eto

FINAL
STATEMENT OF REASONS
22 CALIFORNIA CODE OF REGULATIONS

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

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 it 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 October 3, 1989, the Agency issued a notice of proposed rulemaking advising that the Agency intended to adopt a "no significant risk" level for ethylene oxide. Pursuant to such notice, on November 28, 1989, a public hearing was held to receive public comments on the proposed regulation. Two comments regarding ethylene oxide 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 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 regulation was proposed, or would be as effective and less burdensome to affected private persons than the proposed regulation. 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). However, because regulations other than Section 12705(b) were also the topic of the public hearing on November 28, 1989, the rulemaking file contains some material not relevant to Section 12705(b). This final statement of reasons cites only the relevant material. Comments regarding the regulations other than Section 12705(b) discussed at the November 28, 1989 hearing have been or will be discussed in separate final statements of reasons.

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

Section 12705(b)

This regulation adopts a no significant risk level for ethylene oxide of 2 micrograms per day for purposes of the Act in Section 12705(b), and repeals the no significant risk level for this chemical 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 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 risk assessment document prepared by the California Department of Health Services (CDHS) utilizing the principles in Section 12703 ("Proposition 65 Risk-Specific Intake Levels, Ethylene Oxide," Reproductive and Cancer Hazard Assessment Section, Office of Environmental Health Hazard Assessment, California Department of Health Services, July 1, 1988).

A cancer potency of 9×10^{-5} $(\text{micrograms/m}^3)^{-1}$, based on the incidence of mononuclear cell leukemias in female rats, was used to estimate the upper-limit incremental risk to humans exposed to ethylene oxide. Based on this estimate, the air concentration associated with a 10^{-5} risk of cancer is 110 ng/m^3. The intake levels associated with a 10^{-5} risk of cancer is 2 micrograms per day.

One commentor (C-16) stated that the risk assessment document provided little detail concerning methods and rationale, and that the document contains a number of errors that the commentor acknowledged do not affect the accuracy of the intake determinations, but "raise the question concerning the accuracy of other details in the report" (e.g., ethylene oxide was listed as a carcinogen on July 1, 1987, not February 27, 1987 as indicated in the document). The commentor contends that the assumptions used in calculating the cancer potency estimate are not consistent with the default assumptions in Section 12703. The commentor argued that the use of a surface area scaling factor equivalent to the ratio of human to animal body weight taken to the one-third power results in an overly conservative estimate and is not consistent with the approach used by other California agencies such as the Department of Food and Agriculture. The commentor recommends a level approximately 6 times higher than the CDHS level as one that poses no significant risk.

The Agency disagrees with this commentor's assertion that the risk assessment for ethylene oxide did not follow the principles and

assumptions outlined in Section 12703. As this commentor noted, a surface area scaling factor equivalent to the ratio of human to animal body weight taken to the one-third power was used. This approach is consistent with the default assumptions in the regulations. It is also consistent with the approach used by other California agencies, including the Department of Health Services in its assessments for the Air Resources Board. It is also consistent with the approach used by the U.S. Environmental Protection Agency. The difference between the CDHS level and the level recommended by this commentor primarily reflects the commentor's belief that body weight should be used as the basis for interspecies scaling, rather than surface area. The Agency disagrees, and believes the conservative surface area correction to be appropriate. However, as with any person subject to the Act, the commentor always has the option of using an alternative no significant risk level based on his own risk assessment, utilizing data, principles and assumptions which he can establish as being scientifically valid. Pursuant to section 12701, 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 its users as being scientifically valid.

Another commentor (C-17) included comments regarding the presentation of information in the risk assessment documents that discuss the significance of animal data and various human epidemiologic data, but which are not directed to the proposed regulatory level. Such points, while of scientific interest, are beyond the scope of quantification of a level for regulatory purposes. However, as was pointed out above, if this commentor believes the animal and human data support a different approach, the regulations allow the use of a scientifically valid alternative. 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 same commentor also stated that the no significant risk level should be 2.4 micrograms per day instead of 2.2 micrograms per day. Both values can be rounded off to 2 micrograms per day, the Agency's no significant risk level.

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 ethylene oxide and the risk assessment document which provides the basis for the proposed regulation were submitted to the Scientific Advisory Panel at a meeting held September 16, 1988. No panelists presented specific recommendations on, or objections to, the proposed level for ethylene oxide.