FINAL
STATEMENT OF REASONS
22 CALIFORNIA CODE OF REGULATIONS DIVISION 2

Section 12902.
Formally Required to be Labeled or Identified As
Causing Cancer or Reproductive Toxicity

The Safe Drinking Water and Toxic Enforcement Act of 1986 (Act) was adopted as an initiative measure (Proposition 65) by California voters on November 4, 1986. The Act imposed new restrictions on the use and disposal of chemicals which are known to the State to cause cancer or reproductive toxicity.

Part of the Act specifically prohibits persons in the course of doing business (as defined) from knowingly discharging or releasing such chemicals into the environment in a manner so that such chemicals pass or probably will pass into any source of drinking water (Health & Saf. Code, sec. 25249.5). (Unless otherwise specified, all statutory section references are from the Health and Safety Code.) It further prohibits such persons from knowingly and intentionally exposing any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving a clear and reasonable warning. (sec. 25249.6.)

Under the Act, a chemical is known to the state to cause cancer or reproductive toxicity within the meaning of the Act (1) if in the opinion of the state's qualified experts it has been clearly shown through scientifically valid testing according to generally accepted principles to cause cancer or reproductive toxicity, or (2) if a body considered to be authoritative by such experts has formally identified it as causing cancer or reproductive toxicity, or (3) if an agency of the state or federal government has formally required it to be labeled or identified as causing cancer or reproductive toxicity. (sec. 25249.8(b).)

The Act requires the Governor to cause to be published a list of those chemicals known to the state to cause cancer or reproductive toxicity within the meaning of the Act, and to cause this list to be revised and republished in light of additional knowledge at least once per year. (sec. 25249.8(a).)

One year after the date the Governor lists a chemical known to the state to cause cancer or reproductive toxicity, the warning requirement of section 25249.6 becomes applicable to the chemical. Twenty months after the date of listing, the discharge prohibition applies to the chemical. Violations of the Act may be enjoined and made subject to a civil penalty not to exceed

$2500 per day for each such violation, in addition to any other penalty established by law.

The Act requires the Governor to identify and consult with the state's qualified experts as necessary to carry out his duty regarding the list. (sec. 25249.8(d).) The Act further requires that the Governor designate a lead agency, and such other agencies as may be required to implement the provisions of the Act. These agencies are authorized to adopt and modify regulations, standards, and permits as necessary to conform with and implement the provisions of the Act and to further the purposes of the Act. (sec. 25249.12.)

By Executive Order D-61-87, the Governor designated the Health and Welfare Agency ("Agency") as the lead agency for the implementation of the Act (sec. 25249.12). The Agency subsequently adopted section 12302 of Title 22 of the California Code of Regulations, which created in the Health and Welfare Agency the Scientific Advisory Panel (Panel) as the "state's qualified experts" to advise and assist the Governor in the implementation of section 25249.8.

Presently, the primary way by which chemicals have been added to the Governor's list is by actions of the Panel. This proposed regulation would interpret, clarify, and make specific that portion of Section 25249.8(b) of the Act which relates to the listing of chemicals that are formally required by a state or federal agency to be labeled or identified as causing cancer or reproductive toxicity.

Procedural Background

On October 3, 1989, the Agency issued a notice of rulemaking advising that the Agency intended to adopt Title 22, section 12902 (hereinafter "original version"). Notices were also issued that the Agency intended to adopt or amend three other regulations implementing the Act. Pursuant to such notices a public hearing was held on November 28, 1989, to receive public comments on the proposed regulations, including section 12902. Out of 23 pieces of correspondence received commenting on the regulations, and two exhibits submitted at the hearing, six contained comments regarding section 12902.

On January 8, 1990, the Agency issued a Notice of Public Availability of Changes to Proposed Regulations Regarding the Safe Drinking Water and Toxic Enforcement Act of 1986 (hereinafter the final version"). The notice afforded interested parties the opportunity to comment on proposed modifications to the original version which were made in response to public comment. The comment period for the January 8 proposal closed January 23, 1990. One piece of correspondence was received.

Purpose of Final Statement of Reasons

This final statement of reasons sets forth the reasons for the final language adopted by the Agency for section 12902 and responds to the objections and recommendations submitted regarding that section. Government Code section 11346.7, subsection (b)(3) requires that the final statement of reasons submitted with an amended or adopted regulation contain a summary of each objection or recommendation made regarding the adoption or amendment, together with an explanation of how the proposed action has been changed to accommodate each objection or recommendation, or the reasons for making no change. It specifically provides that this requirement applies only to objections or recommendations specifically directed at the Agency's proposed action or to the procedures followed by the Agency in proposing or adopting the action.

