

TITLE 22, Division 2, Part 2, Subdivision 1, Chapter 3, California Code of Regulations

ARTICLE 1. Preamble and Definitions

Preamble

(a) It is the practice of the Office of Environmental Health Hazard Assessment, as lead agency for implementing the Safe Drinking Water and Toxic Enforcement Act of 1986 (Health and Safety Code Section 25249.5 et seq., “the Act”) to answer inquiries of individuals and organizations, whenever appropriate, as to the application of the Act to their activities. One of the lead agency’s functions is to issue public rulings on the requirements of the Act.

(b) It is the practice of the lead agency to respond to inquiries concerning the Act as expeditiously as possible. Requests for consideration of an interpretive guideline, safe use determination or information letter ahead of its regular order or by a specified date will be considered as circumstances warrant. However, persons or organizations making such requests should consider the time necessary to comply with public notice and hearing requirements specified in these procedures and any additional delay that may result from compliance with the California Environmental Quality Act (Public Resources Code Section 21000 et seq.), if necessary prior to issuing a guideline or determination. Therefore, no assurance can be given that any request will be processed by the time requested.

§ 12102. Definitions.

The following definitions shall apply to the regulations contained in this chapter:

(a) The “Act” means the Safe Drinking Water and Toxic Enforcement Act of 1986 (Health and Safety Code Sections 25249.5 et seq.) which was originally adopted by California voters as Proposition 65 on November 4, 1986.

(b) “Certified emergency medical personnel” includes emergency medical technicians I and II and emergency medical technician-paramedics as those terms are defined in Health and Safety Code Sections 1797.80, 1797.82, and 1797.84 (1980).

(c) “Committees” means the Carcinogen Identification Committee and the Developmental and Reproductive Toxicant (DART) Identification Committee of the Office of Environmental Health Hazard Assessment’s Science Advisory Board.

(1) The members of the “Carcinogen Identification Committee” shall be the “state’s qualified experts” as the term is used in Section 25249.8 of the Act with respect to those functions identified in subsection (a) of Section 12305.

(2) The members of the “Developmental and Reproductive Toxicant (DART) Identification Committee,” hereafter referred to as the “DART Identification Committee” shall

be the “state’s qualified experts” as the term is used in Section 25249.8 of the Act with respect to those functions identified in subsection (b) of Section 12305.

(d) “Dental personnel” includes, dentists and dental auxiliary staff as that term is defined in Business and Professions Code Section 1741(e) (1974).

(e) “Director” means the Director of the Office of Environmental Health Hazard Assessment.

(f) “Discharge or release into water or onto or into land” includes a discharge or release to air that is directly and immediately deposited into water or onto land. Except as provided in paragraphs (1) and (2) this subsection, “discharge or release into water or onto or into land” includes the direct or indirect transfer by any person in the course of doing business of any listed chemical to any person within the meaning of Section 25249.11(a) of the Act for the purpose of discharging or releasing the chemical to land or water in a manner which, if committed by the transferor, would violate Section 25249.5 of the Act.

(1) “Discharge or release into water or onto or into land” does not include the sale, exchange or other transfer of a listed chemical to a solid waste disposal facility as defined in Public Resources Code Sections 40121 and 40191, or a hazardous waste facility as defined in Health and Safety Code Section 25117.1 provided that the disposal to such facility complies with all applicable state and federal statutes, rules, regulations, permits, requirements and orders. “Sale, exchange or other transfer,” as used in this paragraph, does not include disposal to a facility owned or operated by the transferor.

(2) “Discharge or release into water or onto or into land” does not include the sale, exchange or other transfer of a listed chemical to any treatment works as defined in 33 United States Code Section 1292 provided that the discharge or release to such treatment works complies with all applicable standards and limitations imposed, and permits required, under federal law or an approved state program. “Sale, exchange or other transfer,” as used in this paragraph, does not include disposal to a facility owned or operated by the transferor.

(g) “Emergency or urgent medical or dental care” means immediate care administered for the alleviation of severe pain, or immediate diagnosis and treatment of unforeseeable medical or dental conditions, which, if not immediately diagnosed or treated, would lead to serious disability or death.

(h) “Employee” shall have the same meaning as it does in Unemployment Insurance Code Section 621 and in Labor Code Section 3351. Generally, and without limiting the applicability of the definitions in these two statutes, this means that an employee is a person who performs services for remuneration under any appointment or contract of hire or apprenticeship, express or implied, oral or written, whether lawfully or unlawfully employed.

In computing whether a person employs ten or fewer employees in his business, all full-time and part-time employees on the date on which the discharge, release or exposure occurs must be counted. Thus, the prohibitions on discharge or release and exposures to certain

chemicals will apply to any person who has ten or more full-time or part-time employees on the date in question.

(i) “Expose” means to cause to ingest, inhale, contact via body surfaces or otherwise come into contact with a listed chemical. An individual may come into contact with a listed chemical through water, air, food, consumer products and any other environmental exposure as well as occupational exposures.

(j) “General public knowledge” means knowledge which has been disseminated to the general public, including information in newspapers of general circulation or radio or television reports in the geographic area affected by the discharge. In order to demonstrate general public knowledge, it shall not be necessary to prove that any members of the public have actually acquired such knowledge but only that the information has been disseminated.

(k) “In the course of doing business” means any act or omission, whether or not for profit, or any act or omission of any employee which furthers the purpose or operation of the business, or which is expressly or implicitly authorized within the meaning of Section 25249.6 of the Act to a listed chemical, except:

(1) as excluded by subdivision (b) of Section 25249.11 of the Act; or

(2) when caused by acts of war or grave and irresistible natural disasters such that no reasonable amount of resistance or advance preparation would be sufficient to avoid the discharge, release or exposure.

(3) 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.

(l) “Information letter” means a statement issued by the lead agency which does no more than call attention to an established interpretation of the Act or a related principle, without applying it to a specific set of facts.

(m) “Interpretive guideline” means a draft regulatory proposal which has been published for the information, comment, and guidance of California businesses, law enforcement agencies and others concerned.

(n) “Knowingly” refers only to knowledge of the fact that a discharge of, release of, or exposure to a chemical listed pursuant to Section 25249.8(a) of the Act is occurring. No knowledge that the discharge, release or exposure is unlawful is required. However, a person in the course of doing business who, through misfortune or accident and without evil design, intention or negligence, commits an act or omits to do something which results in a discharge, release or exposure has not violated Sections 25249.5 or 25249.6 of the Act.

(o) “Lead agency” means the Office of Environmental Health Hazard Assessment as designated by the Governor in Executive Order W-15-91, dated July 17, 1991.

(p) “Listed chemical” means a chemical listed pursuant to Section 25249.8(a) of the Act.

(q) “Medical personnel” includes, physicians, nurse practitioners, physician assistants, and nurses.

(r) “Probably will pass into any source of drinking water” means a discharge or release which more likely than not will pass into any source of drinking water.

(s) “Safe use determination” means a written statement issued by the lead agency to a person affected by the Act or an authorized representative which interprets and applies the Act to a specific set of facts.

(t) “State’s qualified experts” as the term is used in Section 25249.8 of the Act includes the Carcinogen Identification Committee and the DART Identification Committee.

(u) “Substantial injury” means a real and immediate physical injury or a resulting adverse physical condition of a substantial nature to one or more persons.

(v) “Threatened illegal discharge” means the creation of a condition or the taking of an action which is intended to or will foreseeably create a substantial probability that an illegal discharge will occur.

(w) “Water” includes both surface and ground water.

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Sections 25180.7, 25249.5, 25249.6, 25249.8, 25249.9, 25249.10, 25249.11 and 25249.12, Health and Safety Code.

§ 12103. Interpretive Guideline Request.

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

§ 12104. Safe Use Determination

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Sections 25249.10 and 25249.12, Health and Safety Code.

ARTICLE 2. Guideline and Safe Use Determination Procedures

§ 12201. Definitions.

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Sections 25180.7, 25249.5, 25249.6, 25249.9, 25249.10, and 25249.11, Health and Safety Code.

§ 12203. Interpretive Guideline Request.

(a) Any interested person may request the lead agency to issue an interpretive guideline concerning any subject related to the Act. A request for interpretive guideline shall contain:

(1) A clear and concise description of the substance or nature of the guideline requested; and

(2) A description of the reason for the request.

(b) Upon receipt of a request for interpretive guideline, the lead agency shall notify the requester in writing of the receipt and provide an estimate of the time required to determine whether an interpretive guideline will be proposed or adopted. Except where the proposed guideline will be considered by the appropriate Committee, a decision on the request will normally be made within 60 days. Where the proposed guideline is considered by the appropriate Committee, a decision will normally be made not later than 30 days after the guideline is considered by such Committee.

(c) When appropriate, in the discretion of the lead agency, a request for interpretive guideline may be treated as a request for a safe use determination under these procedures, or the lead agency may issue an information letter to the requester.

(d) All interpretive guidelines issued by the lead agency will be numbered and published either by the lead agency or in the California Regulatory Notice Register.

(e) Within a reasonable time after an interpretive guideline is published pursuant to paragraph (d), the lead agency may rescind the interpretive guideline, propose that it be formally adopted as originally published, or modify it and either republish it as an interpretive guideline for further comment or propose formal regulatory adoption of the modified interpretive guideline. Nothing in this section shall preclude the lead agency from making proposals for formal regulatory adoption which have not been published as interpretive guidelines.

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

§ 12204. Safe Use Determination

(a) As a part of its overall responsibility to provide guidance to persons or organizations that are or may be affected by the Act, the lead agency will consider the applicability of the Act or the exemptions specified in the Act to business activities or prospective business activities. A safe use determination issued by the lead agency represents the state's best judgment concerning the application of the Act to the particular facts presented in the request. A safe use determination is advisory only. It does not affect the authority of the Attorney General, district attorneys, certain city attorneys and any other person in the public interest to prosecute violations of the Act pursuant to Section 25249.7 of the Act nor does it affect the responsibility of courts to interpret the Act and apply the provisions of the Act to particular facts.

(b) Safe use determinations will not be issued under the following circumstances:

(1) Where the subject matter of a request for safe use determination is at issue in a civil or criminal case pending in any court.

(2) Where the individual or organization requesting the safe use determination is not directly required to enforce or comply with the provisions of the Act provided, however, when two or more businesses which are members of the same trade association share a business practice which may be the subject matter of a request for a safe use determination, the request may be made by the trade association on behalf of such members.

(3) Where the request for determination concerns compliance with laws other than the Act, or with regulations, permits, requirements or orders of any federal, state or local agency. For example, questions concerning whether chemical discharges comply with the Water Code, state regulations and waste discharge requirements should be addressed to the appropriate Regional Water Quality Control Board.

(4) Where the request for determination does not involve a current or planned activity of the requester. Safe use determination will not be issued concerning hypothetical situations or on each of several alternative plans in a proposed activity.

(5) Where, in the discretion of the lead agency, issuance of a safe use determination will not further the public interest, or is otherwise inappropriate under the circumstances presented in or related to a particular request for safe use determination. For example, where the subject matter of the request is at issue in an administrative proceeding before a government agency or does not concern a chemical listed pursuant to Section 25249.8 of the Act.

(c) A request for a safe use determination shall be submitted in writing to the lead agency and shall contain the following:

(1) A complete statement of all relevant facts related to the activity for which the safe use determination is requested. Such facts include the names and addresses of all interested parties, a description of the business reason for the activity and a carefully detailed description of the activity.

(2) True copies of any contracts, agreements, instruments, reports, analyses or other documents directly related to the activity for which the safe use determination is requested and to the applicability of the Act to the activity.

(3) A clear statement of the issue or issues on which a safe use determination is sought.

(4) If the determination request includes references to a specific chemical, the request should include the chemical name and the Chemical Abstract Services (CAS) Registry Number, if applicable.

