remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

For additional information, see the direct final rule which is located in the Rules section of this **Federal Register**.

Dated: August 11, 2005.

Ira W. Leighton,

Acting Regional Administrator, EPA New England.

[FR Doc. 05–21195 Filed 10–21–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[OAR–2003–0197; FRL –7987–5]

RIN 2060–AK09

Ethylene Oxide Emissions Standards for Sterilization Facilities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed decision; request for public comment.

SUMMARY: On December 6, 1994, we promulgated Ethylene Oxide Emission Standards for Sterilization Facilities (59 FR 62585). The national emission standards limit and control hazardous air pollutants (HAP) that are known or suspected to cause cancer or have other serious health or environmental effect.

Section 112(f)(2) of the Clean Air Act (CAA) directs EPA to assess the risk remaining (residual risk) after the application of national emission standards controls and revise as necessary to protect public health. Also, CAA section 112(d)(6) requires us to review and to revise the national emission standards as necessary by taking into account developments in practices, processes, and control technologies. The proposal announces a decision and requests public comments on the residual risk assessment and technology review for the national emission standards. We are proposing no further action at this time to revise the national emission standards.

DATES: *Comments.* Comments must be received on or before December 8, 2005. *Public Hearing.* If anyone contacts EPA requesting to speak at a public hearing by November 8, 2005, a public hearing will be held approximately 20 days following publication of this notice in the **Federal Register**.

ADDRESSES: Submit your comments, identified by Docket ID No. OAR–2003–0197 (Legacy Docket A–88–03), by one of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- Agency Web site: *http://www.epa.gov/edocket*. EDOCKET, EPA's electronic public docket and comment system, is EPA's preferred method for receiving comments. Follow the on-line instructions for submitting comments.
- E-mail: *a-and-r-docket@epa.gov*.
- Fax: (202) 566–1741.
- Mail: Air Docket, EPA, Mailcode: 6102T, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. Please include a total of two copies.
- Hand Delivery: EPA, 1301 Constitution Avenue, NW., Room B102, Washington, DC 20460. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. OAR–2003–0197 (Legacy Docket A–88–03). The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.epa.gov/edocket*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through EDOCKET, regulations.gov, or e-mail. The EPA EDOCKET and the Federal regulations.gov Web sites are ''anonymous access'' systems, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through EDOCKET or regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket*. Although listed in the index, some information is not publicly available, *i.e.*, CBI 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 in EDOCKET or in hard copy at the Air and Radiation Docket, EPA/DC, EPA West, Room B102, 1301 Constitution Avenue, NW., Washington, DC. The Public Reading Room 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.

Public Hearing. If a public hearing is held, it will begin at 10 a.m. and will be held at the EPA's campus in Research Triangle Park, North Carolina, or at an alternate facility nearby. Persons interested in presenting oral testimony or inquiring as to whether a public hearing is to be held should contact Mr. David Markwordt, Policy Planning and Standards Group, Emission Standards Division, U.S. EPA (C439–04), Research Triangle Park, NC 27711, telephone (919) 541–0837.

FOR FURTHER INFORMATION CONTACT: For additional information on this proposed decision, review the reports listed in the **SUPPLEMENTARY INFORMATION** section.

General and technical information. Mr. David Markwordt, EPA, Office of Air Quality Planning and Standards, Emission Standards Division, Policy Planning and Standards Group (C439–04), Research Triangle Park, North Carolina 27711, telephone (919) 541–0837, facsimile number (919) 541–0942, electronic mail (e-mail) address: *markwordt.david@epa.gov*.

Residual risk assessment information. Mr. Mark Morris, EPA, Office of Air Quality Planning and Standards, Emission Standards Division, Risk and Exposure Assessment Group (C404–01), Research Triangle Park, North Carolina 27711, telephone (919) 541–5416, 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*	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.

* 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 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 proposed decision will also be available on the WWW through the Technology Transfer Network (TTN). Following signature, a copy of the proposed 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.

Reports for Public Comment. We have prepared two summary memoranda covering the rationale for the proposed decision and the residual risk analyses. These memoranda are entitled: ''Technology Review and Residual Risk Development for the Ethylene Oxide Commercial Sterilization NESHAP,'' and ''Residual Risk Assessment for the Ethylene Oxide Commercial Sterilization Source Category.'' Both reports are in the Docket No. OAR–2003–0197 (Legacy Docket A–88–03). See the preceding Docket section for docket information and availability.

