FINAL STATEMENT OF REASONS
22 CALIFORNIA CODE OF REGULATIONS

TITLE 22, CALIFORNIA CODE OF REGULATIONS

REPEAL OF SECTION 12901
METHODS OF DETECTION
SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986

BACKGROUND

On June 4, 2004, OEHHA issued a Notice of Proposed Rulemaking announcing that the Office of Environmental Health Hazard Assessment (OEHHA) was proposing changes to the Proposition 65 regulations, specifically; Title 22, California Code of Regulations, Division 2, Chapter 3, Section 12901[1]. A public hearing was held on July 20, 2004 to receive comments on the proposed changes. Comments were received orally at the public hearing and in writing during the 45-day public comment period. Following review of the oral and written comments on the proposed amendments to Section 12901, OEHHA determined that the proposed amendments to the regulation that were included with the June 4, 2004 notice would not adequately address the legal and technical concerns that prompted the regulatory action and may have exacerbated the problems that had been experienced by the regulated community, courts and litigants in interpreting the regulation. OEHHA determined that there is a stronger argument for repeal of the regulation and that it is not possible at this time to amend the existing regulation into a form that will not conflict with existing California Law on evidence or create additional cause for litigation concerning the intent or application of the regulation.

OEHHA received five oral comments at the hearing on July 20, 2004, of these, two supported repeal of the regulation, two opposed repeal and one was neutral. Of the eight written comments received, four supported repeal and four took no apparent position on repeal and only addressed issues or concerns with the amended language for the regulation that had been proposed by OEHHA. In reviewing the comments received, it became apparent that additional attempts to amend the regulation would most likely fail to add clarity or certainty concerning the appropriate methods of detection to be used for chemicals listed under Proposition 65 (the Safe Drinking Water and Toxic Enforcement Act of 1986, codified at Health and Safety Code section 25249.5 et seq. (hereafter referred to as Proposition 65 or the Act.)

Based upon the comments received concerning this regulation, OEHHA believes that there generally are scientific test methods and protocols in existence that can be used by regulated businesses to determine whether a given exposure to a listed chemical may require a warning under Proposition 65, or whether a given discharge or release of a listed chemical may violate the discharge prohibition under the Act. These methods and protocols vary depending upon the chemical involved, route of exposure, type of medium causing the exposure or release, and other factual circumstances. There appears to be no consensus in the regulated or enforcement community

[1] All further references are to Title 22 of the California Code of Regulations, unless otherwise indicated.

regarding any standard approach that may be applied to all exposure, release and discharge scenarios that arise under Proposition 65 that could be captured in this regulation. There are also fundamental disagreements among the various stakeholders concerning the scope and effect of the existing regulation that would be very difficult to satisfactorily resolve in a rule of general application. Therefore, given that an existing body of statutory and case law concerning the conduct of scientific tests and the admissibility of scientific evidence already exists in California,[2] OEHHA determined that Section 12901 is not necessary and that the regulation does not further the purposes of the Act because it fails to provide clarity or certainty for either the regulated community or those involved in the enforcement of Proposition 65 concerning the appropriate methods of detection for chemicals regulated under the Act.

A notice of further modifications to the regulatory text in the form of a Notice of Intent to Repeal Section 12901 was issued by OEHHA on September 17, 2004. This notice initiated a 15-day public comment period that closed on October 4, 2004. Post-hearing comments were received. Summaries of the comments received during the 45-day and 15-day comment periods and responses to them are provided below.

In addition to the required 15-day notice period for the notice of intent to repeal the regulation and the written responses to these comments that is included below, OEHHA took the additional step of inviting all those who commented on the Notice of Intent to Repeal Section 12901 to meet with the Director and other staff from the Office in order to discuss the concerns that were raised in their written comments and to develop a reasonable solution. A copy of the electronic invitation to stakeholders is included in the record for this regulatory action. The stakeholder meeting was held in Sacramento on November 15, 2004. More than a dozen individuals attended the meeting representing a variety of interested parties including the metals industry, grocery manufacturers, environmental groups and the Attorney General's Office. The group met for two hours to discuss the various issues raised in the written comments that are summarized and responded to here. A list of attendees for this meeting is included in the record for this regulatory action. Following the meeting, counsel for OEHHA drafted a proposed new regulation, more limited in scope than the existing regulation that could replace Section 12901 if it were repealed. Counsel attempted to address the key issues raised by the various stakeholders in the meeting on November 15. A copy of the "unofficial" working draft for a new Section 12901 is included in the regulatory file for this action. Counsel for OEHHA then circulated the "unofficial" working draft of a new Section 12901 to the individuals who had attended the meeting on November 15. The draft was acceptable to some of the participants in the meeting, with minor changes. On the other hand, the draft was rejected entirely by some of those representing the various business interests.

OEHHA notes that an alternative proposal offered after the close of the comment period by certain business representatives that suggested extensive amendments to the existing regulation. OEHHA believes that these alternative amendments to Section 12901 would increase the complexity of the regulation and would likely not further the purposes of the Act. In particular, the suggestion that the regulation should provide a conclusive presumption that a prohibited discharge, release or exposure has not occurred based upon a particular test result cannot be seen as supporting the express

[2] See for example California Evidence Code sections 210 (relevance) 350 (admissibility) 500 (burden of proof); and *People v Kelly* (1976) 17 Cal.3d. 24, *People v Leahy* (1994) 8 Cal. 4th 587, *People v Bonin* (1999) 47 Cal 3d. 808 (scientific methodology, use and admissibility of scientific evidence.)

provisions of the Act. Copies of the written comments received on the "unofficial" working draft, including the proposed amendments offered after the close of the comment period are included in the rulemaking file.

OEHHA has determined that the appropriate action at this time is to proceed with repeal of the regulation as proposed in the notice, dated September 17, 2004. At the same time, OEHHA is proposing a new regulation that it believes will meet the basic needs of the various stakeholders, at the same time that it furthers the purposes of the Act and is consistent with California evidentiary law. This proposed regulation will be the subject of a separate rulemaking action. OEHHA believes that the existing law of evidence in California will adequately address issues concerning scientific testing methods and procedures, without Section 12901.

SUMMARY AND RESPONSE TO COMMENTS RECEIVED DURING THE INITIAL NOTICE PERIOD OF JUNE 4, 2004 THROUGH JULY 20, 2004

OEHHA received a total of eight (8) written comments concerning the proposed amendments to Section 12901 and also heard five (5) comments at the public hearing on July 20, 2004. OEHHA's responses to comments are summarized below.

In general, the comments received on this regulation can be divided into three categories or combinations of the three. Those that support a repeal of the regulation, those that support changes to the regulation, and those that prefer to keep the regulation as it currently exists. It is also interesting to note that the concerns and arguments raised in the comments on this regulation to some extent mirror the arguments concerning the application of Section 12901 in the *Mateel v Edmund Gray*[3] case.

In *Mateel*, the plaintiffs argued that they need only prove that any amount of a listed chemical had been discharged and that such amount was "detectable" by a method of analysis consistent with the regulation's requirements and that if such a showing were made, the burden of proof would shift to the defendants to prove that the amount discharged is not detectable. On the other hand, the defendants in *Mateel* argued that they need not prove anything other than that the method of analysis used by the plaintiffs was from the wrong "tier" of the regulation, because if that were the case, plaintiff could not establish all the necessary elements of the violation alleged in their complaint. Finally, the Attorney General argued in an amicus curiae brief that the plaintiffs should be allowed to prove that a detectable amount of a listed chemical was discharged by the defendant through the use of any admissible evidence and should not be restricted by Section 12901's requirements on methods of analysis.