(5) If the activity for which the safe use determination is sought is only one step of a larger integrated process, the description of the activity shall include a description of the entire process.

(6) If the requester is contending for a particular result in the determination, the request shall include an explanation of the grounds for the contention together with an identification of any relevant authorities which support such view.

(7) If the request for safe use determination contains any information which the requester claims should not be available for public inspection under the Public Records Act (Government Code Section 6250 et seq.), the request shall specifically identify the information and the basis for the claim.

(A) If the request for determination contains information which the requester claims should not be available for public inspection, it shall be accompanied by a copy of the request and any supporting documents on which shall be indicated, by the use of brackets, the material which the requester contends should be deleted.

(B) All requests for safe use determination shall be open for public inspection except as otherwise specifically identified by the requester under this section. If the lead agency determines that information which the requester claims should not be available for public inspection must be released to the public under the Public Records Act (Government Code Section 6250 et seq.), it will promptly notify the requester by telephone or in writing of this determination and provide a reasonable opportunity for the requester to submit additional justification for the claim or to contest the determination in an appropriate proceeding.

(8) If the requester claims that fees or other charges for safe use determination should be waived, the request shall include an explanation of the basis for the claim.

(9) A statement concerning whether to the best of the requester's knowledge the subject matter of the request is:

(A) An issue in a civil or criminal case pending in any court.

(B) An issue in any administrative proceeding pending before a federal, state or local agency.

(C) The subject of a notice of violation to the Attorney General, a district attorney or a city attorney as described in Section 25249.7(d) of the Act.

(10) The signature of the person making the request for determination. Where the request is made by an authorized representative for an individual or organization, the request shall indicate the source of the authority to make the request.

(d) Each request for a safe use determination shall be accompanied by a nonrefundable processing fee of \$500. In addition, the requester shall be assessed a charge in the amount of any costs to the lead agency or other state agency which are necessarily incurred in considering the request and which exceed \$500. Such additional assessment shall be made only after the requester has been provided an estimate of the amount, has elected to proceed with the request for safe use determination and has agreed to pay the additional assessment. All or part of the processing fee or other charges assessed pursuant to this section may be waived if the lead agency determines that payment of the fee would present a hardship to the requester or that it is otherwise in the public interest to proceed with the request without payment of such fees or charges.

(e) Any request for safe use determination that does not comply with these procedures will be acknowledged in writing within 30 days of receipt by the lead agency, with an indication of the requirements that have not been met. If the request lacks essential information, the requester will be advised that the request will be closed if the additional information is not received within 30 days. If the information is received after the request is closed, the request will be reopened and treated as a new request as of the date of receipt.

(f) A request for safe use determination that appears to comply with these procedures will be acknowledged in writing within 30 days of receipt by the lead agency and a public notice of the receipt of the request will be published in the California Regulatory Notice Register and sent to interested persons. The public notice will include the text or a summary of the request as appropriate. It will advise interested parties that they can comment on the request in writing or in person at a public hearing which shall be held on a date not less than 30 days after the notice is published.

(g) At any time while a request for a safe use determination is pending, the lead agency or any other state agency that is considering the request may ask for any additional information or explanation from the requester as necessary to complete a consideration of the request.

(h) After considering the request, any comments of the public received in writing or at the public hearing, and the comments of any other state agencies that have considered the request, the lead agency shall in response to the request:

(1) Issue a safe use determination.

(2) Decline to issue a safe use determination because the facts are insufficient to clearly establish the basis for the requested determination or for any other reason.

(3) Issue an information letter to the requester.

(4) Issue an interpretive guideline.

(i) The lead agency's response to the request shall be sent to the requester and the text or a summary of the response shall be published in the California Regulatory Notice Register and sent to interested persons, including any person who submitted comments on the request.

(j) Safe use determinations issued by the lead agency are limited to the particular facts on which they are based and they reflect the lead agency's view of the best interpretation of the Act and the state of scientific knowledge at the time they are issued. Whenever the issuance of a safe use determination requires the performance by a state agency of a risk assessment of the carcinogenicity or reproductive toxicity of a chemical, such assessment shall be performed pursuant to the methodologies adopted by the lead agency. A safe use determination found to be in error or not in accord with the best interpretation of the Act or the current state of scientific knowledge may be modified or revoked. Modification or revocation of a safe use determination may be effected by a notice to the individual or organization that requested the ruling along with notice in the California Regulatory Notice Register or by the issuance of an interpretive guideline.

(k) A safe use determination shall be issued to a particular individual or organization with respect to the application of particular provisions of the act to particular facts. Determinations are not intended to affect other individuals or organizations, or other activities of the requester.

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Sections 25249.10 and 25249.12, Health and Safety Code.

ARTICLE 3. Science Advisory Board: Carcinogen Identification Committee and Developmental and Reproductive Toxicant (DART) Identification Committee

§ 12301. Definitions.

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Sections 25249.8 and 25249.12, Health and Safety Code.

§ 12302. Science Advisory Board.

(a) There are created in the lead agency two Committees of the Science Advisory Board, the Carcinogen Identification Committee and the DART Identification Committee defined in paragraphs (1) and (2), respectively, of subsection (b) of Section 12102, to advise and assist the Governor and the Director in the implementation of Section 25249.8 of the Act.

(b)(1) The Carcinogen Identification Committee shall be composed of no less than seven (7) members and no greater than eleven (11) members, and shall include experts from among the following areas of specialization: epidemiology, oncology, pathology, medicine, public health, biostatistics, biology, toxicology, and related fields.

(2) The DART Identification Committee shall be composed of no less than seven (7) members and no greater than eleven (11) members, and shall include experts from among the following areas of specialization: epidemiology, developmental toxicology, reproductive toxicology, teratology, medicine, public health, biostatistics, biology, toxicology, and related fields.

(3) The members of the Committees shall be appointed by the Governor and shall serve at the pleasure of the Governor.

The terms shall be for a period of four years, except that any person chosen to fill a vacancy shall be appointed only for the unexpired term of the member whom he or she succeeds. Members of each Committee shall be eligible for reappointment.

(c) The Carcinogen Identification Committee and the DART Identification Committee shall meet not less than once in any calendar year. The Governor shall designate from among the members of each Committee respective Chairpersons who will call and preside over Committee meetings, and shall designate an Executive Secretary who shall be a state employee who has expertise in one or more of the areas of specialization listed in subsection (b). Each Chairperson, with the consent of the other Committee members, shall designate from among the respective Committee members such subcommittees as may be appropriate in fully discharging the responsibilities of that Committee.

(d)(1) Except as otherwise expressly authorized by statute, all meetings of the Committees, and all subcommittee meetings shall be open to the public and convened only after reasonable public notice of the meeting, including the date, time, location and agenda of items of business to be transacted or discussed, has been provided.

(2) All correspondence to or from the Committees, or any subcommittee shall be available for public inspection as provided in the Public Records Act (Government Code Section 6250 et seq.).

(e) Members of the Committees may be asked to provide advice and counsel at formally convened Committee meetings and other subcommittee meetings and individually in response to written materials submitted to them by the lead agency, the Executive Secretary, or the Governor. Each of the two Committees shall act, as a body in making recommendations to the Governor or the lead agency.

(f) A quorum of the Committee shall be a majority of the members appointed to the Committee. An affirmative vote of the majority of the appointed members shall be required for any action of each Committee. A vacancy on a Committee shall not impair the right of the remaining members to exercise all powers of the Committee.

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Section 25249.8, Health and Safety Code.

§ 12303. Compensation.

Members of the Committees shall be entitled to reimbursement for actual and necessary expenses incurred while attending meetings or otherwise carrying out the duties of their respective committees. In addition, members of the Committees shall be entitled to compensation for time spent attending Committee meetings and on the other actual and necessary work of the Committee as determined by the lead agency.

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Section 25249.8, Health and Safety Code.

§ 12304. Financial Disclosure.

Upon appointment and annually thereafter, Committee members shall, consistent with the Political Reform Act of 1974 commencing with Section 81000 through 91015 of the Government Code and Title 2, California Code of Regulations, Division 6, Chapters 1 through 10, make a public disclosure on forms provided of investments in, income from or business positions in any partnership, corporation, or other entity that imports, manufactures, distributes, sells, buys, or uses chemicals that are or may be considered carcinogens or reproductive toxicants. Such disclosure made upon appointment shall cover the twelve-month period immediately prior to the date of appointment. Committee members shall, in addition to the requirements of Sections 81000 through 91015 of the Government Code and Title 2 CCR, Division 6, Chapters 1 through 10, also provide a description of funding sources for all professional activities undertaken during the twelve months immediately prior to their appointment, and annually thereafter during their service on the Committee. In order to vote on an official action of a Committee, Committee members must be in compliance with Sections 81000 through 91015 of the Government Code and Title 2 CCR, Division 6, Chapters 1 through 10.

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Section 25249.8, Health and Safety Code.

§ 12305. Powers and Duties.

(a) As an advisory body to the Governor and the lead agency, the Carcinogen Identification Committee may undertake the following activities:

(1) Render an opinion, pursuant to subdivision (b) of Section 25249.8 of the Act, as to whether specific chemicals have been clearly shown, through scientifically valid testing according to generally accepted principles, to cause cancer.

(2) Identify bodies which are considered to be authoritative and which have formally identified chemicals as causing cancer.

(3) Identify specific chemicals that are required by state or federal law to have been tested for potential to cause cancer but which have not been adequately tested.

(4) Review or propose standards and procedures for determining carcinogenicity of chemicals.

(5) Review or propose standards, procedures and definitions related to the implementation, administration or interpretation of the Act in support of the duties specified in the Section 25249.8 of the Act and upon request by the lead agency.

(b) As an advisory body to the Governor and the lead agency, the DART Identification Committee may undertake the following activities:

(1) Render an opinion, pursuant to subdivision (b) of Section 25249.8 of the Act, as to whether specific chemicals have been clearly shown, through scientifically valid testing according to generally accepted principles, to cause reproductive toxicity.

(2) Identify bodies which are considered to be authoritative and which have formally identified chemicals as causing reproductive toxicity.

(3) Identify specific chemicals that are required by state or federal law to have been tested for potential to cause reproductive toxicity but which have not been adequately tested.

(4) Review or propose standards and procedures for determining reproductive toxicity of chemicals.

(5) Review or propose standards, procedures and definitions related to the implementation, administration or interpretation of the Act in support of the duties specified in Section 25249.8 of the Act and upon request by the lead agency.

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Section 25249.8, Health and Safety Code.

§ 12306. Chemicals Formally Identified by Authoritative Bodies.

(a) Pursuant to Section 25249.8(b) of the Act, a chemical is known to the state to cause cancer or reproductive toxicity if the lead agency determines that an authoritative body has formally identified the chemical as causing cancer or reproductive toxicity, as specified in this section.

(b) A “body considered to be authoritative” is an agency or formally organized program or group which utilizes one of the methods set forth in subsection (d), for the identification of chemicals, and which the Carcinogen Identification Committee has identified as having expertise in the identification of chemicals as causing cancer or the DART Identification Committee has identified as having expertise in the identification of chemicals as causing reproductive toxicity. For purposes of this section, “authoritative body” means either a “body considered to be authoritative” in the identification of chemicals as causing cancer by the Carcinogen Identification Committee or a “body considered to be authoritative” in the identification of chemicals as causing reproductive toxicity by the DART Identification Committee. The Carcinogen Identification Committee and the DART Identification Committee shall have the authority to revoke or rescind any determination that a body is authoritative on the grounds that the respective Committee no longer considers the body to have expertise in the identification of chemicals as causing cancer or reproductive toxicity, respectively, in which case chemicals listed pursuant to this section prior to the effective date of the revocation shall remain on the list. Nothing in this section shall be construed to limit or otherwise interfere with such authority.

