APPENDIX 1
SUMMARY AND RESPONSE TO COMMENTS RECEIVED DURING THE INITIAL NOTICE PERIOD OF FEBRUARY 18, 2005 THROUGH THE EXTENDED DATE OF APRIL 18, 2005

COMMENT NO.	COMMENTER & AFFILIATION	COMMENT	RESPONSE
C-1	John W. Stump Attorney	Referencing the Safe Drinking Water Act. When governmental entities are required to notify public of violations of the Act, the notice should include names of responsible elected representatives; the estimated cost of the error; and who will bear the cost.	• This comment does not appear to relate to the proposed regulatory action and so it is not responded to here.
C-2	George G. Verbryck Spa and Pool Chemical Manufacturers' Association	Insufficient time to review proposal. Request 60-day postponement of public hearing and comment period.	• OEHHA provided an adequate public comment period of 45 days for this proposed regulatory action. In addition, OEHHA extended the public comment period 2 weeks to allow additional comments to be provided following the hearing and is providing a 45-day public comment period for the proposed amendments to the regulation.
C-2a (and oral comment at hearing)	George G. Verbryck	• Does not respond to regulated community's needs, does not add clarity and fails to accomplish stated purpose. • OEHHA's responsibility to establish methodology, not other Federal, State, and Local agencies. • Many new chemicals may become subject to P65 regulation with advances in test methodology and ability to detect at lower limits. • OEHHA must first establish "Safe Use Levels" or "No Observable Effects Levels" for all listed chemicals. • P65 implementation and enforcement must be uniform throughout the State. In subsection (b), method of detection can be through any acceptable methodology required or sanctioned by named governmental entities. Unacceptable for businesses operating in more than	• OEHHA believes that the proposed regulation addresses all of the main issues that were identified by stakeholders during the repeal of the former regulation (Section 12901) that can be addressed in a manner that is consistent with the intent and purposes of the Act. • Nothing in Health and Safety Code section 25249.12(a) requires the lead agency to establish testing methodologies for chemicals listed under the Act. The Act expressly places the burden of proving that an exposure does not require a warning on the business causing the alleged exposure, not with the lead agency.

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C-2a (continued)	George G. Verbryck	one state location. • Proposed regulatory text fails to establish acceptable test methodology and verification that the "acceptable" test methodology is the most "sensitive." • OEHHA's Costs and Savings to State Agencies analysis are flawed. There are probable significant costs associated with establishing methodologies, detection limits, safe use levels, and no observable effect levels for all listed chemicals. • OEHHA's Adverse Impact on Small Business analysis is flawed. "Small Business" is not defined by number of employees, but by annual sales (generally defined as $50 – 100,000,000). Determining the "most sensitive test" would cost small business thousands of dollars. • "No detectable level" should be defined by the "practicable quantitative level." • Discourages monitoring. Provisions must be made for retesting false positive results. • Subsection (b) does not require uniformity in testing. No provision for technological development advances. Chemicals that are not detectable today, might be detectable in subsequent years. Represents a potentially significant burden on business to either reduce concentrations of listed chemicals not previously known to exist or retain a toxicologist to calculate exposure. • Additional time needed for regulated community and OEHHA to address above issues. SPCMA offers to meet with OEHHA and others for a "work session."	• OEHHA agrees that advances in technology will enable businesses to detect listed chemicals at lower levels. The business must still determine whether a given exposure may require a warning under the Act. The simple presence of the chemical does not automatically require that a warning be given. The proposed regulation does not affect that requirement as it only applies where the listed chemical has not been detected. • The establishment of safe harbor levels for listed chemicals is not relevant to the proposed regulation since its provisions would only apply where a chemical has not been detected. • The proposed regulation lists possible sources of methods of detection and analysis, some of which are local agencies that have limited jurisdiction. These are included because they are most likely to have required or sanctioned a particular method of detection and analysis through the issuance of a permit or other official action. The regulation requires the use of the most sensitive methodology among those authorized or required *by the agencies listed*. Nothing in the proposed regulation requires a business to conduct any testing at all. • In addition, the amended proposed regulation gives a preference to testing done under permit, even where such

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C-2a (continued)	George G. Verbryck		testing is not the most sensitive. • It is not feasible for OEHHA to develop a regulation that would establish a specific method of detection and analysis that is appropriate for every listed chemical, in every medium and every exposure, discharge or release scenario. USEPA does provide an index of its approved test methods that may be useful to regulations businesses. This is available from USEPA at the following link: http://www.epa.gov/NE/oarm/testmeth.pdf • Regulated businesses are in the best position to identify the most appropriate testing methodologies. The proposed regulation is simply providing an affirmative defense option for those businesses that voluntarily conduct testing to ensure compliance with the Act. • The commenter is correct that the costs to the State of the activities noted by the commenter are substantial. However, none of those activities are required to be performed by the proposed regulation, and therefore those costs are not discussed in the context of this regulatory action. • Similarly, no small business is required by the proposed regulation to do any testing of its products, discharges or releases. The regulation simply provides them with an incentive to do so. • The proposed regulation is intended to apply only to those situations in which the

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C-2a (continued)	George G. Verbryck		chemical in question has not been detected. On the other hand, the "practical quantitation limit" may be useful in those situations in which a listed chemical is detected. In the event the chemical is detected, other provisions of existing regulations would need to be used to determine whether a warning is required or a discharge or release is prohibited under the Act (see for example Title 22, Cal. Code of Regs., §§ 12703 and 12801). • Additional time for comments will be available following the release of the amended proposed regulation.
C-3	Joseph J. Green Collier Shannon Scott, Counsel to Leathers Industries of America	• Supports the concept of clarifying regs; however, proposed reg unnecessarily limits the scope of test methods that may be used, especially for consumer products for which no formal agency-approved test methods exists. • There are valid scientific test methods for leather goods, for determining presence and concentration of various chemicals in product; however, in many cases none of the listed agencies in subsection (b) have jurisdiction over consumer product, or if they have jurisdiction, no adopted test method for specific chemical in product. • None of the listed agencies in subsection (b) have jurisdiction over leather products. No agency has adopted test methods for evaluating chemicals in leather goods. • Proposed reg should be amended to clarify that if no agency has jurisdiction over the product, then valid scientifically established test methods may be used.	• The proposed regulation does not require businesses to conduct product testing. It simply provides businesses that do conduct testing with an opportunity to assert an affirmative defense to an enforcement action if the chemical has not been detected. • Nothing in the proposed regulation prohibits businesses from using any test methodology they deem appropriate for a given product. The regulation is intended to provide an affirmative defense for those businesses that conduct testing using a method that has been authorized or required by one of the listed agencies. If another agency should be added to those listed, OEHHA would consider such an addition.

