakes States have a history of cooperating to protect the Great Lakes resource, and may find a need to agree on a consistent pathogen indicator for the Great Lakes. Because both the *E. coli* and enterococci freshwater criteria in the 1986 bacteria criteria have the same illness rate they provide equal protection against acute gastrointestinal illness. In light of these considerations, EPA does not want to create a barrier to this cooperation by promulgating only one of the two freshwater criteria in some Great Lakes States and both indicators in other Great Lakes States.

2. Bacteria Criteria Values

EPA is promulgating a geometric mean of 35/100 ml for enterococci in marine coastal recreation waters and four different single sample maximums, which vary for marine coastal recreation waters based on intensity of use as shown in Table 2. These are the same values as in the 1986 bacteria criteria document and in the proposed rule.

TABLE 2.—AMBIENT MARINE WATER QUALITY CRITERIA FOR BACTERIA

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 1106.1 or 1600 or any equivalent method that measures viable bacteria.
[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.

For fresh coastal recreation waters, EPA is also promulgating a geometric mean of 126/100 ml for *E. coli* and a geometric mean of 33/100 ml for enterococci with four different single sample maximums, which vary based on intensity of use. As described above, only the criteria for one of these indicators will apply in freshwaters at the choice of the State. These values are shown in Table 3, and are the same values as in the 1986 bacteria criteria document. For *E. coli*, these values are the same as those that EPA proposed.

EPA is also promulgating criteria for enterococci in freshwater based on the request of two Great Lakes States and used the values from the 1986 bacteria criteria document for these enterococci criteria.

TABLE 3.—AMBIENT FRESHWATER QUALITY CRITERIA FOR BACTERIA

A Indicator[d]	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)
E. coli	126/100 ml[a]	[b]235	[b]298	[b]409	[b]575
Enterococci	33/100 ml[c]	[b]61	[b]78	[b]107	[b]151

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

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[a] This value is for use with analytical methods 1103.1, 1603, or 1604 or any equivalent method that measures viable bacteria.
[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.
[c] This value is for use with analytical methods 1106.1 or 1600 or any equivalent method that measures viable bacteria.
[d] The State may determine which of these indicators applies to its fresh coastal recreation waters. Until a State makes that determination, *E. coli* will be the applicable indicator.

In proposed 40 CFR 131.41(c), EPA included footnotes to the geometric mean values for *E. coli* and enterococci stating that "[t]his value is for use with [specified] analytical methods * * * or any equivalent viable method." The specified methods are based on measurement of viable bacteria. New analytical methods that rely on genetic material for measurement may yield different results that are not appropriately calibrated to the numeric criteria in today's rule. To address this concern, EPA is identifying, as in the proposal, the specific methods that must be used to apply the bacteria criteria.

In today's rule, EPA is also making two minor changes to this aspect of the proposal. First, EPA had incorrectly identified the analytical methods for enterococci as being for *E. coli* and the analytical methods for *E. coli* as being for enterococci, and is correcting this technical error in the footnotes in the final rule. Second, EPA has revised the footnotes to explain more clearly what the methods are. The footnotes state: "This value is for use with [specific methods] or any equivalent method that measures viable bacteria."

EPA notes that today's rule does not specify the duration over which the geometric mean is calculated. The criteria in the tables at 40 CFR 131.41(c) are identical to those in table 4 of the 1986 bacteria criteria document, which does not specify the duration for computing the geometric mean. The 1986 bacteria criteria document discusses the duration over which the mean is calculated in two places. The first is in the discussion of the basis for the criteria (page six). Here, EPA calculated the geometric mean bacteria density over a summer swimming season (recreation season). The second place is in the summary of the criteria (page 16) where EPA stated that "[b]ased on a statistically sufficient number of samples (generally not less than 5 samples equally spaced over a 30-day period), the geometric mean.* * *" EPA considers this statement in the 1986 bacteria criteria document to provide guidance on how a regulatory agency could compute the geometric mean, and not as a definition of the specific period over which the mean must be computed. For the geometric mean to be only computed over a 30-day period would mean that regulatory agencies would need to sample more than once a month, which is contrary to the guidance on monitoring provided in the 1986 bacteria criteria document. EPA expects from current practice by States and Territories that they will compute the geometric mean on either a monthly or recreation season basis.

EPA is not specifying in the final rule how the averaging period for the geometric must be applied. EPA recommends that the averaging period be applied as a "rolling" or "running" average. EPA expects that most States will in fact apply the averaging period as a rolling average; however, EPA also recognizes that it would be technically appropriate to apply the averaging period on a set basis such as monthly or recreation season. EPA therefore has concluded that it is appropriate to allow the States to exercise discretion in deciding how to apply the averaging period for the geometric mean.

3. Use of the Single Sample Maximum

EPA is promulgating the single sample maximum values that it proposed without change, but is clarifying its expectations with regard to how these values could be used in the context of beach notification and closure decisions, and in the context of the implementation of other Clean Water Act programs. EPA expects that the single sample maximum values would be used for making beach notification and closure decisions. EPA recognizes, however, that States and Territories also use criteria in their water quality standards for other purposes under the Clean Water Act in order to protect and improve water quality. Other than in the beach notification and closure decision context, the geometric mean is the more relevant value for ensuring that appropriate actions are taken to protect and improve water quality because it is a more reliable measure, being less subject to random variation, and more directly linked to the underlying studies on which the 1986 bacteria criteria were based. Nevertheless, the single sample maximum can play a role in identifying potential pollution episodes, especially in waters that are prone to short-term spikes in bacteria concentrations, *e.g.*, waters that may be affected by a combined sewer overflow outfall. Having identified that a water is prone to short-term spikes in bacteria concentrations due to pollution episodes, States and Territories have significant flexibility in how they address those episodes consistent with the Clean Water Act and implementing regulations. (Note that additional guidance on making water quality standard attainment status determinations may be found in EPA's guidance to States on integrated reporting of water quality for sections 303(d) and 305(b) purposes.)

EPA received considerable comment on this topic. Some comments addressed the issue of whether the single sample maximum should be part of the criteria that applies in all applications, including beach closure, waterbody assessment, Total Maximum Daily Load establishment, and National Pollutant Discharge Elimination System permitting decisions, or instead was only designed for beach notification and closure decisions. Most commenters expressed their interpretation of the 1986 bacteria criteria document as discussing the single sample maximum only in the context of making beach decisions based on limited data. Several of these commenters argue that the geometric mean criterion was included in the 1986 bacteria criteria document for protection against acute gastrointestinal illness in other contexts, and that the single sample maximum was included as a tool to implement the criteria in beach monitoring situations, and therefore, was not necessary to provide protection in other contexts. Other commenters asserted that the single sample maximum should be used for all Clean Water Act purposes.

EPA notes that the 1986 bacteria criteria document clearly identifies the single sample maximum values as part of the criteria, in addition to the geometric mean values. Therefore, consistent with section 303(i)(2)(A) of the Clean Water Act, EPA is promulgating them today. EPA recognizes that the single sample maximum discussion in the 1986 bacteria criteria document refers only to beach monitoring, and does not discuss how or whether the single sample maximum should be implemented for other Clean Water Act applications, such as establishing Total Maximum Daily Loads or National Pollutant Discharge Elimination System permit limitations. EPA agrees that the single sample maximum values in the criteria

are best used for making beach notification and closure decisions. However, as noted above, they may, but need not, also play a role in implementing other Clean Water Act programs. Except in the beach notification and closure context, EPA expects that States will determine how to use the single sample maximum criteria in the context of their broader programs implementing the Clean Water Act.

For beach monitoring and beach notification and closure decisions, beach managers frequently need to make beach decisions based on one or very few data points. Thus, having a trigger level for a single sample value enables beach managers to make an immediate decision for the protection of public health at beaches. The beach manager will frequently not be able to obtain sufficient samples to compute a geometric mean for the purposes of making a decision to close a beach or issue a beach advisory. Of the 2,823 beaches reporting information to EPA in 2002, 65% reported that pathogen levels were monitored at least once per week (*EPA's Beach Watch Program: 2002 Swimming Season*, EPA 823-F-03-007, May 2003, *http://www.epa.gov/waterscience/beaches/beachwatch2003-newformat.pdf*). This means that at 35% of the beaches, the beach managers had fewer than four samples each month for making decisions to open or close the beach and in many cases only had one sample in any week. Furthermore, beach management programs need to be able to respond rapidly to short-term changes in water quality. Because a geometric mean provides information pertaining to water quality that looks backwards in time, it is not necessarily useful in determining whether a beach is safe for swimming on a particular day.

EPA's *National Beach Guidance and Required Performance Criteria for Grants* (EPA-823-B-02-004, June 2002) requires States and Territories receiving Clean Water Act section 406 implementation grants to either immediately issue a public notification or, if there are reasons to doubt the accuracy of the first sample, resample when any sample surpasses a water quality standard at beaches. Although this requirement pertains only to the States and Territories receiving these grants, given that the States and Territories covered by this rule receive Clean Water Act section 406 implementation grants, it reflects the actions that States and Territories will be expected to take when a sample shows an exceedance of the applicable single sample maximum in today's rule. (EPA notes that all 35 eligible coastal States and Territories received grants in 2003, and most have received these grants in 2004.) In other words, States and Territories will use a single sample maximum to trigger a notification or closure action at beaches; whether the action taken is an advisory or a closure depends on the decision rules established by the State, Territory or local beach management authority, although the *National Beach Guidance and Required Performance Criteria for Grants* requires the State or Territory to provide a notification of the exceedance. Using a single sample maximum 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 combined sewer overflow outfalls. Thus, consistent with the 1986 bacteria criteria document, EPA expects that States and Territories would apply the single sample maximums for making beach notification decisions as values that if exceeded would trigger a notification or closure action at the beach.

Numerous commenters said that application of the single sample maximum values in the criteria as never-to-be-surpassed limitations in other contexts could lead to consequences which were not contemplated in the 1986 bacteria criteria document, including, for example, Total Maximum Daily Loads and National Pollutant Discharge Elimination System permit limitations which might be technologically and economically unattainable at a particular location. EPA agrees that the 1986 bacteria criteria document did not discuss using the single sample maximum as a never-to-be-surpassed value for all implementation applications under the Clean Water Act.

In developing the 1986 bacteria criteria document, EPA derived single sample maximums as upper percentiles of the frequency distributions around the geometric mean. The 1986 bacteria criteria document recognizes that there will be instances where the concentration of bacteria in one or more individual samples will be higher than the acceptable geometric mean concentration. This is to be expected when dealing with water quality criteria expressed as average concentrations over a period of time. For example, in a waterbody with a 30-day average concentration exactly at the water quality criterion, it can be expected that approximately half of the samples collected will have a concentration above the criterion concentration (*e.g.*, 126/100 ml for *E. coli*), while the other half of the samples will have lower concentrations. Thus, that the value of one sample is greater than the numerical value of the geometric mean criterion, or even the numerical value of the single sample maximum, does not necessarily indicate that the geometric mean criterion has actually been exceeded. Furthermore, the single sample maximum values in the 1986 bacteria criteria document were not developed as acute criteria; rather, they were developed as a statistical construction to allow decision makers to make informed decisions to open or close beaches based on small data sets. This does not mean single sample maximums serve no purpose outside of beach notification decisions. For example, they may give States and Territories the ability to make waterbody assessments where they have limited data for a waterbody. However, the single sample maximums were not designed to provide a further reduction in the design illness level provided for by the geometric mean criterion.