Some parties included in their written or oral comments remarks and observations about these regulations or other regulations which do not constitute an objection or recommendation directed at the proposed action or the procedures followed. Also, some parties offered their interpretation of the intent or meaning of the proposed regulation or other regulations, sometimes in connection with their support of or decision not to object to the proposed action. Again, this does not constitute an objection or recommendation directed at the proposed action or the procedures followed. Accordingly, the Agency is not obligated under Government Code section 11346.7 to respond to such remarks in this final statement of reasons. Since the Agency is constrained by limitations upon its time and resources, and is not obligated by law to respond to such remarks, the Agency has not responded to these remarks in this final statement of reasons. The absence of response in this final statement of reasons to such remarks should not be construed to mean that the Agency agrees with them.

Specific Findings

Throughout the adoption process of this regulation, the Agency has considered the alternatives available to determine which would be more effective in carrying out the purpose for which the regulation was proposed, or would be as effective and less burdensome to affected private persons than the proposed regulation. The Agency has determined that no alternative considered would be more effective than, or as effective and less burdensome to affected persons than, the adopted regulation.

The Agency has determined that the regulation imposes no mandate on local agencies or school districts.

Rulemaking File

The rulemaking file submitted with the final regulation and this final statement of reasons is the complete rulemaking file for section 12902. However, because regulations other than section 12902 were also the topic of the public hearing held on November 28, 1990, the rulemaking file contains some material not relevant to section 12902. This final statement of reasons cites only the relevant material. Comments regarding the regulations other than section 12902 discussed at the November 28, 1990, hearing will be discussed in separate final statements of reasons.

Necessity for Adoption of Regulation

The Agency has determined that it is necessary to interpret, clarify, and make specific section 25249.8 of the Act with regard to chemicals formally required by a state or federal agency to be labeled or identified as causing cancer or reproductive toxicity. This is because the discharge prohibition and warning requirement of the Act apply only to chemicals known to the state to cause cancer or reproductive toxicity, and that portion of section 25249.8 which is the subject of this regulation contains several terms which are subject to differing constructions. This regulation provides uniform definitions and establishes a process by which the lead agency can evaluate chemicals for listing pursuant to this provision of the Act.

Subsection (a)

Subsection (a) restates the relevant portions of section 25249.8, and provides that the lead agency will determine which chemicals have been formally required by an agency of the state or federal government to be labeled or identified as causing cancer or reproductive toxicity.

One commentor noted that the regulation did not actually state that the lead agency would list a chemical that it had determined was formally required by a state or federal agency to be labeled or identified as causing cancer or reproductive toxicity. (C-22 page 1-2.) This commentor acknowledged that the Initial Statement of Reasons indicated that the Health and Welfare Agency intended such a result but had not specifically included the listing step when drafting the regulation.

This commentor was correct. The Act itself requires listing of any chemical known to the state to cause cancer or reproductive toxicity by any of the routes set forth in Section 25249.8 (see discussion on pages 1-2 of this document). However, it seemed preferable to eliminate the possibility of any such misunderstanding and the final version of subsection (a) was changed to specifically state the duty to list.

Subsection (b)

Subsection (b) sets forth the definitions contained in relevant portions of the Act and used in the regulation.

Paragraph (1) of that subsection defines the lead agency as being the Health and Welfare Agency. Since the lead agency is designated by executive order, it is necessary to let the reader know the identity of the current lead agency and also to provide for the possibility that the Governor might designate another lead agency. The wording of paragraph (1) eliminates the need for an amendment to the regulation if the lead agency is changed.

Paragraph (2) defines an agency of the state or federal government. In light of the broad goals of the Act in terms of listing known carcinogens and reproductive toxicants, the definition of government agency was made very broad so that any segment thereof which is or may become empowered to make such determinations could be considered within this provision.

One commentor felt that the definition of what constitutes a federal or state agency was too broad and should be restricted to those which have an appropriate level of scientific expertise, not merely statutory or regulatory authority. The Congress and the State Legislature were cited by this commentor as examples of entities which do not have such scientific expertise. (C-19 Page 1.) The Agency disagrees. The Act does not impose any such requirement and the Agency does not have the legal authority to change the clear language of the statute.

Paragraph (3) defines the phrase "has formally required." The definition makes it clear that the regulation applies only to requirements of labeling or identification imposed by the government agency against a person or other legal entity outside of the agency involved. An agency's identification of a chemical as a carcinogen or reproductive toxicant by itself is not an action that meets this definition. The rest of this definition provides that the method of imposing the formal requirement is up to that agency and any policies or procedures established by the agency in question will be recognized by the lead agency.

