

State of California
AIR RESOURCES BOARD

Notice of Public Availability of Modified Text

**PUBLIC HEARING TO CONSIDER THE ADOPTION OF AN ETHYLENE OXIDE
AIRBORNE TOXIC CONTROL MEASURE FOR STERILIZERS AND AERATORS**

Public Hearing Date: May 21, 1998
Public Availability Date: June 11, 1998
Deadline for Public Comment: June 26, 1998

At a public hearing held on May 21, 1998, the Air Resources Board (the "Board") approved the adoption of sections 93108, 93108.5, and 94143, Title 17, California Code of Regulations ("CCR"). Section 93108 is an Airborne Toxic Control Measure for Non-Commercial Sterilizers and Aerators and Commercial Sterilizers and Aerators Using Less Than 2,000 Pounds of Ethylene Oxide Per 12 Consecutive Months. Section 93108.5 is an Airborne Toxic Control Measure for Commercial Sterilizers and Aerators Using 2,000 Pounds or more of Ethylene Oxide Per 12 Consecutive Months. Section 94143 is the ARB Test Method 431, Determination of Ethylene Oxide Emissions From Stationary Sources. The regulatory action is described in detail in the Staff Report, released in April 1998.

At the hearing, the Board approved the adoption of sections 93108, 93108.5, and 94143, Title 17, CCR, with modifications to the originally proposed regulatory language as follows: Staff proposed to make one major change and several non-substantive changes to the text of the regulation. Enclosed is a copy of Board Resolution 98-20 approving the above described regulatory action. Attachment B to the resolution shows the approved modifications, with additions to the originally proposed text denoted by double underline and deletions by *italic strikeout*.

In accordance with section 11346.8 of the Government Code, the Board directed the Executive Officer to adopt the control measure as new section 93108, 93108.5, and 94143, Title 17, Subchapter 7.5, Airborne Toxic Control Measure, California Code of Regulations, as approved after making the modified regulatory language available to the public for comment for a period of at least 15 days. The modified regulatory language will be denoted by double underline and the deletion by *italic strikeout*. The Executive Officer shall consider such written comments as may be submitted during this period, shall make such modifications as may be appropriate in light of the comments received, and shall present the regulation to the Board for further consideration if he determines that this is warranted.

Written comments must be submitted to the Clerk of the Board, Air Resources Board,
P. O. Box 2815, Sacramento, California 95812, no later than June 26, 1998 for consideration by

the Executive Officer prior to final action. Only comments relating to the modification described in this notice will be considered by the Executive Officer.

Enclosures

Enclosure 1

Final Resolution for the Amended Sterilizer ATCM

State of California
AIR RESOURCES BOARD

Resolution 98-20

May 21, 1998

Agenda Item No.: 98-5-2

WHEREAS, sections 39600 and 39601 of the Health and Safety Code authorize the Air Resources Board (the "Board") to adopt standards, rules and regulations and to do such acts as may be necessary for the proper execution of the powers and duties granted to and imposed upon the Board by law;

WHEREAS, sections 39658 and 39666 of the Health and Safety Code authorize the Board to establish airborne toxic control measures (ATCM) for toxic air contaminants in accordance with specified criteria;

WHEREAS, on May 10, 1990, the Board approved section 93108 of Title 17, California Code of Regulations, Ethylene Oxide Airborne Toxic Control Measure for Sterilizers and Aerators (Sterilizer ATCM), to reduce emissions of ethylene oxide, a probable human carcinogen, from sterilizers and aerators;

WHEREAS, on December 6, 1994, the United States Environmental Protection Agency (U.S. EPA) promulgated the National Emission Standards for Ethylene Oxide Commercial Sterilization and Fumigation Operations (Sterilizer NESHAP) (40 Code of Federal Regulations Part 63, subpart O), a regulation that is similar to the existing Sterilizer ATCM;

WHEREAS, the federal Clean Air Act provides a mechanism to allow states to substitute their own equivalent rules or programs for the corresponding federal requirements (section 112(l));

