Message

From: Mascarenhas, Brendan [Brendan_Mascarenhas@americanchemistry.com]
Sent: 2/4/2025 10:13:08 PM
To: Tardif, Abigale (Abbie) [Tardif.Abigale@epa.gov]; Dominguez, Alexander [dominguez.alexander@epa.gov]
Subject: ACC Meeting Request on Petition for Reconsideration on EPA Final Rule: NESHAP and NSPS for SOCMI and Group I and II P&R
Attachments: Petition for Reconsideration - ACC AFPM SOCMI PRI and II 1-31-25 Filed.pdf; Attachment A - HON Petition for Reconsideration - Sterilizer Rule Synopsis 1-31-25.pdf; Attachment B - HON Petition for Reconsideration - Final EO Questions 1-31-25.pdf

Hi Abigale and Alex,

Hope all is well with you both. ACC would like to request a meeting with EPA OAR staff to discuss priority issues as highlighted in our joint petition for reconsideration on the final HON rulemaking submitted last Friday, January 31st. If you are available, we would greatly appreciate any availability over the next 2-3 weeks. In the past, I have completed a form for this type of meeting request and I would be happy to do so again with the appropriate scheduling contact. Separately, ACC would also request that you coordinate this meeting with Aaron Szabo, who is also included on the original distribution of the petition. If you have any questions, please let me know. Thanks very much.

Regards,
Brendan

American Chemistry Council

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RESPONSIBLE CARE
Driving Safety & Sustainability

From: Mascarenhas, Brendan
Sent: Friday, January 31, 2025 6:43 PM
To: Zeldin.Lee@epa.gov
Cc: Tardif.Abigale@epa.gov; Szabo.Aaron@epa.gov; donahue.sean@epa.gov; dominguez.alexander@epa.gov;

Tsirigotis.Peter@epa.gov; Lassiter, Penny <Lassiter.Penny@epa.gov>; Lessard.Patrick@epa.gov; Bouchard, Andrew <Bouchard.Andrew@epa.gov>; White, Kimberly <Kimberly_White@americanchemistry.com>; Zenick, Elliott <Elliott_Zenick@americanchemistry.com>; Leslie Bellas <LBellas@afpm.org>
Subject: ACC & AFPM Petition for Reconsideration on EPA Final Rule: NESHAP and NSPS for SOCMI and Group I and II P&R

Dear Administrator Zeldin,

The American Chemistry Council (ACC) and the American Fuel & Petrochemical Manufacturers (AFPM) respectfully request that EPA consider the attached joint petition for reconsideration (and attachments) on EPA's final National Emission Standards for Hazardous Air Pollutants and New Source Performance Standards for the Synthetic Organic Chemical Manufacturing Industry and Group I & II Polymers and Resins Industry (89 Fed. Reg. 42932) as published on May 16, 2024, or the HON rule. ACC and AFPM request that EPA take expeditious action to provide time-sensitive, critical relief in connection with the final HON provisions.

If you or your staff have any questions, please feel free to reach out to me or Leslie Bellas (CC'd here). We appreciate the Agency's consideration and we look forward to the opportunity to provide continued feedback on these important matters.

Thanks very much.

Regards,
Brendan Mascarenhas

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RESPONSIBLE CARE
Driving Safety & Sustainability

American Chemistry Council℠

AFPM
American
Fuel & Petrochemical
Manufacturers

January 31, 2025

The Honorable Lee Zeldin
Administrator
Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
Mail Code: 1101A

RE: Petition for Reconsideration In Re: New Source Performance Standards for the Synthetic Organic Chemical Manufacturing Industry and National Emission Standards for Hazardous Air Pollutants for the Synthetic Organic Chemical Manufacturing Industry and Group I & II Polymers and Resins Industry (89 Fed. Reg. 42932). Docket ID: EPA-HQ-OAR-2022-0730.

Dear Administrator Zeldin,

The American Chemistry Council (ACC) and the American Fuel & Petrochemical Manufacturers (AFPM) respectfully request that you take expeditious action to provide time-sensitive, critical relief in connection with the provisions of EPA's New Source Performance Standards for the Synthetic Organic Chemical Manufacturing Industry and National Emission Standards for Hazardous Air Pollutants (NESHAP) for the Synthetic Organic Chemical Manufacturing Industry and Group I & II Polymers and Resins Industry, 89 Fed. Reg. 42932 (May 16, 2024) (the "HON rule").

EPA's final rule threatens to jeopardize essential manufacturing capacity and economic production from domestic manufacturers across several states and has already put our member companies in an impossible position with respect to the ability to meet upcoming deadlines while already expending substantial effort and resources to comply with an illegally promulgated rule. Unfortunately, the prior Administration asserted unprecedented authority, ignored relevant science, and failed to consider the significant practical concerns, resulting in a final rule that exceeds the Agency's statutory authority; does not reflect sound science; imposes unnecessary burdens on manufacturers of chemicals critical to public health, welfare, and national security; and that will not provide the benefits on which the rule is premised. Urgent action is needed to protect the economy and avoid significant and irreparable harm from the HON rule, to conform to EPA's statutory authority, and to put in place appropriate, science-based requirements that will protect public health without imposing unnecessary regulatory burdens on domestic manufacturers and the public as a whole.

For these reasons and those explained in more detail below, ACC and AFPM respectfully request that EPA take the following immediate actions. *First*, the Agency should grant reconsideration, acknowledge the fundamental legal and technical flaws with the rule, remove its numerous illegal, ineffectual, and harmful requirements, and replace them with findings based on sound science and that conform to EPA's statutory authority. *Second*, the Agency should take immediate action to (i) stay the rule, (ii) grant alternative relief from the current compliance obligations, or (iii) facilitate appropriate extensions, recognizing that the industry is not able to meet the existing unrealistic deadlines. Forcing massive investments to meet the rule's requirements would be inefficient and inappropriate until the new Administration is given an opportunity to decide which requirements should be maintained, which should be modified, and which should be rejected.

ACC, AFPM, and their member companies are committed to working with EPA and the new Administration to develop appropriate, science-based requirements that protect health and safety without imposing an illegal unnecessary and unreasonable burden on regulated parties. We are confident that if EPA grants reconsideration and evaluates the rule, it will recognize that the rule is fundamentally flawed and that the best course is to grant immediate relief from looming deadlines and undertake a new rulemaking proceeding on an expedited basis that will provide a durable correction of the arbitrary impediments to industry created by the prior Administration.

Indeed, simply reversing the prior Administration's statutory overreach and addressing the unreasonableness of its decision to conduct a second risk review could be implemented swiftly through targeted rulemaking.

We also note that it is imperative that the current Administration prioritize consideration of these issues as the previous Administration recently proposed two additional rules[1] relying on the same suspect legal theories and technical analyses. In some aspects, these proposals use these flawed analyses to go even further than the HON rule. The rules are both subject to consent decree deadlines of December 10, 2025, and January 15, 2026 and they appear to be subject to review under the Regulatory Pause EO.[2]

We would be pleased to discuss any of these issues with you in more detail and to provide any assistance that the new Administration may need as it considers these important issues, which are of the highest priority to ACC, AFPM, and their members.

Sincerely,

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[1] 89 Fed. Reg. 105986. EPA Proposed Review of NESHAP for Polyether Polyols Production Industry. EPA-HQ-OAR-2023-0282. December 27, 2024; 90 Fed. Reg. 7942. EPA Proposed NESHAP: Chemical Manufacturing Area Sources Technology Review. EPA-HQ-OAR-2024-0303. January 22, 2025.

[2] "Regulatory Freeze Pending Review." The White House, The United States Government, 20 Jan. 2025, www.whitehouse.gov/presidential-actions/2025/01/regulatory-freeze-pending-review/.

cc: Aaron Szabo, Senior Advisor to the Administrator, Office of the Administrator
Abbie Tardif, Principal Deputy Assistant Administrator, Office of Air and Radiation
Sean Donahue, Principal Deputy General Counsel, Office of General Counsel
Alex Dominguez, Deputy Assistant Administrator for Mobile Sources, Office of Air and Radiation
Peter Tsirigotis, Director, Office of Air Quality Planning and Standards
Penny Lassiter, Director, Sector Policies and Programs Division, Office of Air Quality Planning and Standards
Patrick Lessard, Refining and Chemicals Group Leader, Office of Air Quality Planning and Standards
Andrew Bouchard, General Engineer, EPA Office of Air Quality Planning and Standards

BEFORE THE ADMINISTRATOR
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

IN RE: NEW SOURCE PERFORMANCE STANDARDS FOR THE SYNTHETIC ORGANIC CHEMICAL MANUFACTURING INDUSTRY AND NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR THE SYNTHETIC ORGANIC CHEMICAL MANUFACTURING INDUSTRY AND GROUP I & II POLYMERS AND RESINS INDUSTRY 89 FED. REG. 42932 (MAY. 16, 2024)	DOCKET NO. EPA-HQ-OAR-2022-0730

PETITION FOR RECONSIDERATION

SUBMITTED BY

THE AMERICAN CHEMISTRY COUNCIL

AMERICAN FUEL & PETROCHEMICAL MANUFACTURERS

The American Chemistry Council (ACC) and American Fuel & Petrochemical Manufacturers (AFPM) petition the United States Environmental Protection Agency (EPA or the Agency) to reconsider the final rule entitled *New Source Performance Standards for the Synthetic Organic Chemical Manufacturing Industry and National Emission Standards for Hazardous Air Pollutants for the Synthetic Organic Chemical Manufacturing Industry and Group I & II Polymers and Resins Industry*, 89 Fed. Reg. 42932 (May 16, 2024) (HON, Final Rule, or SOCMI/P&R I&II) and take appropriate action to stay the rule or otherwise address its significant and immediate implementation concerns.

I. Failure to act expeditiously will result in facility shutdowns and threaten critical supply chains.

In the final rule, EPA imposed new and onerous controls without regard to cost or feasibility for facilities. EPA's decision also imposes a two-year compliance deadline for the most stringent requirements. Those deadlines mean that member companies must take immediate actions to make management decisions, install significant new controls, and potentially undertake substantial facility redesigns later this year into 2026. Those regulations create pressing business and technical issues for our members right now. If EPA's decisions and the implementation of the rule's requirements continue unabated, facility shutdowns to ensure compliance and address potential minor leaks are likely –imperiling jobs and threating a broad set of supply chains.[3]

Member companies have already informed both their state regulatory agencies as well as EPA that they cannot meet the two-year deadline contained in the rule by requesting deadline extensions.[4] These requests have presented, in varying level of detail, the significant challenges associated with compliance with the requirements of the HON rule, difficulties that in some cases have been exacerbated by issues related to the legality of certain control options. In the waning days of the Biden Administration, many, if not all, of these extension requests were denied, which has only created more regulatory uncertainty.

The outgoing Administration's decisions have created a path for which at least some U.S. facility shutdowns appear inevitable if they are forced to comply with the control technology standards and unreasonable deadlines to install controls. Without immediate intervention, companies will likely need to make significant capital expenditures on engineering controls and re-designs and potentially take facilities off-line, all to comply with a rule that is both imprudent and unlawful. As reflected in the facility extension requests, these efforts and expenditures are not likely to be sufficient for many facilities to be in a position to comply.

As a result, companies will likely need to take their operations off-line for an extended period to complete the physical and equipment changes required by the rule. These shutdowns impact not only the EO producers, but because EO derivatives and end products that use EO-based

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[3] The Agency has multiple tools available that it can use directly to provide relief or to help facilitate relief. For example, a stay pending judicial review would be appropriate as there is a high likelihood of success on the merits given the impropriety of promulgating the rule as well as numerous other failings discussed below and because the equities strongly favor member companies and third parties generally given the impossible compliance deadlines and significant disparities in costs and benefits. Section 112 also allows for compliance extensions. With respect to 112(f) extensions, member companies have submitted materials to EPA and the states which they believe demonstrate that the compliance dates cannot be met, While we understand that many of these have been denied we would urge the Agency to revisit the legal interpretation that led to these denials. Alternatively, the Agency could request the President provide national security exemptions based on the submitted materials, appropriately recognizing that national security includes economic security. As discussed herein, the rule threatens numerous critical supply chains. Finally, this submittal and positions presented in the litigation demonstrate the fundamental flaws with the rule. EPA could acknowledge these flaws and undertake an expedited rulemaking process based on the material presented in Section_II as well as the other statutory interpretation flaws noted below. Given the narrow set of issues that would need to be tackled and nature of the flaws, such a rulemaking could be conducted expeditiously. We welcome the opportunity to discuss appropriate relief.

[4] The Final Rule imposed a 90-day compliance deadline on the country's only Neoprene manufacturing facility, which is owned by Denka Performance Elastomer (Denka) and located in LaPlace, Louisiana. This deadline was intended to shut down the facility unless and until Denka could install millions of dollars of new pollution control equipment, but the Louisiana Department of Environmental Quality granted Denka's request for a 21-month extension of the compliance deadline. Were it not for this extension (which EPA is contesting in the Fifth Circuit), the facility would already be shut down. The 90-day deadline, and an unprecedented 2023 lawsuit that EPA brought against DPE under Section 303 of the Clean Air Act, were based on a desire by former EPA Administrator Michael Regan to satisfy the demands of local environmental justice groups--and were not based on an allegation that risks posed by emissions from Denka's facility are higher than those posed emissions from other chemical plants regulated by EPA. Even without the Final Rule, the costs associated with defending itself from EPA's 2023 lawsuit have threatened Denka's viability.

materials are found throughout our economy, such shutdowns threaten multiple supply chains. The outgoing Administration's approach in the HON rulemaking jeopardizes the ability of domestic manufacturing facilities to continue to support these critical, EO-supported supply chains, while the Agency simultaneously ignores the sweeping impacts of these decisions, thus impacting the national security interests of the United States.[5] A few examples include:[6]

> Medical sterilization: for about 20 billion medical devices each year, helping prevent disease and infection for our nation's citizens. EO is also used in the manufacture of numerous other medical supplies and devices. Medical sterilization is independently threatened by a separate rule promulgated by the outgoing administration relying on the same flawed legal theories and science,[7]and, according to the attached information provided by the Ethylene Oxide Sterilizers Association (EOSA), raised significant compliance concerns with that separate rulemaking.[8]
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> Energy Production: EO derivates contribute to securing our nation's energy security through applications in the production of natural gas, which was reiterated and reinforced in the current Administration's January 20, 2025 Executive Order "Unleashing American Energy."[9] The derivatives of EO are leveraged in several key contexts, including natural gas purification to reduce corrosion and scale in oil and gas processing, oil well remediation, enhanced oil recovery aids, gas dehydration, and carbon capture in gas processing, among others. The use of EO-based compounds allows for faster drilling and completion of oil and gas wells, which helps to lower the overall cost of petroleum products and reduce the frequency of replacing equipment and pipelines. These uses contribute to the strength of our

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[5] As President Trump explained in the December 2017 National Security Strategy of the United States of America: "'For the first time, American strategy recognizes that economic security is national security,'"…"'Economic vitality, growth and prosperity at home is absolutely necessary for American power and influence abroad.'" https://www.jcs.mil/Media/News/News-Display/Article/1400686/trump-announces-new-whole-of-government-national-security-strategy/ (visited https://www.jcs.mil/Media/News/News-Display/Article/1400686/trump-announces-new-whole-of-government-national-security-strategy/ and https://trumpwhitehouse.archives.gov/wp-content/uploads/2017/12/NSS-Final-12-18-2017-0905-2.pdf (visited Jan. 29, 2025) (quoting President Donald Trump).

[6] EO is also a primary building block critical to numerous supply chains and industries including agriculture, manufacturing, building and construction, cleaning, and transportation.

[7] National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review, 89 Fed. Reg. 24,090 (April 5, 2024); *see also The Ethylene Oxide Sterilization Association* (EOSA) v. *EPA,* No. 24-1180, Brief of Petitioner EOSA (D.C. Cir.).

[8] *See* Attachment A.

[9] As stated in the Executive Order, domestic energy production "will restore American prosperity…[and] will also rebuild our Nation's economic and military security, which will deliver peace through strength." Further, as the Executive Order explains, any regulatory activity that impedes the development of this production "weak[ens] our national security." Presidential Executive Order "Unleashing American Energy," January 20, 2025. https://www.whitehouse.gov/presidential-actions/2025/01/unleashing-american-energy/.

domestic energy production, boosting both our nation's energy independence and overall security.

Semiconductors: EO plays a major role in the production of a wide variety of solvents, amines, and surfactants that are essential in semiconductor chip manufacturing processes like wafer cutting, chemical mechanical planarization, photoresist, and photoresist residue cleaner. These products target the semiconductor industry's specific needs and are crucial to technologies including aerospace, automotive, cloud computing, medical devices, and telecommunications.

Automotive: EO and its derivatives are also critical for the current automotive industry and are used in applications for automotive seating, hydraulic and brake fluids, anti-icing additives, and antifreeze. It also plays a key role in EV batteries.

Food Processing: EO is used to sterilize dried foods, spices, nuts, fruits, vegetables, herbs and other food products to prevent foodborne illnesses without damaging the spices or food products. It is used to eliminate pathogens like Salmonella and E. coli as well as fungi, yeasts, and spore formers. It is also used as a fumigant to control insects in the storage and transport of grain, seeds, and nuts.

Agriculture: EO derivatives are used in agricultural products to help protect crops and boost crop production. It is used to produce active ingredients in insecticides, pesticides, and herbicides. It is also used to produce surfactants (wetting agents) and dispersants which reduce the amount of pesticides, insecticides, and herbicides required in agriculture and enhances the effectiveness of the application of those products.

II. Immediate action is justified because the rule is infected with significant legal errors.

The most sweeping problem with the HON is also the simplest to solve. The prior Administration based the majority of requirements in the rule on statutory interpretations that have support neither in the text of the Clean Air Act nor in EPA's traditional interpretations of the relevant provisions. Correcting these legal errors does not require significant new factual development and would go a long way toward addressing the most significant problems with the HON rule.

First, EPA adopted an improper interpretation of CAA §112(f)(2) to find that it had authority to conduct a second residual risk review for the SOCMI source category. EPA has long interpreted §112(f)(2) as authorizing only a one-time residual risk review. In this case, EPA previously promulgated MACT standards that apply to SOCMI in 1994[10] and later satisfied its statutory obligation to conduct a residual risk and technology review (RTR) in a subsequent

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[10] 59 Fed. Reg. 19,454.

rulemaking finalized in 2006.[11] Separately, EPA finalized MACT standards for the Group I and II Polymers and Resins Industries in 1995[12] (P&R II) and 1996[13] (P&R I) and completed RTRs for these industries in 2008[14] and (P&R I and II) and 2011[15] (P&R I).

In promulgating the HON, EPA acknowledges that it already performed its residual risk review for the SOCMI source category, but nonetheless the Agency conducts a second review and imposes numerous requirements under this purported authority. In the Final Rule, EPA acknowledges that there is no statutory text explicitly authorizing it to conduct a second risk review. Nonetheless, the Agency asserted that it had inherent authority to update its prior review. As explained in depth in recent briefing before the D.C. Circuit, the statutory text and structure, especially when interpreted applying traditional tools of statutory construction, do not support this view. Rather, interpreted properly, the clear language of §112(f) allows for only a one-time review, which was completed for this category in 2006.[16] EPA cannot avoid this limitation simply by revisiting its prior action.[17]

We note that comment on the rule occurred before the Supreme Court's decision in *Loper Bright.* Accordingly, the Agency did not thoroughly analyze or address if it was adopting the best reading of the statute. Neither the preamble nor the response to comments contain in-depth analysis using traditional tools of statutory construction. For example, EPA did not consider the D.C. Circuit's recent admonition against interpretations that allow for imposition of additional controls since compliance may be "draconian" if not "impossible." And we should not lightly assume that a statute is "draconian," or "demands the impossible." [18] Nor did it consider the Supreme Court's admonition that costs are generally a required consideration unless Congress has expressed otherwise.[19] The answer is clear that had EPA conducted such an analysis, it would have concluded that its interpretation of its authority to conduct a second risk assessment does not reflect the best reading of the statute.

Likewise, EPA did not provide a comprehensive analysis of statutory structure and intent, further underscoring its lack of clear statutory authority to conduct a second review.[20] Accordingly, we request the Agency acknowledge the lack of authority and revoke the final standards

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[11] 71 Fed. Reg. 76,603.
[12] 60 Fed. Reg. 12,670.
[13] 61 Fed. Reg. 46,906.
[14] 73 Fed. Reg. 76,220.
[15] 76 Fed. Reg. 22,566.
[16] 71 Fed. Reg. 76603. EPA Final "National Emission Standards for Organic Hazardous Air Pollutants From the Synthetic Organic Chemical Manufacturing Industry." December 21, 2006.
[17] *See Denka* v. EPA, 24-1135 Opening Brief of Petitioners at 26-35 (D.C. Cir. Jan. 17, 2025) (explaining how neither the structure and legislative history of 112(f) support subsequent risk reviews). We also note that even if EPA could conduct a second review and doing so was not arbitrary, it would first have needed to submit a report to Congress and given Congress a chance to act. *Id.* at 36.
[18] *United States Sugar Corp. v. Env't Prot. Agency*, 113 F.4th 984 (D.C. Cir. 2024) (citations omitted)
[19] *See*, e.g. *Michigan v. EPA*, 576 U.S. 743, 769 (2015) (Kegan, J. dissenting) ("But (absent contrary indication from Congress) an agency must take costs into account in some manner before imposing significant regulatory burdens.")
[20] *See Denka*, Opening Brief of Petitioners at 26-35.

promulgated under this purported authority, and restore EPA's traditional interpretation that CAA §112(f) authorizes only a one-time review and that any additional changes to CAA §112 standards must comport with the requirements for updates under CAA §112(d)(6).

Second, EPA misinterpreted its authority under CAA §112(d)(6). Unlike the one-time residual risk review, this provision allows EPA to "review, and revise as necessary (taking into account developments in practices, processes, and control technologies), emission standards promulgated under this section no less often than every 8 years." But here too the HON rule overreached. While EPA has long recognized that §112(d)(6) requires EPA to take "into account developments in practices, processes, and control technologies" in deciding whether amendment is necessary, as well as the "technical feasibility of requiring the implementation of these developments, along with any impacts (costs, emission reductions, risk reductions, etc.),"[21] the HON rule imposes several requirements that lack any true nexus to a technological development, let alone a development that renders revision necessary. This includes, for example, the HON rule's removal of a valuable and well-established total resource effectiveness ("TRE") compliance tool and the imposition of a fenceline monitoring program for multiple pollutants. As with the §112(f)(2) requirements in the Final Rule, applying the plain text of §112(d)(6) and traditional tools of statutory construction shows that these requirements were beyond the scope of §112(d)(6) and should be removed.

A. EPA Should Act Quickly to Afford Immediate Interim Relief.

While the above action can and should be undertaken promptly to afford material relief, the Agency also has multiple tools available that it can use directly to provide interim relief, or to help facilitate interim relief, from immediate irreparable harm from the HON rule while EPA takes regulatory action or addresses the more detailed issues below. While all of these actions would be justified, we welcome the opportunity to discuss with the Agency what approach is best under these unusual but dire circumstances.

First, a stay pending judicial review is appropriate as there is a high likelihood of success on the merits given the impropriety of promulgating the rule as well as numerous other failings discussed in the petition. A stay is required to avoid the irreparable harm to industry and because the equities strongly favor a stay given the impossible compliance deadlines and significant disparities in costs and benefits, the detrimental impacts to national security and critical supply chains, and the widespread harm to third parties from this ill-advised rule.

Second, §112 also allows for compliance extensions. With respect to §112(i)(3) extensions, member companies have submitted materials to EPA and the states which they believe demonstrate that the compliance dates cannot be met, which may be supplemented by additional member submissions. While we understand that applications have been denied in the final days of the prior Administration, we urge the Agency to revisit the legal interpretation that led to these denials and to

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[21] 75 Fed. Reg. 65,068, 65,083 (Oct. 21, 2010).

instead support States in their necessary work of providing adequate time for compliance.

Third, the Agency should request that the President provide national security exemptions under §112(i)(4) based on the submitted materials, and a recognition that national security includes economic security and protection of domestic production of chemicals vital to public health and the production of so many necessary materials. As discussed herein, the rule threatens numerous critical supply chains and imposes numerous obligations that are not feasible on the current timeline, if at all.

Finally, while this submittal and the positions presented in the litigation cited in this petition demonstrate many fundamental flaws with the rule critical aspects can be corrected through separate expedited regulatory action. Should EPA find that rulemaking providing comprehensive relief will take considerable time, EPA should consider taking initial action on the narrow set of issues for which expeditious rulemaking can proceed.

III. Even if EPA had Authority to Conduct A Second Risk Review, The Agency's Decision To Do So Was Arbitrary.

ACC pointed out in its comments that even if §112 permitted a second risk review, EPA's discretionary decision to conduct a second risk review needed to be grounded in rational decision-making, which would require, among other things, consideration of potential cost and benefits. The Agency did not address this comment but instead focused on a lack of authority to consider cost in conducting the §112(f) review, rather than in deciding if such a review should be conducted.[22]

Assuming that EPA had authority to conduct a second risk review, its decision to do so in the HON does not constitute reasoned decision-making. First, the Agency's reliance on updated values from EPA's Integrated Risk Information System (IRIS) was misplaced. Not only was the EO IRIS value deeply scientifically flawed at its inception, EPA's Office of Research and Development (ORD) has ignored newer information that casts additional doubt on the scientific integrity of the value, or at least suggests greater uncertainty in its risk estimate. Under the benzene NESHAP, which Congress incorporated into §112(f) and thereby helps establish the regulatory framework for these types of rulemakings, such uncertainties cannot be ignored in conducting a review and should be considered in a decision to conduct a review in the first instance. Additionally, the Agency's decision to rely on the IRIS value in a discretionary action is further arbitrary in the context of its continued decision to ignore relevant recommendations of the National Academy of Sciences.

Second, the costs associated with a second risk review so greatly outweigh the benefits that EPA's decision to conduct it was arbitrary. In the final rule, the Agency indicates that for each

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[22] EPA-HQ-OAR-2022-0730-2764. EPA Summary of Public Comments and Responses for New Source Performance Standards for the Synthetic Organic Chemical Manufacturing Industry and National Emission Standards for Hazardous Air Pollutants for the Synthetic Organic Chemical Manufacturing Industry and Group I & II Polymers and Resins Industry. May 16, 2024.

cancer case prevented, the rule imposes $87 million in costs ($87M/cancer case prevented). This calculation of the cost per cancer case prevented is itself unreasonable because the Agency did not properly consider the costs associated with its rule. In reality, the true costs are actually much higher and the benefits in terms of cancer cases prevented are much lower.

1. The Updated IRIS Values Cannot Support a New Risk Review.

EPA's sole stated justification for conducting a new risk review is the existence of updated IRIS values for EO and chloroprene.[23] But simply pointing to a new IRIS value cannot be the basis for conducting a new review. Until recently, EPA has continuously indicated that while IRIS values can help inform decision-making, they should not be themselves used as the basis for regulatory decision-making. This includes explicit statements from OAQPS noting the inappropriateness of using them and statements to Congress in the residual risk report noting that EPA would not be relying solely on them for regulatory decision-making under §112.[24] The same should apply both when deciding if to regulate and how much regulation is appropriate.

Problems with the IRIS value for EO have been evident since it was finalized. Those issues have been in ACC's filing a Data Quality Act petition and by TCEQ launching its own independent analysis of the IRIS value. The inhalation cancer risk assessments for EO conducted by USEPA and TCEQ are based on the same NIOSH study and exposure data. The major reason for differences in cancer estimates is because the two agencies' risk estimates are derived using different statistical dose-response models. Despite several rounds of comments, EPA has either misunderstood the comments, provided a superficial and dismissive response, or relied on reasoning that is clearly contradicted by the technical record. Through this approach, EPA was able to give itself sufficient cover to obtain a favorable decision from the D.C. Circuit on its determinations given that Court's application of an "extreme degree of deference" to EPA.[25]

The D.C. Circuit's decision did not reach the substance or technical integrity of the IRIS value itself. Indeed, the court's decision to defer to EPA does not mean the IRIS value is scientifically sound in any way. As a foundational administrative principle, sound science is critical

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[23] Denka's Neoprene production facility is the only significant emitter of chloroprene in the country and the only facility required to comply with EPA's residual risk standards for chloroprene. Denka's explanation about why the use of that value was flawed is discussed on pp. 1-25 of the Opening Brief of Petitioners Denka Performance Elastomer LLL, the State of Louisiana, and the Louisiana Department of Environmental Quality, Denka v. EPA, 24-1135 (D.C. Cir. Jan. 17, 2025).

[24] EPA specifically assured Congress that it would "not be relying exclusively on IRIS values" but instead would "be considering all credible and readily available assessments." EPA, *Residual Risk Report to Congress,* at 57 (Mar. 1999). *Available at*: https://www.epa.gov/sites/default/files/2013-08/documents/risk_rep.pdf (last visited Aug. 14, 2023); *See also* John Seitz, Director OAQPS, Memorandum Re: Guidance on the Use of Integrated Risk Information System (IRIS) Values To: All OAQPS Personnel (Aug. 26 1994)(" IRIS values are "only a starting point for risk assessment" and "not meant to replace careful thought and analysis necessary" for making regulatory decisions.").

[25] *Huntsman Petrochemical v. EPA*, 114 F.4th 727, 735 (D.C. Cir. 2024). The court did not address the statutory argument that and IRIS value cannot suffice legally for a residual risk determination and provided no substantive response to the arguments that the Court could not ignore the issue in light of *Loper Bright.*

in any regulatory action and especially when that action is completely discretionary. The EO IRIS value is simply not such science and should not be relied upon. We have included with this petition an Attachment B, providing scientific questions which to date the Agency has either not addressed or are raised by EPA's Response to Comments on the HON. We believe that an unbiased appraisal of the issues raised by these question leads to the inexorable conclusion that the IRIS value is not scientifically sound. Given the importance of the issue, it may well be that additional independent peer review[26] of the responses is appropriate, or for that matter reassignment of the matter away from ORD.

Putting aside the scientific failings generally, EPA itself has previously acknowledged uncertainties related to the IRIS value.[27] These uncertainties make using the IRIS value as the sole basis for launching a discretionary review inappropriate (especially when coupled with the other issue discussed below related to overestimation of emissions). Indeed, it is critical to give these facts full and complete consideration before taking any action related to the IRIS value, especially in a potential regulatory context. From a risk management perspective, there is little value in regulatory decision-makers' attempts to manage risks with costly controls and potential shutdowns to address external exposures of EO at levels that are a small fraction of levels all humans endogenously experience.

