FINAL
STATEMENT OF REASONS
22 CALIFORNIA CODE OF REGULATIONS

Section 12705(b) - Specific Regulatory Levels Posing No Significant Risk: Benzene

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 & Saf. Code Sec. 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 & Saf. Code Sec. 25249.5).

For chemicals known to the state to cause cancer, an exemption is provided by the Act when a person in the course of doing business is able to demonstrate that an exposure for which the person is responsible poses no significant risk, or that a discharge which otherwise complies with applicable requirements would result in an exposure through drinking water at a level which poses no significant risk (Health & Saf. Code Sec. 25249.10 and 25249.11).

A determination that a level of exposure poses no significant risk can be made utilizing regulations that have previously been adopted by the Health and Welfare Agency (Agency) (Sec. 12701 to 12721, Title 22, California Code of Regulations) (unless otherwise specified, all section references are to Title 22, CCR). 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. A level specified in Section 12705(b) supersedes Section 12709 (Exposure to Trace Elements), Section 12711 (Levels Based on State or Federal Standards), or Section 12713 (Exposure to Food, Drugs, Cosmetics and Medical Devices).

Procedural Background

On June 1, 1990, the Agency issued a notice of proposed rulemaking advising that the Agency intended to adopt a "no significant risk" level for benzene. Pursuant to such notice, on July 20, 1990, a public hearing was held to receive public comments on the proposed regulation. Three pieces of correspondence commenting on Section 12705(b) were received. No comments were received at the public hearing.

Purpose of Final Statement of Reasons

This final statement of reasons sets forth the reasons for the final regulation adopted by the Agency for Section 12705(b), 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 Agency's proposed action or to the procedures followed by the Agency 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, the Agency is not obligated under Government Code section 11346.7 to respond to such remarks in this final statement of reasons. Since the Agency is constrained by limitations upon its time and resources, and is not obligated by law to respond to such remarks, the Agency has not responded to these remarks in this final statement of reasons. The absence of response in this final statement of reasons to such remarks should not be construed to mean that the Agency agrees with them.

Specific Findings

Throughout the adoption process of this regulation, the Agency has considered the alternatives available to determine which 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 regulations. The Agency has determined that no alternative considered would be more effective than, or as effective and less burdensome to affected persons than, the adopted regulation.

The Agency 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 12705(b).

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.

This regulation provides a "safe harbor" no significant risk level for benzene, which will allow persons to determine whether a discharge, release or exposure involving benzene is exempt from the provisions of the Act.

Section 12705(b)

This regulation adopts a no significant risk level of 7 micrograms per day for benzene in Section 12705(b), and simultaneously repeals the no significant risk level for benzene in Section 12711. Although Section 12701 explicitly states that Section 12711 applies only when no specific level is established for the chemical in Section 12705, deletion of the chemical and its level from Section 12711 is necessary for clarity and to avoid confusion.

The no significant risk level represents 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 is based on the following risk assessment documents, which were reviewed by the California Department of Health Services (CDHS), Office of Environmental Health Hazard Assessment, Reproductive and Cancer Hazard Assessment Section, in accordance with the principles in Section 12703:

> "Report to the Scientific Review Panel on Benzene," prepared by the California Air Resources Board and California Department of Health Services, November 27, 1984.
>
> "Interim Quantitative Cancer Unit Risk Estimates Due to Inhalation of Benzene," EPA 600/X-85-022. Internal Report. United States Environmental Protection Agency, dated February 15, 1985.

These documents are summarized as follows:

CDHS cancer potency values ranging from 0.03 to 0.2 $(mg/kg\text{-}day)^{-1}$ were calculated by fitting the Crump Multistage Polynomial to dose response data from epidemiological studies and animal cancer bioassays. The animal data used included data on Zymbal gland carcinomas in rats exposed via inhalation or gavage, and Zymbal gland carcinomas, preputial gland carcinomas, and lymphoma or leukemia in male mice or mammary carcinomas in female mice exposed by gavage. The epidemiological studies analyzed were those of leukemia in workers exposed via inhalation.

The U.S. Environmental Protection Agency estimated similar potency values from leukemia incidence data for humans occupationally exposed via

inhalation to benzene. EPA concluded that the most credible cancer potency estimate is that which was derived from data reported by Rinsky, et al. (described in further detail in the EPA risk assessment). The maximum likelihood estimate calculated from this study is 0.041/ppm, or 0.044 $(mg/kg\text{-}day)^{-1}$, and the upper 95% confidence bound, 0.088/ppm, or 0.095 $(mg/kg\text{-}day)^{-1}$.

