FINAL
STATEMENT OF REASONS
22 CALIFORNIA CODE OF REGULATIONS DIVISION 2
SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986
(R-48-87)

On August 19, 1987, a public hearing was held to receive public comment on the regulatory proposal designated R-48-87. At the hearing oral testimony was given, and a transcript of the proceedings was made part of the record. Also received for the record were written comments submitted before 5:00 p.m. on that date. The Health and Welfare Agency, as lead agency, has reviewed these written and oral comments as part of the rulemaking process. Modifications to the proposed text of R-48-87 have been made based upon the objections and recommendations made in these comments. This Final Statement of Reasons explains the lead agency's reasons for accepting some of the objections and recommendations, while declining to follow others.

Throughout the adoption process of R-48-87, the lead agency has considered the alternatives available to determine which would be more effective in carrying out the purpose for which the regulation is proposed, or would be as effective and less burdensome to affected private persons than the proposed regulation. The lead agency has determined that no alternative considered would be more effective than, or as effective and less burdensome to affected private persons than, the adopted regulations.

Section 12101. General Practice

This section describes the function of the Health and Welfare Agency, as lead agency for implementation of the Safe Drinking Water and Toxic Enforcement Act, to answer inquiries as appropriate by issuance of public rulings on the requirements of the Act. These rulings may take the form of interpretive guidelines, safe use determinations, or information letters depending on the nature of the inquiry.

The time frame within which the lead agency will process an inquiry is an important aspect of the response procedures. Subsection (b) clarifies that the lead agency will respond to requests as quickly as possible, and will consider a request for expedited processing as circumstances warrant. However, there can be no assurance that a request will be processed by the time requested because additional time may be required for public notice and hearing pursuant to these procedures, or for environmental review if a ruling may have a significant adverse impact upon the environment.

One comment observed that use of the term "formal" in subdivision (a) is inappropriate, since none of the procedures proposed to obtain public rulings would produce binding results. (Exhibit 9, p.1). Accordingly, the term "formal" has been deleted from

subdivision (a of this section.

Section 12102. Definitions

Definitions of the terms "interpretive guideline", "safe use determination", and "information letter" are provided in order to clarify some of the processes by which the state will implement Proposition 65. The remaining terms are shorthand references to Proposition 65 as the "Act", and to the Health and Welfare Agency as "lead agency".

The proposed definition of "interpretive guideline" has been modified to provide that such guidelines are draft regulations published for the information and guidance of California businesses, law enforcement agencies and others. Several parties objected that this proposal would define an interpretive guideline as an official interpretation of the Act, which would not have the necessary force and effect of law. (Exh. 9, p. 1; Exh. 5, p. 3, T 28:22-29:10; Exh. 6, pp. 6-8, T 36: 13-25; Exh. 19, p. 1; Exh. 20, p. 5; Exh 22, pp. 3-4.) It is clear that interpretive guidelines do not have the binding effect of regulation which these commentators would apparently prefer. They are simply statements reflecting the lead agency's current construction of the Act. As such, they lack the force and effect of law and, at best, may provide guidance to a court construing the Act.

One party recommended that § 12102 (b) define "interpretive guideline" as an official and binding interpretation of the Act that is published for the use, not just the information and guidance of interested parties. (Exh. 20, p. 5.) However, only interpretations which have been formally adopted as regulations may be binding. Of course, once an interpretation has been formally adopted, there would be no reason to refer to it as merely an interpretive guideline.

Another party recommended that § 12102 (b) refer to interpretive guidelines as draft regulations. (Exh. 6, pp. 6-8.) Generally speaking, it has been the lead agency's practice to consult with interested parties to arrive at a proper interpretation of the Act, publish that interpretation as an interpretative guideline with a request for additional comments, then propose the same or modified language for formal regulatory adoption. In this sense, interpretive guidelines have been treated as regulatory proposals in their draft form. Therefore, it is appropriate that the definition of this term be amended accordingly.

Two parties objected to the definition of "interpretive guideline" because it does not make clear that such guidelines would have no enforceable effect. (Exh. 16, pp. 3-4; Exh. 25, p. 3.) However, the lack of enforceability of interpretive guidelines was not lost upon other parties commenting on this proposal. In any event, the amended definition of "interpretive guideline" as a draft regulation should make clear that it does not have the same effect as a final regulation.

Section 12103. Interpretive Guideline Request

This section describes the procedure whereby any interested person may request an administrative interpretation of the Act by the lead agency.

Since the Act may raise a variety of issues related to law, risk assessment, hydrogeology, chemistry, industrial hygiene, biology and several other disciplines, it may be difficult for persons or organizations affected by the Act to obtain complete and timely resolution of these issues. Also, many of these issues may become more difficult to resolve over time if answers are forthcoming only from litigation concerning alleged violations of the discharge, release, or exposure restrictions. The variety of charges which can be made, and the possibility of inconsistent judgments in the difficult areas of law and science involved in such litigation, will make it very difficult for businesses or other persons to predict what activities are permissible under the Act.

In order to provide some direction in the implementation and interpretation of the Act, the lead agency proposes to issue uniform interpretive guidelines which express the lead agency's current construction of the terms of the Act, its restrictions and exemptions, and which propose procedures for state implementation of the Act. The interpretive guideline process will be a means for the public to bring to the attention of the lead agency issues related to the Act, organized in a manner which will allow the lead agency to respond to the inquiry by adopting an administrative interpretation.

In order for the lead agency and other state agencies to understand the issue raised by the request and to decide whether the guideline should be proposed or adopted, each request must contain a clear, concise description of the substance of the guideline requested and the reasons for the guideline. Written acknowledgment of receipt and an estimated date of review completion will be sent to the requester so that the parties concerned will know when to expect a decision. Subsection (b) also provides some rough time frames for processing under normal circumstances. Some requests for interpretive guidelines are better addressed as requests for a safe use determination or an information letter, depending on the nature or specificity of the inquiry, and subsection (c) allows the lead agency to make that determination as appropriate.

As noted in the comments to the preceding section, many parties objected that interpretive guidelines as proposed would not have the force and effect of law. Therefore, some parties recommended that this section require their formal regulatory adoption. (Exh. 5, p. 3, T 28:22-29; Exh.20, p. 5-6; Exh. 28, p. 2.)

It has been the practice of the lead agency, in issuing interpretive guidelines, to solicit the comments of interested

parties to determine whether further amendment or modification of the guideline is necessary or appropriate, then propose that language or modified language for regulatory adoption. This practice is consistent with the amended definition of "interpretive guideline" as a draft regulation. Of course, any draft is subject to modification, clarification or refinement. To require in these regulations that the published version of an "interpretive guideline" be proposed for formal regulatory without modification would deny the benefits of such modification, clarification or refinement.

On the other hand, where no comment in opposition to an interpretive guideline is received within a reasonable time after its publication, both regulators and the regulated would be best served by its proposal for formal adoption. Accordingly, subdivision (e) of this section has been modified to provide that interpretive guidelines are intended to reflect the lead agency's current construction of the Act and will be proposed for formal regulatory adoption within a reasonable time after its publication, provided that no public opposition is received by the lead agency. If opposition is received, the lead agency is not required to propose such formal adoption, but may, in its discretion, modify and republish it as an interpretive guideline, modify and propose it for formal adoption, rescind it altogether, or propose it for formal adoption as published.

Subdivision (d) has been amended to provide that all interpretive guidelines will be made available to interested parties either through the lead agency or publication in the California Regulatory Notice Register. This amendment is intended to provide the lead agency with greater flexibility in making guidelines available to interested parties.

Two parties recommended that the modification of interpretive guidelines be preceded by notice and opportunity to comment. (Exh. 17, p. 4; Exh 24, p. 2-3.) Such modifications, however, would generally be the result of public comment. Moreover, the result of such modification would not be binding and, if proposed for formal adoption as a regulation, would be subject to notice and public hearing requirements. Therefore, this proposal was not adopted.

Two parties recommended that, following the modification of an interpretive guideline, a grace period should be provided before it becomes enforceable. (Exh. 17, p. 4; Exh. 24, p. 3.) It appears, however, that no grace period is necessary, since neither the interpretive guideline nor the modification would be enforceable.

One commentator suggested that the difference between an interpretive guideline and a safe use determination should be clarified. (Exh. 28, p. 2.) The amended definition of interpretive guideline further clarifies the difference between the guidelines and safe use determinations.

Section 12104. Safe Use Determination

Health and Safety Code section 25248.5 prohibits any person in the course of doing business from knowingly discharging certain listed chemical carcinogens or reproductive toxicants into the environment where they pass or will probably pass into any source of drinking water. Health and Safety Code section 25249.6 also prohibits the knowing and intentional exposure of any individual to these chemicals without first giving clear and reasonable warning. Persons who violate these restrictions are subject to lawsuits for injunctions and civil penalties of up to $2500 per day pursuant to Health and Safety Code section 25249.7.

Many persons doing business need to know how the discharge, release and exposure prohibitions apply to the circumstances of their particular business. Interpretive guidelines can only provide general interpretations which may not completely resolve questions regarding specific applications. It is important that these questions, like the general questions addressed in interpretive guidelines, be answered in a consistent and accessible way. Thus, the lead agency is proposing the issuance of safe use determinations which would address specific issues and facts presented in writing to the lead agency.

Nine parties commented generally on the SUD process

Three commentators objected to SUDs on the ground that the SUD process shifts the burden of proving no significant risk for purposes of enforcement actions from businesses to the state. (Exh. 13, p. 1; Exh. 21, p. 2; Exh. 25, p. 2.) However, to the extent that SUDs are requested regarding issues of "no significant risk", the requester continues to bear the burden of proving his case, i.e. producing sufficient evidence to support a conclusion that the discharge or exposure in question in fact poses no significant risk. Subdivision (a) makes clear that a SUD is advisory only. It is not a binding determination. It is, therefore, merely evidence which the requester may present in a subsequent enforcement action in order to carry his burden of proof.

One commentator contended that the SUD process is inconsistent with the definition of knowingly, because it suggests that a business which has obtained a SUD concluding that its discharge or exposure poses no significant risk cannot be said to knowingly discharge or expose within the meaning of the Act. (Exh. 15, p. 6.) In other words, there is no "knowing" discharge or exposure where there is a good faith belief, based upon the SUD, that the discharge or exposure presents no significant risk.

The amended definition of "knowingly" makes clear that knowledge of a discharge or exposure to a listed chemical is all that is required to satisfy that element of the Act in an enforcement action. A belief that it poses no significant risk would be irrelevant.

Two commentators observed that the SUD process is premature in the absence of general criteria regarding risk assessments. (Exh. 16, pp. 10-11; Exh. 25, p.2.) This view appears to assume that the SUD process will be used only for the purpose of risk assessments. In fact, the SUD process is intended to address specifically the whole spectrum of issues which may arise under the Act. Therefore, while the present lack of risk assessment criteria may affect the lead agency's ability to issue SUDs regarding specific chemicals, it does not render the entire process premature.

The lead agency has provided assurances that risk assessments performed in response to SUD requests will utilize the methodologies set forth in these regulations or the interpretive guidelines adopted by the lead agency where no specific "no significant risk" level has been promulgated. (Exh. 16, p. 2, see letter attached.) The proposed language has been modified accordingly.

One commentator objected generally to the SUD process on the ground that it will encourage the use of toxic substances by businesses which have received a positive safe use determination, contrary to the intention of the Act. The Act, this comment contends, was intended as a disincentive to use toxics at all. (Exh. 15, p. 4.) However, as the commentator points out, Section 1 of the Act states that its purpose is to "deter actions that threaten public health and safety". (Id.) If a SUD concludes that a discharge or exposure poses no significant risk, it is doubtful that there is any such threat.

Another commentator objected that the term "safe use" is deceptive, noting that there is a "vigorous debate among scientists . . . as to whether any level of a carcinogen, however small, should be considered scientifically 'safe' for the exposed population". (Exh. 16, p. 11.) This comment also appears to be referring to determinations whether a discharge, release or exposure poses "no significant risk". It should be noted that the term "safe" was regarded to be synonymous with "insignificant" by the proponents to the Act. In the ballot pamphlet "Rebuttal to Argument Against Proposition 65", it was specifically stated that "Proposition 65 does not apply to Insignificant (safe) amounts of chemicals." Therefore, it appears to be consistent with the intent of the Act that determinations that a chemical discharge, release or exposure which poses "no significant risk" be referred to as "safe".

One commentator suggested that, instead of SUDs, the state should establish generic safe exposure levels for all listed chemicals. (Exh. 26, p.1.) It is the intention of the lead agency to establish in regulation levels of exposure which pose no significant risk for carcinogens and which are one one-thousandth of the no observable effect level for reproductive toxicants, in addition to providing SUDs.

