

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 63****[EPA-HQ-OAR-2008-0008; FRL-8724-5]****RIN 2060-AO91****National Emission Standards for Hazardous Air Pollutant Emissions: Group I Polymers and Resins (Epichlorohydrin Elastomers Production, Hypalon™ Production, Nitrile Butadiene Rubber Production, Polybutadiene Rubber Production, and Styrene Butadiene Rubber and Latex Production); Marine Vessel Loading Operations; Mineral Wool Production; Pharmaceuticals Production; and Printing and Publishing Industry****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Proposed rule.

SUMMARY: This proposed action requests public comment on the residual risk and technology reviews for nine industrial source categories regulated by five national emission standards for hazardous air pollutants. The five national emission standards and nine source categories include: National Emissions Standards for Group I Polymers and Resins (Epichlorohydrin Elastomers Production, Hypalon™ Production, Nitrile Butadiene Rubber Production, Polybutadiene Rubber Production, and Styrene Butadiene Rubber and Latex Production); National Emission Standards for Marine Vessel Loading Operations; National Emission Standards for Hazardous Air Pollutants for Mineral Wool Production; National Emission Standards for Pharmaceuticals Production; and National Emission Standards for the Printing and Publishing Industry. The underlying national emission standards that are under review in this action limit and control hazardous air pollutants.

We are proposing that no revisions to the five national emission standards regulating these nine source categories are required at this time under section 112(f)(2) or 112(d)(6) of the Clean Air Act.

DATES: *Comments.* Comments must be received on or before November 24, 2008.

Public Hearing. If anyone contacts EPA requesting to speak at a public hearing by October 20, 2008, a public

hearing will be held on October 27, 2008.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-OAR-2008-0008, by one of the following methods:

- <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- E-mail: a-and-r-Docket@epa.gov.
- Fax: (202) 566-9744.
- Mail: U.S. Postal Service, send comments to: EPA Docket Center (2822T), Docket ID No. EPA-HQ-OAR-2008-0008, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. Please include a total of two copies.

- Hand Delivery: In person or by courier, deliver comments to: EPA Docket Center (2822T), EPA West Building, Room 3334, 1301 Constitution Ave., NW., Washington, DC 20004. Please include a total of two copies. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information. We request that a separate copy of each public comment also be sent to the contact person listed below (see **FOR FURTHER INFORMATION CONTACT**).

Instructions: Direct your comments to Docket ID No. EPA-HQ-OAR-2008-0008. 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.regulations.gov>, 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 <http://www.regulations.gov> or e-mail. The <http://www.regulations.gov> Web site is an "anonymous access" system, 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 <http://www.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 the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>.

Docket: All documents in the docket are listed in the <http://www.regulations.gov> index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in <http://www.regulations.gov> or in hard copy at the EPA Docket Center, Docket ID No. EPA-HQ-OAR-2008-0008, EPA, West Building, Room 3334, 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 EPA Docket Center is (202) 566-1742.

FOR FURTHER INFORMATION CONTACT: For questions about this proposed action, contact Ms. Mary Tom Kissell, Office of Air Quality Planning and Standards, Sector Policies and Programs Division, Coatings and Chemicals Group (E143-01), U.S. Environmental Protection Agency, Research Triangle Park, NC 27711; telephone number: (919) 541-4516; fax number: (919) 685-3219; and e-mail address: kissell.mary@epa.gov. For specific information regarding the modeling methodology, contact Ms. Elaine Manning, Office of Air Quality Planning and Standards, Health and Environmental Impacts Division, Sector Based Assessment Group (C539-02), U.S. Environmental Protection Agency, Research Triangle Park, NC 27711; telephone number: (919) 541-5499; fax number: (919) 541-0840; and e-mail address: manning.elaine@epa.gov. For information about the applicability of these five national emission standards for hazardous air pollutants (NESHAP) to a particular entity, contact the appropriate person listed in Table 1 to this preamble.

TABLE 1—LIST OF EPA CONTACTS FOR GROUP I POLYMERS AND RESINS, MARINE VESSEL LOADING, MINERAL WOOL, PHARMACEUTICALS, AND PRINTING AND PUBLISHING

NESHAP for:	OECA contact ¹	OAQPS contact ²
Polymers and Resins Production, Group I	Scott Throwe, (202) 564-7013, throwe.scott@epa.gov .	David Markwordt, (919) 541-0837, markwordt.david@epa.gov .
Marine Vessel Loading Operations	Maria Malave, (202) 564-7027, malave.maria@epa.gov .	David Markwordt, (919) 541-0837, markwordt.david@epa.gov .
Mineral Wool Production	Scott Throwe, (202) 564-7013, throwe.scott@epa.gov .	Jeff Telander, (919) 541-5427, telander.jeff@epa.gov .
Pharmaceuticals Production	Marcia Mia, (202) 564-7042, mia.marcia@epa.gov .	Randy McDonald, (919) 541-5402, mcdonald.randy@epa.gov .
Printing and Publishing Industry	Len Lazarus, (202) 564-6369, lazarus.leonard@epa.gov .	David Salman, (919) 541-0859, salman.dave@epa.gov .

¹ OECA stands for EPA's Office of Enforcement and Compliance Assurance.

² OAQPS stands for EPA's Office of Air Quality Planning and Standards.

SUPPLEMENTARY INFORMATION: Regulated Entities. The nine regulated industrial source categories that are the subject of this proposal are listed in Table 2 to this preamble. Table 2 is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by the proposed action for the source categories listed. These standards, and any changes considered in this rulemaking, would be directly applicable to sources as a Federal program. Thus, Federal, State, local, and tribal government entities are not affected by this proposed action. The regulated categories affected by this action include:

TABLE 2—NESHAP FOR NINE INDUSTRIAL SOURCE CATEGORIES

Category	NAICS ¹ code	MACT ² code
Epichlorohydrin Elastomers Production	325212	1311
Hypalon™ Production	325212	1315
Nitrile Butadiene Rubber Production	325212	1321
Polybutadiene Rubber Production	325212	1325
Styrene Butadiene Rubber and Latex Production	325212	1339
Marine Vessel Loading	4883	0603
Mineral Wool Production	327993	0409
Pharmaceuticals Production	3254	1201
Printing and Publishing Industry	32311	0714

¹ North American Industry Classification System.

² Maximum Achievable Control Technology.

To determine whether your facility would be affected, you should examine the applicability criteria in the appropriate NESHAP. If you have any questions regarding the applicability of

any of these NESHAP, please contact the appropriate person listed in Table 1 of this preamble in the preceding **FOR FURTHER INFORMATION CONTACT** section.

Submitting Comments/CBI. Direct your comments to Docket ID No. EPA-HQ-OAR-2008-0008. If commenting on changes to the residual risk and technology reviews (RTR) database, please submit your comments in the format described in sections III and IV of this preamble. Do not submit CBI to EPA through <http://www.regulations.gov> or e-mail. Instead, send or deliver information identified as CBI only to the following address: Mr. Roberto Morales, OAQPS Document Control Officer (C404-02), U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, Research Triangle Park, NC 27711, Attention Docket ID No. EPA-HQ-OAR-2008-0008. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on a disk or CD-ROM that you mail to Mr. Morales, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI.

In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. If you submit a CD-ROM or disk that does not contain CBI, mark the outside of the disk or CD-ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice.

If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified in the **FOR FURTHER INFORMATION CONTACT** section. Information marked as CBI will not be disclosed except in accordance

with procedures set forth in 40 CFR part 2.

Worldwide Web (WWW). In addition to being available in the docket, an electronic copy of this proposed action will also be available on the WWW through the Technology Transfer Network (TTN). Following signature, a copy of the proposed action 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.

As discussed in more detail in sections III and IV of this preamble, additional information is available on the RTR Phase II Web page at <http://www.epa.gov/ttn/atw/rtrisk/rtrpg.html>. This information includes source category descriptions and detailed emissions and other data that were used as inputs to the risk assessments.

Public Hearing. If a public hearing is held, it will begin at 10 a.m. on November 10, 2008 and will be held at 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 Ms. Mary Tom Kissell, Office of Air Quality Planning and Standards, Sector Policies and Programs Division, Coatings and Chemicals Group (E143-01), U.S. Environmental Protection Agency, Research Triangle Park, NC 27711; telephone number: (919) 541-4516.

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

I. Background

- What is the statutory authority for this action?
- Overview of RTR
- Overview of the Five NESHAP
- How did we estimate risk posed by the nine source categories?

- E. What are the results of the risk assessment?
- F. What are our proposed decisions on acceptability and ample margin of safety?
- G. What are the results of the technology review?
- II. Proposed Action
 - A. What is the rationale for our proposed action under CAA section 112(f)?
 - B. What is the rationale for our proposed action under CAA section 112(d)(6)?
- III. Request for Comments
- IV. How do I submit suggested data corrections?
- V. Statutory and Executive Order Reviews
 - A. Executive Order 12866: Regulatory Planning and Review
 - B. Paperwork Reduction Act
 - C. Regulatory Flexibility Act
 - D. Unfunded Mandates Reform Act
 - E. Executive Order 13132: Federalism
 - F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments
 - G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks
 - H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
 - I. National Technology Transfer and Advancement Act
 - J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

I. Background

A. What is the statutory authority for this action?

Section 112 of the 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 section 112(b) of the CAA, section 112(d) of the CAA calls for us to promulgate NESHAP for those sources. "Major sources" are those that emit or have the potential to emit any single HAP at a rate of 10 tons or more per year of a single HAP or 25 tons per year of any combination of HAP. For major sources, these technology-based standards must reflect the maximum degree of emission reductions of HAP achievable (after considering cost, energy requirements, and non-air quality health and environmental impacts) and are commonly referred to as maximum achievable control technology (MACT) standards.

The MACT "floor" is the minimum control level allowed for MACT standards promulgated under section 112(d)(3). For new sources, the MACT floor cannot be less stringent than the emission control that is achieved in practice by the best-controlled similar

source. The MACT standards for existing sources can be less stringent than standards for new sources, but they cannot be less stringent than the average emission limitation achieved by the best-performing 12 percent of existing sources in the category or subcategory (or the best-performing five sources for categories or subcategories with fewer than 30 sources). In developing MACT standards, we must also consider control options that are more stringent than the floor. We may establish standards more stringent than the floor based on the consideration of the cost of achieving the emissions reductions, any non-air quality health and environmental impacts, and energy requirements.

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, under CAA section 112(d)(6). In this proposed rule, we are publishing the results of our 8-year technology review for the nine industrial source categories listed in Table 3, which we have collectively termed "Group 2A."

The second stage in standard-setting focuses on reducing any remaining "residual" risk according to CAA section 112(f). 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 of emitting sources, and recommendations as to legislation regarding such remaining risk. EPA prepared and submitted this report (Residual Risk Report to Congress, EPA-453/R-99-001) in March 1999. Congress did not act in response to the report, thereby triggering EPA's obligation under CAA section 112(f)(2) to analyze and address residual risk.

CAA section 112(f)(2) requires us to determine for source categories subject to certain CAA section 112(d) standards whether the emissions limitations provide an ample margin of safety to protect public health. If the MACT 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 1-in-1 million," EPA must promulgate residual risk standards for the source category (or subcategory) as necessary to provide an ample margin of safety to

protect public health. In doing so, EPA may adopt standards equal to existing MACT standards (*NRDC v. EPA*, No. 07-1053, slip op. at 11, D.C. Cir., decided June 6, 2008). EPA must also adopt more stringent standards, if necessary, to prevent an adverse environmental effect,¹ but must consider cost, energy, safety, and other relevant factors in doing so. Section 112(f)(2) of the CAA expressly preserves our use of a two-step process for developing standards to address any residual risk and our interpretation of "ample margin of safety" developed in the National Emission Standards for Hazardous Air Pollutants: Benzene Emissions from Maleic Anhydride Plants, Ethylbenzene/Styrene Plants, Benzene Storage Vessels, Benzene Equipment Leaks, and Coke By-Product Recovery Plants (Benzene NESHAP) (54 FR 38044, September 14, 1989).

The first step in this process is the determination of acceptable risk. The second step provides for an ample margin of safety to protect public health, which is the level at which the standards are set (unless a more stringent standard is required to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect).

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) directs us to use the interpretation set out in the Benzene NESHAP. See also, A Legislative History of the Clean Air Act Amendments of 1990, volume 1, p. 877 (Senate debate on Conference Report). We notified Congress in the Residual Risk Report to Congress that we intended to use the Benzene NESHAP approach in making CAA section 112(f) residual risk determinations (EPA-453/R-99-001, p. ES-11).

In the Benzene NESHAP, 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-1 million] the estimated risk that a person

¹ "Adverse environmental effect" is defined in CAA section 112(a)(7) as any significant and widespread adverse effect, which may be reasonably anticipated to wildlife, aquatic life, or natural resources, including adverse impacts on populations of endangered or threatened species or significant degradation of environmental qualities over broad areas.

living near a facility would have if he or she were exposed to the maximum pollutant concentrations for 70 years.

The Agency also stated that, "The EPA also considers incidence (the number of persons estimated to suffer cancer or other serious health effects as a result of exposure to a pollutant) to be an important measure of the health risk to the exposed population. Incidence measures the extent of health risk to the exposed population as a whole, by providing an estimate of the occurrence of cancer or other serious health effects in the exposed population." The Agency went on to conclude that "estimated incidence would be weighed along with other health risk information in judging acceptability." As explained more fully in our Residual Risk Report to Congress, EPA does not define "rigid line[s] of acceptability," but considers rather broad objectives to be weighed with a series of other health measures and factors (EPA-453/R-99-001, p. ES-11). The determination of what represents an "acceptable" risk is based on a judgment of "what risks are acceptable in the world in which we live" (Residual Risk Report to Congress, p. 178, quoting the *Vinyl Chloride* decision at 824 F.2d 1165) recognizing that our world is not risk-free.

In the Benzene NESHAP, we stated that "EPA will generally presume that if the risk to [the maximum exposed] individual is no higher than approximately 1 in 10 thousand, that risk level is considered acceptable." 54 FR at 38045. We discussed the maximum individual lifetime cancer risk as being "the estimated risk that a person living near a plant would have if he or she were exposed to the maximum pollutant concentrations for 70 years." *Id.* We explained that this measure of risk "is an estimate of the upperbound of risk based on conservative assumptions, such as continuous exposure for 24 hours per day for 70 years." *Id.* We acknowledge that maximum individual lifetime cancer risk "does not necessarily reflect the true risk, but displays a conservative risk level which is an upperbound that is unlikely to be exceeded." *Id.*

Understanding that there are both benefits and limitations to using maximum individual lifetime cancer risk as a metric for determining acceptability, we acknowledged in the 1989 Benzene NESHAP that "consideration of maximum individual risk * * * must take into account the strengths and weaknesses of this measure of risk." *Id.* Consequently, the presumptive risk level of 100-in-1 million (1-in-10 thousand) provides a benchmark for judging the acceptability

of maximum individual lifetime cancer risk, but does not constitute a rigid line for making that determination.

The Agency also explained in the 1989 Benzene NESHAP the following: "In establishing a presumption for MIR [maximum individual cancer risk], rather than rigid line for acceptability, the Agency intends to weigh it with a series of other health measures and factors. These include the overall incidence of cancer or other serious health effects within the exposed population, the numbers of persons exposed within each individual lifetime risk range and associated incidence within, typically, a 50 kilometer (km) exposure radius around facilities, the science policy assumptions and estimation uncertainties associated with the risk measures, weight of the scientific evidence for human health effects, other quantified or unquantified health effects, effects due to co-location of facilities, and co-emission of pollutants." *Id.*

In some cases, these health measures and factors taken together may provide a more realistic description of the magnitude of risk in the exposed population than that provided by maximum individual lifetime cancer risk alone.

As explained in the Benzene NESHAP, "[e]ven though the risks judged 'acceptable' by EPA in the first step of the Vinyl Chloride inquiry are already low, the second step of the inquiry, determining an 'ample margin of safety,' again includes consideration of all of the health factors, and whether to reduce the risks even further. In the second step, EPA strives to provide protection to the greatest number of persons possible to an individual lifetime risk level no higher than approximately 1 in 1 million. In the ample margin decision, the Agency again considers all of the health risk and other health information considered in the first step. Beyond that information, additional factors relating to the appropriate level of control will also be considered, including costs and economic impacts of controls, technological feasibility, uncertainties, and any other relevant factors. Considering all of these factors, the Agency will establish the standard at a level that provides an ample margin of safety to protect the public health, as required by section 112." 54 FR at 38046.

B. Overview of RTR

We have begun to conduct the RTR for 96 MACT standards covering 174 sources categories. In an effort to streamline the RTR process and focus

our resources on source categories with the greatest potential for risk to human health and the environment, we combined source categories to create several groups, e.g., RTR Group 2A (which is the subject of this proposed rule), and decided the order in which we would propose each source category group. In deciding how to group source categories, we considered factors such as the promulgation date of the NESHAP, our preliminary analysis of the level of risk, completeness of available emissions data, complexity of the risk assessment, and whether we anticipated promulgating additional regulations pursuant to the RTR.

In general, we are addressing source categories with the earliest NESHAP promulgation dates first because they have the earliest RTR due dates and because the 2002 National Emission Inventory (NEI) contains emissions data which reflect implementation of the NESHAP. Additionally, we are addressing lower risk source categories first because they typically require less effort to complete the necessary analysis than higher risk source categories. We expect that the higher risk source categories will require more time to evaluate because we will likely need to perform more refined risk assessments, and because they may have more complex issues to address, such as the emissions of persistent and bioaccumulative HAP. Moreover, we believe our reviews of the higher risk source categories will benefit from an understanding of the public's concerns about our RTR approaches (through the comments we receive on the earlier proposals).

For the nine source categories in today's proposal for RTR Group 2A, we have concluded that emissions levels remaining after compliance with the existing MACT standards: (1) Pose no unacceptable maximum individual cancer risks (i.e., because the MIR is less than 100-in-1 million the risk is acceptable); (2) pose no significant chronic noncancer health effects (i.e., maximum individual target organ-specific hazard index (HI) values are all less than or equal to 1); (3) are unlikely to result in acute adverse health effects from peak short-term excursions; and (4) are unlikely to result in any adverse environmental effect. Thus, we are proposing that the existing standards provide an ample margin of safety to protect public health and prevent adverse environmental effects.

Future RTR actions for other source categories may require changes to existing MACT standards to achieve the protection of public health with an ample margin of safety and/or to

prevent adverse environmental effects. Future actions may also require additional emission reductions pursuant to the technology review. We plan to conduct RTR assessments for 12 source categories (RTR Groups 2B and 2C, which were included in an advanced notice of proposed rulemaking in March 2007) and propose our findings.² In addition, we plan to publish at least three more advanced notices of proposed rulemaking. We may also

publish some RTR for individual MACT standards because of special circumstances such as court ordered deadlines. (See, for example, the proposed RTR for Petroleum Refineries, 72 FR 50716, 09/04/2007.)

