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U.S. Environmental Protection Agency
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RE: Comments on EPA's Proposed National Emission Standards for Hazardous Air Pollutants: Chemical Manufacturing Area Sources Technology Review. Docket ID No. EPA-HQ-OAR-2024-0303, 90 Fed. Reg. 7,942 (January 22,2025).

1. INTRODUCTION

The Society of Chemical Manufacturers and Affiliates (SOCMA) submits these comments on the U.S. Environmental Protection Agency's ("EPA") proposed National Emission Standards for Hazardous Air Pollutants: Chemical Manufacturing Area Sources Technology Review.

SOCMA is the national trade association dedicated to the specialty and fine chemical industry. Founded in 1921, SOCMA represents a diverse membership of chemical companies who batch manufacture new and innovative chemistries used in a wide range of commercial, industrial, and consumer products. SOCMA maintains a strong record of member service through programs that maximize commercial opportunities, enhance regulatory and legal compliance, and promote industry stewardship. SOCMA's members also implement ChemStewards®, an EHS&S performance improvement program that is a mandatory component of membership.

Our association members operate across the country in compliance with existing local, state, and federal statutory requirements. The environmental impacts of our member facilities' operations are also assessed according to permit conditions approved by state regulators and administered under the Clean Air Act (CAA), Clean Water Act (CWA), Resource Conservation and Recovery Act (RCRA), and others regulatory frameworks. Our members also have a longstanding commitment to transparently communicating with community residents about processes and products through the use of important tools like Community Advisory Panels, which help facilities build relationships with members of their communities, share information about operations, identify any community concerns, and work with community stakeholders to try to resolve them.

While we support updating emissions standards in a technically feasible and economically efficient manner, we have substantial concerns with several aspects of EPA's rulemaking for which revisions, further clarification, or potential withdrawal would be beneficial.

The proposal also contains significant additional control provisions for ethylene oxide (EO) emissions from process vents, storage vessels, heat exchange systems, wastewater, pressure relief devices, pressure vessels, and equipment leaks. Most of the proposed provisions are consistent with those that the Agency finalized as part of their 2020 risk and technology review (RTR) for the National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical Manufacturing[1] rule (referred to as the MON) and the 2024 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[2] rule (referred to as the HON). The provisions also mirror standards recently proposed by EPA as part of their review of the National Emission Standards for Hazardous Air Pollutants for Polyether Polyols Production Industry (the 2024 PEPO rule).[3] however, this proposed rule, the MON, the HON, and the 2024 PEPO rule contain provisions that far exceed existing requirements in other NESHAPs and for other pollutants covered by those rules. As described in detail below, we are particularly concerned with EPA's decision to continue to use the IRIS value for EO.

Relatedly, we are concerned that the Agency has proposed broadly applicable requirements without consideration of the substantial costs imposed on facilities that do not pose a threat of adverse effect on human health, when instead the Agency could have taken a more targeted and less costly approach through other means at its disposal. Our members oppose the one-size-fits-all approach EPA is taking in this proposed rule, particularly for SOCMA members who comprise diverse specialty chemical manufacturers.

As described below, we urge the Agency to withdraw these overly burdensome portions of the proposal and repropose standards based on subcategorization and the technology review provisions. Such a proposal could achieve meaningful reductions of EO, and we stand ready to engage with the Agency on options that achieve such outcomes while providing feasible reductions and protecting the supply chain.

In addition, we have significant concerns regarding EPA's proposed fenceline monitoring program targeting EO. As described further in our comments below, the applicability of the requirements is ambiguous, the costs associated with implementing the requirements has not been properly

[1] 85 Fed. Reg. 49084.
[2] 89 Fed. Reg. 42932.
[3] 89 Fed. Reg. 105986.

considered, and the feasibility of implementing the monitoring program in the prescribed timeframe is questionable at best. Furthermore, the proposed fenceline monitoring requirements appear to impose emissions standards on operations not included in the source category to which this proposed rule applies.

In terms of costs, some of SOCMA's members have expressed concerns with the requirement to meet the 99.9% removal from air emissions and effluent release, as the estimated costs for a thermal oxidizer would be about $3 million just for a small facility with five emissions being considered. There would also be additional costs from additional stack monitoring (continuous emissions monitoring systems could be another $500,000 minimum), the costs for fenceline monitoring. Members have expressed concerns about the lack of adequate infrastructure to support the new requirements which may require additional support from their water supply, their effluent flow, electrical grid support, natural gas supply, and limited facility footprint. Members are concerned that the cost of these requirements would likely not see a positive return on investment even in a 5-year outlook.

While we appreciate that the Agency provided a short extension, it was unfortunately not sufficient given the complexity of the rule or consistent with the length of comment provided in other actions, thus limiting public input. We recognize EPA's obligation to complete the rulemaking on a timeline under a signed consent decree. However, that factor is of no consequence to this issue since EPA could have focused on proposing requirements necessary to meet that deadline rather than on provisions that for which it has no statutory mandate (risk) or questionable authority /support (e.g., fenceline monitoring requirements that reach beyond the source category).
We offer the below comments on several aspects of EPA's proposed rule revisions including specific concerns and recommendations designed to support and improve EPA's proposed requirements. The following points highlight key elements of our detailed comments:

- EPA's approach to addressing emissions of EO is inconsistent with the statute and the Agency should follow the technical review process while considering costs and options available to subcategorize and/or target emissions standards.
- EPA should address the numerous issues with the EO IRIS value that have to date been raised but dismissed out of hand by the Agency.
- The proposed thresholds for "in ethylene oxide service" are arbitrary and unjustified. If EPA proceeds to address risk, EPA must perform a well-reasoned analysis to determine appropriate control applicability thresholds.
- EPA has not properly considered the impacts associated with eliminating delay of repair (DOR) provisions for equipment and heat exchange systems in EO service. Eliminating delay of repair will require more frequent shutdowns to repair minor leaks, contributing to additional emissions of EO. Furthermore, more frequent shutdowns will require additional

purging of equipment and equipment openings impacting facilities ability to comply with the proposed fenceline monitoring action levels.

- EPA has failed to properly justify the proposed fenceline monitoring requirements, which do not represent GACT under CAA Section 112(d)(5) and are not cost-justified. As such, they should not be finalized because as proposed they represent an unwarranted emissions standard for which EPA has not properly considered a cost-to-benefit ratio. The proposed requirements also impose emissions standards on operations beyond the source category.
- If EPA proceeds to finalize fenceline monitoring requirements, the Agency must provide adequate time to establish monitoring programs. The Agency must also provide further transparency with regards to how the action levels were developed, and revise those action levels, particularly for EO, such that they are attainable by facilities when in compliance with the other proposed requirements in this rulemaking.
- We support EPA's proposal to allow 3 years for compliance with most of the proposed standards; however, EPA should also allow 3 years (or more) for facilities to comply with standards that address emissions of EO and the fenceline monitoring requirements.

The remaining sections of this letter provide our detailed comments on the proposed rulemaking.

2. COMMENTS ON EPA'S APPROACH TO CONSIDERATION OF RISKS AND COSTS IN CLEAN AIR ACT 112(D)(5) RULEMAKING

2.1 EPA failed to consider the marginal costs of its approach to regulating ethylene oxide emissions.

- EPA overestimated the benefits and underestimated the costs of the proposed rule.
    - EPA uses several assumptions to create model plants that do not represent actual emissions as reflected in the emissions inventories used for risk modeling.
- EPA's estimated total annualized cost for proposed EO controls is: $30,794,600/yr
    - Equipment leaks: $1,129,400/yr
    - HES: $117,900/yr
    - Process Vents: $2,126,000/yr
    - Wastewater: $5,471,300/yr
    - Flares: $960,000/yr
    - FLM: $20,990,000/yr
- EPA's estimated reduction in annual cancer incidence is 0.2 cases per year within 50 km of facilities.
- Marginal cost-effectiveness: $153,973,000/cancer case prevented.