The following examples help demonstrate the severe technical flaws associated with the IRIS value, contributing to its significant lack of scientific integrity:

> Smoking data: In connection with the MON rulemaking,[28] ACC submitted data from the CDC which clearly demonstrated that smokers are exposed to EO in cigarette smoke at a level where, if EPA's IRIS value was correct, one would expect to see lymphoid cancer at a rate as high as 1-in-10 Americans. Yet, not only does the lymphoid cancer rate fail to reach EPA's absurd 1-in-10 threshold, but lymphoid cancer has not been identified as associated with smoking in the first instance. Rather than accounting for the uncertainty that this data raised, EPA dismissed it out of hand because EPA claimed the estimates of EO exposures in smokers had not been "validated" and thus the ACC-estimated exposures to EO associated with cigarette smoking were not reliable for estimating lymphoid cancer risk.
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> In response, ACC identified robust data published in the scientific literature describing EO concentrations in cigarette smoke that were fully suitable for measurement of total daily smoking related EO exposures and reliable for validation of the model presented

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[26] We would note that the National Academy of Sciences is conducting a review of TCEQs alternative value. EPA ORD provided a presentation to NAS as part of the current review.

[27] *See* National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing Residual Risk and Technology Review, proposed rule 84 Fed. Reg. 69,182, 218 (Dec. 17, 2019); 85 Fed. Reg. at 49,102 (affirming position from the proposal).*Huntsman,* at 742 ("EPA acknowledged that if, as petitioners suggested, there were reliable and high measurements of endogenous and background levels, that would make it more difficult to measure risks from marginal additional exposures").

[28] Petitioners' Brief at 54-61 provides a full history of the presentation of smoker data.

by ACC. The separate smoking analyses independently validated the exposure assumptions based on the prior method that ACC had previously submitted to the Agency. Once again, EPA simply ignored the submittal of this data, this time claiming that no data on EO in cigarette smoke had been submitted, and then claiming that even if it were, additional information would needed because (to paraphrase) "maybe cigarette smoke prevents or cures EO induced lymphoid cancer."[29] Putting aside the prima facie absurdity of the Agency's supposition that cigarette smoke could prevent or cure cancer, the lack of scientific grounding for such a position, and its inconsistency with Agency policy, EPA still failed its obligation to at minimum consider the likelihood of such interactions and the uncertainty created by the smoker data with respect to the validity and accuracy of the IRIS value prior to its launch and finalization of a completely discretionary, sweeping, and precedent-setting regulatory action based in large part on it.

Ambient air concentrations: Throughout the regulatory process ACC has presented ambient concentration data, much of which is EPA's own data, demonstrating that non-facility background ambient EO air concentrations are substantially higher than those described in and relied on in the EPA IRIS (2.4ppt[30] versus 50-70ppt). While acknowledging that if true, the information would be probative, the Agency has consistently and illogically dismissed such submittals on the basis that it does not have the same level of faith in concentrations near facilities compared to those at a distance despite the analytical measurements conducted by identical methods. In response to comments EPA has not provided an analysis to demonstrate that there is a meaningful difference between near- and far-facility analytical determinations, but rather has simply appealed to unsubstantiated uncertainty between these measurements,, even getting the D.C. Circuit to defer to its statement in the MON. EPA's position is, however, contrary to the record evidence which often demonstrates little or no statistical difference between concentrations near industrial facilities and those at a distance. Moreover, this remains the case both under the prior test method and the more recently adopted test method that EPA developed to address the concerns it had with accuracy of the prior test method.[31]

Endogenous levels: Most daily exposure to EO is from our bodies' own metabolism of endogenous ethylene rather than exogenous (external) exposure from inhalation of EO in

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[29] *See* "Summary of Public Comments and Responses for New Source Performance Standards for the Synthetic Organic Chemical Manufacturing Industry and National Emission Standards for Hazardous Air Pollutants for the Synthetic Organic Chemical Manufacturing Industry and Group I & II Polymers and Resins Industry" at 93 ("[c]hemicals in a chemical mixture may have synergistic or antagonistic interactions"). EPA-HQ-OAR-2022-0730-2764. May 16, 2024.

[30] Final IRIS assessment at 4-61 n.43.

[31] Georgia Department of Natural Resources. Cobb Air Quality Monitoring Test Results. https://epd.georgia.gov/cobb-monitoring-results (accessed on 2 August 2024). Georgia Department of Natural Resources. Covington Air Quality Monitoring Test Results. Available online: https://epd.georgia.gov/covington-monitoring-results (accessed on 2 August 2024). Georgia Department of Natural Resources. Fulton County Air Quality Monitoring Test Results. Available

> ambient air (Kirman et al. 2021; ACC comments). As a reality check, TCEQ's 10^{-5} risk specific concentration is approximately equivalent to the concentration of EO in air that would be required to result in EO levels estimated in the body from endogenous (internal) production. In contrast, EPA's risk-specific concentration is a very small fraction (1/1000) of endogenous levels that is not expected to be biologically meaningful. Thus, TCEQ's approach is not only more scientifically and statistically defensible (see Attachment B), but is also more useful for managing risks from exposures (i.e., it is able to discern between biologically meaningful and negligible exposures).

Ultimately, where the Agency's responses to data submitted is "maybe cigarette smoke cures cancer," and "we do not believe our own data," EPA's unquestioning reliance on its prior analysis is arbitrary at best and fundamentally inappropriate for use as the sole basis of a massive new discretionary rule and regulatory campaign.

2. Even if the IRIS value was technically valid, EPA ignored the cost of conducting a second risk review, leading to arbitrary results.

EPA over-estimated the benefits and underestimated the costs of conducting a second risk review. While that action is arbitrary even taking EPA's stated value for the rule, $87 million per cancer case prevented,[32] EPA has vastly understated the costs and overstated the purported benefits of the rule. As described below, the true cost of the rule could readily exceed $2.5 billion per cancer case prevented (even assuming that the IRIS value is not fundamentally flawed).

Those reasons include:

- The $87 million reflects EPA's estimated total cost and total benefits of the rule, not the marginal cost of conducting a risk review. As we explained in our amicus brief filed in the sterilizers litigation, the marginal control cost could readily be 10-times that or more. [33]At

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online: https://epd.georgia.gov/fulton-county-monitoring-results (accessed on 2 August 2024). Georgia Department of Natural Resources. General Coffee State Park Air Quality Monitoring Test Results. Available online: https://epd.georgia.gov/gneral-coffee-monitoring-results (accessed on 2 August 2024). Georgia Department of Natural Resources. South DeKalb Air Quality Monitoring Test Results. Available online: https://epd.georgia.gov/south-dekalb-monitoring-results (accessed on 2 August 2024). Utah Department of Environmental Quality. Ethylene oxide monitoring data from Ambient Monitoring and Health Risk Assessment of Ethylene Oxide Emissions from Commercial sterilizers in Utah provided on September 6, 2024, based on a Request for Public Records.

[32] This figure, $87 million per averted cancer case, is calculated based the equivalent annualized value of the costs associated with the HON Rule which is $130 million using a 7% discount rate as stated in the Regulatory Impact Analysis for the HON (RIA for HON Rule) (Table 1-1, page 8). To determine the cost-effectiveness in terms of cancer incidence reduction, $130 million is divided by 1.6, which represents the EPA estimated annual reduction in cancer cases from 2 to 0.4 per year due to HAPS reductions (1.6 cases per year) "The cancer incidence would be reduced from 2 excess cancer cases per year to 0.4 excess cancer cases per year." (89 Fed. Reg. 42,932, 42,961). This calculation results in $81.25 million (in 2021$) per averted cancer case. This value is adjusted to $87 million (2022$) using GDP deflator data from FRED.

[33] *The Ethylene Oxide Sterilization Association* v. *EPA,* No. 24-1180, Brief of Amicus American Chemistry Council in Support of Petitioner, at 9-10 (D.C. Cir) (Oct. 25, 2024)

10-times[34] the marginal cost would approach a billion dollars cancer case prevented ($870 million dollars).

- EPA has previously acknowledged that the IRIS value could be off by a factor of 3,[35] meaning that the cost per cancer case prevented would be in the range of $87 million to $261 million based on this adjustment alone.

Accordingly, if one were to account for just these two adjustments, the actual costs result in a range between $87 million and $2.61 billion dollars.

EPA more generally overestimated the benefits of the rule and underestimated the costs:

- EPA's modeling overestimated the risks from the source category by:
  - Including cherry-picked and non-representative events for pressure relief devices (PRDs) and process heat exchange systems in the modeling file. EPA's improper inclusion of PRDs generally, and cherry-picking of specific PRD events in particular, created, according to EPA, three quarters of the risk from the facility it determined to be highest risk;[36]
  - Using outdated emissions information from the 2017 National Emissions Inventory (NEI), which failed to account to facility modeling updates, including some that had previously been accepted by EPA in separate regulatory contexts.
- Underestimating the cost of controls (which is not accounted for here).

As presented in Table 1 below, had EPA made these corrections, the alleged cancer incidence would have been cut in half and the cost range would be $170 million to $511 million per cancer case prevented, without accounting for the other potential multipliers discussed above. Applying a 10-times multiplier to account for the marginal cost would mean that the marginal cost of conducting a §112(f) risk review could be as much as $50 billion per cancer case prevented.

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[34] We acknowledge that the 10X multiplayer is speculative but since EPA did not conduct a technology review or discuss marginal cost, let alone consider them, we have made reasonable extrapolations based on the record.

[35] *Id.* at 12 fn.22

[36] It is worth noting generally that both PRDs and heat exchange systems are not continuous emissions, but rather event based, which are short term and timely corrected upon discovery. This contrasts directly with EPA's modeling assumption of exposure of 24 hours/day for 70 years.

Table 1: Cancer Incidence and Associated Cost Based on Corrected Emissions and Risk Uncertainty acknowledged in The HON Rulemaking

Facility EIS ID	EPA modeled Risk	Associated cancer incidence	Low end cancer incidence given acknowledged uncertainties (divide by 3)	Corrected modeled Risk	Associated cancer incidence	Low end cancer incidence given acknowledged uncertainties (divide by 3)
4945211	2000	0.476	0.159	749	0.119	0.039
7202911	700	0.130	0.043	239	0.052	0.017
5846511	600	0.017	0.006	166	0.007	0.002
4941511	500	0.099	0.033	369	0.065	0.021
7445611	400	0.043	0.014	233	0.017	0.006
4926611	200	0.257	0.086	268	0.260	0.087
8467311	200	0.018	0.006	205	0.018	0.006
4057911	200	0.233	0.078	85	0.110	0.037
8465611	100			96		
8468011	100			59		
4945611	100			36		
Total cancer risk		1.273			0.649	
Cost per cancer case prevented in millions		$87	$261		$170	$511

3. EPA still has not adequately responded to concerns regarding its consideration of National Academy of Sciences (NAS) recommendations on IRIS program improvements.

ACC has repeatedly raised concerns with EPA's lack of consideration and response to NAS' 2011 recommendations to improve the IRIS process and EPA's approach to identifying scientific evidence, evaluating that evidence, and integrating the evidence to reach conclusions about the risks to human health from environmental exposures. Generally, the 2011 NAS recommendations highlight EPA's shortcomings across the following areas: (1) lack of transparency and clarity in assessments (e.g., NAS recommended that the exclusion and inclusion of criteria by which studies are selected be clearly articulated in all assessments); (2) misapplication of systematic review (i.e., EPA's IRIS assessments do not integrate different types of scientific evidence in a systematic and balanced way to reach conclusions); (3) IRIS's continued commitment to no safe threshold models (i.e., the "no threshold" hypothesis results in the IRIS program often reaching conclusions that are not consistent with the full body of scientific literature); and lack of peer review (i.e., the final model adopted in the IRIS assessment was not peer-reviewed).[37] Although these recommendations were available, EPA did not incorporate the NAS' long-term recommendations into the IRIS assessment of EO despite the assessment ultimately being finalized in 2016, well after the NAS completed its review in 2014. The recommendations speak directly to many of the flaws associated with EPA's IRIS value for EO. However, despite multiple rounds of review and comment in different regulatory contexts, EPA has still refused to meaningfully consider the recommendations themselves or respond to associated stakeholder concerns.

EPA continued to dismiss these concerns in its December 2022 summary and response to comment document that supported the final MON reconsideration rulemaking.[38] In that document, EPA acknowledged ACC's concerns as raised in comments on the proposed MON rulemaking and reconsideration that the Agency had not fully addressed the NAS recommendations or paused the use of the flawed EO IRIS value to properly apply them and address its critical shortcomings. However, instead of providing a thoughtful response, EPA simply referred to its prior response on the MON and its over-simplified, dismissive retort that the NAS recommendations only referred to "the IRIS program" generally and somehow not on the EO IRIS value, which is a key piece of that program.[39] EPA's response is informed by its illusory distinction between the IRIS program more broadly and the specific values it generates. Indeed, EPA's responses to date ignore its initial acknowledgement that the recommendations were relevant, but according to the Agency, simply came too late to be addressed in the IRIS development process.[40]

To date, EPA continues to ignore the NAS recommendations with respect to the EO IRIS value. In the absence of proper consideration of these important fixes, EPA should pause any current or pending future regulatory activity informed by the EO IRIS value.

IV. Additional Flaws with EPA's Second Residual Risk Review

As demonstrated in section I above, EPA exceeded its legal authority under the CAA in conducting a second risk review as part of this rulemaking, an arbitrary decision that EPA itself acknowledges is not explicitly authorized by the clear language of the CAA. Even if this is not corrected, however, as discussed in section II above, EPA's decision to conduct a second residual risk review was flawed in numerous ways, from the failure to consider necessary factors such as cost to the improper application of EPA's IRIS value, for which both previous judicial and agency review have not meaningfully assessed or responded to the significant technical flaws, to improper

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[37] National Research Council, Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde (2011). Available at https://download.nap.edu/catalog.php?record_id=13142 (last visited January 31, 2025).

[38] EPA-HQ-OAR-2018-0746-0327. Summary of Public Comments and Responses for the Reconsideration of the 2020 National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing Residual Risk and Technology Review. December 21, 2022.

[39] Ibid at 14.

[40] 2016 EO IRIS assessment at K-1.

use of the data in the administrative record. For the reasons outlined above, we respectfully request that EPA take action to provide expeditious relief and act to revoke the standards promulgated under §112(f).

Given the significance of this issue, however, and the large number of flaws with EPA's second risk review, we also providing in this section III several critical corrections to EPA's risk review in the event EPA both concludes that it has authority to conduct a second residual risk review *and* that a second residual risk review is justified by the record.

Further, if the Agency concludes, properly, that regulation under §112(f) is not appropriate, but that some future amendment under §112(d) is justified, the discussion of §112(f) related issues in this section may also help inform discussions related to the appropriate standards. In that event, we request an opportunity to discuss these issues with the Agency to identify viable paths for resolution.

1. EPA's risk-based standards were not properly tailored to addressing perceived risk.

EPA has developed a two-step process for assessing risk under §112(f). At step one, EPA determines whether emissions from the source category pose "unacceptable risk" without regard to cost. Second, EPA determines what level of risk will provide an "ample margin of safety," considering cost, technical feasibility, adverse environmental impacts, and other factors. In the HON, EPA misapplies this process to the setting of standards to address the risk. The result is that EPA imposed standards to address a risk purportedly found at step 1 without considering the cost, feasibility, or even adverse environmental impacts of the *standards* it was imposing. This misreads the Clean Air Act and applicable case law and should be corrected on reconsideration.

Further, we have previously explained that no matter which level of risk addressed by EPA, it has a statutory duty to direct controls to the identified risk; in other words, to the facilities and emissions that are causing an unacceptable risk or that are interfering with an ample margin of safety.

In the HON, EPA imposes nationally uniform standards purportedly to address an unacceptable risk under step one. This does not tailor the level of control that EPA imposed to only that needed to address the unacceptable risk and resulted in the imposition of significant burdens on many more facilities and emission units than needed to address the identified risk. If EPA wants to impose control on additional units, or impose additional controls as needed to provide for an "ample margin of safety" it must justify those additional controls on the record.[41] EPA has not done so here.

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[41] *Denka*, Petitioners Brief at 37-47.

We therefore request that on reconsideration, even if §112(f)(2) standards remain, that they be tailored to the emissions that EPA finds create an unacceptable risk.

2. Revisions to the Risk Model

The accuracy of risk modeling is relevant to both the question of whether to conduct a new review (discussed above) and what standards should look like if a review were conducted. Accurate modeling is needed to determine from which sources and units emission reductions are necessary to achieve acceptable risk.

As explained in our July 2023 comments on the proposed rulemaking, EPA should have revised the emissions data used in its risk modeling file to inform the risk analysis portions of the rulemaking. Petitioners disagree with EPA's decision to reject updated emissions data provided by facilities to reflect current operations and improvements to emissions controls and emissions estimation methodologies since reporting year 2017 (the basis of emissions estimates used in EPA's risk modeling). As described below, ACC did not have an opportunity to comment on EPA's rationale to use fenceline monitoring data as the basis for rejecting necessary updates to the emissions data. Additionally, EPA changed the standard that it used to decide whether to accept or reject updated data without providing notice that it would do so providing even more reason that the Administration should be concerned about the final rule and go back to the drawing board.

We provided several examples of updated emissions data in our comments; however, EPA rejected these updates wholesale and stated:

> *...due to insufficient information when numbers were updated without a clear or substantive explanation of why emissions changed and where EPA could not fully verify the changes.*[42]

EPA based this decision on its judgment that commenters did not provide sufficient explanation and documentation supporting the suggested changes (e.g., detailed calculations, stack test reports, etc.). We note that although reporting year 2017 (RY2017) may have been a reasonable place for EPA to start compiling the information for the risk modeling file, essentially all regulated facilities provide **annual** emissions inventories to their state and/or local air pollution control agencies. Thus, more recent emissions data, which are updated annually, would be available for EPA's use in this rulemaking.

Since emissions data are updated annually and these programs allow industry to provide corrections for any given year, EPA should have used more recent information and incorporated updated emissions data provided by industrial sources for RY2017 or subsequent years. Also, the use of RY2017 emissions data does not account for emission reductions that industrial sources made after year 2017 when the rule was proposed in 2023: the types of changes that in previous rulemakings EPA has stated represent the best available data. Notably, this emissions information

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[42] 89 Fed. Reg. 42,965.

would not account for any changes or updates made to several facilities' processes and emissions controls to address ethylene oxide after EPA's finalization of the IRIS risk value for EO in 2018. This fact is particularly concerning as EPA has considered similar updates to emissions information on a comparable basis in prior rulemakings. Nor does it reflect efforts to collect more refined EO related emissions information after facilities became aware of EPA's concerns related to EO with the release of the 2017 National Air Toxics Assessment (NATA).

For example, in 2020, Huntsman Corporation (Huntsman) submitted comments[43] to EPA regarding the National Emissions Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing Residual Risk and Technology Review proposed rule[44] (the MON). In their comments, Huntsman provided updated emissions rates for EO from direct monitoring conducted in 2019 of all relevant MON valves, pumps, and connections. Part of that monitoring included removing insulation from components to allow direct monitoring and replacing previously estimated values with the results. The data provided by Huntsman included a description of the changes and revised emissions rates. EPA incorporated these changes into the risk assessment for the final MON while stating:

> *The EPA believes that the updated data represents the best available data because* ***it is more recent (i.e., 2019), is based on actual emissions measurements, reflects recent physical and operating changes made to the process since the 2014 NEI emissions were reported,*** *and conservatively considers results below the detection limit as being present at the detection limit.*[45]

However, in the final SOCMI/P&R I&II rulemaking, EPA rejected similar submissions, even when Huntsman provided the same level of supporting documentation, including several updated emissions rates for fugitive components based on actual monitoring data, just as they provided – and EPA later accepted -- in the MON rulemaking.[46] That EPA was going to change the standard by which it evaluated information was one for which commenters had no notice.

Moreover, similar additional documentation was provided for multiple facilities. For example, in the case of corrections for Facility 7445611, Attachment 3 of our July 2023 comments included air permitting documentation supporting lower emissions rates than those used by EPA. EPA's response does not address why revised permitted emissions rates are an insufficient basis for revisions to the model especially since they limited the legally allowed emissions.

Petitioners are also aware that Facility 4941511 had previously provided EPA with information related to emissions updates beyond the information presented by the Agency in the

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[43] EPA-HQ-OAR-2018-0746-0073.
[44] 84 Fed. Reg. 69,182.
[45] EPA-HQ-OAR-2018-0746-0189, emphasis added.
[46] EPA-HQ-OAR-2022-0730-0097, Appendix S (Huntsman [SPB 6-27-2022] Attorney Client -NEI Review Supplement 06012022 V2.pdf).

rulemaking docket.[47] Facility representatives indicate that they provided detailed heat exchange system monitoring data and emissions calculations supporting revisions prior to the proposed rulemaking, which is exactly the type of data EPA claims it did not have in order to verify and incorporate revisions.[48] We are aware that facility representatives are resubmitting these data along with additional information supporting emissions revisions in conjunction with this petition under separate cover to EPA.

As an additional rationale for rejecting revisions, EPA indicates that:

> *...in many cases we also rejected corrections listed by commenters related to pollutants that drive cancer risks for HON (i.e., EtO) and neoprene production sources (i.e., chloroprene) given that we contend, based on the fenceline data, that the modeling file emissions for these pollutants are underestimated.*[49]

As a preliminary point, EPA did not indicate at proposal that it would be considering fenceline data as a factor in its consideration of whether to accept or reject emissions information updates. Accordingly, we did not have an opportunity to comment on EPA's approach, resulting in a procedural defect that arose in the final rule. As a procedural defect, this lack of comment opportunity on EPA's rationale for considering revisions warrants mandatory reconsideration on this issue under CAA 307(d).

Additionally, EPA does not specifically indicate which emissions updates they rejected based on this reasoning; however, after further review of EPA's monitor-to-model analysis, Petitioners disagree with EPA's assertion. We re-assessed EPA's monitor-to-model ratio for EO presented in Table 6 of the memorandum titled "Clean Air Act Section 112(d)(6) Technology Review for Fenceline Monitoring located in the SOCMI Source Category that are Associated with Processes Subject to HON and for Fenceline Monitoring that are Associated with Processes Subject to Group I Polymers and Resins NESHAP,"[50] to account for pollutant background levels. Despite EPA's claim to the contrary,[51] accounting for background resulted in a monitor-to-model ratio of less than one for multiple facilities, including Facility 4941511 which EPA identified as a risk driver for equipment leaks. We accounted for background levels by subtracting the lowest reported concentration value for each sampling period from the remaining values in the sampling period.

EPA's reliance on its monitor-to-model ratio is also questionable considering previous studies on background EO concentrations. As we noted in comments on the proposed rule, background concentrations of EO are significant when compared to EPA's fenceline monitoring

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[47] EPA-HQ-OAR-2022-0730-0097, Appendix S.

[48] Refer to email from Steve Gossett to Brenda Shine and Jennifer Caparoso dated February 25, 2019.

[49] 89 Fed. Reg. 42,965.

[50] EPA-HQ-OAR-2022-0730-0091.

[51] EPA-HQ-OAR-2022-0730-2764, pg 294 "While the commenter is correct in stating that the modeled values presented in these tables do not consider background pollutant concentration or the method detection limits, inclusion of either or both would not change the conclusions drawn by the exercise."

action level and can vary over time. For example, our analysis of EO concentration data from EPA's Ambient Monitoring Archive for Hazardous Air Pollutants for South DeKalb, GA[52] revealed background concentrations ranging from a low of 0.10 $\mu g/m^3$ to a high of 3.7 $\mu g/m^3$. We also noted that the monthly difference between the highest and lowest reported concentration value ranged from 0.22 $\mu g/m^3$ to 3.2 $\mu g/m^3$, with an average monthly difference of 0.88 $\mu g/m^3$.

Additionally, background concentration data collected by the West Virginia Department of Environmental Protection (WVDEP) tells a similar story. The Department collected background concentration data in Guthrie and Buffalo, West Virginia. From January to July 2022, 11 background measurements were made in Guthrie that ranged from 0.059 µg/m3 to 1.74 µg/m3. From April to July of 2022, background concentration measurements at the Buffalo sample location ranged from 0.20 µg/m3 to 1.31 µg/m3.[53] The average EO monitor concentrations presented in EPA's Table 6 are below the range of background concentrations in both West Virginia and Georgia for all but one of the listed facilities making conclusions that rely on the average monitor concentration presented in Table 6 unreliable.

EPA's reliance on monitor-to-model comparisons should be viewed with uncertainty for additional reasons. The Agency's analysis compares long-term (i.e., annual) modeled average concentrations to the average of 7 to 10 sampling events all performed in a similar time frame (e.g., weeks to months). EPA's comparison does not consider the inherent uncertainty associated with the derivation of each value. First, some of the monitoring data used in the comparison were collected using Method TO-15 to which EPA attributes "precision issues" [54] possibly skewing the results. Second, a set of seven to ten 24-hour measurements is not an adequate sample size compared to an annual average of 8,760 model-predicted concentrations (for comparison, EPA exhibits concern about the representativeness of 52 samples vs. 73 samples in its rejection of commenters request to perform canister sampling every 7 instead of every 5 days).[55] Third, model concentration results are based on steady-state emissions with no accounting for local meteorology (only the nearest National Weather Service site), building downwash, or off-site/unknown sources of emissions. EPA's analysis of monitor and model results for lead (Pb) in Attachment A to the risk assessment background document acknowledges these influences where 4 of 6 monitors exhibited higher annual average concentrations than model predictions.[56] Finally, it should also be noted that EPA bases its risk estimate in part on leaks, which are necessarily variable and likely already addressed by a facility's best available control technology (BACT) program for LDAR. This approach also does not properly account for material factors, including meteorological issues

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[52] Available: https://www.epa.gov/amtic/amtic-ambient-monitoring-archive-haps. We analyzed data for AMA site code 130890002.

[53] *See* West Virginia Department of Environmental Protection. Ethylene Oxide Monitoring – Characterization of South Charleston and Institute, West Virginia and Surrounding Areas. February 21, 2023. Available: https://dep.wv.gov/key-issues/Documents/EO/Final%20Report/Final%20Report%20Body%202-21-2023.pdf

[54] EPA-HQ-OAR-2022-0730-2764, pg. 274

[55] Id., pg. 262

[56] EPA-HQ-OAR-2022-0730-2807, Attachment A, Table 2, pg. A-4.

like wind, which shifts considerably over a 24-hour period, or the fact that some of the measured concentrations of EO do not originate from the HON facility. The full scope of these challenges are further exacerbated by EPA's considerably small sample size.

Despite the uncertainties described above, we also investigated potential reasons for elevated monitor-to-model ratios at the facilities. In the case of Facility 5633411, we determined the reason for the high EO ratio was most likely that the modeling was based on 2017 emissions which did not include contributions from a yet-to-be constructed ethylene glycol unit. Emissions from this ethylene glycol were captured in the monitoring performed in response to the ICR. Thus, EPA's average model concentration would have most likely included zeros or very low concentration values for the monitors located in proximity to the ethylene glycol unit, significantly skewing the comparison to the measured values.

Additionally, EPA's monitor-to-model analysis also did not appear to account for emissions from sources within a facility fenceline that are not owned or operated by the facility. For example, EPA's Table indicates a monitor-to-model ratio of 1,033 for ethylene dichloride (EDC) at Facility 8467311; however, the company identified in EPA's Table 6 only emits 0.3% of the total EDC emissions at the site. Over 99% of the site-wide EDC emissions are attributable to another company (17640911) within Facility 8467311's fenceline: emissions that were likely measured by monitors, but likely not included in EPA's modeling analysis and monitor-to-model ratio. Given the above, EPA's reliance on a small sample set of fenceline monitoring data as justification to reject the use of the best available emissions data is unwarranted and should be reconsidered.

Further, in some cases, additional documentation such as detailed calculations and stack test reports simply would not have been warranted. Our comments explained that companies identified multiple sources that are not part of the affected source category but that were included in the source category modeling file. For example, we noted that facility 8468011 had previously indicated to EPA that sources CEDH0076 and CEDN0137 were not subject to the HON, yet EPA continued to include these sources in the source category risk modeling input files.[57] It is unclear from EPA's response to comment what additional rationale is needed to exclude non-affected sources from the source category modeling file.

There are further practical issues that highlight the technical feasibility issues associated with EPA's final EO action levels in the fenceline program as supported by real-world facility experience and data. For example, one ACC member conducted fenceline air monitoring at a facility location in May 2024 to collect information about EO concentrations on site. The data from the facility's monitoring, presented to EPA directly in August 2024, found that even when the facility had no EO on site, the delta C was still well above EPA's action level of 0.2 $\mu g/m^3$ for EO. Perhaps just as concerningly, the monitoring data showed that the difference in concentrations

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[57] EPA-HQ-OAR-2022-0730-2807.

between one sample and a duplicate at the exact same location was greater than 0.2 μg/m^3, again somehow above the final rule's action level for EO despite having no EO onsite.

Petitioners remain concerned with EPA's inclusion of startup, shutdown, and malfunction (SSM) events in its voluntary risk analysis.[58] As stated in our comments, and acknowledged by EPA, the Agency is statutorily obligated to address startup, shutdown, and malfunction (SSM) events, including pressure relief device (PRD) releases, in standards established under CAA Section 112(d)(2) and (d)(3); thus, the Agency should have excluded such events from the risk assessment or at least evaluated the risk remaining after implementation of §112(d)(2)/(d)(3) standards. As noted by the Agency "Section 112(f) of the CAA requires the EPA to assess the risk to public health remaining *after* the implementation of MACT emissions standards promulgated under CAA section 112(d)(2)"[59] [emphasis added]. But contrary to this requirement, EPA evaluated risk from PRDs prior to implementation of the §112(d)(2) standards established as part of the rulemaking[60] that will undoubtedly reduce emissions of EO through monitoring, root cause analysis, and completion of corrective actions. Therefore, to adhere to the plain language of CAA Section 112(f), we request EPA reconsider the risk model inputs used as the justification for standards to address risk in the final rule by accounting for the emissions reductions expected as a result of the concurrent §112(d)(2)/(d)(3) requirements established as part of the rulemaking, that is the work practices.

We reiterate that it is inappropriate to model emissions from PRD events as if they occur constantly, over a period of 70 years, whereas in reality, the emissions are infrequent and of short duration. As EPA states in the preamble to the final rule:

> *...it is not generally possible to model malfunctions in the risk assessment, because by nature they are infrequent and unpredictable, and we generally have insufficient information to model these types of events.*[61]

Other than asserting that the event that EPA is modeling here is somehow different, EPA does not explain in what way it is meaningfully different from other malfunction events that EPA regularly declines to model because of their unpredictability. As part of their comments, Indorama indicated that the releases were unanticipated events, outside of facility control, caused by unusual freezing weather, power surges and loss of power. Indorama also pointed out that EPA's position declining to model or include such events in the risk modeling has been upheld by the courts:

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[58] For further discussion regarding the inappropriateness of including this PRD release see *Denka*, Petitioners Brief at 65-70.

[59] 88 Fed. Reg. 25,083.

[60] As described in more detail in Section II.E of this petition, EPA established work practice standards for PRDs in organic HAP (OHAP) service [see §63.165(e)]. To comply with these standards, facilities must monitor PRDs to detect releases to the atmosphere. Facilities must also implement redundant release prevention measures and conduct root cause analyses and complete corrective actions for any releases.

[61] 89 Fed. Reg. 42,966.

