This fact sheet addresses questions regarding the appropriate risk level (or levels) a state may choose when adopting into the state’s water quality standards bacteria criteria to protect its coastal recreation waters. This fact sheet is intended to answer key questions states may have about what EPA considers to be appropriate acceptable risk levels in the context of what EPA promulgated in the Water Quality Standards for Coastal and Great Lakes Recreation Waters (or BEACH Act) rule (69 FR 67217, November 16, 2004) and what EPA recommended in the 1986 Ambient Water Quality Criteria for Bacteria document (also known as the 1986 bacteria criteria document).

What are coastal recreation waters?
Coastal recreation waters are those Great Lakes and marine 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. Inland waters or waters upstream from the mouth of a river or stream having an unimpaired natural connection with the open sea are not considered coastal recreation waters. (See CWA Section 502(21) and 40 CFR 131.41(b)).

What does the BEACH Act Rule say about risk levels?
In the November 16, 2004 rule, EPA promulgated water quality criteria corresponding to an illness rate of 0.8% for swimmers in freshwater and 1.9% for swimmers in marine waters. In determining whether to include a state in the rule, EPA considered states that used an illness rate of 1.0% or less for fresh waters to have criteria as protective of human health as the 1986 bacteria criteria, and therefore, EPA did not promulgate the criteria for these states.

Why did EPA take the approach in the BEACH Act Rule of establishing different risk levels for fresh and marine waters?
As EPA explained in the proposed Water Quality Standards for Coastal and Great Lakes Recreation Waters (69 FR 41719, 41724, July 9, 2004), there is no a priori reason to establish a higher level of protection for fresh waters than for marine waters. The difference in acceptable risk levels in the 1986 bacteria criteria document (8 illnesses per 1000 swimmers in fresh waters vs. 19 per 1000 in marine waters) was based solely on the calculated risk levels for the previously recommended criterion of 200 fecal coliforms per 100 ml, which were different in marine and fresh waters. If the data upon which the 1986 bacteria criteria were based supported a reliable correlation between bacteria concentrations and higher illness rates, EPA could have, in judging whether a fresh water criterion is “as protective of human health as” EPA’s 1986 bacteria criteria, considered fresh water criteria associated with risk levels up to 1.9% of swimmers to be sufficient. However, EPA could not determine, based on the available data that relate E. coli and enterococci levels to illness rates, what bacteria concentration would correlate with risk levels over 1.0% in freshwater. Therefore, EPA determined that existing data relating risk levels to bacteria concentrations in fresh coastal recreation waters were not reliable beyond 1.0% risk to swimmers.
Peer review of EPA’s analysis of the study data relating illness rates to bacteria concentrations supports the conclusion that the existing data do not support the relationship between rates beyond the level of 1.0% of swimmers and their correlating bacteria concentrations (External Peer Review of EPA Analysis of Epidemiological Data from EPA Bacteriological Studies, February 2004, available in the public record for the BEACH Act rule, Docket ID No. OW-2004-0010). The peer reviewers recommended that EPA should not extrapolate beyond the 1.0% risk level, based on the observed data. Based on that peer-reviewed information, EPA does not believe at this time that a state’s water quality standards for fresh waters based on any geometric mean or SSM higher than the levels associated with an illness rate of 1.0% would be as protective of human health as EPA’s 1986 bacteria criteria. As discussed earlier, however, in evaluating any new or revised state water quality standards for bacteria, EPA will review information states provide showing a scientifically defensible relationship between higher illness rates and corresponding indicator concentrations.

**How did EPA determine these risk levels were appropriate?**

EPA developed the criteria values for enterococci and *E. coli* based on indicator concentrations from EPA’s epidemiological studies that roughly corresponded to the estimated illness rate associated with the 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.

The analyses upon which these risk level estimates are based include some uncertainties because at the time they were developed, there was little correlation between illness rate and fecal coliform density. These estimated risk levels were used to calculate the specific bacteria density values presented in tabular form in the 1986 bacteria criteria document. These estimated illness rates are correctly described in the 1986 bacteria criteria document as approximate, and as “EPA’s best estimates at the time.”

**Would EPA approve a state’s water quality standards for bacteria in freshwater with a risk level higher than 0.8% of swimmers?**

Yes. EPA would approve up to and including 1% without any additional data. Higher risk levels would require additional data to be collected and submitted because existing data are not adequate to establish the relationship in freshwater between an illness rate of above 1.0% up to 1.9% and the corresponding bacteria concentrations. Levels higher than 1.9% for fresh waters would not be as protective of human health as the 1986 bacteria for either fresh waters or marine waters because 1.9% is the upper limit of the acceptable risk range in the 1986 bacteria criteria. More information can be found in the “Why did EPA take this approach in the BEACH Act Rule?” section below.

**Does a state have to conduct a Use Attainability Analysis to adopt a fresh water risk level higher than 0.8% but below 1.0%?**

No. Risk levels in the 0.8% to 1.0% range all protect primary contact recreation. For states that change the risk level and thus change the numeric value of the criterion, if such changes may be the basis for less stringent permit limits anti-backsliding provisions may apply to such permits.
More information can be found in the “What is the flexibility in how a State may choose an appropriate risk level?” section.

**Can a state adopt criteria for similar risk levels for their fresh and marine coastal recreation waters?**

Yes, states may adopt criteria for marine waters with the same risk level as their fresh water criteria. However, for fresh waters, the available data do not allow extrapolating beyond a 1.0% risk level. This means that states that want to use the same or similar risk levels for their fresh and marine coastal recreation waters have several options: they could reduce the risk level for marine waters to no higher than 1%; they could develop the data needed in freshwaters to establish in a scientifically sound manner the relationship between a 1.9% illness rate in freshwater and the corresponding concentration of indicator bacteria in their fresh waters; or they could develop the data needed in freshwaters to establish in a scientifically sound manner the relationship between an illness rate higher than 1% but less than 1.9% and corresponding indicator concentrations in freshwater.

**What is the flexibility in how a State may choose an appropriate risk level for their Great Lakes coastal recreation waters?**

In utilizing risk management discretion, states may wish to establish more than one category of primary contact recreation use in their Great Lakes coastal recreation waters. States opting to protect their fresh coastal recreation waters with criteria associated with risk levels within the 0.8% to 1.0% range should recognize that this is a risk management decision analogous to selecting alternate risk levels when adopting human health criteria for carcinogens, and thus would not require a use attainability analysis (UAA) as described by the federal regulations at 40 CFR 131.10. Additionally, in exercising such discretion, states should assure, however, that downstream uses are protected, including downstream uses across state or tribal boundaries. As with any addition or revision to a state or authorized tribe’s water quality standards, any changes resulting from these risk management decisions are subject to the public participation requirements at 40 CFR 131.20(b).

**To get more information**

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