- EPA failed to consider less stringent options that are likely more cost effective, such as adding EO to table one without further specifying rule applicability based on arbitrary thresholds of 1 ppmv in process vents or 1 ppmw in liquid streams.
- Furthermore, EPA did not consider the marginal costs of the proposed EO specific control requirements in addition to the updates EPA is proposing under 112(d)(6).
- EPA's proposed standards are not cost-effective and do not represent GACT under 112(d)(5). We provide potential alternative standards or standard setting approaches in Section 4 of this comment letter that EPA could rely on to mitigate the threat of adverse effects on human health.

2.2 EPA has tools to direct controls to the units for which EPA has determined risk is unacceptable.

EPA proposes to find that EO emissions from area sources present a threat of adverse effect on human health[4] based on the maximum cancer risk from seven of 33 facilities that emit EO. For the 26 remaining facilities, the maximum cancer risk is at or below EPA's presumptive acceptable threshold of 100-in-1 million.[5] Accordingly, it is apparent that no one facility needs to control all units that are driving risk across the source category to make a determination that the facility and the source category no longer present a threat of adverse effect on human health. Based on EPA's own analysis EPA is imposing on every facility controls that are not needed to address risk, and indeed is often imposing burdensome controls with little or no claimed environmental benefit. Such an approach is arbitrary and we urge the Agency to adopt a more targeted approach to addressing any risk that needs to be addressed.

Additionally, EPA would determine risks are acceptable even without additional controls if it were to use a more scientifically based value than the EO IRIS value, either by adopting the TECQ alternative value or by considering the full body of scientific information and incorporating a recognition of the fundamental problems with the IRIS value into its analysis, as is contemplated by long standing EPA policy. *See*, e.g., Preamble to National Primary Drinking Water Regulations: Minor Revisions to Public Notification Rule and Consumer Confidence Report Rule, Proposed Rule, 66 Fed. Reg. 46928 at 46929 (Sept. 7, 2001); [6]

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[4] 90 Fed. Reg. 7,945.
[5] 54 Fed. Reg. 38,045.
[6] SAB Review, MACT I Petroleum Refining Sources and Portland Cement Manufacturing (May 7, 2010) "To assist in comparing alternative chronic toxicity values, the Panel recommends that a table be created, including all the chemicals under consideration and all of the eligible dose-response values, along with the source of the value, the year it was last updated, and a qualitative description of the effect. *If the chronic dose-response values are significantly different, especially if the value is a driver for the risk assessment, a review should be conducted to understand why the values differ, with professional judgment used to select values for the assessments.*")

Where EPA believes that there are facilities where risks need to be addressed, the Agency is not without tools to target emission controls where needed so as to avoid over-controlling risks, or requiring extremely economically or technically burdensome, controls to achieve little or no risk reduction. Congress explicitly granted EPA the authority to consider variations among sources in promulgating emission standards under CAA § 112 through subcategorization; yet, EPA has failed to utilize this statutorily available tool here. Additionally, it directed EPA to address adverse effects to human health or the environment, without specifying that the same standards had to apply uniformly. Accordingly, EPA should exercise its subcategorization authority to ensure that the facilities that do not present adverse effects are not subject to additional, unnecessary controls. Such subcategorization would also allow EPA to direct controls to the specific units at facilities where needed to address risk. Alternatively, EPA could simply set a standard directed at the units as needed to address adverse effects. It is arbitrary and capricious for EPA to fail to consider such authority when evaluating the need for additional emissions reductions.

First, EPA could address this issue through subcategorization. Under CAA § 112(d)(1), EPA "may distinguish among classes, types, and sizes of sources within a category or subcategory in establishing such standards except that, there shall be no delay in the compliance date for any standard applicable to any source under subsection (i) as the result of the authority provided by this sentence." The purpose of CAA §112(c)(3) and (5) is to provide authority for EPA to identify area source categories that present a threat of adverse effects to human health or the environment. It is reasonable then for EPA to promulgate standards that account for variations in sources. EPA's proposal subverts the intent of Congress by reading out its own authority to set standards for subcategories of facilities. As discussed above, Congress intended for cost to be considered in control options except in limited circumstances. Interpreting the statute to allow subcategorization for area source categories is the approach "most harmonious with its scheme and with the general purposes that Congress manifested." *Comm'r v. Engle*, 464 U.S. 206, 217 (1984) (*citing Nat'l Lab. Rels. Bd. v. Lion Oil Co.*, 352 U.S. 282, 296 (1957)). This is because subcategorization would direct controls to only those sources (and units at those sources) where such controls are needed to address adverse effects and reduce or eliminate costs where controls are not needed. This approach would allow EPA to address the proposed risks in a targeted manner that would achieve the protective intent of the statute. Accordingly, if EPA proceeds with its proposal to impose more stringent emissions standards on CMAS sources that emit EO, the Agency should exercise its subcategorization authority and focus its standards on the sources with the highest likelihood of exhibiting adverse effects, and then only on the units at those sources contributing to the alleged effects at each facility. We recognize that this may well result in different control requirements for each facility.[7]

[7] For example, even among the facilities with LDAR as a driver of unacceptable risk, the frequency of LDAR or leak definition needed to address risk could vary.

Even if the Agency chooses not to subcategorize, EPA has recognized that it is unreasonable to require controls on all facilities when a more targeted and less costly option may achieve an acceptable level of risk. Indeed, EPA has now proposed to do so twice for EO emissions.

First, in the proposed National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review, for example, EPA tailored its acceptability analysis to address risk from the highest risk sources. EPA, however, failed to propose similarly tailored controls for the CMAS category. In that rule, EPA indicated:

> [W]e consider two options for reducing risks. Control Option 1 would require (1) 99.94 percent emission reduction for each SCV at facilities using at least 40 tpy EO and (2) 2.8E–3 lb/hr emission limit for Group 2 room air emissions at area source facilities using at least 20 tpy. Control Option 2 would require (1) 99.94 percent emission reduction for each SCV at facilities using at least 40 tpy EO; (2) 2.8E–3 lb/hr emission limit for Group 2 room air emissions at area source facilities using at least 20 tpy, except for 2 facilities with MIR > 100-in-1-million after imposition of the requirements under Control Option 1; and (3) for these two facilities, work practice standards that would bring their MIR to 100-in-1-million.[8]

EPA did not finalize target controls due to a lack of authority; rather, the Agency determined that after correcting emissions files, no source in the source category posed unacceptable risk.

Recently, EPA proposed a similar approach as part of the sterilizers NESHAP where it directed controls at a subset of sources and implicitly considered costs in tailoring its standards. For the Commercial Sterilization Facilities, the maximum individual lifetime cancer risk (MIR) was largely driven by EO from one facility that uses 44 tons per year (tpy) of EO. In that proposed rule, EPA focused controls in several ways, reflecting both a recognition that the same controls were not needed for all facilities, and in some instances costs.

- EPA considered sterilization chamber vent (SCV) standards for facilities that use at least 40 tpy and determined that "this is feasible because our evaluation of performance tests indicates that 27 out of 36 facilities with SCVs and using at least 40 tpy of EO are already exceeding this emission reduction from their SCVs. Of those 27 facilities, 14 use wet scrubbers, six use catalytic oxidizers, four use a wet scrubber and gas/solid reactor in series, two use thermal oxidizers, and one uses a wet scrubber and catalytic oxidizer in series."[9]

[8] 88 Fed. Reg. 22790, 22827-28 (Apr. 13, 2023).
[9] 88 Fed. Reg. at 22826-27.

- EPA also proposed standards for Group 2 room air emissions for facilities that use more than 20 tpy of EO to capture the three facilities where their MIRs exceeded 100-in-1 million.
- EPA proposed work practice standards for two high risk facilities but noted that this "could require significant costs."[10]

EPA has not, in the immediate case, explained why a similar approach would not be equally as effective in this rulemaking context given the limited number of sources that it has determined present a threat of adverse effect on human health and the variation of the drivers of risk among them. Imposition of broad, uniform control on all facilities within a category—regardless of risk posed or cost—when less stringent requirements may mitigate the threat of adverse effects on human health amounts to arbitrary overcontrol and goes beyond EPA's CAA § 112 authority to set standards under § 112(c)(3) and (d)(5).

