POSTAL SERVICE

39 CFR Part 960

Implementation of the Contract With America Advancement Act

AGENCY: Postal Service.

ACTION: Final rule.

SUMMARY: The Postal Service is amending the rules implementing the Equal Access to Justice Act in Postal Service proceedings to reflect the statutory increase in the amount of the hourly fees payable.

EFFECTIVE DATE: November 2, 2001.

FOR FURTHER INFORMATION CONTACT: Diane M. Mego, (703) 812–1905.

SUPPLEMENTARY INFORMATION: The Contract with America Advancement Act of 1996 (Pub. L. 104–121, 110 Stat. 857 (1996)) increased the maximum amount of attorney fees under the Equal Access to Justice Act from $75 per hour to $125 per hour. This rulemaking amends 39 CFR part 960 to conform with the statutory change. In addition, language specifying the allowable fees for expert witnesses is being deleted.

These are statutorily mandated changes in agency rules of procedure before the Judicial Officer and, therefore, it is appropriate for their adoption by the Postal Service to become effective immediately.

List of Subjects in 39 CFR Part 960

Administrative practice and procedure, Equal access to justice, Postal Service.

Accordingly, the Postal Service adopts amendments to 39 CFR part 960 as specifically set forth below:

PART 960—[AMENDED]

1. The authority citation for part 960 continues to read as follows:

Authority: 5 U.S.C. 504 (c) (1); 39 U.S.C. 204, 401 (2).

§ 960.6 [Amended]

2. Section 960.6(b) is amended by removing ''$75.00 per hour'' and adding $125.00 per hour, or such rate as prescribed by 5 U.S.C. 504''.

3. Section 960.6(b) is further amended by removing '', which is generally $50.00 per hour''.

§ 960.7 [Amended]

4. Section 960.7(a) is amended by removing ''$75 per hour'' and adding ''$125.00 per hour, or such rate as prescribed by 5 U.S.C. 504,''.

Stanley F. Mires,

Chief Counsel, Legislative.

[FR Doc. 01–27626 Filed 11–1–01; 8:45 am]

BILLING CODE 7710–12–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[AD–FRL–7096–1]

RIN 2060–AC28

Ethylene Oxide Emissions Standards for Sterilization Facilities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; amendments.

SUMMARY: This action finalizes amendments to the emissions standards for sterilization facilities by eliminating maximum achievable control technology (MACT) requirements for chamber exhaust vents. This action reduces safety problems associated with the existing requirements. This action also amends testing and monitoring requirements for sterilization chamber, aeration, and chamber exhaust vents to correct technical problems associated with the existing requirements.

EFFECTIVE DATE: November 2, 2001.

ADDRESSES: Docket No. A–88–03 contains supporting information used in developing the standards for the ethylene oxide commercial sterilization source category. The docket is located at the U.S. EPA, 401 M Street, SW., Washington, DC 20460 in Room M–1500, Waterside Mall (ground floor), and may be inspected from 8:30 a.m. to 5:30 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. David W. Markwordt, Policy, Planning, and Standards Group, Emission Standards Division (MD–13), U.S. EPA, Research Triangle Park, North Carolina 27711, telephone number (919) 541–0837, facsimile (919) 541–0942, electronic mail address: *markwordt.david@epa.gov.*

SUPPLEMENTARY INFORMATION: *Docket.* The docket is an organized and complete file of all the information considered by EPA in the development of this rulemaking. The docket is a dynamic file because material is added throughout the rulemaking process. The docketing system is intended to allow members of the public and industries involved to readily identify and locate documents so that they can effectively participate in the rulemaking process. Along with the proposed and promulgated standards and their preambles, the contents of the docket will serve as the record in the case of judicial review. (See section 307(d)(7)(A) of the Clean Air Act (CAA).) The regulatory text and other materials related to this rulemaking are available for review in the docket or copies may be mailed on request from the Air Docket by calling (202) 260–7548. A reasonable fee may be charged for copying docket materials.

World Wide Web (WWW). In addition to being available in the docket, an electronic copy of today's final rule amendments will also be available on the WWW through the EPA's Technology Transfer Network (TTN). Following signature, a copy of the rule amendments will be posted on the TTN's policy and guidance page for newly proposed or promulgated rules, *http://www.epa.gov/ttn/oarpg.* The TTN provides information and technology exchange in various areas of air pollution control. If more information regarding the TTN is needed, call the TTN HELP line at (919) 541–5384.

Regulated Entities. Categories and entities regulated by this action include:

Category	SIC [a]/NAICS [b]	Examples of regulated entities
Industry	3841, 3842 ...	Medical suppliers.
	2834, 5122, 2831, 2833	Pharmaceuticals.
	2099, 5149, 2034, 2035, 2046	Spice manufacturers.
	7399, 7218, 8091	Contract sterilizers.

[a] Standard Industrial Classification Code.
[b] North American Information Classification System.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. To determine whether your facility is regulated by this action, you should examine the applicability criteria in § 63.2131 of the final rule.

