6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA-HQ-OAR-2003-0161, FRL-]

RIN 2060-AK23

National Emission Standards for Magnetic Tape Manufacturing Operations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final action.

SUMMARY: On December 15, 1994, we promulgated national emission standards for hazardous air pollutants for Magnetic Tape Manufacturing Operations. The standards limit and control emissions of hazardous air pollutants 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 directs EPA to assess the risk remaining (residual risk) after the application of national emission standards for hazardous air pollutants controls 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, section 112(d)(6) of the Clean Air Act requires EPA to review and revise the national emission standard for hazardous air pollutants, as necessary, taking into account developments in practices, processes, and

control technologies. On October 24, 2005, based on the findings from our residual risk and technology review, we proposed no further action to revise the national emission standards for hazardous air pollutants and requested public comment. Today's final action responds to public comments received on the proposed action and announces EPA's final decision not to revise the standards.

DATES: This final action is effective on [INSERT DATE OF PUBLICATION OF THE FINAL ACTION IN THE FEDERAL REGISTER].

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA-HQ-OAR-2003-0161. 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, i.e., confidential business information (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 through www.regulations.gov or in hard copy at the HQ EPA Docket Center, Docket ID No. EPA-HQ-OAR-2003-0161, EPA West Building, 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 HQ 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 final action, contact Mr. H. Lynn Dail, U.S. EPA, Office of Air Quality Planning and Standards, Sector Policies and Programs Division, Natural Resources and Commerce Group (C539-03), Research Triangle Park, North Carolina 27711; telephone number: (919) 541-2363; fax number: (919) 541-5689; e-mail address: dail.lynn@epa.gov. For questions on the residual risk analysis, contact Ms. Maria Pimentel, U.S. EPA, Office of Air Quality Planning and Standards, Health and Environmental Impacts Division, Sector Based Assessment Group (C404-01), Research Triangle Park, North Carolina 27711; telephone number: (919) 541-5280; fax number: (919) 541-0840; e-mail address: pimentel.maria@epa.gov.

SUPPLEMENTARY INFORMATION:

Regulated Entities. The regulated categories and entities affected by the national emission standards for hazardous air pollutants (NESHAP) include:

Category	**NAICS[a] Code**	**Examples of Regulated Entities**
Industry	334613 322222 325992	Operations at major sources that are engaged in the surface coating of magnetic tape.
Federal government		Not affected.
State, local, tribal		Not affected.

government

[a] North American Industry 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 Magnetic Tape NESHAP. To determine whether your facility would be affected by the Magnetic Tape NESHAP, you should examine the applicability criteria in 40 CFR Part 63.701(a) of subpart EE (NESHAP for Magnetic Tape Manufacturing Operations). If you have any questions regarding the applicability of the Magnetic Tape NESHAP to a particular entity, contact Mr. Leonard Lazarus, U.S. EPA, Office of Enforcement and Compliance Assurance, Office of Compliance, Air Compliance Branch (2223A), Ariel Rios Building, 1200 Pennsylvania Avenue, NW, Washington, DC 20460; telephone number: (202) 564-6369; fax number: (202) 564-0050; e-mail address: lazarus.leonard@epa.gov.

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

Judicial Review. Under section 307(b)(1) of the CAA, 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 "only 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, "if 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, D.C. 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, D.C. 20004.

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

I. Background

A. What is the statutory authority for this action?

Section 112 of the Clean Air Act (CAA) establishes a two-stage regulatory process to address emissions of hazardous air pollutants (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 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.

The EPA is then required to review these technology-

based standards and to 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 that EPA prepare a Report to Congress describing, among other things, methods of estimating risks 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 risks to persons in proximity to emitting sources, and recommendations as to legislation regarding such remaining risk. The EPA prepared and submitted this report (“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 stage.. Section 112(f)(2) requires us to determine for each section 112(d) source category, except area source categories for which we issued a generally available control technology standard, whether the NESHAP protects public health with an ample margin of safety. 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 a 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 an 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 the Magnetic Tape NESHAP accomplish?