WHEREAS, section 39659 of the Health and Safety Code provides that the Board may adopt regulations which: 1) 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 which have been listed as toxic air contaminants pursuant to subdivision (b) of section 39657, and 2) meet the requirements of subsection (l) of section 112 of the federal Clean Air Act (42 U.S.C. Secs. 7412(l)) and the guidelines and regulations promulgated by the U.S. EPA pursuant to those sections; and in adopting such regulations, the Board is required to the extent necessary to ensure that the requirements of the federal Clean Air Act are met, to use the definitions contained in subsection (a) of section 112 of the federal Clean Air Act (42 U.S.C. Sec. 7412(a));

WHEREAS, the purpose of the proposed amendments is to integrate California's requirements for ethylene oxide sterilizers and aerators with the federal requirements for large commercial facilities such that the Sterilizer ATCM will be approved by the U.S. EPA and so substitute for the Sterilizer NESHAP, and to clarify and simplify the Sterilizer ATCM requirements for small commercial and non-commercial facilities;

WHEREAS, the staff has worked closely with the districts, affected sources, and U.S. EPA to develop an amended Sterilizer ATCM that will satisfy both the existing State requirements and the federal requirements;

WHEREAS, the proposed amended Sterilizer ATCM was developed through discussions of draft versions that were made available to the public for review and comment at public meetings on November 19 and 21, 1996, and February 24, 1998;

WHEREAS, in accordance with Health and Safety Code section 39665(c), the staff report and proposed amendments to the Sterilizer ATCM were made available for public review and comment 45 days prior to the public hearing to consider the proposed amendments;

WHEREAS, as a result of further analysis and comments received during the public comment period, the staff has proposed several changes to the draft regulations initially made available for public comment;

WHEREAS, the Board has considered the impact of the proposed amendments on the economy of the State;

WHEREAS, the California Environmental Quality Act and Board regulations require that no project which may have significant adverse environmental impacts be adopted as originally proposed if feasible alternatives or mitigation measures are available to reduce or eliminate such impacts;

WHEREAS, a public hearing and other administrative proceedings have been held in accordance with the provisions of Chapter 3.5 (commencing with section 11340), Part 1, Division 3, Title 2 of the Government Code;

WHEREAS, based on the information presented by the staff and the written and oral comments received prior to and at the hearing, the Board finds that:

1. The amendments are proposed to integrate the State and federal requirements for large commercial ethylene oxide sterilizers and aerators, and to clarify and simplify the Sterilizer ATCM requirements for small commercial and non-commercial facilities.

2. The amendments to the Sterilizer ATCM: add a new section 93108.5 to separate the Sterilizer ATCM into two parts, one for non-commercial and small commercial facilities, and the other for large commercial facilities subject to the Sterilizer NESHAP which includes the essential requirements of the Sterilizer NESHAP; incorporate changes to the compliance testing method, ARB Method 431 (Title 17 California Code of Regulations, section 94143), to streamline compliance testing requirements; add alternative control requirements to provide compliance flexibility; and, include other modifications to clarify and improve the effectiveness of the Sterilizer ATCM.
3. The emissions from ethylene oxide sterilizers have already been reduced by at least 99 percent and another 95 to 99 percent from ethylene oxide aerators through compliance with the existing Sterilizer ATCM for such operations, and these emission reductions continue to represent the lowest achievable emission rate based on the use of the best available control technology in consideration of risk and cost of control.
4. Large commercial ethylene oxide sterilizers and aerators in California are subject to two similar regulations which represent a burden to the facility operators by requiring expenditure of additional resources for compliance with no significant emissions reduction benefit.
5. Adoption of the proposed amendments to the Sterilizer ATCM will incorporate provisions that are necessary for the U.S. EPA to approve the Sterilizer ATCM as the substitute for the federal regulation for large commercial sterilization and fumigation operations.
6. The economic and cost impacts of the amendments have been analyzed as required by California law, and the analysis of these impacts is set forth in the Staff Report for this regulatory action.
7. No alternative considered would be more effective at carrying out the purpose for which the amendments to the Sterilizer ATCM are proposed, or be as effective and less burdensome to the affected private persons than the amendments as proposed.

