

State of California
California Environmental Protection Agency
AIR RESOURCES BOARD

STAFF REPORT

INITIAL STATEMENT OF REASONS FOR THE
PROPOSED AMENDMENTS TO THE ETHYLENE OXIDE
AIRBORNE TOXIC CONTROL MEASURE FOR STERILIZERS AND AERATORS

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State of California
California Environmental Protection Agency
AIR RESOURCES BOARD

INITIAL STATEMENT OF REASONS
FOR PROPOSED RULEMAKING

Public Hearing to Consider
PROPOSED AMENDMENTS TO THE ETHYLENE OXIDE
AIRBORNE TOXIC CONTROL MEASURE FOR STERILIZERS AND AERATORS

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A. Introduction

In November 1987, the Air Resources Board (Board) identified ethylene oxide (EtO) as a toxic air contaminant. Ethylene oxide is used as a biocide to sterilize medical products and fumigate foodstuffs and other materials. Ethylene oxide has been classified as a probable human carcinogen by the California Department of Health Services (now the Office of Environmental Health Hazard Assessment), and by the International Agency for Research on Cancer. Inhalation of ethylene oxide may lead to an increased risk of contracting leukemia and stomach cancer. As part of the ethylene oxide identification regulation, the Board determined that ethylene oxide is a toxic air contaminant for which there is not sufficient evidence to identify a threshold exposure level. A threshold exposure level is that level below which no significant adverse carcinogenic health effects are anticipated to occur.

After ethylene oxide was identified as a toxic air contaminant, the ARB staff developed an Airborne Toxic Control Measure (ATCM) for EtO sterilizers and aerators. While developing the ATCM, the staff consulted with potentially affected facilities, the air pollution control districts and air quality management districts (districts), sterilizer and control equipment manufacturers, and other interested parties. The Board approved the staff proposal in May 1990, and it became effective as State law in May 1991. The districts adopted the ATCM or equivalent district rules, and facility operators took action to comply with the recordkeeping and emission control requirements of those rules.

In 1994, the United States Environmental Protection Agency (U.S. EPA) promulgated a National Emission Standards for Hazardous Air Pollutants for Ethylene Oxide Commercial Sterilization and Fumigation Operations (NESHAP). The NESHAP affects large commercial sterilizers, fumigators, and aerators throughout the United States. Six facilities in California (operated by five companies) are subject to the NESHAP. The emission control requirements of the NESHAP are less stringent than those of the ATCM, but the NESHAP contains more detailed and prescriptive monitoring, recordkeeping, and reporting requirements than the ATCM.

The ARB staff is proposing to amend the ATCM for four reasons. First, we are proposing to streamline the compliance testing requirements and source testing method; the principle change is the inclusion of an alternative to calculate rather than directly measure the EtO passing into the control device. Second, we are proposing to include limits for EtO in water to simplify the emission limit performance standards for certain types of control devices. Third, we are making other modifications to clarify or improve the effectiveness of the ATCM; for instance, we are proposing a change to the definition of "leak-free" to include EtO supply piping as well as exhaust vents. These modifications also include minor non-substantive changes to definitions. Fourth and last, we are proposing to simplify and incorporate into the ATCM the requirements of the NESHAP. This involves the restructuring of the ATCM into sections for non-commercial/small commercial facilities and large commercial facilities based on the amount of EtO used, and inclusion of additional monitoring, recordkeeping, and reporting requirements as needed to establish equivalency with the NESHAP. These changes will make it easier for the affected

facilities to comply with the requirements, while retaining the same degree of EtO emission reductions and resulting public health protection as the existing ATCM.

B. Background

1. What are ethylene oxide sterilizers and aerators?

An ethylene oxide sterilizer is a chamber in which EtO is used as a biocide to kill microorganisms or other organisms on materials, including medical products, foodstuffs, and other items. Following sterilization, a process called aeration is carried out, during which the EtO is removed from the treated materials until the EtO level in the materials is low enough that they are deemed safe to use. In most cases, aeration is done in the same chamber in which sterilization was done; in other cases, the materials are transferred to a separate device or space for aeration. The device or space in which materials previously sterilized with EtO are placed to allow the residual EtO to dissipate is called an aerator.

2. What are the potential health effects associated with ethylene oxide exposure?

Ethylene oxide has been classified as a probable human carcinogen by the International Agency for Research on Cancer (IARC) and the California Department of Health Services (DHS), now the Office of Environmental Health Hazard Assessment (OEHHA). Inhalation of EtO may lead to an increased risk of contracting leukemia and stomach cancer. DHS, the Scientific Review Panel, and the ARB determined that EtO has no identifiable threshold exposure level. A threshold exposure level is that level below which carcinogenic effects are not anticipated to occur.

3. Why are we proposing to changes some of the compliance testing requirements of the ATCM?

The ATCM includes specific requirements for compliance determination testing. For instance, the ATCM requires that the efficiency of the control device be measured while a typical load of material is being sterilized, and that the EtO be measured at the inlet and the outlet of the control device. The ATCM includes a provision that an alternative approach can be used, but it must be formally approved by the Executive Officer of the ARB. We found during the implementation of the ATCM that a particular alternative to the testing requirements was commonly requested to simplify the testing and improve worker safety. These changes allow testing of the control device with no load in the chamber, and they will allow the tester to calculate (rather than directly measure) the EtO at the inlet of the control device. By incorporating these changes into the ATCM and test method, we are eliminating the need for case-by-case approval of this alternative method.