On December 15, 1994, we promulgated the NESHAP for Magnetic Tape Manufacturing Operations (59 FR 64580) and required existing sources to comply with the NESHAP by December 15, 1996.

The Magnetic Tape NESHAP covers HAP emissions from surface coatings used in the manufacture of magnetic and optical recording media used in audio, video, computer and magnetic stripe tape and disks. The emission units regulated by the Magnetic Tape NESHAP are storage tanks, mix

preparation equipment, coating operations, waste handling devices, condenser vents in solvent recovery, particulate transfer operations, wash sinks for cleaning removable parts, equipment for flushing fixed lines, and wastewater treatment operations. The Magnetic Tape NESHAP regulates only those sources located at major sources. During the development of the NESHAP, we identified 25 existing magnetic recording media and magnetic stripe facilities, of which 14 were considered major and, therefore, subject to the NESHAP. Currently, there are only six magnetic tape manufacturing facilities remaining in the United States, all of which are major.

In general, the current NESHAP requires an overall HAP control efficiency of at least 95 percent for emissions from each solvent storage tank, piece of mix preparation equipment, coating operation, waste handling device, or condenser vent in solvent recovery. If an incinerator is used to control these emissions points, an outlet HAP concentration of no greater than 20 parts per million by volume by compound may be met, instead of achieving 95 percent control, as long as the efficiency of the capture system is 100 percent. If a coating with a HAP content no greater than 0.18 kilograms per liter (1.5 pounds per gallon) of coatings solids is used, that coating operation does not require further control.

Several solvents and particulate HAP are used in the magnetic tape manufacturing industry. Currently, the solvents used to the greatest extent are methyl ethyl ketone (MEK) and the HAP toluene, and the particulate HAP are cobalt and cobalt compounds. At the time of promulgation of the NESHAP, however, the solvents in use included MEK, cyclohexanone, acetone, and isopropyl alcohol and the HAP toluene, methyl isobutyl ketone, toluene diisocyanate, ethylene glycol, methanol, xylenes, ethyl benzene, and acetaldehyde; and the particulate HAP included chromium, cobalt, and their respective compounds. Several of these compounds are no longer used in the industry. The compound MEK and the HAP toluene are used at all facilities. At the time of promulgation of the magnetic tape NESHAP, MEK was a listed HAP, and we estimated that HAP emissions, including MEK and toluene, would be reduced by 2,080 megagrams per year (Mg/yr) (2,300 tons per year (tpy)) from a baseline of 4,060 Mg/yr (4,470 tpy). Methyl ethyl ketone was later delisted by EPA in 70 FR 75047, December 19, 2005.

C. What were the conclusions of the residual risk assessment?

As required by section 112(f)(2) of the CAA, we prepared a risk assessment to determine the residual risk posed by magnetic tape manufacturing operations after implementation of the NESHAP. We compiled a list of the six

magnetic tape manufacturing facilities still in operation in the United States based on inventory information we gathered from a number of manufacturing facilities and State environmental program offices (e.g., whether these facilities were still operating and manufacturing magnetic tape).

The major compounds emitted by the magnetic tape manufacturing source category are MEK and the HAP toluene, which comprise 97 percent, by tpy, of all emissions in the source category. The six magnetic tape manufacturing facilities have MEK and HAP emissions ranging from 3.9 to 214 Mg/yr (4.3 to 236 tpy). At the time of proposal, MEK was a listed HAP, and the nationwide annual HAP emissions, including MEK and toluene, were estimated to be 468 Mg/yr (516 tpy). Methyl ethyl ketone has since been delisted.

Using these data, we modeled exposure concentrations surrounding the six facilities, calculated the risk of possible chronic cancer and noncancer health effects, evaluated whether acute exposures might exceed relevant health thresholds, and investigated human health multipathway and ecological risks.

The emissions data used in the residual risk assessment represent actual levels of emissions for the base year. We have no reason to believe that there is a substantial amount of over control compared to what is allowed under the MACT

standard. Therefore, the results of the risk assessment represent our approximation of the maximum risks which would be allowed under compliance with the NESHAP.

