FINAL
STATEMENT OF REASONS
22 CALIFORNIA CODE OF REGULATIONS DIVISION 2

Section 12306 - Chemicals Formally identified by Authoritative Bodies

The Safe Drinking Water and Toxic Enforcement Act of 1986 (Health & Saf. Code, sec. 25249.5, et seq.) (hereinafter the "Act") was adopted as an initiative statute at a general election on November 4, 1986. The Act prohibits any person in the course of doing business from knowingly discharging or releasing a chemical known to the state to cause cancer or reproductive toxicity into water or onto or into land where such chemical passes or probably will pass into a source of drinking water. (Health & Saf. Code, sec. 25249.5.) 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. (Health & Saf. Code, sec. 25249.6.)

Under the Act, a chemical is known to the state to cause cancer or reproductive toxicity (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, (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. (Health & Saf. Code, 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, and to cause this list to be revised and republished in light of additional knowledge at least once per year. (Health & Saf. Code, sec. 25249.8(a).) The Act also requires the Governor to identify and consult with the state's qualified experts as necessary to carry out his duty regarding the list. (Health & Saf. Code, 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 further the purposes of the Act. (Health & Saf. Code, 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. The Agency subsequently adopted section 12302 of Title 22 of the California Code of Regulations, which created in the Agency the Scientific Advisory Panel (Panel as the "state's qualified experts" to advise and assist the

Governor in the implementation of Health and Safety Code section 25249.8. As an advisory body to the Governor and the lead agency, the Panel was authorized (1) to 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), and (2) to identify bodies which are considered to be authoritative and which have formally identified carcinogens or reproductive toxicants. (22 C.C.R., sec. 12305, subd. (a) and (b).)

One year after the date a chemical is added to the list of chemicals known to the state to cause cancer or reproductive toxicity, the warning requirement of Health and Safety Code section 25249.6 becomes applicable to the chemical. Twenty months after the date of listing, the discharge prohibition applies to the chemical. Violations af 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 purpose of this proposed regulation is to implement and make specific the provision of Health and Safety Code section 25249.8 which provides that a chemical is known to the state to cause cancer or reproductive toxicity "if a body considered to be authoritative by [the Panel] has formally identified it as causing cancer or reproductive toxicity."

Procedural Background

The concept of this regulation was conceived following the Panel's meeting of October, 1987. In that meeting, the Panel expressed strong reservations about designating any body as authoritative due to its concern that the designation would result in the unrestrained listing of chemicals. Consequently, the Agency determined that it would be necessary to implement and make specific the provisions of the Act relating authoritative bodies to enable the Panel to take advantage of this listing mechanism. Subsequently, the Agency commenced drafting this regulatory proposal. Copies of early proposals were circulated to interested persons and the Panel.

On April 14, 1989, following a command from the Sacramento Superior Court, the Panel considered the question whether the United States Environmental Protection Agency (EPA) is an "authoritative body" within the meaning of the Act and concluded that EPA is authoritative, but conditioned the designation upon application of certain controls to the listing of chemicals pursuant to that designation, and asked the Agency to draft rules embodying these controls. The terms of the condition were similar to the controls in the draft regulatory proposal. Subsequently, on July 17, 1989, the Agency proposed section 12306 for adoption.

Public hearing on the proposed regulation was held on September 13, 1989. Fourteen written comments were submitted. The Agency reviewed these comments and the regulation, and on October 13, 1989, noticed proposed changes to the regulation. One post-hearing comment was received. In response to that comment, and based upon the Agency's own continuing review, further proposed changes were noticed on December 13, 1989. The commentor on the October 13 notice orally resubmitted its comment in response to the December 13 notice, and one additional comment was received.

Necessity for the Regulation

The regulation is necessary because the language of section 25249.8 contains several terms which are subject to differing constructions. The Panel has expressed serious concerns about what would constitute an "authoritative body," about what constitutes "formal identification," and about which chemicals would be identified as "causing cancer or reproductive toxicity." Persons subject to the Act, and persons enforcing the Act, need to know specifically which chemicals are subject to the Act.

Purpose of Final Statement of Reasons

This final statement of reasons sets forth the reasons for the final language adopted by the Agency section 12306, and responds to the objections and recommendations submitted regarding that section as originally proposed in the July 17 proposal and modified by the October 13 and December 13 proposals. 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 or 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 regulations or other regulations, sometimes in connection with their support of or decision not to object to the July 17, the October 13, or December 13 proposals. 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 lead 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 regulations were proposed, or would be as effective and less burdensome to affected private persons than the proposed regulations. 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

The rulemaking file submitted with the final regulation and this final statement of reasons is the complete rulemaking file for section 12306. However, because regulations other than section 12306 were also the topic of the public hearing on September 13, 1989, the rulemaking file contains some material not relevant to section 12306. This final statement of reasons cites only the relevant material. Comments regarding the regulations other than section 12306 in comments submitted concurrently have been or will be discussed in separate final statements of reason.

SECTION 12306

Subsection

Subsection (a) of the proposed regulation restates the relevant portions of Health and Safety Code section 25249.8, and provides that the designation of authoritative bodies and of chemicals formally identified as causing cancer or reproductive toxicity shall be conducted as described in section 12306. This makes clear that the definitions and procedures described in the regulation will govern the listing of chemicals pursuant to the designation of a body which the Panel considers to be authoritative.

One commentor recommended that the Agency add at the end of subsection (a) ", and it has been clearly shown through scientifically valid testing to cause cancer or reproductive toxicity." (C-13, p. 5.) In effect, the adoption of this recommendation would require that each chemical which has been formally identified by a designated authoritative body meets the same criteria which the Panel would apply if the Panel were considering the chemical individually. In other words, there

would need to be some scientific review prior to the listing of the chemical, presumably conducted by the Panel. As discussed below, one purpose of the authoritative bodies provision is to avoid duplicative scientific review in order to streamline the listing process and free the Panel to consider chemicals the hazards of which have not been throroughly evaluated. The adoption of this recommendation would defeat this purpose. Accordingly, this recommendation was not adopted.

Subsection (b)

Subsection (b) makes specific the phrase "body considered to be authoritative" found in Health and Safety Code section 25249.8(b). Under subsection (b), a body considered to be authoritative "is an agency or formally organized program or group which utilizes one of the methods set forth in subsection (c)(1) for the identification of chemicals, and which the Panel has identified as having expertise in the identification of chemicals as causing cancer or reproductive toxicity."

There are many organizations which potentially may be identified by the Panel as "authoritative." The organizations may be governmental or non-governmental. The reference to "an agency or formally organized program or group" was chosen to include both types of organizations. It was also chosen to make certain that the term "body considered to be authoritative" does not include individuals. The body must consist of a group of individuals in a formal organization, such as a program or agency.

One commentor recommended that the regulation make clear that an authoritative body can be a public agency only, not a private program or group, since private programs and groups do not allow public access to their processes. (C-9, p. 2.) The fact that a program or group may limit public access to its process is simply one factor which may be considered when deciding whether the program or group is "authoritative." The Panel may have a difficult time determining that a body which completely excludes outside input and review is "authoritative." However, the Agency cannot conclude that the ability of a private program or group to limit public input precludes them from consideration as authoritative bodies. Accordingly, this recommendation was not adopted.