Judicial Review. Under section 307(b) of the CAA, judicial review of this final rule is available only by filing a petition for review in the U.S. Court of Appeals for the District of Columbia Circuit by January 2, 2002. Under section 307(d)(7)(B) of the CAA, only an objection to these rule amendments which was raised with reasonable specificity during the period for public comment can be raised during judicial review. Moreover, under section

307(b)(2) of the CAA, the requirements established by today's final action may not be challenged separately in any civil or criminal proceeding we bring to enforce these requirements.

I. Background

On July 11, 1997, we learned of reports of explosions at several ethylene oxide sterilization facilities. Some of the explosions occurred at facilities affected by the ethylene oxide emissions standards. As a result, we took immediate steps to suspend the rule until December 1998 pending an investigation of the explosions and to notify facility owners.

We completed our investigation in 1998 to determine if the emission control equipment mandated by the emissions standards was in any way associated with the problems at these facilities. We agreed with industry that, in the cases where explosions occurred, the catalytic oxidizer units were overfed with ethylene oxide in concentrations above the safe operations limit due to abnormal activation of the chamber exhaust (backvent). In June 1998, the Ethylene Oxide Sterilization Association (EOSA) recommended ''additional time to consider safe and economical control, installation, operation, and maintenance alternatives applicable to aeration and chamber exhaust (backvent) emissions.'' The EOSA provided a time line of approximately 12 months beyond December 1998 to enable implementation of the appropriate changes to ensure safe operation. We agreed with EOSA's recommendation and further extended the compliance date for chamber exhaust and aeration room vents for all sources affected by the ethylene oxide emissions standards by 1 year, until December 8, 1999. The two affected emission points, the chamber exhaust and aeration room vent, represent approximately 1 and 3 percent of the uncontrolled emissions, respectively.

In June 1999, the EOSA requested elimination of the requirement for chamber exhaust vent controls. In December 1999, we again suspended the compliance dates for chamber exhaust and aeration room vents. A 1-year suspension of control requirements for aeration room vents was based on the fact that many facilities are routing chamber exhaust emissions to the emission control device for aeration room vents. Since control of the aeration room vent by itself does not pose any known safety problems, we did not anticipate any further suspensions of requirements for aeration room vents beyond December 6, 2000. We provided a 2-year suspension of control requirements for chamber exhaust vent emissions based on the anticipated time required to propose and promulgate changes in the **Federal Register**. We committed to reconsidering the original MACT determination for chamber exhaust vents and proposing a course of action in the near future.

The use of existing technology by some sources in the relevant industry category presumes the ability to operate that technology in a proven safe manner. Nonetheless, at the time of promulgation (December 1994), state-of-the-art control technology for chamber exhaust vent emissions apparently involved safety hazards not known at that time. To date, solutions to the safety problems have not been developed, and there is no indication that resolution of the safety issues is forthcoming. Consequently, on March 6, 2001, we proposed eliminating the MACT requirements for chamber exhaust vents (66 FR 13464). We also proposed amendments to testing and monitoring requirements for sterilization chamber, aeration, and chamber exhaust vents.

II. What Are the Final Rule Amendments?

A. Chamber Exhaust Vents

We have removed the requirement to control the ethylene oxide emissions from the chamber exhaust vents. See the March 6, 2001 proposal preamble for the detailed reasons for this change. For all facilities (i.e., both major and area sources), we have removed the 5,300 parts per million per volume (ppmv) concentration limit requirement for chamber exhaust vents.

B. Catalytic Oxidizer Monitoring

We have removed the requirement to operate at the average temperature to demonstrate continuous compliance. We are now requiring facilities to maintain a minimum temperature for catalytic oxidizers based on manufacturer design and perform a work practice. Facilities can do either of the following work practices: periodically replace catalyst, or annually test control device performance and if necessary restore the catalyst.

We have made changes to the monitoring requirements to provide facilities an alternative to continuous catalyst temperature monitoring. Facilities can monitor either temperature or ethylene oxide concentration for catalytic oxidizers. In the final rule, we have added several additional test method to measure ethylene oxide concentration.

III. What Major Changes Have We Made to the Rule Since Proposal?

In response to comments received on the proposed amendments, we made several changes for the final rule. While some of the changes we made were clarifications designed to make our intentions more clear, some of the changes do alter the requirements as proposed. The substantive comments and/or changes and responses made since the proposal are summarized in the following sections. Our complete responses to public comments are contained in a memorandum that can be obtained from docket A–88–03.

A. Elimination of 5,300 ppmv Concentration Requirement

To ensure that the current amount of ethylene oxide being evacuated via the sterilization pump continues to be routed to a control device rather than exhausted via an uncontrolled vent, we proposed a concentration-based limit on emissions from major source chamber exhaust vents. In the original, existing rule, this requirement currently applies to area sources but not to major sources.

Comments: Commentors questioned ''the Agency's reliance on the 5,300 ppmv empty chamber concentration as a suitable limitation when such test conditions have zero connection to the reality of operations in a commercial sterilization facility.'' The commentor also stated that their research showed ''no reliable justification for the 5,300 ppmv MACT and we are convinced from our own experience that this level, however determined, was unfounded at the time the regulation was originally drafted.''

