FINAL STATEMENT OF REASONS
22 CALIFORNIA CODE OF REGULATIONS

Section 12711: Levels Based on State or Federal Standards: Benzyl chloride, and Bromodichloromethane.

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 responsible can show to pose no significant risk (Health and Safety Code Section 25249.10). A determination that a level of exposure poses no significant risk can be made utilizing regulations in Title 22, California Code of Regulations (Section 12701 to 12721). (Unless otherwise indicated, all section references are to Title 22, California Code of Regulations.)

These regulations provide that one method of making a determination that a given level of exposure poses no significant risk is by application of Section 12711, in the absence of a level for that chemical in Section 12705 (Specific Regulatory Levels Posing No Significant Risk) or in Section 12709 (Exposure to Trace Elements), and if Section 12707 (Routes of Exposure) and Section 12713 (Exposure to Food, Drugs, Cosmetics and Medical Devices) are not applicable.

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 benzyl chloride, bromodichloromethane and propylene oxide in Section 12711. 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, and two commentors presented oral comments during the public hearing.

By notice dated June 12, 1992, OEHHA made changes to the proposed regulation (deleting propylene oxide from the proposal), and provided a 15-day comment period during which interested persons could comment on the changes. Three 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 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 benzyl chloride and bromodichloromethane, 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 12711

Levels posing no significant risk of cancer which are calculated using cancer potency estimates from state or federal risk assessments are established in subsection (a)(2) of Section 12711. A person in the course of doing business may establish that a given exposure poses no significant risk by application of these levels.

The levels in subsection (a)(2) represent the daily 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). The levels are calculated based on a 70-kilogram body weight, using assumptions of 2 liters of drinking water ingested per day and 20 m^3 of air inhaled per day.

This amendment to Section 12711 would add "no significant risk" levels for two chemicals, as follows:

Benzyl chloride	4 micrograms per day
Bromodichloromethane	5 micrograms per day

These levels were calculated using cancer potency estimates published in the U.S. Environmental Protection Agency's Integrated Risk Information System (IRIS) database (1990).

OEHHA had also proposed to adopt no significant risk levels for inhalation and ingestion of propylene oxide. Due to procedural considerations, however, these levels were not adopted (see the following paragraph).

One commentor (E-1) requested that the public comment period for the proposed rulemaking be extended, claiming that OEHHA was required under Government Code Section 11346.4 to mail the notice of proposed rulemaking to them "as the holder of the only pesticide registration on propylene oxide, and as a company which has publicly appeared at public hearings on propylene oxide". (On March 22, 1991, the Health and Welfare Agency (the lead agency for the implementation of the Act at the time) issued a notice of proposed rulemaking to adopt a no significant risk level for propylene oxide in Section 12711.) The commentor was concerned that interested parties who did not receive notice of the public hearing may not have had the opportunity to present comments, and that those who submitted comments in response to last year's notice may incorrectly believe that comments they had submitted at the time will be made part of the public record for this rulemaking.

OEHHA has deleted propylene oxide from the proposal in response to this commentor's concerns (see "Procedural Background"). OEHHA may propose a no significant risk level (which may be route-specific) for propylene oxide in a future rulemaking.

Since this rulemaking does not include a level for propylene oxide, substantive comments on the proposed level (C-1, E-2) are not addressed in this final statement of reasons. Post-hearing comments received (PH-1, PH-2, PH-3) did not present any objections or recommendations relating to the deletion of propylene oxide from the rulemaking, and are likewise not addressed herein.

One commentor (C-2) urged OEHHA to delay the promulgation of the no significant risk level for bromodichloromethane until the U.S. Environmental Protection Agency (EPA) completes its reevaluation of its cancer potency values. The commentor claims that EPA is considering a 10^{-5} risk level for bromodichloromethane of 14 μg per liter, which the commentor believes corresponds to an intake level of 7 μg/day, assuming consumption of 2 liters of drinking water per day.

Since a no significant risk level provides more certainty to both the regulated community and persons seeking to enforce the Act, a greater benefit is provided by the adoption of a regulatory level for a listed chemical than by postponing action until a later time. In the absence of a regulatory level, a business subject to the Act must conduct its own risk assessment to determine whether an exposure or discharge for which it is responsible is exempt. While OEHHA is willing to reevaluate the no significant risk level for bromodichloromethane at a later time in light of new scientific information such as a revised EPA cancer potency value, the commentor should note that, as with any level established under Section 12711, the regulatory level is intended to provide a "safe harbor" for persons subject to the Act, and does not preclude the use of alternative levels that can be demonstrated by their users to be scientifically valid. (It appears that the commentor is in error in his calculation of the intake level corresponding to a concentration of bromodichloromethane in water of 14 μg/liter; assuming consumption of 2 liters of water per day, this concentration corresponds to an intake level of 28 μg/day, rather than 7 μg/day.)

The same commentor also expressed concern over discharges by water suppliers that contain trihalomethanes, including bromodichloromethane, which are products of chlorine disinfection necessary to protect the public health against waterborne microbial diseases.

The commentor's concerns are unwarranted, in light of existing statutory and regulatory provisions. Any entity in its operation of a public water system is exempt from the Act [Health and Safety Code Section 25249.11(b)]. Furthermore, 22 CCR Section 12703(b) provides that the no significant risk level may be other than a 10^{-5} cancer risk in situations where sound considerations of public health support a cancer risk level other than 10^{-5}, as is the case "where chlorine disinfection in compliance with all applicable state and federal safety standards is necessary to comply with sanitation requirements".