U.S. ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF INSPECTOR GENERAL

Improving air quality

EPA Should Conduct New Residual Risk and Technology Reviews for Chloroprene- and Ethylene Oxide-Emitting Source Categories to Protect Human Health

Report No. 21-P-0129 **May 6, 2021**

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Abbreviations

µg/m^3	microgram per cubic meter
CAA	Clean Air Act
C.F.R.	Code of Federal Regulations
EPA	U.S. Environmental Protection Agency
Fed. Reg.	Federal Register
GACT	Generally Available Control Technology
HAP	Hazardous Air Pollutant
IRIS	Integrated Risk Information System
MACT	Maximum Achievable Control Technology
NATA	National Air Toxics Assessment
NESHAP	National Emission Standards for Hazardous Air Pollutants
OAQPS	Office of Air Quality Planning and Standards
OIG	Office of Inspector General
RTR	Residual Risk and Technology Review
URE	Unit Risk Estimate
U.S.C.	United States Code

Cover Image: The EPA should conduct new residual risk and technology reviews to address ethylene oxide and chloroprene emissions from various types of stationary sources. (EPA OIG image)

U.S. Environmental Protection Agency
Office of Inspector General

21-P-0129
May 6, 2021

At a Glance

EPA Should Conduct New Residual Risk and Technology Reviews for Chloroprene- and Ethylene Oxide-Emitting Source Categories to Protect Human Health

Why We Did This Audit

We conducted this audit to determine whether the U.S. Environmental Protection Agency's **residual risk and technology review**, known as RTR, process has sufficiently identified and addressed any elevated cancer risks from air toxics emitted by facilities.

The Clean Air Act requires the EPA to conduct residual risk reviews to assess the health and environmental risks that remain after implementation of technology standards limiting air toxics emissions. If health risks are determined to be unacceptable, the EPA is required to revise the standards to reduce the risks. Separately, the EPA is required to review each of the technology-based standards at least every eight years and, if necessary, revise them, considering developments in practices, processes, and control technologies. The EPA calls this the **technology review**. For efficiency, the EPA combines RTRs in the same regulatory package.

This audit addresses the following:

- *Improving air quality.*

This audit addresses a top EPA management challenge:

- *Integrating and leading environmental justice.*

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List of OIG reports.

What We Found

The EPA should conduct new RTRs for chloroprene- and ethylene oxide-emitting source categories to address elevated individual lifetime cancer risks impacting over 464,000 people, as found in a modeling tool, and to achieve environmental justice.

Results from the EPA's modeling and monitoring efforts indicate that people in some areas of the country may be exposed to unacceptable health risks from chloroprene and ethylene oxide emissions. Despite the EPA classifying chloroprene as a likely human carcinogen in 2010 and ethylene oxide a carcinogen in 2016, the EPA has not conducted new RTRs for most types of industrial sources, referred to as **source categories**, that emit chloroprene or ethylene oxide. The EPA should take the following steps to ensure its RTR process sufficiently identifies and addresses these emissions:

- Conduct new residual risk reviews for four major source categories that emit chloroprene or ethylene oxide using new risk values for these pollutants.
- Conduct a residual risk review for the hospital sterilizers area source category using the new risk value for ethylene oxide.
- Conduct overdue technology reviews for four source categories.
- Develop new National Emission Standards for Hazardous Air Pollutants, or NESHAPs, for chemical plant area sources that emit ethylene oxide.
- Develop a process to initiate timely reviews of existing and uncontrolled emission sources when new or updated risk information becomes available.

New RTRs should be conducted because the EPA issued new risk values for chloroprene and ethylene oxide in 2010 and 2016, respectively, to reflect their potent carcinogenicity, as found in newer scientific evidence. The EPA should exercise its discretionary authority to conduct new residual risk reviews under the Clean Air Act whenever new data or information indicates an air pollutant is more toxic than previously determined. Use of such discretionary authority is consistent with the Agency's position, stated in its April 2006 commercial sterilizer RTR rule.

Recommendations and Planned Agency Corrective Actions

We recommend that the assistant administrator for Air and Radiation (1) develop and implement an internal control process with specific criteria to determine whether and when new residual risk reviews of existing NESHAPs and uncontrolled emission sources are needed to incorporate new risk information; (2) conduct new residual risk reviews for Group I polymers and resins, synthetic organic chemical manufacturing industry, polyether polyols, commercial sterilizers, and hospital sterilizers; (3) revise the NESHAP for chemical manufacturing area sources to regulate ethylene oxide and conduct a residual risk review; and (4) conduct overdue technology reviews for the source categories listed in Recommendations 2 and 3. Recommendations 1, 2, and 3 are unresolved. Recommendation 4 is resolved with corrective actions pending.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

THE INSPECTOR GENERAL

May 6, 2021

MEMORANDUM

SUBJECT: EPA Should Conduct New Residual Risk and Technology Reviews for Chloroprene- and Ethylene Oxide-Emitting Source Categories to Protect Human Health
Report No. 21-P-0129

FROM: Sean W. O'Donnell

TO: Joseph Goffman, Acting Assistant Administrator
Office of Air and Radiation

This is our report on the subject audit conducted by the Office of Inspector General of the U.S. Environmental Protection Agency. The project number for this audit was OA&E-FY19-0091. This report contains findings that describe the problems the OIG has identified and corrective actions the OIG recommends. Final determinations on matters in this report will be made by EPA managers in accordance with established audit resolution procedures.

The Office of Air and Radiation is responsible for the issues discussed in this report.

In accordance with EPA Manual 2750, your office provided acceptable planned corrective actions and estimated milestone dates for Recommendation 4. This recommendation is resolved with corrective actions pending.

Action Required

Recommendations 1, 2, and 3 are unresolved. The resolution process, as described in the EPA's Audit Management Procedures, begins immediately with the issuance of this report. Furthermore, we request a written response to the final report within 60 days of this memorandum. Your response will be posted on the OIG's website, along with our memorandum commenting on your response. Your response should be provided as an Adobe PDF file that complies with the accessibility requirements of Section 508 of the Rehabilitation Act of 1973, as amended. The final response should not contain data that you do not want to be released to the public; if your response contains such data, you should identify the data for redaction or removal along with corresponding justification.

We will post this report to our website at www.epa.gov/oig.

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Chapter 1
Introduction

Purpose

The Office of Inspector General for the U.S. Environmental Protection Agency conducted this audit to determine whether the EPA's residual risk and technology review, or RTR, process has sufficiently identified and addressed any elevated cancer risks from air toxics emitted by facilities.

Top Management Challenge

This audit addresses the following top management challenge for the Agency, as identified in OIG Report No. 20-N-0231, *EPA's FYs 2020–2021 Top Management Challenges*, issued July 21, 2020:

- Integrating and leading environmental justice.

Background

Hazardous air pollutants, known as **HAPs**, are those air pollutants known or suspected to cause cancer or other serious health effects—such as reproductive effects or birth defects—or adverse environmental effects. HAPs are also known as toxic air pollutants or air toxics. The Clean Air Act, known as the CAA, Amendments of 1990 established a list of 189 air toxics that the EPA is required to regulate. Since 1990, the EPA has revised the list slightly to regulate 187 air toxics.[1]

According to the EPA, most air toxics originate from human-made sources, both stationary and mobile. A **stationary source** is any building, structure, facility, or installation that emits or may emit any air pollutant. Stationary sources are further divided into two groups: **major** and **area sources**. Table 1 provides descriptions of the sources of air toxics.

Table 1: Definitions of stationary and mobile sources of air toxics emissions

Source	Description
Stationary major	Stationary sources that emit or have the potential to emit ten tons or more per year of any of the listed toxic air pollutants or 25 tons or more per year of a combination of listed air toxics.
Stationary area	Stationary sources that emit or have the potential to emit less than ten tons per year of a single listed toxic air pollutant and less than 25 tons per year of a combination of air toxics.
Mobile	Pollution sources that move. They include vehicles and motorized equipment that produce exhaust and evaporative emissions.

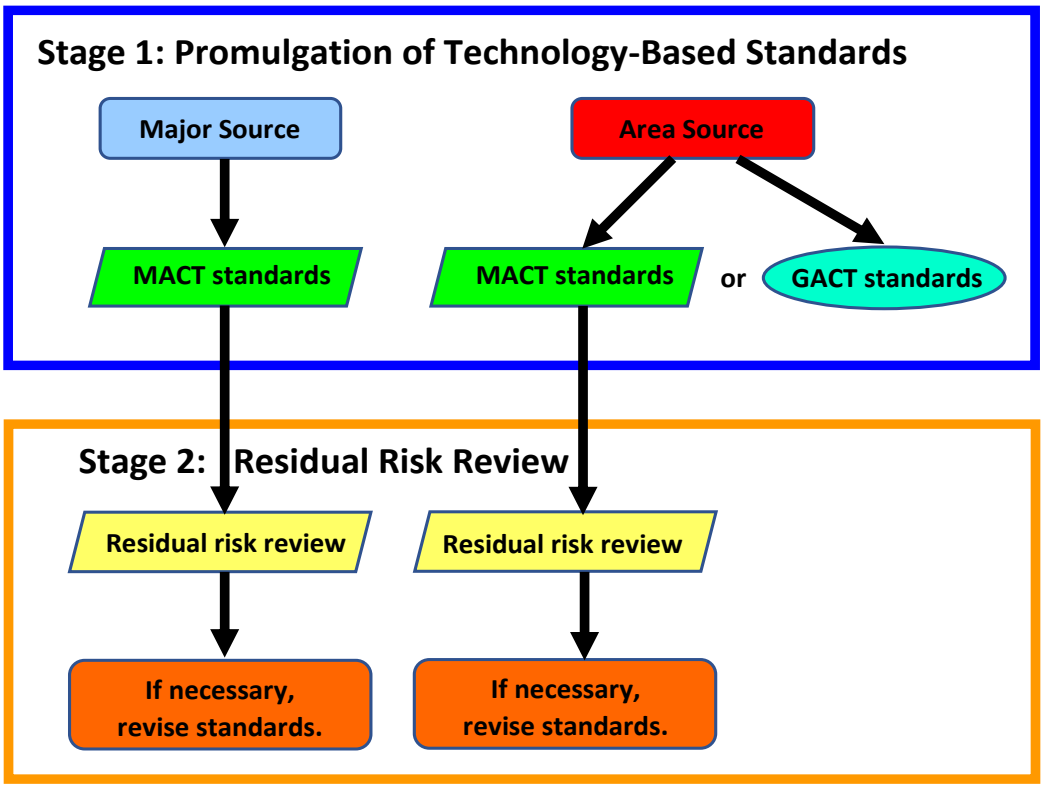
Source: OIG summary of CAA and information from the EPA. (EPA OIG table)

[1] On June 18, 2020, the EPA granted petitions to add 1-bromopropane to the list of air toxics contained in the CAA. The EPA stated in the petition grant that it will take a separate regulatory action to add 1-bromopropane to the list of air toxics under CAA § 112(b)(1). Once this separate regulatory action is completed, the number of listed air toxics will be 188.

Two-Stage Regulatory Process to Control Air Toxics Emissions from Stationary Sources

Section 112 of the CAA outlines a two-stage regulatory process for addressing air toxics emissions from stationary sources. In the first stage, the EPA is required to promulgate technology-based **National Emission Standards for Hazardous Air Pollutants**, or **NESHAPs**, for categories of sources. For major sources, the EPA must promulgate **maximum achievable control technology**, or **MACT**, standards. MACT standards reflect, at a minimum, the level of emissions that the best performing 12 percent of sources in the category were achieving in practice. For area sources, the CAA gives the EPA discretion to set standards that are based on **generally available control technologies** or management practices, or **GACT** standards, in lieu of MACT standards. The CAA outlines a series of deadlines and the number of source categories for which MACT or GACT standards are to be promulgated, with the last of them to be promulgated by November 15, 2000. The EPA has promulgated these standards, as required under the first stage of the process, for almost all source categories. Figure 1 is a schematic of the two-stage regulatory process.