Consistent with the tiered modeling approach described in the Residual Risk Report to Congress of March 1999 (EPA-453/R-99-001), the risk assessment for this source category started with a simple assessment, which used health-protective assumptions in lieu of site-specific data. The results demonstrated negligible risks for potential chronic cancer, chronic noncancer, and acute noncancer health endpoints. Also, no significant human health multipathway or ecological risks were identified. Had the resulting risks been determined to be non-negligible, a more refined analysis with site-specific data would have been necessary.

The assessment is described in detail in the memorandum "Residual Risk Assessment for the Magnetic Tape Manufacturing Source Category," available in the docket. Since our assessment shows that sources subject to the Magnetic Tape Manufacturing NESHAP pose maximum lifetime excess cancer risks which are significantly less than 1 in 1 million, EPA concluded that public health is protected with an ample margin of safety, and since noncancer health risks and ecological risks were also found to be insignificant for this source category, EPA is not obligated to adopt standards under section 112(f) of the CAA. Because risks

contributed by MEK are a negligible part of the overall risk, the delisting of MEK has essentially no effect on the risk assessment performed for the proposed rule.

D. What were the conclusions of the technology review?

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. As we stated in the preamble to the Coke Ovens residual risk rule (70 FR 20009), and as discussed below, the facts underlying a section 112(f) determination should be key factors in making any subsequent section 112(d)(6) determinations. For this and several other source categories, we were under consent decree deadlines to complete both the section 112(d)(6) technology review and the section 112(f)(2) residual risk analysis by the same date. As a result, we conducted the two reviews concurrently and did not have the results of the section 112(f)(2) analysis before we began the section 112(d)(6) technology review.

We reviewed available information about the industry, talked with industry representatives, and contacted several facilities in the industry to investigate available emission control technologies and the potential for additional emission reductions. We did not identify any additional

control technologies beyond those that are already in widespread use within the source category (e.g., carbon adsorbers, condensers). The only developments identified involve improvements in the performance of existing technologies or increased frequency of inspections and testing, which would achieve only small incremental emission reductions. However, we did discover that new product developments (optical recording media and solid state recording media) may eventually supplant magnetic tape, but these media are not considered magnetic tape and would not be covered under the Magnetic Tape NESHAP. Therefore, our investigation did not identify any significant developments in practices, processes, or control technologies in the magnetic tape manufacturing industry since promulgation of the original standards in 1994. We undertook the technology assessment for this source category consistent with our policy in the Coke Ovens residual risk rule (70 FR 20008-20009).

E. What was the proposed action?

On October 24, 2005, based on the findings from our residual risk and technology review, we proposed no further action to revise the NESHAP (70 FR 61417) and requested public comment.

II. Today's Action

A. What is today's final action?

Today's final action responds to public comments received on the proposed action and announces our final decision not to revise the standards.

B. What comments were received on the proposed action?

In the proposed action, we requested public comment on our residual risk review and our technology review and on issues of delisting the source category and conducting future technology reviews. By the end of the public comment period, comments from five entities had been received. A summary of these comments and EPA's responses are provided in the sections below.

1. Residual Risk Determination

Comment: Three commenters supported EPA's decisions for the magnetic tape source category. The commenters supported EPA's conclusion that no changes to the existing NESHAP for magnetic tape manufacturing were required to satisfy the requirements of section 112(f). The commenters noted that EPA correctly reviewed the magnetic tape sources, followed the tiered risk assessment approach described in its Residual Risk Report to Congress, and, using a conservative methodology, determined that no source in the category had a maximum individual cancer risk exceeding the 1-in-1-million level for triggering promulgation of a residual risk standard under section 112(f).

Two of the commenters stated that EPA was correct to

focus its section 112(f) residual risk analysis on the sources in the magnetic tape source category subject to section 112(d) requirements, and not consider risk from outside that source category. According to the commenters, the statutory language and construction of section 112(f) shows that Congress was directing EPA to perform residual risk analyses for individual source categories.