Based on the derivation of the single sample maximums as percentiles of a distribution around the geometric mean, using the single sample maximums as values not to be surpassed for all Clean Water Act applications, even when the data set is large, could impart a level of protection much more stringent than intended by the 1986 bacteria criteria document. For example, in marine waters the geometric mean criterion for enterococci is 35/100 ml, and the single sample maximum is 104/100 ml at designated bathing beach waters based on the 75th percentile of the distribution of individual values around the mean. If that single sample maximum were used as a value-not-to-be-surpassed, it would become a maximum value and all other values in the statistical distribution of individual measurements would have to be less than the maximum. EPA typically uses the 99th percentile of a distribution to derive regulatory maximums. Assuming a waterbody had the same standard deviation in concentrations of bacteria employed in deriving the single sample maximums (*e.g.*, 0.7 for marine waters), the waterbody geometric mean needed to keep the waterbody concentration below 104/100 ml 99% of the time would be 2/100 ml. This would be far more stringent than the level of protection provided by the actual geometric mean criterion for enterococci of 35/100 ml. Therefore, EPA intends that States and Territories should retain the discretion to use single sample maximum values as they deem appropriate in the context of Clean Water Act implementation programs other than beach notification and

closure, consistent with the Clean Water Act and its implementing regulations.

The final rule does not constrain States and Territories flexibility in how they use the single sample maximum values in the context of Clean Water Act implementation programs such as Total Maximum Daily Loads and National Pollutant Discharge Elimination System permit requirements, as long as the geometric mean criteria for *E. coli* and enterococci are met. The flexibility afforded to States and Territories in applying the single sample maximum values in the National Pollutant Discharge Elimination System permitting program does not mean that maximum daily or seven-day average permit limits for bacteria are inappropriate for National Pollutant Discharge Elimination System permits. EPA notes that maximum daily and 7-day average effluent limits can be calculated based on 30-day average conditions and an understanding of effluent variability. See Section 5.4.4 of EPA's *Technical Support Document for Water Quality-based Toxics Control* (EPA-505-2-90-001, March 1991). (These procedures are based on statistical methodologies similar to those employed in deriving the single sample maximums in the 1986 water quality criteria for bacteria.) EPA's recommendation that the single sample maximum values in the 1986 bacteria criteria document should be used primarily for making beach notification and closure decisions does not constrain States' use of maximum daily permit limits in accordance with current State permitting procedures.

EPA received a few comments about the specific use of single sample maximums in making waterbody assessment decisions, for example, in the development of Clean Water Act section 305(b) reports or developing section 303(d) lists. One commenter stated that the single sample maximum should not be used solely as the means for deciding if a waterbody was impaired. Another commenter stated that one sample should not be used to characterize a waterbody. Yet another commenter suggested that the single sample maximum only be used when there were insufficient data to compute a geometric mean.

In general, EPA agrees with these comments. As discussed above, EPA recognizes the utility of single sample maximums where there are insufficient data (generally fewer than five samples over a given period) to compute a geometric mean for the purposes of assessing waterbodies, and expects that States and Territories will use single sample maximums in these instances. While it is far preferable for States and Territories to obtain more robust data for making decisions about waterbody impairments (the 1986 bacteria criteria document recommends determining the geometric mean using generally not less than 5 samples equally spaced over a 30-day period), EPA recognizes that in some instances States and Territories will have limited data and may decide to use the single sample maximums or other similarly derived statistical constructs for making waterbody impairment decisions.

4. Intensity of Use Categories of Coastal Recreation Waters

EPA is promulgating the same intensity of use categories of coastal recreation waters as in the proposal, specifically, the four categories of waters with a corresponding single sample maximum as described in the 1986 bacteria criteria document. Only one single sample maximum applies 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. EPA is also promulgating the definitions of the categories as proposed. By providing definitions for the four categories, EPA provides clear guidance to States and Territories and information for the public to identify the category in which 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 rule to list all those waters in the rule according to the four categories defined in 40 CFR 131.41(b). Therefore, EPA does not 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 website). As explained in the preamble to the proposed rule (69 FR 41726), States and Territories could use their existing beach tiering process for BEACH Act implementation grants as a source of information for determining frequency in categorizing a coastal recreation water for purposes of determining the applicable single sample maximum.

Today's rule does not require that States and Territories apply the definitions at 40 CFR 131.41(b) such that the State or Territory finds at least one water for each of the four categories of waters. A State or Territory could, at its discretion, apply the single sample maximum for designated bathing beaches (the lowest single sample maximum) to all its coastal recreation waters because this approach would be more protective of human health than the structure for single sample maximums in 40 CFR 131.41(b) and (c). Thus, a State or Territory that had commented that it preferred that EPA promulgate only one category of waters could exercise its discretion and apply the single sample maximum for designated bathing beaches to all of its waters. Alternatively, a State or Territory may choose to place their coastal recreation waters in only two of the four single sample maximum categories, such as the 75% confidence level single sample maximum for designated bathing beaches and the 95% confidence level single sample maximum for all other coastal recreation waters, if the recreational usage of the waters matches the definitions at 40 CFR 131.41(b). This approach would be appropriate if the State or Territory determined that the "infrequent use" definition was the most appropriate categorization for its coastal recreation waters that were not identified as designated bathing beaches. Although the rule does not specify which State waters belong in which use category, the definitions in the rule must be used to determine which single sample maximum would apply to a particular coastal recreation water.

A number of comments requested that EPA promulgate only the 75% confidence level criterion for all coastal recreation waters because having only one single sample maximum would provide for consistency in all coastal recreation waters, and provide the same level (and highest level) of protection to all users of coastal recreation waters, no matter what the use intensity of that particular water might be.

EPA declines to take this approach in today's rule. EPA acknowledges the reasons expressed in the comments. However, EPA believes this would be more restrictive than necessary to ensure that the promulgated water quality criteria are as protective of human health as the 1986 bacteria criteria document, which provides single sample maximums for four categories of waters. Thus, such an approach would unnecessarily restrict the flexibility of States and Territories to determine when to impose standards more protective than EPA's 1986 bacteria criteria. EPA normally defers to a State's or Territory's decision on what criteria apply to protect a designated use subject to the State or Territory

providing information to show that the water quality criteria are sufficient to protect the designated uses, and for coastal recreation waters, that the water quality criteria are as protective of human health as the criteria for the pathogen or pathogen indicators that EPA has published. EPA does not consider the benefits of identical standards in the States and Territories covered by this rule to outweigh the negative effects of unnecessarily constraining the flexibility that the Clean Water Act and EPA's rules give States and Territories in establishing water quality standards, particularly because there is already variation in the single sample maximums in use among States and Territories that are not covered by today's rule.

5. Intrastate vs. Interstate Determinations of Use Intensity

In today's final rule, as in the proposal, single sample maximums apply to categories of waters based on intensity of use. These categories are based on intrastate comparisons of frequency of use (*i.e.*, relative to the other waters within that State or Territory). Using this approach, a State or Territory will identify its designated bathing beach waters first and then evaluate all other waters in comparison to those waters. However, today's rule does not require that a State or Territory use all four categories of intensity of use. Rather, EPA expects that States and Territories will first identify portions of waters as designated bathing beaches based on the factors listed in 40 CFR 131.41(b)(2) and then categorize the remaining waters based on their intensity of use relative to those beaches. In interpreting the phrase "heavily used," EPA expects States will make reasonable judgments about the level of use at a given beach. EPA does not intend that States should exclude heavily used waters from the designated bathing beach category merely because they can identify other beaches, either within the State or in other States, that are more heavily used.

While several commenters supported intrastate comparison of intensity of use, others suggested using an interstate comparison of intensity of use because beach use varies significantly across States and Territories. While EPA recognizes that beach use intensity varies significantly across the nation, EPA does not agree that interstate comparisons are the best approach for categorizing use intensity. An interstate approach could result in some States or Territories comparing their beaches only to the most heavily used beaches in the nation and determining that they have no beaches warranting protection at the 75% confidence level. Rather, States and Territories will need to evaluate the intensity of use of their own beaches, independent of beaches in the rest of the nation, and assign the beaches to categories based on the definitions provided in 40 CFR 131.41(b). This does not mean that there is any minimum number or percentage of beaches that must be placed in the designated bathing beach category. Rather, States should identify those beaches, if any, in the State which satisfy the criteria for this category and then assign the remaining waters to one or more of the lower intensity of use categories as appropriate. Intrastate comparison of use will allow States and Territories the flexibility to provide the level of protection that is appropriate to visitors to beaches with different intensities of use.

In today's rule, EPA is also making a minor change to this aspect of the proposed rule. The Agency added text to the definition of "designated bathing beach" in 40 CFR 131.41(b)(2) to provide expressly that the determination of "heavy use" is based on an evaluation of use within the State, which is consistent with the above discussion.

6. State Calculation of Site-Specific Single Sample Maximums

EPA is promulgating, as proposed, default single sample maximums based on the 75, 82, 90, and 95% confidence levels, along with the equation to calculate site-specific single sample maximums. EPA calculated the values for the single sample maximums in tables 2 and 3 using the standard deviations observed during the EPA epidemiological studies. The Agency recognizes that standard deviations observed in EPA's epidemiological studies may not coincide with that for a particular waterbody. States and Territories may decide to collect data to calculate site-specific standard deviations. To compute the site-specific log standard deviation in a statistically meaningful way as explained in the preamble to the proposed rule (69 FR 41727), today's rule requires that the States and Territories collect at least 30 samples in a single recreation season (see 40 CFR 131.41(c)(3)). If this requirement is met, the State or Territory may use the resulting site-specific standard deviation to calculate a corresponding single sample maximum.

EPA considers that the calculation of site-specific single sample maximums as specified in 40 CFR 131.41(c)(3) provides enough detail on the calculation that States and Territories can implement the provision of the rule without needing to adopt it as a site-specific water quality criterion. As a result, States and Territories do not need EPA review and approval under 40 CFR Part 131 in their application of 40 CFR 131.41(c)(3).

All commenters that addressed this issue supported EPA's proposal to require 30 samples to derive a site-specific standard deviation; however, one commenter stated that States and Territories should be allowed to collect the samples over two recreation seasons if there were not significant differences in bacteria concentrations over the two-year period. The commenter explained that States and Territories may find it difficult to collect 30 samples in one recreation season. EPA recognizes the difficulty in collecting the required number of samples over a single recreation season, but the Agency has nonetheless concluded that collecting this data during a single season is necessary in order to capture the variability inherent in bacteria concentrations at a site over the period of a single season without introducing additional variability from extreme weather conditions such as drought or El Niño conditions. Using 30 samples over more than one recreation season could affect the outcome of the single sample maximum such that it may not be as protective of human health as EPA's 1986 bacteria criteria.