> *The D.C. Circuit Court of Appeals has also ruled that malfunction emissions have no proper role in setting standards under CAA § 112. U.S. Sugar Corporation v. EPA, 830 F.3d 579, 606-610 (D.C. Cir. 2016). In briefing before the U.S. Sugar court, EPA explained that there are practical reasons not to consider malfunctions in setting MACT standards: "Virtually no malfunction is foreseeable in terms of its nature, timing or effect on emission levels," making it "wholly impracticable for EPA to factor unforeseeable, random malfunction incidents into emissions standards." Respondent's Brief, Case No. 11-1108, Doc. No. 1521657 at 38, 41.*[62]

Contrary to EPA's stated position and court opinion, the Agency included "emissions from one single PRD release"[63] in the risk modeling as if the release was not unforeseeable and random, but rather as if it occurred continuously, over a period of several years. EPA's treatment of the PRD release ignores the steps taken by both the facility and their electric utility to improve the reliability of the process operation and the incoming power supply to reduce the incidence and duration of such potential releases.

EPA also indicates that it chose to include and model PRD releases from one facility that is subject to an enforcement action since the releases did not constitute a violation. The releases, however, constituted permit exceedances of permit requirements, which is supported by comments submitted by Indorama Ventures Oxides LLC (Indorama) noting that the PRD emissions included in EPA's risk modeling are subject to an enforcement action by the Texas Attorney General (AG).[64] In that complaint, the Texas AG alleges that the PRD release clearly violated Indorama's NSR permits. As the release was in violation of applicable requirements, it should not have been included in the risk modeling.

Similarly, EPA's treatment of emissions from a single heat exchange system leak at facility 5846511 is also a mischaracterization of emissions that do not contribute to a lifetime of exposure. EPA states that the heat exchanger system leak in question was included in the model "for the same reasons"[65] PRD releases were included, presumably because the Agency's model indicated elevated risk. But for EPA's premise to be true, the one-time emissions from the leaking heat exchanger would have to occur over a long period of time (e.g., decades), which, as indicated in our comments,[66] is not the case. Contrary to the Agency's assertion, EPA has taken an infrequent and, in fact, a one-time event and artificially modeled it as a continuous and regularly occurring source of emissions by assuming that such emissions would occur over a lifetime.

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[62] EPA-HQ-OAR-2022-0730-0152, pg. 16.

[63] 89 Fed. Reg. 42,966.

[64] EPA-HQ-OAR-2022-0730-0152, pg. 16. See also *Texas v. Huntsman Petrochemical, L.L.C.,* District Court of Texas, 419th Judicial District, Travis County, No, D-1-GN-21-003481, at ¶¶5.21-5.31 7.3 (reciting 2018 emissions events alleged to be in violation of the standards and seeking civil penalties).

[65] EPA-HQ-OAR-2022-0730-2764, pg. 7.

[66] As stated in our comments, the facility reviewed records from 2016 to 2020 and noted no other heat exchange system leaks of EO.

We reiterate that EPA's treatment of PRD and heat exchange system releases is inconsistent with the intent of CAA Section 112(f), inconsistent with EPA's standardized approach for assessing risk, and a misrepresentation of facility emissions over a 70-year lifetime. Additionally, EPA has improperly decided not to update their modeling inputs to reflect the best available data, even where reasonable justification for such updates was provided to the Agency. As such, we request EPA reconsider the inputs used to form the basis of the risk modeling file, the resulting changes to the risk assessment results, and the standards based on those results as detailed later in this petition.

3. Revisions to the Analysis Used to Determine "In Ethylene Oxide Service"

We are also concerned by EPA's response to our recommended changes to the definitions of "in ethylene oxide service" for process vents, storage tanks, equipment, heat exchange systems, and wastewater. Sections 4.2 through 4.5 of our comments suggested alternative definitions based on our review of available data during the comment period that are commensurate with the risk EPA contends is associated with the given concentration and mass emissions rate levels. For each emissions source category, EPA rejected our proposed alternative definition stating, for example, that:

> *...we consider the [threshold] reasonable in terms of being measurable and quantifiable, and also appropriate for the vent stream characteristics we intended to regulate that resulted in risk reductions. We acknowledge that every facility is different. Some facilities may pose less risks than others, but in a densely populated area with a nearby receptor and under specific conditions, the risks could none-the-less be unacceptable. In order to be protective of public health, we took a conservative approach.*[67]

EPA further supported their rejection by stating:

> *...in codifying the Benzene NESHAP approach CAA section 112(f)(2) does not allow us to consider cost at the first step of the residual risk analysis in identifying what standards are needed to reduce unacceptable risk to an acceptable level, and at proposal, and in the final rule, we determined that prior to application of the control requirements being finalized, the risk was unacceptable. It is only if the EPA adopts more stringent standards to further reduce emissions and reduce risks below acceptable levels if needed to provide an ample margin of safety to protect public health, at the second step of the residual risk analysis, that costs may be considered among other relevant factors.*

In its response, EPA takes the position that the definitions for "in ethylene oxide service" are the only reasonable "first-options" in controlling emissions of EO (which they are not). By pointing to an ambiguous, hypothetical future scenario, EPA's response rejects that alternative,

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[67] 89 Fed. Reg. 42,972. See similar responses for equipment leaks at 89 Fed. Reg. 42,975, and heat exchange systems at 89 Fed. Reg. 42,977.

less stringent definitions for "in ethylene oxide service" can achieve acceptable risk. If EPA wants to go further, it needs to justify such under the ample margin of safety, which would require consideration of cost. We have explained elsewhere why such "overcontrol" is not consistent with the statute.[68].

As demonstrated in our comments, EPA's overly conservative control threshold is not the only option to reduce risks to acceptable levels. For example, for equipment leaks, we explained that equipment containing less than 5 wt% EO does not significantly contribute to risk. As shown in the table below, the maximum contribution to risk from equipment leaks from equipment with an EO concentration of less than 5% is 9.2% (percentage calculations based on the Microsoft Excel worksheet titled "Equipment Leaks" in Attachment 4 of July 2023 comments).

Facility ID	**Percent of Risk from Equipment with <5% and ≥5% EO**	
	< 5% EO	**≥ 5%EO**
4945211	0.31%	99.5%
7202911	Undetermined percentage of equipment service processes with EO <5%, though majority of emissions are from process areas with 100% EO.	
5846511	Undetermined percentage of equipment service processes with EO <5%, though majority of emissions are from process areas with 100% EO.	
4941511	9.2%	91%
7445611	0.02%	99.98%
4926611	(No equipment serving processes with <5% EO)	100%
8467311	(No equipment serving processes with <5% EO)	100%

A review of storage tanks provides a similar conclusion. As explained in our comments, risk from storage tank EO emissions is driven by pressurized storage spheres containing 100% EO, and EPA had not adequately demonstrated that control of additional units beyond such storage spheres was necessary to address unacceptable risk. EPA again pointed to an undefined

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[68] *See Denka*, Petitioners Brief at 37-47.

hypothetical scenario in its explanation of why it is necessary to control additional units instead of determining the proper control threshold to address unacceptable risk.[69]

Wastewater streams provide another example. As explained in our comments, setting the "in ethylene oxide service" threshold at 1 ppmw is not required to address the larger Group 2 process wastewater streams. As noted in our comments decreasing the threshold from 27 ppmw to 1 ppmw will only result in 1% additional emission reductions (corresponding to an average reduction in MIR of approximately 5% across the 6 facilities included in our analysis) but will significantly increase the complexity of projects and costs of compliance. Thus, EPA could have set the threshold at a level of 25 ppmw and achieved essentially the same level of emissions and subsequent risk reduction. Alternatively, EPA could consider adding needed flexibility through the inclusion of a mass-based threshold for wastewater control applicability. For example, elsewhere in the HON and in other rules, EPA includes an exemption for smaller wastewater streams with total mass flowrates of <1 mg/yr. In these rules, the Agency appropriately recognizes that control requirements for smaller streams would not yield any significant emissions reduction and environmental benefit, and thus would not be necessary.[70]

EPA's conservatism is also unwarranted considering our revised assessment of the fenceline monitoring data as described earlier in Section II.A of this petition. Based on our revised analysis, one of the facilities that EPA identified as a driver of risk from emissions of EO from equipment leaks has a monitor-to-model ratio of less than 1 when accounting for background. The other facility identified by EPA as a risk driver for equipment leaks has a monitor to model ratio of 1.65 instead of 3.3. We request that EPA reconsider the finalized definitions for "in ethylene oxide service" for all sources of EO emissions and work with regulated entities to determine appropriate thresholds that address unacceptable risk without unnecessary burden for sources that have negligible contributions to risk.

V. The Fenceline Monitoring Provisions Should be Removed or Alternatively Corrected.

We have previously explained that EPA failed to comply with the requirements of §112(d) in imposing fenceline monitoring requirements. For example, EPA has not:

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[69] 89 Fed. Reg. 42,973.

[70] *See* 40 CFR 63.138(i)(2) which provides that (emphasis added) "Untreated and partially treated Group 1 wastewater streams. The owner or operator shall demonstrate that the total source mass flow rate for untreated Group 1 wastewater streams and Group 1 wastewater streams treated to levels less stringent than required in paragraph (b) or (c) of this section is **less than 1 megagram per year** using the procedures in paragraphs (i)(2)(i) and (i)(2)(ii) of this section. The owner or operator shall manage these wastewater streams in accordance with paragraph (i)(2)(iii) of this section, and shall comply with paragraph (i)(3) of this section;" *See also* 40 CFR 61.342(c)(3)(ii)(B) Benzene Waste Operations NESHAP, providing "The total annual benzene quantity in all waste streams chosen for exemption in paragraph (c)(3)(ii) of this section does not exceed 2.0 Mg/yr (2.2 ton/yr) as determined in the procedures in § 61.355(j)."

- Adequately explained why fenceline monitoring is a development—let alone a development that renders revision necessary— within the meaning of §112(d), which it is not.
- Failed to account for all costs associated with fenceline monitoring (corrective action is not accounted for) and balance emission reductions, if any, with the full cost of the rule.
- Imposed requirements on units that are not in the regulated source category
- Imposed work practices on units that are subject to emission standards in contravention of §112(h)'s limitation.
- Imposed an ambient air quality standard that is not authorized by CAA §112. [71]

For these reasons, the fenceline monitoring provisions should be removed in their entirety. To the extent EPA retains a fenceline monitoring requirement, however, several aspects of the program implemented in the HON should be reconsidered.

1. Applicability

In our July 2023 comments, we asked EPA to clarify the applicability of the fenceline monitoring provisions for several reasons, including ambiguity regarding the use of the words "site" and "facility" and the need to specify a minimum threshold for "uses, produces, stores, or emits." EPA finalized the applicability criteria for fenceline monitoring of the six target analytes (benzene, 1,3-butadiene, chloroprene, ethylene dichloride, EO, and vinyl chloride) at §63.184(a)(1) and (b)(1). EPA partially addressed the comment by replacing the word "site" with "affected source," such that fenceline monitoring is required "if an affected source uses, produces, stores, or emits" any of the six compounds. While this provides some additional clarity regarding the applicability of the fenceline monitoring provisions, significant uncertainty remains. As indicated in our comments and further explained in Appendix 1 to this petition, the lack of a de minimis threshold for use, produce, store, or emit will result in confusion from both regulators and the regulated community when determining whether the fenceline monitoring requirements are applicable in a specific scenario. We appreciate that EPA attempted to address the concern through the following response at 89 Fed. Reg. 43,006:

> *For the HON, only those sources manufacturing as a primary product one or more of the chemicals in Table 1 to NESHAP subpart F, or tetrahydrobenzaldehyde, or crotonaldehyde; or using as a reactant or manufacturing as a product, or coproduct, one or more of the HAP listed in Table 2 to NESHAP subpart F are subject to the provisions. For NESHAP subpart I, only those emissions specified from the processes subject to 40 CFR 63.190(b)(1) through (6) are subject to the fenceline provisions. Therefore, any concerns about obligations to meet fenceline monitoring requirements for pollutants developed as impurities or found in*

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[71] *See Denka*, Petitioners Brief at 79-85, 86-90.

> *feedstock in trace amounts are unfounded, as these materials are not ''products,'' which, by definition, exclude by-products, isolated intermediates, impurities, wastes, and trace contaminants per the definition at 40 CFR 63.101 or, in the case of NESHAP subpart I, are not the specified pollutants from the processes to which the subpart applies. For P&R I sources subject to NESHAP subpart U, we note that the fenceline monitoring requirements reference 40 CFR 63.101 and the same logic can be applied.*
>
> *To the commenter's assertion about emissions from boilers, housekeeping, building maintenance, or lab and research activities triggering fenceline monitoring requirements, we note that these are not considered within SOCMI or P&R I sources per the applicability of the term at 40 CFR 63.100. Thus, there would be no need to implement fenceline monitoring if these are the only sources emitting benzene, 1,3 butadiene, ethylene dichloride, vinyl chloride, EtO, or chloroprene at a facility. Therefore, for the reasons previously stated, there is no need to set a minimum threshold for fenceline monitoring as the rule already provides criteria targeting only SOCMI or P&R I sources using, producing, storing, or emitting one or more of the six considered pollutants and will not be triggered by low-level emissions from non-source category processes.*

By referencing back to the definition of "product" in §63.101 and directly addressing impurities found in trace amounts in feedstock, EPA has provided some clarification as to what was meant by the term "produce." However, the response does not explicitly address the remaining terms, leaving the reader to interpret EPA's intent behind the use of the words "uses or stores." If one of the analytes is present as an impurity in raw materials, unintentionally formed in trace quantities in a side reaction and transported downstream for additional processing, or generated from the decomposition of other compounds, the final rule language and EPA's comment response do not go far enough in clarifying whether fenceline monitoring would be required.

Regarding the regulatory phrase "emitted," it remains unclear as to whether very small emissions rates will result in the need to conduct fenceline monitoring. EPA addressed the concerns on specific activities (boilers, housekeeping, building maintenance, lab and research activities) that are not part of the affected source and that were referenced in our comment. However, the comment was not intended to provide a comprehensive list of emissions sources or activities with negligible emissions for EPA to review and determine applicability of the fenceline monitoring requirements, but to invite the opportunity to discuss with EPA appropriate language to address *de minimis* emission sources. There are too many possible unique situations to address through a single set of exclusions.

For example, while EPA's response addresses boilers that are used exclusively for the purposes of producing steam or electricity that are not part of the HON affected source, boilers are also utilized as a control device in which case they would be considered part of the chemical manufacturing process unit (CMPU). This would also apply to a thermal oxidizer, catalytic incinerator, or a flare that burns natural gas. Many facilities utilize the emissions factors in Chapter 1.4 of AP-42 for permitting and reporting emissions of HAP from the combustion of natural gas. In nearly all cases, these emissions factors are used as a conservative approach and there is no site-specific data collected to verify the presence of these compounds. There will be situations where the only source of one of the target analytes is from natural gas-fired equipment where these emissions factors have been used. Without additional clarification from EPA or specific *de minimis* values, it could be interpreted that a fenceline monitoring program is required due to the combustion of natural gas.

One of our members is currently evaluating how their facility will address the removal of the startup, shutdown, and malfunction provisions (SSM), specifically with respect to the operation of their catalytic incinerator during startup of the CMPU. As a result of eliminating the SSM provisions, the facility will likely be required to fire auxiliary fuels (i.e., natural gas) to pre-heat the catalytic incinerator prior to introduction of regulated material whereas, prior to the rule revisions, low temperatures recorded during startup were not included in the compliance demonstration and thus combustion of natural gas for pre-heating was unnecessary. The member indicates that emissions from firing auxiliary fuel during startup could potentially be the only source of benzene at the facility; thus, fenceline monitoring would be required for no other reason than the revisions to the HON requiring compliance during periods of SSM. This example and similar facility examples are further detailed in Appendix 1 with additional questions and recommendations for clarification.

Another member is evaluating fenceline monitoring applicability to an existing MACT CC site with HON affected sources that use, produce, store, or emit a listed program analyte requiring fenceline monitoring (compound A). Another analyte could be present at the site and emitted from non-HON covered sources (compound B). The member is considering that the fenceline monitoring provisions only apply to compound A, the analyte that is used, produced, stored, or emitted by the HON affected source. However, without additional clarification from EPA, it could be interpreted that a fenceline monitoring program is required for both compounds A and B, the latter emitted from a non-affected source. Effectively, this result would amount to EPA using the final HON rule to regulate sources outside the covered category, an outcome that would exceed EPA's statutory authority. Similar examples and concerns related to this issue are provided in Appendix 1 to this petition.

Another example is the case where one of the six analytes is present as an impurity in feedstocks, intermediates, or final products. EPA asserted that the definition of "product" alone would not trigger fenceline monitoring. However, it is possible that very small / trace quantities of the compound are emitted as the materials are used or stored in the process. Without a minimum threshold, affected sources are left to interpret the final rule such that a fenceline monitoring program is required if trace quantities are "used, stored," or "emitted," regardless of whether they were "produced" by the CMPU. This particular example is in direct contradiction to EPA's response and demonstrates that the response is not sufficient to address the original concern laid out in our comment.

Due to the significant uncertainty that remains in the final rule, EPA must reconsider the current language for determining whether the fenceline monitoring requirements are applicable. In its current form, there will be many cases where fenceline monitoring is implemented at no benefit to the community due to the negligible emissions of the target analytes that triggered the program requirements. As detailed above, some facilities' only source of emissions is combustion of natural gas or equipment leak fugitives where the compound is present as an impurity, which makes it unlikely that monitoring will result in any detectable readings. Furthermore, without a *de minimis* applicability threshold, facilities are not incentivized to reduce low-level usage of such compounds, particularly if modeling suggests existing emissions will not result in a Δc exceedance. Additionally, the resource strain on laboratories and equipment suppliers has been acknowledged by the industry. When fenceline monitoring is conducted unnecessarily at sites with trace presence or very low emissions of these pollutants, the program will compete for valuable resources with facilities that have more noteworthy emissions of the target analytes. A more commonsense and practical approach to fenceline monitoring requirements would establish a realistic threshold above which the potential emissions are a concern and clearly exclude certain activities and emissions sources where monitoring should not be required.

2. Ethylene Oxide Action Level

EPA finalized a fenceline monitoring action level of 0.2 $\mu g/m^3$ for EO at §63.184(d)(3). We continue to be concerned with the technical challenges our members will face in attempting to comply with this action level, particularly with respect to how background levels of EO will negatively interfere with compliance efforts in addition to other complicating factors and the compliance timeline. Through this petition, we hope to engage the Agency in technical discussions so there is a common understanding of these challenges and their impact.

As indicated in our comments, our review of the EO fenceline monitoring data collected in response to EPA's January 18, 2022, ICR indicated that 11 pairs of duplicate EO samples (13%) had an absolute difference at or above the EO action level. In response to these comments, EPA noted that

> *...some precision issues were a direct result of sampling errors or nonconformance with the additional sampling and analytical procedures required in the CAA Section 114 request for Method TO-15 sampling.*[72]

We acknowledge that some issues could be a result of facilities being unable to follow the additional sampling and analytical procedures; however, facilities either received approval for such deviations from the ICR methods or notified EPA of nonconformances that were outside of facilities' control. More importantly, we received indication from both the Huntsman Conroe and

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[72] EPA-HQ-OAR-2022-0730-2764, pg. 274.

Indorama Port Neches facilities that the additional sampling and analytical requirements were followed as part of their EO fenceline monitoring sampling campaigns; however, each of these facilities saw at least one duplicate result where the difference of the measured values exceeded the EO action level.

Such disparities in duplicate samples are concerning on their own in the face of a low action level, but even more so when combined with EPA's treatment of detection limits. According to the final requirements at §63.184(d)(1)(i), if the lowest value of a compound is below the detection limit, the facility must use a zero value for the lowest sample when calculating Δc. If all sample results are below the detection limit, the facility must set Δc equal to the method detection limit. In response to our concerns with this approach, EPA cited two reasons supporting its view: (1) that by requiring a zero value, facilities are encouraged to improve their detection limits, and (2) that where a facility cannot determine concentrations by measurement, "a conservative approach must be taken," because a facility could have "elevated fenceline concentrations but the resulting annual average Δc remains below the action level."[73]

In response to EPA's first justification, it is unclear how the Agency expects facilities to directly drive lower detection limits, especially in a short two-year timeframe. Facilities may influence detection limits at environmental labs through market pressure (by selecting one lab over another), but this process is expected to occur over a timeframe longer than two years. In fact, even EPA's concerted effort to drive lower detection limits since 2019 has not yielded significant changes.[74]

EPA's second justification runs contrary to the evidence regarding background concentrations of EO. As presented in our comments and cited in the above section, both the Georgia Department of Natural Resources Environmental Protection Division (GAEPD) and the West Virginia Department of Environmental Protection (WVDEP) have conducted studies showing background EO concentrations of between 0.10 $\mu g/m^3$ to 3.7 $\mu g/m^3$.

Additionally, several member companies' facilities are located in industrial complexes with neighboring sources that use and emit EO. For example, the Bayport industrial complex in Pasadena, TX has about ten potential EO emitters within close proximity. Although EPA concluded that background concentrations were addressed through the Δc calculation methodology,[75] EPA's reasoning does not account for nearby off-site sources that may only impact a limited number of monitors, or the fact that winds can often shift directions, even over 24-hour monitoring periods. Based on a review of calendar year 2020 meteorology data for Harris,

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[73] EPA-HQ-OAR-2022-0730-2764.

[74] See slide 9 of the presentation "Ethylene Oxide Measurements by TO-15 Method" by EPA/OAQPS/AQAD available: https://www.epa.gov/sites/default/files/2021-03/documents/eto-method-for-natts-labs-2019.pdf, which indicates MDLs of 0.025-0.061 ppb. EPA determined an RDL of 0.068 $\mu g/m^3$ or 0.04 ppb (see EPA-HQ-OAR-2022-0730-0091, attachment 6) for this rulemaking.

[75] 80 Fed. Reg. 43,005.

Orange, and Newton Counties, TX,[76] winds in the TX gulf region shift by 90° or more at least once a day for an average of 11 days per month. Thus, it is arbitrary to require facilities to use a zero value in Δc calculations when background concentrations of EO are widely established and nearby sources can influence one or more individual monitors at a facility.

EPA's treatment of detection limits in this context is also arbitrary given EPA's use of three times the representative detection limit (3xRDL) in setting the action level and in establishing maximum achievable control technology (MACT) floor limits. EPA set the action level using 3xRDL because "this is the minimum concentration that can be measured with reasonable certainty."[77] It is a potentially conflicting juxtaposition to establish an action level ensuring that it can be measured with reasonable certainty, but then require facilities to use zero and the MDL as part of their compliance calculations, as these values cannot be measured with any reasonable certainty.

We also remain concerned about the value of the EO action level. In both its response to comments document and the preamble to the final rule, EPA asserts that most facilities are already "achieving" the action level, i.e.:

> *...the primary action levels, including those for EtO and chloroprene, are set based on post-control modeled concentrations, which included the application of the CAA section 112 controls adopted in the final rule, and reflect levels that subject sources are already largely achieving...*[78]
>
> and
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> *...for EtO, the lower action level reflects concentrations that all HON-subject facilities, except for one, are currently meeting...*[79]

From its assertion that most facilities are already achieving the EO action level, the Agency concludes that the levels are cost-effective under CAA Section 112(d)(6); however, EPA's conclusion is flawed. As described in Section B of this petition, EPA established overly conservative thresholds for controlling EO under CAA Section 112(f) without appropriately considering cost, i.e., less stringent control thresholds than those set by EPA can achieve acceptable risk. Had EPA appropriately determined the actual EO control thresholds necessary to achieve acceptable risk, it would have likely found that additional controls under either an ample margin of safety analysis or a CAA Section 112(d)(6) analysis are not cost-effective, thus calling into question the Agency's conclusion that the fenceline monitoring EO action level is cost-effective.

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[76] https://www.tceq.texas.gov/permitting/air/modeling/aermod-datasets.html (last visited January 31, 2025).
[77] 88 Fed. Reg. 25,145.
[78] EPA-HQ-OAR-2022-0730-2764, pg. 273.
[79] 89 Fed. Reg. 42,999.

Even considering the controls imposed by EPA under CAA Section 112(f), we question whether EPA's modeling results are levels that most facilities are "currently meeting." EPA presents the results of its post-control modeling analysis in Table 11 of the background memorandum for fenceline monitoring.[80] Of the 10 predicted concentrations, 8 are below a value of 0.10 µg/m^3. EPA's analysis does [not] consider background concentration because, as described earlier, previous studies indicate average background levels of 0.27 µg/m^3 to 0.37 µg/m^3 [81] – values significantly higher than the predicted model concentrations. Additionally, EPA's approach does not appear to consider influence from nearby sources of EO (e.g., other industrial and non-industrial sources such as roadways, etc.), building downwash,[82] or increases in emissions due to more frequent shutdowns to address leaking equipment resulting from the elimination of delay-of-repair provisions. The validity of EPA's modeling results is also uncertain given the Agency's reliance on 2017 NEI emissions that do not accurately represent current facility configurations as evidenced by our previous example of EPA's errant monitor-to-model ratio analysis for Facility 5633411 where the Agency did not consider the impacts of a newly constructed ethylene glycol unit. We contend that the combination of the factors stated above warrant reconsideration of the fenceline action level for EO and the treatment of non-detect values in the Δc calculation. Due to the potential influence of background concentrations, nearby emissions sources, building downwash, emissions sources constructed since 2017, and the resulting potential for under-predicted modeling concentrations, **EPA should consider the potential remedy of both increasing the action level to 1.0 µg/m^3 and revising the value in a future technology review based on a more robust fenceline monitoring dataset.**

3. Summa Canister Sampling Logistics

EPA finalized canister sampling requirements for EO and vinyl chloride at §63.184(b). The approach requires a 24-hour sampling period, with a collection frequency of once every five calendar days, such that the beginning of each sampling period begins approximately 96 hours (± 24 hours) from the end of the previous sample. In our comments, we identified several concerns around the five-day frequency and sampling logistics that EPA included in the proposal. These concerns included the number of canisters that would be required across the country to support at least 47 facilities[83] who will be required to conduct the sampling, the original 120 ± 6-hour

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[80] EPA-HQ-OAR-2022-0730-0091, pg. 30.

[81] Presentation titled: "Georgia's Experience in Ethylene Oxide Monitoring" on August 25, 2022, at the National Ambient Air Monitoring Conference.

[82] As discussed previously in this petition, EPA's own monitor-to-model analysis for lead included in Attachment A to the risk assessment background document attributes a model under-prediction by a factor of 40 to potential building downwash and unaccounted for lead emissions (see EPA-HQ-OAR-0730-2807, Attachment A, pg. A-4). These same factors are likely to impact modeling of EO emissions and should be considered when establishing a fenceline action level.

[83] This is the number of facilities EPA estimates will be required to conduct canister monitoring in Tables 19 and 20 of the fenceline monitoring background memorandum; however, given our concerns presented in Section C.1 regarding applicability of the fenceline monitoring program and the absence of any *de minimis* threshold, we anticipate that the number of facilities required to conduct canister sampling will be much higher than estimated by EPA.

window between samples, logistical challenges associated with collecting, shipping, and receiving samples during the inevitable weekends and holidays, and the requirement to rotate the sampling location for sites with a monitoring perimeter greater than 5,000 meters. In response to our comments, EPA did revise the sampling frequency to the aforementioned value of 96 hours ± 24 hours and added a burden reduction option for sites monitoring vinyl chloride that have a monitoring perimeter of less than 5,000 meters (8 sample points). However, the five-day frequency was retained along with the requirement to rotate the sampling locations.

In EPA's response, it was indicated that the five-day frequency was purposefully chosen so that the sampling did not fall on the same day of the week for each sampling episode. The rationale for this was that it was necessary for EPA to require this frequency to accommodate facilities with batch operations where the same types of activities occur on the same day of the week. Additionally, EPA stated that the more frequent sampling will produce a more representative annual fenceline concentration, will cause the canister sampling to be closer to the continuous monitoring associated with the sorbent tube sampling, and will reduce the chance of missing an emissions episode that results in elevated fenceline concentrations.[84]

The selection of a five-day sampling frequency to ensure that the measurements capture inherent variability in emissions from the process is not consistent with how these facilities operate. For most chemical manufacturing companies that are major sources of HAP and subject to the HON and P&R I, the equipment runs continuously (24 hours per day/7 days per week/52 weeks per year). As indicated by the data submitted by facilities in response to EPA's Section 114 ICR, only approximately 10% of all process vents reported are considered batch (52 of 522 vents).[85] Production decisions, including type, grade, and quantity of products, and planned maintenance, including startups and shutdowns, are not based exclusively on the day of the week. This is true for both continuous and batch operations, with customer demand driving much of the activity that occurs on a specific day of the week. For batch operations, as uncommon as they are at HON and P&R I sources, it is unusual for production to occur in exactly the same way on the same day of the week. In some cases, multiple batch processes will run simultaneously, such that the emissions profile looks more like a continuous process.

Although operations are not tied to a specific day, periods of reduced activity are more likely to occur during the weekend. Therefore, any sampling frequency that results in weekend sampling will generate more results associated with diminished industrial activity. Given a seven-day frequency, most companies would likely plan their sampling to occur during the most convenient times. With the logistical challenges associated with executing the fenceline monitoring program, the middle of the week will typically be the most convenient time to collect, ship, and analyze samples. This means that the proportion of samples corresponding to maximum

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[84] EPA-HQ-OAR-2022-0730-2764, pg. 262.

[85] EPA-HQ-OAR-2022-0730-0097, Appendix D, CMATTR_114_Survey_2022_10_11_NonCBI.accdb, Table "data_03_1_process_vent."

industrial output is likely to be highest with a seven-day sampling frequency. Finally, the ability to follow a seven-day frequency will allow operators to conduct their sampling on the same day most weeks. This streamlining will reduce the unnecessary potential for error that is generated by constantly having to change the day on which samples are collected, shipped, and analyzed.

While it is possible that emissions episodes may be identified up to two days earlier when following a five-day vs. seven-day frequency, the total emissions difference will be negligible. Management of upset releases is already a key concern of chemical manufacturers. Following implementation of the new requirements for PRDs and bypasses, most pathways to atmosphere for hazardous air pollutants will be monitored, with the ability to detect when a discharge is occurring. In most cases, when an emissions episode is occurring, operations or environmental staff detect the event and mobilize to stop it completely or minimize the impacts. These work practices will continue and will not depend on whether a fenceline monitoring exceedance is detected.

EPA responded and explained that the reason they retained the requirement to rotate sampling locations for larger sites is that they want to ensure sampling occurs from as many locations as feasible while keeping costs as reasonable as possible.[86] The proposal did not include a justification for the number of sampling locations that have been prescribed for the monitored perimeter lengths. EPA also did not provide any additional clarification in the final rule. While we generally support approaches that mindfully consider costs, EPA's requirement to rotate the sampling location introduces error and does not allow for a direct comparison of the data from an earlier sampling period to the next sampling period. Without the ability to conduct this comparison, it is difficult to judge the effectiveness of a corrective action.

