Notice of Emergency Rulemaking; outline reasons for adoption of emergency rules

Bill Carroll



TITLE 22. CALIFORNIA HEALTH AND WELFARE AGENCY

ACTION: Notice of Emergency Rulemaking
Section 12201, subdivision (a) - In the Course of Doing Business

SUBJECT: Safe Drinking Water and Toxic Enforcement Act of 1986

PUBLIC PROCEEDINGS: Notice is hereby given that the California Health and Welfare Agency will hold a public hearing commencing at 10:00 a.m. on July 29, 1988 in the Auditorium at 714 P Street, Sacramento, CA, at which time any person may present statements or arguments orally or in writing relevant to the action described in this notice. Any written statements or arguments must be received by the Office of Regulations, Department of Health Services, 714 P Street, Room 1000, P.O. Box 942732, Sacramento, CA 94234-7320 by 5:00 p.m. on July 29, 1988 which is hereby designated as the close of the written comment period. It is requested but not required that written statements or arguments be submitted in duplicate.

CONTACT: Inquiries concerning the action described in this notice may be directed to Dr. Steven A. Book, Science Advisor to the Secretary and Executive Secretary to the Scientific Advisory Panel at (916) 445-6900.

INFORMATIVE DIGEST:

Health and Safety Code section 25249.5 prohibits any person in the course of doing business from knowingly discharging or releasing a chemical known to the state to cause cancer or reproductive toxicity to a source of drinking water. Health and Safety Code section 25249.6 prohibits any person in the course of doing business from knowingly and intentionally exposing any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving a clear and reasonable warning. The term "person in the course of doing business" is defined to exclude some small businesses, public entities and public water systems. However, the Act does not specify which acts or omissions are "in the course of doing business".

On February 27, 1988, the Health and Welfare Agency adopted by emergency an amendment to section 12201, subdivision (a). It provided that "in the course of doing business" means any act or omission of a business subject to the Act, other than acts caused by war or grave and irresistible natural disaster. It further provided that "in the course of doing business" includes any act or omission of any employee which furthers the purpose or operation of the business or is authorized by the business, excepting acts for the personal comfort of the employee which the employer cannot know will result in an exposure to a listed chemical.

It is the intention of the Health and Welfare Agency to receive and respond to public comment on the emergency regulation in compliance with the Administrative Procedure Act.

AUTHORITY: Health & Safety Code § 25249.12

REFERENCE: Health & Safety Code §§ 25249.5, 25249.6, 25249.11

FISCAL IMPACT ESTIMATE:

A. Fiscal Effect on Local Government: No additional costs or savings.

B. Fiscal Effect on State Government: No additional costs or savings.

C. Fiscal Effect on Federal Funding of State Programs: No fiscal impact exists.

D. Fiscal Effect on Private Persons or Businesses Directly Affected: Undetermined cost savings resulting from clarification of the applicability of the Act.

E. Fiscal Effect on Small Businesses: No additional costs or savings.

DETERMINATIONS: The Agency has determined that the regulations would not impose a mandate on local agencies or school districts, nor are there any costs, for which reimbursement is required by Part 7 (commencing with Section 17500) of Division 4 of the Government Code.

The Agency has also determined that the regulations would not have a significant adverse economic impact on small businesses.

AVAILABILITY OF STATEMENT OF REASONS AND TEXT OF REGULATIONS: The Agency has prepared and has available for public review an initial statement of reasons for the emergency regulation, all the information upon which the emergency regulations are based, and the text of the emergency regulations. A copy of the initial statement of reasons and a copy of the text of the emergency regulations are available upon request by writing to the Office of Regulations at the address noted above, which address will also be the location of public records, including reports, documentation and other materials related to the emergency regulations.

AVAILABILITY OF CHANGED OR MODIFIED TEXT: The full text of any regulation which is changed or modified from the express terms of the emergency action will be made available by the Office of Regulations at least 15 days prior to the date on which the Agency adopts, amends or repeals the resulting regulation.

ADDITIONAL COMMENTS: In accordance with Government Code Section 11346.5(a)(7), the Agency must determine that no alternative

considered by the Agency would be more effective in carrying out the purpose for which the emergency action was taken or would be as effective and less burdensome to affected private persons than the emergency action. Other regulation changes may be scheduled for hearing at the same time appointed for public hearing on the action described in this notice. An agenda for the public hearing will be posted at the time and place of hearing designated above.

HEALTH AND WELFARE AGENCY

Dated: May 20, 1988

CLIFFORD L. ALLENBY
Secretary

22 CALIFORNIA CODE OF REGULATIONS DIVISION 2
STATE OF CALIFORNIA
HEALTH AND WELFARE AGENCY
CHAPTER 3 SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986

ARTICLE 2 DEFINITIONS

12201. In The Course of Doing Business

*The term "business" as used in the phrase "in the course of doing business" is not limited to commercial or proprietary activities. A person is considered to be in the course of doing business without regard to whether a business activity is conducted for profit. The provisions of the Act apply to any person who has ten or more employees and who is not otherwise excluded by the definition of "person in the course of doing business" in Health and Safety Code section 25249.11(b).*

(a) For purposes of Health and Safety Code sections 25249.5 and 25249.6, "in the course of doing business" means any act or omission, whether or not for profit, except:

(1) as excluded by subdivision (b) of section 25249.11 of the Health and Safety Code; or

(2) when caused by acts of war or grave and irresistible natural disasters.

(b) "In the course of doing business" includes any act or omission of any employee which furthers the purpose or operation of the business, or which is expressly or implicity authorized, except for the personal use, consumption or production of listed chemicals by an employee on the business premises or while performing activities for the business, unless the employer knows or should know of such use, consumption or production and knows or should know that such use, consumption or production will

expose other individuals within the meaning of Health and Safety Code section 25249.6 to a listed chemical.

AUTHORITY: Health and Safety Code section 25249.12
REFERENCE: Health and Safety Code sections 25249.5, 25249.6, 25249.11

INITIAL
STATEMENT OF REASONS
22 CALIFORNIA ADMINISTRATIVE CODE DIVISION 22

Section 12201, subdivision (a) - In the Course of Doing Business

The Safe Drinking Water and Toxic Enforcement Act of 1986 (Act) prohibits certain discharges, releases and exposures by "persons in the course of doing business." That term is defined by the Act to exclude businesses of less than a specified size, governmental entities, and entities in their operation of a public water system. However, the definition does not specify what acts or omissions are "in the course of doing business."

The Health and Welfare Agency (HWA) has defined "in the course of doing business" by regulation. Originally, section 12201, subsection (a), defined "in the course of doing business" to include any business activity, whether or not conducted for profit. During the adoption of this original language, several comments were received requesting clarification about which acts or omissions by a business or its employees are in the course of doing business. The Health and Welfare Agency declined to make such modifications to the regulation proposed at that time due to the proposal's relatively limited scope.

Subsequently the HWA amended section 12201, subdivision (a) on an emergency basis effective February 27, 1988, to reflect these earlier comments. The emergency definition includes as "in the course of doing business" any act or omission of a business, whether or not for profit. Thus, the emergency rule is all-inclusive, except for specified exceptions. This approach is consistent with the broad purpose of the Act to protect the public health.

The exceptions include acts or omissions caused by acts of war or grave and irresistible natural disaster. As with true accidents or misfortune (22 C.C.R. § 12201(c)), there appears to be little benefit to be derived from the imposition of civil penalties upon blameless victims of circumstance such as war or natural disaster. This exception is limited. The discharge, release or exposure must be caused by an act of war or grave natural disaster. The natural event must constitute a disaster of grave or serious proportions, and it must be irresistible, i.e., no reasonable amount of resistance or advance preparation would be sufficient to avoid the discharge, release or exposure.

This emergency regulation includes within the meaning of "in the course of doing business" acts or omissions of employees which either further the purpose or operation of the business, or are

expressly or implicitly authorized by the employer. Again, this is intended to broadly include all acts of employees in connection with business operations.

Comments regarding section 12201, subdivision (a) in earlier regulatory proceedings suggested that both a furtherance of business purpose and employer authorization be required. However, the emergency regulation does not adopt this suggestion. Employees may act or omit to act without specific authorization if they perceive that it will further their employer's purpose, and such acts or omissions may result in a discharge, release or exposure. Further, the employer's authorization would likely be implied due to the benefit it received.

The comments further suggested that the employer's authorization be express. This suggestion is not adopted, since such a requirement would be contrary to generally accepted concepts of the law of agency, and might reduce many enforcement actions to a dispute over whether the employer gave some order directing the act or omission.

The emergency regulation excludes the use, consumption or production by employees of a listed chemical on the employer's premises or elsewhere while on duty. Such use, consumption or production is treated as not being "in the course of doing business" unless the employer knows of it, and knows that it will expose individuals to a listed chemical.

This qualification is predicated upon the rationale that an employer may not know what listed chemicals his employees will use, consume or produce personally, and may not know whether anyone will be exposed to such chemicals. If not, liability should not attach. However, where the employer does know, the exception should not apply.

TITLE 22. CALIFORNIA HEALTH AND WELFARE AGENCY

ACTION: Notice of Proposed Rulemaking
Repeal Sections 12501, 12503 and 12505
Adopt New Sections 12501 and 12503

SUBJECT: Safe Drinking Water and Toxic Enforcement Act of 1986

PUBLIC PROCEEDINGS: Notice is hereby given that the California Health and Welfare Agency will hold a public hearing commencing at 10:00 a.m. on July 29, 1988 in the Auditorium at 714 P Street, Sacramento, CA, at which time any person may present statements or arguments orally or in writing relevant to the action described in this notice. Any written statements or arguments must be received by the Office of Regulations, Department of Health Services, 714 P Street, Room 1000, P.O. Box 942732, Sacramento, CA 94234-7320 by 5:00 p.m. on July 29, 1988 which is hereby designated as the close of the written comment period. It is requested but not required that written statements or arguments be submitted in duplicate.

CONTACT: Inquiries concerning the action described in this notice may be directed to Dr. Steven A. Book, Science Advisor to the Secretary and Executive Secretary to the Scientific Advisory Panel at (916) 445-6900.

INFORMATIVE DIGEST:

Health and Safety Code section 25249.6 prohibits any person in the course of doing business from knowingly and intentionally exposing any individual to a chemical listed under section 25249.8(a) without first giving a clear and reasonable warning. Existing section 12501 of Title 22 provides that human consumption of food containing a listed chemical shall not constitute an exposure to the extent that it can be shown that (1) the chemical is present in the food as a result of the use of drinking water from specified sources and the person causing the contact did not add a significant amount of the chemical to the water, or (2) the chemical is naturally occurring. Existing section 12503 of Title 22 provides, among other things, that causing a person to come into contact with a chemical in water, including water in consumer products, or in air does not constitute an exposure to the extent it can be shown that the water or air was received from specified sources and the person causing the contact did not add a significant amount of the chemical to the water or air. Existing section 12505 provides that products washed, prepared or processed with drinking water will be deemed to contain chemicals which are lawfully present in the drinking water, and provides that, where there are several sources of a chemical in a product, exposure occurs only as to that portion derived from sources other than drinking water or natural sources.

This proposal would repeal sections 12501, 12503 and 12505, and readopt certain provisions in a consolidated form. Section 12501 would provide that human consumption of food containing a listed chemical shall not constitute an exposure to the extent that it can be shown that the chemical is naturally occurring and not the result of human activity. "Human activity" would exclude certain agricultural practices. It would further provide that causing a person to come into contact with a listed chemical in a consumer product is not an exposure to the extent that the chemical is naturally occurring in a food which is used in the manufacture, production or processing of the consumer product.

Section 12503 would provide that causing a person to come into contact with a chemical in water, including water in a food or other consumer product, or with a chemical in air does not constitute an exposure to the extent it can be shown that the water or air was received from specified sources. It would further provide that, where there are several sources of a chemical in a product, exposure occurs only as to that portion derived from sources other than drinking water.

AUTHORITY: Health & Safety Code § 25249.12

REFERENCE: Health & Safety Code §§ 25249.5, 25249.6, 25249.11

FISCAL IMPACT ESTIMATE:

A. Fiscal Effect on Local Government: No additional costs or savings.

B. Fiscal Effect on State Government: No additional costs or savings.

C. Fiscal Effect on Federal Funding of State Programs: No fiscal impact exists.

D. Fiscal Effect on Private Persons or Businesses Directly Affected: Undetermined cost savings resulting from clarification of the applicability of the Act.

E. Fiscal Effect on Small Businesses: No additional costs or savings.

DETERMINATIONS: The Agency has determined that the regulations would not impose a mandate on local agencies or school districts, nor are there any costs, for which reimbursement is required by Part 7 (commencing with Section 17500) of Division 4 of the Government Code.

The Agency has also determined that the regulations would not have a significant adverse economic impact on small businesses.

AVAILABILITY OF STATEMENT OF REASONS AND TEXT OF REGULATIONS: The Agency has prepared and has available for public review an initial statement of reasons for the emergency regulation, all

the information upon which the emergency regulations are based, and the text of the emergency regulations. A copy of the initial statement of reasons and a copy of the text of the emergency regulations are available upon request by writing to the Office of Regulations at the address noted above, which address will also be the location of public records, including reports, documentation and other materials related to the emergency regulations.

AVAILABILITY OF CHANGED OR MODIFIED TEXT: The full text of any regulation which is changed or modified from the express terms of the emergency action will be made available by the Office of Regulations at least 15 days prior to the date on which the Agency adopts, amends or repeals the resulting regulation.

ADDITIONAL COMMENTS: In accordance with Government Code Section 11346.5(a)(7), the Agency must determine that no alternative considered by the Agency would be more effective in carrying out the purpose for which the emergency action was taken or would be as effective and less burdensome to affected private persons than the emergency action. Other regulation changes may be scheduled for hearing at the same time appointed for public hearing on the action described in this notice. An agenda for the public hearing will be posted at the time and place of hearing designated above.

HEALTH AND WELFARE AGENCY

Dated: May 20, 1988

CLIFFORD L. ALLENBY
Secretary

22 CALIFORNIA CODE OF REGULATIONS DIVISION 2
STATE OF CALIFORNIA
HEALTH AND WELFARE AGENCY
CHAPTER 3. SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986

ARTICLE 5. EXTENT OF EXPOSURE

12501. Exposure To Naturally Occurring Chemicals In Food

(a) Human consumption of food shall not constitute an exposure to a listed chemical in the food to the extent that the person responsible for the contact can show that the chemical is naturally occurring in the food.

(1) For the purposes of this section, a chemical is "naturally occurring" if it is a natural constituent of a food, or if it is present in a food solely as a result of natural absorption or accumulation of the chemical which is naturally present in the environment in which the food is raised, or grown, or obtained; for example, minerals present in the soil solely as a result of natural geologic processes, or toxins produced by the natural growth of fungi.

(2) The "naturally occurring" level of a chemical in food may be established by determining the natural background level of the chemical in the area in which the food is raised, or grown, or obtained, based on reliable local or regional data.

(3) A chemical is naturally occurring only to the extent that the chemical did not result from any known human activity. Where a food contains a chemical, in part naturally occurring and in part added as a result of human activity, "exposure" can only

occur as to that portion of the chemical which resulted from such human activity. For purposes of this section, "human activity" does not include sowing, planting, irrigation, or plowing or other mechanical preparation of soil for agricultural purposes; but does include the addition of chemicals to irrigation water applied to soil or crops.

(4) Where a chemical contaminant can occur naturally in food, the chemical is naturally occurring only to the extent that it was not avoidable by good manufacturing practices or other intervening measures.

(b) A person otherwise reponsible for an exposure to a listed chemical in a consumer product, other than food, does not "expose" an individual within the meaning of section 25249.6, to the extent that the person can show that the chemical was a naturally occurring chemical in food, and the food was used in the manufacture, production, or processing of the consumer product. Where a consumer product contains a listed chemical, and the source of the chemical is in part from a naturally occurring chemical in food and in part from other sources, "exposure" can only occur as to that portion of the chemical from other sources.

Authority: Health & Safety Code section 25249.12
Reference: Health & Safety Code section 25249.6

12503. Environmental Exposures

(a) A person otherwise responsible for an exposure to a listed chemical which involves the use of drinking water, including the use of drinking water in food or any other consumer product, does not "expose" an individual within the meaning of section 25249.6 to the extent that the person can show that the listed chemical

was contained in drinking water which was received from:

(1) a public water system, as defined in Section 4010.1 of the Health and Safety Code;

(2) a commercial supplier of drinking water; or

(3) a source of drinking water in compliance with all state or federal primary drinking water standards and the chemical is the result of treatment of the water in order to achieve such compliance.

Where the source of the listed chemical is in part from such drinking water and in part from other sources, "exposure" can occur only as to that portion of the listed chemical from sources other than drinking water.

(b) A person otherwise responsible for an exposure to a listed chemical does not "expose" an individual within the meaning of Health and Safety Code section 25249.6 to the extent that the person can show that the chemical was contained in water which moved or was handled in the manner described in section 12401. Nothing in this subdivision shall be interpreted to affect the responsibility for an exposure which occurs before such an event.

(c) A person otherwise responsible for an exposure to a listed chemical in air does not "expose" an individual within the meaning of Health and Safety Code section 25249.6 to the extent that the person can show that the listed chemical was contained in air that the person received from the ambient air. Where the source of the listed chemical is in part from the ambient air and in part from other sources, "exposure" can occur only as to that portion of the listed chemical from sources other than the ambient air.

Authority: Health & Safety Code section 25249.12
Reference: Health & Safety Code sections 25249.6, 25249.11

Article 5. Extent of Exposure

12501. Exposure to Food.

Human consumption of food shall not constitute an exposure to any chemicals in the food to the extent that the person reponsible for the contact can show that:

(a) The chemical is present in food as a result of washing, or preparing, or processing the food with drinking water which is received from a public water system as defined in Health and Safety Code Section 4010.1 or from a commercial supplier of drinking water, or which meets state or federal primary drinking water standards for the chemical, provided that the responsible person has not added a listed chemical in excess of the no significant risk level to the drinking water; or

(b) The chemical present in food is naturally occurring.

(1) For the purposes of this section, a chemical is "naturally occurring" if it is a natural constituent of a food, or if it is present in a food solely as a result of natural absorption or accumulation of the chemical which is naturally present in the environment in which the food is raised, or grown, or obtained; for example, mineral present in the soil solely as a result of natural geologic processes, or toxins produced by the natural growth of fungi.

(2) The "naturally occurring" level of a chemical in food may be established by determining the natural background level of the chemical in the area in which the food is raised, or grown, or obtained, based on reliable local or regional data.

(3) A chemical is naturally occurring only to the extent that the chemical did not result from any known human activity other than ordinary cultivation practices. Where a food contains a chemical, in part naturally occurring and in part added as a result of human activity, "exposure" can only occur as to that portion of the chemical which resulted from such human activity.

(4) Where a chemical contaminant can occur naturally in food, the chemical is natually occurring only to the extent that it was not avoidable by good manufacturing practices or other intervening measures.

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Section 25249.6, Health and Safety Code.

HISTORY:

1. New section filed 2-24-88 as an emergency; operative 2-27-88 (Register 88, No. 11). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 6-27-88.

(Register 88, No. 11—3-12-88)

12503. Environmental Exposures.

(a) A person otherwise responsible for an exposure to a listed chemical in water, including water in any consumer product, does not "expose" an individual within the meaning of Section 25249.6 to the extent that the person can show that the listed chemical was contained in water which was received from:

(1) a public water system, as defined in Section 4010.1 of the Health and Safety Code;

(2) a commercial supplier of drinking water; or

(3) a source of drinking water in compliance with all state or federal primary drinking water standards and the chemical is the result of treatment of the water in order to achieve such compliance; and the person did not add a listed chemical, in excess of the no significant risk level, to the water.

(b) A person otherwise responsible for an exposure to a listed chemical does not "expose" an individual within the meaning of Health and Safety Code Section 25249.6 to the extent that the person can show that the chemical was contained in water which the person discharged or released in the manner described in Section 12401.

(1) Nothing in this subdivision shall be interpreted to affect the responsibility for an exposure which occurs before such discharge or release.

(c) A person otherwise responsible for an exposure to a listed chemical in air does not "expose" an individual within the meaning of Health and Safety Code Section 25249.6 to the extent that the person can show that:

(1) The listed chemical was contained in air that the person received from the ambient air, and

(2) The responsible person did not add the listed chemical at a significant level to the ambient air.

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Sections 25249.6 and 25249.11, Health and Safety Code.

HISTORY:

1. A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 6-27-88.

12505. Miscellaneous.

(a) Where a product is washed, prepared or processed with drinking water, a chemical may be established to be present in the product as a result of that water by reliable scientific evidence and shall be deemed to be present as a result of that water to the extent that the amount of that chemical does not exceed the primary drinking water standard.

(b) Where a product contains a chemical in part from water or natural sources and in part from other sources, "exposure" occurs only as to that portion of the chemical present in the product from the other sources.

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Sections 25249.6 and 25249.11, Health and Safety Code.

HISTORY:

1. New section filed 2-24-88 as an emergency; operative 2-27-88 (Register 88, No. 11). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 6-27-88.

INITIAL
STATEMENT OF REASONS
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Section 12501. Exposures To Naturally Occurring Chemicals In Food

The Safe Drinking Water and Toxic Enforcement Act provides that no person in the course of doing business shall knowingly and intentionally expose any individual to chemicals known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning. (Health and Saf. Code § 25249.6.) The Act does not differentiate between exposures to naturally occurring chemicals and exposures to chemicals added by man. However, due to the abundance of foods which in their natural unprocessed state inherently contain low levels of carcinogens or reproductive toxicants, warnings could appear on a large number of food products, and consequently, diminish the overall significance of food warnings.

The proposed regulation would provide that human consumption of food containing a listed chemical does not constitute an "exposure" within the meaning of the Act to the extent that it is shown that the chemical is naturally occurring. This exemption is derived from the distinction in state and federal food adulteration laws between naturally occurring substances in food and those which are added substances. (Health and Saf. Code § 26520; 21 U.S.C. § 342(a).) The laws make it easier to prove adulteration where a deleterious substance was introduced into food by man, than where a substance was naturally occurring in the food. This distinction is limited to food, and has not been extended to drugs, cosmetics, or other consumer products. The rationale for this special treatment of food is the historical desire to preserve naturally occurring foods in the American food supply, despite the presence in those foods of small amounts of potentially deleterious substances, as well as a recognition of the general safety of unprocessed foods as a matter of consumer experience. (O'Reilly, Food and Drug Administration, Section 9.01, p. 9-5; U.S. v. Coca-Cola, 241 U.S. 265 (1916).) For these same reasons, it is reasonable and appropriate to implement the Act so that warnings are not required for naturally occurring chemicals in food. Moreover, this exemption is consistent with the intent of Proposition 65 and the concerns expressed in the ballot arguments about preventing exposures from toxic chemicals "put" into the environment, which indicate that the Act was primarily directed at added chemicals rather than naturally occurring substances in food.