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C-4	Donald C. Burns California Spa and Pool Industry Education Council	Insufficient time to review proposal. Request 60-day extension of public comment period.	• Additional time for comments will be available following the release of the amended proposed regulation.
C-5 (*and oral comment at hearing*)	Fred Simonelli, Ph.D. California Metals Coalition	• Proposal is flawed. OEHHA proposes "a three-step system of assessment and testing that would be an unmitigated disaster for small manufacturers in California." Proposal is vague, unspecific, conflicted, and would not be understood by most of the 10,000 companies in their coalition. • OEHHA does not fully appreciate the significant differences in regulating major manufacturers and small manufacturers – things that are possible and doable for a large manufacturer is entirely different for a small manufacturer. • When constructing regulations, they should be clear, understandable, doable, and affordable such that litigation is not the only resolution, which would be the "death knell" for small manufacturers. • Concept of safe harbors need to be refined and clarified.	• The proposed regulation does not require businesses to conduct compliance testing. It simply provides businesses that do conduct testing with an opportunity to assert an affirmative defense to an enforcement action if the chemical has not been detected. • Small businesses may choose to identify possible exposures to listed chemicals that may require a warning through other means such as their knowledge of the raw materials used to produce a product. • OEHHA believes the proposed regulation will provide a benefit to those businesses, large or small that conduct compliance testing that complies with the provisions of the regulation. • The proposed regulation does not directly address the issue of "safe harbors" so this comment is not relevant to the proposed regulatory action.
C-6 (*and oral comment at hearing*)	Peter H. Weiner Paul, Hastings, Janofsky & Walker Peter H. Weiner	• Testing need not be voluntary. Inclusion of the word "voluntary" is not relevant, testing required by law should be equally appropriate. • Subsection (a) can be interpreted to require annual testing. Creates an arbitrary cut-off and should instead incorporate the concept of the safe harbor extending back for a "reasonable time."	• The inclusion of the word "voluntary" in the title of the regulation refers to the fact that compliance testing for Proposition 65 is voluntary. This is further clarified by viewing the title of the regulation in context with subsection (e), which states that use of the affirmative defense provided by the proposed regulation is

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C-6 (continued)	Peter Weiner	• Lacks definition for "same medium" in subsection (a); however, in subsection (b) medium is described as generally including air, water, soil, and food. Recommend adding concept that it is "the medium most proximal to the discharge, release, or exposure that is to be tested." • Good faith requirement in subsection (a) is irrelevant and adds nothing to the testing requirement. • No definition for "no detectable level," should adopt a practical quantitation limit. • In subsection (b), "required or sanctioned" is not the same as a test that is mandated; as such a business cannot rely on mandatory testing results. Should be able to rely on mandatory testing. • In subsection (c), a more sensitive voluntary test required or sanctioned by an agency is irrelevant to a business conducting mandatory testing. Only when 2 agencies require a business to use different tests for the same chemical should the most sensitive method be required. Proposal appears to be a worse alternative than simply to have left Section 12901 in place. • Nothing is said about what should be done if none of the listed agencies have jurisdiction. In the absence of clarity, admissibility of scientific evidence will be governed by the California Evidence Code and case law. • In subsection (d), "any enforcement action" is ambiguous. Clause could be read as requiring person asserting affirmative defense to meet the burden of proof as described in (d) even if plaintiff has not made its prima facie case. "Does OEHHA's proposal do more than restate the defendant's burden with regard to	voluntary. • In addition, in the proposed amended regulation, the title has been changed to delete the reference to voluntary testing. • The regulation does not require anyone to conduct testing. The one-year time frame is based upon the statute of limitations for filing actions under Proposition 65. Using the term "reasonable time" would invite litigation concerning the meaning of the phrase. OEHHA determined that a specific time frame should be set and that the statute of limitations period seemed most appropriate. • Regulated businesses can still defend any enforcement action with test results or data from testing that was completed more than one year prior to the filing of the notice or complaint. They would simply need to offer that as evidence to the court under the normal rules of evidence. The proposed regulation is not intended to preclude the offering of such evidence if it is otherwise relevant and admissible. • The amendments to the proposed regulation eliminate the term "medium" and replace it with a term that is more appropriate to the issue being addresses by this regulation, (e.g. "matrix"). • The phrase "good faith" has been deleted in the amended proposed regulation. • The proposed regulation is intended to apply only to those situations in which the

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C-6 (continued)	Peter Weiner	mounting a successful affirmative defense? Does use of the words "burden of proof" shift the actual burden of proof in the case from plaintiff to defendant?" Because this is not clear, should remove provision. • "Burden of proving that in <u>all</u> instances and <u>every</u> protocol and procedure … have been followed," may cause a validly conducted test to be thrown out because of a technicality (wrong box checked or not checked on a form). Concept of "materiality" should be included. • Wording in subsection (e) suggests that proposed Section 12900(a) may limit admissibility of certain evidence for plaintiffs and defendants. Useful and appropriate to limit admissibility of evidence by plaintiff if defendant is within safe harbor limits of (a), but a defendant's rights should not be limited. • Should not be possible to establish an alleged discharge, release, or exposure solely by applying any fractional scientific inference of the listed chemical's presence. • Effectiveness of subsection (f) is somewhat limited in application, due to the additional uncertainty businesses face by failing to satisfy the safe harbor requirements of subsection (a). • Cannot in good faith abandon any testing hierarchy at all. Should be able to rely on something that has been vetted, proved effective, proved scientific, reviewed by peers.	chemical in question has not been detected. The "practical quantitation limit" may be useful in those situations in which a listed chemical is detected. In the event the chemical is detected, other provisions of existing regulations would need to be used to determine whether a warning is required or a discharge or release is prohibited under the Act. • The terms "required or sanctioned" in the proposed regulation would include test methodologies that are "mandatory" as can be seen by reference to the definition for the phrase contained in subsection (e). • The proposed regulation expressly states in subsection (e) that it does not change the existing burdens of proof for enforcement actions. Defendants always have the burden of proving the elements of their affirmative defenses; this duty is not changed by the terms of the proposed regulation. • The term "material" has been added to subsection (d) of the proposed regulation to clarify this issue. • Subsection (e) expressly states that a plaintiff or defendant may produce all admissible evidence of the existence or non-existence of a prohibited discharge, release or exposure, except where the affirmative defense established in subsection (a) is established, or where a plaintiff attempts to "prove" an exposure