Response: We acknowledge the commenters' support for our health-protective methodology and our conclusions in the proposed notice. However, we do not agree that our section 112(f) residual risk analyses must always focus only on the sources in the category subject to section 112(d) requirements or that Congress intended to limit all residual risk analyses to the individual source categories in question. As we stated in the preamble to the Coke Ovens residual risk rule, "EPA disagrees that section 112(f) precludes EPA from considering emissions other than those from the source category or subcategory entirely." Rather, we have concluded that, when the statutory risk trigger is exceeded, the two-step approach set forward in the Benzene NESHAP remains the approach that we should follow in determinations under section 112(f). At the first step, when determining "acceptable risk," we will consider risks that result from emissions from the source category only. However, during the second step, we must determine whether

additional reductions should be required to protect public health with "an ample margin of safety." One of the factors that we can consider in this second step is environmental levels of HAP due to emissions from sources outside the source category being assessed. This could include ambient background concentrations of HAP, as well as co-location of other emission sources that augment the identified risks from the source category.

2. Delisting the Source Category

At proposal, we requested comment on whether it would be appropriate to delist the magnetic tape source category under section 112(c)(9) based on the possibility that HAP emissions from the source category would be sufficiently low even in the absence of MACT standards.

Comment: One commenter opposed delisting the magnetic tape source category, stating that if the source category was delisted, there would be nothing to prevent sources from increasing their HAP emissions substantially or changing their processes to emit new HAP, resulting in HAP levels unacceptable to public health and the environment. The commenter indicated that such an approach ignores the possibility that HAP emissions were reduced to an acceptable level because of the MACT requirements and that emissions could increase again without the MACT standard in place. Furthermore, the commenter believed that Congress did not

intend for the residual risk review to result in delisting of regulated source categories; if Congress had wanted to make delistings dependent on or linked to the outcome of the residual risk process, it would have specifically mandated this in the CAA, which it did not.

Two commenters argued that delisting a source category does not affect the applicability of an existing NESHAP and cited the delisting action following the Asbestos NESHAP as support for their argument. They also noted that EPA said in its proposal that no further section 112(d)(6) reviews are required unless there is a significant change to the source category. Consequently, the commenters saw no benefit in delisting the magnetic tape source category. However, they were not opposed to such an action.

One commenter supported delisting the magnetic tape source category under the authority of section 112(c)(9) based on EPA's finding of negligible risks (0.01 in 1 million). The commenter stated that EPA's request for comment implied that it interpreted the CAA to allow delisting on the basis of low risk only before a MACT standard is issued; however, section 112(c)(9) provides EPA with the authority to delist a source category whenever the Administrator makes a determination that the risks are below the risk criteria in the CAA and does not limit this authority to sources not yet subject to a MACT or GACT

standard. According to the commenter, limiting EPA's discretion to delist source categories prior to issuing MACT or GACT standards also conflicts with the required sequence of duties under section 112, which does not require EPA to conduct a risk analysis until a residual risk evaluation is required 8 years after MACT standards are issued; consequently, EPA is unlikely to have sufficient data on which to base a delisting decision until many years after MACT standards have been promulgated. Furthermore, the commenter stated it is possible that source categories found to be low-risk after MACT standards were imposed may have been low-risk before the standards were imposed, especially magnetic tape facilities, where the risk assessment showed risks two orders of magnitude below the statutory criteria for delisting under section 112(c)(9). Finally, the commenter noted that if EPA was concerned that the source category would exceed risk levels if MACT controls were not applicable, it could use section 112(c)(9) to keep in place those MACT requirements needed to sustain the low-risk determination and delisting. According to the commenter, those requirements could be established as part of the delisting decision and maintained in the title V permit, as was done in the NESHAP for Plywood and Composite Wood Products.