We are proposing to include an alternative emission limit for combined sterilizer and aerator EtO control efficiency. The combined efficiency performance standard is equivalent to the existing separate standards. The separate standards will be retained for those instances where it is more appropriate to measure the control device efficiencies separately.

Based on our experience in reviewing the requests from the districts and facility operators to use alternative methods, we are also proposing to change the ATCM to authorize the districts to approve alternative methods for non-commercial facilities. This will streamline testing in those instances where it's necessary or advantageous to use an alternative compliance testing approach. The proposed change in the ATCM requires the districts to consult with ARB concerning the technical aspects of alternative methods.

4. Why are we proposing to include a limit for EtO in liquid discharges and add a test method for EtO in water to ARB Method 431?

We are proposing to add a limit on EtO in liquid discharged from sterilizers and aerators to simplify the compliance demonstration for a new type of technology.

When we developed the existing ATCM, we evaluated control methods available to reduce EtO emissions. Based on the demonstrated performance of control equipment, we defined the "lowest achievable emission rates" achievable through the application of the best available control technology (BACT), in consideration of risk and cost, as dictated by Health and Safety Code section 39666(b). The technologies identified as able to achieve BACT emission levels were based on the destruction of the EtO using incineration, catalytic combustion, or acid scrubbing. The emission limit performance standards in the ATCM were designed in consideration of the operation and performance of these control devices.

During the implementation of the ATCM, a new technology--one which reclaims the EtO for re-use--began to be used to comply with the ATCM. The reclamation systems are fundamentally different in their operation and emission characteristics than the destruction systems. We found that such systems typically recovered 50 percent to 90 percent of the EtO used. The remaining 10 to 50 percent was released to the environment through EtO-laden water discharge and ultimately was emitted to the atmosphere as the EtO disassociated from the water. The manufacturers of reclamation equipment developed modifications to their systems that could reduce the amount of EtO released in water. Reclamation systems at facilities were modified to meet the requirements of the ATCM by achieving emissions equal to the lowest achievable emission rate possible with BACT.

The emission limit performance standards in the ATCM were not designed to apply to these systems, so application of the ATCM directly was not possible. To ensure that public health was protected, the ARB staff worked with the reclamation system manufacturers, the facility operators, consultants, and the districts to evaluate these systems and develop permitting criteria guidance for use by the districts. The permitting criteria developed are equivalent to the BACT-based requirements of the ATCM. Reclamation systems are successfully operating in California in compliance with these criteria.

We are proposing to incorporate into the ATCM requirements to address the EtO discharged from reclamation systems. These proposed requirements are concentration limits for

EtO in water discharged from EtO control systems. The proposed limits are equivalent to the direct air emissions limits developed for destruction-based systems, and will clarify and simplify compliance demonstration for reclamation systems.

We are also proposing to modify test Method 431 to add a procedure to measure EtO in water to the method so that the requirements limiting discharge of EtO can be implemented and enforced.

5. Why are we proposing to incorporate the NESHAP requirements into the ATCM?

We are proposing to incorporate the NESHAP requirements (with some simplification) into the ATCM so that the operators of facilities that are subject to the NESHAP can comply with one regulation and one set of requirements.

The U.S. EPA promulgated a NESHAP for commercial sterilizers and fumigators on December 6, 1994. It affects commercial facilities using more than 2,000 pounds per year of EtO to sterilize medical products or fumigate foodstuffs or other materials. Commercial facilities include medical product manufacturers which sterilize material they produce, contract sterilizers which treat products manufactured by others, and spice fumigators. There are six facilities (operated by five companies) in California which are subject to the NESHAP.

Our intent in incorporating the NESHAP requirements into the ATCM is to reduce the regulatory burden to the facility operators and to the districts, who are the implementing agencies for the NESHAP. The proposed amendments to the ATCM for commercial facilities will add additional recordkeeping, reporting, and monitoring requirements to satisfy the NESHAP, but there will be no change in the ATCM's stringency or requirements for emission control for facilities in the state.

The proposed amendments include a change in the control requirement for the large commercial aeration-only category. This is for consistency with the NESHAP. There are no known facilities of this type operating in California.

6. What are the differences between the ATCM and the NESHAP?

The NESHAP differs from the ATCM in three aspects--applicability, control requirement stringency, and administrative requirements. The NESHAP applies to six facilities in California that use more than 2,000 pounds per year of ethylene oxide to sterilize medical products or supplies, or to fumigate spices and other foodstuffs. This is a small subset of the sources affected by the ATCM, which covers approximately 400 facilities including commercial facilities, hospitals, medical clinics, and some other operations (such as museums) that use EtO sterilizers. The NESHAP's emission control requirements are less stringent than the applicable requirements of the ATCM. The NESHAP contains more detailed and prescriptive monitoring, recordkeeping,

and reporting requirements than the ATCM. A summary comparison the ATCM and the NESHAP is included in Appendix B.