Subsection (a)(2) defines the term "naturally occurring" for the purpose of the exemption. The Federal Food and Drug

Administration (FDA) has adopted a regulation which defines a "natural occurring substance" as one which is an "inherent natural constituent of a food, and is not the result of environmental, agricultural, industrial, or other contamination". (21 CFR 109.3.) Several federal cases have held that "added substances" are those toxins which were added through human activity, including past environmental pollution. (U.S. v. Anderson Seafoods, Inc., 62 F.2d 157 (1980) [mercury in swordfish]; Seabrook International Foods v. Harris, 501 F.Supp. 1086 (1980) [salmonella in shrimp]; Continental Seafood v. Schweiker, 674 F.2d 38 (1982) [salmonella in shrimp].) Under this interpretation, which has been incorporated in part into the proposed regulation, chemicals in food which are caused by cooking, fermentation, or any other processing are not naturally occurring because the chemicals are added to the food by human agency. Given the difficulty of establishing the exact amount of "naturally occurring" chemical in a particular food, subsection (a)(2) allows the level of chemical in food to be established using the natural background level of chemical in the area in which the food was raised, grown, or obtained, based on relevant and reliable local or regional data.

Since naturally occurring chemicals do not give rise to an "exposure", subsection (a)(3) clarifies that where a food contains a chemical which is part natural and part added, only that portion of the chemical which was added as a result of human activity can result in an "exposure." The definition of "human activity" excludes ordinary cultivation practices, such a planting, plowing, and irrigation, which are basic to crop production and are not likely to cause an increased level of a listed chemical in food. However, under this definition, a chemical in food is not naturally occurring to the extent that it results from the addition of fertilizers, pesticides, nematocides, or other chemicals to the irrigation water applied to soil or crops.

Subsection (a)(4) provides that even where a chemical contaminant in food may be naturally occurring, any increase in the amount of chemical which was avoidable by good manufacturing practices or other intervening measures is not naturally occurring. This is because some chemicals, such as aflatoxin, which is produced by the natural growth of fungi on food in moist environments, are naturally occurring substances in that the presence of the chemical may not be the result of human activity. However, the level of these toxins will increase with prolonged storage in damp unventilated areas, a condition which could have been avoided by better storage practices. Contaminated food items may also be eliminated by careful inspection and sorting.

Subsection (b) provides that where human consumption of a naturally occurring chemical in a food would not cause an "exposure" pursuant to subsection (a), the same naturally occurring chemical will similarly not give rise to an "exposure" if the food is subsequently used in the production or processing of a consumer product other than food. In general, chemicals are

more readily absorbed into the body by way of ingestion than by dermal contact or other routes. Therefore, it is reasonable to provide that where there is not an "exposure" to a naturally occurring chemical in food by the route of ingestion, there is not an "exposure" to the same chemical when the food is used as a component of a consumer product other than food.

Although the existing emergency language in section 12501 is proposed for repeal, the substance of the existing regulation is carried over with little change into the new proposed regulations. Subsection (a), governing the use of drinking water in food, is now merged into proposed section 12503(a), a similar provision relating to any exposure "which involves the use of drinking water, including the use of drinking water in food or any other consumer product." By eliminating unnecessary repetitive verbiage, clarity is enhanced and the regulation is allowed to focus on exposures to naturally occurring chemicals in food.

Furthermore, for the purpose of determining whether a chemical in food is naturally occurring or added by human activity, the reference in existing section 12501(b)(3) to human activity "other than ordinary cultivation practices" is overbroad in that it may be interpreted to exempt the application of fertilizers or other agricultural chemicals, contrary to the intent of the Agency. This ambiguity is corrected in proposed section 12501(a)(3) by specifically listing those agricultural practices which fall outside the scope of "human activity."

Section 12503. Environmental Exposures

Entities in the operation of a public water system are exempt from the Act pursuant to Health and Safety Code section 25249.11(b), and thus are not required to provide warnings for exposure to chemicals in drinking water which they serve to their customers' tap. Since most businesses have little control over the drinking water which comes to them from a public water system, it is reasonable that businesses which have little choice but to use this drinking water should not be required to provide warnings for chemicals which were in the drinking water. The proposed regulation provides an exemption from the warning requirement for chemicals contained in water which was received from a public water system. For consistency, the exemption also applies to the use of drinking water from sources other than public water systems, so long as the water meets the same water quality standards for chemicals as public water systems are expected to meet. Where the source of a listed chemical is partly from drinking water and partly from other sources, this exemption applies only to that portion of the chemical which originated from drinking water as specified in subsection (a), and not to the portion from any other sources.

Similarly, although the Act regulates exposures by inhalation of toxic chemicals in the air, most individual businesses are not in a position to control the quality of the

ambient air which enters their property, or to avoid exposing people to ambient air. Subsection (c) provides an exemption from the warning requirement for chemicals which are contained in air that the responsible person received from the ambient air. Where the source of a listed chemical is partly from the ambient air and partly from other sources, this exemption applies only to that portion of the chemical which is in the air solely as a result of its presence in the ambient air, not to the portion from any other sources, including that which is added into the ambient air by the person responsible for the exposure.

Subsection (b) provides that where the movement of water containing a listed chemical is not deemed a "discharge" or "release" pursuant to section 12401, the chemicals in that water will likewise not give rise to an "exposure" within the meaning of the Act. This provision would make the application of the exposure requirement more consistent with the proposed discharge provisions.

The existing emergency regulation section 12505, titled "Miscellaneous", is proposed for repeal because it deals with an area already more appropriately addressed in proposed section 12503 regarding environmental exposures associated with the use of drinking water. The existing language in section 12505(a) relating to products "washed, prepared or processed with drinking water" could be misinterpreted to authorize an unintended expansion of the exemption for chemicals associated with the use of drinking water. This subject is now covered in proposed section 12503 in a manner which more accurately reflects the intent of the Agency.

The existing language of section 12505(b), except for an ambiguous reference to chemicals from "natural sources", has been incorporated into proposed section 12503(a) and (c). This language presents a clearer statement of the limited application of the exemption from the warning requirement when the source of the listed chemical is partly from drinking water or the ambient air, and partly from other sources. It replaces language in existing emergency regulation section 12503(a) and (c), relating to the "addition" of a listed chemical to drinking water or to the ambient air, which has caused some confusion. Since the proposed text for section 12503 accomodates the above-described revisions, existing section 12503 is proposed for repeal.

TITLE 22. CALIFORNIA HEALTH AND WELFARE AGENCY

ACTION: Notice of Emergency Rulemaking
Sections 12701, 12703, 12705, 12707, 12709, 12711, 12713, 12721 - No Significant Risk
Sections 12801, 12803, 12805, 12821 - No Observable Effect

SUBJECT: Safe Drinking Water and Toxic Enforcement Act of 1986

PUBLIC PROCEEDINGS: Notice is hereby given that the California Health and Welfare Agency will hold a public hearing commencing at 10:00 a.m. on July 29, 1988 in the Auditorium at 714 P Street, Sacramento, CA, at which time any person may present statements or arguments orally or in writing relevant to the action described in this notice. Any written statements or arguments must be received by the Office of Regulations, Department of Health Services, 714 P Street, Room 1000, P.O. Box 942732, Sacramento, CA 94234-7320 by 5:00 p.m. on July 29, 1988 which is hereby designated as the close of the written comment period. It is requested but not required that written statements or arguments be submitted in duplicate.

CONTACT: Inquiries concerning the action described in this notice may be directed to Dr. Steven A. Book, Science Advisor to the Secretary and Executive Secretary to the Scientific Advisory Panel at (916) 445-6900.

INFORMATIVE DIGEST:

The Safe Drinking Water and Toxic Enforcement Act of 1986 (Act) has two principal provisions. It prohibits persons in the course of doing business from knowingly discharging or releasing a chemical known to the state to cause cancer or reproductive toxicity into water or onto or into land where it passes or probably will pass into a source of drinking water. It also prohibits persons in the course of doing business from knowingly and intentionally exposing any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving a clear and reasonable warning.

The Act also creates limited exceptions to these prohibitions. Among other things, it provides that no warning is required for exposure to a chemical known to the state to cause cancer where the person responsible for the exposure can show that it poses no significant risk at the level of the exposure, or to a chemical known to the state to cause reproductive toxicity where the person responsible for the exposure can show that it will have no observable effect assuming exposure at one thousand times the level of exposure.

The Act also provides an exception to the prohibition on discharges or releases of chemicals where the discharge or

release complies with other legal requirements and does not cause a significant amount of the chemical to enter a source of drinking water. A significant amount of a chemical is defined as a detectable amount or an amount which would not require a warning for an exposure in drinking water under the exception previously noted.

The Act does not establish levels of exposure which present no significant risk for chemicals known to the state to cause cancer or describe methods for establishing such levels. Similarly, the Act provides no specific levels of no observable effect for chemicals known to the state to cause reproductive toxicity and no methods for calculating those levels.

On February 27, 1988, the Health and Welfare Agency adopted as an emergency measure regulations to establish methods and principles for determining levels of chemicals that pose no significant risks of cancer and produce no observable effect for reproductive toxicants. In addition, the regulations established levels of exposure and means of exposure that pose no significant risk or produce no observable effect. It is the intention of the Health and Welfare Agency to receive and respond to public comment on the emergency regulations in compliance with the Administrative Procedure Act.

The emergency regulations may be summarized as follows:

1. Article 7. No Significant Risk Levels.

a. Section 12701. General.

This section sets forth general principles concerning the determination of whether a chemical poses no significant risk of cancer, and describes the methods by which a determination of no significant risk may be made under this article.

b. Section 12703. Quantitative Risk Assessment.

This regulation establishes standards and describes evidence which can be used to perform a quantitative risk assessment unless more scientifically appropriate means are available. Also, this section sets forth a level of risk one excess case of cancer in an exposed population of 100,000, which represents no significant risk.

c. Section 12705. Specific Regulatory Levels Posing No Significant Risk Levels.

The section sets out a procedure for establishing chemical-specific levels of no significant risk under the Act. It provides for review by the Scientific Advisory Panel (Panel) prior to adoption of such levels. No levels are being established under this provision at this time.

d. Section 12707. Routes of Exposure.

This section describes the circumstances under which it can be shown that a chemical known to the state to cause cancer does not pose a significant risk by a particular route of exposure. It establishes that certain specific chemicals present no significant risk by route of ingestion.

e. Section 12709. Exposure to Trace Elements.

This section sets forth levels of no significant risk for certain elements, trace amounts of which are widely distributed in nature.

f. Section 12711. Levels Based on State or Federal Standards.

Here, it is established that no significant risk may be demonstrated by application of risk levels adopted by other state or federal agencies, if such levels are calculated to result in no more than one excess case of cancer in an exposed population of 100,000. Chemical-specific levels of no significant risk based on state or federal risk assessments are set forth.

g. Section 12713. Exposure to Food, Drugs, Cosmetics and Medical Devices.

This section provides that, on an interim basis, exposure to chemicals present in food, drugs, cosmetics and medical devices which comply with applicable legal requirements related to safety, do no pose a significant risk of cancer under the Act. This section does not apply to chemicals for which a specific risk assessment has been adopted under the Act.

e. Section 12721. Level of Exposure to Carcinogens.

This section clarifies terms used in Health and Safety Code section 25249.10(c) related to no significant risk and describes principles for determining the level of exposure to a chemical known to the state to cause cancer.

2. Article 8. No Observable Effect Levels.

a. Section 12801. General.

This section sets forth general principles concerning the determination of whether a level of exposure to a chemical has no observable effect and describes methods by which a determination of no observable effect may be made under this article.

b. Section 12803. Assessment.

Establishes standards and describes evidence which can be

used to determine no observable effect in the absence of more scientifically appropriate means.

c. Section 12805. Specific Regulatory Levels: Reproductive Toxicants.

This section includes levels for exposure for specific chemicals which produce no observable effect at 1,000 times the specified levels. In the absence of specified levels, this section allows use of an assessment by a state or federal agency under specified conditions.

d. Section 12821. Level of Exposure to Reproductive Toxicants.

This section clarifies terms used in Health and Safety Code section 25249.10(c) related to no observable effect and describes principles for determining the level of exposure to a chemical known to the state to cause reproductive toxicity.

AUTHORITY: Health & Safety Code § 25249.12

REFERENCE: Health & Safety Code §§ 25249.9, 25249.10, 25249.11

FISCAL IMPACT ESTIMATE:

A. Fiscal Effect on Local Government: No additional costs or savings.

B. Fiscal Effect on State Government: No additional costs or savings.

C. Fiscal Effect on Federal Funding of State Programs: No fiscal impact exists.

D. Fiscal Effect on Private Persons or Businesses Directly Affected: Undetermined cost savings resulting from clarification of the applicability of the Act.

E. Fiscal Effect on Small Businesses: No additional costs or savings.

DETERMINATIONS: The Agency has determined that the regulations would not impose a mandate on local agencies or school districts, nor are there any costs, for which reimbursement is required by Part 7 (commencing with section 17500) of Division 4 of the Government Code.

The Agency has also determined that the regulations would not have a significant adverse economic impact on small businesses.

AVAILABILITY OF STATEMENT OF REASONS AND TEXT OF REGULATIONS:

the information upon which the emergency regulations are based, and the text of the emergency regulations. A copy of the initial statement of reasons and a copy of the text of the emergency regulations are available upon request by writing to the Office of Regulations at the address noted above, which address will also be the location of public records, including reports, documentation and other materials related to the emergency regulations.

AVAILABILITY OF CHANGED OR MODIFIED TEXT: The full text of any regulation which is changed or modified from the express terms of the emergency action will be made available by the Office of Regulations at least 15 days prior to the date on which the Agency adopts, amends or repeals the resulting regulation.

ADDITIONAL COMMENTS: In accordance with Government Code Section 11346.5(a)(7), the Agency must determine that no alternative considered by the Agency would be more effective in carrying out the purpose for which the emergency action was taken or would be as effective and less burdensome to affected private persons than the emergency action. Other regulation changes may be scheduled for hearing at the same time appointed for public hearing on the action described in this notice. An agenda for the public hearing will be posted at the time and place of hearing designated above.

HEALTH AND WELFARE AGENCY

Dated: May 20, 1988

CLIFFORD L. ALLENBY
Secretary

22 CALIFORNIA CODE OF REGULATIONS DIVISION 2
STATE OF CALIFORNIA
HEALTH AND WELFARE AGENCY
CHAPTER 3. SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986

ARTICLE 7. No Significant Risk Levels

12701. General.

(a) The determination of whether a level of exposure to a chemical known to the state to cause cancer poses no significant risk for purpose of Health and Safety Code section 25249.10(c) shall be based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of the chemical as known to the state to cause cancer. Nothing in this article shall preclude a person from using evidence, standards or levels not described in this article to establish that a level of exposure to a listed chemical poses no significant risk.

(b) The determination that exposure to a listed chemical poses no significant risk under this article may be made:

(1) By means of a quantitative risk assessment that meets the standards described in section 12703;

(2) By application of section 12707 (Routes of Exposure); or

(3) By one of the following, as applicable:

A. If a specific regulatory level has been established for the chemical in question in section 12705, by application of that level.

B. If no specific level is established for the chemical in question in section 12705, by application of section 12709 (Exposure to Trace Elements), 12711 (Levels Based on State or Federal Standards) or 12713 (Exposure to Food, Drugs, Cosmetics and Medical Devices).

(c) The chemicals, routes of exposure and conditions of use specifically listed in this article do not include all chemicals, routes of exposure and conditions of use that may pose no significant risk. The fact that a chemical, route of exposure or condition of use does not appear in this article does not mean that it poses a significant risk.

(d) This article establishes exposure levels posing no significant risk solely for purposes of Health and Safety Code section 25249.10(c). Nothing in this article shall be construed to establish exposure or risk levels for other regulatory purposes.

AUTHORITY: Health and Safety Code section 25249.12
REFERENCE: Health and Safety Code sections 25249.5, 25249.6, 25249.9, 25249.10, 25249.11

12703. Quantitative Risk Assessment.

(a) Where a quantitative risk assessment is used for the purpose of establishing the level at which a chemical poses no significant risk, it shall be based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for listing the chemical as known to the state to cause cancer. In the absence of any more scientifically appropriate principles or data, the following default assumptions should be considered in any such assessment:

(1) Animal bioassay studies for quantitative risk assessment should meet generally accepted scientific principles, including the thoroughness of experimental protocol, the degree to which dosing resembles the expected manner of human exposure, the temporal exposure pattern, the duration of study, the purity of test material, the number and size of exposed groups, the route of exposure, and the extent of tumor occurrence.

(2) The quality and suitability of available epidemiologic data should be appraised to determine whether the study is appropriate as the basis of a quantitative risk assessment, considering such factors as the selection of the exposed and reference groups, reliable ascertainment of exposure, and completeness of follow-up. Biases and confounding factors should be identified and quantified.

(3) Risk analysis should be based on the most sensitive study deemed to be of sufficient quality.

(4) The results obtained for the most sensitive study deemed to be of sufficient quality shall be applicable to all routes of exposure for which the results are relevant.

(5) The absence of a carcinogenic threshold dose should be assumed and no-threshold models shall be utilized. In the absence of other scientifically appropriate extrapolation models, methods utilizing the linearized multistage model for extrapolation from high to low doses, with the upper 95 percent confidence limit of the linear term the most appropriate for

expressing the upper bound of potency are preferred. Time-to-tumor models may be appropriate where data are available on the time of appearance of individual tumors, and particularly when survival is poor due to competing toxicity.

(6) Human cancer potency may be derived from data on human or animal cancer potency. Potency shall be expressed in milligrams of chemical per kilogram of bodyweight per day. Interspecies conversion of animal cancer potency to human cancer potency may be determined by multiplying by a surface area scaling factor equivalent to the ratio of human to animal bodyweight, taken to the one-third power. Alternatively, a scaling factor of 14 may be used when extrapolating from mouse data, and a scaling factor of 6.5 may be used when extrapolating from rat data.

(7) When available data are of such quality that physiologic, pharmacokinetic and metabolic considerations can be taken into account with confidence, they may be used in the risk assessment for inter-species, inter-dose, and inter-route extrapolations.

(8) When the cancer risk applies to the general population, human body weight of 70 kilograms should be assumed. When the cancer risk applies to a certain subpopulation, the following assumptions should be made, as appropriate:

| Subpopulation | Kilograms of Body Weight |
|---|---|
| Man (18+ years of age) | 70 |
| Woman (18+ years of age) | 58 |
| Women with conceptus | 58 |
| Adolescent (11-18 years of age) | 40 |
| Child (2-10 years of age) | 20 |
| Infant (0-2 years of age) | 10 |

(b) For chemicals assessed in accordance with this section, the risk level which represents no significant risk shall be one which is calculated to result in one excess case of cancer in an exposed population of 100,000, assuming lifetime exposure at the level in question, except where sound considerations of public health support an alternative level.

AUTHORITY: Health and Safety Code section 25249.12
REFERENCE: Health and Safety Code sections 25249.5, 25249.6, 25249.9, 25249.10, 25249.11

12705. Specific Regulatory Levels Posing No Significant Risk

(a) Exposure to a chemical at a level which does not exceed the level set forth in subsection (b) for such chemical poses no significant risk within the meaning of Health and Safety Code section 25249.10(c).

(b) (reserved)

(c) Whenever the lead agency proposes to formally adopt a level at which a chemical known to the state to cause cancer which poses no significant risk established solely for the purposes of the Safe Drinking Water and Toxic Enforcement Act of 1986, it shall provide to each member of the Scientific Advisory Panel notice of the proposed action, a copy of the proposed level, and a copy of initial statement of reasons supporting the proposal. The close of the public comment period for any such proposal shall be scheduled by the lead agency so as to permit the Scientific Advisory Panel the opportunity to review such proposal and provide comment to the lead agency. Any such comment by the Scientific Advisory Panel shall become a part of the formal

rulemaking file. Nothing in this subdivision shall be construed to prevent members of the Scientific Advisory Panel from providing comments individually on any such proposal, or to require the Scientific Advisory Panel to submit any comment.

AUTHORITY: Health and Safety Code section 25249.12
REFERENCE: Health and Safety Code sections 25249.5, 25249.6, 25249.9, 25249.10, 25249.11

12707. Routes of Exposure

(a) Where scientifically valid absorption studies conducted according to generally accepted standards demonstrate that absorption of a chemical through a specific route of exposure can be reasonably anticipated to present no significant risk of cancer at levels of exposure not in excess of current regulatory levels, the lead agency may identify the chemical as presenting no significant risk by that route of exposure. Any exposure, discharge or release of a chemical so identified shall be deemed to present no significant risk to the extent that it results in exposure to humans by the identified route, and does not exceed the level established in any other applicable federal or state standard, regulation, guideline, action level, license, permit, condition, requirement or order.

(b) The following chemicals present no significant risk of cancer by the route of ingestion:

(1) Beryllium and beryllium compounds

(2) Cadmium and cadmium compounds

(3) Chromium (hexavalent compounds)

AUTHORITY: Health and Safety Code section 25249.12
REFERENCE: Health and Safety Code sections 25249.5, 25249.6, 25249.9, 25249.10, 25249.11

12709. Exposure To Trace Elements.

(a) Except where a specific regulatory level is established in 12705, exposure to a trace element listed in (b) poses no significant cancer risk so long as the reasonably anticipated level of exposure to the chemical does not exceed the level set forth in (b).

| (b) Element | No Significant Risk Level in micrograms per day |
|---|---|
| Arsenic (inorganic) | 10 |
| Beryllium | 0.1 |
| Cadmium | 1 |

AUTHORITY: Health and Safety Code section 25249.12
REFERENCE: Health and Safety Code sections 25249.5, 25249.6, 25249.9, 25249.10, 25249.11

12711. Levels Based on State or Federal Standards.

(a) Except as otherwise provided in section 12705, 12707, 12709, or 12713, levels of no significant risk may be determined as follows:

(1) Where a state or federal agency has developed a regulatory level for a chemical known to the state to cause cancer which is calculated to result in not more than one excess case of cancer in an exposed population of 100,000, such level shall constitute the no significant risk level.

