

Vista Chemical Company

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[Handwritten initials and a circle]

March 29, 1988

VISTA

Don McQuillen
Henkel Corporation
Organic Products Division
300 Brookside Avenue
Ambler, PA 19002

Dear Don:

As we discussed on the phone, I have enclosed a copy of the Proposition 65 regulations that were promulgated on February 16.

In regards to the analytical methods for residual ethylene oxide, someone from our Lake Charles Chemical Plant laboratory will be contacting you with specific information on our methods. Please feel free to call me at 713/531-3445 if you have further questions.

Sincerely,

[Handwritten signature of Thomas G. Grumbles]

Thomas G. Grumbles, C.I.H.
Environmental Quality Manager

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Attachment

cc Mike Cox

VVV 000009851

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

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

(b) An "interpretive guideline" is a draft regulatory proposal which has been published for the information, comment, and guidance of California businesses, law enforcement agencies and others concerned.

(c) A "safe use determination" is 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.

(d) An "information letter" is 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.

(e) The "lead agency" refers to the Health and Welfare Agency as designated by the Governor in Executive Order D-61-87, dated January 6, 1987.

Authority: Health & Safety Code Section 25249.12

Reference: Health & Safety Code Section 25249.12

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12103. 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

CHAPTER 3 SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986
ARTICLE 1 GUIDELINE AND SAFE USE DETERMINATION PROCEDURES

12101. General Practice

(a) It is the practice of the Health and Welfare Agency, as lead agency for implementing the Safe Drinking Water and Toxic Enforcement Act of 1986 (Health and Safety Code section 25249.5 et seq.) to answer inquiries of individuals and organizations, whenever appropriate, as to the application of the Safe Drinking Water and Toxic Enforcement Act of 1986 to their activities. One of 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.

Authority: Health & Safety Code Section 25249.12
Reference: Health & Safety Code Section 25249.12

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12102. Definitions

agency from making proposals for formal regulatory adoption which have not been published as interpretive guidelines.

Authority: Health & Safety Code Section 25249.12

Reference: Health & Safety Code Section 25249.12

12104. Safe Use Determinations

(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 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:

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(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, where two or more businesses which are members of the same trade association share

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 panel of qualified experts referred to in Health and Safety Code section 25249.8, a decision on the request will normally be made within 60 days. Where the proposed guideline is considered by the panel of qualified experts, a decision will normally be made not later than 30 days after the guideline is considered by the panel.

(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.

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(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

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.

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(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

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 Health and Safety Code section 25249.8.

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(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

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.

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(f) A request for safe use determination that appears to

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, 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 the 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.

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(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 Health and Safety Code section 25249.7(d).

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 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.

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Authority: Health & Safety Code Section 25249.12

Reference: Health & Safety Code Sections 25249.10 and 25249.12

ARTICLE 2 DEFINITIONS

12201. In The Course of Doing Business

(a) For purposes of Health and Safety Code sections 25249.5

and 25249.6 in the course of doing business

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 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 an 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 Notice Register and sent to

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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.

(c) Knowingly

"Knowingly" refers only to knowledge of the fact that a discharge of, release of, or exposure to a chemical listed pursuant to Health and Safety Code section 25249.8 (a) 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 Health and Safety Code sections 25249.5 or 25249.6.

(d) Discharge or Release to Water or Land

(1) The term "water" includes both surface and groundwater.

(2) A discharge or release into water or onto or into land which is in hydraulic continuity with a source of drinking water "probably" will pass to that source whether or not it is upgradient or upstream. For purposes of this paragraph, the ocean, saline bays, the Salton Sea, and Mono Lake, are not in hydraulic continuity with any source of drinking water unless such saline bodies are identified or designated in a water quality control plan adopted by a regional board as being suitable for domestic or municipal uses.

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(3) "Discharge or release into water or onto or into land" includes a discharge or release to air that is directly and

omission, whether or not for profit, except:

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

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

(b) "In the course of doing business" includes any act or omission of any employee which furthers the purpose or operation of the business, or which is expressly or implicitly authorized, except for the personal use, consumption or production of listed chemicals by an employee on the business premises or while performing activities for the business, unless the employer knows or should know of such use, consumption or production and knows or should know that such use, consumption or production will expose other individuals within the meaning of Health and Safety Code section 25249.6 to a listed chemical.

(b) Employee

The term "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.