The purpose of designating a "body considered to be authoritative" is to place chemicals on the list of chemicals known to the state to cause cancer or reproductive toxicity. In order for a chemical to be listed as the result of the Panel's designation of a body considered by to authoritative, Health and Safety Code section 25249.8(b) requires that the chemical must be "formally identified" by the body as causing cancer or reproductive toxicity. The term "formally identified" is defined in subsection (d) of the regulation, and includes certain limitations. It would be a useless act for the Panel to spend

the time and resources necessary to designate a body considered to be authoritative if the body does not utilize at least one of the mechanisms of formal identification set forth in subsection (c)(1). Accordingly, "body considered to be authoritative" is further defined with the limitation that the agency or formally organized program or group must utilize at least one of the mechanisms for the identification of chemicals set forth in subsection (c)(1).

One commentor recommended that the words "or more" be inserted after "one." (C-13, Exhibit "A", p. 1.) This amendment does not appear to be necessary. The purpose of this section is to make certain that a body under consideration utilizes at least one of the methods for the identification of chemicals, so that the authoritative body designation will have some practical effect. Obviously, if the body utilizes more than one of the methods, that will be sufficient. Therefore, this recommendation was not adopted.

As originally proposed, subsection (b) made reference only to subsection (c), not subsection (c)(1). However, some of the criteria in subsection (c) require a review of the identification of each individual chemical. The Panel would not be in a position to apply these criteria, since the task of determining which chemicals are "formally identified" belongs to the lead agency. Accordingly, the limitation in subsection (b) was limited in the December 12 proposal. The Panel need only consider whether the agency, program or group issues a list, publishes a report, or otherwise documents their conclusions that certain chemicals cause cancer or reproductive toxicity.

Under subsection (b), a "body considered to be authoritative" must, in the Panel's opinion, have "expertise in the identification of carcinogens or reproductive toxicants." In arriving at such a determination, it is assumed that the Panel will consider the reputation of the body in identifying carcinogens or reproductive toxicants on which the Panel can rely. As originally proposed, subsection (b) provided that the Panel must identify "a body considered by it to have an established and recognized expertise in the identification of chemicals." This language proved to be awkward. The December 12 proposal adopted the present language to simplify the expression of the Agency's intent.

The phrase "body considered to be authoritative" in section 25249.8(b) is too cumbersome to use throughout the regulation. Thus, subsection (b) provides that "authoritative body" shall be a shorthand form having the same meaning as "body considered to be authoritative."

Implicit in the power to designate authoritative bodies is the power to revoke or rescind such a designation. Subsection (b) makes this power explicit by specifying that the Panel shall have

the authority to revoke or rescind any designation on the grounds that the Panel no longers considers the body to demonstrate sufficient expertise in the identification of chemicals.

As originally proposed, subsection (b) simply provided that the Panel had the authority to revoke or rescind its determination that a body is authoritative. One commentor recommended that the regulation specify the bases for the revocation of an authoritative body, i.e. either it no longer utilizes one of the methods set forth in subsection (c) or it no longer has established and recognized expertise. (C-11, p. 3.) The October 13 proposal amended subsection (b) to further provide the grounds on which the revocation may be made. If the Panel no longer considers the body to have expertise in the identification of chemicals as causing cancer or reproductive toxicity, the Panel may revoke its determination that the body is authoritative. It was decided that requiring the Panel to find that the body no longer has an "established and recognized" expertise would be unworkable, since a body which has ceased to produce work of acceptable quality may still have an "established and recognized expertise." Accordingly, the words "established and recognized" were not included.

It was further determined that the failure of an authoritative body to continue using one of the methods set forth in subsection (c), now subsection (d)(1), should not provide a basis for revocation. The requirement that the body use one of the methods in subsection (d)(1) was designed to prevent the Panel from undertaking the useless act of finding a body authoritative when no listing of chemicals could result. Once a body is considered authoritative, further action on the part of the Panel is unnecessary. If the body stops using any of the methods set forth in subsection (d)(1), no Panel action would be required. Thus, the Panel would not be in the position of performing a useless act. In addition, if the body ceases to use any of the methods described in subsection (d)(1), it could just as easily begin again. Therefore, the fact that a body ceases to use one of the methods set forth in subsection (d)(1) was not made a basis for revocation.

Subsection (b) further provides that section 12306 shall not be construed to limit or otherwise interfere with the authority to revoke or rescind an authoritative body designation.

Subsection (c

Subsection (c) provides that the lead agency designated pursuant to Health and Safety Code section 25249.12 shall determine which chemicals are "formally identified as causing cancer or reproductive toxicity" within the meaning of the Act. The Act provides that the state's qualified experts may consider a body to be authoritative, but does not specify the mechanism for determining which chemicals have been "formally identified as

causing cancer or reproductive toxicity" after a body has been found to be authoritative. The fact that the task of determining which spcific chemicals to list by this process was not delegated to the state's experts suggests that the voters intended a different approach.

Under the primary approach to listing, the Panel must determine whether a chemical has been clearly shown, based upon scientifically valid testing according to generally accepted principles, to cause cancer or reproductive toxicity. This can be a time-consuming process. The apparent purpose of the authoritative bodies provision is to establish a streamlined process for the Panel. Rather than review each chemical already subjected to review by another organization, the Panel needs only to determine the organization's competence. The chemicals which the organization has formally identified as causing cancer or reproductive toxicity can then be listed. This permits the Panel to focus its attention on chemicals which have not previously been evaluated.

To determine which chemicals have been "formally identified as causing cancer or reproductive toxicity," it will be necessary to review those identifications which the body has made, both for their formality and scientific basis. Requiring that the Panel make this determination could consume substantial amounts of the time which the authoritative bodies provision was intended to save, distracting the Panel from its other responsibilities.

Determining which chemicals are formally identified as causing cancer or reproductive toxicity is essentially ministerial. If there is sufficient documentation of an identification based upon valid epidemiologic or animal bioassay data, the chemical is listed. This simply involves a review of the literature, and does not require a panel of experts to conduct. Since the task of making such determinations is essentially ministerial, it is more suited to full-time staff than to part-time experts.

Accordingly, the original version of the regulation assigned to the Agency the task of determining which chemicals an authoritative body has formally identified as causing cancer or reproductive toxicity. This approach takes full advantage of the resources available through the Agency, and conserves the energies of the Panel as the Act apparently intended.

Some commentors objected that the regulation would shift to the Agency the authority to determine which chemicals have been "formally identified." (C-14, p. 2.) Some supported the rule. (C-12, p. 1.) One alleged that (1) the Act gives this role to the Panel, (2) giving the responsibility for scientific determinations to the lead agency rather than the Panel undermines the credibility of the process, and (3) the efforts of the lead agency in determining what is "formally identified" will be duplicative of the Panel's designation of the body as

authoritative, since Panel will need to look at what has been formally identified to determine whether a body is authoritative. (C-8, p. 2-5.) However, as indicated above, the Act assigns the Panel the role of determining what bodies are authoritative, but does not assign the task of determining which chemicals are "formally identified as causing cancer or reproductive toxicity." Second, the task of determining which chemicals are "formally identified as causing cancer or reproductive toxicity" under this section are essentially ministerial. The limited time and resources of the state's experts should not be expended performing ministerial functions. Finally, subsection (b) describes what the Panel must find to designate a body as authoritative. The Panel does not need to reexamine every hazard identification issue considered by the body to conclude that the body has expertise in the identification of chemicals causing cancer or reproductive toxicity.