(c) The lead agency shall determine which chemicals have been formally identified by an authoritative body as causing cancer or reproductive toxicity.

(d) For purposes of this section a chemical is “formally identified” by an authoritative body when the lead agency determines that:

(1) the chemical has been included on a list of chemicals causing cancer or reproductive toxicity issued by the authoritative body; or is the subject of a report which is published by the authoritative body and which concludes that the chemical causes cancer or reproductive toxicity; or has otherwise been identified as causing cancer or reproductive toxicity by the authoritative body in a document that indicates that such identification is a final action; and

(2) the list, report, or document specifically and accurately identifies the chemical, and has been:

(A) Reviewed by an advisory committee in a public meeting, if a public meeting is required, or

(B) Made subject to public review and comment prior to its issuance, or

(C) Published by the authoritative body in a publication, such as, but not limited to, the federal register for an authoritative body which is a federal agency, or

(D) Signed, where required, by the chief administrative officer of the authoritative body or a designee, or

(E) Adopted as a final rule by the authoritative body, or

(F) Otherwise set forth in an official document utilized by the authoritative body for regulatory purposes.

(e) For purposes of this section, “as causing cancer” means that either of the following criteria has been satisfied:

(1) Sufficient evidence of carcinogenicity exists from studies in humans. For purposes of this paragraph, “sufficient evidence” means studies in humans indicate that there is a causal relationship between the chemical and cancer.

(2) Sufficient evidence of carcinogenicity exists from studies in experimental animals. For purposes of this paragraph, “sufficient evidence” means studies in experimental animals indicate that there is an increased incidence of malignant tumors or combined malignant and benign tumors in multiple species or strains, in multiple experiments (e.g., with different routes of administration or using different dose levels), or, to an unusual degree, in a single experiment with regard to high incidence, site or type of tumor, or age at onset.

(f) The lead agency shall find that a chemical does not satisfy the definition of “as causing cancer” if scientifically valid data which were not considered by the authoritative body clearly establish that the chemical does not satisfy the criteria of subsection (e), paragraph (1) or subsection (e), paragraph (2).

(g) For purposes of this section, “as causing reproductive toxicity” means that either of the following criteria have been satisfied:

(1) Studies in humans indicate that there is a causal relationship between the chemical and reproductive toxicity, or

(2) Studies in experimental animals indicate that there are sufficient data, taking into account the adequacy of the experimental design and other parameters such as, but not limited to, route of administration, frequency and duration of exposure, numbers of test animals, choice of species, choice of dosage levels, and consideration of maternal toxicity, indicating that an association between adverse reproductive effects in humans and the toxic agent in question is biologically plausible.

(h) The lead agency shall find that a chemical does not satisfy the definition of “as causing reproductive toxicity” if scientifically valid data which were not considered by the authoritative body clearly establish that the chemical does not satisfy the criteria of subsection (g), paragraph (1) or subsection (g), paragraph (2).

(i) At least 60 days prior to adding a chemical determined to have been formally identified by an authoritative body as causing cancer or reproductive toxicity to the list of chemicals known to the state to cause cancer or reproductive toxicity, the lead agency shall cause to be published in the California Regulatory Notice Register a notice identifying the authoritative body and the chemical, and stating the lead agency’s intention to cause the chemical to be added to the list. Copies of the notice shall be provided to the Carcinogen Identification Committee or the DART Identification Committee, as appropriate, to permit the appropriate Committee at least 30 days to review and comment on the proposed action. Within 30 days following the publication of the notice, interested parties, including any member of the appropriate Committee, shall submit to the lead agency their written objections to the addition of the chemical to the list of chemicals known to the state to cause cancer or reproductive toxicity, along with any supporting documentation. Objections shall be made on the basis that there is no substantial evidence that the criteria identified in subsection (e) or in subsection (g) have been satisfied. The lead agency shall review such objections. If the lead agency finds that there is no substantial evidence that the criteria identified in subsection (e) or in subsection (g) have been satisfied, the lead agency shall refer the chemical to the appropriate Committee to determine whether, in the Committee’s opinion, the chemical has been clearly shown through scientifically valid testing according to generally accepted principles to cause cancer or reproductive toxicity.

(j) Subsequent to the addition of a chemical determined to have been formally identified by an authoritative body as causing cancer or reproductive toxicity to the list of chemicals known to the state to cause cancer or reproductive toxicity, the lead agency shall reconsider its

determination that the chemical has been formally identified as causing cancer or reproductive toxicity if the lead agency finds:

(1) there is no substantial evidence that the criteria identified in subsection (e) or subsection (g) have been satisfied, or

(2) the chemical is no longer identified as causing cancer or reproductive toxicity by the authoritative body.

Reconsideration may be initiated by the lead agency on its own motion, or on a request from an interested party, including any member of the appropriate Committee. The lead agency shall refer chemicals under reconsideration pursuant to this subsection to the appropriate Committee for a recommendation concerning whether the chemical should continue to be included on the list of chemicals known to the state to cause cancer or reproductive toxicity. Pending such reconsideration, the chemical shall remain on the list.

(k) The Carcinogen Identification Committee or the DART Identification Committee may condition any determination that a body is considered to be authoritative upon the subsequent application of the controls set forth in this section to the determination of which chemicals have been formally identified by the body as causing cancer or reproductive toxicity. In the event that this section or any portion thereof is found to be invalid by any court of competent jurisdiction, the Carcinogen Identification Committee or the DART Identification Committee may determine that such invalidation constitutes a failure of the condition. Upon finding such failure of condition, the determination that the body is authoritative shall be deemed to be revoked. Chemicals which the lead agency has determined have been formally identified by the body as causing cancer or reproductive toxicity pursuant to the controls set forth in this section and which have been placed upon the list of chemicals known to the state to cause cancer or reproductive toxicity prior to such revocation shall remain on the list.

(l) The following have been identified as authoritative bodies for purposes of this section for the identification of chemicals as causing reproductive toxicity.

(1) International Agency for Research on Cancer solely as to transplacental carcinogenicity

(2) National Institute for Occupational Safety and Health

(3) U.S. Environmental Protection Agency

(4) U.S. Food and Drug Administration

(m) The following have been identified as authoritative bodies for the identification of chemicals as causing cancer.

(1) International Agency for Research on Cancer

(2) National Institute for Occupational Safety and Health

(3) National Toxicology Program

(4) U.S. Environmental Protection Agency

(5) U.S. Food and Drug Administration

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Sections 25249.8 and 25249.12, Health and Safety Code.

ARTICLE 4. Discharge

§ 12401. Discharge of Water Containing a Listed Chemical at Time of Receipt.

(a) Whenever a person otherwise responsible for the discharge or release receives water containing a listed chemical from:

(1) a public water system, as defined in Section 116275 of the Health and Safety Code (1997);

(2) a commercial supplier of drinking water; or

(3) a source of drinking water in compliance with all primary drinking water standards and the chemical is the result of treatment of the water in order to achieve such compliance; the person does not “discharge” or “release” within the meaning of the Act to the extent that the person can show that the listed chemical was contained in the water received. “Discharge or release” shall apply only to that amount of the listed chemical derived from sources other than the drinking water.

(b) Whenever a person otherwise responsible for the discharge or release receives water containing a listed chemical from a source other than a source specified in subsection (a) the person does not “discharge” or “release” within the meaning of the Act to the extent that the person can show that the listed chemical was contained in the water received, and “discharge or release” shall apply only to that amount of the listed chemical derived from sources other than the water, provided that:

(1) The water is returned to the same source of water supply, or

(2) The water meets all primary drinking water standards for the listed chemical or, where there is no primary drinking water standard established for the listed chemical, the water shall not contain a significant amount of the chemical.

(c) Stormwater runoff from a place of doing business containing a listed chemical, the presence of which is not the direct and immediate result of the business activities conducted at the place from which the runoff flows, is not a “discharge” or “release” within the meaning of the Act. For purposes of this subsection, “business activities” does not include parking lots.

(d) The movement of naturally occurring chemicals as the result of the application, unavoidable runoff, or percolation of agricultural irrigation water is not a “discharge” or “release” within the meaning of Section 25249.5 of the Act. For purposes of this subsection, “naturally occurring chemicals” means chemicals present in the soil solely as a result of natural geologic processes.

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Sections 25249.5, and 25249.11, Health and Safety Code.

§ 12403. Discharges from Hazardous Waste Facilities.

(a) For a discharge or release of a listed chemical from a low-level radioactive waste disposal facility licensed pursuant to Chapter 7.6 of Division 20 (commencing with Section 25800) of the Health and Safety Code, a solid waste “disposal facility” as defined in Public Resources Code Section 40121 (1990) or a hazardous waste “disposal site” as defined in Health and Safety Code Section 25114, it shall be presumed that the chemical probably will not pass into any source of drinking water for purposes of Section 25249.5 of the Act provided that the operator of the facility or site can show that the facility or site is subject to and in compliance with requirements of state or federal statutes, regulations, permits and orders adopted to avoid contamination of surface or groundwater.

(b) The presumption in subsection (a) may be rebutted by any admissible evidence including, but not limited to, that compliance with the same or substantially the same requirements of state or federal statutes, regulations, permits and orders adopted to avoid contamination of surface or groundwater has failed to prevent surface or groundwater contamination at similar facilities or sites under similar circumstances.

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Section 25249.5, Health and Safety Code.

§ 12405. Discharge of Pesticide

For a discharge or release of a listed chemical which is an active ingredient, other specified ingredient, or degradation product of a pesticide as defined in Section 12753 of the Food and Agricultural Code (1996), if the person responsible for the application can show that the registrant of the pesticide has completely and adequately satisfied all of the data submission requirements of Section 13143(a) of the Food and Agricultural Code (1996) and that the pesticide has not been placed on the Groundwater Protection List described in Section 13145 of the Food and Agricultural Code (1996) and that the application is otherwise in compliance with the Pesticide Contamination Prevention Act of 1985 (1996) and all regulations promulgated thereunder, then it shall be presumed that the chemical probably will not pass into any source of drinking water for purposes of Section 25249.5 of the Act. For purposes of this section only, the person responsible for the application may rely upon information regarding a registrant’s compliance with Section 13143(a), Food and Agricultural Code (1996), which is obtained from the Department of Pesticide Regulation through the office of a county agriculture commissioner.

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Section 25249.5, Health and Safety Code.

ARTICLE 5. Extent of Exposure

§ 12501. Exposure to a Naturally Occurring Chemical in a Food.

(a) Human consumption of a food shall not constitute an “exposure” for purposes of Section 25249.6 of the Act to a listed chemical in the food to the extent that the person responsible for the exposure 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 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 a 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 known 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 a food, the chemical is naturally occurring only to the extent that it was not avoidable by good agricultural or good manufacturing practices. The producer, manufacturer, distributor, or holder of the food shall at all times utilize quality control measures that reduce natural chemical contaminants to the “lowest level currently feasible,” as this term is used in Title 21, Code of Federal Regulations, Section 110.110, subdivision (c) (2001).

(b) A person otherwise responsible 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 of the Act 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.

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

§ 12502. Exposure to a Listed Chemical in Drinking Water.

(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 of the Act 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 116275 of the Health and Safety Code (1997);

(2) a commercial supplier of drinking water, or

(3) a source of drinking water in compliance with all applicable primary drinking water standards for all listed chemicals and the chemical in question is the result of treatment of the water in order to achieve compliance with primary drinking water standards.

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 such drinking water.

(b) For purposes of subsection (a), the amount of a listed chemical contained in drinking water shall be determined by sampling of the drinking water at the point of delivery and by testing pursuant to Section 12901. If sampling and testing is impractical, the amount of a listed chemical shall be based on test results of the most recent sample of the drinking water taken by the public water system or the commercial drinking water supplier, provided that all sampling and testing has been conducted at the frequency and in the manner required by law, or alternatively, such amount shall be calculated at five percent of the maximum contaminant level set forth in the primary drinking water standard for the listed chemical.

