SMALL BUSINESS ENVIRONMENTAL ASSISTANCE PROGRAM
Serving Small Businesses and the Environment

National Steering Committee

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Comments on Pesticide Registration Review: Proposed Interim Decision and Draft Risk Assessment Addendum for Ethylene Oxide

Dear EPA:

The National Steering Committee (NSC) for the national network of state Small Business Ombudsman (SBO) and Small Business Environmental Assistance Programs (SBEAP) appreciates the opportunity to comment on the U.S. Environmental Protection Agency (EPA) Pesticide Registration Review: Proposed Interim Decision and Draft Risk Assessment Addendum for Ethylene Oxide (Docket ID: EPA-HQ-OPP-2013-0244-0044).

The NSC supports the increased focus on rules and regulations to protect the health and safety of communities near commercial ethylene oxide (EtO) sterilizers. However, the NSC would also like to caution EPA against a "one size fits all" approach in their regulations and requirements for EtO emissions. Some of the proposed monitoring and control methods would be prohibitively expensive to smaller businesses that would also be much smaller emitters of EtO. It is felt that it is not justifiable to require the same level of controls on a facility that emits 100 pounds per year as one that emits 1,000,000 pounds per year.

As such, the NSC recommends reinstatement of a subcategory of small use sterilizers with dramatically reduced requirements. We believe that use of 1,000 pounds or less would be an appropriate threshold that demarcates the smaller, single use, ampule and cartridge technologies that use a fraction of a pound per charge over the bulk cylinder technologies that can use far more. We believe EPA can establish a reasonable use threshold, either per annum or per batch, below which abatement is not required.

Please incorporate more and stronger flexibilities as recommended by the Small Business Advocacy Review (SBAR) Report. Small businesses incur far more financial burden from regulations such as this proposed rule due in large part to economies of scale. They struggle to compete due to these disparities. Due to their very low emissions and very high relative compliance costs, providing small firms with a subcategory will be more equitable and aid in bringing the cost-to-sales ratios more in line. As you note on page 22854 of the NESHAP proposal, "relative to revenues, large firms are much less affected by the proposed rule than small firms." This rule should incentivize efficiency through pollution prevention. Technologies such as flexible chambers can greatly reduce emissions by eliminating excess air. A concentration limit, however, could then have the unintended consequence of disfavoring this technology.

Ideally, this efficiency would be understood via an EtO usage relative to the surface area of the parts being treated, but we are unable to propose a simple, cost-effective manner for capturing this data given the variance in surface area from load to load. Due to their extremely limited EtO charging amounts, these sources should have a simple, easy and inexpensive method to demonstrate compliance. It is cost-prohibitive and unnecessary to require separation of office and sterilization area HVAC systems, modified storage space ventilation, physical separation of sterilization spaces, outdoor venting 25 feet away, negative pressure, supplied air or SCBA (especially when unloading already aerated batches) and continuous monitoring. Small businesses need the lowest-cost, most simplified standards, monitoring, recordkeeping, and reporting possible that also assures compliance.

There is also the concern that there may be a domino effect, or supply chain disruption, should the proposed rule lead to a significant number of small businesses being adversely affected in the commercial sterilization market and thus potentially harming those depending on required sterilization medical devices. It is encouraged that EPA consult with the FDA to understand the potential impact and include flexibilities that may be necessary to maintain adequate sterilization capacity while businesses are making upgrades to their control techniques.

We appreciate your consideration of our comments. If you have any questions or require additional information, please contact me at Donovan.Grimwood@tn.gov or 629.266.1862.

Sincerely,

Donovan Grimwood, Chair, National Steering Committee

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