Figure 1: Schematic of the two-stage regulatory process for addressing air toxics emissions from stationary sources (major and area sources)



Source: OIG summary of the EPA's two-stage regulatory process for addressing air toxics emissions from stationary sources. (EPA OIG image)

For NESHAPs that require MACT standards, Section 112(f)(2) requires the EPA to complete the second stage of the regulatory process, known as the **residual risk review**, within eight years of promulgation of the MACT standard. In the residual risk review, the EPA is required to assess the health and environmental risks that remain after implementation of the MACT standards. The EPA has not completed the second stage—that is, residual risk review—of the two-stage regulatory process for all source categories. Residual risk reviews are still needed for 21 of 119 source categories with MACT standards. Appendix A provides more details on the status of the residual risk reviews for source categories with MACT standards. The CAA does not require the EPA to conduct residual risk reviews for area source categories subject to GACT standards.

The EPA bases its approach to the residual risk review on the CAA, which incorporates the approach used to develop the 1989 Benzene NESHAP.[2] This approach is a two-step process, as follows, intended to protect human health with an ample margin of safety:

1. In the first step, the EPA determines whether risks are acceptable. If risks are unacceptable, the EPA must determine the emission standards necessary to reduce risk to an acceptable level without considering costs. A maximum individual risk level of less than 100 in one million is generally considered acceptable, but the overall determination of risk acceptability is also dependent on other health measures and factors, including the chronic and acute noncancer risks, number of people exposed at various risk levels, and uncertainties.[3]

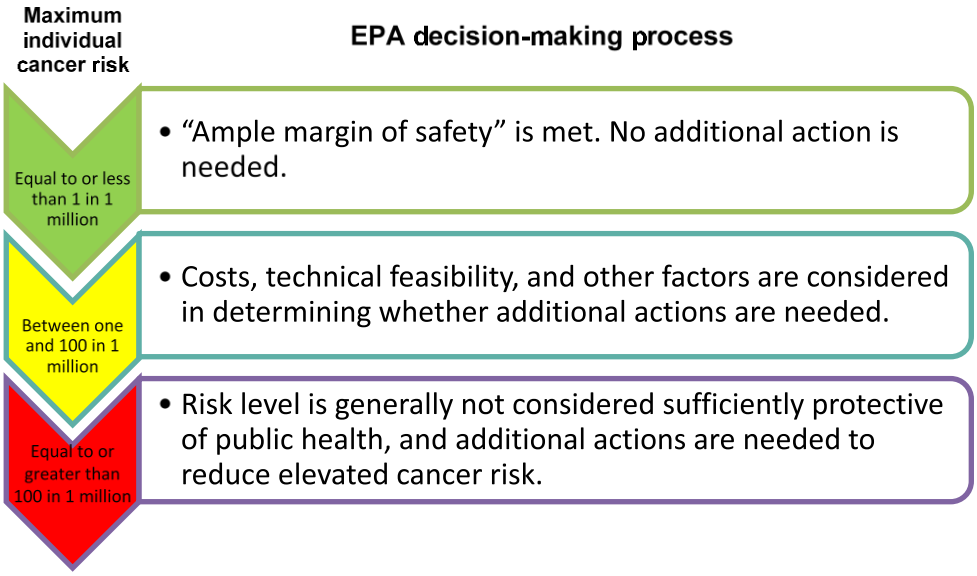
2. In the second step, the EPA considers whether the emission standards provide an ample margin of safety to protect public health, taking into consideration health information, including the number of people subject to risk levels higher than one in one million, and other relevant information, such as technological feasibility, costs, and economic impacts. In this step, the EPA strives to protect the greatest number of people possible to a maximum individual risk level no higher than approximately one in one million.

Figure 2 shows the decision-making process that the EPA uses to address residual risk to public health from inhaling carcinogens. After conducting the ample-margin-of-safety analysis, the EPA considers whether a more stringent emission standard is necessary to prevent an adverse environmental effect, taking into consideration safety, costs, energy, and other relevant factors.

[2] "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," 54 Fed. Reg. 38044 (September 14, 1989). See also CAA § 112(f)(2)(B), 42 U.S.C. § 7412(f)(2)(B).
[3] *Maximum individual risk* or *maximum individual lifetime cancer risk* is the estimated cancer risk if an individual were continuously exposed to the maximum level of a pollutant for a lifetime of 70 years.

Separately, under Section 112(d)(6), the EPA must also review each of the technology-based standards at least every eight years and, if necessary, revise them, taking into account developments in practices, processes, and control technologies. The EPA calls this the **technology review**. Based on the results of the residual risk review, the technology review, or both, the EPA revises the NESHAP or determines that revisions are not necessary. For efficiency, the EPA combines the residual risk review and the first required technology review in the same regulatory package and calls the rulemaking the RTR. Appendix B provides a comparison of residual risk reviews and technology reviews.

Figure 2: EPA decision-making process for addressing residual risk for carcinogens in the Agency's regulatory program



Source: OIG summary of information from the EPA. (EPA OIG image)

Note: A maximum individual risk level of less than 100 in one million is generally considered acceptable, but the overall determination of risk acceptability and ample margin of safety are also dependent on other health measures and factors, including the chronic and acute non-cancer risks, number of people exposed at various risk levels, and uncertainties.

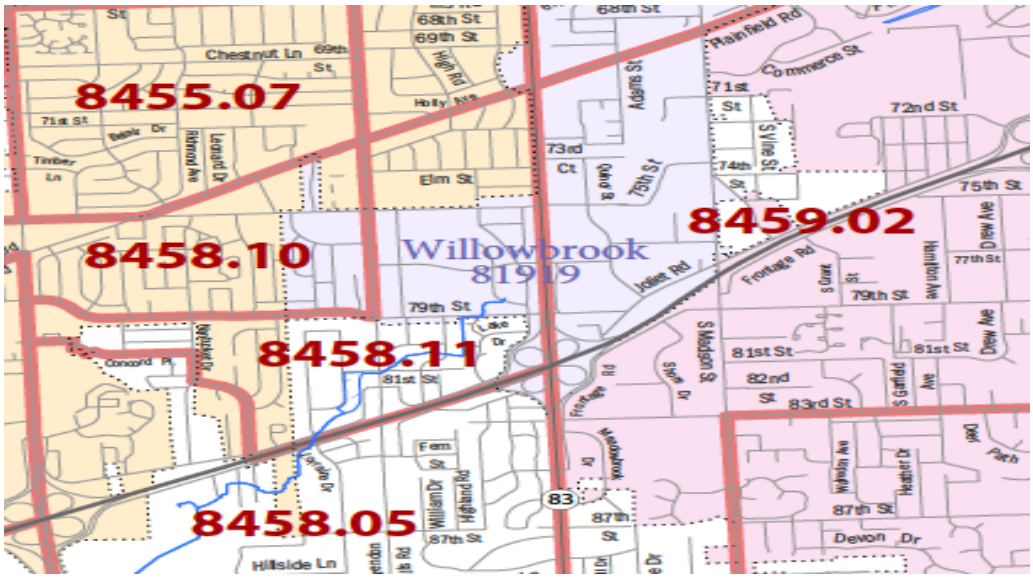
Air Toxics Driving Cancer Risks

The EPA periodically conducts the **National Air Toxics Assessment**, known as **NATA**, to assess the public health risk from exposure to air toxics. NATA is not required by regulation. The results of the NATA are not used to set regulatory standards for sources of air toxics emissions, as would the results of assessments conducted in the RTR program. NATA is a screening tool that can assist the EPA and state, local, and tribal air agencies in identifying geographic areas, pollutants, or emission sources for further examination.

The EPA's latest NATA—that is, the 2014 NATA, which was based on 2014 emissions data and was published on August 22, 2018—estimated that more than 472,000 people lived in 106 census tracts where the individual lifetime cancer risk was elevated or equal to or greater than 100 in one million.

Census tracts are small, relatively permanent statistical subdivisions of a county with boundaries that normally follow visible features, such as roads and rivers. Figure 3 is a map showing what census tracts look like. The U.S. Census Bureau designs census tracts with a goal that each tract contains about 4,000 people and 1,600 housing units. The elevated cancer risks in these 106 census tracts were driven by ethylene oxide, chloroprene, and coke oven emissions, with the risks in the majority of the census tracts driven by ethylene oxide emissions. These 106 census tracts are located in 19 metropolitan areas.

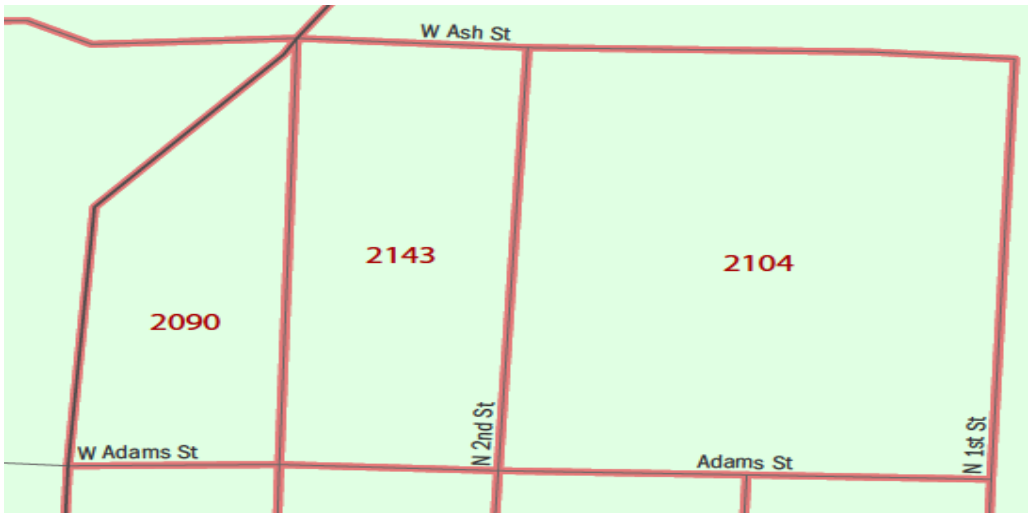
Figure 3: Map showing census tracts in the Willowbrook, Illinois area with red numbers representing the census tract numbers and pink lines representing the census tract boundaries from the 2010 census



Source: U.S. Census Bureau. (U.S. Census Bureau image)

Each census tract is made up of at least one block group, which is a statistical division of census tracts. A block group consists of clusters of blocks covering a contiguous area within the same census tract. Census blocks represent smaller statistical areas bounded by visible features, such as roads and streams, and by nonvisible boundaries, such as property lines. A block is the smallest geographic unit for which the U.S. Census Bureau tabulates decennial census data. Figure 4 is a map showing what census blocks look like.

Figure 4: Map showing census blocks in Tract 4703 in Verona, Missouri, with pink numbers representing census block numbers and pink lines representing census block boundaries from the 2010 census



Source: U.S. Census Bureau. (U.S. Census Bureau image)

Chloroprene

Chloroprene is a chemical used in the production of a class of synthetic rubber called "neoprene." Neoprene is used to make a variety of products, including wetsuits, gaskets, hoses, and adhesives. The EPA classifies chloroprene as a likely human carcinogen, which means there is sufficient evidence to conclude that a chemical is suspected to be carcinogenic to humans.

Short-Term Effects of Chloroprene Exposure

- Headaches.
- Irritability.
- Dizziness.
- Rapid heartbeat.
- Gastrointestinal disorders.
- Dermatitis.
- Temporary hair loss.
- Corneal damage.
- Negative effects on lungs, liver, kidneys, and immune system.

Long-Term Effects of Chloroprene Exposure

- Cancer.
- Respiratory, eye, and skin irritation.
- Chest pains.
- Temporary hair loss.
- Dizziness.
- Headaches.
- Fatigue.
- Rapid heartbeat and reduced blood pressure.
- Changes in blood cell parameters.

EPA Standards Used to Control Chloroprene Emissions

The Denka facility in LaPlace, Louisiana, is the only facility in the United States that produces chloroprene. Denka is subject to the following NESHAPs that regulate chloroprene emissions:

- Synthetic organic chemical manufacturing industry, outlined in 40 C.F.R. Part 63, Subparts F, G, H, and I.

- Group I polymers and resins, which covers neoprene production, outlined in 40 C.F.R. Part 63, Subpart U.

