6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA-HQ-OAR-2003-0197, FRL-____]

RIN 2060-AK09

Ethylene Oxide Emissions Standards for Sterilization Facilities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final decision; and final rule, amendment.

SUMMARY: This action finalizes our decision not to revise the Ethylene Oxide Emission Standards for Sterilization Facilities, originally promulgated on December 6, 1994. Within 8 years of promulgating these standards, the Clean Air Act directs us to assess the risk and to promulgate more stringent standards if necessary to protect public health with an ample margin of safety and to prevent adverse environmental effects. Also, within 8 years of promulgating the national emission standards, the Clean Air Act requires us to review and revise the standards as necessary, taking into account developments in practices, processes, and control technologies. Today's action reflects our findings that after conducting these risk and technology reviews, no additional control requirements are warranted.

EFFECTIVE DATE: [INSERT DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER].

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA-HQ-OAR-2003-0197. All documents in the docket are listed on the www.regulations.gov web site. Although listed in the index, some information is not publicly available, e.g., confidential business information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through www.regulations.gov or in hard copy at the Air and Radiation Docket, EPA/DC, EPA West, Room B-102, 1301 Constitution Ave., NW, Washington, DC. The Public Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the Air and Radiation Docket is (202) 566-1742.

FOR FURTHER INFORMATION CONTACT:

General and Technical Information. Mr. David Markwordt, Office of Air Quality Planning and Standards, Sector Policies and Programs Division, Coatings and

Chemicals Group (E-143-01), Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone (919) 541-0837, facsimile number (919) 685-3195, electronic mail (e-mail) address: markwordt.david@epa.gov.

Residual Risk Assessment Information. Mr. Mark Morris, Office of Air Quality Planning and Standards, Health and Environmental Impacts Division, Sector Based Assessment Group (C539-02), Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone (919) 541-5470, facsimile number (919) 541-0840, electronic mail (e-mail) address: morris.mark@epa.gov.

SUPPLEMENTARY INFORMATION:

Regulated Entities. The regulated categories and entities affected by the national emission standards include:

Category	**NAICS[a]**	**(SIC[b])**	**Examples of regulated entities**
Industry	329112 339113 325412 311942 311423	(3841) (3842) (2834) (2099) (2034)	Operations at major and area sources that sterilize or fumigate medical supplies, pharmaceuticals, and spice.
Federal/State/ local/tribal governments ...			

[a] North American Industry Classification System.
[b] Standard Industrial Classification.

This table is not intended to be exhaustive, but

rather provides a guide for readers regarding entities likely to be affected by the national emission standards. To determine whether your facility would be affected by the national emission standards, you should examine the applicability criteria in 40 CFR 63.360. If you have any questions regarding the applicability of the national emission standards to a particular entity, consult either the air permit authority for the entity or your EPA regional representative as listed in 40 CFR 63.13.

Worldwide Web (WWW). In addition to being available in the docket, an electronic copy of today's final decision will also be available on the WWW through the Technology Transfer Network (TTN). Following signature, a copy of the final decision will be posted on the TTN's policy and guidance page for newly proposed or promulgated rules at the following address: http://www.epa.gov/ttn/oarpg/. The TTN provides information and technology exchange in various areas of air pollution control.

Judicial Review. Under Clean Air Act (CAA) section 307(b)(1), judicial review of this final decision is available only by filing a petition for review in the United States Court of Appeals for the District of Columbia Circuit by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER]. Under section

307(d)(7)(B) of the CAA, only an objection to a rule or procedure 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 the final decision may not be challenged separately in civil or criminal proceedings brought to enforce these requirements.

Section 307(d)(7)(B) of the CAA further provides that "[o]nly an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised during judicial review." This section also provides a mechanism for us to convene a proceeding for reconsideration, "[i]f the person raising an objection can demonstrate to the EPA that it was impracticable to raise such objection within [the period for public comment] or if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule." Any person seeking to make such a demonstration to us should submit a Petition for Reconsideration to the Office of the Administrator, U.S. EPA, Room 3000, Ariel Rios Building, 1200 Pennsylvania Ave., NW, Washington, DC 20460, with a copy to both the

person(s) listed in the preceding FOR FURTHER INFORMATION CONTACT section and the Associate General Counsel for the Air and Radiation Law Office, Office of General Counsel (Mail Code 2344A), U.S. EPA, 1200 Pennsylvania Ave., NW, Washington, DC 20004.

Outline. The information presented in this preamble is organized as follows:

I. Background

A. What is the statutory authority for these actions?

Section 112 of the CAA establishes a comprehensive regulatory process to address hazardous air pollutants (HAP) from stationary sources. In implementing this process, we have identified categories of sources emitting one or more of the HAP listed in the CAA, and ethylene

oxide sterilization facilities are identified as both major and area source categories. Section 112(d) requires us to promulgate national technology-based emission standards for sources within those categories that emit or have the potential to emit any single HAP at a rate of 10 tons or more per year or any combination of HAP at a rate of 25 tons or more per year (known as major sources), as well as for certain area sources emitting less than those amounts. These technology-based national emission standards for HAP (NESHAP) must reflect the maximum reductions of HAP achievable (after considering cost, energy requirements, and nonair health and environmental impacts) and are commonly referred to as maximum achievable control technology (MACT) standards. We promulgated the National Emission Standards for Ethylene Oxide Commercial Sterilization and Fumigation Operations Facilities at 59 FR 62585 on December 6, 1994 (Ethylene Oxide Sterilization NESHAP). As for area sources, we established MACT standards for certain emission points pursuant to section 112(d)(2) and generally available control technology (GACT) standards for other emission points pursuant to section 112(d)(5).