7. Addressing Non-Human Sources of Bacteria

EPA is adopting the approach preferred in the proposal for addressing non-human sources of bacteria. In today's rule, EPA added footnote "e" to 40 CFR 131.41(c)(1) and footnote "c" to 40 CFR 131.41(c)(2) to describe this approach for addressing non-human sources of bacteria. The footnotes state: "These values apply to [*E. coli* or enterococci] regardless of origin unless a sanitary survey shows that sources of the indicator bacteria are non-human and an epidemiological study shows that the indicator densities are not indicative of a human health risk." Specifically, States and Territories must apply the E. coli and enterococci criteria to all coastal recreation waters. If, however, sanitary surveys and epidemiological studies show the sources of the indicator bacteria to be non-human and the indicator densities do not indicate a human health risk, then it is reasonable for the State or Territory to not consider those sources of fecal contamination in determining whether the standard is being attained. This is the approach taken in the 1986

bacteria criteria document. It would be reasonable for a State or Territory to use existing epidemiological studies rather than conduct new or independent epidemiological studies for every waterbody if it is scientifically appropriate to do so.

EPA also anticipates that a State or Territory that has conducted a sanitary survey and an epidemiological study to show that the sources of the indicator bacteria in a waterbody are non-human and that the indicator densities do not indicate a health risk to those swimming in the waters, will apply the criteria in today's rule where a change in circumstances affecting the waterbody makes it appropriate to do so. For example, the criteria would apply to a waterbody in which there is a subsequent sewer line break or other later occurrence that results in the introduction in the waterbody of bacteria that is a human health risk to those using the waters for primary contact recreation.

EPA is promulgating this approach because Clean Water Act section 303(i)(2)(A) requires EPA to propose criteria which are "as protective of human health as" EPA's 1986 bacteria criteria in cases where a State or Territory has failed to do so. While EPA's scientific understanding of pathogens and pathogen indicators has evolved since 1986, data characterizing the public health risk associated with non-human sources is still too limited for the Agency to promulgate another approach.

Almost half of the commenters addressed some or all of the approaches to exempting non-human sources of fecal contamination described in the proposed rule (69 FR 41729–41731). Several commenters expressed support for EPA's preferred approach. EPA agrees that the criteria should apply unless sanitary surveys and epidemiological studies show the sources of the indicator bacteria to be non-human and that the indicator densities are not indicative of a human health risk. This is the approach taken in the 1986 bacteria criteria document.

Some commenters expressed a preference for not allowing any exclusion of non-human sources from the criteria. They emphasized the significance of the human health risk associated with any type of fecal contamination and asserted that this approach would be most protective of human health. EPA does not agree that this approach is necessary for States to adopt if an epidemiological study demonstrates that non-human sources do not pose a risk to human health at a given waterbody.

Several commenters supported a non-human source exclusion based on sanitary surveys only. In general, these commenters expressed concern about the cost of epidemiological studies, especially in areas where evidence of human fecal contamination was absent. EPA has found the scientific understanding of the human health risks associated with non-human sources of fecal contamination is still too incomplete to promulgate this option. In the proposed rule (69 FR 41730–41731), EPA cited several instances where studies have attributed disease outbreaks to non-human sources of fecal contamination. Given the potential human health risk from non-human sources of fecal contamination, EPA concludes that this option would not be as protective of human health as the 1986 bacteria criteria.

Some commenters supported exclusion of bacteria from wildlife sources from the criteria because wildlife sources may pose less of a risk to human health than human sources or domestic animal and livestock sources. Other commenters raised issues with the reliability of current bacteria source tracking methods that may be needed to support this exclusion. EPA finds the scientific understanding of the human health risks associated with wildlife sources of fecal contamination still too incomplete to support promulgation of this option. Once again, EPA concludes that this option is not as protective as the 1986 bacteria criteria.

Many commenters expressed the need for more research on non-human sources. Commenters emphasized two major areas of needed research: research on bacterial source tracking methods to better distinguish between different types of bacteria contamination and research on the health risks associated with different types of non-human fecal contamination. EPA expects to conduct research in these areas as time and resources allow. EPA also encourages others to continue to conduct research in these areas.

C. Applicability of Today's Rule

1. Applies in Addition to Any State/Territorial Criteria

EPA is promulgating the rule as proposed with respect to the interaction of today's criteria with existing State and Territorial water quality criteria. Under today's rule, the promulgated 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 promulgated criteria apply for Clean Water Act purposes in addition to any existing State or Territorial criteria already applicable to those waters. 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 waterbody 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 rule, 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.*, National Pollutant Discharge Elimination System, Clean Water Act section 305(b), and Clean Water Act 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. 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 Clean Water Act actions related to protection of primary contact recreation on both fecal coliform and the new, preferred indicators. However, if States believe their existing standards are as protective as the criteria in today's rule, they may submit data to EPA to support this determination, and if EPA then determines that the State standards are at least as protective as the criteria in today's rule, EPA will withdraw the Federal criteria for that State. (See section V.C.) States and Territories are encouraged to expeditiously revise their water quality standards to remove fecal coliform criteria as an indicator for primary contact recreation where it has been replaced by the new indicators in their implementation of the Clean Water Act. Today's rule also provides in 40 CFR 131.41(d)(1) that new EPA-approved bacteria criteria in State or Territorial water quality standards become the effective Clean Water Act criteria upon their approval, replacing the criteria in today's rule.

EPA received very few comments on this topic. All commenters addressing this topic supported EPA's proposal that once EPA approves a State's or Territory's standards as being as protective of human health as EPA's 1986 bacteria criteria, the EPA-approved bacteria criteria in State or Territorial water quality standards would become effective for Clean Water Act purposes and EPA's promulgated criteria would no longer apply. EPA will still remove the State or Territory from 40 CFR 131.41, but any delay in that process would not delay the approved State criteria from becoming the sole applicable criteria for Clean Water Act purposes.

2. Role of State/Territorial General Rules of Applicability

Today's rule, like the proposal, makes today's criteria subject to States' and Territories' general rules of applicability in the same way and to the same extent as are other Federally-adopted or State-adopted numeric criteria. EPA received a few comments on this topic and these generally pertained to mixing zones. One commenter suggested that the final rule prohibit the use of mixing zones to comply with today's criteria. The commenter said that the use of mixing zones would not be as protective of human health as the 1986 bacteria criteria. Another commenter supported allowing States to apply their existing mixing zone provisions.

EPA appreciates the concerns of commenters regarding human health risks of exposure to fecal contamination within mixing zones. However, EPA has determined that the Agency's existing guidance provides sufficient direction to permitting authorities as they implement State or Territorial mixing zone policies. EPA's *Water Quality Standards Handbook: Second Edition* (EPA–823–B–94–005a, August 1994) as well as EPA's *Technical Support Document for Water Quality Based Toxics Control* (EPA–505–2–90–001, March 1991) advise against the use of mixing zones where the location may pose a significant health risk. These documents stress the importance of determining the appropriate placement and size of mixing zones depending on the potential effects to human health and the environment. As a result, EPA is not prohibiting the application of mixing zones in the final rule in cases where they would be allowed under existing State and Territorial programs.

D. Compliance Schedules

Where a State or Territory does not have a regulation that is in effect for Clean Water Act purposes authorizing compliance schedules for water quality-based effluent limits, EPA proposed to authorize, but not require, the permit issuing authority to include compliance schedules in permits under appropriate circumstances. EPA also proposed that if a State or Territory has a regulation in effect authorizing compliance schedules for Clean Water Act purposes then that compliance schedule regulation could be used in implementing the water quality standards in this rule; it would not be affected by the final rule. Because EPA recognizes that a State or Territory without a regulation authorizing compliance schedules may not want such a regulation, in the preamble to the proposed rule, EPA asked such States to notify EPA prior to promulgation. No State or Territory notified EPA that it does not want the ability to use the compliance schedule provision in today's rule. Therefore, EPA is not including in today's final rule any regulatory text identifying States or Territories that do not want a compliance schedule provision for their standards.

EPA received several comments in support of the allowance for compliance schedules. One commenter requested that EPA remove the requirement that a permittee request a compliance schedule; this commenter believed that the permitting authority could determine whether the permittee needed time to comply with the new effluent limitation based on the criterion. EPA disagrees that it needs to make this change because the rule does not impose a requirement for a request. The rule at 40 CFR 131.41(f)(3) provides permittees with the opportunity to request a compliance schedule where the permittee reasonably believes it will be infeasible to immediately achieve the new limitation, but it does not require them to do so. The permitting authority also has the discretion to suggest the need for compliance schedules as part of the permit even if the permittee does not initiate a request for one.

One commenter supported the definition of a new pathogen discharger. Another commenter requested clarification that the definition does not apply to relocated combined sewer overflow outfalls. EPA agrees that the definition does not apply to relocated combined sewer overflow outfalls. The rule at 40 CFR 131.41(f)(2) does not authorize compliance schedules for new pathogen dischargers because EPA recognizes that a new discharger could design and build a new treatment system, which will meet the new water quality-based requirements more efficiently (69 FR 41736). However, a relocated combined sewer overflow outfall is not a new discharge, rather it is an existing discharge being released at an alternate location. The relocating of the outfall does not necessarily provide an opportunity for the discharger to apply additional controls or reduce pathogen loads to the extent anticipated for a new pathogen discharger. EPA's Combined Sewer Overflow Control Policy, published on April 11, 1994, recommends that Long Term Control Plans consider relocating overflow away from sensitive areas wherever physically possible and economically achievable (59 FR 18688, 18692). In today's final rule, EPA has added text to the definition of a "new pathogen discharger" in 40 CFR 131.41(b)(6) to provide expressly that "[i]t does not include relocation of existing combined sewer overflow outfalls."

Many commenters addressed the length of the compliance schedule. Some commenters supported capping the length of the compliance schedule at five years, while one commenter suggested that three years should be sufficient. Other commenters suggested that compliance schedules longer than five years may be necessary, or that the rule should not specify the length of a compliance schedule, but rather allow the permitting authority to exercise discretion in determining how much time is necessary for each discharger. Finally, several commenters noted that combined sewer overflow systems may need compliance schedules longer than five years, and that the compliance schedule provision of the rule should be consistent with EPA's Combined Sewer Overflow Control Policy and the requirements of Clean Water Act section 402(q).