C. Overview of the Five NESHAP

The nine industrial source categories and five NESHAP that are the subject of this proposal are listed in Table 3 to this preamble. NESHAP limit and control

HAP that are known or suspected to cause cancer or that may cause other serious human health or environmental effects. The NESHAP for these nine source categories generally require implementation of emissions reduction technologies such as combustion devices, recovery devices, scrubbers, and fabric filters for point sources and work practice and equipment standards for fugitive sources.

TABLE 3—LIST OF NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS (NESHAP) AND INDUSTRIAL SOURCE CATEGORIES AFFECTED BY TODAY'S PROPOSAL

Title of NESHAP	Source categories affected by this proposal	Promulgated rule reference	Compliance date	NESHAP as referred to in this preamble
NESHAP: Group I Polymers and Resins ¹ .	Epichlorohydrin Elastomers Production Hypalon™ Production. Nitrile Butadiene Rubber Production. Polybutadiene Rubber Production. Styrene-Butadiene Rubber and Latex Production.	61 FR 46905 (09/05/96)	07/31/97	Polymers and Resins I.
National Emission Standards for Marine Vessel Loading Operations.	Marine Vessel Loading Operations.	60 FR 48388 (09/19/95)	09/19/99	Marine Vessels.
NESHAP for Mineral Wool Production.	Mineral Wool Production	64 FR 29489 (06/01/99)	06/01/02	Mineral Wool.
National Emission Standards for Pharmaceuticals Production.	Pharmaceuticals Production ...	63 FR 50280 (09/21/98)	09/21/01	Pharmaceuticals.
National Emission Standards for the Printing and Publishing Industry.	Printing/Publishing (Surface Coating).	61 FR 27131 (05/30/96)	05/30/99	Printing and Publishing.

¹ The Polymers and Resins I NESHAP regulates nine source categories. We are performing the RTR for five of these in this proposal. The four other Polymers and Resins I source categories are being addressed in a separate RTR rulemaking. (See National Emission Standards for Hazardous Air Pollutant Emissions: Group I Polymers and Resins (Polysulfide Rubber Production, Ethylene Propylene Rubber Production, Butyl Rubber Production, Neoprene Production); National Emission Standards for Hazardous Air Pollutants for Epoxy Resins Production and Non-Nylon Polyamides Production; National Emission Standards for Hazardous Air Pollutants for Source Categories: Generic Maximum Achievable Control Technology Standards (Acetal Resins Production and Hydrogen Fluoride Production), proposed on December 12, 2007, at 72 FR 70543.)

1. Polymers and Resins I

The National Emission Standards for Hazardous Air Pollutant Emissions: Group I Polymers and Resins were promulgated on September 5, 1996 (62 FR 46925). The Polymers and Resins I NESHAP applies to major sources and regulates HAP emissions from nine source categories. In this proposal, we address five of the Polymer and Resins I sources categories—Epichlorohydrin Elastomers Production, Hypalon™ Production, Nitrile Butadiene Rubber Production, Polybutadiene Rubber Production, and Styrene Butadiene Rubber and Latex Production.

The Polymers and Resins I NESHAP regulate HAP emissions resulting from the production of elastomers (i.e., synthetic rubber). An elastomer is a synthetic polymeric material that can

stretch at least twice its original length and then return rapidly to approximately its original length when released. Elastomers are produced via a polymerization/copolymerization process, in which monomers undergo intermolecular chemical bond formation to form a very large polymer molecule. Generally, the production of elastomers entails four processes: (1) Raw material (i.e., solvent) storage and refining; (2) polymer formation in a reactor (either via the solution process, where monomers are dissolved in an organic solvent, or the emulsion process, where monomers are dispersed in water using a soap solution); (3) stripping and material recovery; and (4) finishing (i.e., blending, aging, coagulation, washing, and drying).

Sources of HAP emissions from elastomers production include raw

material storage vessels, front-end process vents, back-end process operations, wastewater operations, and equipment leaks. The “front-end” processes include pre-polymerization, reaction, stripping, and material recovery operations; and the process “back-end” includes all operations after stripping (predominately drying and finishing). Typical control devices used to reduce organic HAP emissions from front-end process vents include flares, incinerators, absorbers, carbon adsorbers, and condensers. In addition, hydrochloric acid formed when chlorinated organic compounds are combusted are controlled using scrubbers. Emissions from storage vessels are controlled by floating roofs or by routing them to a control device. While emissions from back-end process operations can be controlled with

² RTR Group 2B: Oil and Natural Gas Production; Natural Gas Transmission; and Aerospace

Operations. RTR Group 2C: Primary Aluminum;

Polymers and Resins IV (seven source categories); and Ship Building.

control devices such as incinerators, the most common method of reducing these emissions is the pollution prevention method of reducing the amount of residual HAP that is contained in the raw product going to the back-end operations. Emissions from wastewater are controlled by a variety of methods, including equipment modifications (e.g., fixed roofs on storage vessels and oil water separators; covers on surface impoundments, containers, and drain systems), treatment to remove the HAP (steam stripping, biological treatment), control devices, and work practices. Emissions from equipment leaks are typically reduced by leak detection and repair work practice programs, and in some cases, by equipment modifications.

Each of the five Polymers and Resins I source categories addressed in this proposal are discussed further below.

a. Epichlorohydrin Elastomers Production

Epichlorohydrin elastomers are prepared from the polymerization or copolymerization of epichlorohydrin or other monomers. Epichlorohydrin elastomers are produced by a solution polymerization process, typically using toluene as the solvent in the reaction. The main epichlorohydrin elastomers are polyepichlorohydrin, epi-ethylene oxide (EO) copolymer, epi-allyl glycidyl ether (AGE) copolymer, and epi-EO-AGE terpolymer. Epichlorohydrin elastomers are widely used in the automotive industry.

We identified one epichlorohydrin elastomers production facility currently subject to the Polymers and Resins I NESHAP. This facility produces epichlorohydrin elastomers primarily, but the plant site also has equipment regulated by other NESHAP, which have been or will be addressed in separate RTR rulemaking actions.

Toluene accounts for the majority of the HAP emissions from the epichlorohydrin production processes at this facility (approximately 105 tons per year (TPY) and 99 percent of the total HAP emissions by mass). This facility also reported relatively small emissions of epichlorohydrin and ethylene oxide. The majority of HAP emissions are from back-end process vents (approximately 75 percent of the total HAP by mass). We estimate that the MACT allowable emissions (i.e., the maximum emission levels allowed if in compliance with the NESHAP) from this source category are approximately equal to the reported, actual emissions.³

b. Hypalon™ Production

Hypalon™ or chlorosulfonated polyethylene, is a synthetic rubber produced by reacting polyethylene with chlorine and sulfur dioxide, transforming the thermoplastic polyethylene into a vulcanized elastomer. The reaction is conducted in a solvent reaction medium containing carbon tetrachloride. These elastomers are commonly used in wire insulation and jacketing, automotive components, adhesives, and protective coatings.

We identified one Hypalon™ production facility currently subject to the Polymers and Resins I NESHAP. The plant site for this facility also has other HAP-emitting sources which are regulated under separate NESHAP, including Marine Vessel Loading Operations, 40 CFR part 63, subpart Y. Marine Vessel Loading Operations are addressed separately in this proposed rule, but RTR for the other NESHAP have been or will be addressed in separate rulemaking actions.

Carbon tetrachloride accounts for the majority of the HAP emissions from the Hypalon™ production processes at this facility (approximately 22 TPY and 71 percent of the total HAP emissions by mass). This facility also reported relatively small emissions of chlorine, chloroform, and hydrochloric acid. The majority of HAP emissions are from front-end process vents (approximately 63 percent of the total HAP by mass) and back-end process operations (approximately 33 percent of the total HAP by mass). We estimate that MACT allowable emissions from this source category are approximately equal to reported, actual emissions.

c. Nitrile Butadiene Rubber Production

Nitrile butadiene rubber (NBR) is a copolymer of 1,3-butadiene and acrylonitrile, and the NBR production source category includes any facility that polymerizes 1,3-butadiene and acrylonitrile. While NBR is the primary product at these facilities, styrene-butadiene rubber can also be produced as a minor product by substituting styrene for acrylonitrile as a monomer. Depending on its specific composition, NBR can be resistant to oil and chemicals, a property that facilitates its use in disposable gloves, hoses, seals, and a variety of automotive applications.

We identified four NBR production facilities currently subject to the

Polymers and Resins I NESHAP. Two of these facilities are at plant sites that also have operations which produce styrene-butadiene rubber and latex, another Polymers and Resins I source category. The styrene-butadiene rubber and latex processes and emissions are addressed separately in today's proposed action under the Styrene Butadiene Rubber and Latex source category. Some of these facilities also have other HAP-emitting sources that are regulated under separate NESHAP, which have been or will be addressed in separate RTR rulemaking actions.

Styrene, 1,3-butadiene, and acrylonitrile account for the majority of the HAP emissions from this source category (approximately 46 TPY and over 99 percent of the total HAP emissions by mass). The facilities in this source category also reported relatively small emissions of carbon disulfide. The majority of HAP emissions are from back-end process operations (approximately 43 percent of the total HAP by mass) and front-end process vents (approximately 34 percent of the total HAP by mass) for this source category. However, the emissions from one facility were not included in this estimation of emissions by source type, as it was not possible to positively discern which types of emission sources were responsible for emissions from this facility in all instances. Based on the emissions release characteristics for this facility, we estimate that of the facility's 48 TPY of HAP emissions, the majority are from back-end process operations and equipment leaks (approximately 58 and 23 percent by mass, respectively). We estimate that MACT allowable emissions from this source category are approximately equal to reported, actual emissions.

d. Polybutadiene Rubber Production

Polybutadiene rubber (PBR) is a homopolymer of 1,3-butadiene (i.e., 1,3-butadiene is the only monomer used in the production of this polymer). While both the solution and emulsion polymerization processes can be used to produce PBR, all currently operating facilities in the United States use a solution process. In the solution process, the reaction is conducted in an organic solvent (hexane, toluene, or a non-HAP organic solvent), which helps to dissipate heat generated by the reaction and control the reaction rate. While PBR is the primary product at these facilities, styrene-butadiene rubber can also be produced as a minor product by adding styrene as a monomer. Most of the PBR manufactured in the United States is used in the production of tires in the construction of the tread and

³ Our analysis of the impacts of the worst case MACT allowable emissions as compared to reported

actual emissions for each of the nine source categories is discussed in more detail in "Estimation of MACT Allowable Emission Levels and Associated Risks and Impacts for the RTR Group 2A Source Categories."

sidewalls. PBR is also used as a modifier in the production of other polymers and resins (e.g., polystyrene).

We identified five PBR production facilities currently subject to the Polymers and Resins I NESHAP. Some of these facilities are located at plant sites that also have other HAP-emitting sources regulated under separate NESHAP, which have been or will be addressed in separate RTR actions.

Three of the PBR production facilities use hexane as the solvent in their solution process, one facility uses toluene as its solvent, and the fifth uses a non-HAP organic solvent. Overall, hexane accounts for the majority of the HAP emissions from this source category (approximately 1,455 TPY and 72 percent of the total HAP emissions by mass). The facilities in this source category also reported substantive emissions of styrene and 1,3-butadiene and relatively minor quantities of three other HAP. The majority of HAP emissions are from back-end process operations (approximately 73 percent of the total HAP by mass). We estimate that MACT allowable emissions from this source category could be as high as five times the actual emissions.

e. Styrene Butadiene Rubber and Latex Production

Styrene butadiene rubber and latex are elastomers prepared from styrene and butadiene monomer units. The source category is divided into three subcategories due to technical process and HAP emission differences: (1) The production of styrene butadiene rubber by emulsion, (2) the production of styrene butadiene rubber by solution, and (3) the production of styrene butadiene latex. Styrene butadiene rubber is coagulated and dried to produce a solid product, while latex is a liquid product. For both styrene butadiene rubber processes, the monomers used are styrene and butadiene; either process can be conducted as a batch or a continuous process. These elastomers are commonly used in tires and tire-related products.

We identified two styrene butadiene rubber production facilities using the emulsion process and 12 styrene butadiene rubber latex production facilities currently subject to the Polymers and Resins I NESHAP. Other than the polybutadiene plants that produce styrene butadiene rubber as a minor product, we did not identify any styrene butadiene rubber produced in a solution process. Two of these facilities are located at plant sites that also have operations which produce NBR, another Polymers and Resins I source category.

The NBR processes and emissions are addressed separately in this proposed action under the Nitrile Butadiene Rubber source category. Some of these facilities are located at plant sites that also have other HAP-emitting sources regulated under separate NESHAP, which have been or will be addressed in separate RTR actions.

Overall, styrene accounts for the majority of the HAP emissions from these facilities (approximately 276 TPY and 90 percent of the total HAP emissions by mass). These facilities also reported relatively small emissions of 13 other HAP. The majority of HAP emissions are from back-end process operations (approximately 80 percent of the total HAP by mass). We estimate that MACT allowable emissions from this source category could be as high as four times the actual emissions.

2. Marine Vessels

The National Emission Standards for Marine Vessel Loading Operations were promulgated on September 19, 1995 (60 FR 48388). The Marine Vessel Loading Operations NESHAP applies to major sources and regulates HAP emissions from: Land-based terminals, off-shore terminals, and the Alyeska Pipeline Service Company's Valdez Marine Terminal.

Marine vessel loading operations are facilities that load and unload liquid commodities in bulk, such as crude oil, gasoline, and other fuels, and some chemicals and solvent mixtures. The cargo is pumped from the terminal's large, above-ground storage tanks through a network of pipes and into a storage compartment (tank) on the vessel. Emissions occur as vapors are displaced from the tank as it is being filled. Most marine tank vessel loading operations are associated with petroleum refineries, synthetic organic chemical manufacturers, or are independent terminals.

The primary emission sources of displaced vapors at marine vessel loading operations include open tank hatches and overhead vent systems. Other possible emission points are hatch covers or domes, pressure-vacuum relief valves, seals, and vents. Emissions may also occur during ballasting (i.e., the process of drawing ballast as water into a cargo hold). The NESHAP requires control of all displaced vapors that occur during product loading. Typical control devices used to reduce HAP emissions include vapor collection systems routed to combustion or recovery devices, such as flares, incinerators, absorbers, carbon adsorbers, and condensers.

Additional data indicate that approximately 800 terminals load HAP-containing organic liquids. An unknown fraction of these are containerized liquids that are not subject to the Marine Vessel Loading Operations NESHAP. Therefore, we estimate up to 800 facilities may be subject to the Marine Vessel Loading Operations NESHAP. However, data in the 2002 NEI were available for only 135 facilities and our analyses are based on these 135 modeled facilities. We believe the 135 modeled facilities are representative of the source category because we expect that generally the same HAP, in the same range of quantities, are emitted from the 135 modeled facilities as are emitted from rest of the facilities in the source category. We extrapolated the risk results for the 135 modeled facilities up to the approximately 800 facilities in the source category and believe the resulting cancer and noncancer risks either represent or overstate risk from the 800 facilities in source category. However, we request comment on this approach, additional data on pollutant-specific emissions from facilities in the NEI, and identification of emissions from marine vessel loading facilities not included in the NEI.

Marine terminals that are part of the petroleum refineries source category are not regulated by the Marine Vessel Loading Operations NESHAP. Therefore, marine terminals that are part of the petroleum refineries source category were not included in this risk assessment. The petroleum refineries marine terminals are being addressed in a separate RTR rulemaking action. (See the proposed RTR for Petroleum Refineries, 72 FR 50716, 09/04/2007.)

Hexane, methanol, toluene, and mixed xylenes account for the majority of the HAP emissions from the 135 NEI facilities (approximately 184 TPY and 73 percent of the total HAP emissions by mass). These facilities also reported relatively small emissions of 42 other HAP. These emissions are from the loading operations at the terminals. MACT allowable emission levels from this source category could be higher than actual emission levels due primarily to states requiring controls (typically 90 percent reduction) for some marine terminals that are not controlled by the Marine Vessel Loading Operations NESHAP. Based on typical state rule emission reduction requirements we estimate that the MACT allowable emissions from this source category would be 10 times the actual emissions for terminals not controlled by the Marine Vessel Loading Operations NESHAP and approximately

two times the actual emissions for marine terminals that are controlled by the Marine Vessel Loading Operations NESHAP.

3. Mineral Wool Production

The National Emission Standards for Mineral Wool Production were promulgated on June 1, 1999 (64 FR 29489). The Mineral Wool Production NESHAP applies to major sources of HAP.

Mineral wool is a fibrous, glassy substance made from natural rock (such as basalt), blast furnace slag, or other similar materials. In the mineral wool manufacturing process, rock and/or blast furnace slag and other raw materials (e.g., gravel) are melted in a furnace (cupola) using coke as a fuel. The molten material is then formed into fiber. Mineral wool is manufactured as either a "bonded" product that incorporates a binder to increase structural rigidity or a less rigid "nonbonded" product. Products made from mineral wool are used for insulation, sound control and attenuation, and fire protection. The industry is declining significantly due to economic and competitive reasons (e.g., availability of alternative products such as cellulose insulation).

Emission sources at mineral wool production facilities include the cupola furnace where the mineral charge is melted; a blow chamber, in which air or a binder is drawn over the fibers, forming them into a screen; a curing oven that bonds the fibers (for bonded products); and a cooling chamber. The majority of the emissions originate from the cupolas and curing ovens. The NESHAP requires control of particulate matter emissions from the cupolas and formaldehyde emissions from the curing ovens. Typical control devices used to reduce HAP emissions from the cupola include baghouses/fabric filters, and emissions from the curing ovens are generally controlled with thermal incinerators.

We identified eight facilities currently subject to the Mineral Wool Production NESHAP. Some of these facilities also have other HAP-emitting sources that are regulated under separate NESHAP, which have been or will be addressed in separate RTR rulemaking actions.

Carbonyl sulfide accounts for the majority of the HAP emissions from these facilities (approximately 416 TPY and 87 percent of the total HAP emissions by mass). These facilities also reported relatively small emissions of 16 other HAP. The majority of HAP emissions are from the cupolas (approximately 80 percent of the total HAP by mass). The majority of HAP

emissions (primarily formaldehyde) that were significant in evaluating risk are from the cooling chambers. We estimate that MACT allowable emissions from this source category could be as high as two times the actual emissions.

4. Pharmaceuticals Production

The National Emission Standards for Pharmaceuticals Production were promulgated on September 21, 1998 (63 FR 50280). The Pharmaceuticals Production NESHAP applies to major sources of HAP.

The pharmaceutical manufacturing process consists of chemical production operations that produce drugs and medication. These operations include chemical synthesis (deriving a drug's active ingredient) and chemical formulation (producing a drug in its final form).