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 two-stage regulatory process to address emissions of HAP from stationary sources. In the first stage, after EPA has identified categories of sources emitting one or more of the HAP listed in the CAA, section 112(d) calls for 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 must reflect the maximum reductions of HAP achievable (after considering cost, energy requirements, and non-air health and environmental impacts) and are commonly referred to as maximum achievable control technology (MACT) standards.

For area sources, CAA section 112(d)(5) provides that in lieu of MACT, the Administrator may elect to promulgate standards or requirements which provide for the use of generally available control technologies or management practices and such standards are commonly referred to as generally available control technology (GACT) standards.

On December 6, 1994 (59 FR 62585), we promulgated national emission standards for Ethylene Oxide Commercial Sterilization and Fumigation Operations. In that final rule, we set MACT for major sources under section 112(d)(2). As for area sources, we established MACT standards for certain emission points pursuant to section 112(d)(2) and GACT standards for other emission points pursuant to section 112(d)(5).

Section 112(d)(6) provides that EPA review these technology-based standards and revise them ''as necessary (taking into account developments in practices, processes and control technologies)'' no less frequently than every 8 years.

The second stage in standard setting is described in section 112(f) of the CAA. This provision requires, first, that EPA prepare a Report to Congress discussing (among other things) methods of calculating risk posed (or potentially posed) by sources after implementation of the MACT standards, the public health significance of those risks, the means and costs of controlling them, actual health effects to persons in proximity to emitting sources, and recommendations as to legislation regarding such remaining risk. EPA prepared and submitted the ''Residual Risk Report to Congress,'' EPA–453/R–99–001, in March 1999. The Congress did not act on any of the recommendations in the report, triggering the second stage of the standard-setting process, the residual risk phase.

Section 112(f)(2) requires us to determine for each section 112(d) source category whether the national emission standards protect public health with an ample margin of safety. If the national emission standards 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,'' EPA must promulgate residual risk standards for the source category (or subcategory) as necessary to provide an ample margin of safety. EPA must also

adopt more stringent standards to prevent an adverse environmental effect (defined in section 112(a)(7) as ''any significant and widespread adverse effect * * * to wildlife, aquatic life, or natural resources * * *.''), but must consider cost, energy, safety, and other relevant factors in doing so.

Section 112(f)(5) expressly provides, however, that EPA is not required to conduct any review under section 112(f) or promulgate any emissions limitations under that subsection for any area source listed pursuant to section 112(c)(3) for which EPA has issued GACT standards. Thus, although EPA has discretion to conduct a residual risk review under section 112(f) for area sources for which it has established GACT, it is not required to do so. See CAA section 112(f)(5).

B. What is our approach for developing residual risk standards?

Following our initial determination that the individual most exposed for the emissions category considered exceeds a 1-in-1 million lifetime excess cancer risk, our approach to developing residual risk standards is based on a two-step determination of acceptable risk and ample margin of safety. The first step, consideration of acceptable risk, is only a starting point for the analysis that determines the final standards. The second step determines the ample margin of safety which corresponds to the levels at which the standards are set.

The terms ''individual most exposed,'' ''acceptable level,'' and ''ample margin of safety'' are not specifically defined in the CAA. However, CAA section 112(f)(2)(B) refers positively to the interpretation of these terms in our 1989 rulemaking (54 FR 38044, September 14, 1989), ''National Emission Standards for Hazardous Air Pollutants (NESHAP): Benzene Emissions from Maleic Anhydride Plants, Ethylbenzene/Styrene Plants, Benzene Storage Vessels, Benzene Equipment Leaks, and Coke By-Product Recovery Plants,'' (Benzene NESHAP). We read CAA section 112(f)(2)(B) as essentially directing us to use the interpretation set out in that notice [1] or to utilize approaches affording at least the same level of protection.[2] We likewise notified Congress in its Residual Risk Report that we intended to use the Benzene NESHAP approach in making CAA section 112(f) residual risk determinations.[3]

In the Benzene NESHAP (54 FR 38044–45, September 14, 1989), we stated as an overall objective:

> * * * in protecting public health with an ample margin of safety, we strive to provide maximum feasible protection against risks to health from hazardous air pollutants by: (1) protecting the greatest number of persons possible to an individual lifetime risk level no higher than approximately 1 in 1 million; and (2) limiting to no higher than approximately 1 in 10 thousand [*i.e.*, 100 in a million] the estimated risk that a person living near a facility would have if he or she were exposed to the maximum pollutant concentrations for 70 years.