In what is referred to as the technology review, we are required under section 112(d)(6)of the CAA to review these

technology-based standards no less frequently than every 8 years. Further, if we conclude that a revision is necessary, we have the authority to revise these standards, taking into account "developments in practices, processes, and control technologies."

The residual risk review is described in section 112(f) of the CAA. Section 112(f)(2) requires us to determine for each section 112(d) source category, except area source categories for which we issued a GACT standard, whether the NESHAP protects public health with an ample margin of safety (AMOS). If the NESHAP for HAP "classified as a known, probable, or possible human carcinogen do not reduce lifetime excess cancer risks to the individual most exposed to emissions from a source in the category or subcategory to less than one in one million," we must decide whether additional reductions are necessary to provide an ample margin of safety. As part of this decision, we may consider costs, technological feasibility, uncertainties, or other relevant factors. We must determine whether more stringent standards are necessary to prevent adverse environmental effect (defined in section 112(a)(7) as "any significant and widespread adverse effect, which may reasonably be anticipated to wildlife, aquatic life, or other natural resources, including adverse impacts on

populations of endangered or threatened species or significant degradation of environmental quality over broad areas," but in making this decision we must consider cost, energy, safety, and other relevant factors.

B. What did we propose?

We promulgated the Ethylene Oxide Sterilization NESHAP in 1994. On October 24, 2005 (70 FR 61406), we proposed not to revise the Ethylene Oxide Sterilization NESHAP and requested public comments on the residual risk and technology review for the Ethylene Oxide Sterilization NESHAP.

II. Risk and Technology Review Final Decision

In our proposal, we presented the analysis and conclusions on residual risk and technology review, concluding that the maximum individual cancer risk for this source category already meets the level we generally consider acceptable, and that further control requirements would achieve, at best, minimal emission and risk reductions at a very high cost from emission vents controlled with MACT at both major and area sources. Further, the analyses showed that both the chronic noncancer and acute risks from this source category are below their respective relevant health thresholds, and that there are no adverse impacts to the environment (i.e.,

ecological risks). As a result, we concluded that no additional control should be required because an ample margin of safety (considering cost, technical feasibility, and other factors) has been achieved by the NESHAP MACT requirements for the ethylene oxide major and area source categories.

In the technology review, we concluded that additional controls at existing sources would achieve, at best, minimal emission and risk reductions at a very high cost. Additionally, we did not identify any significant developments in practices, processes, or control technologies since promulgation of the original standards in 1994 which represent the best controls that can be implemented nationally. Thus, we proposed no additional controls under the technology review under CAA section 112(d)(6).

We conclude in this rulemaking, as proposed, that there is not a need to revise the Ethylene Oxide Sterilization NESHAP under the provisions of CAA section 112(f) or 112(d)(6).

III. Summary of Comments and Responses

The proposal provided a 45-day comment period ending December 8, 2005. We received comments from eight commenters. Commenters included three State agencies, one

State and local agency association, three industry trade associations, and one coalition of trade associations. We have considered the public comments as discussed below and did not find that the comments changed any of our determinations.

1. Source Category Risk Approach

Comment: One commenter disagreed that EPA can utilize approaches different from that specified in the Benzene NESHAP. The commenter believes that EPA misinterpreted the CAA legislative history stating that EPA could read section 112(f)(2)(B) as directing it to use the interpretation set out in the Benzene NESHAP or use approaches affording the same level of protection. According to the commenter, EPA must use only the Benzene NESHAP approach and cannot use any other approach by relying on a Senate manager's statement that EPA should interpret the section 112(f)(2)(B) requirement to establish standards reflecting an ample margin of safety in a manner no less protective of the most exposed individual than the policy set forth in the Benzene NESHAP.

Response: In the proposed rule, EPA followed the approach set out in National Emission Standards for Hazardous Air Pollutants (NESAHP): Benzene Emissions from Maleic Anhydride Plants, Ethylbenzene/Styrene Plants, Benzene

Storage Vessels, Benzene Equipment Leaks, and Coke By-Product Recovery Plants, 54 FR 38044 (September 14, 1989). EPA used the two-step decision process of first determining a level of acceptable risk followed by finding an ample margin of safety. As the commenter concedes EPA's approach is fully consistent with the Benzene NESHAP approach and therefore acceptable. Since, in this instance, EPA did not use any other approach the comment is not applicable to this particular rulemaking.

Comment: One commenter stated that Congress was clear in requiring EPA to evaluate only the risks from an individual source category or subcategory in establishing residual risk standards. The commenter stated EPA should not include the risk from area sources in determining whether risks from the major source category exceeds the one-in-a–million risk trigger under section 112(f)(2) or in making judgments on acceptable risk and ample margin of safety for major sources.