One commentor objected on the ground that authorizing the lead agency to make the determination is inconsistent with the recommendation of the Panel that the Panel make the determination. (C-13, p. 5.) On April 14, 1989, the Panel expressly charged the Agency with developing limitations on the listing of chemicals which would follow the designation of EPA as an authoritative body. Nothing in the Panel's charge suggested that the Panel intended to reserve unto itself the task of deciding which chemicals to list. Subsequently, the Panel designated IARC and NTP, as well as EPA, as authoritative bodies subject to the controls of this section.

One commentor recommended that the designation of an authoritative body form the basis for a list of candidate chemicals, which would then be considered by the Panel on a priority basis. (C-5, p. 3.) This interpretation, however, would write the authoritative bodies provision out of the Act. The Act provides that a chemical is "known to the state to cause cancer or reproductive toxicity" if it is formally identified by an authoritative body as causing cancer or reproductive toxicity, and must be listed under the Act. It does not provide that the Panel must subsequently find that it has been clearly shown through scientifically valid testing to present a cancer or reproductive hazard.

One commentor recommended that the NTP should not be designated as an authoritative body because NTP does not regard its reports as an authoritative statement of carcinogenicity, and most of the NTP listings are for chemicals which are merely "reasonably anticipated" carcinogens, not "known" carcinogens. (C-6, p. 1-2.) At the time this comment was made, the regulation did not reflect that the NTP was considered to be authoritative. Subsequently, the Panel concluded that NTP is authoritative, and the regulation was amended accordingly.

Under the Act, the Panel determines whether it considers a body

to be authoritative. The fact that a body under consideration may not consider itself to be authoritative for certain purposes is something for the Panel to weigh in its considerations. However, it does not appear to preclude the Panel from finding that the body is authoritative.

One commentor objected that the regulation is unconstitutional on the ground that, allegedly, it would effectively delegate to "authoritative bodies" the unfettered discretion to make determinations that would be binding as a matter of law. This commentor contends (1) that a regulation may not delegate to another jurisdiction unchecked authority to promulgate rules, regulations, or standards that will be binding as a matter of law, (2) that the regulation must provide procedural checks that will ensure that the body to which power has been delegated will exercise its authority in conformity with the fundamental policy decisions made in the statute, and (3) that this regulation would completely delegate an aspect of its rulemaking authority without a workable mechanism for meaningful state review. The commentor does not describe how the regulation grants unfettered discretion to authoritative bodies, but concludes that it does. (C-13, p. 1-5.)

Even assuming that the commentor's exposition of the law regarding delegations of authority is correct, the regulation does not grant unfettered discretion to authoritative bodies. To the contrary, it limits which bodies may be designated as "authoritative," and it limits the listing of chemicals based upon such a designation to chemicals which the lead agency determines have satisfied certain procedural and scientific criteria. The Panel's concern that the designation of an authoritative body could lead to the unrestricted listing of chemicals provided the motivation for adoption of the regulation. Consequently, this commentor's fundamental premise appears to be flawed. The regulation does provide procedural checks to ensure that the consequences of designating a body as "authoritative" will conform with the policies expressed in the Act. Accordingly, the regulation does not make an unconstitutional delegation of authority.

As originally proposed, subsection (c) also contained the criteria which the lead agency would apply to determine that a chemical has been "formally identified" as causing cancer or reproductive toxicity. To simplify that subsection, the December 13 proposal separated this definition from the charge to the Agency, moving the criteria to a new subsection (d).

Subsection (d)

Subsection (d) defines the circumstances under which a chemical is "formally identified" within the meaning of section 25249.8. The lead agency must make a determination that specified requirements of identication and formality have been satisfied. Subsection (d) goes on to describe these requirements in paragraphs (1) and (2).

Paragraph (d)(1) requires some kind of written identification. Specifically, the chemical must (1) be included on a list of chemicals causing cancer or reproductive toxicity, or (2) be the subject of a report which is published by the authoritative body concluding that the chemical causes cancer or reproductive toxicity, or (3) be otherwise identified as causing cancer or reproductive toxicity by the authoritative body in a document which indicates that such identification is a final action. Lists and reports are methods of identification commonly used by governmental and non-governmental entities alike to identify chemical hazards. However, in order to permit the designation of authoritative bodies which use other methods to identify chemical hazards, this paragraph permits identification of such hazards in other documents dealing with the chemical which include some indication that the identification of the chemical as a carcinogen or reproductive toxicant is a final action.

The Agency recognizes that many organizations which may be considered authoritative do not treat the identification of chemical hazards as a regulatory endpoint. For them, the regulatory endpoint is the adoption of an exposure or discharge limit for a chemical, once it has been determined that the chemical poses a hazard. Hazard identification is simply one step toward the ultimate determination of a regulatory exposure limit, tolerance, level, etc. Documents explaining or noticing the progression of an exposure or discharge limit, tolerance or other standard through the regulatory process will likely identify a chemical as a cancer or reproductive hazard with finality long before the standard is finally adopted. It is the intention of the Agency that such an identification will be sufficient indication of a "final action" on the issue of hazard identification to conclude that the chemical has been "formally identified."

The words "indicates that such identification is a final action" are intended to prevent the listing of chemicals on the basis of preliminary discussions as to whether a chemical should be considered a cancer or a reproductive hazard, or draft documents dealing with the identification of a chemical hazard. The requirement is not intended to limit the formal identification of a chemical to documents which take final action on the regulatory endpoint. It is not intended to require specific language within the document stating that the identification of the chemical as a cancer or reproductive hazard is a final action.

Whether the identification of a chemical as a cancer or reproductive hazard is final should be determined from the circumstances surrounding the issuance of the document, not just from the document's language.

One commentor recommended that the word "formally" be inserted before the word "issued" with regard to lists issued by the authoritative body. (C-9, p. 2) The purpose of subsection (d)(1), however, is to specify what forms of identification the authoritative body must utilize. Subsection (d)(2) specifies what formality is required. Inserting the word "formally" in subsection (d)(1) would only raise further questions about the requisite formality, e.g. what is a formally issued list. Since this recommendation would add nothing to the regulation, the Agency did not adopt it.

Similarly, another commentor recommended that the regulation add the phrase "stating the authoritative body's formal conclusion" after the word "report." (C-13, p. 6.) Again, subsection (d)(1) specifies what forms of identification must be used, and subsection (d)(2) specifies what formality is required. Injecting into subsection (d)(1) formality criteria more suited to subsection (d)(2) would only serve to confuse. Accordingly, this recommendation was not adopted.

One post-hearing commentor recommended that the lists and reports relied upon for identification be "final" or "issued as a final action. (PH2-1, p. 1.) This recommendation, however, was not directed at any change to the regulation noticed for public availability. Under Government Code section 11346.7(b)(3) and 11346.8(c), the Agency is obligated to respond to objections and recommendations directed at the Agency's proposed actions. In the case of post-hearing changes, the proposed action is the change to the proposed regulation, not the unchanged language. Since this comment is not directed at any change to the proposed language, and is directed at unchanged language, the Agency is not obligated to respond to the recommendation.