Four commentors objected to this approach whereby the Agency would defer to the state or federal agency in question in terms of the way that such agency came to a decision to formally require labeling or identification. (C-13, C-18, C-19, C-20.)

Two of these commentors felt that the regulation should be amended to include consultation with the Scientific Advisory Panel as a requirement prior to a final decision to list a chemical under this section. (C-18 Page 3; C-19 Page 1.)

One of these commentors felt that the regulation was too broad and should be revised to conform more closely with the approach the Agency proposed in section 12306, Title 22, California Code of Regulations for implementing the "authoritative body" portion of Section 25249.8. (C-13 Pages 2-5.) This commentor stated that a federal agency rule may require that a chemical be identified as posing a known or suspected risk of cancer, even though the federal agency itself has not reviewed the data or reached an independent determination of whether the chemical is indeed a known or suspected carcinogen. The commentor claimed that sometimes an agency will have indeed examined the cancer causing potential of a substance and come to its own determination. However, in other cases, the commentor stated that a federal agency may be merely recognizing determinations made by other agencies or entities.

This commentor believed that, without having evaluated the chemical on its own, the Agency should not conclude that a federal or state agency has formally required the chemical to be labeled or identified as causing cancer. Alternatively, this commentor recommended that section 12902 could be revised to provide that where a federal or state labeling requirement is predicated solely on the scientific findings of someone other than the government agency in question, section 12902 would not be invoked to list a chemical unless the chemical also satisfies the "formal identification" criteria set forth in the authoritative bodies regulation (section 12306).

The last of these four commentors stated that, under a reasonable reading of the plain meaning of the Act section 25249.8(b) must be seen as referring to those state or federal label or identification requirements that are based particularly on some formal scientific finding of causation of either cancer or reproductive toxicity. This commentor felt that the statute cannot be interpreted as requiring listing of chemicals which are required to be labeled or identified without a government agency finding of carcinogenicity or reproductive toxicity. (C-20 Page 11.)

This same commentor also believed that, unlike the process for listing chemicals by way of the Scientific Advisory Panel or by the authoritative bodies provision, the proposed regulation does not have as its basis the application of scientific principles nor is there a provision for public review and comment of those decisions. The commentor stated that the regulation should include scientific criteria or procedures for designating chemicals to be added to the Proposition 65 list. At a minimum, the commentor felt that this regulation should be amended to provide for public development of scientific standards and criteria for possible listing, and procedures should be included that ensure opportunity for public notice and comment as specific chemicals are considered for listing under this regulation. (C-20 Pages 5-6, 13-14, 18-22, 24.)

The Agency interprets Section 25249.8 quite differently than did these four commentors. The Agency believes that the plain meaning of the statute is clear. The provision of the Act which underlies this regulation is clearly intended to be a totally separate and distinct method of listing chemicals under the Act. The provision was designed to recognize the determinations of other federal and state agencies and does not contain any authority by which the Agency could impose a requirement of making an independent determination of carcinogenicity or reproductive toxicity. The only question which is relevant is whether a state or federal government agency possessing the requisite legal authority, has formally required a third party to label or identify a chemical as causing cancer or reproductive toxicity. Once that question has been answered in the affirmative, listing of the chemical must occur. As a result, the Agency has made no change in the regulation in response to these comments.

Paragraph (4) specifies what the lead agency will consider to be a "label." Since the Act does not define "label", it has been presumed that a broad definition was intended. The definition is designed to cover the wide variety of product packaging which may be encountered. The lead agency's intent in adopting this definition is to avoid having determinations made using technical distinctions which frustrate the intent of the Act.

One commentor stated that paragraph (4) went beyond the intent of the Act. (C-14 page 1.) This commentor felt that, as currently written, this regulation would recognize statements contained in a Material Safety Data Sheet (MSDS) formally required by the Federal Occupational Safety Health Administration (OSHA) as well as a Pesticide Safety Information Sheet (PSIS) required by the California Department of Food and Agriculture. This commentor felt that neither of these documents should fall within the definition of a "label" as described in the proposed regulation. The commentor recommended that the regulation should be rewritten to exclude from the definition of a "label" any of these documents or any other similar document designed to convey general information about a chemical's properties. One other commentor raised the same issue and made a similar recommendation but specifically mentioned only the MSDS. (C-18 Pages 1-2.)

The Agency has made no change in this provision because an MSDS and a PSIS are among the types of material which the Agency intended to include within the definition of "labeled." Since these two documents are a primary method of communicating safety and health information to potentially affected individuals, including these documents within the scope of the regulation is well within the scope of the stature as either a required label, required identification, or both.