WHEREAS, the Board further finds that adoption of the proposed amendments to the Sterilizer ATCM will not result in any significant adverse environmental impacts;

NOW, THEREFORE, BE IT RESOLVED that the Board hereby approves sections 93108, 93108.5, and 94143, Title 17, California Code of Regulations, as set forth in Attachment A, with the modifications to the originally proposed text as set forth in Attachment B hereto.

BE IT FURTHER RESOLVED that the Board directs the Executive Officer to adopt the amendments set forth in Attachment A with the modifications as set forth in Attachment B, after making the modified regulatory language available for public comment for a period of at least 15 days; provided that the Executive Officer shall consider such written comments regarding the modification as may be submitted during this period, shall make modifications as may be appropriate in light of the comments received, and shall present the regulations to the Board for further consideration if he determines that this is warranted.

BE IT FURTHER RESOLVED that the Board directs the Executive Officer, to submit upon adoption, the relevant sections of the amended Sterilizer ATCM to U.S. EPA for approval as the substitute for the Sterilizer NESHAP.

BE IT FURTHER RESOLVED that the Board directs the staff to inform the air pollution control and air quality management districts of the amendments to the Sterilizer ATCM, and to provide technical assistance to the districts in implementing the amended Sterilizer ATCM.

BE IT FURTHER RESOLVED that the Board directs the staff to survey California's commercial sterilizers to determine if they have safety concerns related to operation of emission control equipment, and if so, to inform them of the opportunity to pursue a variance to address their concerns, and to monitor any such variance application to ensure that the variance process is adequate to address their concerns.

BE IT FURTHER RESOLVED that the Board directs the staff to track and evaluate alternative technology that will meet the Sterilizer ATCM emission standards and provide greater employee safety.

I hereby certify that the above is a true and correct copy of Resolution 98-20, as adopted by the Air Resources Board.

Pat Hutchens, Clerk of the Board

Resolution 98-20

May 21, 1998

Identification of Attachments to the Resolution

- Attachment A: Proposed amendments to sections 93108 and 94143 and adoption of section 93108.5, Title 17, California Code of Regulations, as set forth in the Initial Statement of Reasons (not included).
- Attachment B: Staff's Suggested Changes to the Original Proposal (distributed at the Board hearing on May 21, 1998 plus changes made during the Board Hearing on May 21, 1998).

Enclosure 2

Regulation Order

Ethylene Oxide Airborne Toxic Control Measure for Sterilizers And Aerators

ATTACHMENT B

FOR CONSIDERATION BY THE AIR RESOURCES BOARD AT THE PUBLIC HEARING ON THE PROPOSED AMENDMENTS TO THE ETHYLENE OXIDE AIRBORNE TOXIC CONTROL MEASURE FOR STERILIZERS AND AERATORS

MAY 21, 1998

Staff's Suggested Modifications to the Original Proposal

The attachment shows the staff's suggested modifications to the originally proposed amendments. Only those portions containing the suggested modifications are included.

I. Part 1, Non-Commercial Sterilizers and Aerators and Commercial Sterilizers and Aerators using less than 2,000 pounds of Ethylene Oxide per 12 Consecutive Months.

1. Reporting

Change to read: "...available to the district upon request. Commercial sterilizers shall maintain copies of these reports on site for 5 years. This report shall..."

Section Affected: Section 93108 (d).

2. Requirements

Make the following change: "the average concentration of ethylene oxide shall not exceed:"

Section Affected: Section 93108 (e)(3).

3. Change statement to read "Source testing shall be conducted according to ARB Test Method 431 (title 17, CCR, section 94143) and the method evaluations cited therein or an acceptable source test method approved by the district ~~in consultation~~ with the concurrence of the Executive Officer of the Air Resources Board."

