April 26, 2021

The Honorable Michael Regan
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Dear Administrator Regan:

Enclosed for your consideration is the Report of the Small Business Advocacy Review Panel (SBAR Panel or Panel) convened for EPA's planned proposed rulemaking entitled "National Emission Standards for Hazardous Air Pollutants (NESHAP): Ethylene Oxide (EtO) Commercial Sterilization and Fumigation Operations." This notice of proposed rulemaking is being developed by the U.S. Environmental Protection Agency (EPA) under the Clean Air Act (CAA).

EPA promulgated standards for EtO emissions from sterilization activities Under Title 40 CFR Part 63, Subpart O on December 6, 1994 (59 FR 62585). The rulemaking addressed EtO emissions originating from three major types of emission points: the sterilization chamber vent (SCV), the aeration room vent (ARV), and the chamber exhaust vent (CEV). Following promulgation of the rule, the EPA suspended certain compliance deadlines and ultimately removed the 1994 standards for CEVs due to safety concerns. In the late 1990s, there were multiple explosions at EtO commercial sterilization facilities, and in response, the EPA suspended all rule compliance dates pending the investigation of the explosions (62 FR 64736, December 9, 1997). In 1998, the suspension of the compliance dates was extended for the ARVs and the CEVs (63 FR 66990, December 4, 1998) and the requirements for the SCVs went into effect. EPA later determined that EtO emissions from aeration rooms could be safely controlled, and the suspensions for the ARVs were not extended past December 2000 (64 FR 67789, December 3, 1999). For CEVs, EPA determined that the primary contributing issue leading to the explosions was that EtO concentrations within the exhaust streams were above the safe limit (i.e., above the lower explosive limit (LEL)), and the EPA extended the suspension of the rule requirements for CEVs. The EPA could not conclude at the time that the CEVs could be safely controlled, so requirements for CEVs were removed in 2001 (66 FR 55577, November 2, 2001) and have not been reinstated.

In addition, in 2005 the EPA proposed a residual risk analysis and a technology review under Clean Air Act (CAA) section 112(f)(2) and CAA section 112(d)(6), respectively, and issued a final decision on the risk and technology review (67 FR 17712, April 7, 2006). No changes were made to the rule as part of that action. Section 112(d)(6) requires EPA to conduct such a technology review every 8 years so the subsequent review was due in 2014. The purpose of the Panel Report is to inform the proposed technology review rule.

Stakeholders have suggested a broad range of program improvements through a variety of mechanisms including EPA's review of previous standards for CEVs, quantification and regulation of fugitive emissions, and accounting for front-end process improvements. From these suggested improvements, EPA identified those which required a regulatory change, and those which would provide the most protective impact. Sections 2.3.4, 2.3.5, and 2.3.6 of the Panel Report contain regulatory revisions currently being considered and evaluated by EPA. The revisions considered in the Panel Report are not final. The control options under consideration for the upcoming proposed rule for EtO commercial sterilizers include strengthening the current rule requirements and implementing requirements for emissions sources not currently covered by the rule.

On December 10, 2020, EPA's Small Business Advocacy Chairperson convened this Panel under section 609(b) of the Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA). In addition to its chairperson, the Panel consists of the Director of the Sector Policies and Programs Division within EPA's Office of Air Quality Planning and Standards (OAQPS), the Acting Administrator of the Office of Information and Regulatory Affairs within the Office of

Management and Budget (OMB), and the Acting Chief Counsel for Advocacy of the Small Business Administration (SBA). It is important to note that the Panel's findings and discussion are based on the information available at the time this report was drafted. EPA is continuing to conduct analyses relevant to the proposed rule, and additional information may be developed or obtained during this process as well as from public comment on the proposed rule. The options the Panel identified for reducing the rule's economic impact on small entities will require further analysis and/or data collection to ensure that the options are practicable, enforceable, protective of public health, environmentally sound and consistent with the CAA.

