



**United States
General Accounting Office
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Office of the General Counsel

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October 1, 1997

The Honorable John H. Chafee
Chairman
The Honorable Max Baucus
Ranking Minority Member
Committee on Environment and Public Works
United States Senate

The Honorable Thomas J. Bliley, Jr.
Chairman
The Honorable John D. Dingell
Ranking Minority Member
Committee on Commerce
House of Representatives

Subject: Environmental Protection Agency: Standards of Performance for New Stationary Sources and Emission Guidelines for Existing Sources: Hospital/Medical/Infectious Waste Incinerators

Pursuant to section 801(a)(2)(A) of title 5, United States Code, this is our report on a major rule promulgated by the Environmental Protection Agency (EPA), entitled "Standards of Performance for New Stationary Sources and Emission Guidelines for Existing Sources: Hospital/Medical/Infectious Waste Incinerators" (RIN: 2060-AC62). We received the rule on September 16, 1997. It was published in the Federal Register as a final rule on September 15, 1997. 62 Fed. Reg. 48348.

The final rule promulgates new source performance standards for hospital/medical/infectious waste incinerators (HMIWI) and emission standards for existing HMIWI's to reduce air emissions.

Enclosed is our assessment of the EPA's compliance with the procedural steps required by section 801(a)(1)(B)(i) through (iv) of title 5 with respect to the rule. Our review indicates that the EPA complied with the applicable requirements.

If you have any questions about this report, please contact James Vickers, Assistant General Counsel, at (202) 512-8210. The official responsible for GAO evaluation

work relating to the Environmental Protection Agency is Peter Guerrero, Director, Environmental Protection Issues. Mr. Guerrero can be reached at (202) 512-6111.

Robert P. Murphy
General Counsel

Enclosure

cc: Mr. Thomas E. Kelly
Director, Office of Regulatory
Management and Information
Environmental Protection Agency

ANALYSIS UNDER 5 U.S.C. § 801(a)(1)(B)(i)-(iv) OF A MAJOR RULE
ISSUED BY
THE ENVIRONMENTAL PROTECTION AGENCY
ENTITLED
"STANDARDS OF PERFORMANCE FOR NEW STATIONARY SOURCES AND
EMISSION GUIDELINES FOR EXISTING SOURCES:
HOSPITAL/MEDICAL/INFECTIOUS WASTE INCINERATORS"
(RIN: 2060-AC62)

(i) Cost-benefit analysis

EPA performed a Regulatory Impact Analysis which included a cost-benefit analysis. The analysis discusses the costs and benefits of six regulatory options which were considered by EPA. The costs of the selected options in the final rule are estimated to be between \$71 million and \$146 million per year. The costs depend on the degree to which entities switch their current methods of disposal and the degree to which additional waste segregations (infectious and non-infectious waste) are performed.

EPA states that it cannot quantify or monetize many of the benefits, such as the reduction in the emission of hazardous air pollutants which include cadmium, hydrogen chloride, lead, mercury, and dioxin/furan. In addition, reductions in emissions of particulate matter, sulfur dioxide, carbon monoxide, and nitrogen oxides are expected. EPA did quantify the benefits from the reduction in particulate matter to be \$6075/ton reduced, resulting in benefits valued at \$5.5 million to \$5.8 million per year

(ii) Agency actions relevant to the Regulatory Flexibility Act, 5 U.S.C. §§ 603-605, 607, and 609

Following an analysis of the impacts of the emission guidelines and new stationary source performance standards on small entities, the Administrator of the EPA has determined that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, EPA determined that it was not necessary to prepare a Regulatory Flexibility Analysis under the act.

(iii) Agency actions relevant to sections 202-205 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. §§ 1532-1535

Based on the cost-benefit analysis performed by EPA, it is estimated that the final rule will impose costs on the private sector and governmental entities in excess of

\$100 million per year. Therefore, EPA has prepared the statement required by the Unfunded Mandates Reform Act of 1995.

EPA's statement, contained in the preamble to the final rule, gives the statutory authority for the action; a summary of the costs and benefits contained in the Regulatory Impact Analysis, in both qualitative and quantitative terms; and a description of EPA's consultation efforts with state, local, and tribal officials. Also, EPA describes the regulatory alternatives it considered and why it finds the rule to be the most cost-effective alternative for regulation of these sources which meets the statutory requirements of the Clean Air Act.

(iv) Other relevant information or requirements under acts and executive orders

Administrative Procedure Act, 5 U.S.C. §§ 551 et seq.

Instead of the notice and comment procedures in the Administrative Procedure Act, EPA promulgated this rule using the procedures, which have similar notice and comment requirements, contained in section 307(d) of the Clean Air Act, as amended. 42 U.S.C. § 7607(d). The use of these procedures regarding rules pertaining to standards of performance is mandated by section 307(d)(1)(C) of the Clean Air Act. 42 U.S.C. § 7607(d)(1)(C).

On February 27, 1995 (60 Fed. Reg. 10654), EPA issued proposed new source performance standards and emission guidelines for HMIWI's. After receiving over 700 comments, EPA reevaluated every aspect of the proposed standards and guidelines.

This resulted in an announcement on June 20, 1996 (61 Fed. Reg. 31736), in the Federal Register advising the public of the availability of the new information and how EPA may change the standards and guidelines in response. Based on comments received, EPA considered the June 20 announcement as a re-proposal and held a public meeting to review the contents of the re-proposal. In addition, EPA received another 70 comments. EPA discusses the comments it received and its response to them in the preamble to the final rule.

Paperwork Reduction Act, 44 U.S.C. §§ 3501-3520

The final rule contains an information collection requirement that is subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. EPA has submitted the collection requirement to OMB for approval and it will not have to be complied with until OMB issues its approval.

The preamble summarizes the information forwarded to OMB. The requirement, based on EPA's prediction of 14 new HMIWI's constructed in a year, has an

estimated total burden hours for completing the required report of 14,106 person hours per year. EPA also explains the need for the report and the steps it took to reduce the burden, including test emissions once every 3 years instead of annually if they demonstrate that they consistently meet the emissions requirement.

Statutory authorization for the rule

The final rule was promulgated pursuant to sections 111 and 129 of the Clean Air Act, as amended, 42 U.S.C. §§ 7411 and 7429.

Executive Order No. 12866

The final rule has been determined to be an "economically significant regulatory action" by the Office of Management and Budget and was approved by OMB on August 14, 1997, as complying with the requirements of the executive order.