U.S. SMALL BUSINESS ADMINISTRATION
OFFICE OF ADVOCACY
REGULATION • RESEARCH • OUTREACH

June 23, 2023

VIA ELECTRONIC SUBMISSION

The Honorable Michael S. Regan
Administrator
Environmental Protection Agency
Washington, DC 20460

**Re: National Emission Standards for Hazardous Air Pollutants: Commercial Ethylene Oxide Sterilization Technology Review (Docket ID No. EPA-HQ-OAR-2019-0178) & Ethylene Oxide Proposed Interim Registration Review Decision (Docket ID No. EPA-HQ-OPP-2013-0244)**

Dear Administrator Regan:

On April 13, 2023, the Environmental Protection Agency (EPA) published two proposed actions that would restrict use of Ethylene Oxide (EtO) for sterilization: a proposed rule titled National Emission Standards for Hazardous Air Pollutants (NESHAP): Ethylene Oxide Emissions Standards for Sterilization Facilities Residual Risk and Technology Review;[1] and notice of availability for Pesticide Registration Review; Proposed Interim Decision and Draft Risk Assessment Addendum for Ethylene Oxide.[2] This letter constitutes the Office of Advocacy's (Advocacy) public comments on these proposed actions.

Advocacy is concerned that these actions would lead to a significant number of small entities leaving the market for commercial sterilization, harming small medical device manufacturers, causing significant supply chain disruptions, and hurting patients needing sterilized medical devices. EPA has the discretion under the Clean Air Act to consider the costs and consequences of these actions and should reconsider these policies to reduce the impact on small entities and reduce the likelihood they will leave the market.

[1] 88 *Fed. Reg.* 22790 (Apr. 13, 2023)

[2] 88 *Fed. Reg.* 22447 (Apr. 13, 2023)

## I. Background

### A. The Office of Advocacy

Congress established the Office of Advocacy under Pub. L. 94-305 to represent the views of small entities before Federal agencies and Congress. Advocacy is an independent office within the U.S. Small Business Administration (SBA). As such, the views expressed by Advocacy do not necessarily reflect the views of the SBA or the Administration. The Regulatory Flexibility Act (RFA),[3] as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA),[4] gives small entities a voice in the rulemaking process. For all rules that are expected to have a significant economic impact on a substantial number of small entities, the RFA requires federal agencies to assess the impact of the proposed rule on small entities and to consider less burdensome alternatives.

The Small Business Jobs Act of 2010 requires agencies to give every appropriate consideration to comments provided by Advocacy.[5] The agency must include a response to these written comments in any explanation or discussion accompanying the final rule's publication in the *Federal Register*, unless the agency certifies that the public interest is not served by doing so.[6]

Advocacy's comments are consistent with Congressional intent underlying the RFA, that "[w]hen adopting regulations to protect the health, safety, and economic welfare of the nation, federal agencies should seek to achieve statutory goals as effectively and efficiently as possible without imposing unnecessary burdens on the public."[7]

### B. Ethylene Oxide in Commercial Sterilization of Medical Devices.

EtO is used as a sterilizer for new, single use, and reusable medical devices and equipment. EtO is highly valuable in the medical device supply chain because it can sterilize medical devices in their final packaging on pallets, increasing the efficiency of the supply chain and reducing the labor necessary to sterilize end products. EtO is used on approximately 50% of all sterilized medical devices annually, including an estimated 95% of all surgical kits.8 It is particularly useful for surgical kits because EtO is appropriate for a wide range of device materials, from metals to plastics and resins to bandages. Presently, there are no viable alternatives to EtO for the sterilization of certain medical devices and equipment. Gamma irradiation and e-beam irradiation, the next most commonly employed methods for medical device sterilization, cannot be used on certain materials. Other technologies (e.g., hydrogen peroxide, chlorine dioxide, vaporized peracetic acid) are limited due to issues with material compatibility, scalability, and

[3] 5 U.S.C. §601 et seq.

[4] Pub. L. 104-121, Title II, 110 Stat. 857 (1996) (codified in various sections of 5 U.S.C. §601 et seq.).

