

State of California
AIR RESOURCES BOARD

Staff Report: Initial Statement of Reasons
for Proposed Rulemaking

Public Hearing to Consider the Adoption of a Regulatory Amendment
Identifying Ethylene Dichloride as a Toxic Air Contaminant

Agenda Item No.: 85- -
Scheduled for Consideration: September 19, 1985
Release Date: August 5, 1985

(This report has been reviewed by the staff of the California Air Resources Board and approved for release. Approval does not signify that the contents necessarily reflect the views and policies of the Air Resources Board, nor does mention of trade names or commercial products constitute endorsement or recommendation for use.)

OVERVIEW AND RECOMMENDATION

I. INTRODUCTION

The Air Resources Board ("ARB" or "Board") identifies toxic air contaminants and develops regulations for the control of their emissions according to the requirements of state law. A toxic air contaminant (TAC) is an air pollutant that the Board or the Department of Food and Agriculture* finds "may cause or contribute to an increase in mortality or an increase in serious illness, or which may pose a present or potential hazard to human health."** This report recommends that the Board find ethylene dichloride ("EDC," $\text{ClH}_2\text{C}-\text{CH}_2\text{Cl}$) to be a toxic air contaminant.

Section II of this Overview to the report presents the regulatory background and reviews the procedures by which the Board considers substances for the TAC designation. The Overview also summarizes the technical and toxicological information that supports the staff's recommendation. Section IIIA is a summary of Part A, which presents data on the uses of EDC, its emissions, and the public's exposure to EDC via the ambient air. Section IIIB summarizes the Department of Health Services' (DHS) analysis in Part B of the health effects of EDC. Section IV of this Overview discusses potential environmental effects of the recommended action, and Section V contains the staff's recommendation to the Board.

II. REGULATORY BACKGROUND AND PROCEDURES

Division 26, Chapter 3.5 of the Health and Safety Code* and Food and Agriculture Section 14021 et seq. set forth the procedure for identifying and controlling toxic air contaminants in California. (These provisions were enacted in September 1983 as Assembly Bill 1807, Stats. 1983, ch. 1047; see Part C to this report.) The Department of Food and

* See Section II.

** Health and Safety Code Section 39655.

Agriculture is responsible for identifying and controlling TACs in their pesticial uses. The ARB has authority over TACs in all their other uses.

HSC Section 39650 sets forth the Legislature's findings about substances which may be TACs. The Legislature has declared:

"That public health, safety, and welfare may be endangered by the emission into the ambient air of substances which are determined to be carcinogenic, teratogenic, mutagenic, or otherwise toxic or injurious to humans."

The findings also include directives on the consideration of scientific evidence and the basis for regulatory action. With respect to the control of TACs, the Legislature has declared:

"That it is the public policy of this state that emissions of toxic air contaminants should be controlled to levels which prevent harm to the public health."

The Legislature has further declared that, "while absolute and undisputed scientific evidence may not be available to determine the exact nature and extent of risk from toxic air contaminants, it is necessary to take action to protect public health."

In the evaluation of substances, the Legislature has declared that the best available scientific evidence, gathered from both public agencies and private sources including industry, should be used. The Legislature has also determined that this information should be reviewed by a scientific review panel and by the public.

*HSC; all statutory references are to the Health and Safety Code, except as otherwise stated.

The Board's determination of whether or not a substance is a toxic air contaminant includes several steps specified by HSC. First, we request the DHS to evaluate the health effects of a substance (Section 39660). The evaluation includes a comprehensive review of all available scientific data. Upon receipt of a report on health effects from DHS and in consideration of their recommendations, we prepare and submit a report to the Scientific Review Panel (SRP) for its review (Section 39661). The report consists of the DHS report (Part B), material prepared by the ARB staff on the use, emissions and ambient concentrations of the substance (Part A), and various supporting documents in Part C. It serves as the basis for future regulatory action by the Board. The report is also made available to the public, which may submit comments on the report to the SRP.

