SACRAMENTO METROPOLITAN AIR QUALITY MANAGEMENT DISTRICT

08

Meeting Date: 4/28/2016

Report Type: Public Hearing

Report ID: 2016-0428-08

Title: Amend Rule 464 – Organic Chemical Manufacturing Operations and Repeal Rule 455 – Pharmaceuticals Manufacturing

Recommendation: Conduct a Public Hearing and 1) adopt resolutions approving Rule 464 amendments and repealing Rule 455, and 2) determine that the amendments to Rule 464 and the repeal of Rule 455 are exempt from CEQA.

Rationale for Recommendation: Pharmaceutical manufacturing operations are subject to two separate District rules: Rule 455 – Pharmaceuticals Manufacturing and Rule 464 – Organic Chemical Manufacturing Operations. In 2015, EPA evaluated the District's 2006 Analysis of Reasonably Available Control Technology (RACT) and determined that the District does not meet the RACT requirements of the Clean Air Act for the pharmaceuticals manufacturing source category. As a result, EPA has proposed a limited approval/limited disapproval of the District's RACT submittal. EPA found that Rule 455 does not establish the test methods and recordkeeping requirements necessary to make the rule enforceable, while Rule 464 does not establish requirements for pharmaceuticals manufacturing that are as stringent as the federal RACT recommendations.

Staff is proposing to amend Rule 464 to meet federal RACT requirements and state air quality mandates. The amendments to Rule 464 will eliminate the need for Rule 455, which Staff is proposing to repeal. The proposed actions will affect only pharmaceutical manufacturing plants. Requirements for other types of organic chemical manufacturing operations will remain unchanged.

Contact: Aleta Kennard, Program Supervisor, 916-874-4833

Presentation: ☒ yes ☐no

Attachments:

ATTACHMENT 1 – ANALYSIS
ATTACHMENT 2 – RESOLUTIONS
ATTACHMENT 3 – EXHIBIT A TO THE RESOLUTION AMENDING RULE 464
ATTACHMENT 4 – REDLINE VERSION OF PROPOSED RULE 464
ATTACHMENT 5 – STATEMENT OF REASONS
ATTACHMENT 6 – EVIDENCE OF PUBLIC NOTICE
ATTACHMENT 7 – WRITTEN COMMENTS

Approvals/Acknowledgements

Executive Director or Designee:	District Counsel or Designee:
Report Approved	Approved as to Form
Larry Greene	Kathrine Pittard

Financial Considerations: The proposed amendments to Rule 464 and proposed repeal of Rule 455 are not expected to result in additional costs to the District.

Rule Justification: Section 182(b)(2) of the federal Clean Air Act (CAA) requires air districts in ozone nonattainment areas to implement Reasonably Available Control Technology (RACT) for VOC sources covered by a Control Technique Guidelines (CTG) document issued by EPA. RACT is defined as "the lowest emission limitation that a particular source is capable of meeting by the application of control technology that is reasonably available considering technological and economic feasibility"[1]. One source category covered by a CTG is pharmaceutical manufacturing operations[2].

Rule 455 was adopted in 1983 to meet the RACT requirements by limiting the VOC emissions from pharmaceutical manufacturing operations. In 2015, EPA evaluated the District's 2006 Analysis of Reasonably Available Control Technology (RACT)[3] and determined that the District does not meet the RACT requirements for the pharmaceuticals manufacturing source category. Specifically, EPA found that Rule 455 lacks test methods and recordkeeping requirements that are necessary to ensure that the rule is enforceable[4]. As a result, EPA has proposed a limited approval/limited disapproval of the District's 2006 RACT submittal[5].

Rule 464 – Organic Chemical Manufacturing Operations applies to all organic chemical manufacturing, including pharmaceutical manufacturing. Although Rule 464 established VOC limits for organic chemical plants as well as test methods and recordkeeping requirements, some rule requirements were not as stringent as the requirements established in the CTG for pharmaceuticals manufacturing. EPA stated that if the District plans to use Rule 464 to demonstrate compliance with the federal RACT requirements for pharmaceutical manufacturing, Rule 464 must be amended to incorporate elements missing from the rule to satisfy RACT.