Finally, one party recommended that the so-called "bounty hunter" provisions of the Act apply only where SUDs have not been requested. (Exh. 3, p. 11.) However, the entities and individuals who may file lawsuits to enforce the Act are specifically listed in Health and Safety Code § 25249.7. These regulations do not and could not limit the terms of this statute.
Section 12104 (a)

The safe use determination process cannot and should not be viewed as a means of insuring that a particular business will not incur liability under the Act or any other statute governing its handling of carcinogens or reproductive toxicants, because the Act does not give the lead agency or any other government agency the authority to grant immunity from prosecution or liability. Subdivision (a) clarifies that a safe use determination is only advisory and does not affect the authority to prosecute violators pursuant to Health and Safety Code section 25249.7.

Six commentators objected that SUDs will be advisory only, rather than binding effect. (Exh. 2, p. 2, T 14:18--15:12; Exh. 4, pp. 1-2, T 23:7-24:11; Exh. 5, p. 2, T 31:2-19; Exh. 3, p. 11; Exh. 19, p. 2, T: 9:22-23; Exh 22.) One commentator argued that this limitation made the entire SUD process unnecessary and unclear within the meaning of Government Code § 11349. (Exh 15, pp. 4-5.) Three commentators specifically urged that SUDs be formally adopted either as regulations or as permits. (Exh. 9; Exh. 22, p. 2; Exh. 28, p. 3.)

Unlike interpretative guidelines, which are in effect draft regulations, SUDs are not intended to have general application. They apply only to a "specific set of facts" (Section 12102, subdivision (c)), are limited to the particular facts on which they are based (Section 12104, subdivision (j)), and are not intended to affect other individuals or organizations. (Section 12104, subdivision (k)) Therefore, it would be inappropriate to promulgate them as regulations.

A permit, on the other hand, is a privilege conferred upon a person to do something which he or she might not otherwise have the right to do. In this case, the Act itself allows discharge or exposure to the extent that it poses no significant, unless the discharge is out of compliance with other legal requirements. Accordingly, it is not necessary to require permits for such discharges and exposures.

One commentator recommended that SUDs be made inadmissible evidence as an alternative to deleting the SUD process altogether. (Exh. 15, p. 6.) The Evidence Code provides generally that all relevant evidence is admissible. (§ 351) SUDs address specific situations, and if that situation became the subject of an enforcement action under the Act the SUD would clearly be relevant. It does not appear that the lead agency, in adopting these regulations, could deprive the courts of relevant facts which could bear upon their decisions. If a court believes that admitting a SUD would cause undue delay or prejudice, it has

the discretion to exclude it. (Evidence Code § 352)

One commentator recommended that the regulations clarify that SUDs have no enforceable legal status. (Exh. 25, pp. 2-3) It does not appear that such clarification is necessary. By definition a SUD is merely a written statement, not a regulation. (Section 12102, subdivision (c)) SUDs are "advisory only", and expressly have no affect upon the authority to bring actions under the Act, and no effect upon the duty of the courts to interpret the Act and apply it to the facts in question. (Section 12104, subdivision (a)) Clearly, SUDs have no enforceable effect and to amend the proposal to expressly so provide would be repetitive.

One commentator suggested that this section be amended to state that a safe use determination represents the state's best judgment of the application of the Act to the particular facts presented in the request ". . . and any other facts known by government agencies involved." (Exh. 28, p. 3.) However, the safe use determination process is intended to assist in applying the Act to the particular facts and circumstances presented by the requester. (See § 12104, subd. (j)) It is not clear that the process would be responsive to particular requests if additional facts are added to the request by the lead agency or other state agencies. If additional facts are necessary these regulations permit the agency to request them. (§ 12104, sub. (g)) Therefore, this suggestion appears to be inappropriate.

Section 12104 (b)

For consistent and effective administration of the safe use determination process, the lead agency will not provide safe use determination in circumstances, as specified in subsection (b), where issuance of such ruling would not further the purposes of the Act or the public interest.

In order to make the most productive use of limited resources, the lead agency needs to focus its energies on requests where there is a greater likelihood that a safe use determination will actually be applied to a current or planned business activity. Subsections (b)(2) and (b)(4) would exclude hypothetical situations, alternative plans and situations where the requester is not directly required to enforce or comply with the Act. Without these basic exclusions, it would be more difficult for requesters to obtain timely responses for legitimate inquiries. Safe use determinations will not be issued where the request pertains to pending litigation because it is not the role of the lead agency to provide expert opinions in preparation of trial. Questions concerning compliance with orders, permits, regulations or laws other than the Act should be answered, not by the lead agency, but by the agencies responsible for administering those laws.

Section 12104 (b)(1)

One commentator recommended that section 12104, subdivision (b)(1) be modified to preclude the issuance of a SUD only where the very scientific issue presented is in fact being litigated under the Act. (Exh.24, p. 4.) Under the current proposal, no SUD could be issued where the request "relates to the subject matter of a civil or criminal case pending in any court". Apparently the author of this comment is concerned that many aspects of a SUD can relate to the "subject matter" of a pending case.

A similar proposal for administrative proceedings was made in § 12104, subd. (b)(5). However, in that provision issuance of the SUD would be precluded if the subject matter of the request is at issue in the proceeding. This appears to be a clearer statement. Therefore, for the sake of consistency, this provision has been amended to conform to subdivision (b)(5).

By definition, SUDs may be requested only for a very narrow and specific set of facts. Therefore, the subject of such a request would relate to a very narrow range of issues in any pending cases. If a SUD request is so closely related to a pending case that its subject matter is at issue, then a SUD properly should not issue. The purpose of this provision is to prevent businesses from using the SUD process to prepare for litigation of any type, not just enforcement actions under the Act. The lead agency has limited resources to provide this service, and a large influx of requests unrelated to the administration of the Act could prove overwhelming.

Section 12104 (b)(2)

Four commentators recommended that SUDs be issued when requested by trade associations. (Exh. 17, p. 5; Exh. 14, p. 2, T 34:3-5; Exh. 12, p. 2, T 28:9-12; Exh. 24, p. 6.) Under the current proposal, the requesting party must be "directly required to enforce or comply with the provisions of the Act. As one commentator put it, in cases in which many companies face the same problem, the agency would make better use of its limited resources by allowing trade association to obtain" SUDs. (Exh. 17, p. 5.)

This comment appears to have merit. It may be that several members of an industry association share identical business practices which could properly be the subject of joint SUD request.

There appear to be two alternatives available to make this modification. Section 104, subdivision (b)(2) could be deleted or it could be modified to allow a limited exception for trade association.

Modification of this provision appears to be more desirable. Deletion of the provision would permit anyone to request a SUD on behalf of any business, individually or jointly. Thus, law firms might make requests on behalf of individual clients. Since the

purpose of this modification is to permit joint requests where appropriate, the lead agency has concluded that modification of this provision to allow trade associations to make such requests is preferable.

Section 12104 (b)(3)

The purpose of establishing a safe use determination process is to provide guidance to individuals who must comply with or enforce the Act. It is not the lead agency's intent to provide guidance or clarification concerning laws, regulations, permits, requirements or orders administered or issued by other state or federal agencies. Therefore, this provision excludes requests for safe use determinations which concern compliance with other laws, regulations, permits, requirements or orders of other agencies.

One commentator requested that this provision be clarified. (Exh. 28, p. 4.) They suggest that compliance with laws which facilitate compliance with the Act must be considered. The lead agency agrees that compliance with other laws should be considered in issuing safe use determinations, where relevant and necessary to a determination of compliance with the Act. However, safe use determinations will be issued only where the request concerns compliance with the Act. Questions of compliance with other laws, regulations, permits, requirements or orders should be addressed to the agencies that administer or enforce them.

Section 12104 (b)(4)

This proposed provision would deny the issuance of a SUD where the request does not involve a current or planned activity of the requester. If the request is hypothetical, or is made on each of several alternative plans in a proposed activity, the SUD would not be issued.

One commentator complained that it is unclear what "current or planned activity" encompasses, and suggested that it should be read in conjunction with "prospective business activities" as used in Section 12104 (a). The lead agency agrees that the two terms should be read each in light of the other.

One commentator recommended that this provision be deleted, particularly that portion which would prevent SUDs addressing each of several alternative plans. (Exh. 19, p. 2, T 9:23-24) The SUD process, however, was not designed to be a planning tool. It was intended to provide businesses engaged in a course of conduct, or which have settled upon a planned course of conduct not yet implemented, a means to obtain a determination whether that course of conduct is in compliance with the various provisions of the Act. Moreover, to permit the SUD process to be used as a planning tool might overwhelm the limited resources of the state, and prevent businesses presently engaged in a course of conduct which may risk liability under the Act from obtaining

SUDs in a timely fashion. Therefore, this recommendation was not adopted.

Section 12104 (b)(5)

Under this provision, if the subject matter of a SUD request is at issue in an administrative proceeding before a government agency, the SUD may not be issued. One commentator recommended that this provision be modified to prohibit issuance of the SUD only where there is exact correlation between the issues in the request and the administrative proceeding. (Exh. 24, p. 6.) Again, by definition the subject matter of a SUD is intended to be very specific. Accordingly, in order for the subject matter of a SUD request to be at issue in an administrative proceeding, there will need to be very close correlation. Therefore, it does not appear that this provision as proposed will preclude significantly more requests than the modification proposed, and would provide greater flexibility. The recommendation was not adopted.

Two commentators recommended clarification that SUDs will be issued for listed chemicals only. (Exh. 16, p. 11; Exh. 25, p. 3.) This appears to be a reasonable recommendation, one which will further the goal of preserving the SUD process for business actually affected by the Act. Accordingly, reference has been made in this subdivision to requests which do not concern a listed chemical.

Section 12104, subdivision (c)

Safe use determinations are intended to provide guidance as to businesses whose operations are sufficiently well defined to allow a ruling. In order to ensure that each request contains sufficient information for the lead agency to understand the fact situation at issue and to arrive at a determination, the requester is required to submit all pertinent information and documentation as listed in subsection (c). Information on pending litigation, administrative hearings, or notices of violation as described in subdivision (c)(9) is relevant to the purpose of the request and whether a formal ruling would be an appropriate response.

Since all determination requests will be published in the California Regulatory Notice Register and otherwise made available for public inspection, subsection (c)(7) requires each request to specifically identify anything in the request or other documents submitted which the requester claims should be kept confidential pursuant to the Public Records Act. The procedure for handling these claims protects the privacy interests of the requester in a way which is consistent with the Public Records Act.

One commentator suggested that subdivision (c) be amended to allow requesters to apply for safe use determinations applicable to many individuals, to request specific outcomes and to require

provision of only facts known to the requester. (Exh. 28, pp. 4-5) As noted above, the regulations have been revised to allow requests for safe use determination by trade associations under some circumstances. Further, it is clear in these regulations that "any interested person" may request an interpretive guideline concerning any subject related to the Act. (§ 12103, subd. (a)) The lead agency believe that these provisions provide ample opportunity for individuals, association or groups to request appropriate guidance in interpreting or complying with the Act. The regulations currently allow requesters for safe use determinations to specify the result they are seeking (§ 12104, (c)(6)) The regulations cannot and do not require persons who request safe use determinations to provide facts other than those known to them. If the facts provided are insufficient to allow a safe use determination to be made the lead agency will decline to issue the determination as provided in § 12104, subd. (h)(2). It does not seem necessary to clarify that a requester need not provide facts they don't have.

One commentator recommended that subdivision (c)(2) be amended to provide that only documents necessary to a SUD be required. (Exh. 19, p. 2, T 9:24 - 10:1.) As proposed this provision requires that the requester submit copies of any contracts, agreements, instruments, reports, analyzes or other documents directly related to the activity for which the SUD is requested or to the applicability of the Act to the activity. The lead agency agrees with this commentator that as currently drawn, this requirement may be overbroad. Accordingly, this provision has been amended to provide that documents which are both directly related to the activity for which the SUD is requested and directly related to the applicability of the Act to the activity.

Two commentators recommended that subsection (c)(7) be modified to provide that, where a request for confidentiality has been denied, withdrawal of the information should be expressly permitted to prevent public disclosure. (Exh. 17, p. 5; Exh. 19, p. 2, T 10:2-3.) However, information retained by the lead agency relating to the conduct of the public's business is a public record (Government Code § 6252, subd. (d)) and subject to inspection (Government Code § 6253) unless exempted from disclosure under Government Code § 6254. If confidentiality is denied for portions of a request, therefore, the information becomes a public record and subject to inspection. It does not appear that the lead agency is authorized to provide that such information is confidential, and returning the information to the requester to avoid disclosure would create the impression that the lead agency is attempting to withhold records from the public.