EPA has determined that five years is a reasonable limit on the length of a compliance schedule within a National Pollutant Discharge Elimination System permit. EPA expects that most continuous dischargers will look to optimize their existing disinfection treatment, and that five years is sufficient time to do so. As discussed in section VIII, EPA believes that experiences from facilities with bacteria effluent limits that are currently meeting the *E. coli* and enterococci criteria, as well as the current fecal coliform criteria, suggest that disinfection processes can be upgraded or adjusted to produce the levels of bacteria necessary for compliance with the rule. EPA has used five years for compliance schedules where permittees were expected to design, construct, and operate new treatment processes, and not just optimize their current treatment. (See 40 CFR 131.38(e)(6) and

40 CFR Part 132, Appendix F, Procedure 9.B.1.)

EPA does not regard the five-year cap on compliance schedules as inconsistent with either EPA's Combined Sewer Overflow Control Policy or Clean Water Act section 402(q). Section 402(q) requires that National Pollutant Discharge Elimination System permits conform to EPA's Combined Sewer Overflow Control Policy published on April 11, 1994 (59 FR 18688). EPA's Combined Sewer Overflow Control Policy recommends that permittees develop a construction and financing schedule for implementation of combined sewer overflow controls (59 FR 18694). The Combined Sewer Overflow Control Policy recommends that permitting (and water quality standards setting) authorities include, in an appropriate enforceable mechanism, compliance dates, on the soonest practicable schedule, for requirements to implement Long Term Control Plans (59 FR 18696). In addition, permits need to include water quality-based effluent limits requiring compliance by no later than the date allowed under the water quality standards that apply. The Combined Sewer Overflow Control Policy itself does not require compliance schedules in water quality standards (or otherwise constrain the authority of water quality standard setting agencies). Finally, the Combined Sewer Overflow Control Policy recommends, in cases where water quality standards do not allow compliance schedules and the permittee cannot, on the effective date of the permit, comply with effluent limitations established in the permit, that the compliance schedule be placed in a judicial order for major permittees (59 FR 18697). EPA recognizes that combined sewer overflow systems often need more than five years to meet the requirements of the Clean Water Act. In these situations, the permitting authority can provide sufficient time for the combined sewer overflow system to comply by using the enforceable mechanisms identified in the Combined Sewer Overflow Control Policy.

Finally, in today's final rule, EPA is making two corrections to the proposed rule at 40 CFR 131.41(f)(3)–(4) to refer to paragraph (c) as the paragraph containing the water quality criteria for bacteria.

V. EPA Review of State and Territorial Standards

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

EPA evaluated the water quality standards for bacteria for all 35 coastal States and Territories with coastal recreation waters to determine whether the water quality standards for such waters are as protective of human health as the 1986 bacteria criteria document, as required by Clean Water Act section 303(i)(1)(A). If a State's or Territory's approved 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 today's rule, EPA is not including the State or Territory in the promulgated rule.

EPA described the five considerations used to evaluate the State and Territorial water quality standards in detail in the proposed rule (69 FR 41728–41731). Today, EPA uses the same five considerations to evaluate State and Territorial water quality standards for inclusion in the final rule. The following five sections summarize the considerations.

1. Are the standards based on EPA's recommended indicators of *E. coli* and enterococci as pathogen indicators for freshwaters and enterococci for marine waters?

As discussed in section IV.B.1 of the preamble to today's rule, EPA is promulgating water quality criteria for *E. coli* and enterococci for use as standards for State and Territorial coastal and Great Lakes recreation waters. These are the indicator bacteria for which EPA published criteria in the 1986 bacteria criteria document.

EPA received a number of comments asserting that a fecal coliform water quality criterion of 14/100 ml for the protection of a shellfishing use should generally be as protective of human health as the enterococci criterion of 35/100 ml. Some of these commenters referenced the statement in the 1986 bacteria criteria document that EPA selected the value of the enterococci criterion to be no more protective of human health than the then current fecal coliform criterion of 200/100 ml for recreation protection in support of their argument that if there is equal protection between the 1986 bacteria criteria and a fecal coliform value of 200/100 ml, then a fecal coliform value of 14/100 ml should be even more protective of human health than an enterococci value of 35/100 ml for marine waters. EPA disagrees that this statement in the 1986 bacteria criteria document provides a basis for determining that a fecal coliform criterion of 14/100 ml is "as protective as" an enterococci criterion of 35/100 ml. EPA explicitly acknowledged in the 1986 bacteria criteria document that these illness rates for fecal coliform were only approximations, but were the best available estimates. (The fecal coliform criteria were developed long before EPA calculated the corresponding estimated illness rates.) EPA used these estimated illness rates for one purpose: to select illness rates for the enterococci and *E. coli* criteria in marine and fresh waters that would be least likely to cause a change in the stringency of the water quality standards for bacteria. However, that discussion in the 1986 bacteria criteria document must be considered along with the purpose of the 1986 bacteria criteria document: to recommend that States replace their fecal coliform criteria for recreation with enterococci or *E. coli* criteria because studies showed low correlation between fecal coliform densities and illness rates. In EPA's view, it would not be reasonable to rely on the equivocal discussion regarding the after-the-fact approximation of an illness rate for fecal coliform in light of the unequivocal conclusion of the entire document: That the fecal coliform criteria for recreation is not a reliable indicator of illness to swimmers.

One commenter, the Washington Department of Ecology, supplied EPA with recently-collected ambient water monitoring data for both fecal coliform and enterococci, and stated that the data for enterococci and fecal coliform, when compared to each other, show that, in Washington State coastal recreation waters, when fecal coliform concentrations were at 14/100 ml or less (a level substantially below the 200/100 ml level that EPA recommended prior to 1986), the enterococci concentrations were almost always at 35/100 ml or less. The State currently has a fecal coliform criterion of 14/100 ml as a geometric mean and 43/100 ml as a value not to be exceeded more than 10% of the time for its Class AA and A waters, which for marine waters are the only classes with primary recreation uses. The data submitted to EPA are from 37 locations in the King County area of the Puget Sound for the years 1995 through 2004, 155 locations in the Kitsap County area of the Puget Sound and its embayments for early 1997, and 36 locations across the Puget Sound, Strait of Juan de Fuca, and two Pacific Ocean embayments from November 2000 through July 2001.

EPA reviewed the data provided by the Washington Department of Ecology. EPA analyzed the data that were collected from stations located close to shore and within the upper two meters of depth, because these are the areas where people most frequently swim. EPA also excluded data that the State identified as invalid. From these data, there are 3535 samples with both fecal coliform and enterococci bacterial counts. From these samples, EPA calculated 241 summertime geometric means for both fecal coliform and enterococci for the data from King County. EPA could not calculate summertime geometric means for the other locations because there were insufficient data in these data sets to do so.

These geometric mean calculations show that, for King County, the attainment of the State's current fecal coliform geometric mean criterion of 14/100 ml always assures attainment of an enterococci geometric mean of 35/100 ml. Further, there were 67 of 191 relevant occasions (35% of the time) when the State's fecal coliform geometric mean criterion was exceeded but the geometric mean enterococci criterion was not.

The data also show that attainment of the State's current fecal coliform criterion also ensures attainment of the enterococci 75th percentile single sample maximum criterion (04/100 ml) in 99% of the samples collected at all locations in Washington. Of 2194 relevant data points, the State's upper bound fecal coliform criterion of 43/100 ml assures attainment of the Federal enterococci 75th percentile single sample maximum criterion on 2166 occasions. Finally, there were 570 of 2736 relevant occasions (21% of the samples) when use of the State's fecal coliform criterion could be used to close a beach or issue an advisory but the Federal enterococci criterion (expressed as a single sample maximum) would not support closure or an advisory. Based on this analysis, EPA agrees that the data provided by the State of Washington for the Puget Sound, Strait of Juan de Fuca, and the Pacific Ocean embayments shows that use of the State's 14/100 ml fecal coliform criterion is as protective of human health as the 1986 bacteria criteria for the State of Washington.

In the proposed rule, EPA solicited comment on its interpretation that Clean Water Act section 303(i) requires States and Territories to adopt criteria for *E. coli* or enterococci to comply with the provisions of that section. 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 considered to be the Clean Water Act section 304(a) criteria referred to in Clean Water Act section 303(i)(1)(A). The *Ambient Water Quality Criteria for Bacteria—1986* strongly recommended the use of *E. coli* and enterococci as pathogen indicators for fresh waters and strongly recommended enterococci for marine waters.

Clean Water Act section 303(i)(2)(A) requires EPA to propose water quality standards regulations for a State "[i]f a State fails to adopt water quality criteria and standards * * * that *are as protective of human health* as the criteria for pathogens and pathogen indicators for coastal recreation waters published by the Administrator * * *" (emphasis added). EPA solicited comment on whether section 303(i)(2)(A) could be read to require that EPA need only promulgate for a State or Territory if the State or Territory failed to adopt any criteria (not necessarily *E. coli* or enterococci) that were as protective of human health as EPA's 1986 bacteria criteria. In other words, EPA solicited comment on whether it was required to promulgate *E. coli* or enterococci under section 303(i)(2)(A) in situations where a State or Territory adopted a low fecal coliform criterion for protection of primary contact recreation that was demonstrated to provide protection equal to the protection provided by EPA's 1986 bacteria criteria. EPA has reconsidered its interpretation and believes that there is some ambiguity in section 303(i)(2)(A) and that given this ambiguity that it should interpret section 303(i)(2)(A) as allowing EPA to approve standards based on other indicators provided they are as protective as EPA's 1986 bacteria criteria because this approach is most consistent with the purposes of the Clean Water Act. Thus, EPA is taking the position that EPA is not required to promulgate *E. coli* or enterococci criteria if a State demonstrates that other criteria, based on other bacteria indicators, are as protective of human health as EPA's 1986 bacteria criteria. That is, if a State or Territory adopts criteria, even though they are not for *E. coli* or enterococci, that are demonstrated to be as protective of human health as EPA's 1986 bacteria criteria, section 303(i)(2)(A) does not require EPA to promulgate criteria for *E. coli* or enterococci. Promulgation of criteria for *E. coli* or enterococci in that situation would not provide any greater level of public health protection. Protection of public health was Congress's primary intent in enacting the BEACH Act. Therefore, if a State or Territory can show that in waters in which the State or Territory intends to protect primary contact recreation uses with its criteria for fecal coliform, that such uses will be protected at a level equal to or greater than the protection provided by EPA's 1986 bacteria criteria for enterococci and *E. coli*, EPA does not believe Congress intended EPA to promulgate water quality criteria for pathogens or pathogen indicators for those waters in that State or Territory where this has been demonstrated. The facts presented by the Washington Department of Ecology highlight the reasonableness of this interpretation.

In addition, EPA considers it to be an appropriate exercise of Federal discretion to take this approach with Washington State. Congress intended through Clean Water Act section 303(c) to give States the paramount role in weighing any available credible information for establishing water quality standards that are protective of the designated uses of their waters. Congress maintained this same approach in Clean Water Act section 303(i) by giving States the responsibility to adopt water quality standards for protecting human health, with EPA's role being to promulgate standards for those States that had not adopted standards as protective of human health as the 1986 bacteria criteria. This interpretation is supported by the legislative history of Clean Water Act section 303(i). For example, S. Rep. No. 106–366 states in the section-by-section analysis of the Act:

> These provisions are consistent with the applicable requirements of the Clean Water Act and specifically section 303(c) and the regulations implementing that section. States must incorporate into their water quality standards, water quality criteria for pathogens and pathogen indicators that are at least as protective of human health as criteria EPA publishes under section 304(a). The State's criteria may be as protective as those of EPA without being numerically equivalent. However, if a State adopts criteria differing from those published by EPA, the State has a duty to defend the criteria from a scientific perspective. EPA's approval or disapproval of the criteria is based upon the information provided by the State. (S. Rep. No. 106–366, at 4 (2000)).

EPA believes that this language demonstrates Congress's intent that section 303(i) be interpreted within the broader context of section 303, and that section 303(i) not be interpreted to preclude a State's adopting alternative criteria from those published by EPA

under section 304(a), provided that the State demonstrates (and EPA agrees) that the alternative criteria are as protective of human health as EPA's published criteria.

H. Rep. No. 106–98 has similar language in its section-by-section analysis as follows:

> The Committee intends that the legal standard for determining when a State water quality standard is consistent with the applicable requirements of the Clean Water Act be governed by the existing requirements of section 303(c) of the Clean Water Act, and the regulations implementing that section. This standard has been interpreted to mean that State water quality criteria must be at least as protective of human health as EPA's water quality criteria. Thus, a State must incorporate into its water quality standards water quality criteria for pathogens and pathogen indicators that are at least as protective as criteria that EPA has published under section 304(a), including EPA's 1986 criteria for enterococcus and Escherichia coli. (H. Rep. No. 106–98, at 8 (1999)).

Here again, EPA believes Congress is clarifying its intent that State criteria to be approvable under section 303(i), must be at least as protective as EPA's 1986 bacteria criteria, but not necessarily the same as the 1986 criteria.

With respect to the State of Washington, EPA looked at the process that the State took in reviewing its fecal coliform standards for protecting recreation uses in marine waters. The State did this as part of its triennial review of water quality standards. The State undertook a multi-year process starting in the summer of 1996 and finishing in 2003. In this period, the State convened a multi-stakeholder technical workgroup to examine the technical merits of the State's bacteria criteria, and documented the technical and policy issues evaluated by the work-group and its predecessor (see *http://www.ecy.wa.gov/pubs/0010072.pdf*). The State used this information to focus discussions with numerous advisory panels both internal and external to the Washington Department of Ecology. The State held a formal 60-day public review and comment period on proposed revisions to its water quality standards (including adoption of EPA's recommended enterococci criteria for Class AA and Class A marine waters), and as part of the public notification process, directly mailed out approximately 3320 announcements, 550 email announcements, and 621 CDs to potential interested citizens, regulated businesses, governmental officials, and every city, county, and Tribe in the State. The State conducted eight public workshops and hearings regarding proposed changes to its standards at locations across the State. Finally, the State made all documents available to the public at its Web site at *http://www.ecy.wa.gov/programs/wq/swqs/supporting_docs/supporting_docs.html*.

Based on the input from the various stakeholders in the State and the paired monitoring data for fecal coliform and enterococci, the State concluded that its fecal coliform criteria for marine waters is protective of the recreation use in these waters, and also is at least as protective of human health as EPA's 1986 bacteria criteria. Many stakeholders in Washington share this conclusion, as expressed in the public comments by many stakeholders on the State's proposed water quality standards (see *http://www.ecy.wa.gov/programs/wq/swqs/supporting_docs/public_comments.html*) and comments by a Puget Sound public interest group and a Northern Pacific Ocean shellfish group on EPA's proposed rule. Given this conclusion, the State and some stakeholders were concerned that the State adoption of the enterococci standard and the attendant new monitoring that this would entail would limit the State's ability to monitor as comprehensively for fecal coliform as it does currently and thus provide the maximum assurance that its waters are meeting its protective 14/100 ml fecal coliform standard. However, this rule does not require monitoring.

As discussed previously in this preamble, EPA reviewed the State's data and determined that it shows that the State's fecal coliform criterion is as protective as the 1986 bacteria criteria. Accordingly, EPA considers it appropriate and consistent with Congressional intent to exclude Washington from today's Federal promulgation because the State has fully met its obligations under the Clean Water Act using a full and open public process and is ensuring protection of human health in the coastal recreation waters of Washington.

EPA considers its analysis of the data provided by the State of Washington to only be relevant to the State's waters. EPA does not agree that the Washington data show that use of a fecal coliform criterion of 4/100 ml is as protective of human health as the 1986 bacteria criteria for any other coastal recreation waters in the United States because the conditions of the Washington State waters may differ from waters of other States. The relationship between fecal coliform and enterococci in the data provided by the Washington Department of Ecology is an empirical relationship, and reflects the conditions of the water from which the samples were collected. EPA cannot determine without water-specific data the extent to which the Washington State waters where the samples were collected are representative of other waters in other parts of the United States. The Washington data reflect the pathogen sources in that area, the local rainfall which has an effect on pathogen loadings, the tidal flushing in the waters, and the temperature of the waters. Further, as noted above, the legislative history indicates that any State wishing to adopt criteria other than those in the 1986 bacteria criteria document, "has a duty to defend the criteria from a scientific perspective" and specifically to demonstrate that they are as protective of human health as EPA's 1986 bacteria criteria.

No other comments received by EPA included the type and amount of information that EPA views as necessary to demonstrate that fecal coliform criteria (or any other pathogen indicator) in any other State or Territory are as protective of human health as the 1986 bacteria criteria. However, if following promulgation of this rule, some other State or Territory provides data to EPA sufficient to make this demonstration, EPA will approve such other criteria as meeting the requirements of section 303(i) and withdraw today's Federal criteria from that State's coastal recreation waters. EPA cautions, however, that given the focus of the BEACH Act on the specific indicators in EPA's 1986 bacteria criteria document, there is a substantial burden of proof for States wishing to adopt criteria based on alternative indicators. EPA believes that both the process and quantity of information and data provided by Washington State in making this determination may provide guidance to any other State that wished to make a similar showing.

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 Clean Water Act Section 303(i)?

As discussed in section IV.B.2 of the preamble to today's rule, EPA is promulgating water quality criteria that correspond to an illness rate of 0.8% for swimmers in freshwater and 1.9% for swimmers in marine waters. In deciding which States and Territories have already adopted water quality criteria as protective of human health as these criteria, EPA considered an illness rate of 1.0% of swimmers to be as protective as the 1986 bacteria criteria in determining whether to include a State or Territory in the rule. EPA explained

its reasons for this consideration in the proposed rule (69 FR 41724–41725). EPA would consider State or Territorial bacterial criteria for fresh coastal recreation waters to not be as protective of human health if the risk level of the criteria was above 1.0%.

Some commenters addressed this topic. Of these, a majority agreed with EPA that a 1.0% illness rate in swimmers in freshwater is as protective of human health as the 1986 bacteria criteria for different reasons. One commenter said that a 1.0% illness rate would result in only a small increase in risk of illness and that would still be below the risk of illness in marine waters. Another commenter stated that the difference between 0.8% and 1.0% was well within the inherent variability in the criteria. One commenter expressed support for the 1.0% risk level but only if EPA had examined and analyzed all available updated epidemiological data in identifying an acceptable risk level. As explained in the proposal (69 FR 41724–41725), EPA conducted an external peer review of EPA's analysis of the epidemiological data from EPA's bacteriological studies on which the 1986 bacteria criteria document is based.

Of the commenters who did not agree that the 1.0% illness rate was as protective of human health of the 1986 bacteria criteria, most argued that there is no logical reason to allow for different acceptable illness rates in marine and freshwater. One commenter said that the increase from 0.8% to 1.0% in freshwater would increase the incidence of gastrointestinal illness by 25%. Three commenters believed that the illness rate for freshwater should be 0.8%, while one commenter felt that EPA should promulgate additional geometric mean and single sample maximum values relative to other risk levels. EPA disagrees that it should only consider an illness rate of 0.8% to be as protective of human health as the 1986 bacteria criteria document. As explained in the proposal, EPA does not see any a priori reason to require a greater level of protection for freshwaters than for marine waters, which account for the vast majority of swimming days in coastal recreation waters subject to section 303(i) of the Clean Water Act. See the proposed rule (69 FR 41724) for further discussion of EPA's reasoning.

3. Do the Standards Include Appropriate Single Sample Maximums for All Coastal Recreation Waters?

As discussed in sections IV.B.3 and IV.B.4 of the preamble to today's rule, EPA is promulgating water quality criteria that include separate single sample maximums for four categories of waters based on intensity of use, which allows the State or Territory to assign waters to the four use intensity categories. In determining whether existing State or Territorial water quality standards for coastal recreation waters are as protective of human health as EPA's 1986 bacteria criteria, EPA determined whether the water quality standards include a single sample maximum for all coastal recreation waters and if designated bathing beaches have a single sample maximum based on at least the 75% confidence level. EPA considers this approach to be as protective as the 1986 bacteria criteria and also consistent with the criteria as discussed in section IV.B of the preamble to today's rule. EPA included in the rule any State or Territory that does not cover all coastal recreation waters with a single sample maximum and that for designated bathing beaches does not have a single sample maximum based on at least the 75% confidence level. EPA does not expect a State or Territory to use all four of the use categories identified in the criteria document for its standards to be at least as protective as the 1986 bacteria criteria. For example, a State that applied the 75% confidence based maximum to all waters would clearly be as protective as the 1986 bacteria criteria, even though it would only have a single use category.

Most commenters agreed with this approach. Those that disagreed with it commented that the single sample maximum should not be a part of the water quality criteria but rather available for use as an implementation tool for monitoring at beaches. EPA addressed these comments in sections IV.B.3 and IV.B.4 of today's preamble.

EPA notes that all of the 35 coastal and Great Lakes States and Territories have identified coastal recreation waters where there are beaches or similar points of access (*National List of Beaches*, EPA–823–R–04–004, 69 FR 24597, May 4, 2004). Also, all 35 of these States and Territories have received Clean Water Act section 406 grants since 2002 for monitoring and notification of beach advisories or closures at beaches adjacent to coastal recreation waters. Today's rule specifies that the highest use category with a single sample maximum based on the 75% confidence level applies to all beaches meeting the definition of designated bathing beaches in 40 CFR 131.41(b)(2) ("* * * coastal recreation waters that, during the recreation season are heavily-used (based on an evaluation of use within the State) and may have: a lifeguard, bathhouse facilities, or public parking for beach access") and that the other use categories apply to lower use waters accordingly. Based on the applications for Clean Water Act section 406 grants, EPA expects that many coastal and Great Lakes States will have at least some beaches in the higher use categories.

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

For the reasons discussed in section IV.B.7 of the preamble to today's rule, EPA is promulgating the exemption for non-human sources expressed in the 1986 bacteria criteria document. EPA is including in today's rule those States and Territories for which the criteria include exemptions for non-human sources that are inconsistent with the exemption provision in the criteria document, as promulgated in today's final rule. EPA addressed comments on this issue in section IV.B.7 of the preamble to this rule.

5. Has EPA Approved the Standards?

Under section 303(i)(1)(A) of the Clean Water Act, States and Territories must 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 adopted after May 30, 2000, in order for those standards to be in effect for Clean Water Act purposes. Therefore, EPA must have approved State and Territorial standards for enterococci or *E. coli* adopted after May 30, 2000, as consistent with Clean Water Act section 303(i) in order for EPA to exclude the State or Territory from the final rule. State and Territorial standards adopted prior to May 30, 2000, that are consistent with Clean Water Act section 303(i) are in effect for Clean Water Act purposes even without explicit EPA approval.