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

§ 12503. Exposure to Water.

A person otherwise responsible for an exposure to a listed chemical does not “expose” an individual within the meaning of Section 25249.6 of the Act to the extent that the person can show that the listed chemical was contained in water which the person moved or which was handled in the manner described in Section 12401. Nothing in this section shall be interpreted to affect the responsibility for an exposure which arises from any activity other than that described in Section 12401.

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

§ 12504. Exposure to Air.

A person otherwise responsible for an exposure to a listed chemical in air does not “expose” an individual within the meaning of Section 25249.6 of the Act 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” does not occur as to that portion of the listed chemical from the ambient air to the extent that the person did not put the listed chemical into the ambient air.

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

§ 12505. Miscellaneous.

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

ARTICLE 6. CLEAR AND REASONABLE WARNINGS

§ 12601. Clear and Reasonable Warnings

(a) Whenever a clear and reasonable warning is required under Section 25249.6 of the Act, the method employed to transmit the warning must be reasonably calculated, considering the alternative methods available under the circumstances, to make the warning message available to the individual prior to exposure. The message must clearly communicate that the chemical in question is known to the state to cause cancer, or birth defects or other reproductive harm. Nothing in this section shall be construed to preclude a person from providing warnings other than those specified in subsections (b), (c), and (d) which satisfy the requirements of this subsection, or to require that warnings be provided separately to each exposed individual.

(b) Warnings for consumer products exposures which include the methods of transmission and the warning messages as specified by this subsection shall be deemed to be clear and reasonable. A “consumer products exposure” is an exposure which results from a person’s acquisition, purchase, storage, consumption, or other reasonably foreseeable use of a consumer good, or any exposure that results from receiving a consumer service.

(1) The warning may be provided by using one or more of the following methods singly or in combination:

(A) A warning that appears on a product’s label or other labeling. The term “label” means a display of written, printed or graphic matter upon a product or its immediate container. The term “labeling” means any label or other written, printed or graphic matter affixed to or accompanying a product or its container or wrapper.

(B) Identification of the product at the retail outlet in a manner which provides a warning. Identification may be through shelf labeling, signs, menus, or a combination thereof.

(C) A system of signs, public advertising identifying the system and toll-free information services, or any other, system, that provides clear and reasonable warnings.

(D) For alcoholic beverages, including, without limitation, beer, malt beverages, wine and distilled spirits:

1. Primarily intended for consumption off the premises where sold or distributed:

(i) at least one notice or sign, no smaller than 10 inches wide by 10 inches high, and bearing the warning message set forth in subparagraph (4)(E) of this subsection; or

(ii) at least one horizontal strip marker no smaller than 10 1/2 inches wide by 1 1/4 inches high, and bearing the warning message set forth in subparagraph (4)(E) of this subsection; or

(iii) a notice no smaller than 5 inches by 5 inches, and bearing the warning message set forth in subparagraph (4)(E) of this subsection.

(iv) If signs 10 inches high by 10 inches wide are used, the word “warning” shall be centered three-quarters of an inch from the top of the sign in ITC Garamond bold condensed type face all in one-inch capital letters. Three-sixteenths of an inch from the base of the word “warning” shall be a line extending from left to right across the width of the sign one-sixteenth of an inch in thickness. Centered one-half inch below the line shall be the body of the warning message in 36/50 ITC Garamond bold condensed type face with the initial letter of each word other than the conjunctive “and,” capitalized. For the body of the warning message, left and right margins of at least one-half of an inch, and a bottom margin of at least one-half inch shall be observed. Larger signs shall bear substantially the same proportions of type size and spacing to sign dimension as the sign 10 inches high by 10 inches wide.

(v) If the 10 1/2 inch by 1 1/4 inch horizontal strip markers are used, the word “WARNING,” punctuated by a colon, shall be justified left and located three-sixteenths of an inch from the top of the strip notice in ITC Garamond bold condensed type face all in capital letters measuring eleven sixteenths of an inch in height. Three thirty-seconds of an inch from the base of the word “WARNING” shall be a line extending from left to right across the width of the word “WARNING” and the punctuating colon one thirty-second of an inch in thickness. Located one-fourth of an inch from the top and one-fourth of an inch from the bottom of the strip notice, and to the immediate right of the word “WARNING,” shall be the body of the warning message in 12/16 point ITC Garamond bold condensed type face with the initial letter of each word, other than the conjunctive “and” capitalized. The word “WARNING” shall be one-half inch from the left edge of the strip notice and the requisite warning message shall extend to within one-half inch from the right edge.

(vi) If the 5 inch by 5 inch signs are used, they shall bear substantially the same proportions of type size and spacing to sign dimension as the sign 10 inches high by 10 inches wide, with both the word “WARNING” and the warning text set in white on a contrasting red background.

(vii) Such sign or notice shall be placed in the retail establishment so as to assure that it is readable and likely to be read either at each retail point of sale or each point of display. Such sign or notice shall be placed either at all retail points of sale or all points of display, but need not be placed at both. If 10 inch by 10 inch signs or notices are placed at the point of display, each shall be placed no more than ten feet from any alcoholic beverage container and in a manner associating the sign or notice with the display. If horizontal strip notices are used, they shall be placed at ten-foot intervals horizontally along the display. If a 5 inch by 5 inch sign is used, it shall be conspicuously placed at each retail point of sale (e.g., checkout counter, cash register, cash box) so that it is likely to be read and understood during the sales transaction.

(viii) All measurements specified or referred to in paragraphs (iv), (v) and (vi), above, are not required to be precisely accurate.

2. Provided for consumption on the premises at tables served by food or beverage persons, or sold or distributed through over the counter service;

(i) a notice or sign displayed at each of the tables where alcoholic beverages are served or may be consumed at least 5 inches high by 5 inches wide bearing substantially the same type face and substantially the same proportion of type size and spacing to sign dimension as described in paragraph (D)1. (vi); or

(ii) the warning message set forth in subparagraph (4)(E) of this subsection, placed upon a menu or list in association with the alcoholic beverages listed thereon and served at such premises, or if alcoholic beverages are not listed thereon, on any menu or list provided to patrons in association with the listing of food or beverage offerings, in type size and design, such that the text is conspicuous and likely to be read prior to consumption of alcoholic beverages or,

(iii) at least one 10 inch by 10 inch sign, meeting the specifications set forth in paragraph (D)1. (iv) of this subsection, placed so that it is readable and likely to be read by patrons as they enter each public entrance to the establishment. If the establishment does not have clearly defined physical boundaries delineating those areas where, by permit or license, alcoholic beverages are served, the 10 inch by 10 inch sign shall be posted so that it is readable and likely to be read by patrons as they enter the area or areas where, by permit or license, alcoholic beverages are served; and

(iv) If sold or distributed through over-the-counter service, at least one sign, meeting the specifications set forth in paragraph (D)1. (iv) of this subsection, placed in the retail establishment so that the warning message is, prior to the consumption of alcoholic beverages, readable and likely to be read from all counter locations available to the public. Therefore, a retail establishment providing a warning pursuant to the preceding sentence, also would be required to provide a warning in accordance with either paragraph 2.(i), 2.(ii) or 2.(iii) of this subsection.

3. For premises which are specially licensed to sell and serve alcoholic

beverages both on and off the licensed premises (e.g., in facilities that offer both “tasting” and retail sales), the off-sale portion of the premises shall comply with the provisions of subparagraph (D)1, above, and the portion of the premises where alcoholic beverages are served shall comply with the provisions of subparagraph (D)2, above.

4. For alcoholic beverages sold or distributed to consumers through the mail or package delivery services, warnings may be provided by incorporating or placing the warning message set forth in subparagraph (4)(E) on or in the shipping container or delivery package in such a manner so that the warning message is likely to be read by the recipient prior to consumption of the alcoholic beverage(s).

5. All signs or notices referred to in subparagraphs (D)1., (D)2. and (D)3., above, shall be displayed so that they are clearly visible under all lighting conditions normally encountered during business hours.

(2) To the extent practicable, warning materials such as signs, notices, menu stickers, or labels shall be provided by the manufacturer, producer, or packager of the consumer product rather than by the retail seller. For alcoholic beverages, the placement and maintenance of the warning shall be the responsibility of the manufacturer or its distributor at no cost to the retailer, and any consequences for failure to do the same shall rest solely with the manufacturer or its distributor, provided that the retailer does not remove, deface, or obscure the requisite signs or notices, or obstruct, interfere with, or otherwise frustrate the manufacturer’s reasonable efforts to post, maintain, or periodically replace said materials.

(A) For prescription drugs, the labeling approved or otherwise provided under federal law and the prescriber’s accepted practice of obtaining a patient’s informed consent shall be deemed to be a clear and reasonable warning.

(B) For exposures resulting from emergency or urgent medical or dental care as defined in Section 12102(g) the accepted practice of obtaining the patient’s informed consent shall be deemed to be a clear and reasonable warning when any of the following circumstances exists:

1. the patient is unconscious; or
2. the procedure must be undertaken because the licensed medical personnel, licensed dental personnel, or certified emergency medical personnel responsible for administering the care, as these terms are defined in Sections 12102(q), 12102(d), and 12102(b), respectively, reasonably believes that the procedure should be undertaken immediately; and therefore, there is insufficient time to fully inform the patient; or
3. the procedure must be performed on a person legally incapable of giving consent, and the licensed medical personnel, licensed dental personnel, or certified emergency medical personnel responsible for administering the care reasonably believes the procedure should be undertaken immediately; and

therefore, there is insufficient time to obtain the informed consent of a person authorized to give such consent for the patient.

(3) The warnings provided pursuant to subparagraphs (1)(A) and (1)(B) shall be prominently placed upon a product's label or other labeling or displayed at the retail outlet with such conspicuousness, as compared with other words, statements, designs, or devices in the label, labeling or display as to render it likely to be read and understood by an ordinary individual under customary conditions of purchase or use.

(4) The warning message must include the following language:

(A) For consumer products that contain a chemical known to the state to cause cancer:

“WARNING: This product contains a chemical known to the State of California to cause cancer.”

(B) For consumer products that contain a chemical known to the state to cause reproductive toxicity:

“WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.”

(C) For food, other than alcoholic beverages, sold, served, or otherwise provided in food facilities, as defined in Health and Safety Code Section 27521(a), which is intended for immediate consumption:

“WARNING: Chemicals known to the State of California to cause cancer, or birth defects or other reproductive harm may be present in foods or beverages sold or served here.”

(D) For fresh fruits, nuts and vegetables:

“WARNING: This product may contain a chemical known to the State to cause cancer, or birth defects or other reproductive harm.”

(E) For alcoholic beverages, including, without limitation, beer, malt beverages, wine and distilled spirits:

“WARNING: Drinking Distilled Spirits, Beer, Coolers, Wine and Other Alcoholic Beverages May Increase Cancer Risk, and, During Pregnancy, Can Cause Birth Defects.”

(5) A person in the course of doing business, who manufactures, produces, assembles, processes, handles, distributes, stores, sells or otherwise transfers a consumer product which he or she knows to contain a chemical known to the state to cause cancer or reproductive toxicity in

an amount which requires a warning shall provide a warning to any person to whom the product is sold or transferred unless the product is packaged or labeled with a clear and reasonable warning.

(c) Warnings for occupational exposures which include the methods of transmission and the warning messages as specified by this subdivision shall be deemed clear and reasonable. An “occupational exposure” is an exposure, in the workplace of the employer causing the exposure, to any employee.