[5] Small Business Jobs Act of 2010 (PL. 111-240) §1601.

[6] *Id*.

[7] *Id.*

[8] EPA, *Memorandum re: Ethylene Oxide (PC#042301): Use, Usage, Benefit, and Impacts of Cancellation* (Dec. 1, 2022), regulations.gov Document ID EPA-HQ-OPP-2013-0244-0051.

because they lack accepted validation measures.[9] Although the Food and Drug Administration (FDA) has challenged industry to develop replacements for EtO, the consensus is that none will be available for many years.[10]

FDA has primary regulatory authority over the manufacture of medical devices, including sterilization of the final product. Sterilization procedures are specific to each commercial sterilization facility, medical device, and packaging, and a change in either requires validation of the sterilization method. "EtO facilities in the United States typically run 24/7 with facilities operating at maximum capacity. Thus, when EtO facilities close (even temporarily), there are downstream implications for the medical device supply chain."[11] Commercial sterilization services cannot be replaced quickly because of regulatory constraints and are not easily replaced because of limited capacity in the marketplace.

According to EPA, there are 86 existing EtO sterilization facilities in the United States. Twenty-four of these facilities are owned by 20 small businesses. EtO is also used by hospitals in specialty 'all-in-one' appliances for sterilization of reusable devices.

### C. The Proposed NESHAP

On April 13, 2023, EPA published proposed amendments to the NESHAP for the Commercial Sterilization Facilities source category. This action is in response to a 2016 update to EPA's Integrated Risk Information System (IRIS) toxicological assessment of the hazards of EtO, in which the agency significantly increased the projected risk of cancer due to inhalation of EtO.[12] In preparation for this proposed rule, EPA issued an advance notice of proposed rulemaking[13] and convened a SBREFA panel.[14]

Under section 112(f)(2) of the Clean Air Act, EPA is required to conduct a residual risk review after promulgation of the initial NESHAP. Under section 112(d)(6), EPA is required to conduct a review at least every 8 years, taking into account developments in practices, processes, and control technologies. "EPA notes that it completed a residual risk and technology review under CAA sections 112(f)(2) and 112(d)(6), respectively, for this source category in 2006 (71 FR 17712). While CAA section 112(f)(2) requires only a one-time risk review, which is to be conducted within eight years of the date the initial standards are promulgated, it does not limit

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[9] *Id.*

[10] *See* https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/sterilization-medical-devices (last accessed June 16, 2023).

[11] Food and Drug Administration Center for Devices and Radiological Health (FDA-CDRH) *Medical Device Benefits Statement*. (March 15, 2023), regulations.gov Document ID EPA-HQ-OPP-2013-0244-0049.

[12] *Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide* (December 2016), regulations.gov Document ID EPA-HQ-OAR-2019-0178-0477.

[13] 84 *Fed. Reg.* 67889 (Dec. 12, 2019).

[14] *See Small Business Advocacy Review Panel - Final Report* (April 2021), regulations.gov Document ID EPA-HQ-OAR-2019-0178-0422 [hereinafter "SBREFA panel report"].

the EPA's discretion or authority to conduct another risk review should the EPA consider that such review is warranted."[15]

For area sources[16] under section 112(d)(5), EPA has the discretion to set a standard based on generally available control technology (GACT). Although EPA is not required to conduct reviews under (d)(6) or (f)(2) for area sources, "EPA is now exercising its discretionary authority to conduct another CAA section 112(f)(2) analysis and to include in this analysis area sources of commercial sterilizers using EtO for which the EPA has promulgated, or is now proposing, GACT standards."[17]

In this proposal, EPA would require various measures to capture and control EtO emissions from sterilization chamber vent, aeration room vents, chamber exhaust vents, and room air. Most of this proposal's costs are due to the requirement for permanent total enclosure (PTE), which channels all air in the facility through an air emission control device (AECD). EPA also proposes requiring all commercial sterilizers using EtO to obtain Clean Air Act Title V permits and requiring compliance within 18 months of the final rule.