As explained more fully in our Residual Risk Report to Congress, these goals are not ''rigid line[s] for acceptability,'' but rather broad objectives to be weighed ''with a series of other health measures and factors.'' [4]

C. What are the current standards?

The Ethylene Oxide Emission Standards for Sterilization Facilities were promulgated on December 6, 1994 (59 FR 62585) and cover ethylene oxide, the only HAP emitted from the sterilization/fumigation process. The national emission standards regulate both major and area sources; the emission points regulated are the main sterilization and aeration room vents. The standards for major sources require that sources reduce main sterilization and aeration room vent emissions by 99 percent. The standards for area sources require that sources reduce main sterilization vent emissions by 99 percent.

During the development of the national emission standards, we estimated that there were approximately 188 facilities nationwide, of which 47 were major sources. Usually, these operations are not located at facilities with other types of HAP-emitting sources. The majority of sterilization facilities process on a contract basis, but some medical supply and spice manufacturers sterilize their own products. We estimated that the national emission standards would reduce emissions of ethylene oxide by 1,000 tons annually.

D. What are the results of the residual risk assessment?

Pursuant to CAA section 112(f)(2), we prepared a risk assessment to determine the residual risk posed by ethylene oxide sterilization facilities after implementation of the ethylene oxide national emission standards. The number of facilities in the source category has decreased since the development of the national emission standards for various reasons, including industry consolidation. We developed a list of 76 facilities that currently comprises both the major and area source categories, based on information primarily from the following three sources: (1) The 1999 National Emissions Inventory (NEI), (2) the 2000 Toxics Release Inventory (TRI), and (3) the Ethylene Oxide Sterilization Association (EOSA). We used these data sources for emissions and emission point release parameters in dispersion modeling.

As stated previously, consistent with section 112(f)(2), EPA must determine for each section 112(d) source category whether the MACT standards protect public health with an ample margin of safety. Because MACT and GACT are both required of some area sources, risk attributed to GACT emission points are included in the overall modeled risks for MACT. Therefore, the risks presented below are higher than just those risks attributed solely to emission points for which we established MACT in 1994.

Using the above-noted information, we modeled ambient concentrations near these facilities and calculated the risk of possible chronic cancer and noncancer health effects and evaluated whether acute exposures might exceed relevant health thresholds. We found that individual lifetime cancer risks exceeded 1-in-1 million in areas near 44 of the 76 modeled sources, and approximately 250,000 people live in these areas. Individual lifetime cancer risks exceeded 10-in-1 million in areas near 19 sources, and approximately 7,300 people live in these areas. The highest calculated individual lifetime cancer risk was 90-in-1 million at one facility.

An EPA assessment for ethylene oxide is currently under way. The EPA has not yet completed a full evaluation of the data on which it will determine an EPA cancer unit risk estimate for ethylene oxide. The EPA is also developing an acute reference exposure value for ethylene oxide. The schedule for both of these actions can be found at: *http://cfpub.epa.gov/iristrac.*

[1] This reading is confirmed by the Legislative History to CAA section 112(f); see, *e.g.*, ''A Legislative History of the Clean Air Act Amendments of 1990,'' vol. 1, page 877 (Senate Debate on Conference Report).

[2] Legislative History, vol. 1, p. 877, stating, ''* * * the managers intend that the Administrator shall interpret this 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 Administrator's benzene regulations * * *.''

[3] ''Residual Risk Report to Congress,'' March 1999, EPA–453/R–99–001, page ES–11.

[4] *Id.*

Under section 112(o)(7) of the CAA, we are required to issue revised cancer guidelines prior to the promulgation of the first residual risk rule under section 112(f) (an implication being that we should consider these revisions in the various residual risk rules). We have issued revised cancer guidelines and also supplemental guidance which deal specifically with assessing the potential added susceptibility from early-life exposure to carcinogens. The supplemental guidance provides an approach for adjusting risk estimates to incorporate the potential for increased risk due to early-life exposures to chemicals that are thought to be carcinogenic by a mutagenic mode of action. We are currently evaluating the available scientific information associated with ethylene oxide to see if ''age dependent adjustment factors'' should be applied when assessing cancer risk for early-life exposures which cause cancer through a mutagenic mode. If the scientific information indicates that it is appropriate to apply age dependent adjustment factors, then we will reassess the risks from exposure to ethylene oxide prior to the promulgation of the final rule.