ORAL COMMENT #1 - William Funderburke, Jr., Stanzler, Funderburke & Castellon LLP
ORAL COMMENT #2 - Jim Embree, Geomatrix,
ORAL COMMENT #3 - James Simonelli, California Metals Coalition: Several persons representing various regulated businesses did not support repeal of the regulation and further alleged that the regulatory amendments were proposed by OEHHA in an effort to influence the outcome of pending litigation.

[3] Mateel v Edmund Gray et al. (2003) 115 Cal. App. 4th 8

Response: The regulatory action proposed by OEHHA was partially initiated in response to court decisions in which it appeared that the regulation was difficult to understand and apply, particularly in the context of consumer products exposures. The proposed regulation was not developed with the intent to influence the outcome of any pending court cases. No change was made to the proposed regulation based upon these comments.

ORAL COMMENT #2 - Jim Embree, Geomatrix: There are technical aspects of the regulation that need to be addressed as well as those that were more legal in nature.

Response: Some technical issues with the regulation were addressed by the proposed amendments including the proposed definition of "medium" and proposed additions to other portions of the regulation. However, after review of the comments received on the proposed amendments to the regulation, OEHHA determined that a better course of action would be to repeal the regulation in its entirety and rely instead on existing California law concerning the conduct of and admissibility of scientific evidence.

ORAL COMMENT #1 - William Funderburke, Jr., Stanzler , Funderburk & Castellon LLP,
ORAL COMMENT #3 - James Simonelli, California Metals Coalition: Some comments alleged that elimination of the regulation could cost "billions" of dollars and adversely affect small business. No information was provided that supported this allegation. One commenter suggested that OEHHA survey "the industry" to determine the potential impact of the proposed amendments to the regulation. This commenter pointed out that it costs money to have attorneys and toxicologist interpret regulations and that his constituency wants certainty and predictability.

Response: None of the comments received by OEHHA concerning the proposed regulatory action gave any specific examples showing that businesses rely on this regulation by routinely testing their products, discharges or releases to determine their compliance with the Act or use these test results defensively in the event an enforcement action is brought against them. This was the original intent of Section 12901. Instead, the regulations' provisions are used "offensively" to attack the test methods employed by plaintiffs. Therefore, the existing regulation, and to some extent the proposed amendments to the regulation, fail to add clarity or certainty because they are not used for their intended purpose. Given that existing law[4] provides well-established structure for the conduct of and admissibility of scientific test results, there is no need for the current regulation. Because the regulation does not encourage compliance with the Act, it does not further its purposes and will be repealed. Rather than propose additional amendments to the existing regulation, OEHHA will propose the adoption of a new regulation to replace the existing regulation in a separate rulemaking.

ORAL COMMENT #2 - Jim Embree, Geomatrix: The proposed amendments make compliance harder rather than easier. The commenter suggested adding a new regulation that would address technical issues especially concerning consumer products exposures, extrapolation of test results, hand-to-mouth transfers of chemicals, and differentiates between "important" and "not important" exposures. The commenter suggested changes be made to other regulations instead, specifically

[4] See for example California Evidence Code sections 210 (relevance) 350 (admissibility) 500 (burden of proof); and *People v Kelly* (1976) 17 Cal.3d. 24, *People v Leahy* (1994) 8 Cal. 4th 587, *People v Bonin* (1999) 47 Cal 3d. 808 (scientific methodology , use and admissibility of scientific evidence.

Sections 12709, 12721 and 12821. No proposed amendments to the existing Section 12901 were proposed.

Response: As was stated in the initial statement of reasons, the primary issues that were addressed in the proposed regulatory action were legal in nature because they were highlighted in the litigation context. Technical changes to the regulation were proposed initially, including the addition of a definition for the term "medium." The current regulatory action was limited to the amendment or repeal of Section 12901 and so the comments concerning other suggested regulatory sections are not addressed here. OEHHA determined, following review of all the comments received, that the most appropriate action was to repeal the regulation in its entirety and simultaneously initiate a new rulemaking that proposes a new regulation to replace the existing regulation.

COMMENT #3 - Jeffrey Margulies, Fulbright & Jaworski LLP: Businesses want clarity and a scientific approach to methods of detection in order to reduce baseless enforcement actions. The commenter generally agreed with OEHHA's approach in its proposed amendments to the existing regulation. Commenter agreed with elimination of "tiered" system of testing methods because it encourages litigation, but felt proposed language should be refined to better align with California evidence law. The commenter specifically pointed out several areas of concern including issues with the proposed definition of "medium" because it does not take into account the specific potential route of exposure, "generally accepted in scientific community" language should be expanded to require that the given methods be intended for the particular use, and the burden of proof should not be on defendants to prove non-detect, such a test result would instead show that the defendant did not create a knowing, intentional exposure or discharge in violation of the Act.

Response: OEHHA determined upon review of the comments received that the best approach would be to repeal the regulation in its entirety rather than attempt to amend it. Existing California law provides a clear, time-tested approach to scientific testing and methodology that was not enhanced by the existing regulation. Many of the suggested changes to the proposed regulation in this comment as well as others, would have simply restated existing California law concerning scientific evidence, relevance, admissibility and burden of proof issues. No changes were made to the proposed regulation based upon this comment because OEHHA has determined that the best approach is to repeal the regulation in its entirety. However, in a new rulemaking that will be initiated simultaneously with the repeal of the existing regulation, OEHHA is proposing a new regulation to replace the existing regulation that will address some of the issues raised in this comment.

COMMENT #2 - Andrew Packard Esq., Law Office of Andrew Packard
COMMENT # 5 - Alan Maler, Greenberg Traurig LLP
COMMENT # 6 - Michael Lakin PhD and Michael Easter, Esq., Ensight: The proposed amendments to the regulation might not address all the problems with the regulation and may in turn create more. Several comments noted that there is a need for clarification as to whether the regulation was intended to apply to both discharges and exposures and if so, how to reconcile the two within the context of the regulation.

Response: OEHHA determined upon review of the all the comments received during the initial comment period that the best approach would be to repeal the regulation in its entirety rather than

attempt to amend it. Existing California law provides a clear, time-tested approach to the application of scientific methodology and the admissibility of scientific test results that was not enhanced by the existing regulation. The issue raised by several comments concerning the applicability of the regulation to both discharges and exposures is one example of how the existing regulation fails to add clarity or certainty for the regulated community. No changes were made to the proposed regulation based upon this comment because OEHHA has determined that the best approach is to repeal the regulation in its entirety. However, in a new rulemaking that will be initiated simultaneously with the repeal of the existing regulation, OEHHA is proposing a new regulation that will address some of the issues raised in this comment.

COMMENT #5 - Alan Maler, Greenberg Traurig LLP: OEHHA should split the regulation into two so that discharges are treated separately from exposures. As to exposures, the commenter suggested defining the term "exposure" to include only those exposures that may occur through "meaningful pathways." This comment suggested that OEHHA consider US EPA's "Guidelines for Exposure Assessment" document as a model for looking at "meaningful pathways" and as an approach to exposure assessment.

