

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.

It has been determined that this rule is not a "significant regulatory action" under the terms of Executive Order 12866 and is therefore not subject to OMB review.

#### 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.* This action promulgates new test methods for *E. coli*, enterococci, *Cryptosporidium*, and *Giardia* for use in ambient water monitoring programs. If the regulating authority replaces the indicator organism from fecal coliforms to one of the bacterial organisms (*E. coli* or enterococci) and the relevant NPDES permit requires ambient water monitoring, then the permittee would be required to use one of these approved methods for these organisms. Currently, permittees generally are not required to monitor for *Cryptosporidium* or *Giardia* because EPA has not developed water quality criteria for these protozoans. Burden means that 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 purpose 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 are listed in 40 CFR part 9 and 48 CFR chapter 15.

#### C. Regulatory Flexibility Act

The RFA 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 as defined by the U.S. Small Business Administration definitions at 13 CFR 121.201; (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 final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This regulation promulgates testing procedures for the measurement of *E. coli* and enterococci bacteria, and *Cryptosporidium* and *Giardia* protozoa in ambient water. EPA anticipates that the methods will be used by some State regulatory authorities for evaluating attainment of water quality standards or ambient monitoring requirements. EPA NPDES regulations do not require monitoring of ambient water conditions in NPDES permits. In a few instances, ambient water monitoring requirements may be included in an EPA-issued permit where site-specific circumstances warrant. EPA regulations, do however, require NPDES permittees to use EPA-approved test methods for all monitoring data reported to the Agency (40 CFR 122.21). Consequently, to the extent that an NPDES permit requires monitoring and reporting of ambient water for *E. coli*, enterococci, *Cryptosporidium*, or *Giardia*, EPA approval of these test methods arguably may impose costs on NPDES permit holders, including small entities. EPA is unaware, however, of any EPA-issued NPDES permits that currently require monitoring of ambient water for such pollutants. Hence, EPA does not expect approval of these methods to impose any additional costs as a result of their applicability to EPA issued permits. As

noted above, EPA's NPDES regulations do not require monitoring of ambient water conditions. Consequently, to the extent that a State requires such monitoring, those requirements are imposed under State, rather than Federal, authority. Because States have the discretion not to require such monitoring, any increased costs to small entities arising from use of the methods approved by EPA today that are imposed as a result of State law are not attributable to this regulation.

Nonetheless, EPA evaluated these potential costs to determine whether EPA approval of the methods will have a significant impact on a substantial number of small entities. As previously noted, States may require ambient water monitoring to evaluate attainment of water quality standards. A few States currently require NPDES permit holders to monitor ambient waters. Thus, some NPDES permittees are already testing ambient water for these parameters. The impact of using EPA approved methods for such dischargers may represent little or no increased burden since, for these permittees, the replacement of fecal coliforms with *E. coli* or enterococci would simply require different methods.

The small entities that might be affected by this rule include small governmental jurisdictions that have publicly-owned treatment works (POTWs) and small businesses with water quality-based discharge permits. The average costs for total and fecal coliform were comparable to those for *E. coli* and enterococci (\$35) because the analytical procedures generally employ similar techniques, media, equipment, and require comparable laboratory time and effort. Some States are already using the methods for *E. coli* and enterococci in State ambient water quality monitoring programs. This rule would formalize current practice in those States. Furthermore, EPA expects that any modest potential increase in costs for enterococci analyses will be reduced once the promulgated methods are broadly implemented by environmental laboratories and State water quality monitoring programs.

EPA also reviewed the costs for testing for *Cryptosporidium* and *Giardia*. The costs for Methods 1622 and 1623 analysis of *Cryptosporidium* and *Giardia* range from \$400 to \$500 for each sample (with matrix spikes being assessed as individual samples) for each method. Because of the relatively high costs, EPA does not anticipate that these test methods will be used for daily or ongoing monitoring, but they may be used for program-specific occurrence assessments.