Estimated annual cancer incidence rates were also calculated from predicted individual cancer risks for the people reported to reside in the U.S. census blocks within the modeled area around each facility (*i.e.*, within 50 kilometers). For the 44 facilities for which estimated maximum individual cancer risk is greater than 1-in-1 million, the summed estimated annual cancer incidence is 0.01 cases per year. Across all 76 modeled facilities, the total estimated annual incidence is 0.04 cases per year. We estimated that values presented here are incremental rates based on modeled concentrations and 2000 U.S. census data, and they should not be interpreted as actual cancer incidence rates derived from observations of disease occurrence over time (such as cancer incidence rates that may be reported based on epidemiological studies).

The highest chronic noncancer hazard index was 0.03. This means that the highest lifetime exposures to ethylene oxide were only 3 percent of the chronic noncancer reference concentration (RfC). Finally, we found that acute exposures, which were calculated by assuming the maximum hourly emissions rate and worst-case meteorological conditions, did not exceed any of the relevant health thresholds for acute effects for ethylene oxide.

We also consider an adverse environmental effect as a part of a residual risk assessment. Regarding the inhalation exposure pathway for terrestrial mammals, we conclude that human toxicity values for the inhalation pathway are generally protective of terrestrial mammals. Because the maximum cancer and noncancer hazards to humans from inhalation exposure are relatively low, we expect no significant and widespread adverse effects to terrestrial mammals from inhalation exposure to ethylene oxide from commercial sterilization facilities.

Some HAP which are persistent and bioaccumulative can also pose risks via pathways other than inhalation (*e.g.*, by depositing to the ground and entering the food chain). The EPA has developed a list of persistent, bioaccumulative, and toxic (PBT) HAP based on information from the Pollution Prevention program, the Great Waters program, the TRI, and additional analysis conducted by the Office of Air Quality Planning and Standards. Ethylene oxide is not on the list of PBT. Consequently, we conclude the noninhalation risks to be minimal, and we conclude that a quantitative risk assessment for multipathway exposures is unnecessary.

The details of this analysis can be found in our ''Memorandum: Data and Assumptions Used for the Screening-level Residual Risk Analysis of the Commercial Ethylene Oxide Sterilizers and Fumigators Source Category'' and the supporting ''Memorandum: Residual Risk Assessment for Ethylene Oxide Commercial Sterilization Source Category.'' See ''Reports for Public Comment'' in the **SUPPLEMENTARY INFORMATION** section above for information on obtaining these reports.

E. What are our conclusions regarding the need for more stringent standards under section 112(f)(2)?

In the first step of the decision-making process under section 112(f)(2), the determination of acceptability, we note that the maximum individual excess lifetime cancer risk associated with any facility with MACT is less than what we would normally consider as the upper limit of acceptable risk (*i.e.*, less than 100-in-1 million).[5] Therefore, we are satisfied that these sources represent acceptable risk without the need for further more stringent controls.

In the second step of the ample margin of safety framework under section 112(f)(2), we consider setting standards at a level which may be equal to, or lower than, the acceptable risk level and which protects public health with an ample margin of safety. In making the determination, 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.

Because our conservative risk estimates suggest facilities in the category continue to pose risks exceeding 1-in-1 million after the application of MACT, we considered additional controls, such as new technology or alternative controls, to reduce emissions and associated risks. In 2001, while investigating the safety issue associated with chamber exhaust vents, we did not find any new technology or alternative controls for any of the vents—chamber, sterilizer or aeration room vents. We also found no data to support the addition of down stream control devices to existing control means as a way of further reducing emissions. This discussion can be found in our ''Memorandum: Technology Review and Residual Risk Data Development for the Ethylene Oxide Commercial Sterilization NESHAP.'' We concluded that further controls would not meaningfully reduce emissions from emission vents controlled with MACT at both major and area sources.

While no additional control measures for emission vents controlled with MACT have been identified that would result in a meaningful reduction of emissions, we are aware of existing State rules which have control limits exceeding the 99 percent MACT requirement. The State of California's emissions reductions requirement for the main sterilizer vent is 99.9 percent; this requirement was enacted prior to promulgation of the Federal requirements.

