STAPPA / ALAPCO

STATE AND TERRITORIAL
AIR POLLUTION PROGRAM
ADMINISTRATORS

ASSOCIATION OF
LOCAL AIR POLLUTION
CONTROL OFFICIALS

S. WILLIAM BECKER
EXECUTIVE DIRECTOR

December 8, 2005

Attention Docket ID No. OAR-2003-0197
Air and Radiation Docket and Information Center
U.S. Environmental Protection Agency
Mailcode: 6102T
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Dear Sir or Madam:

On behalf of the State and Territorial Air Pollution Program Administrators (STAPPA) and the Association of Local Air Pollution Control Officials (ALAPCO), thank you for this opportunity to comment on the Proposed Decision related to the Ethylene Oxide Emission Standards for Sterilization Facilities, which was published in the *Federal Register* on October 24, 2005 (70 *Federal Register* 61404).

Ethylene oxide (EtO) is a very toxic substance. It is a known human carcinogen, a powerful mutagen and a reproductive and developmental toxicant. As such, it is very important for the U.S. Environmental Protection Agency (EPA) to ensure that the Residual Risk assessment (under Section 112[f] of the Clean Air Act) for this source category is rigorous. Unfortunately, we do not believe that the risk assessment used in developing the proposal is adequate to make a determination that the current MACT for EtO Sterlizers is protective of public health with an adequate margin of safety. Our concerns with EPA's methodology are described below. The issues with the methodology that we have identified are especially important if EPA plans to use a similar process for making future Residual Risk determinations for other source categories.

Property-line Concentrations

In assessing the cancer risks related to the source category, EPA used long-term concentrations affecting the most highly-exposed census block for each facility. This analysis dilutes the effect of sources' emissions by estimating the impact at the centroid of the census block instead of at the property line. Census blocks can be large geographically, depending on the population density, so the maximum point of impact can be far from the centroid, including at or near the property line where people may live or work. Further, even if the area near the property line is not developed, over time homes and businesses could locate closer to the facility. While it is possible that population distribution is homogenous over a census block, this

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assumption is not necessarily accurate in considering the predicted impacts from a nearby point source. Accordingly, STAPPA and ALAPCO recommend that the impact from all of the sources in this category be recalculated based on concentrations at the property line and beyond and take into account the maximum exposed individual.

Actual Emissions

In evaluating Residual Risk, EPA considered only actual reported emissions instead of potential emissions. Since facility emissions could increase over time for a variety of reasons, and with them the associated impacts, EPA should have considered the risks based on potential emissions. We believe EPA's analysis, based on actual emissions, underestimates the Residual Risk from this or any source category using this methodology. Further, the major source hazardous air pollutant thresholds are based on maximum potential-to-emit, as opposed to actual emissions, and air agencies issue permits based on potential emissions. Limiting the scope of this risk evaluation to actual emissions would be inconsistent with the applicability section of Part 63 rules. We recommend that EPA conduct a new Residual Risk assessment using up-to-date data on potential emissions.

Updated Risk Estimates

EPA indicates in the proposal that the agency is developing a cancer unit risk estimate for ethylene oxide. The agency notes that it will reevaluate whether the risks are acceptable and whether an ample margin of safety has been achieved "[i]f the EPA value becomes available before the promulgation of the final rule." Since EPA is already in the process of updating this information, we believe the agency should plan to reevaluate the risks associated with this source category whenever the new cancer unit risk estimate is made final, regardless of whether or not the final rule has been published.

Acute Exposure

Potentially significant acute exposures are dismissed in this risk assessment because EPA has mistakenly used Acute Exposure Guideline Levels (AEGLs) to judge the significance of short-term exposures. STAPPA and ALAPCO do not endorse the use of AEGLs, Emergency Response Planning Guidelines (ERPGs) or Immediately Dangerous to Life or Health (IDLH) values to address acute exposures in the Residual Risk assessment. These limits were developed for accident release emergency planning and are not appropriate for assessing daily human exposure scenarios. In the December 2002 EPA document, "A Review of the Reference Dose and Reference Concentration Processes", EPA states that the primary purpose of the AEGL program is to develop guidelines for once-in-a-lifetime short-term exposures to airborne concentrations of acutely toxic chemicals. They are not meant to evaluate the acute impacts from routine emissions of ethylene oxide that occur over the life of a facility. The AEGL-2 and AEGL-3 values for ethylene oxide are calculated to be the concentration at which discomfort, irritation, and life threatening health effects may occur. Unlike the reference concentrations (RfCs) for chronic exposures, the AEGLs do not include *adequate* safety and uncertainty factors and cannot be relied upon to protect the public from the adverse effects of exposure to toxic air pollutants. The use of AEGLs in this assessment does not ensure that public health is adequately

protected from the acute impacts of ethylene oxide exposure. We recommend that EPA re-evaluate the acute effects of ethylene oxide at these facilities and utilize the new acute reference exposure value when it becomes available.

Approach for "Mixed" Emission Standards

For area sources with "mixed" emission standards (i.e., both MACT and GACT standards at the same facility), we disagree with EPA's approach of excluding those emission points subject to a GACT standard from the Residual Risk assessment. We do not think Congress envisioned this type of situation, and therefore do not think the language of the Clean Air Act provides any guidance on the intent of Congress in this manner. Lacking such guidance, and given that EPA has the discretion to promulgate Section 112(f) standards for any area source, EPA should use the most scientifically appropriate approach in considering Residual Risk standards for these sources, which would include considering all emission points, both GACT and MACT, in the risk assessment. People living around these facilities are exposed to ethylene oxide from both types of emission points, not just the MACT emission points. To ignore ethylene oxide emissions from the GACT emission points provides an erroneous assessment of the potential risks from this source category.

Controls on EtO Sterilizers

In the proposal, EPA indicates that the agency had considered increasing the emission reduction limit to 99.9 percent in the national emission standards but that “we do not have data to confirm that facilities are capable of achieving 99.9 percent on a continuous basis” (page 61409). We encourage EPA to review state data on this source category, including information from New York and New Jersey, indicating that such levels are achievable.

Thank you again for this opportunity to comment on this important proposal. Please do not hesitate to contact us for additional information.

Sincerely,

Robert H. Colby
Chair
STAPPA/ALAPCO Air Toxics Committee