As part of the risk review process, EPA prepared a residual risk assessment.[18] EPA estimated that the total cancer incidence due to EtO emissions from all commercial sterilizers is currently approximately 1 excess case of cancer in the population every 1.2 years and that this rule would reduce that incidence to 1 excess case every 7 years.[19]

In support of the rulemaking, EPA prepared a Regulatory Impact Analysis[20] and Initial Regulatory Flexibility Analysis.[21] EPA estimates that for the 86 existing EtO sterilization facilities in the U.S and two new facilities expected soon, the direct cost of compliance would be $74 million per year annualized at a 7 percent discount rate. The following table shows these direct annualized compliance costs as a percentage of their annual revenue for the small businesses in the industry.

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[15] 88 *Fed. Reg.* at 22794.

[16] An area source emits or has the potential emit less than in the aggregate, 10 tons per year or more of any hazardous air pollutant or 25 tons per year or more of any combination of hazardous air pollutants. Clean Air Act sec. 112(a), 42 U.S.C. § 7412(a)

[17] 88 *Fed. Reg.* at 22794.

[18] *Residual Risk Assessment for the Commercial Sterilization Facilities Source Category in Support of the 2022 Risk and Technology Review Proposed Rule* (December 2022), regulations.gov Document ID EPA-HQ-OAR-2019-0178-0482.

[19] *Id.* at 7-8.

[20] *Regulatory Impact Analysis for the Proposed National Emission Standards for Hazardous Air Pollutants: Ethylene Oxide Commercial Sterilization and Fumigation Operations* (March 2023), regulations.gov Document ID EPA-HQ-OAR-2019-0189-0483 [hereinafter *RIA*].

[21] *Id.* § 5.2

| Annualized compliance cost as a percentage of annual revenue | Number of small businesses |
|---|---|
| Less than 3 percent | 8 |
| Between 3 percent and 10 percent | 2 |
| Between 10 percent and 20 percent | 4 |
| Between 20 percent and 50 percent | 4 |
| Above 50 percent | 2 |

Source: *Costing Workbook for Ethylene Oxide Emissions Standards for Sterilization Facilities Rule Proposal*, regulations.gov Document ID EPA-HQ-OAR-2019-0178-0472.
Note: Compliance costs annualized over 20 years at 7.75 percent.

According to EPA's calculations, no large business affected would have a cost as a proportion of annual revenue exceed one percent.

### D. The Proposed Registration Review Interim Decision

On the same day as EPA published the proposed amendments to the NESHAP, the agency also made available for comment a proposed Interim Registration Review Decision for the use of EtO as a sterilizer under the Federal Insecticide, Fungicide, and Rodenticide Act.[22] EPA conducts a review of registered pesticides on a regular basis to show that the pesticide will not have an unreasonable adverse effect on the environment when used in accordance with its label, which requires EPA to consider the costs and benefits of each pesticide.[23]

In this action, EPA proposes changes to the label that would require commercial sterilizers to take a significant number of actions to change their existing facilities and processes, including the following:

- Reduce the maximum concentration of EtO used in sterilization cycles.[24]
- Establish air pressure gradient so that air is always flowing from low-EtO concentration to high-concentration spaces.
- Install enclosed conveyors to automate movement of sterilized and aerated materials.
- Combine sterilization and aeration chambers.[25]

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[22] *Ethylene Oxide: Proposed Interim Registration Review Decision Case Number 2275* (March 2023), regulations.gov Document ID EPA-HQ-OPP-2013-0244-0045 [hereinafter *PID*].

[23] 'The term "unreasonable adverse effects on the environment" means (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide. . .. The Administrator shall consider the risks and benefits of public health pesticides separate from the risks and benefits of other pesticides. In weighing any regulatory action concerning a public health pesticide under this subchapter, the Administrator shall weigh any risks of the pesticide against the health risks such as the diseases transmitted by the vector to be controlled by the pesticide.' FIFRA, § 2(bb), 7 U.S.C. §136(bb).

[24] *PID* at 48.

[25] *Id.* at 56. EPA would exempt sterilization of pressure sensitive devices from the requirement that sterilization and aeration chambers be combined, but it is unclear whether sterilizers that maintain separate chambers for that purpose would be prohibited from sterilizing other products in the same cycle.