The definition of "identified" contained in paragraph (5) is likewise intended to be interpreted broadly. The method of transmitting a required warning message is irrelevant. Furthermore, it is irrelevant whether or not the warning is placed or given in physical proximity to the chemical.

One commentor noted that the original version of paragraph (5) referred to "the required message". This commentor suggested that it should instead refer to "a required message."

(matching the wording of that portion of paragraph (4)), in order to avoid any conclusion that only a particular type or form of message might trigger a finding under the regulation. (C-22 Page 4.) The Agency agreed with that recommendation and made that change in the final version of the regulation.

Paragraph (6) contains the definitions of the type of warning message which will be considered as "causing cancer or reproductive toxicity." The definitions are intentionally phrased in a generic manner because currently, there is no uniform or standard message or format for either cancer or reproductive toxicity health warnings. Different statutes, regulations, and standards have required quite different wording and manner of presentation for the same or similar risk. In some situations, no particular words are expressly required. The definitions contained in this regulation are therefore to be interpreted in the broadest sense that will meet the Act's requirement of listing those chemicals which a state or federal government agency has determined to cause cancer or reproductive toxicity and thereafter required third parties to provide warnings concerning the risk posed by those chemicals.

It is specifically not intended that the definitions contained in paragraph (6) be interpreted as needing to be consistent with the definitions which may be used by the Scientific Advisory Panel or an authoritative body which that Panel might designate. The lead agency is interpreting the provision of the Act to which this regulation relates as accepting the definitions which are used by the state or federal government agency involved.

Three commentors felt that the definition in the original version of this regulation relating to "causing cancer" (listed in subsection (b)(6)(A)) was far too broad based on a review of the definitions used by all other state or federal agencies as well as compared to previous determinations under the Act. (C-14 Page 1; C-18 Pages 2-3; C-19 Page 1.) These three commentors felt that the original version of the definition would have required the listing of a chemical even if there was only a suspected risk of cancer in animals. They recommended that the regulation be revised to limit its application to those chemicals for which there was a known or probable risk of cancer in humans. (C-14 Page 1; C-18 Pages 2-3; C-19 page 1.) One of these commentors specifically recommended that "suspected risk" should be replaced with "probable risk", all references to "tumors" should be stricken, and the reference to "animal" should be deleted. (C-19 Page 1)

In response to these objections, the Agency changed the definition of "causing cancer" in the final version of the regulation. "Probable" and "suspected" were both dropped as well as the reference to "animals." The reference to "tumors" was retained. The phrase "refers to" was replaced with a more specific phrase "uses any words or phrases intended to communicate." This new definition has addressed most of the specific objections raised by these commentors.

The Agency did not go so far as to limit the regulation to only known human carcinogens because such an approach does not appear to be applicable to a listing under 25249.8(b). Further, such a limitation would be contrary to generally accepted scientific principles of cancer risk assessment. It is obvious that performing cancer studies on humans must be limited to the gathering of data. Intentional exposure of test animals to chemicals is the only currently available scientific method for performing controlled experiments about the carcinogenicity and dose response relationship of specific cancer suspect agents. Such studies would result in a finding that a particular chemical may cause cancer in humans when the chemical has been found to cause cancer or tumors in animals, or, in some cases, when there is a scientifically valid basis for assuming that the chemical is carcinogenic, based upon other considerations about the chemical (e.g., its structure or biological considerations).

Four commentors felt that the definition in the original version of this regulation relating to "causing . . . reproductive toxicity" (listed in subsection (b)(6)(B)) was far too broad based on a review of the definitions used by all other state or federal agencies as well as compared to previous determinations under the Act. (C-14 Page 1; C-18 Pages 2-3; C-19 Page 1; C-20 Pages 2-4, 10-18, 23.)

Two of these commentors felt that, as currently written, the regulation could have the effect of requiring the listing of all non-prescription drugs which currently bear the federally required pregnancy-nursing warning. (C-14 page1; C-20 Pages 2-4, 10-18, 23.) The wording of that warning message is:

> "as with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product."

One of these commentors felt that, for many of these substances, there is no scientific evidence whatsoever that they cause reproductive toxicity but have merely been required by the United States Food and Drug Administration (FDA) to carry the pregnancy-nursing warning solely because they are designed for systemic absorption. The commentor believes that such a wholesale incorporation of chemicals onto the list would be scientifically indefensible.