CDHS recommends a cancer potency value of 0.1 $(mg/kg\text{-}day)^{-1}$ for estimating risk specific intake levels from exposure to benzene. This value falls within the range of estimates derived by CDHS and EPA, and is the upper 95% confidence bound estimate from the analysis of human data considered most credible by EPA. For this potency value, the intake associated with a 10^{-5} risk of cancer is 7 micrograms per day.

One commentor objected to the level, and recommended that a no significant risk level of 25 micrograms per day be adopted instead. This commentor questioned the basis for CDHS' use of animal data, given the fact that epidemiological studies of acceptable quality are available for benzene, and the route of exposure used (gavage) and types of tumors observed (Zymbal gland and preputial gland carcinomas) in the animal study are not relevant to humans. The commentor pointed out that the EPA's best judgement cancer potency value for benzene is 0.026/ppm or 0.029 $(mg/kg/day)^{-1}$, which corresponds to a no significant risk level of 25 micrograms per day. This cancer potency value reflects an analysis of data from three epidemiological studies, rather than a single study. The commentor further maintains that if the Agency should continue to rely on the Rinsky study, the risk assessment should utilize data reflecting "the most complete, detailed, and up-to-date exposure information." Using reevaluated data, a cancer potency value of 0.026/ppm was calculated by the commentor (this corresponds to a no significant risk level of 35 micrograms per day). (C-3)

Another commentor objected to the level, stating that it is "not supported by the best available scientific data," and that it "departs from generally accepted risk assessment practice by using animal data to adjust the cancer potency value for benzene developed from adequate human studies." The commentor claims that the use of animal data overestimates the actual risk to humans. A detailed justification for changing the potency value by including additional animal data would be helpful. The commentor also expressed concern about CDHS' reference to EPA's "most credible potency estimate." EPA recommends a cancer potency estimate of 0.026/ppm, not 0.088/ppm, as cited by CDHS. (C-8).

As discussed above, the cancer potency estimate which was used as the basis for the adopted level was derived from the Rinsky study, not from animal data. The commentors should note, however, that the use of animal data of sufficient quality is consistent with the risk assessment guidelines in Section 12703. The guidelines do not require that preference be given to either animal or human data.

Contrary to one of the commentor's assertions (C-8), animal data was not used to "adjust" the cancer potency derived from human data. The potency estimates calculated from animal data were found to be concordant with those calculated from human data. In fact, the cancer potency estimate calculated by CDHS from the animal data representing the most sensitive species, sex, and site was within an order of magnitude of the estimate from the Rinsky data. The CDHS risk assessment states:

> "Given that this estimate is the expectation of the highest risk and is a surrogate for all cancers that might result from exposure, CDHS considers this value to be comparable to the estimate based on the epidemiologic data."

EPA's "best judgement" cancer potency estimate is the geometric mean of four estimates derived from human data. The most sensitive epidemiological study was determined by CDHS to be the Rinsky study (which was identified by EPA as the data set "that has the most credibility associated with it"). Selection of the most sensitive study deemed to be of sufficient quality is required by Section 12703. In response to Commentor C-8's concern about CDHS' reference to the cancer potency estimate derived from the Rinsky study, it should be noted that CDHS characterizes this value as that which was calculated using human data which EPA considers the most credible, and was not referred to as EPA's recommended cancer potency.

Commentor C-3 made reference to using data from an updated re-evaluation of exposure information. Because the re-evaluation referenced by the commentor has not undergone peer-review, the Agency is not in a position to make a determination about its scientific validity. However, any person subject to the Act who is able to demonstrate that certain data is scientifically valid may rely on such data in conducting the risk assessment.

As with any person subject to the Act, the commentors always have the option of using an alternative no significant risk level based on a risk assessment utilizing data, principles and assumptions which they believe are scientifically valid. Pursuant to Section 12701, the no significant risk levels in Section 12705 are intended to provide safe harbors and do not preclude the use of alternative levels that can be demonstrated by their users to be scientifically valid.

The third commentor supported the Agency's regulation (C-9)

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 benzene and the risk assessment document which provides the basis for this level were submitted to the Scientific Advisory Panel on April 14, 1989. No panelists presented specific recommendations on, or objections to, the proposed level.