The unit at Denka that produces chloroprene is subject to the NESHAP for synthetic organic chemical manufacturing industry, while the unit at Denka that makes neoprene is subject to the NESHAP for Group I polymers and resins. Both units emit chloroprene.[4]

The EPA conducted the RTR for synthetic organic chemical manufacturing industry and published the final rule on December 21, 2006.[5] The Agency made no changes to the control requirements in the final rule, but it published technical amendments designed to clarify provisions of the existing NESHAP and to provide for effective implementation.

The EPA conducted the RTR for Group I polymers and resins that covered neoprene production and published the final rule on December 16, 2008.[6] Based on the results of this RTR, the EPA decided not to revise the NESHAP because air toxics emissions from eight source categories under Group I polymers and resins did not pose cancer risks equal to or greater than one in one million and there had been no significant developments in practices, processes, or control technologies since promulgation of the MACT standards. Furthermore, the air toxics emitted from neoprene production were not known, probable, or possible human carcinogens at that time.

EPA Set New Risk Values for Chloroprene

In September 2010, the EPA's Integrated Risk Information System, or IRIS, program completed a toxicological review of chloroprene. The IRIS program calculated an adult-based inhalation **unit risk estimate**, known as a **URE**, of 3×10^{-4} (microgram per cubic meter, or $\mu g/m^3)^{-1}$ and determined that the pollutant was a likely human carcinogen.[7] When adjusted to include early-life susceptibility as part of a default lifetime exposure of 70 years, the chloroprene URE increased to 5×10^{-4} $(\mu g/m^3)^{-1}$. At the time that the IRIS program issued a new URE for chloroprene, the Agency had already completed the RTRs for the two source categories that apply to chloroprene or neoprene production. A URE provides the

[4] According to an EPA inspector, while the majority of Denka's chloroprene emissions come from the chloroprene and neoprene production units, approximately 1 percent of chloroprene emissions are emitted from the facility's hydrochloric acid production furnace that is regulated under the hazardous waste combustor MACT standards.
[5] "National Emission Standards for Organic Hazardous Air Pollutants from the Synthetic Organic Chemical Manufacturing Industry," 71 Fed. Reg. 76603, December 21, 2006.
[6] "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) (Risk and Technology Review)," 73 Fed. Reg. 76220, December 16, 2008.
[7] (Microgram per cubic meter)$^{-1}$ or $(\mu g/m^3)^{-1}$ is also referred to as "per microgram per cubic meter" or "per $\mu g/m^3$". In this document, we refer to the units as $(\mu g/m^3)^{-1}$.

upper-bound excess individual lifetime, assumed to be 70 years, cancer risk estimated to result from continuous exposure to a single chemical at a concentration of one microgram per cubic meter in air. The EPA did not become aware of the impact of the newly developed URE on individual lifetime cancer risk until it conducted the 2011 NATA in 2015.

Ethylene Oxide

Ethylene oxide is a flammable colorless gas used to make chemicals to manufacture a variety of products, including antifreeze, textiles, plastics, detergents, and adhesives. It is also used to sterilize medical equipment or other devices that cannot be sterilized by other methods, such as steam, and to fumigate spices. The EPA classifies ethylene oxide as carcinogenic to humans. Studies show that breathing air containing elevated ethylene oxide levels over many years increases the risk of developing lymphoid cancers in males and females and breast cancer in females.

EPA Standards Used to Control Ethylene Oxide Emissions

According to information from the EPA, the following are the source categories or types of facilities that can emit ethylene oxide and the corresponding regulations, if any, that limit the emissions of ethylene oxide:

- Ethylene oxide-emitting sterilization facilities, also known as commercial sterilizers (40 C.F.R. Part 63, Subpart O).
- Miscellaneous organic chemical manufacturing (40 C.F.R. Part 63, Subpart FFFF).
- Polyether polyols production (40 C.F.R. Part 63, Subpart PPP).
- Synthetic organic chemical manufacturing industry (40 C.F.R. Part 63, Subparts F, G, H, and I).
- Organic liquids distribution (nongasoline) (40 C.F.R. Part 63, Subpart EEEE).
- Hospital sterilizers (40 C.F.R. Part 63, Subpart WWWWW).
- Chemical plant area sources (No applicable NESHAP).

Table 2 shows the date of the RTR final rule, if applicable, for the source categories or types of facilities that emit ethylene oxide and whether revisions were made to the NESHAP as a result of the RTR.

Table 2: Applicable NESHAPs and RTRs for source categories with facilities that emit ethylene oxide

Facility type	HAP major/ area source	NESHAP (subpart)	Date of RTR final rule	Revisions made to NESHAP as a result of RTR?
Commercial sterilizers	Major	Ethylene oxide-emitting sterilization facilities (O)	April 7, 2006	No
	Area			
Hospital sterilizers	Area	Hospital ethylene oxide sterilizers (WWWWW)	N/A [a]	N/A
Chemical plants	Major	Synthetic organic chemical manufacturing industry (F, G, H, and I) [b]	December 21, 2006 [c]	No [d]
		Miscellaneous organic chemical manufacturing (FFFF)	August 12, 2020 [e, f]	Yes
		Polyether polyols production (PPP)	March 27, 2014 [g]	Yes [h]
		Organic liquids distribution (nongasoline) (EEEE) [i]	July 7, 2020 [f, j]	Yes
	Area	N/A	N/A	N/A

Source: OIG analysis based on review of NESHAPs and information from the EPA. (EPA OIG table)

[a] Although the EPA is not required to conduct a residual risk review for area sources subject to GACT standards, it is required to conduct a technology review for these sources every eight years. The technology review for hospital ethylene oxide sterilizers was due on December 28, 2015.

[b] The synthetic organic chemical manufacturing industry NESHAP is also applicable to Denka, which emits chloroprene.

[c] "National Emission Standards for Organic Hazardous Air Pollutants from the Synthetic Organic Chemical Manufacturing Industry," 71 Fed. Reg. 76603 (December 21, 2006).

[d] Although no changes to the control requirements were made, the EPA published technical amendments designed to clarify provisions of the existing rule and provide for effective implementation.

[e] "National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing Residual Risk and Technology Review," 85 Fed. Reg. 49084 (August 12, 2020).

[f] With the exception of the RTRs for miscellaneous organic chemical manufacturing and organic liquids distribution (nongasoline) source categories, RTRs for other source categories were conducted prior to the IRIS program's issuance of a revised URE for ethylene oxide and any changes made to those NESHAPs were not due to ethylene oxide.

[g] "National Emission Standards for Hazardous Air Pollutant Emissions: Group IV Polymers and Resins; Pesticide Active Ingredient Production; and Polyether Polyols Production," 79 Fed. Reg. 17340 (March 27, 2014).

[h] The EPA made revisions in three areas. First, it eliminated the exemption for periods of startup, shutdown, and malfunction. Second, it required electronic reporting of performance test results. Finally, it required monitoring of pressure relief devices in organic HAP service that release to the atmosphere.

[i] Subpart EEEE applies to two types of facilities: (a) chemical plants with a distribution terminal not subject to another major source NESHAP or that have a few miscellaneous storage tanks or transfer racks that are not otherwise subject to another major source NESHAP and (b) petrochemical terminals primarily in the business of storing and distributing organic liquids.

[j] "National Emission Standards for Hazardous Air Pollutants: Organic Liquids Distribution (Nongasoline) Residual Risk and Technology Review," 85 Fed. Reg. 40740 (July 7, 2020).

EPA Updated Risk Values for Ethylene Oxide

In December 2016, the EPA IRIS program completed an evaluation of the inhalation carcinogenicity of ethylene oxide. It found ethylene oxide to be more carcinogenic, changing its cancer descriptor from "probably carcinogenic to humans" to "carcinogenic to humans." The IRIS program also changed ethylene oxide's adult-based inhalation URE from 0.0001 $(\mu g/m^3)^{-1}$ to 0.003 $(\mu g/m^3)^{-1}$. When adjusted to include early-life susceptibility as part of a default lifetime

exposure of 70 years, the updated URE of 0.005 $(\mu g/m^3)^{-1}$ is approximately 57 times greater than the 8.8×10^{-5} $(\mu g/m^3)^{-1}$ value, which was based on animal data, used previously by the EPA in its risk assessments. At the time that the EPA issued a revised URE for ethylene oxide in December 2016, the Agency had already conducted RTRs for commercial sterilizers, synthetic organic chemical manufacturing industry, and polyether polyols production in April 2006, December 2006, and March 2014, respectively.

Two-Pronged Strategy to Address Ethylene Oxide Emissions

In 2018, the EPA developed a two-pronged approach to address ethylene oxide emissions. The approach consists of (1) reviewing existing regulations and (2) gathering information to inform regulatory efforts and determine whether more immediate reduction steps are necessary in any particular location. With regard to the first prong of the two-pronged strategy, the EPA has:

- Promulgated the final RTR rules for the organic liquids distribution (nongasoline) and miscellaneous organic chemical manufacturing source categories on July 7, 2020, and August 12, 2020, respectively, both of which incorporated the revised URE for ethylene oxide.

- Issued an advance notice of proposed rulemaking for the commercial sterilizers source category technology review on December 12, 2019,[8] but has not scheduled technology reviews for the synthetic organic chemical manufacturing industry and hospital sterilizers source categories.

With regard to the second prong, the EPA gathered information to inform the recent RTR rulemaking for the miscellaneous organic chemical manufacturing source category and the upcoming commercial sterilizers technology review.

EPA's Mission

The EPA's mission is to protect human health and the environment. The Agency achieves its mission in part by ensuring that:

- U.S. residents have clean air, land, and water.
- National efforts to reduce environmental risks, including those that impact human health, are based on the best available scientific information.

[8] 84 Fed. Reg. 67889, December 12, 2019.

EPA's Commitment to Environmental Justice

Signed on February 11, 1994, Executive Order 12898 requires that each federal agency:

> [M]ake achieving environmental justice part of its mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority populations and low-income populations in the United States.

On June 30, 2020, the EPA administrator reaffirmed the Agency's commitment to environmental justice in a press release announcing funding for environmental justice small grants, stating that "[r]egardless of zip code, the EPA works day in and day out to provide clean air, clean water, and clean land to all Americans."[9]

The EPA defines **environmental justice** as "the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income, with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies." According to the EPA, **fair treatment** "means no group of people should bear a disproportionate share of the negative environmental consequences resulting from industrial, governmental and commercial operations or policies." Integration of environmental justice principles into all EPA programs and across all regions is necessary to achieve environmental equity across all communities.

Responsible Office

The EPA's Office of Air Quality Planning and Standards, known as OAQPS, within the Office of Air and Radiation, conducts RTRs and periodic NATAs. OAQPS works with regional offices and states to ensure the accuracy of the emissions data used in conducting NATAs and also coordinates the release of NATA results with them.

Scope and Methodology

We conducted our work from February 2019 to January 2021. We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our objectives.

[9] EPA, "EPA Releases Additional Funding for 2020 Environmental Justice Small Grants," News Release, June 30, 2020.

To understand how the EPA addresses air toxics, including the RTR process, we interviewed OAQPS personnel. We also reviewed the EPA's website on RTR of the NESHAP and the following statutes, policies, guidance, and documents:

- CAA, as amended.
- *Residual Risk Report to Congress,* March 1999.
- Scientific Advisory Board Review of the EPA's draft *Risk and Technology Review (RTR) Risk Assessment Methodologies: For Review by the EPA's Science Advisory Board with Case Studies – MACT I Petroleum Refining Sources and Portland Cement Manufacturing.*
- *Screening Methodologies to Support Risk and Technology Reviews (RTR): A Case Study Analysis*, May 2017.
- *CAA Section 112 Risk and Technology Reviews: Statutory Authority and Methodology*, December 14, 2017.

We limited our audit to RTRs conducted for the source categories that emit chloroprene or ethylene oxide, since the 2014 NATA found these pollutants contributed to the majority of the individual lifetime cancer risks in census tracts with the highest individual lifetime cancer risks greater than 100 in one million. The source categories are:

- Group I polymers and resins, focusing on neoprene production.
- Commercial sterilizers.
- Synthetic organic chemical manufacturing industry.
- Polyether polyols production.
- Miscellaneous organic chemical manufacturing.
- Organic liquids distribution (nongasoline).