SUMMARY OF SMALL ENTITY OUTREACH

To identify the small entities within the source category, EPA used SBA's small business definitions to identify 23 facilities (out 103 facilities in the source category) that are owned by small businesses at the parent company level and that could be affected by this proposed rule.

Outreach to the full source category began in early 2019, when EPA met with the Ethylene Oxide Sterilization Association (EOSA), whose members include small businesses, and with whom EPA has since maintained regular contact. On March 18, 2019, EPA conducted an informational site visit to a small business facility in Virginia to learn more about the facility and its processes. Further site visits to facilities owned by small businesses were planned but not conducted due to the ongoing COVID-19 pandemic. In 2019, at least two EPA regional offices worked with facilities that are owned by small businesses to reduce their EtO emissions. In Region 2, a facility owned by a small business is re-testing one of its control systems to ensure that it is reducing EtO emissions in accordance with the current standards. In Region 7, a facility owned by a small business recently installed a wet scrubber system to control its CEV emissions. In addition, on December 9, 2019, EPA issued a Clean Air Act section 114 request that included four small businesses that own 11 EtO sterilization facilities.

Prior to convening the Panel, EPA conducted an online solicitation to identify small businesses and trade associations interested in participating in the Small Business Advocacy Review (SBAR) Panel process by serving as Small Entity Representatives (SERs). EPA issued a press release inviting self-nominations by affected small entities to serve as SERs and asked interested small entities to submit an email indicating their interest. EPA accepted self-nominations until December 20, 2019. EPA also contacted potential SERs throughout 2020 to generate additional interest. After identifying a list of potential SERs (shown in Section 4 of the Panel Report), on June 11, 2020, EPA invited SBA, OMB, and six potentially affected SERs to a Pre-Panel outreach meeting and solicited comments from them on preliminary information sent to them. The materials shared with the potential SERs during the Pre-panel outreach meeting are included in Appendix A1 of the Panel report. EPA shared the small entities' written comments with the Panel as part of the Panel convening document. A total of 6 potential SERs participated in the Pre-panel meeting. EPA presented an overview of the SBAR Panel process, an explanation of the planned rulemaking, and technical background. Written comments appear in Appendix B1 of the Panel Report.

After the SBAR Panel was convened, the Panel distributed additional information to the SERs on November 25, 2020 for their review and comment and in preparation for another outreach meeting. The materials shared with the SERs during Panel outreach meeting are included in Appendix A2 of the Panel Report. On December 10, 2020, the Panel met with the SERs to hear their comments on the information distributed in these mailings. The SERs were asked to provide written feedback on ideas under consideration for the proposed rulemaking. The Panel received written comments from the SERs in response to the discussions at this meeting and the outreach materials. See Section 6 of the Panel Report for a complete discussion of SER comments. Their full written comments are also included in Appendix B2. In light of these comments, the Panel considered the regulatory flexibility issues specified by RFA/SBREFA and developed the findings and discussion summarized below.

PANEL FINDINGS AND DISCUSSION

Under section 609(b) of the RFA, the Panel is to report its findings related to these four items:

1) A description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply.

2) A description of the projected reporting, recordkeeping and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record.

3) Identification, to the extent practicable, of all relevant federal rules which may duplicate, overlap or conflict with the proposed rule.

4) A description of any significant alternatives to the planned proposed rule which would minimize any significant economic impact of the proposed rule on small entities consistent with the stated objectives of the authorizing statute.

The Panel's most significant findings and discussion with respect to each of these items are summarized below. To read the full discussion of the Panel findings and recommendations, see Section 7 of the Panel Report.

A. Number and Types of Entities Affected

The proposed rule potentially affects facilities that use EtO in any equipment that destroys bacteria, viruses, fungi, insects, or other unwanted microorganisms or materials when such facilities are engaged in the growth, manufacture, construction, transportation, retail or wholesale trade, or storage of commercial products, or when such facilities are engaged in the operation of museums, art galleries, arboreta, or botanical or zoological gardens or exhibits. Hospitals, doctor offices, veterinary offices, clinics and other facilities where medical services are rendered are not included in the source category. If there is no active sterilization occurring at a facility, then it is not considered to be part of the source category. EPA estimates that there are approximately 103 companies including 23 small entities that would be impacted by this rulemaking.