The fenceline monitoring requirements for vinyl chloride and EO are a logistical challenge. Although we believe EPA exceeded its authority under CAA Section 112(d)(6) with this program, the individual conditions should be fashioned in a manner that minimizes regulatory burden while collecting meaningful and actionable data. Considering the points above, we request EPA reconsider the requirement to conduct canister sampling every five days and instead require sampling every seven days. We also request EPA revise the requirement to rotate sample locations for facilities with a monitoring perimeter greater than 5,000 meters. We also request an opportunity to discuss with EPA regulatory changes to provide facilities with optional sampling approaches based on their specific operations, such as a 48-hour instead of a 24-hour sampling period, alternative number of required canisters, and alternative siting/sample collection approaches.

4. Additional Time Beyond 45 Days is Needed to Perform Effective Root Cause/Corrective Action Analysis and Implement Changes

EPA finalized a requirement at § 63.184(e) that within five days of determining that an action level has been exceeded, the root cause analysis must be initiated, and that both the root

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[86] *Id.* at 263.

cause analysis and initial corrective actions must be completed no later than 45 days after determining there is an exceedance of the action level. As we indicated in our comments on the proposed rule, 45 days is not sufficient time to conduct a comprehensive and accurate root cause analysis and initiate corrective action. EPA seems to acknowledge the difficulty in completing these actions quickly in its response to Comment 210:

> *Fenceline monitoring can be used to diagnose fugitive emission exceedances but cannot immediately determine the source due to the broad nature of the fenceline measurement. Requiring facilities to immediately begin corrective action without allowing time to identify the source and potential solutions to the problem is unreasonable….difficult nature of diagnosing fugitive emission sources. Fugitive emissions may be intermittent depending on the process…*[87]

However, the 45-day period was retained in the rule, without any option to extend the period required to complete the root cause analysis. EPA's only response was that facilities can submit a corrective action plan if they can't complete the necessary corrective actions within 45 days.[88] We reiterate that **a root cause analysis may not be able to be completed in 45 days**, much less the initial corrective actions, and we request the final rule be revised to allow for an extension.

Our members learned from experiences with fenceline monitoring implemented under other requirements that it takes time to identify the source of an elevated fenceline monitoring result and to implement corrective action. In some cases, it may be straightforward to identify one source, such as a storage tank, at an isolated, less complex facility. If a storage tank is identified as the source of the exceedance of the action level, a facility would need to develop a plan to remove the tank from service, clean the tank, inspect the tank and its roof, and repair or replace leaking components as necessary. Even this relatively direct sequence of events takes more than 45 days to execute, especially if the roof must be replaced. Our members' experience with situations where there are shared fencelines and multiple operators in close proximity to each other or even operating as tenants indicates that it can be difficult and time consuming to identify the cause of a fenceline monitoring exceedance. When there are many potential contributors that may not be able to share detailed information with different companies, it can be a long and drawn-out process to perform a root cause analysis and come to a conclusion on what corrective actions should be taken and by whom. For example, the Bayport industrial complex in Pasadena, TX has about ten potential EO emitters within close proximity. Not all the facilities in the area that have EO emissions are subject to the HON or to fenceline monitoring requirements. In any one fenceline monitoring period, the winds at this location can originate from multiple directions. In fact, one member facility experience indicates that on a single day, its facility windrose showed winds originating from all 360 degrees of the compass. This phenomenon is well understood in the context of ozone nonattainment and is referred to as flow reversal. If there is a flow reversal

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[87] EPA-HQ-OAR-2022-0730-2764, pg. 282.
[88] *Id.* at 283.

during a fenceline monitoring period, there will be multiple contributors both upwind and downwind. In this case, successfully completing a root cause analysis and initiating corrective action within 45 days could be impossible. We also note that ambient monitoring in the Bayport area has shown values at or above the action level for EO.

We are also concerned about the potential for false positive readings and measurement variability, especially with respect to EO. Based on an action level of 3xRDL, observed measurement variability and background concentrations described in Section C.2 above, and EPA's treatment of non-detect values, the potential exists for a false positive result to cause an exceedance of the annual average action level. The fenceline monitoring provisions do not address how facilities should handle false positive values.

Finally, we reiterate our concerns that requiring a root cause analysis and initial corrective actions to be completed within 45 days of an action level exceedance will result in equipment shutdown in situations where the cause of the exceedance cannot be determined quickly or if the only way to initiate corrective action is to shut down the equipment. Minimizing shutdowns minimizes emissions; often, the process associated with shutting a plant down causes more emissions than addressing a leaking component. As described later in this petition, by removing the ability to delay corrective action, EPA is effectively increasing emissions and may impact the ability of critical industries to meet demand. Unplanned shutdowns also lead to safety concerns through a higher risk of safety incidents, especially given the extremely reactive and explosive nature of EO. We would like to work with the Agency to develop a provision that supports an expeditious root cause analysis, while providing the time needed to ensure the analysis is complete and minimizes emissions.

5. Fenceline Monitoring Should Not Apply to Non-affected Sources

The Refinery MACT at 40 CFR Part 63, Subpart CC includes a fenceline monitoring program, but specifically excludes certain onsite sources [see §63.640(g)] and offsite sources [see §63.658(c)] from the fenceline monitoring provisions in the rule. We request that EPA revise the HON and P&R I rules to specifically exclude non-affected sources from the fenceline monitoring provisions. EPA states that the fenceline monitoring action levels were developed based on "the highest concentration anticipated, considering the emission reductions anticipated under the additional standards[89]" being adopted for HON and P&R I affected sources, not based on controlling all emissions of a monitored compound at complex operations that involve multiple source categories with variable emission rates or to offsite sources over which an affected facility has no control. EPA cannot regulate sources beyond those subject to the rules it reviewed with the fenceline monitoring provisions. EPA also states the action levels "reflect concentration levels that are largely already resulting from sources subject to the rules and are therefore cost-effective.[90]" This seems to indicate that EPA believes emissions from existing HON and P&R I affected

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[89] 89 Fed. Reg. 42,999.

[90] Ibid.

sources are not likely to be the root cause of a fenceline monitoring exceedance unless there is a known instance of excess emissions that is not reflective of normal operations. Therefore, EPA should add provisions to the rule similar to those at §63.658(c)(2)[91] to clarify that non-affected sources do not trigger root cause and corrective action requirements for an exceedance of an action level.

6. Action Levels Should be Revised to Account for Short-Term Emissions

We request EPA reconsider the fenceline monitoring action levels to account for short-term emissions, possibly using a multiplier or upper predictive limit (UPL) type calculation. In EPA's response to comment document, the Agency states that "action levels must be the same as our post-control modeled concentrations, which are on an annual average;"[92] however, EPA did not set the EO or chloroprene action level based on post-control modeled concentrations, nor did the Agency properly account for short-term, post-control emissions, even using annual averaging.

Based on our review of the final source category baseline and post control emissions modeling input files included in the docket, it appears that EPA did not account for increased emissions from maintenance events during more frequent startup and shutdown events resulting from eliminating delay-of-repair provisions for equipment and heat exchange systems in EO service. Our review of the pre- and post-control source category modeling input files included in the docket indicated no increase in maintenance emissions for any fenceline pollutant. The elimination of delay-of-repair will not only increase emissions of EO, but also the other fenceline monitoring pollutants due to the low 0.1% EO threshold for "in ethylene oxide service" for equipment and heat exchange systems. We would welcome the opportunity to have a separate future discussion with EPA focused on fenceline action levels that would account for short-term emissions, including maintenance vents.

7. Reduced Sampling Frequencies Should be Available for Ethylene Oxide and Vinyl Chloride

In our July 2023 comments, we requested EPA establish a process that would allow facilities to reduce the sampling frequency of their fenceline monitoring programs if sample results are consistently below a given threshold. In the Final Rule, EPA partially accepted our request by allowing reduced sampling frequency for benzene, 1,3-butadiene, and ethylene dichloride. EPA also finalized provisions for reduced sampling frequency of vinyl chloride at smaller sites; however, EPA did not include an option for reduced sampling frequency for EO or chloroprene, or for vinyl chloride at facilities with a monitoring perimeter more than 5,000 meters.

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[91] "The owner or operator may collect one or more background samples if the owner or operator believes that an offsite upwind source or an onsite source excluded under § 63.640(g) may influence the sampler measurements. If the owner or operator elects to collect one or more background samples, the owner or operator must develop and submit a site-specific monitoring plan for approval according to the requirements in paragraph (i) of this section. Upon approval of the site-specific monitoring plan, the background sampler(s) should be operated co-currently with the routine samplers."

[92] EPA-HQ-OAR-2022-0730-2764, pg. 274.

EPA stated they did not allow for reduced sampling for vinyl chloride at large facilities because the canisters move locations between sample periods and as a result, "it would be difficult to determine that a particular sampling location is consistently less than one-tenth of the action level."[93] EPA's justification appears arbitrary in context of the fenceline monitoring requirements. Facilities are required to use the measured concentrations at each sampling location in their calculations. It is unreasonable that a sample value from a rotating sampling location is reliable when determining whether to initiate root cause analyses and corrective actions, but that the value is unreliable when determining whether the vinyl chloride concentration at the particular monitoring site is below 0.3 $\mu g/m^3$. Furthermore, EPA's own criteria for reduced sampling relies, in part, on samples taken more than 3 weeks apart once sampling frequency is initially reduced [see for example §63.184(a)(3)(iii)(B)-(E)]. EPA has not adequately explained why a sufficient number of samples taken 10 or 15 days apart for vinyl chloride cannot demonstrate a consistently low concentration at a given monitoring location, particularly when monthly, quarterly, and annual samples are sufficient to demonstrate low concentrations for other pollutants. EPA should reconsider its decision to exclude large facilities from the reduced monitoring option for vinyl chloride by allowing facilities to demonstrate consistently low concentrations with a sufficient number of samples. We also note that the provisions in §63.184(b)(2)(iii) should be revised to address a 7-day or a 5-day sampling period instead of a 14-day sampling period (a 5-day period if EPA does not revise the period between sampling events as outlined in our comments in Section C.3 of this petition).

We are also concerned with EPA's justification for not providing reduced monitoring for EO and chloroprene. In the Final Rule, EPA allowed for reduced monitoring if concentrations were consistently measured at or below 10% of the action level [see, for example, §63.184(a)(4)]: a threshold EPA indicates was based on the burden reduction option promulgated under NESHAP Subpart CC. EPA states that "current detection capabilities with Method 325A/B and Method 327 would not be able to prove that a monitoring location is less than one-tenth of the action level" for EO and chloroprene.[94] We note, however, that in developing the 10% threshold under Subpart CC, EPA stated that 10% of the action level approximated the benzene background concentrations the Agency observed from pilot studies.[95] We request that EPA allow for a sampling frequency reduction option for EO and chloroprene if the site can demonstrate monitoring locations are consistently at or below background concentrations. Referring to our concerns regarding applicability of the fenceline monitoring procedures outlined in Section C.1 above, a burden reduction option is warranted for those facilities that use, produce, store, or emit trace levels of EO and chloroprene in such a manner that emissions will never exceed an action level.

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[93] EPA-HQ-OAR-2022-0730-2764, pg. 263.

[94] Ibid.

[95] EPA-HQ-OAR-2010-0682-0802, pg. 243.

8. Overlap Exclusions for Fenceline

In our comments on the proposed rulemaking, we requested that EPA include overlap provisions in the final rule such that a HON CMPU may elect to comply with the fenceline monitoring requirements in 40 CFR Part 63, Subpart CC if the CMPU is within the property boundary of a refinery subject to and compliant with the fenceline monitoring requirements in Subpart CC, if the only fenceline monitoring pollutant used, produced, stored, or emitted by the CMPU is benzene. EPA rejected this request on the basis that the Subpart CC provisions allow refineries to subtract on-site near-field sources subject to the HON from their fenceline monitoring calculations, and providing such an exemption would defeat the purpose of limiting fugitive emissions from HON CMPUs. We request EPA revise the final rule to specify that a HON CMPU can only comply with the Subpart CC provisions if the refinery *does not* elect to subtract near-field, on-site sources from its fenceline calculations.

9. Revise §63.184(e)(1)(ii)(B) to Allow, Under Certain Conditions, the Use of Real-Time Sampling Techniques "As Soon as Practical"

EPA finalized a requirement at §63.184(e)(1) that real-time sampling techniques must be employed if the root cause of an action level exceedance has not been determined within 30 days of determining the action level has been exceeded. We request that EPA allow, under specified conditions, that the use of real-time sampling techniques be employed “as soon as practical” rather than 30 days. As mentioned in our comments, our members with experience using external contracts to employ real-time monitoring indicate that the appropriate staff and equipment are not always available within 30 days. This situation is likely to be exacerbated as EPA adds fenceline monitoring requirements to its rules. EPA’s response to our comment was (1) that allowing an indefinite time period for the problem to persist without action is unreasonable and (2) that an exceedance of an action level is typically not sudden and unexpected and that facilities will know more than 30 days in advance of exceeding an action level because elevations in concentrations at monitors will be seen “well before an action level is exceeded.”[96] Irrespective of the factual inaccuracies of these statements, this response does not address the reality that facilities cannot always get external contractors and equipment onsite immediately. Our members agree that the use of these techniques can be a meaningful addition to a root cause analysis, but facilities cannot control the availability of outside resources (either contractor staff or equipment). We would like to discuss with EPA adding a provision that allows facilities to document the need for an extension of the 30-day requirement based on a showing that they have requested resources and received responses that the necessary resources are not available to be deployed within 30 days of the exceedance.

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[96] EPA-HQ-OAR-2022-0730-2764, pg. 281.

10. Meteorological Station Requirement for Canister Sampling

EPA also finalized a requirement at §63.184(c)(1) that requires an on-site meteorological station be operated in accordance with Section 8.3 of Method 325A if a facility must conduct canister sampling under §63.184(b), if the facility incorporates near-field correction, or uses an alternative test method. In our comments on the proposed rule, we requested EPA remove the reference to §63.184(b) as one of the criteria requiring operation of an on-site meteorological station to reduce burden and streamline requirements. EPA denied this request on the basis that localized wind information is necessary to understand the source of emissions.[97] While we understand EPA's refusal to a blanket elimination of the requirement to operate an on-site meteorological station, we ask EPA to allow the use of off-site meteorological data if the meteorological station is near the facility. Some of our member facilities are within 25 kilometers (km), and some within 10 km of National Weather Service (NWS) stations. The proximity of these stations is such that the data collected should be considered representative of localized conditions, especially in areas where the elevation and topography is similar to nearby NWS stations.

11. Method 327, Section 8.1.2 Flow Control Checks

We continue to be concerned with the requirements in Section 8.1.2 of the finalized EPA Method 327 which requires flow control checks prior to and after each field sampling event. Section 8.1.2.2 requires that the flow controller be attached to a separate canister and allow sufficient time for the system to stabilize and record the flowrate upstream of the flow control device for a total of three additional flow rate measurements. Then, Section 8.1.2.3 requires that the flow check is considered valid if within ± 10% of the reference flow rate. At proposal we stated our concerns with conducting these types of detailed checks in the field (difficulty of demonstrating flow is within 0.347 liters per minute of the reference flow rate in the field, ability of a field technician to demonstrate this level of accuracy multiple times, feasibility of adjusting flow controllers in the field, time required to complete the check and the possibility of not meeting the requirement of Section 8.7.3.1 of Method 327 for all canisters to initiate sampling with 60 minutes of each other).

In response to comments, EPA stated that the flow control check in Section 8.1.2 is necessary to identify any issues that developed with a device after shipping and handling that may cause the collection of an invalid sample. EPA also noted that the Agency is allowing the use of sample collection timers to provide facilities with flexibility in synchronizing sample period start and stop times.[98] As initially raised in our comments, we continue to assert that pre-set orifice, pre- and post-vacuum checks, and the flow control verification test requirements in Section 8.1.1 of Method 327 are duplicative of the checks in Section 8.1.2. If EPA is concerned about issues developing during shipping and handling, facilities should be allowed to conduct the checks in Section 8.1.2 just prior to and just following field deployment of the canisters. Furthermore, we

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[97] *Id.* at 297.
[98] EPA-HQ-OAR-2022-0730-2764, pg. 252.

are concerned with EPA's suggestion to use sample collection timers because stand-alone sample collection timers are known to leak and thus invalidate sampling runs. As described in a memorandum[99] from Greg Noah of EPA, timers result in leaks due to the following:

- Adding a timer creates more connections that can become loose and leak;
- Fittings in the flow controller assembly can become loose and leak;
- Leaks can occur within the timer unit itself;
- Contraction and expansion around the seals withing the timer may create leaks in temperature extremes; and
- Functionality of timers degrade with low battery life.

The use of timers can also add considerable expense to an already costly fenceline monitoring program as stand-alone timers can cost approximately $2,500[100] to $3,000.[101] This does not include the additional expense related to periodically servicing, testing, and repairing timers. To avoid additional complexity and cost while complying with the requirement to deploy samplers within an hour, EPA could achieve its objectives by updating Method 327 to remove the flow check requirements in Section 8.2.1 and rely on the pre-set orifice, pre- and post-vacuum checks, and the flow control verification test requirements in Section 8.1.1.

In addition, the rule does not address what operators should do in the event of a monitoring failure (e.g., pressure test failure after canister sampling is completed, lack of an adequate amount of sample, contamination of the sampling system, etc.). It is inevitable that these types of failures will occur, and we would like the opportunity to discuss with EPA how the rule should address them, such as incorporating data availability criteria.

VI. Delay of Repair Should be Restored[102]

We request that EPA reconsider the elimination of delay-of-repair (DOR) for equipment and heat exchange systems in EO service. In our comments on the proposed rule, we detailed our concerns with elimination of DOR regarding increased numbers of shutdowns, safety, and the impact on our members' ability to meet demand in critical industries. Most importantly, we provided a detailed explanation of how the elimination of DOR provisions for equipment and heat exchange systems in EO service will result in increased emissions of EO and other pollutants, the opposite of EPA's intent. As EPA acknowledges with its inclusion of maintenance vent

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[99] https://www.epa.gov/sites/default/files/2021-04/documents/use_of_stand-alone_timer_timer_guidance_for_voc_sampling.pdf (last visited January 31, 2025).

[100] https://www.thomassci.com/Laboratory-Supplies/Chromatography-Sample-Preparation/_/Canister-Air-Sampling-Timer (last visited January 31, 2025).

[101] https://us.vwr.com/store/product/18812791/canister-air-sampling-timer-restek (last visited January 31, 2025).

[102] See Denka v. EPA, 24-1135 Opening Brief of Petitioners.

provisions, when shutting down a process it is often necessary to open equipment to the atmosphere, which results in emissions of material that cannot be purged to a control device. Furthermore, we described how allowing DOR actually reduces emissions [the provisions in §63.171(c)] if the operator determines that the emissions resulting from immediate repair would be greater than the emissions from delaying the repair: emissions reductions that result in risk reduction.

With a minor exception for equipment that was removed from EO service, EPA rejected our request on the basis that "allowing delay of repair would allow increased emissions of EtO and increased risk."[103] It is important to note that our request explicitly only covered situations where not delaying repair would result in more emissions. That is, by definition, it would only apply in circumstances inconsistent with EPA's statement because of the additional emissions associated with a shutdown activity when compared to a minor delay of repair. Accordingly, if EPA were correct, delay of repair would never be invoked and, at worse, including the provision would have no impact.

Further, EPA disagreed with our statements that increased startup and shutdown events will lead to additional EO emissions, but the Agency's additional explanation implies that additional emissions will indeed occur. EPA states that

> *…we have removed the exemptions for periods of SSM. As a result, facilities must be in compliance with the rule requirements at all times and must control EtO emissions at all times. Therefore, while there may be additional EtO entering the control device as a result of SSM, the finalized control provisions ensure risk remains acceptable.*[104]

EPA states that additional EO will be sent to control devices as a result of more frequent startups and shutdowns but seems to suggest that because emissions from startup and shutdown must be controlled, there will not be an emissions increase. This is incorrect. If additional emissions over baseline are sent to control from unplanned startups and shutdowns to address leaks, emissions will invariably increase even if controlled.

EPA's response to comment also includes means of addressing the increased emissions that the Agency earlier contended did not exist. The Agency discusses the maintenance vent provisions that allow facilities to emit up to 1.0 ton per year of EO because of startup, shutdown, maintenance, or inspection where equipment is emptied, depressurized, degassed, or placed into service. EPA states that "…shutdowns resulting from the identification of leaks could be included under the 1.0 tpy EtO limit."[105] Including these emissions as part of the maintenance vent provisions will be necessary. As we discussed in our comments, emissions of EO from shutdown events can range from a few pounds to a few hundred pounds.

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[103] 89 Fed. Reg. 42,976.
[104] Ibid.
[105] Ibid.

The above discussion demonstrates that EPA's justification for not including DOR provisions is arbitrary. On the one hand, EPA states that allowing DOR would increase emissions and thus increase risk, which presumably, is unacceptable. But on the other hand, EPA's response indicates that up to 1.0 ton per year of additional emissions from shutting down units to address leaks is acceptable – a clear contradiction. EPA's reasoning does not address why it is acceptable to have hundreds or even thousands of pounds of additional EO emissions from additional shutdowns to address leaks as long as the emissions remain below 1.0 TPY, but why it is unacceptable to allow for DOR and reduce emissions to the order of tens of pounds.

As an example, a 200 ppm leak of 100 wt% EO from a light liquid valve equates to 8.4 lb/yr assuming 8,760 hr/yr of operation and using the SOCMI leak rate screening value correlation equations from Table 2-9 of EPA's "Protocol for Equipment Leak Emission Estimates."[106] To shut down and address the leak will result in 50 lbs. of additional EO emissions from maintenance vents, but the facility has a planned maintenance shutdown in 8 months.[107] There are complicated logistics involved in scheduling a maintenance turnaround such as planned order and length of product runs leading up to the shutdown, lead time for scheduling or ordering equipment or parts necessary to perform work during the shutdown, and contractor schedules. Due to equipment and contractor schedule constraints, the maintenance work cannot be moved forward. Thus, the facility will be required to shutdown to address the leak, re-start, and release 100 lbs of EO from the combination of the unplanned and planned shutdown; however, if the facility was allowed to place the leaking component on DOR until the next shutdown, the facility would avoid releasing 44.4 lbs of EO (100-50-8.4*8/12). The facility still must shut down to complete its scheduled maintenance as well, and then restart. In this example, EPA's elimination of DOR directly results in additional emissions of EO. Allowing for DOR becomes more favorable from an emissions standpoint if the fluid in the leaking component is 1 wt% EO. For example, a 100 ppm leak of 1 wt% EO from a light liquid valve equates to 0.049 lb/yr of EO. Using the shutdown emissions and the 8-month timeline in the previous example, DOR would avoid 49 lbs. of EO emissions (100-50-.049*8/12).

EPA's premise that allowing DOR will invariably lead to additional emissions is incorrect. We would like to discuss with EPA how to best address DOR for equipment and heat exchange systems in EO service. This would include options such as a limitation on the number of components with 5 wt% or more EO for which repair is delayed so that facilities are allowed to

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[106] EPA-HQ-OAR-2022-0730-0003, Attachment 5(EPA-453/R-95-017).

[107] Other member experience indicates that planned maintenance shutdowns can take up to 2 to 3 years to plan to fabricate specially designed equipment. This experience separately demonstrates the risk of an increase in emissions with this proposed requirement. Specifically, the member notes that they perform plant shutdowns and maintenance on a 5-year basis to minimize unreasonable mechanical stress on equipment and piping, which can lead to premature failure and result in excess emissions that could occur. Given the monthly monitoring schedule, that same unit could be shutting down and starting up every month. Each time the unit starts up, the temperature cycle and mechanical stress imposed with significant pressure and flow changes have the potential to initiate leaks that would not normally occur with more continuous operation. In addition to the additional emissions created by start-up and shutdown, this could also lead to an increase in emissions, not a decrease.

utilize DOR if a process shutdown is required to fix the leak, and as long as emissions from delaying the repair do not exceed those that would otherwise occur from the unplanned shutdown of the CMPU, considering all applicable emissions limitations (e.g., process vent control requirements and the annual maintenance vent limit of 1.0 TPY of EO).

VII. Classification of Releases from Pressure Relief Devices as Violations Should be Removed.

1. In Ethylene Oxide Service

EPA finalized provisions classifying release events from pressure relief devices (PRDs) in EO service as violations at §63.165(e)(3)(v)(D). Historically, PRDs needed for safety purposes were exempt from the bypass line provisions for process vents, transfer operations, and closed vent systems at §63.114(d), §63.127(d), and §63.172(j) respectively. As mentioned in our comments, PRDs are a critical component to the design of a chemical process and are included to relieve pressure and prevent catastrophic equipment failure. The acknowledgment in the original version of the rule that PRDs used for this purpose warrant differential treatment is a commonsense approach to regulating emissions from sources in the industry. Additionally, EPA continues to acknowledge this reality based on the work practice standards in the revised version of the rule for PRDs that are in organic HAP (OHAP) service, but not EO service [see §63.165(e)]. For these OHAP PRDs, EPA has mandated that sources install monitoring systems that will both immediately detect a release is occurring and notify operators. They also require that sources implement "three redundant prevention measures" that will function in tandem to help prevent future releases. While these requirements are more stringent than the previous version of the rule, EPA is allowing up to three releases in a three-year period unless two releases share the same root cause or they are due to operator error or poor maintenance. In the rule itself, therefore, EPA recognizes the necessity of having PRDs in place at facilities and the need to ensure that they continue to operate safely and protect the health and welfare of personnel and the community.

Considering the importance of PRDs to the safe operation of a chemical manufacturing process unit and the many challenges associated with their control, it is imperative that the standards for EO PRDs reflect these same necessities and that EPA reconsiders treating any release from a PRD in EO service as a violation.

To the extent EPA continues to conduct a second residual risk review, EPA should also correct its approach for evaluating the risk from PRDs in EO service. The risk review process involves an estimation of excess risk remaining after accounting for existing control requirements, emissions limits, and work practice standards. When determining what that excess risk looked like from EO emissions from facilities in the SOCMI source category, EPA included emissions from uncontrolled PRD releases during the 2018 emissions inventory reporting year. As previously discussed in this petition, this data should not have been included in EPA's risk modeling. Among the reasons discussed above, this dataset does not account for reductions in emissions that would occur as a result of implementing the work practice standards for all PRDs in OHAP service that were included as part of the actions related to CAA Sections 112(d)(2) and (3). All PRDs in EO service are going to be subject to these requirements as they must be in OHAP service before they can be considered in EO service. Therefore, without the classification of releases from PRDs in EO service as violations, there will already be a decrease in emissions from the 2018 period that was used to evaluate the excess risk. EPA should evaluate the remaining risk after facilities begin complying with the new work practice standards. We believe this will reduce the risk to an acceptable level such that EPA can determine it is appropriate to apply the same work practice requirements and violation determination criteria as for other PRDs that are in OHAP service only.

During the comment period, commenters provided numerous examples as to why pressure releases of EO can be unsafe to control. SOCMI facility pressure releases are episodic in nature and can have very high flow rates with high concentrations of EO. In some cases, there are licensing entities that have specifically designated the control of a pressure release as a liability due to safety concerns. In these cases, it would void the ability of a source to continue to operate in compliance with the licensor which presents an impossible situation. The examples demonstrate that it is impossible to control all PRDs, and thus EPA has promulgated a standard for which compliance is not possible. Whether or not the intent is for sources to route discharges from these PRDs to a control device, the classification of all atmospheric releases as violations has led to a significant amount of uncertainty among the regulated community regarding how best to proceed for compliance purposes. Generally, EPA has not addressed very real circumstances that exist among HON facilities where it is unsafe to control a release of EO. EPA must reconsider its approach of excluding PRDs in EO service from the pressure release management work practice standards that are applicable to other PRDs and create a standard that facilities can comply with.

In addition to safety concerns, there are other practical issues that arise due to the classification of releases from PRDs in EO service as violations. Although it is not possible to control all of these types of PRDs, there will be many facilities that are considering controlling them in an existing control device or building an entirely new control device. Due to the non-routine, infrequent, and episodic nature of these PRD releases, a control system capable of accommodating all the possible scenarios that could occur becomes impractical in design.

The only readily demonstrated and proven options for controlling these streams and achieving the control efficiencies required by the new standards are flares and oxidizers. As mentioned in our comments, one ACC member company assessed the feasibility of installing a flare that could control many (but not all) of the PRDs in EO service at their EO production facility. The results indicated that it would require a very large, elevated flare (approximately 250-300 ft high, with a diameter of 54 inches or larger) that would not physically fit within the space constraints at the facility. Additionally, a flare large enough to accommodate all the PRDs was similarly not technically feasible. For a control device dedicated to these types of infrequent releases, flares are the preferred option over oxidizers due to the quick ramp up time. However, in the case of the necessary flare being too large to fit at a facility, a thermal oxidizer system would also need to be very large. EPA should reconsider the control requirements for PRDs in EO service to account for the unique considerations associated with these releases while also ensuring acceptable risk.

2. Under NSPS IIIa, NNNa, and RRRa

EPA finalized new subparts for Standards of Performance for VOC Emissions from SOCMI Air Oxidation Processes, Distillation Operations, and Reactor Processes at Subparts IIIa, NNNa, and RRRa respectively. Historically, the NSPS for these sources excluded relief valve discharges from the definition of a vent stream, thereby exempting these types of releases from the applicable control requirements. As part of the CAA 111(b)(1)(B) review, EPA concluded based on the RACT, BACT, and LAER database (RBLC) that the best system of emissions reduction (BSER) for relief valve discharges from air oxidation reactors, distillation operations, and reactors was that no discharges should be allowed, with any necessary releases being routed to a closed vent system and control device rather than to atmosphere. This conclusion was based on TCEQ's approach to regulating atmospheric discharges from PRDs and a *single* lowest achievable emissions rate (LAER) entry in the RBLC database for the "Linear Alpha Olefins Plant," which is operated by INEOS Oligomers USA, LLC (ID TX-0813)).

When responding to concerns on the prohibition of relief valve discharges in the new NSPS subparts, EPA referenced the TCEQ guidance document, "Air Permit Technical Guidance for Chemical Sources Fugitive Guidance (June 2018)"[108]. The guidance document that EPA references includes a BACT discussion indicating that the minimum expected BACT for relief valve discharges is that they would be expected to be routed to a control device unless there are safety concerns with doing so. It is important to note that in many cases, relief valve discharges are considered unplanned and unauthorized events, which EPA itself recognizes,[109] and thus would not be a uniquely identified emissions source in an air permit application for which a BACT review would be conducted. Therefore, the language in this guidance document is only comparable to routine relief valve discharges upon which an air permit has been issued and does not imply that TCEQ considers all relief valve discharges, including those associated with process upset conditions, to be technically and economically feasible to route to control. It also does not explicitly prohibit all atmospheric relief valve discharges and acknowledges that there may be cases for which these types of releases are necessary to ensure the safety of personnel and property.

In addition to referencing the TCEQ guidance document, EPA also references a special condition that TCEQ regularly inserts into permits that restricts relief valve discharges when the

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[108] 89 Fed. Reg. 43,013.

[109] *See* 63.101: "Pressure relief device or valve means a valve, rupture disk, or similar device used only to release an unplanned, nonroutine discharge of gas from process equipment in order to avoid safety hazards or equipment damage."

