STAFF REPORT/EXECUTIVE SUMMARY

PROPOSED IDENTIFICATION OF



VINYL CHLORIDE

AS A TOXIC AIR CONTAMINANT

OCTOBER 1990

State of California Air Resources Board Stationary Source Division This report has been reviewed by the staffs of the California Air Resources Board and the Department of Health Services and approved for publication. Approval does not signify that the contents necessarily reflect the views and policies of the Air Resources Board or the Department of Health Services, nor does mention of trade names of commercial products constitute endorsement or recommendation for use.

PROPOSED IDENTIFICATION OF VINYL CHLORIDE AS A TOXIC AIR CONTAMINANT

March 13, 1991

Please note the following change to the Staff Report/Executive Summary:

page 12 The second paragraph, second line should be changed from "3 to 36 cancers may occur" to "3 to 26 cancers may occur."

Please note the changes for Part B on the attached errata sheet.

ERRATA:	Technical Support Document, Part B: Proposed Identification of Vinyl Chloride as a Toxic Air Contaminant. October 1990
page ii	"Norman Gravitz, Ph.D." should appear as an author under the heading, "Prepared by: California Department of Health Services."
page 1-2	Second line from bottom change "36 to 26".
page 6-1	At beginning of the second line of text after the initial parenthesis add "IARC, 1987a;
page 7-1	At the end of the second line of text add "IARC, 1987b.
page 8-12	In the label for the dashed horizontal line, insert "(1984b)" between "EPA" and "air." Add a similar horizontal line at .000ll ppb on the vertical scale. The label for this line is "EPA (1985b) air."
page B-5	At the end of the definition of E, delete the phrase following the word, "cohort".
page B-6	line 27: "ppm-persons" should read "ppm-person-yr;" line 28: "persons" should read, "person-yr."
<u>References</u>	
Insert:	Howe RB, Clump KS, Van Landingham C. (1986) <u>GLOBAL 86: A computer</u> program to extrapolate quantal animal toxicity data to low doses. K.S. <u>Crump and Company</u> .

International Agency for Research on Cancer (IARC) (1987b) <u>IARC</u> <u>Monographs on the Evaluation of Carcinogenic Risk to Humans. Supplement</u> 7, Overall Evaluations of Carcinogencity: An Updating of IARC <u>Monographs Volume 1 to 42</u>. Lyon, France pp. 373 376.

Add to the second IARC reference as printed at the top of page R-8;

"a" following "1987,"

Genetic and Related Effects: An Updating of Selected IARC Monographs from Volumes 1 to 42" following Supplement 6."

STAFF REPORT/EXECUTIVE SUMMARY

PROPOSED IDENTIFICATION OF VINYL CHLORIDE AS a TOXIC AIR CONTAMINANT

Prepared by the Staffs of the Air Resources Board and the Department of Health Services

October 1990

What is a toxic air contaminant?

According to section 39655 of the California Health and Safety Code, a toxic air contaminant is "an air pollutant which may cause or contribute to an increase in mortality or en increase in serious illness, or which may pose a present or potential hazard to human health. In addition, substances which have been identified as hazardous air pollutants pursuant to Section 7412 of Title 42 of the United States Code shall be identified by the state board as toxic air contaminants."

What Is vinyl chloride?

Vinyl chloride is a readily flammable, sweet smelling, colorless gas at ambient temperature and pressure. Because vinyl chloride polymerizes in ultraviolet light or the presence of a catalyst, the monomer of this highly volatile compound is used in the commercial production of polyvinyl chloride (PVC).



Vinyl Chloride Monomer

Does the Air Resources Board (ARB) staff recommend Identification of vinyl chloride as a toxic air contaminant?

Yes, the ARB staff recommends that the Board adopt the proposed amendment to section 9300, Titles 17 and 26 of the California Code of Regulations identifying vinyl chloride as-a toxic air contaminant because:

- o there is sufficient evidence that exposure to vinyl chloride poses a public health hazard,
- o vinyl chloride is detected in ambient and indoor air near known emission sources and does not break down in the atmosphere at a rate that would eliminate public exposure,
- vinyl chloride is listed as a hazardous air pollutant by the federal government pursuant to section 7412 of Title 42 of the United States Code; therefore, pursuant to section 39655 of the California Health and Safety Code, vinyl chloride is required to be identified as a toxic air contaminant, and
- o the Department of Health Services (DHS) staff recommends that vinyl chloride be identified as a toxic air contaminant and that vinyl chloride be treated as having no threshold exposure level below which no significant adverse health impacts are anticipated.

Why does the ARB staff recommend the identification of vinyl chloride as a toxic air contaminant when a State ambient air quality standard already exists?

The State ambient air quality standard of 10 ppbv averaged over 24 hours reflects the limit of detection (LOD) for vinyl chloride ambient air concentration analysis in 1978 when the standard was promulgated (the method for calculating the LOD is discussed in Section A, Chapter III, Part A, of the Technical Support Document). This technology-basad standard was developed in response to information which associated the development of cancer in humans with vinyl chloride exposure and is not currently recognized as health-protective. The identification of vinyl chloride as a toxic air contaminant would allow health-protective control measures to be implemented at concentrations below 10 ppbv.