Emission sources at pharmaceutical production facilities include breathing and withdrawal losses from chemical storage tanks, venting of process vessels, leaks from piping and equipment used to transfer HAP compounds (equipment leaks), and volatilization of HAP from wastewater streams.

Typical control devices used to reduce HAP emissions from process vents include flares, incinerators, scrubbers, carbon adsorbers, and condensers. Emissions from storage vessels are controlled by floating roofs or by routing them to a control device. Emissions from wastewater are controlled by a variety of methods, including equipment modifications (e.g., fixed roofs on storage vessels and oil water separators; covers on surface impoundments containers, and drain systems), treatment to remove the HAP (steam stripping, biological treatment), control devices, and work practices. Emissions from equipment leaks are typically reduced by leak detection and repair work practice programs, and in some cases, by equipment modifications.

We identified 27 facilities currently subject to the Pharmaceuticals Production NESHAP. Some of these facilities are located at plant sites that also have other HAP-emitting sources regulated under separate NESHAP, which have been or will be addressed in separate rulemaking actions.

Methylene chloride, methanol, acetonitrile, and toluene account for the majority of the HAP emissions from these facilities (approximately 891 TPY and 90 percent of the total HAP emissions by mass). These facilities also reported relatively small emissions of 65 other HAP. The majority of HAP emissions are from the process vents (approximately 70 percent of the total

HAP by mass emitted from process vents, with 20 percent and 10 percent of the total HAP by mass emitted from equipment leaks and wastewater operations, respectively). We estimate that MACT allowable emissions from this source category could be up to 25 percent greater than the actual emissions, primarily from process vents, as it is possible that the control devices used at some facilities achieve greater emission reductions from these emission sources than what is required by the NESHAP.

5. Printing and Publishing Industry

The National Emission Standards for the Printing and Publishing Industry were promulgated on May 30, 1996 (61 FR 27132). The Printing and Publishing NESHAP applies to major sources of HAP.

Printing and publishing facilities are those facilities that use rotogravure, flexography, and other methods, such as lithography, letterpress, and screen printing, to print on a variety of substrates, including paper, plastic film, metal foil, and vinyl. The Printing and Publishing NESHAP focuses on two subcategories: (1) Publication rotogravure printing and (2) product and packaging rotogravure and wide-web flexographic printing. Emissions at printing and publishing facilities result from the evaporation of solvents in the inks and from cleaning solvents. The emission points include printing presses and associated dryers and ink and solvent storage. Control techniques include recovery devices, combustion devices, and the use of non-HAP/low-HAP inks and cleaning solvents.

We estimate that approximately 200 facilities are subject to the Printing and Publishing NESHAP based on the information we gathered in support of the rule development in 1996. As data were available for 179 major source facilities in the 2002 NEI, our analyses are based on these 179 facilities. We believe the 179 facilities represent the source category because: (1) We have no reason to believe that emissions from the other facilities are different from the facilities we modeled; (2) the difference between the number of facilities counted in 1996 and 2002 might be accounted for by facility closures and by some facilities achieving area source status for HAP before the first compliance date of the Printing and Publishing NESHAP; and, (3) we believe in most cases data on 90 percent of the facilities in a source category will be representative of the source category as a whole. Some of these facilities are located at plant sites that also have other HAP-emitting sources regulated

under separate NESHAP, which have been or will be addressed in separate RTR rulemaking actions.

Toluene accounts for the majority of the HAP emissions from these facilities (approximately 6,606 TPY or 88 percent of the total HAP emissions by mass). These facilities also reported relatively small emissions of 56 other HAP. These emissions are primarily from the evaporation of HAP present in the inks and other materials applied with rotogravure and flexographic processes. We estimate that MACT allowable emissions from this source category could be up to 5 times greater than the actual emissions, as it is possible that the capture systems and control devices used at some facilities achieve greater emission reductions than what is required by the NESHAP.

D. How did we estimate risk posed by the nine source categories?

To support the proposed decisions presented in today's notice, EPA conducted a risk assessment that provided estimates of MIR, maximum individual cancer risk distribution within the exposed populations, cancer incidence, hazard indices for chronic exposures to HAP with non-cancer health effects, hazard quotients (HQ) for acute exposures to HAP with non-cancer health effects, and estimates of the potential for adverse environmental effects. The risk assessment consisted of seven primary activities: (1) Establishing the nature and magnitude of emissions from the source categories, (2) identifying the emissions release characteristics (e.g., stack parameters), (3) conducting dispersion modeling to estimate the concentrations of HAP in ambient air, (4) estimating long-term and short-term inhalation exposures to individuals residing within 50 km of the modeled sources, (5) estimating individual and population-level inhalation risks using the exposure estimates and quantitative dose-response information, (6) estimating the potential for adverse human health multipathway risks and for adverse environmental effects, and (7) characterizing risk. In general, the risk assessment followed a tiered, iterative approach, beginning with a conservative (worst case) screening-level analysis and, where the screening analyses indicated the potential for non-negligible risks, following that with more refined analyses. The following sections summarize these activities. For more information on the risk assessment inputs and models, see "Residual Risk Assessment for Nine Source Categories," available in the docket.

We engaged in a consultation with a panel from the Science Advisory Board (SAB) on the "Risk and Technology Review (RTR) Assessment Plan" in December of 2006. The results of this consultation were transmitted to us in June 2007 in a letter from the SAB which also contained a summary listing of the key messages from the panel. The letter is available from the docket and from [http://yosemite.epa.gov/sab/sabproduct.nsf/33152C83D29530F08525730D006C3ABF/\\$File/sab-07-009.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/33152C83D29530F08525730D006C3ABF/$File/sab-07-009.pdf). In developing the risk assessments for the nine source categories covered by this proposal, we followed the RTR Assessment Plan, addressing the key messages from the panel, where appropriate and relevant to these assessments.

1. Emissions and Emissions Release Characteristic Data

The basic approach taken to obtain the most accurate and reliable emissions and emissions release characteristic data was to compile preliminary data sets using readily available information for each source category and to share these data with the public via an Advanced Notice of Proposed Rulemaking (ANPRM). The data sets were then updated based on comments received on the ANPRM and, in some cases, with additional information gathered by EPA.

For the five Polymers and Resins I source categories (Epichlorohydrin Elastomers Production, Hypalon™ Production, Nitrile Butadiene Rubber Production, Polybutadiene Rubber Production, and Styrene Butadiene Rubber and Latex Production), we collected emissions data and emissions release characteristic data directly from industry. These data generally formed the data sets used in our analyses for these source categories.

For the remaining four source categories (Marine Vessel Loading, Mineral Wool, Pharmaceuticals, and Printing and Publishing), we created the preliminary data sets using the data in the 2002 NEI Final Inventory, Version 1 (made publicly available on February 26, 2006) supplemented by data collected directly from industry when available. The NEI is a database that contains information about sources that emit criteria air pollutants and their precursors, and HAP. The database includes estimates of annual air pollutant emissions from point, nonpoint, and mobile sources in the 50 States, the District of Columbia, Puerto Rico, and the Virgin Islands. EPA collects this information and releases an updated version of the NEI database every 3 years.

On March 29, 2007, we published an ANPRM (72 FR 29287) specifically to request comments and updates to these preliminary data sets. We received comments on emissions data and emissions release characteristics data for facilities in these nine source categories. These comments were reviewed, considered, and the emissions information was adjusted where we concluded the comments supported such adjustment. After incorporation of changes to the data sets from this public data review process, the final data sets were created. These data sets were used to conduct the risk assessments and other analyses that form the bases for these proposed actions.

In addition to gathering information regarding the actual emissions from the sources in the nine source categories, we also examined the underlying NESHAP to determine whether the emissions that a source was allowed to emit when in compliance with the NESHAP would significantly vary from the actual emissions data we had gathered. Where such "MACT allowable" emission levels could be higher than the actual emission levels, we extrapolated the risks associated with the MACT allowable emission levels from the risks associated with the actual emission levels.

The data sets for these nine source categories and documentation of the emissions data sets used for each source category are available in the RTR Group 2A docket. The documentation of the emission data sets provides a description of the changes in the dataset for each source category since the ANPRM, describes the data changes requested in public comments, and documents the analysis of MACT allowable emissions for each source category.

2. Dispersion Modeling, Inhalation Exposures, and Individual and Population Inhalation Risks

Both long-term and short-term inhalation exposure concentrations and health risk from each of the nine source categories addressed in this proposal were estimated using the Human Exposure Model (Community and Sector HEM-3 version 1.1.0). The HEM-3 performs three of the primary risk assessment activities listed above: (1) Conducting dispersion modeling to estimate the concentrations of HAP in ambient air, (2) estimating long-term and short-term inhalation exposures to individuals residing within 50 km of the modeled sources, and (3) estimating individual and population-level inhalation risks using the exposure

estimates and quantitative dose-response information.

The dispersion model used by HEM-3 is AERMOD, which is one of EPA's preferred models for assessing pollutant concentrations from industrial facilities.⁴ To perform the dispersion modeling and to develop the preliminary risk estimates, HEM-3 draws on three data libraries. The first is a library of meteorological data, which is used for dispersion calculations. This library includes 1 year of hourly surface and upper air observations for 130 meteorological stations, selected to provide thorough coverage of the United States and Puerto Rico. A second library of United States Census Bureau census block internal point locations and populations provides the basis of human exposure calculations (Census, 2000). In addition, the census library includes the elevation and controlling hill height for each census block, which are also used in dispersion calculations. A third library of pollutant unit risk factors and other health benchmarks is used to estimate health risks. These risk factors and health benchmarks are the latest values recommended by EPA for HAP and other toxic air pollutants. These values are available at <http://www.epa.gov/ttn/atw/toxsource/summary.html> and are discussed in more detail later in this section.

In developing the risk assessment for chronic exposures, we used the estimated annual average ambient air concentration of each HAP emitted by each source for which we have emissions data in the source category at each nearby census block⁵ centroid as a surrogate for the chronic inhalation exposure concentration for all the people who reside in that census block. We calculated the MIR for each facility as the risk associated with a lifetime (70-year) exposure to the maximum concentration at the centroid of an inhabited census block. Individual cancer risks were calculated as the lifetime exposure to the ambient concentration of each HAP multiplied by its Unit Risk Estimate (URE), which is an upper bound estimate of an individual's probability of contracting cancer over a lifetime of exposure to a concentration of one microgram of the pollutant per cubic meter of air. For residual risk assessments, we generally use URE values from EPA's Integrated

Risk Information System (IRIS). For carcinogenic pollutants without EPA IRIS values, we look to other reputable sources of cancer dose-response values, often using California Environmental Protection Agency (CalEPA) URE values, where available. In cases where new, scientifically credible dose-response values have been developed in a manner consistent with EPA guidelines and have undergone a peer review process similar to that used by EPA, we may use such dose-response values in place of or in addition to other values. Total cancer risks were the sum of the risks of each carcinogenic HAP (including known, probable, and possible carcinogens) emitted by the modeled source. Air concentrations of HAP from sources other than the modeled source were not estimated. Total cancer incidence and the distribution of individual cancer risks across the population within 50 kilometers of any source were also estimated as part of these assessments by summing individual risks. We are using 50 kilometers to be consistent with both the analysis supporting the 1989 Benzene NESHAP (54 FR 38044) and the limitations of Gaussian dispersion modeling.

To assess risk of noncancer health effects from chronic exposures, we summed the HQ for each HAP that affects a common target organ system to obtain the HI for that target organ system (or target organ-specific HI, TOSHI). The HQ is the estimated exposure divided by the chronic reference level, which is either the U.S. EPA Reference Concentration (RfC), defined as "an estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime," or in cases where an RfC is not available, we use the CalEPA Chronic Reference Exposure Level (REL), which is defined as "the concentration level at or below which no adverse health effects are anticipated for a specified exposure duration," or the ATSDR Chronic Minimum Risk Level (MRL), which is defined as "an estimate of daily human exposure to a substance that is likely to be without an appreciable risk of adverse effects (other than cancer) over a specified duration of exposure." In cases where new, scientifically credible dose-response values have been developed in a manner consistent with EPA guidelines and have undergone a peer review process similar to that used by EPA, we may use

such dose-response values in place of or in addition to other values.

Screening estimates of acute exposures and risks were also evaluated for each HAP at any location off-site of each facility (*i.e.*, not just the census block centroids) assuming the combination of a peak (hourly) emission rate and hourly dispersion conditions for the 1991 calendar year that would tend to maximize exposure. In each case, acute HQ values were calculated using best available short-term health threshold values. These acute threshold values include REL, Acute Exposure Guideline Levels (AEGL), and Emergency Response Planning Guidelines (ERPG) for 1-hour exposure durations. Also, for those pollutants where no other threshold values (REL, AGEL, or ERPG) were available, we used ATSDR MRL values for 24-hour and greater exposure durations.

As described in the California Environmental Protection Agency's "Air Toxics Hot Spots Program Risk Assessment Guidelines, Part I, The Determination of Acute Reference Exposure Levels for Airborne Toxicants," an acute REL (<http://www.oehha.ca.gov/air/pdf/acuterel.pdf>) is defined as "the concentration level at or below which no adverse health effects are anticipated for a specified exposure duration is termed the reference exposure level (REL). RELs are based on the most sensitive, relevant, adverse health effect reported in the medical and toxicological literature. RELs are designed to protect the most sensitive individuals in the population by the inclusion of margins of safety. Since margins of safety are incorporated to address data gaps and uncertainties, exceeding the REL does not automatically indicate an adverse health impact."

Acute Exposure Guideline Levels, or AEGLs, were derived in response to recommendations from the National Research Council. As described in "Standing Operating Procedures (SOP) of the National Advisory Committee on Acute Exposure Guideline Levels for Hazardous Substances" (<http://www.epa.gov/opptintr/aeagl/pubs/sop.pdf>),⁶ "the NRC's previous name for acute exposure levels—community emergency exposure levels (CEELs)—was replaced by the term AEGLs to reflect the broad application of these values to planning, response, and prevention in the community, the workplace, transportation, the military, and the remediation of Superfund

⁴ Environmental Protection Agency. Revision to the Guideline on Air Quality Models: Adoption of a Preferred General Purpose (Flat and Complex Terrain) Dispersion Model and Other Revisions (70 FR 68218). November 9, 2005.

⁵ A typical census block is comprised of approximately 40 people or about 10 households.

⁶ National Academies of Science, 2001. Standing Operating Procedures for Developing Acute Exposure Levels for Hazardous Chemicals, page 2.

sites.” This document also states (page 2) that AEGLs “represent threshold exposure limits for the general public and are applicable to emergency exposures ranging from 10 min to 8 h.” The document lays out the purpose and objectives of AEGLs by stating (page 21) that “the primary purpose of the AEGL program and the NAC/AEGL Committee is to develop guideline levels for once-in-a-lifetime, short-term exposures to airborne concentrations of acutely toxic, high-priority chemicals.” In detailing the intended application of AEGL values, the document states (page 31) that “It is anticipated that the AEGL values will be used for regulatory and nonregulatory purposes by U.S. Federal and State agencies, and possibly the international community in conjunction with chemical emergency response, planning, and prevention programs. More specifically, the AEGL values will be used for conducting various risk assessments to aid in the development of emergency preparedness and prevention plans, as well as real-time emergency response actions, for accidental chemical releases at fixed facilities and from transport carriers.”

The AEGL-1 value is then specifically defined as “the airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience notable discomfort, irritation, or certain asymptomatic nonsensory effects. However, the effects are not disabling and are transient and reversible upon cessation of exposure.” The document also notes (page 3) that, “Airborne concentrations below AEGL-1 represent exposure levels that can produce mild and progressively increasing but transient and nondisabling odor, taste, and sensory irritation or certain asymptomatic, nonsensory effects.” Similarly, the document defines AEGL-2 values as “the airborne concentration (expressed as ppm or mg/m³) of a substance above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting adverse health effects or an impaired ability to escape.”

ERPG are derived for use in emergency response, as described in the American Industrial Hygiene Association’s document entitled, “Emergency Response Planning Guidelines (ERPG) Procedures and Responsibilities” (<http://www.aiha.org/1documents/committees/ERP-SOPs2006.pdf>), which states that, “Emergency Response Planning Guidelines (ERPGs) were developed for emergency planning and are intended as

health based guideline concentrations for single exposures to chemicals.”⁷ The ERPG-1 value is defined as “the maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to 1 hour without experiencing other than mild transient adverse health effects or without perceiving a clearly defined, objectionable odor.” Similarly, the ERPG-2 is defined as “the maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to one hour without experiencing or developing irreversible or other serious health effects or symptoms which could impair an individual’s ability to take protective action.”

As can be seen from the definitions above, the AEGL and ERPG values include the similarly defined severity levels 1 and 2. For many chemicals, the available information does not allow development of a severity level 1 value AEGL or ERPG; in these instances, higher severity level AEGL-2 or ERPG-2 values are compared to our modeled exposure levels to screen for potential acute concerns.

Acute REL values for a 1-hour exposure duration are typically lower than their corresponding AEGL-1 and ERPG-1 values. Even though their definitions are slightly different, AEGL-1 values are often the same as the corresponding ERPG-1 values, and AEGL-2 values are often equal to ERPG-2 values. Maximum HQ values from our acute screening risk assessments typically result when basing them on the acute REL for a particular pollutant. In cases where our maximum acute HQ value exceeds 1, we also report the HQ value based on the next highest acute threshold (usually the AEGL-1 and/or the ERPG-1).

In cases where no acute REL, AEGL or ERPG value is available for the pollutant being assessed, we have calculated HQ values based on the Agency for Toxic Substances and Disease Registry’s Minimal Risk Levels (MRL) to determine whether we can clearly assert that there is no potential for acute impact of concern. The MRL (<http://www.atsdr.cdc.gov/mrls/>) is defined as “an estimate of the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse noncancer health effects over a specified duration of exposure.” Since acute exposure is defined by ATSDR in the context of MRL as “exposure that occurs for a short time (1 to 14 days),”

⁷ ERP Committee Procedures and Responsibilities, 1 November 2006. American Industrial Hygiene Association.

and since we are most interested in trying to assess the potential impact of shorter-duration high-emission events, we only use these HQ based on MRL values in the context of a screening check, wherein we adjust our maximum 1-hour exposures to estimate potential maximum 24-hour exposures using a meteorological adjustment factor of 0.4.⁸ Because these MRL values are based on longer exposure durations than our peak 1-hour exposure estimates, they are generally more stringent than 1-hour thresholds, and therefore provided a very conservative screen. Thus, HQ values based on MRL which do not exceed 1 provide a strong indication that acute impacts are not of potential concern. HQ values based on the MRL which exceed 1, however, do not automatically indicate an adverse health impact and may require further analysis.

