

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 are listed in 40 CFR part 9 and 48 CFR chapter 15.

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 impact of today's final rule on small entities, a small entity is defined as (1) a small business with gross revenue under \$6 million (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 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. It merely clarifies applicable dates, corrects an inadvertent error and omission, and makes other non-substantive edits. As explained above, the change to the PSNS sections of the regulation merely removes any ambiguity about the applicability of the earlier 1983 pretreatment standards during the 10-year protection period prior to November 20, 1998, and makes them consistent with the latest NSPS sections. The PSNS revision does not

establish any new requirements with respect to those subject to the regulation. The other changes similarly would have either no effect on the regulated entities, or at most an inconsequential effect. The deletion of methyl Cellosolve would reduce the economic impacts of the regulation on those entities, including small entities, subject to pretreatment standards in the two subparts which currently contain methyl Cellosolve as a regulated parameter. In addition, as noted above, the revision to re-establish the minimum concentration for BOD₅ would correct an earlier inadvertent omission and reflect the requirements of existing discharge permits.

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. 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 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.

EPA has determined that this final rule does not contain a Federal mandate that may result in expenditures of \$100 million or more for State, local and tribal governments, in the aggregate, or the private sector in any one year. It merely clarifies applicable dates, corrects an inadvertent error and omission, and makes other non-substantive edits. Thus, today's rule is not subject to the requirements of sections 202 and 205 of UMRA.

For the same reason, EPA has determined that this final rule contains no regulatory requirements that might significantly affect small governments. The final rule does not uniquely affect small governments because small and large governments are affected in the same way. Thus, today's rule is not subject to the requirements of section 203 of UMRA.

E. Executive Order 13132: Federalism

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

This 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. Today's rule amends effluent limitations and pretreatment standards which impose requirements that apply to facilities when they discharge wastewater or introduce wastewater to a POTW. It merely clarifies applicable dates, corrects an inadvertent error, and omission, and makes other non-substantive edits. EPA has determined that there are no pharmaceutical facilities owned and/or operated by State or local governments that would be subject to today's rule. Further, the rule would only incidentally affect State and local governments in their capacity as implementers of CWA NPDES permitting programs. Thus, Executive Order 13132 does not apply to this rule.