

State of California  
AIR RESOURCES BOARD

Resolution 98-20

May 21, 1998

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RESOURCES AGENCY OF CALIFORNIA

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 modifications 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 evaluate the concerns and to track and evaluate alternative technology that will meet the Sterilizer ATCM emission standards and provide greater employee safety if warranted.

BE IT FURTHER RESOLVED that the Board directs the staff to inform operators of commercial sterilizers of the opportunity to pursue a variance to address any legitimate safety concerns, and to monitor any such variance requests to ensure that the variance process adequately addresses those concerns.

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



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Pat Hutchens, Clerk of the Board