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

The proposed rule contains a State-by-State summary of the status of each State or Territory (69 FR 41731–41735). EPA did not include any Tribes in the proposal because although there are Federally-recognized Tribes located next to either coastal or Great Lakes waters, none of those Tribes have coastal recreation waters as defined in 40 CFR 131.41(b)(1). (See 69 FR 41735.)

Today, EPA is promulgating a rule that is identical with respect to the water quality criteria values to what EPA proposed. While there were some changes in other provisions of the rule,

none of these affected EPA's determination with regard to specific States. Therefore, EPA is not excluding any other States from the final rule based on changes in the provisions of the final rule.

Table 4 contains a summary of the status of each of the 35 States and Territories under today's rule. EPA considered three possible reasons for a change in a State's or Territory's status from that described in the proposal: (1) Since the publication of the proposed rule, the State or Territory may have adopted (and EPA approved) water quality standards that are as protective of human health as the 1986 bacteria criteria; (2) the State's or Territory's water quality standards may now be viewed as being as protective of human health in light of EPA's final decision with respect to the application of the single sample maximum in the final rule; and (3) new information submitted following publication of the proposal may have caused EPA to reassess its previous determination. During the period between publication of the proposal and the final rule, four States—Delaware, Hawaii, Maryland, and South Carolina—and the Commonwealth of the Northern Mariana Islands adopted revised water quality criteria for pathogens. In addition, the State of Washington provided information that caused EPA to reassess its determination as to whether the State's fecal coliform criterion of 14/100 ml is as protective of human health as the 1986 bacteria criteria. Below, EPA describes the status of these States and Territory and provides an update on the status of several other States working to adopt water quality standards, as described in the preamble to the proposed rule.

TABLE 4.—CATEGORIZATION OF 35 STATES/TERRITORIES WITH COASTAL RECREATION WATERS

Not subject to 40 CFR 131.41	Subject to 40 CFR 131.41
Alabama	Alaska
American Samoa	California
Connecticut	Florida
Delaware [1]	Georgia
Guam	Hawaii
Indiana	Illinois
Michigan	Louisiana
New Hampshire	Maine
New Jersey	Maryland
Northern Mariana Islands [1]	Massachusetts
South Carolina [1]	Minnesota
Texas	Mississippi
Virginia	New York
Washington [1]	North Carolina
	Ohio
	Oregon
	Pennsylvania
	Puerto Rico
	Rhode Island
	Virgin Islands
	Wisconsin

[1] These States were removed from 40 CFR 131.41 following publication of the proposed rule.

Commonwealth of the Northern Mariana Islands

The Attorney General for the Commonwealth of the Northern Mariana Islands certified the adoption of revisions to their water quality standards on September 30, 2004. These revisions add single sample maximum standards of 104/100 ml for Class AA waters and 276/100 ml for Class A waters in the Commonwealth of the Northern Mariana Islands. Along with the bacteria standards that Commonwealth of the Northern Mariana Islands adopted and EPA approved in 1997, the revised standards will fully satisfy the requirements of the Clean Water Act. On October 28, 2004, EPA approved the revised standards and the Commonwealth of the Northern Mariana Islands is not included in the rule.

Delaware

On September 17, 2004, Delaware submitted to EPA newly adopted criteria for all its coastal recreation waters. The State's criteria specify a geometric mean of 35/100 ml and a single sample maximum of 104/100 ml for enterococci for all primary contact recreation marine waters. Delaware's regulations also limit the application of the criteria when the bacteria comes from wildlife sources. The State has submitted documentation to EPA in support of its source tracking methodology for bacteria, together with epidemiological work on illness rates from bacteria of wildlife origin. The State uses the source information to apply a factor to bacteria from wildlife sources that accounts for illness risk from such bacteria. EPA reviewed the submitted criteria in accordance with this rule and on November 4, 2004, approved the specific numeric criteria as meeting the requirements of both sections 303(c) and 303(i) of the Clean Water Act. EPA is discussing the State's methodology for source tracking with the State and is reviewing it to determine whether it meets the requirements of the Clean Water Act and this rule. Until EPA approves this limitation, for purposes of the Clean Water Act, Delaware's bacteria criteria for primary contact recreation apply to enterococci bacteria regardless of the source. As a result, Delaware is not included in today's rule.

Hawaii

On September 21, 2004, Hawaii adopted bacteria criteria for its coastal estuaries, and a single sample maximum for coastal waters within 300 meters (1000 feet) of the shore. The criteria are for enterococci and have a geometric mean of 33/100 ml and a single sample maximum of 89/100 ml in coastal estuaries. These newly adopted criteria also contain a single sample maximum of 100/100 ml in coastal waters within 300 meters from shore to complement the existing geometric mean for coastal waters. On October 28, 2004, EPA approved these criteria. However, Hawaii still 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 rule but only for the lack of criteria in State waters beyond 300 meters from shore.

Maryland

On July 5, 2004, Maryland adopted new criteria for all its coastal recreation waters. These criteria specify a geometric mean of 35/100 ml enterococci for all recreation waters and at least a single sample maximum of 104/100 ml for those waters that are designated natural bathing areas under the State regulations. EPA is reviewing these criteria in accordance with this rule and is consulting with the State regarding the intent and meaning of the State regulations. EPA and Maryland have not concluded discussions of the applicability of the State criteria. Because Maryland does not yet have approved criteria, EPA is including Maryland in this rule. If EPA determines that Maryland's standards comply with Clean Water Act 303(i), they will become immediately effective for Clean Water Act purposes, as specified in 40 CFR 131.41(d)(1).

South Carolina

On June 25, 2004, South Carolina adopted criteria for all of its coastal recreation waters consistent with EPA's 1986 bacteria criteria. The criteria are for enterococci and have a geometric mean of 35/100 ml, a single sample

presumably because Congress thought the 1986 bacteria criteria are better than what it characterized as "outdated" criteria used by some States. (See H. Rep. No. 106–98, at 6 (1999); see generally S. Rep. No. 106–366 (2000) and H. Rep. No. 106–98.)

EPA had reviewed its original studies supporting its recommended 1986 water quality criteria for bacteria and the literature on human health research conducted since EPA completed the original studies of health effects associated with swimming in marine and freshwater, as discussed on pages 10–13 of the *Implementation Guidance for Ambient Water Quality Criteria for Bacteria* (EPA–823–B–02–003, May 2002 Draft). Based on these reviews, EPA has confirmed that the 1986 EPA recommended water quality criteria for bacteria are protective of human health against acute gastrointestinal illness.

The epidemiological studies used to develop the criteria were themselves peer reviewed. The marine studies were peer reviewed in the Journal of the American Public Health Association. EPA's Office of Research and Development reviewed the freshwater studies. The Harvard School of Public Health evaluated the epidemiology test protocol for both fresh and marine studies, and the University of Pittsburgh Center for Excellence provided an independent review of the results of the epidemiology studies. Finally, the 1986 bacteria criteria were reviewed by the public when EPA published a **Federal Register** notice concerning the criteria (49 FR 21987, May 24, 1984).

While Congress directed in Clean Water Act section 303(i) that, by April 9, 2004, States and Territories adopt criteria as protective as EPA's current criteria, Congress also recognized that "EPA's 1986 criteria need to be updated to improve the scientific basis for identifying pathogens in coastal waters." S. Rep. No. 106–366, at 2. To address this concern, Congress amended Clean Water Act section 304(a) to require EPA to "publish [within five years of enactment of the BEACH Act] new or revised water quality criteria for pathogens and pathogen indicators (including a revised list of testing methods, as appropriate), based on the results of the studies conducted * * * for the purpose of protecting human health in coastal recreation waters." See Clean Water Act section 304(a)(9). Thus, while Congress recognized that the 1986 bacteria criteria need improvement, Congress still required States and Territories to adopt water quality standards as protective of human health as the 1986 bacteria criteria. EPA is currently conducting epidemiological studies on potential health risks resulting from exposure to pathogens or pathogen indicators in coastal recreation waters, as required under this section of the Clean Water Act. Once EPA publishes these new criteria, EPA expects that States and Territories will begin to adopt water quality standards as protective of human health as the new criteria for coastal and Great Lakes recreation waters, as required by Clean Water Act section 303(i)(1)(B).

B. Economics

Some commenters noted that, if the rule imposes single sample maximums as "not-to-be-exceeded" values, the geometric mean component of the criteria would be significantly different from the geometric mean values in most State current fecal coliform bacteria criteria for recreation. For fecal coliform criteria to protect recreational uses, most State criteria include a geometric mean value and a threshold value not to be exceeded in more than 10% of the samples. Some commenters state that there will be a substantial cost difference to regulated entities if the rule imposes single sample maximums for *E. coli* or enterococci as "not-to-be exceeded" values, noting that EPA's economic analysis in the proposal does not address the cost of controlling discharges from combined sewer overflows, sanitary sewer overflows, and municipal separate storm sewer systems to meet such single sample maximums, and that EPA's cost estimates for controlling these sources in other regulatory and policy actions are not based on a single sample maximum as a never-to-be exceeded criterion for Clean Water Act purposes.

Today's rule does not treat single sample maximums as a requirement that may never be exceeded in all instances. Single sample maximums are values that indicate, with a certain degree of confidence, that a waterbody may exceed the geometric mean. The State can collect additional data on a receiving water if it believes that the violation of the single sample maximum does not indicate violation of the geometric mean, as described in the preamble to today's rule.

For its economic analysis, EPA evaluated the potential controls for publicly owned treatment plants and industrial facilities likely to discharge bacteria to meet permit limits based on the single sample maximums as never-to-be exceeded values to provide a conservatively high estimate of cost. In reality, States and Territories have flexibility in implementing the criteria in National Pollutant Discharge Elimination System permits. EPA also assumed that none of the States covered by the rule had adopted *E. coli* or enterococci as the applicable water quality standard whereas several of the States in today's rule have water quality standards for *E. coli* or enterococci already in place for some of their coastal recreation waters. This also led to a higher estimate of cost than may actually be incurred. EPA addresses discharges of bacteria from municipal separate storm sewers, combined sewer overflows, sanitary sewer overflows, and nonpoint sources (*e.g.*, agriculture) to coastal waters in existing regulations and policies, and has tallied potential control costs to comply with those regulations and policies as part of analyses for those actions. In general, the best management practices or treatment controls for wet weather discharges that are designed to meet fecal coliform standards in a waterbody are also the best management practices or treatment controls used to address *E. coli* and enterococci. Because of the substantial variability in bacterial indicators and the site-specific effectiveness of control measures, EPA is not able to determine at this time if additional measures will ultimately be necessary to meet criteria based on the new indicators. Compliance with pathogen standards is best achieved through an adaptive management approach based on cost-effective management practices and control measures coupled with on-going monitoring and revision of control plans as necessary.