Four commentators objected that confidentiality be afforded to any SUD information. (Exh 13, p. 1; Exh. 15, pp. 2-4; Exh. 16, p. 12; Exh. 25, p. 3.) Yet confidentiality for such items as trade secrets and official information where the need for confidentiality outweighs the public's need to know are essential to promoting access to the SUD process. There appears to be no

reason to treat information confidential for other purposes as public information under the Act. Therefore, the confidentiality provisions have been retained.

One commentator suggested that a mechanism be developed for compensating requesters of SUDs for costs incurred in developing data or submitting a request. (Exh. 28, p. 5.) This suggestion raises issues not addressed in the original regulatory proposal. The basis for and the mechanics of seeking cost sharing by individuals who did not request a SUD is unclear. While there is nothing in the Act or these regulations that preclude such cost sharing, the lead agency has determined that it is neither necessary no appropriate to require such sharing in these regulations.

This same commentator requested a clarification of the criteria for requesting a waiver of fees as provided in subdivision (c)(8). (Exh. 28, p. 5.) The criteria for waiving all or part of a SUD processing fee or other charges is included in § 12104 (d). Subdivision (c)(8) was intended to require that requests for fee waiver be included in the request for a SUD along with a statement of the reason for the waiver.

Section 12104 (d)

Because safe use determinations are directed at specific fact situations and business operations described in individual requests, the determination process should be financed by user charges. The nonrefundable $500 processing fee and additional special assessments described in subsection (d) are necessary to make the program financially self-supporting. To ensure accessibility, all or part of the fees may be waived on grounds of hardship or in furtherance of the public interest.

One commentator objected to the state charging for SUDs. (Exh. 10, p. 4.) Such charges, however, are essential to provide this service at all. The legislature has specifically directed that fees be set at a level sufficient to fund the total state cost of administering SUD requests. (Budget Act of 1987, § 23.00, subsection (m))

One commentator urged that the $500 fee is exorbitant, since the lead agency needs merely to obtain manufacturer's data and apply it. (Exh. 12, p. 3.) This comment appears to assume that the lead agency will simply be conducting generic risk assessments. In fact, the issues addressed by SUDs will be specific to the activities of the requester. For example, does a particular exposure present a significant risk? This may involve a whole range of issues, such as where the exposure is measured, the nature of the exposed population, the frequency of the exposure, etc. Given the range of information which may need to be considered, and the processing necessary to consider a request, a $500 base fee is reasonable and necessary.

Two commentators recommended clarification whether SUDs involving

more than one issue will require a separate processing fee. (Exh. 10, p. 4-5; Exh. 12, p. 2-3.) Nothing in this section limits SUDs to a single issue, nor levies the $500 fee on an issue by issue basis. The $500 non-refundable fee is intended to cover the cost of reviewing the request. If it appears that providing the SUD will require more than $500, an additional assessment may be made. Thus, the cost of addressing additional issues may require such an additional assessment, but not an additional processing fee.

Section 12104 (e)

All requests will be acknowledged in writing, and requesters will be advised of the status of their requests. If deficiencies in the request are not corrected within 30 days, the request will be closed. This requirement is essential to keep the request files active and to reduce the number of requests on "hold" status.

Two commentators recommended clarification whether a new processing fee will be required to reopen a "closed" request. (Exh. 10, p. 5; Exh 27, p. 1.) It is not the lead agency's intention that a processing fee be imposed when such a request is reopened.

One commentator requested additional time to respond to requests for further information. (Exh. 27, p. 1.) Although it is conceded that allowing only thirty days, as opposed to a longer period, for a requester to provide additional information may impose some burden upon the requester, it furthers the policy of maintaining SUDs in an active status, and encourages the requester to initially provide as much information as possible.

One commentator recommended that the processing fee be refunded where a request is closed. (Exh. 17, p. 6.) Yet, if this were the case, the state would be forced to bear the expense of the requester's failure to provide complete information.

If a request complies with all the requirements, public notice of the request, including the text or a summary of the request, will be published in the California Regulatory Notice Register at least 30 days before the public hearing is held. The text or summaries of responses to the requests will also be published in the Notice Register, and will be sent to the requester and other interested persons. All the notice, public comment, and hearing requirements contained in this section are intended to make the safe use determination process as accessible and as public as possible.

Subsection (g) is intended to allow any state agency considering a request for a safe use determination to ask the requester for additional information or explanation which may assist the agency in its review.

Depending on the nature of the request for safe use determination, issuance of an interpretive guideline or an

information letter may be a more appropriate response than a safe use determination. Subsection (h) is designed to give lead agency the flexibility to make such a determination, after a complete review of the requests and any comments received, as well as the discretion to not issue a determination at all because of an insufficient factual basis or for any other reason.

One commentator suggested development of criteria for determining an appropriate response to a SUD as provided in subdivision (h)(1)-(4). (Exh. 28, p. 5.) Whether the lead agency will issue a SUD, an interpretive guideline, an information letter or make some other response to a SUD request will be determined on a case by case basis. If general criteria are developed as experience with SUD requests is gained, then the agency will consider

One commentator recommended that processing fees should be refunded where a SUD request is treated as an interpretive guideline or an information letter, since no such charge is made for those services. (Exh. 17, p. 6.) However, regardless of the eventual outcome, each SUD request must be reviewed for sufficiency of data and its appropriateness as the subject of a SUD. The state would still incur the cost for this review, which the processing fee is designed to cover. Therefore, this recommendation was not adopted.

Section 12104 (j)

Subsection (j) describes procedures for modification and revocation of safe use determinations, including notice to the requester and publication in the Notice Register. As with interpretive guidelines, safe use determinations may be modified or revoked as necessary to provide current and reliable guidance on the lead agency's interpretation of the Act. Subsections (j) and (k) clarify that safe use determinations are limited to the particular facts of the request as opposed to interpretive guidelines which have a more general application.

Two commentators recommended that opportunity for notice and comment be provided prior to the modification of SUDs. (Exh. 17, p. 4; Exh. 24, p. 6.) This recommendation appears to mistake the reason for public comment regarding SUDs. SUDs are not like regulations, which require notice and comment because they have general application. Such determinations do not have such binding general application. Therefore, it is unnecessary to provide notice of its modification to anyone but the party originally requesting it.

Section 12201

The Health and Welfare Agency has determined that it is necessary and appropriate to define several terms used in the Act. These definitions will provide a source of consistent interpretation of the Act for state agencies in the adoption or amendment of regulations. In addition, they will provide guidance to businesses, law enforcement agencies and others who must comply with or enforce the provisions of the Act.

These proposed regulations are taken from the Interpretive Guideline first issued by the Agency on February 27, 1987.

One commentator objected that § 12201 provides for non-binding interpretive guidelines and is written in a discursive style which is difficult to use. (Exh. 6, p. 10-11) It is the intention of the lead agency that these definitions have the force and effect of law. Therefore, this section has been modified to delete all reference to interpretive guidelines, and to change the style into a regulatory format.

(a) In the course of doing business

The terms "doing business" or "business" have been interpreted by California courts and the Legislature in various ways depending on the purpose of a particular enactment. See Westinghouse Electric Corp. v. Superior Court, 17 Cal.3d 259, 269 (1976). They have been defined to include only those activities conducted for gain, profit or advantage (for example, Revenue & Taxation Code section 6013), and to include governmental activities, professions, occupations and the operation of institutions "whether carried on for profit or not". (Evidence Code section 1270)

Although the Act does not define "business", the definition of "person in the course of doing business" in Health & Safety Code section 25249.11 (b) does exclude governmental entities. The need for such an exclusion implies that the term "business" was intended to include activities of persons who have ten or more employees without regard to whether those activities are conducted for gain, profit or advantage.

Further, a broad interpretation of "business" is consistent with the purposes of the Act. Section 1 of Proposition 65 on the November 4, 1986 ballot declared the peoples' rights to protect themselves and the water they drink against chemicals that cause cancer, birth defects and other reproductive harm and to be informed about exposures to such chemicals. These rights are furthered by including activities of persons who have ten or more employees within those regulated by the Act regardless of whether they are conducted for gain, profit or advantage.

Therefore, it is appropriate to consider the activities of

persons who have ten or more employees as covered by the prohibitions of the Act unless such persons are specifically excluded by the definition of "person in the course of doing business". Section 25249.11 (a)

Seven parties commented on this provision. Five commentators objected that the definition does not clarify what acts or omissions which occur on the business premises are not in the course of business. (Exh. 1, p. 3; Exh. 2, pp. 1-2, T 15:15-16:19; Exh. 6, p. 11; Exh. 22, p. 4; Exh. 26, p. 2.) Two recommended that this term include only those acts or omissions by employees which are within the scope of employment, meaning those acts taken at the employer's direction and which would further the business purpose. (Exh. 2, pp. 1-2; Exh. 6, p. 11-12.) One recommended that the term exclude acts or omissions by employees which are unauthorized or illegal. (Exh. 22, p. 4.)

Three commentators recommended the express exclusion from the definition of the term the personal use, consumption or production of a listed chemical on the premises of the employer or while performing activities for the employer. (Exh. 2, pp. 1-2; Exh. 6, p. 12; Exh. 22, p. 4.)

Two commentator recommended the express exclusion from the definition of the term acts or omissions resulting from acts of war and natural disaster or phenomena. (Exh. 6, p. 13; Exh. 22, p. 4.)

One commentator recommended that the party causing a prohibited discharge be required to indemnify those businesses wrongly prosecuted therefore. (Exh. 3, p. 12.) Another recommended exclusion of any reference to the requirement that affected businesses have ten or more employees, on the ground that this distinction violates both the state and federal constitutions. (Exh. 12, p. 3.)

One commentator recommended that the acts or omissions of third parties, including independent contractors be expressly excluded in the definition of this term. (Exh. 22, p. 4.)

One party objected that the definition fails to clarify whether persons outside of California whose business activities result in exposures in California are subject to the Act. (Exh. 26, p. 2.)

As proposed, this definition was intended to have the very limited effect of including within the meaning of the Act non-profit and for-profit businesses. Government Code § 11346.8 prohibits the adoption of a regulation which has been changed from that originally made available to the public unless the change is "sufficiently related to the original text that the public was adequately placed on notice that the change could result from the originally proposed regulatory action". These recommendations and objections are so expansive when compared to the limited scope of the original test that there adoption at this time would, in the lead agency's view, violate this

Government Code provision. The lead agency will consider them as a possible subject for future regulatory action.

(b) Employee

The prohibitions in the Act apply to each "person in the course of doing business". (Health & Safety Code sections 25249.5 and 25249.6). A "person in the course of doing business" is defined in the Act to exclude "any person employing fewer than ten employees in his business". (Health & Safety Code section 25249.11 (b)) The Act does not otherwise define employee or describe the method of counting employees.

In order to provide some certainty in determining whether an individual is an employee, the Health and Welfare Agency has concluded that it is appropriate to combine the widely used definitions of "employee" in current state law. Thus, a person will be considered to be an employee under the Act if he or she is an employee for purposes of Unemployment Insurance Coverage under Unemployment Insurance Code section 621 or Worker's Compensation and Insurance under Labor Code section 3351. It is the intent of the Health and Welfare Agency to include as an "employee" under the Act, any individual who is covered by unemployment insurance or Worker's Compensation.

These definitions were adopted because they are well established and widely used by businesses which are subject to the prohibitions in the Act. Thus, it is appropriate to interpret the definitions of "employee" in Unemployment Insurance Code section 621 and Labor Code section 3351 in light of court decisions which further refine those terms. In this way, individual employers may readily be able to determine whether they are covered by the prohibitions in the Act by counting the number of individuals for whom they are required by law to provide unemployment insurance or Worker's Compensation coverage

The proposed regulation also specifies a method of counting employees for the purpose of determining whether an employer is a "person in the course of doing business" within the meaning of the Act. Although the prohibitions in the Act apply only to certain persons who have ten or more employees, the Act does not specify a method for counting employees. There are many employers in California who employ more than ten individuals during a three-month, six-month or twelve-month period but who do not have ten employees at any time during such period. Similarly, there are many employers in California who have ten or more employees at one time but only for a portion of the year. Examples of this latter group include retail businesses that add sales staff during the December holiday season and farmers who hire additional employees to harvest seasonal crops.