Response: We listed separate source categories for major and area commercial sterilization facilities under section 112(c) of the CAA, and we agree with the commenter that a separate determination of acceptable risk and ample margin of safety should be made for each source category under section 112(f) of the CAA. Our risk assessment for

commercial sterilization facilities includes risk estimates for all known sources, including mostly major sources and the area sources with the highest emissions. Only two area sources have estimated cancer risk greater than 1 in 1 million (highest is 20 in 1 million), and no area sources have modeled ethylene oxide concentrations near the reference concentration. For additional information on our risk assessment of area sources see section III.2.

In the preamble to the proposed rule, we stated that risks were acceptable considering all known sources (major and area sources) and that an ample margin of safety was achieved without control requirements beyond those in the current standards. Although the preamble to the proposed rule does not discuss separate determinations of acceptability and ample margin of safety for major and areas source categories, our conclusions would not have changed whether we had considered all sources together, or separately for major sources and area sources.

Comment: One commenter stated that EPA did not comprehensively consider the plants' impacts because it did not consider all HAP emissions or all source categories at the facilities. The commenter stated that in considering only a portion of the facilities' emissions, the determination of low-risk is based on a distorted and

unrealistic view of their impact. The commenter included an example of a facility that uses and emits methyl bromide from its sterilization operations.

Response: In general, there is much less co-location of commercial sterilization operations with other industrial processes than there is for the typical source category. Many facilities are contract sterilizers with no co-location. In some cases, there is co-location of commercial sterilizers with other processes, such as pharmaceuticals production. We do not have sufficiently detailed information to analyze the possibility of controls on the various specific sources within a facility but outside the commercial sterilizer source category. As a result, we could not evaluate the existing levels of control or the potential for applying additional controls at the facilities where HAP emissions from other sources contribute to the risk. Therefore, we did not consider emissions from co-located sources in our decision to require no additional controls because we did not have the control cost and feasibility data necessary to do so. Our position on the potential consideration of co-located source categories is fully discussed in the coke oven final rule (70 FR 19995-19998).

Regarding emissions of methyl bromide, we searched the

1999 National Emissions Inventory (NEI) for the 76 identified ethylene oxide sterilization facilities to determine which emit both ethylene oxide and methyl bromide. According to the NEI data base, only two of the facilities emit both HAP. One of the facilities emits so little methyl bromide that the risk estimates would not be significantly different if methyl bromide were considered. The other facility emits more methyl bromide than ethylene oxide (about 2 to 3 times as much). However, because there is no cancer unit risk estimate for methyl bromide, the emissions of methyl bromide would not affect our cancer risk estimate (3 in 1 million). Considering effects other than cancer, the reference concentration for chronic inhalation exposures to methyl bromide is approximately six times lower than that of ethylene oxide. Consequently, the methyl bromide emissions could result in an increase in our estimate of the hazard index for the facility by as much as a factor of 20 (assuming similar source release parameters like stack height, etc.). This is not a concern because our current estimate of the hazard index is 0.001, and a factor greater than 1000 would be necessary before a hazard index of 1 would be exceeded. Therefore, even considering these emissions would not change our regulatory decision.

Comment: One commenter stated EPA should not conduct a

separate technology review for ethylene oxide sources under section 112(d)(6). The commenter believes that once EPA has made a residual risk determination under section 112(f), emissions from the category are “safe,” and the Agency must find a revision of the MACT standard under section 112(d)(6) is unnecessary. Another commenter urges EPA to avoid expenditure of resources by conducting further analysis geared to tightening control requirements when an AMOS has already been provided by a protective standard.

Response: As discussed in the preamble to the proposed rule, we performed a separate technology review for both the area and major source categories under section 112(d)(6), but recommended no changes to the NESHAP. It is possible that future advances in control technologies for this source category could allow for meaningful emission reductions at a reasonable cost. We believe that the technology review required under section 112(d)(6) was appropriate here.

Comment: One commenter believes that there is no mechanism to revisit section 112(f) assessments and, therefore, that the risk assessment should be corrected to account for reasonably foreseeable changes that could result in increased risk, such as new residences being

built closer to the facility, or increases in actual emissions within the current permit limitations.

Response: We disagree with the commenter's assertion that there is no mechanism to revisit risks from the source category, and that, therefore, the risk assessment must include consideration of foreseeable changes that may occur in the future. We have the authority to revisit (and revise, if necessary) any rulemaking if there is sufficient evidence that changes within the affected industry or significant improvements to science suggests the public is exposed to significant increases in risk as compared to the risk assessment prepared for the rulemaking (e.g., CAA section 301).

2. Area Source Category – MACT and GACT

Comment: One commenter stated that EPA has discretion to not regulate MACT or GACT area sources under section 112(f). One commenter stated that EPA has the discretion under section 112(f)(5) of the CAA to avoid residual risk analysis for area sources subject to GACT, regardless of whether such sources are subject to both MACT and GACT under section 112(d). The commenter reasoned that since the CAA does not require residual risk analysis of area sources subject to GACT only, area sources subject to more stringent requirements under both MACT and GACT should also

not require analysis. Two commenters stated that EPA should not omit sources subject to GACT from the residual risk analysis because it could result in serious underestimation of the health risks from area sources. One commenter believes that both section 112(d) and 112(f) of the CAA were satisfied when area sources were addressed under section 112(d)(5); since GACT controls alone would have been sufficient for EPA to avoid a residual risk review, clearly requiring both MACT and GACT controls obviates the need for any further Agency review of these area sources under both 112(d) and 112(f).