We reviewed the proposed and final rulemakings for these RTRs, including the residual risk assessments. Because our scope comprises only source categories that emit chloroprene, ethylene oxide, or both, we are not commenting on the adequacy of other NESHAPs not reviewed as part of this audit.

We also reviewed the EPA's two-pronged strategy to address ethylene oxide emissions. We assessed whether the EPA has sufficiently addressed ethylene oxide emissions from other source categories or types of facilities not required to have residual risk reviews, such as hospital sterilizers, or that lack NESHAPs, such as chemical plant area sources that emit ethylene oxide.

Prior OIG Reports

EPA OIG Report No. 08-P-0020, *Improvements in Air Toxics Emissions Data Needed to Conduct Residual Risk Assessments*, issued October 31, 2007, found that the reliability of National Emissions Inventory data for site-specific emissions varied considerably, but the EPA had not established objectives to define an acceptable level of quality for National Emissions Inventory data used in the residual risk assessments. The OIG recommended that the EPA develop data quality objectives for using the National Emissions Inventory data in conducting residual risk assessments and establish requirements for state reporting of air toxics emissions data and compliance-monitoring information. The EPA disagreed with the recommendations, but according to the Agency, it completed the recommendations in 2013.

EPA OIG Report No. 20-N-0128, *Management Alert: Prompt Action Needed to Inform Residents Living Near Ethylene Oxide-Emitting Facilities About Health Concerns and Actions to Address Those Concerns*, issued March 31, 2020, found that, while the EPA or state personnel or both have met with residents living near nine of the 25 high-priority ethylene oxide-emitting facilities, communities near 16 facilities have yet to be afforded public meetings or other direct outreach to learn about the health risks and actions being taken to address those risks. The EPA provided an alternative recommendation with corrective actions that the OIG did not accept. Subsequently, the recommendation went into audit dispute resolution, and the EPA administrator sided with the Office of Air and Radiation's proposed corrective action plan, which committed the EPA to, among other things, conduct additional, more-refined risk assessments and outreach to affected communities.

EPA OIG Report No. 21-P-0123, *EPA Delayed Risk Communication and Issued Instructions Hindering Region 5's Ability to Address Ethylene Oxide Emissions*, issued April 15, 2021, found that the EPA delayed communicating health risks to residents in Illinois who lived near ethylene oxide-emitting facilities. Further, we found that the Office of Air and Radiation's senior leaders issued instructions that hindered Region 5's ability to effectively address ethylene oxide emissions. The Agency's response to the draft report stated that the Agency's air toxics strategy would address these recommendations. We reviewed the draft air toxics strategy, and it did not address our concerns. As of May 2021, we consider the two recommendations unresolved.

Chapter 2
EPA Should Conduct New RTRs for Source Categories That Emit Chloroprene or Ethylene Oxide or Both to Ensure Protection of Human Health

Results from the EPA's modeling and limited monitoring efforts indicate that there are potentially unacceptable risks from chloroprene and ethylene oxide emissions in some areas of the country. These results are not unexpected because the EPA issued a new URE for chloroprene after determining the pollutant was a likely human carcinogen and a revised URE for ethylene oxide after determining the pollutant was a human carcinogen. The URE changes occurred after the Agency had already completed the RTR rulemakings for many of the NESHAPs that control these emissions. In the absence of new RTRs for the applicable source categories that use the updated UREs, the Agency cannot provide assurance that its current NESHAPs are sufficiently protective. We identified five steps that the EPA should take within its RTR process to provide better assurance that the Agency is sufficiently identifying and addressing chloroprene and ethylene oxide emissions. These steps would also help the EPA meet its requirement to address environmental justice for overburdened minority and low-income communities.

Modeling and Monitoring Results Indicate Elevated Cancer Risks from Chloroprene and Ethylene Oxide Emissions

Elevated cancer risks have been estimated in areas where people are exposed to emissions of chloroprene, ethylene oxide, or both, according to the:

- 2014 NATA.
- Modeling conducted as part of the residual risk review for the miscellaneous organic chemical manufacturing RTR rulemaking.
- Chloroprene monitoring data collected in LaPlace, Louisiana, and ethylene oxide monitoring data collected in Willowbrook, Illinois.

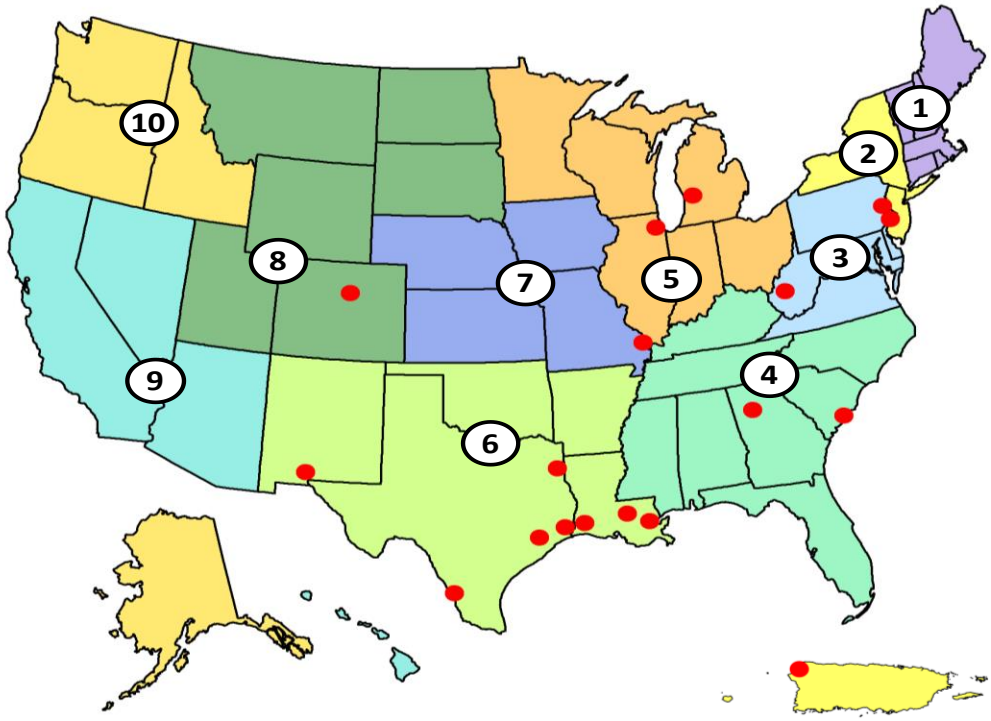
The EPA has stated that none of these sources of information can definitively be used to characterize the risks from ethylene oxide and chloroprene emissions in certain areas and that the risk assessments conducted through the RTR process would be the appropriate process to determine risks from source categories emitting ethylene oxide and chloroprene. Given that available information generated by the EPA indicates elevated cancer risks and that the EPA has not conducted residual risk assessments with current UREs for ethylene oxide or chloroprene for Group I polymers and resins, synthetic organic chemical manufacturing industry, polyether polyols production, commercial sterilizers, and hospital sterilizers, the Agency cannot provide assurance that its current NESHAPs are sufficiently protective of human health. In addition, according to

information from the EPA, other emission sources, specifically chemical plant area sources that emit ethylene oxide, lack applicable NESHAP standards given that the chemical manufacturing area source NESHAP does not regulate ethylene oxide emissions.

2014 NATA Results Indicate Significant Number of People Live in Areas with Elevated Cancer Risks from Chloroprene and Ethylene Oxide Emissions

Based on our analysis of the data reported in the 2014 NATA, over 464,000 people live in 103 census tracts located in the 18 metropolitan areas with individual lifetime cancer risks equal to or greater than 100 in one million where ethylene oxide or chloroprene are the primary risk drivers, as shown in Figure 5. According to information from the EPA, the individual lifetime cancer risks in the census tracts with elevated cancer risks in 17 of these 18 metropolitan areas are driven by ethylene oxide emissions. The individual lifetime cancer risks in the census tracts with elevated cancer risks in the remaining metropolitan area are driven by chloroprene emissions from the Denka facility. While the majority of the individual lifetime cancer risks for the nearby residents of Denka are primarily attributed to chloroprene emissions, a significant portion of those risks are also attributed to ethylene oxide emissions from two nearby chemical plants.

Figure 5: Metropolitan areas in the United States where there is at least one census tract in which chloroprene or ethylene oxide is the risk driver and the individual lifetime cancer risk is equal to or greater than 100 in one million (numbers indicate EPA regions)



Source: OIG summary of data from 2014 NATA and other information from the EPA. (EPA OIG image)

Note: According to the EPA, the New Mexico facility installed a control device that reduced ethylene oxide emissions prior to the 2014 NATA release.

Based on the 2014 NATA results, the EPA identified Denka and 22 ethylene oxide-emitting facilities that contribute to individual lifetime cancer risks equal to or greater than 100 in one million at the census tract level. The 22 ethylene oxide-emitting facilities are listed in the OIG's March 31, 2020 management alert report, along with three census block facilities that the EPA prioritized as contributing to elevated estimated cancer risks.

In addition, in NATA working files used by the Agency to calculate census tract risks, the EPA included 29 additional ethylene oxide-emitting facilities where preliminary data showed individual lifetime cancer risks from these facilities at the census block level equal to or greater than 100 in one million.[10] These 29 ethylene oxide-emitting facilities are listed in Appendix C.

OAQPS told us there was significant uncertainty in the risk estimates for these facilities when compared to the risks associated with facilities at the census tract level. The EPA noted in its NATA documentation that NATA results apply best to larger areas, not specific places, and an OAQPS manager told us that the census tract level is the spatial scale that the EPA feels most confident in expressing NATA risk estimates. The Agency stated that more localized studies are often needed to better characterize local-level risk. However, it has only conducted additional investigations of risk for nine of these 29 facilities. These additional investigations suggest that all nine facilities likely contribute to individual lifetime cancer risks of equal to or greater than 100 in one million. The modeling efforts indicate that these facilities contribute to elevated cancer risks despite all of them being subject to NESHAPs that regulate their air toxic emissions. Tables 3 and 4 show the NESHAPs under which these 23 facilities contributing to individual lifetime cancer risks equal to or greater than 100 in one million at the census tract level and the 29 facilities at the census block level are regulated. Some of the chemical plant major sources are regulated under multiple NESHAPs, and as such, Tables 3 and 4 add up to more than 23 and 29, respectively. Under the Agency's residual risk review process, a cancer risk equal to or greater than 100 in one million is generally considered unacceptable.

As noted in Chapter 1, the 2014 NATA is a screening tool and there are uncertainties associated with the census tract level-risks in it. Sources of uncertainties in NATA are components that predict (1) ambient air concentrations, such as emissions estimates; (2) exposure, such as activity patterns; and (3) risk, such as UREs. Block-level data were used to inform the census tract-level risk estimates, but the EPA has less confidence in the block-level risk estimates. The EPA's technical support document for the 2014 NATA states, however, that "no scientific statement (in risk assessment or

[10] During the process of conducting the 2014 NATA, the EPA also identified five additional ethylene oxide-emitting facilities that contribute to individual lifetime cancer risks equal to or greater than 100 in one million at the census block level. Four of the five facilities have closed or no longer use ethylene oxide in their processes. Refined modeling indicated the fifth facility no longer contributes to elevated cancer risk. These five facilities are not included in Table 4 or Appendix C.

other areas of science) can be made with complete confidence. Risk estimates are always uncertain to some degree."[11] It also states "that uncertainty does not prevent EPA from making a statement of risk, nor does it prevent EPA from taking reasonable actions."

Nevertheless, the results indicating elevated individual lifetime cancer risks associated with the facilities in Tables 3 and 4 suggest that the EPA should conduct new residual risk reviews for these source categories or types of facilities. Indeed, in the recent August 2020 RTR for the miscellaneous organic chemical manufacturing source category, the EPA conducted more refined modeling that confirmed six facilities in Table 3 and nine facilities in Table 4 contributed to elevated cancer risks.