7. What is the status of the NESHAP?

The NESHAP was promulgated on December 6, 1994. The U.S. EPA delayed the NESHAP compliance date of December 6, 1997, to December 6, 1998. The U.S. EPA took this action because of concerns over the possible role of emission control equipment in fires and explosions at commercial facilities. Two commercial sterilizer facilities and one EtO packaging facility, all outside of California, were operating control equipment in advance of the NESHAP compliance date, and experienced fires and explosions. Although no formal findings are available on the incidents, the information available to us indicates that the fires or explosions were either triggered by causes other than the control equipment, or were caused by a combination of human error and inadequate safety design of the sterilizer and control equipment. One fire and explosion has occurred in California at a commercial sterilizer facility. We understand that this incident was due to human error and inadequate safety design of the sterilizer-control device system. That facility is operating under a variance while it modifies its equipment to prevent any recurrence.

8. Will the amended ATCM automatically replace the NESHAP?

No, the amended ATCM will not automatically replace the NESHAP. When the federal Clean Air Act was amended in 1990, a provision was included that allows states to receive delegation for their own toxic rules or programs as equivalent to the corresponding NESHAP. We must formally seek approval from the U. S. EPA for the amended ATCM to replace the NESHAP. We have worked closely with U.S. EPA staff in developing the proposed amendments to identify and address equivalency issues. We intend to submit an application to the U.S. EPA for equivalency of the ATCM if the Board approves the proposed amendments. If the U.S. EPA approves the amended ATCM as equivalent to the NESHAP, the ATCM would then replace the NESHAP.

9. How did the staff develop the amendments to the ATCM?

The ARB staff developed the proposed amendments to the ATCM through extensive consultation with facilities affected by the ATCM, the districts, the U.S. EPA, consultants, and manufacturers and vendors of sterilization and emissions control equipment. During the development of the proposed amendments, we mailed approximately 800 notices concerning the development of the proposed amendments to facility operators, held three public consultation meetings to discuss the proposal, conducted numerous telephone conferences and calls with affected parties, visited 30 facilities, conducted engineering evaluations of approximately 20 facilities, tested emissions from 10 facilities and evaluated test data and reports from approximately 20 additional facilities. The emission testing done by the ARB staff consisted of comprehensive measurement of EtO emissions and discharge from control systems. ARB staff

also worked with testing consultants and the Environmental Health Laboratory Branch of the Department of Toxics Substances Control to evaluate and develop the water testing method.

10. What is our recommendation?

We recommend that the Board approve the proposed amendments to the Ethylene Oxide ATCM for Sterilizers and Aerators to incorporate changes to streamline the compliance testing requirements and source testing method; to include limits for EtO in water to simplify the emission limit performance standards for certain types of control devices; to make other modifications to clarify or improve the effectiveness of the ATCM (for instance, a change to the definition of “leak-free” to include EtO supply piping as well as exhaust vents); to make minor non-substantive changes to definitions; and, to simplify and incorporate into the ATCM the requirements of the NESHAP. This involves the restructuring of the ATCM into two sections, one for non-commercial/small commercial facilities and a new one (as a new regulation, section 93108.5) for large commercial facilities (based on the amount of EtO used), and inclusion of additional monitoring, recordkeeping, and reporting requirements to the regulation for large commercial facilities as needed to establish equivalency with the NESHAP. These changes will make it easier for the affected facilities to comply with the requirements, while retaining the same degree of EtO emission reductions and resulting public health protection as the existing ATCM.

C. Rationale and Basis for Amendments to the ATCM

This section describes the rationale and basis for the proposed amendments. The discussion generally follows the order in which the modifications or additions appear in the proposed amended ATCM.

The ATCM was separated into two parts, one of which is a new regulation for large commercial facilities. Part 1 (section 93108) addresses standards and requirements for non-commercial sterilizers and aerators and commercial sterilizers and aerators using less than 2,000 pounds of EtO per consecutive 12 month period. Part 2 (section 93108.5) addresses commercial sterilizers and aerators using 2,000 or more pounds of EtO per consecutive 12-month period. The division between commercial facilities is based on EtO use in a consecutive a 12-month period, because this is the applicability criterion used in the NESHAP, and U.S. EPA staff required it for equivalency. The EtO use categories which dictate control requirements for the non-commercial and small commercial facilities continue to be based on EtO use per calendar year, as in the existing ATCM.

This change is proposed to make it easier to implement the ATCM. The commercial facilities using 2,000 pounds or more of EtO per continuous 12 month period are subject to the NESHAP-equivalent requirements, which comprise considerable additional monitoring, recordkeeping, and reporting requirements. Separating the elements of the regulation that pertain to large commercial facilities makes the ATCM more “user-friendly” to the majority of facilities which have to meet the simpler requirements. Separating the requirements for the two categories of facilities also will facilitate our application to the U.S. EPA for equivalency of the ATCM with the NESHAP and ensure that the requirements for the smaller facilities will not become federally enforceable.

1. Part 1 (a) Definitions

We are proposing to make the following changes to the definitions. Note that sections have been renumbered to reflect additions and deletions. The numbers shown below reflect the new section numbers; the old numbers are deleted.