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C-6 (continued)	Peter Weiner		solely on the basis of a presumption that a chemical is present at one-half the detection limit of detection for the particular method used. • OEHHA is not aware of any standard analytical presumption, other than the "one-half the limit of detection" presumption noted in the proposed regulation. • Subsection (f) is intended to clarify that the adoption of the proposed regulation should not be construed in such a way as to require anyone to conduct compliance testing. • OEHHA believes that those methods of detection and analysis that are authorized or required by the entities listed in the proposed regulation will have been adequately vetted, proved effective and scientifically peer-reviewed. Experience has shown the hierarchy approach that was adopted in former Section 12901 was confusing to courts and litigants and failed to further the purposes of the Act.
C-7	William Verick Klamath Environmental Law Center on behalf of Mateel Environmental Justice Foundation	• Might be interpreted to give more weight to defendant's "no detect" test results than those conducted by plaintiff or governmental agency. No opportunity to refute defendant's "no detect" results if identical tests conducted by plaintiff or government show detectable results. • Clarify reg to allow plaintiff or others to refute defendant's tests with the same tests conducted during the relevant time period.	• The proposed regulation is intended to provide an affirmative defense for businesses that have test results showing that the chemical in question has not been detected. The only provision of the regulation that directly applies to plaintiffs is subsection (e). The question of the admissibility of plaintiff's test results would be subject to the general rules of

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C-7 (continued)	William Verick	• Unclear what "the same medium in which the discharge, release or exposure is alleged to have occurred" means. Should be redrafted to require that defendant show that the chemical cannot be detected at the point of discharge or exposure and the presumption granted should be only as to a particular day or batch of product on which test was conducted. • "Good faith" language is not sufficient to deter defendant from testing at a convenient time, location or medium that would guarantee a no detect. • Subsection (a) should be clarified that the application is to a particular listed chemical. Suggest that, "no knowing and intentional discharge release or exposure occurs **with regard to a particular listed chemical** if the person responsible … has … conducted a test for **that** listed chemical at any time…"	evidence and procedure. • The term "medium" has been replaced in the amended proposed regulation with the term "matrix" along with a proposed definition for the term. This change is intended to clarify what is being referred to in the proposed regulation. • The additional changes to the regulation that are proposed in this comment were not adopted because they could result in a situation in which a defendant company could be required to conduct item by item, or daily testing of its products, discharges, releases and this does not seem to be a reasonable or workable requirement in every situation. • The phrase "good faith" was deleted from the proposed regulation based on another comment. The methods of detection and analysis that are identified by the agencies listed in the proposed regulation should specify requirements for frequency, location and other procedural requirements for sampling. The person who wishes to assert the affirmative defense is required by subsection (d) to show compliance with all these requirements. Additional regulatory language is therefore unnecessary. • Changes that have been made to subsections (a) and (b) of the proposed regulation should clarify that a method of detection and analysis must be applied that

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C-7 (continued)	William Verick		can detect the particular chemical in question.
C-8	Eileen M. Nottoli Allen Matkins Leck Gamble & Mallory	• Reg as written will result in greater uncertainty and more litigation. • In subsection (a), "properly" is not defined. Proposal obligates a business to conduct tests annually. Extremely burdensome and costly. • In subsection (b) businesses may rely on methods required or sanctioned by certain federal or state agencies. Difficulties: 1) in almost all settlements, new test methods are developed because there are no methods required or sanctioned by agencies. 2) some methods sanctioned by agencies are poorly described with questionable repeatability or reproducibility. 3) because reg does not identify specific testing methods, uncertainty remains as to what tests to conduct to assure compliance. 4) there may be more than one agency method, which might be potentially applicable. Unless methods correlate, may need to conduct several tests with no certainty of assurance. 5) in some cases, federal agency has test method for specific products, but private plaintiffs have not agreed that the method controls. • Subsection (c) requires "most sensitive method of detection and analysis" which effectively means businesses are constantly required to test. Even possible that methods of analysis specified in consent agreements may no longer provide assurance for future compliance. • Businesses better served if OEHHA would develop regs which identify specific methodology for various media required or sanctioned; where such methods not available, provide methods on how to determine	• OEHHA believes that proposed Section 12900 is more clear and easier to understand and apply than the previous Section 12901. • The term "properly" retains its common meaning in the proposed regulation and does not require a definition. • Subsection (b) of the proposed regulation identifies sources of methods of detection and analysis that may be used for purposes of establishing the affirmative defense allowed by subsection (a) of the proposed regulation. It does not change or abrogate the terms of any settlement. The provision of subsection (c) that requires the use of the most sensitive method of detection and analysis available among those that meet the criteria in subsection (b) should assist businesses in determining which is the appropriate method to use in the event more than one is available. • In addition, the amended proposed regulation allows businesses to use a test required under permit, even where such testing is not the most sensitive. • The proposed regulation does not require businesses to conduct compliance testing. It simply provides businesses that do conduct testing with an opportunity to assert an affirmative defense to an enforcement action if the chemical has not