- Additional respirator requirements for anyone handling EtO or products sterilized with EtO.

EPA also proposes new engineering controls for healthcare facilities that use all-in-one EtO sterilization appliances, including separate containment areas for the appliance, negative air pressure to contain EtO, and exterior venting.

In general, EPA acknowledges broad categories of costs that these requirements will impose on commercial sterilizers, device manufacturers, healthcare facilities, and patients. For example, EPA explains:

> The Agency acknowledges that there would be impacts to commercial sterilization facilities from implementation of engineering controls. Through discussions with industry leaders, the Agency determined that some facility-level engineering control measures described in this section may already be common practice while others would impose significant costs to retrofit existing facilities to meet the new proposed engineering controls. The cost of retrofitting would include the costs of new equipment, installation, operation and maintenance, and the loss of revenue associated with any necessary downtime required for installation. EPA also acknowledges the corresponding potential impacts on the supply chain of sterilized medical devices related to the costs and potential downtime of sterilizing equipment.[26]

However, except for per-unit costs for respirators, EPA does not provide cost estimates in its proposal.

## II. Advocacy's Small Business Concerns

Advocacy is concerned that, together, these actions will put a significant number of small commercial sterilizers out of business and significantly harm small medical device manufacturers that rely on commercial sterilizers as part of their supply chain.

### A. EPA has underestimated the costs on small commercial sterilizers.

By EPA's estimates, a substantial number of small entities will be facing compliance costs that threaten their viability. Most small businesses would find it challenging to obtain financing for a capital investment that required installment payments making up a fifth or more of their projected revenue. It is hard to envision if they were able to obtain such financing it would be at such favorable terms as 7.75% over 20 years, especially since the investment would not increase productive output of the facility. It is highly likely given these figures that some small businesses will exit the market, even with the hypothetical ability to pass through the full costs of compliance on to medical device manufacturers and patients. However, EPA's analysis does not monetize significant categories of costs on sterilizers and excludes other costs. The scale of some of these costs could imply an even more drastic exit of small commercial sterilizers from the market.

[26] *Id.* at 58.

**1. The proposed compliance period is unreasonable for small businesses.**

In the SBREFA panel consultation, SERs said that they would likely need more than the maximum 3 years available under section 112 to comply with requirements to install new AECD. The panel recognized this concern and recommended that EPA highlight the availability of an additional year at the discretion of the permitting authority. Instead, EPA disregarded the concerns of the SERs.

As Advocacy has repeatedly noted to EPA, small businesses are frequently the lowest priority customer for specialized capital investments, such as AECDs, or engineering services, like those necessary to plan, design, and install PTE. An expedited compliance schedule will further disadvantage small businesses, requiring either significantly higher costs or ceasing of operations.

Further, the proposed compliance schedule makes compliance with the PID even more difficult. The PID would require significant changes to facilities and processes, including redesign of the sterilization and aeration chambers to be combined, enclosed conveyor systems, and a pressure gradient requirement that would need to be aligned with PTE. These changes could also require a subsequent amendment to the Title V permit. EPA needs to align the compliance periods of these two actions and provide the maximum time permitted to avoid adding unnecessary costs to these investments.

In the final rule, EPA should provide the full 3 years for compliance allowed by statute and as recommended by the SBREFA panel "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."[27]

**2. Title V permitting is a significant burden for small businesses.**

EPA proposes that all commercial sterilizers should be required to obtain Title V permits from their local permitting authority, usually their state government. These permits require businesses to prepare significant amounts of paperwork, negotiate compliance with the permitting authority, and subject their operations and permit application to public comment. EPA writes:

> The additional public participation and compliance benefits of additional informational, monitoring, reporting, certification, and enforcement requirements that exist in title V should be required for these sources. These additional requirements are important to ensure that these sources are maintaining compliance with the requirements of this rule. While there is additional burden associated with title V permitting on the affected facilities, this burden is not significant compared to the expected benefits to public health and compliance.[28]

EPA further continues in a footnote:

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[27] *SBREFA Panel Report* at 48.