- (a)(7) “Commercial sterilizer.” A definition for commercial sterilizer is added. This is necessary because of the proposed different requirements for commercial and non-commercial sterilize.
- (a)(9) “Date of Compliance.” This is proposed to be deleted because facilities in California are required to already be in compliance by the existing ATCM. Therefore, no future compliance dates are needed.
- (a)(12) “Facility.” This is modified to clarify that the term “parcel” means “parcel of land”.

- (a)(16) “Non-commercial sterilizer.” A definition of non-commercial sterilizer is added. This is necessary because the proposed ATCM requirements are different for large commercial and for small commercial and non-commercial sterilizers.
- (a)(19) “Sterilizer cycle.” This was modified to reflect the operation of reclamation systems, which use steam washes rather than air washes after the initial evacuation of EtO after the sterilization is complete.
- (a)(22) “Sterilizer exhaust vacuum pump.” This was clarified to use terms defined in the ATCM (“start of the sterilizer cycle,” sterilizer cycle being defined, to replace “introduction of ethylene oxide”).

2. Part 1 (b) Applicability

This section is changed to exclude commercial sterilizer and aerators using 2,000 pounds or more of EtO per consecutive 12-month period after December 6, 1996. Under the proposed amendments, such facilities will be subject to the requirements in Part 2, section 93108.5.

3. Part 1 (e) Requirements

The reference to the “applicable date” (for compliance) is deleted. See change to definition (a)(9), above.

- (e)(1) The requirement that there be no discharge of sterilizer exhaust vacuum pump working fluid to wastewater streams is deleted. It is no longer needed because of the proposed new requirement (e)(3), which is a limit on EtO in any liquid discharge associated with the sterilizer cycle. The limit on EtO in the liquid discharge is sufficiently low that no sterilizer exhaust vacuum pump working fluid can be discharged to wastewater. As a consequence, recirculating pumps will continue to be used.
- (e)(1) The requirement that the sterilizer and control equipment be leak-free is modified to include the EtO gas supply to the sterilizer. This is a potential source of EtO emissions which generally is kept leak-free for protection of worker health and safety. We became aware during implementation of the regulation that leaks in supply piping are more frequent than we expected. This requirement will encourage facility operators to keep supply piping leak-free, and will help protect air pollution inspectors from EtO exposure.
- (e)(3) New requirements limiting EtO in liquid discharges from the sterilizer cycle (30 ug/ml) and the aerator cycle (10 ug/ml) are added. These requirements will address the release of EtO from reclamation control systems. In normal operation, reclamation systems have no direct air emission of EtO, but do emit EtO via wastewater streams. Based on the operating characteristics and measured emissions/discharges of EtO from these systems, we have concluded that 30 micrograms per milliliter ($\mu\text{g/ml}$) of EtO in the sterilizer

discharge and 10 $\mu\text{g}/\text{ml}$ of EtO in the aerator discharge represent the lowest achievable emission rate, and are equivalent to the BACT emission limits set for destruction-based technologies. These limits will result in emissions equal to or less than those from a system meeting the existing percent efficiency standard. It will be simpler and less costly for operators of reclamation systems to demonstrate compliance with the concentration-based performance standards.

Table I

The “Date of Compliance” column is deleted. See rationale in definition (a)(9), above.

A new control efficiency is added for combined sterilizer and aerator emissions. We are proposing to add an alternative performance standard emission limit of 99.7 percent combined sterilizer and aerator control efficiency for the 600 to 5,000 pound per year control category. The proposed combined sterilizer and aerator control efficiency emission standard is derived from the mass-weighted average of the separate emission stream efficiency requirements. Its inclusion in the ATCM will provide flexibility in the compliance testing of catalytic oxidizer control systems in particular. The South Coast Air Quality Management District rule for sterilizers and aerators includes such an option.

4. Part 1 - (f) Compliance

The reference to the compliance date in column (d) of Table I is deleted. See rationale in definition (a)(9), above.

5. Part 1 - (g) Alternative Compliance Date

This section is deleted. It allowed, for a limited time which has already passed, operation of a facility at a less stringent level of control than had been determined to be technically feasible and cost-effective. It was intended to address the needs of a facility which was considering discontinuing EtO sterilizer operations. It is no longer needed, because the alternative compliance dates are already passed, and the underlying rationale and basis for the alternative compliance dates no longer exists.

6. Part 1 - (h) Source Testing

This section is modified to provide authority to the district to approve alternative source testing methods in consultation with the Executive Officer of the ARB. Previously the ATCM vested that authority in the Executive Officer of the ARB. During implementation of the regulation, we found that the districts and source testing consultants used good technical judgement in developing and proposing alternative source testing methods. We believe that allowing the district the authority to approve alternative source testing methods will streamline

source testing, and with it the compliance process, and that districts will act in good faith in consulting with the ARB to ensure that any alternative testing method is technically sound.