The lead agency has considered several alternative ways to count the number employees including averaging the number over a fixed period such as a quarter or a year or simply including all persons that have ten or more employees at any time during a

quarter or a year within the definition of "person in the course of doing business". These alternatives which include counting employees over long periods of time do not provide fair and reasonable results in all cases. For example, a business that is contracting for economic reasons could be required to comply with the prohibitions in the Act for several months after it has had fewer than ten employees. Also, a business that is expanding could become responsible for complying with the prohibitions in the Act for some period of time before it hired the tenth employee.

In order to minimize such problems, the Agency has determined that the Act should be interpreted to include as a "person in the course of doing business" only an employer who has ten or more employees on the date of the discharge, release or exposure in question. Thus, all employers are subject to the requirements and the prohibitions in the Act where they have ten or more employees on the date of the allegedly prohibited activity.

The proposed regulation also specifies that in counting employees for the purpose of determining whether an employer is a "person in the course of doing business", both full-time and part-time employees are considered. It has been argued that the number of employees should be counted as full time equivalent positions. Thus, a person employing eighteen employees half-time would only be considered to have nine employees. This argument is inconsistent with the definition of "employee" adopted in this regulation and it could require complicated calculation of individual employee working hours on specific dates in order to determine whether an employer is a "person in the course of doing business" under the Act. Therefore, the Agency has determined that prohibitions in the Act apply to an employer who has ten or more employees on the day of an alleged discharge, release or exposure regardless of how many hours employees work that day.

One commentator recommended that the number of employees of an employer be determined by averaging the number of employees from the previous year. (Exh. 9, p. 2.) As has already been indicated, the lead agency has considered and rejected this alternative. The suggestion was offered based upon the assumption that exposure to agricultural products occurs on the date that the product is consumed, and that it will be difficult for the farmer to determine how many employees it has on that date. In fact, nothing provides that exposure occurs only at the time a particular consumer good is consumed. The term "expose" generally means "to lay open", as to something which is injurious or dangerous. Laying an individual open to a chemical hazard through a consumer product could result from any act which propels the product toward the individual. Thus, the assumption upon which this comment is based does not appear to be correct. The lead agency has not adopted the strict interpretation of exposure which might provide the need for this proposed modification.

Moreover, this proposed modification would itself pose problems,

particularly for new businesses without previous years' employment figures. Therefore, this modification was not adopted.

Three commentators recommended clarification whether independent contractors are included within the meaning of "employee". (Exh. 10, p. 6; Exh. 22, pp. 4-5; Exh. 23, p. 1.) Under the lead agency's proposal, "employee" means every person in the service of an employer (Labor Code § 3351), or any individual who, under the usual common law rules applicable in determining the employer-employee relationship, has the status of an employee (Unemployment Insurance Code § 621). Under either of these definitions, independent contractors are not employees. Further, there is sufficient case authority on the distinction between employees and independent contractors that further clarification in these regulations is unnecessary, and may be unduly confining.

One commentator recommended clarification that "employee" does not include "agent", noting that this is the case under the common law. (Exh. 10, p. 6.) However, if the common law already so provides, then under the lead agency's proposal this concern has been sufficiently addressed.

One commentator recommended clarification whether a joint employee is an employee of each employer at the time of the discharge. (Exh. 10, p. 6.) While it may present an issue for worker's compensation or unemployment insurance purposes which employer a joint employee is serving at a specific point in time, under the Act the question is simply whether at the time of a discharge, release or exposure a person is an employee. This question can be resolved by applying the definition as proposed, and no modification appears to be necessary.

One commentator objected that the reference to Unemployment Code § 621 is confusing. (Exh. 6, p. 13-14.) This confusion appears to arise out of remarks in the initial statement of reasons that other provisions of the Unemployment Insurance Code could provide guidance in applying the definition. The object of the lead agency in referring to the statutory definitions in § 621 and Labor Code § 3351 was not to adopt all the statutory provisions related to those sections, but rather to adopt a single definition with an established body of case law upon which businesses could rely in determining whether they are subject to the provisions of the Act. To the extent that the text of the initial statement of reasons was inconsistent with this purpose, it is superseded by this final statement of reasons.

Finally, one commentator recommended clarification that "date or dates in question" refers to the date on which acts or omissions constituting a violation of the Act occur. (Exh. 6, pp. 15-16.) The lead agency's proposal has been amended accordingly.

(c Knowingly

Under Health and Safety Code § 25249.5, persons are prohibited

from "knowingly" discharging listed chemicals. Under § 25249.6, persons must provide a warning whenever they "knowingly" and intentionally expose others to listed chemicals. The Act does not define the term "knowingly". As initially proposed by the lead agency, this definition would provide that "knowingly" refers only to knowledge of the act of discharging or exposing. It would further have provided that if through misfortune or accident and without evil design, intention or culpable negligence, a person commits an act or omits to do something which results in a discharge, release or exposure, no violation of either § 25249.5 or § 25249.6 has occurred.

Seven commentators recommended that knowledge that the chemical in question is on the Governor's list also be required. (Exh. 9, p. 2; Exh. 17, p. 3; Exh. 16, pp. 13-14; Exh. 6, pp. 16-17, Exh. 19, p. 3; Exh. 22, pp. 5-6; Exh. 25, p. 3.) They point to language in the ballot argument in support of Proposition 65, which states:

> "These new laws will not take anyone by surprise. They apply only to businesses that <u>know</u> they are putting one of the chemicals out into the environment, and that <u>know</u> the chemical is actually on the Governor's list." (Emphasis in the original.)

Accordingly, this proposal has been modified to provide that the term refers not only to knowledge of the fact that a discharge, release or exposure is occurring, but to knowledge that the chemical in question is on the Governor's list.

Two commentators recommended that knowledge that the discharge, release or exposure poses a significant risk should be required. (Exh. 10, pp. 8-10; Exh. 4, pp. 2-3, T 24: 21-25:4.) Four commentators recommended that knowledge that a discharge or release "probably will pass" be required. (Exh. 6, pp. 16-17; Exh. 19, p. 3; Exh. 22, p. 5-6; Exh. 26, p. 2.) Three commentators recommended that knowledge that an exposure was without warning be required. (Exh. 19, p. 3; Exh. 22, pp. 5-6; Exh. 6, pp. 16-17.)

As indicated above, the ballot arguments in support of Proposition 65 specifically describe the knowledge which §§ 25249.5 and 25249.6 require. It does not appear that there is sufficient authority to require additional knowledge. Some of these commentators cited the Penal Code as support for their recommendation, pointing out that in criminal cases "knowing" requires knowledge of each element of the offense. However, § 25249.5 and § 25249.6 are not criminal statutes. The remedies made available for violation of those sections, both monetary and injunctive, are civil in their nature. Therefore, to define "knowing" based upon principles of criminal law would appear to be inappropriate.

One commentator recommended that knowledge of a manufacturer that a product was manufactured after the date upon which the warning requirement became applicable to a chemical in the product be

required. (Exh. 5, p. 7; T 32:5-15.) However, the warning requirement becomes effective one year after a chemical is listed. One apparent purpose of this one year delay is to provide the manufacturer and others in the chain of supply with an opportunity to identify which products contain the listed chemical, and provide warning where an exposure will result. To adopt this proposed modification would ignore the fact that, for an entire year before the date upon which the warning requirement takes effect for a particular chemical, the manufacturer knows that a chemical is listed. To permit the manufacturer to continue manufacturing and dispatching products to market without warning despite this knowledge would be unjustifiable, and contrary to the apparent of the voters. Therefore, it does not appear that the lead agency is authorized to adopt this modification.

Three commentators objected to the provision regarding accident or misfortune. One commentator thought unnecessary the requirement that such accident or misfortune be without evil design, intention or culpable negligence, since he contends there can be no accident when these are present, and recommended replacing the conjunctive "and" between "misfortune" and "without" with the disjunctive "or". (Exh. 9, pp. 2-3.) However, this provision was not intended to apply to all acts committed without evil design, intention or culpable negligence. It applies only to accidents or misfortune. Further, while no accident occurs where it is intended, it is quite conceivable that accidents can happen by design or as the result of negligence which is a significant contributory cause.

One commentator thought the accident provision to be unnecessary, since accidents cannot be knowing. (Exh. 25, pp. 3-4.) However, under the lead agency's definition of "knowing", only knowledge of a discharge, release or exposure of a listed chemical is required. It could be argued that, in the case of an accident, a person in the course of doing business has this knowledge, even though he may be helpless to avoid the discharge, release or exposure. In the view of the lead agency, little benefit is to be derived from the imposition of civil penalties upon blameless victims of circumstance. Thus, the purpose of this provision is to state that liability does not attach to such accidents.

One commentator objected that this proposal is contrary to Health and Safety Code § 25249.5, since the proposal would require that discharges or releases be intentional. This same commentator objected that the proposal refers to a criminal, rather than civil, mens rea. (Exh. 16, p. 14.)

This provision merely recognizes that in order for there to be a discharge, there must be some act or omission on the part of a business which causes the discharge. In the case of the accidents and misfortunes described in the proposed language, no such act or omission occurs. A business engaged in innocent conduct is the victim of circumstance. Thus, to the extent that the business can prove accident or misfortune as described in

this provision, no discharge or release within the meaning of the Act has occurred.

Regarding the appropriate mens rea, the source of concern appears to be the phrase "culpable negligence", which suggests that liability attaches under the Act only where there is criminal negligence. Other commentators questioned the meaning of "culpable". (Exh. 26, p. 2; Exh. 10, p. 10.)

There is no doubt that enforcement actions under the Act are civil in nature. Only civil penalties may be imposed in actions brought under § 25249.7. As applied to civil actions, the words "culpable negligence" often mean about the same as actionable negligence. (Hauck v. Crawford, 62 N.W. 2d 92; State v. Studebaker, 66 S.W. 2d 877.) In making this proposal, such a definition was intended by the lead agency. To avoid confusion over the intended meaning, the proposed language has been modified to refer to "negligence", rather than culpable negligence. Thus, if a business's negligence is a significant contributory cause of an accident or some misfortune, any resulting discharge, release or exposure may be a violation of the Act.

One commentator recommended that a discharge which is discovered not become a "knowing" discharge if the business takes all reasonable steps to stop it. (Exh. 26, pp. 2-3.) This proposed regulation is not designed to address all the problems which might arise under the Act. Therefore, the lead agency will consider this suggested modification as a possible candidate for future regulatory adoption, but does not adopt it here.

(d) Passes or probably will pass into a source of drinking water

This definition is intended to clarify several aspects of the Act's prohibition on discharging listed chemicals onto or into land where such chemicals pass or probably will pass into a source of drinking water. As proposed by the lead agency, it would have clarified that "water" and "source of drinking water" include both surface and groundwater. However, this provision has been amended to define only the term "water", the Act already provides that "source of drinking water" includes "water which is identified or designated in a water quality control plan adopted by a regional board as being suitable for domestic or municipal uses". This includes both surface and groundwater.

One commentator objected to this provision on the ground that "source of drinking water" should not include all surface and groundwater, but only water which people will drink. (Exh. 6, pp. 17-18.) It is clear, however, that "source of drinking water" applies to water which, in the view of the regional water quality control boards, may be suitable for drinking, even though it is not at present used as a source of drinking. (Health and Safety Code § 25249.11, subd. (d).) The purpose of the Act is to keep listed chemicals out of present and potential drinking water

supplies. (See ballot Argument in Favor of Proposition 65.) The deletion of "source of drinking water" in this sentence should not be construed to mean that "source of drinking water" does not include both surface and groundwater.

The definition also clarifies that a discharge to land which is in hydraulic continuity with a source of drinking water probably will pass to that source whether or not it is upgradient or upstream.

Eight commentators objected that the term "hydraulic continuity" is overly broad because it could conceivable include all water, and because it is physically impossible for a discharge or release in hydraulic continuity with a source of drinking water but downgradient or downstream from a source of drinking water to migrate into that source of drinking water. (Exh. 9, p.4; Exh. 11, p. 2; Exh. 6, PP. 19-20; Exh. 19, p. 3; Exh. 22, p. 6; Exh. 23, pp. 1-2; Exh. 26, pp. 3-4; T 57:4-12.)

These comments appear to assume that "source of drinking water" refers to a location where water is in fact drawn for drinking purposes. For example, as one comment stated, the fact that hydrogeologic units in contact with one another can allow water to flow between the units, "alone does not in itself lead to any conclusions about the probability of migration to a source of drinking water." (Exh. 6, p. 19.) Accordingly, several comments declared that the question whether a discharge or release probably will pass into any source of drinking water must be determined on a case-by-case basis, considering several factors such as the nature of the discharge or release, its quantity, location, and the location of the drinking water source. (Exh. 2, p. 2, T 16:24-17:10; Exh. 6, p. 19; Exh. 11, p. 2; Exh. 23, p. 2; Exh. 26, p. 4.) Thus, unless the discharge or release occurs at the place at which drinking water is presently drawn, these comments contend that there must be additional factors which would propel the discharged or released chemical to that location.

