FINAL STATEMENT OF REASONS
22 CALIFORNIA CODE OF REGULATIONS

Establishment of Specific Regulatory Levels Posing No Significant Risk for: Hexachlorodibenxodioxin and 2,3,7,8-Tetrachlorodibenzo-p-dioxin

Amendment to:
Section 12705. Specific Regulatory Levels Posing No Significant Risk
Section 12711. Levels Based on State or Federal Standards.

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 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 in Section 12705 for hexachlorodibenzodioxin (HCDD) and 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD), and to delete the level for TCDD which had previously been established in Section 12711. Pursuant to such notice, on May 29, 1992, a public hearing was held to receive public comments on the proposed regulation. No written or oral comment regarding this rulemaking was 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.

No objections or recommendations relating to this rulemaking were received

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 altenative 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 HCDD and TCDD, 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, subsection (b) for the following chemicals:

Hexachlorodibenzodioxin (HCDD)	0.0002 microgram per day
2,3,7,8-Tetrachlorodibenzo-p-dioxin (TCDD)	0.000005 microgram per day

A level established for a carcinogen in Section 12705 supersedes any existing level for that carcinogen in Section 12709 or 12711. A specific regulatory level currently exists for TCDD in Section 12711. In order to minimize potential confusion, this rulemaking action seeks to add the new level for TCDD to Section 12705, while simultaneously deleting the TCDD level from Section 12711.

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 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 Chlorinated Dioxins and Dibenzofurans," California Department of Health Services, 1986.

"Health Assessment Document for Polychlorinated Dibenzo-p-Dioxins," U.S. Environmental Protection Agency (EPA/600-8-84/014F), Office of Health and Environmental Assessment, 1985.

"A Cancer Risk-Specific Dose Estimate for 2,3,7,8-TCDD, Review Draft, U.S. Environmental Protection Agency (EPA/600/6-88/007Aa), 1988.

"Review of Draft Documents, 'A Cancer Risk-Specific Dose Estimate for 2,3,7,8-TCDD,' and 'Estimating Exposure to 2,3,7,8-TCDD,' U.S. Environmental Protection Agency Science Advisory Board, Ad Hoc Dioxin Panel, 1989.

"Results of a two-year chronic toxicity and oncogenicity study of 2,3,7,8-tetrachlorodibenzo-p-dioxin in rats," Kociba, et al., Toxicology and Applied Pharmacology 46:279-393, 1978.

The no significant risk levels for TCDD and HCDD are based on the 1986 DHS risk assessment, which was conducted using principles and assumptions which are the same as those described as standard default assumptions in Section 12703. A linearized multistage model is employed to estimate cancer potency, and extrapolation of results from laboratory animals to humans incorporates surface area scaling.

DHS fit the linearized multistage model to dose response data for liver tumors (hepatocellular adenomas and carcinomas) in male mice administered TCDD orally (by gavage), and obtained a cancer potency value of 130,000 $(mg/kg\text{-}day)^{-1}$. For HCDD, DHS used the Hildebrandt evaluation of liver tumor (neoplastic nodules and

carcinomas) occurrence in female rats receiving HCDDs by gavage, and calculated a cancer potency value of 3,300 $(mg/kg\text{-}day)^{-1}$.

RCHAS also reviewed the current scientific literature and the U.S. Environmental Protection Agency documents referenced above, and concluded that the current information on the carcinogenesis of TCDD and HCDD does not justify an approach different from that used in the DHS risk assessment. RCHAS recommended that the risk assessments for TCDD and HCDD follow the default assumptions specified in Section 12703, as did the 1986 DHS risk assessment.

Based on the cancer potency values in the DHS risk assessment, the intake level associated with a 10^{-5} cancer risk is 0.0002 $\mu g/day$ for HCDD and 0.000005 $\mu g/day$ for TCDD.

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 levels for HCDD and TCDD and the risk assessment document which provides the basis for this levels were submitted to the Scientific Advisory Panel on April 6, 1990. No panelists presented specific recommendations on, or objections to, the proposed level.