Response: For area source ethylene oxide sterilizers, EPA issued MACT standards under section 112(d)(2) for sterilizer vents and chamber exhaust vents and GACT standards for aeration room vents. EPA undertook a section 112(f)(2) analysis for area source emissions standards that were issued as MACT standards and exercised its discretion under section 112(f)(5) to not do an 112(f)(2) analysis for those emission points for which GACT standards were established. EPA appreciates the responses to its question regarding the range of discretion that the Agency has under section 112(f)(5) and will consider the points made by commenters in developing future relevant proposals. However, for purposes of this rulemaking, EPA believes that

it exercised its discretion appropriately by conducting a 112(f)(2) analysis for those emission points subject to MACT standards.

3. Risk Analysis Assumptions

Comment: Two commenters stated that EPA must use the best available science to establish a cancer unit risk estimate for ethylene oxide, and that it is scientifically indefensible for EPA to use the California Environmental Protection Agency cancer unit risk factor in risk assessments when more recent epidemiological data exist. One commenter states that the basis for the California unit risk factor (mononuclear leukemia in female rats) is not relevant to humans. One commenter states that a sound scientific estimate of the cancer unit risk for ethylene oxide has been derived by Kirman, et al.[1] based partly on two epidemiological studies[2,3] that include exposure estimates for more than 20,000 workers. Two commenters stated that EPA should plan to reevaluate the risks associated with this source category whenever the new

[1] Kirman, C.R., et al. 2004. Addressing nonlinearity in the exposure-response relationship for a genotoxic carcinogen: cancer potency estimates for ethylene oxide. Risk Anal. 24(5):1165-83.
[2] Steenland, K.L., et al. 1991. Mortality among workers exposed to ethylene oxide. New England Journal of Medicine, 324(20):1402-1407.
[3] Teta, M.J., et al. 1993. Mortality study of ethylene oxide workers in chemical manufacturing: A 10-year update. British Journal of Industrial Medicine, 50:704-709.

cancer risk estimate is made final, regardless of whether or not the final rule has been published.

Response: In estimating potential excess cancer risk associated with ethylene oxide sterilizers, EPA has considered all available, credible, and relevant information. In 1985, the EPA health assessment for ethylene oxide[4] concluded, based on the information available at that time, that ethylene oxide is "probably carcinogenic to humans," and derived a cancer unit risk estimate. California EPA subsequently relied on the EPA assessment in developing their cancer unit risk estimate using the same rat study as basis.[5,6] The California EPA assessment received concurrence from their Scientific Review Panel.[7] In 1994, the International Agency for Research on Cancer categorized ethylene oxide in their Group 1 (Carcinogenic to Humans). In 2000, the United States Department of Health and Human Services revised its

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[4] USEPA. 1985. Health Assessment Document for Ethylene Oxide, EPA/600/8-84/009F. Office of Health and Environmental Assessment, Washington, DC.
[5] CARB. 1987. Staff Report: Initial Statement of Reasons For Proposed Rulemaking and Report of the Scientific Review Panel. California Air Resources Board. http://www/oehha.ca.gov/air/toxic contaminants/pdf1/ethylene%20oxide.pdf
[6] CalEPA. 2005. Technical Support Document for Describing Available Cancer Potency Factors. California Environmental Protection Agency, Office of Environmental Health Hazard Assessment. Air Toxicology and Epidemiology Section. http://www.oehha.ca.gov/air/hot_spots/pdf/May2005Hotspots.pdf
[7] CARB. op. cit.

listing for ethylene oxide to "known to be a human carcinogen" in the Ninth Report on Carcinogens.[8] Support for this listing includes epidemiological evidence from studies of workers exposed to ethylene oxide and animal studies. Cancer in both human and animal studies has included multiple sites, including reported associations with leukemia.[9]

EPA is currently developing an updated cancer assessment for ethylene oxide (http://cfpub.epa.gov/iristrac/index.cfm?fuseaction=viewChemical.showChemical&iris_sub_id=897). EPA's updated cancer assessment for ethylene oxide will consider all relevant literature and studies including the Kirman, et al. paper and the epidemiological studies referred to in the comment. However, until completion of that assessment and given the peer review status of the work done by the State of California, the California EPA unit risk estimate must be considered to be the best-available science and has therefore been used in assessing cancer risk for this rulemaking.

The EPA cancer assessment will not receive external

[8] DHHS. 2000. Report on Carcinogens, Eleventh Edition; United States Department of Health and Human Services, Public Health Service, National Toxicology Program.

peer review until mid-2006, which is after the promulgation date of the residual risk rule for this source category. Our authority to revisit any rulemaking is addressed in Section III.1.

