FINAL
STATEMENT OF REASONS
22 CALIFORNIA CODE OF REGULATIONS

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 & Saf. Code Sec. 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 & 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) (Section 12701 to 12721, Title 22, California Code of Regulations) (unless otherwise specified, all section references are to Title 22, CCR). 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 Sections 12705 (Specific Regulatory Levels Posing No Significant Risk) and 12709 (Exposure to Trace Elements), and if Sections 12707 (Routes of Exposure) and 12713 (Exposure to Food, Drugs, Cosmetics and Medical Devices) are not applicable.

Procedural Background

On June 1, 1990, the Agency issued a notice of proposed rulemaking advising that the Agency intended to amend Section 12711 to add "no significant risk" levels for sixteen chemicals to subsection (b), which lists regulatory levels which are based on existing State or federal risk assessments. Pursuant to such notice, on July 20, 1990, a public hearing was held to receive public comments on the proposed regulation. Four pieces of correspondence commenting on the proposal were received. No comments were received at the public hearing.

On August 31, 1990, the Agency issued a Notice of Public Availability of Changes to Proposed Regulations and Supporting Documents and Information Regarding the Safe Drinking Water and Toxic Enforcement Act of 1986. The notice afforded interested parties the opportunity to inspect materials added to the rulemaking file, and to provide to the Agency their

post-hearing comments on proposed modifications to proposed Section 12711 during a 15-day comment period. The comment period closed September 19, 1990. 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 the Agency for Section 12711, 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 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 exposure posing no significant risk. Existing regulations describe methods for calculating levels which pose no significant risk.

This regulation will allow persons responsible for an exposure, discharge or release involving any of the sixteen chemicals for which levels were adopted to determine whether such exposure, discharge or release is exempt from the Act.

Section 12711

Levels posing no significant risk of cancer which are calculated using cancer potency estimates from existing 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 individual, 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 adds no significant risk levels for 16 chemicals. The proposed levels are derived from risk assessments conducted by the U.S. Environmental Protection Agency (EPA), and the California Department of Health Services.

The following no significant risk levels are based on the cancer potency estimates published in Table 7-18, pages 7-82 through 7-85 of Health Assessment Document for Beryllium, EPA/600/8-84/026F, U.S. Environmental Protection Agency (EPA), November 1987:

Hexachlorocyclohexane	
alpha isomer	0.3 microgram per day
beta isomer	0.5 microgram per day
gamma isomer	0.6 microgram per day

The same reference was originally used by the Agency in proposing to adopt a no significant risk level of 1500 micrograms per day for allyl chloride. Subsequent to the issuance of the notice of proposed rulemaking, however, it was determined by the Agency that the cancer

potency estimate listed in Table 7-18 (4.7×10^{-4} $(mg/kg\text{-}day)^{-1}$) was the slope calculated from animal data, and had not been scaled to humans, nor corrected for the experimental dosing pattern (Preliminary Risk Assessment on Allyl Chloride, Carcinogen Assessment Group, U.S. Environmental Protection Agency, September 1, 1979). In its risk assessment for allyl chloride (Health and Environmental Effects Profile for Allyl Chloride, Environmental Criteria and Assessment Office, U.S. Environmental Protection Action, EPA/600/X-86/198, July 1986), EPA recommends a human cancer potency estimate of .0206 $(mg/kg/day)^{-1}$. Based on this estimate, a no significant risk level of 30 micrograms per day was adopted in Section 12711 for allyl chloride.

The following no significant risk levels are based on the cancer potency estimates in EPA's Integrated Risk Information System (IRIS) database:

Acrylamide	0.2	microgram per day
Aniline	100	micrograms per day
Azobenzene	6	micrograms per day
DDVP (Dichlorvos)	2	micrograms per day
Folpet	200	micrograms per day
Furmecyclox	20	micrograms per day
Hydrazine	0.04	microgram per day
Hydrazine sulfate	0.2	microgram per day
4,4'-Methylene bis(N,N-dimethyl)-benzeneamine*	20	micrograms per day
N-Nitrosodiethanolamine	0.3	microgram per day
N-Nitrosomethylethylamine	0.03	microgram per day

* Identified in IRIS by its synonym 4,4'-Methylene bis(N,N'-dimethyl)aniline.

A no significant risk level of 40 micrograms per day was adopted for pentachlorophenol, based on the applied action levels established by the California Department of Health Services (CDHS), Toxic Substances Control Program ("Applied Action Levels," AAL List No. 89-2, December 28, 1989). These applied action levels -- 2 micrograms per liter (water) and 0.2 micrograms per m^3 (air) -- represent a 10^{-6} cancer risk. Using the assumptions that 2 liters of drinking water are ingested per day, or 20 m^3 of air are inhaled per day, a daily intake of 4 micrograms per day is calculated for a 10^{-6} cancer risk. The daily intake level corresponding to a 10^{-5} cancer risk is computed to be 40 micrograms of pentachlorophenol per day.

One commentor objected to the level originally proposed for allyl chloride, stating that the level appears to be at odds with EPA's recommended unit risk value, as cited by the California Air Resources Board. This commentor suggested that a no significant risk level of 34 micrograms per day be adopted instead, based on the EPA assessment. (C-9) As mentioned earlier, the cancer potency estimate published for allyl chloride in the reference originally relied upon by the Agency was in error. The adopted level for allyl chloride, which was calculated using the same EPA unit risk estimate identified by the commentor, should satisfy this commentor's concern.

Commentor C-9 also objected to the no significant risk level for pentachlorophenol, stating that it was at odds with the potency values most recently published by EPA in an external review draft. The intake levels corresponding to a 10^{-5} cancer risk calculated using these potency values range from 1 to 6 micrograms per day; the commentor recommends that the most conservative level (1 microgram per day) be used.