To meet the federal RACT requirements and eliminate duplication, Staff is proposing to amend Rule 464 and repeal Rule 455. If approved by the District's Board of Directors, amended Rule 464 will be submitted to EPA for inclusion in the SIP, and the District will simultaneously request that EPA remove Rule 455 from the SIP. In addition, Staff is proposing changes to Rule 464 that will meet state mandates to adopt Best Available Retrofit Control Technology (BARCT) and all feasible measures.

Summary of Amendments: The proposed amendments will ensure that the requirements in Rule 464 are as stringent as the requirements in the CTG for pharmaceutical manufacturing

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[1] 44 FR 53762, September 17, 1979.

[2] "Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products," U.S. EPA, EPA-450/2-78-029, December 1978.

[3] "Analysis of Reasonably Available Control Technology for the 8-Hour Ozone State Implementation Plan (RACT SIP)," Sacramento Metropolitan Air Quality Management District, September 26, 2006.

[4] "Technical Support Document for EPA's Notice of Proposed Rulemaking for the California State Implementation Plan – EPA's Evaluation of Sacramento Metropolitan Air Quality Management District, Ozone State Implementation Plan Revision Reasonably Available Control Technology as Applicable to the 8-hour Ozone Standard - Adopted 26, 2006 ("2006 RACT SIP TSD")." November 2015.

[5] "Revisions to the California State Implementation Plan, Sacramento Metropolitan Air Quality Management District, Proposed Rule." 81 Federal Register (January 15, 2016), pp. 2136 – 2140.

operations, which will meet federal RACT requirements, and no less stringent than the existing requirements in Rule 455, which will prevent a relaxation when Rule 455 is repealed. The amendments will also ensure that the requirements, as discussed below, are as stringent as the requirements in other ozone nonattainment areas, which is required to satisfy state requirements. Please refer to Appendix B of the Statement of Reasons (Attachment 5) for a detailed description of all changes.

Decreases in Exemption Thresholds: Rule 464 exempts individual vents or entire facilities from control requirements if the VOC emissions are less than specific thresholds. The proposed amendments will decrease the exemption thresholds for an entire pharmaceutical or cosmetic manufacturing plant and for any individual vent stream from any reactor, distillation column, evaporator, crystallizer or centrifuge at a pharmaceutical or cosmetic manufacturing plant from the current threshold of 15 pounds per day to 10 pounds per day.

Equipment Standards: The proposed amendments will change the standards for the following equipment or operations at pharmaceutical and cosmetic manufacturing plants.

- Reactors, Distillation Columns, Crystallizers, Evaporators or Centrifuges: Staff is proposing to increase the overall control efficiency required for equipment emitting more than 15 pounds per day from the current 85% to 90%. Equipment that emits more than 10 pounds per day but not more than 15 pounds per day must be controlled with a minimum overall efficiency of 90%, or alternatively, with a condenser that cools the outlet gas below a specified temperature that depends on the VOC vapor pressure. These changes will be effective 18 months after the date of adoption.
- Dryers or Production Equipment Exhaust Systems: Staff is proposing to require emissions less than 330 pounds per day from air dryers or other production equipment exhaust systems at a pharmaceutical or cosmetic manufacturing plant to be vented to a control system with a combined system efficiency of at least 90%, effective 18 months after the date of adoption. The current requirement is to reduce such emissions to less than 33 pounds per day.

Petition of Exemption: For process vents that are exempt, Staff is proposing to require the facility to submit a new petition of exemption to identify the process vents that are below the proposed exemption threshold of 10 pounds per day. The petition of exemption must be submitted to the District within 6 months after date of adoption of the proposed amendments.

Authority to Construct Application: A permit application is required if a facility installs or modifies an emission control device to comply with the proposed rule requirements. An application for an Authority to Construct must be submitted within 6 months after the date of adoption.