What evidence exists that exposure to vinyl chloride poses a public health hazard?

Acute exposure to vinyl chloride has lead to narcosis, cardiovascular and respiratory irregularity, convulsions, cyanosis, and death. Chronic exposure of workers to vinyl chloride has induced acro-steolysis, vasospasm of the hands, dermatitis, circulatory and central nervous system alterations, thrombocytopenia, splenomegaly, and changes in liver function. However, these noncarcinogenic effects occur at vinyl chloride concentrations near or above 10 ppmv. Because vinyl chloride has never been detected in samples collected from the ARB's 20-station ambient toxic air contaminant network and measured ambient hot spot concentrations range from 10 to 15 ppbv, the California Department of Health Services (DHS) staff do not expect noncarcinogenic adverse health effects from exposures to current concentrations of vinyl chloride found in ambient air.

The International Agency for Research on Cancer (IARC) lists vinyl chloride in

Group 1 of its carcinogen classification scheme. The United States Environmental Protection Agency

-3-

(EPA) lists vinyl chloride in Group A of its carcinogen classification scheme. The IARC, the

EPA, and the DHS have designated vinyl chloride a chemical for which there is sufficient evidence of carcinogenicity in both humans and experimental animals. Epidemiological studies of occupationally exposed human workers have linked vinyl chloride exposure to the development of a rare cancer, liver angiosarcoma, and have suggested a relationship between exposure and cancers of the lung and brain. Chronic inhalation and oral exposures of rats, mice, and hamsters to vinyl chloride have been associated with an increased incidence of malignant and benign tumors at several sites including the liver, lungs, mammary glands, and the nervous system. Vinyl chloride is mutagenic in both prokaryotic and eukaryotic test systems.

Is there a threshold level for vinyl chloride?

Since vinyl chloride is carcinogenic end mutagenic and there is not sufficient evidence at this time to support the designation of an exposure level below which no significant adverse health impacts are anticipated, the DHS staff recommend that vinyl chloride be treated as having no threshold exposure level.

Is vinyl chloride produced or used In California?

Vinyl chloride is not produced in California, however, it is estimated that several thousand tons are used each year by two facilities producing polyvinyl chloride: Polyvinyl chloride is used by fabricators for the production of materials employed by the construction, packaging, electrical, and transportation industries.

What are the sources of vinyl chloride emissions?

Landfills, publicly-owned treatment works (POTWs), and polyvinyl chloride (PVC) production and fabrication facilities are the major identified sources of vinyl chloride emissions in California.

In 1987, section 41805.5 of the California Health and Safety Code required the testing of landfills for specified compounds including vinyl chloride. The data gathered in the Landfill Gas Tasting Program will be used by air pollution control districts to provide a relative ranking of the sites based on the potential for emissions of toxic compounds and the potential for exposure. The data show that vinyl chloride concentrations ranging from a detection limit (the Testing Guidelines example method for calculating the detection limit is discussed in Chapter II, Part A of the Technical Support Document) of 106 ppbv to 72,000 ppbv were detected in the internal gas of 160 (47 percent) out of the 340 landfills at which internal gas testing was conducted. he presence of vinyl chloride in internal landfill gas represents a potential source of vinyl chloride emissions.

The South Coast Air Quality Management District (SCAQMD) conducted long-term, intensive ambient vinyl chloride monitoring on two landfills in the South Coast Area Basin (SCAB): Operating Industries Incorporated (OII) Landfill and BKK Landfill. OII Landfill is located near Monterey Park, California and BKK Landfill is located near West Covina, California. The test data for the OII Landfill was obtained from January 1986 through December 1986, while data for the BKK Landfill was obtained from January 1987 through December 1987. Based on 24-hour averaged ambient data from these testing periods, cumulative vinyl chloride emissions were estimated to range from 50 to 250 tons per year. The vinyl chloride emissions of OII and

-4-

BKK are not likely to be typical of other California landfills. However, monitoring required by the Landfill Gas Testing Program mentioned above showed 24-hour averaged ambient vinyl chloride concentrations ranging from the detection limit (the Testing Guidelines example method for calculating the LOD is discussed in Chapter II, Part A of the Technical Support Document) of 2 ppbv to 15 ppbv at 24 (10 percents out of the 251 landfills tested for ambient concentrations.

-5-

Since the SCAQMD's study, the vinyl chloride emissions at OII and BKK landfills are expected to have decreased because subsequent ambient levels in perimeter monitoring samples were typically below the detection limit in the late 1980's. This decrease in ambient vinyl chloride concentrations near the landfills is attributed to the installation of gas collectors and flares.

POTWs emitted an estimated 1.7 tons of vinyl chloride in 1985. PVC production facilities emitted lass than 0.5 tons of vinyl chloride in 1988 while PVC fabrication facilities emitted an estimated 0.75 tons of vinyl chloride in 1982.