As the Agency has failed to propose such directed controls, it must withdraw the proposed rule and repropose or issue a supplemental notice and solicit comment on narrowly tailored controls to address the perceived threat of adverse effects on human health.

3. EPA'S RISK ANALYSIS SIGNIFICANTLY OVERSTATES THE RISKS ASSOCIATED WITH LOW-LEVEL EXPOSURE TO ETHYLENE OXIDE

SOCMA is concerned that EPA's risk analysis on which the Agency relies to proposing a new source category has artificially inflated risks, which has led to significantly burdensome and overly stringent requirements that will result in less environmental benefit than projected. The following comments provide additional details on EPA's overstatement of risk and recommended approaches to mitigate the unnecessary conservatism applied by the Agency.

3.1 EPA's Inaccurate Ethylene Oxide IRIS Value.

EPA's sole stated justification for adding EO emissions from CMAS sources as a new area source category is the existence of updated IRIS values for EO.[11] But simply pointing to a new IRIS value cannot be the basis for conducting a new review and regulating a new source category. 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

[10] 88 Fed. Reg. at 22827.
[11] 90 Fed. Reg. 7,945.

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.[12] 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. The inhalation cancer risk assessments for EO conducted by EPA 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.[13]

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 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 these comments an Attachment 1, 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 questions 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[14] 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

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[12] 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.").

[13] *Huntsman Petrochemical v. EPA*, 114 F.4th 727, 735 (D.C. Cir. 2024). The court did not address the statutory argument that an 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.*

[14] We 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.

uncertainties related to the IRIS value.[15] These uncertainties make using the IRIS value as the sole basis for launching a discretionary review and listing a new source category inappropriate. 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,[16] the American Chemistry Council (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 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."[17] Putting aside the

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[15] *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").

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

[17] *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

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 of the 2024 HON rule, ACC 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.[18]

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 ambient air (Kirman et al. 2021; ACC comments). As a reality check, TCEQ's 10^{-5} risk

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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.

[18] 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 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.

> 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 1), 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.

3.2 EPA's Overly Conservative Risk Model.

SOCMA is concerned that EPA's use of conservative modeling approaches results in an overestimate of source-category risk for several facilities, specifically related to emissions of EO. EPA's risk assessment is based on numerous conservative assumptions and approaches that tend to overestimate risk. This includes EPA's use of census block centroids to evaluate chronic exposure. EPA states that

> *The predicted risk estimates are generally conservative with respect to the modeled emission because they are not adjusted for attenuating exposure factors (such as indoor/outdoor concentration ratios, daily hours spent away from the residential receptor site, and years of lifetime spent living elsewhere than the current residential receptor site).*[19]

EPA's use of the census block centroid is generally considered health protective, especially since EPA assumes that the exposed population is continuously present (24 hours/day, 365 days/year) at that location for 70 years. In reality, the vast majority of the exposed population does not exhibit such limited mobility, but would leave the location for work, school, vacation, errands, etc., thus reducing exposure. Furthermore, the census block centroid is also generally considered health protective because EPA does not account for the fact that people spend the majority of their time indoors. According to EPA, "For many of the HAP, indoor levels are roughly equivalent to ambient levels, but for very reactive pollutants or larger particles, indoor levels are typically lower. This factor has the potential to result in an overestimate of 25 to 30 percent of exposures."[20] EPA's

[19] EPA-HQ-OAR-2024-0303-0041, HEM4 User's Guide pg. 3.
[20] EPA-HQ-OAR-2022-0730-0085, pg. 62

approach is also conservative based on the assumption that an individual will be exposed to modeled concentrations for 24 hours per day, 52 weeks per year for 70 years. People rarely live in the same location for this long. In fact, EPA has estimated that the 50th percentile for years lived in a current home is 8 years, with a 90th percentile value of 32 years.[21] As a point of comparison, the current EPA regional screening levels were developed assuming a 26-year exposure duration for residents[22]; California EPA's California Office of Environmental Health Hazard Assessment (OEHHA) recommends using 30 years for evaluation of cancer risks for residents.[23] EPA has consistently relied on these conservative assumptions in previous risk reviews, but we encourage EPA to consider the resulting overstatement of risk when determining appropriate controls to reduce source-category risk in this rulemaking.

4. ALTERNATIVE APPROACHES FOR GACT STANDARDS TO ADDRESS ETHYLENE OXIDE EMISSIONS

4.1 Standards for EO Emissions from Wastewater

- EPA has not evaluated the incremental cost-effectiveness of applying the current CMAS wastewater provisions to EO compared to EPA's proposed requirement to treat any wastewater with 1 ppmw of EO or more as a Group 1 wastewater stream under the HON.
- EPA should evaluate the emissions reductions from controlling EO according to the existing requirements in §63.11498 and Table 6 to Subpart VVVVVV as a result of adding EO to Table 1 [without specifying additional control applicability thresholds for wastewater as EPA proposes at § 63.11494(a)(2)(v)]

4.1.1 Definition of "In Ethylene Oxide Service."

- If EPA insists on setting control applicability thresholds for EO beyond those in the existing CMAS rule, the Agency must appropriately justify those thresholds.
- The proposed thresholds of 1 ppmw at any flow rate are arbitrary and do not represent GACT nor the level of control necessary to mitigate a threat of adverse effects to human health.

[21] EPA. 2011. Exposure Factors Handbook. Office of Research and Development, Washington DC. U.S. EPA/600/R-09/052F. September.
[22] EPA. 2019. Regional Screening Levels User's Guide. November.
[23] Cal/EPA, OEHHA. 2015. Air Toxics Hot Spots Program Risk Assessment Guidelines: The Air Toxics Hot Spots Program Guidance Manual for Preparation of Health Risk Assessments. February.

4.1.2 Addition of Wastewater to Heat Exchange Systems

- EPA proposes to prohibit the injection or disposal in a heat exchange system of any wastewater or water that contains EO or that has contacted EO.
- EPA provides no rationale for this prohibition, other than "to eliminate these types of EtO emissions from wastewater being injected into heat exchange systems." (90 Fed. Reg. 7,958)
- EPA has failed to justify that such a standard represents GACT under CAA § 112(d)(5).
- As part of meeting sustainability and water reduction goals, facilities need the option to utilize treated wastewater and/or stormwater collected from process areas in heat exchange systems instead of discharging it. EPA's proposed prohibition on use of any wastewater in heat exchange systems is a significant barrier to water reuse projects being developed at CMAS facilities. EPA should allow the use of stormwater and treated wastewater that would meet National Pollutant Discharge Elimination System (NPDES) discharge requirements in heat exchange systems. EPA should also clarify that wastewater may be injected into heat exchange systems after it has been treated in accordance with the requirements of § 63.11498.

4.2 Standards for EO Emissions from Process Vents and Storage Tanks

- Similar to wastewater, EPA has not evaluated the incremental cost-effectiveness of applying the current CMAS process vent and storage tank control requirements to EO compared to EPA's proposed requirements to reduce emissions of EO by venting to a flare meeting the operating and monitoring requirements of 40 CFR Part 63, Subpart CC, or to reduce emissions by 99.9%, to 1 ppmv, or to less than 5 lb/yr for all combined process vents.
- EPA should first evaluate the emissions reductions from controlling EO according to the existing requirements in §63.11496 and Table 6 to Subpart VVVVVV for process vents and in §63.11497 and Table 5 to Subpart VVVVVV for storage tanks as a result of adding EO to Table 1 [without specifying additional control applicability thresholds as EPA proposes at § 63.11494(a)(2)(v)]
- Alternatively, EPA should analyze less stringent control options (such as the alternative definition of in EO service as proposed below coupled with a 98% DRE) that would reduce the most significant emissions while minimizing the threat of adverse effect on human health as well as minimizing cost. (Use EPA's cost/emissions reductions analysis with a more reasonable threshold to analyze the incremental impacts of an XX ppmv/% threshold and 98% reduction compared to EPA's 1 ppmv/0.1% threshold and 99.9% reduction).