(2) The following levels based on state or federal risk assessments shall be deemed to pose no significant risk:

| Chemical Name | Level (micrograms/day) |
|---|---|
| Acrylonitrile | 3 |
| Asbestos | 100 fibers inhaled/day |

| | 140 million fibers ingested/day |
|---|---|
| Benzene | 20 |
| Benzidine | 0.003 |
| Benzo[a]pyrene | 0.06 |
| Bis(chloromethyl)ether | 0.6 |
| Carbon tetrachloride | 5 |
| Chloroform | 9 |
| Chromium (hexavalent) | 0.001 |
| Coke oven emissions | 0.3 |
| DDT | 2 |
| 3-3'-Dichlorobenzidine | 0.4 |
| Epichlorohydrin | 70 |
| Ethylene dibromide | 3 |
| Ethylene dichloride | 9 |
| Ethylene oxide | 2 |
| Hexachlorobenzene | 0.4 |
| Hexachlorocyclohexane (technical grade) | 0.4 |
| Nickel refinery dust | 0.8 |
| Nickel subsulfide | 0.4 |
| N-Nitrosodi-n-butylamine | 0.1 |
| N-nitrosodiethylamine | 0.02 |
| N-nitrosodimethylamine | 0.03 |
| N-Nitrosopyrrolidine | 0.3 |
| N-nitroso-N-ethylurea | 0.02 |
| N-nitroso-N-methylurea | 0.002 |
| Polychlorinated Biphenyls (PCBs) | 0.09 |
| Tetrachlorodibenzo-p-dioxin (TCDD) | 0.000005 |
| Toxaphene | 0.6 |
| 2,4,6-Trichlorophenol | 40 |
| Vinyl chloride | 0.3 |

AUTHORITY: Health and Safety Code section 25249.12
REFERENCE: Health and Safety Code sections 25249.5, 25249.6, 25249.9, 25249.10, 25249.11

12713. Exposure to Food, Drugs, Cosmetics and Medical Devices. The Health and Welfare Agency has determined, based on the recommendation of the Scientific Advisory Panel, that exposure to a listed chemical in a food, drug, cosmetic or medical device regulated under state and federal food safety laws poses no significant risk as described in this section. This section is

an interim standard. As quantitative risk assessments are performed or identified for listed chemicals and specific regulatory levels are adopted under section 12705, those levels will supersede the provisions of this section.

(b) For purposes of this section:

(1) "Food" shall have the same meaning as set forth in subsection (f) of section 321 of Title 21 of the United States Code (21 USC § 321 (f)).

(2) "Cosmetic" shall have the same meaning as set forth in subsection (i) of section 321 of Title 21 of the United States Code (21 USC § 321 (i)).

(3) "Drug" shall have the same meaning as set forth in subsection (g) of section 321 of Title 21 of the United States Code (21 USC § 321 (g)).

(4) "Medical device" shall have the same meaning as set forth in subsection (h) of section 321 of Title 21 of the United States Code (21 USC § 321 (h)).

(5) "Administrative standards" means all legal requirements that relate to safety by the state or federal agencies responsible for administering state or federal statutes, including regulations, product approvals or licenses, enforcement action levels, and related requirements.

(c) Except as otherwise provided in section 12705, exposure to a chemical known to the state to cause cancer and present in a

food, drug, medical device, or cosmetic (including constituents and contaminants) shall be deemed to pose no significant risk within the meaning of Health and Safety Code section 25249.10(c), provided that:

(1) the chemical is a food additive within the meaning of section 321 of Title 21 of the United States Code, including any food packaging material, approved for use at a specified level by the federal Food and Drug Administration pursuant to section 348 of Title 21 of the United States Code, or the California Department of Health Services, and is in compliance with all applicable administrative standards.

(2) the chemical is a food substance identified by the federal Food and Drug Administration or the California Department of Health Services to be generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use, and is in compliance with all applicable administrative standards.

(3) the chemical is a food substance used in accordance with a sanction or approval granted prior to January 1, 1958 pursuant to the federal Food, Drug and Cosmetic Act, the Poultry Products Inspection Act (21 U.S.C. 451, et seq.), or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21

U.S.C. 71, et seq.), and is in compliance with all applicable administrative standards.

(4) the chemical is a color additive within the meaning of section 321 of Title 21 of the United States Code approved for use at a specified level by the federal Food and Drug Administration, or the California Department of Health Services, and is in compliance with all applicable administrative standards.

(5) the chemical is a substance which is required in the production of food or which cannot be avoided by good manufacturing practice, and for which a specific tolerance level has been established by the federal Food and Drug Administration, or the California Department of Health Services, and is in compliance with all applicable administrative standards.

(6) the chemical is a pesticide chemical within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C., §§ 135 - 135k) which is used in the production, storage, or transportation of agricultural commodities within the meaning of section 321 of Title 21 of the United States Code and for which a specific tolerance level has been established and is in compliance with all applicable administrative standards.

(7) the chemical is an animal drug within the meaning of section 321 of Title 21 of the United States Code approved for use at a specified level by the federal Food and Drug Administration, or the California Department of Health Services, and is in compliance with all applicable administrative standards.

(8) the chemical is a drug within the meaning of section 321 of Title 21 of the United States Code, including a drug generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, and is in compliance with all applicable administrative standards.

(d) If a chemical known to the state to cause cancer in a food, drug, medical device, or cosmetic (including constituents and contaminants) is not subject to a specific regulatory level set forth in section 12705, or paragraphs (1) through (8) of subdivision (b) of this section, an exposure to such chemical shall be deemed to pose no significant risk within the meaning of Health and Safety Code section 25249.10(c), provided that the exposure is in compliance with all applicable administrative standards.

(e) This section shall not apply to any drug the labeling of which contains a statement that the drug is carcinogenic.

(f) Paragraphs (c) and (d) of this section are intended to establish safe levels of exposure to chemicals present in foods, drugs, medical devices, or cosmetics, and are based on assumptions about the level and type of exposures occurring in these media.

AUTHORITY: Health and Safety Code section 25249.12
REFERENCE: Health and Safety Code sections 25249.5, 25249.6, 25249.9, 25249.10, 25249.11

12721. Level of Exposure to Carcinogens.

(a) For the purposes of the Act, "level in question" means the chemical concentration of a listed chemical for the exposure in question. The exposure in question includes the exposure for which the person in the course of doing business is responsible, and does not include exposure to a listed chemical from any other source or product.

(b) For purposes of the Act, "lifetime exposure" means the reasonably anticipated rate of exposure for an individual to a given medium of exposure measured over a lifetime of seventy years.

(c) For purposes of Health and Safety Code section 25249.10(c), the level of exposure to a listed carcinogen, assuming lifetime exposure at the level in question, shall be determined by multiplying the level in question (stated in terms of a concentration of a chemical in a given medium) times the reasonably anticipated rate of exposure for an individual to the given medium of exposure measured over a lifetime of seventy years.

(d) The following assumptions shall be used to calculate the reasonably anticipated rate of exposure to a listed carcinogen, unless more specific and scientifically appropriate data are available:

(1) For an exposure reasonably expected to affect the general population in any geographic area:

A. The exposed individual ingests two liters of drinking water per day.

B. The exposed individual inhales twenty cubic meters of air per day.

C. The exposed individual has a lifespan of seventy years.

(2) For an exposure reasonably anticipated to affect a certain subpopulation of the general population in any geographic area, specific data (if available) relating to that subpopulation shall be used to determine the level of exposure.

A. In the absence of more specific and scientifically appropriate data, the following assumptions should be made as appropriate:

| Subpopulation | Water liters/day | Air cubic meters/day |
|---|---|---|
| Man (18 + years of age) | 2 | 20 |
| Woman (18 + years of age) | 2 | 20 |
| Mother with conceptus | 2 | 20 |
| Adolescent (10-18 years of age) | 2 | 20 |
| Child (2-10 years of age) | 2 | 15 |
| Infant (0-2 years of age) | 1 | 4 |

B. For an exposure reasonably expected to affect the conceptus (embryo or fetus), the gestation period for the exposed conceptus is nine months.

(3) For workplace exposures, the exposed worker inhales ten cubic meters of workplace air per eight-hour day, forty hours per week, fifty weeks per year over a forty-year period. The exposed individual from the general population who occasionally enters a workplace inhales 1.25 cubic meters of workplace air for one hour per month for a seventy-year lifetime.

(4) For exposures to consumer products, lifetime exposure shall be calculated using the average rate of intake or exposure for users of the consumer product, and not on a per capita basis for the general population. The average rate of intake or exposure shall be based on data for use of a general category or categories of consumer products, such as the United States Department of Agriculture Home Economic Research Report, Foods Commonly Eaten by Individuals: Amount Per Day and Per Eating Occasion, where such data are available.

AUTHORITY: Health and Safety Code section 25249.12
REFERENCE: Health and Safety Code sections 25249.5, 25249.6, 25249.9, 25249.10, 25249.11

ARTICLE 8. No Observable Effect Levels

12801. General.

(a) The determination of whether a level of exposure to a chemical known to the state to cause reproductive toxicity has no observable effect for purposes of Health and Safety Code section 25249.10(c) shall be based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of a chemical as known to the state to cause reproductive toxicity. Nothing in this article shall preclude a person from using evidence, standards or levels not described in this article to establish that a level of exposure has no observable effect at one thousand (1,000) times the level in question.

(b) The determination that exposure to a listed chemical has no observable effect for purpose of Health and Safety Code section 25249.10(c) may be made under this article by:

(1) conducting an assessment that meets the standards described in section 12803 to determine the maximum dose level having no observable effect, and dividing that level by one thousand (1,000) to arrive at the maximum allowable dose level; or

(2) by application of a specific regulatory level for the chemical in question as provided in section 12805.

(c) For purposes of this article, "NOEL" shall mean that no observable effect level, which is the maximum dose level at which a chemical has no observable effect.

AUTHORITY: Health and Safety Code section 25249.12

REFERENCE: Health and Safety Code sections 25249.5, 25249.6, 25249.9, 25249.10, 25249.11

12803. Assessment.

(a) Where an assessment is conducted for the purposes of establishing the NOEL, such assessment shall be based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for listing the chemical as known to the state to cause reproductive toxicity. In the absence of any more scientifically appropriate principles or data, the following default assumptions should be considered in any such assessment:

(1) Only studies producing the reproductive effect which provides the basis for the determination that a chemical is known to the state to cause reproductive toxicity should be utilized for the determination of the NOEL. Where multiple reproductive effects provide the basis for the determination that a chemical is known to the state to cause reproductive toxicity, the reproductive effect for which studies produce the lowest NOEL shall be utilized for the determination of the NOEL. The NOEL shall be the highest dose level which results in no observable reproductive effect, expressed in milligrams of chemical per kilogram of bodyweight per day.

(2) The quality and suitability of available epidemiologic data should be appraised to determine whether the study is appropriate as the basis of an assessment considering such factors as the selection of the exposed and reference groups, the reliable ascertainment of exposure, and completeness of follow-up. Biases

and confounding factors should be identified and quantified.

(3) Animal bioassay studies for assessment should meet generally accepted scientific principles, including the thoroughness of experimental protocol, the degree to which dosing resembles the expected manner of human exposure, the temporal exposure pattern, the duration of study, the purity of test material, the number and size of exposed groups, and the route of exposure and the extent of occurrence of effects.

(4) The NOEL should be based on the most sensitive study deemed to be of sufficient quality.

(5) The results obtained for the most sensitive study deemed to be of sufficient quality shall be applicable to all routes of exposure for which the results are relevant.

(6) When available data are of such quality that anatomic, physiologic, pharmacokinetic and metabolic considerations can be taken into account with confidence, they may be used in the assessment.

(7) When data do not allow the determination of a NOEL, the lowest observable effect level (LOEL) shall be divided by 10 to establish a NOEL for purposes of assessment.

(b) The NOEL shall be converted to a milligram per day dose level by multiplying the assumed human body weight by the NOEL. When the applicable reproductive effect is upon the male, human body weight of 70 kilograms shall be assumed. When the

applicable reproductive effect is upon the female or conceptus, human body weight of 58 kilograms shall be assumed.

AUTHORITY: Health and Safety Code section 25249.12
REFERENCE: Health and Safety Code sections 25249.5, 25249.6, 25249.9, 25249.10, 25249.11

12805. Specific Regulatory Levels: Reproductive Toxicants.

(a) Exposure to a chemical at a level which does not exceed the level set forth in subsection (b) for such chemical has no observable effect assuming exposure at one thousand (1000) times that level.

| (b) | Chemical Name | Level (Micrograms/day) |
|---|---|---|
| | Ethylene Oxide | 20.0 |
| | Lead | 0.5 |

(c) Unless a specific level is otherwise provided in this section, an assessment by an agency of the state or federal government that is the substantial equivalent of the assessment described in subdivision (a) of section 12803, and establishes a maximum allowable daily dose level in the manner provided in paragraph (b)(1) of section 12801, shall constitute the allowable daily dose level having no observable effect within the meaning of Health and Safety Code Section 25249.10(c).

AUTHORITY: Health and Safety Code section 25249.12
REFERENCE: Health and Safety Code sections 25249.5, 25249.6, 25249.9, 25249.10, 25249.11

12821. Level of Exposure to Reproductive Toxicants.

(a) For purposes of the Act, "level in question" means the chemical concentration of a listed chemical for the exposure in question. The exposure in question includes the exposure for which the person in the course of doing business is responsible,

and does not include exposure to a listed chemical from any other source or product.

(b) For purposes of Health and Safety Code section 25249.10(c), the level of exposure to a listed reproductive toxicant shall be determined by multiplying the level in question (stated in terms of a concentration of a chemical in a given medium) times the reasonably anticipated rate of exposure for an individual to a given medium. The reasonably anticipated rate of exposure shall be based on the pattern and duration of exposure that is relevant to the reproductive effect which provided the basis for the determination that a chemical is known to the state to cause reproductive toxicity. (For example, an exposure of short duration is appropriate for a teratogenic chemical, whereas a chronic or protracted exposure is appropriate for one that retards fetal growth.)

(c) The following assumptions shall be used to calculate the reasonably anticipated rate of exposure to a listed reproductive toxicant, unless more specific and scientifically appropriate data are available:

(1) The assumptions set forth in subdivision (d) of section 12721 shall be used to calculate the reasonably anticipated rate of exposure to a listed reproductive toxicant, unless more specific and scientifically appropriate data are available.

(2) For exposures to consumer products, the level of exposure shall be calculated using the reasonably anticipated rate of

intake or exposure for users of the consumer product, and not on a per capita basis for the general population. The rate of intake or exposure shall be based on data for use of a general category or categories of consumer products, such as the United States Department of Agriculture Home Economic Research Report, Foods Commonly Eaten by Individuals: Amount Per Day and Per Eating Occasion, where such data are available.

(3) Where a maternal exposure to a listed reproductive toxicant has an effect on the conceptus (embryo or fetus), the level of exposure shall be based on the reasonably anticipated rate of exposure for the mother during the nine-month gestation period.

AUTHORITY: Health and Safety Code section 25249.12
REFERENCE: Health and Safety Code sections 25249.5, 25249.6, 25249.9, 25249.10, 25249.11

INITIAL
STATEMENT OF REASONS
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Sections 12701, et seq. - No Significant Risk Levels
Sections 12801, et seq. - No Observable Effect Levels

The Safe Drinking Water and Toxic Enforcement Act of 1986 (Act) prohibits any person in the course of doing business to knowingly discharge or release a chemical known to the state to cause cancer or reproductive toxicity into water or onto or into land where such chemical passes or probably will pass into a source of drinking water. (Health & Saf. Code § 25249.5.) It further prohibits such persons to knowingly and intentionally expose any individual to such a chemical without first giving a clear and reasonable warning. (Health & Saf. Code § 25249.6.)

The Act also creates limited exceptions to these prohibitions. Section 25249.9 provides that section 25249.5 does not apply where a discharge or release complies with all other legal requirements and does not cause "any significant amount" of the chemical to enter any source of drinking water. The term "significant amount" is defined in section 25249.11, subsection (c) as any detectable amount except an amount which, pursuant to section 25249.10, subsection (c), poses "no significant risk assuming lifetime exposure at the level in question" for substances known to the state to cause cancer, or would produce "no observable effect assuming exposure at one thousand (1,000) times the level in question" for substances known to the state to cause reproductive toxicity. Section 25249.10, subsection (c) makes the "no significant risk" and "no observable effect" exceptions apply to the prohibition against exposure without warning.

Any claim of exemption under 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 substance as a chemical known to the state to cause cancer or reproductive toxicity. However, the Act does not further clarify what risks are not "significant," specify levels of chemical exposure posing no significant risk, or describe methods for calculating those levels. Similarly, the Act does not specify levels of exposure to reproductive toxins which have no observable effect, and provides no methods for determining those levels.

There are several steps to a determination whether a chemical exposure poses no significant risk. Generally, data on the chemical risk are assessed to determine what amount of the chemical, usually expressed in terms of milligrams per day, provokes the biologic response of concern in humans. A particular level of human response must be determined to be "significant", a determination which may be influenced by issues of policy and the methodology employed in the underlying risk

assessment. Finally, the level of chemical exposure must be assessed. Under the Act, exposure assessment must be designed to anticipate what exposures will occur, since warnings must be given prior to exposure.

Similarly, a determination whether a chemical exposure would produce "no observable effect" involves several steps. Again, the chemical risk generally must be assessed to determine what amount of the chemical provokes the biologic response of concern in humans. An appropriate safety factor expressed as a divisor is applied to reflect the assessor's confidence in the data upon which he or she has relied. Under the Act, the safety factor is fixed at one thousand (1,000). The level of chemical exposure is then assessed to determine whether it would, as assessed, produce an observable effect or no observable effect.

There is generally no fixed way to perform the steps necessary to determine no significant risk or no observable effect. The methods used may vary depending upon the data available, and the objectives of the risk assessor or risk manager. The fact that there are many steps involved in such determinations, that there are many methods and considerations available at each step, and the possibility that real or potential plaintiffs and defendants in enforcement actions under the Act may be highly motivated to conduct risk assessments in a manner which suits their immediate purposes and objectives, creates the likelihood that, without some guidance from the Health and Welfare Agency (Agency), determinations of what constitutes "no significant risk" or "no observable effect" may vary on a case-by-case basis and persons enforcing the Act or attempting to comply with it could not be certain in advance of the correctness of their actions.

The purpose of these regulations is to provide such guidance regarding the conduct of risk assessments and exposure assessments, and to establish specific levels of exposure, discharge or release which pose no significant risk within the meaning of the Act for chemicals known to the state to cause cancer, or which would produce no observable effect within the meaning of the Act for chemicals known to the state to cause reproductive toxicity.

The regulations are divided into two articles. Article 7, commencing at section 12701, addresses the determination of exposure levels to carcinogens listed under the Act which pose no significant risk. Article 8, commencing at section 12801, addresses the determination of exposure levels to listed reproductive toxins which produce no observable effect within the meaning of the Act.

Section 12701

Subsection (a) describes the scientific standards which must be applied to "no significant risk" determinations. It requires that such determinations be based on evidence and standards of comparable scientific validity to the evidence and standards

which form the scientific basis for the listing of the chemical. In other words, a showing of no significant risk must be based upon data and protocols which are scientifically valid according to generally accepted principles, sharing a comparable degree of scientific acceptance to the data and protocols which supported the listing of the chemical. The purpose of this provision is to ensure that whatever methods are used to conduct risk and exposure assessments conform to a high standard of scientific validity.

However, subsection (a) also provides that nothing in Article 7 is intended to preclude the use of evidence, standards or levels not described in the article to establish that an exposure poses no significant risk. Therefore, the methodologies, data, principles, assumptions and levels described in the sections following section 12701 are not exclusive and do not prevent a plaintiff or defendant in an enforcement action from establishing "no significant risk" by other means. However, such a showing must be based upon data, protocols, evidence and standards which are scientifically valid as provided in subsection (a).

Subsection (b) provides a menu of the methods for determining no significant risk set forth in the regulations. The Agency has recognized in this article several alternative routes for arriving at a "no significant risk" level. They are not, however, afforded equal dignity. It is intended that some methods, such as the use of the no significant risk levels in section 12705 when available, will supersede many of the other methods identified, though not all. Subsection (b) is intended to afford persons enforcing the Act and persons in the course of doing business an easy reference to the use of the regulations which follow section 12701.

Generally, a determination of the level posing "no significant risk" may be made (1) through the performance of a risk assessment in accordance with principles set forth in section 12703, (2) by a determination that the exposure is to a specific chemical by a route, such as ingestion, which poses no significant risk of absorption of the chemical, or (3) the application of specific no significant risk levels set forth in the regulations or other California or federal law. Where specific "no significant risk" levels are to be applied, the regulation establishes a preference for those levels which are adopted solely for purposes of the Act and, in the absence of such levels, permits the use of levels adopted by other California and federal regulatory agencies for other regulatory purposes, levels developed for certain ubiquitous trace elements, and levels approved by the federal Food and Drug Administration for food, drugs, cosmetics and medical devices.

The article does not expressly address "no significant risk" levels, routes of exposure or conditions of use for every listed chemical. Subsection (c) is intended to make clear that the absence of levels, routes of exposure or conditions of use in the

regulations does not mean that there is no level for the chemical which poses no significant risk.

The concept of "no significant risk" may bear similarity to other statutory standards under which specific chemical exposure, discharge, tolerance or contamination levels may have been developed for the protection of the public health. Where levels are established in this article, persons regulated under or enforcing other statutory standards or levels may be motivated to contend that such other levels are superseded or undermined by the levels established herein. Subsection (d) is intended to clarify that the levels set forth in these regulations are established solely for the purposes of implementing the Act, and not to affect any other regulatory program.

Section 12703

This section provides guidelines for conducting quantitative risk assessments for the purpose of establishing "no significant risk" levels. There are many reasons why it is important to have such guidelines in these regulations. For many chemicals, levels which pose no significant risk may not have been developed either for purposes of the Act or other regulatory programs. Thus, persons in the course of doing business involving the chemicals may not have specific numbers on which to rely in determining whether they are in compliance with the Act. As a result, such businesses may unnecessarily alter their business practices, or provide unnecessary warnings which may dilute the effectiveness overall of warnings under the Act. Finally, some persons in the course of doing business may disagree with the specific levels which have been established because, for example, the established level may have been derived from data which is outdated. These persons may choose to conduct their own risk assessments to ascertain a level posing no significant risk.