B. Recordkeeping, Reporting, and Other Compliance Requirements

The potential reporting, recordkeeping, and compliance requirements are still under development. However, the Panel anticipates that the requirements will be the minimum necessary to ensure compliance with the regulatory option chosen. The Panel agrees that reporting and recordkeeping requirements should be streamlined to the extent practicable. The full list of reporting, recordkeeping, and compliance requirements that are under consideration are described in section 2.3.6 of the Panel Report.

C. Related Federal Rules

There are several federal rules related to commercial EtO sterilization, spanning various agencies:

- EPA, Office of Air and Radiation: 40 CFR Part 63, Subpart WWWWW
    - In addition to the commercial sterilization source category, the Hospital Sterilizers area source category also covers EtO sterilization. The NESHAP for the hospital sterilizers was developed under the Urban Air Toxics Strategy[1] and covers EtO used to sterilize medical equipment at all hospitals nationwide. The Hospital Sterilizers NESHAP was finalized in December 2007 (72 FR 22 73611). Hospital sterilizers are not covered under the commercial EtO sterilization source category (Subpart O).
- EPA, Office of Pesticide Programs: (see discussion of their EtO Draft Risk Assessment in Section 7.3)
- Food and Drug Administration (FDA)

[1] 64 FR 387065.

    - FDA validates sterilization processes, based on the characteristics of a given device, in accordance with FDA-recognized standards.
    - Sterilization facilities follow FDA regulations in 21 CFR (Food and Drugs). FDA does not directly regulate EtO emissions to outdoor air.
    - FDA regulations point to voluntary consensus standards that describe how to develop the validation cycles for EtO, gamma and e-beam sterilization for medical devices. FDA defines quality management system requirements for medical devices and the acceptable EtO residual levels for sterilized products. The standards the FDA points to include ISO 11135:2014, ISO 10993-7:2008(R)2012, ISO 11137, and ISO 13485:2016.
    - For spice fumigation, requirements are prescribed within the Food Safety Modernization Act (FSMA) regulations at 21 CFR Part 117.
- Occupational Safety and Health Administration (OSHA): 29 CFR §1910.1047
    - These regulations, which were set in 1984, address permissible worker exposure limits to EtO within sterilization facilities. There are no immediate plans from OSHA to update these requirements.
- Department of Transportation: 49 CFR §173.323
    - The regulations deal with drums in which EtO is transported.

D. Regulatory Flexibility Alternatives

Increased removal efficiencies for SCVs and ARVs.

Based upon SER comments related to increased removal efficiencies, the Panel recommends that EPA review the technical and economic feasibility of the efficiencies under consideration. One SER stated that increasing control efficiencies from 99% to 99.9% may seem like a small increase, however, it can be a very complex process. Increases in control efficiencies almost always require additional equipment and sometimes require facilities to replace the existing equipment all together. The SER also stated that certain performance efficiencies may also exceed certain technical and economical limits.

Based upon SER comments related to removal of the 1 ppmv alternative standard for ARV, the Panel recommends that EPA should consider an outlet EtO concentration that correlates with the increased removal efficiency standards. This would likely include requirements to ensure that the volumetric flow rate does not exceed that which was established during the stack test. EPA recognizes that a removal efficiency standard is more difficult to achieve when starting from a lower EtO concentration. Furthermore, the EPA does not wish to disincentivize process changes that would result in lower EtO use and lower EtO concentrations being observed downstream.