To develop screening estimates of acute exposures, we developed estimates of maximum hourly emission rates by multiplying the average annual hourly emission rates by a factor of 10. The factor of 10 is intended to cover routinely variable emissions and startup, shutdown, and malfunction emissions. We chose to use a factor of 10 based on: (1) Engineering judgment, and (2) an analysis of short-term emissions data that compared hourly and annual emissions data for volatile organic compounds (VOC) for all facilities in a heavily-industrialized 4-county area (Harris, Galveston, Chambers, and Brazoria Counties, TX) over an 11-month time period in 2001.⁹ The analysis is provided in Appendix 4 of the Draft Residual Risk Assessment for 9 Source Categories and is available in the docket for this rule. In this study, most peak emission events were less than twice the annual average hourly emission rate and the highest peak emission event was 8.5 times the annual average hourly emission rate. We request comment on the interpretation of these data and the appropriateness of using a factor of 10 times the average annual hourly emission rate in these acute exposure screening assessments.

In cases where all acute HQ values from the screening step were less than or equal to 1, acute impacts were deemed negligible and no further analysis was performed. In the cases where an acute HQ from the screening step was greater than 1, additional site-specific data were considered to develop a more refined estimate of the

⁸ See “Screening Procedures for Estimating the Air Quality Impact of Stationary Sources” (Revised); EPA-454/R-92-019; Chapter 4; page 15.

⁹ See http://www.tceq.state.tx.us/compliance/field_ops/eeer/index.html or docket to access the source of these data.

potential for acute impacts of concern. The data refinements considered included using a better representation of the peak-to-mean hourly emissions ratio (instead of using the default factor of 10) and using the site-specific facility layout to distinguish facility property from an area where the public could be exposed. Ideally we would prefer to have continuous measurements over time to see how the emissions vary by each hour over an entire year. Having a frequency distribution of hourly emission rates over a year would allow us to perform a probabilistic analysis to estimate potential threshold exceedances and their frequency of occurrence. We recognize that having this level of data is rare, hence our use of the factor of 10 multiplier approach. Such an evaluation could include a more complete statistical treatment of the key parameters and elements adopted in this screening analysis.

In the final step of the acute impacts screening, HQ values exceeding 1 based on REL, AEGL, ERPG, or MRL values are interpreted on a case-by-case basis, considering the implications of the appropriate definitions and the related supporting documentation for that specific value, as well as the context of the HQ based on the next highest acute threshold value, where one is available.

3. Multipathway Human Health Risks and Environmental Effects Assessment

The potential for significant human health risks due to exposures via routes other than inhalation (i.e., multipathway exposures) and the potential for adverse environmental impacts were evaluated in a two-step screening process. In the first step, each source category was screened by determining whether any sources emitted any of the 14 HAP known to be persistent and bioaccumulative in the environment (also known as PB-HAP)¹⁰, as identified in EPA's Air Toxics Risk Assessment Library (available at http://www.epa.gov/ttn/fera/risk_atra_vol1.html). As a result of this screening, we determined that four of the RTR Group 2A source categories—Marine Vessel Loading Operations, Mineral Wool Production, Pharmaceuticals Production, and the Printing and Publishing Industry—were responsible for air emissions of four PB-HAP—cadmium compounds, mercury

compounds, lead compounds, and polycyclic organic matter (POM).

In the second step of the screening process, we determined if the facility-specific emission rates of each of the specific PB-HAP were large enough to create the potential for significant non-inhalation risks. To facilitate this step, we developed emission rate thresholds for each PB-HAP using a hypothetical screening exposure scenario developed for use in conjunction with the TRIM.FaTE model. The hypothetical screening scenario was subjected to a sensitivity analysis to ensure that its key design parameters were established such that environmental media concentrations were not underestimated (i.e., to minimize the occurrence of false positives, or results that suggest that risks might be acceptable when, in fact, actual risks are high), and to also minimize the occurrence of false positives for human health endpoints. We call this application of the TRIM.FaTE model TRIM-Screen. The facility-specific emission rates of each PB-HAP in each source category were compared to the emission threshold values for each of the four PB-HAP identified in the source category datasets. None of the emission rates for the facilities source categories addressed in this action exceeded the emission threshold values; therefore, none of the facilities show the potential for causing any significant multipathway exposures and risks. Had this not been the case, the source categories would have been further evaluated for potential non-inhalation risks and adverse environmental impacts through site-specific refined assessments using EPA's TRIM.FaTE model. For further information on the multipathway screening see the "Residual Risk Assessment for 9 Source Categories" document (see Docket EPA-HQ-OAR-2008-0008).

4. Risk Characterization

The final product of the risk assessment is the risk characterization, in which the information from the previous steps is integrated and an overall conclusion about risk is derived. Estimates of health risk are considered in the context of uncertainties and limitations in the data and methodology. In general, we have attempted to reduce both uncertainty and bias to the greatest degree possible in these assessments. A brief discussion of the major uncertainties associated with the derivation of risk estimates is provided below. The first section discusses the consideration of "MACT allowable" emissions in risk characterization, followed by a

discussion of uncertainties in risk assessments. Following these sections, we have provided summaries of risk metrics for each source category (including MIR and noncancer hazards, as well as cancer incidence estimates).

We note here that several of the carcinogens emitted by these source categories (i.e., benzo[a]pyrene, dibenz[a,h]anthracene, and vinyl chloride) have a mutagenic mode of action¹¹, EPA's "Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens"¹² was applied to the risk estimates for these four compounds. This guidance has the effect of adjusting the URE by factors of 10 (for children aged 0–1), 3 (for children aged 2–15), or 1.6 (for 70 years of exposure beginning at birth), as needed in risk assessments. In this case, this has the effect of increasing the estimated lifetime risks for these pollutants by a factor of 1.6. In addition, although only a small fraction of the total POM emissions were reported as individual compounds, EPA expresses carcinogenic potency for compounds in this group in terms of benzo[a]pyrene equivalence, based on evidence that carcinogenic POM have the same mutagenic mechanism of action as does benzo[a]pyrene. For this reason EPA implementation policy¹³ recommends applying the Supplemental Guidance to all carcinogenic PAHs for which risk estimates are based on relative potency. Accordingly, we have applied the Supplemental Guidance to all unspesiated POM mixtures.

Finally, we screened chronic ambient concentration levels of all individual HAP against their chronic noncancer human health thresholds in an effort to gauge the potential for adverse environmental impacts, under the assumption that chronic human toxicity values are generally protective of direct inhalation impacts on animals and direct contact impacts on plants. We believe that this assumption is reasonable in most cases, but acknowledge that it is an uncertainty. Although not verified for many HAP

¹¹ U.S. EPA, 2006. Performing risk assessments that include carcinogens described in the Supplemental Guidance as having a mutagenic mode of action. Science Policy Council Cancer Guidelines Implementation Workgroup Communication II: Memo from W.H. Farland dated 14 June 2006. http://epa.gov/osa/spc/pdfs/CGIWGCommunication_II.pdf.

¹² U.S. EPA, 2005. Supplemental Guidance for Assessing Early-Life Exposure to Carcinogens. EPA/630/R-03/003F. http://www.epa.gov/ttn/atw/childrens_supplement_final.pdf.

¹³ U.S. EPA, 2005. Science Policy Council Cancer Guidelines Implementation Workgroup Communication I: Memo from W.H. Farland dated 4 October 2005 to Science Policy Council. <http://www.epa.gov/osa/spc/pdfs/canguid1.pdf>.

¹⁰ Persistent and bioaccumulative (PB) HAP are HAP that have the ability to persist in the environment for long periods of time and may also have the ability to build up in the food chain to levels that are harmful to human health and the environment.

because of lacking environmental testing data, this assumption has been shown to be valid for some organic compounds¹⁴ where such test data are available.

a. Consideration of Actual and MACT Allowable Emissions

We discussed the use of both MACT allowable and actual emissions in the final Coke Oven Batteries residual risk rule (70 FR 19998–19999, April 15, 2005) and in the proposed and final Hazardous Organic NESHAP (HON) residual risk rules (71 FR 34428, June 14, 2006, and 71 FR 76609, December 21, 2006, respectively). In those previous actions, we noted that assessing the MACT allowable levels of emissions (i.e., the highest emission levels that could be emitted while maintaining the same activity level and still complying with the NESHAP requirements) is inherently reasonable since they reflect the maximum level sources could emit and still comply with national emission standards. But we also explained that it is reasonable to consider actual emissions, where such data are available, in both steps of the risk analysis, in accordance with the Benzene NESHAP. (54 FR 38044, September 14, 1989). It is reasonable to consider actual emissions because sources typically seek to perform better than required by emission standards to provide an operational cushion to accommodate the variability in manufacturing processes and control device performance. Failure to consider actual emissions data in developing risk estimates would unrealistically inflate estimated risk levels.

We performed our risk assessments based on estimates of actual emission levels as developed through the process described earlier in the preamble. For the nine source categories addressed in this action, we do not have detailed information regarding MACT allowable emission levels. However, we estimated the potential differences in MACT allowable and actual emission levels for each source category and where MACT allowable emission levels were greater than actual emission levels, we scaled the risk results by the ratio of MACT allowable to actual emission levels. In many cases, the requirements of the regulation result in actual emission levels being a reasonable approximation of or the same as MACT allowable emission levels. In section I.E. of this preamble, the potential risk based on

consideration of MACT allowable emission levels is discussed for each source.

b. Uncertainties in Risk Assessments

Uncertainty and the potential for bias are inherent in all risk assessments, including those performed for the nine source categories affected by this proposal. We reduced some of these uncertainties by soliciting input from industry and the public to develop the best emissions data sets possible. Although uncertainty exists, we believe the risk assessments performed for the nine source categories most likely overestimate the potential for risks due to the health-protective assessment approach. A brief discussion of the uncertainties in the emissions data set, dispersion modeling, inhalation exposure estimates, and dose-response relationships is presented in this section of the preamble. A more thorough discussion of these uncertainties is included in both the “Residual Risk Assessment for 9 Source Categories” (April 2008) and the “Risk and Technology Review (RTR) Assessment Plan” (November 2006), both of which are available in the docket.

Uncertainties in the Emissions Data Sets. Although the development of the RTR data sets involved quality assurance/quality control processes, the accuracy of emissions values will vary depending on the source of the data present, incomplete or missing data, errors in estimating emissions values, and other factors. The emission values considered in this analysis are annual totals that do not reflect short-term fluctuations during the course of a year or variations from year to year. These annual emissions estimates generally do not include operations such as startup/shutdown and malfunctions;¹⁵ however, such emissions are not known to contribute significantly to total annual emissions. In contrast, the estimates of peak hourly emission rates for the acute effects screening assessment were based on the generally health-protective default assumption of 10 times the annual average hourly rate which is intended to account for emission fluctuations due to normal facility operations as well as emissions from startup, shutdown and malfunctions events. More refined estimates were used for source categories where the screening estimates

did not “screen out” all sources and more specific information was available.

Facilities in seven of the source categories (Epichlorohydrin Elastomers Production, Hypalon™ Production, Marine Tank Vessel Loading, Pharmaceuticals Production, Polybutadiene Rubber Production, Printing and Publishing, and Styrene Butadiene Rubber and Latex Production) emit chlorinated compounds and use incineration devices, creating the possibility for the formation of polychlorinated dioxins. However, we have no test reports or measurements, conducted by manufacturers or anyone else, indicating the presence of dioxins in the emissions from any of these source categories, and EPA’s dioxin inventory does not specifically link dioxins emissions to any of these source categories. Furthermore, in our judgment, it is improbable that dioxins are emitted in measurable amounts from these seven source categories given the low quantity of particulate matter present. Therefore, we did not consider dioxins in our assessment of these source categories.

Overall we believe that the emissions data considered in this assessment are accurate representations of the actual emissions for facilities in the nine source categories for the stated purpose. Nevertheless, we request comment on our emissions data set in general (including information on individual sources), and specifically on our approach for estimating: short-term emissions used in assessing acute risk; emissions and associated risk from start-ups, shutdowns, and malfunctions (SSM); and on the potential for dioxins emissions from the source categories affected by this proposal. We also request comment on evaluating potential emissions mitigation (emission limits, work practice standards, and best management practices) for SSM events and the associated reduction in emissions and risks and the associated costs.

Uncertainties in Dispersion Modeling. While the analysis employed EPA’s suggested regulatory dispersion model, AERMOD, there is uncertainty in ambient concentration estimates associated with EPA’s choice and application of the model. Where possible, model options (e.g., rural/urban, plume depletion, chemistry) were selected to provide an overestimate of ambient air concentrations. However, because of practicality and data limitation reasons, some factors (e.g., meteorology, building downwash) have the potential in some situations to overestimate or

¹⁴ “Evaluation of Wildlife Inhalation Exposure Pathway from Wood Products Plant Emissions.” Memorandum to Tim Hunt/AF&PA from David F. Mitchell and Julie A.F. Kabel, February 25, 2002. This memorandum is in the docket.

¹⁵ The mass balance used to determine emissions from the publication rotogravure subcategory of the Printing and Publishing source category includes emissions from startup, shutdown, and malfunction events.

underestimate ambient impacts. For example, meteorological data were taken from a single year (1991), and facility locations can be a significant distance from the site where these data were taken. Despite these uncertainties, we believe that at off-site locations and census block centroids, the approach considered in the dispersion modeling analysis should generally yield overestimates of ambient concentrations.

Uncertainties in Inhalation Exposure. The effects of human mobility on exposures were not included in the assessment. Specifically, short-term mobility and long-term mobility¹⁶ between census blocks in the modeling domain were not considered. As a result, this simplification will likely bias the assessment toward overestimating the highest exposures. In addition, the assessment predicted the chronic exposures at the centroid of each populated census block as surrogates for the exposure concentrations for all people living in that block. (On average census blocks are populated by approximately 40 people.) Using the census block centroid to predict chronic exposures tends to overpredict exposures for people in the census block who live further from the facility and underpredict exposures for people in the census block who live closer to the facility. Thus, using the census block centroid to predict chronic exposures may lead to a potential understatement or overstatement of the true maximum impact, but is an unbiased estimate of average risk and incidence.

The assessments evaluate the cancer inhalation risks associated with pollutant exposures over a 70-year period, the assumed lifetime of individuals. In reality, both the length of time that modeled emissions sources at facilities actually operate (i.e., more or less than 70 years), and the domestic growth or decline of the modeled industry (i.e., the increase or decrease in the number or size of United States facilities), will influence the risks posed by a given source category. Depending on the characteristics of the industry, these factors will likely result in an overestimate (or possibly an underestimate in the extreme case where a facility maintains or increases its emission levels beyond 70 years and residents live beyond 70 years at the same location) both in individual risk levels and in the total estimated number

of cancer cases. Annual cancer incidence estimates from exposures to emissions from these sources would not be affected by uncertainty in the length of time emissions sources operate.

The exposure estimates used in these analyses assume chronic exposures to ambient levels of pollutants. Because most people spend the majority of their time indoors, actual exposures may not be the same, depending on characteristics of the pollutants modeled. For many HAP, indoor levels are roughly equivalent to ambient levels, but for very reactive pollutants or larger particles, these levels are typically lower. This factor has the potential to result in an overstatement of 25 to 30 percent of exposures.¹⁷

In addition to the uncertainties highlighted above, there are several factors specific to the acute exposure assessment that need to be highlighted. The accuracy of an acute inhalation exposure assessment depends on the simultaneous occurrence of independent factors that may vary greatly, such as hourly emissions rates, meteorology, and human activity patterns. In this assessment, we assume that individuals remain for 1 hour at the point of maximum ambient concentration as determined by the co-occurrence of peak emissions and worst-case meteorological conditions. These assumptions would tend to overestimate actual exposures since it is unlikely that a person would be located at the point of maximum exposure during the time of worst-case impact.

Uncertainties in Dose-Response Relationships. There are uncertainties inherent in the development of the reference values used in our risk assessments for cancer effects from chronic exposures and noncancer effects from both chronic and acute exposures. Some uncertainties may be considered quantitatively, and others generally are expressed in qualitative terms. We note as a preface to this discussion a point which pertains to this whole discussion on dose-response uncertainty and which is brought out in EPA's 2005 Cancer Guidelines; namely, that "the primary goal of EPA actions is protection of human health; accordingly, as an Agency policy, risk assessment procedures, including default options that are used in the absence of scientific data to the contrary, should be health protective." (EPA 2005 Cancer Guidelines, pages 1–7) This is the approach followed here as summarized in the next several paragraphs. A complete detailed discussion of

uncertainties and variabilities in dose response relationships is given in the risk assessment document.

Cancer URE values used in our risk assessments are those that have been developed to generally provide an upper bound estimate of risk. That is, they represent a "plausible upper limit to the true value of a quantity" (although this is usually not a true statistical confidence limit).¹⁸ In some circumstances, the true risk could be as low as zero; however, in other circumstances the risk could also be greater.¹⁹ When developing an upper bound estimate of risk and to provide risk values that do not underestimate risk, health-protective default approaches are generally used. EPA typically uses the upper bound estimates rather than lower bound or central tendency estimates in our risk assessments, an approach that can have limitations for other uses (e.g., priority-setting or expected benefits analysis).

Chronic noncancer reference (RfC and RfD) values represent chronic exposure levels that are intended to be health-protective levels. Specifically, these values provide an estimate (with uncertainty spanning perhaps an order of magnitude) of daily oral exposure (RfD) or of a continuous inhalation exposure (RfC) to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. To derive values that are intended to be "without appreciable risk," the methodology relies upon an uncertainty factor (UF) approach (U.S. EPA, 1993, 1994) which includes consideration of both uncertainty and variability. When there are gaps in the available information, UF are applied to derive reference values that are intended to be protective against appreciable risk of deleterious effects. Uncertainty factors are commonly default values,²⁰ e.g.,

¹⁸ IRIS glossary (http://www.epa.gov/NCEA/iris/help_gloss.htm).

¹⁹ An exception to this is the URE for benzene, which is considered to cover a range of values, each end of which is considered to be equally plausible, and which is based on maximum likelihood estimates.

²⁰ According to the NRC report *Science and Judgment in Risk Assessment* (NRC, 1994) "[Default] options are generic approaches, based on general scientific knowledge and policy judgment, that are applied to various elements of the risk-assessment process when the correct scientific model is unknown or uncertain." The 1983 NRC report *Risk Assessment in the Federal Government: Managing the Process* defined default option as "the option chosen on the basis of risk assessment policy that appears to be the best choice in the absence of data to the contrary" (NRC, 1983a, p. 63). Therefore, default options are not rules that bind the agency; rather, the agency may depart from them in evaluating the risks posed by a specific

¹⁶ Short-term mobility is movement from one microenvironment to another over the course of hours or days. Long-term mobility is movement from one residence to another over the course of a lifetime.