One commentor stated that industry does not have knowledge of any proven instrumentation it could employ to comply with the proposed requirement to determine the concentration of ethylene oxide in the sterilization chamber immediately prior to the operation of the chamber exhaust. The commentor stated it is universally known and understood that a safe, reliable and accurate technology capable of providing a determination of the exhaust vent concentration is not available. The commentor also stated that a separate system (suitable for small exhaust, high concentration, for a short time period of 5 minutes or less) would be needed, probably for each chamber. If gas chromatography (GC)-based systems are used, costs are $60,000–$100,000 per chamber, provided some existing system could somehow be made safe, reliable, and accurate. Also,

units for area and process control are not satisfactory because they are set up differently and measure different concentration levels.

Response: As stated previously, the Agency is removing the control requirement for the major source chamber exhaust vent as proposed. The Agency had also proposed a 5,300 ppmv concentration limit on the chamber exhaust vent for larger facilities (i.e., major sources). The 5,300 ppmv concentration limit was required in the original rule for smaller facilities (i.e., area sources with 1 to 10 tons of ethylene oxide use) which were not required to control chamber exhaust vent emissions.

We agree with the commentor that the 5,300 ppmv concentration limit was based on ''Agency modeling, not actual operating conditions.'' We also agree with the commentor that there is no proven instrumentation which could be employed to comply with the proposed requirement to determine the concentration of ethylene oxide in the sterilization chamber immediately prior to the operation of the chamber exhaust. For these reasons, we have reconsidered the proposed and existing concentration limit requirement.

The sterilization chamber vent emissions are currently controlled with add-on control devices; these devices are required to reduce inlet emissions by 99 percent. For small facilities, under the existing rule the MACT floor for new and existing source chamber exhaust vents requires no reduction in emissions from these vents. The purpose of the existing rule's 5,300 ppmv limitation on the small chamber exhaust vents is to ensure that the current amount of ethylene oxide being evacuated via the sterilization pump continues to be routed to a control device rather than exhausted via an uncontrolled vent. The 5,300 ppmv requirement maintained the status quo for emissions from the chamber exhaust vent, and did not require the use of any control technologies. In promulgating the existing rule, the Administrator determined that the use of this limit did not constitute measures beyond the MACT floor for these sources (59 FR 10591). The chamber exhaust concentration limit was added to the rule as a precautionary measure; the Agency did not know of any plant operators by-passing main sterilization vent control devices.

Comment: One commentor recommended a 7,500 ppmv limit (25 percent of the lower explosive limit); the limit would be determined based on empty chamber cycle calculations for all cycles. This approach does not require test equipment. The commentor stated that it is common industry practice to analyze the safety of a sterilization cycle by calculating the residual sterilant in an empty sterilizer at the completion of the process. Most sterilization facilities require that the safety analysis be performed on every new sterilization cycle. The intent of the safety analysis is to demonstrate that the concentration of ethylene oxide gas in the sterilizer at the end of processing is below 1 percent (10,000 ppmv). This ensures that during routine processing the sterilizer environment is non-flammable when the door is opened and the exhaust vent is activated. The determination of this empty chamber concentration relies on simple dilution formulas and the ideal gas laws. Using partial pressure data of ethylene oxide in the sterilizer following the initial charge, one can determine concentration through the subsequent evacuation and purging sequences. The commentor stated that sterilization cycles in question are generally validated to meet the requirements of the Food and Drug Administration (FDA).

Another commentor believes the present regulations provide adequate assurance to ensure that ethylene oxide from the sterilization chamber vent continues to be routed through a control device. The EPA specifically defines sterilization chamber vent as ''* * * the point (prior to the vacuum pump) through which the evacuation of ethylene oxide from the sterilization chamber occurs following sterilization or fumigation, including any subsequent air washes.'' The rule also specifically requires that sources using greater than 1 ton per year of ethylene oxide ''* * * shall reduce ethylene oxide emissions to the atmosphere by at least 99 percent from each sterilization chamber vent.''

Rerouting sterilization chamber vents to exhaust out the uncontrolled chamber exhaust vent would be in direct violation of the present regulation.

Response: After considering the comments and additional information, we decided that the concentration limit approach is not feasible because there is no known way to safely measure concentration. A gas chromatograph is a logical testing approach but it includes a flame source which introduces a safety issue.

Today, we have less concern regarding by-passing the main sterilization control equipment by routing ethylene oxide to the chamber exhaust vent. As stated previously, there were no data suggesting plant operators were by-passing the main control device. Since initial work on the rule in the 1980's, significant regulatory changes have occurred which have affected the sterilization industry. In response to the phase-out of chlorofluorocarbon production, industry switched from a mixture of chlorofluorocarbons and ethylene oxide to pure ethylene oxide for processing. The Occupational Safety and Health Administration (OSHA) tightened workplace ethylene oxide concentration exposure limits, and on October 7, 1996, the FDA revised the Current Good Manufacturing Practice (CGMP) requirements for medical devices and incorporated them into a quality system regulation.

