ADDENDUM TO
FINAL STATEMENT OF REASONS
TITLE 22, CALIFORNIA CODE OF REGULATIONS

SECTION 12900

USE OF SPECIFIED METHODS OF DETECTION AND ANALYSIS AS A DEFENSE TO AN ENFORCEMENT ACTION

SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986

At the request of the Office of Administrative Law (OAL), OEHHA is providing clarification as to the technical, theoretical, and/or empirical studies, reports or documents relied upon in proposing the adoption of these regulations. The predecessor regulation, Title 22, Cal. Code of Regs., section 12901 was repealed effective April 2, 2005. That regulation attempted to provide regulatory guidance regarding methods of detection for chemicals listed under Proposition 65. OEHHA reviewed the comments offered as part of the regulatory action repealing Section 12901 as it developed the rulemaking file for the subject regulation for general background and historical context for the new proposed Section 12900. The comments did not materially effect the adoption of Section 12901, however, and OEHHA did not expressly rely on them in this rulemaking. Therefore the comments were not included in the rulemaking file for this action.

In addition, OAL requested additions to the responses to comments, these additional are included the revised Appendix 1 attached.

REVISED 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-10	Kristin Power Grocery Manufacturers of America	• A "state of the art within the industry" standard would more likely achieve stated purposes of reg. If defendants were 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. (previously on page 11, Appendix 1) • 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. (previously on page 12, Appendix 1)	• The term, "state of the art" is ambiguous and could lead to additional litigation concerning what is meant by that term. It also creates a "moving target" because what is "state of the art" today could change tomorrow. "State of the art" technologies may not be readily available to all businesses. • Quality control testing may differ between businesses. Inclusion of a reference to quality control testing would add uncertainty to the types of methods of detection and analysis that are acceptable in order to establish the affirmative defense. OEHHA believes that the provisions of subsections (b) and (c) better describe the type of methods of detection and analysis that should be used for compliance testing because the methods will have been adequately vetted, proved effective and scientifically peer-reviewed. If the quality control testing employed by a business is required under permit, the business may use it even if such testing is not the most sensitive. Annual testing is not required by this regulation. The regulation does not require anyone to conduct testing. The one-year time frame

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			for testing under this regulation is based upon the statute of limitations for filing actions under Proposition 65.
C-12	Mike Wang WSPA	• 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. (previously on page 14, Appendix 1)	• Amendments to the proposed regulation allow businesses to use a method of detection and analysis required under permit even if such test is not the most sensitive. By providing this exception, OEHHA believes it has addressed this commenter's concern about onerous requirements. Further, under subsection (b), not all of the listed entities will have jurisdiction over the product or business activity of concern. Only those entities with jurisdiction would apply. Therefore, a business would not be required to survey all test methodologies required or sanctioned by all the listed entities in order to determine which to use. 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. The regulation does not require anyone to conduct testing.

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C-15	Gene Livingston Livingston & Mattesich on behalf of the Cosmetic, Toiletry and Fragrance Association	• A "no exposure" case should be resolvable on a motion for summary judgment. (previously on page 15, Appendix 1)	• By adopting Section 12900 OEHHA intends to provide businesses with the ability to assert a defense to an enforcement action if the business meets the criteria set forth in the regulation. OEHHA does not intend to create an irrebuttable presumption through the adoption of this regulation. Businesses will have to provide proof of each element of the defense if they chose to assert it. Plaintiffs will have the opportunity to prove that a requirement of the defense has not been met. It may be possible to assert the defense as part of a motion for summary judgment under C.C.P. section 437c. However, it will then be up to the court to decide the evidentiary and procedural issues in a given case. By adopting this regulation, OEHHA does not intend to alter the general rules of pleading or proof in California Law in any respect.