Response: OEHHA determined after review of this and other comments that the best approach would be to repeal the regulation in its entirety rather than attempt to amend it. Existing California law provides a clear, time-tested approach to scientific testing and methodology that was not enhanced by the existing regulation. As pointed out in this comment existing federal and state guidance is available concerning exposure assessment methodology and approach. The appropriateness of such guidance may vary depending on the particular factual situation presented and may not lend itself to a strict regulatory requirement. The suggested changes to the proposed regulation in this comment as well as others, would primarily restate existing California law concerning scientific evidence, relevance, admissibility or burden of proof issues. No changes were made to the proposed regulation based upon this comment because OEHHA has determined that the best approach is repeal of the regulation in its entirety. However, in a new rulemaking that will be initiated simultaneously with the repeal of the existing regulation, OEHHA is proposing a new regulation that will address some of the issues raised in this comment.

COMMENT #5 - Alan Maler, Greenberg Traurig LLP: A comment questioned the constitutionality of the proposed amendments, possibly on due process grounds, and suggested the proposed regulation does not provide adequate prospective guidance for the regulated community.

Response: OEHHA has carefully followed all the requirements of the Administrative Procedure Act concerning this regulatory action and believes that no constitutional violation has occurred. It has become clear from the comments received concerning the existing and proposed regulation, that neither provides adequate clarity for the regulated community and that the best approach would be to repeal the regulation in its entirety. No changes were made to the proposed regulation based upon this comment. However, in a new rulemaking that will be initiated simultaneously with the repeal of the existing regulation, OEHHA is proposing a new regulation that will address some of the issues raised in this comment.

COMMENT # 1 - William Verick, Klamath Environmental Law Center
COMMENT # 2 - Andrew Packard Esq., Law Office of Andrew Packard

COMMENT # 4 - Ann Grimaldi, McKenna Long & Aldridge
COMMENT # 5 - Alan Maler, Greenberg Traurig LLP
COMMENT # 6 - Michael Lakin PhD and Michael Easter, Esq., Ensight: Several comments identified problems with the proposed definition of "medium." These comments made various suggestions concerning ways to better define the term including a suggestion that the "medium" in the context of a Proposition 65 exposure is the transport mechanism that causes the exposure, not the product itself and a suggestion that the definition should apply to both discharges and exposures.

Response: The proposed definition of "medium" was primarily intended to assist businesses in determining how to test consumer products for compliance with the Act. The term "medium" probably does not need to be defined in the context of chemical discharges to sources of drinking water or environmental exposures such as those occurring through contact with the air, water or soil. However, given the range of issues raised concerning the proposal to adopt a general definition for the term, it appears there is no agreement among the various stakeholders as to what the definition should be, or how it should be applied. No changes were made to the proposed regulation based upon this comment because OEHHA has determined that the best approach is to repeal the regulation in its entirety. However, in a new rulemaking that will be initiated simultaneously with the repeal of the existing regulation, OEHHA is proposing a new regulation that will address some of the issues raised in this comment.

COMMENT #2 - Alan Maler, Greenberg Traurig LLP: One comment suggested that OEHHA create a conclusive presumption based on defendant's tests even if a more sensitive test was employed by plaintiffs, and also proposed deletion of burden of proof provision based on the fact that it adds nothing to existing law.

Response: OEHHA believes that a conclusive presumption based upon any test result, no matter how gross the testing methodology or how old the test result might be, would not further the purposes of the Act because it could allow significant discharges, releases or exposures to occur with impunity. No changes were made to the proposed regulation based upon this comment because OEHHA has determined that the best approach is to repeal the regulation in its entirety. However, in a new rulemaking that will be initiated simultaneously with the repeal of the existing regulation, OEHHA is proposing a new regulation that will address some of the burden of proof issues raised in this comment.

COMMENT #8- Jackie Sample, US Navy: A suggestion was made to define the term "any detectable amount" in the regulation by incorporating by reference a federal definition for "method detection limit" found in 40 Code of Federal Regulations, section 139, Appendix B as follows: "The method detection limit (MDL) is defined as the minimum concentration of a substance that can be measured and reported with 99% confidence that the analyte concentration is greater than zero and is determined from analysis of a sample in a given matrix containing the analyte."

Response: OEHHA has determined that the best course of action is to repeal the regulation in its entirety. However, in a new rulemaking that will be initiated simultaneously with the repeal of the existing regulation, OEHHA is proposing a new regulation that will address some of the issues raised in this comment. In the interim, regulated businesses and those considering enforcement

actions are free to use this federal definition, if appropriate, for the particular discharge or exposure being analyzed.

COMMENT # 1 - William Verick, Klamath Environmental Law Center
COMMENT #2 - Andrew Packard Esq., Law Office of Andrew Packard: The initial purpose of Section 12901 was to encourage proactive testing of products by businesses, but this does not routinely occur. Even with the proposed amendments businesses and those involved in enforcement will need to search for analytical methods adopted or employed by state or federal agencies. The proposed regulation does not address the issue of how a state agency uses a particular test, (i.e. a product specific measure vs. a general chemical limit measurement).

Response: No specific changes were made based upon this comment given that OEHHA has determined that the best course of action is to repeal the regulation in its entirety, rather than attempt to amend the existing language sufficiently to address all the problems associated with its application and interpretation. However, in a new rulemaking that will be initiated simultaneously with the repeal of the existing regulation, OEHHA is proposing a new regulation that will address some of the issues raised in this comment.

COMMENT # 2 - Andrew Packard Esq., Law Office of Andrew Packard:
Not clear how to define the terms "adopted" or "employed" in existing regulation.

Response: OEHHA has determined that the best course of action is to repeal the regulation in its entirety, rather than attempt to amend it sufficiently to address all the problems associated with its application and interpretation including the issue raised by this comment. However, in a new rulemaking that will be initiated simultaneously with the repeal of the existing regulation, OEHHA is proposing a new regulation that will address some of the issues raised in this comment and does not use the terms "adopted" or "employed."

COMMENT #1 - William Verick, Klamath Environmental Law Center
COMMENT #4 - Ann Grimaldi, McKenna Long & Aldridge
COMMENT #7 - James Simonelli, California Metals Coalition (Per written comment adopting by reference Ann Grimaldi's comments)
ORAL COMMENT #4 - Michael Schmitz, CLEEN
ORAL COMMENT # 5 - Andrew Packard Esq., Law Office of Andrew Packard: Several of the comments noted that existing California Law already governs matters such as the admissibility of evidence and litigant's burdens of proof; therefore the regulation is not needed. These comments supported repeal of the regulation or in the alternative suggest changes to the proposed amendments.

Response: OEHHA agrees that the best course of action is to repeal the regulation in its entirety, rather than attempt to amend it sufficiently to address all the problems associated with its application and interpretation. However, in a new rulemaking that will be initiated simultaneously with the repeal of the existing regulation, OEHHA is proposing a new regulation that will address some of the issues raised in this comment.

COMMENT #1 - William Verick, Klamath Environmental Law Center: The proposed amendments, such as the description of methods of analysis and definition of "medium" are too restrictive. The burden of proof should only shift if a non-detect test result is based on accurate scientific data, not defense interpretation of test result.