The Panel recommends that EPA take comment on SCV and ARV control and removal efficiencies. The EPA should also request comments on what specific pieces of information EPA would need to set and justify concentration compliance alternatives. For example, if EPA offers a concentration compliance alternative to a subcategory of facilities, it may need facility-specific information on EtO concentration and flowrate from performance test data, along with ongoing EtO concentration and flowrate measurements. The Panel also recommends that EPA explore regulatory alternatives that will incentivize lower EtO usage, as well as potential subcategories that would minimize cost burden to small businesses while also minimizing risk to nearby populations as appropriate.

Control requirements for fugitive emissions.

The Panel appreciates the SER concern that some facilities may not have yet demonstrated compliance with the emission standards in their permits or permit applications. Based on current information and data, only the BD facilities in Georgia are still in the permit application phase, with the Covington facility demonstrating success in capturing emissions from post-aeration handling of sterilized material. All other

facilities have either reported room air capture or have it listed in their permit. If it is reported that a facility is routing the air from a room area to an APCD, or if that air is cascaded to some other room where the air is routed to an APCD, then it is included as part of the MACT floor calculations. For recent permit applications, newly issued permits, and other information sources, stack test data may not yet be available, however EPA continues to collect and review performance test data that demonstrate the control efficiencies achieved. If the capture efficiency is not explicitly stated, then EPA assumes it to be 100%, unless there is information to suggest otherwise. This assumption is a placeholder, and EPA will work to confirm capture efficiencies. At this time, EPA Method 204 is the only method that ensures 100% capture efficiency. There are at least two facilities similar in size to the SER's major source facilities, including Medline (Waukegan, IL) and Sterigenics (Atlanta, GA), that retrofit capture at their facility and have successfully demonstrated compliance with Method 204. However, the Panel recommends that EPA continue to observe those facilities that have either implemented or are in the process of implementing Method 204 to identify any potential issues with compliance, as well as potential remedies. The Panel recommends that EPA confirm the status of facilities with respect to whether they have implemented or are implementing capture and control for fugitive emissions from room areas.

Based upon SER comments related to sterilization cycle changes, the Panel recommends the EPA consider regulatory alternatives based on process changes that lower EtO concentration in downstream, post-sterilization and post-aeration areas. Based on CAA section 112(d), the EPA can sub-categorize based on class, size, or type. Changing certain factors during the sterilization process (e.g., EtO dose, number of gas washes, aeration time, etc.) can impact downstream air EtO concentrations. Given the wide range of possible combinations of these elements, however, we have yet to identify a clear basis to sub-categorize based on class or type. One approach for determining whether a facility is in a certain class or type of sterilization could be to look at the downstream room air EtO concentration. Therefore, the Panel recommends EPA investigate whether subcategories based on class, size, or type could be developed based on observed differences in downstream room air concentration. There may be potential issues due to a lack of corrective actions available (the process parameters mentioned are dictated by FDA-validated cycles), and safeguards would need to be put in place to ensure that a facility does not artificially dilute the air to meet the standard if it is determined to be a viable option.

Based upon SER comments, the Panel recommends that EPA review the post-aeration fugitive areas for shipping and warehouse and clearly define the activities, per the EPA's obligation to set standards for unregulated emissions at major sources. *LEAN v. EPA*, 955 F.3d 1088 (D.C. Cir. 2020). EPA should also clearly explain future intended actions related to reduction of EtO fugitive emissions at offsite shipping and warehouse facilities. Based on section 112(d)(3), the EPA can sub-categorize based on class, size, or type. The EPA notes that with the way the source category is currently defined, if there is no active EtO sterilization taking place at a facility, then it is not part of the source category. The EPA does recognize, however, that this could create a potential gap in EtO regulations. For example, a shipping and warehouse or distribution center in Covington, GA was recently estimated to have EtO emissions of 5,600 lb per year. Currently, EPA does not have enough information to justify expanding the source category to include these offsite distribution centers not located at a sterilization facility. The EPA also notes that as part of an upcoming information collection request, sterilization facilities will be asked to report where their sterilized product is being sent and how long it stays at those facilities. The Panel also recommends that EPA explore regulatory alternatives that will incentivize lower EtO usage, as well as potential subcategories that would minimize cost burden to small businesses while also minimizing risk to nearby populations as appropriate.