The commentor stated that the federal pregnancy-nursing warning was adopted by the FDA to encourage pregnant or nursing women to seek advice on whether to use a particular over-the-counter (OTC) drug from a knowledgeable health professional capable of assessing her situation with respect to that drug. The commentor stated that the FDA stressed that the regulation was promulgated as a general preventive measure to educate the public about drug use, and not because there was scientific evidence establishing that a given OTC drug ingredient would cause harm to the fetus or nursing infant. This commentor recommends that subsection (b)(6)(B) should be clarified so that chemicals in non-prescription drugs intended for systemic absorption are not mechanically deemed to cause reproductive toxicity for purposes of the Act. (C-20 Pages 2-4, 10-18, 23)

This commentor also stated that the federal pregnancy/nursing warning constitutes federal law that expressly governs in a manner that pre-empts state authority over OTC drugs with respect to the reproductive toxicity issue. The commentor was of the opinion that this express administrative pre-emption must be given force and effect under the plain language of section 25249.10(a) of the Act. (C-20 Pages 22-23)

Turning first to the issue of federal pre-emption discussed in the previous paragraph, the Agency has concluded that no express or implied pre-emption was intended. The commentor apparently considered that FDA restrictions on a state imposed labeling requirement meant that the OTC products which carry the pregnancy-nursing warning could not be held to the warning requirements of the Act. However, the Act requires only that a warning be given when an exposure is involved; the method of providing the warning is up to the person responsible for the exposure.

With regard to the language of the definition of causing reproductive toxicity, the Agency agrees that the Act cannot be interpreted as requiring listing of the pregnancy-nursing warning label products under the "formally required to be labeled or identified" as causing cancer or reproductive toxicity portion of the Act. The language of the federal pregnancy-nursing warning label is obviously just a general health information message directed at pregnant and nursing women. It makes no reference to causing anything or involving any kind of specific risk. The Agency certainly never intended to have this regulation be applied to a label with the wording of the pregnancy-warning message. As a result, the final version modified the definition about causing reproductive toxicity to more carefully express that intent.

Subsection (c)

Subsection (c) provides the mechanism by which a person can petition the lead agency to consider a chemical for listing under this section. Since there is no way to guarantee that the lead agency would know of all chemicals which are potentially covered by this section, this subsection provides a formal mechanism by which persons can bring such information to the attention of the lead agency. The person filing the petition is required to include substantial evidence relevant to the determinations which would be made under this section so that the lead agency will have a reasonable amount of documentation with which to proceed.

One commentor felt that the public petition process specified in subdivision (c) did not require the Agency to take any action by any particular time. The commentor felt that as a result, the Agency could indefinitely consider such a petition and thereby fail to give effect to this provision of the law. (C-22 Page 3) The Agency decided to make no change in the language because the purpose of the provision was strictly to establish appropriate controls over such submissions so that the Agency can be reasonably assured that the time it will spend evaluating such a request for listing will have some chance of success. Otherwise, much time could be spent researching vague assertions that had no basis in fact. Since there is no way to predict in advance how much time might be necessary to research and evaluate a request for listing under this subsection, it would not be appropriate to specify a particular processing time.

Another commentor felt that subsection (c), which would allow any person to petition for the listing of a chemical under the Act, is unnecessary and should be deleted. The commentor stated that anybody can write the Agency regarding one of its determinations and encouraging petitions from the general public on such a highly technical scientific matter jeopardizes the objectiveness of the listing proceee by opening it up to those who may have "a special ax to grind" against a specific chemical. (C-19 Page 2)

While the Agency agrees that the public always has a right to communicate with state government, the Agency does not agree that setting appropriate guidance on what to submit will somehow jeopardize the objectivity of Agency staff. As stated above, setting certain controls over submissions is necessary in order to protect against the potential waste of valuable government staff resources.

Subsection (d)

Subsection(d) provides specific authority for the lead agency to rescind or modify a determination made previously under this section. Such an action would be taken in situations when information not previously considered indicates that a change in the earlier action would be appropriate.

One commentor felt that subsection (d) did not specify what that additional information must show or what facts such information must address. (C-22 Page 2) The Agency did not make any change in the provision because it was felt that there was not a need to be any more specific. The information which could support a decision to rescind or modify would obviously have to be relevant to the basis for the original findings and decision to list. Any information which could have affected a decision to not list under this section could serve as the basis for rescinding or modifying the original action.

Post Hearing Comments

There was one piece of correspondence received commenting on the changes made to the original version of the regulation. That single communication was filed by a commentor who filed essentially the same material and comments as part of its submission regarding the original version. As a result, the reader is directed to the Agency's responses to comments filed by commentor C-20.

Conclusion

The final version of the regulation reflects a consideration of all the comments received during the adoption process and of the circumstances under which the listing of a chemical under this regulation would be accomplished. The Agency believes that this final version is a necessary and helpful clarification of the requirements of the Act.