VOC concentration is greater than one percent in the gas stream.[108] Regarding the special condition, TCEQ issues case-by-case New Source Review (NSR) preconstruction permits that contain special conditions enforcing compliance with the representations in air permit applications. Although many of the special conditions in the final permits are unique, TCEQ utilizes boilerplate conditions and standardized language for consistency and efficiency when writing permits. One boilerplate special condition that TCEQ regularly inserts in its permits is the restriction on atmospheric relief valve discharges unless authorized by the permit's maximum allowable emissions rate table (MAERT). This aligns with TCEQ's stance that these releases are often unplanned, nonroutine events that are not authorizable by a permit and thus this language explicitly communicates that they would be an upset event. The special condition is not the result of a technical or economic evaluation on the feasibility of controlling relief valve discharges and does not imply an expectation that all relief valve discharges should be controlled. It simply mandates that they be treated as an unauthorized release and reported as such if required.

The use of the TCEQ guidance document and TCEQ's NSR permit boilerplate condition language as the basis of BSER for atmospheric relief valve discharges does not meet the statutory requirements under the CAA. In addition to consideration of cost, non-air quality health and environmental impacts and energy requirements, there are multiple other factors that must be evaluated when determining whether it is appropriate to revise an NSPS. While TCEQ likely included some of these, there is no indication that they were all considered when the state established its stance on how to handle atmospheric relief valve discharges. Therefore, they cannot be used as the sole justification that classifying atmospheric relief valve discharges as violations is considered BSER for SOCMI reactor processes, air oxidation unit processes, and distillation operations. As we identified in our comments, LAER is not an appropriate reference for determining BSER. The reason for this is that LAER does not consider economic, energy, or other environmental factors while the CAA specifically states that the cost of achieving such reduction and any non-air quality health and environmental impact and energy requirements should be considered when establishing BSER. If cost had been considered when establishing BSER, EPA would have concluded that it is not economically feasible to route existing PRDs to a control device. EPA demonstrated this to be true as part of its CAA 112(d)(2) and (3) review of PRDs associated with the revisions to HON and P&R I/II. As a result of that review, EPA established the MACT floor as work practice standards intended to limit the number of relief valve discharges and to minimize their impact through continuous monitoring and root cause analyses in response to release events. Additionally, in the preamble to the original proposal, EPA discusses that control of PRDs would be considered beyond the MACT floor and would require considerable cost such that it would be economically infeasible to mandate that all PRDs be collected and routed to process or control[110]. There are also technical limitations to consider that would prevent the possibility of all PRDs being controlled. Processes are designed with these PRDs to ensure the

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[110] 88 Fed. Reg. 25,159.

safety of personnel and equipment, and they will need to be retained. Modifications will occur on existing air oxidation reactors, distillation operations, and reactor processes such that they will be required to comply with the new NSPS subparts. Absent plans to completely rebuild the affected source and associated infrastructure, legacy PRDs will often be retained. If there are safety concerns with routing these to control, it will be impossible for the facility to comply with the language as finalized.

With inclusion of PRDs in the CAA 111(b)(1)(B) review of the SOCMI NSPS for air oxidation reactor processes, distillation operations, and reactor processes, it is unexplainable that the outcome of that review for a general VOC emissions control rule should result in the same work practice standards as proposed for the HON and P&R I/II. EPA should reconsider the classification of PRD releases as violations in §60.612a(b)(2), §60.662a(b)(2), and 60.702a(b)(2). The conclusion that BSER for PRDs is that they all must be considered violations does not align with EPA's own acknowledgment that it is not cost effective to implement and does not provide the flexibility needed within the source categories to ensure that they continue to operate safely. Incorporating work practice standards similar to those finalized at §63.165(e)(3) would ensure proper management of pressure releases while allowing facilities to operate safely as designed.

VIII. Monthly Monitoring for Equipment in Ethylene Oxide Service Should be Revised

1. Connectors

EPA has not properly addressed concerns related to monthly monitoring of connectors in EO service, instead selecting an option that is not cost-effective. The connector monitoring requirements for equipment in a HON CMPU are included in §63.174. Historically, the section mandated that connectors in gas/vapor and light liquid service be monitored on at least an annual basis, with skip periods allowed of up to once every two or four years depending on the percentage of leaking components that were found during the previous interval. To address risk, EPA reduced the monitoring frequency to a monthly basis with no skip periods allowed. We carefully reviewed the documentation EPA included to support the risk evaluation and we provided detailed comments identifying the shortcomings with the Agency's analysis. Based on our review, we provided solutions that would result in a maximum individual lifetime risk (MIR) below the presumptive limit of 100-in-1 million without requiring the costly monthly Method 21 monitoring in the proposal. EPA responded with a brief statement that the proposed requirements would be finalized as-is. The basis for this decision was that equipment leaks are the largest contributor to the unacceptable risk posed by EO and connectors are the largest number of equipment leak sources.[111] This risk determination was not only wrong, it is also nonresponsive to the comments we submitted showing that EPA had drawn the wrong conclusions about what emission standards

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[111] EPA-HQ-OAR-2022-0730-2764, pg. 161.

were required to address this risk. If EPA does not remove these requirements from the HON entirely, we would like to speak with the Agency about its risk analysis, the logistical impact of its final options, and other cost-effective options that can achieve comparable risk reductions, given that the Agency's inflated risk can be traced in additional part to its flawed foundational assumptions in its modeling approaches.[112]

Were EPA to seek to regulate connectors under either the second step of the risk review or the technology review section of §112, it could not have justified the costs. In the second step of the risk review process, where standards are established to provide an ample margin of safety, consideration is given to cost, technological feasibility, and other relevant factors. The requirement to monitor connectors in EO service monthly is a significant change from the annual frequency that is required for the remaining connectors in OHAP service. The number of connectors that are present within a HON CMPU may range from thousands to tens of thousands of components. In most cases, facilities utilize external contractors to assist with their LDAR monitoring programs. Thus, it is clear that monthly monitoring will require substantial additional cost that may not yield appreciable reductions.

The cost of a particular control technology or standard is quantified based on the anticipated emissions reduction and the costs of implementation. EPA evaluated emissions reductions associated with varying leak definitions and monitoring frequencies and included the final cost effectiveness values in the proposal preamble. We reviewed the approach and assumptions that were used in the analysis and determined that the baseline emissions of EO used to quantify the emissions reductions for each monitoring option were nearly five times higher than their actual values. In our comments, we noted that this is presumably due to EPA utilizing a higher leak frequency than what is supported by the data that was collected in response to the January 2022 Information Collection Request (ICR). The incorporation of the more representative leak frequency results in a correction to the baseline emissions downward, and a large increase in the cost per ton such that the monthly monitoring is clearly not cost effective (~$397,000/ton).

In addition to concerns on the cost analysis, there are other logistical and practical issues that we identified in our comments on the proposal. Based on the supporting analysis of the equipment leak control options, EPA assessed[113] the following options for connectors in EO service in addition to those discussed in the preamble and supporting documentation:

1. Reduced leak definitions for valves, pumps, and connectors, with monthly monitoring of valves and pumps and quarterly monitoring of connectors;
2. Reduced leak definitions for valves, pumps, and connectors, with monthly monitoring of

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[112] As one example, EPA's model that predicts downwind, offsite concentrations of EO is not specifically designed for fugitive emissions modeling as it assumes an area from which multiple components presumably emit EO and assigns it a point source location. Essentially, EPA's modeling approach treats fugitive emissions in a broad area of the plant as a point source of emissions at the centroid of the area.

[113] EPA-HQ-OAR-2022-0730-0003, attachment 2.

valves and pumps and annual monitoring of connectors coupled with monthly optical gas imaging (OGI);

3. Reduced leak definitions for valves, pumps, and connectors, with monthly monitoring of valves and pumps and quarterly monitoring of connectors coupled with monthly OGI; and
4. Reduced leak definitions for valves, pumps, and connectors, with monthly monitoring of all three components.

With the lowest leak definition and the shortest frequency, Option No. 4 results in the greatest emissions reduction and therefore the lowest MIR from the source/equipment category. However, based on our analysis, Option No. 1 resulted in comparable reductions (64% vs. 74% for facility 4941511) with substantially lower costs. In our review, we estimated a reduction in the total annual cost of approximately $2,000,000 and an improvement in the cost effectiveness of nearly $200,000/ton (which we note is still not cost-effective).

Due to the potential large number of components, there are practical concerns with a monthly Method 21 monitoring on the connectors in EO service. One scenario that we referenced in our comments was a month during which there is a two-week outage. In this case, the operator will only have 15 days to finish the monitoring of all of the components. We have at least one member who indicated that the change from annual to monthly monitoring would result in 80,000 additional monitoring events, with connectors accounting for approximately 60,000 of those additional events. There will likely be cases where the resource constraints on executing this large of a monitoring program will result in missed monitoring as additional technicians will be necessary.

Due to the significant impact of monthly monitoring on connectors in EO service, EPA must carefully reconsider the selection of a monthly Method 21 program versus the other options that were evaluated. As discussed, our review of the initial analysis identified an error with the baseline emissions rate that was used to assess the emissions reductions and cost effectiveness for each option. The quantification of the baseline emissions rate for connectors was based on a leak frequency that is substantially larger than what has been observed in the industry. The use of this erroneous baseline emissions rate results in a calculated emissions reduction that is also unrealistically high and a final cost effectiveness that significantly under-represents the actual costs of implementing a monthly LDAR program on connectors. Additionally, there was more than one option that resulted in an acceptable MIR, thus implying that there is a more cost-effective monitoring program that will still result in a suitable ample margin of safety analysis. Due to cost being a factor that is considered in the second step of the analysis, EPA should remain consistent with the approach followed for other risk evaluations and select the option that is the most cost effective. If the true cost of monthly connector monitoring is incorporated into the analysis, EPA will find that there are less costly options that achieve comparable results.

2. Valves

In addition to addressing monthly monitoring of connectors in EO service, EPA must reconsider the requirement to monitor gas/vapor and light liquid valves in EO service on a monthly basis, with no reductions in monitoring frequency allowed. For gas/vapor and light liquid valves in OHAP service, HON requires quarterly monitoring unless more than two percent of the valves in the process unit are leaking. Additionally, when the percentage of valves in the process unit that are leaking is between 0.5-1.0%, further reductions in the monitoring frequency are allowed. This is a commonsense approach to regulating fugitive emissions. A CMPU with a very low overall percentage of leaking equipment can be monitored less frequently as the emissions are already very low and more frequent monitoring is not going to result in significant reductions in emissions. The re-monitoring of all equipment in a CMPU is less likely to identify a leak when the results from multiple consecutive monitoring periods identify only a small number of leaking components. When evaluating control alternatives for gas/vapor and light liquid valves in EO service, EPA only considered two options, both of which include a monthly monitoring frequency without the ability to reduce based on performance. There are other options that will likely yield an acceptable MIR, including quarterly monitoring coupled with two months of monthly monitoring following the detection of a leak as well as monthly monitoring with the ability to reduce the frequency based on performance as the rule currently allows for gas/vapor and light liquid valves in OHAP service. EPA must revisit their evaluation on this type of equipment to ensure that the review is comprehensive, and the new standards adequately balance performance with cost effectiveness and technical feasibility.

IX. EPA Should Incorporate Alternate Standards to Accommodate Startup and Shutdown Emissions

Our comments indicated standards for startup and shutdown emissions are needed and we provided several examples.[114] However, Response to Comment 327 did not address these examples, stating instead that the Section 114 responses contained no information that indicated process operations during startup and shutdown would interfere with control device operation, and reiterated their expectation that air pollution control devices would operate during startup and shutdown conditions.[115] We respectfully disagree with EPA's reasoning because not all affected sources were represented by the Section 114 responses. EPA did not have a comprehensive dataset representing all operating conditions at each affected facility from its Section 114 responses, but our comments were meant to augment the information available to EPA.

EPA also points to the fact that maintenance vent standards had been finalized and that

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[114] Examples included temperature of combustion control devices at startup, unsafe combustion conditions during startup, performance of catalytic oxidizers during startup.

[115] EPA-HQ-OAR-2022-0730-2764, pg. 361

facilities could designate vents during startup and shutdown as maintenance vents. The maintenance vent standards are not sufficient to cover all situations. Per the Response to Comment 296, "The standards we proposed and are finalizing are intended to address equipment openings that result from startup, shutdown, maintenance, or inspection of equipment where equipment is emptied, depressurized, degassed, or placed into service."[116] One requirement at §63.113(k) is that prior to venting to the atmosphere, the facility must "remove liquids from the equipment as much as practical and depressurize the equipment;" this is not reflective of starting up a piece of equipment in a situation where it is unsafe to vent emissions to a control device. Just because the rule indicates a facility may declare a vent as a maintenance vent during startup does not make that provision practicable for all startup situations.

EPA established work practices for startup and shutdown in other Part 63 standards that reflect the difficulties that can sometimes occur when starting a process (e.g., an industrial boiler) and properly operating a control device. For example, EPA developed the startup and shutdown work practices for industrial boilers and process heaters in Table 3 to 40 CFR Part 63, Subpart DDDDD, based on the recognition that certain control devices do not perform optimally during startup and requires them to be started as expeditiously as possible. 40 CFR Part 63, Subpart MM also allows a certain number of control device parameter operating exceedances at 63.684(k) before becoming a violation of the standards and excludes certain parameters from being classified as monitoring exceedances, such as scrubber pressure drop during startup and shutdown. Facilities are required to implement corrective action when monitoring exceedances occur, which "can include completion of transient startup and shutdown conditions as expediently as possible." These work practice standards were based on reviews of permits and comments from affected sources, and not solely on Section 114 information. We simply request the same treatment as these other source categories.

EPA also recognized the importance of considering safety along with good air pollution control practices when adding "general duty" provisions as work practices to rules that require "[a]t all times, the owner or operator must operate and maintain any affected source, including associated air pollution control equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions."[117] The reality of operating an industrial source like a chemical plant is that transient conditions occur during startup and shutdown and it is not possible to achieve all standards instantaneously. When certain processes start up, they can produce such a large volume of exhaust that the control device cannot immediately accept the vent gas until the process has stabilized. When a catalytic oxidizer is used as the control device, it cannot achieve the required destruction efficiency during startup for a short period of time because the required catalyst temperature is not immediately achieved (not all facilities preheat their catalytic oxidizers by burning auxiliary natural gas, which may have been

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[116] *Id.* at 343.

[117] 40 CFR 63.860(d).

EPA's assumption based on the limited Section 114 responses). We reiterate our desire to work with EPA to develop work practice standards for startup/shutdown-related transient vent conditions that are unsafe to control or that cannot be controlled at the efficiency required during all other periods of operation. Some work practice standards:

- Two facilities report that safe and efficient operation of combustion control devices is dependent on combustible process off-gases that are not always available in the right amount during startup. As a result, the control device might not be at full operating temperature during some period of startup, or some of the gases might need to be vented to atmosphere to prevent conditions of unsafe combustion. A work practice could include the requirement to vent to controls upon indication that it is safe to combust the gases.
- Two facilities stated that achieving a safe, steady state condition before introduction of streams to the control device is required during startup because hazardous over-pressurization of vents can occur unpredictably, which could potentially lead to uncontrolled venting. Pointing again to the industrial boiler work practices in Subpart DDDDD, facilities that find it unsafe to engage and operate controls within 1 hour of firing certain fuels can request a variance [see §63.7555(d)(13)].
- One facility identified a process stream that, during startup and shutdown only, would add too much air (oxygen) to the control device and needs to reduce oxygen levels prior to introduction to the control to prevent unstable/unsafe combustion. The facility's air permit allows limited venting during startup or shutdown of the process, so long as each occurrence of venting is recorded and the mass of pollutants during periods of startup/shutdown do not exceed a specified mass limit.
- A facility that produces chlorinated hydrocarbons is unable to use its thermal oxidizer/scrubbers during startup because of concentration spikes of combustible materials that would cause potentially hazardous combustion upsets. During startup, the facility currently and in accordance with its permit routes one or several process vents to a water scrubber. A different process at the same facility must be inerted during its shutdown, and during these periods, the facility routes these inerted vent streams to a water scrubber rather than the oxidizer/scrubber to avoid likely and potentially unsafe combustion upsets in the oxidizer. In this example, a work practice could allow the use of a safer but less effective control during startup than the control strategy used during normal operation.
- A facility's initial concentration of VOC in the process vent stream being controlled is at too low a concentration to maintain the required temperature of the catalytic oxidizer. The flows and concentration needed by the control device are established within a few hours of startup. This is precisely the situation contemplated by the industrial boiler work practices that allow delayed operation of catalytic controls during startup. Addition of natural gas combustion to preheat the catalytic oxidizer would actually create emissions of benzene and trigger the

requirement for fenceline monitoring; this is an unreasonable outcome that should be addressed by the addition of startup work practices for catalytic oxidizers.

X. Total Resource Effectiveness Concept Should Be Restored

The removal of Total Resource Effectiveness (TRE) concept from HON, P&R I, and the SOCMI NSPS subparts (40 CFR Part 60, Subparts IIIa, NNNa, and RRRa) was retained as proposed. The TRE is a measure of the resource burden necessary to control the VOC or HAP in a stream by thermal oxidation and enables affected sources to evaluate whether controlling a stream is cost effective. Process vents with a TRE index greater than one are classified as Group 2 process vents and thus do not require control. EPA included the removal of the TRE concept as part of their CAA Section 112(d)(6) technology review and Section 111(b)(1)(B) NSPS review. In the proposal,[118] they noted that the action is considered a "development in practices, processes, and control technologies" for the following reasons:

- There is at least one chemical manufacturing NESHAP, ethylene production, that does not include the TRE index value as criteria for determining whether a process vent should be controlled;
- Some facilities are voluntarily controlling Group 2 streams that have TRE index values greater than one and for which control is not required;
- Most facilities route multiple process vents to a single control device. The TRE index was not developed for this type of configuration and is strictly based on controlling a single process vent with a single control device; and
- The practical execution of the TRE calculation and enforcement of the representations is very difficult for some sources. The calculation often includes uncertainty such that multiple assumptions are required to arrive at a conclusion, and third-party verification without intimate knowledge of the process is challenging.

There are several issues with the justification EPA presents for the removal of the TRE threshold that we identified in our comments. EPA should reconsider its classification that removal of the TRE index is considered a "development in practice, process, or control technology". Although TRE was not included in Ethylene MACT, the rule does not differentiate between Group 1 or Group 2 process vents because "there are relatively few process vents at ethylene manufacturing facilities.[119]" The utility of the TRE index value was explicitly excluded not because of the reasons EPA has listed in this rulemaking, but simply because it didn't make sense for that specific source category. The use of an industry that is covered by the broader group of generic MACT standards as an example in this case does not support removal of the TRE index

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[118] 88 Fed. Reg. 25,129.

[119] 64 Fed. Reg. 76429.

as there are other industries (e.g., acetal resins, polycarbonate production) that continue to include TRE as a way of determining the control standards that are applicable to process vents.

The fact that some facilities are controlling process vents with a TRE greater than one does not imply that they are voluntarily doing so and also does not mean that the control of those vent streams is cost effective. There are several reasons why a source might control a vent stream that are not voluntary. These can include state and federal regulations, a condition upon which a preconstruction permit was issued (air dispersion modeling, state boilerplate, etc.), a BACT or LAER review, safety concerns, or internal standards/guidelines specified by the licensing organization or corporate leadership. Additionally, there are multiple facilities that control process vents with a TRE greater than the applicable thresholds that incorporate the approach to comply with the emissions averaging provisions in §63.150. EPA has not evaluated how the changes to the TRE will impact facilities that use emissions averaging for compliance and it is not clear how the emissions averaging program can continue to exist with the requirement to control process vents that are currently designated as Group 2 vents.

The potential complexity of the TRE index value calculations does not justify its removal. There are multiple examples of state and federal regulatory requirements that include the mandatory use of complex mathematical formulas. There remain multiple federal regulations that continue to include the TRE index value, including MON for which the TRE index was retained as part of a recently completed RTR.[120] Additionally, as we discussed in our comments, there are facilities which have few organic compounds and site-specific data that simplify the calculations. Sources in the chemical manufacturing industry have become very comfortable with the TRE index value since its inception and its successful use is demonstrated through the fact that streams with higher TRE index values are consistently those with very low net heating value, low concentrations of organic compounds and HAPs, and higher concentrations of inert compounds such as water and nitrogen.

EPA has not properly considered cost associated with the removal of the TRE concept in its review. With this change, any stream with more than 1 lb/hr of organic HAP under any operating condition must be controlled. EPA has asserted that the analysis that was prepared to support the new threshold of 1 lb/hr of organic HAP for a Group 1 process vent shows that the control of all of these vents is cost effective[121]. However, as noted in our initial comments, the analysis that was conducted to support that conclusion is flawed. The results are skewed as they take credit for decreases from streams already controlled. Not only was the discrepancy not explained in the final rule, but EPA erroneously adjusted the claimed reductions up to 538 tpy for HON facilities and 130 tpy for P&R I facilities (from 436 tpy and 51 tpy respectively). The reason for the increase in the claimed emissions reductions is that EPA is now including estimated reductions from existing Group 2 process vents that are not in EO service and ***are*** already voluntarily controlled in the

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[120] 85 Fed. Reg. 49,084.
[121] 88 Fed. Reg. 25,129.

estimated average reduction per vent for vents that ***are not*** already voluntarily controlled.

The costs associated with installation of a thermal oxidizer are also unrealistically low. In response to our comments, EPA has revised the cost up to $167,000, which remains far too low.

In addition to capital investment for new control devices, there are other costs that will be incurred. Without the TRE option, there is extensive testing required to maintain process vents as Group 2 to show that they are less than the 1 lb/hr threshold. There are also going to be new vents that will now require performance testing. In one case, the elimination of the TRE index will require that performance testing be conducted on eight (8) different recovery devices (Absorbers) which have very low emissions of HAPs.

We believe that with a proper reconsideration given to the justification for why the TRE index value was removed as well as the cost associated with doing so, EPA will find that complete removal is unwarranted. Either the TRE index should be retained as-is, or, if EPA believes the record shows revision is needed - which we do not see a basis for in the current record - the threshold should at most be changed to a value EPA determines is supported by the record.

If after a careful reconsideration of the removal of the TRE index value, EPA continues to believe that this change is cost effective and justified, we would like to request a meeting to discuss compliance options for intermittent vents, including alternatives such as an annual total limit of 1.0 tpy that corresponds to an annual average hourly emissions rate of 0.25 lb/hr.

XI. Compliance Timelines Should be Changed

To the extent they are not withdrawn on reconsideration, EPA should reconsider the compliance timelines for various requirements. First, EPA finalized a compliance date of only two years from the effective date for compliance with the standards addressing risk from EO.[122] EPA states this is because CAA Section 112(f) only provides for a compliance period between 90 days and two years. We disagree. In this instance, EPA conducted a second residual risk review for the SOCMI source category after completing its one-time obligation to do so under CAA Section 112(f). It is doing so "due to the EPA's 2016 updated IRIS inhalation URE for EO, which shows EO to be significantly more toxic than previously known."[123] As discussed above, there is no statutory provision supporting authority to conduct a second risk review, but rather EPA asserted it "retains discretion to revisit its residual risk reviews where the Agency deems that is warranted."[124] If EPA continues to assert that it nonetheless has authority to voluntarily conduct a second risk review, EPA is clearly not bound to follow the timelines in §112(f)(4) for mandatory initial risk reviews. As discussed above, the additional requirements create significant compliance difficulties in general that are made more difficult by the two-year compliance deadline.

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[122] 89 Fed. Reg. at 42954.
[123] 88 Fed. Reg. at 25090.
[124] 88 Fed. Reg. at 25089.

In general, facilities need time to comply with any revised regulatory requirements because they must review the new requirements, develop a plan to comply with the new requirements, determine if process changes or additional controls are needed, engineer and implement any process changes or additional controls, determine if new monitoring equipment is needed to meet the new flare monitoring requirements, install the new monitoring equipment, determine if an air permit application is needed, prepare and submit the permit application, obtain the air permit approval from the agency, revise regulatory compliance plans and procedures, update recordkeeping and reporting procedures, and roll out new requirements to facility staff. Specifically, it is a significant effort to understand and then implement the myriad changes EPA has made to the SOCMI rules, and both internal and external resources are required. Two years is not enough time to conduct the activities that are required to comply with the new EO requirements. Companies must complete sampling and analysis on an array of process vents and heat exchange systems and review available information for equipment and storage tanks to determine whether sources are in EO service. Once sources are identified, time is required to review the performance of existing control devices to determine whether existing controls can meet the emissions standards. According to EPA's impact analyses included in the rulemaking docket, facilities will be required to install new closed vent systems, control devices, monitoring equipment, and develop new standard operating procedures, recordkeeping templates, and reporting methodologies. Additional time is needed to engineer, order, install, and commission any new controls. Due to the reactive nature of EO and associated process safety requirements an appropriate amount of time and process engineering expertise is needed to properly engineer controls and associated process control systems to ensure worker and community safety. **Further time is needed to conduct performance testing, make necessary notifications, and modify existing permits. We ask EPA to reconsider its position that it was bound by §112(f) compliance deadlines and provide in the rule the three-years permitted for standards promulgated pursuant to EPA's recurrent review obligations. EPA should then also permit additional extensions as permitted under 112(i)(3).**

Second, if EPA maintains a fenceline monitoring requirement, we ask for a full three years to implement the fenceline monitoring requirements, and that the requirements for corrective actions be required starting in the fourth year. As we outlined above, there are many steps involved in commencing a new regulatory program and the rule is difficult to read and understand. With a new fenceline monitoring program, facilities must also select contractors and laboratories after a competitive bid process and then acquire an adequate supply of canisters, flow controllers, and tubes in time for compliance. Most contractors assisting our members with implementing the fenceline monitoring requirements have stated that a pilot study is necessary to guide the development of a fenceline monitoring program specific to each facility. This pilot program will take six months at best to complete. Our members expect they will be required to hire and train additional staff and/or contractors to implement the sampling program and perform the associated data analysis and RCA/CA.

Our members are concerned that two years is not enough time for the supply chain to be able to accommodate a significant increase in demand for equipment and analysis. At least 10 sampling canisters will be needed every 5 days at some locations. One site alone will need to acquire 60 canisters and 50 to 75 tubes to ensure smooth operation of the fenceline monitoring program. We are unsure if canisters can be reused due to uncertainty with cleaning methods. Our members are also concerned about availability of accredited laboratories in time for initial implementation of the fenceline monitoring program. Laboratories will need to expand their capacities to be able to handle a large increase in the demand for analysis, cleaning, shipping, etc. They will need to purchase, install, and validate additional equipment such as cleaning ovens, air concentrators, auto samplers, and gas chromatography/mass spectrometry instruments to handle the sampling increase.

Additionally, we expect several facilities will need to develop and submit site-specific monitoring plans to account for offsite upwind sources to be excluded from monitoring requirements. Refineries were given two years to begin their fenceline monitoring programs for benzene,[125] but several of our members will be required to perform fenceline monitoring for multiple pollutants. This will further complicate site-specific monitoring plans because of the need to address different chemicals from differing facilities due to proximity of nearby sources. Locating offsite monitors will likely be a lengthy process due to the need to identify representative, accessible, and secure monitoring locations and obtain permission from the property owner to both place and routinely access the monitor, prior to submission of a site-specific monitoring plan. Facilities also indicate they will be required to make physical improvements to their fence lines to be able to site monitors. These improvements will include construction of access roads, physical fencing, and potential drainage improvements, all of which may require additional permitting and approval according to local jurisdiction. Such facilities will additionally require time for standard approvals of capital expenditures. All of these activities and concerns add up to a conclusion that it will be almost impossible for all facilities to successfully implement a fenceline monitoring program in two years.

Third, we ask EPA to adjust the compliance timing for the new requirements at §63.119(b)(5)(ix) through (xii) for internal floating roof tanks in EO service to upgrade certain fittings and at (b)(7) for facilities that use a sweep, purge, or inert blanket between an internal floating roof and the fixed roof to route emissions through a closed vent system to a control device. Our comments described the difficulties that may be encountered when implementing these requirements. Rather than requiring compliance with the new requirements within two or three years of the effective date, we request EPA allow facilities to delay implementation of the requirement until the next planned tank outage, up to 10 years. With respect to the additional requirements for tank fittings for vessels in EO service added as a result of EPA's CAA Section 112(f) review, we believe that EPA can extend the two-year compliance date because the second

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[125] Refer to 40 CFR Part 63, Subpart CC. Additionally, see 80 Fed. Reg. 75186.

risk review was conducted voluntarily, not as a result of the CAA requirement to conduct a one-time initial risk review, as we detailed in our comments on the proposed rule. EPA has allowed the timeline we are requesting in other rules such as 40 CFR Part 63, Subpart WW at §63.1063. Indeed, EPA should be able to provide a similar approach even if it proceeds under 112(f) since it is imposing requirements upon promulgation. Requiring a tank outage prior to the next scheduled outage just to install these controls will result in additional waste generation and emissions from startup, shutdown, and maintenance, just as we discussed in our comments on lack of delay of repair for equipment in EO service.

XII. Limits for Chlorinated Dibenzo Dioxins/Chlorinated Dibenzo Furans Should be Corrected.

In our comments on the proposed rule, we recommended that EPA not finalize the proposed limit for chlorinated dibenzodioxins and chlorinated dibenzofurans (CDD/CDF) and instead collect additional emissions data from affected units and properly consider the Agency's ability to apply different limits to subcategories of HON, P&R I, and P&R II units, as allowed by the CAA. EPA rejected our comments stating that "no additional information was provided by industry to support the request for subcategorization."[126] EPA also rejected our comments on the basis that the test data from ethylene dichloride/vinyl chloride monomer (EDC/VCM) plants represent sources with the maximum chloride loading expected in a HON, P&R I, or P&R II process, thus, the MACT floor should provide control devices for less chlorinated streams a wider compliance margin. We request EPA reconsider the final emissions limits for CDD/CDF for the reasons stated below.

In response to EPA's statements that commenters did not provide additional data, we request that the Agency consider the compressed timeline available to submit comments (i.e., 71 days) on a package encompassing multiple rules under both 40 CFR Part 60 and Part 63. Limits for CDD/CDF were just one of the multitudes of technically complex changes requiring commenters to prioritize resources. Due to the volume of rule revisions requiring review we were unable to collect additional stack test data during the comment period. We note that EPA provided the January 2022 ICR respondents over 180 days to perform sampling, review results, and submit the information to EPA. We request EPA reconsider the CDD/CDF emissions limit to allow sources adequate time to develop and execute test programs to collect additional data to inform revised emissions limits.