¹⁷ National-Scale Air Toxics Assessment for 1996. (EPA 453/R-01-003; January 2001; page 85.)

factors of 10 or 3, used in the absence of compound-specific data; where data are available, uncertainty factors may also be developed using compound-specific information. When data are limited, more assumptions are needed and more uncertainty factors are used. Thus there may be a greater tendency to overestimate risk in the sense that further study might support development of reference values that are higher (i.e., less potent) because fewer default assumptions are needed. However, for some pollutants it is possible that risks may be underestimated.

While collectively termed "UF", these factors account for a number of different quantitative considerations when utilizing observed animal (usually rodent) or human toxicity data in the development of the reference concentration. The UF are intended to account for: (1) Variation in susceptibility among the members of the human population (i.e., inter-individual variability); (2) uncertainty in extrapolating from experimental animal data to humans (i.e., interspecies differences); (3) uncertainty in extrapolating from data obtained in a study with less-than-lifetime exposure (i.e., extrapolating from subchronic to chronic exposure); (4) uncertainty in extrapolating the observed data to obtain an estimate of the exposure associated with no adverse effects; and (5) uncertainty when the database is incomplete or there are problems with the applicability of available studies.

Many of the UF used to account for variability and uncertainty in the development of acute reference values are quite similar to those developed for chronic durations, but more often using individual UF values that may be less than 10. UF are applied based on chemical-specific or health effect-specific information (e.g., simple irritation effects do not vary appreciably between human individuals, hence a value of 3 is typically used), or based on the purpose for the reference value (see the following paragraph). The UF

applied in acute reference value derivation include: (1) Heterogeneity among humans; (2) uncertainty in extrapolating from animals to humans; (3) uncertainty in LOAEL to NOAEL adjustments; and (4) uncertainty in accounting for an incomplete database on toxic effects of potential concern. Additional adjustments are often applied to account for uncertainty in extrapolation from observations at one exposure duration (e.g., 4 hours) to derive an acute reference value at another exposure duration (e.g., 1 hour).

Not all acute reference values are developed for the same purpose and care must be taken when interpreting the results of an acute assessment of human health effects relative to the reference value or values being exceeded. Where relevant to the estimated exposures, the lack of threshold values at different levels of severity should be factored into the risk characterization as potential uncertainties. Further, when we compare our peak 1-hour exposures against MRL values (which are derived for 1- to 14-day exposure durations), we note that peak emission events are unlikely to last more than an hour. As such, these comparisons are a very conservative screen which is only useful in ruling out potential exposures of concern, limiting our ability to interpret situations where MRL values are exceeded.

Although every effort is made to identify peer-reviewed reference values for cancer and noncancer effects for all pollutants emitted by the sources included in this assessment, some pollutants have no peer-reviewed reference values for cancer or chronic non-cancer or acute effects. Since exposures to these pollutants cannot be included in a quantitative risk estimate, an understatement of risk for these pollutants at environmental exposure levels is possible.

Additionally, chronic reference values for 26 of the compounds included in this assessment are currently under EPA IRIS review and revised assessments

may determine that these pollutants are more or less potent than the current value. We will re-evaluate residual risks if, as a result of these reviews, a dose-response metric changes enough to indicate that the risk assessment supporting today's notice may significantly understate human health risk.

Uncertainties in the Multipathway and Environmental Effects Assessment. We generally believe that when exposure levels are not anticipated to adversely affect human health, they also are not anticipated to adversely affect the environment. While there are special considerations for certain HAP, we generally rely on the levels of PB-HAP emissions to determine whether a full assessment of the multipathway and environmental effects is necessary. Because emissions of these chemicals may not be well characterized due to lack of testing requirements specific to these chemicals (e.g., these compounds may be aggregated into testing requirements for particulate matter), risks may be understated.

E. What are the results of the risk assessment?

The human health risks estimated for the nine source categories are summarized in this section of the preamble. Details of the assessment are located in the docket (Docket EPA-HQ-OAR-2008-0008), especially see "Residual Risk Assessment for 9 Source Categories." We believe that our assessment covers all potential health risks associated with HAP emissions from the nine source categories affected by this proposal.

For each of the nine source categories, the cancer MIR from one or more exposure routes was greater than 1-in-1 million and/or the maximum HQ for acute exposure was greater than 1. Table 4 provides an overall summary of the inhalation risk assessment results, and the sections below provide more detailed discussions about the risk assessment results for each of the nine source categories.

TABLE 4—SUMMARY OF ESTIMATED INHALATION RISKS FOR THE NINE SOURCE CATEGORIES

Source category	Number of facilities ¹	Maximum individual cancer risk (in a million) ²	Population at risk \geq 1-in-a-million (1,000's)	Annual cancer incidence	Maximum chronic non-cancer TOSHI ³	Maximum off-site acute non-cancer HQ ⁴
Epichlorohydrin Elastomers Production.	1	30	4	0.0004	0.2	HQ _{REL} = 0.1 epichlorohydrin
Hypalon™ Production	1	1	0.4	0.0004	0.1	HQ _{REL} = 0.7 chlorine

substance when it believes this to be appropriate. In keeping with EPA's goal of protecting public health and the environment, default assumptions

are used to ensure that risk to chemicals is not underestimated (although defaults are not intended to overtly overestimate risk). See EPA 2004 *An*

examination of EPA Risk Assessment Principles and Practices, EPA/100/B-04/001 available at: <http://www.epa.gov/osa/pdfs/ratf-final.pdf>.

TABLE 4—SUMMARY OF ESTIMATED INHALATION RISKS FOR THE NINE SOURCE CATEGORIES—Continued

Source category	Number of facilities ¹	Maximum individual cancer risk (in a million) ²	Population at risk \geq 1-in-a-million (1,000's)	Annual cancer incidence	Maximum chronic non-cancer TOSHI ³	Maximum off-site acute non-cancer HQ ⁴
Nitrile Butadiene Rubber Production.	4	60	47	0.004	0.9	HQ _{REL} = 0.3 styrene
Polybutadiene Rubber Production	5	10	16	0.002	0.2	HQ _{REL} = 0.3 toluene
Styrene Butadiene Rubber and Latex Production.	9	7	26	0.004	0.1	HQ _{REL} = 0.3 styrene
Marine Vessel Loading Operations.	<800	1	2.4	0.01	0.006	HQ _{AEGL-2} = 0.9 chloroform
Mineral Wool Production	8	30	110	0.008	0.4	HQ _{REL} = 8 HQ _{AEGL-1} = 0.7 formaldehyde HQ _{REL} = 4 arsenic
Pharmaceuticals Production	27	10	4.9	0.001	0.2	HQ _{REL} = 2 chloroform HQ _{AEGL-1} = 0.5 acetonitrile
Printing and Publishing Industry ...	179	0.05	0	0.000009	0.08	HQ _{REL} = 10 HQ _{AEGL-1} = 0.5 toluene

¹ Number of facilities evaluated in the risk analysis.

² Maximum individual excess lifetime cancer risk.

³ Maximum target organ specific hazard index (TOSHI). Target organ system represented by the TOSHI varies across source categories. Maximum TOSHI is respiratory for the printing and publishing industry, mineral wool production, epichlorohydrin elastomers production, and Hypalon[®] production. Maximum TOSHI for marine vessel loading operations is based on immunological effects. Maximum TOSHI for nitrile butadiene rubber production, polybutadiene rubber production, and styrene butadiene rubber and latex production is based on reproductive effects. Maximum TOSHI for pharmaceutical production is based on neurological effects.

⁴ The maximum estimated acute exposure concentration was divided by available short-term threshold values to develop an array of hazard quotient (HQ) values. HQ values shown use the lowest available acute threshold value, which in most cases is the REL. When HQ values exceed 1, we also show HQ values using the next lowest available acute threshold. For the Mineral Wool Production Category, there were potential exceedances of the REL for arsenic (maximum HQ = 4, as noted in the table), but there is no corresponding AEGL-1 value to facilitate further interpretation of these exceedances. See Section 2 of this preamble for explanation of acute threshold values.

As shown in Table 4, we estimate, based on actual emissions, that the MIR remaining from HAP emissions from these nine source categories affected by this proposal range from 0.05-in-1 million to 60-in-1 million. Cancer incidence ranged from 0.000009 excess cancer cases per year (or nine cases every 1,000,000 years) to 0.01 excess cancer cases per year (or one excess cancer case every 100 years). No chronic noncancer inhalation human health thresholds were exceeded at off-site receptors for any of the nine source categories. The maximum acute HQ using the REL ranged from 0.1 to 10 and were all less than 1 (ranging from 0.3 to 0.9) for the AEGL or ERPG where available. We extrapolated risks based on MACT allowable emissions in "Estimation of MACT Allowable Emission Levels and Associated Risks and Impacts for the RTR Group 2A Source Categories" in Docket No. EPA-HQ-OAR-2008-0008).

For several source categories, no PB-HAP emissions were reported, while very low levels were reported for other source categories. Our analyses, based on these low levels of emissions, indicate these source categories do not pose potential for human health multipathway risks or adverse environmental impacts.

1. Epichlorohydrin Elastomers Production

Lifetime maximum individual cancer risks associated with emissions modeled from the only one epichlorohydrin elastomer production facility are estimated to be less than 100-in-1 million. The highest maximum lifetime individual cancer risk was estimated at 30-in-1 million. The total estimated cancer incidence from this facility is 0.0004 excess cancer cases per year. We estimate that 4,000 people exposed to HAP from this source category may experience an increased individual lifetime cancer risk of greater than or equal to 1-in-1 million.

We found no significant risk of adverse noncancer health effects associated with the modeled acute or chronic inhalation exposures from the Epichlorohydrin Elastomers Production source category. The maximum chronic noncancer TOSHI value associated with emissions from this epichlorohydrin elastomer production facility is 0.2, and the maximum acute screening HQ value was 0.1. There were no reported PB-HAP emissions for this source category. Our analysis, based on the absence of PB-HAP, indicates this source category does not pose potential for human health multipathway risks or adverse environmental impacts.

These risks are based on reported actual emission levels. Our analysis of

potential differences between actual emission levels and emissions allowable under the NESHAP indicated that actual and MACT allowable emission levels are approximately equal. Therefore, we expect no appreciable differences in risks with consideration of MACT allowable emission levels.

2. Hypalon[™] Production

Lifetime maximum individual cancer risks associated with emissions modeled from the Hypalon[™] production facility are estimated to be less than 100-in-1 million. The highest maximum lifetime individual cancer risk was estimated at 1-in-1 million. The total estimated cancer incidence from this facility is 0.0004 excess cancer cases per year. We estimate that 400 people exposed to HAP from this source category may experience an increased individual lifetime cancer risk of greater than or equal to 1-in-1 million. We found no significant risk of adverse noncancer health effects associated with the modeled acute or chronic inhalation exposures from the Hypalon[™] Production source category. The maximum chronic noncancer TOSHI value associated with emissions from this Hypalon[™] production facility is 0.1, and the maximum acute screening HQ value was 0.7. There were no reported PB HAP emissions for this source category. Our analysis, based on the absence of PB HAP, indicates this

source category does not pose potential for human health multipathway risks or adverse environmental impacts.

These risks are based on reported actual emission levels. Our analysis of potential differences between actual emission levels and emissions allowable under the NESHAP indicated that actual and MACT allowable emission levels are approximately equal. Therefore, we expect no appreciable differences in risks with consideration of MACT allowable emission levels.

3. Nitrile Butadiene Rubber Production

All lifetime cancer risks associated with emissions modeled from the four NBR production facilities are estimated to be less than 100-in-1 million. The highest maximum lifetime individual cancer risk was estimated at 60-in-1 million. We estimate that 47,000 people exposed to HAP from this source category may experience an increased individual lifetime cancer risk of greater than or equal to 1-in-1 million. The total estimated cancer incidence from these facilities is 0.004 excess cancer cases per year. We found no significant risk of adverse noncancer health effects associated with the modeled acute or chronic inhalation exposures from the Nitrile Butadiene Rubber Production source category. The maximum chronic noncancer TOSHI value associated with emissions from these NBR production facilities is 0.9, and the maximum acute screening HQ value for styrene is 0.3 (relative to the acute REL). The maximum HQ for acrylonitrile based on the highest acute threshold, the AEGL-1, was 0.07, so we do not have any concerns regarding potential acute impacts. There were no reported PB-HAP emissions for this source category. Our analysis, based on the absence of PB-HAP, indicates this source category does not pose potential for human health multipathway risks or adverse environmental impacts.

These risks are based on reported actual emission levels. Our analysis of potential differences between actual emission levels and emissions allowable under the NESHAP indicated that actual and MACT allowable emission levels are approximately equal. Therefore, we expect no appreciable differences in risks with consideration of MACT allowable emission levels.

4. Polybutadiene Rubber Production

All lifetime cancer risks associated with emissions modeled from the five PBR production facilities are estimated to be less than 100-in-1 million. The highest maximum lifetime individual cancer risk was estimated at 10-in-1 million. The total estimated cancer

incidence from these facilities is 0.002 excess cancer cases per year. We estimate that 16,000 people exposed to HAP from this source category may experience an increased individual lifetime cancer risk of greater than or equal to 1-in-1 million. We found no significant risk of noncancer health effects associated with the modeled acute or chronic inhalation exposures from the Polybutadiene Rubber Production source category. The maximum chronic noncancer TOSHI value associated with emissions from these PBR production facilities is 0.2, and the maximum acute screening HQ value was 0.3. There were no reported PB-HAP emissions for this source category. Our analysis, based on the absence of PB-HAP, indicates this source category does not pose potential for human health multipathway risks or adverse environmental impacts.

These risks are based on reported actual emission levels. While we estimate that MACT allowable emissions could be as high as five times the actual emission levels, we expect no appreciable differences in risks between actual emission levels and emissions allowable under the NESHAP because over 99 percent of the HAP comprising the additional emissions attributable to MACT allowable emission levels have no cancer potency estimates and because the noncancer risk contribution from these additional emissions is minimal.

5. Styrene Butadiene Rubber and Latex Production

All lifetime cancer risks associated with emissions modeled from the nine styrene butadiene rubber and latex production facilities are estimated to be less than 100-in-1 million. The highest maximum lifetime individual cancer risk was estimated at 7-in-1 million. The total estimated cancer incidence from these facilities is 0.004 excess cancer cases per year. We estimate that 26,000 people exposed to HAP from this source category may experience an increased individual lifetime cancer risk of greater than or equal to 1-in-1 million. We found no significant risk of adverse noncancer health effects associated with the modeled acute or chronic inhalation exposures from the Styrene Butadiene Rubber and Latex Production source category. The maximum chronic noncancer TOSHI value associated with emissions from these styrene butadiene rubber and latex production facilities is 0.1, and the maximum acute screening HQ value was 0.3. There were no reported PB-HAP emissions for this source category. Our analysis, based on the absence of PB-HAP, indicates this

source category does not pose potential for human health multipathway risks or adverse environmental impacts.

These risks are based on reported actual emission levels. While we estimate that MACT allowable emissions could be as high as five times the actual emission levels, we expect no appreciable differences in risks between actual emission levels and emissions allowable under the NESHAP because over 99 percent of the HAP comprising the additional emissions attributable to MACT allowable emission levels have no cancer potency estimates and because the noncancer risk contribution from these additional emissions is minimal.

6. Marine Vessel Loading Operations

All individual lifetime cancer risks associated with emissions from the marine vessel loading operations facilities are estimated to be less than 100-in-1 million. The highest maximum lifetime individual cancer risk was estimated at 1-in-1 million. The total estimated cancer incidence from these facilities is 0.01 excess cancer cases per year. We estimate that 2,400 people exposed to HAP from this source category may experience an increased individual lifetime cancer risk of greater than or equal to 1-in-1 million. We found no significant risk of adverse noncancer health effects associated with the modeled acute or chronic inhalation exposures from the Marine Vessel Loading Operations source category. The maximum chronic noncancer TOSHI value associated with emissions from these marine vessel loading operations facilities is 0.006, and the maximum acute screening HQ value was 0.9 (using the REL). There were a few reported emissions of small amounts of PB-HAP including lead and POM. Our screening analysis, based on these low emission levels of PB-HAP, indicates this source category does not pose potential for human health multipathway risks or adverse environmental impacts.

These risks are based on reported actual emission levels. Our analysis of potential differences between actual emission levels and emissions allowable under the NESHAP indicated that MACT allowable emission levels may be 2 to 10 times greater than actual emissions. Considering this difference, the highest maximum lifetime individual cancer risk could be as high as 10-in-1 million, the maximum chronic noncancer TOSHI value could be up to 0.06, and the maximum acute HQ value using the REL could be as high as 9. Considering MACT allowable emissions, we still do not expect

potential for human health multipathway risks or adverse environmental impacts, based on the very low emissions of PB-HAP.

7. Mineral Wool Production

All lifetime cancer risks associated with emissions modeled from the eight mineral wool production facilities are estimated to be less than 100-in-1 million. The highest maximum lifetime individual cancer risk was estimated at 30-in-1 million. The total estimated cancer incidence from these facilities is 0.008 excess cancer cases per year. We estimate that 110,000 people exposed to HAP from this source category may experience an increased individual lifetime cancer risk of greater than or equal to 1-in-1 million. We found no significant risk of adverse noncancer health effects associated with the modeled chronic inhalation exposures. The maximum chronic noncancer TOSHI value associated with emissions from these mineral wool production facilities is 0.4. There were a few reported emissions of small amounts of PB-HAP including cadmium, lead, and mercury. Our screening analysis, based on these low emission levels of PB-HAP, indicates this source category does not pose potential for human health multipathway risks or adverse environmental impacts.

Potential acute impacts of concern were identified in the acute inhalation screening assessment for facilities emitting formaldehyde and arsenic. Emissions of each of these pollutants showed the potential to create maximum offsite exceedances of acute screening HQ values of 40 and 20 for formaldehyde and arsenic, respectively. One potential exceedance of the AEGL-1 value ($HQ_{AEGL-1} = 3.0$) was identified for formaldehyde. No AEGL or ERPG values at any severity level are available for elemental arsenic, and this makes the interpretation of any potential exceedances of the arsenic REL more uncertain than when such values are available. Subsequent discussions with industry experts indicated that the continuous nature of the process would not lead to large fluctuations in the hourly emission rates, and that a more reasonable, yet still health-protective, ratio of peak-to-mean hourly emission rate is 2, rather than 10. (See emissions documentation in the "Residual Risk for 9 Source Categories" document in EPA Docket EPA-HQ-OAR-2008-0008). Application of this factor to our assessment still indicates the potential for acute concerns at two facilities, but reduces the maximum potential offsite impacts to HQ values of 8 and 4 based on the acute REL for formaldehyde and

arsenic, respectively, and no HQ values exceeding 1 based on the AEGL or ERPG values for formaldehyde ($HQ_{AEGL-1} = HQ_{ERPG-1} = 0.7$). Assuming peak hourly emissions occur throughout the year, meteorological conditions consistent with exceedances of the formaldehyde acute REL are estimated to occur 9 percent of the time, and such conditions occur roughly 13 percent of the time for arsenic exceedances. Details on the refined acute assessment can be found in Appendix 7 of the "Residual Risk Assessment for 9 Source Categories" document. Further, under certain meteorological conditions, the potential to exceed the REL values for formaldehyde and arsenic exists even at average emission levels; this is estimated to potentially occur 7 percent of the time for formaldehyde and 4 percent of the time for arsenic. Exceedances of the formaldehyde REL indicate the potential for eye irritation; exceedances of the arsenic REL indicate the potential for effects to reproductive and developmental systems. In addition, the threshold exceedance was of the REL value only and not of the AEGL or ERPG values. As noted in the acute REL documentation, "RELs are based on the most sensitive, relevant, adverse health effect reported in the medical and toxicological literature. RELs are designed to protect the most sensitive individuals in the population by the inclusion of margins of safety. Since margins of safety are incorporated to address data gaps and uncertainties, exceeding the REL does not automatically indicate an adverse health impact."