4.2.1 *Definition of "In Ethylene Oxide Service" for Process Vents and Storage Tanks*

- If EPA insists on setting control applicability thresholds for EO beyond those in the existing CMAS rule, the Agency must appropriately justify those thresholds.
- The proposed thresholds are arbitrary and do not represent GACT nor the level of control necessary to mitigate a threat of adverse effects to human health.

4.2.2 *EPA Should Reconcile the Initial and Continuous Compliance Demonstration Requirements for Process Vents*

If EPA revises its analysis and determines that it is necessary to finalize control requirements for EO emissions from process vents by referencing the HON, we request EPA make the initial and continuous compliance demonstration requirements for process vents in EO service consistent. If facilities choose to comply with the 1 ppmv concentration option and install a CEMS, they may use either an FTIR or a GC CEMS [See § 63.124(a)(3)(i)] for their initial compliance demonstration. However, only an FTIR CEMS is allowed for the continuous compliance demonstration according to § 63.124(b)(2). EPA should reconcile this difference and allow facilities to use a GC CEMS for continuous compliance.

4.2.3 *Process Vent and Storage Tank Control Device Requirements*

EPA should not finalize the requirements to monitor and comply with a maximum flue gas flow rate for thermal oxidizers used to control EO in §63.124(a)(2)(vii)(B) and (b)(5)(ii) via reference from Tables 2 and 3 of Subpart VVVVVV. Because oxidizers are designed with a minimum residence time, flue gas flow rate is often not monitored. Fan operation is sometimes monitored as an indicator that exhaust gas is passing through the oxidizer, and pressure drop may be monitored as an indicator that flow through the oxidizer is not impeded. Furthermore, if the oxidizer is not equipped with heat recovery, flue gas temperatures will range from 1,500 °F to 1,600 °F, making flow measurements with an annubar (at least with normal materials of construction) or an ultrasonic flowmeter impracticable. We recommend that the requirement to measure flue gas flow rate be removed from the final rule because it is well established that combustion chamber temperature is the key variable to ensuring high destruction efficiency.

EPA has also proposed to add requirements at §63.124(a)(2) via reference from Tables 2 and 3 of Subpart VVVVVV for determining the control efficiency of non-flare control devices. We request EPA add flexibility to use an engineering approach where it is unsafe to sample the amount of EO at the inlet to the control device.

4.3 Comments on Ethylene Oxide Provisions for Equipment in Ethylene Oxide Service

- Separate standards for EO are unjustified given the cost-effective reductions of EO that will be achieved resulting from EPA's proposed revisions to the equipment leak standards under CAA §112(d)(6).
    - EPA estimates a 98% emissions reduction of EO.
    - EPA's option 1 under the 112(d)(6) analysis results in an 85% reduction of EO.
        - VOC reduction claimed by EPA is 67%, but this is 67% over AVO inspections.
        - "No Control" to option 1 represents an 85% reduction – and achieves 86% of the EO reductions EPA claims under the EO specific standard.
        - Option 1 costs $8,900/yr w/o recovery credits and $3,490 with recovery credits.
        - The EO cost-effectiveness for 112(d)(6) option 1 is $3,500 without recovery credits and $1,400 including credits.
        - The incremental cost to go from 112(d)(6) option 1 to the EO option is $87,177 per ton of EO and $89,106 per ton of EO.

4.3.1 EPA Should Revise the Definition of "In Ethylene Oxide Service" for Equipment

- If EPA insists on setting control applicability thresholds for EO beyond those in the existing CMAS rule, the Agency must appropriately justify those thresholds.
- The proposed thresholds are arbitrary and do not represent GACT nor the level of control necessary to mitigate a threat of adverse effects to human health.

4.3.2 Delay of Repair Should Not Be Eliminated for Equipment in Ethylene Oxide Service

- EPA is proposing to eliminate the delay of repair (DOR) provisions for connectors and valves in gas/vapor service and light liquid service, and for pumps in light liquid service.
- EPA is also proposing to eliminate the monitoring skip periods for valves and connectors in gas/vapor service and light liquid service.
- EPA's proposal to eliminate this flexibility will increase emissions of EO and increase costs for industry; therefore, we request that EPA refrain from finalizing the provisions as proposed and instead continue to allow for delay of repair for these components.
- EPA's impacts assessment inaccurately estimates EO leaks from certain process fugitive components. The Agency's analysis overstates the baseline emissions of EO from valves and connectors in gas/vapor and light liquid service, and from pumps in light liquid service.
- Delay of repair provisions provide a critical flexibility for facilities to operate in a continuous manner without frequent shutdowns to repair leaking equipment

- The delay of repair provisions also minimize emissions if the operator determines that the emissions resulting from immediate repair would be greater than the fugitive emissions from delaying the repair. By removing facilities' ability to delay repair, EPA is effectively increasing emissions of EO.
- EPA should also take into consideration that removing the delay of repair provisions will potentially impact our members' ability to meet demand for critical industries. EO is used for sterilization of medical devices that cannot be sterilized via other means such as high heat or steam. Additionally, EO derivatives are used in several medical applications such as medicinal tableting, medical coatings, films, solvents, or aids in the production of pharmaceuticals and vaccines. As previously described, facilities will be required to shut down equipment more frequently and for extended periods of time, potentially impacting the supply of this important component. Further, impacts on supply could well impact broader EPA and Administration priorities, for example, EPA's recent proposal to electrify motor vehicles is dependent upon EV battery production. Such battery production is currently generally dependent upon ethylene carbonate, which is produced by reacting EO with carbon dioxide.

4.3.3 Reduced Monitoring Frequencies Should Not Be Eliminated for Equipment in Ethylene Oxide Service

- EPA is also proposing to not allow reduced monitoring periods for valves and connectors in EO service.[24]
- Similar to elimination of the delay of repair provisions, EPA's proposal to remove this flexibility will result in increased costs for industry without appreciable reductions in emissions. EPA does not appear to quantify a difference in emissions with and without skip periods. In fact, EPA's memo analyzing control options for EO from equipment leaks under the PEPO rule indicates there is no emissions reduction when skip periods are eliminated (See Table 6-3 of EPA-HQ-OAR-2023-0282-0069). In fact, EPA even asserts that "emission reductions are insignificant" as a result of eliminating skip periods.[25]
- Unlike valves and pumps, connectors lack moving parts and have a low rate of leaks. Gasket failure is the primary reason for connector leaks; once repaired, connectors have a low frequency of repeat leaks. Thus, monitoring the same connectors every month when leaks are generally not expected to recur results in a waste of company resources. The data collected by EPA's ICR for PEPO sources supports this assertion. Of the nine process units, one monitors connectors quarterly and had an average leak rate of 0.13% in 2017. Six process units monitor connectors annually, and two monitor connectors every four years,

[24] See proposed §63.1434(a) by reference to the HON, EPA-HQ-OAR-2023-0282-0060.
[25] EPA-HQ-OAR-2023-0282-0069, Table 6-3, footnote c, pg. 13, presumably referring to the difference between monitoring

none of which recorded any leaks in 2017. The reported leak rates are well below the subsequent leak frequency EPA assumes after implementing the proposed control option for connectors (0.42%).[26]

- Reduced monitoring frequency based on good performance is an important aspect of several existing chemical rules and it should not be excluded for equipment in EO service without an appropriate justification showing that eliminating emissions from skip periods is cost effective under a well-reasoned GACT analysis.