Subsection (d)(2) specifies what formality is required. Paragraph (d)(2) requires that the list, report or document specifically and accurately identify the chemical. In addition, the list report or document must have been (A) reviewed by an advisory committee in a public meeting, if a public meeting is required, or (B) made subject to public review and comment prior to its issuance, or (C) published in a manner appropriate to the authoritative body, or (D) signed by the chief administrative officer of the body, or (E) adopted as a final rule or regulation by the body, or (F) otherwise set forth in an official document utilized by the authoritative body for regulatory purposes.

The requirements for formality are based on limitations suggested by the Panel at its April 14, 1989, meeting on its designation of the U.S. Environmental Protection Agency (EPA) as an

authoritative body. The limitations were:

> "(a) EPA's designation is by means of a notice in Federal Register signed by the Administrator;
>
> "(b) EPA's designation addresses specifically and unambiguously the chemical formula, the valence state, the routes of exposure and the identity of members within a class of chemical for which designation as a carcinogen or reproductive toxicant is warranted by the scientific information available;
>
> "(c) The designation and its rationale have been reviewed by the EPA's Science Advisory Board at a public hearing at which interested parties have had the opportunity to make comment;
>
> "(d) The EPA's Science Advisory Board has concurred in a written report to the EPA Administrator that the designation is clearly warranted by the scientific information available."

Since the proposed regulation is intended to be generic in its application, some of the limitations proposed by the Panel for EPA may not be applicable to other potential authoritative bodies. Hence, the requirements for formality are presented in the disjunctive, rather than the conjunctive. An identification must satisfy at least one of the requirements set forth in subsection (d)(2). The Agency considered requiring that each requirement for formality be satisfied and rejected this alternative, since different bodies observe different formalities in identifying chemicals, and many bodies use one or more of the formalities specified, but few use them all.

One commentor objected that the procedural steps in subparagraphs (A) through (F) are listed in the disjunctive, and recommended that all steps should be required in the conjunctive. (C-3, p.4; C-9, p. 2; C-13, p. 6.) However, as indicated above, the Agency considered requiring that each requirement for formality be satisfied and rejected this alternative. Requiring each of the steps in the conjunctive would impose such stringent requirements of formality before a chemical could be listed that few, if any, would survive the process and be listed. As a consequence, the majority of chemicals considered by the authoritative body would need to be referred to the Panel for its consideration whether the chemicals have been clearly shown through scientifically valid testing to cause cancer or reproductive toxicity. In effect, the primary purpose of the authoritative bodies provision, which is to relieve the Panel of the burden of a chemical-by-chemical review for substances already well considered by reputable organizations so that the Panel can freely pursue other issues, would be defeated.

One commentor recommended that the regulation be amended to assure that listing is limited to chemicals which have been formally and finally adopted by authoritative bodies as causing cancer or reproductive toxicity, pointing out that during EPA review of pesticides, final determination is often not made because new information indicates that the chemical is not carcinogenic. (C-4, p. 1.) Subsection (d)(1) does make reference to finality, as discussed above. As for formality, the purpose of subsection (d)(2) is to prescribe what constitutes sufficient formality. Injecting references to finality will only serve to confuse. Prescribing that formality means that the chemical has been formally adopted by the authoritative body would be circular. Therefore, no modification was made.

The alternative provision in paragraph (d)(2)A. that the list, report or document have been reviewed by an advisory committee simply recognizes that peer review (within the authoritative body itself or by an advisory committee) is generally utilized by the scientific community to validate the results and/or conclusions of a study or a scientific document, a process similar to that utilized by the Panel to evaluate chemicals for listing under the Act. One commentor recommended that the phrase "and formally accepted or approved by" be added before the words "an advisory committee." (C-13, p. 6.) This, however, would use the word "formally" to define formality, and would raise issues as to when the advisory committee has accepted and approved the document, list or report. Whether a document, list or report has been reviewed by an advisory committee should be simple to determine, and the requirement that the document, list or report reflect that the chemical causes cancer or reproductive toxicity will often imply acceptance or approval. Accordingly, this recommendation was not adopted.

The provision that the list, report or document be made subject to public review and comment prior to its issuance takes into account that some potential authoritative bodies may be regulatory agencies which afford opportunities for comment by the public and the regulated community. One commentor recommended that formal public review, where required, should be required. (C-13, p. 6.) However, as currently drafted, the regulation encourages public review, even where it is not required. Other commentors have pointed out that public input is beneficial. Therefore, the Agency believes that the less restrictive approach is preferable.

The alternative that the list, report or document be published acknowledges that published reports generally are subjected to a thorough review prior to publication. By way of illustration, the regulation refers to the Federal Register as a manner of publication appropriate to a federal agency. This is not intended to suggest that publication in the Federal Register is the only means by which a list, report or document issued by a federal agency will satisfy this requirement for formal

identification. For example, EPA documents not published in the Federal Register may be sufficient.

The signature of the chief administrative officer of the body or a designee is also evidence of formality. It is unlikely that such an officer would sign such a document prior to completion of all necessary levels of internal review. The adoption of the list, report or document by the body as a final rule or regulation would also indicate a thorough internal review and consideration of public comment as well.

Similarly, the use of the list, report or document in an official document utilized by the body for regulatory purposes indicates completion of necessary internal review. One commentor recommended that the regulation be amended to delete the phrase "utilized by the authoritative body for regulatory purposes" and replace it with the phrase "that identifies chemicals that are regulated as carcinogens by said authoritative body." (C-13, p. 7.) This recommendation was not adopted because it would require that the chemical in fact be regulated before this standard of formality could be utilized, and did not otherwise improve upon the language proposed.

As proposed, this regulation did not require use of the list, report or document in an "official" document. This adjective was added in the December 13 proposal to clarify that the document utilized for regulatory purposes must be the official product of a government agency.

Subsection (e)

Subsection (e) provides that, for purposes of section 12306, the phrase "as causing cancer" means that either of two scientific criteria have been satisfied. Generally, the authoritative body may rely on either studies in humans or studies in animals. These criteria are consistent with the criteria the Panel presently uses in evaluating chemicals for listing. The Panel utilizes the EPA's Classification System for Categorizing Weight of Evidence for Carcinogens From Human and Animal Studies (51 Fed. Reg. 33999 (Sept. 24, 1986)). The same, or substantially similar criteria have been adopted by many regulatory agencies and scientific organizations involved in hazard identification. The use of these criteria will ensure that the standards applied by an authoritative body are the same as or substantially similar to those used by the Panel to evaluate chemicals.

As originally proposed, subsection (e) (then subsection (d) provided:

> "Except as provided in subdivisions (e), (h) or (i), the lead agency shall determine that a chemical is formally identified by an authoritative body as causing cancer

when either of the following criteria has been satisfied: . . . ."

One commentor recommended clarification that the criteria of subsection (c) and subsection (d) must be satisfied, urging that the phrase ", in addition to the requirements of subsection (c)," be added after the word "when." (C-3, p. 5.) This recommendation was accepted in the October 13 proposal of the regulation, but subsequent review revealed a potential for confusion, since both subsections proposed criteria for determining that a chemical has been "formally identified by an authoritative body as causing cancer or reproductive toxicity." To avoid this confusion, subsection (e) was amended in the December 13 proposal to resemble subsection (d), and simply provide, "For purposes of this section, 'as causing cancer' means that either of the following criteria has been satisfied: . . . ." This made clear that subsections (d) and (e) implement different terms. Subsection (d) implements the terms "formally identified," and subsection (e) implements the terms "as causing cancer."