Table 3: EPA-identified facilities that contribute to individual lifetime cancer risks equal to or greater than 100 in one million at the census tract level based on the 2014 NATA results and the NESHAPs they must meet [a]

Facility type	HAP major/ area source	NESHAP (subpart)	Number of facilities subject to NESHAP [b]	Number of facilities that emit chloroprene [b, c]	Number of facilities that emit ethylene oxide [b]
Commercial sterilizers	Major	Ethylene oxide-emitting sterilization facilities (O)	6	0	11
	Area		5		
Chemical plants[2]	Major	Synthetic organic chemical manufacturing industry (F, G, H, and I)	5	1	4
		Miscellaneous organic chemical manufacturing (FFFF)	1	0	1
		Polyether polyols production (PPP)	3	0	3
		Organic liquids distribution (Nongasoline) (EEEE) [d]	1[e]	0	1
		Group I polymers and resins (U)	1	1	0
	Area	N/A	5	0	5

Source: OIG summary of information from the EPA and facility permits. (EPA OIG table)

[a] Elevated individual lifetime cancer risks from six facilities were confirmed with more refined modeling in the miscellaneous organic chemical manufacturing RTR.

[b] Some of the chemical plant major sources are subject to more than one NESHAP. As such, the fourth and sixth columns add up to more than 23.

[c] Denka is the only facility in the United States that emits chloroprene and is subject to the synthetic organic chemical manufacturing industry NESHAP and Group I polymers and resins NESHAP.

[d] Subpart EEEE applies to two types of facilities: (a) chemical plants with a distribution terminal not subject to another major source NESHAP or that have a few miscellaneous storage tanks or transfer racks that are not otherwise subject to another major source NESHAP and (b) petrochemical terminals primarily in the business of storing and distributing organic liquids.

[e] While a portion of this facility's ethylene oxide emissions are regulated under the organic liquids distribution (nongasoline) NESHAP, the majority of its ethylene oxide emissions are regulated under the synthetic organic chemical manufacturing industry NESHAP.

[11] EPA, *Technical Support Document, EPA's 2014 National Air Toxics Assessment*, August 2018.

Table 4: EPA-identified ethylene oxide-emitting facilities that contribute to individual lifetime cancer risks equal to or greater than 100 in one million at the census block level during the process of conducting the 2014 NATA and the NESHAPs they must meet [a]

Facility type	HAP major/ area source	NESHAP (subpart)[2]	Number of facilities subject to NESHAP [b]
Commercial sterilizers	Major	Ethylene oxide-emitting sterilization facilities (O)	1
	Area		5
Hospital sterilizers	Area	Hospital ethylene oxide sterilizers (WWWWW)	4
Chemical plants [a]	Major	Synthetic organic chemical manufacturing industry (F, G, H, and I)	10
		Miscellaneous organic chemical manufacturing (FFFF)	5 [c]
		Polyether polyols production (PPP)	5
		Organic liquids distribution (Nongasoline) (EEEE) [d]	2 [e]
	Area	N/A	8

Source: OIG summary of information from the EPA and facility permits. (EPA OIG table)

[a] Elevated individual lifetime cancer risks from nine facilities were confirmed with more refined modeling in the miscellaneous organic chemical manufacturing RTR.

[b] Some of the chemical plant major sources are subject to more than one NESHAP standard. As such, the last column adds up to more than 29.

[c] While a portion of each of these five facilities' ethylene oxide emissions is regulated under the miscellaneous organic chemical manufacturing NESHAP, the majority of the facilities' ethylene oxide emissions are regulated under the synthetic organic chemical manufacturing industry NESHAP or polyether polyols production NESHAP.

[d] Subpart EEEE applies to two types of facilities: (a) chemical plants with a distribution terminal not subject to another major source NESHAP or that have a few miscellaneous storage tanks or transfer racks that are not otherwise subject to another major source NESHAP and (b) petrochemical terminals primarily in the business of storing and distributing organic liquids.

[e] While a portion of each of these facilities' ethylene oxide emissions was regulated under the organic liquids distribution (nongasoline) NESHAP, the majority of their ethylene oxide emissions are regulated under the synthetic organic chemical manufacturing industry NESHAP and/or polyether polyols production NESHAP.

Residual Risk Review for the Miscellaneous Organic Chemical Manufacturing Source Category Identified Elevated Cancer Risks from Chloroprene and Ethylene Oxide Emissions from Three Source Categories' Processes

Since the release of the 2014 NATA in August 2018, the EPA has performed more refined modeling through a residual risk review for the miscellaneous organic chemical manufacturing RTR rulemaking that was finalized on August 12, 2020. The residual risk review included determining facilitywide cancer risks from miscellaneous organic chemical manufacturing facilities that also emitted air toxics from processes regulated under other source category NESHAP, including Group I polymers and resins; synthetic organic chemical manufacturing industry; and polyether polyols production processes, if present, since not all facilities have these processes.

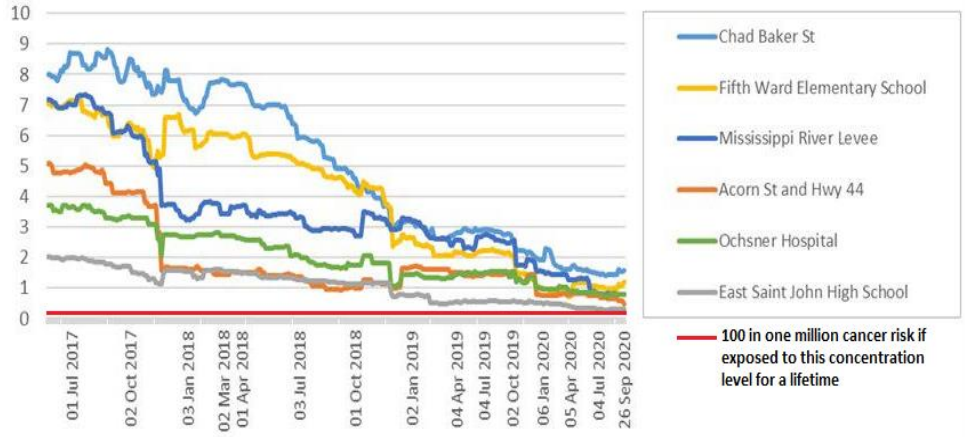
According to the EPA, facilitywide cancer risks in RTR rulemakings are generally more uncertain because the emissions data for the other source categories may not have undergone the same level of data quality review as those being assessed in the regulatory assessment. For the miscellaneous organic chemical manufacturing RTR, however, the facilitywide cancer risks that were determined likely had fewer

uncertainties than those determined for other RTR rulemakings. According to information in the rulemaking docket and information from the EPA, the EPA communicated with 20 of 24 facilities regulated under the miscellaneous organic chemical manufacturing NESHAP that emit ethylene oxide about their emissions and processes to ensure risks were determined accurately. The four facilities that the EPA did not communicate with during the RTR rule development have facilitywide cancer risks equal to or less than ten in one million. Based on facility permits, information from the residual risk review for the miscellaneous organic chemical manufacturing RTR rulemaking, and other information in the rulemaking docket, we determined that individual lifetime cancer risks attributed to chloroprene or ethylene oxide emissions from Group I polymers and resins, synthetic organic chemical manufacturing industry, and polyether polyols production processes are likely to be equal to or greater than 100 in one million, suggesting that the existing NESHAPs for these source categories may not be protective of human health.

Monitoring Data Indicated Elevated Cancer Risks in LaPlace, Louisiana, and Willowbrook, Illinois

Monitoring data indicate that existing NESHAPs for the synthetic organic chemical manufacturing industry, which covers chloroprene production; Group I polymers and resins, which covers neoprene production; and commercial sterilizers may not be protective of human health. Since May 2016, the EPA has measured chloroprene concentrations in the air at six different locations near Denka in LaPlace, Louisiana. Figure 6 shows the EPA-calculated "rolling annual average" ambient chloroprene concentrations at the six different monitoring locations, represented by six different color points. A **rolling annual average** is calculated by taking the sample results for the 12 months preceding a sampling day, averaging them, and placing that value as a data point in the figure. With every subsequent sampling day, those 12 months roll forward to capture the 12 months preceding that day, the results are averaged, and this rolling annual average is shown as the next data point.

Figure 6: Rolling annual average ambient chloroprene concentrations (µg/m^3) at six sites near Denka in LaPlace, Louisiana, from 2017 to 2020



Source: EPA-developed image with OIG-inserted line for the 100 in one million cancer risk level if exposed to an ambient chloroprene concentration level of 0.2 µg/m^3 for a lifetime. (EPA OIG image)

The rolling annual average ambient chloroprene concentrations at all six monitoring locations generally decreased after March 2018. This reduction was the result of Denka voluntarily entering into an administrative order on consent, a legal agreement, with the Louisiana Department of Environmental Quality. In the 2017 order, Denka agreed to install a series of new control technology and measures that are not required under NESHAPs for Group I polymers and resins or synthetic organic chemical manufacturing industry to reduce chloroprene emissions. The last of the chloroprene emission-control devices became fully operational in March 2018. Despite Denka's efforts, the annual average ambient chloroprene concentrations remained above 0.2 μg/m^3 at all six monitoring locations near Denka at the conclusion of the EPA's community air-monitoring effort on September 26, 2020. According to the EPA, rolling annual average ambient chloroprene concentrations in the community would be lower except for occasional elevated measurements, or spikes, that contribute to the rolling annual averages. To better understand the magnitude and frequency of occasional, but recurring, spikes that contribute significantly to the long-term chloroprene averages, the EPA deployed a Continuous Air Monitoring Program in March 2020. Data from the Continuous Air Monitoring Program show that spikes above 0.2 μg/m^3 continued into 2021.

The horizontal red line in Figure 6 delineates the 0.2 μg/m^3 chloroprene concentration level, which is the concentration that, if exposed to for a lifetime, is equivalent to a cancer risk of 100 in one million. A cancer risk of 100 in one million is generally considered unacceptable and would require the EPA to take action to reduce that risk. In a May 5, 2016 memorandum to Region 6, OAQPS recommended that Denka aim for emission reductions such that the maximum annual average chloroprene concentration is no higher than 0.2 μg/m^3 chloroprene at the highest modeled off-site location. The high rolling annual average ambient chloroprene concentrations since 2017 in Figure 6 indicate that the existing NESHAPs for Group I polymers and resins and synthetic organic chemical manufacturing industry may not be protective of human health.

EPA short-term monitoring around the Sterigenics facility in Willowbrook, Illinois, from November 2018 to March 2019 helped to inform the August 2019 risk assessment that the Agency conducted to assess human health risks posed by ethylene oxide emissions from the facility. The risk assessment estimated that risks from lifetime exposure while the facility was operating ranged from less than 100 in one million to 1,000 in one million in residential areas closest to the facility.[12] For areas where people worked near the facility, the estimated risks while the facility was operating ranged from 200 in one million to 1,000 in one million closest to the facility. The risk assessment also estimated that future risks in residential areas and areas where people work near the facility would be below 100 in one million and potentially as low as one in one million if the

[12] The short-term monitoring was conducted from November 2018 to March 2019.

facility was more highly controlled. These results indicate that the existing NESHAP for commercial sterilizers may not be protective of human health.

EPA Should Ensure RTR Process Sufficiently Identifies and Addresses Elevated Cancer Risks from Chloroprene and Ethylene Oxide Emissions

Despite indications of elevated cancer risks from chloroprene and ethylene oxide emissions, the EPA has not incorporated new or revised UREs for chloroprene and ethylene oxide into the RTR process for many source categories that emit these pollutants. In the absence of updated reviews for the applicable source categories, the Agency cannot provide assurance that its current NESHAPs are protective. There are five steps that the EPA should take to ensure its RTR process identifies and addresses elevated cancer risks from chloroprene and ethylene oxide emissions. The five steps are to:

- Conduct new residual risk reviews for four major source categories: (1) Group 1 polymers and resins, (2) synthetic organic chemical manufacturing industry, (3) polyether polyols production, and (4) commercial sterilizers, since a new risk value for chloroprene was set for the first time and a higher revised risk value for ethylene oxide was issued after RTRs had already been conducted for these source categories.