We also disagree with EPA's assertion that a limit established using EDC/VCM test data (collected over a decade ago) will provide an adequate compliance margin for all other potential sources of CDD/CDF. First, the record lacks adequate justification from the Agency on how it established that there are at least 34 HON CMPUs. A closer examination of the number of sources

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[126] EPA-HQ-OAR-2022-0730-2764, pg. 351

emitting CDD/CDF should be conducted to ensure the appropriate approach to calculating the MACT floor is selected [i.e., CAA Section 112(d)(3)(A) or (B)]. Although chlorine loading can influence CDD/CDF formation, it is not the only factor affecting the concentration of emissions in the control device exhaust. Residence time, combustion temperature, post combustion cooling, the presence of particulate in the exhaust gas, as well as the presence of various elements and compounds other than chlorine can affect the CDD/CDF formation rate.[127] It is unclear how EPA could conclude that a limit based on a relatively homogeneous dataset of EDC/VCM sources is representative of all affected sources, much less the best performers, without consideration of these other factors.

We are particularly concerned that the dataset EPA used did not include emissions test data for process vents co-controlled with liquid and gas streams, such as those vents that are controlled in halogen acid production furnaces (HAPF) and other combustors subject to both HON and the National Emissions Standards for Hazardous Air Pollutants from Hazardous Waste Combustors (40 CFR Part 63, Subpart EEE). Our members have several chlorinated process vents that are co-controlled in combustors subject to Subpart EEE that also control chlorinated organic liquid streams and in some cases liquid and gaseous process vents. Liquids require a different type of combustor for destruction and recapture of hydrochloric acid and typically operate at different conditions than thermal oxidizers that only control gaseous vent streams. These units are clearly not a “similar” source as contemplated by the CAA. Thus, we request EPA reconsider the CDD/CDF limits, provide adequate time to collect additional data to understand the differences between sources, and establish appropriate CDD/CDF limits.

XIII. Requirement at 40 CFR 63.119(b)(7) for Sweep, Purge, or Inert Blankets Between Internal Floating Roofs and Fixed Roofs Should be Reconsidered

We request that EPA reconsider the provisions at 40 CFR 63.119(b)(7) to control continuous emissions of organic HAP of 1.0 lb/hr or more to the atmosphere. More specifically, we request that EPA remove these provisions from the rule until the Agency can properly justify the requirements under CAA Section 112(d)(6).

At proposal, EPA provided no justification for the proposed changes, other than as a “technical and editorial change.”[128] In our comments, we explained that even though EPA failed to present the basis for the revision, the change was not cost-effective and should not be implemented under a beyond the floor analysis. It was not until EPA promulgated the final rule that the Agency offered an explanation of their justification for the revisions, i.e., that use of a sweep, purge, or blanket that results in a continuous emission from the tank “effectively creates a continuous process vent,” and that the Agency “proposed to address this regulatory gap pursuant to CAA

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[127] https://www.dcceew.gov.au/sites/default/files/documents/incineration-review.pdf

[128] 88, Fed. Reg, 25,173.

section 112(d)(2) and (3)…"[129] This statement is factually incorrect. EPA included the proposed change without reference to any CAA provision under section III (*Proposed Rule Summary and Rationale*) E (*What other actions are we proposing, and what is the rational for those actions?*) 5 (*Technical and Editorial Changes*). The preamble to the proposed rule contained a distinctly separate section for changes related to CAA Section 112(d)(2) and (d)(3) and even if the Agency did not reference the CAA in their explanation of the change, they could place the explanation under the appropriate section if they were proposing the change pursuant to CAA Section 112(d)(2) and (d)(3). Because EPA failed to explain the basis of the change at proposal, commenters were not provided with adequate notice of the Agency's justification and the Agency is thus required to grant reconsideration on this issue.

Even though EPA did not explain their justification at proposal, the basis of the requirement offered at the final rule is fatally flawed. First, EPA claims that the "continuous sweeping, purging, or blanketing between the [internal floating roof (IFR)] and the fixed roof of the vessel effectively creates a continuous process vent." We disagree: the term process vent is specifically defined at §63.107 which states that some or all of the gas stream must originate from a continuous flow from an air oxidation reactor, distillation unit, or reactor during operation of the CMPU. Further, the definition excludes storage vessels, i.e., "the gas stream is not any of the items identified in paragraphs (h)(1) through (9) of this section… (7) a storage vessel vent or transfer operation vent subject to § 63.119 or §63.126." Thus, the vent from a storage vessel is not a process vent. Process vents and storage vessels are two distinctly separate, and separately regulated, sources under the rule.

EPA also claims that a continuous vent from a purge, sweep, or blanket between an IFR and fixed roof is a regulatory gap – this is also factually incorrect. Any emissions resulting from such a purge, sweep, or blanket are **post-control**. The emissions from the storage tank have already been controlled via the IFR, which EPA previously established as MACT. Moreover, in the April 22, 1994 rule, EPA established an IFR or an external floating roof (EFR) as MACT. EPA's assertion that a purge stream from an IFR is a regulatory gap does not comport when considering that the controlled emissions from an EFR would be practically equivalent to those from the IFR purge, if not greater than the IFR purge. It is unexplainable that the conversion of an EFR to an IFR via the addition of a fixed roof would create a regulatory gap.

Even if a gap were present (it is not), EPA's claim that the uncontrolled emissions threshold of 1.0 lb/hr of total organic HAP is consistent with CAA section 112(d) controls and reflects the MACT floor is also flawed. At the outset, EPA previously established the MACT floor for storage vessels in the April 22, 1994 rulemaking: any additional control of post-controlled emissions requires a CAA Section 112(d)(6) technology review and thus a consideration of cost. EPA cannot bypass the consideration of cost through an improperly applied MACT floor analysis. Next, EPA has inappropriately linked storage vessel emissions to a process vent analysis and, as

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[129] 89 Fed. Reg., 43,023.

previously stated, these are two separate sources that warrant separate MACT floor analyses. Had EPA needed to establish MACT, it should have evaluated the performance of similarly controlled sources (i.e., other storage vessels with an IFR) and not process vents. Additionally, EPA erred when it implied that 1.0 lb/hr of organic HAP represents the MACT floor for process vents. EPA established the 1.0 lb/hr threshold as part of its technology review for process vents, not a MACT floor analysis (we maintain that EPA's technology review and elimination of TRE is also flawed as detailed previously in our comments and in this petition.).

For the reasons detailed above, EPA is required to reconsider the provisions at 40 CFR 63.119(b)(7) and remove the requirements to control a purge, sweep, or blanket from and IFR from the rule text. EPA failed to provide adequate notice of its justification for the revisions at proposal, and the explanation offered at the promulgation of the final rule contained several technical errors. The rule change represents a misapplication of MACT and should have been evaluated by considering cost under CAA Section 112(d)(6). Had it done so, EPA would have determined that the changes are not cost-effective and therefore are unwarranted.

1. Options for Inspection Requirements for Group 1 Internal Floating Roofs

We request that EPA include necessary flexibility for Group 1 storage vessel inspections. Specifically, based on the Agency's approach in other rules for comparable sources, it is appropriate for EPA to consider requirements in the HON that include an option to perform in-service 10-year inspections similar to current MACT WW standards and NSPS Kc.[130]

In previous rulemakings, EPA has included alternative compliance options to allow the inspection of storage vessels with internal floating roofs to be conducted from within the tank while the tank is in-service.[131] In these contexts, EPA has previously acknowledged that requiring a storage vessel to be emptied and degassed only for the purpose of conducting this inspection involves associated costs and emissions, and these costs and emissions would be avoided if the inspection were conducted with the tank in-service. In the final NSPS Subpart Kb, EPA stated:

> Conducting the in-service top-side-of-the-floating-roof inspection per NESHAP subpart WW affords the inspector the same ability to examine all the listed components for all of the listed defects/inspection failures as if the storage vessel was emptied and degassed, but avoids the cost and emissions associated with that empty and degas event.
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> Emptying and degassing events are undesirable primarily because owners or operators must take the storage vessel completely out of service, which includes additional non-routine labor costs, results in the need for extra storage capacity, and creates VOC emissions.

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[130] 89 Fed. Reg. 83,296, 83,311 (Oct. 15, 2024).
[131] 86 Fed. Reg. at 5013 (January 19, 2021).

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> Thus, conducting the in-service top-side-of-the-floating-roof inspection per NESHAP subpart WW rather than taking the storage vessel out of service reduces both the costs incurred by the owners or operators and the VOC emissions that are otherwise released during emptying and degassing events.[132]

Given EPA's acknowledgment that requiring tanks to be emptied and degassed for these up-close inspections would result in avoidable costs and emissions, and that nothing in the current regulatory text appears to alter that conclusion for this source category, EPA should provide for conducting these inspections in-service in the HON. This could be achieved by editing the text with language similar that in 40 CFR part 63 subpart WW as shown below:[133]

> §60.113c(a)(2) Inspect the internal floating roof as specified in paragraph (a)(2)(i) of this section at least once every 12 months after initial fill, and inspect the internal floating roof as specified in paragraph (a)(2)(ii) of this section each time the storage vessel is emptied and degassed, or at a frequency no greater than every 120 months, whichever occurs first. The inspection specified in paragraph (a)(2)(ii) of this section may be performed entirely from the top side of the floating roof, as long as there is visual access to all deck components specified in §60.112c(b). [Inspections that are required every 12 or every 120 months must be conducted before the end of the calendar year in which the inspection deadline occurs, provided there is at least 3 months between successive inspections.] This could also be achieved by incorporating an alternative means of compliance, similar to § 60.110b(e), which allows the owner or operator to comply with part 63 subpart WW that allows for in service, top-side inspections.

EPA could also achieve the same result by including an alternative means of compliance, similar to §60.110b(e), which allows the owner or operator to comply with part 63 subpart WW that allows for in service, top-side inspections.

XIV. Standards for Wet Strength Resin Manufacturers

EPA finalized requirements at 40 CFR 63.524(a)(3) and (b)(3) as proposed, which mandate that wet strength resin (WSR) sources meet both the production-based HAP emissions limits (pounds of HAP per million pound of resin produced from process vents, storage tanks, and wastewater systems) and the HON LDAR monitoring requirements in 40 CFR Part 63, Subpart H. WSR sources were historically allowed to comply with either the HON LDAR monitoring or the production-based standard and will now need to comply with both requirements. The production-

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[132] 85 Fed. Reg. at 65779 (October 16, 2020).
[133] 40 CFR § 63.1063(d)(1).

based standard for WSR sources limits emissions from process vents, storage tanks, and wastewater systems to 10 pounds of HAP per 1 million pounds of WSR production (lbs HAP/MMlbs WSR produced) for existing affected sources and 7 pounds of HAP per 1 million pounds of production for new or reconstructed affected sources. EPA justified this change by stating that because there are two WSR sources that are complying with the HON LDAR monitoring, the legacy determination that the MACT floor for equipment leaks is "no control" is no longer valid and that the new MACT floor for WSR sources is compliance with both standards. EPA asserted that WSR sources are already complying with both standards and thus there are no impacts associated with the change[134]. For this reason, EPA did not provide any supporting documentation to support the updated MACT floor for emissions from the WSR source category.

It is not true that all WSR sources already comply with both standards, and it is not clear that they can do so based on the rule as finalized. It is true that process vents at WSR sources are typically controlled and have very low HAP emissions. However, not all storage tanks are controlled in a similar manner. Specifically, epichlorohydrin (EPI) storage tanks can have uncontrolled potential HAP emissions that result in an exceedance of the production limitations established in 40 CFR 63.524(a)(1) and (b)(1), necessitating the implementation of costly control measures. Of particular concern are emissions from wastewater systems where streams from both the WSR affected source and a separate process unit are comingled. There are no distinctions in the wastewater definitions or the WSR emissions standards that provide a method of isolating the emissions associated with the WSR source. The standard for basic liquid resin (BLR) manufacturer's at §63.523(b)(3) addresses this by defining uncontrolled emissions from wastewater systems as the "total amount of HAP discharged to the drain system". One member operates a WSR source with wastewater effluent discharged to a waste management unit that is shared with another process unit that also discharges HAP containing wastewater. It is currently unclear that, after combining the emissions with storage tanks and process vents, compliance with the production-based standard can be achieved even after controlling the wastewater emissions.

The approach EPA used to redefine the MACT floor for WSR sources does not follow the process statutorily required by the CAA. The MACT floor for a source category is either the average emission limitation achieved by the best performing 12 percent of the existing sources in a category with more than 30 sources or the average emission limitation achieved by the best performing 5 sources when the category has less than 30 sources. Cost must be considered when requiring reductions beyond the MACT floor. When the original standards for WSR sources were promulgated, MACT floors were separately established for equipment leaks and the combination of emissions from process vents, storage tanks, and wastewater systems. At that time, it was determined that there were no WSR sources conducting LDAR monitoring for equipment leaks, and thus the MACT floor was effectively "no control". The MACT floor for the remaining emission points was found to be equivalent to the production-based standards currently in the rule for new

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[134] 88 Fed. Reg. 25166.

and existing sources. Because the MACT floor for equipment leaks was "no control", and the potential for emissions reductions from equipment leaks was significantly higher than the other sources, EPA intentionally offered the alternative option to conduct HON LDAR monitoring in lieu of complying with the production-based standard. It was explicitly acknowledged that it would be less costly than adding controls and was preferable due to the greater emissions reduction that would be achieved. In response to this, as expected, some WSR sources proceeded with implementing the HON LDAR monitoring option as allowed by the rule. For this reason, there are some facilities that chose to comply with the HON LDAR monitoring option. This choice does not imply that these WSR sources are also complying with the production-based standard as they may have never installed controls to achieve compliance. Additionally, the use of two WSR sources is not sufficient to re-establish a MACT floor as there are fewer than 30 WSR sources and thus it must be compared against the best performing five sources in the category. EPA must reconsider the mandate that all WSR sources comply with both standards and evaluate how the best performing five sources are controlling emissions from equipment leaks, storage tanks, process vents, and wastewater systems. If the finding is that compliance with both standards is beyond the MACT floor and EPA would like to retain the requirement, EPA must also consider the costs associated with compliance. These costs will include installation of control devices on both EPI storage tanks and wastewater systems.

If after reconsidering the final rule, EPA chooses to retain the requirement to comply with both the HON LDAR monitoring and the production-based standard, EPA must revise rule language to provide clarity where it is needed and to ensure that the rule only regulates emissions generated from emissions points in the WSR source. Specifically, 40 CFR Part 63, Subpart W lacks sufficient clarification regarding how to handle WSR sources that operate in conjunction with other process units that are not part of the source category. In cases where wastewater is shared between a WSR source and other process units, the absence of more specific language necessitates that all emissions of HAP from the wastewater system be accounted for in the total emissions, irrespective of the originating source. There are also no provisions on how to address overlaps with other potentially applicable rules. For example, there are no provisions addressing how to allocate storage tanks between a WSR source or other process unit if they are shared and routinely change service depending on what is being produced at the facility. Additionally, other MACT subparts allow for compliance with a single standard for storage tanks when multiple federal emissions standards apply. By incorporating overlap provisions and addressing compliance for WSR sources that operate at a facility with other process units, EPA will reduce confusion and streamline compliance.

XV. Conclusion

In summary, we believe the issues we have raised in this petition warrant reconsideration of the revised SOCMI/P&R I and II NESHAP and NSPS regulations, and that in some instances reconsideration is required. Industry needs clarity, certainty, and flexibility in order to comply with EPA's complex new requirements. We look forward to working with you to resolve our concerns. Please feel free to contact ACC at 202-249-6423 or Brendan_Mascarenhas@americanchemistry.com or AFPM at 202-457-0480 or LBellas@afpm.org, if you have questions or need more information.

Sincerely,

Brendan Mascarenhas
Senior Director, Regulatory & Scientific Affairs
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Leslie Bellas

Leslie Bellas
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American Fuel & Petrochemical Manufacturers

Appendix 1

Requests for Clarification re: NSPS and NESHAP for SOCMI and Group I & II Polymers and Resins Industry Final Rule

EPA-HQ-OAR-2022-0730 (89 FR 42932; May 16, 2024)

On July 23, 2024, ACC met with EPA OAQPS to raise several pending issues for clarification/further discussion associated with the requirements promulgated by EPA in the final "New Source Performance Standards for the Synthetic Organic Chemical Manufacturing Industry and National Emission Standards for Hazardous Air Pollutants for the Synthetic Organic Chemical Manufacturing Industry and Group I & II Polymers and Resins Industry" as published in the May 16, 2024 Federal Register (89 FR 42932). As follow-up to that discussion, ACC presents the following list of issues for additional consideration and action by EPA.

As EPA considers the issues presented in this appendix, we strongly encourage the Agency to provide necessary clarifications in a formalized document, e.g., additional regulatory text, technical corrections, frequently asked questions (FAQ) resources, or general guidance posted for reference on the EPA website. Any written resource of EPA interpretations will help reduce future uncertainty and streamline the implementation process, particularly during any future engagement with local regulatory authorities.

I. FENCELINE MONITORING PROGRAM

A. Can EPA confirm that for the fenceline monitoring program, the presence of impurities do not trigger applicability?

Reference at 63.184(a)(1) "The owner or operator must monitor the target analyte(s), as specified in paragraphs (a)(1)(i) through (iv) of this section. The owner or operator must follow the procedure in Section 9.6 of Method 325B of appendix A to this part to determine the detection limit of benzene, 1,3-butadiene, chloroprene, and ethylene dichloride for each sampler used to collect samples and blanks. (i) If an affected source uses, produces, stores, or emits benzene, the owner or operator must include benzene as a target analyte. . . ."

In EPA's Response to Comment document, they noted on pg. 272 the proposed language to base requirements on "site" vs. affected source:

> 1. "However, we agree with the commenter that the proposed language could be interpreted such that emissions from non-HON or P&R I processes could trigger the fenceline monitoring requirement. As such, we are revising 40 CFR 63.184(a)(1)(i) through (iv) and 40 CFR 63.184(b)(1)(i) and (ii) to state that owners and operators with an affected source that uses, produces, stores, or emits one or more of the target analytes must conduct fenceline monitoring for the analyte(s) at their site. At proposal, we inadvertently used the word site in these sections instead of affected source, which may have led to confusion that non-HON or P&R I processes could have triggered fenceline monitoring obligations when there were no HON or P&R I processes at the site that use, produce, store, or emit benzene, 1,3 butadiene, ethylene

> dichloride, vinyl chloride, EtO, or chloroprene. We believe this change clarifies our original intent and helps to more clearly target those facilities that were identified as needing fenceline monitoring as part of our original analysis (see Docket Item No. EPA-HQ-OAR-2022-0730-0091)."

According to the EPA's preamble of the new fenceline monitoring requirements:

> 1. Per 40 CFR 63.184, the fenceline monitoring provisions are applicable ''for each source as defined in § 63.101, and for each source as defined in § 63.191.'' The definitions of source at 40 CFR 63.101 and 40 CFR 63.191 point to 40 CFR 63.100 and 40 CFR 63.190, respectively, where applicability is stated. For the HON, only those sources manufacturing as a primary product one or more of the chemicals in Table 1 to NESHAP subpart F, or tetrahydrobenzaldehyde, or crotonaldehyde; or using as a reactant or manufacturing as a product, or coproduct, one or more of the HAP listed in Table 2 to NESHAP subpart F are subject to the provisions. For NESHAP subpart I, only those emissions specified from the processes subject to 40 CFR 63.190(b)(1) through (6) are subject to the fenceline provisions. **Therefore, any concerns about obligations to meet fenceline monitoring requirements for pollutants developed as impurities or found in feedstock in trace amounts are unfounded, as these materials are not ''products,'' which, by definition, exclude by-products, isolated intermediates, impurities, wastes, and trace contaminants per the definition at 40 CFR 63.101** or, in the case of NESHAP subpart I, are not the specified pollutants from the processes to which the subpart applies. See 89 Fed. Reg. 43006 (May 16, 2024.)

Regarding applicability, EPA's RTC also states that that sources would be defined per the terms at 40 CFR 63.100, so "there is no need to set a minimum threshold for fenceline monitoring as the rule already provides criteria targeting only SOCMI or P&R I sources using, producing, storing, or emitting one or more of the six considered pollutants and will not be triggered by low-level emissions from non-source category processes."

In addition, EPA provides additional comments in the preamble that indicate that the deletion of the word "site" and addition of "affected source" to the final regulation for FLM applicability was designed to limit only an affected HON source using a target analyte in the manufacture of a listed chemical to the Fence Line Monitoring requirements.

Based on the foregoing, an example for EPA's consideration is provided. A facility receives benzene as an impurity in the raw material OHAP used as a reactant (listed in Table 2) to manufacture a product chemical listed in Table 1 of § 63.100. The impurity (benzene) is not utilized and does not serve a useful purpose in the production of the primary product that is covered within a HON CPMU. Since the benzene is not utilized in the production process, some of it is emitted from the HON covered process vent exhaust stack to the

atmosphere. However, given the language above regarding the fact that the benzene is only present as an impurity, this example facility would NOT be subject to fenceline monitoring (even though it is otherwise subject to HON or P&R I and II).

Our members' experience indicates that for some facilities, a methylene chloride process does not use benzene as a raw material or manufacture it as a product or co-product but still may have small amounts of benzene that enter as a contaminant in raw materials or streams from other processes. EPA's proposed burden reduction measures do not provide adequate relief for these types of circumstances. As such, if analysis of the liquid stream shows no detectable benzene, then fenceline monitoring is not warranted and should not be required.

Separately, if there is detectable benzene, would facilities need to set up fenceline monitoring because of the reference to "emit" in 63.184(a)(1)(i)? We note again that where analysis of the liquid stream shows no detectable benzene, fenceline is not warranted and should not be required.

B. Additional Applicability Issues

It is unclear when the fenceline monitoring requirements apply for some instances where plants that are covered HON CMPU's. For example, in some instances there may be trace levels of the compounds of interest either present in raw materials or in the process. Some examples are:

1. Production of ethylene oxide – Some of our sites use ethyl chloride or ethylene dichloride in small amounts to control reaction rates. Both compounds can break down to ppm levels of vinyl chloride in some portions of the process. A reaction byproduct present in the ppm range will not be emitted at a level detectable at the fenceline. As such, we believe that fenceline monitoring requirements would not be warranted and should not be required.

2. One company has an EO unit that has a combustion control device that controls an EO stream. The control device is fired by pipeline quality natural gas. If benzene or 1,3 butadiene is present in the natural gas as an impurity or is a minor constituent combustion byproduct, then fenceline monitoring is not warranted and should not be required.

   In a similar situation, another company has a combustion control device that controls a HAP stream that is not a fenceline target HAP. The control device is fired by pipeline quality natural gas. There are trace amounts of benzene and 1,3-butadiene present in the natural gas and it is not quite all combusted. However, other than the natural gas fuel, the unit/facility does not use, produce, or emit these other 2 pollutants. We believe that fenceline monitoring would not be required for this facility; does EPA concur with this assessment?

3. Multiple companies operate within the boundary of a chemical complex. Company A operates an incinerator subject to HON. Company B produces a stream which contains ethylene oxide, and the stream is sent to Company C within the property boundary. Company C uses the ethylene oxide containing stream in their process and produces a vent stream, which still contains some ethylene oxide. The stream does not contain enough ethylene oxide to be a Group 1 Process Vent. Company C sends that stream to A where the material is combusted as a secondary fuel source for the incinerator. Can EPA clarify which companies would be subject to fenceline monitoring?

4. If an incinerator that is a control device for a CMPU unit emits one of the six target compounds due to combustion of natural gas, the facility should not be subject to fenceline monitoring for combustion by-products (i.e. benzene) that are not manufactured or used in CMPU unit and the control device should not be considered to be part of the CMPU unit.

5. One ACC member has pumps that use ethylene glycol as a pump seal fluid. This is the only instance where ethylene glycol is used at the facility that is subject to the HON rule for HAPs not associated with fenceline monitoring. We believe that this situation would not trigger fenceline monitoring applicability for ethylene oxide. Does EPA concur with our assessment?

6. One ACC member operates a site that is not a major source that is applicable to the NSPS VV LDAR rules. To stay a minor source, the facility was given approval from the state environmental agency to monitor using HON Subpart H LDAR leak thresholds in order to use HON Subpart H emission factors while still being applicable to reporting under NSPS VV only. Does EPA agree that only the HON Subpart H LDAR monitoring requirements would apply, and not the fenceline monitoring (which was added to the updated HON Subpart H) since the constituents monitored at the site are not the fenceline target HAPs?

C. Existing Programs for Benzene

In some instances, a facility may already maintain a fenceline air monitoring program for benzene (sorbent tubes) and have monitoring locations in place. **For these circumstances, can EPA allow the facility to locate canisters for EO or vinyl chloride at existing locations?**

For example, if a site has 20 monitoring locations, would it be possible to locate 10 canisters at the odd numbered locations and then 10 canisters at the even numbered locations instead of locating 8 canisters at new locations around the fenceline? (rule says if > 10,000 meters or 32,800 feet) that we have to locate 24 monitoring spots for canisters (e.g., for 40,000 feet that equals every 1,666 feet) so these monitoring locations for canisters will be different.

We request that EPA consider a potential carve out for certain types of facilities, including refineries that don't use on-site near field subtraction. In the final rule RTC, EPA rejected our request for an exemption for facilities with HON CMPUs that produce only benzene and are co-located with refineries performing monitoring under NESHAP CC, on the grounds that the provisions at "40 CFR 63.658(i) which allow petroleum refineries to subtract on-site near-field sources subject to the HON from their fenceline concentrations" would "defeat one of the primary purposes of the finalized fenceline monitoring provisions of this action, which is to limit fugitive emissions from HON CMPUs." For sites that do not use on-site near field subtraction, it seems reasonable to allow some type of exemption.

D. Practical Considerations

1. Lab Capacity - If external labs indicate that they cannot meet all requirements of the new Method 327, **can EPA provide guidance for facilities that must monitor for ethylene oxide and vinyl chloride? Would EPA consider some type of communication from the lab to confirm when and for what areas they cannot meet requirements?**

Given that many of the available labs will continue to face challenges around capacity and technical issues, would EPA consider providing an additional year of compliance time for the fenceline monitoring program?

2. Trace Amounts - **Would EPA consider an exemption or de minimis threshold for facilities that can demonstrate through sampling, testing, and analysis that target analytes at covered sources are only present in trace amounts?**

3. Sampling Frequency **- Can EPA provide any additional rationale on its choice to require a 5-day sampling frequency?**

As we detailed in our coalition comments, this short timeframe significantly increases the burden associated with compliance with the requirements. To reiterate, the 5-day sampling period increases the potential for errors: sampling day changes each week, rather than the same day each week; shipping logistics are a problem on the weekend; receiving logistics at the lab are a problem on the weekend; and limited lab capacity will make meeting the reporting requirement very difficult due to number of samples (if 20 sites and 10 canisters per site, then 200 samples will need to analyzed, cleaned, and shipped every five days).

4. Data Sharing - Some of our sites have multiple companies operating process plants within the same site (Industrial Park concept). **Would EPA consider allowing one fenceline air monitoring program to be set up that would allow each company to share the data from the one monitoring program?**

For example, one site has a plant that emits EO and another company on-site emits vinyl chloride. These companies should be allowed to share one program to satisfy the fenceline monitoring requirements.

5. 63.152(h) - **Can EPA please confirm the timeline for submission of the required electronic testing?**

Specifically, we would like to confirm the language at 63.152(h) that states "owners and operators must submit performance test reports in accordance with this paragraph…within 60 days after the date of completing each performance test required by this subpart, owners and operators must submit the results of the performance test following the procedures specified in § 63.9(k) of subpart A. Data collected using test methods supported by the EPA's Electronic Reporting Tool (ERT) as listed on the EPA's ERT website (https://www.epa.gov/electronic-reporting-air-emissions/electronic-reporting-tool-ert) at the time of the test must be submitted in a file format generated through the use of the EPA's ERT. Alternatively, owners and operators may submit an electronic file consistent with the extensible markup language (XML) schema listed on the EPA's ERT website. Data collected using test methods that are not supported by the EPA's ERT as listed on the EPA's ERT website at the time of the test must be included as an attachment in the ERT or alternate electronic file."

II. EO REQUIREMENTS (NON-FLM)

A. HON EO Process Vents & Analyzer Vents

Unlike MON and EMACT, the updated HON rule does not seem to categorize analyzer vents as process vents. Analyzer vents are still excluded from process vent characteristics. The only exemption removed for analyzer vents is in bypass provisions. Process vents in EO service (> 1ppm) require controls (to flare or non-flare 99.9%). We assume analyzer vents in EO service will need controls from a bypass perspective. Even though analyzer vents don't meet the "process vent" characteristics, they still will be considered bypasses of a control device and therefore, will need to be routed to control, especially if in EO service regardless of the list of process vent characteristics.

The requirement for in EO service process vents applies to Group 1 and Group 2 vents in EO service but analyzer vents are not considered process vents. The removal of analyzer vents from being exempt under bypass provisions seems contradictory and could result in all analyzer vents (receiving streams from sources in EO service) requiring controls. **Can EPA provide any clarification regarding the intent of removing analyzer vents from the list of equipment exempt from the bypass provisions?**

Citations:

a. HON 63.107(h)(9):
    i. (h) The gas stream is not any of the items identified in paragraphs (h)(1) through (9) of this section.
    ii. (9) A gas stream exiting an analyzer.
b. MON's language 63.2550:
    i. Continuous operation means any operation that is not a batch operation. Continuous process vent means the point of discharge to the atmosphere (or the point of entry into a control device, if any) of a gas stream if the gas stream has the characteristics specified in § 63.107(b) through (h), or meets the criteria specified in § 63.107(i), except:
    ii. (9) On and after August 12, 2023, § 63.107(h)(9) no longer applies.

B. EO Compliance Options

For facilities that reduce emissions of EO by venting emissions through a closed vent system to a non-flare control device that reduces EO to less than 1 ppmv, the rule's initial compliance option of using a CEMS allows either a FTIR CEMS or a GC CEMS. However, the continuous compliance option only specifies allowing use of a FTIR CEMS. **If this is correct, is there a reason that EPA would allow a GC CEMS for initial but not continuous compliance?** References included below.

1. Initial Compliance: Install a continuous emissions monitoring system (CEMS) to continuously monitor the ethylene oxide concentration at the exit of the control device. The CEMS must meet the requirements of either paragraph (a)(3)(i)(A) or (B) of this section. Comply with the requirements specified in §63.2450(j) of subpart FFFF of this part for CEMS.

2. (A) An FTIR CEMS meeting the requirements of Performance Specification 15 of 40 CFR part 60, appendix B.

> 3. (B) A gas chromatographic CEMS meeting the requirements of Performance Specification 9 of 40 CFR part 60, appendix B.
>
> 4. Continuous Compliance: If you choose to reduce emissions of ethylene oxide by venting emissions through a closed-vent system to a non-flare control device that reduces ethylene oxide to less than 1 ppmv as specified in §63.113(j)(2) or §63.119(a)(5)(ii), and you choose to comply with paragraph(a)(3)(i) of this section, then continuously monitor the ethylene oxide concentration at the exit of the control device using an FTIR CEMS meeting the requirements of Performance Specification 15 of 40 CFR part 60, appendix B and §63.2450(j) of subpart FFFF of this part. If an owner or operator uses an FTIR CEMS, then the owner or operator does not need to conduct the performance testing required in paragraph (b)(3) of this section or the operating parameter monitoring required in paragraphs (b)(4) through (6) of this section.