It has been the Agency's practice to use only final risk assessment documents as the basis for regulatory levels. Hence, the document referred to by this commentor cannot be used in this rulemaking. However, when the EPA document is adopted as a final, it will be evaluated as part of the process for establishing a no significant risk level in Section 12705.

One commentor objected to the adoption of a no significant risk level for acrylamide (C-2). The commentor stated that the EPA, in promulgating regulations for contaminants in drinking water, establishes either a maximum contaminant level or -- in the absence of an approved analytical method for the chemical -- a treatment technique. Because there is no approved analytical method for acrylamide, EPA has adopted a treatment technique based on the acceptable level of acrylamide allowed in polyacrylamide. The commentor argued that establishment of a regulatory level for the chemical is not appropriate because, in the absence of an approved analytical method, a discharger would have no way of knowing whether it is releasing the chemical above this level.

The warning requirement and the discharge prohibition for a listed chemical become effective twelve months and twenty months, respectively, after the chemical is listed. These provisions are not suspended until the establishment of a regulatory level by the Agency. (For acrylamide, warnings will be required as of January 1, 1991, and discharges prohibited as of September 1, 1991, regardless of whether a no significant risk level is adopted or not.) The adopted no significant risk level will enable businesses and persons enforcing the Act to determine whether an exposure to, or discharge of acrylamide is exempt. Further justification for the establishment of regulatory levels has been provided in the final statement of reasons for the adoption of Sections 12701 through 12721 (filed July 10, 1989).

In determining the level of acrylamide in a discharge, the commentor should, pursuant to Section 12901, use any method which is generally accepted by the scientific community, in the absence of a method adopted or employed by a State, local or federal regulatory agency. If no such method exists, then any scientifically valid method shall be used. Alternatively, the commentor may calculate the expected level of acrylamide in a discharge, based on the amount of the chemical present in the polymer used to treat the water.

A second commentor objected to the no significant risk level for acrylamide, claiming that the level is not based on the most appropriate data set (C-10). The commentor stated that the best estimate for the no significant risk level, based on a risk assessment using data on

testicular mesothelioma from a study conducted by American Cyanamid, is 1 microgram per day. The commentor contends that the Cyanamid study is more appropriate for determining the cancer risk associated with acrylamide than the study relied upon by EPA for a number of reasons, including the greater number of animals per dose group, the higher dose levels used and the absence of confounding variables.

The purpose of Section 12711 is to specifically allow the use of existing State or federal standards and risk assessments in determining whether an exposure or discharge poses no significant risk. Adopting no significant risk levels based on risk assessments conducted by parties other than State or federal agencies would not be consistent with the purpose of Section 12711. In adopting a level for a chemical in subsection (a)(2), the Agency simply determines whether federal or State risk assessments have been published for the chemical, identifies the cancer potency estimates recommended in the risk assessment, and calculates the daily intake level corresponding to a 10^{-5} cancer risk. A more detailed evaluation of the data, principles and assumptions used in the risk assessment is carried out as part of the process of adopting levels under Section 12705. It is doubtful, however, that the Cyanamid data described by the commentor will be used in such risk assessment, as the study does not appear to have undergone peer review. The levels in both Section 12705 and 12711 provide "safe harbors" for persons subject to the Act and, pursuant to Section 12701, do not preclude the use of alternative levels that can be demonstrated by their users to be scientifically valid. If the commentor is convinced that a risk assessment using data from the Cyanamid study is scientifically valid, he or she may rely on such risk assessment.

One comment was received regarding dichlorvos (DDVP) (C-4). The commentor stated that the weight of the evidence does not show that DDVP causes cancer in animals, and that the EPA has downgraded the classification of DDVP from Group B2 (probable human carcinogen) to Group C (possible human carcinogen). The commentor should note that the issue of listing DDVP as a carcinogen is not the subject of this regulation.

The same commentor further stated that the data from EPA IRIS which was used by the Agency as the basis for the regulatory level are out-of-date. The cancer potency estimate published in IRIS (.29 $(mg/kg\text{-}day)^{-1}$) -- which is the geometric mean of the cancer potencies calculated from data on tumors of the forestomach in mice, tumors of the pancreas in rats, and leukemia in rats -- is no longer correct. Instead, in calculating the current cancer potency estimate for DDVP (.2 $(mg/kg\text{-}day)^{-1}$), EPA no longer includes data on rat pancreatic tumors. Additionally, EPA does not include inhalation exposure in the estimation of risk. The commentor cites a "Memorandum of the Fourth Peer Review of Dichlorvos (DDVP)," EPA, 1989 as the reference for this information. The commentor believes that dermal exposures should also be excluded, and that "if any tumors are used to calculate the risk, they should be the mouse forestomach tumors." Using this data set, a cancer potency estimate of .11 $(mg/kg\text{-}day)^{-1}$ is calculated, which yields a no significant risk level of 6.4 micrograms per day.

The EPA document cited by the commentor does not appear to be a final document. As stated earlier in response to a comment on pentachlorophenol, it is the Agency's practice to rely only on final, adopted documents as the basis for no significant risk levels in Section 12711. However, the "current" cancer potency from the document cited by the commentor (.29 $(mg/kg\text{-}day)^{-1}$) is not much different from that which was used as the basis for the regulatory level (.2 $(mg/kg\text{-}day)^{-1}$).

With regard to the comments regarding which data set to use in estimating risk, as with any person subject to the Act, the commentor may use an alternative no significant risk level that he or she is able to defend as being based on a scientifically valid risk assessment. The regulatory levels in Section 12711 provide "safe harbors" for persons subject to the Act and, pursuant to Section 12701, do not preclude the use of alternative levels.