One commentor recommended that the lead agency rely upon a "weight-of-the-evidence," rather than a "strength-of-the-evidence" approach when determining which chemicals have been identified "as causing cancer." Apparently, this commentor perceives "strength-of-the-evidence" to mean that hazard identifications are based upon studies showing carcinogenic activity, ignoring studies showing a lack of carcinogenic activity. Weight-of-the evidence would consider both negative and positive studies.

If an authoritative body uses the weight-of-the-evidence approach, the results will be reflected in the document, list or report which the body issues. In other words, chemicals which did not meet the body's weight-of-the-evidence test would not be formally identified as causing cancer. Therefore, the recommended approach would have practical effect only where the authoritative body uses the strength-of-the-evidence approach. It would place the Agency in the position of superimposing a weight-of-the-evidence test upon the authoritative body's conclusions.

One commentor recommended that subsection (e) provide that the same or substantially similar criteria be "determined by the authoritative body to be, or is in fact, satisfied: . . ." (PH1-1) This would have the opposite effect of the previous recommendation. It could place the Agency in the position of deferring to the conclusions of the authoritative body, even where the criteria had not been satisfied.

As indicated below, it is not the intention of the Agency in adopting this regulation to substitute its scientific judgment for the judgment of the authoritative body where sufficient

evidence exists. Thus, if there are four animal studies on a particular chemical, two of them positive and two of them negative, and the authoritative body concludes on the basis of the positive tests that the chemical causes cancer, the Agency does not intend to revisit the issue. Thus, if an authoritative body properly applies a strength-of-the-evidence approach, the Agency will not substitute its judgment on the basis of negative data, unless new data not considered by the authoritative body clearly establishes that there is not sufficient evidence in either animals or humans.

On the other hand, where there is in fact an insufficient number of positive animal or human studies, but the authoritative body has concluded anyway that the chemical causes cancer, the Agency will be prevented by the regulation from bringing the chemical to the list. The Agency will not completely defer to the authoritative body, and will at least determine that the body relied upon the requisite human or animal studies.

This same commentor recommended that the Agency should consider the differences in listing substances as "possible," "probable," "known," "reasonably anticipated to be," or "suspect" carcinogens by various governmental and nongovernmental groups before automatically adopting such lists under the Act. (C-6, Attachment 1, p. 3.) Under the regulation, there is no automatic adoption of an authoritative body's list. The Agency will investigate to make certain that there are sufficient animal or human data. As indicated below, the terms "possible," "probable," "known," "reasonably anticipated to be," and "suspect" are often used to describe the certainty afforded by sufficient data in animals. Therefore, it appears that these differences have been adequately considered.

Paragraph (e)(1) describes the criteria for determining that a chemical causes cancer where the authoritative body relied on studies in humans. The regulation requires that sufficient evidence exist from studies in humans which indicate that there is a causal relationship between the chemical and cancer. This definition of "sufficient evidence" is well-established in the scientific community, and several references to this concept are offered by way of illustration in the bibliography to the regulation. Under these references, chemicals for which there is sufficient evidence based upon evidence in humans have been identified as chemicals "known to be carcinogens" (NTP, Fourth Annual Report on Carcinogens, Summary, 1985, p. 8), "Group I-- carcinogenic to humans" (International Agency for Research on Cancer (IARC), IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Overall Evaluations of Carcinogenicity: An Updating of IARC Monographs Volumes 1 to 42, Supplement 7, 1987, p. 30), and "Group A-- human carcinogens" (EPA, Guidelines for Carcinogen Risk Assessment, 51 Fed. Reg. 33999 (Sept. 24, 1986)).

The use of the term "sufficient evidence" is not offered to create or impose an additional legal standard or burder of proof. The term has its own special significance within the scientific community and is used in this context only for that purpose.

It is not the intention of the Agency to substitute its scientific judgment for that of the authoritative body. The Agency's inquiry will be limited to whether the authoritative body relied upon scientific data in an amount sufficient to conclude that the chemical causes cancer. The Agency does not intend by this section to go behind the studies relied upon by the authoritative body to determine their scientific validity. Because the body is considered authoritative, and the body utilizes the same or substantially the same criteria as set forth in subsection (e), it will be assumed that the data relied upon is scientifically valid. The Agency will look to determine whether the authoritative body relied upon animal or human data in an amount sufficient to satisfy the criteria. If so, the chemical will be proposed for listing.

Two commentors recommended that the words "scientifically valid" be inserted before "studies," and that the words "clearly show" be inserted after "humans." (C-13, p. 7; C-4, p. 1.) When the Panel evaluates individual chemicals to determine whether it has been clearly shown according to scientifically valid studies to cause cancer, it follows the criteria adopted by the EPA to evaluate carcinogenic hazards. The definition of "sufficient evidence" in the regulation is derived directly from the EPA criteria. This promotes reasonable consistency between the listing of chemicals by the Panel and the listing of chemicals following the Panel's designation of an authoritative body. Adopting this recommendation would not enhance that consistency, and may lead to confusion. Further, adopting this recommendation would be duplicative, since the EPA criteria already imply the use of scientifically valid data, and a clear showing of the causal relationship between the chemical and cancer. Accordingly, this recommendation was not adopted.

Paragraph (e)(2) describes the criteria for determining that a chemical causes cancer where the authoritative body relied on studies in animals. Again, the regulation requires that sufficient evidence exist from such studies, and defines "sufficient evidence" to mean that studies in experimental animals indicate that there is an increased incidence of malignant tumors or combined malignant and benign tumors in multiple species or strains, in multiple experiments (e.g., with different routes of administration or using different dose levels), or, to an unusual degree, in a single experiment with regard to high incidence, site or type of tumor, or age at onset. This definition of "sufficient evidence" is also well-established in the scientific community, and several references to this concept are further offered by way of illustration in the bibliography. Under these references, chemicals having

sufficient evidence from animal studies have been identified as chemicals "reasonably anticipated to be carcinogens" (NTP), and "Group 2A-- probably carcinogenic to humans" or "Group 2B--possibly carcinogenic to humans" (IARC). Whether a chemical is given IARC's 2A or 2B classification depends generally on the presence or absence of limited human data and the presence or absence of sufficient animal data.

EPA identifies chemicals having sufficient evidence in animals as "Group B-- probable human carcinogens." EPA subdivides its Group B into B1 (with limited human evidence) and B2 (sufficient animal evidence and inadequate or absent human data).

Again, the use of the term "sufficient evidence" is not offered to create or impose an additional legal standard or burden of proof. The term has its own special significance within the scientific community and is used in this context only for that purpose.

It should be noted that the definition of "sufficient evidence" in this section does not include evidence of short-term in vitro testing. In vitro tests are not studies in animals, and the Panel has not included such testing in its own criteria for listing chemicals. The criteria utilized by IARC, NTP and EPA do utilize short-term testing. Consequently, the chemicals which are identified as causing cancer pursuant to this section will not necessarily include all the chemicals included in EPA's Group B. Similarly, not all of NTP's "reasonably anticipated" carcinogens or IARC's Group 2 carcinogens will necessarily be among the chemicals identified as causing cancer pursuant to this section.