Now that the use of pure ethylene oxide dominates industry practice, there are serious safety issues associated with by-passing the main control device. Venting pure ethylene oxide to the atmosphere could cause an explosion. Additionally, it is probable that venting would result in workplace exposure concentrations which would violate the OSHA limits. Industry is very aware of these safety concerns.

The FDA quality system regulation includes requirements related to the methods used in, and the facilities and controls used for, designing, manufacturing, packaging, labeling, storing, installing, and servicing of medical devices intended for human use. The action was necessary to add preproduction design controls and to achieve consistency with quality system requirements worldwide. The regulation sets forth the framework for device manufacturers to follow and gives them greater flexibility in achieving quality requirements (61 FR 52601).

These requirements apply to contract sterilization and specify quality system requirements including management controls, design controls, material controls, equipment controls, production and process controls, corrective and preventive action, and documentation. For sterilization operations, the objectives of the quality system regulation apply only to the safety and effectiveness of medical devices following sterilization. However, compliance with its requirements may also provide an assurance that processing will be performed in a way which meets concerns regarding vent emissions. For example, in meeting the requirement in the quality system regulation for a definition of specifications for all steps of the process, a sterilizing facility must specify the number of air washes in the ethylene oxide sterilization process. By meeting the requirements for documentation to demonstrate that each process step has been performed as specified, the facility will establish

procedures to document performance of the air washes. The requirements of the quality system are already in place; compliance with the quality system regulation will ensure that specifications for process steps are defined and met.

The Agency believes there are sufficient practical reasons (i.e., safety considerations as well as existing OSHA and FDA regulatory requirements) for eliminating our original presumptive need for the chamber exhaust emission limit. The Agency sees no practical benefit to adding additional requirements to accomplish the same thing. Therefore, because the concentration cannot be measured and there is now little or no value to the requirement, we are not promulgating the chamber exhaust concentration limit for large facilities and are withdrawing the requirement for small facilities.

B. Alternative to Catalyst Replacement Requirement

We proposed a requirement to replace catalytic oxidizer catalyst every 2 years to ensure that the catalyst remains active and in continuous compliance with the control device performance requirement. The proposed replacement of catalyst every 2 years was opposed by commentors because the practice was believed to be wasteful and costly. Some commentors stated that the compliance test should suffice to indicate compliance.

We agreed with the commentors that performance testing is a viable alternative to routine replacement of catalyst in ensuring continuous compliance. Therefore, we have added a test alternative to the rule. If test results show the control efficiency is below the performance standard, the facility will have to restore the catalyst as soon as practicable but no later than 180 days after the performance test.

IV. Summary of Environmental, Energy and Economic Impacts

There are negligible environmental, energy, and economic impacts associated with these amendments. Ethylene oxide emissions from the chamber exhaust vent comprise less than 1 percent of the uncontrolled emissions from the sterilization process.

V. Administrative Requirements

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), we must determine whether the regulatory action is ''significant'' and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. The Executive Order defines ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the 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 this Executive Order.

Pursuant to the terms of Executive Order 12866, it has been determined that these rule amendments are not a ''significant regulatory action'' under the terms of Executive Order 12866. Consequently, this action was not submitted to OMB for review under Executive Order 12866.

B. Paperwork Reduction Act

The information collection requirements of the ethylene oxide national emission standards for hazardous air pollutants (NESHAP) were submitted to and approved by OMB. A copy of the Information Collection Request (ICR) document (OMB control number 2060–0283) may be obtained from Ms. Sandy Farmer by mail at the U.S. EPA, Office of Environmental Information, Collection Strategies Division (2822), 1200 Pennsylvania Avenue, Washington, DC 20460, by e-mail at *farmer.sandy@epa.gov*, or by calling (202) 260–2740. A copy may also be downloaded off the Internet at *http://www.epa.gov/icr*.

Today's action has little or no impact on the information collection burden estimates made previously. Today's action eliminates requirements for chamber exhaust vents and clarifies testing and monitoring requirements for sterilization and aeration room vents. These changes revise existing requirements and do not impose new additional burdens; consequently, the ICR has not been revised.

C. 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.''

These final rule amendments 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 final rule is mandated by statute and does not impose requirements on States; however, States will be required to implement the rule by incorporating the rule into permits and enforcing the rule upon delegation. States will collect permit fees that will be used to offset the resource burden of implementing the rule. Thus, the requirements of section 6 of the Executive Order do not apply to this rule. Although section 6 of Executive Order 13132 does not apply to this rule, the EPA did consult with State and local officials in developing these rule amendments.

D. Executive Order 13175, Consultation and Coordination with Indian Tribal Governments

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 6, 2000), requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.''

These final rule amendments do not have tribal implications. They will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. This is because no tribal governments own or operate an ethylene oxide sterilization facility. Thus, Executive

Order 13175 does not apply to these rule amendments.