Emission Impact: Two permitted facilities in the District are subject to Rule 464. Only one of these is a pharmaceutical manufacturing facility, and it already complies with the proposed changes. Therefore, no emission reduction is expected from these amendments.

Economic Impact: The one pharmaceutical manufacturing facility subject to this rule already complies with the proposed Rule 464 amendments. Therefore, no compliance cost is expected from these amendments.

Public Outreach/Comments: Staff held a public workshop to discuss the proposed amendments to Rule 464 and the proposed repeal of Rule 455 on March 16, 2016. The noticing for the workshop and today's hearing included:

- Mailing and/or emailing notices to:
    - California Air Resources Board (CARB) and U.S. Environmental Protection Agency (EPA);
    - Interested and affected parties, including the permitted stationary sources subject to Rule 464; and
    - All persons who have requested rulemaking notices.
- A notice in the Sacramento Bee.
- A notice on the District website with links to the proposed rule and Statement of Reasons.

Staff received questions from the attendees at the public workshop. No oral or written comments from the public or affected parties were received. CARB and EPA reviewed the proposed Rule 464 amendments. CARB had no comments. EPA had two comments, which resulted in some changes that were discussed at the public workshop. After the revisions to the rule were made, EPA had no further comments on the rule. The responses to EPA's comments are included in Appendix E of the Statement of Reasons (Attachment 5). EPA's written comment letter is included in Attachment 7.

Environmental Review: California Public Resources Code Section 21159 requires an environmental analysis of the reasonably foreseeable methods of compliance. Proposed amendments to Rule 464 and proposed repeal of Rule 455 are not expected to require any source within the District to change its operations to comply. Therefore, Staff has concluded that no environmental impacts will be caused by compliance with the proposed amendments.

Staff finds that the proposed amendments to Rule 464 and proposed repeal of Rule 455 are exempt from the California Environmental Quality Act as an action by a regulatory agency for the protection of the environment (Class 8 Categorical Exemption, Section 15308 State CEQA Guidelines) and because it can be seen with certainty that there is no possibility that the activities in question may have a significant adverse effect on the environment (Section 15061(b)(3), State CEQA Guidelines).

SACRAMENTO METROPOLITAN AIR QUALITY MANAGEMENT DISTRICT

RESOLUTION NO. _____

Rule 455 – PHARMACEUTICALS MANUFACTURING

WHEREAS, the Board of Directors of the Sacramento Metropolitan Air Quality Management District is authorized by California Health and Safety Code Sections 40001, 40702, and 41010 (Health and Safety Code Section 40727(b)(2)) to adopt, amend or repeal rules and regulations; and

WHEREAS, the Board of Directors of the Sacramento Metropolitan Air Quality Management District has determined that a need exists to repeal Rule 455 to eliminate duplication of requirements for pharmaceutical and cosmetic manufacturing because both Rule 455 and Rule 464 – ORGANIC CHEMICAL MANUFACTURING OPERATIONS set requirements for the same source types (Health and Safety Code Section 40727(b)(1)); and

WHEREAS, the Board of Directors of the Sacramento Metropolitan Air Quality Management District has determined that the repeal of Rule 455 will remove the entire text of the rule (Health and Safety Code Section 40727(b)(3)); and

WHEREAS, the Board of Directors of the Sacramento Metropolitan Air Quality Management District has determined that the repeal of Rule 455 will not be in conflict with or contradictory to, existing statutes, court decisions, or state or federal regulations (Health and Safety Code Section 40727(b)(4)); and

WHEREAS, the Board of Directors of the Sacramento Metropolitan Air Quality Management District has determined that the repeal of Rule 455, together with the adoption of amendments to Rule 464, implements Section 182(b)(2)(A) of the federal Clean Air Act (Health and Safety Code Section 40727(b)(5)); and