What is the persistence of vinyl chloride in the atmosphere?

Vinyl chloride is estimated to be degraded In 1.6 to 3.9 days through its reaction with hydroxyl radicals in the atmosphere. Therefore, vinyl chloride is sufficiently persistent to be transported throughout an air basin before it is degraded.

What is the ambient concentration of vinyl chloride?

Vinyl chloride has never been detected in samples collected at the 20 monitoring stations of the ARB's ambient toxic air contaminant monitoring network. Since detectable levels in California are limited to locations near identified emission sources such as landfills, vinyl chloride exposure poses a potential near-source risk rather than a statewide risk.

The monitoring required by the Landfill Gas Tasting Program (section 41805.5 of the

California Health and Safety Code effective in 1987) showed 24-hour average ambient vinyl chloride concentrations ranging from the detection limit (the Testing Guidelines example method for calculating the LOD is discussed in Chapter II, Part A of the Technical Support Document) of 2 ppbv to 15 ppbv at 24 out of 251 landfills tested for ambient concentrations.

-6-

The South Coast Air Quality Management District (SCAQMD) obtained vinyl chloride ambient monitoring from locations near two landfills in the South Coast Air Basin. The LOD for the SCAQMD vinyl chloride monitoring study was 2 ppbv (the SCAQMD's method for calculating the LOD is discussed in Chapter III, Part A of the Technical Support Document). At the OII Landfill from January through December of 1986, 24-hour average concentrations of vinyl chloride ranged from below the LOD to 9.8 ppbv with a mean of 1.0 to 2.0 ppbv. The U.S. Environmental Protection Agency (EPA) states, "The Operating Industries, Incorporated (OII) Landfill is currently a federally listed Superfund site. Subsequent to the SCAQMD's vinyl chloride sampling during 1986, the Environmental Protection Agency (EPA) has implemented more stringent landfill gas control measures. The EPA has also selected a remedy for landfill gas control that is expected to substantially reduce landfill gas emissions from the OII Landfill. It is fully anticipated that these control measures will substantially lower the levels of vinyl chloride in the ambient air in the vicinity of the OII Landfill." At the BKK Landfill from January through December of 1987, 24-hour average concentrations of vinyl chloride ranged from below the LOD to 15 ppbv with a mean of 1.2 to 2.6 ppbv.

What is the exposure level of people living near sources such as landfills?

Population-weighted exposure estimates, based on computer modeling by the ARB staff, showed that the maximum exposed individual living near OII Landfill was estimated to be exposed to an annual average vinyl chloride concentration ranging from 0.6 to 9 ppbv. Modeled cumulative population exposure estimates (not population-weighted) predicted that 0 to

6,000 people living close to OII may have been exposed to annual average concentrations of at least 3 ppbv (see Table I). Population-weighted exposure results estimated that approximately four million people living within about 25 square miles of OII Landfill may have been exposed to estimated annual average vinyl chloride concentrations ranging from 0.004 to 0.06 ppbv in 1986.

-7-

TABLE I

RANGE OF CUMULATIVE POPULATION EXPOSED TO VINYL CHLORIDE NEAR OII

Range of Cumulative Population			Exposed to Vinyl Chloride
Lower-bound Estimate ^a		Upper-bound Estimate ^b	Concentrations (ppbv) at or above:
4,287,300	-	4,287,300	>0 but <0.01 ^c
272,000	-	3,111,000	0.01
33,000	-	1,073,000	0.05
12,000	-	445,000	0.10
0	-	22,000	1.0
0	-	12,000	1.5
0	-	6,000	2.0
0	-	6,000	3.0

^a - The exposure estimate is based on an emission rate of $0.31 \,\mu g/m^2 s^{-1}$.

^b - The exposure estimate is based on an omission rata of 4.42 μ g/m²s⁻¹.

^c - According to the model, the entire cumulative population studied was at least exposed to vinyl chloride concentrations between 0 and less than 0.01 ppbv. In addition, calculated population-weighted exposure for this population was estimated to range from an annual average of 0.004 to 0.06 ppbv vinyl chloride.

For the BKK Landfill, the population-weighted exposure results showed that the maximum exposed individual living near BKK was estimated to be exposed to an average annual concentration of 2 to 10 ppbv. Modeled cumulative population exposure estimates (not population-weighted) predicted that 0 to 2,500 people living close to BKK may have been exposed to annual average concentrations of at least 7 ppbv (see Table II). Population-weighted exposure results estimated that approximately two million people living within about 25 square miles of BKK Landfill may have been exposed to annual average vinyl chloride concentrations ranging from 0.08 to 0.34 ppbv in 1987.

