ETHYLENE OXIDE TASK FORCE
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Via E-mail

Ms. Jessica Bailey
Chemical Review Manager
Reevaluation Branch
Antimicrobials Division (7510M)
Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20004

Re: Ethylene Oxide

Dear Jessica:

The Ethylene Oxide Task Force (EOTF) appreciates the opportunity to continue to work with the U.S. Environmental Protection Agency's (EPA) Office of Pesticide Programs (OPP) as the Interim Decision (ID) for ethylene oxide (EtO) is being developed. In response to our discussions, we would like to submit the following information for consideration in the ID requirements.

Background

In the Proposed Interim Decision, OPP originally proposed engineering controls as possible ways to reduce employee exposure. As previously discussed with OPP, these items come with significant risk of reduction of sterilization facility capacity, up to and including shutdown of facilities, and do not actually guarantee reduction of worker exposure.

- Facility modifications to allow for engineering controls, such as covered conveyors and other automation to reduce the potential for worker exposure, are not feasible for existing sites. Implementation of these requirements would cause the need to tear many facilities to the ground and rebuild them, which would significantly impact capacity and medical device supply.

- Other means to reduce potential worker exposure, such as mandating reduced sterilization cycle concentration, and other cycle or packaging modifications, would cause the need for very large amounts of sterilization cycle revalidation. This would severely and negatively affect sterilization

capacity and cause significant interruptions with sterilized medical device supply.

As outlined in the more recent discussions with OPP, focusing on a reduced 8-hour time-weighted average (TWA) would better help to address worker exposure concerns, particularly given the issues described above. EOTF/EOSA is committed to finding ways to achieve the lowest possible worker exposure while implementing the modifications for the National Emission Standards for Hazardous Air Pollutants (NESHAP) final rule requirements.

No commercial sterilization facility that we are aware of has demonstrated the ability to meet a 0.1 parts per million (ppm) 8-hour TWA worker exposure limit, and implementation of the NESHAP final rule requirements will have a significant impact on current ventilation designs, and potentially, indoor air EtO levels, thus making it significantly more difficult to meet a given worker exposure level with a prescribed timeline, for several reasons outlined below.

- The NESHAP's requirements for Permanent Total Enclosure (PTE) and very high destruction-removal efficiency (DRE) requirements on emissions control devices, including those handling fugitive emissions streams, will significantly limit the amount of ventilation airflow that sterilization facilities will be able to utilize to reduce employee exposure.

- The NESHAP's PTE requirements will make it difficult to meet the reduced worker exposure requirements. Currently, sterilization facilities have the ability to move large amounts of ventilation air to help reduce worker exposure. This ventilation air does not currently need to be routed through an emissions control device. This ability to move significant volumes of ventilation air (many thousands of cubic feet per minute (CFM)) is a critically important tool in facilities' toolboxes to reduce employee exposure. Achievement of any given worker exposure limit will become significantly more difficult going forward, based on implementation of the new sterilizer NESHAP requirements over the next two to three years.

- The NESHAP's very high DRE requirements will make it difficult to meet the reduced worker exposure requirements. All final DRE requirements, including the 98 percent for Group 1 and Group 2 fugitive emissions for the majority of the contract sterilizers, are higher than what were proposed in the draft rule. Meeting these very stringent DRE requirements makes it even more impossible to predict the timeline for meeting reduced worker exposure requirements.

Regarding the use of respiratory protection to meet a reduced 8-hour TWA requirement -- although this is a method that sterilization facilities have used, and will continue to use, to help reduce worker exposure -- the use of respiratory protection has its limitations. It is not feasible to require respiratory protection over extended periods of time (*e.g.*, high percentage of the time during a given work shift), due to health concerns, as well as employee retention concerns around extended use of respiratory protection.

In summary, EOTF and EOSA are highly committed to worker safety and reduction of worker exposure. We do not believe 0.1 ppm 8-hour TWA is possible in any known timeframe at this point. Requiring a 0.1 ppm value without knowing the pathway to achieve this, puts at serious risk the capacity of the sterilization industry and supply of sterilized medical devices. For these reasons, EOTF/EOSA's proposal is reduction of the current Occupational Safety and Health Administration's (OSHA) 1 ppm 8-hour Permissible Exposure Limit (PEL) requirement to 0.5 ppm TWA in five years, and then 0.25 ppm TWA in eight years.

