

## CHAPTER 8. STATUTORY AND EXECUTIVE ORDER REVIEWS

### *A. Executive Order 12866: Regulatory Planning and Review*

Under section 3(f)(1) of Executive Order (EO) 12866 (58 FR 51735, October 4, 1993), this action is an “economically significant regulatory action” because it is likely to have an annual effect on the economy of \$100 million or more. Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under EO 12866 and any changes made in response to OMB recommendations have been documented in the docket for this action (EPA-HQ-OAR-2006-0735). In addition, EPA prepared this Regulatory Impact Analysis (RIA) of the potential costs and benefits associated with this action. However, the CAA and judicial decisions make clear that the economic and technical feasibility of attaining ambient standards are not to be considered in setting or revising NAAQS, although such factors may be considered in the development of State plans to implement the standards. Accordingly, although an RIA has been prepared, the results of the RIA have not been considered in issuing the final rule.

### *B. Paperwork Reduction Act*

The information collection requirements in this final rule will be submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. The information collection requirements are not enforceable until OMB approves them.

The information collected under 40 CFR part 53 (e.g., test results, monitoring records, instruction manual, and other associated information) is needed to determine whether a candidate method intended for use in determining attainment of the National Ambient Air Quality Standards (NAAQS) in 40 CFR part 50 will meet the design, performance, and/or comparability requirements for designation as a Federal reference method (FRM) or Federal equivalent method (FEM). While this final rule amends the requirements for Pb FRM and FEM determinations, they merely provide additional flexibility in meeting the FRM/FEM determination requirements. Furthermore, we do not expect the number of FRM or FEM determinations to increase over the number that is currently used to estimate burden associated with Pb FRM/FEM determinations provided in the current ICR for 40 CFR part 53 (EPA ICR numbers 0559.12). As such, no change in the burden estimate for 40 CFR part 53 has been made as part of this rulemaking.

The information collected and reported under 40 CFR part 58 is needed to determine compliance with the NAAQS, to characterize air quality and associated health and ecosystem impacts, to develop emissions control strategies, and to measure progress for the air pollution program. The proposed amendments would revise the technical requirements for Pb monitoring sites, require the siting and operation of additional Pb ambient air monitors, and the reporting of the collected ambient Pb monitoring data to EPA’s Air Quality System (AQS). We have estimated the burden based on the final

monitoring requirements of this rule. Based on these requirements, the annual average reporting burden for the collection under 40 CFR part 58 (averaged over the first 3 years of this ICR) for 150 respondents is estimated to increase by a total of 42,165 labor hours per year with an increase of \$3,207,407 per year. Burden is defined at 5 CFR 1320.3(b).

### *C. Regulatory Flexibility Act*

The Regulatory Flexibility Act (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 this rule on small entities, small entity is defined as: (1) a small business that is a small industrial entity as defined by the Small Business Administration's (SBA) regulations 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 this final rule on small entities, the Administrator certified this action will not have a significant economic impact on a substantial number of small entities. This final rule will not impose any requirements on small entities. Rather, this rule establishes national standards for allowable concentrations of Pb in ambient air as required by section 109 of the CAA. *American Trucking Ass'ns v. EPA*, 175 F. 3d 1027, 1044-45 (D.C. cir. 1999) (NAAQS do not have significant impacts upon small entities because NAAQS themselves impose no regulations upon small entities). Similarly, the amendments to 40 CFR part 58 address the requirements for States to collect information and report compliance with the NAAQS and will not impose any requirements on small entities.

### *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. Unless otherwise prohibited by law, 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 required under section 202, section 205 of the UMRA generally requires EPA to identify and

consider a reasonable number of regulatory alternatives and to 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.

This action is not subject to the requirements of sections 202 and 205 of the UMRA. 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. The revisions to the Pb NAAQS impose no enforceable duty on any State, local or Tribal governments or the private sector. The expected costs associated with the increased monitoring requirements are described in EPA's ICR document, but those costs are not expected to exceed \$100 million in the aggregate for any year. Furthermore, as indicated previously, in setting a NAAQS EPA cannot consider the economic or technological feasibility of attaining ambient air quality standards. Because the Clean Air Act prohibits EPA from considering the types of estimates and assessments described in section 202 when setting the NAAQS, the UMRA does not require EPA to prepare a written statement under section 202 for the revisions to the Pb NAAQS.