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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

(e) Expose

The term "expose" means to cause to ingest, inhale, contact via body surfaces or otherwise come into contact with a chemical. An individual may come into contact with a chemical through water, air, food, consumer products and any other environmental exposure as well as occupational or workplace exposures.

(f) Threatened Illegal Discharge

A "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.

(g) Substantial Injury

The term "substantial injury" means a real and immediate physical injury or a resulting adverse physical condition of a substantial nature to one or more persons.

(h) General Public Knowledge

The term "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.

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

(4) Except as provided in paragraphs (5) and (6),
"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 Health and Safety Code section 25249.11 (a) for the purpose
of discharging or releasing the chemical to land or water in a
manner which, if committed by the transferor, would violate
Health and Safety Code § 25249.5.

(5) "Discharge or release into water or onto or into land"
does not include the sale, exchange or other transfer of a
chemical to a solid waste disposal facility as defined in
sections 66714 and 66719 of the Government Code, or a hazardous
waste facility as defined in 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.

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(6) "Discharge or release into water or onto or into land"
does not include the sale, exchange or other transfer of a
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.

members a Chairperson who will call and preside over meetings, and 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). The Chairperson, with the consent of the other Panel members, shall designate from among the Panel members such subcommittees as may be appropriate in fully discharging the responsibilities of the Panel.

(d) Except as otherwise expressly authorized by statute, all meetings of the Panel 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 an agenda of items of business to be transacted or discussed, has been provided. All official correspondence to or from the Panel, any subcommittee, or any member of the Panel shall be available for public inspection as provided in the Public Records Act.

(e) Panel members may be asked to provide advice and counsel both at formally convened Panel and subcommittee meetings and individually in response to written materials submitted to them by lead agency, the Executive Secretary, or the Governor. The Panel shall act as a body in making recommendations to the Governor or the lead agency. Questions posed to the members of the Panel shall be decided by a majority of those voting. However, no official action of the Panel may be taken unless at least one-half of the authorized number of members has voted on a question.

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Authority: Health & Safety Code Section 25249.12
Reference: Health & Safety Code Section 25249.8

12301. Definitions

(a) The "Scientific Advisory Panel" or the "Panel" refers to the Safe Drinking Water and Toxic Enforcement Act Scientific Advisory Panel.

(b) The "Act" refers to the Safe Drinking Water and Toxic Enforcement Act of 1986 (Health and Safety Code section 25249.5 et seq.) which was originally adopted by California voters as Initiative Measure Proposition 65 on November 4, 1986.

(c) The "lead agency" refers to the Health and Welfare Agency as designated by the Governor in Executive Order D-61-87, dated January 6, 1987.

Authority: Health & Safety Code Section 25249.12

Reference: Health & Safety Code Sections 25249.12 and 25249.8

12302. Scientific Advisory Panel

(a) There is created in the Health and Welfare Agency a Scientific Advisory Panel to advise and assist the Governor in the implementation of Health and Safety Code Section 25249.8. The Panel shall be the "state's qualified experts" as the term is used in that section.

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(b) The Panel shall be composed of twelve members. The members shall include experts in each of the following areas of specialization: epidemiology, oncology, pathology, reproductive toxicology, teratology, and toxicology. The members of the Panel shall be appointed by the Governor and shall serve at the pleasure of the Governor. Vacancies which occur on the Panel shall be filled only by the Governor.

(c) The Panel shall meet not less than once in any six-

(a) Determine whether specific chemicals are "known to the state to cause cancer or reproductive toxicity" pursuant to Health and Safety Code Section 25249.8(b).

(b) Identify bodies which are considered to be authoritative and which have formally identified carcinogens or reproductive toxicants.

(c) Identify specific chemicals that are 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.

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

(e) Review or propose standards, procedures and definitions related to the implementation, administration or interpretation of the Act upon request by the lead agency.

Authority: Health & Safety Code Section 25249.12

Reference: Health & Safety Code Section 25249.8

ARTICLE 5. EXTENT OF EXPOSURE

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12501. Exposure To Food

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

(a) The chemical is present in food as a result of washing, or preparing, or processing the food with drinking water which is received from a public water system as defined in Health and Safety Code section 4010.1 or from a commercial supplier of

Panel members shall be entitled to reimbursement for actual and necessary expenses incurred while attending meetings or otherwise carrying out the duties of the Panel. In addition, a Panel member who is not an officer or employee in the State Civil Service or an appointed state official shall be entitled to compensation for time spent on attending the Panel meetings and other actual and necessary work of the Panel, as determined by the lead agency and pursuant to a consulting services contract executed prior to appointment of the member to the Panel.