Comment: Several commenters stated that Acute Exposure Guideline Levels (AEGL), Emergency Response Planning Guidelines (ERPG), and Immediately Dangerous to Life or Health (IDLH) values should not be used in assessing the risk from acute exposures to ethylene oxide because these values were developed for accidental release planning and are not appropriate for assessing daily human exposure scenarios. One commenter stated that EPA's acute assessment discounted the use of the National Institute of Occupational Safety and Health (NIOSH) 10-minute ceiling value of 5 parts per million (ppm) (9 mg/m^3), and noted that EPA's maximum acute exposure estimate for this source category (23 mg/m^3) exceeds the NIOSH value. Two of the commenters stated that EPA's new acute reference concentration value for ethylene oxide should be used when it becomes available.

Response: We are continuing to evaluate the role of acute health effects in our section 112(f) analysis. In any event, we have concluded that this source category does not

[9] DHHS, *op. cit*.

present acute health risks that warrant further regulation. Our authority to revisit any rulemaking is addressed in Section III.1.

Comment: Three commenters stated that EPA should consider the risks from chronic exposure at facility property boundaries instead of at the geographic centroids of census blocks. The commenters state that census blocks can be large and that the point of maximum impact can be far from the census block centroid.

Response: We believe that, in a national-scale assessment of lifetime inhalation exposures and health risks from a category of facilities, it is appropriate to identify exposure locations where an individual may reasonably be expected to spend a majority of his or her lifetime. Further, we believe that it is appropriate to use census block information on where people actually reside, rather than points on a fence-line, to locate the estimation of exposures and risks to individuals living near such facilities.

Census blocks are the finest resolution available for the nationwide population data set (as developed by the US Census Bureau); each is typically comprised of approximately 40 people or about 10 households. In our risk assessments, we use the geographic centroid of each

census block containing at least one person to represent the location where all the people in that census block live. The census block centroid with the highest estimated exposure then becomes the location of maximum exposure, and the entire population of that census block experiences the maximum individual risk. In some cases, since actual residence locations may be closer to or farther from facility emission points, this may result in an overestimate or underestimate of the actual chronic risks. However, given the relatively small dimensions of census blocks in densely-populated areas and the relatively large number of sources being assessed for any given source category, we believe that these uncertainties are small and do not bias our estimates of maximum individual risks for a source category.

Comment: One commenter stated that the risk assessment for ethylene oxide sterilization facilities lacks a reliable facility-specific inventory of emissions. The commenter stated that EPA did not acquire the ethylene oxide usage records and emissions data needed to perform the residual risk assessment, but instead relied on industry-supplied data from the Toxics Release Inventory (TRI) and the National Emissions Inventory (NEI). The commenter implied that EPA should have requested data from facilities under

its authority under section 114 of the CAA. The commenter strongly recommend that the EPA re-conduct this residual risk assessment by requiring the sources subject to this proposed rulemaking to report five years of usage data and/or throughput data. The EPA should then select the maximum usage value to calculate emissions for each facility in the residual risk assessment based on the current percent control requirement prescribed by the NESHAP. One commenter stated that EPA's risk assessment considered only actual reported emissions instead of potential emissions. The commenter stated that since facility emissions (and associated impacts) could increase over time for a variety of reasons EPA should have considered the risks based on potential emissions. Two commenters stated residual risk assessments must be performed on allowable emissions to fully understand the potential public health implications for a source category.

Response: Our position on the use of allowable emissions is fully discussed in the final Coke Oven Batteries NESHAP (70 FR 19998-19999).

We used reported emissions (from the National Emissions Inventory database and company reports) for the ethylene oxide source category risk analysis. The reported emissions are a mix of actual, allowable, and potential

emissions, but we do not have the necessary information to distinguish between the types of data reported. While we generally recognize that most facilities over comply with the MACT requirements (thus, actual emissions are lower than allowable), we do not have data to determine the degree of over compliance that facilities are achieving or reporting. For example, chamber exhaust emissions in some cases may be lower because they are controlled by some States although not by EPA because of the safety issue discussed in the proposal. The removal of chamber exhaust vent controls by the States would likely result in a significant increase in risk. However, as discussed in section III. 3, we have no basis to change conclusions presented in the proposal and will not impose controls on chamber exhaust emissions for either new or existing facilities.

The commenter also recommended we use the authority under section 114 of the CAA to gather data rather than use data bases like the TRI or data submitted by the facility but not under authority of the CAA. Since the data ultimately is supplied by the facility we believe the data is comparable to data gathered under section 114. The commenter also recommended we base rule-making on 5 years of data. The commenter provided no basis which

demonstrates modeled results based on the previous 5 years are any more representative of risks than those based on the most recent emission estimates.

