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OCT 16 1980

Resources Agency of California

State of California
AIR RESOURCES BOARD

Resolution 80-47

August 28, 1980

WHEREAS, the Air Resources Board (Board) and the Environmental Protection Agency have established health-based ambient air quality standards for oxidant and ozone, respectively, and these standards are frequently exceeded in several of the State's air basins, including the South Coast Air Basin; and

WHEREAS, Health and Safety Code Sections 39003, 39500, 39602, and 41500 authorize the Board to coordinate, encourage, and review efforts to attain and maintain state and national ambient air quality standards; and

WHEREAS, Health and Safety Code Sections 39600 and 39605 authorize the Board to do such acts as may be necessary to execute the powers and duties granted to and imposed upon the Board and to assist the air pollution control districts; and

WHEREAS, the suggested control measure for the control of emissions of volatile organic compounds (VOC) from pharmaceutical and cosmetics manufacturing was developed by the South Coast Air Quality Management District (SCAQMD) as a part of that District's participation in a statewide effort to develop suggested control measures, and has been approved under the Suggested Control Measure Development Process and by a technical review group comprised of representatives of EPA, ARB, and several air pollution control districts; and

WHEREAS, the California Environmental Quality Act(CEQA) and ARB regulations require that the Board not approve any action proposed for which significant environmental effects have been identified if there are feasible mitigation measures or feasible alternatives available which would substantially lessen any such effects which the action may cause; and

WHEREAS, the Board, after at least 45 days notice, has held a public meeting on this matter, and has heard and considered the comments presented by the ARB staff, affected industries, and other interested persons; and

WHEREAS, the Board finds:

1. That emissions of volatile organic compounds from pharmaceutical and cosmetics manufacturing contribute to violations of the state and

national ambient standards for oxidant and ozone, in several of the State's air basins;

2. The VOC emissions from existing sources can be reduced by up to 90 percent of the present emission rate, resulting in an air quality benefit.

3. That such emission reductions are technologically feasible and cost-effective.

4. That the measure as proposed would exempt from control requirements 1,1,1-trichloroethane, trichlorotrifluoroethane and methylene chloride with the result that there may be an expanded use of these compounds as substitutes for controlled compounds since they are relatively photochemically unreactive;

5. That the uncontrolled use of 1,1,1-trichloroethane, trichlorotrifluoroethane, and methylene chloride may result in adverse environmental impacts as discussed in the staff report;

6. That no other significant environmental effects are likely to result from the approval of this measure by the Board and by its adoption and implementation by the districts.

NOW, THEREFORE, BE IT RESOLVED, that the Air Resources Board approves the suggested control measure for the control of VOC emissions from pharmaceutical and cosmetics manufacturing as set forth in revised Attachment I to this Resolution; and

BE IT FURTHER RESOLVED, that the Executive Officer is directed to forward the suggested control measure along with this resolution to districts which need reductions in VOC emissions to achieve and maintain state and national ambient air quality standards with a recommendation that these districts consider adoption of a rule of equivalent effectiveness; and

BE IT FURTHER RESOLVED, that the Executive Officer is directed to forward the suggested control measure along with this resolution to districts which have already adopted similar rules with the recommendation that such rules be re-examined and amended as appropriate to make them consistent with this measure; and

BE IT FURTHER RESOLVED, that subsequent investigations which confirm alleged or suspected adverse environmental impacts associated with the uncontrolled use of 1,1,1-trichloroethane, trichlorotrifluoroethane or methylene chloride may trigger reconsideration of this measure by the Board to include mitigation requirements for such impacts pursuant to the California Environmental Quality Act. Where such impacts are identified for one or more of the above compounds, the additional mitigation requirements would depend on the expected impacts, and could include: 1) removal of the exemption for such compound(s) from this and possibly other district control measures, or 2) requiring the application

of best available control technology to reduce emissions of such compound(s) from existing sources, or 3) partially or totally banning atmospheric emissions of such compound(s), or 4) any other action deemed necessary by the Board in order to satisfy the requirements of Division 26 of the Health and Safety Code, the CEQA, and ARB regulations; and

BE IT FURTHER RESOLVED, that the Board revises the proposed, suggested control measure by the addition of Sections d(6) and d(7) to provide for regulating increases in emissions of 1,1,1-trichloroethane, trichlorotrifluoroethane, and methylene chloride in order to mitigate potential, harmful environmental effects which would result from increased use of such compounds.