Response: OEHHA has determined that the best course of action is to repeal the regulation in its entirety, rather than attempt to amend it sufficiently to address all the problems associated with its application and interpretation including the issues raised by this comment. However, in a new rulemaking that will be initiated simultaneously with the repeal of the existing regulation, OEHHA is proposing a new regulation that will address the issues raised in this comment.

COMMENT #1 - William Verick, Klamath Environmental Law Center: For many chemicals and other substances, there is no standard test method that would meet the criteria in the existing or proposed regulation, thus potentially triggering the provision in subsection (g) that says if the chemical cannot be detected, there can be no illegal discharge or exposure.

Response: OEHHA believes that businesses subject to the Act should be aware of the chemicals that are present in their products or discharges, whether this awareness comes from specific testing methods or general knowledge of the make-up of their products and processes or from any other source. The fact that a standardized test method for a particular listed chemical or combination of chemicals such as tobacco smoke may not exist, should not be a complete defense to an enforcement action for violation of the Act. Any otherwise admissible evidence should be allowed to prove such a violation, as provided by existing California law. This provision in the existing regulation unnecessarily limits the types of evidence that may be used to prove or disprove an alleged exposure or discharge that may be in violation of the Act. OEHHA believes that the California Evidence Code adequately addresses issues concerning burdens of proof and presumptions in civil cases. No changes were made to the proposed regulation based upon this comment because OEHHA has determined that the best approach is to repeal the regulation in its entirety. However, in a new rulemaking that will be initiated simultaneously with the repeal of the existing regulation, OEHHA is proposing a new regulation that will address some of the issues raised in this comment.

ORAL COMMENT #5 - Andrew Packard Esq., Law Office of Andrew Packard: Exposure and discharge scenarios are too varied and novel to be adequately covered by a rigid paradigm such as is found in the existing or proposed amended regulation.

Response: OEHHA agrees that the existing regulation and the proposed amendments to the regulation do not adequately address the myriad of situations in which discharges of, or exposures to, listed chemicals may occur and the appropriate analytical test methods that should be applied to each situation. Maximum flexibility can be achieved through repeal of the regulation, since this allows regulated businesses and those who bring enforcement actions to choose an analytical method that is most appropriate for a given situation and rely on existing California Law when litigating cases brought under Proposition 65. No changes were made to the proposed regulation based upon this comment because OEHHA has determined that the best approach is to repeal the regulation in its entirety. However, in a new rulemaking that will be initiated simultaneously with the repeal of the existing regulation, OEHHA is proposing a new regulation that will address some

of the issues raised in this comment in a regulation with a more limited application and scope than the existing regulation.

SUMMARY AND RESPONSE TO COMMENTS RECEIVED DURING THE 15-DAY COMMENT PERIOD OF SEPTEMBER 17, 2004 THROUGH OCTOBER 4, 2004

OEHHA received 20 written comments concerning the proposed repeal of Section 12901

POST-HEARING (PH) COMMENT #1 - Tim Strelitz, California Metal-X: Opposes repeal, requests small business impact analysis.

Response: The California Code of Regulations, Title 1, Section 4 defines the criteria to be applied by an agency when attempting to determine if a proposed regulatory action affects small business. The regulation states that:

"…For purposes of this section, an adoption or amendment affects small business if a small business…

(1) Is legally required to comply with the regulation:
(2) Is legally required to enforce the regulation;
(3) Derives a benefit from the enforcement of the regulation; or
(4) Incurs a detriment from the regulation."

The regulation goes on to provide that "If an agency determines that the regulation does not affect small business, the agency shall include in the notice of proposed action a brief explanation of the reason(s) for the agency's determination."

In this case, OEHHA initially determined that its proposed action to amend or repeal Section 12901 would not have a significant, adverse impact on small business in the state. Using the criteria noted above, and applying them to OEHHA's decision to repeal the regulation in its entirety, OEHHA finds that if the regulation is repealed, small business will not be legally required to comply with or enforce the regulation. Further, given that the regulation was used, primarily as an affirmative defense to litigation that was filed against businesses, it is true that small business will no longer be able to derive a benefit from the regulation, nor incur a detriment from it. Instead, businesses will be free to use, or continue to use whatever test methods they chose to determine whether they are in compliance with the requirements of the Act. Any alleged increase in litigation against small business that may result from repeal of the regulation is speculative at best. Further, the statutory requirement for plaintiffs to file a certificate of merit with the Attorney General's Office (Health and Safety Code section 25249.7(d)) prior to commencing any legal action should provide adequate protection against the filing of unmeritorious actions.

Therefore, OEHHA has determined that no change to the intended action to repeal Section 12901 in its entirety is necessary based upon this comment.

PH COMMENT #2 - Peter Weiner, Paul, Hastings, Janofsky & Walker LLP: Oppose repeal of regulation. Generally agree with comments filed by Ann Grimaldi on July 20, 2004. Believe the tiered hierarchy in the regulation is important to the regulated community, government agencies and

others. Regulation provides security to regulated entities that certain test results are acceptable under Proposition 65. Such determinations should not be left to general requirements of the Evidence Code or *Kelly* rule. Believes that if Section 12901 is repealed, a chemical could be assumed to be present in a product at half the limit of detection of a particular test. Gives example of totally encapsulated asbestos in marble. Repeal could result in disincentive for companies to minimize exposures to listed chemicals. Companies may instead opt to provide a warning on everything. They propose alternate language for the regulation.

Response: OEHHA believes that the current regulation does not provide regulated entities with any level of certainty they would not already have through reliance on general California Law on the admissibility of scientific evidence. Section 12901 does not identify or directly sanction the use of any particular testing method of analysis that is to be used for any particular chemical. Instead, the regulation provides a hierarchy by which a regulated entity might determine which test method among those that might be available would be considered by OEHHA to be the most appropriate for determining compliance with the provisions of the statute. The regulation assumes that an analytical test method has been developed for every chemical and every possible discharge, release or exposure situation, which is simply not the case.

Questions that may arise concerning which testing method is appropriate for a particular chemical in a given medium, along with issues concerning how the test was conducted and what the test results mean, still must ultimately be decided by the courts. Therefore any certainty or security against potential litigation that might appear to be provided by this regulation is illusory. OEHHA notes that staff requested examples of actual situations in which the results of routine testing using test methods consistent with the existing regulation were used to prevent the filing of litigation or to prove that a prohibited discharge or exposure had not occurred. Not a single example was provided.

Further, the current regulation does not address the issue raised in this comment concerning totally encapsulated asbestos, since that is a question of exposure, not detection and is therefore not relevant to this regulatory action. The potential application of a scientific assumption that a chemical is present at half the limit of detection for the particular testing method would not necessarily impact the determination that an illegal discharge or exposure has occurred in a particular case. A court would have to determine if such a presumption should be applied to a particular factual situation and whether application of such a presumption would result in a discharge of a "significant amount" of the chemical or an exposure to a chemical that exceeds the regulatory limit.

Regulated companies, even in the absence of this regulation, are free to reformulate their products or otherwise reduce the potential exposures to listed chemicals in order to avoid the necessity of providing a warning and will likely continue to do so.

Therefore, OEHHA has determined that no change to the intended action to repeal Section 12901 in its entirety is necessary based upon this comment. However, in a new rulemaking that will be initiated simultaneously with the repeal of the existing regulation, OEHHA is proposing a new regulation that will address some of the issues raised in this comment.