-8-

TABLE II

RANGE OF CUMULATIVE POPULATION EXPOSED TO VINYL CHLORIDE NEAR BKK

Range of Cumulative Population			Exposed to Vinyl Chloride Concentrations (ppbv) at or above:
Lower-bound Estimate ^a	Upper-bound Estimate ^b		
2,154,000	-	2,154,000	>0 but <0.01 ^c
2,026,000	-	2,154,000	0.01
732,000	-	1,970,000	0.05
374,000	-	1,431,000	0.1
0	-	131,000	1.0
0	-	54,000	2.0
0	-	28,000	3.0
0	-	20,000	4.0
0	-	14,000	5.0
0	-	7,000	6.0

0 -	2,500	7.0
-----	-------	-----

- ^a The exposure estimate is based on an emission rate of 0.75 μ g/m²s⁻¹.
- ^b The exposure estimate is based on an emissions rate of $3.32 \,\mu g/m^2 s^{-1}$.
- According to the model, the entire population was at least exposed to vinyl chloride concentrations between 0 and 0.01 ppbv. In addition, the calculated population-weighted exposure for this population was estimated to range from an annual average of 0.08 to 0.34 ppbv vinyl chloride.

These exposure estimates are based on ambient date only end do not include any possible elevated indoor exposures that may occur inside homes near landfills.

-9-

Is there evidence of Indoor air exposure to vinyl chloride?

In California, vinyl chloride in indoor air has been detected only in houses near landfills. In 1985, a South Coast Air Quality Management District (SCAQMD) indoor air grab-sample study showed vinyl chloride concentrations ranging from 8 to 100 ppbv in some homes near OII Landfill. Present indoor vinyl chloride concentrations in the residences near OII are believed to be lower due to OII's installation of gas collectors and flares subsequent to the SCAQMD study. In order to test this idea, additional indoor air monitoring at homes adjacent to the landfill is being considered. To date, no indoor vinyl chloride has been detected in studies of homes not located near landfills.

Are there other routes of exposure to vinyl chloride?

Exposure to vinyl chloride may also occur from ingestion of food and water that contain residues of the substance.

Prior to 1975, vinyl chloride monomer levels as high as 20 ppmw were found in food packaged in vinyl chloride polymer containers or materials. In 1986, the Food and Drug Administration (FDA) proposed to limit the maximum amount of residual vinyl chloride monomer in rigid and semi-rigid food containers to 10 ppbw and the maximum amount of vinyl chloride monomer allowed in polymeric coatings and films which contact food to 5 ppbw. According to an FDA official, the regulation was not promulgated because it was believed that monomer stripping processes reeve no residue of vinyl chloride monomer. An estimate of the potential for vinyl chloride exposure from food ingestion is not possible because, to our knowledge, current information on the levels in food and food packaging is not available. The vinyl chloride exposure estimates in this Staff Report/Executive Summary and in the accompanying Technical Support Document do not account for potential exposure from polymeric food packaging.

-10-

In California, surface water and ground water from public water systems are generally free of vinyl chloride. Since it is not typically detected in drinking water, exposure through this route is not expected to significantly contribute to the cancer burden attributed to vinyl chloride.

What is the risk assessment for exposure to vinyl chloride?

The DHS analyzed many human occupational and animal studies in the cancer risk assessment for vinyl chloride exposure. Predictions from the majority of the studies of humans exposed to vinyl chloride occupationally are uncertain due to inadequate exposure data, insufficient follow-up time, and methodological problems. Based on the exposure estimates for vinyl chloride workers in the Waxweiler, et al. (1976) study, the 95% upper confidence limit on the lifetime unit risk of contracting cancer from vinyl chloride ranged from 2.5 x 10^{-5} ppb⁻¹ to 4.5×10^{-5} ppb⁻¹. Evaluation of animal experiments using the linearized multistage model leads to predictions of upper confidence limits on unit risks for humans ranging from 3.7×10^{-5} ppb⁻¹ to 20×10^{-5} ppb⁻¹. Considering tumorgenicity data as well as the results of human and animal studies, the DHS staff conclude that the overall range of upper confidence limits on cancer unit risk is 2.5×10^{-5} ppb⁻¹ to 20×10^{-5} ppb⁻¹. In order to ensure protection of public health, the DHS has identified the best estimate of cancer unit risk to be 20×10^{-5} ppb⁻¹, the top of the upper

confidence limits range. Using the best estimate of cancer unit risk, an estimated 200 cancers may occur in one million people exposed to 1 ppbv of vinyl chloride for a 70-year lifetime.

Because vinyl chloride has not been detected in statewide ambient air monitoring, 24-hour averaged hot spot concentrations detected by monitors near two South Coast landfills ware used in a model to estimate annual average outdoor concentrations and to assess the probable impact of vinyl chloride on the cancer burden for people living near these landfills.

Population-weighted modeled estimates of peak exposure concentrations for maximally exposed receptors ranged from 0.6 to 9 ppbv at the OII Landfill and from 2 to 10 ppbv at the BKK Landfill.

-11-

An estimated 17,000 to 131,000 persons were exposed to 1 ppbv of vinyl chloride near the BKK Landfill where the highest exposures ware predicted from the monitoring results of 1987. Using the upper confidence limits range of risks, the DHS estimated that 3 to 36 cancers may occur in 131,000 persons due to lifetime exposure to 1 ppbv of vinyl chloride.