4.3.4 EPA has not Properly Justified Monthly Connector Monitoring for Equipment in Ethylene Oxide Service

- EPA proposes to require monitoring of connectors in EO service on a monthly basis without skip periods.
- EPA has failed to adequately justify that this frequency represents a cost-effect GACT standard.
- EPA should revise its analysis and conclude that quarterly connector monitoring is a cost-effective GACT standard and that the incremental cost of monthly monitoring is not cost-effective. Cost to go from quarterly to weekly is an additional $401,000/yr, for an additional 0.25 tpy of EO reduction, an incremental cost effectiveness of $1.6 million per ton.
- Monthly connector monitoring poses difficulties due to the large number of components that will require monitoring on a continuous basis. The situation is further complicated if the CMPU or facility is shut down for a portion of the month (e.g., a 2-week outage), because all components will require monitoring within a 15-day period.
- EPA's impacts assessment overstates the baseline emissions of EO from valves and connectors in gas/vapor and light liquid service, and pumps in light liquid service, further skewing the GACT analysis.
- Because connectors have a low frequency of repeat leaks, we encourage EPA to consider an annual or semi-annual connector monitoring frequency. If the Agency cannot justify annual or semi-annual monitoring, we encourage EPA to evaluate the high incremental cost and minimal emissions reductions of monthly connector monitoring compared to quarterly monitoring.

4.3.5 PRD Releases from Equipment in Ethylene Oxide Service Should Not be Automatic Deviations

EPA has proposed at § 63.11495(a)(7) via reference to the HON that any release event from a pressure relief device (PRD) in EO service is a violation of the PRD management work practice

[26] Ibid, Table 6-2, pg. 11.

standards. EPA contends that classifying PRD releases as a deviation represents GACT because of similarities between CMAS, MON, and SOCMI facilities, and because the Agency does not expect additional costs as a result. EPA also states that such a standard is necessary to "ensure that EtO is not released to atmosphere from a PRD."[27] EPA should not finalize the revisions as proposed but instead apply the deviation determination criteria at §63.165(e)(3)(v)(A) through (C) to PRDs in EO service.

- EPA has not adequately explained why "ensur[ing] that EtO is not released to atmosphere from a PRD," represents GACT:
    - EPA is incorrect in its assumption that such a provision will not result in additional costs.
    - Under MON and HON, EPA felt compelled by § 112(f) to address unacceptable risk from PRDs. Here EPA must follow the GACT provisions which do not require elimination of all emissions.
    - EPA has not considered the technical limitations that apply to PRDs.

The same technical limitations that apply generally to PRDs apply to those in EO service. PRDs are used to prevent catastrophic equipment failure, which in turn protects the health and welfare of personnel and the community. PRD releases are typically non-routine, infrequent, and episodic. Although the work practices at §63.165(e) are an effective means of potentially reducing PRD releases, there are no actions that facilities can reasonably take to avoid PRD releases that result from conditions that are beyond their control. Additionally, not all releases from PRDs in EO service can be controlled because of technical or site-specific safety concerns such as hydraulic limitations of flare systems or other controls, PRD backpressure, EO incompatibility with other collected compounds, and polymerization of EO in closed vent systems. Additionally, controlling all PRDs in the EO reactor area would require a flare so large it may or may not be feasible to construct, due to the additional flow of ethylene and methane that would require control during PRD releases.

The work practice standards under §63.165(e)(3) provide an effective framework for managing and reducing releases from all PRDs, including those in EO service because PRD releases are non-routine, infrequent, and episodic. Rather than characterizing any release from a PRD in EO service as a deviation, facilities should be able to comply with the provisions of §63.165(e)(3)(v)(A) through (C) when determining whether or not a release from a PRD in EO service is a deviation. Because PRDs in EO service function in the same manner, serve the same purpose, and are subject the same technical limitations as other regulated PRDs, we urge EPA to allow facilities to comply

[27] 90 Fed. Reg. 7,962.

with the provisions at §63.165(e)(3)(v)(A) through (C) when determining whether or not a release from a PRD in EO service is a deviation.

4.4 Comments on Ethylene Oxide Provisions for Heat Exchange Systems in Ethylene Oxide Service

- For heat exchange systems in ethylene oxide service, EPA is proposing quarterly monitoring using the Modified El Paso Method and a 6.2 ppmv leak definition. EPA is also proposing that facilities must fix leaks within 15 days without delay of repair.

4.4.1 Delay of Repair Should Not Be Eliminated for Equipment in Ethylene Oxide Service

- EPA's proposal to eliminate this flexibility will increase emissions of EO and increase costs for industry; therefore, we request that EPA refrain from finalizing the provisions as proposed and instead to allow for delay of repair for heat exchange systems.
- Delay of repair provisions provide a critical flexibility for facilities to operate in a continuous manner without frequent shutdowns to repair leaking equipment
- The delay of repair provisions also minimize emissions if the operator determines that the emissions resulting from immediate repair would be greater than the fugitive emissions from delaying the repair. By removing facilities' ability to delay repair, EPA is effectively increasing emissions of EO.
- EPA should also take into consideration that removing the delay of repair provisions will potentially impact our members' ability to meet demand for critical industries. EO is used for sterilization of medical devices that cannot be sterilized via other means such as high heat or steam. Additionally, EO derivatives are used in several medical applications such as medicinal tableting, medical coatings, films, solvents, or aids in the production of pharmaceuticals and vaccines. As previously described, facilities will be required to shut down equipment more frequently and for extended periods of time, potentially impacting the supply of this important component. Further, impacts on supply could well impact broader EPA and Administration priorities, for example, EPA's recent proposal to electrify motor vehicles is dependent upon EV battery production. Such battery production is currently generally dependent upon ethylene carbonate, which is produced by reacting EO with carbon dioxide.

4.4.2 EPA Should Not Finalize Separate Standards for Heat Exchange Systems in Ethylene Oxide Service.

- EPA's 0.1 wt% definition for heat exchangers in ethylene oxide service is arbitrary under § 112(d)(5).

- EPA points to the recent HON revisions of the basis of the threshold; however, EPA the threshold developed for the HON was based on reducing perceived risk to an acceptable level, not a cost-effect GACT standard. Furthermore, our comments on the recent PEPO proposal indicate that a threshold level of 0.1% is unnecessary to reduce risk to acceptable levels at similar facilities (we found that the EO concentration could be as high a 9% while still achieving acceptable risk.

4.5 Comments on Ethylene Oxide Provisions for Flares that Control Ethylene Oxide Emissions

- EPA proposes that flares controlling EO emissions must meet the operating and monitoring requirements specified in 40 CFR §§ 63.670 and 63.671.
- EPA presents a cost of $606,700 per ton of EO reduced and asserts this value is cost-effective given EO's toxicity (90 Fed. Reg. 7,959). This cost-benefit ratio is not justified for X reasons:
    - EPA continues to overstate the risk of EO by its continued use of the flawed 2016 IRIS value.
    - The two CMAS facilities for which EPA has EO emissions data from flares do not pose unacceptable risk under EPA's presumptive limit on maximum individual lifetime cancer risk (100-in-1 million – 54 Fed. Reg. 38,045). EPA's risk modeling indicates the total source category risk from these facilities is 70-in-1 million and 10-in-1 million.
    - However, risks from these flares are likely much lower than EPA's modeling results indicate. As demonstrated by our comments on the HON (EPA-HQ-OAR-2022-0730-0168, pg. 20) by accounting for the heat release of the flare and buoyancy of combustion gases, the maximum off-site impact from flaring as indicated by modeling can be reduced by up to an order of magnitude.

4.6 *Fenceline Monitoring Requirements*

As a general matter, we support monitoring efforts that are accurate, technically and economically feasible, and based on the best available scientific methods. We strongly believe that any monitoring programs are created to provide the most useful scientifically reliable information to all stakeholders, including regulators, regulated entities, and the local communities in which our members operate. To ensure that monitoring programs can achieve such a result, we strongly believe that any monitoring program must use well-developed, technically practical monitoring methods that generate reliable data. The information produced by quality monitoring programs must also have ample time for quality assurance and control review to identify any potential errors

or inconsistencies that may impact the conclusions drawn from the data. Further, the monitoring programs should be conducted by trained and qualified personnel who have some level of technical and practical experience with such programs. Finally, it is critical for the reviewed data to be distributed and communicated in a way that places the information in appropriate context, particularly when discussing potential risks associated with emissions.