4. Additional Issues

Comment: One commenter stated EPA concludes that "further controls would not meaningfully reduce emissions from emission vents" but indicates that the Agency is aware that the State of California's requirement for the main sterilizer vent is 99.9 percent as contrasted with the 99 percent MACT requirement. The Agency therefore requests further data from the public in the form of five questions dealing primarily with technology and costs. (70 FR 61408) EPA does not clearly set out what decision criteria will be applied to the information that the public is being asked to supply. The commenter also stated that EPA does not explicitly state the decision criteria used in making ample margin of safety decisions under the residual risk program. Specifically, the commenter stated that for ethylene oxide sterilization facilities, the EPA did not explicitly state that incremental emission control costs were compared to incremental risk reductions in making the ample margin of safety decision, as it has in past rulemakings such as the Benzene NESHAP and radionuclide standards. The commenter also stated that the public would better understand and

accept EPA's ample margin of safety decisions if EPA were to better educate the public regarding its estimated risk estimates and the contribution of stationary sources to the overall risk. One commenter stated EPA indicates that the agency had considered increasing the emission reduction limit to 99.9 percent in the national emission standards but that "we do not have data to confirm that facilities are capable of achieving 99.9 percent on a continuous basis" (70 FR 61409). The commenter encouraged EPA to review state data on this source category, including information from New York and New Jersey, indicating that such levels are achievable. Another commenter stated that EPA needs to re-evaluate the control technologies and exemptions from the current NESHAP. The emissions of ethylene oxide from the largest fugitive sources evaluated in the residual risk assessment equates to over 28 tons per year. The EPA should assess the risk reductions associated with the additional control percentages on the sterilizer chamber vent and aeration room vents for sources which use between 1 and less than 10 tons and 10 tons or greater per year of ethylene oxide.

Response: EPA stated in the proposal, "we considered the estimate of health risk and other health information along with additional factors relating to the appropriate level

of control, including costs and economic impacts of controls, technological feasibility, uncertainties, and other relevant factors." We used the same decision criteria today to address the data submitted in response to the proposal. The EPA does not have definitive criteria such as a specific cost effectiveness value which dictates the final outcome.

We solicited comments concerning both the control effectiveness and costs associated with increasing the performance limit to 99.9 percent. The summary test data submitted by the commenters lend support to the technical feasibility of complying with a higher limit for the main sterilizer vent. Commenters did not supply data supporting continuous compliance with a higher limit.

Many of the outlet concentrations are reported at the detection limit. This implies the measurement devices were showing zero concentration of ethylene oxide in the outlet stream. Because both the 1990s and 2000s data show no ethylene oxide in the outlet stream, we believe there isn't a measurable difference in the control efficiencies of the tested devices.

We did not receive comments addressing the safe control of emissions from the chamber exhaust vent. As we stated in the "Memorandum: Technology Review and Residual

Risk Data Development for the Ethylene Oxide Commercial Sterilization NESHAP" (Docket # EPA-HQ-OAQ-2003-0197-0027): "Many, if not all, source facilities utilize a chamber exhaust fan while personnel are removing product from the sterilization chamber. This fan removes ethylene oxide off-gassing from the product. The Ethylene Oxide Commercial Sterilization and Fumigation NESHAP promulgated in 1994 (59 FR 62585) required control of the chamber exhaust vent. In 1997 there were a series of explosions associated with control of the chamber exhaust vent (62 FR 64736). We subsequently reassessed the control requirements and removed the requirement to control the chamber exhaust in November 2001 (66 FR 55577); the Agency continues to believe that the action taken in 2001 is reasonable and we have found no safe way to impose controls on the chamber exhaust vents. Approximately 1 percent of the ethylene oxide used in the process is emitted through the chamber exhaust vent."

Therefore, we have no basis to change conclusions presented in the proposal and will not impose controls on chamber exhaust emissions for either new or existing facilities.

To assess the risk reduction associated with increasing the stringency of the standard for the main

sterilizer vent from 99 to 99.9 percent emission reduction, we looked at the five facilities with the highest estimated cancer risk (ETO 4,5,8,18,19, and 27). Only one commenter provided cost estimates to retrofit existing facilities to comply with a higher standard. This commenter estimated the retrofit costs to be approximately one million dollars per facility. Emissions from these five facilities range from approximately 0.3 to 4.5 tons per year and total 18 tons per year (Docket item EPA-HQ-OAR-2003-0197 – 0003, Table 2). Approximately 12 of the 18 tons are fugitive emissions from the chamber exhaust. Residual emissions i.e., emissions after the application of emission control devices from the main chamber and aeration vents for the five facilities with the highest estimated cancer risk (ETO 4,5,8,18,19, and 27) range from approximately 0 to 1.6 tons per year, and are 4 tons per year in total (Docket item EPA-HQ-OAR-2003-0197 – 0003 Table 2). Based on a $1 million capital investment per facility, a 7 percent discount rate, and a 10-year capital recovery period, the average cost per ton of emissions reduced for the five facilities is approximately $35,000. These estimates assume facilities complying with the 99 percent limit do not in practice achieve a higher efficiency than 99 percent and there are zero emissions from control devices complying

with the 99.9 percent limit.

To test the commenter's assertion that more stringent controls on the main and aeration vents would reduce risk levels, we remodeled the five facilities with the highest estimated cancer risk (ETO 4,5,8,18,19, and 27) with the assumption that main vent and aeration vent emissions are essentially zero after a 99.9 percent reduction and we compared the results to the baseline risks estimates. The risks (estimated to one significant figure) changed for only one facility, for which the maximum individual risk was reduced from 90 in 1 million to 80 in 1 million. Although we did not remodel all facilities, similar results would be expected for the other facilities because of the high chamber exhaust emissions relative to the emissions from the main vent and aeration vent after 99 percent control. Therefore, for existing major sources we conclude in our ample margin of safety decision that further controls would achieve minimal emission and risk reductions at a very high cost.