When the evidence from experimental animals concerning the carcinogenicity of a chemical is not sufficient, the NTP list of carcinogens does not include it. IARC calls the chemical "Group 3--not classifiable" or "Group 4--probably not carcinogenic." When EPA's evaluation of studies in experimental animals indicates that the evidence of carcinogenicity is "limited" rather than "sufficient," EPA identifies the chemical as belonging to "Group C--possible human carcinogen." Depending on the evidence, the Panel has listed some EPA Group C chemicals and not others. Under this regulation, Group C carcinogens or their equivalents will continue to be evaluated on a chemical by chemical basis, and involve determinations by the Panel.

It is not the intention of the Agency to substitute its scientific judgment for that of the authoritative body. The Agency's inquiry will be limited to whether the authoritative body relied upon scientific data in an amount sufficient to conclude that the chemical causes cancer. The Agency does not intend by this section to go behind the studies relied upon by the authoritative body to determine their scientific validity. Because the body is considered authoritative, it will be assumed

that the data relied upon is scientifically valid. The Agency will look to determine whether the authoritative body relied upon animal or human data in an amount sufficient to satisfy the criteria. If so, the chemical will be proposed for listing.

Two commentors recommended that the words "scientifically valid" be inserted before "studies," and that the words "clearly show" be inserted after "animals." (C-13, p. 7; C-4, p. 1.) When the Panel evaluates individual chemicals to determine whether it has been clearly shown according to scientifically valid studies to cause cancer, it follows the criteria adopted by the EPA to evaluate carcinogenic hazards. The definition of "sufficient evidence" in the regulation is derived directly from the EPA criteria. This promotes reasonable consistency between the listing of chemicals by the Panel and the listing of chemicals following the Panel's designation of an authoritative body. Adopting this recommendation would not enhance that consistency and may lead to confusion. Further, adopting this recommendation would be duplicative, since the EPA criteria already imply the use of scientifically valid data, and a clear showing of the causal relationship between the chemical and cancer. Accordingly, this recommendation was not adopted.

Subsection (f)

Subsection (f) states that a chemical does not satisfy the definition of "as causing cancer" if scientifically valid data not considered by the authoritative body clearly establish that there is not sufficient evidence that the chemical causes cancer or reproductive toxicity. The science of hazard identification is not static. Studies relied upon today may, in the light of new data, be unreliable tomorrow. The identification of chemicals under the Act was intended by the voters to be based upon scientific testing. (Ballot pamphlet, Rebuttal to Argument Against Proposition 65 as presented to the voters (Nov. 4, 1986).) It would make little sense to have chemicals listed under the Act where the data relied upon by an authoritative body is outdated and clearly contradicted by newer data. Further, the lists, reports or documents of an authoritative body may not always be intended to have practical or regulatory effect. The authoritative body, therefore, may not have a legal duty or the need to expeditiously re-evaluate its conclusions in the light of new data, especially when its resources are limited. However, the regulatory implications of listing under the Act require a consideration of current data.

One commentor objected that the lead agency, rather than the Panel, will make the determination whether the criteria have been met. (C-13, p. 8.) As a practical matter, however, assigning responsibility for the initial determination could cause the Panel to be overwhelmed by petitions from interested parties demanding review of new data to prevent the Agency from listing the chemical. This could place a substantial burden on the

Panel's resources and its members. Nothing in the regulation prevents the Agency from seeking the advice of the Panel in the event the newer data clearly shows that the old data is insufficient. However, the Agency appears to be in the best position to make the initial determination.

As originally proposed, subsection f) then subsection (e)) provided:

> "A chemical has not been formally identified by an authoritative body as causing cancer if the lead agency makes a determination, based upon scientifically valid data not considered by the authoritative body, that subsection (d) is not applicable."

One commentor recommended that the section be rewritten to read:

> "A chemical shall not be added to the list of chemicals known to the State to cause cancer if the Panel or lead agency makes a determination, based upon scientifically valid data not considered by the authoritative body, that the criteria set forth in subsection (d) have not been satisfied." (C-13, p. 8.)

This comment brought to the Agency's attention the potential for confusion in the original version. It was unclear whether the newer data which provides the basis for the Agency's determination means that the chemical had not been formally identified, or whether the new data would mean that the chemical does not cause cancer. To make clear that the affected term is "as causing cancer," subsection (f) was amended by the December 13 proposal to provide that a chemical does not satisfy the definition of "as causing cancer" if there is sufficient new data.

Subsection (g)

Subsection (g) provides that, for purposes of section 12306, the phrase "as causing reproductive toxicity" means that either of two scientific criteria have been satisfied. Generally, the authoritative body may rely on either studies in humans or studies in animals.

Paragraph (g)(1) describes the criteria for determining that a chemical causes reproductive toxicity where the authoritative body relied on studies in humans. As with carcinogens discussed above, the proposed regulation requires that sufficient evidence exist from such studies, in that studies in humans indicate that there is a causal relationship between the chemical and reproductive toxicity.

Paragraph (g)(2) describes the criteria for determining that a chemical causes reproductive toxicity where the authoritative

body relied on studies in animals for its identification of a chemical as a reproductive toxicant. Again, the proposed regulation requires that sufficient evidence exist from such studies. "Sufficient evidence" is defined to mean that there is sufficient data, which take into account the adequacy of the experimental design and other specified parameters, indicating that an association between adverse reproductive effects in humans and the toxic agent in question is biologically plausible. This is consistent with the criteria utilized by the Panel when it evaluates reproductive hazards.

It is not the intention of the Agency to substitute its scientific judgment for that of the authoritative body. The Agency's inquiry will be limited to whether the authoritative body relied upon scientific data in an amount sufficient to conclude that the chemical causes reproductive toxicity. The Agency does not intend by this section to go behind the studies relied upon by the authoritative body to determine their scientific validity. Because the body is considered authoritative, and the body utilizes the same or substantially the same criteria as set forth in subsection (g), it will be assumed that the data relied upon is scientifically valid. The Agency will look to determine whether the authoritative body relied upon animal or human data in an amount sufficient to satisfy the criteria. If so, the chemical will be proposed for listing.

One commentor objected that the standard requiring "studies that indicate a biologically plausible association" cannot be squared with a statutory standard which requires that causation be clearly shown through scientifically valid testing. (C-13, p. 8.) However, biological plausibility is the standard applied by the Panel when it determines on a chemical-by-chemical basis that a chemical has been clearly shown through scientifically valid testing according to generally accepted principles. It appears that, in the case of reproductive toxicity, a biologically plausible association based upon animal data can constitute a clear showing.

One post-hearing commentor recommended that the subsection (g)(2) require that studies in experimental animals "clearly" indicate that there is an association between the "chemical" and adverse reproductive effects. (PH2-1, pp. 1-2.) This recommendation, however, was not directed at any change to the regulation noticed for public availability. Under Government Code section 11346.7(b)(3) and 11346.8(c), the Agency is obligated to respond to objections and recommendations directed at the Agency's proposed actions. In the case of post-hearing changes, the proposed action is the change to the proposed regulation, not the unchanged language. Since this comment is not directed at any change to the proposed language, and is directed at unchanged language, the Agency is not obligated to respond to the recommendation.