There are many variables in the performance of a risk assessment. There are competing theories about the mechanisms of carcinogenesis. There are often several studies or sets of data of varying quality upon which the assessment may be based. There are a variety of assumptions which may need to be applied. There are sometimes differences of opinion about what risks are significant. By selecting data of high quality, choosing more conservative and accepted theories and assumptions, and assigning significance to levels of risk in a manner tending toward the protection of the public health, persons in the course of doing business should be able to calculate "no significant risk" levels which can withstand scientific or legal challenge. However, persons enforcing the Act and persons in the course of doing business may be motivated to base their analyses upon less reliable data, less accepted or more controversial theories and assumptions, and assignments of "significance" to exposures at excessively low or high levels to suit their immediate purposes and objectives.

The purpose of this section is to provide a collection of

principles for the conduct of risk assessments which will, if observed, to produce a "no significant risk" level which is conservative, reliable and consistent with the purposes of the Act. The section is not designed to require that all risk assessments be performed according to rigid methodologies. Rather, it is intended to encourage the use of the most scientifically appropriate principles, data and assumptions for each risk assessment.

Subsection (a) requires that all risk assessments be based upon evidence and standards of comparable scientific validity to the evidence and standards which formed the basis for the listing of the chemical. The listing of chemicals under Health and Safety Code section 25249.8(b) must be based upon "scientifically valid testing according to generally accepted principles." Therefore, the same standard applies to the performance of risk assessments used to support a showing of "no significant risk."

The subsection goes on to provide certain default assumptions or principles which the Agency considers to be "generally accepted." However, the regulation provides that other assumptions, principles or data sets should be used where scientifically more appropriate.

The default assumptions set forth in the regulation are based on methods currently used by the state Department of Health Services as set forth in "Guidelines for Chemical Carcinogen Risk Assessments and their Scientific Rationale," November 1985, by the state Department of Food and Agriculture as set forth in "Risk Assessment Guidelines: Oncogenicity," March 9, 1987, and by federal agencies (e.g., the Environmental Protection Agency's Carcinogen Assessment Group) in conducting risk assessments. These methods are generally accepted by the scientific community.

Paragraph (a)(1) provides that animal bioassay data sets used for quantitative risk assessments should conform to generally accepted scientific principles, such as thoroughness of experimental protocol, the relevance of dosing to human exposure, etc. These examples are offered for purposes of illustration, and are not intended as a limitation. The intended purpose of this provision is to assure that the data upon which risk assessments are based are of high quality.

Paragraph (a)(2) makes provisions similar to paragraph (a)(1) applicable to epidemiologic data. Again, the factors of data selection specified in the paragraph are offered for purposes of illustration, and are not intended as a limitation.

Paragraph (a)(3) provides that the risk analysis should be based upon the most sensitive of the studies which, under paragraphs (a)(1) and (a)(2), are deemed to be of sufficient quality. Because of the wide range of sensitivity to chemicals observed in humans, it is likely that the response of the most sensitive animal species will be representative of the response of some individuals. In the absence of a scientifically more appropriate

assumption, basing risk analysis on the most sensitive study will provide an appropriate level of protection to humans.

Paragraph (a)(4) provides that the result obtained from the most sensitive study shall be applicable to all routes of exposure, except those routes for which the results are irrelevant. Absent studies demonstrating a relationship between different routes of administration and differences in carcinogenic response by those routes, it is appropriate and health protective to assume that a chemical that is carcinogenic by ingestion is also carcinogenic by other routes, such as inhalation, and vice versa.

Absorption studies may reveal that a chemical administered by a particular route will be poorly absorbed. If according to generally accepted principles data obtained from such an exposure route are irrelevant to exposures by other routes, this assumption may yield and a different data set may be more appropriate. However, when scientifically based interpretations of these data are able to allow predictions of exposure by other routes, the assumption should apply and the data ought to be utilized.

Paragraph (a)(5) provides assumptions for the extrapolation of animal bioassay data, which is normally based upon responses to maximum tolerated doses of the subject chemical, to low-dose responsiveness. The absence of a carcinogenic threshold is assumed, and the use of no-threshold models is prescribed. Due to the nature of the carcinogenic process, a dose level below which a carcinogenic response is not expected (a "threshold" level) cannot, generally speaking, be experimentally verified at this time. The initial target for carcinogenic action appears to be genetic material or other macromolecules, and there is evidence that carcinogenisis may commence in a single cell. Even assuming that a threshold level exists, it is likely that the threshold dose for the most sensitive individual will approach a zero dose. Therefore, in the absence of data to the contrary, it appears more appropriate to assume that no threshold exists, and that any dose presents some risk.

In the absence of extrapolation models which are appropriate for use according to generally accepted scientific principles, this paragraph prefers the linearized multistage model, with the upper 95 percent confidence limit of the linear term deemed the most appropriate for expressing the upper bound of potency. This model is based on the theory that several distinct changes are necessary to transform a normal cell into a malignant one, and that human cancer can arise from such a single transformed cell. The linearized multistage model forces a linear term in the estimation of the upper confidence limits, and produces a conservative result. However, where data are available on the time of appearance of individual tumors, time-to-tumor models may provide more accurate estimates of carcinogenic effect. This is particularly the case when the toxicity of the test substance causes the premature death of the subjects.

Paragraph (a)(6) provides that the results of low dose extrapolation must be expressed in milligrams of chemical per kilogram of body weight per day. This is the typical measure of exposure in carcinogenicity studies, and the expression of assessment results in a uniform and familiar manner is an important element in arriving at a result which is consistent with the overall risk assessment scheme. Thus, where experimental exposures are expressed in other units (e.g., parts per million of chemical in air or diet), an appropriate conversion to milligrams per kilogram of body weight per day is required to provide a standard for conversion to human exposures.

This paragraph also provides a formula for interspecies scaling and, in the alternative, provides a default factor of 14 when extrapolating mouse data to humans, and a factor of 6.5 when extrapolating rat data to humans. Both the formula and the default factors are based on the state Department of Health Services' "Guidelines for Chemical Carcinogen Risk Assessments." A similar surface scaling factor is used by the U.S. Environmental Protection Agency.

Paragraph (a)(7) allows the use of physiologic, pharmacokinetic and metabolic considerations in inter-species, inter-dose and inter-route extrapolations, where such data may be taken into account with confidence. The susceptibility of different animal species to a given chemical may vary due to differences in metabolism and pharmacokinetics. This provision allows the use of such data to support the validity of extrapolations between species and routes of exposure. It may also be used to identify limitations of those extrapolations. For example, such data may support or contradict the relevance of results obtained by one route of exposure to other routes. However, the data must be of sufficient quality that it may be taken into account with confidence.

Paragraph (a)(8) provides specific assumptions about human body weight. Once the dose or number of milligrams of chemical per kilogram of body weight necessary to produce a particular response has been determined, it is necessary to determine the daily dose level as expressed in milligrams per day. This is accomplished by multiplying the number of milligrams by the assumed body weight of the exposed population. Where the cancer risk from a chemical is to the public in general, the assumed human body weight is equivalent to the assumed body weight of the adult male (i.e., 70 kilograms). This is appropriate because cancer is generally regarded as a risk resulting from exposure over a 70-year lifetime. However, where the cancer risk applies to a certain subpopulation, such as women or infants, different assumptions must be made. The specific assumed body weights set forth in the regulation are derived from the Report of the Task Group on Reference Man, published in 1975 by the International Commission on Radiation Protection.

Subsection (b) provides the level of human response at or below which the Agency concludes there is "no significant risk" from

the exposure. It defines the "no significant risk" level as the level which results in no more than one excess case of cancer in an exposed population of 100,000 ($1 \times 10^{-5}$), assuming lifetime exposure at the level in question. The $10^{-5}$ risk level is commonly used as an acceptable risk level by many regulatory agencies. Generally speaking, regulatory levels range from $10^{-4}$ to $10^{-6}$ or lower. (See C. C. Travis, et al., "Cancer Risk Management: A Review of 132 Federal Regulatory Decisions," Environmental Science and Technology, Vol. 21, No. 5, p. 415 (1987).) These fluctuations are often imposed due to differences in the methodologies employed in the underlying risk assessment. Under these regulations, it is intended that risk assessments based upon default assumptions will produce fairly conservative results. In effect, applying a $10^{-5}$ standard to a conservative risk assessment can produce the same result as applying a $10^{-6}$ standard to an assessment employing less conservative methodologies.

Moreover, the application of a $10^{-5}$ standard for the purposes of the Act appears to be no less protective than the application of a $10^{-6}$ or lower standard under other regulatory programs. The purpose of the Act is to regulate exposures to specific chemicals. The purpose of most other programs is to control the risk from a particular medium, such as food, water or air. Therefore, these other programs must, in adopting a particular standard, consider issues of mixture, interaction, bioconcentration and transformation of several chemicals as part of the cumulative risk presented by chemicals in that medium. This often demands that the standards applied under such programs to the chemicals of concern be individually set at more restrictive levels.

Accordingly, the Agency believes that setting the level of "no significant risk" at a $10^{-5}$ level will in effect provide no less protection than other levels set at $10^{-6}$ or lower, and is consistent overall with the regulation of cancer-causing chemicals.

Section 12705

Subsection (a) provides that exposure to a level of a listed chemical at or below the level set forth for the chemical in subsection (b) poses no significant risk within the meaning of the Act. The purpose of this section is to set forth "no significant risk" levels established solely for purposes of the Act.

The establishment of specific "no significant risk" levels is necessary. Most businesses do not have the resources to conduct their own risk assessments, whether or not under the principles of section 12703. Yet each business with ten or more employees needs the ability to determine whether its activities comply with the Act, require a warning, or require change. If the Agency did not establish specific "no significant risk" levels, these businesses might have no way of making this determination.

This section provides for specific levels established solely for purposes of the Act. At this time, no such levels have been established. Until such levels are set, businesses may rely upon levels derived from other regulatory programs as provided in sections 12707 and following. The Agency has begun conducting risk assessments on a number of chemicals of particular concern to establish "no significant risk" levels for those chemicals at a level calculated to result in no more than one excess case of cancer in an exposed population of 100,000. This section will be amended to include these levels as soon as appropriate levels are determined. The Agency intends to conduct these assessments according to the principles set forth in section 12703, which should result in levels which are both scientifically appropriate and health protective.

Subsection (c) requires the Agency to include the Safe Drinking Water and Toxic Enforcement Act Scientific Advisory Panel (Panel) in the rulemaking process establishing "no significant risk" levels by providing them with notice and copies of proposed levels, along with copies of the supporting statements of reason. The Panel may submit comments to become part of the rulemaking file, and members of the Panel may comment individually. However, nothing requires that either the Panel or any of its members submit any comment on such a proposal.

This is consistent with the policy of the Agency to consult with the Panel on scientific matters and with a recommendation of the Panel. The Panel is composed of experts in a variety of disciplines related to the study of carcinogenicity and reproductive toxicity, and is an important source which the Agency believes should be utilized. This section is intended to afford to the "no significant risk" levels proposed by the Agency a high quality scientific review.

Section 12707

Subsection (a) of this section provides that, where scientifically valid absorption studies conducted according to generally accepted standards or principles establish absorption of a chemical through a specific route of exposure to be low, so that exposure at or below applicable levels under current regulation by such route can be reasonably anticipated to present no significant risk of cancer, the Agency may designate the chemical as presenting no significant risk by such route. If so designated, exposures, discharges and releases of the chemical resulting in exposure by that route which do not exceed applicable formal and informal regulatory levels are deemed to pose no significant risk within the meaning of the Act.

The general approach for the evaluation of carcinogens, which finds expression in section 12703(a)(4), is to apply results obtained from one route of exposure to all routes of exposure. However, as expressed in section 12703(a)(7), when data are of sufficient quality that certain physiologic, pharmacokinetic, and

metabolic considerations can be taken into account with confidence, those data may be used in the risk assessment for, among other things, interroute extrapolations. Section 12707 represents a specific application of the interaction between these principles.

Subsection (b) provides that three listed chemicals pose no significant risk by the route of ingestion: (1) beryllium and beryllium compounds, (2) cadmium and cadmium compounds, and (3) chromium (hexavalent compounds). So long as the presence of beryllium and its compounds, cadmium and its compounds, and compounds of hexavalent chromium are in compliance with all other administrative standards for those substances, the Agency views their presence in any situation by which they would be ingested to pose no significant cancer risk.

The reasons for this are several-fold. First, the Agency believes the available data to suggest that the cancer risk from ingestion of these listed substances is minimal, principally due to the poor absorption of these substances across the intestinal mucosa and into the blood stream of those who may ingest them. Second, the Agency believes that, because many of these substances occur in nature, there is difficulty in identifying them, and there is difficulty in taking action to remove them, particularly when their presence may be widespread. Third, the Agency believes that current regulation of these substances, where it exists, together with the evidence of poor absorption, should adequately protect the public any significant risk of cancer from such chemicals by the route of ingestion.

This regulation is based upon current scientific knowledge. Should the Agency acquire new information which establishes that the identification of a chemical in subsection (b) is inappropriate, it may remove the chemical from this section. Nothing in this section is intended to prevent the establishment of a "no significant risk" level under section 12705 for any chemical set forth in subsection (b) of this section. Further, this section presently applies only to exposure by route of ingestion. Those who would apply this section to discharges into sources of drinking water should pay attention to possible inhalation exposures which may result from the use of drinking water supplies for purposes other than drinking (e.g., showering.)

Compounds of hexavalent chromium are included in subsection (b) because chromium is poorly absorbed from the gastrointestinal tract. The International Commission on Radiological Protection (Report of Committee II on Permissible Dose for Internal Radiation, Recommendations of the International Commission on Radiological Protection, ICRP Publication 2, Pergamon Press, New York, 1959), (ICRP Report) recommended use of an absorption value of 0.5 percent of the administered oral dosage from the gastrointestinal tract, as contrasted with a 25 percent absorption from the lungs. Further, the majority of the information on the carcinogenicity of hexavalent chromium

compounds is based upon inhalation studies. Information derived from studies other than inhalation is limited. (California Department of Health Services, Report to the Air Resources Board on Hexavalent Chromium, December 9, 1985.)

Cadmium and its compounds are similarly limited in the absorption from the gastrointestinal tract. The ICRP Report recommended the use of 0.25 percent absorption across the gut, and 25 percent absorption across the lungs, a two order-of-magnitude difference. The information on the carcinogenicity of cadmium and cadmium compounds is also restricted to inhalation and injection studies.

Beryllium and its compounds were recommended for listing primarily because of the presence of positive data following the injection of those substances. The Agency believes it is appropriate to consider these substances as posing no significant risk via ingestion, for reasons similar to those cited for hexavalent chromium and cadmium; that is, gastrointestinal absorption is poor. The ICRP above recommended using 0.2 percent uptake from the gut and 25 percent from the lungs. Deposition in bone from an oral exposure is given in the ICRP report as 0.064 percent, while deposition from an inhalation exposure is 8 percent. Data are lacking on ingestion studies.

One correspondent, during the time of informal comment period on interpretive guidelines issued by the Agency, viewed that beryllium ought to be treated as posing no significant risk by the route of inhalation. However, as evidenced above absorption and deposition in bone are significantly higher following inhalation than they are following ingestion. In fact, representatives of the beryllium industry indicated to the Agency that it is "well documented" that "beryllium, when introduced by inhalation, has produced tumors in animal species such as rats and monkeys." The Agency believes that these data cannot be ignored for purposes of its regulations. If they choose, persons in the course of doing business may demonstrate the absence of significant cancer risk by inhalation by other methods of quantitative risk assessment such as described in section 12703.

Section 12709

This section provides that, unless a specific "no significant risk" level has been established pursuant to section 12705, exposures to certain trace elements not exceeding specified amounts pose no significant risk.

There are some listed substances that are ubiquitous in nature. Because of their widespread existence, they are present in the air people breathe, the food they eat and the water they drink. These elements would be in the air, food and water, regardless of any past or present human activity, because of their occurrence in the environment.

The elements listed in section 12709 are ingested or inhaled in considerable quantities each day. For example, the International

Commission on Radiological Protection's (ICRP) Task Group on Reference Man (ICRP Report No. 23, Pergamon Press, New York, 1975) identified the daily intake from air, food and water to be 1,000 micrograms of arsenic, 12 micrograms of beryllium and 150 micrograms of cadmium. More recently, the United States Environmental Protection Agency identified the daily intake of those elements to be 20 to 50 micrograms of inorganic arsenic per day. (US EPA, Health Assessment Document for Inorganic Arsenic, p. 2-23, 1964), 0.4 micrograms of beryllium per day (US EPA, Health Assessment Document for Beryllium, p. 3-16, 1986), and 50 micrograms of cadmium per day (US EPA, Health Assessment Document for Cadmium, p. 4-28, 1981).

Because these elements are ubiquitous, it is likely that virtually every exposure, whether through a product, the workplace or the environment, will contain some amount of the chemical. Persons in the course of doing business may be aware of their presence, but can do little or nothing about it. For example, persons in the course of doing business who produce paper products or fertilizers may find themselves with trace amounts of a number of substances in their products which were not necessarily added to those products as specific chemical ingredients, but are nonetheless there as a result of their presence in plants or soils.

If every person in the course of doing business warned about the presence of these chemicals, the public might be inundated with warnings which would provide little benefit themselves and obscure other warnings about risks which are truly significant. Hence, the Agency believes it appropriate to treat ubiquitous trace elements differently than other listed substances. When a person in the course of doing business exposes an individual to a ubiquitous trace element which was not specifically added as a chemical to the product (as opposed to a raw material which contained the trace element), the Agency believes the limit on the exposure ought to take into account the origin of that element, as well as the daily intake of the element. Therefore, the Agency has identified levels for several elements in subsection (b).

The levels in subsection (b) are derived from consideration of the average daily intake of the chemical. For arsenic, the level is 10 micrograms per day. This value is low compared to the daily intake of 20-1000 micrograms of arsenic from air, food and water. It is also 10 percent of the daily intake of arsenic allowed in drinking water, based on an intake of two liters of water per day and the maximum contaminant level of 50 parts per billion for total arsenic. For beryllium, the level is 0.1 micrograms per day. This value is low compared to the daily intake of 0.4-12 micrograms of beryllium per day. No drinking water standard exists for beryllium; hence, this comparison is not available. For cadmium, the level is one microgram per day. This value is low compared to the daily intake of 50-150 micrograms per day. Ingestion from drinking water at the maximum

contaminant level would be 20 micrograms of total cadmium per day.

Again, the Agency emphasizes that these values are intended to be applied to the ubiquitous substances that are natural trace elements in raw materials and are not intended to be used for substances that are added as chemicals to products. Also, these values are intended to be used in the absence of levels posing no significant risk for the listed elements, or specific compounds of the listed elements, which will appear in section 12705.

Section 12711

Section 12711 provides that, in the absence of specific levels in this article for chemicals in sources of exposure other than food, drugs, cosmetic and medical devices, "no significant risk" levels may be based upon levels developed by California or federal agencies for a carcinogen calculated to result in not more than one excess case of cancer in an exposed population of 100,000 persons, or upon levels for specific chemicals described in subsection (b) which correspond to a risk level of one excess case of cancer per 100,000 people exposed.

Subsection (a) permits the limited use of existing regulatory levels because persons in the course of business may already be complying with such levels. Provided that these levels afford a sufficient degree of human protection, these persons should be able to rely upon their compliance with existing law as an assurance that they are in compliance with the Act as well.

Section 12711(a)(2) identifies some specific levels based on state or federal risk assessments. The levels listed here draw upon state levels established by the California Department of Health Services for the California Air Resources Board, under the latter's Toxic Air Contaminant Program, or upon federal levels established by the United States Environmental Protection Agency's Carcinogen Assessment Group, unless otherwise indicated.

The specific levels include levels set forth below derived from state risk assessments, using assumed parameters of 20 cubic meters of air inhaled per day, and a 70-kilogram body weight for the exposed individual.

| | |
|---|---|
| Asbestos (inhaled) | 100 fibers per day* |
| Carbon tetrachloride | 5 micrograms per day |
| Chromium, hexavalent | 0.001 microgram per day |
| Dioxin (TCDD) | 0.000005 microgram per day |
| Ethylene dibromide | 3 micrograms per day |
| Ethylene dichloride | 9 micrograms per day |
| Ethylene oxide | 2 micrograms per day |

* Fibers are equal to or greater than 5 micrometers in length and 0.3 micrometers in width, with a length/width ratio of greater

Source documents:

California Department of Health Services, Report to the Air Resources Board on Asbestos, January, 1986.

California Department of Health Services, Report to the Air Resources Board on Hexavalent Chromium, December 1985.

California Department of Health Services, Report to the Scientific Review Panel (Air Resources Board) on Chlorinated Dioxins and Dibenzofurans, February 1986.

California Department of Health Services, Report on Ethylene Dibromide to the Scientific Review Panel (Air Resources Board), April 1985.

California Department of Health Services, Report on Ethylene Dichloride to the Scientific Panel (Air Resources Board), June 1985.

California Department of Health Services, Report to the Air Resources Board on Ethylene Oxide, September 1987.

The specific levels also include levels set forth below derived from federal risk assessments.

Except for the value for ingested asbestos fiber, which relates to fibers greater in size than 10 micrometers (medium versus long fibers derived from a document published in the Federal Register (50 FR 46961 - 46963)), the following levels were presented in the US EPA report, Health Assessment Document for Beryllium, 1987, Table 7-18, pp. 7-82 through 7-85. EPA routinely publishes a table of information containing the results of its carcinogenic risk assessments in its health assessment documents. The document relied upon is entitled "Relative Carcinogenic Potencies Among 59 Chemicals Evaluated by the Carcinogen Assessment Group as Suspect Human Carcinogens." Levels equivalent to one excess case of cancer per 100,000 people exposed for a 70-year lifetime were calculated from the cancer potencies published by EPA.