III. TOTAL RESOURCES EFFECTIVENESS

A. 63.115 (g)(5)(iv) – Process Vent Testing

Transition from TRE Index to 1.0 lbs/hr - Process vent testing for showing < 1 lbs/hr total organic HAPs. EPA says that we can use testing that was conducted in the last 60 months. **Does this mean 60 months back from the effective date of the rule (July 15, 2024)? Or 60 months back from some other date(s) like the compliance date?**

The rule text states that "(iv) the previously-conducted measurement or performance test was completed within the last 60 months."

B. 63.115(g)(5) - Follow-Up Testing for Group 2 Process Vents

The text at 63.115(g)(5) states that an "initial performance test" does not apply if (i) no changes have been made since the last test but also that (iv) the previous test must have been completed within the last 60 months. **Are we to read 63.115(g)(5)(iv) to say that performance tests will have to be maintained every 60 months for Group 2 vents into the future even if no changes have been made to the process?**

C. De Minimis Levels

Would EPA consider any potential reduction in sampling requirements for facilities that demonstrate process streams are below a certain level of HAP, e.g., some lb/hour threshold or some threshold number of vents? More detail is provided below.

At 63.115(d)(1)(i), the current rule states that If the TRE index value calculated using such engineering assessment and the TRE equation in paragraph (d)(3) of this section is greater than 4.0, then the owner or operator is not required to perform the measurements specified in paragraph (d)(2) of this section. For the proposed transition from the TRE index value to a 1.0 lbs/hr standard , when we commented that the engineering assessments should be allowed to demonstrate compliance with the new proposed 1.0 lbs/hr emission limit, EPA's response in their Response to Comments (pg. 239) stated that "we disagree with the commenters' request to allow companies to use engineering calculations or process knowledge to initially demonstrate that a process vent is a Group 2 process vent under 40 CFR 63.115(g). As with our concerns relative to the TRE index value, the ability to use assessments leads to greater uncertainty with regard to characterization of vent streams and their emission potential"

For these situations, we believe it is appropriate for EPA to create some sort of burden reduction provision for the site's required process vent testing. For example, if a facility's HAP emission rate is < 0.2 lbs/hr (20% of the standard) from engineering assessments or calculations then the owner or operator is not required to perform the measurements specified in 63.115(g).

D. 63.115(d)(2)(v)(A) – Halogenated Vent Streams

ACC would like to better understand the ability of a facility to use process knowledge/engineering assessment to determine if a vent stream is halogenated. Currently, at §63.115(d)(2)(v), the rule states that the facility must use the provisions at (d)(2)(v) to determine whether a vent stream is halogenated and to calculate the mass emission rate of halogen atoms contained in organic compounds. Additional details and references are included below.

1. §63.115(d)(2)(v)(A) states the vent stream concentration of each organic compound containing halogen atoms (parts per million by volume, by compound) shall be determined based on the following procedures:

2. §63.115(d)(2)(v)(A)(2) allows an applicable engineering assessment as discussed in paragraph (d)(1)(iii)

3. §63.115(d)(2)(v)(B) provides an equation that states that Q = Flow rate of gas stream, dry standard cubic meters per minute, determined according to paragraph (d)(1) or (d)(2)(i) of this section.

4. The issue is that 63.113(a)(4) states that the provisions specified in paragraphs (a)(4)(i) through (a)(4)(xv) of this section no longer apply which includes (a)(4)(iii) "§63.115(d), except §63.115(d)(2)(v)".

ACC has two questions:

How can facilities comply with determining the vent stream concentration of each organic compound containing halogen atoms (parts per million by volume, by compound) according to paragraph (d)(1)(iii) if (d) no longer applies with the exception of (d)(2)(v) per 63.113(a)(4)(iii)?

How can facilities comply with determining the flow rate of the gas stream according to paragraph (d)(1) or (d)(2)(i) if (d) no longer applies with the exception of (d)(2)(v) per 63.113(a)(4)(iii)?

It seems that a clarification is necessary that would note that if a facility is using §63.115(d)(2)(v) then the provisions specified within §63.115(d)(2)(v) (for example - (d)(1)(iii), (d)(1), (d)(2)(i)) should be applicable and not have that contradict 63.113(a)(4)(iii).

Additional References for this section:

1. §63.115(d) Except as specified in §63.113(a)(4), to determine the TRE index value, the owner or operator shall conduct a TRE determination and calculate the TRE index value according to the procedures in paragraph (d)(1) or (d)(2) of this section and the TRE equation in paragraph (d)(3) of this section.
2. §63.115(d)(1) Engineering assessment may be used to determine vent stream flow rate, net heating value, TOC emission rate, and total organic HAP emission rate for the representative operating condition expected to yield the lowest TRE index value.
3. §63.115(d)(2) Except as provided in paragraph (d)(1) of this section, vent stream flow rate, net heating value, TOC emission rate, and total organic HAP emission rate shall be measured and calculated according to the procedures in paragraphs (d)(2)(i) through (v) of this section and used as input to the TRE index value calculation in paragraph (d)(3) of this section.
4. §63.115(d)(2)(i) The vent stream volumetric flow rate (Qs), in standard cubic meters per minute at 20 degrees Celsius, shall be determined using Method 2, 2A, 2C, or 2D of 40 CFR part 60, appendix A, as appropriate. If the vent stream tested passes through a final steam jet ejector and is not condensed, the vent stream volumetric flow shall be corrected to 2.3 percent moisture.
5. §63.115(d)(2)(v) In order to determine whether a vent stream is halogenated, the mass emission rate of halogen atoms contained in organic compounds shall be calculated.

6. §63.113(a) The owner or operator of a Group 1 process vent as defined in this subpart shall comply with the requirements of paragraph (a)(1), (a)(2), (a)(3), or (a)(34) of this section, and paragraph (a)(5) of this section. The owner or operator who transfers a gas stream that has the
7. characteristics specified in §63.107 (b) through (h) or meets the criteria specified in §63.107(i) to an off-site location or an on-site location not owned or operated by the owner or operator of the source for disposal shall comply with the requirements of paragraph (i) of this section.
8. §63.113(a)(4) For each source as defined in §63.101 of subpart F of this part, beginning no later than the compliance dates specified in §63.100(k)(10) of subpart F of this part, the provisions specified in paragraphs (a)(4)(i) through (a)(4)(xv) of this section no longer apply. Instead, an owner or operator of a Group 1 process vent as defined in §63.101 of subpart F of this part must comply with the requirements of paragraph (a)(1) or (a)(2) of this section; and an owner or operator of a Group 2 process vent as defined in §63.101 of subpart F of this part must comply with the requirements of paragraph (f) or (g) of this section.

IV. PRESSURE RELIEF DEVICES NOT IN HAP SERVICE

The new bypass provision language at §63.114(d)(3)(ii)(A) exempts pressure relief devices (PRDs) covered by Subpart H (i.e., those in organic HAP service) from the bypass requirements. However, a PRD on a closed vent system that transports a Group 1 process vent may not necessarily be in organic HAP service, and thus would not be subject to Subpart H. **Can EPA provide more rationale for this apparent distinction for PRDs not in organic HAP service? Can facilities voluntarily comply with Subpart H and the PRD monitoring and work practice requirements for PRDs that are not in HAP service but that may potentially release regulated material in order to avoid considering a release of regulated material as a bypass?**

V. WASTEWATER PROVISIONS

Would EPA consider any alternative mass-based emission standards for process wastewater streams > 1 ppmw? Currently, it appears that the only option in the rule is to reduce to less than 1 ppmw regardless of the mass loading to the sewer.

VI. PRESSURE STORAGE VESSEL PROVISIONS

EPA's new language at 63.119(a)(7)(v) states that a release of total organic HAP from a PRD on a pressure vessel is a violation, not subject to the work practice standard in 63.165(e)(3)(v). Did EPA intend for these PRD to still be subject to the pressure release management provisions in 63.165(e)(3)(i)-(iii)?

The current list of exceptions at 63.119(a)(7)(ii) seems to be incomplete (see i through iii below). For non-EO components, there is not an exception for equipment that is already subject to fugitive emissions components. Was this EPA's intent?

i. Connectors, gas/vapor/light liquid valves, light liquid pumps, and PRDs in EO service
ii. Equipment that meet the criteria in 168(h) & (i) [unsafe-to-monitor and difficult-to-monitor valves in G/V/LL service]
iii. Equipment that meet the criteria in 174(f) & (h) [unsafe-to-monitor and inaccessible connectors in G/V/LL service]

VII. HEAT EXCHANGE SYSTEM REQUIREMENTS

At §63.104 (pg. 851), there seems to be an inconsistency in paragraph (l) which allows for a pass from doing the Modified El Paso approach in paragraph (g) by complying with paragraph (b) when a facility passes the low Henry Law Constant test. It appears that EPA did not include a provision in paragraph (c) noting that using a surrogate indicator of heat exchangers leaks would still be require the modified El Paso Method in paragraph (g) if the facility passed the low Henry Law Constant test.

Even if a facility has a very low Henry Law constant for 99% of their chemicals, a facility still will have to do the Modified El Paso method if it uses the surrogate approach for compliance in paragraph (c). And if it does not pass the low Henry Law Constant test for all organic chemicals present, a facility still will have to do the Modified El Paso method since not all chemicals have a low Henry Law constant and facility will still have to do the surrogate monitoring in paragraph (c) or the full sampling regime under paragraph (b). With the current language, it is impossible to avoid doing redundant monitoring approaches (b or c along with g) unless all of a facilities' chemicals pass the low Henry Law Constant test of less than 5.0E-6 atmospheres-cubic meters/mol at 25 degrees Celsius then you can do only (b) to comply.

Can EPA confirm if this interpretation is correct? Did EPA intend that the Modified El Paso method would replace monitoring 63.104(b) or (c)? We have read section (a) as requiring both.

Additional Background:

> §63.104 Heat exchange system requirements, paragraph (a) was modified: (a) Unless one or more of the conditions specified in paragraphs (a)(1) through (6) or paragraph (l) of this section are met, owners and operators of sources subject to this subpart shall monitor each heat exchange system used to cool process equipment in a

chemical manufacturing process unit meeting the conditions of §63.100(b)(1) through (3), except for chemical manufacturing process units meeting the condition specified in §63.100(c), according to the provisions in either paragraph (b) or (c) of this section, and if applicable, paragraph (g) of this section. Whenever a leak is detected, the owner or operator shall comply with the requirements in paragraph (d) of this section, and if applicable, paragraphs (h) through (j) of this section. Owners and operators of heat exchange systems in a chemical manufacturing process unit meeting the conditions of §63.100(b)(1) through (3) must also comply with paragraph (k) of this section.

If a site does not meet (a)(1) through (6) or paragraph (l), then compliance is required to meet the provisions in either paragraph (b) or (c) of this section, and if applicable, paragraph (g) of this section. Paragraphs (b) was not revised and requires a full sampling regime of cooling water at the inlet and outlet of heat exchange systems, with minimum of 3 sets of samples and statistical analysis of results. Paragraph (c) was not revised and allows the facility to use a surrogate indicator of heat exchangers leaks which is one of our plant's current means of compliance.

At pg. 859 of the preamble, new paragraph (g) requires sampling of the cooling water at the return line for total strippable hydrocarbons using the "Air Stripping Method (Modified El Paso Method) for Determination of Volatile Organic Compound Emissions from Water Sources" using a flame ionization detector (FID) analyzer for on-site determination as described in Section 6.1 of the Modified El Paso Method. If total strippable hydrocarbons exceed 6.2 ppmv then need to follow leak repair requirements in paragraph (h) and if necessary, delay of repair requirements in paragraph (i).

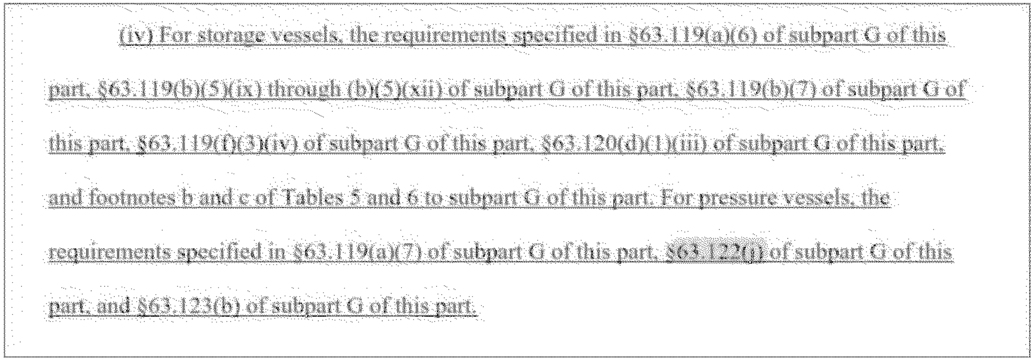
At pg. 865, new paragraph (l) allows for monitoring of leaks in cooling water in accordance with steps in paragraph (b) in lieu of the Modified El Paso method if 99% by weight of the organic compounds that could leak into the cooling water have a Henry's Law Constant less than 5.0E-6 atmospheres-cubic meters/mol at 25 degrees Celsius. This would indicate that the organic chemicals present will persist in water and have a low potential to volatize from water to air.

VIII. Errors for Correction

1. Typo – 63.119(b)(5)(i) is referenced rather than 63.119(b)(5)(ii) in 63.119(b)(5)(ix).
2. Typo – 63.107(j) refers to paragraph (h)(9)(i), when it should say paragraph (i).

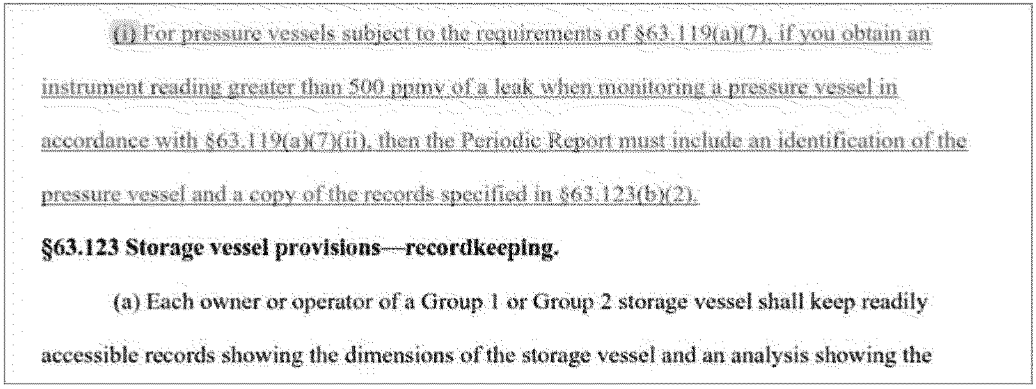
3. Missing - 63.100(k)(10)(iv) refers to 63.122(j). 63.122 does not have a paragraph (j). Last paragraph in 63.122 is (i).

   c. 63.100(k)(10)(iv):

   (iv) For storage vessels, the requirements specified in §63.119(a)(6) of subpart G of this part, §63.119(b)(5)(ix) through (b)(5)(xii) of subpart G of this part, §63.119(b)(7) of subpart G of this part, §63.119(f)(3)(iv) of subpart G of this part, §63.120(d)(1)(iii) of subpart G of this part, and footnotes b and c of Tables 5 and 6 to subpart G of this part. For pressure vessels, the requirements specified in §63.119(a)(7) of subpart G of this part, §63.122(j) of subpart G of this part, and §63.123(b) of subpart G of this part.

   d. 63.122(i):

   (i) For pressure vessels subject to the requirements of §63.119(a)(7), if you obtain an instrument reading greater than 500 ppmv of a leak when monitoring a pressure vessel in accordance with §63.119(a)(7)(ii), then the Periodic Report must include an identification of the pressure vessel and a copy of the records specified in §63.123(b)(2).

   §63.123 Storage vessel provisions—recordkeeping.

   (a) Each owner or operator of a Group 1 or Group 2 storage vessel shall keep readily accessible records showing the dimensions of the storage vessel and an analysis showing the

4. Typo - FLM alternative sampling frequency for burden reduction for 5-day sampling frequency EPA used language for 14-day sample period rather than 5-day sample period (highlighted in yellow below):

   §63.184(b)(2)(iii)(A) If every sample at a monitoring site is at or below 0.3 µg/m3 for 2 years (52 consecutive samples), every other sampling period can be skipped for that sampling site, i.e., sampling will occur approximately once per month.

   (B) If every sample at a sampling site that is monitored at the frequency specified in paragraph (b)(2)(iii)(A) of this section is at or below 0.3 µg/m3 for 2 years (i.e., 26 consecutive "monthly" samples), five 14-day sampling periods can be skipped for that sampling site following each period of sampling, i.e., sampling will occur approximately once per quarter.
   (C) If every sample at a sampling site that is monitored at the frequency specified in paragraph (b)(2)(iii)(B) of this section is at or below 0.3 µg/m3 for 2 years (i.e., 8

consecutive quarterly samples), twelve 14-day sampling periods can be skipped for that sampling site following each period of sampling, i.e., sampling will occur twice a year.

(D) If every sample at a sampling site that is monitored at the frequency specified in paragraph (b)(2)(iii)(C) of this section is at or below 0.3 µg/m3 for 2 years (i.e., 4 consecutive semiannual samples), only one sample per year is required for that sampling site. For yearly sampling, samples shall occur at least 10 months but no more than 14 months apart.

5. Missing definition – Regarding maintenance vents, §63.113(k)(1)(i) requires that the source reduce the concentration of the vapor in the equipment served by the maintenance vent to less than 10% of its lower explosive limit (LEL) and has an outlet concentration less than or equal to 20 ppmv hydrogen halide and halogen HAP. The language appears to be taken verbatim from the maintenance vent provisions that were recently promulgated in 40 CFR Part 63, Subpart FFFF [National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing (MON)]. The MON explicitly identifies what is meant by “hydrogen halide and halogen HAP”, and defines it as hydrogen chloride, hydrogen fluoride, and chlorine. However, HON only contains a definition for “halogens and hydrogen halides”, which are defined as hydrogen chloride (HCl), chlorine (Cl2), hydrogen bromide (HBr), bromine (Br2), and hydrogen fluoride (HF). While the same compounds described in MON are included in the HON definition, without the exact definition being included in HON, it has caused some confusion as to which compounds are supposed to be in scope and compared against the 20 ppmv limit. EPA should either revise the existing definition or add a new definition to HON for “hydrogen halide and halogen HAP”.

6. Missing Exemption Language at 63.104(a)(5) and (a)(6): At 63.104, EPA provides heat exchange system requirements that should be replicated verbatim in the Government Printing Office Electronic Code of Federal Regulations (eCFR). Unfortunately, the eCFR version of this section is missing the exemptions provided at 63.104(5) and (6), which provide:

    (5) The recirculating heat exchange system is used to cool process fluids that contain less than 5 percent by weight of total hazardous air pollutants listed in table 4 of this subpart.
    (6) The once-through heat exchange system is used to cool process fluids that contain less than 5 percent by weight of total hazardous air pollutants listed in table 9 of subpart G of this part.

In the May 2024 final rule (screenshot below for reference), we note that EPA’s use of asterisks indicates that the remaining language after 63.104(a) remains unchanged, which would presumably include 63.10(a)(5) and (6) along with 63.104(b), (c), (d), and (e). We request that EPA clarify that these exemptions should be carried over in the eCFR as a technical correction and clarification.

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subpart and subpart G of this part shall be no later than April 22, 1997, or as otherwise specified in § 63.100(k)(2)(ii), unless an extension has been granted by the EPA Regional Office or permitting authority as provided in § 63.6(i).

(g) An owner or operator who elects to use the compliance extension provisions of § 63.100(k)(6)(i) or (ii) shall submit a compliance extension request to the appropriate EPA Regional Office no later than 45 days before the applicable compliance date in § 63.100(k)(3), but in no event is submittal required earlier than May 10, 1995. The request shall contain the information specified in § 63.100(k)(5)(iv) and the reason compliance cannot reasonably be achieved without a process unit shutdown, as defined in 40 CFR 63.101 or without replacement of the compressor or recasting of the distance piece.

(h) An owner or operator who elects to use the compliance extension provisions of § 63.100(k)(8) shall submit to the appropriate EPA Regional Office a brief description of the process change, identify the HAP eliminated, and the expected date of cessation of use or production of HAP. The description shall be submitted no later than May 10, 1995, or with the Notice of Compliance Status as required in § 63.182(c), whichever is later.

■ 47. Amend § 63.104 by revising paragraphs (a) and (f) and adding paragraphs (g) through (l) to read as follows:

§ 63.104 Heat exchange system requirements.

(a) Unless one or more of the conditions specified in paragraphs (a)(1) through (6) or paragraph (l) of this section are met, owners and operators of sources subject to this subpart shall monitor each heat exchange system used to cool process equipment in a chemical manufacturing process unit meeting the conditions of § 63.100(b)(1) through (3), except for chemical manufacturing process units meeting the condition specified in § 63.100(c), according to the provisions in either paragraph (b) or (c) of this section, and if applicable, paragraph (g) of this section. Whenever a leak is detected, the owner or operator shall comply with the requirements in paragraph (d) of this section, and if applicable, paragraphs (h) through (j) of this section. Owners and operators of heat exchange systems in a chemical manufacturing process unit meeting the conditions of § 63.100(b)(1) through (3) must also comply with paragraph (k) of this section.

(1) The heat exchange system is operated with the minimum pressure on the cooling water side at least 35 kilopascals greater than the maximum pressure on the process side.

(2) There is an intervening cooling fluid, containing less than 5 percent by weight of total hazardous air pollutants listed in table 4 of this subpart, between the process and the cooling water. This intervening fluid serves to isolate the cooling water from the process fluid and the intervening fluid is not sent through a cooling tower or discharged. For purposes of this section, discharge does not include emptying for maintenance purposes.

(3) The once-through heat exchange system is subject to a National Pollution Discharge Elimination System (NPDES) permit with an allowable discharge limit of 1 part per million or less above influent concentration or 10 percent or less above influent concentration, whichever is greater. For each source as defined in § 63.101, beginning no later than the compliance dates specified in § 63.100(k)(10), this paragraph (a)(3) no longer applies.

(4) Except as specified in paragraph (a)(4)(v) of this section, the once-through heat exchange system is subject to an NPDES permit that:

(i) Requires monitoring of a parameter(s) or condition(s) to detect a leak of process fluids into cooling water;

(ii) Specifies or includes the normal range of the parameter or condition;

(iii) Requires monitoring for the parameters selected as leak indicators no less frequently than monthly for the first six months and quarterly thereafter; and

(iv) Requires the owner or operator to report and correct leaks to the cooling water when the parameter or condition exceeds the normal range.

(v) For each source as defined in § 63.101, beginning no later than the compliance dates specified in § 63.100(k)(10), this paragraph (a)(4) no longer applies.

* * * * *

(f)(1) *Required records.* The owner or operator shall retain the records identified in paragraphs (f)(1)(i) through (iv) of this section, and if applicable, paragraph (f)(3) of this section, as specified in § 63.103(c)(1).

(i) Monitoring data required by this section indicating a leak and the date when the leak was detected, and if demonstrated not to be a leak, the basis for that determination;

(ii) Records of any leaks detected by procedures subject to paragraph (c)(2) of this section and the date the leak was discovered;

(iii) The dates of efforts to repair leaks; and

(iv) The method or procedure used to confirm repair of a leak and the date repair was confirmed.

(2) *Reports.* If an owner or operator invokes the delay of repair provisions for a heat exchange system, the following information shall be submitted in the next semi-annual periodic report required by § 63.152(c). If the leak remains unrepaired, the information shall also be submitted in each subsequent periodic report, until repair of the leak is reported. In addition, if an owner or operator is complying with paragraph (g) or (l) of this section, then the semi-annual periodic report must include the information specified in paragraph (f)(2)(vi) of this section.

(i) The owner or operator shall report the presence of the leak by identifying the heat exchange system and the date that the leak was detected.

(ii) The owner or operator shall report whether or not the leak has been repaired.

(iii) The owner or operator shall report the reason(s) for delay of repair. If delay of repair is invoked due to the reasons described in paragraph (e)(2) of this section, documentation of emissions estimates must also be submitted.

(iv) If the leak remains unrepaired, the owner or operator shall report the expected date of repair.

(v) If the leak is repaired, the owner or operator shall report the date the leak was successfully repaired.

(vi) For each heat exchange system subject to paragraph (g) or (l) of this section, the following information must be submitted in each semi-annual periodic report required by § 63.152(c).

(A) The number of heat exchange systems at the plant site subject to the monitoring requirements in paragraph (g) or (l) of this section during the reporting period.

(B) The number of heat exchange systems subject to the monitoring requirements in paragraph (g) or (l) of this section at the plant site found to be leaking during the reporting period.

(C) For each monitoring location where a leak was identified during the reporting period, identification of the monitoring location (e.g., unique monitoring location or heat exchange system ID number), the measured total strippable hydrocarbon concentration (in ppmv as methane) or total hydrocarbon mass emissions rate (in kg/hr as methane) (if complying with paragraph (g) of this section) or the measured concentration of the monitored substance(s) (in ppmv) (if

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ATTACHMENT A

The Sterilizer Rule[1] - Background, Legal Flaws, and Likely Harms

Ethylene Oxide ("EtO") and its Importance to the Medical Sterilization Process

- EtO is the primary modality used to sterilize essential medical equipment.
- As EPA knows, "for many medical devices, sterilization with ethylene oxide may be the only method that effectively sterilizes and does not damage the device."[2]
- According to the FDA, about fifty percent of all sterile medical devices in the U.S. are sterilized with ethylene oxide. These include around 95% of all surgical kits.
- The FDA warned that even temporary sterilizer facility shutdowns will cause "downstream implications for the medical device supply chain" because these facilities "typically run 24/7 . . . operating at maximum capacity."[3]

EtO Sterilizers' Regulatory History and the Rule

- In 1994, EPA issued a rule promulgating its first EtO emissions standards for sterilization facilities under section 7412(d). 94 Fed. Reg. 29,823 (Dec. 6, 1994).
- EPA completed its first Section 112(d) technology review and a Section 112(f) one-time risk review in 2006, finding "no additional control requirements are warranted." 71 Fed. Reg. 17,712 (Apr. 7, 2006).
- Nearly two decades later, EPA completed its next periodic technology review—but also revised standards based on a *second* residual risk review under Section 112(f) using the 2016 EtO IRIS value.
- Almost half of the emission standards set in the Rule—including the most stringent—were established pursuant to the Section 112(f) risk review. These include:
    - A 99.<u>99</u>% DRE (destruction and removal efficiency) standard for Sterilization Chamber Vents and a 99.<u>9</u>% DRE standard for Aeration Chamber Vents using 30+ tpy EtO.[4]
    - A 99.<u>9</u>% DRE standard for Chamber Exhaust Vents at area sources using 400+ tpy of EtO.
    - A 98% DRE standard for both "Group 1" room emissions at area sources using 40+ tpy EtO and "Group 2" room emissions at area sources using 20+ tpy EtO. These standards are also a change in form from the proposed mass-per-hour limit.
- The Rule eliminates the choice to comply through an alternative concentration standard.
- The Rule also requires all sources using 100+ lb/year of EtO to demonstrate compliance using Continuous Emissions Monitoring Systems (CEMS) at both inlets and outlets, thus making a costly and complex monitoring regime even more costly and complex.

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[1] 89 Fed. Reg. 24,090 (Apr. 5, 2024).

[2] *Id.* at 24,092 (Apr. 5, 2024).

[3] FDA Center for Devices and Radiological Health, *Medical Device Benefits Statement* (Mar. 15, 2023).

[4] All new and revised standards set in the Rule are listed at 89 Fed. Reg. at 24,093–Table 1.

The Sterilizer Rule's Major Flaws

- To set the most stringent emission standards, EPA relied on CAA Section 112(f)(2)—a one-time risk review provision—to conduct a second round of risk review, instead of relying on its established authority to revise standards based on a technology review under Section 112(d).
- EPA set first-ever standards for some sources under Section 112(f)(2) even though Congress requires standards first be set via technology review under Section 112(d).
    - EPA regulated room air emissions (Group 1 and Group 2 sources) for the first time relying *solely* on section 7412(f)(2), even though Congress provided that such standards may only be promulgated "within 8 years *after promulgation of standards* for each category … of sources pursuant to subsection (d)[.]" 42 U.S.C. § 7412(f)(2)(A).
- EPA failed to reasonably assess the Rule's costs to sterilizers—and ignored economic and social costs to the medical industry and medical patients.
- EPA also did not balance the costs it considered against the Rule's claimed health benefits.
- The Rule's EtO standards are not supported by the record; they are based on performance test data EPA admitted does not reflect normal operations.
- The standards require emissions control beyond what equipment manufacturers can guarantee. There is thus no assurance for sterilizers that, if they incur the huge costs required to redesign their facilities and install new equipment, they will be able to meet the standards.
- The Rule is entirely premised on EPA's flawed 2016 IRIS value for EtO, but EPA declined to respond to comments challenging its reliance on that IRIS value in this Rule.
- The Rule unreasonably requires sterilizers to demonstrate compliance through CEMS instead of parametric monitoring, and to install CEMS on *inlets and outlets*, a regime that is costly, technically difficult, and unprecedented—and that commenters did not have a chance to address.

The Sterilizer Rule's Likely Harms

- The Rule is highly likely to disrupt the medical device supply chain, including because a significant number of sterilizers likely will close shop or move offshore rather than incur the high costs to redesign their facilities, acquire new emissions control equipment, and install CEMS.
    - EPA estimates the Rule's total annual costs will be around $88 million. 89 Fed. Reg. at 24,137. But that does not include capital costs to redesign and retrofit facilities.
    - The Small Business Association estimated that many U.S. sterilizers will need to spend *over 20% of their revenue* on compliance annually. That, in turn, will force many smaller facilities to exit the market entirely, resulting in a shortage of medical devices.
- Even facilities that choose to try to comply with the Rule will have to cease operations for long periods to install new control equipment; test that equipment; and then install and test CEMs.
- Some sterilizers are specialized to supply particular devices like catheters. If one of those facilities goes offline, temporarily or permanently, that would disrupt the domestic supply of those devices.
- If even one patient death resulted from a shortage of medical devices caused by the Rule, that would eliminate the Rule's claimed health benefits.

ATTACHMENT B

Questions for EPA Regarding EO IRIS Assessment

Introduction

The major scientific issue regarding the EPA IRIS (2016) ethylene oxide (EO) risk assessment is whether EPA's or TCEQ's (2020) model is the most appropriate statistical computer model to apply to the NIOSH human data set. TCEQ's (2020) model is superior to EPA's model in satisfying key EPA IRIS (2016, p. 116) objectives for model selection (Table 1).