Subsection (h)

Subsection (h) states that a chemical does not satisfy the definition of "as causing reproductive toxicity" if scientifically valid data not considered by the authoritative body clearly establish that there is not sufficient evidence that the chemical causes reproductive toxicity. Again, as with carcinogens, the science of hazard identification is not static. Studies relied upon today may, in the light of new data, be unreliable tomorrow. The identification of chemicals under the Act was intended by the voters to be based upon scientific testing. (Ballot pamphlet, Rebuttal to Argument Against Proposition 65 as presented to the voters (Nov. 4, 1986).) It would make little sense to have chemicals listed under the Act where the data relied upon by an authoritative body is outdated and clearly contradicted by newer data. Further, the lists, reports or documents of an authoritative body may not always be intended to have practical or regulatory effect. The authoritative body, therefore, may not have a legal duty or the need to expeditiously re-evaluate its conclusions in the light of new data, especially when its resources are limited. Thus, several years may lapse before an authoritative body amends its list of reproductive toxicants to reflect the newer data. The listing of a chemical under the Act, on the other hand, does have regulatory implications. This requires a more expeditious consideration of current data.

As originally proposed, subsection (h) (then subsection (g)) provided:

> "A chemical has not been formally identified by an authoritative body as causing cancer if the lead agency makes a determination, based upon scientifically valid data not considered by the authoritative body, that subsection (f) is not applicable."

One commentor recommended that the section be rewritten to read:

> "A chemical shall not be added to the list of chemicals known to the State to cause reproductive toxicity if the Panel or lead agency makes a determination, based upon scientifically valid data not considered by the authoritative body, that the criteria set forth in subsection (f) have not been satisfied." (C-13, p. 9.)

This comment brought to the Agency's attention the potential for confusion in the original version. It was unclear whether the newer data which provides the basis for the Agency's determination means that the chemical had not been formally identified, or whether the new data would mean that the chemical does not cause reproductive toxicity. To make clear that the affected term is "as causing reproductive toxicity," subsection

(f) was amended by the December 13 proposal to provide that a chemical does not satisfy the definition of "as causing reproductive toxicity" if there is sufficient new data.

Subsection (i

Subsection (i) sets forth a procedure to be followed by the lead agency prior to the listing of chemicals on the ground that they are formally identified by authoritative bodies as causing cncer or reproductive toxicity. At least 60 days prior to causing the chemical to be added to the list of chemicals known to the state to cause cancer or reproductive toxicity, the lead agency must publish a notice identifying the authoritative body and the chemical, stating its intention to cause the chemical to be added to the list. Interested parties will have 30 days within which to object to the proposed listing on the ground that there is no substantial evidence that the scientific criteria set forth in subsection (e) and (g) have been satisfied. Such objections must be in writing and be accompanied by supporting documentation.

One commentor recommended that the Agency invite public comment on all aspects of a decision to identify a substance which has been listed by another authoritative body, not just the satisfaction of the criteria for identification of a chemical "as causing cancer" or reproductive toxicity in subsections (e) and (g). (C-9, p. 3.) Subsection (i) arises out of concerns that chemicals formally identified by authoritative bodies might be listed even though the criteria utilized by the Panel had not been satisfied. The Panel applies scientific, not procedural, criteria when recommending chemicals for listing. The purpose of subsection (i) is to establish a procedure for determining which chemicals should be referred to the Panel for its scientific review. It is for this reason that the regulation limits objections to scientific criteria.

If a scientific objection is valid, Panel review will be appropriate. The Panel's expertise is not necessary to determine whether the identification of a chemical as a carcinogen or reproductive toxicant has been properly documented. To permit objections on the basis of procedure would require that procedural issues be referred to the Panel. Thus, a portion of the Panel's limited time would be absorbed resolving essentially ministerial matters, which would contravene the purpose of the authoritative bodies provision. Accordingly, this recommendation was not accepted.

One commentor objected that, under the regulation, the Panel may not even review a chemical unless there is no substantial evidence. The commentor contends that this turns the statute on its head, since the Panel can prevent listing only if it can be shown that the chemical is not a carcinogen. The commentor recommended that the regulation be amended to read:

"If objections are made on the basis of substantial evidence that the criteria identified in subsection (d) or in subsection (f) have not been satisfied, then prior to listing, the Panel shall advise the Agency as to whether the criteria in subsection (d) or subsection (f) have been met." (C-13, p. 9.)

As indicated above, the Agency does not intend to substitute its scientific judgment for that of the authoritative body. It does not intend to reevalute the science to determine whether the authoritative body should have reached a different result. In effect, there is a presumption that the authoritative body properly applied the criteria. Adopting this recommendation would require that the Agency reweigh the science. Requiring that objections show there is no substantial evidence preserves this presumptive effect, and limits chemicals referred to the Panel to those which do not satisfy the authoritative body's own standards, again preserving the Panel's limited and valuable time.

Subsection (j)

Subsection (j) requires the reconsideration by the lead agency of its determination that a chemical is identified by an authoritative body as causing cancer or reproductive toxicity after the chemical has been added to the list of chemicals known to the State to cause cancer or reproductive toxicity where (1) there is no substantial evidence that the criteria identified in subsections (e) or (g) have been satisfied, or (2) the authoritative body no longer identifies the chemical as causing cancer or reproductive toxicity. This will permit an ongoing review to ensure the accuracy of the list of chemicals. Since the issues involved are essentially scientific, chemicals under reconsideration will be referred to the Panel for the its recommendation. However, until this review has been completed, this subsection provides that the chemical under review will continue to be listed.

One commentor recommended that the regulation be amended to make clear that the Panel can recommend removal of a chemical from the list if there is "substantial evidence" that the listing criteria have not been met. (C-13, p. 10.) Similar objections were made to subsection (i), which authorizes objections to be made at the time the Agency proposes to list a chemical as formally identified by an authoritative body as causing cancer or reproductive toxicity on the ground that there is <u>no</u> substantial evidence that scientific criteria have been satisfied. For the same reasons, this recommendation was not adopted.

One commentor objected that criteria for removing a chemical from the list are narrow, observing that the Agency lists on the basis of criteria, and this subsection would permit reconsideration only if it does not meet these criteria. This approach, the

commentor contends, would virtually eliminate review. (C-14, p. 3.) The purpose of this regulation is to permit reconsideration where the Agency has listed a chemical in error, and where the authoritative body itself has changed its conclusion. The Agency would err if it listed a chemical even though there is no substantial evidence to do so.

Limiting reconsideration in this manner may limit the review of chemicals by the Panel, but the purpose of this subsection is not to permit a review of each chemical by Panel. Permitting expanded reconsideration criteria might encourage interested persons to seek reconsideration where a chemical has been properly listed, which might place an undue burden on the Agency and the Panel.

Subsection (k)

As originally proposed, section 12306 contained no provision governing the designation of authortative bodies and the listing of chemicals if the regulation is declared invalid. It became apparent that such a provision is necessary because authoritative bodies are designated by the Panel, the Panel has serious concerns that the listing of chemicals as the result of such a designation should be controlled, and competing interest groups differ strongly on the extent of the controls which should be applied.

One commentor recommended the addition of a new subsection (k), which would read:

> "(k) in the event that any provision of this section 12306 shall be held by any court to be invalid for any reason, the entire section 12306 and each subsection hereof shall be deemed to be void and of no effect, and any determination made hereunder that any body is authoritative, or that any chemical has been formally identified by an authoritative body as a carcinogen or a reproductive toxicant, or that by virtue of any such identification any chemical has been added to the list of chemicals known to the state to cause cancer or reproductive toxicity, shall be similarly void and of no effect." (C-5, p. 3.)