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C-8 (continued)	Eileen M. Nottoli	exposures that may occur from touching a product; how to evaluate possible exposures from sources other than manufacturing plants, and the analytical methods to use.	been detected. • OEHHA may develop additional regulations that address other technical issues related to test methodologies or procedures but has not proposed such a regulatory action at this time.
C-9	Jeffrey B. Marguilies Fulbright & Jaworski	• Support the comments submitted by Eileen Nottoli, & Peter Weiner. • Attached comments he submitted in response to the repeal of Section 12901. [Do not repeal Section 12901, adopt technical guidance for regulated community.] • Section 12900 should address scientific standards that parties must meet in enforcement actions and that OEHHA is empowered to adopt.	• OEHHA may develop additional regulations that address other technical issues related to test methodologies or procedures but has not proposed such a regulatory action at this time.
C-10	Kristin Power Grocery Manufacturers of America	• As drafted, contains features making its use impracticable as affirmative defense for businesses and contravenes P65's statutory placement of the burden of proof on a plaintiff. • Reg imposes a far greater and more impractical burden on potential defendants than did former Section 12901. • Where more than one method of detection and analysis exists, business must use the most sensitive method – believes this to be ambiguous and impracticable. • A "state of the art within the industry" standard would more likely achieve stated purposes of reg. If defendants allowed to rely on state of the art methodology used within the industry for quality control purposes, greater likelihood that test was identifiable and probably already conducted annually. • Reg states an affirmative defense exists if a defendant "has properly and in good faith conducted a test for the	• OEHHA believes that the proposed regulation addresses all of the issues that were identified by stakeholders during the repeal of the former regulation (Section 12901) that are consistent with the intent and purposes of the Act. • Nothing in Health and Safety Code section 25249.12(a) requires the lead agency to establish testing methodologies for chemicals listed under the Act. In fact, the Act expressly places the burden of proving that an exposure does not require a warning on the business causing the exposure, not on the lead agency. • The proposed regulation does not require businesses to conduct compliance testing. It simply provides businesses that do

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C-10 (continued)	Kristin Power	listed chemical at any time within the year prior to the service or filing of a notice or complaint concerning the alleged discharge, release, or exposure…" Effectively requires defendants to conduct annual testing. Unless the test method in one already used for quality control, an annual requirement for an academically-oriented most sensitive test method is too heavy a burden to expect businesses to take on just to qualify for a safe harbor that would likely be challenged by plaintiffs. • In response to a comment received concerning the repeal of Section 12901, OEHHA responded that based in part on an assumption that businesses were conducting routine testing under various regulatory programs, they should be allowed to use those results to determine compliance with P65. Still remains the case. Requiring a business to annually determine the most sensitive testing method, applying it, and conducting special tests does not serve a useful purpose. • Reg should apply to plaintiffs as well as defendants. To be consistent with the statute, plaintiffs and defendants need to be bound by the methods of analysis they seek to legitimize. Under proposed reg, plaintiff bound only by the "any admissible evidence" constraint, and can hire an expert to give a declaration that exposure to a listed chemical is more likely than not to occur and avoid summary judgment despite the absence of any test data that shows a detectable amount of the chemical exists.	conduct testing with an opportunity to assert an affirmative defense to an enforcement action if the chemical has not been detected. • OEHHA believes that those methods of detection and analysis that are authorized or required by the entities listed in the proposed regulation will have been adequately vetted, proved effective and will have been scientifically peer-reviewed. • The provision of subsection (c) that requires the use of the most sensitive method of detection and analysis available among those that meet the criteria in subsection (b) should assist businesses in determining which is the appropriate method to use in the event more than one is available. • In addition, the amended proposed regulation allows businesses to use a test required under permit, even where such testing is not the most sensitive. • The proposed regulation lists possible sources of methods of detection and analysis, some of which are local agencies that have limited jurisdiction. These are included because they are most likely to have required or sanctioned a particular method of detection and analysis through the issuance of a permit or other official action. The regulation requires the use of the most sensitive methodology among

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C-10 (continued)	Kristin Power		those authorized or required by the agencies listed. Nothing in the proposed regulation requires a business to conduct any testing at all. • The proposed regulation is intended to provide an affirmative defense for businesses that have test results showing that the chemical in question has not been detected. The only provision of the regulation that directly applies to plaintiffs is subsection (e). The question of the admissibility of plaintiff's test results would be subject to the general rules of evidence and procedure. • The proposed regulation expressly states in subsection (e) that it does not change the existing burdens of proof for enforcement actions. Defendants always have the burden of proving the elements of their affirmative defenses.
C-11 (and oral comment at hearing by Charles White)	Curt Fujii Allied Waste John McNamara CRRC Southern District Pat Sullivan SCS Engineers Sean Edgar CRRC Northern District Don Gambelin Norcal Waste Systems Charles A. White	• MDL vs. PQL – suggest language be added that clearly defines "method of detection," "no detectable level," and "measuring the presence and concentration" of a constituent be specifically defined to mean at a level above the analytical methodology PQL. Only data reported above the PQL should be used for making a regulatory decision and that not detecting a constituent above the PQL demonstrates compliance with P65. • False Positives and an Opportunity for Verification Re-sampling. Would like OEHHA confirm that the verification re-sampling procedures in Title 27 regulations may be relied upon as part of the proposed P65 rule.	• The proposed regulation is intended to apply only to those situations in which the chemical in question has not been detected. The "practical quantitation limit" may be useful in those situations in which a listed chemical is detected. However, in the event the chemical is detected, other provisions of existing regulations would need to be used to determine whether a warning is required or a discharge or release is prohibited under the Act. • Generally, laboratory QA/QC procedures

