

## UPDATED INFORMATIVE DIGEST

### Amendments to the Airborne Toxic Control Measure for Emissions of Ethylene Oxide From Sterilizers and Aerators

**Sections Affected:** Title 17, California Code of Regulations, section 93108, Ethylene Oxide Airborne Toxic Control Measure for Non-Commercial and Small Commercial Facilities; section 93108.5, Ethylene Oxide Airborne Toxic Control Measure for Large Commercial Facilities; and, section 94143, Test Method 431, Determination of Ethylene Oxide Emissions from Stationary Sources.

#### Background

In 1990, the Air Resources Board (ARB/Board) adopted the existing Ethylene Oxide Airborne Toxic Control Measure (Ethylene Oxide ATCM). This regulation sets emissions limits for Ethylene Oxide (EtO) for all operators of EtO sterilizers or fumigators, including hospitals, commercial sterilizers, and commodities fumigators.

However, since the Ethylene Oxide ATCM has been in effect, several events prompted staff to consider amending it. First, the Ethylene Oxide ATCM includes a provision that alternative compliance testing methods or conditions may be used, but must be formally approved by the Executive Officer of the ARB. We found during the implementation of the Ethylene Oxide ATCM that certain alternatives to the testing requirements were commonly requested to simplify the testing and improve worker safety.

Second, devices identified during the development of the control measure as achieving the lowest possible emission levels (Best Available Control Technologies for toxics or T-BACT) were based on the destruction of the EtO using incineration, catalytic combustion, or acid scrubbing technologies. During the implementation of the Ethylene Oxide ATCM, a new technology--one which reclaims the EtO for re-use--began to be used to comply with the Ethylene Oxide ATCM. The reclamation systems are fundamentally different in their operation and emission characteristics than the destruction systems, therefore requiring different testing approaches and procedures.

Third, in December 1994, the United States Environmental Protection Agency (U.S. EPA) promulgated federal requirements for large commercial sterilizers. These requirements are contained in 40 CFR Part 63, Subpart O--Ethylene Oxide Emission Standards for Sterilization Facilities. The sources subject to the Ethylene Oxide ATCM have already achieved the emission reductions requirements for ethylene oxide facilities contained in 40 CFR Part 63, Subpart O--National Emission Standards for Hazardous Air Pollutants (Ethylene Oxide NESHAP). Rather than subject source owners and operators to two regulations, staff decided to include in the amended Ethylene Oxide ATCM the requirements of the Ethylene Oxide NESHAP, with the intent to submit the amended regulation to U.S. EPA for approval as the substitute for

the federal requirements.

Health and Safety Code sections 39658 and 39666 authorize the ARB to establish ATCMs for toxic air contaminants in accordance with specified criteria. Furthermore, ARB may impose monitoring requirements, establish procedures for permits, and take any other action that may be necessary to establish, implement, and enforce programs for the regulation of hazardous air pollutants listed as toxic air contaminants pursuant to subdivision (b) of section 39657. Regulations adopted for these purposes may be deemed to be equivalent to the NESHAP if they meet the requirements of section 112(l) of the federal Clean Air Act (42 U.S.C. Secs. 7412(l)) and the guidelines and regulations adopted by the U.S. EPA pursuant to those sections. In adopting such regulations, the ARB is required to ensure that the requirements of the federal act are met and use the definitions contained in section 112(a) of the federal Clean Air Act (42 U.S.C. Sec. 7412(a)). We worked closely with staff of the U. S. EPA to ensure that these criteria were met.

### **Description of the Regulatory Action**

The staff amended the Ethylene Oxide ATCM for ethylene oxide sterilizers and aerators to clarify and simplify the compliance and testing requirements, and to consolidate the State and federal requirements for these large commercial operations into a single regulation, while maintaining the same degree of public health protection as the existing Ethylene Oxide ATCM.

The amendments also streamline several of the compliance determination requirements of the Ethylene Oxide ATCM for non-commercial and small commercial facilities. These amendments do the following: allow calculation instead of measurement of EtO entering the control device; add an alternative combined sterilizer/aerator control efficiency requirement; substitute a liquid discharge EtO limit for the existing prohibition of discharge of sterilizer exhaust vacuum pump working fluid; and, modify the source testing method, ARB Method 431, to include a water test method and to clarify and improve the method.

The amendments separate the Ethylene Oxide ATCM into two parts, creating a new section (regulation) for large commercial sterilizers and aerators, and adding to that section performance test requirements, inspection and maintenance requirements, monitoring provisions, recordkeeping and reporting requirements, and requirements for requesting alternative provisions.

### **Replacing the Ethylene Oxide NESHAP with the Ethylene Oxide ATCM**

Two regulations currently affect ethylene oxide operations in California: the State Ethylene Oxide ATCM and the federal Ethylene Oxide NESHAP for sterilization facilities. The Ethylene Oxide NESHAP requires similar emissions control as the State's Ethylene Oxide ATCM but has less stringent control requirement for sterilizer emissions. Also, the Ethylene Oxide NESHAP emission standards only applies to large (facilities using 2,000 or more pounds of EtO annually)

commercial facilities. The State Ethylene Oxide ATCM applies to any facility using 25 or more pounds of ethylene oxide annually. The amended Ethylene Oxide ATCM incorporates the federal requirements in a format that is clearer and easier to understand than the Ethylene Oxide NESHAP.

The amended Ethylene Oxide ATCM will not automatically replace the Ethylene Oxide NESHAP. The federal Clean Air Act Amendments of 1990 added a new section 112(l) that provides a mechanism to allow states to substitute their own toxic rules or programs for the corresponding NESHAP. In a rulemaking set forth in 40 CFR part 63, subpart E, U.S. EPA promulgated guidance for seeking delegation of authority to implement a state program or regulation. The subpart E guidance requires states to seek approval from U.S. EPA and allows U.S. EPA 180 days to approve or disapprove the request. Once U.S. EPA approves the amended Ethylene Oxide ATCM as equivalent to the federal requirements, the Ethylene Oxide ATCM will replace the federal requirements.