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(footnote continued) than or equal to 3:1. These fibers can be measured by phase contrast microscopy (PCM) and for historical reasons represent the basis for all recent asbestos risk assessments. Such fiber counts can be converted to total fibers measurable by transmission electronic microscopy (TEM) by multiplying by 100 to 1,000. Hence, 5 fibers per cubic meter of air, as measured by PCM would equal 500 to 5,000 fibers per cubic meter of air, as measured by TEM, and 100 fibers per day, measured by PCM, would be the equivalent of 10,000 to 100,000 fibers per day, measured by TEM.

| Chemical | Micrograms per day intake |
|---|---|
| Acrylonitrile | 3. |
| Asbestos (ingested) | 140. million fibers per day |
| Benzene | 20 |
| Benzidine | 0.003 |
| Benzo(a)pyrene | 0.06 |
| Bis(2-chloroethyl)ether | 0:6 |
| Bis(chloromethyl)ether | 0.6 |
| Chloroform | 9. |
| Coke oven emissions | 0.3 |
| DDT | 2. |
| 3-3'-Dichlorobenzidine | 0.4 |
| Epichlohydrin | 70. |
| Hexachlorobenzene | 0.4 |
| Hexachlorocyclohexane (technical grade) | 0.4 |
| Nickel refinery dust | 0.8 |
| Nickel subsulfide | 0.4 |
| N-Nitrosodi-n-butylamine | 0.1 |
| N-Nitrosodiethylamine | 0.02 |
| N-Nitrosodimethylamine | 0.03 |
| N-Nitrosopyrrolidine | 0.3 |
| N-Nitroso-N-ethylurea | 0.02 |
| N-Nitro-N-methylurea | 0.002 |
| Polychlorinated biphenyls | 0.09 |
| Toxaphene | 0.6 |
| 2,4,6-Trichlorophenol | 40. |
| Vinyl chloride | 0.3 |

Section 12713

This section provides generally that, unless a specific "no significant risk" level is set forth in section 12705, a chemical in a food, drug, cosmetic or medical device poses no significant risk if the exposure through the food, drug, cosmetic or medical device is in compliance with all applicable federal and California safety standards.

The concept underlying this regulation has been extensively considered over several months. The Agency has received and reviewed six petitions requesting the promulgation of regulations governing the applicability of the Act to food, drug, medical device and cosmetic products. Each of these petitions requested the Agency to promulgate regulations determining that compliance with existing statutory and administrative standards under state and federal food, drug, medical device and cosmetic safety laws is sufficient to determine that no warning is required under sections 25249.6 and 25249.10(c). Hearings on these petitions were conducted by the Agency, pursuant to public notice, in Sacramento and in Los Angeles on June 15, June 16, and July 17, 1987.

Subsequently, the United States Commissioner of Food and Drugs wrote the Governor on August 28, 1987, requesting that the Governor take into consideration "the comprehensive regulatory scheme Congress enacted in the Federal Food, Drug, and Cosmetic Act" (the FD&C Act) and urging the Governor to consider recognizing that the products regulated by the Food and Drug Administration (the FDA) under the FD&C Act "present no significant risk." Because of the importance of and the widespread interest in this matter, the Agency wrote the Chairman of the Scientific Advisory Panel on November 20; 1987, requesting the Panel's opinion on whether existing state and federal standards for food, drugs, medical devices and cosmetics constitute assurance that chemicals in these products pose no significant risk within the meaning of section 25249.10(c). In accordance with this request, the Panel held a public hearing on this matter on December 11, 1987. The current Commissioner on Food and Drugs, a former Commissioner of Food and Drugs, a former director of the Food and Drug Administration's Bureau of Foods, a representative of the United States Department of Agriculture (the USDA), the Chief of the Food and Drug Branch of the state Department of Health Services, and a large number of interested individuals and organizations presented testimony. The Panel concluded that current state and federal regulation provides considerable protection for food, drug, medical device and cosmetic products and thus recommended that the existing state and federal statutory and administrative standards for these products be adopted as a determination of "no significant risk" pending the establishment of specific levels under the Act.

This regulation is based upon the recommendation of the Panel. The Agency finds that existing state and federal food, drug, cosmetic and medical device safety standards are sufficient to protect consumers from substances in such products that pose any significant risk of cancer within the meaning of section 25249.10(c), pending the establishment of specific "no significant risk" levels. The Agency's conclusion is based on the comprehensive nature of state and federal safety standards reflected in numerous regulatory decisions prohibiting or restricting the presence of carcinogens in such products.

In deciding to follow the recommendation of the Panel, the Agency has considered the fact that the safety of food, drugs, medical devices and cosmetics has been the subject of intensive state and federal regulation, under complex and detailed statutory and administrative safety standards, for more than 80 years. Applying the policy of preservation of existing statutory and administrative standards, (Health & Saf. Code section 25249.13), the general principles of comity among coordinate administrative agencies, the express legislative policy of uniformity in regulation of food, drug, medical devices and cosmetics in Health and Safety Code section 26204, and the policy favoring a construction of the Act which furthers the intent to make meaningful warnings about chemical hazards available to the public, the Agency has determined that existing safety standards under these state and federal laws should be utilized in

establishing levels of "no significant risk" for carcinogens pending the establishment of specific levels for the chemical constituents and contaminants of foremost concern in such products.

Subsection (a) plainly reflects that the authority to determine that a chemical exposure poses no significant risk under this section is temporary. The regulation recognizes certain existing state and federal standards, but provides that the Agency may determine that those existing state and federal standards do not meet the requirements of sections 25249.6 and 25249.10(c) and may, by rulemaking, establish different standards for that purpose. The establishment of specific "no significant risk" levels for purposes of the Act will preclude any determination regarding food, drugs, cosmetics and medical devices on the basis of existing levels or standards as specified in this section.

Subsection (b) defines the four categories of products to which this section applies: food, cosmetics, drugs and medical devices. In each case, the definition is based upon applicable federal safety law. This makes section 12713 consistent with the federal law to which it refers and confines the scope of the regulation to identifiable categories for which standards exist.

Under existing federal and state law and precedent, the term "food" is defined broadly to encompass all substances that, in any way, find their way into the products that are consumed as food. Thus, it includes not only raw agricultural commodities (including meat, poultry and eggs) that are commonly regarded as food, and their natural chemical constituents, but also all of the chemical constituents and ingredients, of natural or synthetic origin, that result from the production or processing of those commodities.

Subsection (b) also broadly defines the term "administrative standards" to include all legal requirements that relate to the safety of these products imposed by the state or federal agencies responsible for administering those requirements. This avoids the need for repeated references in each subparagraph to statutes, regulations, action levels and other formal and informal legal requirements.

Food, drug, medical device and cosmetic products are subject to existing state and federal legal standards that come from two primary sources. First, these products are subject to statutory standards set forth in the laws themselves. These statutory standards apply to all four categories of products, including all constituents and ingredients of those products. There are no products that fall within these four categories that are not subject to these statutory standards. The legal requirements imposed by these statutory standards, moreover, are self-executing, and must be complied with even if there are no implementing regulations or other legal requirements. Thus, these statutory standards represent the first level of assurance that food, drug, medical device and cosmetic products pose no

significant risk of cancer.

In addition to the state and federal statutory standards, there are thousands of other formal and informal legal requirements that are imposed by administrative standards adopted by the state and federal agencies responsible for administering the statutes involved.

Subsection (c) provides that exposure to a chemical which is subject to specific administrative standards applicable to identified categories of chemicals shall be deemed to pose no significant risk within the meaning of the Act. Eight categories of chemicals subject to administrative standards under the FD&C Act are identified. These categories, which often include standards based on quantitative risk assessments for specific chemicals, contain restrictions on chemical risks which are comparable to those in the Act. For each category, all applicable administrative standards must be met before a chemical exposure will be considered to pose no significant risk.

Subparagraph (1) makes subsection (c) applicable to "food additives" within the meaning of the FD&C Act approved for use at a specified level. The FD&C Act requires that food additives intended for use as ingredients in food be approved as safe prior to such use. Premarket approval is also required for food additives that, through use in articles that contact food, such as packaging, become components of food. (21 United States Code sections 321(s) and 348(a)(2).) Although the FD&C Act excludes certain substances from the category of food additives, those food substances are subject to other regulatory controls.

The term "food additive" encompasses thousands of food substances, including substances that are intentionally incorporated into food to achieve a specific function ("direct" food additives), substances that are used to process food but which have no specific function in the food itself ("secondary direct" food additives) and substances that migrate into food but that have no functional use in the food ("indirect" or "incidental" food additives). (21 Code of Federal Regulations section 170.3(e).) Only those added substances that are "accidental and unforeseeable" are regarded as falling outside the regulatory definition of "food additive." (39 Federal Regulations 42743, 42744 (December 6, 1974).)

Food additives include food packaging materials that may migrate into and therefore become components of food. It is assumed that all packaging materials in contact with food may migrate into food and they are, therefore, presumptively classified as food additives. Such substances are excluded from the definition only upon a showing that the level of migration is sufficiently low that no more than a de minimis level of risk is presented to the public. (Monsanto Co. v. Kennedy, 613 F2d 947 (D.C. Cir. 1979); 49 Fed. Reg. 36635 (September 19, 1984) (acrylonitrile in plastic bottles).) FDA regulations governing use of packaging materials in food contact applications are set forth at 21 C.F.R. Parts

170-199.

Any substance that is a food additive must be subject to a food additive regulation promulgated by FDA before it may lawfully be used in food. The proponent of a food additive has the burden of showing that it will be safe under the conditions of its intended use. (21 U.S.C. section 348(a).) The FD&C Act contains a provision, the Delaney Clause, which reinforces this requirement by prohibiting the approval of a food additive that has been shown to induce cancer in man or animals. (21 U.S.C. section 348(c)(3)(A).)

Under FDA's "constituents policy," the Agency will approve a food additive containing a constituent that is carcinogenic in animals only if it presents an "insignificant risk" of human cancer. (47 Fed. Reg. 14464 (April 2, 1982).) This policy was upheld in Scott v. FDA, 728 F.2d 322 (6th Cir. 1984). FDA considers a food additive containing such a constituent to be unsafe and thus illegal if it represents a "significant risk" of human cancer.

Subparagraph (2) makes subsection (c) applicable to substances in food generally recognized as safe. Normally, carcinogens will not be generally recognized as safe. Therefore, if a food is generally recognized as safe, it should be considered to pose no significant risk within the meaning of the Act pending the establishment of specific "no significant risk" levels.

Subparagraph (3) makes subsection (c) applicable to substances in food sanctioned for use by the FDA or the USDA prior to 1958, since prior sanctions are generally based upon a determination of the safety of the use. Again, the exposure must comply with all applicable administrative standards. Thus, a failure to comply with the conditions of the prior sanction, a determination that the sanctioned substance in fact may render it injurious to health, or that a nonadded substance is ordinarily injurious to health would make this subparagraph and subsection (c) inapplicable.

Subparagraph (4) makes subsection (c) applicable to "color additives" within the meaning of the FD&C Act approved for use at a specified level. Exposure to such color additives must comply with all applicable administrative standards. The administrative standards which apply to substances used to color food, drugs, medical devices and cosmetics closely resemble those for food additives. The color additive standards require premarket safety testing and FDA promulgation of a color additive regulation approving any substance used to color food.

Before a color additive may be approved, there must be reasonable certainty that the additive does not pose a significant risk to human health. (21 U.S.C section 276(B)(4).) The Delaney Clause precludes approval of any color additive shown to induce cancer in man or animals. (21 U.S.C. section 376(b)(5)(B).) Food that contains an unapproved color additive or an additive whose use deviates from the terms of any approval is adulterated under the

FD&C Act. (21 U.S.C. section 342(c).)

Under Health and Safety Code sections 26203 and 26207, the FDA color additive regulations are automatically adopted and are independently enforceable as California law. The state also reserves the right to promulgate its own color additive regulations that differ from the FDA regulations.

Subparagraph (5) makes subsection (c) applicable to substances which are required in the production of food or which cannot be avoided by good manufacturing practices for which a specific tolerance level has been established. The exposure must comply with all applicable administrative standards.

Subparagraph (6) makes subsection (c) applicable to pesticide chemicals used in the production, storage or transportation of agricultural commodities for which a specific tolerance level has been established. The exposure must comply with all applicable administrative standards. Under FD&C Act section 408, a food is adulterated if it contains a pesticide residue that has not been approved as safe for use on that food. (21 U.S.C. section 346a.)

FD&C Act section 408 permits a tolerance for a pesticide only upon a determination that the permitted residue will not endanger human health. A tolerance or action level may also be issued under FD&C Act section 406 to permit a safe level of a pesticide residue in food other than the specific commodities on which its use has been approved under FD&C Act section 408, where the pesticide has drifted to other crops during application or has otherwise left a residue in the food. (21 U.S.C. section 346.) Tolerance levels for pesticides are established by EPA and EPA has issued guidelines for carcinogenic risk assessment, 51 Fed. Reg. 33992 (September 24, 1986).

Federal pesticide tolerance regulations are automatically incorporated as state law under Health and Safety Code sections 26203 and 26205. The state also reserves the right to promulgate pesticide tolerance regulations that differ from those imposed at the federal level. Further, Health and Safety Code section 26205 was amended in 1984 to require the Department of Health Services to evaluate whether a pesticide tolerance, or exemption from tolerance, is sufficiently protective of the public health whenever certain events occur that raise concern about the safety of the pesticide.

Subparagraph (7) makes subsection (c) applicable to animal drugs within the meaning of the FD&C Act approved for use at a specified level. The exposure must comply with all applicable administrative standards. Federal and state administrative standards for animal drug residues limit levels of chemical exposure to eliminate any significant risk. Substances administered to food-producing animals as feed or drugs, and which leave a residue in the human food produced by the animal, are subject to premarket approval under the FD&C Act. The procedures for approval of animal feed additives and animal drugs

are similar to those applicable to ingredients of human food. (21 U.S.C. sections 321(s), 348 and 360b.)

The primary inquiry under the standards is whether the residue of the substance in human food is safe. The statutory criteria include a Delaney Clause prohibiting the use of cancer causing additives. If an additive is found to induce cancer in animals, it may be approved only if no residue will be found, by methods of examination prescribed by FDA, in any edible portion of such animals after slaughter or in any human food yielded by or derived from the living animals. (21 U.S.C. sections 348(c)(3)(A) and 360b(d)(1)(H).)

Health and Safety Code sections 26010, 26012, 26013 and 26021 regulate animal feed in the same manner as human food and animal drugs in the same manner as human drugs, and contain essentially identical authority over any residues in human food as exists under the FD&C Act.

Subparagraph (8) makes subsection (c) applicable to drugs. The exposure must be in compliance with all applicable administrative standards. Prescription drugs are subject to premarket approval by the FDA or the Department of Health Services. Most are "new drugs" within the meaning of the FD&C Act and the Sherman Law, which cannot lawfully be sold unless they are subject to an approved new drug application (NDA). (21 U.S.C. sections 321(p) and 355; Health and Safety Code sections 26021 and 26670.) The requirements for approval of an NDA are essentially the same under the state and federal laws, and drugs for which NDAs have been approved under the FD&C Act are deemed to comply with Health and Safety Code section 26670(a). These requirements apply not only to genuinely new drugs but also to generic copies of established medicines. (21 U.S.C. section 355(j).)

Three other categories of prescription drugs, which are also within the scope of the regulations, are subject to separate requirements for premarket approval imposed by federal law. These include insulin and antibiotics, which are subject to premarket approval whether or not they are "new drugs" under FD&C Act sections 506 and 507 (21 U.S.C. §§ 356 and 357.) and biological products (e.g., vaccines and blood products), which are subject to licensing requirements under the Biologics Act (42 U.S.C. § 262.). A very small number of prescription drugs first marketed before 1962 are still permitted to be sold without premarket approval of an NDA from FDA, but the FDA is proceeding to subject those products to the NDA requirements and has in the meantime imposed restrictions on changes in the formulation of those products. (21 C.F.R. §§ 201.200 and 310.6.)

FDA imposes elaborate requirements for determining the safety of new drug ingredients throughout the drug development process, from synthesis of a new chemical entity until final FDA approval of an NDA. These have been described in "The Food and Drug Administration's Process for Approving New Drugs," Report Prepared by the Subcommittee on Science, Research and Technology

of the House Committee on Science and Technology, 96th Cong., 2d Sess. (1980) (the "House Subcommittee Report").

The new drug approval process is divided into three major stages: preclinical research, clinical investigation and NDA approval. As summarized by the Commissioner of Food and Drugs in his testimony before the House Committee:

> "[T]he system that has evolved for approving new drugs ... is extremely careful and rigorous. Sponsors of new drugs, for example, must present FDA with toxicological data collected from animals before testing can be conducted in humans. Then carefully staged human tests are conducted under FDA guidelines that is intended to show that a drug is both safe and effective. Only when such thorough testing is completed and reviewed by FDA scientists is a new drug permitted to be marketed.
>
> .....
>
> "The more potent or potentially hazardous drugs ... are used through the advice and oversight of a physician or other health care professional, and the labeling for the physician carefully describes the potential hazards of those products."

Substantial research must be undertaken on the chemical, pharmacologic and toxicologic properties of a new chemical entity in order to meet FDA prerequisites for beginning clinical research (i.e., testing of the drug in human volunteers). As the House Subcommittee Report states:

> "[The FDA requirements] affect the type and direction of research and other development activities which must be done once a new chemical entity is identified." House Subcommittee Report 13-14.

The FDA investigational new drug ("IND") regulations require that such preclinical research include sufficient chemical information about the drug to set exact specifications, using sophisticated analytical techniques, to assure little or no variation in the entity. (21 C.F.R. § 312.23(a)(7.)

The IND regulations also require that, before clinical investigation may begin, sufficient pharmacology and toxicology information must be obtained through animal testing to justify use of the chemical in humans. (21 C.F.R. § 312.23(a)(8).) FDA has established both formal and informal guidelines that can include extensive animal testing before an IND can be submitted.

Once adequate preclinical research is completed, an IND can be filed to justify clinical investigation of the new chemical entity in humans, in preparation for filing an NDA. The NDA

provisions impose regulatory requirements on the clinical investigations conducted pursuant to an IND. FDA regulations and guidelines establish requirements for evidence of safety and effectiveness for a new drug. (21 C.F.R. part 314.)

After the requirements for preclinical research and clinical investigation are complete, approval of the drug for marketing must be obtained. An NDA or other application for premarket approval must contain a complete list of all substances used in the manufacture of the drug product, including not only the active ingredient, but also inactive ingredients, trace contaminants, and intermediates and other chemicals used in the production process, whether or not they are present in the finished product. (21 C.F.R. § 314.50(d)(1).) Applicants must submit analyses demonstrating the identity and purity of products at key stages of the manufacturing process. Information on drug ingredients and manufacturing processes is scrutinized to determine whether potentially harmful substances or chemical by-products may be present in the finished drug product.

The requirements of the NDA approval procedure are supplemented by official compendia (the United States Pharmacopoeia and the National Formulary) which establish standards for the purity of ingredients used in drugs, and by FDA regulations that set forth detailed requirements for current good manufacturing practices ("GMP") in the manufacturing, processing, packing and holding of drugs. (21 U.S.C. §§ 351(b), 352(e), 352(g); 21 C.F.R. parts 210 and 211.) The GMP regulations govern all aspects of the production process, including personnel, facilities, equipment, control of components, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, returned and salvaged products and records.

Accordingly, the Agency has concluded that approved prescription drugs generally pose no significant risk of cancer, and should be considered to pose no significant risk within the meaning of the Act pending the establishment of specific "no significant risk" levels. However, the Agency recognizes that some drugs which may present a cancer hazard are allowed to be marketed with a mandatory warning if the beneficial properties of the drug outweigh the cancer risk. The Agency acknowledges that such drugs may pose a "significant risk" within the meaning of the Act and the use of such drugs should be preceded by a warning. Therefore, subsection (e) specifically provides that section 12713 shall not apply to any drug the labeling of which contains a statement that the drug causes or may cause cancer, whether in humans or animals. It would appear to make little sense to provide that a drug requires no warning where federal law requires its labeling to contain a cancer-related warning.

As with prescription drugs, there are also comprehensive systems of regulation that govern nonprescription drugs under state and federal administrative standards. The Agency has concluded that nonprescription drugs in compliance with all such applicable

statutes and standards generally pose no significant risk of cancer, and such finding should adequately protect the public health pending the establishment of "no significant risk" levels under the Act.

A comprehensive regulatory program has been established under the FD&C Act that ensure that nonprescription or over-the-counter ("OTC") drugs do not expose consumers to toxic substances. The program includes a recent review of the safety of all nonprescription drugs by expert panels, as well as procedures for prompt action to ban drugs from the market whenever new scientific evidence indicates that certain drugs or ingredients pose a medical risk to the consumer. As the Commissioner of Food and Drugs testified:

> "For over-the-counter drugs, we have been conducting an OTC Review for several years of OTC drugs, many of which have been widely used for decades. Under the guidance of expert advisory groups from outside government, we have carefully developed monographs that summarize our conclusions about the safety and effectiveness of those drugs. Those that are found by that process to be unsafe or ineffective are removed from the market."

This review is conducted by one of seventeen panels formed to review all OTC drugs within therapeutic classes of OTC drugs, which under the prescribed procedures address the issue of carcinogenicity. FDA requires consideration of the following:

> "... which tests are adequate to prove the safety of a particular drug.... If it is decided that carcinogenicity and reproductive studies are necessary for a particular drug, then that fact will be reflected in the panel recommendations [to FDA]." (37 Fed.Reg. 9464, 9469 (May 11, 1972).)

Although active ingredients were the main focus of the panels' inquiry, the panels also considered the safety of inactive ingredients where appropriate. Information considered by the panels included safety data on finished drug products, consisting of active ingredients, inactive ingredients and trace constituents. FDA regulations require that an OTC drug contain "only suitable inactive ingredients which are safe in the amounts administered." (21 C.F.R. § 330.1(e).)

After analyzing the scientific data and testimony, the panels submitted reports on 58 OTC drug categories to FDA. These reports evaluated the safety and effectiveness of the reviewed drugs according to the "best scientific evidence available." (37 Fed.Reg. 9464, 9469 (May 11, 1987); 21 C.F.R. § 330.10 (a)(4).) Based on these reports FDA is establishing monographs for categories of OTC drugs. When a final monograph becomes effective, an OTC drug must conform to all of the conditions established by the monograph for its drug category or it will be

subject to regulatory action (unless the monograph is amended or the manufacturer obtains an approved NDA). (21 C.F.R. § 330.10(b).) These conditions should assure that OTC drug products which comply with federal administrative standards pose no significant risk of cancer.