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	Waste Management/West	• Range of Applicable Test Methods – suggest change in subsection (c) in term from "sensitive" in most sensitive test method, to "reliable" and clearly indicate that PQL procedures are to be used. Strongly requests that test methods contained in permits or regulations by agencies having regulatory jurisdiction over that activity are the default test methods applicable under the proposed regulations. • Interference from Background Concentrations – Strongly request provisions be added to allow for consideration of background concentrations when determining whether a facility has a "detectable" release including applying an appropriate statistical method to determine whether background has been exceeded for a constituent.	will effectively address the issues of false positive test results, background concentrations of chemicals and any need for re-sampling. These issues are outside the scope of the proposed regulation since it is intended to apply to situations in which the final reported test results show that the chemical in question has not been detected. The issues noted should be resolved by the laboratory conducting the testing, prior to the issuance of final test results to the business. • Other provisions of the law are more applicable to questions of liability for background levels of listed chemicals (see for example Sections 12401, 12501(a)(2)).
C-12	Mike Wang WSPA Commissioned California EnSIGHT (Michael Easter) to review proposed reg	• Creates Additional Uncertainty Rather Than Resolving It – Proposes a 3-step approach: Requires businesses to familiarize themselves with a list of 10 entities specified in subsection (a); Identify every "method of detection and analysis that may be required or sanctioned" by each of the 10 specified entities; Identify and "use the most sensitive method of detection and analysis available that meets all criteria in subsection (b)." This is an onerous task. Need to define "required," "sanctioned," "other official action of the agency," and "most sensitive." • Will Lead to Greater Costs – the fact that OEHHA may have difficulty in estimating reasonably foreseeable and certain increased costs is not an acceptable basis to conclude such costs will not have a significant statewide adverse economic impact affecting business. Suggest the projected cost for determining the	• The proposed regulation does not require businesses to conduct compliance testing. It simply provides businesses that do conduct testing with an opportunity to assert an affirmative defense to an enforcement action if the chemical has not been detected. • The proposed regulation lists possible sources of methods of detection and analysis, some of which are local agencies that have limited jurisdiction. These are included because they are most likely to have required or sanctioned a particular method of detection and analysis through the issuance of a permit or other official action. The regulation requires the use of the most sensitive methodology among

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C-12 (continued)	Mike Wang	appropriate method and analyzing of samples is estimated at $240.3 million to $2.4 billion. • Proposal to Mitigate Negative Impacts of the Proposed Regulation – Recommend that analytical results developed as part of its on-going environmental and workplace health and safety compliance programs be deemed an irrebuttable presumption that businesses can rely upon for purposes of defending P65 claims. Propose change to subsection (a): "For purposes of both Section 25249.5 and 25249.6 of the Act, no knowing and intentional discharge, release of exposure occurs … using a method or detection and analysis for that chemical in that medium as part of on-going environmental or workplace health and safety compliance programs or described in the following subsection, and that the results of each and every such reliable test conducted any time during that year show that no detectable level of the chemical in question was present. If no detectable chemical in question is present in samples of media collected as part of on-going environmental or workplace health and safety compliance programs, there is an irrebuttable presumption that the chemical in question is not detectable in the media and no discharge, release or exposure has occurred for purposes of the Act."	those authorized or required by the agencies listed. Nothing in the proposed regulation requires a business to conduct any testing at all. • A description of what is meant by the terms "required or sanctioned" is included in the proposed regulation in subsection (g). The other terms should be understood in their common usage meanings and do not require special definitions in this regulation. • Given that businesses are not required to take advantage of the affirmative defense provided by the proposed regulation, OEHHA does not believe the cost impact of the proposed regulation on businesses is significant. • OEHHA has not incorporated the suggested revisions to subsection (a) because the inclusion of the phrase "as part of an on-going environmental or workplace health and safety compliance program" would add uncertainty to the types of methods of detection and analysis that are acceptable in order to establish the affirmative defense. The authorized methods may be part of such a program, but OEHHA believes that the provisions of subsections (b) and (c) better describe the types of methods of detection and analysis that should be used for compliance testing than a reference to such a "program." • OEHHA does not believe that an

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C-12 (continued)	Mike Wang		irrebuttable presumption is consistent with the purposes of the act and instead has chosen to propose a regulation that would provide an affirmative defense.
C-13	Andrew Bopp Society of Glass and Ceramic Decorators	• OEHHA already fails to provide adequate guidance regarding warning thresholds, and these revisions do nothing to change that. • Unless OEHHA were to issue express guidance on warning thresholds, there is no way for any potential defendant to comply with any degree of certainty. • Glass and ceramic decorators cannot simple rely on their own due diligence to determine how exposure to lead should be determined from non-food contact surfaces of glass/ceramic ware or other products. • Without a clear method of warning, P65 should be considered void for vagueness. • Due to this lack of certainty, P65 warning threshold determinations will remain vague and open to multiple interpretations and opinions and over warning is a likely outcome. • During the past 4 years, about 100 private plaintiff P65 notices have been filed related to lead on the outside surfaces of glass or ceramic ware leading to a variety of settlements. The differences in settlements are a direct result of the absence of any guidance from OEHHA regarding warning thresholds and exposure routes.	• The purpose of 12900 is not to clarify warning requirements, but to allow businesses that do conduct testing with an opportunity to assert an affirmative defense to an enforcement action if the chemical has not been detected. • Nothing in Health and Safety Code section 25249.12(a) requires the lead agency to establish testing methodologies for chemicals listed under the Act. In fact, the Act expressly places the burden of proving that an exposure does not require a warning on the business causing the exposure, not on the lead agency. • The establishment of safe harbor levels for listed chemicals is not relevant to the proposed regulation since its provisions would only apply where a chemical has not been detected. • The concern with alleged “over warning” and specific enforcement actions may be best addressed through other regulatory actions, however it is not directly relevant to the proposed regulation.
C-14	Lisa Halko Livingston & Mattesich	• Reg creates several ambiguities which will cause confusion among those trying to comply and will encourage frivolous lawsuits. • Section 12900 appears to allow a plaintiff to use any	• OEHHA believes that proposed Section 12900 is more clear and easier to understand and apply than the previous Section 12901.

