Final Rule

FINAL AIR TOXICS RULE FOR

CONTROLLING ETHYLENE OXIDE EMISSIONS FROM

COMMERCIAL STERILIZATION AND FUMIGATION OPERATIONS

November 15, 1994

TODAY'S ACTION...

The Environmental Protection Agency (EPA) is issuing a final rule to reduce Ethylene Oxide (EO) emissions from commercial sterilization and fumigation operations such as medical equipment manufacturers. EO is one of the hazardous air pollutants (HAPs) or air toxics listed under the Clean Air Act Amendments of 1990.

EO is used as a sterilant for heat or moisture-sensitive materials or as a fumigant to control microorganisms or insects.

WHAT ARE THE HEALTH AND ENVIRONMENTAL BENEFITS?

The final rule will greatly reduce emissions of EO, a probable human carcinogen that causes adverse reproductive and developmental effects (eg. birth defects).

Annual reductions of EO will equal approximately 1,000 tons. The final rule will reduce current emissions by 94% from an estimated 114 sources nationwide.

WHY IS EPA REGULATING COMMERCIAL STERILIZATION AND FUMIGATION OPERATIONS?

Under the Clean Air Act Amendments of 1990, EPA is required to regulate emissions of 189 listed toxic air pollutants. On July 16, 1992, EPA published a list of source categories that emit one or more of these air toxics. For listed categories of "major" sources (those that emit 10 tons/year or more of a listed pollutant or 25 tons or more of a combination of pollutants), the Act requires EPA to develop standards that will require the application of maximum achievable control technology (MACT). "Area" sources are those that emit air toxics below the levels defined for major sources.

On July 16, 1992, EPA published a list of industry groups (known as "source categories") to be regulated, which included major and area sources of EO commercial sterilization and fumigation operations.

WHO MUST COMPLY WITH THE FINAL RULE?

Sources affected by the final rule include medical equipment suppliers, pharmaceuticals, other health related industries, spice manufacturers, large libraries, large museums and archives, and contract sterilizers.

Products that are sterilized with ethylene oxide include medical equipment, spices, cosmetics, and pharmaceuticals. Libraries, museums, and archives use ethylene oxide as a fumigant to control insects and microorganisms on fragile historical materials.

An estimated 114 EO commercial sterilization and fumigation operations will be affected by the sterilization chamber vent and chamber exhaust vent standards. Approximately 47 sterilization and fumigation operations will be affected by the aeration room and chamber exhaust vent standards.

WHAT DO THE FINAL STANDARDS REQUIRE?

Table 1. Standards for Ethylene Oxide Commercial Sterilizers/Fumigators

Existing and New Sources			
Source Size (EO use)	**Sterilization Chamber Vent**	**Aeration Room Vent**	**Chamber Exhaust Vent**
Less Than 1 ton	No controls; some recordkeeping requirements apply.		
1 ton - 10 tons	99% emission reduction	no control	no control (baseline emission cap)
Over 10 tons	99% emission reduction	99% emission reduction	99% emission reduction

Monitoring requirements

All owners or operators that use an air pollution control device to comply with the sterilization chamber vent standards must conduct an initial performance test to demonstrate compliance with the emission reduction standards and to establish values for site-specific operating parameters to be subsequently monitored to ensure continued compliance. In the case of facilities using an acid-water scrubber to control emissions, the ethylene glycol concentration will be monitored and compared to a maximum ethylene glycol concentration established during the performance test. In the case of facilities using catalytic oxidation, the temperature of the catalyst bed will be monitored and compared to a baseline oxidation temperature established during the performance test. Violation of either of these parameters is a violation of the standard.

All owners or operators subject to the chamber exhaust vent standards and the aeration room vent standards must monitor the EO emissions from the vent to the atmosphere to ensure continued compliance. Violation of the maximum EO concentration limits is a violation of the respective standard.

Reporting/Recordkeeping

The owner or operator of any EO commercial sterilization and fumigation operation subject to these standards will be required to fulfill the reporting requirements outlined in section 63.7 through section 63.10 of the proposed General Provisions air toxics rule, unless otherwise specified in the regulation.

The owner or operator of any EO commercial sterilization and fumigation operation will be required to report their annual EO usage as part of their initial notification report.

The owner or operator of any EO commercial sterilization and fumigation operation that violates the emissions standards will be required to provide quarterly reports of these violations.

Owners or operators will be required to maintain all records of compliance for 5 years.

HOW MUCH WILL THE FINAL RULE COST?

The annualized cost of the rule is projected to be less than $7.0 million.

FOR FURTHER INFORMATION

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