[28] 88 *Fed. Reg.* at 22851.

> EPA believes that more involvement from local permitting authorities and the public will result in requirements that properly address the health needs and concerns of individual communities. A benefit in a title V permit is increased transparency and public participation, so that members of affected communities can know where sources are, what they are emitting, and the standards they are subject to, as well as having an opportunity to participate in the process. title V permits also generally include specific monitoring, recordkeeping, and reporting requirements that allow for greater transparency and assurance of sources' compliance with standards.[29]

These justifications are problematic when applied to the small commercial sterilizers.

First, EPA's burden estimate is based on economy-wide averages, which includes experienced practitioners working with local permitting authorities that have experience in their industries. Small businesses in this industry have no experience with Title V permitting, and their local permitting authorities are not necessarily well-versed in their operations. The first Title V permit, issued under significant time pressure, will be a painful learning experience.

Second, EPA ignores the significant cost of uncertainty that Title V permitting introduces to business planning. Rather than hiring an engineer to determine how their facility could meet the requirements set forth by EPA, a small business must engage in a process with multiple partners, develop supporting material that may or may not be sufficient in the eyes of a separate regulatory authority, and prepare a public relations strategy in anticipation of community opposition to the mere existence of their operations. This investment must be made without the certainty of an outcome that will allow continued operation.

Third, EPA's justification seems premised on an expectation of noncompliance. EPA has not alleged that small businesses in this industry have a history of noncompliance. Recent controversies around EtO facilities have centered around large facilities owned by large businesses. It is not clear how an additional bureaucratic step would create additional incentives for compliance or give state enforcement authorities resources and expertise they would not otherwise have to enforce this NESHAP.

Fourth, EPA already provides the transparency it cites as a justification. The public already has access to "where sources are, what they are emitting, and the standards they are subject to," via EPA website and regulations. EPA itself has been engaging in aggressive community outreach to advise the public of the hazards of EtO and directing public attention towards EtO facilities. The additional transparency the Title V permit process provides is minimal.

Finally, EPA's estimate of the burden ignores the factors upon which these justifications are premised: imposition of requirements that exceed the standards proposed in order to "properly address the health needs and concerns of individual communities." Given that EPA projects this rule (without considering the PID) will reduce the total population incidence of cancer to one

[29] *Id.,* fn. 67

case every 7 years, it is unclear what additional measures local permitting authorities, under public pressure, could or should demand moving forward, short of permanent closure of the facilities.

The requirement for Title V permits is particularly troubling giving the proposed expedited compliance timeline. EPA regulations requires air permitting authorities to take final action on a complete permit application within 18 months,[30] the same amount of time EPA would provide existing small businesses to come into compliance with the proposed rule. EPA appears to presume that small businesses are sufficiently familiar with the requirements of the Clean Air Act to have prepared a complete application, acceptable to the local permitting authority, for submission on the day the final rule is to be published, before the final rule and interim registration decision are known to the public. It is unclear that small businesses will have the confidence to plan, finance, and install equipment before the permitting authority has taken final action on the permit application and in the face of a requirement to engage communities that have been primed to oppose their continued operation.

Overall, EPA's requirement for a Title V permit for small commercial sterilizers imposes significant costs and uncertainty on their operations without a justification grounded in emissions reductions. EPA should not include this requirement for area sources in the final rule.

**3. EPA does not recognize the challenges of total enclosure for existing facilities.**

EPA estimates that PTE represents the largest portion of costs the NESHAP would impose on small commercial sterilizers. Nonetheless, small businesses are concerned that EPA does not recognize the difficulties of retrofitting their facilities to these requirements and were very concerned about it during the SBREFA panel.

EPA's cost estimation method presumes facilities do not require structural changes or relocation of equipment and are relatively compact. This is not always the case. For example, one small business stated that a long, narrow building is ill-suited to this kind of retrofit and that multiple independent systems could be necessary to ensure the proper airflow. One small business also said that the electricity requirements exceed the facility's current capacity and will require new permits and new power lines, which add to the capital costs.