OTC drugs which are not "new drugs" within the meaning of the FD&C Act (and, thus, subject to the NDA process previously above) must meet statutory requirements of general recognition of safety and effectiveness. (21 U.S.C. § 321(p).) FDA has taken the position that the requirements for proof of general recognition of safety and effectiveness are the same as those for proof of the safety and effectiveness of new drugs. The FDA regulations provide:

> "A contention that a drug product is generally recognized as safe and effective within the meaning of section 201(p) of the act is required to be supported by submission of the same quantity and quality of scientific evidence that is required to obtain approval of [a new drug] application for the product, unless FDA has waived a requirement for effectiveness ... or safety, or both ...." (21 C.F.R. § 314.200(e)(1).)

The Agency therefore finds that authorized nonprescription drugs which are in compliance with all applicable administrative standards generally pose no significant risk of cancer, and such a finding should be protective of the public health pending the establishment of specific "no significant risk" levels.

Subsection (d) provides, where a chemical known to the state to cause cancer in a food, drug, cosmetic or medical device is not subject to a specific regulatory level as described in subsection (c), exposure shall be deemed to pose no significant risk if the exposure in which the chemical occurs is in compliance with all applicable administrative standards.

In determining the content of the regulation, the Agency considered the alternative of limiting the regulation to instances where a specific administrative standard had been established as a legal requirement with respect to the permissible level of particular chemical in food, drug, medical device or cosmetic products. The Agency rejected this alternative because it failed to recognize the means by which FDA has implemented and enforced the FD&C Act.

In his August 28, 1987, letter to the Governor, the Commissioner of Food and Drugs stated:

> "Even with regard to substances not affirmatively approved by FDA for foods, drugs, cosmetics or other FDA-regulated products, the agency has adequate procedures for determining their safety and taking necessary regulatory action if problems

arise."

In his testimony before the Scientific Advisory Panel, the Commissioner observed that "FDA regulated products are lawfully sold in accordance with Federal Law do not pose a significant risk to human health" and that "warnings on products that do not pose such a risk are unnecessary, are likely to be confusing, and may be very costly to industry and consumers." The Commissioner made it clear that an FDA decision not to take regulatory action under the general statutory standards in the adulteration provisions of the FD&C Act is tantamount to a federal determination that the food is safe and does not pose a significant risk to human health:

> "Looking at the food supply as a whole, premarketing approval of chemicals in food is probably more the exception than the rule. For this reason, the absence of an FDA tolerance or other level of concern does not imply that a chemical in a food poses a safety problem. On the contrary, in the usual case it means that no problem has been associated with the chemical in that situation, and given the FDA's broad monitoring of the safety of the U.S. food supply, lack of regulatory action may fairly be viewed as the agency's conclusion that no regulation is needed."

Thus, the lack of an express FDA approval does not signify that a chemical may pose a health hazard. FDA devotes its attention to those substances that may be present in potentially unsafe amounts. The absence of an explicit determination is, therefore, a strong indication of safety. As explained by the Commissioner of Food and Drugs, FDA is vigilant to initiate regulatory action whenever new evidence concerning a chemical suggests carcinogenicity or other adverse effects.

The regulatory scheme for medical devices includes not only a system of premarket approval or notification to assure the safety and effectiveness of new devices, FDA requires that medical device manufacturers monitor the safety and effectiveness of all marketed medical devices. (21 C.F.R. part 803.) Manufacturers must report to FDA whenever they receive information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury, or has malfunctioned in a way that could cause or contribute to serious injury. The purpose of such reports is described as follows:

> "These reports will enable FDA to protect the public health by helping to ensure that devices are not adulterated or misbranded and are otherwise safe and effective for their intended use." (21 C.F.R. § 803.1(a).)

Since the federal and statutory regulatory scheme provides assurance of the safety of medical devices, the Agency has determined that devices which meet the requirements of federal and state device safety laws generally should be considered to pose no significant risk of cancer pending the establishment of specific "no significant risk" levels under the Act.

The safety of cosmetics is regulated under the existing statutory and administrative standards of the FD&C Act and the Sherman Law. In his testimony, the Commissioner of Food and Drugs states that "Federal regulation of potentially hazardous substances [is] fully sufficient to protect the public health from any significant risks." The Commissioner explained FDA's regulation of cosmetic safety as encompassing premarket approval of color additives used in cosmetics, regulation of some cosmetics as drugs, inspection of cosmetic manufacturing facilities and the banning of hazardous cosmetic ingredients.

As previously noted in the discussion of food regulation, cosmetics only contain color additives that have been approved as safe by FDA. (21 U.S.C. § 376(a).) Use of unapproved color additives or use of approved additives in a manner that does not conform to federal requirements is prohibited by the FD&C Act. Health and Safety Code section 26701 contains a comparable provision.

In addition to the special safety precautions for color additives previously discussed, FDA regulations impose on manufacturers of cosmetic products the duty to substantiate the safety both of every individual ingredient and of every finished product prior to marketing. (21 C.F.R. § 740.10(a).) Failure to meet this safety requirement causes the cosmetic to be misbranded under FD&C Act section 602(c), unless it contains the following conspicuous statement on the principal display panel: "Warning - The safety of this product has not been determined." FDA regulations also require that the label of a cosmetic product "bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product." (21 C.F.R. § 740.1.)

Accordingly, the Agency concludes that levels of chemicals known to the state to cause cancer, if there are any, in food, drug, medical device or cosmetic products which comply with all applicable administrative standards generally pose no significant risk of cancer. Further, because products which pose no significant risk require no warning under the Act, the public health will be enhanced by these regulations. A proliferation of warnings could effectively prevent the public from determining which hazard are truly important and how personal behavior can impose individual and societal safety, and could lead to cynical disregard for all warnings. In his August 28, 1987, letter to the Governor, Commissioner Young stated FDA's concern that a proliferation of health warnings on FDA-related products "might create serious public health problems" because "the consumer may be confused when confronted by warning labels on large numbers of

products and may be less likely to heed those warnings that have been carefully designed by FDA, Congress, and the state to protect against more significant and possibly more immediate harm."

The Agency finds that these concerns are well founded, and that the regulation will prevent this problem by assuring that, where foods, drugs, cosmetics and medical devices contain chemicals listed under the Act, the warnings shall be reserved for levels of chemical exposure that pose a significant risk.

Section 12713 applies only to chemicals known to the state to cause cancer. It does not apply to reproductive toxicants. The "no significant risk" standard of the Act for carcinogens is similar to many standards applied to foods, drugs, cosmetics and medical devices in general. However, existing food, drug, cosmetic and medical device safety law have no equivalent to a "no observable effect" standard that assumes exposure at 1,000 thousand times the level in question. Since there are no existing standards for reproductive toxicants, there is nothing on which a provision similar to section 12713 for reproductive toxicants could be based.

Section 12721

Section 25249.10 (c) of the Act provides an exemption test for discharges, releases and exposures to chemicals known to the state to cause cancer. The test is whether the person responsible can show that the exposure poses no significant risk "assuming lifetime exposure at the level in question." The Act, however, does not define either "level in question" or "lifetime exposure."

Section 25249.6 of the Act requires a clear and reasonable warning prior to exposure to a listed chemical, and prohibits any discharge, unless this exemption applies. Thus, persons in the course of doing business, in order to avoid violation of the Act, will need to determine the applicability of the exemption prior to exposure, discharge or release. Therefore, they will need to know in advance what will be the assumed or expected "level in question" for purposes of the exemption. They will also need to know what will be the assumed lifetime of the individual exposed for the particular type of exposure.

Subsection (a) defines the term "level in question" to mean the chemical concentration of a listed chemical for the exposure in the question, which includes only those exposures for which the person in the course of doing business is responsible. The chemical concentration is usually expressed as micrograms per liter of water, cubic meter of air or gram of food. Because a chemical may exist in a medium of concern due to the acts of some other person, this subsection states what is implied in the Act, namely, that a person is responsible only for exposures to a chemical that result from her or his acts or omissions.

Since it is not possible to determine in advance what individuals will be exposed by a particular act or omission, and since different individuals enjoy different life expectancies, conventional assumptions must be utilized to promote predictability and consistency in the enforcement of the law. Therefore, subsection (b) defines "lifetime" in the term "lifetime exposure" to refer to a life expectancy of 70 years.

The exemption test of section 25249.10(c) is based upon exposure. It is the "exposure" over the 70 year lifetime which must pose no significant risk "at the level in question". Accordingly, subsection (b) defines "exposure" in the term "lifetime exposure" to mean the "reasonably anticipated rate of exposure for an individual to a given medium of exposure."

The reasonably anticipated rate of exposure will vary from case to case. It may be reasonably anticipated that food will be ingested once each day, or once each week, and so on. What rate of exposure is reasonably anticipated from a given medium, such as a certain type of food or a consumer product, will depend upon the medium, its anticipated use and other circumstances. For example, the publisher of a newspaper using inks containing a listed chemical may not reasonably anticipate that a reader will ingest the Sunday edition, but may reasonably anticipate other contact. A manufacturer of cardboard boxes may not reasonably anticipate the ingestion of a box, but may reasonably anticipate that the box will be used to package food products into which a chemical may migrate. A manufacturer of baby cribs might reasonably anticipate that an infant will chew or teethe on the railings.

Subsection (c) combines the definitions of "lifetime exposure" and "level in question" into a working formula. The level of exposure which must pose no significant risk assuming lifetime exposure at the level in question is the product of the concentration of the chemical in the medium and the reasonably anticipated rate of exposure to individuals during a 70-year period to that medium. Under this formula, a certain daily exposure to a chemical in a food product could be calculated, taking into account the concentration of the chemical in the food (in micrograms of chemical per gram of food), and multiplying that concentration times the quantity ingested (in grams of food per day). The product of this multiplication yields the quantity of chemical ingested in that food (in micrograms of chemical per day). This level must not exceed the level derived pursuant to this article.

The rate of exposure to a given medium of exposure is subject to fluctuation. Different individuals take in different amounts of air, water and food. Some may spend considerably more time in an area containing a listed chemical than others. It is, therefore, to establish certain assumptions about particular media. This is accomplished in subsection (d). However, scientifically more appropriate or specific data may be used wher available.

Paragraph (1) makes assumptions for exposures to the general population. Thus, paragraph (1)A. assumes ingestion of two (2) liters of drinking water per day. Paragraph (1)B. assumes inhalation of twenty (20) cubic meters of air per day. These values are drawn from the Report of the Task Group on Reference Man, published in 1975 by the International Commission on Radiological Protection, and are consistent with assumptions utilized in regulatory toxicology for those media.

Paragraph (2) provides that different assumptions must be used where the exposure is expected to affect only a subpopulation to which different assumptions properly apply. Certain subpopulations need to be addressed where circumstances involve particular products or environmental conditions which may pose a possible exposure risk to a distinct group of people. For example, pediatric products may be used only by infants. Paragraph (2) provides different assumptions for various subpopulations for the ingestion of water and inhalation of air.

Paragraph (3) provides a specific set of assumptions for exposures in the workplace, since workers are normally exposed for only a portion of the day, for a limited number of days each week, for a limited number of weeks per year, and only a portion of the assumed 70-year lifetime. The net result of these assumptions, which are based upon well-accepted conventions, is that occupational exposures posing no significant risk under the Act may involve slightly higher concentrations of the chemical.

It is anticipated that exposures will occur in the workplace to persons other than employees, such as customers, visitors or solicitors. These individuals will probably spend less time in that location as an employee. The Agency believes it is appropriate to differentiate between the potential exposure that may befall a temporary visitor and that of an employee. Therefore, this paragraph assumes such persons will visit the premises one hour per month per 70-year lifetime, and further assumes that they will inhale 1.25 cubic meters of workplace air during each visit.

Paragraph (4) provides assumptions for exposure resulting from the consumption of goods or consumer products as are described in section 12601, subsection (b). The average rate of consumption of the product user, not the per capita consumption of the general population, is the standard. The average rate may be based upon consumption data available for the general category of products. For example, a business packaging corn may rely upon the average amount consumed by persons who eat corn. This approach is more health protective than allowing each packager to confine his exposure calculation only to his or her market share or the amount of corn he or she packaged, which may be relatively small when compared to the amount consumed by the consumer overall. If it is reasonably anticipated that the product category containing chemical will be ingested only once per week, once per month, or once per year, the resulting intake of the chemical averaged over a daily basis would be 1/7, 1/30, and

1/365 of the value determined when the food is eaten once each day.

EXAMPLE OF THE PROCESS

The following example of the risk assessment and exposure assessment process under these regulations is provided for purposes of illustration. This example also utilizes concepts from section 12503 regarding exposure to ambient air and section 12901 regarding methods of detection.

Company X owns an office building and leases space in the building for office purposes. Some of the materials in the building contain asbestos fibers. Company X knows about the presence of asbestos in the building, and knows that some of the asbestos is in a deteriorating condition. For purposes of discussion, it is assumed that airborne fibers may reasonably be expected as a result of the presence of asbestos in a deteriorating condition, though this may not always occur.

Section 12503, subsection (c) states that an exposure has not occurred if the listed chemical was contained in air that the person received from the ambient air. Hence, if the detectable asbestos fiber concentration inside the building is indistinguishable from the outside asbestos fiber concentration, then there may be no exposure. Further, if scientifically valid monitoring studies indicate that there are diurnal and seasonal fluctuations in asbestos concentrations inside and outside that make it virtually impossible to differentiate between the two, again an exposure may not have occurred. If, however, despite diurnal and seasonal fluctuations, the inside air concentrations frequently exceed the outside air concentrations, then Company X could proceed to compare the increased level to the applicable level posing no significant risk.

This would involve identifying the level posing no significant risk. The Agency has identified that level as 100 asbestos fibers per day, based on a risk assessment performed by the California Department of Health Services (DHS) in a report to the Air Resources Board (ARB) for its Toxic Air Contaminant Program. We know, further, by referring to the DHS/ARB report, published in January 1986 that the 100 fibers are based upon phase contrast microscopy (PCM), which is equivalent to 10,000 to 100,000 fibers, when measured by transmission electron microscopy (TEM). Using an inhalation rate of 20 cubic meters of air per day for the permanent resident, the concentration posing no significant risk is 5 fibers by PCM per cubic meter of air, equivalent to 500-5,000 fibers by TEM per cubic meter of air.

If the increased level in the building exceeds the no significant risk level, the owner should provide a warning to the building's occupants.

<u>Section 12801</u>

Subsection (a) describes the scientific standards which must be applied to determinations of "no observable effect" within the meaning of the Act. It requires that such determinations be based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of the chemical. In other words, a showing of no observable effect within the meaning of the Act must be based upon data and protocols which are scientifically valid, sharing a comparable degree of scientific acceptance to the data and protocols which supported the listing of the chemical. The purpose of this provision is to ensure that whatever methods are used to conduct risk and exposure assessments conform to a high standard of scientific validity.

However, subsection (a) also provides that nothing in Article 8 is intended to preclude the use of evidence, standards or levels not described in the article to establish that an exposure would have no observable effect. Therefore, the methodologies, data, principles, assumptions and levels described in the sections following section 12801 are not exclusive and do not prevent a plaintiff or defendant in an enforcement action from establishing "no observable effect" by other means. However, such a showing must be based upon data, protocols, evidence and standards which are scientifically valid.

Subsection (b) provides a menu of the methods for determining no observable effect levels set forth in the regulations. The Agency has recognized in this article three alternative routes for arriving at a "no observable effect" level. Subsection (b) is intended to afford persons enforcing the Act and persons in the course of doing business an easy reference to the use of the "no observable effect" level regulations which follow section 12801 .

Generally, a determination of the level producing no observable effect may be made (1) through the performance of an assessment in accordance with principles set forth in section 12803, (2) the application of specific "no observable effect" levels set forth in the regulations or (3) the application of a regulatory level set forth in state or federal law derived from an assessment substantially equivalent to the assessment described in section 12803, and which establishes a maximum allowable daily dose level in the manner provided in this section.

Throughout the article the term "NOEL" is used to refer to the no observable effect level (i.e. the maximum dose level at which a chemical has no observable effect). Subdivision (c) defines this reference.

Section 12803

This section provides guidelines for conducting quantitative risk assessments for the purpose of establishing "no observable effect" levels. There are many reasons why it is important to have such guidelines in these regulations. For many chemicals,

levels of exposure, discharge or release which pose no observable effect within the meaning of the Act may not have been established either for purposes of the Act or other regulatory programs. Thus, persons in the course of doing business involving the chemicals may not be able to determine whether they are in compliance with the Act. As a result, such businesses may unnecessarily alter their business practices, or provide unnecessary warnings which may dilute the effectiveness overall of warnings under the Act. Finally, some persons in the course of doing business may disagree with the specific levels which have been established because, for example, the established level may have been derived from data which is outdated. These persons may choose to conduct their own risk assessments to ascertain the appropriate level posing no observable effect.

There are many variables in the performance of a risk assessment. Although the Act eliminates one variable, since it imposes a mandatory one thousand-fold safety factor, there are often several studies or sets of data of varying quality upon which the assessment may be based. There are a variety of assumptions which may need to be applied. By selecting data of high quality, choosing more conservative and accepted assumptions, persons in the course of doing business should be able to calculate "no observable effect" levels which could easily withstand challenge. However, persons enforcing the Act and persons in the course of doing business may be motivated to base their analyses upon less reliable data and less accepted or more controversial assumptions to suit their immediate purposes and objectives.

The purpose of this section is to provide a collection of principles for the conduct of risk assessments which will, if observed, produce a "no observable effect" level which is conservative, reliable and consistent with the purposes of the Act. This section is not designed to require that all risk assessments be performed according to rigid methodologies. Rather, it is intended to encourage the use of the most scientifically appropriate principles, data and assumptions for each risk assessment.

Subsection (a) requires that all risk assessments be based evidence and standards of comparable scientific validity to the evidence and standards which formed the basis for the listing of the chemical. The listing of chemicals under Health and Safety Code section 25249.8 (b) must be based upon "scientifically valid testing according to generally accepted principles." Therefore, the same standard applies to the performance of risk assessments used to support a showing of "no observable effect."

The subsection goes on to provide certain default assumptions or principles which the Agency considers to be "generally accepted." However, the regulation provides that other assumptions, principles or data sets should be used where scientifically more appropriate.

Paragraph (a)(1) provides that only studies producing the

reproductive effect which formed the basis for the listing of the chemical should be used for determining the NOEL. The Panel has determined that a number of reproductive effects come within the meaning of "reproductive toxicity" including, in females, menstrual disorders, infertility, spontaneous abortion, genetic damage, adverse effect on gonadal function, adverse effects on conception and maternal complications. In males, the effects include impotence, semen quality changes, genetic damage, adverse effects on gonadal function. For the conceptus, the effects include embryonal or fetal toxicity, birth defects, neurodevelopmental abnormalities, transplacental carcinogenisis, genetic damage, stillbirth, and functional or developmental changes.

When recommending a reproductive toxicant for listing pursuant to section 25249.8 of the Health and Safety Code, the Panel relies upon data demonstrating that particular types of reproductive toxicologic effects in humans or animals, in males, females, or the developing young result from exposure to the chemical. Inasmuch as the chemical is listed for a particular effect, it follows that studies producing this effect should be utilized to determine the dose level at which the effect will no longer be observed. Therefore, subsection (a)(1) provides that only such studies should be used.

There will be cases in which a chemical is listed because it produces multiple reproductive effects, each with its own "no observable effect" level. There appear to be three alternatives to choosing the applicable "no observable effect" level for purposes of the Act in such circumstances. First, the level could be based upon studies producing the effect having the lowest "no observable effect" dose level. Second, separate levels could be established for each observable effect. Third, the level could be based upon the combined results of the studies producing the reproductive effects for which the chemical was listed. However, this latter would be more in the nature of an "average observable effect" level, not a NOEL, and there appears to be no scientific basis for such an approach. Since most exposures are directed at the general population, rather than specific subpopulations, separate NOELs for each observable effect generally would produce little benefit. Accordingly, the simpler and more health protective approach is to base the NOEL on the result observed in the most sensitive population. Where the exposure is directed at a specific subpopulation, the application of a different NOEL may be appropriate.

Paragraph (a)(2) provides that epidemiologic data sets used for quantitative assessments should conform to generally accepted scientific principles, such as the selection of the exposed and reference groups, the reliable ascertainment of exposure, the completeness of follow-up, and the identification and quantification of confounding factors. These examples are offered for purposes of illustration, and are not intended as a limitation. The intended purpose of this provision is to assur that the data upon which risk assessments are based is of high

quality.

Paragraph (a)(3) makes provisions similar to paragraph (a)(2) applicable to animal bioassay studies. Again, the factors of data selection specified in the paragraph are offered for purposes of illustration, and are not intended as a limitation.

Paragraph (a)(4) provides that the analysis should be based upon the most sensitive of the studies which, under paragraphs (a)(2) and (a)(3), are deemed to be of sufficient quality. Because of the wide range of sensitivity to chemicals observed in humans, it is likely that the response of the most sensitive animal species will be representative of the response of some individuals. In the absence of a scientifically more appropriate assumption, basing analysis on the most sensitive study will provide a greater level of protection to humans.

Paragraph (a)(5) provides that the result obtained from the most sensitive study shall be applicable to all routes of exposure, except those routes for which the results are irrelevant. Data on the reproductive toxicity of a chemical to both humans and animals are not always available for a particular chemical and route of exposure. The inherent physical characteristics of the chemical in question may dictate a particular study protocol. Therefore, it may be necessary to utilize experimental results from one route of exposure for purposes of another.

Absent studies demonstrating a relationship between different routes of administration and differences in reproductive response by those routes, it is more appropriate to assume that a chemical that produces an an observable adverse reproductive effect by one route, such as ingestion, is also toxic to reproductive functions by other routes, such as inhalation, and vice versa.

Absorption studies may reveal that a chemical administered by a particular route will be poorly absorbed. If according to generally accepted principles data obtained from such an exposure route are irrelevant to exposures by other routes, this assumption may yield and a different data set may be more appropriate. However, when scientifically based interpretations of these data are able to allow predictions of exposure by other routes, the assumption should apply and the data ought to be utilized.

Paragraph (a)(6) allows the use of physiologic, pharmacokinetic and metabolic considerations in the assessment, where such data may be taken into account with confidence. The susceptibility of different animal species to a given chemical may vary due to differences in metabolism and pharmacokinetics. Certain chemicals are known to cause adverse reproductive outcomes in test species but not humans because of differences in anatomy, physiology, metabolism, and other factors. For example, rodent placental physiology is distinctive from that of primates, and chemicals toxic to the rodent placenta may not possess similar properties in primates. This provision allows the use of such

data to explain scientifically differential responses among animal species when determining the relative sensitivity of humans. However, the data must be of sufficient quality that it may be taken into account with confidence.