We do not have data to confirm that all facilities are capable of achieving 99.9 percent on a continuous basis. In 1994, in support of the Federal control limit, we concluded both rules are sufficiently stringent to require application of the same technologies. We concluded it reasonable to assume the same technologies perform similarly, *i.e.*, those facilities outside of California are on average likely to achieve emissions reductions similar to

[5] Although we conducted a risk assessment which included emissions from those vents for which we set GACT in 1994, we are exercising our discretion under section 112(f)(5) not to undertake the section 112(f)(2) analysis for those GACT emission points.

See CAA sections 112(f)(2)(A), (B) and (f)(5). The discussion in this section of the preamble, therefore, is limited to those emission points for which we established MACT in 1994.

those in California. We concluded that tightening the current standards would not meaningfully reduce risks.

The EPA requests comments specifically addressing our conclusion that the tightening of the current standards would not meaningfully reduce emissions or risks. Both EPA's and California's rules require a test to demonstrate compliance with the emissions reductions limit and continuous monitoring of the control equipment to ensure proper operation and maintenance. Initial compliance tests are performed one time and on a very narrow set of operating conditions. The test results are too limited to determine if there are any meaningful differences in control technology lifetime performance associated with a 99 percent and 99.9 percent performance limit. Specifically, there are several questions on which we are requesting public comment:

- Are there available test data demonstrating achievability of 99.9 percent emissions reductions on a continuous basis for the main sterilizer vent?
- Are there available test data demonstrating a meaningful difference in lifetime control performance between the same technology when it is subject to either the 99 or 99.9 percent emissions reductions requirement?
- Are there available test data demonstrating all similar existing control technology is capable of achieving 99.9 percent emissions reductions on a continuous basis?
- Are there available data showing the variance in long-term performance for similar technology complying with the 99 or 99.9 percent emissions reductions limit?
- Are there additional costs associated with increasing the percent reduction from 99 to 99.9 percent?

We also considered prohibiting the use of ethylene oxide for new facilities, which would necessitate the use of an alternative sterilization process. The Food and Drug Administration (FDA) has primary authority to regulate the use of sterilization methods. The FDA issued guidance (510(k) Sterility Review Guidance K90–1, August 30, 2002 (''FDA Guidance'')) to facilitate nontraditional sterilization methods. The FDA stated in the guidance that the FDA ''has had little or no experience with these methods for achieving sterilization and is concerned about a manufacturer's ability to successfully use such methods without adversely affecting the sterility assurance level * * *.'' If the use of ethylene oxide were prohibited, manufacturers of products requiring sterilization would have to reconsider the device and packaging material, its compatibility with the nontraditional sterilizing agent, the packaging configuration, the ability of the nontraditional sterilant to penetrate the packaging, the cost, and availability. Because these nontraditional sterilization methods are less known, manufacturers would have to submit to FDA their validation data for review. Nontraditional sterilization operations cannot be used to sterilize materials until they have been validated. Prohibiting the use of ethylene oxide carries the risk of creating a void where some products may not be able to be sterilized until newer systems are designed and validated. Until such time as these nontraditional sterilization techniques may be used under FDA rules, these techniques are not considered available for the purpose of reducing emissions.

Radiation (gamma and electron beam) can be used to sterilize many products. Radiation sterilization has been used for about half of the products sterilized in the U.S. However, these sterilization techniques are limited in their applications. For example, gamma radiation has potentially damaging effects on products, particularly those products that contain polymers. And, radiation technology is completely different from chamber sterilization. Ethylene oxide and radiation technologies (both gamma and e-beam) share no common equipment. Any conversion would involve scrapping the ethylene oxide chambers and the related specialized equipment and systems, and likely displacing the existing workforce. Additionally, the ethylene oxide sterilization facility would not meet requirements for a radiation facility. To construct a radiation facility, special shielding (huge concrete/lead shields) and storage pools need to be incorporated into the design of both the building and the process.

As stated previously, further controls for emission vents controlled with MACT at both major and area sources do not meaningfully reduce emissions or the corresponding risks. Further, the review has shown that both the noncancer and acute risks from this source category are below their relevant health thresholds. As a result, we conclude 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 national emission standards.

Thus, we conclude that the level of risk resulting from the limits in the national emission standards is acceptable for these source categories, and that changes to the national emission standards are not required to satisfy section 112(f) of the CAA.

As discussed above, the EPA is developing a cancer unit risk estimate for ethylene oxide. If the EPA value becomes available before the promulgation of the final rule, we will reevaluate whether the risks are acceptable and whether an ample margin of safety has been achieved.