(1) The method employed to transmit the warning must include one of the following alternative methods:

(A) A warning that appears on the label or labeling of a product or substance present or used in the workplace. The label or labeling shall be prominently displayed on the product or substance and the product or substance shall be used under circumstances which make it likely that the warnings will be read and understood by employees or other individuals prior to the exposure for which the warning is given.

(B) A warning that appears on a sign in the workplace posted in a conspicuous place and under conditions that make it likely to be read and understood by employees and other individuals prior to the exposure for which the warning is given.

(C) A warning to the exposed employee about the chemical in question which fully complies with all information, training and labeling requirements of the federal Hazard Communication Standard (29 CFR section 1910.1200, as amended on March 7, 1996), the California Hazard Communication Standard (Cal. Code Regs., title 8, section 5194, as amended on March 15, 1999), or, for pesticides, the Pesticides and Worker Safety requirements (Cal. Code Regs., title 3, section 6700 et seq. as amended on June 20, 2001) authorized in Food and Agricultural Code section 12981 as amended by Governor’s Reorganization Plan No. 1 of 1991).

(2) For purposes of subparagraph (1)(A) of this subsection, the warning shall be provided in terms which would provide a clear warning for a consumer product as specified above.

(3) For purposes of subparagraph (1)(B) of this subsection, the following specific warning messages shall be deemed to clearly communicate that an individual is being exposed to a chemical known to the state to cause cancer, or birth defects or other reproductive harm.

(A) For exposure to a chemical known to the state to cause cancer:

“WARNING: This area contains a chemical known to the State of California to cause cancer.”

(B) For exposure to a chemical known to the state to cause reproductive toxicity:

“WARNING: This area contains a chemical known to the State of California to cause birth defects or other reproductive harm.”

(d) Warnings for environmental exposures which include the methods of transmission and the warning messages as specified by this subsection shall be deemed clear and reasonable. An “environmental exposure” is an exposure which may foreseeably occur as the result of contact with an environmental medium, including, but not limited to, ambient air, indoor air, drinking water, standing water, running water, soil, vegetation, or manmade or natural substances, either through inhalation, ingestion, skin contact or otherwise. Environmental exposures include all exposures which are not consumer products exposures, or occupational exposures.

(1) The method employed to transmit the warning must include the most appropriate of the following alternative methods under the circumstances:

(A) A warning that appears on a sign in the affected area. The term “sign” means a presentation of written, printed or graphic matter. The term “affected area” means the area in which an exposure to a chemical known to the state to cause cancer or reproductive toxicity is at a level that requires a warning.

(B) A posting of signs in the manner described in Section 6776(d) of Title 3 of the California Code of Regulations as amended on May 10, 1999 shall be sufficient for purposes of this paragraph.

(C) A warning which is in a notice mailed or otherwise delivered to each occupant in the affected area. Such notice shall be provided at least once in any three-month period.

(D) A warning provided by public media announcements which target the affected area. Such announcements shall be made at least once in any three-month period.

(2) Environmental exposure warnings shall be provided in a conspicuous manner and under such conditions as to make it likely to be read, seen or heard and understood by an ordinary individual in the course of normal daily activity, and reasonably associated with the location and source of the exposure.

(3) For purposes of subparagraph (1)(A) of this subsection, the following specific warning messages shall be deemed to clearly communicate that an individual is being exposed to a chemical known to the state to cause cancer, or birth defects or other reproductive harm.

(A) For exposure to a chemical known to the state to cause cancer:

“WARNING: This area contains a chemical known to the State of California to cause cancer.”

(B) For exposure to a chemical known to the state to cause reproductive toxicity:

“WARNING: This area contains a chemical known to the State of California to cause birth defects or other reproductive harm.”

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

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 purposes of Section 25249.10(c) of the Act 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, risk assessment methodologies, principles, assumptions or levels not described in this article to establish that a level of exposure to a listed chemical poses no significant risk.

(b) A level of exposure to a listed chemical, assuming daily exposure at that level, shall be deemed to pose no significant risk provided that the level is determined:

(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) or 12711 (Levels Based on State or Federal Standards) unless otherwise provided.

(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 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 Section 25249.10(c) of the Act. Nothing in this article shall be construed to establish exposure or risk levels for other regulatory purposes.

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Sections 25249.5, 25249.6, 25249.9, 25249.10 and 25249.11, Health and Safety Code.

§ 12703 Quantitative Risk Assessment.

(a) A quantitative risk assessment which conforms to this section shall be deemed to determine the level of exposure to a listed chemical which, assuming daily exposure at that level, poses no significant risk. The 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 cancer. In the absence of principles or assumptions scientifically more appropriate, based upon the available data, the following default principles and assumptions shall apply in any such assessment:

(1) Animal bioassay studies for quantitative risk assessment shall 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 shall 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 shall be identified and quantified.

(3) Risk analysis shall 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 shall be assumed and no-threshold models shall be utilized. A linearized multistage model for extrapolation from high to low doses, with the upper 95 percent confidence limit of the linear term expressing the upper bound of potency shall be utilized. 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 shall be derived from data on human or animal cancer potency. Potency shall be expressed in reciprocal milligrams of chemical per kilogram of bodyweight per day. Interspecies conversion of animal cancer potency to human cancer potency shall 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. This is equivalent to a scaling factor of 14 when extrapolating from mouse data and a scaling factor of 6.5 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 shall be assumed. When the cancer risk applies to a certain subpopulation, the following assumptions shall be made, as appropriate:

Subpopulation	Kilograms of Body Weight
Man (18+ years of age)	70
Woman (18+ years of age)	58
Woman 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, as, for example:

(1) where chemicals in food are produced by cooking necessary to render the food palatable or to avoid microbiological contamination; or

(2) when chlorine disinfection in compliance with all applicable state and federal safety standards is necessary to comply with sanitation requirements; or

(3) where a clean-up and resulting discharge is ordered and supervised by an appropriate governmental agency or court of competent jurisdiction.

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Sections 25249.5, 25249.6, 25249.9, 25249.10 and 25249.11, Health and Safety Code.

§ 12705. Specific Regulatory Levels Posing No Significant Risk.

(a) Daily exposure to a chemical at a level which does not exceed the level set forth in subsections (b), (c) and (d) for such chemical shall be deemed to pose no significant risk within the meaning of Section 25249.10(c) of the Act.

(b) Levels of exposure deemed to pose no significant risk may be determined by the lead agency based on a risk assessment conducted by the lead agency pursuant to the guidelines set forth in Section 12703, or a risk assessment reviewed by the lead agency and determined to be consistent with the guidelines set forth in Section 12703.

(1) The following levels based on risk assessments conducted or reviewed by the lead agency shall be deemed to pose no significant risk:

Chemical Name	Level (micrograms/day)
Acrylonitrile	0.7
Aldrin	0.04
Arsenic	0.06 (inhalation)
Asbestos	100 fibers inhaled/day*
Benzene	7
Benzidine	0.001
Bis(2-chloroethyl)ether	0.3
Bis(chloromethyl)ether	0.02
Butylated hydroxyanisole	4000
Cadmium	0.05 (inhalation)
Carbon tetrachloride	5
Chloroethane	150
Chromium (hexavalent compounds)	0.001 (inhalation)
DDT, DDE and DDD (in combination)	2
1,2-Dibromo-3-chloropropane (DBCP)	0.1
para-Dichlorobenzene	20
3,3'-Dichlorobenzidine	0.6
Dichloromethane (Methylene chloride)	200 (inhalation)
Dieldrin	0.04
Di(2-ethylhexyl)phthalate (DEHP)	310
1,4-Dioxane	30
Epichlorohydrin	9
Ethylene dibromide	0.2 (ingestion) 3 (inhalation)
Ethylene dichloride	10
Ethylene oxide	2
Hexachlorobenzene	0.4
Hexachlorodibenzodioxin	0.0002
Hexachlorocyclohexane (technical grade)	0.2
Lead	15 (oral)
Lead acetate	23 (oral)
Lead phosphate	58 (oral)
Lead subacetate	41 (oral)

Methylhydrazine	0.058 (oral) 0.090 (inhalation)
Methylhydrazine sulfate	0.18
5-Morpholinomethyl-3-[(5-nitrofurfurylidene)-amino]-2-oxazolidinone	0.18
MX (3-chloro-4-(dichloromethyl)-5-hydroxy-2(5H)-furanone)	0.11
N-Nitroso-n-dibutylamine	0.06
N-Nitrosodiethylamine	0.02
N-Nitrosodimethylamine	0.04
N-Nitrosodiphenylamine	80
N-Nitrosodi-n-propylamine	0.1
N-Nitroso-N-ethylurea	0.03
N-Nitroso-N-methylurea	0.006
Phenylhydrazine	1.0
Phenylhydrazine hydrochloride	1.4
Polybrominated biphenyls	0.02
Polygeenan	1200
2,3,7,8-Tetrachlorodibenzo-p-dioxin	0.000005
Toxaphene	0.6
Trichloroethylene	50 (ingestion) 80 (inhalation)
2,4,6-Trichlorophenol	10
Urethane	0.7
Vinyl chloride	3

*Fibers equal to or greater than 5 micrometers in length and 0.3 micrometers in width, with a length to width ratio of greater than or equal to 3:1 as measured by phase contrast microscopy.

(2) Whenever the lead agency proposes to formally adopt, pursuant to this subsection, a level which shall be deemed to pose no significant risk of cancer, assuming daily exposure at that level, the lead agency shall provide to each member of the Carcinogen Identification Committee notice of the proposed action, a copy of the proposed level, and a copy of the 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 Carcinogen Identification Committee the opportunity to review such proposal and provide comment to the lead agency. Any such comment by the Carcinogen Identification Committee shall become a part of the formal rulemaking file. Nothing in this subsection shall be construed to prevent members of the Carcinogen Identification Committee from providing comments individually on any such proposal, or to require the Carcinogen Identification Committee to submit any comment.

(c) Unless a specific regulatory level for a chemical known to the state to cause cancer has been established in subsection (b), levels of exposure deemed to pose no significant risk may be determined by the lead agency based on state or federal risk assessments.

(1) Any interested party may request the lead agency to reevaluate a level established in this subsection based on scientific considerations that indicate the need for the lead agency to develop its own risk assessment or to conduct a detailed review of the risk assessment used to derive the level in question. Such request shall be made in writing, and shall include a description of the scientific considerations that indicate the need for the lead agency to develop its own risk assessment or to conduct a detailed review of the risk assessment used to derive the level in question. The lead agency may establish a level for the chemical in question in subsection (b) as it deems necessary.

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

Chemical Name	Level (micrograms/day)
Acetaldehyde	90 (inhalation)
Acrylamide	0.2
Aniline	100
Azobenzene	6
Benzo[a]pyrene	0.06
Benzyl chloride	4
Beryllium oxide	0.1
Beryllium sulfate	0.0002
Bromodichloromethane	5
1,3-Butadiene	0.4
Chlordane	0.5
Chloroform	20 (ingestion) 40 (inhalation)
Coke oven emissions	0.3
DDVP (Dichlorvos)	2
Dichloromethane (Methylene chloride)	50
2,4-Dinitrotoluene	2
Folpet	200
Formaldehyde (gas)	40
Furmecyclox	20
Heptachlor	0.2
Heptachlor epoxide	0.08
Hexachlorocyclohexane	

alpha isomer	0.3
beta isomer	0.5
gamma isomer	0.6
Hydrazine	0.04
Hydrazine sulfate	0.2
4,4'-Methylene bis(N,N-dimethyl)benzeneamine	20
Nickel refinery dust	0.8
Nickel subsulfide	0.4
N-Nitrosodiethanolamine	0.3
N-Nitrosomethylethylamine	0.03
N-Nitrosopyrrolidine	0.3
Pentachlorophenol	40
Polychlorinated biphenyls (PCBs)	0.09
Tetrachloroethylene	14

(d) Unless a specific regulatory level has been established for a chemical known to the state to cause cancer in subsection (b) or (c), levels of exposure deemed to pose no significant may be determined by the lead agency using an expedited method consistent with the procedures specified in Section 12703.