PH COMMENT #3 - Bill Verick – Klamath Law Center, Mateel Environmental Justice Center: Supports repeal of Section 12901 because it does not achieve the purposes for which it was intended. Companies do not routinely test their products or discharges. Current law of evidence as interpreted by the courts in *People v Kelly* and *People v Bonin*, among others, is sufficient to provide guidance concerning the proper methods and criteria for scientific testing. Further, there may be no standardized test methodology for some chemicals that are listed under Proposition 65 and a plaintiff should be allowed to offer any type of admissible evidence to prove an exposure to such a substance.

Response: Given that the comments support OEHHA's proposed repeal of Section 12901, no change to the proposed action to repeal this regulation was made based on these comments. OEHHA agrees that the existing laws of evidence as interpreted by California courts are adequate to address the admissibility of scientific test results. Repeal of the regulation will allow courts to consider a full range of evidence when deciding questions of discharge and exposure to listed chemicals. It should be noted that OEHHA intends to propose a new, more narrowly focused regulation at the same time that the existing regulation is repealed.

PH COMMENT #4 - Ann Grimaldi, McKenna Long & Aldridge: Reaffirms prior comments that support repeal of the regulation. Additionally, commenter requests clarification that a regulated business is not specifically required to test its products.

Response: OEHHA notes that the Act prohibits persons in the course of doing business from discharging significant amounts of listed chemicals into sources of drinking water or causing exposures to listed chemicals without first providing a clear and reasonable warning. While neither of these provisions includes an express requirement that a business test its releases or discharges, or test its products for potential exposures, it would seem to be a prudent course of action on the part of regulated entities in order to avoid the potential for violation of the Act. The current regulation was adopted based in part on the assumption that businesses were conducting routine testing under various regulatory programs and should be allowed to use the results of those tests in determining compliance with the Act. Experience has shown that that is not always the case and this comment supports that belief. However, repeal of the regulation does not prevent businesses from continuing to conduct compliance programs that may include routine discharge, release or product testing. The results of such testing, if otherwise admissible, may be offered to disprove an allegation that a business has violated the Act.

Therefore, OEHHA has determined that no change to the intended action to repeal Section 12901 in its entirety is necessary based upon this comment. It should be noted that OEHHA intends to propose a new, more narrowly focused regulation at the same time that the existing regulation is repealed that will expressly provide that under certain circumstances, businesses can rely on test results that show the particular discharge, release or exposure is in compliance with the Act.

PH COMMENT #5 - Nino Mascolo, Southern California Edison: Suggests that if OEHHA decides to repeal the regulation, that subsection (g) of 12901 be allowed to remain with minor modification, thus requiring that a chemical actually be detected in order to establish a violation of Proposition 65.

Response: Section 12901(g) assumes that a testing methodology has been developed for and may be applied to a particular discharge, release or exposure to a listed chemical. This is not always the case. There may be certain chemicals or types of exposures for which there is no standard testing methodology, or there may be situations in which it is not possible to apply a test for a particular chemical. OEHHA believes that it is most appropriate to allow all parties to use any admissible evidence to prove or disprove an alleged discharge, release or exposure to a listed chemical.

Therefore, OEHHA has determined that no change to the intended action to repeal Section 12901 in its entirety is necessary based upon this comment. It should be noted that OEHHA intends to propose a new, more narrowly focused regulation at the same time that the existing regulation is repealed, the proposed new regulation will not include the provision noted in this comment.

PH COMMENT #6 - Dennis Swartz, Burlington Medical Supplies, Inc.: Supports repeal of regulation.

Response: None needed.

PH COMMENT #7 - Michael Lynes, Law Office of Andrew Packard: Supports repeal of the entire regulation. Section 12901 does not assist the regulated community in complying with Proposition 65, the existing case law interpreting the California Evidence Code provides sufficient guidance for both those who wish to comply with Proposition 65 and those who wish to enforce it requirements. The tiered hierarchy in the current regulation created fodder for litigation and does not provide certainty or predictability for businesses or litigants.

Response: Given that the comment supports OEHHA's proposed repeal of Section 12901, no change to the proposed action to repeal this regulation was made based on these comments. OEHHA agrees that the existing laws of evidence as interpreted by California courts are adequate to address the admissibility of scientific test results. Repeal of the regulation will allow courts to consider a full range of evidence when deciding questions of discharge and exposure to listed chemicals and should not increase the volume of litigation regarding these issues.

PH COMMENT #8 - Jeffrey Margulies, Fulbright & Jaworski for the California Retailers Association: Opposes repeal of the regulation. Believes the regulation adds clarity and reduces the number of baseless claims that could be filed under the Act and claims repeal would not further the purposes of the Act. Believes the problem with the existing regulation is that it tries to address too many issues together (defines "detectible" discharge, defines methods of detecting discharge or exposure, addresses burdens of proof, etc.), rather than addressing these issues separately. Requests that if the regulation is repealed that the Office expressly state the effective date for the regulation and its intended effect on pending litigation. Suggests that if the current regulation is repealed, that it is replaced with a technical regulation dealing with scientific methods and principles and that defines which methods to apply for different routes of exposure. Further suggests that the Office adopt a new regulation that would establish the quantum of evidence required to prove a discharge or exposure, define the term "detectible," establish the quantum of proof necessary to establish the defense of "no significant risk," require that plaintiffs prove that an exposure or release has occurred. Also suggests that any repeal of the regulation include a delayed effective date of one year to allow affected businesses to adjust to the change.

Response: OEHHA believes that the current regulation does not provide regulated entities with any level of certainty they would not already have through reliance on general California Law on the admissibility of scientific evidence. Section 12901 does not identify or directly sanction the use of any particular testing method of analysis that is to be used for any particular chemical. Instead, the regulation provides a hierarchy by which a regulated entity might determine which test method among those that might be available would be considered by OEHHA to be the most appropriate for determining compliance with the provisions of the statute. The regulation assumes that an analytical test method has been developed for every chemical and every possible discharge, release or exposure situation, which is simply not the case.

Questions that may arise concerning which testing method is appropriate for a particular chemical in a given medium, along with issues concerning how the test was conducted and what the test results mean, still must ultimately be decided by the courts. Therefore any certainty or security against potential litigation that might appear to be provided by this regulation is illusory. OEHHA notes that staff requested examples of actual situations in which the results of routine testing using test methods consistent with the existing regulation were used to prevent the filing of litigation or to prove that a prohibited discharge or exposure had not occurred. Not a single example was provided.

OEHHA has determined that the appropriate action at this time is to proceed with repeal of the regulation. However, it should be noted that OEHHA intends to propose a new, more narrowly focused regulation at the same time that the existing regulation is repealed. OEHHA anticipates that repeal of the existing regulation will be effective 30 days after filing with the Secretary of State. No grace period appears to be necessary, since businesses are free to continue to test their discharges and releases in the same manner as they are currently using, if any. Repeal of the regulation would not expressly require any change in process by entities subject to the Act. Therefore, OEHHA has determined that no change to the intended action to repeal Section 12901 in its entirety is necessary based upon this comment.