Unfortunately, EPA's proposed fenceline monitoring program for EO fails to meet these goals. As detailed in the following sections, EPA's requirements for fenceline monitoring exceed the Agency's CAA statutory authority and create several technical challenges that may comprise the integrity and clarity of the collected data. As such, EPA should withdraw these proposed requirements from any final rulemaking.

Although we believe that EPA must withdraw the proposed fenceline program, we hope that the Agency is open to establishing a constructive dialogue on ways to leverage all expertise to develop reliable, accurate test methods that can appropriately distinguish and provide context for data collected near facilities. This is particularly critical for situations in which, as in the case of EO concentrations, target substance concentrations near facilities are likely indistinguishable from background. To further these goals, we provide detailed comments in this section.

4.6.1 EPA has exceeded its authority in proposing to require fenceline monitoring under CAA § 112(d)(5).

- EPA has not justified fenceline monitoring as an emissions standard under CAA § 112(d)(5). EPA does not quantify a level of emission reduction from the proposed fenceline monitoring, nor does it account for any of the potential costs associated with achieving such emission reductions. Instead, EPA presents a total annual cost of $20.9 million per year to conduct monitoring only.
- Fenceline monitoring using EPA Method 327 is not "generally available." EPA asserts this claim as a result of finalizing similar requirements under the HON; however, in addition to noting several technical challenges of implementing such a program, we have previously raised our concerns regarding the legal authority for those provisions (reference legal brief). Furthermore, existing sources are not required to comply with those requirements until 2027.
- Nor can the Agency justify fenceline monitoring under CAA § 112(d)(6). Under CAA § 112(d)(6), EPA has the authority to revise emissions standards "as necessary." Even if the proposed fenceline monitoring requirements were emission standards, EPA has not demonstrated that fenceline monitoring is necessary to reduce HAP emissions or to provide an ample margin of safety. To the contrary, the lack of emissions reductions associated

with the proposed requirements show that such requirements are unnecessary to the ultimate goals of CAA § 112.

- As such, fenceline monitoring is neither a revised emission standard nor a development in practices, processes, and control technologies. Even if fenceline monitoring was within the scope of EPA's authority under CAA § 112(d)(5) or (d)(6), the imposition of such requirements is unreasonable, arbitrary, and capricious.

4.6.1.1 Fenceline monitoring is not an emissions standard or work practice within the meaning of CAA § 112.

As a preliminary matter, fenceline monitoring by itself is not an emissions standard. An "emission standard" is "a requirement . . . which limits the quantity, rate, or concentration of emissions of air pollutants on a continuous basis, including any requirement relating to the operation or maintenance of a source to assure continuous emission reduction, and any design, equipment, work practice or operational standard promulgated under this chapter."[28] Fenceline monitoring does not "limit the quantity, rate, or concentration of emissions" from any particular source, not does it "relat[e] to the operation or maintenance of a source to assure continuous emission reduction." By itself, fenceline monitoring does not reduce emissions, rather all that fenceline monitoring does is identify ambient concentrations of a specific chemical. It does not even identify if the chemical is from a regulated source, let alone, a specific regulated unit at such source.

Fenceline monitoring can only potentially reduce emissions when coupled with additional requirements, but, at least in this instance, EPA does not appear to claim associated reductions from the source category.[29] While EPA is proposing an EO "action level," again, this level alone does not "limit the quantity, rate, or concentration of emissions." First, according to the preamble, if the emissions inventories are accurate, 32 of 33 facilities will have fenceline concentrations at or below the action level considering the proposed EO emissions standards.[30] EPA does not account for emissions reductions, or the cost to achieve those reductions form the one facility over the action level, stating that the emissions have a "high degree of uncertainty," because there was only one record of EO emissions from the facility.[31] Thus, even when coupled with the action level, EPA's proposal does not claim that fenceline monitoring will result in any meaningful emissions reductions from the source category. [32] Second, while exceedance of the action level may trigger further requirements, it does not, by itself or combined with fenceline monitoring,

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[28] 42 U.S.C. § 7602(k).
[29] *See* 90 Fed. Reg. at 7,960 ("*When required in conjunction with root cause analysis and corrective action*, fenceline monitoring can reduce uncertainties associated with fugitive emissions estimation and characterization.") (emphasis added).
[30] 90 Fed. Reg. 7,961.
[31] Ibid.
[32] Because fenceline monitoring is not already required from facilities, this differs from situations where EPA is making existing control requirements enforceable.

limit emissions - additional actions are required. And, because EPA's proposal measures ambient concentrations, an exceedance of the proposed action level is not necessarily the result of emissions from the facility in question or from an exceedance of a standard.

Although EPA does not specially present the proposed fenceline monitoring program as a work practice standard, we note that EPA has proposed fenceline monitoring as a work practice standard in recent rulemakings[33] which could fall within the meaning of "any design, equipment, **work practice** or operational standard promulgated under [the CAA]," EPA has not explained here or previously how fenceline monitoring meets the requirements for a work practice standard, potentially because of the issues noted above. EPA has not demonstrated that its proposal meets the statutory requirements for imposition of work practices.

First, work practice standards are authorized only in limited circumstances under CAA § 112(h)(1) when it is not feasible to prescribe or enforce an emission standard for control of HAPs. Specifically, CAA § 112(h)(2) defines infeasibility in this context to mean that either a HAP "cannot be emitted through a conveyance designed and constructed to emit or capture such pollutant, or that any requirement for, or use of, such a conveyance would be inconsistent with any Federal, State or local law" or that "the application of measurement methodology to a particular class of sources is not practicable due to technological and economic limitations." Here, EPA has not demonstrated that these circumstances have been met. Indeed, EPA has imposed several standards on EO that the fenceline monitoring is intended to address (in other words, emission standards are feasible for at least some of the units EPA intends to capture through fenceline monitoring). EPA has conducted no analysis excluding these units or explained how the work practice is permissible for such units.

Second, EPA has not adequately explained what elements of the proposal are work practice standards. For example, in previous actions EPA has stated that it is proposing a "fenceline monitoring work practice standard,"[34] which, on its face, appears to indicate that the actual monitoring component is the work practice standard. However, EPA also refers to fenceline monitoring in combination with root cause analysis and corrective action requirements and may use "fenceline monitoring" to refer to the monitoring combined with root cause and corrective action requirements.[35] In EPA's proposed residual risk and technology review for sterilization facilities, on the other hand, EPA described only the root cause analysis and corrective action requirements as the work practice standards, noting that "[i]f this long-term average exceeds an

[33] *See, for example,* 89 Fed. Reg. at 106,024.
[34] 89 Fed. Reg. at 106,027.
[35] *See* 89 Fed. Reg. at 106,026 ("The proposed fenceline monitoring provisions would require the initiation of root cause analysis upon the facility's annual average concentration exceeding the action level, as determined on a rolling average every sampling period.")

'action-level,' then a facility is required to conduct the associated work practices (*i.e.*, root cause and corrective action) to identify and mitigate the source of the excess emissions."[36] EPA must explain what proposed requirements are workplace standards. It is critical that EPA fully explain its proposal to allow stakeholders a meaningful opportunity to assess the implications of the proposal and provide comments.