Authority: Health & Safety Code Section 25249.12

Reference: Health & Safety Code Section 25249.8

12304. Financial Disclosure

Upon appointment and annually thereafter, panel members shall 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. The disclosure made upon appointment shall cover the two-year period immediately prior to the date of appointment. Individuals serving in academic appointments shall also provide a description of funding sources for all significant research undertaken during the two years immediately prior to their appointment.

Authority: Health & Safety Code Section 25249.12

Reference: Health & Safety Code Section 25249.8

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12305. Duties

As an advisory body to the Governor and the lead agency, the

Reference: Health & Safety Code § 25249.6

12503. Environmental Exposures

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

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

(2) a commercial supplier of drinking water; or

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

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

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

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

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drinking water, or which meets state or federal primary drinking water standards for the chemical, provided that the responsible person has not added a listed chemical in excess of the no significant risk level to the drinking water; or

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

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

(2) The "naturally occurring" level of a chemical in food may be established by determining the natural background level of the chemical in the area in which the food is raised, or grown, or obtained, based on reliable local or regional data. VVV 000009871

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

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

Nothing in this section shall be construed to preclude a person from providing warnings other than those specified in subdivisions (b), (c), and (d) which satisfy the requirements of this subdivision, 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 subdivision 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.

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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.

received from the ambient air, and

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

Authority: Health & Safety Code § 25249.12

Reference: Health & Safety Code §§ 25249.6, 25249.11

12505. Miscellaneous.

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

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

Authority: Health & Safety Code § 25249.12

Reference: Health & Safety Code §§ 25249.6, 25249.11

ARTICLE 6. CLEAR AND REASONABLE WARNINGS

12601. Clear and Reasonable Warnings

VVV 000009873

(a) Whenever a clear and reasonable warning is required under section 25249.6 of the Health and Safety Code, 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.

the tables 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., or placed upon a menu or list in association with the alcoholic beverages listed therein and served at such premises.

3. sold or distributed through over the counter service, at least one sign, meeting the specifications set forth in paragraph D.1. of this subdivision, placed in the retail establishment so that it is readable and likely to be read from all counter locations available to the public.

(2) To the extent practicable, warning materials such as 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 WV 000009874 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 signs or notices. 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.

(3) The warnings provided pursuant to paragraphs (1)A. and (1)B.

1. primarily intended for consumption off the premises where sold or distributed, at least one square notice or sign, no smaller than 10 inches wide by 10 inches high, and bearing the warning message set forth in paragraph (4)E. of this subdivision. For signs 10 inches high by 10 inches wide, 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 54/60 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 three-quarters of an inch, and a bottom margin of at least one and one-quarter 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. Such sign shall be placed in the retail establishment so as to assure that it is readable and likely to be read either at the retail point of sale or each point of display. Signs or notices placed at the point of display shall be placed no more than ten feet from any display of any alcoholic beverage container in a manner associating the sign or notice with the display.

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2. provided for consumption on the premises at tables served by food or beverage persons, a notice or sign displayed at each of

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 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:

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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

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 & 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:

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"WARNING: This product may contain a chemical known to the State of California to

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 subdivision 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. A posting of signs in the manner described in section 6776,

(e)(1) of Title 3 of the California Code of Regulations shall be sufficient for purposes of this paragraph.

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B. A warning which is in a notice mailed or otherwise delivered to each occupant in the affected area. Such notice shall be

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 complies with all information, training and labeling requirements of the federal Hazard Communication Standard (29 CFR § 1910.1200), the California Hazard Communication Standard (8 CCR § 5194), or, for pesticides, the Pesticides and Worker Safety requirements authorized in Food and Agricultural Code section 12980 and following (3 CCR § 6700, et seq.).

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

(3) For purposes of paragraph (1)B. of this subdivision, 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:

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"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

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

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

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

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

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

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

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

(c) The chemicals, routes of exposure and conditions of use

provided at least once in any three-month period.

C. 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 paragraph (1)A. of this subdivision, 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."