E. Unfunded Mandates Reform Act of 1995

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, the 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 by State, local, and tribal governments, in aggregate, or by the private sector, of $100 million or more in any 1 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 the 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 as to why that alternative was not adopted. Before the 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 final rule amendments contain no 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 1 year. These amendments eliminate existing requirements. Thus, today's final rule amendments are not subject to the requirements of sections 202 and 205 of the UMRA. In addition, the EPA has determined that these amendments contain no regulatory requirements that might significantly or uniquely affect small governments because it contains no regulatory requirements that apply to such governments or impose obligations upon them. Therefore, today's final rule amendments are not subject to the requirements of section 203 of the UMRA.

Because these final rule amendments do not include a Federal mandate and are estimated to result in expenditures less than $100 million in any 1 year by State, local, and tribal governments, the EPA has not prepared a budgetary impact statement or specifically addressed the selection of the least costly, most cost-effective, or least burdensome alternative. In addition, because small governments will not be significantly or uniquely affected by these rule amendments, the EPA is not required to develop a plan with regard to small governments. Therefore, the requirements of the UMRA do not apply to this action.

F. Regulatory Flexibility Act (RFA) as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) 5 U.S.C. 601 et seq.

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 final rule amendments on small entities, small entity is defined as: (1) A small business according to the Small Business Administration (SBA) size standards by NAICS code ranging from 500 to 1,000 employees; (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 amendments on small entities, EPA has concluded that this action will not have a significant impact on a substantial number of small entities. We believe there will be little or no impact on any small entities because these amendments do not impose additional requirements but instead either eliminate or streamline some existing requirements of the ethylene oxide NESHAP. Based on the foregoing, the EPA concludes that these rule amendments will not have a significant impact on a substantial number of small businesses.

Although these final rule amendments will not have a significant impact on a substantial number of small entities, EPA nonetheless has tried to reduce the impact on small entities by providing alternatives to compliance and monitoring requirements.

G. National Technology Transfer and Advancement Act of 1995

Section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) of 1995 (Public Law 104–113; 15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in their regulatory and procurement 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, business practices) developed or adopted by one or more voluntary consensus bodies. The NTTAA directs EPA to provide Congress, through annual reports to OMB, with explanations when an agency does not use available and applicable voluntary consensus standards.

These final rule amendments provide technical corrections and minor technical amendments to the Ethylene Oxide Emissions Standards for Sterilization Facilities (40 CFR part 63, subpart O). These amendments include two technical standards: EPA Method 25A and PS–8. Consistent with the NTTAA, the EPA conducted searches to identify voluntary consensus standards in addition to these EPA methods and performance specifications. No voluntary consensus standards were identified for PS–8. The search and review results have been documented and are placed in the Docket No. A–88–03 (see **ADDRESSES** section) for these rule amendments.

The search for emissions monitoring procedures identified two voluntary consensus standards, both for EPA Method 25A. The EPA determined that these two standards identified for measuring emissions of hazardous air pollutants or surrogates subject to emission standards in the final rule would not be practical due to lack of equivalency, detail, and/or quality assurance and/or quality control requirements. Therefore, we did not use this voluntary consensus standard in this rulemaking.

The two voluntary consensus standards, EN 12619:1999 ''Stationary Source Emissions—Determination of the Mass Concentration of Total Gaseous

Organic Carbon at Low Concentrations in Flue Gases—Continuous Flame Ionization Detector Method'' and ISO 14965:2000(E) ''Air Quality—Determination of Total Nonmethane Organic Compounds—Cryogenic Preconcentration and Direct Flame Ionization Method,'' are impractical alternatives to EPA Method 25A for the purposes of this rulemaking because the standards do not apply to solvent process vapors in concentrations greater than 40 ppm (EN 12619) and 10 ppm carbon (ISO 14965). Methods whose upper limits are this low are too limited to be useful in measuring source emissions, which are expected to be much higher.

Section 63.365 of the NESHAP lists the EPA test methods and performance standards included in this rulemaking. Under 40 CFR 63.7(f) of the General Provisions, a source may apply to EPA for permission to use alternative test methods in place of any of the EPA testing methods.

H. Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks

Executive Order 13045 (62 FR 19885, April 23, 1997) applies to any rule that (1) is determined to be ''economically significant,'' as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children and explain why the planned rule is preferable to other potentially effective and reasonable alternatives considered by the Agency.

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5–501 of the Executive Order has the potential to influence the regulation. These final rule amendments are not subject to Executive Order 13045 because they are based on technology performance and not on health or safety risks. No children's risk analysis was performed because no alternative technologies exist that would provide greater stringency at a reasonable cost. Furthermore, these rule amendments have been determined not to be ''economically significant'' as defined under Executive Order 12866.

I. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801, *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing these rule amendments and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). These amendments will be effective November 2, 2001.

J. Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This rule is not subject to Executive Order 13211 (66 FR 28355 May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

List of Subjects in 40 CFR Part 63

Environmental protection, Air pollution control, Hazardous substances, Reporting and recordkeeping requirements.

Dated: October 24, 2001.

Christine Todd Whitman,

Administrator.

For reasons set out in the preamble, title 40, chapter I, part 63 of the Code of Federal Regulations is amended as follows:

PART 63—[AMENDED]

1. The authority citation for part 63 continues to read as follows:

Authority: 42 U.S.C. 7401, *et seq.*

Subpart O—[Amended]

2. Section 63.360 is amended:

a. In Table 1 by revising the entry for ''63.7(a)(2)'';

b. Removing and reserving paragraphs (g)(7) through (10).