All of the above estimates represent the upper range of plausible excess cancer risk. Estimates of actual risks could be much lower.

What are the alternatives to identifying vinyl chloride as a TAC?

California Government Code section 11346.14 requires agencies to describe alternatives to the regulation considered by the agency and the agency's reasons for rejecting those alternatives. The only alternative to identifying vinyl chloride is not to identify it. We are not recommending this alternative because we believe that vinyl chloride meets the definition of a toxic air contaminant and because vinyl chloride is listed as a hazardous air pollutant by the federal government pursuant to section 7412 of Title 42 of the United States Code; therefore, pursuant to section 39665, vinyl chloride is required to be identified as a toxic air contaminant.

What would be the environmental impact of the identification of vinyl chloride as a toxic air contaminant?

The identification of vinyl chloride as a toxic air contaminant is not itself expected to result in any impact on the environment.

The Board's identification of vinyl chloride as a toxic air contaminant may result in the adoption of control measures according to the California Health and Safety Code sections 39665 and 39666. Subsequent to identification, the implementation of control measures would benefit the public health by reducing vinyl chloride emissions resulting in a reduced health risk due to vinyl chloride exposure.

-12-

Environmental impacts identified with respect to specific control measures will be included in the consideration of such control measures pursuant to the California Health and Safety Code sections 39665 and 39666.

What are the findings of the Scientific Review Panel?

In accordance with California Health and Safety Code section 39661, the Scientific Review Panel (SRP) has reviewed the report prepared by the staffs of the Air Resources Board (ARB) and the Department of Health Services (DHS) on the public exposure to, and health effects of vinyl chloride. The Panel has also reviewed the public comments received on this report. Based on this review, the SRP finds that the report on vinyl chloride is without serious deficiencies and agrees with the staffs of the ARB and the DHS that:

 There is strong evidence that exposure to vinyl chloride results in animal and human carcinogenicity. The United States Environmental Protection Agency (U.S. EPA) assigned vinyl chloride to Group A of its classification scheme for carcinogens. In explaining its Group A category, the EPA states, "This group is used only when there is sufficient evidence from epidemiologic studies to support a causal association between exposure to the agents and cancer." The International Agency for Research on Cancer (IARC) assigned vinyl chloride to Group 1 of its classification scheme for carcinogens. In introducing its list of Group 1 carcinogens which included vinyl chloride, the IARC states, "The Working Group concluded that the following agents are carcinogenic to humans." Based on available scientific data, the Panel agrees with the EPA's and the IARC's classification of vinyl chloride as a human carcinogen.

2. Based on available scientific information, the DHS staff found no evidence of a vinyl chloride exposure level below which no carcinogenic effects are anticipated.

-13-

3. Based on the interpretation of available scientific evidence, the DHS staff estimated that the upper 95 percent confidence limits on the lifetime risk of cancer from vinyl chloride ranged from 2.5 x 10^{-5} ppb⁻¹ to 20 x 10^{-5} ppb⁻¹. The DHS staff identified the best estimate of vinyl chloride cancer unit risk as the top of the upper confidence limits range, 20 x 10^{-5} ppb⁻¹ or 7.8 x 10^{-5} (μ g/m³)⁻¹. Table III compares the best estimate of vinyl chloride cancer unit risk with those of other compounds recently reviewed by the SRP.

Compound	Unit Risk (ppbv ⁻¹)	Unit Risk $(\mu g/m^3)^{-1}$
Vinyl Chloride	20 x 10 ⁻⁵	7.8 x 10 ⁻⁵
Chloroform	2.6 x 10 ⁻⁵	5.3 x 10 ⁻⁶
Trichloroethylene	1.1 x 10 ⁻⁵	2 x 10 ⁻⁶
Inorganic Arsenic	particulate	3.3 x 10 ⁻³
Methylene Chloride	3.5 x 10 ⁻⁶	1 x 10 ⁻⁶

TABLE III

Upper bound excess lifetime risks are health-protective estimates; the actual risk may wall be below these values.

- Landfills, publicly-owned treatment works, and polyvinyl chloride producers and fabricators are the mayor identified sources of vinyl chloride emissions in California's outdoor air.
- 5. Based on its gas-phase reactivity with hydroxyl radicals, vinyl chloride's estimated tropospheric lifetime ranges from 1.6 to 3.9 days.

-14-

- 6. Vinyl chloride has not been detected by the ARB's statewide ambient toxic air contaminant monitoring network. However, vinyl chloride has been detected in the ambient air near emission sources such as landfills.
- 7. The limited monitoring conducted in the Landfill Gas Testing Program which began in 1987 was designed to identify landfill sites that pose a potential risk to public health. Preliminary findings show that vinyl chloride concentrations ranging from the detection limit of 106 ppbv to 72,000 ppbv were detected in the internal gas of 160 (47 percent) out of the 340 landfills at which internal gas testing was performed. 24-hour averaged ambient vinyl chloride concentrations ranging from the detection limit of 2 ppbv to 15 ppbv ware detected at 24 (10 percent) out of the 251 landfills at which ambient monitoring was performed. The limited testing conducted was designed to be used for screening purposes. For that reason, vinyl chloride may be present in the ambient air at additional landfills, but was not detected in the one to three days of ambient testing specified in the testing guidelines for the Program. Further interpretation of the data from specific landfill sites must also consider factors such as how the testing was

carried out, along with location, size, and proximity to sensitive receptors.