- Conduct a residual risk review for hospital sterilizers, which are area sources.

- Conduct overdue technology reviews for four source categories.

- Develop emission standards for chemical plant area sources that emit ethylene oxide, which currently lack applicable NESHAP standards.

- Develop an internal control process to assure timely reviews of existing NESHAPs and uncontrolled emission sources when information becomes available that the risk of a pollutant has increased.

EPA Has Not Scheduled Any New Residual Risk Reviews to Be Conducted Despite Issuance of New or Revised Higher Risk Values for Chloroprene and Ethylene Oxide

The EPA's IRIS program issued a new URE for chloroprene for the first time in September 2010 and a revised URE for ethylene oxide in December 2016 that demonstrated that these pollutants were more carcinogenic than previously understood. However, despite chloroprene being classified as a likely human carcinogen and ethylene oxide as a human carcinogen, the EPA has not issued a schedule to conduct new residual risk reviews for Group I polymers and resins, synthetic organic chemical manufacturing industry, polyether polyols production,

and commercial sterilizers. Residual risk reviews for all these source categories were conducted prior to the issuance of new or revised UREs for chloroprene and ethylene oxide.

We asked the Agency whether it was required to conduct new residual risk reviews for the chloroprene and ethylene oxide source categories. OAQPS asserted that, "while the CAA does require EPA to conduct a review of a NESHAP for advancements in technology, it does not require such a review for advancements related to risk."

In addition, the Agency asserted that it is not obligated to conduct a residual risk review under any circumstances at issue in the case of *Citizens for Pennsylvania's Future* v. *Andrew R. Wheeler*, No. 19-CV-02004-VC (N.D. Cal. June 26, 2020). However, the issue before the court in that case was whether the CAA imposes a mandatory duty on the EPA to conduct a new residual risk review whenever the Agency revises technology-based standards for a source category. While the court's analysis may have broader applications, the court did not specifically address whether the EPA is required to conduct a new residual risk review whenever there is new risk data or information.

The EPA has discretionary authority to conduct new residual risk reviews under the CAA whenever new data or information suggests an air pollutant is more toxic than previously determined. The CAA does not state that the Agency must or should conduct only one residual risk review for a source category. Further, as noted by the court in *Citizens for Pennsylvania's Future*, the CAA "expressly contemplates that EPA might revise its risk-based standards," citing CAA § 307(d)(1)(C), which refers to the "promulgation or **revision** of … any standard under section [CAA § 112(f)]" (emphasis added). Section 112(f) of the CAA authorizes the EPA to promulgate risk-based standards. The Agency also asserted in its April 2006 commercial sterilizer RTR rule that it has the authority to revisit and revise rulemakings in light of new information related to risk. In that rule, the EPA stated:

> We [the EPA] have the authority to revisit (and revise, if necessary) any rulemaking if there is sufficient evidence that changes within the affected industry or significant improvements to science suggests the public is exposed to significant increases in risk as compared to the risk assessment prepared for the rulemaking (e.g., CAA § 301).

Section 301 of the CAA contains the EPA's authority to issue rules to implement the CAA. Conducting new residual risk reviews to incorporate the current UREs and risk information for chloroprene and ethylene oxide would assure that the EPA RTR process results in new or revised standards that are protective of human health. We note that, on July 8, 2020, 11 senators urged the EPA to conduct a new RTR for commercial sterilizers because a revised URE was issued for ethylene oxide since the Agency last conducted an RTR for the source category in April 2006.

EPA Has Not Scheduled a Residual Risk Review of Hospital Sterilizers

The EPA is not required to conduct residual risk reviews of area sources with GACT standards, and the EPA has not scheduled one for hospital sterilizers. Given that ethylene oxide has been determined to be more toxic than previously known, the EPA should conduct a residual risk review for hospital sterilizers to ensure the protection of human health.

EPA Is Not Meeting Statutory Time Frames for Conducting Technology Reviews

The Agency has missed deadlines for four technology reviews for four source categories that emit chloroprene, ethylene oxide, or both, and one is due in 2022, as shown in Table 5. While the technology review for commercial sterilizers is being conducted, with an anticipated issuance of the final rule in late 2021 at the earliest, those for the other three source categories were not planned, as they were not in the regulatory agenda at the time of this report.

Table 5: Status of technology reviews for source categories that emit chloroprene, ethylene oxide, or both

Facility type	HAP major/ area source	NESHAP (subpart)	Technology review due date	Technology review status
Commercial sterilizers	Major	Ethylene oxide-emitting sterilization facilities (O)	April 5, 2014 [b]	Overdue
	Area			
Hospital sterilizers	Area	Hospital ethylene oxide sterilizers (WWWWW)	December 28, 2015	Overdue
Chemical plants [a]	Major	Synthetic organic chemical manufacturing industry (F, G, H, and I)	December 19, 2014	Overdue
		Miscellaneous organic chemical manufacturing (FFFF)	August 11, 2028 [c]	Not overdue
		Polyether polyols production (PPP)	March 25, 2022	Not overdue
		Organic liquids distribution (Nongasoline) (EEEE) [d]	July 7, 2028 [e]	Not overdue
		Group I polymers and resins (U)	December 16, 2016	Overdue
	Area	N/A	N/A	N/A

Source: OIG analysis of CAA and information from the EPA. (EPA OIG table)

[a] Some of the chemical plant major sources are subject to more than one NESHAP standard.

[b] The estimated completion date of the technology review is late 2021 at the earliest.

[c] The EPA recently conducted the RTR for the miscellaneous organic chemical manufacturing source category for the first time and issued the final rule on August 12, 2020.

[d] Subpart EEEE applies to two types of facilities: (a) chemical plants with a distribution terminal not subject to another major source NESHAP or that have a few miscellaneous storage tanks or transfer racks that are not otherwise subject to another major source NESHAP and (b) petrochemical terminals primarily in the business of storing and distributing organic liquids.

[e] The EPA recently conducted the RTR for the organic liquids distribution (nongasoline) source category for the first time and published the final rule on July 7, 2020.

According to OAQPS personnel, the Agency has no plans to conduct the overdue technology review for Group I polymers and resins that covers neoprene production because it does not want to expend rulemaking resources on a technology review covering one facility—Denka. Furthermore, the Agency believed that emission reductions could be achieved more quickly by working with the state and the facility—as shown in Figure 6, the large emissions reductions after implementation of the last of the control devices in March 2018—rather than through rulemaking. The technology review for Group I polymers and resins that covers neoprene production was conducted in 2008. Section 112(d)(6) of the CAA requires the EPA to conduct a technology review for each source category at least every eight years after promulgation of MACT or GACT standards and revise the standards, if necessary. The CAA does not provide any exceptions for this requirement. Without revised NESHAP standards developed through another residual risk or technology review, any new facilities built would only have to meet the existing standards, which are not protective of human health.

While a technology review for polyether polyols production is not due until March 2022, we believe that a technology review should be conducted as soon as practicable in light of the potent carcinogenicity of ethylene oxide, as demonstrated by the revised URE. The CAA provides the Agency with the discretion to conduct a technology review sooner than eight years.

The EPA could combine the residual risk reviews with the technology reviews to conduct new RTRs. This should be done not only to protect human health in a timely manner but also to promote efficiency.

EPA Has Not Developed Standards for Chemical Plant Area Sources that Emit Ethylene Oxide

The EPA has not developed standards for chemical plant area sources that emit ethylene oxide. There is a NESHAP for chemical manufacturing area sources outlined in 40 C.F.R. Part 63, Subpart VVVVVV. This NESHAP, however, applies to each chemical manufacturing process unit that uses as feedstock, generates as byproducts, or produces as products any of 15 air toxics listed in the rule. Ethylene oxide is not one of the 15 listed air toxics in Subpart VVVVVV. Therefore, chemical plant area sources may emit ethylene oxide without any controls. An overdue technology review of Subpart VVVVVV is in the EPA's long-term regulatory agenda, but the Agency has not affirmed to us that it will add ethylene oxide to the list of regulated air toxics under Subpart VVVVVV at the conclusion of the overdue technology review.

EPA Lacks a Process to Assure Timely Reviews of Existing NESHAPs and Uncontrolled Emission Sources When Pollutant Risk Increases

The EPA does not have a process to assure timely reviews of existing NESHAPs and uncontrolled emission sources when new or updated risk information becomes available that demonstrates that a pollutant is more toxic than previously known.

The IRIS program issued a URE value for chloroprene for the first time in 2010 and an updated, larger URE value for ethylene oxide in 2016, in both circumstances classifying the chemicals as more carcinogenic than previously known. These assessments were completed after the Agency had already conducted RTRs for the Group I polymers and resins, synthetic organic chemical manufacturing industry, polyether polyols production, and commercial sterilizers.

Although more than ten years have passed since the IRIS program issued a new URE value for chloroprene, the EPA has not scheduled any regulatory reviews for Group I polymers and resins and synthetic organic chemical manufacturing industry, both of which apply to Denka units that emit chloroprene. In addition, although over four years have passed since the IRIS program issued a revised URE for ethylene oxide in December 2016, the EPA has yet to schedule regulatory reviews for synthetic organic chemical manufacturing industry, polyether polyols production, hospital sterilizers, or chemical plant area sources that emit ethylene oxide.

By developing and implementing an internal control process, the EPA could assess the source categories that emit pollutants with new increased risk values to determine the significance of the resultant risks and the need to initiate and prioritize timely regulatory reviews of impacted source categories. These actions would assure that sources emitting air toxics with new increased risk values and sources of air toxics emissions not previously controlled are being addressed to protect public health in a timely manner.

Environmental Justice May Not Be Achieved Without New RTRs or Emission Standards

Minority and low-income populations are disproportionately impacted by chloroprene and ethylene oxide emissions. According to the EPA's environmental justice screening tool, EJSCREEN, 100 percent of the people living in the same census block group where Denka is located are minorities and 49 percent of them are low-income.[13] The LaPlace, Louisiana community is impacted by not only chloroprene emissions from Denka but also ethylene oxide emissions from two nearby chemical plants. The burden from exposure to these two toxic chemicals resulted in the 2014 NATA estimating that these residents have an individual lifetime cancer risk of 2,000 in one million at the census tract level, which is the highest in the country.

According to EJSCREEN, 50 percent or more of the people living in the same census block group as 14 of the 22 ethylene oxide-emitting facilities contributing to cancer risks of 100 in one million or greater at the **census tract** level are minorities or part of low-income households. Further, the same is true of 18 of the 29 ethylene

[13] EJSCREEN defines minorities as individuals who list their racial status as a race other than white alone and/or list their ethnicity as Hispanic or Latino. A household income is defined as low-income when it is less than or equal to twice the federal "poverty level."

oxide-emitting facilities contributing to cancer risks of 100 in one million or greater at the **census block** level. Unless the EPA conducts new RTRs using the new UREs for chloroprene and ethylene oxide for source categories that have not had RTRs using the new UREs or develops emission standards for area source chemical plants that emit ethylene oxide, the Agency may not meet its commitment and responsibility under Executive Order 12898 to achieve environmental justice.

Conclusions

Information generated by the EPA indicates elevated cancer risks from chloroprene and ethylene oxide emissions. The Agency has not incorporated new risk values for these pollutants into residual risk reviews for most source categories. Therefore, the EPA cannot assure that current emission standards are protective of human health. The EPA should exercise its discretionary authority to conduct new residual risk reviews under the CAA whenever new data or information suggests an air pollutant is more toxic than previously determined, which is consistent with the Agency's position in its April 2006 commercial sterilizer RTR rule. If the results of new residual risk reviews show that people are exposed to unacceptable risk levels, the EPA should revise the respective NESHAPs for source categories emitting ethylene oxide or chloroprene without cost considerations to reduce risks to acceptable levels. The EPA has missed deadlines for four technology reviews for four source categories, and one is due in 2022. For efficiency purposes, the EPA could combine the residual risk reviews with the technology reviews to conduct new RTRs for the five source categories. Without new RTRs or emission standards, the EPA may not be able to achieve environmental justice to protect the health of overburdened minority and low-income communities.