Section Affected: Section 93108 (h)

4. "NOTE: Authority cited" and "Reference"

Change to read: "Sections 39600, 39650, ~~395610~~, and 39666, Health and Safety Code. Reference: Sections 39650, 39665, and 39666, Health and Safety Code, and 40 CFR, Part 63 Subpart O."

Sections Affected: 93108 and 93108.5.

II. Part 2, Commercial Sterilizers and Aerators using 2,000 pounds or more of Ethylene Oxide per 12 Consecutive Months.

1. Definitions

Change as follows: “Administrator means the Administrator of the United States Environmental Protection Agency ~~or his or her authorized representative (e.g., a district that has been delegated the authority to implement any portion of this part) (or the~~ implementing agency in accordance with any delegation of authority to approve alternatives from the U. S. Environmental Protection Agency).”

Section Affected: 93108.5 (a)(1)

2. Compliance Procedures

Change to read “Source testing conducted for the purpose of demonstrating compliance must be according to ARB Test Method 431 (title 17, CCR, section 94143) and the method evaluations cited therein or an acceptable source test method approved by the district ~~in consultation with~~ the concurrence of the Executive Officer of the Air Resources Board, and the Administrator.”

Section Affected: 93108.5 (e)(2)(A)

Change “U.S. EPA Test Method 18, section 7.2” in each sentence to “Test Method 431 and subsection (f)(2)(A), (f)(2)(B), and (f)(2)(C)” respectively.

Sections Affected: Section (e)(2)(C)(i), (ii), and (iii).

3. Monitoring Requirements

Change statement to read “For sources/facilities using ~~more than 20,000 pounds~~ 20,000 pounds or more of ethylene oxide per 12 consecutive months,”.

Sections Affected: Section (f)(2), Appendix 1(b)(4).

III. Test Method 431, Determination of Ethylene Oxide Emissions from Stationary Sources.

1. Sampling

Change sentence, “In the very recent past there have been explosions at several EtO sterilization facilities in other states.” to “There have been explosions at several commercial EtO sterilization facilities.” Delete the word “strongly”.

Section Affected: 94143, Page 1

2. Special Precautions

Change sentence, “In the very recent past there have been explosions at several EtO sterilization facilities in other states.” to “There have been explosions at several commercial EtO sterilization facilities.” Delete the word “strongly”.

Section Affected: 94143, Page 2

3. Equipment

Change to read: “1. Gas Chromatograph, flame ionization detector, photo ionization detector, integrator, and columns.”

Section Affected: 94143, Page 2

4. Testing Procedures for Sterilizers with Catalytic Oxidation or Hydrolytic Scrubber Type Control Units - Determination of Ethylene Oxide Concentration at the Inlet of Control Units

Change sentence, “In the very recent past there have been explosions at several EtO sterilization facilities in other states.” to “There have been explosions at several commercial EtO sterilization facilities.” Delete the word “strongly”.

Section Affected: 94143 Appendix A, Page 6

5. Testing Procedures for Sterilizers with Catalytic Oxidation or Hydrolytic Scrubber Type Control Units - Determination of Ethylene Oxide Concentration at the Inlet of Control Units. Option 1, Inlet Estimation

Delete the sentence “The use of the inlet estimation technique is not allowed for sterilizer systems using water ring seal pumps (either flow through or recirculating) for chamber evacuations.” Add the sentence, “These estimation procedures may be used with sterilization systems using recirculating water ring seal pumps for evacuation of the chamber if the correction procedures outlined in Appendix B are followed.”

Section Affected: 94143 Appendix A, Page 6

6. Testing Procedures for Sterilizers with Catalytic Oxidation or Hydrolytic Scrubber Type Control Units - Determination of Ethylene Oxide Concentration at the Inlet of Control Units. Option 2, Inlet Measurement

Delete the sentence, “A loaded chamber must be used when performing compliance tests of sterilization cycles if using this inlet measurement option.”