These risks are based on reported actual emission levels. Our analysis of potential differences between actual emission levels and emissions allowable under the NESHAP indicated that MACT allowable emission levels may be up to two times greater than actual emission levels. Considering this difference, the highest maximum lifetime individual cancer risk could be as high as 60-in-1 million, the maximum chronic noncancer TOSHI value could be up to 0.8, and the maximum acute HQ value could be as high as 16. Considering MACT allowable emissions, we do not expect potential for human health multipathway risks or adverse environmental impacts, based on the very low emissions of PB-HAP.

8. Pharmaceuticals Production

All lifetime cancer risks associated with emissions modeled from the 27 pharmaceuticals production facilities are estimated to be less than 100-in-1 million. The highest maximum lifetime individual cancer risk was estimated at

10-in-1 million. The total estimated cancer incidence from these facilities is 0.001 excess cancer cases per year. We estimate that 4,900 people exposed to HAP from this source category may experience an increased individual lifetime cancer risk of greater than or equal to 1-in-1 million. We found no significant risk of adverse noncancer health effects associated with the modeled chronic inhalation exposures. The maximum chronic noncancer TOSHI value associated with emissions from these pharmaceuticals production facilities is 0.2. There were a few reported emissions of small amounts of PB-HAP including lead, mercury, cadmium, and polynuclear aromatic hydrocarbons. Our screening analysis, based on these low emission levels of PB-HAP, indicates this source category does not pose potential for human health multipathway risks or adverse environmental impacts.

The acute screening identified three facilities with a potential maximum HQ value greater than 1 based on REL values for three pollutants—methylene chloride, methanol, and chloroform—with maximum HQ values of 4, 3, and 2, respectively. We also estimated a maximum HQ value of 2 for acetonitrile based on the AEGL-1 level. For the facilities that exceeded acute thresholds in the screening assessment, we refined the assessment by plotting receptors on facility aerial photographs and determining maximum offsite concentrations. Once we performed these refinements, estimated maximum offsite concentrations were seen to exceed acute REL values at one facility, and there were no exceedances of the AEGL-1 levels for acetonitrile ($HQ_{AEGL-1} = 0.5$). The highest offsite concentration of chloroform exceeds the REL by a factor of 2 ($HQ_{REL} = 2$, $HQ_{AEGL-1} = 0.04$). At this facility, meteorological conditions leading to offsite exceedances of the REL could occur as frequently as 13 hours per year, or about 0.1 percent of the time. HQ values from the refined assessment did not exceed 1 for either methylene chloride ($HQ_{REL} = 1$, $HQ_{AEGL-1} = 0.03$) or methanol ($HQ_{REL} = 0.9$, $HQ_{AEGL-1} = 0.04$). The threshold exceedance was of the REL value for chloroform only. As noted in the acute REL documentation, "RELs are based on the most sensitive, relevant, adverse health effect reported in the medical and toxicological literature. RELs are designed to protect the most sensitive individuals in the population by the inclusion of margins of safety. Since margins of safety are incorporated to address data gaps and uncertainties, exceeding the REL does

not automatically indicate an adverse health impact.” Details on the refined acute assessment can be found in Appendix 7 of the “Residual Risk Assessment for 9 Source Categories” document.

These risks are based on reported actual emission levels. Our analysis of potential differences between actual emission levels and emissions allowable under the NESHAP indicated that MACT allowable emission levels may be up to 25 percent greater than actual emission levels. Considering this difference, the highest maximum lifetime individual cancer risk could be as high as 13-in-1 million, the maximum chronic noncancer TOSHI value could be up to 0.3, and the maximum acute HQ value could be as high as 3. Considering MACT allowable emission levels, we do not expect potential for human health multipathway risks or adverse environmental impacts, based on the very low emissions of PB-HAP.

9. Printing and Publishing Industry

All lifetime cancer risks associated with emissions modeled from the 179 printing and publishing industry facilities are estimated to be less than 100-in-1 million. The highest maximum lifetime individual cancer risk was estimated at 0.05-in-1 million. The total estimated cancer incidence from these facilities is 0.000009 excess cancer cases per year. We estimate that no one exposed to HAP from this source category will experience an increased individual lifetime cancer risk of greater than or equal to 1-in-1 million. We found no significant risk of adverse noncancer health effects associated with the modeled chronic inhalation exposures. The maximum chronic noncancer TOSHI value associated with emissions from these printing and publishing facilities is 0.08. There were a few reported emissions of small amounts of PB-HAP including cadmium, lead, mercury, and POM. Our screening analysis, based on these low emission levels of PB-HAP, indicates this source category does not pose potential for human health multipathway risks or adverse environmental impacts.

The screening assessment for acute impacts suggests that short-term toluene concentrations at seven of the publication rotogravure facilities modeled could exceed the acute REL thresholds for toluene, assuming worst-case meteorological conditions are present, using our default assumption that the maximum hourly emissions of toluene exceed the average hourly emission rate by a factor of ten, and using a default source to receptor

distance of 100 meters. Emissions of toluene showed the potential to create maximum hourly concentrations which could exceed the acute REL by a factor of 20 ($HQ_{REL} = 20$) and potentially reach the level of the AEGL-1 ($HQ_{AEGL-1} = 1$). Additionally, because there is no REL, AEGL, or ERPG value available for ethylene glycol, which was reported as being emitted from this source category, we used the acute MRL value as an acute reference value for screening. The results of this additional assessment indicated that 4 facilities showed the potential to exceed the MRL for ethylene glycol by as much as a factor of 3 ($HQ_{MRL} = 3$). As noted in the documentation for MRL values, “exceeding the MRL does not automatically indicate an adverse health impact.” We also note that, since MRL values can be applied to exposure durations up to 14 days, these estimated MRL exceedances are likely to be overestimated.

For the publication rotogravure facilities that exceeded acute toluene thresholds in the screening assessment, we refined the assessment by plotting receptors on facility aerial photographs and determining maximum offsite concentrations. Once we performed these refinements, estimated maximum offsite concentrations were seen to exceed the acute REL at six publication rotogravure facilities. The highest offsite concentration exceeds the REL by a factor of 10 ($HQ_{REL} = 10$) and is about half of the AEGL-1 value ($HQ_{AEGL-1} = 0.5$). This occurs near a public road north of a facility. At this facility, meteorological conditions leading to offsite exceedances of the REL could occur as frequently as 90 hours per year, or about 1 percent of the time. At the facility where we estimate the REL to be most frequently exceeded, the maximum REL exceedance is by a factor of 4 ($HQ_{REL} = 4$), and meteorological conditions leading to offsite exceedances of the REL could occur as frequently as 138 hours per year, or about 2 percent of the time.

Thus, the highest offsite concentration exceeds the REL by a factor of 10 ($HQ_{REL} = 10$) and the threshold exceedance was of the REL value only. As noted in the acute REL documentation, “RELs are based on the most sensitive, relevant, adverse health effect reported in the medical and toxicological literature. RELs are designed to protect the most sensitive individuals in the population by the inclusion of margins of safety. Since margins of safety are incorporated to address data gaps and uncertainties, exceeding the REL does not automatically indicate an adverse health

impact.” Further, based on the extensive information we have on this source category and on engineering judgment, we estimate that a factor of 10 emissions multiplier is most likely high for publication rotogravure printing. Instead of 10, we believe a more appropriate multiplier would be 5 or less. Using a multiplier of 5 (or less) would reduce the estimated acute impacts by half or more from the values presented. Details on the refined acute assessment can be found in Appendix 7 of the “Residual Risk for 9 Source Categories” document (See Docket EPA-HQ-OAR-2008-0008).

These risks are based on reported actual emission levels. Our analysis of potential differences between actual emission levels and emissions allowable under the NESHAP indicated that MACT allowable emission levels may be up to five times greater than actual emission levels. Considering this difference, the highest maximum lifetime individual cancer risk could be as high as 0.3-in-1 million, the maximum chronic noncancer TOSHI value could be up to 0.4, and the maximum acute HQ value could be as high as 50. Considering MACT allowable emission levels, we do not expect potential for human health multipathway risks or adverse environmental impacts, based on the very low emissions of PB-HAP.

F. What are our proposed decisions on acceptability and ample margin of safety?

Section 112(f) of the CAA requires that EPA promulgate standards for a category if promulgation of such standards is required to provide an ample margin of safety to protect public health or to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect. In determining whether standards are required to provide an ample margin of safety to protect public health, EPA considers both maximum individual cancer risk and risk of non-cancer health effects posed by emissions from the source category, as well as any other relevant public health-related information or factors. With regard to maximum individual cancer risk, the CAA states that if the MACT standards “do not reduce lifetime excess cancer risks [due to HAP emissions] 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.

As discussed in greater detail below, cancer risks to the individual most exposed to emissions from the Printing and Publishing source category are estimated to be below 1-in-1 million. After considering this information as well as an analysis of non-cancer health effects and environmental effects, we have determined that the current MACT standard provides an ample margin of safety to protect public health and prevents an adverse environmental effect. In reaching this conclusion, we did not consider costs.

For each of the other source categories that are the subject of today's proposed rulemaking, we estimated that risks to the individual most exposed to emissions from the category are 1-in-1 million or greater. Following our initial determination that excess lifetime individual cancer risk to the individual most exposed to emissions from the category considered exceeds 1-in-1 million, 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, determining whether risks are acceptable, is only a starting point for the analysis that determines a final standard. The second step determines an ample margin of safety, which is the level at which the standard is set.

In the Benzene NESHAP, we explained that we will generally presume that if the risk to an individual exposed to the maximum level of a pollutant for a lifetime (the MIR) is no higher than approximately 1 in 10 thousand (100-in-1 million), that risk level is considered acceptable. However, in determining acceptability we weigh the magnitude of the MIR with a series of other health measures and factors, including overall incidence of cancer or other serious health effects within the exposed population, the numbers of persons exposed within each individual lifetime risk range and associated incidence within, typically, a 50 km exposure radius around facilities, the science policy assumptions and estimation uncertainties associated with the risk measures, weight of the scientific evidence for human health effects, and other quantified or unquantified health effects. Based on the maximum individual cancer risk estimates and other health factors evaluated for the nine source categories, we have concluded that the residual risk for these source categories is acceptable.

EPA must consider health and risk factors, as well as costs and economic impacts, technological feasibility, and other factors relevant to each particular decision, to complete an overall judgment on whether the public health

is protected with an ample margin of safety. Because our analyses suggest risks to the individual most exposed to emissions equal or exceed 1-in-1 million after application of the NESHAP for the source categories other than Printing and Publishing, we considered the feasibility and costs of additional controls to reduce emissions and associated risks to address whether additional controls were necessary to provide an ample margin of safety for these categories. For each source category (with the exception of the Printing and Publishing), we identified emissions reduction options for each emission point contributing significantly to the risks and evaluated the costs and emission reduction benefits of these options. These analyses can be found in impacts assessment documents for each NESHAP, which are available in the docket.

We did not consider facility-wide risk. Although we believe we can consider facility-wide risk as a relevant factor in determining an ample margin of safety, we do not have cost, technical feasibility, and other data to analyze emission sources at the facility that are outside the source category for the nine source categories in RTR Group 2A.

The sections below and the impact memos in docket EPA-HQ-OAR-2008-0008 provide more detailed discussions about the emissions reduction options, the impacts of the emissions reduction options, and our ample margin of safety decision for each of the nine source categories.

1. Epichlorohydrin Elastomers Production

For the Epichlorohydrin Elastomers Production source category, we identified only one control option to address risks from equipment leaks, which were shown to drive the maximum individual cancer risks for this source category. This control option would require sources to install leakless valves to prevent leaks from those components.

We estimated HAP reduction resulting from this control option is about 0.4 tons per year from the baseline actual emissions level. We estimated that achieving these reductions would involve a capital cost of about \$725,000, a total annualized cost of about \$99,000, and a cost-effectiveness of \$244,000 per ton of HAP emissions reduced.

Based on actual emissions, we estimate the maximum individual lifetime cancer risk is 30-in-1 million, the annual cancer incidence is 0.0004, and the population exposed to individual lifetime cancer risk of greater than or equal to 1-in-1 million is 4,000.

The additional control requirement would achieve approximately 10 percent reduction of all three of these cancer risk metrics at a very high cost. Further, the analysis based on actual emission levels has shown that both the chronic and acute noncancer hazards are below the threshold value of 1, indicating little or no potential for noncancer health effects resulting from actual emissions from the Epichlorohydrin Elastomers Production source category. We estimate that the MACT allowable emissions from this source category are approximately equal to the reported, actual emissions. Therefore, the estimated emission reduction, costs, and risk reduction discussed above would also be applicable to the MACT allowable emissions level. As a result, we propose that, based on actual and MACT allowable emissions, the existing MACT standard provides an ample margin of safety (considering cost, technical feasibility, and other factors) to protect public health.

We are also required to consider the potential for adverse impacts to the environment as part of a residual risk assessment. We believe 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 there to be no potential for significant and widespread adverse effect to terrestrial mammals from inhalation exposure to HAP emitted from the Epichlorohydrin Elastomers Production source category. As this source category had no reported PB-HAP emissions, no potential for an adverse environmental effect exists. Because our results showed no potential for any adverse environmental effect, we also do not believe there is any potential for an adverse effect on threatened or endangered species or on their critical habitat within the meaning of 50 CFR 402.14(a). With these results, we have concluded that a consultation with the Fish and Wildlife Service is not necessary.

In summary, we propose that the current MACT standard provides an ample margin of safety to protect public health. The additional control available is not cost-effective in light of the additional health protection against maximum individual cancer risk and chronic and acute noncancer hazards that the control would provide. In addition, we believe that there is no potential for adverse environmental effects. Thus, we are proposing to re-

adopt the existing MACT standard to satisfy section 112(f) of the CAA.

2. Hypalon™ Production

For the Hypalon™ Production source category, we identified only one control option to address risks from back-end operations, which were shown to drive the maximum individual cancer risks for this source category. This control option would require HAP emissions reduction through pollution prevention or other measures for these operations. We estimated HAP reduction resulting from this control option is about 3.7 tons per year from the baseline actual emissions level. We estimated that achieving these reductions would involve a capital cost of about \$3,500,000, a total annualized cost of about \$1,900,000, and a cost-effectiveness of \$521,000 per ton of HAP emissions reduced.

Based on actual emissions, we estimate the maximum individual lifetime cancer risk is 1-in-1 million, the annual cancer incidence is 0.0004, and the population exposed to individual lifetime cancer risk of greater than or equal to 1-in-1 million is 400. The additional control requirement would achieve approximately 20 percent reduction of all three of these cancer risk metrics at a very high cost. Further, the analysis based on actual emission levels has shown that both chronic and acute noncancer hazards are below the threshold value of 1, indicating little or no potential for noncancer health effects resulting from actual emissions from the Hypalon™ Production source category. We estimate that the MACT allowable emissions from this source category are approximately equal to the reported, actual emissions. Therefore, the estimated emission reduction, costs, and risk reduction discussed above would also be applicable to the MACT allowable emissions level. As a result, we propose that, based on actual and MACT allowable emissions, the existing MACT standard provides an ample margin of safety (considering cost, technical feasibility, and other factors) to protect public health.

We are also required to consider the potential for adverse impacts to the environment as part of a residual risk assessment. As previously noted, we believe 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 there to be no potential for significant and widespread adverse effect to terrestrial mammals from inhalation exposure to HAP emitted

from the Hypalon™ Production source category. As this source category had no reported PB-HAP emissions, no potential for an adverse environmental effect exists. Because our results showed no potential for an adverse environmental effect, we also do not believe there is any potential for an adverse effect on threatened or endangered species or on their critical habitat within the meaning of 50 CFR 402.14(a). With these results, we have concluded that a consultation with the Fish and Wildlife Service is not necessary.

In summary, we propose that the current MACT standard provides an ample margin of safety to protect public health. The additional control available is not cost effective in light of the additional health protection against maximum individual cancer risk and chronic and acute noncancer hazard the control would provide. In addition, we believe that there is no potential for adverse environmental effect. Thus, we are proposing to re-adopt the existing MACT standard to satisfy section 112(f) of the CAA.

3. Nitrile Butadiene Rubber Production

For the Nitrile Butadiene Rubber Production source category, we identified two control options; one to address risks from front-end process vent emissions and another to address risks from equipment leak emissions. Emissions from these sources were shown to drive the maximum individual cancer risk for this source category. The control option for front-end process vents would require controls to be placed on more vents by expanding the applicability of the current control requirements, and the control option for equipment leaks would involve a requirement to install leakless valves to prevent leaks from those components. We estimated HAP reduction resulting from additional front-end process vent controls is about 14.9 tons per year from the baseline actual emissions level. We estimated that achieving these reductions would involve a capital cost of about \$310,000, a total annualized cost of about \$750,000, and a cost-effectiveness of \$50,000 per ton of HAP emissions reduced. We estimated HAP reduction resulting from additional equipment leak controls is about 3.7 tons per year from the baseline actual emissions level. We estimated that achieving these reductions would involve a capital cost of about \$6,600,000, a total annualized cost of about \$910,000, and a cost-effectiveness of \$244,000 per ton of HAP emissions reduced.

Based on actual emissions, we estimate the maximum individual lifetime cancer risk is 60-in-1 million, the annual cancer incidence is 0.004, and the population exposed to individual lifetime cancer risk of greater than or equal to 1-in-1 million is 47,000. The additional control requirement would achieve approximately 25 percent reduction of all three of these cancer risk metrics at a very high cost. Further, the analysis based on actual emission levels has also shown that both the chronic and acute noncancer hazards are below the threshold value of 1, indicating little or no potential for noncancer health effects resulting from actual emissions from the Nitrile Butadiene Rubber source category. We estimate that the MACT allowable emissions from this source category are approximately equal to the reported, actual emissions. Therefore, the estimated emission reduction, costs, and risk reduction discussed above would also be applicable to the MACT allowable emissions level. As a result, we propose that the existing MACT standard, based on actual and MACT allowable emissions, provides an ample margin of safety (considering cost, technical feasibility, and other factors) to protect public health.