PH COMMENT #9 - James Skiles, Grocery Manufacturers of America, California Fisheries and Seafood Institute, and Western Suppliers Association: Opposes repeal of the regulation, alleges the proposed action would be overbroad and procedurally improper (i.e. to repeal the entire regulation since amendments were not proposed for each subsection in the Initial Statement of Reasons). Comment alleges that repeal would remove a needed exemption from the statute for chemicals that are not detectible by a test identified in the current regulation, predictability would be diminished, there would be less certainty for the regulated community, there might be a tendency to over-warn for those products which may contain trace amounts of a particular chemical.

Response: OEHHA has complied with all the requirements of the Administrative Procedure Act in this rulemaking action. The original notice for the action stated that repeal of the regulation was an alternative to the proposed amendments to the regulation being considered by OEHHA. Following review of the comments received during the initial 45-day comment period, OEHHA published another notice specifically stating its intent to repeal the regulation and received comments for longer than the required 15 days. As noted above, OEHHA went further and met with representatives of those entities that made comments on the proposed repeal and is now responding to the written comments received.

OEHHA believes that the current regulation does not provide regulated entities with any level of certainty they would not already have through reliance on general California Law on the admissibility of scientific evidence. Section 12901 does not identify or directly sanction the use of any particular testing method of analysis that is to be used for any particular chemical discharge release or exposure. Instead, the regulation provides a hierarchy by which a regulated entity might determine which test method among those that might be available would be considered by OEHHA to be the most appropriate for determining compliance with the provisions of the statute. The current regulation assumes that an analytical test method has been developed for every chemical and every possible discharge, release or exposure situation, which is simply not the case.

Questions that may arise concerning which testing method is appropriate for a particular chemical in a given medium, along with issues concerning how the test was conducted and what the test results mean, still must ultimately be decided by the courts. Therefore any certainty or security against potential litigation that might appear to be provided by this regulation is illusory. OEHHA notes that staff requested examples of actual situations in which the results of routine testing using test methods consistent with the existing regulation were used to prevent the filing of litigation or to prove that a prohibited discharge or exposure had not occurred. Not a single example was provided.

Therefore, OEHHA has determined that no change to the intended action to repeal Section 12901 in its entirety is necessary based upon this comment. It should be noted that OEHHA intends to propose a new, more narrowly focused regulation at the same time that the existing regulation is repealed that would specifically allow businesses, under certain circumstances, to rely on testing methods and procedures that they may be using in their compliance programs.

PH COMMENT #10 - Patrick Magee Vaughn, American Beverage Association/National Soft Drink Association: Opposes repeal. Wholesale repeal will add uncertainty to compliance programs in place at California businesses and could increase compliance costs.

Response: OEHHA believes that the current regulation does not provide regulated entities with any level of certainty they would not already have through reliance on general California Law on the admissibility of scientific evidence. Section 12901 does not identify or directly sanction the use of any particular testing method of analysis that is to be used for any particular chemical. Instead, the regulation provides a hierarchy by which a regulated entity might determine which test method among those that might be available would be considered by OEHHA to be the most appropriate for determining compliance with the provisions of the statute. The regulation assumes that an analytical test method has been developed for every chemical and every possible discharge, release or exposure situation, which is simply not the case.

Questions that may arise concerning which testing method is appropriate for a particular chemical in a given medium, along with issues concerning how the test was conducted and what the test results mean, still must ultimately be decided by the courts. Therefore any certainty or security against potential litigation that might appear to be provided by this regulation is illusory. OEHHA notes that staff requested examples of actual situations in which the results of routine testing using test methods consistent with the existing regulation were used to prevent the filing of litigation or to prove that a prohibited discharge or exposure had not occurred. Not a single example was provided.

Regulated companies, even in the absence of this regulation, are free to reformulate their products or otherwise reduce the potential exposures to listed chemicals in order to avoid the necessity of providing a warning and will likely continue to do so.

Therefore, OEHHA has determined that no change to the intended action to repeal Section 12901 in its entirety is necessary based upon this comment. It should be noted that OEHHA intends to propose a new, more narrowly focused regulation at the same time that the existing regulation is repealed.

PH COMMENT #11 - Michael Schmitz, CLEEN: Supports repeal, agrees that existing statutory and case law better address the issues this regulation attempts to address. Also, repeal would address growing concerns that businesses are using the existing regulation to delay and confound implementation of Proposition 65.

Response: Given that the comment supports OEHHA's proposed repeal of Section 12901, no change to the proposed action to repeal this regulation was made based on these comments. OEHHA agrees that the existing laws of evidence as interpreted by California courts are adequate to address the admissibility of scientific test results. Repeal of the regulation will allow courts to consider a full range of evidence when deciding questions of discharge and exposure to listed chemicals and should not increase the volume of litigation regarding these issues.

PH COMMENT #12 - Daniel Fuchs, Livingston & Mattesich for International Bottled Water Association, International Dairy Foods Association, and the National Food Processor's Association: Opposes repeal of the regulation because it could increase uncertainty and possibly cause businesses to be unknowingly out of compliance with the Act. Without the regulation, a business may need to hire a toxicologist to conduct a full risk assessment for a consumer product. The manufacturer may not be able to rely on test methodologies that are developed by state or federal agencies such as the U.S. EPA.

Response: OEHHA believes that the current regulation does not provide regulated entities with any level of certainty they would not already have through reliance on general California Law on the admissibility of scientific evidence. Section 12901 does not identify or directly sanction the use of any particular testing method of analysis that is to be used for any particular chemical. Instead, the regulation provides a hierarchy by which a regulated entity might determine which test method among those that might be available would be considered by OEHHA to be the most appropriate for determining compliance with the provisions of the statute. The regulation assumes that an analytical test method has been developed for every chemical and every possible discharge, release or exposure situation, which is simply not the case.

Questions that may arise concerning which testing method is appropriate for a particular chemical in a given medium, along with issues concerning how the test was conducted and what the test results mean, still must ultimately be decided by the courts. Therefore any certainty or security against potential litigation that might appear to be provided by this regulation is illusory. OEHHA notes that staff requested examples of actual situations in which the results of routine testing using

test methods consistent with the existing regulation were used to prevent the filing of litigation or to prove that a prohibited discharge or exposure had not occurred. Not a single example was provided.

The Act prohibits companies from knowingly and intentionally causing an exposure without a clear and reasonable warning. If a company reasonably relies on a test methodology for compliance testing that is generally accepted in the scientific community and is otherwise properly conducted and admissible, there is no reason to expect them to be liable for a knowing and intentional violation of the Act. Following repeal of this regulation, regulated businesses are free to continue to use whatever testing methods they currently use in their compliance efforts and such test result may be used to defend any subsequent enforcement action. The allegation that a company may not be able to rely on test methods developed by U.S. EPA is speculative and assumes that many other test methods are available that might be used by plaintiffs.

Further, companies subject to the Act, even in the absence of this regulation, are free to reformulate their products or otherwise reduce the potential exposures to listed chemicals that may be caused by them in order to avoid the necessity of providing a warning and will likely continue to do so.

Therefore, OEHHA has determined that no change to the intended action to repeal Section 12901 in its entirety is necessary based upon this comment. It should be noted that OEHHA intends to propose a new, more narrowly focused regulation at the same time that the existing regulation is repealed.

PH COMMENT #13 - James Simonelli, California Metals Coalition: Opposes repeal. The companies represented by the Coalition rely on Section 12901. Wants to retain the current hierarchy of test methods in the regulation to conduct compliance programs. Believes compliance costs would increase if the regulation were repealed. Alleges that without Section 12901, plaintiffs can file more frivolous lawsuits. Requests that OEHHA conduct a CEQA-type analysis of the impact of repeal of the regulation on small businesses.

