FINAL STATEMENT OF REASONS
22 CALIFORNIA CODE OF REGULATIONS

Section 12805. Specific Regulatory Levels: Reproductive Toxicants.
(Establishment of a Regulatory Level for Toluene)

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 person in the course of doing 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 reproductive toxicity, an exemption is provided by the Act for exposures which the person responsible can show as producing no observable effect, assuming exposure at 1,000 times the level in question (Health and Safety Code Section 25249.10). The maximum dose level at which a chemical has no observable reproductive effect is referred to as the no observable effect level (NOEL). Thus, the exemption applies when the exposure in question is at a level that does not exceed the NOEL, divided by a 1,000-fold uncertainty factor.

Procedural Background

On March 22, 1991, the Health and Welfare Agency issued a notice of proposed rulemaking advising that the Agency intended to adopt a regulatory level for toluene in Section 12805, Title 22, California Code of Regulations. (Unless otherwise indicated, all section references are to Title 22, California Code of Regulations.) Pursuant to such notice, on May 10, 1991, a public hearing was held to receive public comments on the proposed regulation. One piece of correspondence commenting on the proposal was received. One presenter offered comments during the public hearing.

On July 17, 1991, the role of lead agency for the implementation of the Act was transferred from the Health and Welfare Agency to the California Environmental Protection Agency's (Cal/EPA's) Office of Environmental Health Hazard Assessment (OEHHA or the department) by Executive Order W-15-91. This rulemaking action is submitted by OEHHA in its capacity as lead agency for the implementation of the Act.

Purpose of Final Statement of Reasons

This final statement of reasons sets forth the reasons for the final regulation adopted by the department for Section 12805, 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 the procedures followed by the department in proposing or adopting the action.

Some parties may have 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, the department 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

In accordance with Government Code Section 11346.5(a)(7), OEHHA has, throughout the adoption process of this regulation, considered available alternatives to determine whether any alternative would be more effective in carrying out the purpose for which the regulations were proposed, or would be as effective and less burdensome to affected private persons than the proposed action. OEHHA has determined that no alternative considered would be more effective than, or as effective and less burdensome to affected persons than, the proposed 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 Section 12805.

Necessity for Adoption of Regulations

For chemicals known to the State to cause reproductive toxicity, the Act exempts discharges, releases and exposures which, making certain assumptions, produce no observable effect on reproduction, assuming exposure at 1,000 times the level in question. 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 specify the steps necessary to calculate whether a given level of exposure to a reproductive toxicant is exempt, nor specify specific levels of exposure which represent the one one-thousandth of the no observable effect level (NOEL).

The purpose of this regulation is to provide a "safe harbor" level for toluene, below which the Act does not apply. This level will allow persons to determine whether a discharge, release or exposure involving toluene is exempt from the provisions of the Act.

Although existing regulations describe principles and assumptions for conducting risk assessments to calculate the NOEL, 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. Given that toluene is a widely used chemical, the absence of a regulatory level for the chemical would leave a large number of businesses without a way of determining compliance with the Act.

Section 12805

Existing regulations (Section 12801-12821) provide guidance for determining whether an exposure to, or discharge of, a reproductive toxicant meets the statutory exemption. These regulations provide two ways by which a person in the course of doing business can make such a determination: (1) by conducting a risk assessment in accordance with the principles described in Section 12803 to derive a NOEL, and dividing the NOEL by 1,000; or, (2) by application of the specific regulatory level adopted for the chemical in Section 12805 (which represents one one-thousandth of the NOEL) or, in the absence of such a level, by using a risk assessment conducted by a state or federal agency, provided that such assessment is consistent with the principles in Section 12803, and the maximum allowable daily dose level is one one-thousandth of the NOEL.

This amendment to Section 12805 would adopt a regulatory level of 7,000 micrograms per day (µg/day) (or 7 milligrams/day (mg/day)) for toluene, based on a risk assessment prepared by the Reproductive and Cancer Hazard Assessment Section of the Department of Health Services (Memorandum to Steven A. Book, Ph.D. from Lauren Zeise, Ph.D., re: Toluene Exposure Level Recommendation, dated February 11, 1991, and "Reproductive and Developmental Toxicity of Toluene: A Review"). (The Reproductive and Cancer Hazard Assessment Section is now within OEHHA.)

The study deemed to be the most appropriate for deriving a NOEL is an inhalation study in which pregnant rats were exposed in inhalation chambers to 0, 100, 500 or 2,000 ppm toluene for 6 hours/day. No observable adverse effects were observed in the offspring of rats exposed at 500 ppm.

Exposure of rats to 500 ppm of toluene in air for 6 hours/day is estimated to result in a total daily intake of 112.5 mg/kg/day. Section 12803(b) requires the use of a 58-kilogram body weight assumption when the reproductive effect is upon the female or conceptus. Multiplying the no observable effect level (112.5 mg/kg/day) by 58 kilograms, and dividing by the 1,000-fold uncertainty factor yields a daily intake level of 6.525 mg/day. This value has been rounded off to 7 mg/day, or 7,000 µg/day, the adopted regulatory level.

The department received one piece of correspondence (C-93) during the public comment period. Oral testimony presented during the public hearing reiterated the points made in the written submittal. Both the written comments and the oral testimony were offered on behalf of the same party.

The commentors agreed that the rat reproduction study which was used by the department as the basis for the proposed regulatory level for toluene is the

most appropriate study to use. However, they indicated that their group had initiated a rat developmental toxicity study to provide better dose-response and hazard characterization data on toluene. The preliminary report from this study suggests that toluene is not a selective developmental toxicant, and that the NOEL for developmental toxicity should be 750 ppm. The commentors urged the department to defer the establishment of a regulatory level for toluene until it is possible to incorporate the results of the recently conducted study into the rulemaking process. The commentors stated that the final report will be available in September, 1991.

Since the final report on the study described by the commentors is still not available at this time, the department is unable to judge its usefulness to this rulemaking action. It is the department's view that the regulated community and the public are better served by the establishment of a regulatory level for toluene which is based on the most scientifically appropriate study currently available, than by postponing action until a report of unknown value is completed.

The commentors should note that any person subject to the Act may use an acceptable daily intake level different from that which is established in regulation. Acceptable daily intake levels for reproductive toxicants in Section 12805 are intended to provide "safe harbors" to the regulated community, and do not preclude the use of alternative levels that can be demonstrated by their users to be scientifically valid.