The revision reads as follows:

§ 63.360 Applicability.

(a) * * *

TABLE 1 OF SECTION 63.360.—GENERAL PROVISIONS APPLICABILITY TO SUBPART O

Reference	Applies to sources using 10 tons in subpart O [a]	Applies to sources using 1 to 10 tons in subpart O [a]	Comment
* * *	Yes	*	* *
63.7(a)(2).			
* * *	*	*	* *

[a] See definition.

* * * * *

3. Section 63.361 is amended by removing the definition for ''Parametric monitoring,'' revising the definition for ''Baseline temperature,'' and adding a definition for ''Thermal oxidizer'' and ''Deviation'' in alphabetical order to read as follows:

§ 63.361 Definitions.

* * * * *

Baseline temperature means a minimum temperature at the outlet from the catalyst bed of a catalytic oxidation control device or at the exhaust point from the combustion chamber of a thermal oxidation control device.

* * * * *

Deviation means any instance in which an affected source, subject to this subpart, or an owner or operator of such a source:

(1) Fails to meet any requirement or obligation established by this subpart including, but not limited to, any emission limitation (including any operating limit) or work practice standard;

(2) Fails to meet any term or condition that is adopted to implement an applicable requirement in this subpart and that is included in the operating permit for any affected source required to obtain such a permit; or

(3) Fails to meet any emission limitation (including any operating limit) or work practice standard in this subpart during startup, shutdown, or malfunction, regardless of whether or not such failure is permitted by this subpart.

* * * * *

Thermal oxidizer means all combustion devices except flares.

4. Section 63.362 is amended by:

a. Revising Table 1 of paragraph (a);

b. Removing and reserving paragraph (e).

The revision reads as follows:

§ 63.362 Standards.

(a) * * *

TABLE 1 OF SECTION 63.362.—STANDARDS FOR ETHYLENE OXIDE COMMERCIAL STERILIZERS AND FUMIGATORS

Existing and new sources	Source type	Sterilization chamber vent	Aeration room vent	Chamber exhaust vent
Source size	<907 kg (<1 ton)	No control required; minimal recordkeeping requirements apply (see § 63.367(c)).		
	≥907 kg and <9,070 kg (≥1 ton and < 10 tons).	99% emission reduction (see § 63.362(c)).	No control	No control.
	≥9,070 kg (≥10 tons)	99% emission reduction (see § 63.362(c)).	1 ppm maximum outlet concentration or 99% emission reduction (see § 63.362(d)).	No control.

* * * * *

(e) [Reserved]

5. Section 63.363 is revised (including the section heading) to read as follows:

§ 63.363 Compliance and performance provisions.

(a)(1) The owner or operator of a source subject to emissions standards in § 63.362 shall conduct an initial performance test using the procedures listed in § 63.7 according to the applicability in Table 1 of § 63.360, the procedures listed in this section, and the test methods listed in § 63.365.

(2) The owner or operator of all sources subject to these emissions standards shall complete the performance test within 180 days after the compliance date for the specific source as determined in § 63.360(g).

(b) The procedures in paragraphs (b)(1) through (3) of this section shall be used to determine initial compliance with the emission limits under § 63.362(c), the sterilization chamber vent standard and to establish operating limits for the control devices:

(1) The owner or operator shall determine the efficiency of control devices used to comply with § 63.362(c) using the test methods and procedures in § 63.365(b).

(2) For facilities with acid-water scrubbers, the owner or operator shall establish as an operating limit either:

(i) The maximum ethylene glycol concentration using the procedures described in § 63.365(e)(1); or

(ii) The maximum liquor tank level using the procedures described in § 63.365(e)(2).

(3) For facilities with catalytic oxidizers or thermal oxidizers, the operating limit consists of the recommended minimum oxidation temperature provided by the oxidation unit manufacturer for an operating limit.

(4) Facilities with catalytic oxidizers shall comply with one of the following work practices:

(i) Once per year after the initial compliance test, conduct a performance test during routine operations, i.e., with product in the chamber using the procedures described in § 63.365(b) or (d) as appropriate. If the percent efficiency is less than 99 percent, restore the catalyst as soon as practicable but no later than 180 days after conducting the performance test; or

(ii) Once per year after the initial compliance test, analyze ethylene oxide

concentration data from § 63.364(e) or a continuous emission monitoring system (CEMS) and restore the catalyst as soon as practicable but no later than 180 days after data analysis; or,

(iii) Every 5 years, beginning 5 years after the initial compliance test (or by December 6, 2002, whichever is later), replace the catalyst bed with new catalyst material.

(c) The procedures in paragraphs (c)(1) through (3) of this section shall be used to determine initial compliance with the emission limits under § 63.362(d), the aeration room vent standard:

(1) The owner or operator shall comply with either paragraph (b)(2) or (3) of this section.