F. How are we addressing GACT at area sources for purposes of section 112(f)?

As noted above, section 112(f)(5) provides that EPA may, but is not required to, conduct any review under section 112(f) or promulgate any emissions limitations under that subsection for any area source for which an emissions standard is promugated as GACT. The CAA clearly permits EPA to review area source emissions under section 112(f)(2), even when the agency issued GACT standards under section 112(d)(5) during its initial review. What is less clear is what the approach should be when the agency has ''mixed'' its emission standards (*i.e.*, issued both MACT and GACT standards) for an area source category. In this instance, for example, EPA has issued MACT standards, under section 112(d)(1), for sterilizer vents and chamber exhaust vents; and GACT standards, under section 112(d)(5), for aeration room vents. This leaves open the question of which emissions points should be reviewed under a subsequent section 112(f)(2) review. In this instance, EPA has undertaken an analysis under section 112(f)(2) for the area emissions standards that were issued as MACT standards, but the Agency has exercised its discretion and chosen not to perform an section 112(f)(2) analysis for those emissions points for which we established GACT. The Agency may have other alternatives legally available, however. For example, because the Administrator is not required to perform a residual risk analysis for any area source category when the Agency has previously promulgated ''*an* emissions standard'' pursuant to section 112(d)(5), it is at least arguable that, by using the singular article ''an,'' Congress intended to permit the Agency discretion to decline to review the area source category, in its entirety, under section 112(f)(2) in appropriate ''mixed'' cases. The Agency seeks comment on the Agency's range of discretion under section 112(f)(5) and suggestions on what factors should guide decisions about its approach in future rulemakings.

G. What are the results of the technology review?

Section 112(d)(6) of the CAA requires us to review and revise as necessary (taking into account developments in practices, processes, and control technologies) emission standards promulgated under this section no less often than every 8 years. In the course of our review, we investigated emission control levels and the potential for additional emissions reductions from existing affected facilities within the ethylene oxide commercial sterilization source category. 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.

For new major sources where MACT requires emissions reductions of 99 percent, we considered increasing the emissions reductions limit to 99.9 percent in the national emission standards. A new limit would only apply to affected new sources (a new facility for the standards), while existing sources would still be subject to the current limits. As stated previously, we do not have data to confirm that facilities are capable of achieving 99.9 percent on a continuous basis. Therefore, the 99 percent emissions reductions requirement of the national emission standards is considered to be the best control level in practice nationally. We conclude that the new source standard for the emissions reductions limit should be kept the same as that for existing, and that no further revisions to the National Emission Standards for Ethylene Oxide Sterilization Facilities are needed.

In the original generally GACT determination for new area sources, no control requirements were established due to the high cost (59 FR 10598–99). 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 which would reduce the costs of applying controls to new area sources.

Because the national emission standards continue to represent the best controls that can be implemented nationally, we are proposing not to revise the National Emission Standards for Ethylene Oxide Sterilization Facilities under CAA section 112(f) or 112(d)(6).

II. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), EPA 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.

It has been determined that today's proposed decision is a ''significant regulatory action'' under the terms of Executive Order 12866 because it raises novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. Therefore, today's proposed decision was submitted to OMB for review. However, today's proposed decision will result in no additional cost impacts beyond those estimated for the current national emission standards. 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 under the provisions of the Paperwork Reduction Act, 44 U.S.C. *et seq.* Today's proposed decision will not change the burden estimates from those developed and approved for the national emission standards. In 1994, OMB approved the information collection requirements for the national emission standards under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, and assigned OMB control number 2060–0283.

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 EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15.

EPA has established a public docket for this action, which includes the ICR, under Docket ID number OAR 2003–0197, which can be found in *http://www.epa.gov/edocket.* Today's proposed 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 proposed decision on small entities, small entity is defined as: (1) A small business whose parent company has fewer than 100 or 1,500 employees, or a maximum of $5 million to $18.5 million in revenues, depending on the size definition for the affected North American Industry Classification System (NAICS) code; (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. It should be noted that the small business definition applied to each industry by NAICS code is that listed in the Small Business Administration (SBA) size standards (13 CFR 121).

After considering the economic impacts of today's proposed decision on small entities, I certify that the decision will not have a significant economic impact on a substantial number of small entities. The proposed decision will not impose any requirements on small entities. Today's proposal announces a decision and requests public comments on the residual risk assessment and technology review for the national emission standards and imposes no additional burden on facilities impacted by the national emission standards. We are proposing no further action at this time to revise the national emission standards. We continue to be interested in the potential impacts of the proposed decision on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures 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 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 of why that alternative was not adopted.

Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

The EPA has determined that today's proposed 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 proposed decision is not subject to the requirements of sections 202 and 205 of the UMRA. In addition, today's proposed 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 proposed 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 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.''

Today's proposed 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 proposed 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 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.''

Today's proposed 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 proposed decision.

G. Executive Order 13045: Protection of Children From Environmental Health 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, EPA 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 proposed decision is not subject to the Executive Order because it is not economically significant as defined in Executive Order 12866 and because 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 proposed decision is not a ''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 proposed decision is not likely to have any adverse energy impacts.

I. National Technology Transfer and Advancement Act of 1995

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 proposed decision does not involve technical standards. Therefore, the requirements of the NTTAA are not applicable.

List of Subjects in 40 CFR Part 63

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

Dated: October 18, 2005.

Stephen L. Johnson,

Administrator.

[FR Doc. 05–21187 Filed 10–21–05; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[OAR–2004–0004, FRL–7987–4]

RIN 2060–AK16

National Emission Standards for Hazardous Air Pollutants for Industrial Process Cooling Towers

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed action; request for public comment.

SUMMARY: On September 8, 1994, we promulgated national emission standards for hazardous air pollutants (NESHAP) from industrial process cooling towers (59 FR 46350). The NESHAP eliminated the use of chromium-based water treatment chemicals that are known or suspected to cause cancer or have a serious health or environmental effect.

Section 112(f)(2) of the Clean Air Act (CAA) directs EPA to assess the risk remaining (residual risk) after the application of the NESHAP and promulgate additional standards if warranted to provide an ample margin of safety to protect public health or prevent an adverse environmental effect. Also, section 112(d)(6) of the CAA requires EPA to review and revise the NESHAP as necessary at least every 8 years, taking into account developments in practices, processes, and control technologies. Based on our findings from the residual risk review and technology review, we are proposing no further action at this time to revise the NESHAP. This proposed action requests public comments on the residual risk review and technology review for the NESHAP.

DATES: *Comments.* Comments must be received on or before December 8, 2005.

Public Hearing. If anyone contacts EPA requesting to speak at a public hearing by November 8, 2005, a public hearing will be held approximately 20 days following publication of this action in the **Federal Register**.

ADDRESSES: Submit your comments, identified by Docket ID No. OAR–2004–0004, by one of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- Agency Web site: *http://www.epa.gov/edocket.* EDOCKET, EPA's electronic public docket and comment system, is EPA's preferred method for receiving comments. Follow the on-line instructions for submitting comments.
- E-mail: *a-and-r-docket@epa.gov* and *mulrine.phil@epa.gov.*
- Fax: (202) 566–1741 and (919) 541–5450.
- Mail: U.S. Postal Service, send comments to: EPA Docket Center (6102T), Attention Docket Number OAR–2004–0004, 1200 Pennsylvania Ave., NW., Washington, DC 20460.
- Hand Delivery: In person or by courier, deliver comments to: EPA Docket Center (6102T), Attention Docket ID Number OAR–2004–0004, 1301 Constitution Avenue, NW., Room B–102, Washington, DC 20004. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information. Please include a total of two copies. We request that a separate copy of each public comment also be sent to the contact person for the proposed action listed below (see **FOR FURTHER INFORMATION CONTACT**).

Instructions: Direct your comments to Docket ID No. OAR–2004–0004. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.epa.gov/edocket*, including any personal information provided, unless the comment includes information claimed to be confidential business information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through EDOCKET, regulations.gov, or e-mail. The EPA EDOCKET and the Federal regulations.gov Web sites are ''anonymous access'' systems, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through EDOCKET or regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. (For additional information about EPA's public docket visit EDOCKET on-line or see the **Federal Register** of May 31, 2002 (67 FR 38102.)

Docket: All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., CBI 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 in EDOCKET or in hard copy at the EPA Docket Center, Docket ID Number OAR–2004–0004, EPA West Building, Room B102, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room 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 EPA Docket Center is (202) 566–1742. A reasonable fee may be charged for copying docket materials.

FOR FURTHER INFORMATION CONTACT: For questions about the proposed action, contact Mr. Phil Mulrine, U.S. EPA, Office of Air Quality Planning and Standards, Emission Standards Division, Metals Group (C439–02), Research Triangle Park, North Carolina