Response: The California Code of Regulations, Title 1, Section 4 defines the criteria to be applied by an agency when attempting to determine if a proposed regulatory action affects small business. The regulation states that:

"…For purposes of this section, an adoption or amendment affects small business if a small business…

(1) Is legally required to comply with the regulation:
(2) Is legally required to enforce the regulation;
(3) Derives a benefit from the enforcement of the regulation; or
(4) Incurs a detriment from the regulation."

The regulation goes on to provide that "If an agency determines that the regulation does not affect small business, the agency shall include in the notice of proposed action a brief explanation of the reason(s) for the agency's determination."

In this case, OEHHA initially determined that its proposed action to amend or repeal Section 12901 would not have a significant, adverse impact on small business in the state. Using the criteria noted

above, and applying them to OEHHA's decision to repeal the regulation in its entirety, OEHHA finds that if the regulation is repealed, small business will not be legally required to comply with or enforce the regulation. Further, given that the regulation was used, primarily as an affirmative defense to litigation that was filed against businesses, it is true that small business will no longer be able to derive a benefit from the regulation, nor incur a detriment from it. Instead, businesses will be free to use, or continue to use whatever test methods they chose to determine whether they are in compliance with the requirements of the Act. Any alleged increase in litigation against small business that may result from repeal of the regulation is speculative at best. Further, the statutory requirement for plaintiffs to file a certificate of merit with the Attorney General's Office (Health and Safety Code section 25249.7(d)) prior to commencing any legal action should provide adequate protection against the filing of unmeritorious actions.

Therefore, OEHHA has determined that no change to the intended action to repeal Section 12901 in its entirety is necessary based upon this comment. It should be noted that OEHHA intends to propose a new, more narrowly focused regulation at the same time that the existing regulation is repealed.

PH COMMENT #14 - Larry Fahn, As You Sow: Supports repeal of the regulation because the regulation does not meet its intended purpose of providing clarity concerning the phrase "any detectable amount." Section 12901 adds an unnecessary and complicated step that is better addressed by the existing law of evidence.

Response: Given that the comment supports OEHHA's proposed repeal of Section 12901, no change to the proposed action to repeal this regulation was made based on these comments. OEHHA agrees that the existing laws of evidence as interpreted by California courts are adequate to address the admissibility of scientific test results. Repeal of the regulation will allow courts to consider a full range of evidence when deciding questions of discharge and exposure to listed chemicals and should not increase the volume of litigation regarding these issues.

PH COMMENT #15 - R. Ken Shortle, North American Die Casting Association (NADCA): Opposes repeal, alleges that if the regulation is repealed, their members may be subject to frivolous lawsuits. (Comment received after the close of the public comment period, but is included for completeness of the administrative record.)

Response: Given that the regulation was used primarily as an affirmative defense to litigation that was filed against businesses it is true that businesses will no longer be able to derive a benefit from the regulation. Instead, businesses will be free to use, or continue to use whatever test methods they chose to determine whether they are in compliance with the requirements of the Act. Any alleged increase in litigation against small business that may result from repeal of the regulation is speculative at best. Further, the statutory requirement for plaintiffs to file a certificate of merit with the Attorney General's Office (Health and Safety Code section 25249.7(d)) prior to commencing any legal action should provide adequate protection against the filing of unmeritorious actions.

Therefore, OEHHA has determined that no change to the intended action to repeal Section 12901 in its entirety is necessary based upon this comment. It should be noted that OEHHA intends to

propose a new, more narrowly focused regulation at the same time that the existing regulation is repealed.

PH COMMENT #16 - Geoffrey Blake, All Metals Processing: Opposes repeal, believes it could lead to regulatory uncertainty. Requests that OEHHA conduct a "small business economic analysis." (Comment received after the close of the public comment period, but is included for completeness of the administrative record.)

Response: The California Code of Regulations, Title 1, Section 4 defines the criteria to be applied by an agency when attempting to determine if a proposed regulatory action affects small business. The regulation states that:

"…For purposes of this section, an adoption or amendment affects small business if a small business…

(1) Is legally required to comply with the regulation:
(2) Is legally required to enforce the regulation;
(3) Derives a benefit from the enforcement of the regulation; or
(4) Incurs a detriment from the regulation."

The regulation goes on to provide that "If an agency determines that the regulation does not affect small business, the agency shall include in the notice of proposed action a brief explanation of the reason(s) for the agency's determination."

In this case, OEHHA initially determined that its proposed action to amend or repeal Section 12901 would not have a significant, adverse impact on small business in the state. Using the criteria noted above, and applying them to OEHHA's decision to repeal the regulation in its entirety, OEHHA finds that if the regulation is repealed, small business will not be legally required to comply with or enforce the regulation. Further, given that the regulation was used, primarily as an affirmative defense to litigation that was filed against businesses, it is true that small business will no longer be able to derive a benefit from the regulation, nor incur a detriment from it. Instead, businesses will be free to use, or continue to use whatever test methods they chose to determine whether they are in compliance with the requirements of the Act. Any alleged increase in litigation against small business that may result from repeal of the regulation is speculative at best. Further, the statutory requirement for plaintiffs to file a certificate of merit with the Attorney General's Office (Health and Safety Code section 25249.7(d)) prior to commencing any legal action should provide adequate protection against the filing of unmeritorious actions.

Therefore, OEHHA has determined that no change to the intended action to repeal Section 12901 in its entirety is necessary based upon this comment. It should be noted that OEHHA intends to propose a new, more narrowly focused regulation at the same time that the existing regulation is repealed.

PH COMMENT #17 - Alan Maler, Greenberg Traurig, LLP: Claims that repeal of the regulation would be contrary to the purposes of the Act and possibly unconstitutional. Believes that absent this regulation, businesses cannot determine in advance of litigation, which test methods to use.

This could result in more litigation. (Comment received after the close of the public comment period, but is included for completeness of the administrative record.)

Response: The California Code of Regulations, Title 1, Section 4 defines the criteria to be applied by an agency when attempting to determine if a proposed regulatory action affects small business. The regulation states that:

"…For purposes of this section, an adoption or amendment affects small business if a small business…

(1) Is legally required to comply with the regulation:
(2) Is legally required to enforce the regulation;
(3) Derives a benefit from the enforcement of the regulation; or
(4) Incurs a detriment from the regulation."

The regulation goes on to provide that "If an agency determines that the regulation does not affect small business, the agency shall include in the notice of proposed action a brief explanation of the reason(s) for the agency's determination."

In this case, OEHHA initially determined that its proposed action to amend or repeal Section 12901 would not have a significant, adverse impact on small business in the state. Using the criteria noted above, and applying them to OEHHA's decision to repeal the regulation in its entirety, OEHHA finds that if the regulation is repealed, small business will not be legally required to comply with or enforce the regulation. Further, given that the regulation was used, primarily as an affirmative defense to litigation that was filed against businesses, it is true that small business will no longer be able to derive a benefit from the regulation, nor incur a detriment from it. Instead, businesses will be free to use, or continue to use whatever test methods they chose to determine whether they are in compliance with the requirements of the Act. Any alleged increase in litigation against small business that may result from repeal of the regulation is speculative at best. Further, the statutory requirement for plaintiffs to file a certificate of merit with the Attorney General's Office (Health and Safety Code section 25249.7(d)) prior to commencing any legal action should provide adequate protection against the filing of unmeritorious actions.