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Authority: Health and Safety Code section 25249.12

Reference: Health and Safety Code sections 25249.6, 25249.11

ARTICLE 7. No Significant Risk Levels

12701. General.

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

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

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

(5) The absence of a carcinogenic threshold dose should be assumed and no-threshold models shall be utilized. In the absence of other scientifically appropriate extrapolation models, methods utilizing the linearized multistage model for extrapolation from high to low doses, with the upper 95 percent confidence limit of the linear term the most appropriate for expressing the upper bound of potency are preferred. Time-to-tumor models may be appropriate where data are available on the time of appearance of individual tumors, and particularly when survival is poor due to competing toxicity.

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(6) Human cancer potency may be derived from data on human or animal cancer potency. Potency shall be expressed in milligrams of chemical per kilogram of bodyweight per day. Interspecies

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

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

12703. Quantitative Risk Assessment.

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

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

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

(b) (reserved)

(c) Whenever the lead agency proposes to formally adopt a level at which a chemical known to the state to cause cancer which poses no significant risk established solely for the purposes of the Safe Drinking Water and Toxic Enforcement Act of 1986, it shall provide to each member of the Scientific Advisory Panel notice of the proposed action, a copy of the proposed level, and a copy of initial statement of reasons supporting the proposal. The close of the public comment period for any such proposal shall be scheduled by the lead agency so as to permit the Scientific Advisory Panel the opportunity to review such proposal and provide comment to the lead agency. Any such comment by the Scientific Advisory Panel shall become a part of the formal rulemaking file. Nothing in this subdivision shall be construed to prevent members of the Scientific Advisory Panel from providing comments individually on any such proposal, or to require the Scientific Advisory Panel to submit any comment.

12707. Routes of Exposure

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(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

conversion of animal cancer potency to human cancer potency may be determined by multiplying by a surface area scaling factor equivalent to the ratio of human to animal bodyweight, taken to the one-third power. Alternatively, a scaling factor of 14 may be used when extrapolating from mouse data, and a scaling factor of 6.5 may be used when extrapolating from rat data.

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

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

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

(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.

VVV 000009885

or 12713, levels of no significant risk may be determined as follows:

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

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

<u>Chemical Name</u>	<u>Level (micrograms/day)</u>
<u>Acrylonitrile</u>	<u>3</u>
<u>Asbestos</u>	<u>100 fibers inhaled/day</u> <u>140 million fibers ingested/day</u>
<u>Benzene</u>	<u>20</u>
<u>Benzidine</u>	<u>0.003</u>
<u>Benzo(a)pyrene</u>	<u>0.06</u>
<u>Bis(chloromethyl)ether</u>	<u>0.6</u>
<u>Carbon tetrachloride</u>	<u>5</u>
<u>Chloroform</u>	<u>9</u>
<u>Chromium (hexavalent)</u>	<u>0.001</u>
<u>Coke oven emissions</u>	<u>0.3</u>
<u>DDT</u>	<u>2</u>
<u>3-3'-Dichlorobenzidine</u>	<u>0.4</u>
<u>Epichlorohydrin</u>	<u>70</u>
<u>Ethylene dibromide</u>	<u>3</u>
<u>Ethylene dichloride</u>	<u>9</u>
<u>Ethylene oxide</u>	<u>2</u>
<u>Hexachlorobenzene</u>	<u>0.4</u>
<u>Hexachlorocyclohexane (technical grade)</u>	<u>0.4</u>
<u>Nickel refinery dust</u>	<u>0.8</u>
<u>Nickel subsulfide</u>	<u>0.4</u>
<u>N-Nitrosodi-n-butylamine</u>	<u>0.1</u>
<u>N-nitrosodiethylamine</u>	<u>0.02</u>
<u>N-nitrosodimethylamine</u>	<u>0.03</u>
<u>N-Nitrosopyrrolidine</u>	<u>0.3</u>
<u>N-nitroso-N-ethylurea</u>	<u>0.02</u>
<u>N-nitroso-N-methylurea</u>	<u>0.002</u>

VVV 000009886

cancer at levels of exposure not in excess of current regulatory levels, the lead agency may identify the chemical as presenting no significant risk by that route of exposure. Any exposure, discharge or release of a chemical so identified shall be deemed to present no significant risk to the extent that it results in exposure to humans by the identified route, and does not exceed the level established in any other applicable federal or state standard, regulation, guideline, action level, license, permit, condition, requirement or order.