BE IT FURTHER RESOLVED, that the Board recommends that in considering the adoption of the attached suggested control measure, districts should consider the economic problems of small businesses and other problems of local concern and afford appropriate relief which does not significantly reduce the effectiveness of the measure; and

BE IT FURTHER RESOLVED, that the Board recommends that prior to adopting such control measure, the districts consider the potential adverse environmental effects of the exemption of 1,1,1-trichloroethane, trichlorotrifluoroethane, and methylene chloride and further consider measures to mitigate any such effects which they find would result from such exemptions.

BE IT FURTHER RESOLVED, that the Executive Officer is directed to provide assistance to any district requesting assistance in adopting, interpreting, or implementing the suggested control measure.

I certify that the above is a true and correct copy of Resolution 80-47 as passed by the Air Resources Board.

Sally Rump

Board Secretary

Attachment I

Pharmaceutical and Cosmetics
Manufacturing Operations
September 1980

(a) Definitions

For the purpose of this rule, the following definitions shall apply:

(1) Volatile Organic Compounds (VOC) are compounds of carbon, excluding carbon monoxide, carbon dioxide, carbonic acid, metallic carbides or carbonates, ammonium carbonate, ethane, methane, 1,1,1 trichloroethane, methylene chloride, and trichlorotrifluoroethane, that have an absolute vapor pressure greater than 26 mm Hg (0.5 psi) at 20°C.

(2) A pharmaceutical manufacturing plant is any plant producing or blending chemicals for use in pharmaceutical products and/or manufacturing pharmaceutical products by chemical processes.

(3) A cosmetics manufacturing plant is any plant producing or blending chemicals for use in cosmetic products and/or manufacturing cosmetic products by chemical processes.

(4) In-process tanks are containers used for mixing, blending, heating, reacting, holding, crystallizing, evaporating, or cleaning operations in the manufacture of pharmaceuticals or cosmetics.

(b) Applicability

The provisions of this rule shall apply to:

(1) The manufacture of pharmaceutical and cosmetic products by chemical processes.

(2) The production and separation of medicinal chemicals such as antibiotics and vitamins from microorganisms.

(3) The manufacture of botanical and biological products by the extraction of organic chemicals from vegetative materials or animal tissues.

(4) The formulation of pharmaceuticals into various dosage forms such as tablets, capsules, injectable solutions or ointments, that can be taken by the patient immediately and in an accurate amount; and the formulation of cosmetics into configurations intended for consumer use.

(c) Equipment Requirements

(1) (A) An owner/operator shall not use reactors, distillation columns, crystallizers, centrifuges emitting more than 15 pounds per day of VOC for each permit unit unless the vents are equipped with surface condensers or equivalent control devices.

(B) An operator shall not use surface condensers for the control of organic gases unless the condenser outlet gas temperature is controlled as shown in the following table:

Absolute Vapor Pressure of VOC at 20°C	Maximum Condenser Outlet Gas Temperature
0.5 psi to 1.0 psi	25°C
1.0 psi to 1.5 psi	10
1.5 psi to 2.9 psi	0
2.9 psi to 5.8 psi	-15
over 5.8 psi	-25

(C) Equivalent control devices may be used with the approval of the Executive Officer. Equivalent control is achieved when VOC emissions are reduced by at least as much as would have occurred using a surface condenser per section (b)(1)(B).

(2) An operator shall not use centrifuges, rotary vacuum filters, or any other filters, or devices having an exposed liquid surface where the liquid contains VOC having a total VOC vapor pressure of 0.5 psi or more at 20°C, unless such devices incorporate a hood or enclosure with a delivery system or ductwork to collect VOC emissions, exhausting to a carbon absorber, or equivalent control method approved by the Executive Officer.

(3) An operator shall not use in-process tanks for material containing VOC unless an apparatus or cover which prevents VOC evaporation is provided for the tank. The cover shall be closed or in place on the tank at all times except while loading or unloading the tank.

(d) Operating Requirements and One-Time Reporting Requirement

An operator shall conform to the following operational requirements:

(1) An operator shall not use air dryers or production equipment exhaust systems that emit 330 pounds per day or more of volatile organic compounds for each basic permit unit unless the emission of such organic materials into the atmosphere has been reduced by at least 90 percent by weight.