EPA has determined that this final rule contains no regulatory requirements that might significantly or uniquely affect small governments because it imposes no enforceable duty on any small governments. Therefore, this 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 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. The rule does not alter the relationship between the Federal government and the States regarding the establishment and implementation of air quality improvement programs as codified in the CAA. Under section 109 of the CAA, EPA is mandated to establish NAAQS; however, CAA section 116 preserves the rights of States to establish more stringent requirements if deemed necessary by a State. Furthermore, under CAA section 107, the States have primary responsibility for implementation of the NAAQS. Finally, as noted in section E (above) on UMRA, this rule does not impose significant costs on State, local, or tribal governments or the private sector. Thus, Executive Order 13132 does not apply to this rule.

*F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments*

This action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). It does not have a substantial direct effect on one or more Indian Tribes, since Tribes are not obligated to adopt or implement any NAAQS or monitoring requirements for NAAQS. Thus, Executive Order 13175 does not apply to this action.

*G. Executive Order 13045: Protection of Children from Environmental Health & Safety Risks*

This action is subject to EO 13045 (62 FR 19885, April 23, 1997) because it is an economically significant regulatory action as defined by EO 12866, and we believe that the environmental health risk addressed by this action has a disproportionate effect on children. The final rule establishes uniform national ambient air quality standards for Pb; these standards are designed to protect public health with an adequate margin of safety, as required by CAA section 109. However, the protection offered by these standards may be especially important for children because neurological effects in children are among if not the most sensitive health endpoints for Pb exposure. Because children are considered a sensitive population, we have carefully evaluated the environmental health effects of exposure to Pb pollution among children. These effects and the size of the population affected are summarized in chapters 6 and 8 of the Criteria Document and sections 3.3 and 3.4 of the Staff Paper, and the results of our evaluation of the effects of Pb pollution on children are discussed in sections II.B and II.C of the notice of proposed rulemaking, and section II.A of this preamble.

*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. The purpose of this rule is to establish revised NAAQS for Pb. The rule does not prescribe specific control strategies by which these ambient standards will be met. Such strategies will be developed by States on a case-by-case basis, and EPA cannot predict whether the control options selected by States will include regulations on energy suppliers, distributors, or users. Thus, EPA concludes that this rule is not likely to have any adverse energy effects.

#### *H. National Technology Transfer and Advancement Act*

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law No. 104-113, §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.

This final rule involves technical standards. EPA has established low-volume PM<sub>10</sub> samplers coupled with XRF analysis as the FRM for Pb-PM<sub>10</sub> measurement. While EPA identified the ISO standard “Determination of the particulate lead content of aerosols collected on filters” (ISO 9855: 1993) as being potentially applicable, the final rule does not permit its use. EPA determined that the use of this voluntary consensus standard would be impractical because the analysis method does not provide for the method detection limits necessary to adequately characterize ambient Pb concentrations for the purpose of determining compliance with the revisions to the Pb NAAQS.

#### *J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations*

Executive Order 12898 (59 FR 7629; Feb. 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this final rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it increases the level of environmental protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population. The final rule

establishes uniform national standards for Pb in ambient air. In the Administrator's judgment, the revised Pb NAAQS protect public health, including the health of sensitive groups, with an adequate margin of safety.

However, EPA believes that the newly strengthened Pb standards and the new requirements for ambient air monitoring for Pb will have the greatest benefit in reducing health risks associated with exposure to ambient air Pb in those areas where ambient air concentrations are currently the highest. Thus, to the extent that any population groups, including minorities or low-income populations, are currently experiencing disproportionate exposure to ambient air-related Pb, those groups can be expected to experience relatively greater air quality improvements under the revised standards. Nationwide, these revised, more stringent standards will not have adverse health impacts on any population, including any minority or low-income population.