The PID introduces another challenge since the requirement for a pressure gradient across the facility would need to be incorporated into the plan for the PTE and may limit options.

Again, the uncertainty small commercial sterilizers face is exacerbated by the expedited compliance timeline. If EPA finalizes a requirement for PTE, the rule should provide the maximum compliance period and highlight for state regulators their ability to grant an additional year.

[30] 40 C.F.R. § 70.7(a)(2)

**4. EPA includes almost no estimates for costs related to the PID.**

EPA proposes significant engineering and process changes for every commercial sterilizer, but only addresses the costs in a general qualitative manner. There are significant technical and economic barriers small commercial sterilizers would face in meeting these requirements. EPA has not estimated the costs of these significant requirements, so it is difficult to see how EPA has balanced its requirements against the significant costs and harm to the supply chain that this PID would impose.

These changes would impact every aspect of their businesses. EPA would require every sterilization cycle to be redesigned and revalidated. Small businesses rely on their expertise with their facilities and their equipment to design sterilization cycles that meets the needs of the medical device and the manufacturer. Experience with other similar medical devices shortens development and validation time. The mandate to reduce EtO concentrations alone would require development of new cycles, and the requirement to combine sterilization and aeration cycles would make development and validation more time consuming and expensive.

EPA would also require the installation of new equipment that isn't necessarily compatible with their existing facilities. One small business said that, while they could possibly meet the requirements of the NESHAP, a requirement to install an enclosed conveyor system would be tantamount to requiring the construction of an entirely new facility and would likely force closure of their existing facility.

For healthcare facilities, EPA has similarly proposed requirements for which it has no cost estimates. The requirements for physical separation of EtO appliances from "all other work areas" and negative air pressure has the potential to require significant costs and reworking of the physical plant. Depending on the facility, these requirements could be a *de facto* prohibition on these appliances.

EPA needs to better consider the costs that the PID would impose and whether the risk reduction of each individual measure, when taken in conjunction with other measures in the PID and in the NESHAP, justify the significant potential costs of compliance. In the absence of a better understanding of the impacts of these proposals, EPA should not finalize the proposed engineering controls.

**5. EPA does not consider the loss of capacity due to the NESHAP and PID.**

The impact on small businesses will be greater than EPA's analysis forecasts because the agency does not consider the lost revenue due to the loss in sterilization capacity. In the short term, facilities will need to shut down for weeks to months to install engineering controls. Businesses would also need to devote time in their sterilization and aeration chambers to re-validate existing sterilization cycles and develop new ones that would be compliant with the PID. For many firms, the requirement to combine sterilization and aeration chambers would require every cycle be developed anew and validated with the new configuration.

In the long term, sterilization capacity would be reduced because the PID would require a increase in the amount of time products must remain in chamber, both because the EtO

concentrations are lower and because aeration times would be extended. One small business said that if they are able to comply with the NESHAP and PID, their capacity would be reduced by no less than 20 percent due to changes in the sterilization cycle and up to 50 percent for some devices. Capacity of existing facilities could be further reduced if sterilizers are required to use the minimum concentration of EtO possible on a device-by-device basis, eliminating the ability to run cycles with a wide variety of devices with different sterilization needs.

EPA asserts that the market for sterilization is highly inelastic, since medical device manufacturers must have their services and there are few if any alternatives. This would imply that small businesses will be able to recoup compliance costs and loss of capacity by passing those costs through to their medical device manufacturers.[31] However, highly inelastic markets are rarely inelastic permanently, and medical device manufacturers will have options to lower their costs by seeking alternative suppliers, most likely overseas given the lack of spare domestic capacity.

Overall, the loss of sterilization capacity will have a significant impact on commercial sterilization and will lead to lower revenues.

**6. EPA does not consider the impact the PID would have the cost of compliance with the NESHAP.**

EPA has proposed two significant actions to affecting the same industrial processes. Although EPA discusses both actions and asserts that there is a divide between the risks each action seeks to address, the two proposals overlap in ways that make the requirements of both more costly.