(1) An interested party may request the lead agency to reevaluate a level established in this subsection and to consider the adoption, in subsection (c), of a level based on a state or federal risk assessment. Such request shall be made in writing, and shall include a copy of the state or federal risk assessment which the interested party wishes the lead agency to consider as the basis for a level in subsection (c). The lead agency may establish a level in subsection (c) for the chemical in question based on a state or federal risk assessment as it deems necessary.

(2) An interested party may request the lead agency to reevaluate a level established in this subsection based on scientific considerations that indicate the need for a conventional risk assessment. Such request shall be made in writing, and shall include a description of the scientific considerations that indicate the need for a conventional risk assessment. The lead agency may conduct a conventional risk assessment for the chemical in question, and establish a level in subsection (b) as it deems necessary.

(3) The following levels of exposure based on risk assessments conducted by the lead agency using an expedited method consistent with the procedures specified in Section 12703 shall be deemed to pose no significant risk:

Chemical Name	Level (micrograms/day)
A-alpha-C (2-Amino-9H-pyridol[2,3-b]indole)	2
Acetamide	10

2-Acetylaminofluorene	0.2
Actinomycin D	0.00008
AF-2;[2-(2-furyl)-3(5-nitro-2-furyl)acrylamide]	3
2-Aminoanthraquinone	20
<i>o</i> -Aminoazotoluene	0.2
4-Aminobiphenyl (4-aminodiphenyl)	0.03
3-Amino-9-ethylcarbazole hydrochloride	9
1-Amino-2-methylantraquinone	5
2-Amino-5-(5-nitro-2-furyl)-1,3,4-thiadiazole	0.04
Amitrole	0.7
<i>o</i> -Anisidine	5
<i>o</i> -Anisidine hydrochloride	7
Aramite	20
Auramine	0.8
Azaserine	0.06
Azathioprine	0.4
Benzyl violet 4B	30
beta-Butyrolactone	0.7
Carbazole	4.1
Captafol	5
Captan	300
Chlorambucil	0.002
Chlordecone (Kepone)	0.04
Chlorendic acid	8
Chlorinated paraffins (Average chain length, C12; approximately 60 percent chlorine by weight)	8
Chloromethyl methyl ether (technical grade)	0.3
3-Chloro-2-methylpropene	5
4-Chloro-ortho-phenylenediamine	40
Chlorothalonil	200
<i>p</i> -Chloro- <i>o</i> -toluidine	3
Chlorozotocin	0.003
C.I. Basic Red 9 monohydrochloride	3
Cinnamyl anthranilate	200
<i>p</i> -Cresidine	5
Cupferron	3
Cyclophosphamide (anhydrous)	1
Cyclophosphamide (hydrated)	1
D&C Red No. 9	100
Dacarbazine	0.01
Daminozide	40
Dantron (Chrysazin;1,8-Dihydroxyanthraquinone)	9
2,4-Diaminoanisole	30

2,4-Diaminoanisole sulfate	50
4,4'-Diaminodiphenyl ether (4,4'-Oxydianiline)	5
2,4-Diaminotoluene	0.2
Dibenz[a,h]anthracene	0.2
1,1-Dichloroethane	100
Diethylstilbestrol	0.002
Diglycidyl resorcinol ether (DGRE)	0.4
Dihydrosafrole	20
4-Dimethylaminoazobenzene	0.2
trans-2[(Dimethylamino)methyliminol]-5-[2-(5-nitro-2-furyl)vinyl]-1,3,4-oxadiazole	2
7,12-Dimethylbenz(a)anthracene	0.003
Dimethylcarbanyl chloride	0.05
1,2-Dimethylhydrazine	0.001
Dimethylvinylchloride	20
Direct Black 38 (technical grade)	0.09
Direct Blue 6 (technical grade)	0.09
Direct Brown 95 (technical grade)	0.1
Disperse Blue 1	200
Estradiol 17B	0.02
Ethyl-4,4'-dichlorobenzilate (chlorobenzilate)	7
Ethylene thiourea	20
Ethyleneimine	0.01
2-(2-Formylhydrazino)-4-(5-nitro-2-furyl)thiazole	0.3
Glu-P-1 (2-Amino-6-methyldipyrido[1,2-a:3',2'-d]imidazole	0.1
Glu-P-2 (2-Aminodipyrido[1,2-a:3',2'-d]imidazole	0.5
Gyromitrin (Acetaldehyde methylformylhydrazone)	0.07
HC Blue 1	10
Hexachloroethane	20
Hydrazobenzene (1,2-Diphenylhydrazine)	0.8
IQ (2-Amino-3-methylimidazo[4,5-f]quinoline)	0.5
Lasiocarpine	0.09
Me-A-alpha-C (2-Amino-3-methyl-9H-pyrido[2,3-b]indole)	0.6
MeIQ (2-Amino-3,4-dimethylimidazo[4,5-f] quinoline)	0.46
MeIQx (2-Amino-3,8-dimethylimidazo[4,5-f] quinoxaline)	0.41
Melphalan	0.005
Methyl carbamate	160
3-Methylcholanthrene	0.03
4,4'-Methylene bis(2-chloraniline)	0.5
4,4'-Methylene bis(2-methylaniline)	0.8

4,4'-Methylenedianiline	0.4
4,4'-Methylenedianiline dihydrochloride	0.6
Methyl methanesulfonate	7
2-Methyl-1-nitroanthraquinone (of uncertain purity)	0.2
N-Methyl-N'-nitro-N-nitrosoguanidine	0.08
Methylthiouracil	2
Michler's ketone	0.8
Mirex	0.04
Mitomycin C	0.00009
Monocrotaline	0.07
2-Naphthylamine	0.4
Nitrilotriacetic acid	100
Nitrolotriacetic acid, trisodium salt monohydrate	70
5-Nitroacenaphthene	6
5-Nitro- <i>o</i> -anisidine	10
Nitrofen (technical grade)	9
Nitrofurazone	0.5
1-[(5-Nitrofurfurylidine)-amino]-2-imidazolidinone	0.4
N-[4-(5-Nitro-2-furyl)-2-thiazolyl]acetamide	0.5
<i>p</i> -Nitrosodiphenylamine	30
4-(N-Nitrosomethylamino)-1-(3-pyridyl)-1-butanone	0.014
N-Nitroso-N-methylurethane	0.006
N-Nitrosomorpholine	0.1
N-Nitrosornicotine	0.5
N-Nitrosopiperidine	0.07
Phenacetin	300
Phenazopyridine	4
Phenazopyridine hydrochloride	5
Phenesterin	0.005
Phenobarbital	2
Phenoxybenzamine	0.2
Phenoxybenzamine hydrochloride	0.3
<i>o</i> -Phenylphenate sodium	200
Ponceau MC (D&C Red No. 5)	200
Ponceau 3R (FD&C Red No. 1)	40
Potassium bromate	1
Procarbazine	0.05
Procarbazine hydrochloride	0.06
1,3-Propane sultone	0.3
beta-Propiolactone	0.05
Propylthiouracil	0.7
Reserpine	0.06

Safrole	3
Sterigmatocystin	0.02
Streptozotocin	0.006
Styrene oxide	4
Sulfallate	4
1,1,2,2-Tetrachloroethane	3
Thioacetamide	0.1
4,4'-Thiodianiline	0.05
Thiourea	10
Toluene diisocyanate	20
<i>o</i> -Toluidine	4
<i>o</i> -Toluidine hydrochloride	5
Trimethyl phosphate	24
Tris(1-aziridinyl)phosphine sulfide (Thiotepa)	0.06
Tris(2,3-dibromopropyl)phosphate	0.3
Trp-P-1 (Tryptophan-P-1)	0.03
Trp-P-2 (Tryptophan-P-2)	0.2
Vinyl trichloride (1,1,2-Trichloroethane)	10

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Sections 25249.5, 25249.6, 25249.9, 25249.10 and 25249.11, Health and Safety Code.

§ 12707. Route 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) Asbestos
- (2) Beryllium and beryllium compounds
- (3) Cadmium and cadmium compounds
- (4) Chromium (hexavalent compounds)
- (5) Nickel and nickel compounds

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Sections 25249.5, 25249.6, 25249.9, 25249.10 and 25249.11, Health and Safety Code.

§ 12709. Exposure to Trace Elements.

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

(b) Element	No Significant Risk Level in micrograms per day
Arsenic (inorganic)	10 (except inhalation)
Beryllium	0.1

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Sections 25249.5, 25249.6, 25249.9, 25249.10 and 25249.11, Health and Safety Code.

§ 12711. Levels Based on State or Federal Standards.

(a) Except as otherwise provided in Section 12705, 12707, or 12709, levels of exposure deemed to pose 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 constitute the no significant risk level.

(2) For drinking water, the following levels shall be deemed to pose no significant risk:

(A) Drinking water maximum contaminant levels adopted by the Department of Health Services for chemicals known to the state to cause cancer;

(B) Drinking water action levels for chemicals known to the state to cause cancer for which maximum contaminant levels have not been adopted;

(C) Specific numeric levels of concentration for chemicals known to the state to cause cancer which are permitted to be discharged or released into sources of drinking water by a Regional Water Quality Control Board in a water quality control plan or in waste discharge requirements, when such levels are based on considerations of minimizing carcinogenic risks associated with such discharge or release.

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Sections 25249.5, 25249.6, 25249.9, 25249.10 and 25249.11, Health and Safety Code.

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

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Sections 25249.5, 25249.6, 25249.9, 25249.10 and 25249.11, Health and Safety Code.

§ 12721. Level of Exposure to Chemicals Causing Cancer.

(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 Section 25249.10(c) of the Act, the level of exposure to a chemical listed as causing cancer, 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 chemical listed as causing cancer, 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
Woman 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 average 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 on 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.

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Sections 25249.5, 25249.6, 25249.9, 25249.10 and 25249.11, Health and Safety Code.

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 Section 25249.10(c) of the Act 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, assessment methodologies, principles, assumptions 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) A level of exposure to a listed chemical shall be deemed to have no observable effect, assuming exposure at one thousand times that level, provided that the level is determined:

(1) By means of 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 reproductive effect.

(d) The chemicals specifically contained in this article do not include all chemicals listed as causing reproductive toxicity for which there is a level of exposure which has no observable effect assuming exposure at one thousand times the level in question. The fact that a chemical does not specifically appear in this article does not mean that it has an observable effect at any level.

(e) This article establishes exposure levels solely for purposes of Section 25249.10(c) of the Act. Nothing in this article shall be construed to establish exposure levels for other regulatory purposes.

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Sections 25249.5, 25249.6, 25249.9, 25249.10 and 25249.11, Health and Safety Code.

§ 12803. Assessment.

(a) A quantitative assessment which conforms to this section shall be deemed to determine the level of exposure to a listed chemical which will have no observable effect, assuming the exposure at one thousand times the level in question. The 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 principles or assumptions scientifically more appropriate based upon the available data, the following default principles and assumptions shall apply 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 shall 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 shall 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 shall be identified and quantified.

(3) Animal bioassay studies for assessment shall 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 shall 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.

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Sections 25249.5, 25249.6, 25249.9, 25249.10 and 25249.11, Health and Safety Code.

§ 12805. Specific Regulatory Levels: Chemicals Causing Reproductive Toxicity.

(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 (1,000) times that level.

(b) Chemical Name	Level (micrograms/day)
Benzene	24 (oral) 49 (inhalation)
Cadmium	4.1
Ethylene oxide	20.0
Lead	0.5
Quizalofop ethyl	590
Toluene	7000

(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 subsection (a) of Section 12803, and establishes a maximum allowable dose level in the manner provided in paragraph (b)(1) of Section 12801, shall constitute the allowable dose level having no observable effect within the meaning of Section 25249.10(c) of the Act.