We are also required to consider the potential for adverse impacts to the environment as part of a residual risk assessment. As previously noted, we believe that human toxicity values for the inhalation pathway are generally protective of direct impacts on terrestrial mammals and plants. Because the maximum cancer and noncancer hazards to humans from inhalation exposure are relatively low, we expect there to be no potential for significant and widespread adverse effect to terrestrial mammals from inhalation exposure to HAP emitted from the Nitrile Butadiene Rubber Production source category. As this source category had no reported PB-HAP emissions, no potential for an adverse effect exists. Because our results showed no potential for an adverse environmental effect, we also do not believe there is any potential for an adverse effect on threatened or endangered species or on their critical habitat within the meaning of 50 CFR 402.14(a). With these results, we have concluded that a consultation with the Fish and Wildlife Service is not necessary.

In summary, we propose that the current MACT standard provides an ample margin of safety to protect public health. The additional control available is not cost effective in light of the additional health protection against maximum individual cancer risk and

chronic and acute noncancer hazard the control would provide. In addition, we believe that there is no potential for adverse environmental effect. Thus, we are proposing to re-adopt the existing MACT standard to satisfy section 112(f) of the CAA.

4. Polybutadiene Rubber Production

For the Polybutadiene Rubber Production source category, we identified two control options; one to address risks from front-end process vent emissions and another to address risks from equipment leak emissions. Emissions from these sources were shown to drive the maximum individual cancer risk for this source category. The control option for front-end process vents would require controls to be placed on more vents by expanding the applicability of the current control requirements, and the control option for equipment leaks would involve a requirement to install leakless valves to prevent leaks from those components.

We estimated HAP reduction resulting from additional front-end process vent controls is about 178 tons per year from the baseline actual emissions level. We estimated that achieving these reductions would involve a capital cost of about \$310,000, a total annualized cost of about \$750,000, and a cost-effectiveness of \$4,000 per ton of HAP emissions reduced. We estimated HAP reduction resulting from additional equipment leak controls is about 52 tons per year from the baseline actual emissions level. We estimated that achieving these reductions would involve a capital cost of about \$93,000,000, a total annualized cost of about \$13,000,000, and a cost-effectiveness of \$244,000 per ton of HAP emissions reduced.

Based on actual emissions, we estimate the maximum individual lifetime cancer risk is 10-in-1 million, the annual cancer incidence is 0.002, and the population exposed to individual lifetime cancer risk of greater than or equal to 1-in-1 million is 16,000. The additional control requirement would achieve approximately 10 percent reduction of all three of these cancer risk metrics at a relatively high cost considering that risks are low under the current MACT standard and that the reduction in risks is relatively small. Further, the analysis based on actual emissions has shown that both the chronic and acute noncancer hazards are below the threshold value of 1.

We estimate that the MACT allowable emissions from this source category are as high as five times actual emission levels. However, the additional emissions represented by the MACT

allowable emissions level are released from a part of the production process that does not contribute appreciably to the risks and for which the control option would not affect emission levels. Therefore, we believe that the estimated emission reductions, costs, and risk reduction discussed above would also be applicable to the MACT allowable emissions level. As a result, we propose that, based on actual and MACT allowable emission levels, the existing MACT standard provides an ample margin of safety (considering cost, technical feasibility, and other factors) to protect public health.

We are also required to consider the potential for adverse impacts to the environment as part of a residual risk assessment. As previously noted, we believe 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 there to be no potential for significant and widespread adverse effect to terrestrial mammals from inhalation exposure to HAP emitted from the Polybutadiene Rubber Production source category. As this source category had no reported PB-HAP emissions, no potential for an adverse effect exists. Because our results showed no potential for an adverse environmental effect, we also do not believe there is any potential for an adverse effect on threatened or endangered species or on their critical habitat within the meaning of 50 CFR 402.14(a). With these results, we have concluded that a consultation with the Fish and Wildlife Service is not necessary.

In summary, we propose that the current MACT standard provides an ample margin of safety to protect public health. The additional control available is not cost-effective in light of the additional health protection against maximum individual cancer risk and chronic and acute noncancer hazard the control would provide. In addition, we believe that there is no potential for adverse environmental effect. Thus, we are proposing to re-adopt the existing MACT standard to satisfy section 112(f) of the CAA.

5. Styrene Butadiene Rubber and Latex Production

For the Styrene Butadiene Rubber and Latex Production source category, we identified one available control option to address risks from equipment leaks, which were shown to drive the maximum individual cancer risks for this source category. This control option

would involve a requirement to install leakless valves to prevent leaks from those components.

We estimated HAP reduction resulting from installing leakless valves is about 6 tons per year from the baseline actual emissions level. We estimated that achieving these reductions would involve a capital cost of about \$10,600,000, a total annualized cost of about \$1,500,000, and a cost-effectiveness of \$244,000 per ton of HAP emissions reduced.

Based on actual emissions, we estimate the maximum individual lifetime cancer risk is 7-in-1 million, the annual cancer incidence is 0.004, and the population exposed to individual lifetime cancer risk of greater than or equal to 1-in-1 million is 26,000. The additional control requirement would achieve approximately 25 percent reduction of all three of these cancer risk metrics at a relatively high cost. Further, the analysis based on actual emissions has shown that both the chronic and acute noncancer hazards are below the threshold value of 1.

We estimate that the MACT allowable emissions from this source category are as high as four times actual emission levels. However, the additional emissions represented by the MACT allowable emissions level are released from a part of the production process that does not contribute appreciably to the risks and for which the control option would not affect emission levels. Therefore, we believe that the estimated emission reductions, costs, and risk reduction discussed above would also be applicable to the MACT allowable emissions level. As a result, we propose that, based on actual and MACT allowable emission levels, the existing MACT standard provides an ample margin of safety (considering cost, technical feasibility, and other factors) to protect public health.

We are also required to consider the potential for adverse impacts to the environment (as part of a residual risk assessment). As previously noted, we believe 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 there to be no potential for significant and widespread adverse effect to terrestrial mammals from inhalation exposure to HAP emitted from the Styrene Butadiene Rubber and Latex Production source category. As this source category had no reported PB-HAP emissions, no potential for an adverse effect was identified. Since our results showed no potential for an

adverse environmental effect, we also do not believe there is any potential for an adverse effect on threatened or endangered species or on their critical habitat within the meaning of 50 CFR 402.14(a). With these results, we have concluded that a consultation with the Fish and Wildlife Service is not necessary.

In summary, we propose that the current MACT standard provides an ample margin of safety to protect public health. The additional control available is not cost-effective in light of the additional health protection against maximum individual cancer risk and chronic and acute noncancer hazard the control would provide. In addition, we believe that there is no potential for adverse environmental effect. Thus, we are proposing to re-adopt the existing MACT standard to satisfy section 112(f) of the CAA.

6. Marine Vessel Loading Operations

For the Marine Vessel Loading Operations source category, we identified one control option to address risks from ethylene dichloride emissions, which were shown to drive the maximum individual cancer risks for this source category. This control option would require the same performance standard specified in the original MACT standard to be used at more facilities by lowering the applicability limit for ethylene dichloride emissions from 10 tons per year to approximately 2.6 tons per year. We estimated HAP reduction resulting from this control option is about 15 tons per year from the baseline actual emissions level. We estimated that achieving these reductions would involve a capital cost of about \$57,000,000, a total annualized cost of about \$11,000,000, and a cost-effectiveness of over \$700,000 per ton of HAP emissions reduced.

Based on actual emissions, we estimate the maximum individual lifetime cancer risk is 1-in-1 million, the annual cancer incidence is 0.01, and the population exposed to individual lifetime cancer risk of greater than or equal to 1-in-1 million is 2,400. The additional control requirement would achieve approximately 5 percent reduction of all three of these cancer risk metrics at a very high cost. The analysis based on actual emission levels has also shown that both the chronic and acute noncancer risks are below the threshold value of 1.

We estimate that the MACT allowable emissions from this source category could be 10 times the reported actual emissions, which could potentially result in risk impacts up to 10 times

those estimated for the actual emissions level. Assuming all impacts were proportional to those predicted for actual emissions, this control option would result in an emission reduction of around 150 tons per year (based on a factor of 10). The risk reduction would still be minimal. The cost would not differ, resulting in a cost effectiveness of around \$700,000 per ton based on MACT allowable emissions.

As a result, we propose that, based on actual and MACT allowable emissions, the existing MACT standard provides an ample margin of safety (considering cost, technical feasibility, and other factors) to protect public health.

We are also required to consider the potential for adverse impacts to the environment as part of a residual risk assessment. As previously noted, we believe 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 there to be no significant and widespread adverse effect to terrestrial mammals from inhalation exposure to HAP emitted from the Marine Vessel Loading Operations source category. To assess the potential for adverse effect to other wildlife, we have carried out a screening-level assessment of adverse environmental effects via exposure to PB-HAP emissions. This source category reported PB-HAP emissions, but, based on our application of the screening scenario developed for TRIM.FaTE model, no potential for an adverse environment effect via multipathway exposures was identified. Because our results showed no potential for an adverse environmental effect, we also do not believe there is any potential for an adverse effect on threatened or endangered species or on their critical habitat within the meaning of 50 CFR 402.14(a). With these results, we have concluded that a consultation with the Fish and Wildlife Service is not necessary.

In summary, we propose that the current MACT standard provides an ample margin of safety to protect public health. The additional control available is not cost-effective in light of the additional health protection against maximum individual cancer risk and chronic and acute noncancer hazard the control would provide. In addition, we believe that there is no potential for adverse environmental effect. Thus, we are proposing to re-adopt the existing MACT standard to satisfy section 112(f) of the CAA.

7. Mineral Wool Production

For the Mineral Wool Production source category, we identified one available control option to address risks from fiber collection and cooling chambers, the emission points which were shown to drive the maximum individual cancer risks for this source category. This control option would require sources to add thermal incinerators to control emissions from these areas.

We estimated HAP reduction resulting from this control option is about 48 tons per year from the baseline actual emissions level. We estimated that achieving these reductions would involve a capital cost of about \$65,000,000, a total annualized cost of about \$13,000,000, and a cost-effectiveness of \$270,000 per ton of HAP emissions reduced.

Based on actual emissions, we estimate the maximum individual lifetime cancer risk is 30-in-1 million, the annual cancer incidence is 0.008, and the population exposed to individual lifetime cancer risk of greater than or equal to 1-in-1 million is 110,000. The additional control requirement would achieve less than 10 percent reduction of all three of these cancer risk metrics at a very high cost. The analysis has also shown that the chronic noncancer hazards are low based on actual emissions. While the refined assessment for acute impacts using actual emission suggests that short-term arsenic and formaldehyde concentrations at five modeled facilities could exceed their acute REL values by as much as factors of 4 and 8, respectively, if worst-case meteorological conditions (which occur roughly 10 percent of the time) are present at the same time that maximum hourly emissions of these chemicals exceed the average hourly emission rate by a factor of 2. However, as noted earlier in this preamble, exceedances of these REL values may occur even at average emission rates for roughly 10 percent of the hours in a year. In addition, the threshold exceedance was of the REL value only. As noted in the acute REL documentation, "RELs are based on the most sensitive, relevant, adverse health effect reported in the medical and toxicological literature. RELs are designed to protect the most sensitive individuals in the population by the inclusion of margins of safety. Since margins of safety are incorporated to address data gaps and uncertainties, exceeding the REL does not automatically indicate an adverse health impact."

We estimate that the MACT allowable emissions from this source category could be as high as two times the reported actual emissions, which could potentially result in risk impacts double those estimated for the actual emissions level. Assuming all impacts were proportional to those predicted for actual emissions, this incinerator control option would result in an emission reduction of around 96 tons per year and a risk reduction of approximately 20 percent. The cost would not differ, resulting in a cost effectiveness of around \$135,000 per ton based on MACT allowable emissions. Finally, the REL value for arsenic is designed for a four hour exposure whereas the exposure duration used in the modeling scenario was one hour, making the use of the REL in this application more protective of human health than if the exposure durations were the same. Considering these factors, although we cannot completely rule out the potential for acute impacts from formaldehyde or arsenic at these facilities, we believe it to be unlikely any acute health impacts would actually occur. As a result, we propose that, based on actual and MACT allowable emissions levels, the existing MACT standard, provides an ample margin of safety (considering cost, technical feasibility, and other factors) to protect public health.

We are also required to consider the potential for adverse impacts to the environment as part of a residual risk assessment. As previously noted, we believe 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 there to be no potential for significant and widespread adverse effect to terrestrial mammals from inhalation exposure to HAP emitted from the Mineral Wool Production source category. To evaluate the potential for adverse effects to other wildlife, we carried out a screening-level assessment of adverse environmental effects via exposure to PB-HAP emissions. This source category reported PB-HAP emissions, but, based on our application of the screening scenario developed for TRIM.FaTE model, no potential for an adverse environment effect via multipathway exposures was identified. Because our results showed no potential for an adverse environmental effect, we also do not believe there is any potential for an adverse effect on threatened or endangered species or on their critical

habitat within the meaning of 50 CFR 402.14(a). With these results, we have concluded that a consultation with the Fish and Wildlife Service is not necessary.

In summary, we propose that the current MACT standard provides an ample margin of safety to protect public health. The additional control available is not cost-effective in light of the additional health protection against maximum individual cancer risk and chronic and acute noncancer hazard the control would provide. In addition, we believe that there is no potential for adverse environmental effect. Thus, we are proposing to re-adopt the existing MACT standard to satisfy section 112(f) of the CAA.

8. Pharmaceuticals Production

For the Pharmaceuticals Production source category, we identified one available control option to address risks from equipment leaks, which were shown to drive the maximum individual cancer risks for this source category. This control option would involve a work practice requirement to monitor valves monthly until fewer than 0.5 percent of valves are leaking.

We estimated HAP reduction resulting from this control option is about 107 tons per year from the baseline actual emissions level. We estimated that achieving these reductions would involve no capital costs, a total annualized cost of about \$820,000, and a cost-effectiveness of \$7,600 per ton of HAP emissions reduced.

Based on actual emissions, we estimate the maximum individual lifetime cancer risk is 10-in-1 million, the annual cancer incidence is 0.001, and the population exposed to individual lifetime cancer risk of greater than or equal to 1-in-1 million is 4,900. The application of the additional control option would reduce all three of these relatively low cancer risks metrics by less than 10 percent. We propose that the costs for this option are disproportionate to the limited cancer health benefit potentially achievable with the controls. Further, the analysis has also shown that both the chronic and acute noncancer hazards are low, based on actual emissions. While the assessment for acute impacts using actual emissions suggests that short-term chloroform concentrations at one modeled facility could exceed the acute threshold, this is only if worst-case meteorological conditions are present (estimated at roughly 0.1 percent of the year) at the same time that maximum hourly emissions of these chemicals exceed the average actual hourly

emission rate by a factor of 5. In addition, the threshold exceedance was of the REL value only. As noted in the acute REL documentation, "RELs are based on the most sensitive, relevant, adverse health effect reported in the medical and toxicological literature. RELs are designed to protect the most sensitive individuals in the population by the inclusion of margins of safety. Since margins of safety are incorporated to address data gaps and uncertainties, exceeding the REL does not automatically indicate an adverse health impact." Finally, the REL value for chloroform (the only HAP with the potential for acute impacts in the refined analysis) is designed for a 7-hour exposure, whereas the exposure duration used in the modeled scenario was 1 hour, making the uses of the REL in this application more protective of human health than if the exposure durations were the same. Considering these factors, we believe it to be unlikely any acute health impacts would actually occur.

We estimate that the MACT allowable emissions from this source category could be as much as 25 percent higher than the reported actual emissions, which could potentially result in risk impacts 25 percent higher than those estimated for the actual emissions level. Assuming all impacts are proportional to those predicted for actual emissions, this equipment leak control option would result in an emission reduction of around 130 tons per year. The risk reduction would still be minimal. The cost would not differ, although the cost effectiveness would be somewhat lower at over \$6,000 per ton when based on MACT allowable emissions. As a result, we propose that, based on actual and MACT allowable emissions, the existing MACT standard provides an ample margin of safety (considering cost, technical feasibility, and other factors) to protect public health.

We are also required to consider the potential for adverse impacts to the environment as part of a residual risk assessment. As previously noted, we believe 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 there to be no potential for significant and widespread adverse effect to terrestrial mammals from inhalation exposure to HAP emitted from the Pharmaceuticals Production source category. To evaluate the potential for adverse effect to other wildlife, we carried out a screening-level assessment of adverse

environmental effects via exposure to PB-HAP emissions. This source category reported PB-HAP emissions, but, based on our application of the screening scenario developed for TRIM.FaTE model, no potential for an adverse environment effect via multipathway exposures was identified. Since our results showed no potential for an adverse environmental effect, we also do not believe there is any potential for an adverse effect on threatened or endangered species or on their critical habitat within the meaning of 50 CFR 402.14(a). With these results, we have concluded that a consultation with the Fish and Wildlife Service is not necessary.

In summary, we propose that the current MACT standard provides an ample margin of safety to protect public health. The additional control available is not cost-effective in light of the additional health protection against maximum individual cancer risk and chronic and acute noncancer hazard the control would provide. In addition, we believe that there is no potential for adverse environmental effect. Thus, we are proposing to re-adopt the existing MACT standard to satisfy section 112(f) of the CAA.

9. Printing and Publishing Industry

The Printing and Publishing source category emits HAP which are known, probable, or possible carcinogens. EPA evaluated the emissions of these HAP and determined that they pose maximum individual cancer risks less than 1-in-1 million to the individual most exposed. Because these risks are less than 1-in-1 million, EPA is not required to promulgate standards under 112(f)(2) for the Printing and Publishing source category unless promulgation of standards is required to prevent an adverse environmental effect.

Accordingly, EPA undertook further analysis to assess whether environmental effects might result from emissions from this source category.

Our analysis demonstrated that chronic noncancer risks are expected to be low, based on actual and MACT allowable emissions. We determined that emissions from the Printing and Publishing category would result in chronic noncancer target organ-specific HI less than or equal to 1 for the individual most exposed. Thus we do not anticipate that actual or MACT allowable emissions would result in adverse chronic noncancer health effects.