(2) Determine the concentration of ethylene oxide emitted from the aeration room into the atmosphere (after any control device used to comply with § 63.362(d)) using the methods in § 63.365(c)(1); or

(3) Determine the efficiency of the control device used to comply with § 63.362(d) using the test methods and procedures in § 63.365(d)(2).

(d) [Reserved]

(e) For facilities complying with the emissions limits under § 63.362 with a control technology other than acid-water scrubbers or catalytic or thermal oxidizers, the owner or operator of the facility shall provide to the Administrator or delegated authority information describing the design and operation of the air pollution control system, including recommendations for the operating parameters to be monitored to demonstrate continuous compliance. Based on this information, the Administrator will determine the operating parameter(s) to be measured during the performance test. During the performance test required in paragraph (a) of this section, using the methods approved in § 63.365(g), the owner or operator shall determine the site-specific operating limit(s)for the operating parameters approved by the Administrator.

(f) A facility must demonstrate continuous compliance with each operating limit and work practice standard required under this section, except during periods of startup, shutdown, and malfunction, according to the methods specified in § 63.364.

6. Section 63.364 is amended by:

a. Revising paragraph (b) introductory text;

b. Adding a sentence to the end of paragraph (b)(2);

c. Revising paragraph (c) introductory text;

d. Removing and reserving paragraphs (c)(1), (2) and (3);

e. Adding a sentence to the end of paragraph (c)(4);

f. Revising paragraph (d);

g. Revising paragraph (e); and

h. Removing and reserving paragraph (f).

The additions and revisions read as follows:

§ 63.364 Monitoring requirements.

* * * * *

(b) For sterilization facilities complying with § 63.363(b) or (d) through the use of an acid-water scrubber, the owner or operator shall either:

* * * * *

(2) * * * Monitoring is required during a week only if the scrubber unit has been operated.

(c) For sterilization facilities complying with § 63.363(b) or (c) through the use of catalytic oxidation or thermal oxidation, the owner or operator shall either comply with § 63.364(e) or continuously monitor and record the oxidation temperature at the outlet to the catalyst bed or at the exhaust point from the thermal combustion chamber using the temperature monitor described in paragraph (c)(4) of this section. Monitoring is required only when the oxidation unit is operated. From 15-minute or shorter period temperature values, a data acquisition system for the temperature monitor shall compute and record a daily average oxidation temperature. Strip chart data shall be converted to record a daily average oxidation temperature each day any instantaneous temperature recording falls below the minimum temperature.

(1) [Reserved]

(2) [Reserved]

(3) [Reserved]

(4) * * * As an alternative, the accuracy temperature monitor may be verified in a calibrated oven (traceable to NIST standards).

(d) For sterilization facilities complying with § 63.363(b) or (c) through the use of a control device other than acid-water scrubbers or catalytic or thermal oxidizers, the owner or operator shall monitor the parameters as approved by the Administrator using the methods and procedures in § 63.365(g).

(e) Measure and record once per hour the ethylene oxide concentration at the outlet to the atmosphere after any control device according to the procedures specified in § 63.365(c)(1). The owner or operator shall compute and record a 24-hour average daily. The owner or operator will install, calibrate, operate, and maintain a monitor consistent with the requirements of performance specification (PS) 8 or 9 in 40 CFR part 60, appendix B, to measure ethylene oxide. The daily calibration requirements of section 7.2 of PS 9 or section 2.3 of PS 8 are required only on days when ethylene oxide emissions are vented to the control device.

(f) [Reserved]

7. Section 63.365 is amended by:

a. Revising paragraph (b)(1) introductory text;

b. Revising paragraph (b)(1)(iv)(B);

c. Removing and reserving paragraph (b)(1)(iv)(C);

d. Removing and reserving paragraph (b)(2);

e. Revising paragraph (c);

f. Revising paragraph (d);

g. Removing and reserving paragraph (f);

h. Revising paragraph (h).

The revisions read as follows:

§ 63.365 Test methods and procedures.

* * * * *

(b) * * *

(1) *First evacuation of the sterilization chamber.* These procedures shall be performed on an empty sterilization chamber, charged with a typical amount of ethylene oxide, for the duration of the first evacuation under normal operating conditions (i.e., sterilization pressure and temperature).

* * * * *

(iv) * * *

(B) Test Method 18 or 25A, 40 CFR part 60, appendix A (hereafter referred to as Method 18 or 25A, respectively), shall be used to measure the concentration of ethylene oxide.

(*1*) Prepare a graph of volumetric flow rate versus time corresponding to the period of the run cycle. Integrate the area under the curve to determine the volume.

(*2*) Calculate the mass of ethylene oxide by using the following equation:

$$W_o = C \times V \times \frac{MW}{SV} \times \frac{1}{10^6}$$

Where:

Wo = Mass of ethylene oxide, g (lb)

C = concentration of ethylene oxide in ppmv

V = volume of gas exiting the control device corrected to standard conditions, L (ft^3)

$1/10^6$ = correction factor $L_{EO}/10^6\ L_{TOTAL\ GAS}$ ($ft^3_{EO}/10^6\ ft^3_{TOTAL\ GAS}$)

(*3*) Calculate the efficiency by the equation in paragraph (b)(1)(v) of this section.