This approach appeared too harsh, since it provided no way for the Panel to ratify the designation of authoritative bodies or the listing of chemicals following a successful challenge to the regulation. Consequently, the October 13 proposal provided:

> "In the event that a court holds that this regulation or any portion thereof is invalid, any determination that a body is authoritative shall be deemed void and of no effect, unless subsequently ratified by the Panel."

One post-hearing commentor objected to this proposal, questioning its authority. (PH1-1, p. 4.) Upon further review, the Agency determined that this approach would serve as an invitation for industry groups to challenge the validity of the regulation. If a business or industry uses a chemical listed by the Agency under this section, and an enforcement action is brought against the business or industry for exposures to or discharges of the chemical, the business or industry could collaterally attack this regulation and, under this subsection, invalidate the designation of the authoritative body which caused the chemical to be listed. This appeared to be an undesireable result.

Consequently, the December 13 proposal substituted the following language:

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

If the Panel has discretion in designating authoritative bodies, it may condition its designation. One of the Panel's primary concerns is that the designation of authoritative bodies will result in the uncontrolled listing of chemicals. Therefore, to satisfy its own concerns, it makes sense for the Panel to condition its designation upon the application of suitable controls. This section simply affirms that this solution is available. The Panel may condition its designation of an authoritative body upon the subsequent application of controls. If those controls are found inapplicable, then the Panel may find a failure of condition, in which case the body is no longer considered authoritative, and the Agency may no longer list the chemicals which body formally identifies as causing cancer or reproductive toxicity. Thus, chemicals will be listed only in a controlled manner.

However, unless some provision is made regarding chemicals already listed pursuant to this section, conditioning the designation of an authoritative body upon the application of

controls in this section might continue to serve as an invitation for affected persons to challenge those controls. It could be argued that the failure of condition would have a retroactive effect, removing from the list chemicals added when the controls were in effect. Accordingly, the December 13 proposal further provided that chemicals listed subject to the controls would remain on the list.

Subsection (1

At its meeting on April 14, 1989, the Panel made a provisional decision to designate the EPA as an "authoritative body" for purposes of the Act. Accordingly, the original version of this regulation provided that EPA had been designated as an authoritative body.

One commentor objected that this was inaccurate; that the Panel had identified EPA on a provisional basis on certain terms and conditions. The commentor recommended that the regulation be amended to add the phrase "on the express condition that all the procedures and safeguards set forth in this section 12306 be given full force and effect." (C-13, p. 10.) However, this too would be inaccurate, because at the time the Panel designated EPA as authoritative, section 12306 had not yet been proposed.

On October 20, 1989, the Panel reaffirmed this designation,and further designated IARC and NTP as authoritative bodies, subject to the controls in section 12306, which was adopted as an emergency regulation on that date. Accordingly, subsection (j) states that the Panel has identified the EPA, IARC and NTP as authoritative bodies "for purposes of this section." This subsection is intended to provide an easy reference to designated authoritative bodies, yet be consistent with the conditions established under the regulation. The subsection is structured so that additional authoritative bodies may be added upon designation by the Panel.

ADDENDUM
FINAL
STATEMENT OF REASONS
22 CALIFORNIA CODE OF REGULATIONS DIVISION 2

Section 12306 - Chemicals Formally identified by Authoritative Bodies

Insert at bottom of page 13:

"One commentor recommended the addition of language to subparagraphs (2)(A)-(F) which will make it clear that a condition will apply only where applicable. (C-13, p. 6.) The purpose of subparagraph (2) is to specify what formality is required to accompany an identification of a chemical. Formality can be evidenced in many ways, and a body's process need not be complete in order for the steps taken to indicate formality in the identification of a chemical. A body may require several steps in order to complete its own process, but each of these steps may evidence formality. The Agency considers each step set forth in subparagraph (2)(A)-(F) to be a sufficient indicium of formality for purposes of the Act. Under this commentor's recommendation, however, the authoritative body would likely need to have completed its process and have satisfied several steps in order for the chemical to be listed, even though any single step appears sufficient to demonstrate formality. This could severely limit the chemicals which the Agency could list and effectively defeat the purpose of the authoritative bodies provision to relieve the Panel of unnecessary chemical-by-chemical review. Accordingly, this recommendation was not adopted."

Insert after the first sentence in the third full paragraph on page 15:

"Two commentors objected to subparagraph (2)(F) on the ground that it is vague. (C-3, p. 4, fn. 4; C-13, p. 7.) One commentor observed that the original language could describe "everything from dictionaries to press releases," and recommended that the provision be amended to read:

> 'Otherwise set forth in a document that formally identifies chemicals regulated as carcinogens or reproductive toxicants by said authoritative body.'

"As indicated above, to provide that formality is satisfied where a document "formally identifies" a chemical begs the question as to what is "formal." Therefore, this recommendation was not adopted. The vagueness objection, however, has been addressed by the insertion of the word 'official' before the word 'document.'"

Add new paragraph before subheading for subsection (i on page 24:

"One commentor recommended that a comma be inserted between the words 'body' and 'clearly' in subsection (g), now subsection (h) (C-11, p. 3.) The comma had been inadvertently omitted from the original proposal. The December 13 proposal rewrote subsection (h) and eliminated the language containing this typographical error. No comma is necessary in the revised version."

Insert new paragraph after the last full paragraph on page 24:

"This does not mean that the Agency will refuse objections grounded in procedure. It has been the policy of the Agency to consider public input. If the Agency receives information that a chemical has not been 'formally identified' within the meaning of subsection (d), the Agency will consider the information. If the information comes as an objection to the Agency's notice of intent to list a chemical, it will likewise be considered. If the objection is valid, the Agency will react accordingly. The issue will not, and should not, be referred to the Panel for its consideration for the reasons stated above."

Insert new paragraph after the first paragraph under the "Subsection (j)" subheading on page 25:

"If a chemical is referred to the Panel under this subsection, the Agency believes that listing of the chemical by the authoritative bodies mechanism is no longer justifiable. If the Panel agrees, the Panel may recommend that the chemical be removed from the list, or recommend that the chemical continue to be listed because it has been clearly shown through scientifically valid testing to cause cancer or reproductive toxicity. If the Panel disagrees, it may recommend that the chemical continue to be listed under the authoritative bodies mechanism. In any case, the Agency intends to act on the Panel's recommendation."

Insert new paragraph after the last full paragraph on page 27:

"The term 'controls' was chosen to broadly describe the provisions of this regulation. It refers to any provision in section 12306, including subsection (k). This approach appeared to be preferable to an enumeration of the various provisions of section 12306 which contain the controls, since virtually every subsection contains elements arguably essential to the overall scheme.

"Discretion is vested in the Panel to determine whether the invalidation of any provision in section 12306 frustrates the Panel's intentions in imposing conditions in the first place. This discretion is afforded by providing that the Panel 'may'

find a failure of condition following invalidation. For example, the invalidation of subsection (b) may frustrate the Panel's intention that the designation of a body accurately reflect the Panel's ongoing confidence in the body. The invalidation of subsection (d) could contravene that Panel's desire for constraints on the listing of chemicals once an authoritative body is designated. In either case, the determination whether there is a failure is for the Panel."

Insert before "Accordingly" in the fourth line of the last paragraph on page 28:

"The Panel has apparently concluded that these bodies satisfy the criteria of subsection (b)."