For example, EPA proposes to establish GACT for sterilization chamber vent, aeration room vents, and chamber exhaust vent emissions from area sources based on the efficiency of EtO reduction using AECD. However, EPA sets these standards based on current practice in the industry. However, the industry currently uses average EtO concentrations in sterilization chambers significantly higher than what EPA expects would be required under the PID. Lower concentrations will make compliance with efficiency standards significantly more challenging, if not technically infeasible. This could lead to the perverse incentive for sterilization cycles to be always at the maximum EtO concentration allowed by the label rather than the minimum required for sterilization.

In setting these GACTs, EPA considers an alternative standard to require best management practice (BMP) based on industry accepted ISO standards. EPA rejects these alternatives in part because they do not require a particular level of emissions reduction and thus are not cost effective. EPA also does not want to use BMPs because it could allow commercial sterilizers to disable AECDs already installed. However, the PID also would require commercial sterilizers to follow these ISO standards in meeting the proposed limit on EtO concentrations. Instead of considering regulatory alternatives, EPA would impose both sets of requirements.

[31] *See RIA* at 5-22.

If EPA finalizes the PID restrictions on EtO concentrations in sterilization cycles, it should adopt BMPs that align with PID. EPA should only set AECD standards only after considering the impacts of reduced EtO concentrations in sterilization cycles.

### B. EPA has proposed actions for which the reduction in health risks do not justify the costs.

EPA's calculations of the cost effectiveness of its proposed GACT show extremely high costs per ton. EPA says that these cost effectiveness calculations demonstrate the general availability of the technology, but the agency explicitly references the hazard of EtO to explain why such a high cost per ton reduced is acceptable. Since the agency is using hazard to justify expensive investments, EPA should look to their risk assessment to better evaluate the actual effectiveness of these interventions on human health.

Looking at the NESHAP, EPA is proposing imposing annualized capital and operating costs of $74 million [32] to reduce EtO emissions from commercial sterilizers from 23 tons per year to 4 tons per year, or approximately $3.9 million per ton reduced. By itself, it is difficult to conceptualize what relation this figure has to the purposes of the Clean Air Act or to whether requiring such expenditures are reasonable given the hardship they would impose.

EPA has developed risk evaluations than can inform the discussion. For the $74 million per year, the agency projects that incidence of cancer will drop from 1 case of cancer every 1.2 years (or 0.9 cases per year) to 1 case of cancer every 7 years (or 0.1 cases per year). In other words, this rule imposes $92.5 million in costs to prevent one case of cancer. This amount would be unreasonable, and more so since this is the modeled incidence of cancer cases, not cancer fatalities.

As described above, Advocacy is concerned that even this figure understates the cost that these actions would impose on small commercial sterilizers, small medical device manufacturers, and their customers and patients.

### C. EPA glosses over the significant repercussions that these proposed actions would have for small businesses and the economy.

#### 1. The proposed actions would likely force many small commercial sterilizers out of business.

EPA forecasts that 6 of the 20 small commercial sterilizers will need to spend over 20 percent of their current annual revenue on compliance with the NESHAP, and an additional 4 would need to spend between 10 and 20 percent of their annual revenue. These figures do not account for the costs of compliance with the PID or whether the changes required by the NESHAP and PID are technically feasible for their existing facilities.

Small commercial sterilizers are seriously questioning whether they can continue operating under these proposals. They have concerns about their ability to comply with the PTE and

[32] *RIA* at 1-10. Annualized at 7% over 20 years.

conveyor requirements with their existing facilities. They are uncertain they can maintain the required AECD efficiencies at lower EtO concentrations. They are unsure they can obtain financing for such significant investments that do not increase (and in fact decrease) the productive capacity of their operations. They are also concerned that public sentiment makes getting a Title V permit a highly uncertain endeavor.

EPA has exacerbated this problem by providing only 18 months from the final rule to come into compliance with the NESHAP. Small businesses will need to make decisions about continued operation very rapidly to avoid wasting resources on equipment, expertise, and a Title V permit if compliance is technically or financially infeasible.

Given these factors, it is not unreasonable to believe that more than half of the small commercial sterilizers will exit the market if this proposal and the PID are finalized as proposed.