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Sections 25249.5, 25249.6, 25249.9, 25249.10 and 25249.11, Health and Safety Code.

§ 12821. Level of Exposure to Chemicals Causing Reproductive Toxicity.

(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 Section 25249.10(c) of the Act, the level of exposure to a chemical listed as causing reproductive toxicity 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 chemical listed as causing reproductive toxicity, unless more specific and scientifically appropriate data are available:

(1) The assumptions set forth in subsection (d) of Section 12721 shall be used to calculate the reasonably anticipated rate of exposure to a chemical listed as causing reproductive toxicity, 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 average 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 chemical listed as causing reproductive toxicity 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.

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Sections 25249.5, 25249.6, 25249.9, 25249.10 and 25249.11, Health and Safety Code.

ARTICLE 9. Miscellaneous

§ 12901. Methods of Detection.

(a) For purposes of Section 25249.11, subdivision (c) of the Act, the term “any detectable amount” means a level detected using a method of analysis referred to in this section. For

purposes of this section, “method of analysis” refers to the method of detection or detection and calculation for a listed chemical in a specific medium, including but not limited to, water, air, food, or soil, and shall include methods or procedures concerning the number of samples and the frequency and site of sampling that are specific for the listed chemical in question.

(b) Where the California Department of Health Services, the California Department of Pesticide Regulation, the Air Resources Board, a local air pollution control district, the State Water Resources Control Board, or a Regional Water Quality Control Board has adopted or employs a method of analysis for a listed chemical in a specific medium, such method shall be the method of analysis for that chemical in that medium. Where more than one method of analysis has been adopted or is so employed, each may be utilized as the method of analysis.

(c) Where no state or local agency identified in subsection (b) has adopted or employs a method of analysis, a method of analysis for a listed chemical in a specific medium adopted or employed by a federal agency shall be the method of analysis for that chemical in that medium. When more than one method of analysis has been adopted or is so employed, each may be utilized as the method of analysis.

(d) Where no regulatory agency identified in subsection (b) or (c) has adopted or employs a method of analysis, a method of analysis for a listed chemical in a specific medium which 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, such method shall be the method of analysis for that chemical in that medium. When more than one method of analysis is generally accepted, each may be utilized as the method of analysis.

(e) Where no method of analysis as described in subsection (b) or (c) has been adopted or is employed, or is generally accepted by the scientific community as described in subsection (d), and a scientifically valid method of analysis has been developed for a listed chemical in a specific medium, such method shall be the method of analysis for that chemical in that medium. Where more than one method of analysis has been developed for a chemical in a specific medium, each may be utilized as the method of analysis.

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

(g) For purposes of Sections 25249.5 and 25249.6 of the Act, no discharge, release or exposure occurs unless a listed chemical is detectable as provided in this section.

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Sections 25249.5, 25249.6 and 25249.11, Health and Safety Code.

§ 12902. Formally Required to Be Labeled or Identified as Causing Cancer or Reproductive Toxicity.

(a) In accordance with Section 25249.8(b), of the Act, a chemical is known to the state to cause cancer or reproductive toxicity within the meaning of the Act, and shall be listed pursuant to Section 25249.8(a), of the Act, if the lead agency determines that an agency of the state or federal government has formally required the chemical to be labeled or identified as causing cancer or reproductive toxicity. In making such determination, the lead agency shall act in accordance with this section.

(b) The following definitions shall apply to this section:

(1) “agency of the state or federal government” means the United States Congress or the California State Legislature acting through legislation, any agency, department, office, officer, division, bureau, board or commission of California state government (excluding political subdivisions thereof) or of the United States government, which has the statutory or regulatory authority to require a person or entity outside of that agency to label or identify a chemical as causing cancer or reproductive toxicity.

(2) “formally required” means that a mandatory instruction, order, condition, or similar command, has been issued in accordance with established policies and procedures of an agency of the state or federal government to a person or legal entity outside of the agency. The action of such agency may be directed at one or more persons or legal entities and may include formal requirements of general application.

(3) “labeled” means that a warning message about the carcinogenicity or reproductive toxicity of a chemical is printed, stamped, written, or in any other manner placed upon the container in which the chemical is present or its outer or inner packaging including any material inserted with, attached to, or otherwise accompanying such chemical.

(4) “identified” means that a required message about the carcinogenicity or reproductive toxicity of the chemical is to be disclosed in any manner to a person or legal entity other than the person or legal entity who is required to make such disclosure.

(5) “As causing cancer or reproductive toxicity” means:

(A) For chemicals that cause cancer, the required label or identification uses any words or phrases intended to communicate a risk of cancer or tumors.

(B) For chemicals that cause reproductive toxicity, the required label or identification uses any words or phrases intended to communicate a risk of reproductive harm to men or women or both, or a risk of birth defects or other developmental harm.

(c) Any person may petition the lead agency to consider listing a chemical pursuant to this section. The petition shall be considered only if the petition contains sufficient information to

support a determination by the lead agency that substantial evidence exists to support a finding that the chemical meets the requirements of this section.

(d) Any determination by the lead agency under this section may be rescinded or modified in light of additional evidence received by the lead agency establishing that the listing does not satisfy the definitions set forth in this section. Any such action to rescind or modify shall be done pursuant to this section.

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Section 25249.8, Health and Safety Code.

§ 12903. Notices of Violation

(a) For purposes of Section 25249.7(d) of the Act, “notice of the violation which is the subject of the action” (hereinafter “notice”) shall mean a notice meeting all requirements of this section. No person shall commence an action to enforce the provisions of the Act “in the public interest” pursuant to Section 25249.7(d) of the Act except in compliance with all requirements of this section.

(b) Contents of Notice.

(1) General Information. Each notice shall include as an attachment a copy of “The Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): A Summary” (see Appendix A) prepared by the lead agency. This attachment need not be included in the copies of notices sent to public enforcement agencies. A copy of this attachment may be obtained by writing to the Office of Environmental Health Hazard Assessment at P.O. Box 4010, Sacramento, CA 95812-4010.

(2) Description of Violation. A notice shall provide adequate information from which to allow the recipient to assess the nature of the alleged violation, as set forth in this paragraph. The provisions of this paragraph shall not be interpreted to require more than reasonably clear information, expressed in terms of common usage and understanding, on each of the indicated topics.

(A) For all notices, the notice shall identify:

1. the name, address, and telephone number of the noticing individual or a responsible individual within the noticing entity and the name of the entity;
2. the name of the alleged violator or violators;
3. the approximate time period during which the violation is alleged to have occurred; and
4. the name of each listed chemical involved in the alleged violation;

(B) For notices of violations of Section 25249.5 of the Act, a general identification of the discharge or release and of the source of drinking water into which the discharges are alleged to have occurred, to be occurring or to be likely to occur.

(C) For all notices of violation of Section 25249.6 of the Act, the route of exposure by which exposure is alleged to occur (e.g., by inhalation, ingestion, dermal contact);

(D) For notices of violation of Section 25249.6 of the Act involving consumer product exposures, the name of the consumer product or service, or the specific type of consumer product or services, that cause the violation, with sufficient specificity to inform the recipients of the nature of the items allegedly sold in violation of the law and to distinguish those products or services from others sold or offered by the alleged violator for which no violation is alleged. The identification of a chemical pursuant to subsection (b)(2)(A)4. must be provided for each product or service identified in the notice.

(E) For notices of violation of Section 25249.6 of the Act involving occupational exposures:

1. the general geographic location of the unlawful exposure to employees, or where the exposure occurs at many locations, a description of the occupation or type of task performed by the exposed persons;

2. where the alleged violator is the manufacturer or distributor of the chemical or products causing the exposure, the notice shall identify products in the same manner as set forth for consumer product exposures in subparagraph (b)(2)(D), above;

(F) For notices of violation of Section 25249.6 of the Act involving environmental exposures as defined in subsection 12601(d) of this chapter, the notice shall identify, the location of the source of the exposure. Where numerous sources of the exposure are alleged, the location need not be stated if the notice identifies each facility or source of exposure by stating those common characteristics that result in the allegedly unlawful exposure in a manner sufficient to distinguish those facilities or sources from others for which no violation is alleged. The notice shall state whether the exposure for which a warning allegedly is required occurs beyond the property owned or controlled by the alleged violators.

(3) Where the alleged violations fall within more than one of the categories described in subparagraph (b)(2)(B) to (b)(2)(F) above, then the notice shall comply with all applicable requirements.

(4) A notice is not required to contain the following information:

(A) The specific retail outlet or time or date at which any product allegedly violating the Act was purchased;

(B) The level of exposure to the chemical in question;

(C) The specific admissible evidence by which the person providing the notice will attempt to prove the violation;

(D) For products, the UPC number, SKU number, model or design number or stock number or other more specific identification of products;

(E) For geographic areas, the lot, block, or other legal description of the property in question.

(c) Service of Notice.

(1) Notices shall be served by first class mail or in any manner that would be sufficient for service of a summons and complaint under the California Code of Civil Procedure.

(2) A certificate of service shall be attached to each notice listing the time, place, and manner of service and each of the parties upon which the notice was served.

(3) Notices shall be served upon each alleged violator, the Attorney General, the district attorney of every county in which a violation is alleged to have occurred, and upon the city attorneys of any cities with populations according to the most recent decennial census of over 750,000 and in which the violation is alleged to have occurred.

(4) Where the alleged violator has a current registration with the California Secretary of State that identifies a Chief Executive Officer, President, or General Counsel of the corporation, the notice shall be addressed to one of those persons.

(d) Computation of Time.

(1) An action is deemed to have been “commenced more than sixty days after the person has given notice” where more than sixty days have elapsed from the date of service of the notice, as that date would be calculated for service of a document pursuant to the provisions of Code of Civil Procedure Section 1013.

(2) Where the sixtieth day after giving notice is a day identified as a “holiday” as defined in Code of Civil Procedure Section 12a, then the “sixtieth day” shall be extended to the next day which is not a “holiday”.

(3) Determination of the first and last day shall be made in accordance with Section 12 of the Code of Civil Procedure.

NOTE: Authority cited: Section 25249.12, Health and Safety Code Section. Reference: Section 25249.7, Health and Safety Code.

APPENDIX A

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY

THE SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986
(PROPOSITION 65): A SUMMARY

The following summary has been prepared by the Office of Environmental Health Hazard Assessment, the lead agency for the implementation of the Safe Drinking Water and Toxic Enforcement Act of 1986 (commonly known as “Proposition 65”). A copy of this summary must be included as an attachment to any notice of violation served upon an alleged violator of the Act. The summary provides basic information about the provisions of the law, and is intended to serve only as a convenient source of general information. It is not intended to provide authoritative guidance on the meaning or application of the law. The reader is directed to the statute and its implementing regulations (see citations below) for further information.

Proposition 65 appears in California law as Health and Safety Code Sections 25249.5 through 25249.13. Regulations that provide more specific guidance on compliance, and that specify procedures to be followed by the State in carrying out certain aspects of the law, are found in Title 22 of the California Code of Regulations, Sections 12000 through 14000.

WHAT DOES PROPOSITION 65 REQUIRE?

The “Governor’s List.” Proposition 65 requires the Governor to publish a list of chemicals that are known to the State of California to cause cancer, or birth defects or other reproductive harm. This list must be updated at least once a year. Over 735 chemical listings have been included as of November 16, 2001. Only those chemicals that are on the list are regulated under this law. Businesses that produce, use, release or otherwise engage in activities involving those chemicals must comply with the following:

Clear and reasonable warnings. A business is required to warn a person before “knowingly and intentionally” exposing that person to a listed chemical. The warning given must be “clear and reasonable.” This means that the warning must: (1) clearly make known that the chemical involved is known to cause cancer, or birth defects or other reproductive harm; and (2) be given in such a way that it will effectively reach the person before he or she is exposed. Exposures are exempt from the warning requirement if they occur less than twelve months after the date of listing of the chemical.