The Act defines "source of drinking water" as more than a present source of drinking water. It also includes any water which is identified or designated in a water quality control plan adopted by a regional board as being suitable for domestic or municipal uses" (Health and Safety Code § 25249.11, subd. (d)), regardless whether the water so identified or designated is presently used for drinking purposes. The apparent purpose is to protect all water which might be suitable for domestic or municipal uses, not just the water in fact used at present for those purposes.

"Hydraulic continuity", in its plain sense, means that there is a hydrogeologic area within which water is connected by patterns of flow. Water may be drawn from this hydrogeologic area at one or several locations. Water may flow, because of the hydraulic continuity, from some parts of this area to the point of withdrawal, or it may flow from the point of withdrawal to other parts of the area. However, it is, generally speaking, all part

of the same source.

For example, if a stream segment which is presently used as a point of drinking water uptake also charges a groundwater reserve not presently used as a point of drinking water uptake, contamination of the groundwater may not be likely to flow upwards to the surface stream. However, since the groundwater is composed of water from the surface stream it would be a potential source of drinking water as well. In the view of the lead agency, where hydraulic continuity would present several potential points of uptake, none should be contaminated. Thus, it is important to make clear that discharges may be prohibited by the Act even where they are not made directly to a present source of drinking water or to land where they will directly reach drinking water.

Some commentators contend that this makes no sense, that discharges to the ocean would be in hydraulic continuity with fresh water rivers which flow into the ocean, and therefore prohibited even though the ocean is not a source of drinking water. (Exh. 6, p. 19; Exh 26, pp. 3-4.)

The lead agency concedes that saline bodies of water, even though in hydraulic continuity with fresh water, are not themselves regarded as sources of drinking water, and it was not the purpose of the Act under such circumstances to prevent discharge to such bodies of water. The lead agency also recognizes that in the case of hydraulic continuity with such bodies of water, the flow of water from the saline body to the fresh water body would likely render the fresh water body itself saline and most likely unsuitable for drinking purposes. Therefore, this provision has been modified to provide that for purposes of this subdivision, the ocean, saline bays, the Salton Sea, Mono Lake, New River, and Alamo River are not in hydraulic continuity with any source of drinking water unless identified or designated by a regional water quality control board as being a source of drinking water.

One commentator recommended that the term "source of drinking water" be defined to exclude small or poor quality sources. (Exh.11, p. 3, T 5:21-6:11.) However, the responsibility for determining which particular water bodies are suitable for domestic or municipal uses belongs to the regional water quality control boards. Presumably, bodies of poor quality will not designated as sources of drinking water. Small sources may very well receive such a designation, and the lead agency cannot conceive either the necessity or the authority for providing that small water bodies cannot be sources of drinking supply.

Under the lead agency's initial proposal, a discharge or release to air which the person responsible knows or reasonably should know will be directly and immediately deposited into water or onto land is a discharge or release "into water or onto or into land" within the meaning of the Act. Four commentators objected to this provision's use of the words "reasonably should know", arguing that the Act requires knowledge. (Exh. 11, pp. 3-4, T

6:14-7:18; Exh. 6, pp. 20-21; Exh. 19, p. 4; Exh. 22, pp. 6-7.)

As discussed in the previous section, the operative provisions of the Act require knowledge of (1) the fact of a discharge, release or exposure and (2) the fact that the chemical involved is listed under the Act. Several commentators had proposed that the definition of "knowingly" also require knowledge that a discharge or release probably will pass into a source of drinking water (Exh. 6, pp. 16-17; Exh. 19, p. 3; Exh. 22, p. 5-6; Exh. 26 p. 2.), a recommendation which the lead agency specifically rejects. Upon further review, it appears that requiring knowledge, either actual or constructive, in this provision would have the same effect as adopting that rejected recommendation for discharges to air. Therefore, the lead agency agrees not only with the contention that the phrase "reasonably should know" is inappropriate in this provision, but has determined that the term "knows or reasonable should know" is inappropriate.

Accordingly, this provision has been modified to delete any knowledge requirement. If a business knows of a discharge or release of a listed chemical to air, and the chemical will be directly and immediately deposited into water or onto land, then it is a discharge or release "into water or onto or into land" within the meaning of the Act.

One commentator contended that discharges to the air should not be subject to the Act. (Exh. 26, p. 3.) The fact that a discharge is made into the air does not preclude it from being considered to be into water or onto land. Although the Act does not specifically address discharges to air, businesses should not be permitted to escape liability under Health and Safety Code § 25249.5 simply because they discharge or release chemicals into the air, where the discharged chemical will be deposited into water or onto land at or about the time of discharge.

Finally, the lead agency's initial proposal would provide that the sale, exchange or other transfer of a chemical to a person authorized by law to receive it is not a discharge or release into water or onto or into land, unless the transferor knows or reasonable should know that the transferee will discharge or release the chemical into water or onto land where it passes or probably will pass into any source of drinking water. Two commentators objected to this provision on the grounds that there is no need or authority for this interpretation. (Exh., 6, pp. 21-22; Exh. 19, p. 4.) One contends that this provision is an attempt to impose vicarious liability on the transferor for the acts of transferees over whom the transferors have no control, and is contrary to the requirement that the Act that prohibited acts be committed "knowingly". (Exh. 26, p. 4.)

It clear that these commentators have construed this language more broadly than the lead agency intended. The lead agency recognizes that Health and Safety Code § 25249.11, subd. (b) excludes from the meaning of "person in the course of doing business" businesses with fewer than ten employees. The Act

permits this exclusion because "big businesses . . . produce more than 90% of all hazardous waste in California . . . ." (ballot pamphlet Rebuttal to Argument Against Proposition 65). One purpose of this proposal was to prevent "persons in the course of doing business" from circumventing the Act by transferring chemicals to transferees not subject to the Act for the purpose of committing the discharge or release which, if performed by the transferor, would constitute a violation of the Act.

Obviously some clarification of this purpose is needed in the text of the regulation. Accordingly, this provision has been modified to provide that discharge or release to a source of drinking water includes the direct or indirect transfer by any person in the course of doing business of any listed chemical to any person not subject to Health and Safety Code § 25249.5 for the principal purpose of disposing of the chemical to land or water in a manner which, if committed by the transferor would violate § 25249.5.

This proposal does not impose vicarious liability for acts over which the transferor has no control. In fact, this provision envisions that the transferor knows or reasonably should know that the transferee will make an otherwise prohibited discharge, and can control that behavior simply by not making the transfer. Further, this provision does not conflict with the requirement that discharges or releases prohibited under the Act be committed "knowingly". The transferor would still have actual or constructive knowledge of the discharge of the listed chemical.

One commentator recommended that this proposal not include disposal of chemicals to an authorized dumpsite. (Exh. 10, pp. 10-11.) Generally speaking, chemicals listed pursuant to Health and Safety Code § 25249.8 contained in waste materials are hazardous waste within the meaning of Health and Safety Code § 25117. The Hazardous Waste Management Act is designed to severely restrict the land disposal of hazardous waste to prevent the migration of such waste into ground water sources. No such disposal of liquid hazardous waste is permitted (Health and Safety Code § 25179.5), and other hazardous waste may be so disposed only if treated or it is the result of a hazardous waste cleanup under certain circumstances. (§ 25179.6, subd. (a)) The Department of Health Services issues permits for hazardous waste facilities which may impose a variety of conditions upon the operation of such facilities also designed to prevent the migration of chemicals from the facility. (Health and Safety Code § 25200, et seq.)

Clearly it was not the intention of the Act to prohibit the disposal of hazardous waste to hazardous waste facilities in compliance with applicable statutes and regulations. Section 3 of the Act specifically increased the penalties for disposal of a hazardous waste to a facility which does not have a permit. The ballot arguments emphasized that the Act increased the fines for the dumping of hazardous waste in an unlawful manner. (ballot pamphlet Argument in Favor of Proposition 65) It follows that the Act was intended to promote the disposal of hazardous waste

to a permitted facility in a lawful manner.

Accordingly, this provision has been further amended to provide that discharge and release, within the meaning of the Act, does not include the disposal of waste by a business in compliance with all applicable state and federal statutes, rules, regulations, permits, conditions, requirements and orders to a hazardous waste facility operating under a permit issued by the Department of Health Services.

One commentator recommended that the transferors of listed chemicals should be required to disclose to transferees which listed chemicals are present in the products transferred, and the concentration of those chemicals. (Exh. 23, pp. 2-3.) While this proposal appears to have merit, it does not appear to be within the scope of this regulatory proposal. Accordingly, the lead agency will consider this suggestion for future adoption.

One commentator recommended that a provision similar to the "sale, exchange or other transfer" language be extended to exposures under Health and Safety Code § 25249.6. (Exh. 17, p. 3.) However, the definitions in this subdivision pertain only to discharges and releases under § 25249.5. Therefore, this modification was not made.

One commentator recommended that this definition should exclude publicly-owned treatment works and their collection and conveyance systems. (Exh. 22, p. 7.) on the ground that discharges and releases to such systems are subjected to pretreatment standards and permit conditions to protect drinking water.

The lead agency's initial proposal was intended to permit lawful transfers of chemicals, including transfers to treatment works, at least to the extent that discharges and releases to treatment works meet all pretreatment standards, effluent limitations, and permit conditions, so that the discharge or release from the treatment work does not jeopardize the quality of the drinking water supply into which the treatment work subsequently must discharge. Obviously the expression of the lead agency's intention requires greater clarity than afforded by the initial proposal.

The Act defines "source of drinking water" as either (1) a present source of drinking water, or (2) water which is identified or designated in a water quality control plan adopted by a regional board as being suitable for domestic or municipal uses. Effluent to a treatment work, which includes its collection system, is not used as a present source of drinking water. Further, the State Water Resources Control Board has proposed a policy for the regional boards which would expressly exclude treatment works as sources of drinking water. To the lead agency's knowledge, in no case is the effluent in a treatment work specifically identified or designated by a regional water quality control board as suitable for domestic or municipal uses anyway.

Moreover, compliance with all pretreatment standards, effluent limitations and permit conditions by a business making a discharge or release should protect the quality of any drinking water into which the treatment work subsequently discharges the treated effluent. Accordingly, this definition has been modified to specifically provide that "source of drinking water" does not include treatment works to the extent that the discharge or release in question complies with all applicable standards, limitations and permits under federal law or an approved state program. If the discharge or release to the treatment works does not comply with all such requirements, then for purposes of the discharge in question the treatment work will be regarded as a source of drinking water, and the discharge or release will be subject to the Act.

Finally, one commentator recommended that these regulations require a time-frame within which a chemical "probably will pass". (Exh. 26, p. 4.) This also appears to be unnecessary and unauthorized. A discharge or release is exempt from § 25249.5 if it will not cause any significant amount of the discharged or released chemical to enter any source of drinking water. If there is a question whether, owing to the volatility of a chemical, any significant amount of it will reach drinking water, that determination should be made on a case-by-case basis.

(e) Expose

Because the Act was titled the Safe Drinking Water and Toxic Enforcement Act of 1986 and because its earliest substantive provision is a prohibition on certain discharges to drinking water, there has been some confusion over the scope of the prohibition on exposing individuals to certain chemicals without first giving clear and reasonable warning. It has been assumed by some that this exposure prohibition, like the prohibition on certain discharges or releases in the Act, is directed at drinking water exposure. There is nothing in the language or the history of the Act to support such a limited interpretation of the exposure prohibition. Therefore, the Health and Welfare Agency has broadly defined the term "expose" to include all anticipated means of bringing individuals into contact with chemicals. Examples of these means are provided to further clarify that the Act prohibits all means of directly bringing individuals into contact with chemicals known to the state to cause cancer or reproductive toxicity without clear and reasonable prior warning.

Two commentators recommended that the term "expose" not include contact via routes of exposure for which there is no significant risk. (Exh. 6, p. 23; Exh. 22, pp. 7-8.) Under the Act, a business may defend itself by showing that its exposure poses no significant risk, or is at a level which is one one-thousandth of the no observable effect level. One way to make such a showing may be to establish a lack of absorption or effect by the route in question. The burden of making such a showing is expressly on

the defendant. (Health and Safety Code § 25249.10, subd. (c)) Providing that "expose" includes only those exposures which pose a significant risk by the route in question would effectively shift the burden of proving "no significant risk" from the defendant to the plaintiff in an enforcement action. This does not appear to be authorized.