**2. The proposed actions will harm small medical device manufacturers.**

Small medical device manufacturers are likely to be adversely impacted by these two proposed actions. They will feel these impacts through increased costs of sterilization and the loss of domestic sterilization capacity. In its proposals, EPA discusses these issues briefly, but the impacts are not quantified and are likely significant.

As Advocacy has discussed in previous letters, small businesses are frequently at a disadvantage when procuring goods and services. In general, small businesses believe that they pay more per unit because they require fewer identical items in each order and orders are frequently specialized. This is no less true for medical device manufacturers, and any reduction in domestic sterilization capacity will put them at a disadvantage compared to large manufacturers will more options. They will be less able to absorb significant increases in the cost of sterilization services from their existing providers. These difficulties will be especially true if small commercial sterilizers leave the market, concentrating more market power with large businesses.

**3. The proposed actions will cause short-term and long-term disruptions in the medical device supply chain.**

The major problem for medical device manufacturers will be the loss of domestic sterilization capacity. In the sterilization industry, all available capacity operates 24/7. Without significant new investment, a 20% or more reduction in capacity combined with expected departures due to the regulation means that some devices cannot be sterilized domestically.

In the short term, a significant fraction of medical devices will not be available to the market because they cannot be sterilized at any cost. Some of these medical devices are likely important to the health of a patient in need. Medical device shortages are also more likely to affect disadvantaged or physically isolated communities, raising concerns about the distributional impact of these actions. While EPA does mention the possibility of disruptions, it does not appear that EPA has balanced the healthcare consequences of these shortages against the projected number of cancer cases avoided through these actions.

In the medium term, there may be some shifting of sterilization capacity to medical devices for which a higher price can be charged. This could lead to two possibilities. First, small businesses could have fewer options for sterilization services because they have smaller margins to absorb higher costs. Second, the most expensive, high margin medical devices get priority for sterilization service, reducing the availability of more common products, such as surgical kits and bandages.

Although the NESHAP, RIA, and PID mention the possibility that the medical device supply chain will be disrupted, EPA does not quantify or describe qualitatively the harms that this could have on the businesses themselves or the patients they serve. EPA similarly does not acknowledge the disproportionate impacts supply chain disruptions may have on disadvantaged or physically isolated communities. EPA does not appear to seriously consider these harms in its proposals.

In the long term, device manufacturers would need to drastically shift their operations to follow the available sterilization capacity. It is unlikely that these businesses would bring sterilization in-house, given the highly technical nature of sterilization, the regulatory requirements from FDA and EPA, and the efficiency gains from contract sterilization. It also appears, from consultation with small entities, that in the current environment there is little appetite for investment in additional domestic facilities using EtO. That means that domestic medical device manufacturers would be working more and more with foreign sterilization facilities and may shift their own production overseas to avoid the transportation costs and delay of crossing the border twice. These two EPA actions could undermine efforts to return medical device manufacturing to the United States.

## III. Conclusion

Advocacy is concerned that these actions would lead to a significant number of small entities leaving the market for commercial sterilization, harming small medical device manufacturers, and causing significant supply chain disruptions and harm to patients needing sterilized medical devices.

EPA has the discretion under the Clean Air Act to consider the costs and consequences of these actions, and EPA should reconsider these policies to reduce the impact on small entities and reduce the likelihood they will leave the market. As part of this reconsideration, EPA should:

- Give small commercial sterilizers the maximum amount of time the Clean Air Act allows to comply.
- Adopt the BMP alternatives as GACT for area sources.
- Allow small commercial sterilizers that are area sources to continue operating without Title V permits.
- Exclude the proposed engineering controls from the final Interim Decision.

If you have any questions or require additional information, please contact me or Assistant Chief Counsel Dave Rostker at (202) 205-6966 or by email at david.rostker@sba.gov.

Sincerely,

/s/

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

/s/

Dave Rostker
Assistant Chief Counsel
Office of Advocacy
U.S. Small Business Administration

Copy to: The Honorable Richard L. Revesz
Administrator, Office of Information and Regulatory Affairs
Office of Management and Budget