Table 1. Comparison of TCEQ's and EPA's Model in Fulfilling Key EPA Objectives for Model Selection

Key EPA IRIS (2016, p. 116) Objectives for Model Selection	EPA IRIS	TCEQ
Use the individual-level continuous exposure data	ü	ü
Prioritize models that are more tuned to local behavior in the low exposure data over more global models.		ü
Consider the principle of parsimony		ü
Weigh models on both biological plausibility and statistical considerations		ü

The TCEQ model uses individual-level continuous exposure data and is a more parsimonious (simpler) statistical model with only one parameter. It is a nearly linear model, the shape of which is supported by mode of action data and the biological and epidemiological evidence. The model was validated by proving the TCEQ model accurately predicts the total number of cases across all exposures (globally) as well as at lower exposures (locally). In contrast, the EPA IRIS model over predicts the number of cases locally and globally. EPA's unconventional 2-piece linear spline dose-response model is a complex model with the following 3 modeled parameters: (1) an initial steep slope that ends in (2) an abrupt dose-response bend point (i.e., "knot") followed by (3) a shallower slope. The EPA IRIS model has a comparable statistical p-value to that of the simpler TCEQ model but is less consistent with the biological and epidemiological evidence for EO.

The EPA IRIS (2016) and the follow-up EPA (2019) memo presented a multitude of curve-fitting models but failed to integrate any consideration of the epidemiological and biological evidence. The EPA SAB (2015) review of the draft EO assessment emphasized that "any model that is to be considered reasonable for risk assessment must have a dose-response form that is both biologically plausible and consistent with the observed data". ACC (2020, 2024) provided detailed evidence for why the TCEQ model has greater biological plausibility and greater consistency with the epidemiological evidence. This was done by integrating several lines of evidence from the animal mode of action, toxicokinetic (TK) and cancer bioassay data and the original peer-reviewed conclusions of the NIOSH human study publication.

In contrast, the only instances in which EPA claims they considered biological plausibility is when EPA rejects models with steeper slopes that approach infinity or are based on too few cases. Yet, EPA provides no biological evidence for why the EPA model has greater biologically plausibility than other models, including TCEQ's model. EPA (2016, 2019) ignores its own 2005 Guidelines for Carcinogen Risk Assessment which state:

> "Another problem occurs when a multitude of alternatives are presented without sufficient context to make a reasoned judgment about the alternatives. This form of model uncertainty reflects primarily the availability of different computer models and not biological information about the agent being assessed or about carcinogenesis in general. . . In situations where there are alternative models with significant biological support, the decisionmaker can be informed by the presentation of these alternatives along with their strengths and uncertainties.

EPA relies on statistical and visual fit comparisons to support EPA's model selection. EPA's (2024) Response To Comments (RTC) on the HON includes new evidence of EPA's arbitrary application of statistics and flawed visual comparison. EPA (2024) incorrectly states that the knot parameter was pre-determined visually based on comparisons with the categorical (grouped) estimates, and so does not need to be accounted for statistically. This is a misrepresentation of EPA IRIS (2016) statistically driven search for the knot for both lymphoid mortality and breast cancer incidence. The EPA (2024) also presents new analysis that is essentially the visual comparison that EPA IRIS (2016) Figure 4-7 clearly indicates should not be done[1].

These and other contradictions indicate the EPA IRIS (2016) assessment should be revisited because it is flawed scientifically and does not fulfill key EPA (2016) objectives. We raise several scientific questions which to date the Agency has either not addressed or are raised by EPA's Response to Comments on the HON (EPA 2024). We believe that an unbiased appraisal of the issues raised by these question leads to the inexorable conclusion that the IRIS **value** is not scientifically sound. Given the importance of the issue, it may well be that additional independent peer review of the responses may be appropriate.

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[1] EPA IRIS Figure 4-3 state that "the different models have different implicitly estimated baseline risks; thus, they are not strictly comparable to each other in terms of RR values, i.e., along the y-axis."

Before listing these questions, we first summarize the following areas of agreement with EPA.

1. ACC agrees that the NIOSH study is the most appropriate epidemiological study to use for quantitative risk assessment.
2. ACC agrees with EPA IRIS (2016) that direct-acting mutagenicity is the putative mode of action for EO, and that a default linear no-threshold approach to extrapolating increased cancer risk at very low exposure/risk levels is consistent with established EPA policy.
3. ACC agrees that lymphoid and breast cancers have been associated with EO in the NIOSH study by Steenland et al. (2003, 2004). However, breast cancer mortality and not incidence should be used for quantitative risk assessment because of the substantial number of missing cases for breast cancer incidence reported by Steenland et al, (2003) and subsequent risk deficits in the lower exposures.
4. ACC agrees that correct statistics should play an important role in model selection but disagrees with the EPA (IRIS) rationale for ignoring the knot as 1 of 3 key statistical parameters. EPA's (2024) new rationale is that this parameter was selected visually by comparing it with the categorical estimates. This rationale is contradicted by the EPA IRIS (2016, Appendix D) explanation that a local and overall maximum likelihood value was selected for lymphoid and breast cancer, respectively. When all parameters are considered, the simpler TCEQ CPH model has a comparable p-value but is more parsimonious.
5. ACC agrees that categorical analysis of data is a useful epidemiological tool but disagrees with EPA's reliance on incorrect visual-fit comparisons of continuous models to these categorical grouped estimates.
6. ACC agrees with the important EPA IRIS (2016) warning noted in all Figures of rate ratios (RR) that visual comparisons of different models along the y-axis is inappropriate. However, the EPA (2024) new tabular comparison supporting the EPA model ignores this warning.
7. ACC agrees EO is naturally produced in the body and is pervasive in the environment but disagrees with EPA (2024) that these data are unreliable as reality checks for the risk assessment and risk management decisions.

We urge EPA to address the following scientific questions so that EPA-based actions impacting EO production and use are based on correct statistics, rigorous model validation, and science-based integration of the biological and epidemiological evidence.

Scientific Questions that EPA's Response to Comments has not Adequately Addressed:

EPA's Errors in Statistical and Visual Fit

(1) **Statistical fit:** ACC (2020, 2024) and TCEQ (2020) provided evidence that the p-values for EPA's model are incorrect and leads to a substantive change in the summary tables that EPA SAB (2015) reviewed (Table 1). EPA claims their statistics are correct for calculating the p-value for the 2-slope linear spline model because the knot of 1600 ppm-days connecting the two linear models was selected based on "better visual fit to the lower dose data on lymphoid cancer" rather than the maximum likelihood knot of 100 ppm-days. However, EPA clearly estimated the knot position based on a systematic optimization approach to find the most optimal global or local maximum likelihood knot location for breast cancer incidence and lymphoid mortality, respectively. The strategy to pick the best model for regulatory decision making should be subject to a penalty function reflecting the number of model parameters, thus effectively forcing a trade-off between improving model fit by adding additional model parameters vs. the more parsimonious model (NRC, 2007, pp. 174)

Table 1. Original and Corrected p-values for IRIS 2-slope linear spline and IRIS standard CPH model

	EPA IRIS (original) 2-slope linear spline	EPA IRIS (corrected) 2-slope linear spline	EPA IRIS Standard CPH Model
Lymphoid Mortality	**P= 0.07**	**P=0.14** corrected from 0.07	**P=0.22**
Breast Cancer Incidence	**P= 0.01**	**P=0.04** corrected from 0.01	**P=0.02**

Source: Corrected and IRIS reported p-values are based on IRIS (2016; Tables 4-2, 4-4, 4-6, 4-12, 4-13, Appendix D) and TCEQ (2020).

In light of the EPA IRIS (D29-D30; D40-42) use of statistical methods to select the knot for breast cancer incidence and lymphoid mortality, what is the basis for EPA's claim that it is not a parameter? What reference does EPA rely upon to support its approach?

(2) **Visual Fit:** The EPA (2024) RTC Table 1 is a new table EPA uses to claim that TCEQ's model has poor visual fit because it underestimates the NIOSH categorical estimates. The internal rate ratio (or relative rate, RR) values were derived using the model parameters and the average concentrations for each exposure quartile. In other words, EPA is making comparisons along the y-axis of EPA IRIS Figure 4-3 in direct contradiction to a note in Figure 4-3 specifically stating such comparisons are invalid[1]. Also, the 4 categorical estimates are grouped estimates that are not the individual estimates that were modeled. **Does EPA agree that EPA (2024) Table 1 compares the rate ratios (relative rate) that reflect those on Figure 4-3, and that this analysis is the same as comparing the models along the y-axis? If not, why not? How does EPA explain this approach in light of EPA**

(IRIS) Figure 4-3 footnote warning against such comparisons? What references or citations does EPA have to refute or fail to adhere to the EPA (IRIS) 2016 Figure 4-3 footnote warning?

(3) EPA (2024) incorrectly states that all models are compared with a baseline hazard rate of the unexposed control group. While this is correct for the categorical results, *this is not the way that continuous models of the individual results estimate the implicit baseline hazard rate*! Rather, SAS program generates baseline hazard rates. The resulting y-intercept is the result of the model, which is influenced by both exposed and unexposed workers, but is not a comparison with the same unexposed group as the categorical analysis as stated by EPA (2024). This is an important point because EPA (2024) appears to use this incorrect explanation as the basis to support comparisons of relative rates contrary to the EPA IRIS (2016) warning that this should not be done. **What specific modeling file or other information supports EPA's contention that the continuous models are based solely on a comparison against an unexposed group?**

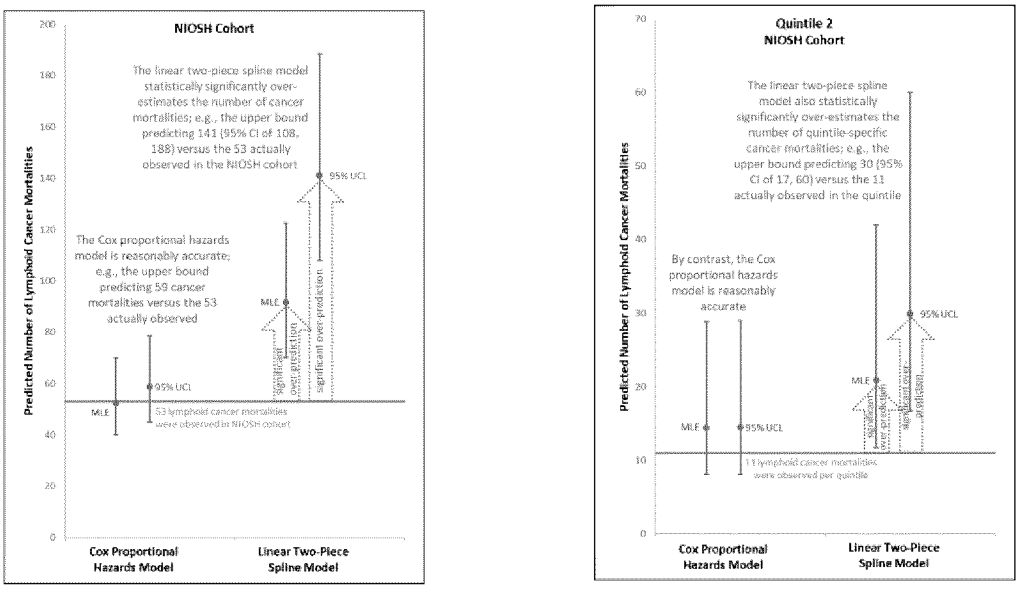
(4) EPA's RTC (2022, 2024) repeatedly claims that EPA's selected continuous model has a better fit based on the shape of the first 2 of 4 categorical (grouped) estimates of the individual data. Yet, SAB (2015) advised EPA to not select the linear regression of categorical estimates unless individual exposure model results are biologically implausible. In fact, EPA SAB advised that if EPA had to rely on the categorical model they should consider using more groupings. In other words, EPA use of EPA's categorical estimates as the gold standard as a basis for selecting a model is incorrect and contradicts advice received from SAB. Valdez-Flores and Sielken (2013) and TCEQ (2020) illustrate how the shape of the exposure-response changes depending on the number of categories selected. While categorical analysis is a well-accepted tool for evaluating epidemiological data, it is inappropriate to use these categorical estimates as the gold standard for selecting continuous models of individual data. **How does EPA reconcile using an individual exposure model while relying ultimately on visual comparisons with the categorical estimates, which SAB advised against using?**

(5) EPA (2022) introduced a new visual evaluation of the lymphoid categorical data as proof that TCEQ's standard CPH approach is a flawed approach and that TCEQ's model explodes upwards at the highest cumulative exposures. The EPA (2022, 2024) RTC failed to address the misstatements and errors in their analysis that were raised by ACC (2020, 2024). For perspective, in TCEQ's and EPA's model equations, the rate ratios are higher for EPA than for TCEQ at 40,000 ppm-days and 64,000 ppm-days. If TCEQ's model is exploding upwards, then this is even more dramatic for EPA's model. **Does EPA agree that applying the CPH model to each categorical estimate using one categorical modeled estimate at a time is incorrect and irrelevant to TCEQ's analysis? If not, why not and what literature supports EPA's approach? Does EPA agree that applying the same approach to the linear spline model focusing on the initial linear CPH model below the knot would result in similar overprediction of the categorical estimates at later exposures? Does EPA agree that this approach is diametrically opposite from SAB's strong recommendation to NOT model the categorical data? If not, why not?**

Validation of Model Fit

(6) TCEQ (2020) includes an objective model validation procedure (Figure 1). Model validation is an objective ground-truthing procedure to statistically determine whether model predictions are consistent with the observed data used to estimate the model parameters. TCEQ's analysis applied EPA's and TCEQ's model to general population background hazard rates of lymphoid cancers to show that the TCEQ model estimates agree with the actual number of lymphoid cancers observed in the NIOSH study with and without a healthy worker effect (HWE) assumption of 16-17% and whether based on the maximum likelihood estimate (MLE) or the associated 95% upper confidence limit (UCL). In contrast, EPA's model statistically significantly over-predicts the number of lymphoid cancers. This applies to the cohort as a whole and to the cumulative exposure groups, including the lowest exposure Quintile 2. ACC's (2023) comments explained that the prediction of Quintile 2 best reflects "local" fit below the knot. **Assuming that a HWE of 16-17% (or less) is accurate, (1) does EPA agree that in TCEQ's model validation procedure, TCEQ correctly applied the central estimate? (2) Does EPA agree that the results of TCEQ's and ACC (2023) comments indicate that the CPH model not only has better local fit below the knot, but also overall? If not, why not?**

Figure 1. TCEQ's (2020) Model Validation Procedure shows TCEQ's model (blue error bars) better predicts the actual number of cases in the NIOSH cohort (green line) and Quintile 2



NIOSH Cohort

The linear two-piece spline model statistically significantly over-estimates the number of cancer mortalities; e.g., the upper bound predicting 141 (95% CI of 108, 188) versus the 53 actually observed in the NIOSH cohort

The Cox proportional hazards model is reasonably accurate; e.g., the upper bound predicting 59 cancer mortalities versus the 53 actually observed

53 lymphoid cancer mortalities were observed in NIOSH cohort

Quintile 2
NIOSH Cohort

The linear two-piece spline model also statistically significantly over-estimates the number of quintile-specific cancer mortalities; e.g., the upper bound predicting 30 (95% CI of 17, 60) versus the 11 actually observed in the quintile

By contrast, the Cox proportional hazards model is reasonably accurate

11 lymphoid cancer mortalities were observed per quintile

(7) EPA dismissed TCEQ's model validation alleging that a healthy worker effect (HWE) of 28% is needed. EPA (2022, p. 90) points to a non-statistically significant SMR of 0.72 for "all haematopoietic" cancers in Steenland et al. (2004) Table 3 in support of a large HWE (i.e., 28%). The "all haematopoietic" classification encompasses many more cancers than just the lymphoid cancers. When one considers NHL which is a major contributor to lymphoid cancers, there is no deficit. Thus, EPA cherry picks a value to support their incorrect conclusion that there is a large HWE and ignores the NIOSH study authors conclusion there is likely no HWE (Steenland et al. 2004). Steenland's conclusion is consistent with basic understanding in epidemiology that indicates that a HWE is not expected with longer term follow up studies, especially for cancer (IARC, 1999). The TCEQ's model better predicts the actual cases even with a reasonable HWE assumption of 16-17%, despite the strong evidence that there is no HWE. **Does EPA agree that the category "all hematopoietic cancers" include cancers that are not lymphoid cancers? Does EPA agree that NHL is a major contributor to lymphoid, and there is no deficit for NHL? What studies or references contradict the Steenland (et al. 2004) and IARC (1999) conclusions that the huge HWE claimed by EPA (2024) is not expected?**

(8) EPA frequently points out differences in the details of the analysis to cast doubt on TCEQ's analysis. However, in many cases TCEQ's analysis is the preferred approach. For example, the EPA RTC (2024, p. 103) also noted that the fact that TCEQ chose to compute standardized mortality ratios (SMRs) for different exposure intervals than NIOSH does present some limitations. EPA states that the change in the category assumption introduces a complication in comparing the TCEQ SMR computations with NIOSH's findings for risks of lymphoid tumors by exposure category. In this case, EPA's RTC (2024) fails to acknowledge that TCEQ split the quantiles optimally by having the same number of responses in each quantile to minimize the variance. This is standard epidemiology procedure for any categorical analysis. In contrast, Steenland et al. (2004) first analyzed all haematopoietic (LH) cancers by evenly dividing LH into different categories of exposure, but this is a category broader than the cancer of concern. When evaluating lymphoid cancers, Steenland et al. (2004) and EPA IRIS (2016) failed to recalibrate how to develop true exposure quartiles for lymphoid, but instead applied the same exposure categories that had been developed for LH. In addition, it can be shown that even if EPA's intervals are used the results reported by TCEQ still hold true. **Does EPA agree that TCEQ's methods are valid and consistent with statistical principles regarding methods for defining exposure quantiles? What basis does EPA have for not making the more correct adjustment that TCEQ did?**

Biological Plausibility and Consistency with the Epidemiological Data

(9) The EPA IRIS (2016) states that an important objective for model selection is biological plausibility, but it never integrated different lines of biological evidence to evaluate EPA's or TCEQ's model selection. The EPA (2024) RTC dismissed the use of biological mode of action evidence provided by ACC (2020) by presenting many different patterns from many different studies without considering which of these studies is most relevant and informative or consideration of the statistical analysis of these studies. The ACC (2023) comments explain why the specific studies ACC evaluated are the most relevant and informative because they represent targets for EtO-induced tumors (lymphoid and breast) that had a range of exposure levels, not just high exposures. In all cases, there is no evidence for a steep initial slope at the low end. As a reactive chemical capable of alkylating DNA, but whose toxicity is modulated by DNA repair and epoxide clearance mechanisms (GSH transferases, epoxide hydrolase) common to rodents and humans, there is no mechanistic rationale to provide biological plausibility to a supralinear exposure response in the low-exposure region, as projected by IRIS as increasing cancer risks. Instead, the PBPK modeling indicates EO

blood concentrations in rats, mice and humans are equivalent and have an identical linear relationship with EO exposures up to 200 ppm, (Fennell and Brown 2001), with a steeper slope at higher exposures consistent with metabolic saturation, which is common. This pattern is opposite to the uncommon one of EPA IRIS. **Does EPA agree that for a direct acting alkylating agent with identical parent EO PBPK-model supported TK patterns in animals and humans are predictive of the shape of the EO dose-response human patterns? If not, what evidence does EPA have to depart from EPA's default assumption that animals are predictive of humans? In view of the lack of statistical difference between EPA's and TCEQ's model, does EPA agree that integration of biological and toxicokinetic evidence from animal data is relevant to dose-response modeling selection in humans? Does EPA agree that the toxicokinetic and most relevant biological data does not indicate a steep dose response at lower exposures? If not, why not?**

(10) ACC (2020, 2023) provided comments that data from the ethylene cancer bioassay can be considered with that of the rat EO carcinogenicity study (IRIS, 2016 Table 3-5) to inform the shape of the EO rat carcinogenicity exposure response at lower exposures. Ethylene was not carcinogenic at any of the exposure levels of 300, 1000 and 3000 ppm using 120 rats/sex/dose group (Hamm et al. 1984). Filser and Klein (2018) used PBPK modeling to estimate that 3000 and 1000 ppm ethylene exposures were equivalent to 5.52 and 5.26 ppm EO, respectively in rats. Thus, these data provide additional biological evidence that the exposure response at lower exposures is not steep. As discussed above, there is no TK difference between rats and humans at blood concentrations up to 200 ppm EO exposures, and the direct alkylating MOA processes are likely to be very similar. **Does EPA agree that in rats there is no evidence of a steep exposure response at lower EO equivalent exposures? Does EPA agree that the TK process between rats and humans are similar?**

Breast Cancer Incidence vs Mortality for Quantitative Risk Assessment

(11) ACC (2020, 2023) raised concerns that EPA is relying on an incomplete data set for breast cancer incidence and EPA's conclusions are based on a deficit of expected cancer cases in lowest exposure group, which resulted from the inability to find individuals in this lowest exposure group in a ratio comparable to the higher exposed group (that is there, was underascertainment in the lowest control group). EPA relies on a statement that the interviews were "complete" to argue that the data set was complete but just because all of the contacted individuals were interviewed is not the same as the database being complete and representative. **What analysis of the data has EPA done to show that the individuals that the study author was not able to find were randomly distributed through the data set, as opposed to being concentrated in the lowest exposed group? What analysis has EPA done to demonstrate that there is no under ascertainment of cases in the lowest exposed group? Does EPA agree that the breast cancer mortality study which is fully ascertained shows a dose-response pattern that is more consistent with the standard CPH model?**

Reality Check Considerations

(12) EPA has noted that ambient EO concentrations near facilities could be probative on the anticipated impacts of EO emissions on residents. However, EPA declined to account for background EO concentrations from sources unrelated to industrial emission due to alleged uncertainty with measurements distant from facilities which they associate with insensitive, unreliable historic test methods. In doing so, EPA infers without analysis that near-facility concentrations are substantially greater than ambient background concentrations and pose a health issue. This approach fails to acknowledge that everyone is exposed to exogenous background EO concentrations as well as endogenous background concentrations. Commenters have previously demonstrated that the measured concentrations close to and away from facilities are often not statistically different. Based on EPA guidance improving the EO test method, state agencies have continued to collect EO data with the new method that continue to show a general pattern of many near facility location concentrations as indistinguishable from ambient background concentrations. Distinguishing higher exogenous exposures is an important initial step is management of EO risk. However, as everyone also has a large endogenous background EO exposure, total background exposure needs to be considered in management of EO risk. **What is the basis for EPA's concern regarding the reliability of background EO concentrations in light of new data using EPA-refined methods? How does EPA plan to consider total background concentration exposure in managing EO risk?**

(13) EPA dismisses multiple lines of converging evidence that everyone in the U.S. is exposed to EO from their own metabolism at concentrations substantially greater than proposed reference dose (Kirman et al. 2021). These data provide important reality checks for selection of dose-response models to apply to the NIOSH data and have important implications for risk management decisions. There is little value in attempting to manage risks from exposures to EO that are orders of magnitude lower than endogenous equivalent values. EPA's primary response is that cancer risk values estimate extra risk so that endogenous levels are already included in the estimate. While EPA's potency estimate technically only applies to exposures above endogenous levels, this is true for both EPA's and TCEQ's potency estimates. Yet only EPA's potency estimate leads to risk specific concentrations that are a fraction of endogenous levels[2]. From a risk management perspective, there is little value in attempting to manage risks from exposures at levels that are orders of magnitude lower than endogenous equivalent levels[2]. **How does EPA reconcile a potency estimate that suggests that EO is a highly potent carcinogen at levels substantially below that which the body produces through natural processes? What scientific rationale does EPA have for ignoring endogenous EO levels as a reality check**

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[2] Endogenous exposures to EO are equivalent to inhalation exposures that range from 1-5 ppb, with an equivalent endogenous mean of 2-3 ppb. As a reality check for the different modeling approaches applied by TCEQ and EPA this mean is compared with the 10^{-5} risk specific concentrations (RSC) resulting from each approach. TCEQ's RSC is approximately equivalent to the endogenous equivalent mean. EPA's RSC is a very small fraction (1/1000) of the endogenous mean in humans, a level that is not expected to be biologically meaningful.

for selection of dose-response models and as a consideration for risk management decisions?

(14) The EPA (2024) RTC states that estimates of EO exposures at ambient exposure levels or of endogenous levels are unreliable because the simple linear model extrapolates below the occupational exposure levels used to develop the model. ACC (2023) provided new evidence based on NHANES biomonitoring data in smokers and in non-smokers that EPA (2024) did not address. There are only three simple assumptions made by Kirman and Hayes (2017) and Kirman et al. (2021): (1) The high quality CDC NIOSH NHANES HEV data can be used to quantify *total* (exogenous and endogenous) exposures to EO; (2) EPA's air monitoring data can be used to quantify exogenous exposure to EO in air; (3) a continuously linear relationship between EO exposures and HEV measurements can be quantified. Yet, the EPA (2024) RTC dismisses the linear model as hypothetical and fails to address the new data and validation exercise provided by ACC (2023**). What is the scientific basis for USEPA's continued skepticism on linear toxicokinetics for EO over the entire low- to mid-exposure range of NIOSH-cohort occupational exposures, when in fact by its own 2005 Carcinogen Risk Assessment Guidelines low-dose linearity serves as the default assumption for toxicokinetics (i.e., below metabolic saturation, co-factor depletion), and also serves as the default assumption for toxicokinetics and toxicodynamic factors for low-dose risk from exposure to chemical carcinogens?**

(15) ACC's comments on the HON (ACC, 2023) provided further validation of the Kirman et al. (2021) linear correlation for low level EO exposures and hemoglobin adduct formation (HEV) based on several different lines of data evidence and PK and PBPK analysis. This correlation was used to provide evidence supporting the estimation of endogenous EO-equivalent levels. Part of the validation of the linear correlation followed EPA's (2022 p. 69) own recommendation for such a "forwards" validation using analytically quantified EtO concentrations in cigarette smoke. The EPA (2024) RTC did not address this new analysis and asserted incorrectly that no data on EO in cigarette smoke had been presented. In light of the strong evidence provided to EPA, the burden of proof is on EPA to reject the well supported evidence for use of a linear model. **What concrete evidence does EPA have to support EPA's current vague claim of "uncertainty" based on some as-yet-to-be-identified source of nonlinear toxicokinetics?**

(16) EPA dismissed the absence of an association between EO lymphoid related cancers with smokers as a reality check based on the potential for antagonistic effects by other chemicals without citing specific evidence. The EPA (2016) IRIS predicts that EO exposures associated with typical cigarette smoking patterns should exhibit a relatively high incidence of lymphoid cancer (10^{-2} to 10^{-1} cancer risk) when in fact this type of cancer is not generally associated with cigarette smoking. Similarly, an association in the Union Carbide study where workers are exposed to high concentrations of EO should also be seen. EPA's dismissal is inconsistent with EPA guidelines for assessing chemical mixtures (USEPA, 2000); "*For low exposure levels when no interactions information is available, default methods using an additivity assumption are given...Response addition is the default approach when the component chemicals are functionally independent...response addition has often been used for the risk assessment of mixtures of carcinogens (Gaylor et al., 1997; U.S. EPA, 1989a).*"

Accordingly, and unless directly supported by countervailing experimental evidence, response addition should serve as the default assumption for cancer risk from mixtures of EO and other chemicals until conclusive evidence is obtained to demonstrate otherwise. Both sets of data do not show an association between EO exposure and the relevant cancers (or at most a weak association). **There are only two potential explanations for the disparity between this data and EPA's model and they are mutually exclusive, either : (1) EPA's model is wrong; or (2) when individuals are exposed to other chemicals, as they are in environmental settings, EO induced cancers are somehow prevented or cured by a strong antagonistic effect attributed to chemical co-exposures. What data does EPA have to support a mechanism for cigarette smoke preventing or curing EO-induced lymphoid cancers?**

Exposure Issues with the NIOSH Study

(17) The exposure model used by the NIOSH study was developed by Hornung et al. (2004). In that paper, the authors make clear that they simply assumed, without supporting data, that practices that would reduce worker exposure after 1978-1980 had not changed during the 1950s all the way through 1978. This NIOSH exposure model led to a prediction that the 90th percentile exposures considered relevant for highly exposed sterilizer operators is lower in earlier years (1940-1970) compared to 1976-1978 (Figure 2). Public comments, including references to a supporting peer-reviewed scientific publication (Bogen et al. 2019) were submitted providing published literature as well as a summary of interviews describing changes that would have resulted in higher worker exposures in earlier periods for sterilizer operators (ACC, 2020, 2023). EPA claims that the summary of interviews is not sufficient to question the Hornung et al. (2004) estimates or to support the exposure modeling by Bogen et al. (2019) but fails to address the published literature and the absence of any attempt by NIOSH to verify exposures in the early 1940-1970 period with data. EPA's exclusive reliance on the NIOSH cohort to estimate EO cancer potency and risk should be re-examined by evaluating other lines of evidence from other epidemiology and animal studies. **Does EPA agree that in general, substantial underestimates of exposures can lead to overestimates of cancer potency? What data or reports in the record demonstrate that there were no changes to practices or storage conditions of EO-treated products that would have increased exposures prior to 1976-1978 (e.g., as considered by Bogen et al. 2019)? What evidence can EPA point to that shows Hornung et al. (1994) did not simply assume that there were no changes in sterilizer worker practices or equipment that would reduce worker exposure prior to 1978?**

Figure 3. NIOSH exposure model predictions of historical 90th percentile 8-h time-weighted occupational EO concentrations during 1936-1986 based on the Hornung et al. (1994) model (Figure 1 of Bogen et al. 2019).

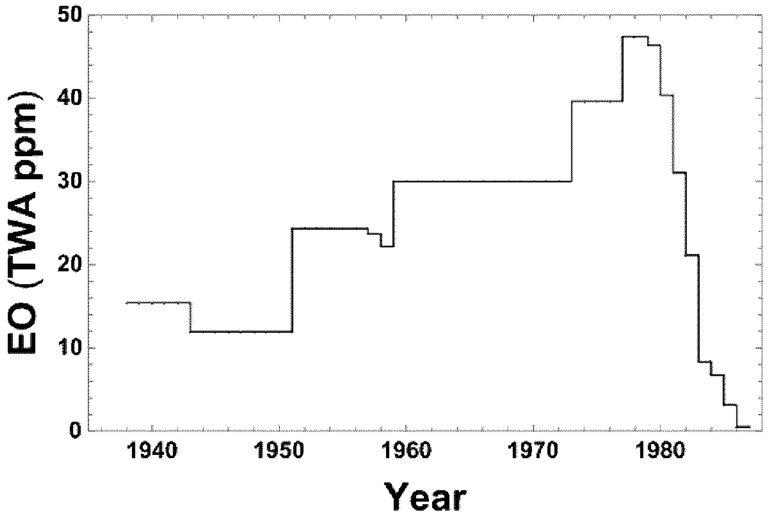

Figure 1. National Institute of Occupational Safety and Health (NIOSH) statistical regression (NSR) exposure model predictions of historical 90th percentile 8-h time-weighted average (TWA) occupational ethylene oxide (EO) concentration (C_{90}) during 1936–1986, specific to all facilities and job categories addressed by that model. Nearly all of the facilities sterilized medical/health products. The NSR model predicts that C_{90} = 47.4, 30.0, and 11.9 ppm in 1978, 1959, and 1949, respectively, and predicts TWA C_{90} values of 34.3, 27.5, and 15.9 ppm during the late, middle, and early periods defined for the present study, respectively.

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