The Panel also recommends that EPA take comment on GACT standards for area sources and that EPA consider GACT standards for area sources to the maximum extent possible.

Common Stack Continuous Monitoring Compliance Alternative.

The Panel recommends proposing this compliance alternative, with specific EtO emission concentration limits. The Panel further recommends EPA specifically solicit comments on what provisions of the current rule and proposed rule should be covered by this alternative and how reporting and recordkeeping can be streamlined. EPA should solicit comment on the appropriate way to set an EtO emission concentration limit, and whether the concentration limit should be set as a site-specific limit based on the particular circumstances of a facility. EPA should also solicit comments on the technical and economic factors for a firm adopting this alternative.

Proximity.

The Panel recommends that EPA take comment on proximity requirements for new sources as described in this report. The Panel also recommends that EPA request comment on whether a proximity restriction could or should substitute or supplement emission control requirements for new or existing sources elsewhere in the proposal.

OSHA standards.

Based upon SER comments, the Panel recommends that EPA should consider changes that a facility has made to comply with OSHA standards when proposing updates to the rule. EPA is not currently considering any changes made to OSHA requirements. In general, to comply with OSHA standards to reduce employee exposures to pollutants, facility efforts may impact the quantity of air flow and the pollutant concentration. To comply with OSHA requirements, air flow to and from a room area is typically increased to dilute the pollutant concentration within the room area and to remove the pollutant from the area. With any facility modifications taken to comply with OSHA requirements, facilities may have increased the volume of air flow from a room area while at the same time decreased the pollutant concentration. Larger air volumes with low pollutant concentrations tend to be more expensive/complicated to control, because the design flowrate for an add-on APCD may be larger, potentially increasing the capital cost, and it can be more difficult to reduce pollutants with low concentration

Compliance timeframe.

The maximum compliance timeline is dictated by statute under section 112(i)(3) of the CAA, which requires existing sources to comply as expeditiously as practicable but no later than 3 years after the effective date (i.e., after the promulgation date). In addition, section 112(i)(3) allows EPA or a delegated State to issue a permit that grants an extension for existing sources up to 1 additional year to comply if needed to install controls. The Panel recommends that EPA highlight the availability of a 1-year extension of the compliance date if the source demonstrates to the state permitting authority or EPA that an extension is necessary for the installation of controls (section 112(i)(3)(B) of the CAA). The Panel recommends that, should a 1-year extension under 112(i)(3) be granted, EPA also take comment on how to implement other available statutory compliance flexibilities that may be necessary to maintain adequate sterilization capacity to protect public health.

Cost analysis and impacts to facility operation.

The Panel recommends EPA consult with FDA to understand the impact to the supply of medical equipment that will occur if all EtO sterilization facilities are concurrently making significant upgrades to their air pollution control techniques and will potentially have simultaneous periods of shutdown.

For additional background on the Panel recommendations, please see section 7 of the Panel Report.

Sincerely,

Nickerson, William

Digitally signed by Nickerson, William
Date: 2021.05.12 14:30:36 -04'00'

William Nickerson
Small Business Advocacy Chair
Office of Policy
U.S. Environmental Protection Agency

Sharon Block

Digitally signed by Sharon Block
Date: 2021.05.11 14:59:05 -04'00'

Sharon Block
Acting Administrator
Office of Information and Regulatory Affairs
U.S. Office of Management and Budget

MAJOR CLARK

Digitally signed by MAJOR CLARK
Date: 2021.05.05 17:21:13 -04'00'

Major L. Clark, III
Acting Chief Counsel
Office of Advocacy
U.S. Small Business Administration

PENNY LASSITER

Digitally signed by PENNY LASSITER
Date: 2021.05.05 08:36:32 -04'00'

Penny Lassiter
Director, Sector Policies and Program Division
Office of Air Quality Planning and Standards
U.S. Environmental Protection Agency

Enclosure