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C-14 (continued)	Lisa Halko	test more sensitive than the required method of detection – no matter how expensive, novel, or unusual – to show that a consumer product contains a "detectable" level of a listed chemical. Businesses cannot rely on their required methods of detection so long as any more sensitive test exists. Section 12900 does not close the gap created by the repeal of Section 12901. • In subsection (a), "no detectable level" is ambiguous. Use of the term "limit of detection" in subsection (e) might suggest that the term "detectable level" in subsection (a) has a different meaning from "limit of detection." Suggest revision in subsection (a) that "no test conducted during that year showed the chemical present at or above that test's limit of quantification." • Subsection (b) states that an agency may "require or sanction" a method by "issuance of a permit, regulation, guideline, or other official action…that specifies or requires the use of a particular method." This sweeping language creates a universe of possible tests that includes any test demanded or required from any business by any local agency. Combined with subsection (c)'s demand for the "most sensitive" test means a business has little ability to rely on a standard, required test so long as any more sensitive test exists. • "Guidelines" may be informal communications or part of confidential settlements, but if any of theses informal communications allows a business to use an unusually sensitive method, it can arguably be required of other businesses. • Suggest as a separate subsection, "Where more than one method of detection and analysis exists that meets the criteria specified in subsection (b), the person in the	• The proposed regulation is intended to provide an affirmative defense for businesses that have test results showing that the chemical in question has not been detected. The only provision of the regulation that directly applies to plaintiffs is subsection (e). The question of the admissibility of plaintiff's test results would be subject to the general rules of evidence and procedure. OEHHA believes that proposed Section 12900 is more clear and easier to understand and apply than the previous Section 12901. • The term "no detectable level" has been modified to "not detected." If a chemical is not detected by a particular method of detection and analysis, it necessarily follows that if the chemical is present, it is below the limit of detection for that method. This is why subsection (c) of the proposed regulation requires the use of the most sensitive test method if more than one is available that meets the other criteria of the proposed regulation. • The phrase "with jurisdiction over the product or activity . . ." in subsection (b), limits the methods of detection and analysis that can be used for purposes of the affirmative defense offered by under this proposed regulation to those that have been required or sanctioned by one of the agencies with jurisdiction over the relevant product or activity. This should

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C-14 (continued)	Lisa Halko	course of doing business may rely upon any method of detection and analysis required of that person by any local, state, or federal law or agency. If more than one method of detection and analysis is required of that person in the course of doing business, the person must use the most sensitive method required."	significantly reduce the number of different test methodologies that might be available to a business seeking to take advantage of the affirmative defense. • In addition, the amended proposed regulation allows businesses to use a test required under permit, even where such testing is not the most sensitive. • The term "guidelines" is used in the proposed regulation to allow businesses to use test methodologies such as those promulgated in official guidance documents issued by USEPA that have not been formally adopted as regulations by USEPA, but nonetheless are commonly used by industry. Informal communications or court settlements fall outside the scope of this proposed regulation. • Subsection (c) is intended to limit the "most sensitive test" requirement to those methods of detection and analysis that meet the other criteria in the regulation. This would not include every possible test methodology that might be in use everywhere in the world. OEHHA believes this limitation is more appropriate than the language offered in this comment.
C-15 (*and oral comment at hearing*)	Gene Livingston Livingston & Mattesich on behalf of the Cosmetic, Toiletry	• Raises Questions of Validity & Interpretation – Former Section 12901 set out hierarchy of tests to determine whether plaintiffs met their burden of proof that exposure occurred. With repeal of 12901 and proposed	• OEHHA believes that proposed Section 12900 is more clear and easier to understand and apply than the previous Section 12901. The proposed regulation is

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	and Fragrance Association	adoption of 12900, potential conflict with the statutory allocation of plaintiff's burden of proof. Could be interpreted that statutory burden of proof does not apply to plaintiff, but shifts to defendant to "disprove." Question the legality of that shift. Provision that would be most helpful to defendants would be if there was some mechanism plaintiffs had to meet to establish discharge or exposure, then defendant can counter or attack position. • Further ambiguities; "what is a 'medium,' what is the effect of an invalid test, what tests are to be used for products not subject to a required or sanctioned test, what is the most sensitive test, and what is the real applicability of Section 12900 to pending cases?" Does 'no detectable level' mean there was no discharge, release or exposure; or does it mean only that the discharge, release or exposure was not knowing and intentional – significant distinction. • Reg refers to medium as "air, water, soil or food" which may address discharges and some environmental exposures, but has no applicability to consumer products except for food. Is testing of consumer products to be performed under circumstances similar to the use and exposure scenarios of the various products? Lack of address will certainly lead to substantial litigation. *Cosmetic products are regulated by FDA, but FDA does not require product testing to determine the presence of P65 chemicals. Is one to assume that Section 12900 does not apply to that situation or those products?* • Subsection (a) requires each and every test to show no detectable level and subsection (d), requires businesses to "establish that, in all instances, every protocol and	intended to provide an affirmative defense for businesses that have test results showing that the chemical in question has not been detected. The only provision of the regulation that directly applies to plaintiffs is subsection (e). • The proposed regulation expressly states in subsection (e) that it does not change the existing burdens of proof for enforcement actions. Defendants always have the burden of proving the elements of their affirmative defenses. • The term "medium" has been replaced in the amended proposed regulation with the term "matrix" along with a proposed definition for the term. This change is intended to clarify what is being referred to in the proposed regulation. • Generally, laboratory QA/QC procedures will effectively address the issues of false positive test results, background concentrations of chemicals and any need for re-sampling. These issues are outside the scope of the proposed regulation since it is intended to apply to situations in which the reported test results show that the chemical in question has not been detected. The issues noted should be resolved by the laboratory conducting the testing, prior to the issuance of final test results to the business. • Nothing in the proposed regulation prohibits businesses from using any test