- (h)(1) The requirement that the test on a control device for a sterilizer exhaust stream shall be run with a typical load in the chamber is deleted. We found during implementation of the ATCM that an alternative approach which provided equivalent information could be used to test the performance of the control device. This change will allow source testing to be done more quickly and so at lower cost, because the entire multi-hour sterilizing cycle need not be run for the test. The requirement that all EtO emission point shall be sampled during the entire testing period is added. This requirement is added to address the operational and emission characteristics of reclamation technology-based control devices which were not in use in California at the time the ATCM was developed. These reclamation systems in normal operation have more than one point of release of EtO. The requirement is needed to ensure that EtO emissions and discharges are measured, to prevent excess emissions and consequent increase in risk of harm to public health.
- (h)(2) The requirement that the test on a control device for an aerator exhaust stream shall be run with a typical load in the chamber is deleted. The proposed amendments to ARB Method 431, the emissions testing method used to determine compliance with the ATCM, stipulate on page 6, "Option 2", that aeration tests shall be run with a load in the chamber. Consequently, this requirement is not necessary in the ATCM.

7. Part 2

The creation of a separate part, section 93108.5, for commercial sterilizers using 2,000 pounds or more of EtO per consecutive 12 month period after December 6, 1996, is added to satisfy the NESHAP requirements. The additional NESHAP requirements for monitoring, recordkeeping, and reporting do not provide any quantifiable emissions reductions benefits. We believe that the existing ATCM requirements and the district permitting systems, procedures, conditions, and enforcement mechanisms provide for sufficient monitoring, recordkeeping, and reporting to provide for effective implementation of the ATCM. However, based on negotiations with staff of the U.S. EPA, the additional requirements are necessary to gain equivalency of the ATCM with the NESHAP.

8. Part 2 - (a) Definitions

Several definitions are added to be consistent with the NESHAP. The additional definitions are: (1) "Administrator", (6) "baseline temperature," (7) "control system," (9) "commercial sterilizer," (10) "date of compliance," (17) "manifolding emissions," (18) "maximum ethylene glycol concentration," (19) "maximum liquor tank level," (20) "modification," (21) "oxidation temperature," and (22) "parametric monitoring." One term is modified to be consistent with the NESHAP definition; it is (5) "Back-draft valve/chamber exhaust vent."

9. Part 2 - (b) Applicability

The applicability is changed to include only commercial sterilizers and aerators using 2,000 pounds or more of ethylene oxide per 12 month consecutive period. This is the subset of facilities to which the NESHAP applies.

The applicability is made effective on the date that the NESHAP becomes effective. This is so that the NESHAP-driven requirements of the amended ATCM take effect coincident with the NESHAP. The existing requirements (as modified by the amendments) are to continue in effect until then. This ensures continued application of the ATCM requirements until the NESHAP becomes effective.

10. Part 2 - (c) Initial Notification

This is a new section which requires the facility operator to provide certain information on the operation of the sterilizer and aerator to the district and the U.S. EPA Administrator. This information (such as location and description of sterilizer, and usage of EtO) is required by the NESHAP.

11. Part 2 - (d) Requirements

(d)(1) This is a new section specific to large commercial sterilizers and aerators. It includes emission control performance standards equivalent to those in the existing ATCM, which are significantly more stringent in most cases than the NESHAP requirements. For instance, the existing ATCM and the proposed amended ATCM require 99.9 percent control of EtO emissions from sterilizers at any facility using more than 600 pounds of EtO per year. The NESHAP requires 99 percent control of EtO only at commercial facilities using 2,000 pounds of EtO per 12 months. The ATCM requires 95 percent control of aerator emissions by facilities using above 600 and less than 5,000 pounds of EtO per year, and 99 percent control of aerator emissions by facilities using 5,000 pounds or more of EtO per year. The NESHAP requires 99 percent control of aerator emissions only at facilities using more than 20,000 pounds of EtO per 12 months. The NESHAP does require 99 percent control of emissions at aeration-only facilities, whereas the existing ATCM requires 95 percent control. Although there are no known aeration-only facilities in the state, we are incorporating the 99 percent requirement for aeration-only facilities to be consistent with our commitment to achieve any public health benefit of the federal regulations.

(d)(3) This is a new section which requires facilities to obtain a Title V permit from the U.S. EPA Administrator. It is included here for consistency with the NESHAP.

12. Part 2 - (e) Compliance Procedures

This section is new and contains compliance testing notification, compliance testing, and reporting requirements as required by the NESHAP.

13. Part 2 - (f) Monitoring Requirements

This is a new section which prescribes monitoring requirements for control system parameters as required by the NESHAP. It references Appendix 1 “Requirements for Continuous Monitoring System,” which is the NESHAP requirement for the continuous monitoring systems.

14. Part 2 - (g) Recordkeeping

This new section requires that certain records be maintained by the facility operator, and includes provisions for waiver of the recordkeeping requirements. These requirements are required by the NESHAP.

15. Part 2 - (h) Reporting

This section is new and dictates that a facility operator report certain compliance information to the U.S. EPA Administrator semi-annually.

16. Part 2 - (i) Construction or Modification

This section is new and requires that written approval of the U.S. EPA Administrator be obtained before any person constructs or modifies a large source subject to the requirements. It also describes the information that must be provided in certain cases in seeking that approval.

17. Compliance Test Method

We are proposing changes to ARB Method 431 that affect the method used to determine the mass of EtO used to calculate the control efficiency. Second, we are also proposing to add a test method to determine the maximum EtO in water.