Therefore, OEHHA has determined that no change to the intended action to repeal Section 12901 in its entirety is necessary based upon this comment. It should be noted that OEHHA intends to propose a new, more narrowly focused regulation at the same time that the existing regulation is repealed.

PH COMMENT #18 - Daniel Twarog, North American Die Casting Association: Opposes repeal because it would reduce regulatory certainty and could increase litigation. Requests that OEHHA conduct a small business impact analysis. (Comment received after the close of the public comment period, but is included for completeness of the administrative record.)

Response: The California Code of Regulations, Title 1, Section 4 defines the criteria to be applied by an agency when attempting to determine if a proposed regulatory action affects small business. The regulation states that:

"…For purposes of this section, an adoption or amendment affects small business if a small business…

(1) Is legally required to comply with the regulation:
(2) Is legally required to enforce the regulation;
(3) Derives a benefit from the enforcement of the regulation; or
(4) Incurs a detriment from the regulation."

The regulation goes on to provide that "If an agency determines that the regulation does not affect small business, the agency shall include in the notice of proposed action a brief explanation of the reason(s) for the agency's determination."

In this case, OEHHA initially determined that its proposed action to amend or repeal Section 12901 would not have a significant, adverse impact on small business in the state. Using the criteria noted above, and applying them to OEHHA's decision to repeal the regulation in its entirety, OEHHA finds that if the regulation is repealed, small business will not be legally required to comply with or enforce the regulation. Further, given that the regulation was used, primarily as an affirmative defense to litigation that was filed against businesses, it is true that small business will no longer be able to derive a benefit from the regulation, nor incur a detriment from it. Instead, businesses will be free to use, or continue to use whatever test methods they chose to determine whether they are in compliance with the requirements of the Act. Any alleged increase in litigation against small business that may result from repeal of the regulation is speculative at best. Further, the statutory requirement for plaintiffs to file a certificate of merit with the Attorney General's Office (Health and Safety Code section 25249.7(d)) prior to commencing any legal action should provide adequate protection against the filing of unmeritorious actions.

Therefore, OEHHA has determined that no change to the intended action to repeal Section 12901 in its entirety is necessary based upon this comment. It should be noted that OEHHA intends to propose a new, more narrowly focused regulation at the same time that the existing regulation is repealed.

PH COMMENT #19 - Geoffrey Blake, Metals Finishing Association of So Cal: Opposes repeal, believes it could lead to regulatory uncertainty. Requests that OEHHA conduct a "small business economic analysis." (Comment received after the close of the public comment period, but is included for completeness of the administrative record.)

Response: The California Code of Regulations, Title 1, Section 4 defines the criteria to be applied by an agency when attempting to determine if a proposed regulatory action affects small business. The regulation states that:

"…For purposes of this section, an adoption or amendment affects small business if a small business…

(1) Is legally required to comply with the regulation:
(2) Is legally required to enforce the regulation;
(3) Derives a benefit from the enforcement of the regulation; or
(4) Incurs a detriment from the regulation."

The regulation goes on to provide that "If an agency determines that the regulation does not affect small business, the agency shall include in the notice of proposed action a brief explanation of the reason(s) for the agency's determination."

In this case, OEHHA initially determined that its proposed action to amend or repeal Section 12901 would not have a significant, adverse impact on small business in the state. Using the criteria noted above, and applying them to OEHHA's decision to repeal the regulation in its entirety, OEHHA finds that if the regulation is repealed, small business will not be legally required to comply with or enforce the regulation. Further, given that the regulation was used, primarily as an affirmative defense to litigation that was filed against businesses, it is true that small business will no longer be able to derive a benefit from the regulation, nor incur a detriment from it. Instead, businesses will be free to use, or continue to use whatever test methods they chose to determine whether they are in compliance with the requirements of the Act. Any alleged increase in litigation against small business that may result from repeal of the regulation is speculative at best. Further, the statutory requirement for plaintiffs to file a certificate of merit with the Attorney General's Office (Health and Safety Code section 25249.7(d)) prior to commencing any legal action should provide adequate protection against the filing of unmeritorious actions.

Therefore, OEHHA has determined that no change to the intended action to repeal Section 12901 in its entirety is necessary based upon this comment. It should be noted that OEHHA intends to propose a new, more narrowly focused regulation at the same time that the existing regulation is repealed.

PH COMMENT #20 - Brad Ward, Small Manufacturers Association of America: Opposes repeal of the regulation, wants OEHHA to conduct a small business impact analysis and include "hard data" in that analysis. (Comment received after the close of the public comment period, but is included for completeness of the administrative record.)

Response: The California Code of Regulations, Title 1, Section 4 defines the criteria to be applied by an agency when attempting to determine if a proposed regulatory action affects small business. The regulation states that:

"…For purposes of this section, an adoption or amendment affects small business if a small business…

(1) Is legally required to comply with the regulation:
(2) Is legally required to enforce the regulation;
(3) Derives a benefit from the enforcement of the regulation; or
(4) Incurs a detriment from the regulation."

The regulation goes on to provide that "If an agency determines that the regulation does not affect small business, the agency shall include in the notice of proposed action a brief explanation of the reason(s) for the agency's determination."

In this case, OEHHA initially determined that its proposed action to amend or repeal Section 12901 would not have a significant, adverse impact on small business in the state. Using the criteria noted above, and applying them to OEHHA's decision to repeal the regulation in its entirety, OEHHA

finds that if the regulation is repealed, small business will not be legally required to comply with or enforce the regulation. Further, given that the regulation was used, primarily as an affirmative defense to litigation that was filed against businesses, it is true that small business will no longer be able to derive a benefit from the regulation, nor incur a detriment from it. Instead, businesses will be free to use, or continue to use whatever test methods they chose to determine whether they are in compliance with the requirements of the Act. Any alleged increase in litigation against small business that may result from repeal of the regulation is speculative at best. Further, the statutory requirement for plaintiffs to file a certificate of merit with the Attorney General's Office (Health and Safety Code section 25249.7(d)) prior to commencing any legal action should provide adequate protection against the filing of unmeritorious actions.

Therefore, OEHHA has determined that no change to the intended action to repeal Section 12901 in its entirety is necessary based upon this comment. It should be noted that OEHHA intends to propose a new, more narrowly focused regulation at the same time that the existing regulation is repealed.

ALTERNATIVES DETERMINATION

OEHHA has determined that no alternative would be more effective in carrying out the purpose for which the repeal of the regulation is proposed or would be as effective and less burdensome to affected private persons than the proposed repeal of the regulation. Certain business representatives offered an alternative proposal, but OEHHA believes that the alternative amendments to Section 12901 would increase the complexity of the regulation and would likely not further the purposes of the Act. Moreover, OEHHA believes that the alternative would be more burdensome to the affected parties than the proposed action.

LOCAL MANDATE DETERMINATION

Pursuant to Health and Safety Code Section 25249.11(b), the provisions of Proposition 65 do not apply to local, state or federal agencies. The proposed repeal of the regulation does not impose any mandate on local agencies or school districts.