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C-15 (continued)	Gene Livingston	procedure" has been followed. Together these provisions raise a question about the impact of a no detectable level test result that was not conducted totally in accordance with every protocol and procedure. Does this one test negate the "safe harbor" feature of this section? • Does not specify what tests to use for products not subject to a required or sanctioned test. Assume that subsection (e) leaves the method of detection to the usual rules of evidence; but ISOR asserts the testing methodologies in 12900 take precedence over, for example, Kelly Frye evidentiary standards. – will result in litigation. • Where a federal agency does require or sanction a test, but it was not conducted within a year prior to notice, would this cause a defendant to lose its right to question an exposure using usual rules of evidence? • The "most sensitive method" provision invites plaintiffs to challenge whatever test method used by defendant, i.e., provide an expert declaration that another test has more sensitive characteristics. A "no exposure" case should be resolvable on a motion for summary judgment. • Related to the "most sensitive method," how to deal with false positives and how to incorporate reliability into test results. Most sensitive may not be the most reliable test. • Subsection (g) provides that it is applicable to any enforcement action pending at the time the reg is adopted. The effect of this is to potentially eliminate a defense that a business established under Section 12901 or the usual rules of evidence. Seems to be directed to benefit plaintiffs, not businesses. Reg	methodology they deem appropriate for a given product. The regulation is intended to provide an affirmative defense for those businesses that conduct testing using a method that has been authorized or required by one of the listed agencies. If another agency should be added to those listed, OEHHA would consider such an addition. • Subsection (e) expressly states that a plaintiff or defendant may produce all admissible evidence of the existence or non-existence of a prohibited discharge, release or exposure, except where the affirmative defense established in subsection (a) is established, or where a plaintiff attempts to "prove" an exposure solely on the basis of a presumption that a chemical is present at one-half the detection limit of the particular method used. • OEHHA believes the "most sensitive method" provision is consistent with the intent and purposes of the Act and encourages businesses to use the best available test methodology that has been required or sanctioned by one of the entities listed in the proposed regulation. • In addition, the amended proposed regulation allows businesses to use a test required under permit, even where such testing is not the most sensitive. • Generally, laboratory QA/QC procedures

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C-15 (continued)	Gene Livingston	should clearly allow the introduction of evidence created after the service of P65 notice or after filing of a complaint. Such evidence is as valid as earlier testing. • Expense and aggravation involved in conducting annual tests is a deterrent to the goal of encouraging businesses to test in advance. No credible rationale exists for limiting affirmative defense unless testing is conducted annually.	will effectively address the issues of false positive test results, background concentrations of chemicals and any need for re-sampling. These issues are outside the scope of the proposed regulation since it is intended to apply to situations in which the reported test results show that the chemical in question has not been detected. The issues noted should be resolved by the laboratory conducting the testing, prior to the issuance of final test results to the business. • OEHHA believes that those methods of detection and analysis that are authorized or required by the entities listed in the proposed regulation will have been adequately vetted, proved effective and scientifically peer-reviewed. • The provision that would have allowed for application of the proposed regulation to any enforcement action pending at the time the regulation is adopted has been deleted based on this and other comments. • Subsection (e) expressly states that a plaintiff or defendant may produce all admissible evidence of the existence or non-existence of a prohibited discharge, release or exposure, except where the affirmative defense established in subsection (a) is established, or where a plaintiff attempts to “prove” an exposure solely on the basis of a presumption that a chemical is present at one-half the

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C-15 (continued)	Gene Livingston		detection limit of the particular method used. In order to take advantage of this affirmative defense, tests must have been conducted within the year prior to the filing of a Prop 65 notice or complaint. • The regulation does not require anyone to conduct testing. The one-year time frame is based upon the statute of limitations for filing actions under Proposition 65. Using the term "reasonable time" would invite litigation concerning the meaning of that phrase.
C-16 (*and oral comment at hearing*)	Michael J. Van Zandt McQuaid, Bedford & Van Zandt on behalf of plumbing importers and distributors	• Section 12900 creates greater ambiguity and uncertainty and will be constitutionally invalid. • Section 12900 is less focused because it refuses to suggest what methodology would be appropriate. Provides no guidance at all. Undermines the Act by guaranteeing that regulated industries will not be able to reasonably comply because there is no possible way to anticipate the appropriate standard of compliance. • If a business is the target of a P65 suit before a test already in use is deemed acceptable under Section 12900, the test must be evaluated by court under California law concerning admission of scientific evidence. This is worse than the Section 12901 tiered hierarchy -- cannot be sure that test designed to ensure compliance will be deemed acceptable. • To test every product or even a representative sample every year would be prohibitively expensive. If the product has not been modified in any way, the prior test result is still the most current, the fact that the results are over one-year old is irrelevant. • Subsection (a) requires a "non detectable level" and	• OEHHA believes that proposed Section 12900 is more clear and easier to understand and apply than the previous Section 12901. • Nothing in Health and Safety Code section 25249.12(a) requires the lead agency to establish testing methodologies for chemicals listed under the Act. In fact, the Act expressly places the burden of proving that an exposure does not require a warning with the business causing the exposure, not with the lead agency. The proposed regulation does not require businesses to conduct compliance testing. It simply provides businesses that do conduct testing with an opportunity to assert an affirmative defense to an enforcement action if the chemical has not been detected. • Experience has shown the hierarchy approach that was adopted in former

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C-16 (continued)	Michael J. Van Zandt	subsection (c) requires the "most sensitive test," taken to an extreme any test could be devised that detected the presence of a listed chemical. The problem with the standard is that no concessions are made for testing a product under conditions of normal use. • Non-detect standard is absurd. Placing defendants in the position of proving an absolute negative is far beyond any burden allowed under due process. • "Most sensitive method of detection and analysis" likely poses significant barriers for litigants. If original test results fail to detect the chemical, a business may rely on the results as evidence of compliance. However, if a plaintiff tests the same products using a later developed more sensitive test and detects the chemical, does the more sensitive test result trump the original? The fact that a chemical is detected at any minuscule level has no relation to its potential to cause an exposure. If one uses the most sensitive test method at the time the test is conducted, then one can take advantage of the safe harbor. In the case of some chemicals where OEHHA has set exposure limits in reg, if the chemical is detected below the exposure level, then they should also be able to use affirmative defense. • Subsection (g) provides for retroactive application of Section 12900 which will violate the due process rights of defendants who conformed their behavior to the reg in effect at the time. Lack of notice poses an enforcement issue since defendants who conformed to Section 12901 could not have had any intent to violate the statute or reg in effect in 2005 or thereafter. • Makes no accounting for a compliance period. Reg is proposed to take effect immediately. Compliance is	Section 12901 was confusing to courts and litigants and failed to further the purposes of the Act. OEHHA believes that proposed Section 12900 is more clear and easier to understand and apply than the previous Section 12901. • The regulation does not require anyone to conduct testing. The one-year time frame is based upon the statute of limitations for filing actions under Proposition 65. Using the term "reasonable time" would invite litigation concerning the meaning of the phrase. • For purposes of raising this affirmative defense, tests are limited to those meeting the requirements of subsections (b) and (c). Presumably, these test methodologies would require that the product be tested under normal use conditions. • OEHHA believes that those methods of detection and analysis that are authorized or required by the entities listed in the proposed regulation will have been adequately vetted, proved effective and scientifically peer-reviewed. • Proposed Section12900 does not require defendants to prove an absolute negative. The person who wishes to take advantage of the affirmative defense provided by the proposed regulation must simply provide test results that are obtained through a method of detection and analysis that complies with the requirement of the