Recommendations

We recommend that the assistant administrator for Air and Radiation:

1. Develop and implement an internal control process with specific criteria to determine whether and when new residual risk reviews of existing National Emission Standards for Hazardous Air Pollutants and uncontrolled emission sources are needed to incorporate new risk information that demonstrates that an air pollutant is more toxic than previously determined.

2. Conduct new residual risk reviews for Group I polymers and resins that cover neoprene production, synthetic organic chemical manufacturing industry, polyether polyols production, commercial sterilizers, and hospital sterilizers using the new risk values for chloroprene and ethylene oxide and revise the corresponding National Emission Standards for Hazardous Air Pollutants, as needed.

3. Revise National Emission Standards for Hazardous Air Pollutants for chemical manufacturing area sources to regulate ethylene oxide and conduct a residual risk review to ensure that the public is not exposed to unacceptable risks.

4. Conduct overdue technology reviews for Group I polymers and resins that cover neoprene production, synthetic organic chemical manufacturing industry, commercial sterilizers, hospital sterilizers, and chemical manufacturing area sources, which are required to be completed at least every eight years by the Clean Air Act.

Agency Response and OIG Assessment

The Agency offered an alternative Recommendation 1 to determine whether regulatory changes are needed because it believes that there are other authorities besides residual risk reviews under CAA Section 112(f) that could be equally effective at addressing air pollutants that are more toxic than previously determined. While the Agency did not state the authorities in its response to our draft report, it asserted during discussions with the OIG that it can adequately consider and account for risk in the process of conducting technology reviews.

We disagree with the Agency's position. We acknowledge that, in some instances, revising standards under the statutorily required recurring eight-year technology review may reduce public health risks to acceptable levels or provide an ample margin of safety regarding air pollutants that have been determined to be more toxic than previously understood. There is no assurance of this, however. The CAA's two-stage process for addressing air toxics emissions from stationary sources **begins** with the promulgation of technology-based standards, but it expressly requires further analysis and more protective standards in cases in which technology-based standards are not adequately protective of public health. The Agency, in essence, argues that a technology review alone pursuant to CAA Section 112(d) can be relied upon to do the work of a residual risk review pursuant to CAA Section 112(f). This is inconsistent with the text of these provisions and with basic principles of statutory interpretation. Since any updates to existing risk values or an establishment of new risk values may or may not result in unacceptable public health risks, we revised Recommendation 1 to include establishing specific criteria to determine whether and when new residual risk reviews are needed. The Agency's proposed corrective actions for its suggested alternative Recommendation 1 do not meet the intent of our revised Recommendation 1. Therefore, Recommendation 1 remains unresolved.

The Agency offered an alternative recommendation for Recommendation 2 to seek to reduce risk from ethylene oxide and chloroprene by conducting reviews that consider risk for the listed source categories. The Agency's alternative recommendation does not commit to completing residual risk reviews even though the EPA's IRIS program issued a URE for chloroprene for the first time in 2010 and a revised URE for ethylene oxide in 2016 that demonstrated that these

pollutants were more carcinogenic than previously understood. Despite chloroprene being classified as a likely human carcinogen and ethylene oxide as a human carcinogen, the EPA has not conducted new residual risk reviews for Group I polymers and resins, synthetic organic chemical manufacturing industry, polyether polyols production, and commercial sterilizers. Residual risk reviews for these source categories were conducted prior to the issuance of new or revised UREs for chloroprene and ethylene oxide. Based on Agency comments on the draft report, we divided the recommendation into two recommendations. We recommend that the Agency conduct residual risk reviews in Recommendation 2 and technology reviews in Recommendation 4. The Agency did not offer any proposed corrective actions to conduct residual risk reviews for the five source categories in Recommendation 2. Therefore, Recommendation 2 is unresolved.

Based on Agency comments on the draft report, we revised Recommendation 3, recommending that the Agency revise the NESHAP for chemical manufacturing area sources to include regulating ethylene oxide and conducting a residual risk review. The Agency proposed corrective actions focused on completing a technology review. Therefore, Recommendation 3 is unresolved.

As stated above, we divided Recommendation 2 from our draft report into two recommendations based on Agency comments and added the chemical manufacturing area sources to Recommendation 4. In its response, the Agency provided dates for the completion of technology reviews for the source categories we included in Recommendations 2 and 3 of our draft report. This meets the intent of the new Recommendation 4; therefore, this recommendation is resolved.

The Agency stated that it did not believe it was necessary to include Appendix C in our report because the census block-level data are even less reliable than the census tract-level data in NATA. The Agency also believed that the census tract-level data in Table 3 already provides a complete picture of the relevant source categories covered in the recommendations. We disagree with the Agency's position. Table 3 does not include hospital sterilizers. Appendix C provides the additional support for our recommendations. In addition, the Agency has not conducted investigations or refined modeling for most of the facilities in Appendix C to determine the current risks attributed to their emissions since the Agency completed the 2014 NATA in August 2018. Furthermore, if the EPA were to conduct only technology reviews, the Agency would not be obligated to assess risk and communicate the resultant risk to the public. Therefore, Appendix C is included in the report.

Appendix D contains the Agency's response to the draft report. The Agency also provided specific technical suggestions for our consideration. We revised the report as appropriate.

Status of Recommendations and Potential Monetary Benefits

RECOMMENDATIONS

Rec. No.	Page No.	Subject	Status[1]	Action Official	Planned Completion Date	Potential Monetary Benefits (in $000s)
1	26	Develop and implement an internal control process with specific criteria to determine whether and when new residual risk reviews of existing National Emission Standards for Hazardous Air Pollutants and uncontrolled emission sources are needed to incorporate new risk information that demonstrates that an air pollutant is more toxic than previously determined.	U	Assistant Administrator for Air and Radiation		
2	26	Conduct new residual risk reviews for Group I polymers and resins that cover neoprene production, synthetic organic chemical manufacturing industry, polyether polyols production, commercial sterilizers, and hospital sterilizers using the new risk values for chloroprene and ethylene oxide and revise the corresponding National Emission Standards for Hazardous Air Pollutants, as needed.	U	Assistant Administrator for Air and Radiation		
3	27	Revise National Emission Standards for Hazardous Air Pollutants for chemical manufacturing area sources to regulate ethylene oxide and conduct a residual risk review to ensure that the public is not exposed to unacceptable risks.	U	Assistant Administrator for Air and Radiation		
4	27	Conduct overdue technology reviews for Group I polymers and resins that cover neoprene production, synthetic organic chemical manufacturing industry, commercial sterilizers, hospital sterilizers, and chemical manufacturing area sources, which are required to be completed at least every eight years by the Clean Air Act.	R	Assistant Administrator for Air and Radiation	4th Quarter Fiscal Year 2024	

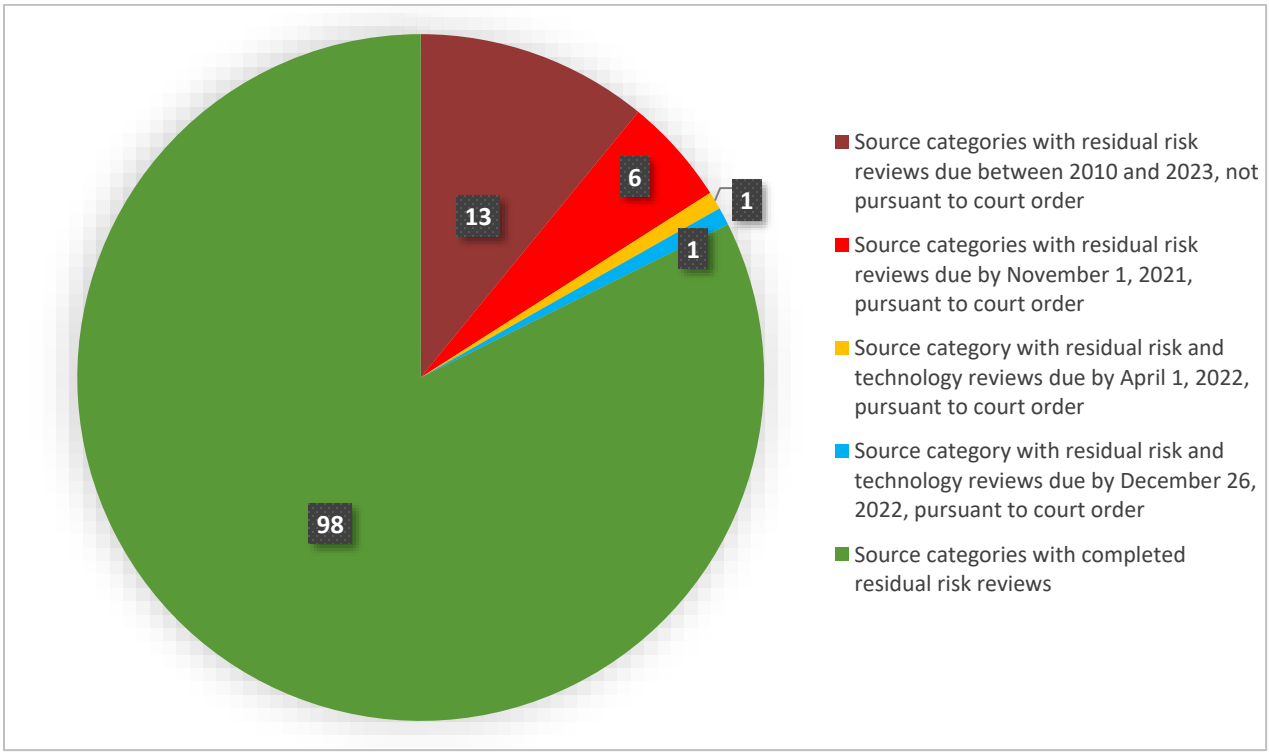
[1] C = Corrective action completed.
R = Recommendation resolved with corrective action pending.
U = Recommendation unresolved with resolution efforts in progress.

Residual Risk Review Status of Source Categories with MACT Standards

The Agency has conducted residual risk reviews for 98 of 119 source categories with MACT standards. The Agency has not conducted residual risk reviews for 21 of 119 source categories with MACT standards, but it is under a court order to conduct residual risk reviews, along with technology reviews, for six of the 21 remaining source categories by November 1, 2021, as shown in the figure below.

In 2020, the EPA completed RTRs for 28 source categories pursuant to court orders and one source category, mercury and air toxics standards for power plants, not pursuant to court orders. According to the Agency, it typically conducted about seven RTRs per year before 2020.

Figure A-1: Universe of 119 source categories with MACT standards controlling air toxics emissions and their residual risk review status



Source: OIG summary based on the CAA and information from the EPA. (EPA OIG image)

Appendix B

Comparison of Residual Risk Review and Technology Review

	Residual risk review	Technology review
Purpose	• The EPA assesses the remaining health and environmental risks from air toxics emissions after implementation of the original MACT standards.	• The EPA assesses advances in practices, processes, and control technologies. • The EPA also takes this opportunity to address unregulated emission points, to require consistent monitoring and add electronic compliance reporting, and to resolve administrative requirements that are duplicative or inconsistent.
Frequency	• The EPA conducts a residual risk review within eight years of promulgating the original MACT standard. The CAA is silent on the frequency of residual risk reviews after the initial one was conducted.[a] The EPA stated in the 2006 commercial sterilizers RTR rulemaking that it has the authority to revisit past rulemakings if improvements to science suggest that the public is exposed to significant increases in risk as compared to the initial residual risk review.	• The CAA requires the EPA to conduct a technology review every eight years after the original standard was developed.
Reason for revising standards	• If risks are determined to be unacceptable, the EPA revises the MACT standards without cost considerations. • If current MACT standards do not provide an "ample margin of safety" to protect public health, the EPA revises the standards if cost effective.	• If the Agency finds cost-effective approaches to further reduce emissions, it revises the MACT standards, taking into account advances in practices, processes, and control technologies.
Whether review is required for area sources with GACT standards	• The EPA is not required to conduct residual risk reviews of area source categories subject to GACT standards.	• The EPA is required to conduct technology reviews of all major and area source categories.