Response: Based on our risk assessment of the magnetic

tape source category, we have concluded that these sources are low-risk and, therefore, that no further standards are required to protect public health with an ample margin of safety or to protect the environment. However, we agree with the commenter who argues that this conclusion is based, at least in part, on the fact that the MACT requirements for these sources limit HAP emissions. Further, we disagree with the comment that delisting will not affect the viability of the existing NESHAP. The commenter cited the delisting action following the Asbestos NESHAP as support for their argument, noting that the applicability of that rule was not affected by delisting. However, the Asbestos NESHAP was established under part 61, which is not directly relevant in this situation since the Magnetic Tape NESHAP is a part 63 rule. If we delist this source category, it is our conclusion that existing magnetic tape sources would no longer be subject to the NESHAP and, thus, HAP emissions would no longer be limited by this rule. If sources begin emitting HAP at levels exceeding those allowed under the NESHAP, risks could increase, and the basis for our finding that the source category is low-risk could be compromised. We have already documented that emissions from magnetic tape manufacturing operations were substantially higher at promulgation, compared to more recent emissions estimates (after the standards were implemented). As noted in the

October 24, 2005 proposal (70 FR 61419) and previously in this action, HAP emissions at promulgation were estimated to be 4,060 Mg/yr (4,470 tpy), while HAP emissions in 2000 were estimated to be 468 Mg/yr (516 tpy)--a difference of almost 90 percent, some of which is due to compliance with the MACT standard and some of which is due to 19 plant closures since 1994. These HAP emissions estimates include MEK, which has since been delisted as a HAP. More recent information suggests that the delisting of MEK may result in one plant reducing its emissions to below the major source levels. If the potential-to-emit limit for this facility is below the major source threshold due to the delisting of MEK, it would become an area source and as such would no longer be subject to the magnetic tape manufacturing NESHAP. Nonetheless, since compliance with the MACT standard is part of the basis for our low-risk determination, we believe that our policy objectives are best served if we do not delist the magnetic tape source category.

Contrary to one commenter’s contention, we did not intend to imply through our request for comments that we interpret section 112(c)(9) of the CAA to apply only before a MACT standard has been promulgated. We were simply seeking comment on the use of section 112(c)(9) after the MACT standard. However, for the reasons presented above, we have decided not to use section 112(c)(9) to delist the

magnetic tape source category

The Agency would like to remove the burden of the repetitive review of Section 112 standards for low risk source categories. At the same time, we think it is appropriate to maintain the MACT controls, in this case. We plan to further investigate approaches for removing low-risk source categories from the Section 112 universe while maintaining MACT-level controls. An example of a similar approach is found in the Plywood and Composite Wood Products MACT where we allow a subcategory of facilities to reduce emissions to acceptable risk levels through Title 5 permits and remove them from the MACT universe.

3. Future Technology Reviews

At proposal, we requested comment on "the notion that, barring any unforeseeable circumstances which might substantially change this source category or its emissions, we would have no obligations to conduct future technology reviews under CAA section 112(d)(6)." We suggested this approach because of the low-risk finding for this source category under section 112(f).

Comment: One commenter disagreed that low risk from a source category at this time should absolve EPA of its obligation to conduct future technology reviews. The commenter stated that, without periodic reviews of source categories and technology in the future reviews, EPA would

not be aware of any technologies that have been developed or any “unforeseeable circumstances” related to the source category to which EPA refers in the notice. Furthermore, the commenter believed that Congress did not intend for the residual risk review to result in the removal of EPA’s obligation to conduct future technology reviews under section 112(d)(6); if Congress had wanted to make technology reviews dependent on or linked to the outcome of the residual risk process, it would have specifically mandated this in the CAA, which it did not.

Three commenters stated that EPA has no obligation to conduct a technology review in the case of Magnetic Tape. According to the commenters, because the residual risk provisions of the CAA were not triggered by the magnetic tape source category’s remaining low risk, even an initial technology review was unnecessary. The commenters noted that EPA only used the results of the section 112(f)(2) residual risk analysis to conclude that future section 112(d)(6) technology reviews would not be required. The commenters stated that EPA’s use of a formal technology review as the basis for its conclusion under section 112(d)(6) that the NESHAP did not need to be revised was inconsistent with EPA’s prior stated position in the Coke Ovens residual risk rule (70 FR 20009) on determining the need for a technology review under section 112(d)(6). One

commenter stated that if the Coke Ovens criteria for when a technology review is not “necessary” under the CAA are sound for subsequent technology reviews, then they are also sound for initial reviews, as in the case of Magnetic Tape. Another commenter stated that, where the ample margin of safety set in the residual risk rule is largely based on cost or technical feasibility, then further future review under section 112(d)(6) may remain viable, and additional controls may not be precluded if feasible, cost-effective control measures are identified in the future.