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

(1) Beryllium and beryllium compounds

(2) Cadmium and cadmium compounds

(3) Chromium (hexavalent compounds)

12709. Exposure To Trace Elements.

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

(b) Element

No Significant Risk Level
in micrograms per day

Arsenic (inorganic)

10

Beryllium

0.1

Cadmium

1

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12711. Levels Based on State or Federal Standards.

subsection (h) of section 321 of Title 21 of the United States Code (21 USC § 321 (h)).

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

(c) Except as otherwise provided in section 12705, exposure to a chemical known to the state to cause cancer and present in a food, drug, medical device, or cosmetic (including constituents and contaminants) shall be deemed to pose no significant risk within the meaning of Health and Safety Code section 25249.10(c), provided that:

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

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(2) the chemical is a food substance identified by the federal Food and Drug Administration or the California Department of Health Services to be generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific

<u>Polychlorinated Biphenyls (PCBs)</u>	<u>0.09</u>
<u>Tetrachlorodibenzo-p-dioxin (TCDD)</u>	<u>0.000005</u>
<u>Toxaphene</u>	<u>0.6</u>
<u>2,4,6-Trichlorophenol</u>	<u>40</u>
<u>Vinyl chloride</u>	<u>0.3</u>

12713. Exposure to Food, Drugs, Cosmetics and Medical Devices.
The Health and Welfare Agency has determined, based on the
recommendation of the Scientific Advisory Panel, that exposure to
a listed chemical in a food, drug, cosmetic or medical device
regulated under state and federal food safety laws poses no
significant risk as described in this section. This section is
an interim standard. As quantitative risk assessments are
performed or identified for listed chemicals and specific
regulatory levels are adopted under section 12705, those levels
will supersede the provisions of this section.

(b) For purposes of this section:

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

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

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

(4) "Medical device" shall have the same meaning as set forth in

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

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

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

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

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procedures (or in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use, and is in compliance with all applicable administrative standards.

(3) the chemical is a food substance used in accordance with a sanction or approval granted prior to January 1, 1958 pursuant to the federal Food, Drug and Cosmetic Act, the Poultry Products Inspection Act (21 U.S.C. 451, et seq.), or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. 71, et seq.), and is in compliance with all applicable administrative standards.

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

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

(6) the chemical is a pesticide chemical within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act (7

given medium of exposure measured over a lifetime of seventy years.

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

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

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

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

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

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

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

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

B. For an exposure reasonably expected to affect the conceptus

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

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

12721. Level of Exposure to Carcinogens.

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

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

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

ARTICLE 8. No Observable Effect Levels

12801. General.

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

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

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

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

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

(embryo or fetus), the gestation period for the exposed conceptus is nine months.

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

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

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

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

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

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

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

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(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 50 kilograms shall be assumed.

12803. Assessment.

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

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

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

of a concentration of a chemical in a given medium) times the reasonably anticipated rate of exposure for an individual to a given medium. The reasonably anticipated rate of exposure shall be based on the pattern and duration of exposure that is relevant to the reproductive effect which provided the basis for the determination that a chemical is known to the state to cause reproductive toxicity. (For example, an exposure of short duration is appropriate for a teratogenic chemical, whereas a chronic or protracted exposure is appropriate for one that retards fetal growth.)

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

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

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

12805. Specific Regulatory Levels: Reproductive Toxicants.

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

<u>(b)</u>	<u>Chemical Name</u>	<u>Level(Micrograms/day)</u>
	<u>Ethylene Oxide</u>	<u>20.0</u>
	<u>Lead</u>	<u>0.5</u>

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

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12821. Level of Exposure to Reproductive Toxicants.

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

(b) For purposes of Health and Safety Code section 25249.10(c), the level of exposure to a listed reproductive toxicant shall be determined by multiplying the level in question (stated in terms

has been adopted, is employed or is generally accepted by the scientific community, and a scientifically valid analytical method has been developed for the detection or measurement of a listed chemical in a specific medium, including, but not limited to, water, air, food or soil, such method shall be the analytical method for that chemical in that medium. Where more than one method has been developed for a chemical in a specific medium, each may be utilized as the method of analysis.

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

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Eating Occasion, where such data are available.

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

ARTICLE 9. MISCELLANEOUS

12901. Methods of Detection

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

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

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(c) Where no method of analysis as described in subsection (b)