While the refined assessment for acute impacts suggests that short-term toluene concentrations at six modeled facilities could exceed acute thresholds,

we believe it unlikely that acute impacts would occur. Acute impacts of policy significance are unlikely because we based the refined assessment on worst-case meteorological conditions (estimated to occur up to 2 percent of the time) being present at the same time that maximum hourly emissions of toluene exceed the average hourly emission rate by a factor of 10, coincident with individuals being in the location of maximum impact. This set of assumptions results in an estimate of a 10-fold exceedance of the toluene REL. As noted in the acute REL documentation, "RELs are based on the most sensitive, relevant, adverse health effect reported in the medical and toxicological literature. RELs are designed to protect the most sensitive individuals in the population by the inclusion of margins of safety. Since margins of safety are incorporated to address data gaps and uncertainties, exceeding the REL does not automatically indicate an adverse health impact."

We are also required to consider the potential for adverse impacts to the environment as part of a residual risk assessment. As previously noted, we believe 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 low, we expect there to be no potential for significant and widespread adverse effect to terrestrial mammals from inhalation exposure to HAP emitted from the Printing and Publishing Industry source category. To evaluate the potential for adverse effect to other wildlife, we carried out a screening-level assessment of adverse environmental effects via exposure to PB-HAP emissions. This source category reported PB-HAP emissions, but, based on our application of the screening scenario developed for TRIM.FaTE model, no potential for an adverse environment effect via multipathway exposures was identified. Because our results showed no potential for an adverse environmental effect, we also do not believe there is any potential for an adverse effect on threatened or endangered species or on their critical habitat within the meaning of 50 CFR 402.14(a). With these results, we have concluded that a consultation with the Fish and Wildlife Service is not necessary.

In summary, we propose that the current MACT standard provides an ample margin of safety to protect public health because the maximum individual cancer risk is below 1-in-1 million, the chronic noncancer risks are low, and the

acute noncancer hazards are below a level of concern. In addition, we believe that there is no potential for adverse environmental effect. In reaching this conclusion, we did not consider costs. Thus, we are proposing to re-adopt the existing MACT standard to satisfy section 112(f) of the CAA.

G. What are the results of the technology review?

Section 112(d)(6) of the CAA requires us to review and revise MACT standards, as necessary, every 8 years, taking into account developments in practices, processes, and control technologies that have occurred during that time. This authority provides us with broad discretion to revise the MACT standards as we determine necessary, and to account for a wide range of relevant factors. We interpret CAA section 112(d)(6) as requiring us to consider developments in pollution control in the industry "taking into account developments in practices, processes, and control technologies," and to assess the costs of potentially stricter standards reflecting those developments (69 FR 48351). We consider "developments in practices, processes, and control technologies" to be:

- Any add-on control technology or other equipment (e.g., floating roofs for storage tanks) that was not identified and considered during MACT development for the source category,
- Any improvements in add-on control technology or other equipment (that was identified and considered during MACT development for the source category) that could result in significant additional emission reduction,
- Any work practice or operational procedure that was not identified and considered during MACT development for the source category, and
- Any process change or pollution prevention alternative that could be broadly applied that was not identified and considered during MACT development for the source category.

For the source categories in RTR Group 2A, our review of developments in practices, processes, and control technologies has been on-going since promulgation of the five NESHAP. In the years since the RTR Group 2A NESHAP were promulgated, EPA has developed air toxics regulations for a number of source categories that emit HAP from the same type of emission sources and have evaluated practices, processes, and control techniques for each rulemaking. Thus, the first source of information about practices, processes, and control technologies is

our own data and experience with the various industry sectors and source categories.

The second source of information is EPA's RACT/BACT/LAER clearinghouse. The RACT/BACT/LAER clearinghouse is an EPA-maintained central data base of case-specific information on the "Best Available" air pollution technologies that have been required to reduce the emissions of air pollutants from stationary sources (e.g., power plants, steel mills, chemical plants, etc.). The third source of information is information received directly from the industry regarding any developments in practices, processes, or controls.

The sections below provide more discussion about the technology review analyses and results for each of the nine source categories. More detail about the technology review can be found in the technology review documents written for each source category. The technology review documents are in the RTR Group 2A docket.

1. Polymers and Resins I

In the decade since the Polymers and Resins I NESHAP was promulgated, EPA has developed 18 air toxics regulations for source categories that emit organic HAP from the same type of emission sources that are present in the five Polymers and Resins source categories in RTR Group 2A. We reviewed the regulatory requirements and/or technical analyses for these 18 regulations for new practices, processes, and control techniques. We also conducted a search of the BACT/RACT/LAER clearinghouse for controls for VOC- and HAP-emitting processes in the Polymers and Resins and the Synthetic Organic Chemical Manufacturing Industry (SOCMI) categories with permits dating back to 1997. In addition to these two sources of information, we obtained information directly from the industry regarding any developments in practices, processes, or controls.

We identified no advancements in practices, processes, and control technologies applicable to the emission sources in the Polymers and Resins I source categories in our technology review.

2. Marine Vessel Loading Operations

In the decade since the Marine Vessel Loading NESHAP was promulgated, EPA has developed eight air toxics regulations for source categories that emit organic HAP from the same type of emission sources that are present in the marine vessel loading source category. We reviewed the regulatory

requirements and/or technical analyses for these eight regulations for new practices, processes, and control techniques. We also conducted a search of the BACT/RACT/LAER clearinghouse for controls for VOC- and HAP-emitting loading processes in the Organic Liquid Storage and Marketing categories with permits dating back to 1997. In addition to these two sources of information, we also obtained information from industries with similar emissions sources with potentially transferable controls to determine if they have any developments in practices, processes, or controls that could be applied here.

We identified no advancements in practices, processes, and control technologies applicable to the emission sources in the Marine Vessel Loading source category in our technology review.

3. Mineral Wool Production

Since the Mineral Wool NESHAP was promulgated, EPA has developed several air toxics regulations for source categories that emit organic HAP from similar types of emission sources that are present in the mineral wool source category. These similar types of emissions sources include both melting furnaces and curing ovens. We reviewed the regulatory requirements and/or technical analyses associated with each of the subsequent regulatory actions to identify any practices, processes, and control techniques considered in these efforts that could possibly be applied to the Mineral Wool Production source category. In addition to the review of subsequent regulatory actions for similar emissions types such as melting furnaces and curing ovens, EPA conducted a review for other VOC- and organic HAP-emitting processes that have similar technology-transferable controls.

We also conducted a search of the BACT/RACT/LAER clearinghouse for the Mineral Wool Production source category and found the following processes, practices, and control technologies: wet scrubbers for particulate matter (PM); baghouse dust collectors for PM; electrostatic precipitators for PM; and thermal oxidizer for VOC. These practices, processes, and control technologies are all examples of the types of emission reduction techniques that were considered in the development of the Mineral Wool MACT standard. In addition to the search for similar processes such as cupolas, melting ovens or furnaces, and curing ovens, we conducted a search for other PM, HAP metals, VOC, and organic HAP processes that have similar, technology-

transferable controls. No developments in practices, processes, or control technologies were revealed as a result of that search.

In addition to these two sources of information, we also obtained information from industries with technology transferable controls regarding developments in practices, processes, or controls.

We identified no advancements in practices, processes, and control technologies applicable to the emission sources in the Mineral Wool Production source category in our technology review.

4. Pharmaceuticals Production

In the decade since the Pharmaceutical NESHAP was promulgated, EPA has developed 10 air toxics regulations for source categories that emit organic HAP from the same type of emission sources that are present in the pharmaceutical source category. We reviewed the regulatory requirements and/or technical analyses for these 10 regulations for new practices, processes, and control techniques. We also conducted a search of the BACT/RACT/LAER clearinghouse for controls for VOC- and HAP-emitting processes in the Pharmaceuticals source category.

We identified no advancements in practices, processes, and control technologies applicable to the emission sources in the Pharmaceuticals Production source categories in our technology review.

5. Printing and Publishing Industry

In the twelve years since the Printing and Publishing NESHAP was promulgated, EPA has developed three air toxics regulations that emit organic HAP from emission sources that are similar to those addressed in the Printing and Publishing NESHAP. We reviewed the regulatory requirements and/or technical analyses associated with each of three subsequent regulatory actions to identify any practices, processes, and control techniques considered in these efforts that could possibly be applied to the Printing and Publishing Industry source category. We also conducted a search of the BACT/RACT/LAER clearinghouse for permits dating back to 1990 for controls for VOC- and HAP-emitting processes in the Printing and Publishing Industry and four additional source categories with emission sources similar to those in the Printing and Publishing Industry source category.

In addition to these two sources of information, we obtained information directly from the printing and

publishing industry and the closely related paper, film, and foil coating industry regarding developments in practices, processes, or controls.

We identified no advancements in practices, processes, and control technologies applicable to the emission sources in the Printing and Publishing source category in our technology review.

II. Proposed Action

We propose that each of the five MACT standards for the nine source categories evaluated in RTR Group 2A—Epichlorohydrin Elastomers Production, Hypalon™ Production, Nitrile Butadiene Rubber Production, Polybutadiene Rubber Production, and Styrene Butadiene Rubber and Latex Production, Marine Vessel Loading Operations, Mineral Wool Production, Pharmaceuticals Production, and the Printing and Publishing Industry—provide an ample margin of safety to protect public health and adverse environmental effect. Thus, we are proposing to re-adopt each of these standards for purposes of meeting the requirements of CAA section 112(f)(2). In addition, we propose that there are no developments in practices, processes, or control technologies that support revision of the five MACT standards pursuant to CAA section 112(d)(6).

A. What is the rationale for our proposed action under CAA Section 112(f)?

Section 112(f) of the CAA requires that EPA promulgate standards for a category if promulgation of such standards is required to provide an ample margin of safety to protect public health or to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect. The approach we use to make this determination is that set forth in the preamble to the Benzene NESHAP. First, we exclusively evaluate health risk measures and information in determining whether risks are acceptable. Second, we may consider costs and other factors in deciding whether further emission reductions are necessary to provide an ample margin of safety to protect public health. The EPA

is not required to promulgate standards for a source category under CAA section 112(f) if the emissions standards protect public health with an ample margin of safety and prevent an adverse environmental effect.

We determined for the printing and publishing industry that the maximum individual cancer risks were less than 1-in-1 million to the individual most exposed, and that emissions were unlikely to cause other adverse human health or environmental effects. For the other eight source categories addressed in this proposal, Epichlorohydrin Elastomers Production, Hypalon™ Production, Nitrile Butadiene Rubber Production, Polybutadiene Rubber Production, Styrene-Butadiene Rubber and Latex Production, Marine Vessel Loading Operations, Mineral Wool Production, and Pharmaceuticals Production, we determined that maximum individual cancer risks were between 1-in-1 million and 100-in-1 million to the individual most exposed. Because the risks to the individual most exposed are greater than 1-in-1 million for these source categories, we considered whether the existing NESHAP provides an ample margin of safety to protect public. In doing so, we took into account chronic non-cancer risks, acute risks, and environmental risks. For each of these eight source categories, we evaluated one or more control options and considered the cost of such controls, the emission reductions that would achieve and the impacts of those options on public health. We determined that the existing NESHAP for each source category provides an ample margin of safety to protect public health and prevents adverse environmental effects. Therefore, we determined that changes to the NESHAP are not required to satisfy section 112(f) of the CAA. This finding considers the additional costs of further control compared with the relatively small reductions in health risks achieved by the options for further control for each source category.

B. What is the rationale for our proposed action under CAA Section 112(d)(6)?

As explained in section I.F. of this preamble, there have been no significant

developments in practices, processes, or control technologies since promulgation of the NESHAP. Because there have been no such significant developments and because existing standards provide an ample margin of safety to protect public health, we conclude that no further revisions to the standards affected by this proposal are needed under section 112(d)(6) of the CAA.

III. Request for Comments

We request comment on all aspects of the proposed action. All significant comments received during the comment period will be considered. In addition to general comments on the proposed actions, we are also interested in additional data to reduce the uncertainties of the risk assessments. Comments must provide supporting documentation in sufficient detail to allow characterization of the quality and representativeness of the data or information.

The facility-specific data for each source category are available for download on the RTR Web page at <http://www.epa.gov/ttn/atw/rrisk/rtrpg.html>. The nine source categories affected by this proposal are referred to as Group 2A of RTR Phase 2. These data files include detailed information for each emissions release point at each facility in the source category. For large integrated facilities with multiple processes representing multiple source categories, it is often difficult to clearly distinguish the source category to which each emission point belongs. For this reason, the data available for download for each source category include all emission points for each facility in the source category, though only the emission points marked as belonging to the specific source category in question were included in the analysis for that source category.

The data files for each source category must be downloaded from the RTR Web page to be viewed (<http://www.epa.gov/ttn/atw/rrisk/rtrpg.html>). These are Microsoft® Access files, which require Microsoft® Access to be viewed (if you do not have Microsoft® Access, contact us by e-mail at RTR@epa.gov). Each file contains the following information from the NEI for each facility in the source category:

Facility data	Emissions data
EPA Region	Pollutant Code.
Tribal Code	Pollutant Code Description.
Tribe Name	HAP Category Name.
State Abbreviation	Emissions (TPY).
	Control Measure in Place (Y/N).
County Name	MACT Code.
State County FIPS	MACT Source Category Name.

Facility data	Emissions data
NEI Site ID	MACT Flag.
Facility Name	MACT Compliance Status Code.
Location Address	SCC Code.
City Name	SCC Code Description.
State Name	Emission Unit ID.
Zip Code	Process ID.
Facility Registry Identifier	Emission Release Point ID.
State Facility Identifier	Emission Release Point Type Code.
SIC Code	Emission Release Point Type.
SIC Code Description	Stack Default Flag.
NAICS Code	Stack Default Flag Description.
Facility Category Code	Stack height.
Facility Category	Exit Gas Temperature.
	Stack Diameter.
	Exit Gas Velocity.
	Exit Gas Flow Rate.
	Fugitive Length.
	Fugitive Width.
	Fugitive Angle.
	Longitude.
	Latitude.
	Location Default Flag.
	Data Source Code.
	Data Source Description.
	HAP Emissions Performance Level Code.
	HAP Emissions Performance Level Description.
	Start Date.
	End Date.

More information on these NEI data fields can be found in the NEI documentation at <http://www.epa.gov/ttn/chief/net/2002inventory.html#documentation>.

IV. How do I submit suggested data corrections?

If you believe that the data are not representative or are inaccurate, please

identify the data in question, provide your reason for concern, and provide improved data, if available. When submitting data, we ask that you provide documentation of the basis for the revised values to support any suggested changes.

To submit comments on the data downloaded from the RTR Web page, complete the following steps:

1. Within this downloaded file, enter suggested revisions in the data fields appropriate for that information. The data fields that may be revised include the following:

Facility data	Emissions data
REVISED Tribal Code	REVISED Emissions (TPY).
REVISED County Name	Emissions Calculation Method Code.
REVISED Facility Name	REVISED MACT Code.
REVISED Location Address	REVISED SCC Code.
REVISED City Name	REVISED Emission Release Point Type.
REVISED State Name	REVISED Start Date.
REVISED Zip Code	REVISED End Date.
REVISED Facility Registry Identifier	REVISED Pollutant Code.
	REVISED Control Measure in Place (Y/N).
	Control Measure.
REVISED Facility Category Code	REVISED Stack height.
	REVISED Exit Gas Temperature.
	REVISED Stack Diameter.
	REVISED Exit Gas Velocity.
	REVISED Exit Gas Flow Rate.
	REVISED Longitude.
	REVISED Latitude.
	North American Datum.
	REVISED HAP Emissions Performance Level.

2. Fill in the following commenter information fields for each suggested revision:

- Commenter Name
- Commenter Organization
- Commenter E-Mail Address
- Commenter Phone Number

- Revision Comments
3. Gather documentation for any suggested emissions revisions (e.g., performance test reports, material balance calculations, etc.).
4. Send the entire downloaded file with suggested revisions in Microsoft®

Access format and all accompanying documentation to Docket ID No. EPA-HQ-OAR-2008-0008 (through one of the methods described in the **ADDRESSES** section of this preamble). To answer questions on navigating through the

data and to help expedite review of the revisions, it would also be helpful to submit revisions to EPA directly at RTR@epa.gov in addition to submitting them to the docket.

5. If you are providing comments on a facility with multiple source categories, you need only submit one file for that facility, which should contain all suggested changes for all source categories at that facility.

We strongly urge that all data revision comments be submitted in the form of updated Microsoft® Access files, which are provided on the <http://www.epa.gov/ttn/atw/rrisk/rtrpg.html> Web page. Data in the form of written descriptions or other electronic file formats will be difficult for EPA to translate into the necessary format in a timely manner.

V. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is a significant regulatory action. This action is a significant regulatory action because it raises novel legal and policy issues. Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under Executive Order 12866 and any changes made in response to OMB recommendations have been documented in the docket for this action.

B. Paperwork Reduction Act

This action does not impose any new information collection burden. This action is proposing no changes to the existing regulations affecting the nine source categories affected by this proposal and will impose no additional information collection burden.

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 this rule on small entities, small entity is defined as: (1) A small business as defined by the Small Business Administration's regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a

city, county, town, school district, or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impact of this rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This proposed rule will not impose any requirements on small entities. EPA is proposing no further action at this time to revise the NESHAP.

We continue to be interested in the potential impacts of the proposed rule on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act

This proposed rule contains no Federal mandates under the provisions of Title II of the Unfunded Mandates Reform Act (UMRA), 2 U.S.C. 1531–1538 for State, local, or tribal governments or the private sector. The rule imposes no enforceable duty on State, local, or tribal governments, or the private sector. Therefore, this proposed rule is not subject to the requirements of sections 202 or 205 of the UMRA.

This proposed rule is also not subject to the requirements of section 203 of the UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments because it contains no requirements that apply to such governments nor does it impose obligations upon them.

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.

This proposed rule 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

facilities in the RTR Group 1 source categories are owned or operated by State governments, and, because no new requirements are being promulgated, nothing in this proposal will supersede State regulations. Thus, Executive Order 13132 does not apply to this proposed rule.

In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicits comment on this proposed rule from State and local officials.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This proposed rule does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). 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 this rule.

EPA specifically solicits additional comment on this proposed rule from tribal officials.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The proposed rule is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is not economically significant as defined in Executive Order 12866, and because the Agency does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This action's health and risk assessments are contained in section I.D., E., and F. of this preamble.

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

This proposed rule 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. It does not impose any new energy requirements. Further, we have concluded that this rule will not have any adverse energy effects.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 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. VCS are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by VCS bodies. NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable VCS.

The proposed rulemaking does not involve technical standards. Therefore, EPA is not considering the use of any VCS.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes Federal executive policy on environmental justice. Its main provision directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this proposed rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations

because it does not affect the level of protection provided to human health or the environment. This proposed rule would not relax the control measures on sources regulated by the rule and, therefore, would not cause emissions increases from these sources.

List of Subjects in 40 CFR Part 63

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

Dated: September 29, 2008.

Stephen L. Johnson,

Administrator.

[FR Doc. E8–23373 Filed 10–9–08; 8:45 am]

BILLING CODE 6560–50–P