After receiving the SRP's written findings on the report, the Board issues a public hearing notice and a proposed regulation stating whether or not the substance is a toxic air contaminant. If, after a public hearing and other procedures to comply with Government Code Section 11340 et seq., the Board determines that a substance is a toxic air contaminant, its findings must be set forth in a regulation (Section 39662). The HSC also sets forth procedures for developing and adopting control measures for substances identified as TACs (Sections 39665-39667).

III. EVALUATION OF ETHYLENE DICHLORIDE

The ARB and the DHS prioritize candidate substances for evaluation and regulation as toxic air contaminants pursuant to HSC Section 39660(f). That section states that the selection of a substance for consideration as a TAC is to be based on the risk to the public posed by the substance, the amount or potential amount of emissions from use of the substance, its manner of usage in California, its atmospheric persistence, and its concentration in the ambient air.

Under these guidelines, we selected EDC for the Board's consideration as a TAC because it is a known animal carcinogen, it is ubiquitously emitted from the evaporation and burning of leaded gasoline and other activities, it is persistent in the atmosphere, and its presence in the atmosphere has been documented.

A. EMISSIONS, PERSISTENCE AND AMBIENT CONCENTRATIONS OF EDC

Data in Part A are summarized in Table I.

In 1983, the use of gasoline and pesticides accounted for most EDC emissions in California. However, actions taken by the U.S. Environmental Protection Agency have largely eliminated EDC's use (and emissions) as a pesticide and, by 1986, should reduce gasoline-related emissions of EDC by about 88 percent. By then, solvents and minor industrial uses of EDC will be the dominant sources of emission. We expect these uses to increase.

EDC is a persistent pollutant that has been documented in the air of the South Coast Air Basin. No point source is known to cause local concentrations greatly exceeding the range of average ambient concentrations in the table.

The draft of Part A was released for public review and comment. Comments and our responses are presented in Part C.

TABLE 1

Summary of Data in Part A

1983 Emissions, tons	Statewide	South Coast Air Basin
Stationary Sources		
Solvents and minor industrial sources	99	13
Gasoline evaporation	4.7	2.3
Pesticides	65	14
Solid fuel production	1.1	0
Landfills	Unknown	(100 ^a)
Vehicular (from gasoline)	61	26
Atmospheric Half-Life, Days		
(OH* attack, polluted atmosphere)	42	42
Ambient Concentration, ppt^b		
Average (1983)	Unknown	between 19 & 110
Highest 24-hour ^c	Unknown	390

^a less reliable than other entries; emissions from this source may have decreased considerably since 1983

^b parts per trillion; away from the immediate locales of major sources; data from four stations

^c January 1983 to May 1984

B. HEALTH EFFECTS AND RISK

In response to the ARB staff's request and according to HSC Section 39660, the Department of Health Services (DHS) evaluated the health effects of EDC and the risks from exposure to EDC. To ensure satisfaction of the requirement in HSC for the consideration of all pertinent information, we provided DHS with a bibliography of all literature concerning the health effects of EDC. The bibliography (included in Part C) was obtained from the MEDLARS II and DIALOG data bases. Also, we sent a letter (included in Part C) to all known users of EDC and other interested parties to request additional information. The information so obtained was forwarded to DHS.

The DHS' draft report (Part B) was released to the public for comment. The comments received are included in Part C. The revised Part B is presented to the Scientific Review Panel after consideration of those comments.

In meeting the requirements in Section 39660 for DHS' evaluation, the DHS addresses these issues in Part B: 1) Is EDC a carcinogen for animals? 2) Should EDC be considered a carcinogen in humans? 3) May health problems other than cancer occur from exposure to ambient concentrations? 4) Is there a Threshold exposure below which EDC will not cause cancer? 5) What is the range of added risk of cancer during a lifetime of exposure to typical ambient concentrations of EDC? In response to these issues, the DHS concludes (in paraphrase of the conclusions in Part 8) that:

- A. EDC at documented ambient concentrations should not have health effects other than cancer.