4.6.1.2 EPA Has Not Justified Fenceline monitoring as a development in technology.

CAA § 112(d)(6) requires EPA to "tak[e] into account developments in practices, processes, and control technologies." EPA does not define "developments" but has interpreted the term broadly[37] to include add-on control technology or equipment, improvements to add-on control technology, "process change or pollution prevention alternative that could be broadly applied to the industry," significant changes in cost, and "[a]ny work practice, management practice, or operational procedure that was not identified or considered during development of the original GACT standards."[38]

Although EPA did not propose adding fenceline monitoring requirements under CAA § 112(d)(6), the Agency asserted that fenceline monitoring is a development in practices, processes, and control technologies.[39] EPA fails to provide a clear tie into how it meets the statutory requirements. It is unclear, for instance what standard EPA is reviewing or how fenceline monitoring constitutes a review of the existing standards with respect to "developments in practices, processes, and control technologies." Similarly, EPA does not explain how fenceline monitoring, which by itself does not reduce emissions, is such a development. Nor does it provide any analysis as to how "root cause analysis and corrective action" are developments with respect to any particular unit/unit type. If EPA decides to further consider fenceline monitoring under CAA § 112(d)(6), it needs to provide such analysis or provide a statutory interpretation as to why its proposal comports with the statutory requirements.

In addition to the above noted issues:

(1) EPA does not adequately explain how monitoring methods are a "development" nor does EPA explain what "development" category fenceline monitoring allegedly falls into (*i.e.*, a work practice standard that was not considered previously.)

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[36] National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review, 88 Fed. Reg. 22,790, 22,847 (Apr. 13, 2023).
[37] While EPA has interpreted "developments" broadly, EPA needs to examine if that interpretation is in fact the best interpretation of the statute.
[38] 90 Fed. Reg. 7,951.
[39] 90 Fed. Reg. 7,973.

(2) According to the proposed rule, at least in places, fenceline monitoring is a work practice standard that "is a development in practices, processes, and control technolgies considered under CAA section 112(d)(6)."[40] Specifically, however, EPA considered two *monitoring methods* - not action levels, root cause analysis, or corrective action—as developments in practices.[41]
(3) How do monitoring methods fall under any other of the broad categories of "developments" previously defined by EPA.[42]
(4) If the root cause analysis and the corrective action requirements are the work practice standards—as EPA stated in the proposed sterilization facility rule—then how are monitoring methods a work practice standard (if they are not they are not a"development" that can be considered under CAA § 112(d)(6)).

4.6.2 EPA's Proposed Facility-Wide Requirements are Arbitrary and Capricious.

EPA is proposing to apply fenceline monitoring and related requirements to all sources at a facility under the same owner/operator.[43] We believe that as currently drafted, EPA's proposed requirements on this issue likely exceed its CAA authority as EPA has been instructed by Congress to set standards for sources in the source category. Attempts to regulate sources outside the source category must be addressed in the context of actions regulating those source categories.

4.6.3 Comments on Method 327.

The following comments are based chemical industry input following review of EPA's Method 327 and based on discussions with analytical laboratory representatives. The comments below are organized by method section.

Comment on Section 8.1.2 of Method 327

In Section 8.1.3.1, Method 327 requires that one install the sampling device on an evacuated canister equipped with a mechanical flow controlling device (MFCD) and tightly cap the inlet to the sampling device. However, in Section 8.1.2, Method 327 requires a flow control check prior to and after each field sampling event. We believe that these requirements will be very difficult and perhaps impossible to meet for the following reasons:

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[40] Ibid.
[41] Ibid.
[42] EPA's interpretation of "developments" is overly broad, arbitrary, and capricious. Yet, even being unreasonably broad, EPA's interpretation does not capture "monitoring methods."
[43] 90 Fed. Reg. 7,961. Parts of the proposal also seem to suggest that the requirements might also apply to leases depending on the circumstances.

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. We have concerns about this requirement as the flow controller is designed to collect a sample volume of approximately 5 liters or 5,000 mL over a 24-hour period (assuming the 6L canisters is not completely filled with ambient air). Thus, the flowrate is approximately 5000 mL/1,440 minutes = 3.47 mL per minute. Thus, to be within 10% of the reference flowrate, the technician must prove that the flow controller is accurate to within ± 0.347 ml per minute, which we believe may not be possible to do with a field measurement. Also, the additional time to conduct these additional flow tests must be considered and will delay the time between when canisters 1,2,3 etc. can be placed into service by the sampling crew.

Further complicating the work in the field, Section 8.7.3.1 requires that all sampling locations must initiate sampling within 60 minutes of each other. Since the method requires the use of 8 canisters plus a duplicate, this requirement means that a sampling team would have less than 7 minutes to conduct the pre-sampling flow controller flow tests and then place each of the nine canisters in service. Our member companies' experience is that it took 15 to 20 minutes to place each canister into service for the Section 114 sampling work in 2022 given the fact that the sampling team has to travel between each monitoring site, attach the canister, record the starting vacuum, and make other records in order to place a canister into service. Thus, placing each canister into service within 60 minutes of each other is not a feasible requirement.

EPA has 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.[44] We reiterate our stance the entire flow control flow check requirement does not appear to be required as the technician can confirm relatively uniform flow into the canister through a pre-set orifice over a 24-hour period by recording the vacuum of the canister prior to the sampling event and then after the sample event. If the canister is still under a slight vacuum at the end of the sampling period, then the sample should be deemed adequate and suitable for analysis in the lab.

We are also 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[45] from Greg Noah of EPA, timers result in leaks due to the following:

[44] EPA-HQ-OAR-2022-0730-2764, pg. 252.
[45] https://www.epa.gov/sites/default/files/2021-04/documents/use_of_stand-alone_timer_timer_guidance_for_voc_sampling.pdf

- 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[46] to $3,000.[47] 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.

Comments on Section 8.7.2.2 of Method 327

> *8.7.2.2 Protect the canister and sampling inlets by placing the canister under shelter, if possible. Do not restrict air flow around inlets and do not locate inlets under building overhangs.*

EPA should remove this requirement from Method 327. Although possible, our member companies would like the flexibility to attach the canisters to a chain link fence or a post in the field without adding a shelter, which potentially could impact flow of ambient air to the sample location. Additionally, members with experience conducting fenceline monitoring for benzene indicate that sorbent tubes can be compromised during severe thunderstorms and it is unlikely that a shelter would have prevented the loss of the sample.

[46] https://www.thomassci.com/Laboratory-Supplies/Chromatography-Sample-Preparation/_/Canister-Air-Sampling-Timer
[47] https://us.vwr.com/store/product/18812791/canister-air-sampling-timer-restek

4.6.4 Root Cause and Corrective Actions.

As part of the referenced fenceline monitoring requirements, § 63.184(e)(1)(ii)(B) requires the owner or operator to employ the appropriate real-time sampling techniques (e.g., mobile GC's, optical spectroscopy instruments, or sensors within 30 days if the root cause of the exceedance has not been determined within 30 days.

Appropriate contract staff and equipment are not always available within 30 days. This situation is likely to be exacerbated as EPA adds fenceline monitoring requirements to more and more rules. While we agree that the use of real-time monitoring techniques can be a useful tool in a root cause analysis, our members cannot control the availability of outside resources. Therefore, we suggest that EPA modify § 63.184(e)(1)(ii)(B) to allow for an extension of the 30-day requirement based on a showing from sources that the necessary resources are unavailable within the 30-day period.

5. COMMENTS ON OTHER STANDARDS PROPOSED UNDER CAA SECTION 112(D)(5)

5.1 Pressure Vessels

5.1.1 EPA Should Adjust the Proposed Requirements for Pressure Vessels

EPA has proposed a prohibition on leaks from pressure vessels at § 63.11497(f). EPA states that they are proposing leak detection and repair (LDAR) requirements,[48] but this is not the case: there are no repair provisions, only a prohibition on leaks. We request EPA adjusted the language at § 63.11497(f) to better reflect a more traditional LDAR program, the goal of which is to find and fix leaks on a certain schedule. EPA should not finalize the language that states any instrument reading greater than 500 ppmv is a deviation.