One commentator expressed the view that the definition should consider the length and duration of the exposure in light of the competing benefits. (T 17:11-22.) Again, if the exposure presents no significant risk, the burden of proving this is on the defendant. It is not an element which the plaintiff must prove as a part of his or her affirmative case. Further, the fact that there may be competing benefits appears to be irrelevant. If there is an exposure, regardless of competing benefits, there must be a warning unless it presents no significant risk.

One commentator objected that, as defined, "expose" could apply to exposures in the workplace. (Exh. 17, p. 2.) The Act, however, provides that no person in the course of doing business shall knowingly and intentionally expose "any individual" to a listed chemical. Persons do not cease to be individuals because they are exposed in the workplace.

Finally, one commentator objected that pharmacists do not knowingly and intentionally cause any exposure, but made no recommendation. (Exh. 12, pp. 3-4.) The peculiar problem presented by the unique physician/pharmacist/patient relationship will be addressed in other regulatory proposals. (See R-87-87)

(f) Significant Risk

The Act does not apply to any exposure to a listed carcinogen which presents no significant risk assuming lifetime exposure at the level in question. (Health and Safety Code § 25249.10, subd. (c)) Discharges or releases at such levels may also be exempt provided that they also conform with all other laws and every applicable regulation, permit, requirement, and order. (Section 25249.9) What constitutes a significant risk from chemical exposure is left unclear.

As proposed by the lead agency, this provision would have defined the term "significant risk" to be an unacceptable risk. Unacceptable risk would be determined after the evaluation of a risk assessment of a chemical's inherent toxicity and of potential human exposure. Thus, a level presenting a significant risk would be the level to avoid in order to have a viable defense against liability.

Two commentators objected that this definition provides no guidance. (Exh. 19, p. 4; Exh. 20, p. 2) Three recommended that the definition further provide that any risk less than one additional cancer case per one million people exposed shall be deemed not to be significant as a matter of law. (Exh. 5, pp. 7-9, T 32:21-33:9, Exh. 6, pp. 24-25; Exh. 20, p. 2.)

Five commentators recommended that this provision specify how a risk assessment should be conducted to determine that level of exposure which presents no significant risk. (Exh. 7, p. 1; Exh. 1, p. 1; Exh. 4, pp. 3-4; Exh. 26, p. 4; T 52:10-18.) One recommended that the state provide a new database for the conduct of risk assessments before establishing no significant risk levels on a chemical specific basis. (Exh. 8, pp. 1-2.) One commentator recommended that this provision require that a risk assessment will be made within a specified number of days after the listing of a chemical. (Exh. 2, p. 3, T 18:1-10.)

One recommended that this provision be deferred until a more comprehensive regulation can be proposed. (Exh. 6, pp. 23-25.) Two commentators recommended that this provision be deleted, and that a workshop be held on the subject of risk assessment. (Exh. 14, pp. 2-3, T 34:8-20; T 61:2-5.)

Four commentators objected that this proposal defines the wrong term, the correct term for definition being "no significant risk". (Exh. 13, p. 1; Exh. 16, p. 5; Exh. 21, pp. 3-4; Exh. 25, p. 4.) Three of these same commentators objected that the term "unacceptable risk" connotes economic considerations irrelevant under the Act. (Exh. 13, p. 1; Exh. 16, p. 6; Exh. 25, p. 4.) Four commentators proposed language which would define "no significant risk" to be a risk of contracting cancer which is no greater than one additional cancer per one million persons exposed. (Exh. 15, pp. 1-2; Exh. 16, pp. 6-8, Attachment 1; Exh. 21, p. 4; Exh. 25, p. 5.) Three proposed that the risk also be "unavoidable". (Exh. 15, pp. 1-2; Exh. 16, pp. 6-8, Attachment 1; Exh. 21, p. 4.)

Obviously, few commentators view this definition to be appropriate, and those that do believe that it does not accomplish enough. Since the time that this definition was proposed, the Health and Welfare Agency has drafted a provision setting forth a proposed methodology for determining what level of exposure to a chemical presents no significant risk. This proposal has been published to solicit public comment, and has been one topic of discussion at a workshop conducted by the Agency. In light of the Agency's intention to adopt a more comprehensive proposal, this definition has been deleted.

(h) Threatened illegal discharge

Section 25180.7 of the Health & Safety Code as added by Section 4 of the Act requires certain government employees to disclose certain information about certain illegal discharges and threatened illegal discharges of hazardous waste. The Health and Welfare Agency has determined that it is appropriate to define the term "threatened illegal discharge" in order to insure that the generation, transportation or storage of hazardous waste is not subject to disclosure. Thus, the proposed definition requires the creation of a condition or an action which presents a substantial probability that an illegal discharge of hazardous

waste may occur. The mere possibility that such a discharge might occur is not enough to require disclosure under section 25180.7.

The definition here is based on the definition of "threaten to violate" contained in Health & Safety Code section 25249.11. It is unlikely that the framers of the Act intended the level of evidence necessary to constitute a "threatened" illegal discharge to be substantially different than that necessary to "threaten to violate". Therefore, it is appropriate that there be a "substantial probability" of an illegal discharge before reporting is required.

One commentator recommended that the term "hazardous waste" in § 25180.7 be limited to refer only to illegal discharges of chemicals listed pursuant to § 25249.8. (Exh. 22, p. 10, footnote 2.) The term "hazardous waste", however, has a meaning which is well-established in the law. (See Health and Safety Code § 25117) It includes much more than chemicals which cause cancer or reproductive toxicity. Had the drafters of the Act intended that § 25180.7 apply only to listed chemicals, they could have easily so provided. Therefore, this recommendation was not adopted.

One commentator suggested that the term "hazardous waste" be defined under this regulation. (Exh. 28, p. 6.) As noted above, the definition of "hazardous waste" is well established in the law. (See Health and Safety Code § 25117.) Presumably, the drafters of the Act were well aware of this definition and intended it to apply here. Therefore, the lead agency has no added no further definition here.

(i) Substantial Injury

The requirement that certain government employees disclose information about illegal discharges or threatened illegal discharges of hazardous waste applies only where an employee ". . cause substantial injury to the public health or safety . . . ." (Health & Welfare Code section 25180.7 (b)) The Health and Welfare Agency has determined that a "substantial injury" as used in this section should be interpreted to include only physical injuries or resulting adverse physical conditions. Thus, the disclosure requirements do not apply to discharges or threatened discharges of hazardous waste that will result in only economic or environmental injury. Further, the injury which is likely to result from the discharge or threatened discharge must be real. An illegal discharge which increases the risk of cancer in one or more persons is subject to the disclosure requirements but a discharge which may contribute to a fear of cancer is not.

One commentator recommended that this definition be modified by replacing "real" with the term "serious" or "significant" because, in that commentator's view, the word "substantial" connotes not only an injury which is actual, but one which is "something beyond trivial". (Exh. 9, pp. 3-4.) This observation is accurate. The word "substantial" may mean "not imaginary;

true; real" and "considerable in importance, value, degree amount or extent". (Houghton & Mifflin, American Heritage Dictionary, 2d College Edition, p. 1213.)

In adopting this provision the lead agency intended merely to clarify that the injury be actual and physical, not to impose any further requirement that the injury be "serious" as opposed to "considerable". However, this comment illustrates that by adopting only a partial definition of "substantial", the proposed regulation implies that the injury need not be "considerable", but merely "actual". It is not the intention of the lead agency that any "actual" injury be subject to the reporting requirement. It was the lead agency's intention that the term substantial would still require that the injury be of some importance. Therefore, in order to clarify its intention, this provision has been modified to provide that the injury be of a substantial nature. This may be less than a serious or significant injury, but connotes something greater than a de minimis harm.

One commentator recommended that this definition be further qualified by additional factors which would determine whether an injury or threatened injury is of a substantial nature. (Exh. 22, pp. 9-10) However, it is not the purpose of this definition to determine what illegal discharges are substantial, and the lead agency believes that any such determination, if necessary at all, is best left to future regulatory action.

(j General public knowledge

The requirement that certain government employees disclose information about illegal discharges or threatened illegal discharges of hazardous waste does not apply where the information is already "general public knowledge" within the locality affected by the discharge or threatened discharge. The Act does not define "general public knowledge". The Agency has determined that it is necessary to define "general public knowledge" in order to avoid the necessity of proving that particular members of the public in the locality are aware of the information in question.

The Act requires that certain government employees disclose information to the local health officer and the Board of Supervisors. The local health officer is then required to make the information available to the public through notification of local news media. It is neither necessary nor appropriate to require government employees to disclose information or the local health officer to supply such information to the local news media after that information has been widely reported. The exception to the disclosure requirement for information that is "general public knowledge" was intended to accomplish this result. Therefore, the term "general public knowledge" is defined here in terms of whether the information has been widely reported. No particular information or understanding needs to have been acquired by the public in order for the exception to apply.

One commentator recommended deletion of the term "widespread" as an adjective to "radio or television reports", since it is vague and ambiguous. (Exh. 19, p. 5.) Even without this adjective, the radio or television reports would still need to be disseminated in the geographic area affected by the discharge. Therefore, the term "widespread" has been deleted.

Sections 12301 to 12305. Scientific Advisory Panel

The Safe Drinking Water and Toxic Enforcement Act Scientific Advisory Panel is authorized by Health and Safety Code § 25249.8, subd. (d), which requires the Governor, in publishing various lists of chemicals, to consult as necessary with the state's qualified experts. Under this proposal, the lead agency provides for establishment of the Scientific Advisory Panel ("Panel") to advise and assist the Governor in carrying out his duties under the Act.

The proposed regulations set forth the functions of and procedural guidelines for the Panel. The Panel members shall include experts in various scientific disciplines pertinent to the identification of chemical carcinogens or reproductive toxicants. Under the lead agency's proposal, members of the Panel are appointed by the Governor and serve at his pleasure. At present, each is retained under a one year contract.

One commentator recommended that members have fixed terms of up to six years with staggered appointments to promote continuity, and termination only for good cause. (Exh. 22, p. 14.)

This suggestion appears to assume that changes in the political climate will influence the manner in which advice is provided to the Governor. Each person appointed to the Panel must be an expert in one of the specified scientific disciplines. Experience with the existing Panel has shown that its decisions whether to list particular chemicals are based upon scientific, not political considerations. There is no reason to believe that the determinations would be any different if there were a change in the Panel's membership.

Therefore, while this may be a subject for future regulatory action, it does not appear necessary to require fixed terms. For purposes of flexibility the term of appointment should remain a contract, rather than a regulatory, matter. As for termination only on good cause, such a requirement could under the current proposal be tantamount to an appointment for life. This does not appear necessary for scientists who are making judgments on matters of science.

Because the lists of chemicals must be revised and republished annually, the Panel is to meet at least once every six months in order to consider possible revisions. In order to ensure that recommendations are representative of the entire Panel, decisions shall be made by majority vote with a quorum of six out of twelve members.

One commentator recommended that the quorum for Panel decisions should be 8 members, and that any decision must be approved by at least 6 members. (Exh. 22, p. 14.) This also does not appear to be necessary. Under the lead agency's proposal, at a minimum four members must approve any item of business, which is not

substantially less than six. Further, it has been the general practice of the lead agency to notice meetings at least 30 days in advance, which generally means that meeting dates are arranged with members more than 30 days in advance. This should ensure that most if not all Panel members will be able to attend each meeting and the desired eight members would be present. However, the lead agency believes that the lower quorum should be retained in the unlikely event that several members of the Panel cease their membership within a short period of time and the lead agency encounters difficulty filling the vacancies.

Business may also be conducted by subcommittees designated by the Chairperson of the Panel. The meetings and work of the Panel and the subcommittees are to be open and available to the public to the maximum extent possible.

Three commentators recommended that notice of Panel meetings include the agenda of items to be discussed or acted upon in addition to the time and the place of the meeting. (Exh. 6, p. 26; Exh. 22, p. 15; Exh. 26, p.4.) It is the stated policy of the lead agency to conduct Panel meetings in accordance with the Bagley-Keene Open Meeting Act (Government Code §§ 11120, et seq.). Government Code § 11125, subd. (b) specifically requires that notice of a meeting shall include a specific agenda for the meeting, which shall include the items of business to be transacted or discussed. Accordingly, proposed § 12302, sub,. (d) has been modified to require that notice of Panel meetings include such an agenda.

One commentator recommended that there be public access to the materials on which the Panel relies. (Exh. 26, p. 4.) Again, it is the policy of the lead agency to conduct Panel meetings in accordance with the state open meeting law. This law requires that materials presented for consideration or discussion become public records. Therefore, such materials are a public record at the time they are submitted to the Panel and available for inspection pursuant to the Public Records Act (Government Code § 6520, et seq.) Subdivision (d) of proposed regulation 12302 already provides that any official correspondence to the Panel shall be available as a public record for inspection.