(C) [Reserved]

* * * * *

(2) [Reserved]

* * * * *

(c) *Concentration determination.* The following procedures shall be used to determine the ethylene oxide concentration.

(1) *Parameter monitoring.* For determining the ethylene oxide concentration required in § 63.364(e), follow the procedures in PS 8 or PS 9 in 40 CFR part 60, appendix B. Sources complying with PS 8 are exempt from the relative accuracy procedures in sections 2.4 and 3 of PS–8.

(2) *Initial compliance.* For determining the ethylene oxide concentration required in § 63.363(c)(2), the procedures outlined in Method 18 or Method 25 A (40 CFR part 60, appendix A) shall be used. A Method 18 or Method 25A test consists of three 1-hour runs. If using Method 25A to determine concentration, calibrate and report Method 25A instrument results using ethylene oxide as the calibration gas. The arithmetic average of the ethylene oxide concentration of the three test runs shall determine the overall outlet ethylene oxide concentration from the control device.

(d) *Efficiency determination at the aeration room vent (not manifolded).* The following procedures shall be used to determine the efficiency of a control device used to comply with § 63.362(d), the aeration room vent standard.

(1) Determine the concentration of ethylene oxide at the inlet and outlet of the control device using the procedures in Method 18 or 25A in 40 CFR part 60, appendix A. A test is comprised of three 1-hour runs.

(2) Determine control device efficiency (% Eff) using the following equation:

$$\% \text{ Eff} = \frac{W_i - W_o}{W_i} \times 100$$

Where:

% Eff = percent efficiency

W_i = mass flow rate into the control device

W_O = mass flow rate out of the control device

(3) Repeat the procedures in paragraphs (d)(1) and (2) of this section three times. The arithmetic average percent efficiency of the three runs shall determine the overall efficiency of the control device.

* * * * *

(f) [Reserved]

* * * * *

(h) An owner or operator of a sterilization facility seeking to demonstrate compliance with the requirements of § 63.363 or § 63.364, with a monitoring device or procedure other than a gas chromatograph or a flame ionization analyzer, shall provide to the Administrator information describing the operation of the monitoring device or procedure and the parameter(s) that would demonstrate continuous compliance with each operating limit. The Administrator may request further information and will specify appropriate test methods and procedures.

8. Section 63.366 is amended by revising paragraph (a)(3) to read as follows:

§ 63.366 Reporting requirements.

(a) * * *

(3) Content and submittal dates for deviations and monitoring system performance reports. All deviations and monitoring system performance reports and all summary reports, if required per § 63.10(e)(3)(vii) and (viii), shall be delivered or postmarked within 30 days following the end of each calendar half or quarter as appropriate (see § 63.10(e)(3)(i) through (iv) for applicability). Written reports of deviations from an operating limit shall include all information required in § 63.10(c)(5) through (13), as applicable in Table 1 of § 63.360, and information from any calibration tests in which the monitoring equipment is not in compliance with PS 9 or the method used for temperature calibration. The written report shall also include the name, title, and signature of the responsible official who is certifying the accuracy of the report. When no deviations have occurred or monitoring equipment has not been inoperative, repaired, or adjusted, such information shall be stated in the report.

* * * * *

9. Section 63.367 is revised to read as follows:

§ 63.367 Recordkeeping requirements.

(a) The owner or operator of a source subject to § 63.362 shall comply with the recordkeeping requirements in § 63.10(b) and (c), according to the applicability in Table 1 of § 63.360, and in this section. All records required to be maintained by this subpart or a subpart referenced by this subpart shall be maintained in such a manner that they can be readily accessed and are suitable for inspection. The most recent 2 years of records shall be retained onsite or shall be accessible to an inspector while onsite. The records of the preceding 3 years, where required, may be retained offsite. Records may be maintained in hard copy or computer-readable form including, but not limited to, on paper, microfilm, computer, computer disk, magnetic tape, or microfiche.

(b) The owners or operators of a source using 1 to 10 tons not subject to § 63.362 shall maintain records of ethylene oxide use on a 12-month rolling average basis (until the source changes its operations to become a source subject to § 63.362).

(c) The owners or operators of a source using less than 1 ton shall maintain records of ethylene oxide use on a 12-month rolling average basis (until the source changes its operations to become a source subject to § 63.362).

(d) The owners or operators complying with § 63.363(b) (4) shall maintain records of the compliance test, data analysis, and if catalyst is replaced, proof of replacement.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301185; FRL–6806–4]

RIN 2070–AB78

Methoxyfenozide; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of methoxyfenozide in or on field corn grain, stover and oil, aspirated grain fractions and soybean forage, hay, oil, and seed. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on field corn and soybeans. This regulation establishes a maximum permissible level for residues of methoxyfenozide in these food commodities. The tolerances will expire and are revoked on December 31, 2003.

DATES: This regulation is effective November 2, 2001. Objections and requests for hearings, identified by docket control number OPP–301185, must be received by EPA on or before January 2, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301185 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Barbara Madden, Registration Division (7505C), Office of Pesticide