(2) Notwithstanding the provisions of paragraph (d)(1), an operator using air dryer or production equipment exhaust systems that emit less than 330 pounds per day of volatile organic compounds shall reduce the emissions of such organic materials into the atmosphere to less than 33 pounds per day.

(3) An operator shall not transfer VOC having a vapor pressure greater than 4.1 psi at 20°C, from any truck or rail car into any storage tank of a 2,000 gallon capacity or greater, unless VOC emissions during transfer are reduced by 90 percent by weight.

(4) An operator shall install pressure/vacuum vents set at $\pm$ 0.03 psig on all storage tanks that store VOC with a vapor pressure greater than 1.5 psia at 20°C, unless a more effective control system, approved by the Executive Officer, is used.

(5) An operator shall repair all leaks from which a liquid, containing VOC, can be observed to be running or dripping. The repair shall be completed the first time the equipment is off-line for a period of time long enough to complete the repair.

(6) Notwithstanding any other provision of this regulation an owner or operator of any pharmaceutical or cosmetics manufacturing

facility shall not increase the use of or substitute 1,1,1-trichloroethane, methylene chloride, or trichlorotrifluoroethane for any other organic solvent, chemical, or compound unless the facility meets the emission limitation requirements of this regulation for the total amounts used of such compounds.

(7) The owner or operator of pharmaceutical or cosmetics manufacturing facilities which emit 1,1,1-trichloroethane, methylene chloride or trichlorotrifluoroethane shall establish the average and maximum daily emission rates of each of these compounds based on actual usage and operating conditions over a three consecutive year period and shall submit such information to the Executive Officer within 90 days of the date of adoption of this Rule.

(e) Exemptions

The provisions of this rule shall not apply to facilities that emit, at the design production rating, 15 pounds per day or less of volatile organic compounds.

(f) Effective Dates

The owner or operator of any pharmaceutical or cosmetics manufacturing facility subject to this rule shall comply with the provisions of this rule on or before January 1, 1983.

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AIR RESOURCES BOARD

Response to Significant Environmental Issues

ITEM: Adoption of a Control Measure of the Control of Volatile Organic Compound Emissions from Pharmaceutical and Cosmetics Manufacturing Operations

PUBLIC HEARING DATE: August 28, 1980

RESPONSE DATE: August 28, 1980

ISSUING AUTHORITY: Air Resources Board

COMMENT: The only environmental issue identified for the proposed measure was the possible increase in the emissions of 1,1,1-trichloroethane, methylene chloride and trichlorotrifluoroethane. The first two of these compounds are suspected of being carcinogenic, mutagenic or teratogenic. Trichlorotrifluoroethane and 1,1,1-trichloroethane are suspected of contributing to stratospheric ozone depletion.

RESPONSE: To satisfy the requirements of Division 26 of the Health and Safety Code, the California Environmental Quality Act and Air Resources Board regulations, the Board amended the suggested control measure, in accordance with the attached resolution (Resolution 80-47), by including Sections d(6) and d(7) in the approved control measure (attached). Section d(6) would require any pharmaceutical or cosmetic manufacturing facilities substituting or increasing the use of 1,1,1-trichloroethane, methylene chloride, or trichlorotrifluoroethane to meet the emission requirements of the suggested control measure. Section d(7) would require the one time reporting of the current usage of 1,1,1-trichloroethane,methylene chloride, or trichlorotrifluoroethane. This last requirement would establish a current baseline emission rate of these compounds from the pharmaceutical and cosmetics industry.

CERTIFIED: Sally Rump
Board Secretary

DATE: 10/14/80

State of California

Memorandum

RECEIVED BY
Office of the Secretary

OCT 16 1980

Resources Agency of California

To : Huey D. Johnson
Secretary
Resources Agency

Date : October 16, 1980

Subject : Filing of Notice of Decision of the Air Resources Board

From : **Air Resources Board**

Pursuant to Title 17, Section 60007(b), and in compliance with Air Resources Board certification under section 21080.5 of the Public Resources Code, the Air Resources Board hereby forwards for posting the attached notice of decision and response to environmental comments raised during the comment period.

Sally Rump

Sally Rump
BOARD SECRETARY

att: Resolution 80-47