Response: We stated in the preamble to the Coke Ovens residual risk rule that if the ample margin of safety analysis for the section 112(f) standard is not based at all on the availability or cost of particular control technologies, then advances in air pollution control technology should not justify revising the MACT standard pursuant to section 112(d)(6) because the section 112(f) standard would continue to assure an adequate level of safety. We agree that a technology review is required every 8 years. However, if the ample margin of safety analysis for a section 112(f) standard shows that 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. In

these situations, it is difficult to conceive of a case where the development of new technology, or of inexpensive control strategies, would cause us to require additional requirements for a source category. 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 with the comment that subsequent technology reviews would be appropriate and revisions may also be appropriate if the ample margin of safety established by the residual risk process considers cost or technical feasibility.

We disagree with the comment that we should not have conducted an initial technology review under section 112(d)(6) for the magnetic tape source category. As we noted in the preamble to the Coke Ovens residual risk rule, we believe that the findings that underlie a section 112(f) determination should be key factors in making any subsequent section 112(d)(6) determinations. As indicated by the inclusion of the word “subsequent” in this rationale, we believe that we are obligated to perform the initial section 112(d)(6) analysis. The timing requirements for the initial section 112(d)(6) analysis coincide with those for the residual risk analysis. Thus, it is appropriate for us 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, even though these results do not negate either the need to perform the initial review or the need to perform subsequent reviews under section 112(d)(6).

4. General Approach to Technology Reviews

Comment: Three commenters stated that action is not necessarily required under section 112(d)(6) even if a residual risk rule does not reduce cancer risks for all persons to a level below 1 in 1 million. Two of the commenters noted that EPA had already rejected such a "bright line" approach under section 112(f) in the Coke Ovens residual risk rule; instead, it serves as a trigger point to evaluate whether additional reductions are necessary to provide an ample margin of safety. The third commenter cited the legislative history of the 1990 amendments to the CAA as support that Congress had rejected provisions requiring sources to meet a 1-in-1-million standard. According to this commenter, EPA's proposed interpretation of section 112(d)(6) of requiring successive reviews unless sources achieve this risk level implies that sources must meet a 1-in-1-million standard to avoid future regulation, and if Congress had intended this "technology-based" downward revision of the standard, there would have been no need for section 112(f).

Noting that EPA's risk estimates are upper bound estimates that likely overstate risks, the first two commenters stated that a "bright line" approach should not be employed under section 112(d)(6) any more than it should be employed under section 112(f); instead, they stated that EPA should make determinations of whether a technology review is necessary on a case-by-case basis for each category.

The third commenter stated that section 112(d)(6) should be more appropriately viewed as a regulatory backstop authority, similar to the case-by-case "MACT hammer" provisions of section 112(j), to ensure that available advances in technology will be applied in the event EPA fails to issue residual risk standards under section 112(f). The commenter stated that once EPA has established a residual risk standard under section 112(f) that is "acceptable" or "safe" and protective with an "ample margin of safety," then it must find that a separate revision of the MACT standard under section 112(d)(6) is not necessary.

Response: We agree with the commenters who indicated that it would be sufficient not to revise MACT standards citing 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 would not be needed because an ample margin of safety has already been assured.

5. Context of the Residual Risk Program

Comment: One commenter strongly recommended that EPA carefully lay out the context and framework of the residual risk program in the determination for each source category. The commenter stated that this was especially important because of the unique nature of the program compared to other EPA programs with which the public is familiar.

The commenter specifically recommended that EPA mention the two-stage regulatory process (MACT and residual risk) used to control HAP emissions from major stationary sources and to determine whether the MACT technology controls provide an ample margin of safety. The commenter noted that the residual risk program is different from other EPA programs, in that additional controls will be necessary for only some of the listed categories of sources, because in some cases, the cancer risk will be less than the 1-in-1-

million trigger, or, if it is greater, EPA may determine that the current emission level provides the public with an ample margin of safety.