Proposal

Our proposal includes the following actions to reduce EtO worker exposures, which are described in greater detail in following sections:

1. Collection and submission to EPA of OSHA-required worker exposure data:

    a. Submissions will be made annually by the registrant to EPA beginning June 30, 2025, (or six months after label changes are approved whichever comes later), and continue until June 30, 2033, (or eight years after first submittal).

    b. Submissions will include:

        i. Average (or Redacted Individual) worker exposure data for previous three calendar years by facility.

        ii. PTE installation status for Group 1 and Group 2 (*e.g.*, not required, started, optimizing, in effect (represents NESHAP effective date)).

    c. Data collection: label requirement for purchase of the product, that data must be collected and submitted by user to counsel for registrants, who would then submit to EPA.

i. Existing worker exposure data in accordance with OSHA requirements will be collected by user and provided to registrant beginning with 2022 data.

ii. Beginning one year following the approved label amendment, worker exposure data must be collected at least annually for workers exposed to 0.1 ppm 8-hour TWA action level proposed below and provided to registrant, and continue until June 30, 2033, (or eight years after first submittal). This is intended to include non-handlers from sterilization facilities (*e.g.*, office workers and warehouse workers).

iii. Worker exposure data collected for workers not subject to the OSHA requirements must follow approved exposure monitoring methods (*i.e.*, OSHA methods).

iv. This requirement ends on June 30, 2033, or eight years after the first submission.

d. Submissions will not include:

i. Medical surveillance information.

ii. Identifiable facility or employee information, but will be provided on a facility basis.

e. How do the data help inform moving to lower employee exposure levels? Collecting OSHA data from all users that sterilize medical products will allow an analysis that will address how quickly the industry is moving towards 0.1 ppm:

i. Collecting data for the time period prior to the implementation of the rule will allow establishment of a more accurate baseline of exposure at sterilization facilities, as these facilities embark on programs to control EtO exposures and comply with new regulations.

ii. Collecting data as NESHAP requirements are being implemented will allow conduct of annual trend analyses to assess progress on reducing exposures and meeting the goal of reducing exposures

below 0.1 ppm. The trend analysis will help to quantify the effects of specific, implemented control measures, which will in turn help to predict better the timeline for achieving the interim TWA targets of 0.5 ppm and 0.25 ppm, as well as 0.1 ppm or lower.

iii. Collecting these data will also allow quantification of required task-specific respirator use to reduce exposures, and annual assessments of the relationship between respirator use and badge exposure. It is expected badge data for employees not wearing respirators, and possibly those wearing respirators, will demonstrate a reduction in worker exposure over time. The annual analysis will show how much progress industry is making towards 0.1 ppm.

f. Information will be collected on a form that the registrants provide to purchasers of the registered EtO commercial sterilization products. Registrants will collect the forms, amalgamate the data, and submit a summary of the amalgamated data to EPA.

2. Phased-in reduction of EtO employee exposure 8-hour TWA:

a. Reduction of the current OSHA 1 ppm 8-hour Permissible Exposure Limit (PEL) requirement to 0.5 ppm TWA in five years, and then 0.25 ppm TWA in eight years.

b. The results of data collection efforts (described in No. 1) may allow for accelerated worker exposure reduction timelines and/or further TWA reductions (*e.g.*, reduction to 0.1 ppm).

c. In addition to the data collection submission, EOTF will make a separate submission addressing whether the data allows for accelerated worker exposure reduction timelines and/or further TWA reductions.

d. Within a month of submission, registrants would meet with EPA regarding this submission to discuss potential changes in timelines or levels based on the submissions. Registrants would also discuss at this meeting progress made on worker exposure best practices made within the last year.

e. This separate submission could potentially be made by June 30, 2025, and annually thereafter assuming amended label requirements for this purpose is approved in sufficient time for this deadline to be met.

f. EOTF would meet with EPA regarding this submission to discuss potential changes in timelines or levels within a month of the submission.

3. Label requirement for an Action Level TWA for EtO to 0.1 ppm (a reduction from the current OSHA 0.5 ppm level):

   a. Reduction would occur with a one-year implementation period from the approved label amendment implementing this requirement.

   b. Meeting or exceeding this action level will trigger the exact same requirements included in the current OSHA standard for EtO.

4. Label requirements for the requirement of an area monitoring system that measures EtO concentration levels in regulated areas:

   a. Required area monitoring system will measure multiple facility area locations in regulated areas within the facility.

   b. Required area monitoring system will measure one location at a time, cycling through each location.

   c. Required area monitoring system will have the ability read to a minimum concentration level of 0.1 ppm.

   d. Required area monitoring system will be required to be installed within a one-year implementation period from the approved label amendment implementing this requirement.

5. Label requirement for task-specific Personal Protection Equipment (PPE) requirements (previously submitted).

The EOTF believes that the outlined approach of the various actions included in this proposal will drive continued reduction of the employee exposure to EtO. These efforts should continue to drive the lowest possible exposure levels within EtO sterilization facilities.

We hope that this information is responsive to EPA's request. Should you have any questions or wish to meet with the EOTF to discuss further its plans, please contact Lisa Campbell at (202) 557-3802 or lcampbell@lawbc.com.

Sincerely,

Chris Klosen
Chair, Ethylene Oxide Task Force