WHEREAS, the Board of Directors of the Sacramento Metropolitan Air Quality Management District has considered a written analysis prepared by Staff (Health and Safety Code Section 40727.2); and

WHEREAS, the Board of Directors of the Sacramento Metropolitan Air Quality Management District has maintained records of the rulemaking proceedings (Health and Safety Code Section 40728); and

WHEREAS, the Board of Directors of the Sacramento Metropolitan Air Quality Management District held a duly noticed public hearing on April 28, 2016, and considered public comments on the proposed repeal of Rule 455 (Health and Safety Code Sections 40725 and 40726); and

WHEREAS, the Board of Directors of the Sacramento Metropolitan Air Quality Management District has considered the socioeconomic impacts of repealing the rule in Staff's Statement of Reasons (Health and Safety Code Section 40728.5); and

WHEREAS, the Board of Directors of the Sacramento Metropolitan Air Quality Management District has determined that the repeal of Rule 455 will not interfere with the District's progress to meet the air quality standards because the requirements in Rule 455 are already in Rule 464 or are incorporated as amendments to Rule 464 (Clean Air Act, Sections 110(I) and 193); and

WHEREAS, the Board of Directors of the Sacramento Metropolitan Air Quality Management District has determined that the repeal of Rule 455 is exempt from the California Environmental Quality Act (CEQA) under Section 15038 of the State CEQA Guidelines, as an action by a regulatory agency for the protection of the environment and under Section 15061(b)(3) of the State CEQA Guidelines, as an action that can be seen with certainty that there is no possibility the action may have a significant adverse effect on the environment.

NOW, THEREFORE, BE IT RESOLVED THAT the repeal of Rule 455 is exempt from CEQA; and

BE IT FURTHER RESOLVED THAT the Board of Directors of the Sacramento Metropolitan Air Quality Management District approves the repeal of the entire text of Rule 455 – PHARMACEUTICALS MANUFACTURING; and

BE IT FURTHER RESOLVED THAT that the repeal of Rule 455 be effective as of April 28, 2016; and

BE IT FURTHER RESOLVED THAT that the Board of Directors of the Sacramento Metropolitan Air Quality Management District directs Staff to forward repealed Rule 455 and all necessary supporting documents to the California Air Resources Board and subsequent submittal to EPA to be removed from the State Implementation Plan.

ON A MOTION by Director _____, seconded by Director _____, the foregoing Resolution was passed and adopted by the Board of Directors of the Sacramento Metropolitan Air Quality Management District, State of California, this 28th day of April, 2016, by the following vote, to wit:

AYES: Directors

NOES: Directors

ABSENT: Directors

_____

Chairperson of the Board
Sacramento Metropolitan Air
Quality Management District
State of California

(SEAL)

ATTEST:_____

Clerk of the Board
Sacramento Metropolitan Air Quality Management District

SACRAMENTO METROPOLITAN AIR QUALITY MANAGEMENT DISTRICT

RESOLUTION NO. _____

Rule 464 – ORGANIC CHEMICAL MANUFACTURING OPERATIONS

WHEREAS, the Board of Directors of the Sacramento Metropolitan Air Quality Management District is authorized by Sections 40001, 40702, and 41010 of the California Health and Safety Code (Health and Safety Code Section 40727(b)(2)) to adopt, amend or repeal rules and regulations; and

WHEREAS, the Board of Directors of the Sacramento Metropolitan Air Quality Management District has determined that a need exists to amend Rule 464 to satisfy Reasonably Available Control Technology requirements for pharmaceuticals manufacturing, as required by Section 182(b)(2)(A) of the federal Clean Air Act (42 U.S.C. §7511a(b)(2)(A)) and to comply with California Health and Safety Code Section 40919(a)(3) requirements for Best Available Retrofit Control Technology and California Health and Safety Code Section 40914(b)(2) requirements for all feasible measures (Health and Safety Code Section 40727(b)(1)); and

WHEREAS, the Board of Directors of the Sacramento Metropolitan Air Quality Management District has determined that the meaning of Rule 464 can be easily understood by the persons affected by it (Health and Safety Code Section 40727(b)(3)); and