One commentator recommended that more than 30 days notice be required when the agenda for a Panel meeting schedules the review of more than twenty chemicals. (Exh. 22, p. 15.) Under the open meeting law, however, only ten days notice must be provided, regardless what is on the agenda. As a matter of general practice the lead agency already provides thirty days notice. Requiring greater notice might require lead agency staff to be preparing and releasing notice at or near the time it is attempting to conduct a previously noticed meeting or implement the decisions of the Panel. Therefore, this recommendation does not appear necessary or practicable.

In order to ensure that the recommendations of the Panel are free of bias and undue influence, Panel members are to make annual

public disclosures of possible conflicts of interest. Two commentators recommended that the disclosure requirement for Panel members be the same as for other public employees, and that failure to comply with the disclosure requirements result in disqualification from the Panel. (Exh. 16, p. 15; Exh. 25, p. 5.) However, the proposed disclosure requirement for Panel members covering a two-year period is greater than that required for other public employees, which requires disclosure merely of the investments or interests held at the time of appointment (Government Code § 87202), and annually thereafter (Government Code § 87203). Further, the proposal requires that those serving in academic appointments describe their funding resources for all significant research undertaken in the previous two years. Due to the importance of the Panel's activity, the lead agency believes that these stronger disclosure provisions are more appropriate.

Since the work of the Panel is expected to require a substantial amount of time, Panel members who are not state employees or officials are to receive compensation for their work by way of a consulting services contract, in addition to reimbursement for necessary expenses.

The scope of the Panel's duties is set forth in Section 12305. Under Health and Safety Code Section 25249.8(b), the "state's qualified experts" are required to render opinions on whether a specific chemical "has been clearly shown scientifically valid testing according to generally accepted principles to cause cancer or reproductive toxicity." The same law also requires the experts to identify "authoritative" bodies which have formally identified carcinogens or reproductive toxicants and to determine whether chemicals which are required to be tested for carcinogenicity or reproductive toxicity by state or federal law have been adequately tested.

One commentator questioned the authority of the lead agency to limit the role of the Panel, arguing that the Panel should be permitted to provide all manner of advice to the Governor. (T 57:13-58:3.) In fact, the proposed regulations do permit the Panel to provide advice to the Governor on a wide range of issues. Presumably this commentator is referring to the limited role of the Panel in the listing of chemicals. Section 25249.8 requires the Governor to identify the state's qualified experts and to consult with them in carrying out his duties under that section. The Governor's only other duty under that section is to publish lists of chemicals identified by the Panel. (Section 25249.8, subd. (a) & (c)). The Act does not authorize the Governor's list to include anything but chemicals. Thus, the Act itself limits what the list may reflect and hence the Panel's role in the listing process, and the lead agency is authorized to define this role in implementing the Act. (Health and Safety Code § 25249.12)

One commentator recommended clarification whether the lead agency (pursuant to proposed § 12101) or the Panel will review standards

and procedures. (Exh. 24, p. 8.) As indicated above, § 25249.8 of the Act requires the Governor to consult the Panel as necessary only with regard to the listing of chemicals. However, the Governor, through the lead agency is also responsible for full implementation of the Act, and may adopt both regulations and standards to do so. Nothing in the Act prevents the Governor from requesting or receiving the Panel's advice where appropriate on matters other than listing. Indeed, it might be a waste of resources not to take advantage of the Panel's collective knowledge so long as they are assembled and available. Therefore, it is intended that the Panel may review, or propose, standards, procedures or protocols for the purpose of advising the lead agency. The Act makes clear that it is within the lead agency's discretion to accept or reject such advice in implementing the Act.

Proposed section 12305 was intended to describe what activities the Panel may undertake. The section, however, states that the Panel shall undertake the enumerated activities. One commentator requested clarification that the section is intended to be mandatory in effect. (Exh. 6, pp. 28-29.) To the contrary, it is intended to be permissive. Therefore, to clarify this provision, the opening sentence of this section has been modified to provide that the Panel may undertake the enumerated activities upon request of the lead agency.

With regard to the listing of chemicals, three commentators recommended that the Panel should also determine levels posing no significant risk. (Exh. 4, p. 6; T 26:11-25; Exh. 6, p. 27, T 42:3-13; Exh. 20, p. 3.) One recommended that the listing should identify routes of exposure. (Exh. 1, p. 2; T 42: 3-13.) One recommended that the Panel conduct safe use determinations. (Exh. 1, p. 2.) As stated above, the Panel may provide any advice it chooses, including advice on levels posing no significant risk and on the risk presented by specific routes of exposure. Requiring the Panel to do so would hinder the Panel's primary responsibility of hazard identification, and has been rejected. As for safe use determinations, the Panel lacks the resources necessary to conduct case-by-case assessments on particular discharges, releases, and exposures. Assigning such a task to the Panel could effectively disable them from their primary responsibility. That assignment is more properly given to agencies with greater resources, and this proposal has been rejected.

One commentator recommended that § 12305 (a) require that determinations under that subsection be made on the basis of standards adopted pursuant to subsection § 12305 (d). (Exh. 6, pp. 27-28.) This requirement does not appear necessary. Logically, the Panel must employ some kind of standard in order to review chemicals, and that standard will be the product either of their own proposals or their review of standards employed by other agencies or organizations. There does not appear to be a need here to state the obvious.

One commentator recommended clarification in proposed § 12305 (b) that the duty to identify chemicals formally required to be identified or labeled as carcinogens or reproductive toxins is the Governor's, not the Panel's. (Exh. 21, p. 5.) Such clarification does not appear to be necessary. Nothing in proposed § 12305 (b), the cited source of the ambiguity, makes any reference to this method of listing chemicals. Section 12305 (b) refers to the consideration of bodies which have formally identified a chemical as causing cancer or reproductive toxicity as authoritative, and is based upon the language of the Act itself.

One commentator recommended that § 12305 (b) require that the Panel identify authoritative bodies within 60 days of the effective date of these regulations. (Exh. 16, pp. 15-16.) Of course, nothing in the Act requires the Panel to conclude that any body is authoritative. It merely provides that if the Panel does consider a body to be authoritative, the chemicals formally identified by such body as causing cancer or reproductive toxicity are "known to the state to cause cancer or reproductive toxicity" and must be added to the Governor's list. The Panel has the discretion whether to consider any body authoritative. Therefore, it does not appear that the Act authorizes the lead agency to require the Panel to identify any authoritative body at any time.

Further, at its meeting of October 30, 1987, the Panel expressly declined to consider the federal National Toxicology Program to be authoritative body, noting that much of that body's work was based upon old data. Thus, it is unnecessary to require the Panel to consider the question of authoritative bodies, since it has already done so.

One commentator recommended that the regulations provide an appeal procedure for the listing of chemicals. (Exh. 22, p. 15.) With regard to chemicals recommended by the Panel for listing pursuant to § 12305 (a) and (b), such a procedure already exists, since nothing prevents the Panel from reconsidering such listed chemicals. The Act prevents any other administrative appeal, since the Governor must list the chemicals which are known to the state to cause cancer.

The development or review of standards and procedures for determining chemical carcinogenicity or reproductive toxicity described in subsection (d) is basic to the Panel's ability to render the required expert opinions. Subsection (e) clarifies that the Panel may lend its scientific expertise to advise the Governor and the lead agency on other issues raised by the Act

Two commentator recommended that subsection (d) and (e) be deleted, on the ground that the duties specified therein are outside the scope of Health and Safety Code § 25249.8. (T 59:21-60:2; Exh. 25, p. 5.) As indicated above, the development of standards for determining whether a chemical causes cancer or reproductive is essential for the Panel to carry out its

functions under subsection (a). Subsection (d), therefore, clearly within the scope of the Panel's duties.

The members of the Panel are the "state's qualified experts" and, as constituted by these regulations, present a considerable resource of collective knowledge, experience and expertise. In implementing the Act, the lead agency will be confronted by a wide range of issues, and the Panel's assistance in resolving these issues, where appropriate, may be invaluable. Nothing in the Act prevents the lead agency from using this resource. Therefore, this recommendation with regard to subsection (e) was not adopted.

One commentator recommended that the Panel's review be limited to scientific standards or procedures. (Exh. 6, pp. 29-31.) The lead agency, however, should preserve its option to have the Panel consider the widest range of possible issues. Therefore, this recommendation was not adopted.

Finally, one commentator recommended that any review and proposal by the Panel be subject to the rulemaking requirements of the Government Code. (Exh. 22, p. 15.) Under the Act, the listing of chemicals is expressly exempt from the requirements of the Administrative Procedure Act. (Health and Safety Code § 25249.8 (e)) Any review or proposal essential to the consideration of chemicals, such as that provided in proposed § 12305 (d), would fall within this exemption. Otherwise, § 25249.8 (e) would be meaningless.

As for proposals or review under proposed § 12305 (e), the Panel is simply giving advice to the lead agency and the Governor, not establishing standards of general application. In following this advice, the lead agency would be subject to the Administrative Procedure Act. Therefore, adoption of this recommendation does not appear to be necessary.

ADDENDUM
FINAL STATEMENT OF REASONS
SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986
(R-48-87)

In response to comments submitted on or before 5:00 p.m. of August 19, 1987, the Health and Welfare Agency made post-hearing modifications to the regulatory proposal designated R-48-87. The modified text of the proposal, with post-hearing changes indicated by strikeout and underlining, was made available for public comment. Comments on the post-hearing modifications were required to be submitted between 8:00 a.m. on January 4, 1988 and 5:00 p.m. on January 19, 1988.

Eighteen comments were received during the designated period. This addendum to the Final Statement of Reasons contains the response of the lead agency to the recommendations and objections regarding the modifications which have not already been adequately addressed in the Final Statement of Reasons.

Section 12102.

One commentator objected to the amended definition of "interpretive guideline" as a "draft regulatory proposal", complaining that the latter is "merely a tentative agency position subject to change during the regulatory process". (P-8, p. 2.) However, one of the principle objections to interpretive guidelines was that such guidelines were not-binding interpretations upon which businesses could not rely. (Exh. 9, p 1; Exh. 5, p. ; T 28:22-29; Exh. 6, pp. 6-8.) Referring to them as draft regulatory proposals appears to be more accurately descriptive of their nature.

One commentator requested clarification that interpretive guidelines are not intended to provide guidance prior to adoption by eliminating the term entirely and omitting all references that such proposals provide guidance or information. (P-11, p. 3.) Whatever interpretive guidelines are called, they represent the lead agency's administrative construction of the Act at the time. If this were not the case, the lead agency would certainly not have published it for comment. It would make little sense for the lead agency to attempt to deny this fact. Nor can the lead agency prevent courts from considering this administrative construction when asked to resolve issues arising out of the Act. The lead agency is confident that, in doing so, courts will be conscious that interpretive guidelines are subject to change. Therefore, this suggestion was not adopted.

Section 12103

One commentator recommended that the lead agency provide adequate public notice of proposals to adopt interpretive guidelines under section 12103 (a). Such notice would include mailings to interested parties, including an informative digest, draft statement of reasons, and the time and place of hearing. (P-11,

p. 5.) This recommendation, however, does not appear to be directed at any of the modifications proposed by the lead agency, and is, therefore, not timely. While it may be desirable that parties requesting interpretive guidelines provide sufficient materials to permit their formal proposal as regulations, any requirement that such materials accompany a request must be the subject of future regulatory action.

One commentator objected that it is unclear what persons will receive the interpretive guidelines published by the lead agency. (P-8, p. 3.) The lead agency maintains a roster of all parties who have requested materials related to the Act. These interested parties would receive any interpretive guidelines published by the lead agency.

One commentator objected that it is unclear whether the publication of interpretive guidelines precludes the filing of petitions for regulations pursuant to Government Code § 11347.1. (P-11, p. 5.) The interpretive guideline process is offered as an alternative to the Government Code procedure, one which provides the lead agency with an opportunity to refine a proposal before placing it into the formal regulatory process. However, it is not intended to preclude petitions under § 11347.1.

Section 12104.

Several commentators again objected that Safe Use Determinations (SUD) will be "advisory only", and urged that they be adopted as regulations. (P-4, p. 1; P-8, p. 2; P-13, p. 2; P-18, p.1.) This objection has been adequately addressed in the Final Statement of Reasons.

One commentator recommended the addition of a provision protecting the party requesting a SUD from prosecution pending its resolution, and for a reasonable time thereafter. (P-12, p.1.) This is similar to earlier comment that the enforcement provisions of the Act apply only where SUDs have not been requested. In both cases, it appears that the recommendation may alter the enforcement provisions expressly included in the Act. Further, this comment does not appear to address the modifications proposed by the lead agency.