The addition of a method to calculate the mass of EtO going to the control device addresses safety concerns over sampling very high concentrations of EtO, and circumstances where it is not technically feasible to directly measure the EtO. This approach has been successfully used to demonstrate compliance with the ATCM, but case-by-case approval is currently required by the ATCM. Testing consultants, the districts, and ARB have amassed sufficient experience in implementing the ATCM to conclude that an inlet calculation approach is technically sound.

We are also adding a test method for determining EtO concentration in water so that a concentration-based standard can be used as an alternative for reclamation systems to a mass-balance, overall efficiency approach. The current test method does not include such a protocol because the existing ATCM does not include a limit for EtO in water. The control technologies deemed to be BACT at the time the ATCM was developed did not discharge EtO in water except as vacuum pump working fluid. The ATCM addresses that EtO discharge in water by prohibiting the discharge of vacuum pump working fluid. EtO in water discharged from the control equipment represents an indirect but potentially significant source of EtO emission to the atmosphere, because the EtO will disassociate from the water.

D. Impact of the Proposed Amended ATCM

1. Are the proposed amendments likely to result in any significant adverse environmental impacts?

Public Resources Code section 21159 of the California Environmental Quality Act (CEQA) requires the ARB to conduct an environmental analysis which includes, at a minimum, all of the following: (1) an analysis of the reasonably foreseeable environmental impacts of the methods of compliance, (2) an analysis of the reasonably foreseeable feasible mitigation methods, and (3) an analysis of the reasonably foreseeable alternative means of compliance with the regulations. Those analyses are summarized below.

- (1) There will be no reasonably foreseeable environmental impacts. The amended ATCM is designed to achieve the same emission reductions as the existing ATCM. Therefore, the proposed amendments will result in the same emissions as before. The principle difference will be greater flexibility in terms of compliance options and testing requirements for noncommercial facilities, and additional monitoring, recordkeeping and reporting requirements for commercial facilities.
- (2) There are no reasonably foreseeable mitigation measures, because the ARB's environmental analysis concludes that the amended ATCM will have no significant adverse impacts on the environment.
- (3) The amended ATCM will retain the same performance standard at the current ATCM. It will improve the effectiveness of the current ATCM by allowing greater flexibility during testing of both traditional and new technology. It will also incorporate the federal monitoring, recordkeeping and reporting requirements. Since the alternative to using the amended ATCM is to continue using the existing ATCM and to comply with the NESHAP, ARB staff expects that no significant adverse impacts will occur due to the "reasonably foreseeable alternative means of compliance."

2. Are the proposed amendments likely to result in any impacts on air quality?

The conclusion reached during the development of the existing Ethylene Oxide ATCM was that the ATCM would result in a significant improvement to air quality and the environment by reducing emissions of ethylene oxide. This reduction represents an overall 99 percent decrease in emissions from ethylene oxide sterilizers and aerators prior to the implementation of the ATCM. Because the proposed amendments will not result in any change in EtO emissions relative to the existing ATCM, there are no expected air quality impacts.

3. Are the proposed amendments likely to result in any significant impacts on water quality and landfills?

Impacts on water quality were analyzed during the development of the existing ATCM. The Board agreed that no significant environmental impact would occur on water quality. Because the proposed amendments embody equivalent emission standards, these same conclusions hold true for the amended ATCM. There are no foreseeable impacts on landfills from these proposed amendments.

4. Are the proposed amendments likely to result in an adverse economic and cost impacts on California businesses, including small businesses?

No. Businesses which uses ethylene oxide are subject to the requirements of the current ATCM. In addition, six commercial facilities must also comply with NESHAP which requires additional monitoring, recordkeeping and reporting compared to the existing ATCM. Incorporating the clarified and simplified NESHAP requirements will reduce the impact of the federal requirements on California businesses.

5. Are the proposed amendments likely to result in any adverse impact on interstate business competitiveness?

The amended ATCM will have no adverse impact on interstate business competitiveness. The amendments to the ATCM simplify and provide additional flexibility to the existing requirements, and incorporate the NESHAP requirements for commercial facilities into the ATCM. Out-of-state commercial facilities will now be subject to similar requirements due to the NESHAP.

6. Are the proposed amendments likely to result in any adverse impact on employment?

The amended ATCM will have no adverse impact on employment. Some additional effort will be in the monitoring, recordkeeping, and reporting aspects of compliance with the amended ATCM for commercial facilities. Whether the amendments are adopted or not, the same facilities remain subject to the NESHAP and must comply with the monitoring, recordkeeping, and reporting requirements. For non-commercial facilities, the amendments provide flexibility in compliance demonstration and are expected to either have no effect or to reduce the cost of compliance with the ATCM.

7. Are the proposed amendments likely to result in any adverse impact on business creation, elimination, and expansion?

The amended ATCM will have no adverse impact on business creation, elimination, and expansion. Very small additional effort arising from the proposed amendments are attributable to

changes in the monitoring, recordkeeping, and reporting provisions. These requirements must be met under the NESHAP whether or not the amendments to the ATCM are adopted.