Source: CAA and information from the EPA. (EPA OIG table)

[a] The court in *Citizens for Pennsylvania's Future v. Andrew R. Wheeler*, No. 19-CV-02004-VC (N.D. Cal. June 26, 2020) found that the CAA did not create a mandatory duty for the EPA to review risk-based standards for potential revision when technology-based standards are revised.

Appendix C

Ethylene Oxide Facilities That EPA Identified as Contributing to Cancer Risks Equal to or Greater Than 100 in One Million in 2014 NATA Interim Work Files at Census Block Level but Not at Census Tract Level

EPA region	Facility	Location	Type of facility	Refined modeling completed after 2014 NATA N = No Y = Yes
2	Ashland Specialty Ingredients	Parlin, NJ	Chemical plant	N
3	Bayer Material Science–South Charleston (Covestro)	South Charleston, WV	Chemical plant	N
3	Union Carbide Corporation–South Charleston Facility	South Charleston, WV	Chemical plant	Y
4	Stepan Company	Winder, GA	Chemical plant	N
4	Frye Regional Medical Center	Hickory, NC	Hospital sterilizer	N
4	Kendall Healthcare Products	Augusta, GA	Commercial sterilizer	N
4	International Sterilization Laboratory	Groveland, FL	Commercial sterilizer	N
4	BASF Whitestone Plant	Whitestone, SC	Chemical plant	N
4	First Health Moore Regional Hospital	Pinehurst, NC	Hospital sterilizer	N
4	Sterigenics U.S. LLC	Charlotte, NC	Commercial sterilizer	N
4	Monument Chemical Kentucky LLC	Brandenburg, KY	Chemical plant	Y
5	Pelron Corporation (Elé)	McCook, IL	Chemical plant	N
5	Cook Medical	Ellettsville, IN	Commercial sterilizer	N [a]
5	Air Products Performance Manufacturing (Evonik)	Milton, WI	Chemical plant	N
6	Huntsman Corporation Conroe Facility	Conroe, TX	Chemical plant	Y
6	Akzo Nobel, Houston Plant	Houston, TX	Chemical plant	N
6	Union Carbide Corp. Seadrift Plant	Seadrift, TX	Chemical plant	Y
6	Baxter Healthcare Corporation	Mountain Home, AR	Commercial sterilizer	N
6	BASF Corp. – Geismar Site	Geismar, LA	Chemical plant	Y
6	LyondellBasell Channelview Plant	Channelview, TX	Chemical plant	Y
6	Dow Chemical Co. – Louisiana Operations	Plaquemine, LA	Chemical plant	Y
6	Arkema Inc. Clear Lake Plant	Pasadena, TX	Chemical plant	Y

EPA region	Facility	Location	Type of facility	Refined modeling completed after 2014 NATA N = No Y = Yes
6	LyondellBasell Bayport Underwood Plant	Pasadena, TX	Chemical plant	N
6	Shell Chemical LP – Geismar Plant	Geismar, LA	Chemical plant	Y
7	Penford Products Co.	Cedar Rapids, IA	Chemical plant	N
7	BCP Ingredients – Verona Plant	Verona, MO	Chemical plant	N
8	North Colorado Medical Center	Greeley, CO	Hospital sterilizer	N
8	Community Hospital	Grand Junction, CO	Hospital sterilizer	N
9	Sterigenics U.S. Inc.	Los Angeles, CA	Commercial sterilizer	N

Source: OIG summary of data from EPA-generated lists of facilities contributing to elevated cancer risks at the census block level and information from the EPA. In addition, we also used data from the residual risk assessment for the miscellaneous organic chemical manufacturing RTR rule issued on August 12, 2020. (EPA OIG table)

[a] According to Region 5, the facility has reduced emissions significantly by operating under permanent total enclosure conditions since the end of 2019. Region 5 did not think it was necessary to conduct refined modeling since the emission reduction was significant enough not to pose an elevated cancer risk.

Agency Response to Draft Report

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 5, 2021

OFFICE OF
AIR AND RADIATION

MEMORANDUM

SUBJECT: EPA Response to OIG Draft Reports titled: "EPA Should Conduct New Residual Risk and Technology Reviews for Chloroprene- and Ethylene Oxide-Emitting Source Categories to Protect Human Health" - Project No. OA&E-FY19-0091, January 14, 2021; and "EPA Delayed Risk Communication and Issued Instructions Hindering Region 5's Ability to Address Ethylene Oxide Emissions" - Project No. OA&E-FY19-0091, February 4, 2021

FROM: Joseph Goffman
Acting Assistant Administrator
Office of Air and Radiation

TO: Renee McGhee-Lenart
Acting Air Director
Office of the Inspector General

The Office of Air and Radiation (OAR) welcomes the opportunity to provide comment on the following two draft reports and their recommendations: *EPA Should Conduct New Residual Risk and Technology Reviews for Chloroprene- and Ethylene Oxide-Emitting Source Categories to Protect Human Health* and *EPA Delayed Risk Communication and Issued Instructions Hindering Region 5's Ability to Address Ethylene Oxide Emissions*. We have provided our comments in the attachments to this memorandum and provide our initial thoughts on the recommendations in each of the two reports below, along with other information requested in the reports.

Section 1: EPA Response to Draft Report "EPA Should Conduct New Residual Risk and Technology Reviews for Chloroprene- and Ethylene Oxide-Emitting Source Categories to Protect Human Health"

OIG Recommendation 1: Develop and implement an internal control process to initiate a new residual risk and technology review of existing National Emission Standards for Hazardous Air

Pollutants (NESHAP) and uncontrolled emission sources whenever new risk information becomes available that demonstrates that an air pollutant is more toxic than previously determined.

Response 1: We recommend that OIG change the recommendation to: Develop and implement an internal control process to review source categories that emit pollutants where new information shows that the pollutants are more toxic than previously understood in order to determine if regulatory changes are needed.

This change is suggested because, as written, the OIG appears to be directing EPA to use a specific statutory authority for rulemaking; however, there are other authorities that could be equally effective at addressing the problem.

Regarding the development of an internal control process, the Office of Air Quality Planning and Standards (OAQPS) is establishing a process as part of its Air Toxics Strategy to identify and effectively address emerging issues, such as changes in health benchmarks. Under the strategy, the Air Toxics Evaluation and Screening Team, which comprises a diverse group of OAQPS and regional staff, meets weekly to discuss, identify, and address new and emerging air toxics issues. Team members leverage contacts to conduct preliminary characterizations of these issues and routinely engage OAQPS senior management on status, options, roles and responsibilities of potential project teams, and communication strategies.

Planned Completion Date: Quarter 4, FY 2021

OIG Recommendation 2: Conduct new risk and technology reviews for Group I polymers and resins that covers neoprene production, synthetic organic chemical manufacturing industry, polyether polyols production, commercial sterilizers, and hospital sterilizers using the new risk values for chloroprene and ethylene oxide and revise the corresponding NESHAP, as needed.

Response 2: We recommend that OIG change the recommendation to: Seek to reduce risk from ethylene oxide and chloroprene by conducting reviews which consider risk for the following source categories: Group I polymers and resins that covers neoprene production, synthetic organic chemical manufacturing industry, polyether polyols production, commercial sterilizers, and hospital sterilizers (an area source category). The reviews should use the new risk values for chloroprene and ethylene oxide and revise the corresponding NESHAP, as needed.

We are already working on the Commercial Sterilizers Technology Review, a project that has included extensive information collection, and we intend to consider the increased risk identified after application of the 2016 Integrated Risk Information System (IRIS) assessment for ethylene oxide in the proposed rule planned for later this year.

We are currently discussing settlement of a lawsuit to conduct a rulemaking for the synthetic organic chemical manufacturing industry, and the schedule provided below will be adjusted based on the outcome of the schedule negotiations, or, if needed, litigation related to the schedule.

Given that no final decision has yet been made on the appropriate statutory authority to utilize for each of the rules identified above, the draft schedules below for issuing a final rulemaking are based on the assumption that we will conduct the statutorily required technology review as part of

any rulemaking action for these rules. EPA will consider risk as part of the rulemakings for these source categories and we will determine whether the Agency should conduct a discretionary residual risk review during the rulemaking. The schedules for these actions are consistent with the amount of time that it takes to conduct the many steps associated with a NESHAP review. These steps include: collecting data; conducting necessary technology and economic analyses; addressing impacts on small businesses, if warranted; considering risks; working through the formal internal and interagency review processes; issuing a notice of proposed rulemaking; soliciting public comment; conducting appropriate outreach; holding a public hearing, if requested; reviewing and responding to all public input; and issuing a notice of final rulemaking. (A full residual risk review may require additional time beyond the projected dates).

Planned Completion Dates: The draft completion dates for each action are as follows:

Commercial Sterilizers: Quarter 4, FY 2022
Hospital Sterilizers: Quarter 4, FY 2023
Group 1 Polymers and Resins (Neoprene): Quarter 2, FY 2024
Synthetic Organic Chemicals Manufacturing Industry: Quarter 2, FY 2024
Polyether Polyols Production: Quarter 4, FY 2024

OIG Recommendation 3: Develop NESHAP for chemical plant area sources that emit ethylene oxide.

Response 3: EPA is currently planning to conduct the technology review for the NESHAP for chemical manufacturing area sources, and we intend to consider ethylene oxide emissions from the source category as part of that review. The schedule for this action is consistent with the amount of time that it takes to conduct the many steps associated with a NESHAP review. These steps include: collecting data; conducting necessary technology and economic analyses; addressing impacts on small businesses, if warranted; considering risks; working through the formal internal and interagency review processes; issuing a notice of proposed rulemaking; soliciting public comment; conducting appropriate outreach; holding a public hearing, if requested; reviewing and responding to all public input; and issuing a notice of final rulemaking. (A full residual risk review may require additional time beyond the projected date).

Planned Completion Dates: The draft completion date for this action is Quarter 4, FY 2024.

In addition, we believe that the inclusion of the information in Appendix C is not necessary and reflects an invalid use of the National Air Toxics Assessment (NATA) results. NATA relies on information at the census tract level to indicate where to look closer at potential risks in certain communities. Even at the census tract, the risk results can be uncertain and do not provide actionable risk information. The census block level risks used by the OIG in developing Appendix C are even less reliable and should not be included here. (Furthermore, as noted in our comments in the attachment, Appendix C provides no additional information in terms of identifying the source categories covered in the recommendations. Table 3 in the draft report already provides a complete picture of the relevant source categories.)

As we have explained to the OIG in the past, these census block level data are not the NATA results; they are based on interim work files generated during the development of NATA and have two important shortcomings which prevent EPA from considering it in characterizing risk:

1. Accuracy of Emissions Data: The most recent NATA relied on 2014 emissions inventory data, which were the most recent available information when NATA was conducted, but which are now, of course, several years old. In addition, because EPA does not require nationwide reporting of air toxics emissions, the data for the approximately 40,000 facilities included in the National Emissions Inventory can be incomplete and uncertain. Additional verification is necessary to determine whether the air toxics emissions estimates in the NEI are correct and reflect current conditions. While attempts to verify emissions information are made during NATA's development, we focus on those facilities with the highest risk at the census tract.

2. Reliability of Receptor Locations: NATA presents risk results at the census tract level, which is the smallest geographic area at which EPA is comfortable presenting screening level estimates of risk. There are more than 73,000 census tracts in the United States. Additional verification is necessary to determine whether the census tract receptor locations used in the modeling to calculate exposure (and, thus, risk) are appropriate (i.e., reflect locations representative of where people actually live). And there are almost seven million census blocks in the United States. No effort is made to verify whether census block receptor locations are appropriate.

The identification of specific facilities in Appendix C likely reflects many false positives, while the omission of others may indicate significant false negatives. Our commitments above to consider risk as part of the review of the various source sector rules noted above will result in the proper identification of areas with elevated risks and produce the necessary accurate information to support responsible risk communication. We, therefore, request that the OIG remove Appendix C from the final report.

OIG Response: For the purpose of this appendix, we only included the relevant section of the Agency's response. We included the section removed herein in the relevant report, *EPA Delayed Risk Communication and Issued Instructions Hindering Region 5's Ability to Address Ethylene Oxide Emissions,* Report No. 21-P-0123.

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