For existing sources under the 8 year review, in the proposal we stated, "Because the three vents associated with these facilities (i.e., the main sterilization, aeration room, and chamber exhaust emission vents) are the same for both major and area sources, the conclusions

concerning technology apply to both source categories. We found that additional controls for emission vents controlled with either MACT or GACT would achieve at best, minimal emission and risk reductions at a very high cost. In our review, we did not identify any significant developments in practices, processes, or control technologies since promulgation of the national emission standards in 1994." The analysis presented above for the five facilities with the highest risk support the conclusion presented in the proposal.

As stated above we believe for new main sterilizer vent and aeration control, increasing the stringency of the control limit from 99 to 99.9 percent achieves only a minimal reduction in risk. Therefore, EPA does not find it necessary to increase the control limit for new facilities.

Comment: One commenter stated EPA appropriately concluded that changes to the standard are not required to satisfy section 112(f) of the CAA. However, the commenter stated EPA did not provide sufficient data in the preamble to the document on the AMOS analysis that led to this conclusion, including its cost versus risk-reduction benefit analysis for a possible increase in the EO reduction requirements from 99 percent to 99.9 percent.

Response: As we stated in the proposal, we did not find

any new technology or alternative controls for any vents for commercial EO sterilizers. We also found no data to support the addition of down stream control devices to existing controls as a way of further reducing emissions. We, therefore, concluded that further controls would achieve minimal reductions at a high cost. While we were aware of more stringent control limits at the State level, we stated in the proposal that we did not have data to confirm that all facilities are capable of meeting a more stringent level and solicited both control and cost data. Based on the data received from commenters we performed a risk assessment which confirmed our earlier qualitative conclusion.

Comment: One commenter stated EPA's language suggests that the decision criterion is whether further reductions would "meaningfully reduce emissions or risks." (70 FR 61408) The commenter stated that introducing the term "meaningfully reduce" without further explaining it is potentially misleading to the public. They were further troubled by the continued insertion of the word "emissions" in this formulation of the decision criteria as reinforced by the specific questions asked in this Federal Register notice.

Response: EPA presented, in the proposal, its analysis and

conclusions on residual risk and technology review. Under section 112(d)(6), EPA is required to review the MACT standards and revise them as necessary taking into account developments in practices, processes and control technologies, no less frequently than every 8 years. Section 112(f)(2) requires us to determine for each source category whether the NESHAP protect public health with an ample margin of safety and prevent an adverse environmental effect. After reviewing and analyzing data under both these sections, EPA concluded that further controls would not meaningfully reduce emissions or risks. EPA reached this conclusion because the maximum individual cancer risk for this source category is already at the level we generally consider acceptable and that further controls would achieve minimal risk reduction at a very high cost. In addition, our conclusion referred to both emissions and risk because EPA's analysis included both the technology review and a residual risk determination.

Comment: One commenter stated EPA's CAA section 112(d)(6) review of the source category correctly concluded that the NESHAP standards did not need to be revised. However, the commenter stated that EPA reached this conclusion after conducting an independent technology review instead of basing it on the conclusions of EPA's CAA section 112(f)(2)

analysis, which showed that the source category achieves an AMOS that is not limited by cost or technological feasibility concerns. The commenter believes that EPA should have based its determination that further controls under 112(d)(6) are not required through the 112(f) AMOS determination. According to the commenter, EPA did not need to conduct a separate technology review because it considered the need for additional controls in its AMOS analysis. The commenter goes on to state that where the AMOS is based in large part on cost or technical feasibility concerns, which according to the commenter was not the case with EO sterilizer facilities, then further future review under CAA section 112(d)(6) may remain viable and additional controls may not be precluded if feasible control measures are identified. Further, the commenter states that in evaluating whether action is necessary under CAA section 112(d)(6), EPA should not apply a "bright line" 1 in 1 million standard for cancer risks, nor a similar "bright line" standard for non-cancer risks.

Response: Section 112(d)(6) of the CAA requires EPA to review, and revise as necessary (taking into account developments in practices, processes, and control technologies), emission standards promulgated under section 112 no less often than every 8 years. We disagree,

therefore, that the Agency did not need to conduct a separate technology review because it considered, among other factors, the need for additional controls under its 112(f) analysis. As we noted in the preamble to the Coke Ovens residual risk rule, the findings that underlie a section 112(f) determination should be key factors in making any subsequent section 112(d)(6) determinations. However, as the word “subsequent” indicates, we believe that we are obligated to perform the initial section 112(d)(6) analysis. Because the timing for the initial section 112(d)(6) analysis coincides with those of the residual risk analysis, it is appropriate for the Agency to conduct both analyses at the same time and for the results of the risk analysis to impact future section 112(d)(6) technology reviews. However, we agree with the commenters that a revision is not necessarily required under section 112(d)(6) even if cancer risks are greater than or equal to 1 in 1 million. For example, it may be the case that a technology review is performed, but no change in the standard results from that review. In the preamble to the residual risk rule for Coke Ovens, we have applied a similar logic to the need for subsequent technology revisions under section 112(d)(6). As we stated in the Coke Ovens rule, if the ample margin of safety analysis for

a section 112(f) standard shows that the remaining risk for non-threshold pollutants falls below 1 in 1 million and for threshold pollutants falls below a similar threshold of safety, then further revision should not be needed because an ample margin of safety has already been assured.