The amended ATCM will make it easier, and to a degree less costly, for facilities with reclamation-based control technology to demonstrate compliance. For large commercial facilities affected by the NESHAP-driven changes, the control equipment is the same is currently in place. Therefore, business creation, elimination, and expansion are not expected to be adversely impacted.

E. Alternatives

Staff considered the following alternatives to the proposed amendments. None were found to be as effective as the recommended amendments in providing enhanced flexibility and streamlining compliance for the facility operators, and protecting public health.

1. No change to current ATCM

If the ATCM is not amended to incorporate the combined sterilizer/aerator control efficiency performance standard, the ethylene oxide discharge limits, and the test method changes, compliance with the ATCM will be more costly than necessary because of the more complex testing necessary to demonstrate compliance, and the required case-by-case approval for alternative test procedures.

If there is no change to the ATCM, there would be two significant opportunities forgone to streamline requirements for the facilities, and simplify and provide flexibility to facilities now in compliance with the ATCM.

If the ATCM is not amended to incorporate the NESHAP requirements, the NESHAP would be enforced directly on affected facilities. Because we have simplified some of the NESHAP requirements, this approach would cause an additional recordkeeping and reporting burden on the six facilities subjected to the NESHAP as well as an additional administrative burden on any district in which a commercial facility is located.

2. Incorporate changes to the ATCM for non-commercial and small commercial facilities, and delete ATCM requirements applicable to the NESHAP-subject facilities

This alternative would result in the direct application of the NESHAP to large commercial facilities. It would result in more complex requirements for the NESHAP-subject facilities than under the proposed amendments. We have simplified and clarified the NESHAP requirements that we propose to include in the ATCM, and believe that the revision of the ATCM to include the simplified NESHAP requirements represents a reduced regulatory burden on facility operators.

3. Incorporate changes to the ATCM for non-commercial and small commercial facilities, and incorporate the NESHAP verbatim in the ATCM

This would provide for a greater convenience to facility operators than alternative 2, in that the requirements could be found in a single document. However, the simplification and clarification of the NESHAP requirements achieved in the amended ATCM will (if adopted) reduce the regulatory burden on facilities, and so represent the preferred alternative.

F. Plain Language Summary of the Proposed Amendments

We are proposing to change the State regulation for ethylene oxide sterilizers and aerators. The proposed changes do not affect the emission limits in the regulation. The proposed changes will make it simpler for facility operators to show that they meet the emission limits of the regulation. The proposed changes involve four areas. These areas are discussed below.

1) We are proposing to separate the requirements for non-commercial and small commercial facilities from the requirements for large commercial facilities. Commercial facilities are manufacturers of products or equipment that sterilize what they make, or are facilities whose main business it is to sterilize products or equipment. A large commercial facility is one that uses 2,000 pounds or more of ethylene oxide in a 12 month period.

We propose to add additional requirements for large commercial facilities. These requirements are for monitoring operation of the control equipment, keeping records, and reporting information to the government. We propose to include these requirements to our regulation because the U.S. EPA has enacted a federal regulation that requires these things to be done. A few facilities in California will have to comply with the federal regulation. It will be simpler for these facilities to have to meet only one regulation.

2) We are proposing to change some of the compliance testing requirements for non-commercial and small commercial facilities. These changes--like being able to calculate instead of measure the ethylene oxide coming out of the sterilizer chamber--are intended to make it easier to test emissions. We are also proposing to make other changes that clarify and improve the effectiveness of the regulation.

3) We are proposing to add an optional emission limit. This is a combined sterilizer and aerator limit. It is equivalent to the separate limits, but will make it easier for some facilities operators to show that their meeting the requirements.

4) We are eliminating the prohibition on discharge of wastewater from the sterilizer exhaust vacuum pump (that contains ethylene oxide), and substituting a limit for ethylene oxide in liquid discharge. This means that a discharge of liquid is O.K. if the ethylene oxide is removed from it to meet the discharge limit.