Section Affected: 94143 Appendix A, Page 6

7. Testing Procedures for Sterilizers with Catalytic Oxidation or Hydrolytic Scrubber Type Control Units - Measurement Methods. Direct Interface Sampling Analysis

Delete the following: “For catalytic oxidation type control units, this procedure shall only be used if the sampling frequency is less than 2 minutes. For hydrolytic scrubber units, this procedure shall only be used if the sampling frequency is less than 1 minute.”

Add the sentence: “This procedure shall only be used if the GC sampling frequency provides at least 10 analysis points over the duration of the primary chamber evacuation.”

Delete the following: “For acid scrubber control systems, sampling will be conducted during the first evacuation and for the duration of any additional evacuation/wash periods (up to the point where aeration begins).”

Add the sentence: “Do not route the sulfuric acid scrubber exhaust back to the control unit as damage may occur to the catalytic bed.”

Section Affected: 94143 Appendix A, Page 7

8. Procedures for Estimating Mass of EtO at the Inlet

Delete the last sentence of the first paragraph, “Use of flow through water ring seal pumps for chamber primary evacuation is specifically prohibited by the EtO ATCM.” Correct the spelling of the word reservoir in several places in this section. Change the definitions in the

last six lines of section 4 on page 10 as follows: "...concentration of EtO in the pump reservoir after the exhaust test (ug/ml); "concentration of EtO in the pump reservoir water before the exhaust test (ug/ml); "volume of water in the reservoir after the exhaust test (ml"); and, "volume of water in the reservoir before the exhaust test (ml)". The word "after" is changed to "before" in the definition of Vol_{before}.

Section Affected: 94143 Appendix B, Page 10

9. Testing Procedures for Aeration Rooms

Delete the last paragraph of the section, "Testers must ...final results."

Section Affected: 94143 Appendix C, Page 11

10. Calculations

Change scfm to scf in the equation for " $W_i=C.....$ " on the next to last line of the page.

Section Affected: 94143 Appendix F, Page 19

11. Method Limitations - Inlet Estimation

Delete the sentence, "The inlet estimation technique should not be used with sterilization systems using water ring seal pumps, either flow through or recirculating."

Section Affected: 94143 Appendix H, Page 23

12. Method Limitations - Acid Scrubber

Delete the sentence, "Use of flow-through water ring seal pumps for chamber primary evacuation is specifically prohibited by the EtO ATCM."

Section Affected: 94143 Appendix H, Page 23

13. Testing Procedures for Sterilizers With Joslyn Recovery Type Control Units - Identified points of EtO emissions from the Joslyn system include:

Delete the term "12/88" from the last line of Paragraph 1. In paragraph 2, change the third sentence to read, "Moisture from the chamber collects in the separator and is discharged from the pump ~~several times per cycle~~ once per cycle at the beginning of the chamber evacuation."

Section Affected: 94143 Appendix K, Page 37

14. Testing Procedures for Sterilizers With Joslyn Recovery Type Control

Units - Sterilization Exhaust

In paragraph 5, change the second sentence to read, “Collect the entire discharge of the heated chamber jacket in separate ½ hour samples for a 2 hour period starting ~~at the beginning of the chamber evacuation~~ 5 minutes before the end of the exposure stage.”

Delete the word “graduated” from the third sentence.

Section Affected: 94143 Appendix K, Page 38

15. Testing Procedures for Sterilizers With Joslyn Recovery Type Control Units - Aeration Exhaust

In paragraph 3, make the following change to the third sentence: “Collect the entire discharge of the water ring seal pump ~~in separate 5 minute samples for a 1 hour period starting at the beginning of the aeration stage.~~ during the first 5 minute evacuation of the aeration stage.” Delete the word “graduated” from the fifth sentence.

Section Affected: 94143 Appendix K, Page 38

16. Method 431- EtO in Water

Delete “ethylene glycol” from the “ANALYTE” heading in the “measurement” column.

Delete the sentence beginning “Samples should be analyzed...” from the “Limitations” section.

Section Affected: 94143 Appendix L, Page 39