Paragraph (a)(7) provides that, where testing produces an observable effect, but the data does not establish a dose level producing no observable effect, the lowest observable effect level (LOEL) should be divided by 10 to produce an assumed NOEL. The practice of dividing a LOEL by an uncertainty factor in order to predict a NOEL is common among regulatory agencies, such as DHS, and will facilitate the establishment of NOELs where circumstances would otherwise prevent their development.

Subsection (b) provides for the conversion of the NOEL to a daily human dose level. Under paragraph (a)(1) the NOEL is to be expressed in terms of milligrams per kilogram of body weight per day. Subsection (b) accomplishes this conversion by multiplying the daily dose per kilogram by the assumed body weight of the affected population. Thus, when the reproductive effect is upon the male, a 70-kilogram body weight is assumed. When the effect is upon the female or the conceptus, the assumed body weight is 58 kilograms. These assumed body weights are derived from the Report of the Task Group on Reference Man, published in 1975 by the International Commission on Radiation Protection. The use of assumed body weights permits persons in the course of doing business to determine in advance whether the levels involved in their activity will produce no observable effect in the exposed population.

The adult female body weight is used where the reproductive effect is upon the conceptus (i.e., the developing child) because the human maternal exposure is the vehicle for exposure to the conceptus, and because it parallels the situation in animal experimentation, where test doses are given to the pregnant animal, based on its body weight.

Section 12805

Subsection (a) provides that exposure to a level of a listed chemical at or below the level set forth for the chemical in subsection (b) produces no observable effect within the meaning of the Act. The purpose of this section is to set forth "no observable effect" levels established solely for purposes of the Act in order to provide a safe harbor for those who would have difficulty identifying such levels if left to their own devices.

Subsection (b) provides levels for two chemicals known to the state to cause reproductive toxicity: ethylene oxide and lead. Both chemicals are identified by the federal Occupational Safety and Health Administration as known human reproductive toxicants based upon evidence of their effects on humans, and this resulted in their inclusion on the Governor's initial list pursuant to section 25249.8 (a) of the Act.

The difficulty in identifying a NOEL for reproductive toxicants when the eff cts of concern are based upon human experience rather than animal bioassays is that there is often no precise data predicting what levels will produce no observable effect. However, there is experience derived from the occupational setting which suggests that exposure to certain regulated levels does not produce the reproductive effect of concern. Hence, the Agency has utilized certain limits for occupational exposures as surrogates for the NOEL in the workplace. The levels set forth in subsection (b) represent one one-thousandth of the occupational exposure limits. This approach, while arguably unconventional, is consistent with the protective purposes of the Act.

The permissible exposure limit for ethylene oxide, as identified in Title 8, California Code of Regulations, General Safety Orders, is 2,000 micrograms per cubic meter of air. One can calculate a daily exposure, based on a workplace inhalation rate of 10 cubic meters of air inhaled per day, of 20,000 micrograms per day. Dividing by 1,000 yields an allowable level of 20 micrograms of ethylene oxide per day.

Similarly, the permissible exposure limit for lead is 50 micrograms per cubic meter of air. One can calculate a daily exposure, as described above, of 500 micrograms per day. Dividing by 1,000 in this case yields an allowable level of 0.5 microgram of lead per day.

Informal comments from some interested parties utilize different methods to identify the allowable levels for lead. One party utilized blood lead levels, as indicators of male reproductive toxicity, and found an allowable level of 0.7 micrograms of lead per day, close to the Agency's value. However, the Agency declines to identify 700 micrograms of lead per day, which is considerably higher than the occupational exposure limit, as a level that would result in no observable reproductive effect.

Another commenting party utilized an animal-derived NOEL, and identified an allowable level of 37 micrograms of lead per day, a value that would require the Agency to accept 37,000 micrograms per day as a level that would result in no observable reproductive effect. Clearly, that would be inappropriate, since that level would exceed the occupational limit by nearly 100-fold.

Section 12821

Section 25249.10 (c) of the Act provides an exemption test for discharges, releases and exposures to chemicals known to the state to cause reproductive toxicity. The test is whether the person responsible can show that the exposure would have no observable effect "assuming exposure at one thousand (1,000) times the level in question." The Act, however, does not define "level in question."

Section 25249.6 of the Act requires a clear and reasonable warning prior to exposure to a listed chemical, and section 25249.5 prohibits any discharge, except where this exemption applies. Thus, persons in the course of doing business, in order to avoid violation of the Act, will need to determine the applicability of the exemption prior to exposure, discharge or release. Therefore, they will need to know in advance what will be the assumed or expected "level in question" for purposes of the exemption.

Subsection (a) defines the term "level in question" to mean the chemical concentration of a listed chemical for the exposure in the question, which includes only those exposures for which the person in the course of doing business is responsible. The chemical concentration is usually expressed as micrograms per liter of water, cubic meter of air, or gram of food. Because a chemical may exist in a medium of concern due to the acts of some other person, this subsection states what is implied in the Act, namely, that a person is responsible only for exposures to a chemical that results from her or his acts or omissions.

The exemption test of section 25249.10(c) is based upon exposure. It is the "exposure" which must produce no observable effect "at the level in question." Accordingly, subsection (b) defines "exposure" for purposes of this exemption to mean the "reasonably anticipated rate of exposure for an individual to a given medium."

The reasonably anticipated rate of exposure will vary from case to case. It may be reasonably anticipated that food will be ingested once each day, or once each week, and so on. An individual may use a product containing a high level of a listed substance, but use the product only once a year. What rate of exposure is reasonably anticipated from a given medium, such as a certain type of food or a consumer product, will depend upon the medium, its anticipated use and other circumstances. For example, the publisher of a newspaper using inks containing a listed chemical may not reasonably anticipate that a reader will ingest the Sunday edition, but may reasonably anticipate other contact. A manufacturer of cardboard boxes may not reasonably anticipate the ingestion of a box, but may reasonably anticipate that the box will be used to package food products into which a chemical may migrate. A manufacturer of baby cribs might reasonably anticipate that an infant will chew or teethe on the railings.

However, unlike chemicals known to the state to cause cancer, averaging the exposure or intake to yield a daily exposure over lifetime may not be appropriate for reproductive toxins. Accordingly, subsection (b) further provides that the "reasonably anticipated rate of exposure" must be based upon patterns and duration of exposure relevant to the reproductive effect for which the chemical was listed. Since some reproductive effects, such as teratogenic responses or birth defects, may reflect an acute response during a brief period of intrauterine exposure,

Therefore, when one evaluates such a reproductive toxin, one needs to view the exposure as the one that may cause the acute effect. For example, if a food is eaten once per week, and if that food contains a teratogen, a proper assessment would require the assumption that ingestion of that food will occur on any day (and, hence, every day of the pregnancy). In other words, averaging to a daily intake would be inappropriate, since the embryonic response ought to be assumed to occur on the day of the ingestion of that food.

Subsection (b) combines the definitions of "exposure" and "level in question" into a working formula. The level of exposure which must produce no observable effect assuming exposure at one thousand times the level in question is the product of the concentration of the chemical in the medium and the reasonably anticipated rate of exposure to individuals to that medium. Under this formula, a certain daily exposure to a chemical in a food product could be calculated by taking into account the concentration of the chemical in the food (in micrograms of chemical per gram of food), and multiplying that concentration times the quantity ingested (in grams of food per day). The product of this multiplication yields the quantity of chemical ingested in that food (in micrograms of chemical per day). This level must not exceed the level derived pursuant to this article.

The rate of exposure to a given medium of exposure is itself subject to fluctuation. Different individuals take in different amounts of air, water and food. Some may have considerably more exposure to a product than others. It is, therefore, also necessary to establish certain assumptions about particular media. This is accomplished in subsection (c). However, scientifically more appropriate or specific data may be used where available.

Paragraph (1) provides that, where appropriate, the assumptions set forth in section 12721, subsection (d) should apply. Paragraph (1)A. of that subsection assumes ingestion of two (2) liters of drinking water per day. Paragraph (1)B. assumes inhalation of twenty (20) cubic meters of air per day. These values are drawn from the Report of the Task Group on Reference Man, published in 1975 by the International Commission on Radiological Protection, and are consistent with assumptions utilized in regulatory toxicology for these media.

Paragraph (d)(2) of section 12721 provides that different assumptions should be used where the exposure is expected to effect only a subpopulation to which different assumptions properly apply. Certain subpopulations need to be addressed where circumstances involve particular products or environmental conditions which may pose a possible exposure risk to a distinct group of people. For example, certain products may be used primarily by women. Paragraph (d)(2) provides different assumptions for various subpopulations for the ingestion of water and inhalation of air.

assumptions for various subpopulations for the ingestion of water and inhalation of air.

Paragraph (d)(3) of section 12721 provides a specific set of assumptions for exposures in the workplace, since workers are normally exposed for only a portion of the day, for a limited number of days each week, for a limited number of weeks per year. The net result of these assumptions, which are based upon well-accepted conventions, is that occupational exposures producing no observable effect within the meaning of the Act may involve slightly higher concentrations of the chemical.

It is anticipated that exposures will occur in the workplace to persons other than employees, such as customers, visitors or solicitors. These individuals will probably spend less time in that location as an employee. The Agency believes it is appropriate to differentiate between the potential exposure that may befall a temporary visitor and that of an employee. Therefore, paragraph (d)(3) of section 12721 assumes such persons will visit the premises one hour per month, and further assumes that they will inhale 1.25 cubic meters of workplace air during each visit.

Paragraph (d)(4) of section 12721 should not be applied to assessments for exposure to products containing reproductive toxicants, since that paragraph refers to the "average rate" of intake. As discussed above, the application of average rates of exposure to reproductive toxicants may not be appropriate.

Accordingly, subsection (c)(2) of this section provides assumptions for exposure resulting from the consumption of goods or consumer products as are described in section 12601, subsection (b). The reasonably anticipated rate of consumption by the product user, not the per capita consumption of the general population, is the standard. Data on the rate of intake should be based on the data available for general categories of products, such as the U.S. Department of Agriculture Home Economic Research Report on Foods Commonly Eaten by Individuals; Amount Per Day and Amount Per Eating Occasion, where available.

Under paragraph (c)(3), for long term exposures affecting the developing young, the level of exposure is to be based on the reasonably anticipated rate of exposure for the mother during the nine-month gestation period, since maternal intake would be the means by which the intrauterine exposure would occur. Thus, if the amount of the chemical from a source of exposure during the entire gestation period exceeds one-one thousandth of the level which produces no observable effect, the exemption does not apply, and a warning must be provided.

TITLE 22. CALIFORNIA HEALTH AND WELFARE AGENCY

ACTION: Notice of Emergency Rulemaking
Section 12901 - Methods of Detection

SUBJECT: Safe Drinking Water and Toxic Enforcement Act of 1986

PUBLIC PROCEEDINGS: Notice is hereby given that the California Health and Welfare Agency will hold a public hearing commencing at 10:00 a.m. on July 29, 1988 in the Auditorium at 714 P Street, Sacramento, CA, at which time any person may present statements or arguments orally or in writing relevant to the action described in this notice. Any written statements or arguments must be received by the Office of Regulations, Department of Health Services, 714 P Street, Room 1000, P.O. Box 942732, Sacramento, CA 94234-7320 by 5:00 p.m. on July 29, 1988 which is hereby designated as the close of the written comment period. It is requested but not required that written statements or arguments be submitted in duplicate.

CONTACT: Inquiries concerning the action described in this notice may be directed to Dr. Steven A. Book, Science Advisor to the Secretary and Executive Secretary to the Scientific Advisory Panel at (916) 445-6900.

INFORMATIVE DIGEST:

Health and Safety Code § 25249.5, one of two operative provisions of the Safe Drinking Water and Toxic Enforcement Act of 1986 (Act) prohibits any person in the course of doing business to knowingly discharge or release a chemical known to the state to cause cancer or reproductive toxicity to any source of drinking water, except as provided in section 25249.9. Section 25249.9 provides that section 29249.5 may not apply to a discharge or release which will not cause any significant amount of the chemical to enter a source of drinking water. Section 25249.11, subsection (c) defines "significant amount" to mean "any detectable amount", other than an amount which poses no significant risk for carcinogens, or would have no observable effect assuming exposure at one thousand times the level in question. However, the Act does not specify how chemicals are to be detected, or what analytical methods must be used.

On February 27, 1988, the Health and Welfare Agency adopted by emergency section 12901. It provides that "any detectable amount" means an amount detected by the methods of sampling and analysis to which the section refers. It further requires that, where specified governmental agencies have adopted or employ a method of analysis, or a method is generally accepted in the scientific community, for the detection or measurement of a listed chemical in a given medium, the method must be employed for purposes of the Act. Where no such method is available, a

scientifically valid method must be used. It further provides that, in the conduct of any such analysis, generally accepted laboratory standards of practice must be observed.

It is the intention of the Health and Welfare Agency to receive and respond to public comment on the emergency regulation in compliance with the Administrative Procedure Act.

AUTHORITY: Health & Safety Code § 25249.12

REFERENCE: Health & Safety Code §§ 25249.5, 25249.6, 25249.11

FISCAL IMPACT ESTIMATE:

A. Fiscal Effect on Local Government: No additional costs or savings.

B. Fiscal Effect on State Government: No additional costs or savings.

C. Fiscal Effect on Federal Funding of State Programs: No fiscal impact exists.

D. Fiscal Effect on Private Persons or Businesses Directly Affected: Undetermined cost savings resulting from clarification of the applicability of the Act.

E. Fiscal Effect on Small Businesses: No additional costs or savings.

DETERMINATIONS: The Agency has determined that the regulations would not impose a mandate on local agencies or school districts, nor are there any costs, for which reimbursement is required by Part 7 (commencing with Section 17500) of Division 4 of the Government Code.

The Agency has also determined that the regulations would not have a significant adverse economic impact on small businesses.

AVAILABILITY OF STATEMENT OF REASONS AND TEXT OF REGULATIONS: The Agency has prepared and has available for public review an initial statement of reasons for the emergency regulation, all the information upon which the emergency regulations are based, and the text of the emergency regulations. A copy of the initial statement of reasons and a copy of the text of the emergency regulations are available upon request by writing to the Office of Regulations at the address noted above, which address will also be the location of public records, including reports, documentation and other materials related to the emergency regulations.

AVAILABILITY OF CHANGED OR MODIFIED TEXT: The full text of any regulation which is changed or modified from the express terms of the emergency action will be made available by the Office of Regulations at least 15 days prior to the date on which the

Agency adopts, amends or repeals the resulting regulation.

ADDITIONAL COMMENTS: In accordance with Government Code Section 11346.5(a)(7), the Agency must determine that no alternative considered by the Agency would be more effective in carrying out the purpose for which the emergency action was taken or would be as effective and less burdensome to affected private persons than the emergency action. Other regulation changes may be scheduled for hearing at the same time appointed for public hearing on the action described in this notice. An agenda for the public hearing will be posted at the time and place of hearing designated above.

HEALTH AND WELFARE AGENCY

Dated: May 20, 1988

CLIFFORD L. ALLENBY
Secretary

22 CALIFORNIA CODE OF REGULATIONS DIVISION 2
STATE OF CALIFORNIA
HEALTH AND WELFARE AGENCY
CHAPTER 3 SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986

ARTICLE 9. MISCELLANEOUS

12901. Methods of Detection

(a) For purposes of section 25249.11, subdivision (c), of the Health and Safety Code, the term "any detectable amount" means a level detected using the methods of sampling and analysis referred to in this section.

(b) Where the California Department of Health Services, the California Department of Food and Agriculture, the Air Resources Board, a local air pollution control district, or a federal agency has adopted or employs a method of analysis, or where a method of analysis is generally accepted by the scientific community, as evidenced by its publication in compilations by professional and scientific associations or societies, such as the Association of Official Analytical Chemists, or in peer-reviewed technical journals published by such associations or societies, for the detection or measurement of a listed chemical in a specific medium, including, but not limited, to water, air, food or soil, such method shall be the analytical method for that chemical in that medium. Where more than one method has been so adopted, is so employed, or is generally accepted, each may be utilized as the method of analysis.

(c) Where no method of analysis as described in subsection (b) has been adopted, is employed or is generally accepted by the scientific community, and a scientifically valid analytical method has been developed for the detection or measurement of a

listed chemical in a specific medium, including, but not limited to, water, air, food or soil, such method shall be the analytical method for that chemical in that medium. Where more than one method has been developed for a chemical in a specific medium, each may be utilized as the method of analysis.

(d) In performing a laboratory analysis to determine the concentration of a chemical known to the state to cause cancer or reproductive toxicity in a given medium, generally accepted laboratory standards and practice for sampling, collection, storage, preparation, chemical analysis, statistical analysis of data, and interpretation of results shall be observed.

AUTHORITY: Health and Safety Code section 25249.12
REFERENCE: Health and Safety Code sections 25249.5, 25249.6, 25249.11

INITIAL
STATEMENT OF REASONS
22 CALIFORNIA CODE OF REGULATIONS DIVISION 2

Section 12901 - Methods of Detection

Health and Safety Code § 25249.5, one of two operative provisions of the Safe Drinking Water and Toxic Enforcement Act of 1986 (Act) prohibits any person in the course of doing business to knowingly discharge or release a chemical known to the state to cause cancer or reproductive toxicity to any source of drinking water, except as provided in section 25249.9. Section 25249.9, subsection (b) provides that section 25249.5 does not apply to a discharge or release which will not cause "any significant amount" of the chemical to enter a source of drinking water. Section 25249.11, subsection (c) defines "significant amount" to mean "any detectable amount", except an amount which poses no significant risk for carcinogens, or would have no observable effect assuming exposure at one thousand times the level in question for reproductive toxicants.

Whether there is a detectable amount of a chemical regulated by the Act in an exposure, discharge or release may be determined by scientific analysis. However, the Act does not specify what analytical methods to use.

As of April 1, 1988, there are 224 substances listed as "known to the state to cause cancer or reproductive toxicity". For each chemical, several analytical methods of varying degrees of accuracy, sensitivity or feasibility may exist for its detection in a given medium, and new methods are frequently developed.

Since the discharge prohibition of section 25249.5 applies to discharges or releases into water or onto or into land, both land and water are media for which available methods of detection may be relevant. Further, although the term "any detectable amount" is used by the Act in reference to an exemption from section 25249.5 only, it may be necessary for purposes of section 25249.6, which prohibits exposure to listed chemicals without prior warning, to detect chemical exposures by analytical methods. Section 25249.6 applies to exposures from all manner of media.

Thus, analytical detection may be used to support or defend enforcement actions for discharges, releases or exposures in a wide range of media for an ever-increasing number of chemicals. Parties to those enforcement actions may be highly motivated to choose the method of analytical detection which will best suit their purposes at the time. For example, where the level of no significant human risk is below the level of detection by any available method, plaintiffs may prefer the method of detection which is most sensitive, even though it may be new and untried, since defendants may have a more difficult time keeping their discharges, releases or exposures below the level which the

method would detect, thus ensuring liability.

Defendants, on the other hand, would probably favor a less sensitive method. However, allowing plaintiffs and defendants to rely upon any analytical detection method of their choosing without limitation may create confusing factual issues in enforcement proceedings, and might prevent persons in the course of doing business from being certain whether their activities comply with the Act.

The purpose of this regulation is to provide some guidance for selecting which of possibly several analytical methods to use to detect a listed chemical in a specific medium. It provides that "any detectable amount" means an amount detected by the methods of sampling and analysis to which the section refers. In order of preference, the section refers to methods adopted or employed by governmental agencies, or currently accepted in the scientific community, for the detection or measurement of a listed chemical in a given medium. If such a method exists, it must be employed for purposes of the Act. If there is more than one such method, each may be utilized. This, in effect, requires that analytical detection be based upon well-accepted science, but preserves flexibility where science provides alternative methods.

Preferring that the analytical method of detection used by California state or federal regulatory agencies also be used for purposes of the Act should enable businesses to continue to monitor releases or exposures through methods that they presently use. It will also allow regulatory agencies which currently monitor for compliance under other existing laws and regulations to monitor for compliance with the Act as well. Enforcement of the Act may be facilitated, since those enforcing the Act may be able to consult with regulatory agencies for assistance in determining compliance or noncompliance.

For many chemicals to which the Act applies, there may be no accepted method of analytical detection. However, scientifically valid methods not yet widely accepted or recognized may have been developed. If a scientifically valid method exists, subsection (c) provides that it should be used. If more than one such method exists, again, each may be utilized. The purpose of this provision is to prevent the use of analytical methods without scientific validity.

Providing for the use of methods that are generally accepted by the scientific community or, in the absence of such methods, methods which are scientifically valid, should minimize confusion by reducing the possibility of conflicting measurements resulting from the competing use of proven and unproven methods of varying sensitivity or accuracy. At the same time, it allows and encourages the development and utilization of new methods, where none currently exists, that are scientifically appropriate and supportable.

Subdivision (d) provides that, in the conduct of any such

analysis, generally accepted laboratory standards of practice must be observed. The general acceptance or scientific validity of any method assumes that such standards will be observed. Therefore, this subdivision requires the observance of such standards.

The Health and Welfare Agency has, as an alternative, considered the possibility of proposing a regulation which would require the use of a specific method of detection for each listed chemical in each medium. However, the growing number of chemicals, the large number of media in which an exposure may occur, the increasing number of detection methods available for some chemicals, the absence of methods for others, and the lack of information readily accessible to the Health and Welfare Agency regarding the relative merit and availability of detection methods appears to make such a regulation and its adoption impracticable and unwieldy. Moreover, requiring the use of a specific method would not permit the use of methods of equal merit.

# Businesses Feel First Impact of California's Toxics Law

**Posting of warnings took effect on Feb. 27, and state gears up to meet regulations that affect firms from oil refineries to supermarkets**

Rudy M. Baum, C&EN San Francisco

To Californians, the world suddenly appears to be a significantly more hazardous place than it used to be. To many companies doing business in California, operations suddenly are much more complex. In the months to come, the appearance of ubiquitous hazard probably will increase, and sweeping new regulations governing toxic substances will affect the activities of businesses ranging from supermarkets to oil refineries.

In short, Proposition 65 is beginning to take effect.