WHEREAS, the Board of Directors of the Sacramento Metropolitan Air Quality Management District has determined that the rule is in harmony with, and not in conflict with or contradictory to, existing statutes, court decisions, or state or federal regulations (Health and Safety Code Section 40727(b)(4)); and

WHEREAS, the Board of Directors of the Sacramento Metropolitan Air Quality Management District has determined that Rule 464 does not duplicate any existing state or federal regulations (Health and Safety Code Section 40727(b)(5)); and

WHEREAS, the Board of Directors of the Sacramento Metropolitan Air Quality Management District has determined that Rule 464 implements California Health and Safety Code Sections 40914(b)(2) and 40919(a)(3) and Section 182(b)(2)(A) of the federal Clean Air Act (Health and Safety Code Section 40727(b)(6)); and

WHEREAS, the Board of Directors of the Sacramento Metropolitan Air Quality Management District has considered a written analysis prepared by Staff (Health and Safety Code Section 40727.2); and

WHEREAS, the Board of Directors of the Sacramento Metropolitan Air Quality Management District has maintained records of the rulemaking proceedings (Health and Safety Code Section 40728); and

WHEREAS, the Board of Directors of the Sacramento Metropolitan Air Quality Management District held a duly noticed public hearing on April 28, 2016 and considered public comments on the proposed amendments to Rule 464 (Health and Safety Code Sections 40725 and 40726); and

WHEREAS, the Board of Directors of the Sacramento Metropolitan Air Quality Management District has considered the socioeconomic impacts of the rule in Staff's Statement of Reasons (Health and Safety Code Section 40728.5); and

WHEREAS, the Board of Directors of the Sacramento Metropolitan Air Quality Management District has determined that the amendments to Rule 464 implement Reasonably Available Control Technology for the source category of pharmaceutical manufacturing as specified in the Control Technique Guidelines titled, Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products (EPA-450/2-78-029); and

WHEREAS, the Board of Directors of the Sacramento Metropolitan Air Quality Management District has determined that the amendments to Rule 464 are exempt from the California Environmental Quality Act (CEQA) under Section 15038 of the State CEQA Guidelines, as an action by a regulatory agency for the protection of the environment and under Section 15061(b)(3) of the State CEQA Guidelines, as an action that can be seen with certainty that there is no possibility the action may have a significant adverse effect on the environment.

NOW, THEREFORE, BE IT RESOLVED THAT the amendment of Rule 464 is exempt from CEQA; and

BE IT FURTHER RESOLVED THAT the Board of Directors of the Sacramento Metropolitan Air Quality Management District approves and adopts the amendment of Rule 464 – ORGANIC CHEMICAL MANUFACTURING OPERATIONS; and

BE IT FURTHER RESOLVED THAT the amendment of Rule 464 (set forth in Exhibit A) be effective as of April 28, 2016; and

BE IT FURTHER RESOLVED THAT the Board of Directors of the Sacramento Metropolitan Air Quality Management District directs Staff to forward amended Rule 464 and all necessary supporting documents, including the public notice and public hearing, to the California Air Resources Board for its approval and subsequent submittal to EPA for final approval as a revision to the State Implementation Plan to satisfy the requirements of Clean Air Act Sections 110, 172, 182, and 40 CFR Parts 51; and

BE IT FURTHER RESOLVED THAT the attached Exhibit A is part of this resolution.

ON A MOTION by Director _____, seconded by Director _____, the foregoing Resolution was passed and adopted by the Board of Directors of the Sacramento Metropolitan Air Quality Management District, State of California, this 28th day of April, 2016, by the following vote, to wit:

AYES: Directors

NOES: Directors

ABSENT: Directors

_____

Chair of the Board
Sacramento Metropolitan Air Quality Management District
State of California

(SEAL)

ATTEST: _____
Clerk of the Board
Sacramento Metropolitan Air Quality Management District