8. Ambient vinyl chloride data from perimeter monitoring by the South Coast Air Quality Management District (SCAQMD) at two landfills in 1986 and 1987 were used in a model to estimate population-weighted exposures near the sites. These exposure estimates ware based on ambient outdoor data and do not include any possible elevated indoor exposures that may occur inside homes near the landfills. The cancer risk from vinyl chloride exposure to people residing in the vicinity of the landfills may be determined using the DHS's best estimate of vinyl chloride cancer unit risk of 20 x 10⁻⁵ ppb⁻¹ (see Finding 3 above) and the modeled population-weighted exposure estimates.

-15-

- a. Population-weighted exposure for maximally exposed individuals living immediately adjacent to the landfills (at the fence line) was estimated to range from an annual average of approximately 0.6 to 9 ppbv vinyl chloride at OII Landfill and from approximately 2 to 10 ppbv at BKK Landfill.
- b. Modeled estimates of exposure (not population-weighted) for 0 to 6,000 people living close to OII and for 0 to 2,500 people living close to BKK are included to provide an idea of the predicted exposure levels and risk directly downwind from the landfills. According to the modal, 0 to 6,000 people near OII may have been exposed to annual average vinyl chloride concentrations of at least 3 ppbv and 0 to 2,500 people near BKK may have been exposed to annual average concentrations of at least 7 ppbv. Using the DHS's best estimate of cancer unit risk, 0 to 4 or more cancers were estimated to occur among the 6,000 people living closest to OII; and 0 to 4 or more cancers were estimated to occur among the 2,500 people living closest to BKK.

- c. Population-weighted exposure results ware calculated for the people living within a. 41 square-kilometer area (or, approximately 25 square-mile area) of each landfill. For OII Landfill, approximately 4 million people may have been exposed to average annual concentrations ranging from 0.004 to 0.06 ppbv. For BKK Landfill, approximately 2 million people may have been exposed to annual average concentrations ranging from 0.08 to 0.34 ppbv. Using the DHS's best estimate of cancer unit risk, 4 to 48 cancers were estimated for the 4 million people living within approximately 25 square miles of OII; and 32 to 136 cancers ware estimated for the 2 million people living within approximately 25 square miles of BKK.
- 9. The limited data available indicate that the vast majority of homes have very low, often undetectable, indoor vinyl chloride concentrations. However, grab samples collected by the South Coast Air Quality Management District (SCAQMD) in 1985 showed concentrations ranging from 8 to 100 ppbv inside a few homes near OII Landfill

-16-

mentioned in Finding 8. Currant indoor concentrations in the homes studied by the SCAQMD in 1985 are expected to be lower because of the subsequent installation of a landfill gas collection and flare system. In order to test this idea, additional indoor air monitoring at homes adjacent to the landfill is being considered.

Since vinyl chloride is not typically detected in indoor air, exposure through this route is not expected to significantly contribute to overall risk, except in the vicinity of certain landfills.

10. Non-carcinogenic health effects are not known to occur at: 1) the highest recorded 24-hour average outdoor concentration in California (15 ppbv) (see Finding 7), 2) the estimated outdoor average annual vinyl chloride concentrations (see Findings 6 and 8), or 3) the highest recorded vinyl chloride concentration from the air inside a California home (100 ppbv) (see Finding 9).

11. Prior to 1975, vinyl chloride monomer levels as high as 20 ppmw were found in food packaged in vinyl chloride polymer containers or materials. In 1986, the Food and Drug Administration (FDA) proposed to limit the maximum amount of residual vinyl chloride monomer in rigid and semi-rigid food containers to 10 ppbw and the maximum amount of vinyl chloride monomer allowed in polymeric coatings and films which contact food to 5 ppbw. According to an FDA official, the regulation was not promulgated because it was believed that monomer stripping processes leave no residue of vinyl chloride monomer. There is no further information available on the levels of vinyl chloride in food containers and packaging. The exposure estimates in Finding 8 do not account for potential exposure from polymeric food packaging.

In California, surface water and ground water from public water systems are generally free of vinyl chloride. Since it is not typically detected in drinking water, exposure

-17-

through this route is not expected to significantly contribute to the cancer burden attributed to vinyl chloride.

- 12. Because vinyl chloride was identified as a hazardous air pollutant under Section 112 of the United States Clean Air Act, identification of vinyl chloride as a toxic air contaminant is required by California Health and Safety Code section 39655.
- 13. Based on all available scientific evidence, including consistent animal and human studies and the small range of dose extrapolation (from the animal studies), we conclude that the data are overwhelming that vinyl chloride is a toxic air contaminant.

We agree with the ARB staff recommendation to its Board that vinyl chloride be listed as a toxic air contaminant.

-18-

	California State University, Fullerton Fullerton California 92634		
Department of Chemistry and Biochemistry (714) 773-3621	Correspondence to: P.O. Box 669		
	San Clemente, CA 92674-669 Phone: (714) 361-1132 FAX: (714) 361-		
1283	Thone. (714) 501-1152 17MX. (714) 501-		

October 22, 1990

Mr. William C. Lockett, Chief Office of External Affairs California Air Resources Board 1102 Q Street Sacramento, California 95814 Dear Bill:

The Scientific Review Panel on Toxic Air Contaminants has reviewed the Report of Vinyl Chloride and has formulated its findings regarding the report. I am formally submitting the Scientific Review Panel's findings to the Air Resources Board.

Sincerely,

//s// Dr. James N. Pitts, Jr. Chair, Scientific Review Panel

Enclosure

cc: Scientific Review Panel

-19-<u>Scientific Review Panel Findings on the</u> <u>Vinyl Chloride Report</u>

As Adopted at the Panel's October 19, 1990 Meeting

In accordance with California Health and Safety Code section 39661, the Scientific Review Panel (SRP) has reviewed the report prepared by the staffs of the Air Resources Board (ARB) and the Department of Health Services (DHS) on the public exposure to, and health effects of vinyl chloride. The Panel has also reviewed the public comments received on this report. Based on this review, the SRP finds that the report on vinyl chloride is without serious deficiencies and agrees with the staffs of the ARB and the DHS that:

1. There is strong evidence that exposure the vinyl chloride results in animal and human

carcinogenicity. The United States Environmental Protection Agency (U.S. EPA) assigned vinyl chloride to Group A of its classification scheme for carcinogens. In explaining its Group A category, the U.S. EPA states, "This group is used only when there is sufficient evidence from epidemiologic studies to support a causal association between exposure to the agents and cancer." The International Agency for Research on Cancer (IARC) assigned vinyl chloride to Group 1 of its classification scheme for carcinogens. In introducing its list of Group 1 carcinogens which included vinyl chloride, the IARC states, "The Working Group concluded that the following agents are carcinogenic to humans." Based on available scientific data, the Panel agrees with the U.S. EPA's and the IARC's classification of vinyl chloride as a human carcinogen.

- 2. Based on available scientific information, the DHS staff found no evidence of a vinyl chloride exposure level below which no carcinogenic effects are anticipated.
- 3. Based on the interpretation of available scientific evidence, the DHS staff estimated that the upper 95 percent confidence limits on the lifetime risk of cancer from vinyl chloride

-20-

ranged from 2.5 x 10^{-5} ppb⁻¹ to 20 x 10^{-5} ppb⁻¹. The DHS staff identified the best estimate of vinyl chloride cancer unit risk as the top of the upper confidence limits range, 20 x 10^{-5} ppb⁻¹ or 7.8 x $10^{-5}(\mu g/m^3)^{-1}$. Table 1 compares the best estimate of vinyl chloride cancer unit risk with those of other compounds recently reviewed by the SRP.

TABLE 1

Compound	Unit Risk (ppbv ⁻¹)	Unit Risk $(\mu g/m^3)^{-1}$
Vinyl Chloride	20 x 10 ⁻⁵	7.8 x 10 ⁻⁵
Chloroform	2.6 x 10 ⁻⁵	5.3 x 10 ⁻⁶
Trichloroethylene	1.1 x 10 ⁻⁵	2 x 10 ⁻⁶

Compound	Unit Risk (ppbv ⁻¹)	Unit Risk $(\mu g/m^3)^{-1}$
Inorganic Arsenic	particulate	3.3 x 10 ⁻³
Methylene Chloride	3.5 x 10 ⁻⁶	1 x 10 ⁻⁶

Upper bound excess lifetime risks are health-protective estimates; the actual risk may wall be below these values.

- 4. Landfills, publicly-owned treatment works, and polyvinyl chloride producers and fabricators are the major identified sources of vinyl chloride emissions in California's outdoor air.
- 5. Based on its gas-phase reactivity with hydroxyl radicals, vinyl chloride's estimated tropospheric lifetime ranges from 1.6 to 3.9 days.
- 6. Vinyl chloride has not been detected by the ARB's statewide ambient toxic air contaminant monitoring network. However, vinyl chloride has been detected in the ambient air near emission sources such as landfills.
- 7. The limited monitoring conducted in the Landfill Gas Testing Program which began in 1987 was designed to identify landfill sites that pose a potential risk to public health. Preliminary findings show that vinyl chloride concentrations ranging from the detection limit of 106 ppbv to 72,000 ppbv were detected in the internal gas of 160 (47 percent) out of the 340 landfills at which internal gas testing was performed. 24-hour averaged ambient vinyl chloride concentrations ranging from the detection limit of 2 ppbv to 15 ppbv were detected at 24 (10 percent) out of the 251 landfills at which ambient

-21-

monitoring was performed. The limited testing conducted was designed to be used for screening purposes. For that reason, vinyl chloride may be present in the ambient air at additional landfills, but not detected in the one to three days of ambient testing specified in the testing guidelines for the Program. Further interpretation of the data from specific landfill sites must also consider factors such as how the testing was carried out, along with location, size, and proximity to sensitive receptors.

8. Ambient vinyl chloride data form perimeter monitoring from the South Coast Air Quality Management District (SCAQMD) at two landfills in 1986 and 1987 were used in a model to estimate population-weighted exposures near the sites. These exposure estimates were based on ambient outdoor data and do not include any possible elevated indoor exposures that may occur inside homes near the landfills. The cancer risk from vinyl chloride exposure to people residing in the vicinity of the landfills may be determined using the DHS's best estimate of vinyl chloride cancer unit risk of 20×10^{-5} ppb⁻¹ (see Finding 3 above) and the modeled population-weighted exposure estimates.

- a. Population-weighted exposure for maximally exposed individuals living immediately adjacent to the landfills (at the fence line) was estimated to range from an annual average of approximately 0.6 to 9 ppbv vinyl chloride at OII landfill and from approximately 2 to 10 ppbv at BKK Landfill.
- b. Modeled estimates of exposure (not population-weighted) for 0 to 6,000 people living close to OII and for 0 to 2,5000 people living close to BKK are included to provide and idea of the predicted exposure levels and risk directly downwind from the landfills. According to the model, 0 to 6,000 people near OII may have been exposed to annual average vinyl chloride concentrations of at least 3 ppbv and 0 to 2,500 people near BKK may have been exposed to annual average concentrations of at least 7 ppbv. Using the DHS's best estimate of cancer unit risk, 0 to 4 or more cancers were estimated to occur among the 2,500 people living closest to BKK.
- c. Population-weighted exposure results were calculated for the people living within a 41 square-kilometer area (or, approximately 25 square-mile area) of each landfill. For OII Landfill, approximately 4 million people may have been exposed to average annual concentrations ranging from 0.004 to 0.06 ppbv. For BKK Landfill, approximately 2 million people may have been exposed to annual average concentrations ranging from 0.08 to 0.34 ppbv. Using the DHS's best estimate of cancer unit risk, 4 to 48 cancers were estimated for the 4 million people living within approximately 25 square miles of OII: and 32 to 136 cancers were estimated for the 2 million people living within approximately 25 square miles of BKK.
- 9. The limited data available indicate that the vast majority of homes have very low, often undetectable, indoor vinyl chloride concentrations. However, grab samples collected by the South Coast Air Quality Management District (SCAQMD) in 1985 showed

-22-

concentrations ranging from 8 to 100 ppbv inside a few homes near OII Landfill mentioned in Finding 8. Current indoor concentrations in the homes studied by the SCAQMD in 1985 are expected to be lower because of the subsequent installation of a landfill gas collection and flare system. In order to test this idea, additional indoor air monitoring at homes adjacent to the landfill is being considered.

Since vinyl chloride is not typically detected in indoor air, exposure through this route is not expected to significantly contribute to overall risk, except in the vicinity of certain landfills.

10. Non-carcinogenic health effects are not known to occur at: 1) the highest recorded 24-hour average outdoor concentration in California (15 ppbv) (see Finding 7), 2) the estimated outdoor average annual vinyl chloride concentrations (see Findings 6 and 8),

or 3) the highest recorded vinyl chloride concentration from the air inside a California home (100 ppbv) (see Finding 9).

11. Prior to 1975, vinyl chloride monomer levels as high as 20 ppmw were found in food packaged in vinyl chloride polymer containers or materials. In 1986, the Food and Drug Administration (FDA) proposed to limit the maximum amount of residual vinyl chloride monomer in rigid and semi-rigid food containers to 10 ppbw and the maximum amount of vinyl chloride monomer allowed in polymeric coatings and films which contact food to 5 ppbw. According to and FDA official, the regulation was not promulgated because it was believed that monomer stripping processes leave no residue of vinyl chloride monomer. There is no further information available on the levels of vinyl chloride in food containers and packaging. The exposure estimates in Finding 8 do not account for potential exposure from polymeric food packaging.

In California, surface water and ground water from public water systems are generally free of vinyl chloride. Since it is not typically detected in drinking water, exposure through this route is not expected to significantly contribute to the cancer burden attributed to vinyl chloride.

- 12. Because vinyl chloride was identified as a hazardous air pollutant under Section 112 of the United States Clean Air Act, identification of vinyl chloride as a toxic air contaminant is required by California Health and Safety Code section 39655.
- 13. Based on all available scientific evidence, including consistent animal and human studies and the small range of dose extrapolation (from the animal studies), we conclude that the data are overwhelming that vinyl chloride is a toxic air contaminant.

-23-

We agree with the ARB staff recommendation to its Board that vinyl chloride be listed as a toxic air contaminant.

I certify that the above is a true and correct copy of the findings adopted by the Scientific Review Panel on October 19, 1990.

//s//

Dr. James N. Pitts, Jr. Chairman, SRP

-24-