Three commentators made recommendations on the modifications to § 12104 (j). One commentator recommended that the word "adopted" in the phrase "adopted by the lead agency" be replaced by the word "established", "approved" or "recognized" because the former connotes formal regulatory action. (P-18, p. 1.) However, it is the intention of the lead agency that SUDs involving risk assessment be based upon formally adopted methodologies.

One commentator recommended the addition of the phrase "or other comparable methodologies". (P-13, p. 2.) Similarly, another commentator recommended that the "methodologies adopted by the lead agency" be replaced with "generally accepted toxicological methodologies". (P-12, p. 1.) This would, in effect, permit the

use of any methodology, making it more difficult to insure that SUDs are accurate and consistent. Therefore, this recommendation was rejected.

Two commentators made recommendations regarding § 12104 (k), even though no modification was made to that section. One recommended that SUDs be given binding effect, and also urged that the Act's enforcement provisions be suspended during the pendency of a SUD request. (P-13, p. 3.) These suggestions have already been rejected. The other recommended clarification that no SUDs will be adopted until the issues raised have been addressed in a regulation. (P-11, p. 7) This would be similar to requiring that SUDs be formally adopted as regulations. The lead agency has rejected this approach, since SUDs are not intended to be standards of general application.

Section 12201

(a) In the Course of Doing Business

Three commentators objected that this provision, as modified, does not address the issue of what acts are committed in the course of doing business, and the issue of personal consumption or production of a listed chemical by employees and guests of an employer. ((P2, p. 3; P-4, p. 1; P-11, p. 7.) This objection has been adequately addressed in the Final Statement of Reasons.

(b) Employee

One commentator objected that the Labor and Unemployment Insurance Code provisions referenced in the regulation still conflict despite the modifications made, but did not specify the nature of the conflict. He recommended deletion of the Unemployment Insurance Code reference. (P-11, p. 11.) The lead agency has reviewed the referenced provisions in light of the modifications made and perceives no conflict.

Knowingly

One commentator requested clarification regarding the modification of the first sentence of 12201 (c), but failed to indicate which portion of the modification he considered ambiguous, or how the sentence should be clarified. (P-11, p. 12.)

Three commentators objected that, as modified, this section does not require knowledge of additional elements of Health and Safety Code §§ 25249.5 and 25249.6. (P-1, p.2; P-5, p. 2; P-11, p. 13.) This objection has been addressed in the Final Statement of Reasons.

One commentator objected to the provision regarding accident and misfortune, because it might exempt foreseeable and avoidable accidents. (P-16, p. 1.) However, as explained in the Final Statement of Reasons, the provision does not apply to accidents

caused by the negligence of the defendant.

Three commentators objected to the deletion of the term "culpable". (P-3, p. 2; P-11, p. 15; P-14, p. 1.) One regarded this modification as an "attempt to broaden the scope of the Act". (P-3, p. 2.) In fact, this modification narrows the scope of an exemption which is based upon the lead agency's interpretation of the Act. Without this exemption, it is conceivable that the Act could be literally construed to apply to accidents.

This provision is not intended to import into the Act concepts of criminal law, even though the wording closely resembles a portion of a Penal Code provision. The term "culpable negligence" may have particular significance in the criminal setting, but in civil cases the term has been construed to refer to simple negligence, and it was this meaning that the lead agency intended. Therefore, deletion of the term "culpable" was essential for purposes of clarity.

One commentator recommended that the lead agency also define the phrase "knowingly and intentionally" in Health and Safety Code § 25249.6. (P-11, p. 16.) The lead agency will consider defining the term "intentionally" in future regulatory action.

(d) Passes or Probably Will Pass Into Any Source of Drinking Water

Five commentators objected to subdivision (d)(2), which provides that a discharge to a place in hydraulic continuity with a source of drinking water probably will pass to that source whether or not it is upgradient or upstream. (P-3, p. 2; P-5, p. 3; P-11, p. 17; P-14, p. 3; P-15 p. 1.) Other than placing it in its own subdivision, this provision was not modified from the initial proposal, and the objections, with one exception, were adequately addressed in the Final Statement of Reasons.

One commentator contends that this provision creates a conclusive presumption which violates the constitutional rights to due process and equal protection. (P-15, p. 4.) This contention has not been previously addressed. As this commentator pointed out, in some cases of insoluble chemicals, there must be a physically defined path through the soil in order for the chemical to pass. In other cases, chemicals may bind to the soil itself and, therefore, not find its way into the water table.

In the view of the lead agency, it should be sufficient for the plaintiff in an enforcement action to show that the land is in hydraulic continuity with the groundwater to establish that the chemical probably will pass into the groundwater. To require the plaintiff to establish that there is a physically defined path through defendants might present the plaintiff with an impossible burden. For all practical purposes, plaintiff might need to wait until the chemical appeared in the groundwater. In effect this would mean that for some chemicals the term "probably will pass"

would be written out of the Act.

In adopting this concept, it was not the intention of the lead agency to create a conclusive presumption, but rather a rebuttal one. Once the plaintiff has established that there is hydraulic continuity between the discharge and a source of drinking water, the burden would shift to the defendant to show that, despite hydraulic continuity, the chemical probably will not pass into the water. To the extent that this is unclear in the current language, the lead agency will address it in subsequent regulatory action.

One commentator recommended that the phrase "in drinking water" be added after "domestic and municipal uses". (P-3, p.3.) The addition of this phrase, however, would not be consistent with the definition of "source of drinking water" in Health and Safety Code § 25249.11 (d), which refers only to water designated as suitable for "domestic or municipal uses".

This same commentator recommended that San Francisco and San Diego Bays be specifically designated as saline bays. (P-3, p. 2.) Such designation, however, is more properly the office of the State Water Resources Control Board and the Regional Water Quality Control Boards. If designated by these agencies as saline bays, and not water suitable for domestic or municipal uses, then these water bodies would qualify as saline bays within the meaning of this regulation.

One commentator objected to subdivision (d)(3), contending that the Act was not intended to apply to emissions to air. (P-5, p. 4) This objection has been adequately addressed in the Final Statement of Reasons.

One commentator objected to the deletion of the sentence of the original proposal concerning responsibility for discharge of a chemical following a sale, exchange or other transfer. This commentator suggested that it should have been retained and expanded to apply to exposures as well as discharges. (P-1, p. 3.) That provision was deleted because it did not accomplish its intended purpose. Subdivisions (d)(4) through (d)(6) more accurately reflect that limited purpose. As for expansion to exposures, that suggestion was made to the initial proposal, and was rejected because it was outside the scope of this definition. It still is.

Two commentators objected that the term "transfer" in subdivision (d)(4) could refer to sales of chemicals. (P-11, p. p. 20; P-14, p. 3.) However, both acknowledge that sales or transfers structured to avoid the terms of the Act could properly be prohibited. This is essentially the intended purpose of subdivision (d)(4). The lead agency will consider further modification to clarify this provision, if necessary, in future regulatory action.

One commentator recommended deletion of the phrase "or indirect

transfer" on the ground that it is vague. (P-3. p. 3.) This phrase is employed to make clear that any transfer, whether directly to the transferee, or through some other medium, is included in the operation of this regulation. Its deletion at this point might imply that the lead agency intends this section to apply only to a limited class of transfers. Therefore, the phrase has been retained.

One commentator correctly pointed out that the definition of "hazardous waste facility" is found at § 25117.1 of the Health and Safety Code, not § 25117. (P-11, p. 25.) This typographical error in subdivision (d)(5) has been corrected.

This same commentator recommended that the regulation refer alternatively to the federal definitions of "hazardous waste management unit" (40 CFR § 260.10) and "hazardous waste management facility" (40 CFR § 270.2). The need for this modification is unclear, since the Health and Safety Code definition appears to include all facilities covered by the federal regulations.

Two commentators objected to the phrase "disposal to such facility" in the proviso to subdivision (d)(5) because it implies that the transferor's liability will depend upon the manner in which the hazardous waste facility handles the disposal. (P-5, p. 4; P-11, p. 24) This was not the lead agency's intention. Rather, it was intended that if the sale, exchange or transfer of the waste to the facility is in compliance with all applicable requirements, then the sale, exchange or transfer is not a discharge or release into water or onto or into land. If the hazardous waste facility improperly disposes of the material, then the facility may be liable under the Act. Appropriate changes to the regulation to further clarify the Agency's intention will be considered for later regulatory action.

Four commentators recommended deletion of the last sentence of subdivision (d)(5). (P-7, p. 1; P-11, p. 26; P-12, p. 1; P-13, p. 4.) The purpose of this provision was to prevent businesses operating their own hazardous waste facilities from escaping liability by transferring their waste to such facilities, and to clarify that the business would still be liable under the Act for a discharge from the hazardous waste facility. As one commentator pointed out, the current provision would prevent a company whose business included the operation of a hazardous waste disposal facility from depositing waste from its other operations at its own site. However, the lead agency does not agree that the regulation has this effect, since it relates only to liability for eventual discharge. In any event, the lead agency will consider later regulatory action to further clarify this provision.

One commentator recommended the insertion of the phrase "or the Clean Water Act and Division 7 of the California Water Code" after the reference to 33 United States Code § 1292. (P-12, p. 1.) No reason was provided, and the lead agency cannot conceive of a good reason for adopting this modification.

This same commentator recommended that subdivision (d)(6) should exempt discharges to private treatment works. (P-12, p. 2.) However, the term "treatment works" appears to include works both privately and publicly owned. Therefore, this modification appears to be unnecessary.

This same commentator also recommended that discharges permitted by the Regional Water Quality Control Board also be exempted. (P-12, p. 2.) This modification, however, would be outside the scope of subdivision (d)(6), which applies only to discharges to treatment works.

Four commentators objected to subdivisions (d)(5) and (d)(6) altogether. (P-9, p. 3; P-10, p. 4; P-16, p. 1; P-17, p. 1.) However, they appear to regard these provisions as exemptions for hazardous waste facilities and treatment works. In fact, they serve only to limit the liability of those who lawfully dispose to such facilities for a discharge or release by the facilities. The facilities themselves remain subject to the requirements of the Act. If such facilities dispose the listed chemicals in such a manner that they pass or probably will pass to any source of drinking water, then they may be subject to liability.

One commentator recommended that a limitation on liability for those businesses lawfully disposing of waste to such facilities should depend upon whether the facility is itself in compliance with all applicable legal requirements. (P-10, p. 5.) However, it does not appear possible that businesses disposing to such facilities can be certain that the facility is complying with all legal requirements. Further, the responsibility under the Act for a discharge by a facility should be the facility's. Therefore, this recommendation appears to be inappropriate. However, the lead agency will consider for possible future regulatory action the issue of transfer to a facility which the transferor knows is discharging chemicals into drinking water.

(e) Expose

One commentator recommended that "expose" should not include contact by a route not reasonably expected to cause cancer or reproductive harm. (P-11, p. 26.) This recommendation has been adequately addressed in the Final Statement of Reasons.

(f) Formerly "Significant Risk"

One commentator objected to the deletion of this provision. (P-18, p. 2.) The Final Statement of Reasons adequately explains the basis for this deletion.

One commentator recommended the inclusion of a provision that a chemical presents no significant risk if in compliance with the federal Food, Drug and Cosmetic Act. (P-13, p. 4.) The lead agency intends to issue a more comprehensive provision on the issue of "no significant risk", which will include provisions

relating to food, drugs, cosmetics and medical devices

Section 12301

One commentator recommended that members of the Scientific Advisory Panel provide annual disclosure statements. (P-16, p.1.) Such disclosure was required in the initial proposal, and has not been deleted.

One commentator recommended clarification of what constitutes Panel action, and urged the provision of voting rules. (P-10, p. 6) This recommendation does not appear to address any of the post-hearing modifications made by the lead agency. Therefore, the lead agency will consider these recommendations for future regulatory action.

Section 12305.

Two commentators objected to the modifications to subdivision (a) of section 12305, contending that the regulations should not reduce the Panel's role in the implementation of the Act. (P-6, p. 1; P-11, p. 27.) The role of the Panel has been adequately treated in the Final Statement of Reasons.

Finally, one commentator recommended that the phrase "or any other state agency" be added after "upon request by the lead agency". (P-18, p. 2.) However, it is the lead agency which is charged with the implementation of the Act. Therefore, access by other state agencies to the Panel, other than through the lead agency, appears to be unnecessary.

The lead agency has determined that these regulations impose no mandate on local agencies or school districts.