C. Analytical Methods

EPA received a few comments on the topic of analytical methods. One commenter expressed concern that EPA has not published EPA-approved analytical methods for measuring enterococci and *E. coli* in effluent. EPA recognizes that it has not yet published analytical methods for measuring enterococci and *E. coli* in effluents. EPA published its methods for measuring enterococci and *E. coli* in ambient waters on July 21, 2003, and is now in the process of proposing methods for measuring these pathogen indicators in effluent. EPA has completed its inter-laboratory study of method 1600 for enterococci and method 1603 for *E. coli* in secondary treated effluents, and has determined that the variability found in this study support publication of a proposed method for effluents. EPA is moving expeditiously to promulgate these methods.

Three commenters noted that the inter-laboratory study for enterococci and *E. coli* methods discussed above did not address pulp and paper effluents,

maximum of 104/100 ml for coastal waters designated by South Carolina as Classes SFH (Shellfish Harvesting) and SA, and a single sample maximum of 501/100ml for coastal waters designated by South Carolina as Class SB. However, the South Carolina water quality standard delays the applicability of the enterococci criteria for permit effluent limits until such time that EPA publishes analytical methods for enterococci in effluents. On October 7, 2004, EPA disapproved part of the South Carolina standards and approved the remainder of the standards that pertain to pathogens and pathogen indicators. EPA considers the approved water quality standards to be as protective of human health as EPA's 1986 bacteria criteria, and South Carolina is not included in the rule.

Washington

The Washington Department of Ecology submitted data consisting of paired samples of fecal coliform and enterococci measurements collected in Puget Sound, the Strait of Juan de Fuca, and the Pacific Ocean embayments. The Department of Ecology considers this information as sufficient to demonstrate that use of the State's fecal coliform criterion of 14/100 ml ensures that enterococci concentrations are below the 1986 bacteria criteria, and requested that EPA consider the State's fecal coliform criterion to be as protective of human health as the 1986 bacteria criteria. As discussed in section V.A.1 of the preamble, EPA reviewed these data and has determined that the Washington fecal coliform criterion of 14/100 ml is as protective of human health as the 1986 bacteria criteria. The Washington fecal coliform criterion applies to all marine waters with primary contact recreation use, and thus applies to all coastal recreation waters. Therefore, Washington is not included in the rule.

Maine

EPA is also making a minor change with respect to including Maine in today's final rule. As explained in the preamble to the proposal (69 FR 41733), EPA intended to exclude Maine's Class SA waters from coverage under the rule; however, EPA failed to list Maine's Class SA waters as excluded in the regulatory text of 40 CFR 131.41(e)(2). EPA has corrected this omission in today's final rule.

Other States

EPA identified two other States or Territories that, at the time of proposal, intended to adopt EPA's 1986 bacteria criteria by September 30, 2004. These were Illinois and the Virgin Islands. However, neither Illinois nor the Virgin Islands adopted the criteria and received EPA approval as of the signature of today's rule.

C. Under What Conditions Will States and Territories Be Removed From Today's Rule?

State and Territorial standards for bacteria approved by EPA pursuant to Clean Water Act sections 303(c) and 303(i) will be in effect for Clean Water Act purposes, and the Federal criteria for 40 CFR 131.41 will no longer apply. EPA recognizes that once it approves the water quality standards of the State or Territory, the Code of Federal Regulations will still include a reference to the State in 40 CFR 131.41 until EPA formally withdraws the State or Territory from the Federal rule, and thereby the Code of Federal Regulations. However, the State and Territorial standards for bacteria approved by EPA pursuant to Clean Water Act sections 303(c) and 303(i) will be in effect for Clean Water Act purposes (and not the Federal criteria at 40 CFR 131.41) between the time EPA approves the State standards and formal withdrawal of the State or Territory from the rule.

A State or Territory may adopt and submit partial water quality standards for EPA's review and approval under today's rule. EPA envisions two types of partial water quality standards submittals with different results. If a State adopts and submits water quality standards that meet all the requirements discussed in today's rule but the standards apply only to a portion of the State's coastal recreation waters, EPA expects to approve the State standards for the coastal recreation waters to which they apply, and today's Federal standards would continue to apply to all coastal recreation waters that are not addressed in the submittal. The combination of the approved State and Federal standards serve to meet the requirements of Clean Water Act section 303(i). If a State adopts and submits standards for all of its coastal recreation waters but the standards do not satisfy all of the considerations described in today's rule as necessary for EPA to make a determination that the State standards are as protective of human health as the 1986 bacteria criteria, EPA expects to disapprove the entire submittal and today's Federal standards would continue to apply to the State's coastal recreation waters. For example, a State might adopt water quality standards that contain *only* a geometric mean for marine waters of 35/100 ml for enterococci and not a single sample maximum provision. This would not be sufficient to satisfy section 303(i). EPA anticipates that it would be administratively unworkable to approve State standards in piecemeal fashion and to supplement piecemeal State standards with components of today's rule, as in the example of a State that adopts a State geometric mean but must still retain a Federal single sample maximum for its coastal recreation waters.

VI. Response to Additional Significant Public Comments

EPA has prepared a Comment Response Document, which addresses the comments that EPA received and is included in the docket for today's rule. Below, EPA provides a summary of its responses to four additional categories of significant comments.

A. 1986 Bacteria Criteria

Some commenters raised concerns about EPA's 1986 bacteria criteria. The bulk of the comments questioned the reliability of the studies on which EPA based the criteria. Some remarked that the studies evaluated in the criteria document did not appropriately select test sites because the test sites were all located on the East Coast and therefore may not represent conditions on the West Coast; the test sites had only one source of pollution (human); and no control sites were used. In addition, commenters characterized the data as anecdotal rather than clinical in nature (*e.g.*, blood and stool samples) and suggested that the studies did not ensure that the reported illnesses were due to pathogens relating to bathing in the water. Others questioned EPA's chosen risk levels. One commenter suggested other possible indicators. Others commented on the lack of EPA follow-up epidemiological studies since 1986.

EPA acknowledges these comments, but notes that Clean Water Act section 303(i) requires States and Territories with coastal recreation waters to adopt water quality criteria for bacteria as protective of human health as the criteria published by EPA under Clean Water Act section 304(a). Section 303(i) was added to the Clean Water Act in 2000 by the BEACH Act. At the time the BEACH Act was enacted, the current Clean Water Act section 304(a) criteria were EPA's 1986 bacteria criteria because these are EPA's only currently recommended bacteria criteria for protection of primary contact recreation waters. The legislative history makes it clear that Congress recognized that EPA's 1986 bacteria criteria have flaws, but also that Congress wanted States to adopt standards based on them by April 10, 2004, despite those flaws.

and that these effluents are suspected of containing *E. coli* and enterococci independent of fecal matter. As a result, the commenters suggest that EPA complete validation studies of enterococci and *E. coli* methods for pulp and paper effluents before requiring States to implement the criteria in National Pollutant Discharge Elimination System permits for pulp and paper facilities. EPA disagrees that it must complete additional validation studies before States use the criteria for permits. EPA has completed its inter-laboratory validation for EPA Methods 1600 and 1603 for effluents, and is in the process of proposing these methods. In addition, EPA is currently completing its inter-laboratory validation for EPA Methods 1103.1 and 1106.1 in effluents, and intends to propose them after the validation process is completed. EPA did not specifically use pulp and paper effluent matrices in the study. EPA method validation studies typically include several representative matrices and are not intended to include every potential effluent matrix to which a method may be applicable. In addition, EPA notes that its National Pollutant Discharge Elimination System regulations do not require that compliance monitoring for National Pollutant Discharge Elimination System permits be based on EPA-approved methods. 40 CFR 122.41(j)(4) provides that monitoring results must be conducted according to test procedures approved under 40 CFR Part 136 unless other test procedures have been specified in the permit. States implementing the criteria in National Pollutant Discharge Elimination System permits may thus specify some other analytical method that the permittee is to use for compliance monitoring. Of course, any such method must be scientifically defensible, which usually means that it has been tested and verified by some other recognized standard setting or method development body. Permittees who believe that a particular method is not appropriate or reliable for their effluent may present documentation of this concern to the permitting authority for consideration in determining compliance monitoring requirements.

D. Effective Date

Section 553 of the Administrative Procedure Act provides that a substantive rule shall be published not less than 30 days before its effective date, except under certain circumstances. EPA is promulgating today's rule with an effective date of 30 days after publication in the **Federal Register** in order to make the water quality criteria effective as soon as possible and available for use in assessing beach safety and for other Clean Water Act purposes. This will serve to protect human health at coastal recreation waters.

EPA received two comments on this issue. One commenter requested that EPA delay promulgating the rule until July 2005 and another commenter suggested that EPA delay the effective date for 90 days so that a State could complete its own promulgation of water quality standards based on the 1986 bacteria criteria. EPA disagrees that it should allow more than 30 days because this would delay the time at which States and Territories will begin using today's water quality criteria to govern decisions about opening and closing beaches and for other Clean Water Act purposes. EPA understands the interest of the commenters in having their State standards serve as the effective standards for Clean Water Act purposes. If a State adopts, and EPA approves, standards satisfying Clean Water Act section 303(i) shortly after the effective date of this rule, the State criteria will immediately replace the criteria in today's rule for Clean Water Act purposes within the State, consistent with 40 CFR 131.41(d)(i). EPA does not expect that a short window during which Federal standards are in effect will unduly disrupt on-going State water quality standards programs. Therefore, EPA is making the rule effective 30 days after publication in the **Federal Register**.

VII. Alternative Regulatory Approaches and Implementation Mechanisms

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 States or Territories for coastal recreation waters covered by this rule to determine if the standards meet the requirements of the Clean Water Act 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 Clean Water Act section 303(c) and the regulations at 40 CFR Part 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 Clean Water Act definition of "coastal recreation waters" or this rule.

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 that do not include the uses specified in Clean Water Act section 101(a)(2) or with subcategories of the designated uses specified in Clean Water Act section 101(a)(2) that require less stringent criteria (see 40 CFR 131.10(j)), than those currently in effect.

VIII. Economic Analysis

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

Any National Pollutant Discharge Elimination System-permitted facility that discharges to waterbodies affected by this rule could potentially incur compliance costs. 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). In addition, EPA addresses discharges of bacteria from municipal separate storm sewer systems, combined sewer overflows, and sanitary sewer overflows to coastal waters in existing regulations and policies, and has tallied potential control costs as part of the analyses for those actions. EPA expects that States and municipalities will continue to use the same types of controls to come into compliance with the revised criteria as are currently used for compliance with existing regulations and policies. Available evidence suggests that if discharges are controlled in such a way that fecal coliform criteria are met, it is likely that enterococci and *E. coli* criteria would also be met, and there would not be an increase in impaired waters, resulting in additional Total Maximum Daily Loads, though not enough is known about the relationship between sources, controls, and the various indicators to conclude this with any certainty at this time. EPA did not evaluate the costs of this rule to Concentrated Animal Feeding

Operations because the regulations for Concentrated Animal Feeding Operations prohibit discharges except in unusual circumstances (*i.e.*, very large storms) and therefore those entities are unlikely to incur any additional costs as a result of today's rule. EPA did not evaluate the potential for costs to nonpoint sources, such as agricultural runoff. Finally, EPA did not attempt to quantify the potential benefits of the rule.