- B. EDC is a carcinogen in animals when ingested and may be carcinogenic when inhaled.

- C. EDC should be regarded as a potential carcinogen in people.
- D. No threshold of carcinogenic response should be assumed for EDC.
- E. The best estimate of the range of added lifetime risk of cancer due to exposure to EDC in the air is 53 to 88 cases per million people per part per billion of lifetime average concentration. The actual risks are not likely to be above this range.

These conclusions were drawn from the following observations:

- o Many non-carcinogenic toxic effects of EDC are documented for animals and people but only at exposures several orders of magnitude greater than those corresponding to known concentrations in the ambient air.
- o EDC is absorbed and eliminated rapidly by rats after oral administration or inhalation.
- o For selected tissues, DNA binding after administering ¹⁴C-EDC is greater for oral exposure than for inhalation.
- o Reproductive effects of EDC on rats have been reported at doses several orders of magnitude above those corresponding to exposure via the ambient air.
- o Genotoxic activity by EDC has been reported in vivo for several organisms and in vitro for others, including human lymphocytes.
- o Two major bioassays have been conducted for the carcinogenicity of EDC. The NCI bioassay of 1978 (gavage) showed in rats statistically significant increases in carcinomas of the forestomach, hemangiosarcomas of the circulatory system, fibromas of subcutaneous tissue, and adenocarcinomas of the mammary gland. In mice, the NCI bioassay showed statistically significant increases in hepatocellular carcinomas

and pulmonary adenomas in males and pulmonary adenomas, mammary carcinomas, and endometrial tumors in females. The Maltoni bioassay of 1980 (inhalation) did not show carcinogenicity in rats or mice.

- o The doses in the Maltoni study were not large enough to induce tumors at a statistically significant rate if the carcinogenic potency of EDC is estimated from the NCI results.
- o No evidence demonstrates a carcinogenic threshold for EDC.
- o DHS applied five risk models to the NCI's results for male rats hemangiomas and male mouse hepatocellular carcinomas. The results for a lifetime human exposure of 100 ppt are, in cases per million people:

	Rats		Mice	
	MLE*	95 UCL**	MLE*	95 UCL**
One-Hit	3.8	6.9	2.8	38
Multistage	4.3	6.3	1.6	4.6
Time-corrected multistage	5.3	8.8	2.9	7.4
Probit	8.3	330	0.00	1.1
Gamma multi-hit	18,000	22,000	4.6	94

* maximum likelihood estimate

** 95 percent upper confidence limit

- o DHS believes that the time-corrected multistage model has the best biological basis for extrapolating bioassay data to ambient concentrations.

To estimate the range of risks-associated with the measured ambient concentrations in the South Coast Air Basin, we applied the 95 percent upper confidence limit

recommended by the DHS, 88 cases per million people per ppb, to the upper bound of the mean annual concentration, .100 ppb; and we applied DHS' maximum likelihood risk estimate, 53 cases per million people per ppb, to the lower bound for the mean, .019 ppb. The resulting range of risk is 1 to 10 cases of cancer per million people in 70 years, or about 10 to 100 total cases in 70 years.

IV. ENVIRONMENTAL EFFECTS

The identification of EDC as a TAC will not in itself have any environmental effects. If the Board lists EDC as a TAC, it and the air pollution control districts will evaluate the need for, and appropriate degree of, controls for emission sources. After this evaluation, the Board and the districts may adopt emission control measures. Hence, the identification of EDC as a TAC may ultimately result in the benefit of reduced concentrations of EDC and in other environmental effects that cannot be predicted now. Any environmental effects associated with control measures will be identified when such control measures are considered pursuant to HSC Sections 39665 and 39666.

V. RECOMMENDATION

Because EDC is a known animal carcinogen and potential human carcinogen and it is known to be emitted in California, the ARB staff recommends its listing as a toxic air contaminant treated as a substance without a carcinogenic threshold.