Prohibition from discharges into drinking water. A business must not knowingly discharge or release a listed chemical into water or onto land where it passes or probably will pass into a source of drinking water. Discharges are exempt from this requirement if they occur less than twenty months after the date of listing of the chemical.

DOES PROPOSITION 65 PROVIDE ANY EXEMPTIONS?

Yes. The law exempts:

Governmental agencies and public water utilities. All agencies of the federal, State or local government, as well as entities operating public water systems, are exempt.

Businesses with nine or fewer employees. Neither the warning requirement nor the discharge prohibition applies to a business that employs a total of nine or fewer employees.

Exposures that pose no significant risk of cancer. For chemicals that are listed as known to the State to cause cancer (“carcinogens”), a warning is not required if the business can demonstrate that the exposure occurs at a level that poses “no significant risk.” This means that the exposure is calculated to result in not more than one excess case of cancer in 100,000 individuals exposed over a 70-year lifetime. The Proposition 65 regulations identify specific “no significant risk” levels for more than 250 listed carcinogens.

Exposures that will produce no observable reproductive effect at 1,000 times the level in question. For chemicals known to the State to cause birth defects or other reproductive harm (“reproductive toxicants”), a warning is not required if the business can demonstrate that the exposure will produce no observable effect, even at 1,000 times the level in question. In other words, the level of exposure must be below the “no observable effect level (NOEL),” divided by a 1,000-fold safety or uncertainty factor. The “no observable effect level” is the highest dose level which has not been associated with an observable adverse reproductive or developmental effect.

Discharges that do not result in a “significant amount” of the listed chemical entering into any source of drinking water. The prohibition from discharges into drinking water does not apply if the discharger is able to demonstrate that a “significant amount” of the listed chemical has not, does not, or will not enter any drinking water source, and that the discharge complies with all other applicable laws, regulations, permits, requirements, or orders. A “significant amount” means any detectable amount, except an amount that would meet the “no significant risk” or “no observable effect” test if an individual were exposed to such an amount in drinking water.

HOW IS PROPOSITION 65 ENFORCED?

Enforcement is carried out through civil lawsuits. These lawsuits may be brought by the Attorney General, any district attorney, or certain city attorneys (those in cities with a population exceeding 750,000). Lawsuits may also be brought by private parties acting in the public interest, but only after providing notice of the alleged violation to the Attorney General, the appropriate district attorney and city attorney, and the business accused of the violation. The notice must provide adequate information to allow the recipient to assess the nature of the alleged violation. A notice must comply with the information and procedural requirements specified in regulations (Title 22, California Code of Regulations, Section 12903). A private party may not pursue an enforcement action directly under Proposition 65 if one of the governmental officials noted above initiates an action within sixty days of the notice.

A business found to be in violation of Proposition 65 is subject to civil penalties of up to \$2,500 per day for each violation. In addition, the business may be ordered by a court of law to stop committing the violation.

FOR FURTHER INFORMATION...

Contact the Office of Environmental Health Hazard Assessment's Proposition 65 Implementation Office at (916) 445-6900.

§ 14000. Chemicals Required By State Or Federal Law To Have Been Tested For Potential To Cause Cancer Or Reproductive Toxicity, But Which Have Not Been Adequately Tested As Required.

(a) The Safe Drinking Water and Toxic Enforcement Act of 1986 requires the Governor to publish a list of chemicals formally required by state or federal agencies to have testing for carcinogenicity or reproductive toxicity, but that the state's qualified experts have not found to have been adequately tested as required [Health and Safety Code Section 25249.8(c)].

Readers should note that a chemical that already has been designated as known to the state to cause cancer or reproductive toxicity is not included in the following listing as requiring additional testing for that particular toxicological endpoint. However, the "data gap" may continue to exist, for purposes of the state or federal agency's requirements. Additional information on the requirements for testing may be obtained from the specific agency identified below.

(b) Chemicals required to be tested by the California Department of Pesticide Regulation

The Birth Defect Prevention Act of 1984 (SB 950) mandates that the California Department of Pesticide Regulation (CDPR) review chronic toxicology studies supporting the registration of pesticidal active ingredients. Missing or unacceptable studies are identified as data gaps. The studies are conducted to fulfill generic data requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which is administered by the United States Environmental Protection Agency (U.S. EPA). The studies are reviewed by CDPR according to guidelines and standards promulgated under FIFRA. Thus, older studies may not meet current guidelines.

The existence of a data gap for a compound does not indicate a total lack of information on the carcinogenicity or reproductive toxicity of the compound. In some cases, information exists in the open scientific literature, but SB 950 requires specific additional information. A data gap does not necessarily indicate that an oncogenic or reproductive hazard exists. For the purposes of this list, a data gap is still considered to be present until the study is reviewed and found to be acceptable.

Following is a listing of SB 950 data gaps for oncogenicity, reproduction, and teratology studies for the first 200 pesticidal active ingredients. This list will change as data gaps are filled by additional data or replacement studies.

For purposes of this section, “onc mouse” means oncogenicity in mice, “onc rat” means oncogenicity in rats, “repro” means reproduction, “tera rodent” means teratogenicity in rodents, “tera rabbit” means teratogenicity in rabbits.

<i>Chemical</i>	<i>Testing Needed</i>
Bendiocarb	onc rat, repro, tera rodent
Chloroneb	onc rat, onc mouse, repro, tera rodent, tera rabbit
PCP	repro
Petroleum distillates, aromatic	onc rat, onc mouse, repro, tera rodent, tera rabbit

(c) Chemicals required to be tested by the U.S. EPA, Office of Toxic Substances.

Under Section 4(a) of the Toxic Substances Control Act, testing of a chemical is required when that chemical may present an unreasonable risk, or is produced in substantial quantities and enters the environment in substantial quantities, or may have significant or substantial human exposure.

For purposes of this section, “tera” means teratogenicity, “rtox” means reproductive toxicity, “onc” means oncogenicity.

<i>Chemical</i>	<i>Testing Needed</i>
Alkyl (C12-13) glycidyl ether	rtox, tera
t-Amyl methyl ether	rtox, tera
Bisphenol A diglycidyl ether	onc, rtox
Cyclohexane*	rtox, tera,
Glycidyl methacrylate*	tera
N-Methylpyrrolidone	onc, rtox
Phenol	rtox

* The Toxic Substances Control Act Section 4 health effects testing programs for cyclohexane and glycidyl methacrylate have been completed and the U.S. EPA’s review of the testing program data is currently underway.

(d) Chemicals required to be tested by the U.S. EPA, Office of Pesticide Programs.

The U.S. EPA is responsible for the regulation of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). FIFRA requires U.S. EPA to register pesticides based on data adequate to demonstrate that they will not result in unreasonable adverse effects to people or the environment when used in accordance with their U.S. EPA-approved labels.

In 1988, FIFRA was amended to strengthen U.S. EPA's pesticide regulatory authority and responsibilities to reregister pesticides registered prior to 1984 to ensure they meet today's stringent scientific and regulatory standards. Reregistration requires registrants to develop up-to-date data bases for each pesticide active ingredient. As part of the reregistration process, modifications may be made to registrations, labels or tolerances to ensure they are protective of human health and the environment. Also, reregistration reviews will identify any pesticides where regulatory action may be necessary to deal with unreasonable risks. U.S. EPA has been directed to accelerate the reregistration process so that the entire process is completed by 1997. The 1988 amendments set out a five-phase schedule to accomplish this task with deadlines applying to both pesticide registrants and the U.S. EPA. These amendments are requiring a substantial number of new studies to be conducted and old studies to be reformatted for U.S. EPA review to ensure they are adequate. U.S. EPA may, in the future, request additional data or information to further evaluate any concerns over the safety of pesticide products.

The chemicals listed below are those for which data are unavailable or inadequate to characterize oncogenicity, teratogenicity, or reproductive effects potential. For purposes of this section, "onc" means oncogenicity, "tera" means teratogenicity, and "repro" means reproductive toxicity.

<i>Chemical</i>	<i>Data Requirements</i>
Acrolein	onc, tera
Alkyl imidazolines	tera
Ametryn	repro, tera
4-Aminopyridine	onc, repro, tera
4-T-Amylphenol	onc, repro
Aquashade	onc, repro, tera
Bensulide	onc, repro, tera
Benzisothiazolin-3-one	onc, repro, tera
Brodifacoum	repro
Bromonitrostyrene	tera
Busan 77	repro
Chlorflurenol methyl	tera
Chlorophacinone	tera
Chloropicrin	onc, repro
Chromated arsenicals	tera
Cycloate	onc
Cypermethrin	onc, repro, tera

DCNA	repro, tera
Dibromodicyanobutane	tera
Diclofop-methyl	onc
Dicrotophos	onc, repro
Dihalodialkylhydantoins	onc, repro, tera
Dimethepin	onc, repro, tera
Dimethyldithiocarbamate	onc, repro, tera
Diphacinone and salts	onc, repro, tera
Diphenylamine	onc, tera
Dipropyl isocinchomeronate	repro
Diuron	onc
Dodine	onc, repro, tera
Endothall and salts	onc, repro, tera
Ethofumesate	onc
Ethoxyquin	tera
Fenthion	tera
Fenvalerate	onc, repro, tera
Fluvalinate	repro
Hydroxy-methyldithiocarbamate	tera
Imazalil	onc
Inorganic chlorates	onc, repro, tera
Inorganic sulfites	onc, repro, tera
Iodine-potassium iodide	tera
Iprodione	tera
Irgasan	onc, repro, tera
Lampicide	onc, repro
Magnesium phosphide	onc
Malathion	onc
Maneb	tera
MCPB and salts	tera
Mefluidide and salts	tera
Mepiquat chloride	tera
Metaldehyde	onc, tera
Methoxychlor	onc, repro, tera
Methyl isothiocyanate	tera
Methyl parathion	tera
Methyldithiocarbamate	repro
MGK 264	tera
Molinate	repro

Naphthalene	onc
Naphthaleneacetic acid	onc, repro
Naphthenate salts	tera
Napropamide	repro
Niclosamide	onc, tera
Nicotine and derivatives	onc, tera
Nitrapyrin	onc
4-Nitrophenol	onc, repro, tera
Octhilinone	tera
Oil of Pennyroyal	tera
Omadine salts	onc, repro, tera
Oxadiazon	repro
Oxyfluorfen	onc
Pebulate	tera
Perfluidone	tera
Phenmedipham	onc
Phenol and salts	tera
2-Phenylphenol and salts	onc, tera
Pine oils	tera
Piperonyl butoxide	tera
Poly (hexamethylene biguanide)	onc, repro
Polyethoxylated aliphatic alcohols	onc, repro, tera
Prometon	tera
Propanil	onc, repro
Propetamphos	tera
Propiconazole	onc
Propylene oxide	tera
Pyrazon	onc, repro
Pyrethrin and derivatives	onc, tera
Pyrimidinone	onc, tera
Sethoxydim	onc
Siduron	onc, repro, tera
Sodium fluoride	tera
Sulfometuron-methyl	onc, tera
TBT-containing compounds	onc, tera
TCMB	onc, repro, tera
Temephos	onc, tera
Tetrachlorvinphos	onc
Tetramethrin	onc
Thiabendazole and salts	onc, repro, tera
Thidiazuron	onc, repro, tera
Thiodicarb	tera

Thiophanate-methyl	onc, tera
Thiram	onc
Triadimefon	onc
Triclopyr and salts	onc
Vernolate	onc, repro

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