EPA recognizes that a State or Territory may decide to require controls for nonpoint sources (*e.g.*, agricultural runoff). However, it is difficult to model and evaluate the potential costs impacts of this rule to those sources 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, and would be extremely time and resource intensive. Finally, it is likely that controls needed to meet existing criteria (assumed for the purpose of costing to be fecal coliform for all States covered by the rule) would also address water quality problems indicated by criteria for *E. coli* or enterococci.

A. Identifying Affected Facilities

EPA identified approximately 734 point source facilities that may be affected by the rule. Of these potentially affected facilities, 306 are classified as major dischargers, and 428 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 with general permits actually discharge to the affected water bodies because facility location information is not available in EPA's Permit Compliance System database.

Of the facilities located in jurisdictions included in the rule, EPA evaluated that subset of facilities with individual permits that discharge within two miles of coastal waters or the Great Lakes. EPA identified these facilities by relating facility information to the potentially affected waters using Geographic Information System software. EPA also assumed that only wastewater treatment plants or facilities with similar effluent characteristics (*i.e.*, facilities having the potential to discharge bacteria in the form of fecal matter) may be affected. For those facilities for which latitude/longitude data are not included in the Permit Compliance System, EPA included only facilities for which the receiving waterbody name in the Permit Compliance System indicates a coastal water (*e.g.*, Pacific Ocean, Lake Erie). Table 5 summarizes these potentially affected facilities by type and category.

TABLE 5.—POTENTIALLY AFFECTED FACILITIES [1]

Category	Number of Facilities			Total
	Major [2]	Minor		
		Municipal	Other [3]	
Coastal	242	233	100	575
Great Lakes	64	75	20	159
Total	306	308	120	734

[1] Facilities from States and Territories included in the rule that discharge within two miles of coastal waters or the Great Lakes.
[2] No major industrial facilities are affected by the rule. However, 4 other facilities (SIC codes 9711 and 9999) are included because their names indicate that they are wastewater treatment plants.
[3] Includes the following standard industrial classifications: 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), national security (9711), and 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 the 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 Permit Compliance System 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 at the sample facilities is *E. coli* because *E. coli* is a type of fecal coliform. EPA assumed that all potentially affected facilities need effluent limits that are required to meet both the applicable geometric mean and single sample maximum values promulgated in today's rule. Based on the last 3 years of data, EPA thus estimated that facilities with average monthly effluent levels exceeding a geometric mean of 126/100 ml, or maximum daily levels exceeding 235/100 ml, would most likely need treatment controls to meet potential permit limits based on today's rule.

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 (as related to enterococci) 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 enterococci criteria. A ratio of 4 translates to fecal coliform levels of 140 fecal coliform per 100 ml (4 * 35 = 140/100 ml); however, for consistency with the Great Lakes analysis, EPA estimated costs based on meeting a more stringent value of 126 fecal coliform per 100 ml. In addition, EPA assumed that coastal facilities with maximum fecal coliform effluent values exceeding 235 colonies per 100 ml would need treatment controls (even though 235/4 = 59, which is more stringent than the single sample maximum value of 104 in the final rule).

Experiences from four facilities currently having effluent limitations to meet *E. coli* and enterococci criteria, as well as the current fecal coliform criteria, suggest that chlorination processes can be upgraded or adjusted to treat the levels of bacteria necessary for compliance with effluent limitations based on today's rule. Therefore, EPA estimated that optimization of existing disinfection processes would enable the sample facilities to comply with the 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 results for the 15 facilities with flows greater than 120 mgd, and extrapolating the sample results to the remaining potentially affected facilities, EPA estimated a total annual cost of approximately $20 million ($13 million for coastal facilities, and $7 million for Great Lakes facilities). EPA estimates that approximately 70 major and 20 minor permittees could incur control costs as a result of permit modifications to include limits based on the criteria in today's rule.

IX. 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 Office of Management and Budget (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." As such, this action was submitted to OMB for review. Changes made in response to OMB suggestions or recommendations are 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 rule on small entities, small entity is defined as: (1) A small business according to RFA default definitions for small business (based on Small Business Administration 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 rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. As discussed below, these water quality standards do not directly apply to any discharger, including small entities.

Clean Water Act 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 National Pollutant Discharge Elimination System program, which limits discharges to navigable waters except in compliance with a National Pollutant Discharge Elimination System permit. The Clean Water Act requires that all National Pollutant Discharge Elimination System permits include any limits on discharges that are necessary to meet applicable water quality standards.

In cases in which a discharger (including a small entity) is discharging pathogens into waters subject to these standards, the permitting authority will

need to determine whether the discharge is or may be discharged at a level which will cause, contribute to, or have the reasonable potential to cause an exceedance of the applicable water quality standard. In making that determination, the permitting authority would need to consider the factors listed in 40 CFR 122.44(d)(1)(ii). Whether a permitting authority will need to require a water quality-based effluent limit depends on the analysis of these factors, which will vary based on the specific facts of each permit decision. Based on that analysis, if the permitting authority finds that the discharger causes, contributes to, or has the reasonable potential to cause an exceedance of the applicable water quality standard, after the application of any required technology-based effluent limits, then the permitting authority will need to impose a water quality-based effluent limit to meet the applicable water quality standard. (See Clean Water Act section 301(b)(1)(C); 40 CFR 122.44(d).) Therefore, as a practical matter, today's rule may or may not necessitate a change in the permit, depending on the specific circumstances. While the Clean Water Act and its implementing regulations may trigger the need for new or revised discharge limits based on the water quality standards in today's rule to be placed on small entities in some cases, the standards themselves do not directly apply to any discharger, including small entities.

In the "Economic Analysis for Final Water Quality Standards for Coastal Recreation Waters," EPA presents an analysis which supports a conclusion that today's rule will likely affect only a few small entities. (See the docket for today's rule.)

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 the Unfunded Mandates Reform Act includes "a territory or possession of the United States." Under section 202 of the Unfunded Mandates Reform Act, 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 Unfunded Mandates Reform Act 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 Unfunded Mandates Reform Act 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 rule contains no Federal mandates (under the regulatory provisions of Title II of the Unfunded Mandates Reform Act) 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 Unfunded Mandates Reform Act.

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

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 final 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 Clean Water Act is well established and has been used on various occasions in the past. The final rule does 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 final rule does not alter the States' or Territories' considerable discretion in implementing these water quality standards. Further, this rule does not preclude the States and Territories from adopting water quality standards that meet the requirements of the Clean Water Act, 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 rule.

Although Executive Order 13132 does not apply to this rule, in the spirit of Executive Order 13132 and consistent with EPA's policy to promote communication between EPA and State and local governments, EPA did consult with representatives of the States and Territories subject to Clean Water Act section 303(i) in developing this rule. Prior to this 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* (EPA-823-B-02-003, May 2002 Draft)) concerning adoption and implementation of EPA's recommended criteria for bacteria. Today's final rule reflects State and Territorial input, and EPA has responded to State and Territorial comment on various topics in the preamble to today's rule and in the Comment Response Document, which is part of the record for this rule.

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."

This final 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 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 could have on Tribal waters.

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 rule on children, and explain why the regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This rule is not subject to the Executive Order because it is not economically significant as defined in Executive Order 12866, and because the Agency does not have reason to believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. As explained in section II.B of the preamble to today's rule, EPA developed the water quality criteria promulgated in today's rule based on concentrations of *E. coli* and enterococci from EPA-sponsored epidemiological studies reflecting all reported illnesses, including those of children. In the marine and freshwater studies, the range of the number of children under age 10 was between 15% and 25% of the total study population. Children in the age range 10 to 19 years old made up a slightly higher percentage of the study population. During the studies, information on gastroenteritis, respiratory symptoms, and other symptoms were collected for all participants, including children. EPA designed the 1986 bacteria criteria to protect all age groups.

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 final rule will create a negligible increase in nationwide energy consumption for point source facilities discharging to coastal recreation waters in affected States. In section VIII, EPA presented its estimated incremental costs to permitted facilities as a result of the final 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 99,000 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.*, 0.000003% of national energy generation).

I. National Technology Transfer and Advancement Act

As noted in the proposal, 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 and none were brought to our attention in comments on the proposed rule. 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, in accordance with Clean Water Act section 304(a), in cases where States fail to do so. Therefore, EPA is not considering the use of any voluntary consensus standards.

J. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A "major rule" cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2). This rule will be effective December 16, 2004.

List of Subjects in 40 CFR Part 131

Environmental protection, Intergovernmental relations, Reporting

and recordkeeping requirements, Water pollution control.

Dated: November 8, 2004.

Michael O. Leavitt,

Administrator.

■ For the reasons set out in the preamble, 40 CFR part 131 is amended 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 Subpart D 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 (based upon an evaluation of use within the State) 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 section 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 December 16, 2004. It does not include relocation of existing combined sewer overflow outfalls.

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

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

(1) Freshwaters:

A Indicator[d]	B Geometric mean	C Single sample maximum (per 100 ml)			
		C1 Designated bathing beach (75% confidence level)	C2 Moderate use costal recreation waters (82% confidence level)	C3 Light use coastal recreation waters (90% confidence level)	C4 Infrequent use coastal recreation waters (95% confidence level)
E. coli[e]	126/100 ml[a]	[b]235	[b]298	[b]409	[b]575
Enterococci[e]	33/100 ml[c]	[b]61	[b]78	[b]107	[b]151

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

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

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.

c. This value is for use with analytical methods 1106.1 or 1600 or any equivalent method that measures viable bacteria.

d. The State may determine which of these indicators applies to its freshwater coastal recreation waters. Until a State makes that determination, *E. coli* will be the applicable indicator.

e. These values apply to *E. coli* or enterococci regardless of origin unless a sanitary survey shows that sources of the indicator bacteria are non-human and an epidemiological study shows that the indicator densities are not indicative of a human health risk.

(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[c]	35/100 ml[a]	[b]104	[b]158	[b]276	[b]501

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

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

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.

c. These values apply to enterococci regardless of origin unless a sanitary survey shows that sources of the indicator bacteria are non-human and an epidemiological study shows that the indicator densities are not indicative of a human health risk.

(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 determined by EPA to meet the requirements of Clean Water Act section 303(i) apply, 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), Florida, Georgia, Hawaii (except for coastal recreation waters within 300 meters of the shoreline), Louisiana, Maine (except for SA waters and 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 § 131.40), Rhode Island, United States Virgin Islands.

(f) *Schedules of compliance.* (1) This paragraph (f) applies to any State that does not have a regulation in effect for Clean Water Act purposes that authorizes compliance schedules for National Pollutant Discharge Elimination System permit limitations needed to meet the criteria in paragraph (c) of this section. 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 December 16, 2004, 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 paragraph (c) of 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 (c) of this section as soon as possible, taking into account the discharger's 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.

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