The commenter also recommended that EPA put into the proper context the relatively small contribution of major stationary sources to the risks from air toxics--about 11 percent in 1999 and expected to be even smaller as sources come into compliance with the latest MACT rules.

Finally, the commenter recommended that EPA present the risks from air toxics in context with the risks from ambient (criteria) air pollutants to make clear to the public how the air toxics risk estimates are much more conservative and to avoid any misperceptions by the public that the risk estimates for ambient air pollutants are comparable to the risk estimates for air toxics. Without a program of public education on this issue, the commenter indicated the public may incorrectly believe that the ample margin of safety decisions in the residual risk rules are less stringent than EPA knows them to be, resulting in public lawsuits against EPA’s decisions or overregulation by EPA to compensate for the gap in public knowledge. The commenter recommended that EPA include preamble language in future EPA decisions describing the criteria it used to determine the ample margin of safety and presenting the incremental risk/incremental cost approach in the fuller context for the

residual risk program.

Response: We agree that it is important to provide context for any residual risk rule. In the preamble of the current rule, we describe the MACT program and its impact on the magnetic tape source category. We also describe our statutory authority and our obligations to assess risks to human health and the environment under section 112(f) of the CAA, as well as the requirement to further regulate categories of sources if any of the estimated individual cancer risks exceed the statutory trigger level of 1 in 1 million.

We agree that our risk assessment for the magnetic tape source category appropriately contains a number of health-protective assumptions, resulting in a screening assessment that is designed to overestimate, rather than underestimate, risks. The results demonstrate negligible risks for potential chronic cancer, chronic noncancer, and acute noncancer health endpoints. Also, no significant human health multipathway or ecological risks were identified. Had the resulting risks been determined to be non-negligible, a more refined analysis with site-specific data would have been conducted. Such an assessment would be more data-intensive; however, it would also present a more accurate estimate of risks which could then be used as the basis for regulatory action. However, since the findings of

the screening risk assessment for the magnetic tape source category were negative (i.e., the statutory cancer risk trigger level was not exceeded), it was not necessary to conduct a more refined risk assessment using more site-specific data. Since these activities were not relevant to this action, a complete discussion of them in the context of a full discussion of the residual risk program was not deemed necessary or appropriate. The details of our risk assessment can be found in the docket in the memo titled, "Residual Risk Assessment for the Magnetic Tape Manufacturing Source Category."

6. IRIS Data for Acrylonitrile

Comment: According to one commenter, EPA should not have relied on the outdated unit cancer risk value for acrylonitrile contained in EPA's Integrated Risk Information System (IRIS) in conducting its residual risk assessment of the magnetic tape manufacturing industry. Although EPA concluded that there were no issues to be addressed regarding acrylonitrile because the facility emitting acrylonitrile presented a potential cancer risk of only 1 in 100 million, the commenter stated that it was inappropriate for EPA to use the acrylonitrile value in IRIS in its assessment because EPA was already aware the value was severely out-of-date. According to the commenter, the IRIS profile itself indicates that there are one or more

significant new studies based on a screening-level review of the more recent toxicology literature. The commenter also noted that EPA was aware that numerous new studies had been conducted on assessing the cancer risk from acrylonitrile because its staff were briefed on an assessment of those new studies, received copies of the assessment report, and attended a peer review meeting on the report. The commenter also noted that a summary of the cancer assessment was published in October 2005.

Response: We agree that our IRIS assessment for acrylonitrile does not consider studies published after 1991, and we are currently developing an assessment that includes newer information. Our staff reviewed the assessment described (and funded) by the commenter and determined that it has several substantial shortcomings. First, the assessment concludes that the mode of action (MOA) is nonlinear, but does not provide evidence or analysis sufficient to demonstrate nonlinearity or to identify a nonlinear MOA. The independent peer panel that reviewed this assessment noted that the data do not allow unequivocal determination of acrylonitrile's MOA(s), and could not rule out a genotoxic MOA. Given the negligible contribution of the acrolitrile risk estimates in this assessment, we determined that it was reasonable and protective to continue to use linear low-dose extrapolation.