The first provisions of California's Safe Drinking Water & Toxic Enforcement Act of 1986, the official name of what is popularly known as Proposition 65, took effect on Feb. 27. As of that date, warnings must be posted by anyone in California who, in the course of doing business, exposes any individual to one of 29 compounds and classes of compounds deemed by the state to cause cancer or reproductive toxicity.

Because some of the substances—such as benzene, vinyl chloride, arsenic, and lead—are not uncommon, warnings are going up in grocery stores, gas stations, hardware stores, and other places of business. Full-page newspaper advertisements have been placed by companies whose plants emit one or more listed substances.

More such warnings are on the way. The state's list of chemicals known to cause cancer or reproductive toxicity, as determined by a scientific advisory panel, already contains about 150 additional substances that will fall under the warning provision of the law by the end of 1988; about 50 more, including ethyl alcohol and tobacco smoke, will be added shortly.

Proponents of Proposition 65, which was passed overwhelmingly by California voters in 1986, say it's about time; opponents continue to predict chaos for businesses in California and for companies that produce products for sale in the state.

One thing is clear: No one currently knows precisely how the law, which also includes a provision concerning the discharge of listed chemicals into drinking water supplies, ultimately will be applied. In mid-February, California's Health & Welfare Agency released a preliminary set of regulations governing primarily the warning provision of Proposition 65.

Neither environmentalist nor business interests are entirely satisfied with the regulations, although businesses apparently obtained at least a temporary respite from two of the potentially more onerous aspects of the law—identification of individual products that contain listed chemicals and meeting stricter standards than those set by the federal government. Environmental activists likely will challenge the regulations in court where many of the details of Proposition 65's application almost certainly will be decided.

"Given the wording of the law, we think Health & Welfare [the California agency] has done a good job of putting together balanced regulations. There are points we disagree with, but that is to be expected," says Richard L. Davis, executive director of the Chemical Industry Council of California. The council was one of numerous business and agricultural organizations that opposed passage of Proposition 65 (C&EN, Oct. 13, 1986, page 17).

By contrast, David B. Roe, senior attorney for the Environmental Defense Fund and coauthor of Proposition 65, sees both positive and negative aspects of the regulations. As a result of Proposition 65, he says, in the past year "more progress has been made on technical issues relating to controlling toxic substances than in the past 12 years at the federal level," and that progress is reflected in the regulations. On the other hand, Roe says, the regulations create two significant "loopholes" that improperly dilute the effect of Proposition 65.

Progress has occurred, Roe says, because the law places the burden of proving that an exposure to a toxic substance poses "no significant risk" on the business causing the exposure. Roe correctly predicted in 1986 that passage of Proposition 65 would induce businesses to reverse past practices and press for establishment of well-defined regulations of what constitutes no significant risk, including specific exposure levels.

Proposition 65 says that "no person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual," except as spelled out in another section of the law. There is some disagreement about how the exemptions apply. However, the law states that the warning requirement does not apply for "an exposure for which the person responsible can show that the expo-

## More than 175 carcinogens and reproductive toxicants listed by California law

| Chemical | Date listed |
|---|---|
| **CARCINOGENS** | |
| 2-Acetylaminofluorene | 7/1/87 |
| Acrylonitrile | 7/1/87 |
| Adriamycin | 7/1/87 |
| AF-2; [2-(2-furyl)-3-(5-nitro-2-furyl)]acrylamide | 7/1/87 |
| Aflatoxins | 1/1/88 |
| *o*-Aminoazotoluene | 7/1/87 |
| 4-Aminodiphenyl | 2/27/87 |
| 2-Amino-5-(5-nitro-2-furyl)-1,3,4-thiadiazole | 7/1/87 |
| Amitrole | 7/1/87 |
| *o*-Anisidine and *o*-anisidine hydrochloride | 7/1/87 |
| Analgesic mixtures containing phenacetin | 2/27/87 |
| Aramite | 7/1/87 |
| Arsenic (inorganic arsenic compounds) | 2/27/87 |
| Asbestos | 2/27/87 |
| Auramine | 7/1/87 |
| Azaserine | 7/1/87 |
| Azathioprine | 2/27/87 |
| Benz[*a*]anthracene | 7/1/87 |
| Benzene | 2/27/87 |
| Benzidine (and its salts) | 2/27/87 |
| Benzo[*b*]fluoranthene | 7/1/87 |
| Benzo[*j*]fluoranthene | 7/1/87 |
| Benzo[*k*]fluoranthene | 7/1/87 |
| Benzo[*a*]pyrene | 7/1/87 |
| Benzotrichloride | 7/1/87 |
| Benzyl violet 4B | 7/1/87 |
| Beryllium and beryllium compounds | 10/1/87 |
| *N,N*-Bis(2-chloro-ethyl)-2-naphthylamine (Chlornapazine) | 2/27/87 |
| Bischloroethyl nitrosourea (BCNU) | 7/1/87 |
| Bis(chloromethyl) ether | 2/27/87 |
| 1,4-Butanediol dimethanesulfonate (Myleran) | 2/27/87 |
| β-Butyrolactone | 7/1/87 |
| Cadmium and cadmium compounds | 10/1/87 |
| Carbon tetrachloride | 10/1/87 |
| Certain combined chemotherapy for lymphomas | 2/27/87 |
| Chlorambucil | 2/27/87 |
| Chlordecone (Kepone) | 1/1/88 |
| 1-(2-Chloroethyl)-3-cyclohexyl-1-nitrosourea (CCNU) | 1/1/88 |
| Chloroform | 10/1/87 |
| Chloromethyl methyl ether (technical grade) | 2/27/87 |
| 4-Chloro-*o*-phenylenediamine | 1/1/88 |
| Chromium (hexavalent compounds) | 2/27/87 |
| Coke oven emissions | 2/27/87 |
| Conjugated estrogens | 2/27/87 |
| *p*-Cresidine | 1/1/88 |
| Cupferron | 1/1/88 |
| Cycasin | 1/1/88 |
| Cyclophosphamide | 2/27/87 |
| Dacarbazine | 1/1/88 |
| Daunomycin | 1/1/88 |
| DDT; 1,1,1-Trichloro-2,2-bis-(*p*-chlorophenyl)ethane | 10/1/87 |
| Degraded carrageenan (not food-grade carrageenan) | 1/1/88 |
| 2,4-Diaminoanisole sulfate | 1/1/88 |
| 4,4'-Diaminodiphenylether | 1/1/88 |
| 2,4' Diaminotoluene | 1/1/88 |
| Dibenz[*a,h*]acridine | 1/1/88 |
| Dibenz[*a,j*]acridine | 1/1/88 |
| Dibenz[*a,h*]anthracene | 1/1/88 |
| 7*H*-Dibenzo[*c,g*]carbazole | 1/1/88 |
| Dibenzo[*a,e*]pyrene | 1/1/88 |
| Dibenzo[*a,h*]pyrene | 1/1/88 |
| Dibenzo[*a,j*]pyrene | 1/1/88 |
| Dibenzo[*a,j*]pyrene | 1/1/88 |
| 1,2-Dibromo-3-chloropropane (DBCP) | 7/1/87 |
| 3-3'-Dichlorobenzidine | 10/1/87 |
| 3,3'-Dichloro-4,4'-diamino-diphenyl ether | 1/1/88 |
| Diepoxybutane | 1/1/88 |
| Di(2-ethylhexyl) phthalate | 1/1/88 |
| 1,2-Diethylhydrazine | 1/1/88 |
| Diethyl sulfate | 1/1/88 |
| Diethylstilbestrol | 2/27/87 |
| Dihydrosafrole | 1/1/88 |
| 3-3'-Dimethoxybenzidine (*o*-Dianiasidine) | 1/1/88 |
| 4-Dimethylaminoazobenzene | 1/1/88 |
| *trans*-2-[(Dimethylamino)-] methylimino-5-[2-5-nitro-2-furyl)vinyl]-1,3,4-oxadiazole | 1/1/88 |
| 3,3' Dimethylbenzidine (*o*-tolidine) | 1/1/88 |
| Dimethylcarbamoyl chloride | 1/1/88 |
| 1,2-Dimethylhydrazine | 1/1/88 |
| Dimethyl sulfate | 1/1/88 |
| 1,4-Dioxane | 1/1/88 |
| Direct Black 38 (technical grade) | 1/1/88 |
| Direct Blue 6 (technical grade) | 1/1/88 |
| Epichlorohydrin | 10/1/87 |
| Estradiol 17 B | 1/1/88 |
| Estrone | 1/1/88 |
| Ethinylestradiol | 1/1/88 |
| Ethylene dibromide | 7/1/87 |
| 1,2-Dichloroethane (ethylene dichloride) | 10/1/87 |
| Ethyleneimine | 1/1/88 |
| Ethylene oxide | 7/1/87 |
| Ethylene thiourea | 1/1/88 |
| Ethyl methanesulfonate | 1/1/88 |

sure poses no significant risk assuming lifetime exposure at the level in question for substances known to cause cancer, and that the exposure will have no observable effect assuming exposure at one thousand times the level in question for substances known to the state to cause reproductive toxicity."

The regulations, about 175 pages long, including administrative comments, set forth in great detail ways by which one can determine that exposure to a listed substance poses no significant risk. For carcinogens assessed following these guidelines, no significant risk is a level of lifetime exposure that results in one excess case of cancer in an exposed population of 100,000.

A company may conduct its own risk assessments following the guidelines. The regulations also contain a provision for the state's Health & Welfare Agency to establish exposure levels that pose no significant risk, but no such levels have yet been set. The regulations do, however, list exposure levels that pose no significant risk for 31 carcinogens based on previous state or federal risk assessments.

Foods, drugs, cosmetics, and medical devices that meet state and federal safety laws also are deemed by the regulations to pose no significant risk. This "interim standard," which will be superceded as quantitative risk assessments are performed and specific safe exposure levels are adopted, represents one of the loopholes in the regulations that Roe objects to. He argues that existing regulations do not protect people from exposure to unsafe levels of carcinogens and reproductive toxins and that the Proposition 65 regulations contain no deadline for setting levels that pose no significant risk. "Many times in toxics law we have seen temporary turn into permanent," he says.

The regulations also spell out in sometimes agonizing detail what constitutes "clear and reasonable warnings." Warnings may appear on product labels, on shelves in retail outlets, or by a "system of signs, public advertising identifying the system, and toll-free information services."

The toll-free telephone number provision, which would encourage

| Chemical | Date listed |
|---|---|
| Formaldehyde (gas) | 1/1/88 |
| Formylhydrazino-4-(5-nitro-2-furyl)thiazole | 1/1/88 |
| Glycidaldehyde | 1/1/88 |
| Gyromitrin (acetaldehyde methylformyl-hydrazone) | 1/1/88 |
| Hexachlorobenzene | 10/1/87 |
| Hexachlorocyclohexane (technical grade) | 10/1/87 |
| Hexamethylphosphoramide | 1/1/88 |
| Hydrazine and hydrazine sulfate | 1/1/88 |
| Hydrazobenzene | 1/1/88 |
| Indeno [1,2,3-*cd*] pyrene | 1/1/88 |
| Iron dextran complex | 1/1/88 |
| Lead acetate | 1/1/88 |
| Melphalan | 2/27/87 |
| Methoxsalen with ultraviolet A therapy (PUVA) | 2/27/87 |
| 2-Methylaziridine (propylene imine) | 1/1/88 |
| 4,4'-Methylene bis(2-chloroaniline) | 7/1/87 |
| 4,4'-Methylenedianiline and its dihydrochloride | 1/1/88 |
| Metronidazole | 1/1/88 |
| Michler's ketone | 1/1/88 |
| Mirex | 1/1/88 |
| Mustard gas | 2/27/87 |
| 2-Naphthylamine | 2/27/87 |
| Nickel refinery dust from the pyrometallurgical process | 10/1/87 |
| Nickel carbonyl | 10/1/87 |
| Nickel subsulfide | 10/1/87 |
| Nitrilotriacetic acid | 1/1/88 |
| Nitrofen (technical grade) | 1/1/88 |
| Nitrogen mustard | 1/1/88 |
| 2-Nitropropane | 1/1/88 |
| *N*-Nitrosodi-*n*-butylamine | 10/1/87 |
| *N*-Nitrosodiethanolamine | 1/1/88 |
| *N*-Nitrosodiethylamine | 10/1/87 |
| *N*-Nitrosodimethylamine | 10/1/87 |
| *p*-Nitrosodiphenylamine | 1/1/88 |
| *N*-Nitrosodi-*n*-propylamine | 1/1/88 |
| *N*-Nitroso-*N*-ethylurea | 10/1/87 |
| *N*-Nitroso-*N*-methylurea | 10/1/87 |
| *N*-Nitrosomethylvinylamine | 1/1/88 |
| *N*-Nitrosomorpholine | 1/1/88 |
| *N*-Nitrosonornicotine | 1/1/88 |
| *N*-Nitrosopiperidine | 1/1/88 |
| *N*-Nitrosopyrrolidine | 10/1/87 |
| *N*-Nitrososarcosine | 1/1/88 |
| Oxymetholone | 1/1/88 |
| Panfuran S | 1/1/88 |
| Phenazopyridine and its hydrochloride | 1/1/88 |
| Phenytoin and sodium salt of phenytoin | 1/1/88 |
| Polybrominated biphenyls | 1/1/88 |
| Polychlorinated biphenyls (containing 60% or more chlorine by molecular weight) | 1/1/88 |
| Procarbazine and its hydrochloride | 1/1/88 |
| Progesterone | 1/1/88 |
| 1,3,-Propane sultone | 1/1/88 |
| β-Propiolactone | 1/1/88 |
| Propylthiouracil | 1/1/88 |
| Sodium saccharin | 1/1/88 |
| Safrole | 1/1/88 |
| Soots, tars, and lubricant base oils[a] | 2/27/88 |
| Streptozotocin | 1/1/88 |
| Sulfallate | 1/1/88 |
| 2,3,7,8-Tetrachlorodibenzo-*p*-dioxin (TCDD) | 1/1/88 |
| Thioacetamide | 1/1/88 |
| Thiourea | 1/1/88 |
| Thorium dioxide | 2/27/87 |
| *o*-Toluidine and its hydrochloride | 1/1/88 |
| Toxaphene (polychorinated camphenes) | 1/1/88 |
| 2,4,6-Trichlorophenol | 1/1/88 |
| Treosulfan | 2/27/87 |
| Tris (1-aziridinyl) phosphine sulfide (thiotepa) | 1/1/88 |
| Tris (2,3-dibromopropyl) phosphate | 1/1/88 |
| Urethane | 1/1/88 |
| Vinyl chloride | 2/27/87 |
| **REPRODUCTIVE TOXICANTS** | |
| Aminopterin | 7/1/87 |
| Chlorcyclizine hydrochloride | 7/1/87 |
| 1,2-Dibromo-3-chloropropane (DBCP) | 2/27/87 |
| Diethylstilbestrol (DES) | 7/1/87 |
| Diphenylhydantoin | 7/1/87 |
| Ethyl alcohol in alcoholic beverages | 10/1/87 |
| Ethylene oxide | 2/27/87 |
| Etretinate | 7/1/87 |
| Isotretinoin | 7/1/87 |
| Lead | 2/27/87 |
| Methyl mercury | 7/1/87 |
| Thalidomide | 7/1/87 |
| Valproate | 7/1/87 |
| Warfarin | 7/1/87 |

a Includes derived products; specifically vacuum distillates, acid-treated oils, aromatic oils, mildly solvent-refined oils, mildly hydrotreated oils, used engine oils, and mineral oils, when used in occupations such as mulespinning, metal machining, and jute processing.

consumers to call for information about toxic substances in a product, is another feature of the regulations that upsets Roe and other environmental activists. They believe it dilutes the effect of the warning and tends to remove what Roe calls the "very strong market incentive" established by Proposition 65 for businesses to limit exposures to below the no-significant-risk levels set by the state.

According to Davis, the response of chemical manufacturers to Proposition 65's warning requirements currently is "all over the board." For suppliers of industrial chemicals, the carcinogenic or reproductive toxicity warning is being incorporated into the material safety data sheets that already are required by law. In addition, some manufacturers are including warnings in shipping papers and separate communications to customers, Davis says.

In the workplace, the new regulations state that warnings that comply with the federal Hazard Communication Standard and California's Hazard Communication Standard, otherwise known as the "employee right-to-know laws," also are in compliance with Proposition 65. Chemical companies generally already have had to deal with these laws. In addition, Davis says, many chemical companies plan to post signs at plant gates and in affected areas for nonemployees such as salesmen and other company visitors.

Regardless of the regulations, chemical companies are proceeding with a great deal of caution with regard to the law's warning requirements. "We are dealing with many unknowns," says Diane Bartolanzo, community affairs manager for Monsanto in St. Louis. The company expects that many aspects of Proposition 65, such as what constitutes no significant risk and the actual meaning of "clear and reasonable warning," will be determined in the courts, Bartolanzo says. What she describes as a "few" Monsanto products sold in California will carry warning labels. However, until Monsanto tells its customers which products are going to be labeled, the company is not disclosing the products' identity.

In terms of community notification, only one Monsanto facility, a

plant in Carson, Calif., that produces detergent products, will be affected by Proposition 65 at this time, Bartolanzo says. The facility uses benzene, one of the 29 chemicals now covered by the law, and emits small amounts of the chemical. At the facility's fence line, the concentration in the air is on the order of 30 ppb, she says, which is well below the workplace standard of 1 ppm.

Nevertheless, "erring on the side of caution," Monsanto is posting warning signs around the perimeter of the Carson plant, Bartolanzo says. The company is also placing advertisements in several local newspapers that state that small amounts of benzene are emitted by the facility while stressing that the emissions meet or are below permitted levels.

New groups of chemicals will fall under Proposition 65's warning provision each quarter beginning in July. On Oct. 27 this year, the law's provision prohibiting discharge of listed chemicals into drinking water will take effect for the first group of 29 chemicals. The regulations governing that aspect of Proposition 65 are still being formulated. □

**EPA's regulatory budget is up 10% . . .**

| $ Millions | 1988* | 1988* | 1987* | % change 1988–89 |
|---|---|---|---|---|
| Superfund | $1632.4 | $1440.3 | $ 987.6 | 13% |
| Hazardous waste | 161.1 | 156.0 | 152.2 | 3 |
| Water quality | 146.1 | 146.8 | 165.6 | 0 |
| Air | 119.2 | 115.7 | 124.2 | 3 |
| Pesticides | 85.7 | 35.0 | 25.6 | 145 |
| Drinking water | 54.0 | 59.1 | 57.6 | -9 |
| Leaking underground storage tanks | 50.0 | 39.4 | 30.8 | 27 |
| Toxic substances | 41.3 | 77.6 | 25.2 | 47 |
| Interdisciplinary | 9.6 | 9.4 | 6.8 | 2 |
| Radiation | 7.2 | 7.9 | 4.0 | -9 |
| TOTAL | $2306.6 | $2097.1 | $1618.8 | 10% |

**. . . OSHA's just 4%**

| $ Millions | 1988* | 1988* | 1987* | % change 1988–89 |
|---|---|---|---|---|
| Enforcement | $158.3 | $153.8 | $148.5 | 3% |
| Federal | 117.0 | 113.0 | 96.7 | 3 |
| State | 41.3 | 40.5 | 51.8 | 2 |
| Compliance assistance | 38.1 | 35.3 | 35.0 | 2 |
| Safety and health | 25.9 | 25.5 | 24.1 | 1 |
| Statistics | 20.2 | 20.0 | 17.4 | 1 |
| Standards | 6.7 | 6.5 | 6.5 | 3 |
| Technical support | 17.5 | 16.8 | 16.4 | 5 |
| Administration | 6.0 | 5.8 | 6.0 | 3 |
| TOTAL | $244.8 | $234.7 | $228.0 | 4% |

**. . . and FDA's down 2%**

| $ Millions | 1988* | 1988* | 1987* | % change 1988–89 |
|---|---|---|---|---|
| Drugs | $174.7 | $194.0 | $176.5 | -10% |
| Foods | 132.3 | 126.4 | 120.4 | 5 |
| Devices and radiological products | 77.8 | 74.9 | 71.0 | 4 |
| Program management | 57.2 | 56.5 | 54.1 | 1 |
| National Center for Toxicological Research | 25.0 | 24.3 | 23.0 | 3 |
| TOTAL | $467.0 | $476.1 | $445.0 | -2 |

*Obligations. a Estimates. b Actual. Source: Office of Management & Budget

# Regulatory agencies' '89 budget a mixed bag

The fiscal 1989 budget proposal that President Reagan presented to Congress late last month is a mixed bag for the regulatory agencies that, in one way or another, interact with the chemical industry.

For instance, the Environmental Protection Agency's regulatory budget is up 10%, or $220 million, to $2.3 billion, following an almost 30% gain for the current fiscal year. But that doesn't mean increases for every program. For example, funding for the toxic substances program has been cut almost in half to $41 million. The largest portion of the reduction, according to the agency, reflects a decision not to request any more money for removing asbestos from school buildings. EPA notes that the federal government has already provided more than $150 million to fund abatement projects that have greatly reduced the problem. Any further activities, it says, should be the responsibility of state and local governments.

Funding for drinking water programs is down almost 10% to $54 million. Still EPA says that in fiscal 1989 it will promulgate standards for 34 toxic chemicals and radionuclides, including radon, the last of the 83 contaminants specified in the Safe Drinking Water Act Amendments of 1986.

In sharp contrast is the pesticides program budget, which is soaring by more than $50 million to reach a total of $86 million. All of the increase, however, will go to fund the transportation, storage, and disposal of canceled and suspended pesticides. That activity is currently funded at $8.4 million. According to EPA, the large increases in 1989 will enable it to make significant progress on final disposal of dinoseb and 2,4,5-T/Silvex.

In the legal area, EPA's enforcement budget is up 7% to $299 million, and funding for the Justice Department's environmental enforcement activities is up 23% to $32 million. Funding for the antitrust division is up 12% to $294 million.

The Occupational Safety & Health Administration's budget, on the other hand is up just 4% to $245 million, following a 3% increase this year. OSHA says it will issue seven health standards in fiscal 1989, up from six this year; increase its number of inspections from 62,200 to 66,500; and issue eight safety standards, double the number planned in the current fiscal year.

The Food & Drug Administration's budget is falling 2% to $467 million, following a 7% increase for fiscal 1988. Hardest hit are FDA's drug activities. That budget account is down 10% to $175 million, at a time when the agency is under pressure to expedite the approval of new drugs, particularly ones developed to combat acquired immune deficiency syndrome.

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