By designating any reading greater than 500 ppmv a deviation, EPA will be placing facilities into an impossible compliance scenario. Operational fittings such as valves and pumps are not 100% reliable. Seals and packing can develop leaks over time and need to be replaced. Traditional LDAR programs have long acknowledged this fact by allowing facilities adequate time to repair leaks after detection, prior to the leak event being considered a violation. Additionally, facilities must be provided with a minimum amount of time to empty the pressure vessel to repair a leak if so required (noting that additional capacity for transferring the stored material may not always be readily available). In the GACT Standard Analysis, EPA states that facilities can design pressure vessels with capture and containment systems for leak interfaces such that facilities can

[48] 90 Fed. Reg. 7,962

avoid willful deviations;[49] however, even closed vent systems that would route these emissions to control devices can occasionally leak, hence the LDAR requirements for closed vent systems under the HON rule at § 63.148.

6. COMMENTS ON EPA'S CAA SECTION 112(D)(6) TECHNOLOGY REVIEW

6.1 Heat Exchange Systems

6.1.1 SOCMA Supports EPA's Proposal to Allow Facilities to use Water Sampling Methods for Heat Exchange System Monitoring with Minor Revisions

EPA proposes to incorporate revisions to the heat exchange system leak monitoring and repair work practice by referencing the requirements to monitoring and fix leaks via the Modified El Paso method at § 63.104(g) through (l). At §63.104(l), EPA is proposing as an option to allow sources to monitor for leaks in heat exchange systems via the provisions in § 63.104(b) if 99% by weight or more of the organic compounds that could leak into the system are water soluble and have a Henry's Law Constant less than 5.0E-6 at 25°C (atmosphere-cubic meter/mol). We request EPA revise the language at §63.104(l) to read "if 99 percent by weight or more of the organic compounds that could leak into the heat exchange system from heat exchangers that are in organic HAP service…"

A heat exchange system is defined at § 63.101 as

> *a device or collection of devices used to transfer heat from process fluids to water without intentional direct contact of the process fluid with the water (i.e., non-contact heat exchanger) and to transport and/or cool the water in a closed-loop recirculation system (cooling tower system) or a once-through system (e.g., river or pond water). For closed-loop recirculation systems, the heat exchange system consists of a cooling tower, all CMPU heat exchangers that are in organic HAP service, as defined in this subpart, serviced by that cooling tower, and all water lines to and from these process unit heat exchangers. For once-through systems, the heat exchange system consists of all heat exchangers that are in organic HAP service, as defined in this subpart, servicing an individual CMPU and all water lines to and from these heat exchangers. Sample coolers or pump seal coolers are not considered heat exchangers for the purpose of this definition and are not part of the heat exchange system. Intentional direct contact with process fluids results in the formation of a wastewater.*

[49] EPA-HQ-OAR-2024-0303-0035_content, pg. 3.

Although the heat exchangers in the regulated heat exchange system are those "in organic HAP service," the heat exchange system may contain heat exchangers that are not in organic HAP service along with those that are. Thus, we request that EPA clarify that the reference to "organic compounds that could leak into the heat exchange system" are only those from heat exchangers in organic HAP service.

6.1.2 Changes to Delay of Repair Allowance

Under the current CMAS rule, facilities may delay repair of a leaking heat exchange system if a shutdown is expected within the next 2 months, or if the shutdown to perform the repair would cause greater emissions than the potential emissions from delaying repair until the next shutdown of the process equipment associated with the leaking heat exchanger. These provisions laid out at § 63.104(e) and referenced by Table 8 of Subpart VVVVVV. EPA is proposing to eliminate these delay of repair options and replace them with the options in §63.104(j) that only allow delay of repair for heat exchangers that are not in EO service if the leak is below a delay of repair action level of 62 ppmv (as methane) in the stripping gas of the Modified El Paso Method, and prohibit delay of repair for heat exchangers in EO service (see §63.104(h)(6)).

The Agency should not eliminate the option that allows facilities to delay the repair if emissions from the process shutdown needed to repair the leak are greater than the potential emissions of delaying the repair until the next shutdown. This option essentially allows facilities to repair the leak with as little emissions and environmental impact as possible by requiring the facility to evaluate the emissions of a continued leak against the emissions from an entire process shutdown. By forcing facilities to repair leaks solely based on a concentration-based threshold, facilities with a smaller recirculation rate will likely emit greater amounts of HAP than if they were allowed to assess the overall mass emissions from the leak versus shutdown and choose the option that minimizes emissions. Further, EPA's calculation of emissions reductions in the heat exchange system technology review ignores emissions as a result of shutting down a process to fix a leak, biasing the Agency's cost to benefit analysis.

Forcing facilities to conduct unplanned shutdowns not only results in additional emissions but also presents safety hazards. Safe execution of facility shutdowns requires careful, advanced planning and coordination among properly trained staff. Imposing a requirement to fix leaks under a scenario that will result in unnecessary emissions and unwarranted additional safety risks is arbitrary. We request that EPA not finalize the new delay of repair requirements as the existing requirements provide flexibility for facilities while minimizing environmental impact and safety risks.

6.1.3 Clarifications to Initial Monitoring Requirements for Heat Exchange Systems

If EPA finalizes the revised requirements for heat exchange systems, we request that EPA clarify, in the preamble to the final rule, the initial monitoring requirements for heat exchange systems. In the preamble to the proposed rule, EPA states the following:

> *"We are proposing Control Option 1…to specify quarterly monitoring for existing and new heat exchange systems (after an initial 6 months of monthly monitoring) using the Modified El Paso Method and a leak definition of 6.2 ppmv of total strippable hydrocarbon concentration (as methane) in the stripping gas."*[50]

With this statement, EPA appears to imply that facilities are required to repeat initial monitoring upon the compliance date of the final rule; however, EPA's statement in the preamble is inconsistent with the proposed rule language. EPA's proposed incorporation of § 63.104(g)(4) requires sources to initially monitor monthly for 6 months beginning upon startup. We do not believe it was EPA's intent to require any source that has already completed 6 months of monthly monitoring under § 63.104 to repeat initial monthly monitoring. Nevertheless, we do not support any requirement to repeat initial monitoring for existing facilities or new facilities that have already completed initial monitoring under the current rule requirements. If EPA promulgates the revised standards for heat exchange systems, we support the initial monitoring requirements only for new and reconstructed sources that have yet to complete monthly monitoring and request EPA clarify their intent in the preamble to the final rule.

6.1.4 Clarifications to the Applicability of § 63.104(b) and (c).

We request EPA amend the language in § 63.104 to clarify that owners and operators are not required to monitor their regulated heat exchange systems using the provisions in either § 63.104(b) or (c) if the heat exchange system is monitored for leaks according to § 63.104(g). Currently, § 63.104(a) requires monitoring according to § 63.104(b) or (c), and "if applicable, paragraph (g)." As proposed via Table 8 of Subpart VVVVVV, sources must begin complying with the Modified El Paso method in paragraph (g) no later than the compliance date specified in § 63.11494(l), but there does not appear to be any language that allows sources to stop monitoring using the methods in paragraphs (b) or (c) once they have begun using the Modified El Paso method. Similarly, neither § 63.104 nor the referencing language at Table 8 of Subpart VVVVVV / § 63.11499 provide a means of ceasing compliance with § 63.104(d) once a facility begins complying with § 63.104(h) through (j). We request EPA revise § 63.104 to clarify that sources are not required to comply with § 63.104(b), (c), or (d) for a heat exchange system once the system is monitored and leaks are addressed via paragraphs § 63.104(g) through (j).

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[50] 90 Fed. Reg. 7,696.

7. OTHER COMMENTS CATEGORIZED BY EMISSION SOURCE

7.1 Compliance Timeline

7.1.1 SOCMA supports EPA's Proposal of a Three-Year Compliance Timeline for Revisions Proposed Under CAA Section 112(d)(5), and (d)(6).

7.1.2 *EPA Should Allow Three Years for Compliance with § 112(d)(5) Standards for Ethylene Oxide*

Regards,

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