

economic impact on a substantial number of small entities. Small entities include small businesses, small organizations and small governmental jurisdictions.

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

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

Under the CWA water quality standards program, States must adopt water quality standards for their waters and must submit those water quality standards to EPA for approval; if the Agency disapproves a State standard and the State does not adopt appropriate revisions to address EPA's disapproval, EPA must promulgate standards consistent with the statutory requirements. EPA also has the authority to promulgate criteria or standards in any case where the Administrator determines that a new or revised standard is necessary to meet the requirements of the Act. These State standards (or EPA-promulgated standards) are implemented through various water quality control programs including the NPDES program, which limits discharges to navigable waters except in compliance with an NPDES

permit. The CWA requires that all NPDES permits include any limits on discharges that are necessary to meet applicable water quality standards.

Thus, under the CWA, EPA's promulgation of water quality standards establishes standards that the State generally implements through the NPDES permit process. In this case, however, EPA Region 2 is the NPDES permitting authority in Puerto Rico. As such, EPA Region 2 has discretion in developing discharge limits as needed to meet the standards. While Region 2's implementation of Federally promulgated water quality standards may result in new or revised discharge limits being placed on small entities, the standards themselves do not apply to any discharger, including small entities.

Today's proposed rule, as explained earlier, does not itself establish any requirements that are applicable to small entities. As a result of this action, EPA Region 2 will need to ensure that permits it issues include any limitations on discharges necessary to comply with the standards established in the final rule. In doing so, the Region will have a number of choices associated with permit writing. While the implementation of the rule may ultimately result in some new or revised permit conditions for some dischargers, EPA's action today does not impose any of these as yet unknown requirements on small entities.

#### D. Unfunded Mandates Reform Act

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

adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation of why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including Tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

Today's proposed rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local or Tribal governments or the private sector. The proposed rule imposes no enforceable duty on the Commonwealth of Puerto Rico, or any other State, local or Tribal governments or the private sector; rather, this rule proposes a designated use for primary contact recreation and associated bacteria criteria for the Subject Waterbodies, which, when combined with Commonwealth adopted water quality criteria, constitute water quality standards for those waterbodies. The Commonwealth and EPA may use these resulting water quality standards in implementing its water quality control programs. Today's proposed rule does not regulate or affect any entity and, therefore, is not subject to the requirements of sections 202 and 205 of the UMRA.

EPA has determined that this proposed rule contains no regulatory requirements that might significantly or uniquely affect small governments. As stated, the proposed rule imposes no enforceable requirements on any party, including small governments. Thus, this proposed rule is not subject to the requirements of section 203 of the UMRA.

#### E. Executive Order 13132: Federalism

Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct