FINAL STATEMENT OF REASONS
22 CALIFORNIA CODE OF REGULATIONS

Section 12705(b): Specific Regulatory Levels Posing No Significant Risk: Dichloromethane (Methylene chloride), Trichloroethylene, Vinyl chloride

The Safe Drinking Water and Toxic Enforcement Act of 1986 (hereinafter the Act) prohibits a person in the course of doing business from knowingly and intentionally exposing any individual to a chemical that has been listed as known to the State to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual (Health and Safety Code Section 25249.6). The Act also prohibits a business from knowingly discharging a listed chemical into water or onto or into land where such chemical passes or probably will pass into a source of drinking water (Health and Safety Code Section 25249.5).

For chemicals known to the state to cause cancer, an exemption is provided by the Act for exposures which the person can show to pose no significant risk (Health and Safety Code Sections 25249.10). A determination that a level of exposure poses no significant risk can be made utilizing existing regulations (Section 12701 to 12721, Title 22, California Code of Regulations). (Unless otherwise indicated, all section references are to Title 22, California Code of Regulations.)

Section 12701 describes alternative methods for making such a determination. One such method is through the application of the specific regulatory level established for the chemical in question in Section 12705. Section 12705(b) supersedes Section 12709 (Exposure to Trace Elements), Section 12711 (Levels Based on State or Federal Standards), and Section 12713 (Exposure to Food, Drugs, Cosmetics and Medical Devices).

Procedural Background

On April 10, 1992, the Office of Environmental Health Hazard Assessment (OEHHA) issued a notice of proposed rulemaking advising that the agency intends to adopt "no significant risk" levels for dichloromethane (methylene chloride), trichloroethylene, and vinyl chloride. Pursuant to such notice, on May 29, 1992, a public hearing was held to receive public comments on the proposed regulation. Two pieces of correspondence were received on this proposed regulation.

By notice dated July 13, 1992, OEHHA made changes to the proposed regulation, and provided a 15-day comment period during which interested persons could comment on the changes. No post-hearing comments were received.

Purpose of Final Statement of Reasons

This final statement of reasons sets forth the reasons for the final regulation adopted by OEHHA for Section 12705, and responds to the objections and recommendations submitted regarding the regulation. Government Code Section 11346.7, subsection (b)(3) requires that the final statement of reasons submitted with an amended or adopted regulation contain a summary of each objection or recommendation made regarding the adoption or amendment, together

with an explanation of how the proposed action has been changed to accommodate each objection or recommendation, or the reasons for making no change. It specifically provides that this requirement applies only to objections or recommendations specifically directed at the proposed action or to the procedures followed in proposing or adopting the action.

Some parties included in their written or oral comments remarks and observations about the regulation which do not constitute an objection or recommendation directed at the proposed action or the procedures followed. Accordingly, OEHHA is not obligated under Government Code Section 11346.7 to respond to such remarks in this final statement of reasons. Since OEHHA is constrained by limitations upon its time and resources, and is not obligated by law to respond to such remarks, OEHHA has not responded to these remarks in this final statement of reasons. The absence of a response in this final statement of reasons to such remarks should not be construed to mean that OEHHA agrees with them.

Specific Findings

Throughout the adoption process of this regulation, OEHHA has considered the alternatives available to determine which would be more effective in carrying out the purpose for which the regulation was proposed, or would be as effective and less burdensome to affected private persons than the proposed regulation. OEHHA has determined that no alternative considered would be more effective than, or as effective and less burdensome to affected persons than, the adopted regulation.

OEHHA has determined that the regulation imposes no mandate on local agencies or school districts.

Rulemaking File

The rulemaking file submitted with the final regulation and this final statement of reasons is the complete rulemaking file for this amendment to Section 12705 and 12711.

Necessity for Adoption of Regulations

For chemicals known to the State to cause cancer, the Act exempts discharges, releases and exposures which, making certain assumptions, pose no significant risk. The Act specifies that any claim of exemption under Health and Safety Code Section 25249.10, subsection (c), must be based upon evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of the chemical. However, the Act does not further clarify when a chemical risk is not significant, nor specify levels of chemical exposures posing no significant risk. Existing regulations describe methods for calculating levels which pose no significant risk.

The purpose of this regulation is to provide "safe harbor" no significant risk levels for dichloromethane (methylene chloride), trichloroethylene and vinyl chloride, below which the Act does not apply. These levels will allow persons to determine whether a discharge, release or exposure involving these chemicals is exempt from the provisions of the Act.

Although existing regulations describe principles and assumptions for conducting risk assessments to calculate the no significant risk levels, most businesses subject to the Act do not have the resources to perform these assessments. Yet each business with ten or more employees needs the ability to determine whether its activities or products are subject to the prohibitions of the Act. In the absence of a regulatory level, some businesses subject to the Act -- as well as persons seeking to enforce violations of the Act -- would not have a way of determining compliance, without investing their own resources to conduct a risk assessment.

Section 12705

This regulation adopts "no significant risk" levels in Section 12705(b) for the following chemicals:

Dichloromethane (Methylene chloride)	200 micrograms per day (inhalation)
Trichloroethylene	50 micrograms per day (ingestion)
	80 micrograms per day (inhalation)
Vinyl chloride	3 micrograms per day

A level established for a carcinogen in Section 12705 supersedes any existing level for that carcinogen in Section 12709 or 12711. In order to minimize potential confusion, this proposed rulemaking action seeks to add the new levels to Section 12705, while simultaneously deleting the levels for trichloroethylene and vinyl chloride from Section 12711. Since the new level for methylene chloride is specific to inhalation, the level which presently exists for this chemical in Section 12711 (50 μg/day) remains available for non-inhalation exposures. (The initial proposal deleted the level for methylene chloride from Section 12711. This level was restored as a post-hearing change.)

The levels represent the level of exposure to the chemical which is calculated to result in no more than one excess case of cancer in an exposed population of 100,000, assuming exposure over a 70-year lifetime (10^{-5} lifetime risk of cancer), and are based on the following risk assessment documents, which were reviewed or prepared by the Reproductive and Cancer Hazard Assessment Section (RCHAS) of the Office of Environmental Health Hazard Assessment for consistency with the principles described in Section 12703.

"Health Effects of Methylene Chloride," California Department of Health Services, April 1989.

"Health Effects of Trichloroethylene," California Department of Health Services, December 1988 (Revised January 1990).

Memorandum to Steven A. Book, Ph.D., Chief, Health Hazard Assessment Division, from Lauren Zeise, Ph.D., Acting Chief, Reproductive and Cancer Hazard Assessment Section, re: Risk Specific Intake Level for Trichloroethylene, September 4, 1990.

"Health Effects of Airborne Vinyl Chloride," California Department of Health Services, October 1990.

"Proposed Maximum Contaminant Level: Vinyl Chloride," California Department of Health Services (no date).

These documents are summarized as follows:

Dichloromethane (Methylene chloride)

A lifetime inhalation bioassay in which both male and female rats and mice were exposed to methylene chloride in air was used. Data on lung tumors in female mice (the most sensitive sex, species and tumor site in the study) were used to calculate the low-dose risk from exposure to methylene chloride.

The Department of Health Services (DHS) derived cancer potency and unit risk values by fitting the Crump Multistage Polynomial to dose response data from the animal bioassay; analyses included corrections for uptake and metabolism using a physiologically-based pharmacokinetic (PBPK) model to correct for differences in metabolism at the high experimental doses and low environmental doses.

DHS calculated the unit risk for a lifetime of continuous exposure to 1 ppb of methylene chloride to be 1×10^{-6} to 10×10^{-6} per ppb. The most likely estimate of the upper limit of risk is 4×10^{-6} per ppb. This estimate was derived using the PBPK model to account for metabolic saturation of the detoxification pathway (mixed function oxidase) at high dose. The saturation leads to a disproportionate (non-linear in dose) production at high doses of the metabolite believed to be responsible for the carcinogenic activity of methylene chloride in the female mouse.

The range of potency values for inhalation are equivalent to 0.001 to 0.01 $(mg/kg\text{-}day)^{-1}$, with the best estimate of the upper limit on risk given as 0.0035 $(mg/kg\text{-}day)^{-1}$ inhaled. Based on a potency value of 0.0035 $(mg/kg\text{-}day)^{-1}$, the intake associated with a 10^{-5} risk of cancer is 200 $\mu g/day$ for inhalation exposures.

A no significant risk level of 50 $\mu g/day$ remains available in Section 12711 for non-inhalation exposures to methylene chloride.

Pursuant to Section 12705(c), which requires the lead agency to provide an opportunity for the Scientific Advisory Panel to review and comment on any proposed no significant risk level, the proposed level for methylene chloride and the risk assessment document which provides the basis for this level were submitted to the Scientific Advisory Panel on October 19, 1990. No panelists presented specific recommendations on, or objections to, the proposed level.

Trichloroethylene (TCE)

Cancer potency and unit risk values were calculated by fitting the Crump Multistage Polynomial to dose response data from animal cancer bioassays.

Using data from inhalation studies in rodents, DHS estimated cancer potency values in the range of 0.8×10^{-3} to 9×10^{-3} per mg/m^3 from inhaling low levels of TCE; the geometric mean estimate was 2.49×10^{-3} per mg/m^3. These potency values for inhalation are equivalent to 0.006 to 0.098 $(mg/kg\text{-}day)^{-1}$, and the

geometric mean to 0.01 $(mg/kg\text{-}day)^{-1}$ inhaled*. A pharmacokinetic model was used to correct for uptake and metabolism.

DHS also calculated cancer potency values for oral exposures to TCE using data from gavage studies in rodents. The potency values ranged from 0.0038 to 0.036 $(mg/kg\text{-}day)^{-1}$, with a geometric mean of 0.015 $(mg/kg\text{-}day)^{-1}$. At low doses, it is assumed that all TCE ingested is absorbed and metabolized. When expressed in terms of metabolized dose following inhalation (0.0098 to 0.098 $(mg/kg\text{-}day)^{-1}$, with a geometric mean of 0.028 $(mg/kg\text{-}day)^{-1}$), these values are comparable to the potency estimates derived from the inhalation studies.

The DHS values are similar to those estimated by the U.S. Environmental Protection Agency (EPA), which are discussed in the DHS risk assessment. EPA derived cancer potency and unit risk estimates of 0.11 $(mg/kg\text{-}day)^{-1}$, and 1.3×10^{-6} per $\mu g/m^3$. EPA reevaluated the unit risk for inhalation and determined it to be 1.7×10^{-6} per $\mu g/m^3$ inhaled TCE.

The cancer potency values of 0.015 $(mg/kg\text{-}day)^{-1}$ and 0.01 $(mg/kg\text{-}day)^{-1}$, respectively, were selected to estimate risk specific intake levels for oral and inhalation exposures to TCE. These values fall within the range of estimates derived by DHS and EPA, and are the geometric means of the upper bound estimates derived from ingestion and inhalation studies. The daily intake levels associated with a 10^{-5} cancer risk using these values are 50 μg/day and 80 μg/day**, respectively, for ingestion and inhalation exposures.

One commentor (C-4) pointed out that the proposed no significant risk level for TCE is not consistent with the unit risk value identified in the January 1992 CAPCOA (California Air Pollution Control Association) Risk Assessment Guidelines for the Air Toxics "Hot Spots" Program. The commentor states that, based on the unit risk value in the CAPCOA Guidelines, 2.0×10^{-6} per $\mu g/m^3$, the no significant risk level should be 100 μg/day.

The unit risk value reported in the CAPCOA document was obtained from the same DHS risk assessment document reviewed by RCHAS. In reporting the best estimate of the unit risk value, however, DHS rounded off the geometric mean of the unit risk values derived from rodent inhalation studies, 2.49×10^{-6} per mg/m^3, to one significant digit and reported the value as 2×10^{-6} per $\mu g/m^3$ (see page 5-23 of the DHS document). The RCHAS unit risk value more accurately reflects the geometric mean of the unit risk values of the rodent inhalation studies than does the value reported in the CAPCOA document.

Pursuant to Section 12705(c), which requires the lead agency to provide an opportunity for the Scientific Advisory Panel to review and comment on any proposed no significant risk level, the proposed level for trichloroethylene and the risk assessment document which provides the basis for this level were submitted to the Scientific Advisory Panel on October 19, 1990. No panelists presented specific recommendations on, or objections to, the proposed level.

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* The geometric mean estimate of 2.49×10^{-3} per mg/m^3 is equivalent to 0.0087 $(mg/kg\text{-}day)^{-1}$, which was rounded off to 0.01 $(mg/kg\text{-}day)^{-1}$ in the DHS report.

** Calculated based on a cancer potency estimate of 0.0087 $(mg/kg\text{-}day)^{-1}$.

Vinyl chloride

DHS derived cancer potency and unit risk values by fitting the multistage models to dose response data from epidemiologic studies and animal cancer bioassays; analyses included adjustments for uptake and metabolism.

Unit risk values estimated from the animal inhalation bioassay data fell in the range of 3.7×10^{-5} to 20×10^{-5} per ppb. The estimates from the occupational study with the best dose-response data were 2.5×10^{-5} per ppb for liver cancers, and 4.5×10^{-5} per ppb for several sites combined. If the ratio of male to female unit risk from the human data follows that seen for the rat, the unit risk calculated from the human data (all tumors combined) corresponds to 14×10^{-5} per ppb.

Based on this analysis, DHS recommended that a value of 20×10^{-5} per ppb be used in estimating risks from inhaling low levels of vinyl chloride. This unit risk value is equivalent to a cancer potency value of 0.27 $(mg/kg\text{-}day)^{-1}$. This estimate applies to both the inhalation and ingestion routes of exposure because: (1) the uptake by either route is estimated to be the same (40%); and (2) it is also consistent with the values found by analyzing the bioassay data on animals exposed orally to vinyl chloride.

Using a cancer potency value of 0.27 $(mg/kg\text{-}day)^{-1}$, the intake level associated with a 10^{-5} cancer risk is 3 $\mu g/day$.

One commentor (C-3) objected to the proposed no significant risk level for vinyl chloride, stating that, for workplace exposures, the proposed level is one ten-thousandth of the current OSHA "real world standard" of ".5/ppm". The commentor contends that it would be extremely difficult for plastic processing companies to measure at the proposed level; that OEHHA's conclusions regarding the fiscal impact of the regulations are untrue; that the adoption of a stringent and unsupported rule will do nothing but lead to more economic harm to business; that there is no good science to support the new low level; and that there is no data to support the fact that a level less than the OSHA standard is necessary.

The commentor may not be aware that the level proposed for vinyl chloride in this rulemaking is ten times higher (i.e., less restrictive) than the no significant risk level previously adopted (based on the U.S. Environmental Protection Agency cancer potency value) for the chemical in Section 12711. The commentor should also note that Section 12901 provides that, when a chemical is not detectable by a State or local regulatory agency's prescribed method, or by a federal agency's prescribed method, or by a method generally accepted by the scientific community, or by any scientifically valid method (in that order of preference), no exposure occurs. Thus, if the no significant risk level is below the limit of detection for the chemical, the limit of detection, in effect, becomes the no significant risk level. The commentor should not be concerned about the need to monitor for vinyl chloride at the no significant risk level, if this level is below the limit of detection of the methods identified above, including the method specified by OSHA for measuring levels of the chemical in the workplace.

The commentor disagrees with OEHHA's conclusions regarding the fiscal impact of the regulation on small businesses and businesses directly affected by the regulation, stating that the regulation would be devastating to small businesses

and would lead to more economic harm to business. It is possible that the commentor does not fully understand that the purpose of adopting a no significant risk level for a listed carcinogen is to provide the regulated community with a "safe harbor" level that would enable affected businesses to make use of the statutory exemption from the warning requirement. At the same time, a business may determine that an exposure level different from the level adopted in Section 12705 is scientifically valid, and rely on that alternative level in making a determination that an exposure is exempt from the Act. The adoption by the State of a specific regulatory level for a listed chemical is not a prerequisite for the warning requirement to go into effect -- i.e., the Act requires businesses to warn about knowing and intentional exposures to a listed chemical twelve months after the chemical is listed, regardless of whether or not a regulatory level has been adopted by the State for that chemical. Thus, in the absence of a safe harbor level for a listed chemical, affected businesses must perform their own risk assessment to calculate the cancer potency of the chemical, quantify the level of exposure for which they are responsible, and demonstrate that that level poses no significant risk of cancer (i.e., is calculated to result in cancer risk which is less than one excess case of cancer in 100,000 people exposed) in order to determine whether an exposure is exempt from the warning requirement. The adoption of a regulatory level for a listed chemical does not result in any costs to businesses beyond those costs which already exist as a result of the statutory requirement. Further, and finally, most workplace warnings that are required for purposes of the Act may be provided by adherence to State and federal worker right-to-know laws, as set forth in Section 12601(c)(1)(C). Hence, in most cases, there would be no additional costs imposed by the Act for worker notification.

The commentor claims that the no significant risk level for vinyl chloride is not supported by good science, but offers no specific comments on the risk assessments used as the bases for the level and how these assessments are scientifically deficient. The commentor also complains about the absence of data to support that a level lower than the OSHA standard is necessary.

A no significant risk level in Section 12705 is a safe harbor exposure level above which warnings are required under the Act. OSHA's action level of 0.5 ppm [Title 8, California Code of Regulations, Section 5210(b)(1)] is the level above which specified requirements for monitoring and medical surveillance are triggered. OEHHA is not required to justify why its regulatory level is lower than OSHA's workplace standard or that of any other regulatory agency. A no significant risk level, for purposes of the Act represents the daily intake level which is calculated to result in no more than one excess case of cancer in 100,000 individuals exposed over a 70-year lifetime. No considerations are given to other toxic effects of the chemical, or non-health factors such as technical feasibility, detectability, costs (as considered in regulations of other agencies, such as OSHA), or concordance with existing levels established for the chemical under other laws or regulations.

Pursuant to Section 12705(c), which requires the lead agency to provide an opportunity for the Scientific Advisory Panel to review and comment on any proposed no significant risk level, the proposed level for vinyl chloride and the risk assessment document which provides the basis for this level were submitted to the Scientific Advisory Panel on April 26, 1991. No panelists presented specific recommendations on, or objections to, the proposed level.

ADDENDUM TO THE FINAL STATEMENT OF REASONS
22 CALIFORNIA CODE OF REGULATIONS
Section 12705(b): Specific Regulatory Levels Posing No Significant Risk
(Adopt levels for dichloromethane (Methylene chloride),
Trichloroethylene, and Vinyl chloride)

Small Business Impact:

This regulation has no fiscal impact on small businesses. It establishes no significant risk levels for three chemicals (dichloromethane or methylene chloride, trichloroethylene, and vinyl chloride) which are listed as carcinogens under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65). As was discussed in the response to a comment claiming that economic harm would result from the adoption of the level for vinyl chloride, levels adopted into regulation are intended to provide the regulated community with "safe harbor" levels that would enable affected businesses to make use of the exemptions provided by the statute, and do not preclude a business from relying on an alternative level that it can demonstrate as being scientifically valid in making a determination that an exposure or discharge is exempt from the Act. The adoption by the State of a specific regulatory level for a listed chemical is not a prerequisite for the provisions of the Act to go into effect. In the absence of a safe harbor level for a listed chemical, affected businesses must perform their own risk assessment to calculate the cancer potency of the chemical, quantify the level of exposure for which they are responsible, and demonstrate that that level poses no significant risk of cancer in order to determine whether an exposure or discharge is exempt.

Thus, the adoption of a regulatory level for a listed chemical benefits the regulated community by providing more specific guidance and greater certainty in determining compliance with the Act, and does not result in any costs to businesses beyond those which already exist as a result of the statute. Businesses with fewer than ten employees are not subject to the Act.

Response to oral comments presented during the public hearing:

Two commentors presented testimony during the public hearing on the proposed level for propylene oxide. Since the adoption of a no significant risk level for propylene oxide was the subject of a separate rulemaking and is not relevant to this rulemaking action, the oral testimonies are not addressed in this final statement of reasons.

Response to comment regarding a subsequent notice of proposed rulemaking:

One commentor noted that the Office of Environmental Health Hazard Assessment (OEHHA) had issued a subsequent notice of proposed rulemaking to amend Section 12705, which listed no significant risk levels -- specifically for trichloroethylene and methylene chloride -- that were inconsistent with those set forth in this rulemaking.

The more recent rulemaking (Notice File Number Z92-0519-04; Regulatory Action Number 92-0915-04S) to which this commentor referred was initiated before the changes proposed by this rulemaking were adopted. Therefore, the text of the regulation that accompanied the later notice of proposed rulemaking was based on the text of Section 12705 as it was and as it appeared in print at the time. OEHHA intends the changes made by the present rulemaking to be incorporated into the subsequent action.