APPENDIX A

PROPOSED REGULATION ORDER ETHYLENE OXIDE AIRBORNE TOXIC CONTROL MEASURE FOR STERILIZERS AND AERATORS

APPENDIX B

SUMMARY COMPARISON OF THE EXISTING ATCM, NESHAP, AND PROPOSED AMENDED ATCM

APPENDIX B

**Summary Comparison of the Existing ATCM,
NESHAP, and Proposed Amended ATCM**

Section	Existing ATCM	Federal NESHAP	Proposed Amended ATCM	
			Part 1 (Small Commercial and Non-Commercial)	Part 2 (Large Commercial)
Applicability	Facility using less than 25 pounds EtO annually--reporting required. Facility using 25 pounds or more of EtO annually--emission standards and other requirements apply also.	Commercial facilities using more than 2,000 pounds per 12 consecutive months--emission standards and other requirements apply.	Facility using less than 25 pounds EtO annually--reporting required. Non-commercial facilities using 25 pounds or more EtO annually and commercial facilities using 25 or more annually but less than 2,000 pounds per 12 consecutive months--emission standards and other requirements apply also.	Commercial facilities using 2,000 pounds or more EtO per 12 consecutive months--emission standards and other requirements apply.
Emissions Standards	<p>Sterilizer emissions</p> <p>99% control for any facility using more than 25 but less than 600 pounds EtO annually.</p> <p>99.9% control for any facility using 600 pounds or more EtO annually.</p>	<p>Sterilizer emissions</p> <p>No control for facilities using less than 2,000 pounds of EtO per 12 consecutive months.</p> <p>99% control for commercial facilities using 2,000 pounds or more EtO per 12 consecutive months.</p>	<p>Sterilizer emissions</p> <p>99% control for non-commercial and commercial facilities using more than 25 but less than 600 pounds EtO annually.</p> <p>99.9% control for non-commercial and commercial facilities using 600 pounds or more EtO annually.</p>	<p>Sterilizer emissions</p> <p>99.9% control for commercial facilities using 2,000 pounds or more but less than 5,000 pounds EtO per 12 consecutive months.</p> <p>99.9% control for commercial facilities using 5,000 pounds or more EtO per 12 consecutive months.</p>

APPENDIX B

**Summary Comparison of the Existing ATCM,
NESHAP, and Proposed Amended ATCM**

Section	Existing ATCM	Federal NESHAP	Proposed Amended ATCM	
			Part 1 (Small Commercial and Non-Commercial)	Part 2 (Large Commercial)
Emissions Standards (continued)	<p>Aerator emissions</p> <p>95% control for any facility using more than 600 but less than 5,000 pounds EtO annually.</p> <p>99% control for facilities using 5,000 pounds or more EtO annually.</p> <p>95% control of Aeration - only facilities using 600 pounds or more EtO annually.</p>	<p>Aerator emissions</p> <p>No control for facilities using less than 20,000 pounds of EtO per 12 consecutive months.</p> <p>1 ppm maximum outlet concentration or 99% control for facilities using 20,000 pounds or more of EtO per 12 consecutive months.</p> <p>No control for aeration-only facilities using less than 20,000 pounds of EtO per 12 consecutive months.</p> <p>99% control for aeration-only facilities using more than 20,000 pounds of EtO per 12 consecutive months.</p>	<p>Aerator emissions</p> <p>95% control for non-commercial facilities using 600 or more but less than 5,000 pounds EtO annually.</p> <p>99% control for non-commercial facilities using 5,000 or more pounds of EtO annually.</p> <p>95% control for commercial facilities using 600 or more pounds EtO annually.</p> <p>95% control for non-commercial and commercial aeration-only facilities.</p>	<p>Aerator emissions</p> <p>95% control for commercial facilities using 2,000 pounds or more but less than 5,000 pounds EtO per 12 consecutive months.</p> <p>1 ppm maximum outlet concentration or 99% control for commercial facilities using 5,000 pounds or more of EtO per 12 consecutive months.</p> <p>95% control for aeration only facility using 2,000 pounds or more EtO but less than 20,000 pounds of EtO per 12 consecutive months.</p> <p>99% control for aeration only facilities using 20,000 pounds or more EtO per 12 consecutive months.</p>
Monitoring	Facilities subject to emission standards must maintain leak-free system.	Facilities using more than 2,000 pounds EtO per 12 consecutive months must monitor key operating parameters of control equipment, such as temperature, liquid levels, etc.	Facilities subject to emission standards must maintain leak-free system.	Facilities using more than 2,000 pounds EtO per 12 consecutive months must monitor key operating parameters of control equipment, such as temperature, liquid levels, etc.
Recordkeeping	All facilities must maintain record of EtO use.	Facilities using more than 2,000 pounds of EtO per 12 consecutive months must maintain records of EtO use, breakdown data, continuous monitoring performance report, and compliance data for five years.	All facilities maintain record of EtO use.	Facilities using more than 2,000 pounds EtO per 12 consecutive months must maintain records of EtO use, breakdown data, continuous monitoring performance data, and compliance data for five years.

APPENDIX B

**Summary Comparison of the Existing ATCM,
NESHAP, and Proposed Amended ATCM**

Section	Existing ATCM	Federal NESHAP	Proposed Amended ATCM	
			Part 1 (Small Commercial and Non-Commercial)	Part 2 (Large Commercial)
Reporting	All facilities must report annual EtO use.	Facilities using more than 2,000 pounds of EtO per 12 consecutive months must submit semi-annual compliance report, annual report of EtO use, and monitoring and breakdown data.	All facilities must report annual EtO use.	Facilities using more than 2,000 pounds EtO per 12 consecutive months must submit semi-annual compliance report, annual report of EtO use, and monitoring and breakdown data.
Testing	ARB Method 431	U. S. EPA Test Methods in 40 CFR part 60 appendix A	ARB Method 431 equivalent to U.S. EPA Method. In addition, added to ARB Method 431 a test procedure to quantify concentration of EtO in water. Added procedure for calculating mass of EtO to the control device.	ARB Method 431 equivalent to U.S. EPA Method. In addition, added to ARB Method 431 a test procedure to quantify concentration of EtO in water. Added procedure for calculating mass of EtO to the control device.

APPENDIX C

PROPOSED TEST METHOD 431, DETERMINATION OF ETHYLENE OXIDE EMISSIONS FROM STATIONARY SOURCES