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C-16 (continued)	Michael J. Van Zandt	expected overnight, an impossible timeframe. Must allow for a reasonable period for industries to bring their products into compliance with new requirements. *To apply reg to current cases that are being litigated is a real due process problem for the defense. It would complicate a significant number of cases that are underway right now.* • Suggest that products should be tested in the context in which they are actually used, such that an exposure is likely to occur. Only way to achieve certainty, finality and reliability from test results. A performance test should be designated for specific type of product, activity or process such as set forth in Code of Federal Regulations by USEPA. Essential that test data is analyzed at normal detection limits for specific substance for specific type of lab equipment used at time test conducted. • In subsection (b) refers to "guideline," which is not subject to the same level of scrutiny that a truly promulgated regulatory test would be. Regulated industries would not know about it without doing significant investigation. • Sometimes a chemical, for example, dioxin, may not actually be detected by a test methodology, but its presence is actually calculated as a theoretical part of an analysis of an effluent indicating that at some point between the process and discharge, dioxin was theoretically present. Enforcement actions have been taken by EPA on this basis. • The more we can get the word out about this requirement about doing business in CA, the better off we'll be, and to make it as straightforward as possible for industry to comply would be helpful and would	regulation and shows that the chemical in question was not detected. • If a business conducts more than one test during the year prior to the filing of the 60-day notice or complaint, each test would have to show a non-detect result in order for the business to take advantage of the affirmative defense offered by this proposed regulation. If the chemical were detected, then other provision of the existing regulations would need to be used to determine if an exposure requires a warning. • The proposed regulation does not require businesses to conduct compliance testing. It simply provides businesses that do conduct testing with an opportunity to assert an affirmative defense to an enforcement action if the chemical has not been detected. • Some entities, such as USEPA may adopt test methodologies in a "guidance" format that are still subject to public review and comment. OEHHA has retained this portion of the proposed regulation to allow businesses to use methods of detection and analysis that are promulgated in the form of "guidance". • The issues raised concerning enforcement actions for dioxin are beyond the scope of the proposed regulation. OEHHA may adopt more technical regulations in the future that deal more specifically with this

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C-16 (continued)	Michael J. Van Zandt	help promote businesses to come to CA and contribute to the economy.	type of scientific issue. • The proposed regulation does not require businesses to conduct compliance testing. It simply provides businesses that do conduct testing with an opportunity to assert an affirmative defense to an enforcement action if the chemical has not been detected.
C-17	Carol R. Brophy Nossaman, Guthner, Knox & Elliott on behalf of the Fishing Sports Coalition	• The combined effect of repealing Section 12901 and proposing Section 12900 does not meet OEHHA's stated purpose and urge OEHHA to reconsider. Instead, it eliminates all guidance concerning the standards that apply to plaintiffs seeking to prosecute an alleged violation and provides an incomplete, unhelpful reg concerning pre-litigation testing for industry. • Do not proceed with "voluntary testing" unless and until it addresses standards determining "level of detection" applicable to both plaintiffs and defendants. • Reg as drafted places potential defendants in a worse position than if they did not attempt to evaluate exposures at all. Many, if not most, exposures do not have state or federally approved test methods that apply. Also appears reg requires annual testing. • Reg goes far, far beyond the statutory requirements, which recognizes that warnings are not required where testing in accordance with Sections 12700 and 12800 shows that, level of exposure is below respective NSRL or MADL. Reg is inappropriate and abusive.	• OEHHA believes that proposed Section 12900 is more clear and easier to understand and apply than the previous Section 12901. OEHHA believes that the proposed regulation addresses all of the issues that were identified by stakeholders during the repeal of the former regulation (Section 12901) that are consistent with the intent and purposes of the Act. • The proposed regulation does not require businesses to conduct compliance testing. It simply provides businesses that do conduct testing with an opportunity to assert an affirmative defense to an enforcement action if the chemical has not been detected. • Nothing in the proposed regulation prohibits businesses from using any test methodology they deem appropriate for a given product. The regulation is intended to provide an affirmative defense for those businesses that conduct testing using a method that has been authorized or required by one of the listed agencies. If another agency should be added to those

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C-17 (continued)	Carol R. Brophy		listed, OEHHA would consider such an addition. The regulation does not require anyone to conduct testing. • Nothing in the proposed regulation limits the other provisions of the existing regulations dealing with NSRLs or MADLs. It is a narrow provision offering an affirmative defense in the event the chemical has not been detected at all. In the event the chemical is detected, the business would need to refer to these and other provisions of the regulations to determine whether a warning is required or not.
C-18 (*oral comment only at hearing*)	David Herbert Severn Trent Laboratories	• Agrees with the discussions about PQLs versus MDLs as far as getting relevant data. • Proposed text does not mention who performs testing methodologies. Lab performing required testing should be certified to perform that method by either the State (DHS) or an approved national accreditation program. To get quality data, need to establish a baseline for competency of a lab.	• The proposed regulation is intended to apply only to those situations in which the chemical in question has not been detected. The "practical quantitation limit" may be useful in those situations in which a listed chemical is detected. However, in the event the chemical is detected, other provisions of existing regulations would need to be used to determine whether a warning is required or a discharge or release is prohibited under the Act. • The proposed regulation has been modified in subsection (a) to require the laboratory conducting the testing to be certified by the State of California.