Second, the assessment provides a supplemental linear unit risk value but bases it upon animal data rather than human data, despite the fact that adequate human data were available. Using these human data would have produced a higher inhalation unit risk estimate (i.e., closer to the current IRIS assessment value). Third, the linear unit risk value came from a reanalysis of animal data already considered in EPA's 1991 IRIS assessment for inhalation carcinogenicity, and rejected because better human data were available even then. For these reasons we concluded that the commentor's study should not be used in lieu of the current IRIS assessment.

III. 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 regulatory action is "significant" and, therefore, subject to Office of Management and Budget (OMB) review and the requirements of the Executive Order. The Executive Order defines a "significant regulatory action" as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more, or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State,

local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, OMB has notified EPA that it considers this a "significant regulatory action" within the meaning of the Executive Order. The EPA has 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 information collection burden. It will not change the burden estimates from those previously developed and approved for the existing NESHAP. However, OMB has previously approved the information collection requirements contained in the existing regulation (59 FR 64580, December 15, 1994) under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501, et seq.) and has assigned OMB control number 2060-0326 (EPA ICR No. 1678.05). A copy of the OMB approved Information Collection Request

(ICR) may be obtained from Susan Auby, by mail at the Office of Environmental Information, Collection Strategies Division, U.S. EPA (2822T), 1200 Pennsylvania Avenue, NW, Washington, DC 20460, by e-mail at auby.susan@epa.gov, or by calling (202) 566-1672. A copy may also be downloaded off the Internet at www.epa.gov/icr. Include the ICR or OMB number in any correspondence.

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 in 40 CFR are

listed in 40 CFR Part 9.

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 impact of today's final action on small entities, a small entity is defined as: (1) a small business whose parent company has fewer than 500 to 1,000 employees, depending on the size definition for the affected NAICS code (as defined by Small Business Administration size standards); (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 impact of today's final action on small entities, EPA has concluded that this final action will not have a significant economic impact on a

substantial number of small entities. The final action will not impose any requirements on small entities. We are taking no further action at this time to revise the NESHAP.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law No. 104-4, establishes requirements for Federal agencies to assess the effect 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 the 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 the final action does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments in the aggregate, or for the private sector in any 1 year. The rule imposes no enforceable duty on State, local, or tribal governments, or the private sector. Thus, today’s final action is not subject to the requirements of sections 202 and 205 of the UMRA. In addition, EPA has determined that the final action contains no regulatory requirements that might significantly or uniquely affect small governments, because it contains no requirements that apply to such governments or impose obligations upon them. Therefore, the final action is not subject to the

requirements of section 203 of the UMRA.

E. Executive Order 13132, Federalism

Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” are 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 action does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. None of the affected facilities are owned or operated by State or local governments. Thus, Executive Order 13132 does not apply to the final action.

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 9, 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." The final action does not have tribal implications as specified in Executive Order 13175. It will not have substantial direct effect 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 action.

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 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 EPA.

The final action is not subject to the Executive Order because it is not economically significant as defined in Executive Order 12866, and because EPA does not have reason to believe the environmental health or safety risks addressed by this action present a disproportionate risk to children.

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

The final action is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001) because it is not an economically significant regulatory action under Executive Order 12866.

I. National Technology Transfer Advancement Act

Under section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law No. 104-113, §12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards (VCS) in its regulatory activities, unless to do so would be inconsistent with applicable law or otherwise impractical. The VCS are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted VCS bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when EPA does not use available and applicable VCS.

The final action does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

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. The EPA will submit a report containing the final action and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the United States prior to publication of the final action in the Federal Register. The final action is not a "major rule" as defined by 5 U.S.C. 804(2). The effective date of this final action is [INSERT DATE OF PUBLICATION OF THE FINAL ACTION IN THE FEDERAL REGISTER].

List of Subjects for 40 CFR Part 63

Environmental protection, Administrative practice and procedures, Air pollution control, Hazardous substances,

Intergovernmental relations, Reporting and recordkeeping requirements.

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Dated:

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Stephen L. Johnson,
Administrator.