We generally agree that where an AMOS is based on cost or technical feasibility future review under § 112(d)(6) may require additional controls if feasible control measures are identified. If the availability and/or costs of technology are part of the rationale for the ample margin of safety determination, it is reasonable to conclude that changes in those costs or in the availability of technology could alter our conclusions regarding the ample margin of safety. For this reason, we agree that revisions may be appropriate if the ample margin of safety established by the residual risk process considers cost or technical feasibility. In the EO proposal, we noted that while some states required the facilities to meet a more a stringent standard, we believed that the costs and feasibility concerns for implementing such a standard did not make adopting this standard a reasonable alternative. In addition, we noted in the preamble to the EO proposal that EPA had evaluated new technologies and alternatives during our investigation of the safety issue regarding

chamber exhaust vents and concluded that controls on those vents were not technologically feasible and additional controls on these vents were limited because of the safety issues. [For a full discussion of the safety issues, see 66 FR Notice 55577]

IV. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), we must determine whether a regulation is "significant" and, therefore, subject to Office of Management and Budget (OMB) review 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 government 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 or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, OMB has notified us that it considers this a “significant regulatory action” within the meaning of the Executive Order. We have submitted this action to OMB for review. Changes made in response to OMB suggestions or recommendations will be documented in the public record.

B. Paperwork Reduction Act

This action does not impose any new information collection burden. However, OMB has previously approved the information collection requirements for the national emissions standards under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. and has assigned OMB control number 2060-0283, EPA ICR number 1666.06. A copy of the OMB approved Information Collection Request (ICR) may be obtained from Susan Auby, Collection Strategies Division; U.S. Environmental Protection Agency (2822T); 1200 Pennsylvania Ave., NW, Washington, DC 20460 or by calling (202) 566-1672.

Burden means 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 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 our regulations are listed in 40 CFR part 9 and 48 CFR chapter 15.

We have established a public docket for this action, which includes the ICR, under Docket ID number EPA-HQ-OAR-2003-0197, which can be found in www.regulations.gov. Today's final decision will not change the burden estimates from those developed and approved in 1994 for the national emission standards.

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 today's rule on small entities, small entity is defined as: (1) a small business as defined by the Small Business Administrations' 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 today's final decision on small entities, we have concluded that this action will not have a significant economic impact on a substantial number of small entities. We are taking no further action at this time to revise the national emission standards. Thus, the final decision will not impose any

requirements on small entities. Today's final decision on the residual risk assessment and technology review for the national emission standards imposes no additional burden on facilities impacted by the national emission standards.

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, we 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 a rule for which a written statement is needed, section 205 of the UMRA generally requires us 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 us 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 of why that alternative was not adopted.

Before we establish any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, we 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 regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

We have determined that today's final decision does not contain a Federal mandate that may result in expenditures of $100 million or more to State, local, and tribal governments in the aggregate, or to the private sector in any 1 year. Therefore, today's final decision is not subject to the requirements of sections 202 and 205 of the UMRA. In addition, today's final decision does not significantly or uniquely affect small governments because it contains no requirements that apply to such governments or impose obligations upon them. Therefore, today's final

decision is not subject to section 203 of the UMRA.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999), requires us 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.”

Today’s final decision does 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. Thus, the requirements of the Executive Order do not apply to today’s final decision.

F. 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 us 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."

Today's final decision does not have tribal implications. It 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. Thus, Executive Order 13175 does not apply to today's final decision.

G. Executive Order 13045: Protection of Children from Environmental Health & 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 we have reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, we must evaluate the environmental health or safety effects of the planned rule on children and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

Today's final decision is not subject to the Executive Order because it is not economically significant as defined in Executive Order 12866, and because, as explained earlier, the Agency does not have reason to believe the environmental health or safety risk addressed by this action present a disproportionate risk to children.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

Today's final decision is not an "economically significant energy action" as defined in Executive Order 13211 (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. Further, we have concluded that today's final decision is not likely to have any adverse energy impacts.

I. National Technology Transfer and Advancement Act

Under section 12(d) of the National Technology Transfer

and Advancement Act of 1995 (NTTAA), Public Law No. 104-113, all Federal agencies are required to use voluntary consensus standards (VCS) 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 requires Federal agencies to provide Congress, through annual reports to OMB, with explanations when the agency does not use available and applicable VCS.

Today's final decision does not involve technical standards. Therefore, the requirements of the NTTAA are not applicable.

J. 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. We will submit a report containing this final decision 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 final decision 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). The final decision becomes effective on (INSERT DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER).

List of Subjects for 40 CFR Part 63

Environmental protection, Administrative practice and procedures, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements.

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Dated:

_____
Stephen L. Johnson,
Administrator.