California Environmental Protection Agency

Air Resources Board

Final Statement of Reasons for Rulemaking,
Including Summary of Comments and Agency Responses

PUBLIC HEARING TO CONSIDER THE ADOPTION OF A NEW TEST METHOD FOR THE DETERMINATION OF VOLATILE ORGANIC COMPOUNDS (VOC) IN CONSUMER PRODUCTS,

AND

THE ADOPTION OF AMENDMENTS TO THE TEST METHOD SECTIONS OF THE CALIFORNIA REGULATIONS FOR REDUCING VOC EMISSIONS FROM ANTIPERSPIRANTS AND DEODORANTS, CONSUMER PRODUCTS, AND AEROSOL COATING PRODUCTS

Public Hearing Date: November 21, 1996
Agenda Item No: 96-9-4

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California Environmental Protection Agency
AIR RESOURCES BOARD

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I. Introduction

A. General Information. At a public hearing held November 21, 1996, the Air Resources Board (the “ARB” or "Board") considered the adoption of a regulation establishing a new Test Method 310 for the Determination of Volatile Organic Compounds (VOC) in Consumer Products (Method 310). The Board also considered the adoption of related amendments to the test method sections of the Regulation for Reducing VOC Emissions from Antiperspirants and Deodorants, the Regulation for Reducing VOC Emissions from Consumer Products, and the Regulation for Reducing VOC Emissions from Aerosol Coating Products (sections 94506, 94515, and 94526, Title 17, California Code of Regulations (CCR)). Collectively, this Final Statement of Reasons (FSOR) will refer to these three regulations as the “California Consumer Products Regulations”.

At the hearing the Board adopted Resolution 96-57, in which the Board approved Method 310 and the related amendments to the test methods sections of the California Consumer Products Regulations. The approved amendments included modifications to the originally proposed language of the test methods sections and Method 310. The “Notice of Public Availability of Modified Text and Availability of Additional Documents and Information”, together with a copy of the full text of the modified Method 310 and test methods sections, with the modifications clearly indicated, was mailed on March 17, 1997 to each of the individuals described in subsections (a)(1) through (a)(4) of section 44, Title 1, CCR. By this action the modified Method 310 and test methods sections were made available to the public for a 15-day comment period from March 17, 1997 to April 1, 1997 pursuant to Government Code section 11346.8.

A Staff Report: Initial Statement of Reasons (ISOR) was prepared for the proposed rulemaking. The ISOR was released to the public on October 4, 1996 and is incorporated herein by reference. This FSOR updates the ISOR by identifying and explaining the modifications that were made to the original proposal. The FSOR also summarizes the written and oral comments received during the rulemaking process, and contains the ARB's responses to those comments.

As defined in Government Code Section 11346.5(a)(6), the Board has determined that this regulatory action will not create costs or savings to any State agency, or affect federal funding to the State. The Board has also determined that the regulation will not create costs or impose a mandate upon any local agency or school district, whether or not it is reimbursable by the State pursuant to Part 7 (commencing with Section 17500), Division 4, Title 2 of the Government Code; or affect other non-discretionary savings to local agencies. In preparing the regulatory proposal, the ARB staff considered the potential economic impacts on California business enterprises and individuals. A detailed discussion of these impacts is included in the ISOR, Chapter III.

The Board has further determined that no alternative was presented or considered which would be more effective in carrying out the purpose for which the regulatory action was proposed, or would be as effective and less burdensome to affected private persons, than the action taken by the Board.

B. Incorporation of Method 310 by Reference. As originally drafted, this regulatory action proposed that Method 310 be incorporated by reference in the test method sections of the California Consumer Products Regulations (sections 94506, 94515, and 94526, Title 17, CCR), instead of including the entire text of Method 310 in the CCR. This proposal was consistent with the longstanding and accepted ARB practice in which all referenced test methods have been incorporated in by reference in these sections. The practice reflects the fact that test methods are typically long and complex documents that are of limited interest to most of the regulated community.

During the 45-day comment period, however, staff became aware that a slight modification of this longstanding practice was necessary to respond to industry concerns. Although the majority of Method 310's text was technical and of limited interest to the regulated community, there were two sections in Method 310 that were of great interest. These were sections 3.5 and 3.6, which describe the process for the Initial and Final Determination of VOC content under Method 310. This process requires staff to request formulation data from a manufacturer, and perform additional testing as necessary, before making a final determination of the product's VOC content. Important language is contained in section 3.6.3, which states:

> 3.6.3 If there exists a discrepancy that cannot be resolved between the results of Method 310 and the supplied formulation data, then the results of Method 310 shall take precedence over the supplied formulation data. The results of Method 310 shall then determine if the product is in compliance with the applicable VOC standards, and may be used to establish a violation of ARB regulations.

This language caused considerable concern to the consumer products industry (see the discussion of industry comments on this issue in Part III of this FSOR), especially since similar language was being added to section 94515, Title 17, CCR by the separate consumer products rulemaking approved by the Board at the hearing (see the discussion of this separate rulemaking below in Part I (C) of this FSOR). To resolve these concerns, industry representatives requested that the language that appears in sections 3.5 and 3.6 of Method 310 be also placed in the test methods sections of the California Consumer Products Regulations. Industry strongly believed that this would help consumer products manufacturers better understand the testing procedures, and would clarify that the process specified in sections 3.5 and 3.6 (i.e., contacting a manufacturer and requesting formulation data) is an integral part of Method 310 which must be followed before the results of Method 310 would take precedence over a manufacturer's formulation data that might differ from these results. ARB staff agreed and included these proposed revisions in the 15-day notice mailed on March 17, 1997.

It should also be noted that the text of Method 310 itself incorporates by reference a number of test methods that are used as components of Method 310. There are 14 of these incorporated test methods, which are listed in section 2.0 of Method 310. These test methods are incorporated by reference because it would be cumbersome and impractical to reproduce them in the text of Method 310. The test methods are complicated, lengthy documents, and the interested audience for these documents is small (primarily laboratories who formulate and test consumer products). The incorporated documents were made available in the context of the subject rulemaking in the manner specified in Government Code section 11346.2, and will continue to be made available by the ARB upon request. The documents are also standard test methods that are readily available from commonly known sources, and are widely used by industry, government agencies, and scientists. For example, the incorporated American Society for Testing and Materials (ASTM) test methods are contained in the "Annual Book of ASTM Standards", which is published annually by ASTM and is available in public and college libraries. The United States Environmental Protection Agency (U.S. EPA) and National Institute for Occupational Safety and Health (NIOSH) test methods are similarly available in libraries and from these agencies. Many of the U.S. EPA test methods are also published in the Code of Federal Regulations.

C. The Two Separate Consumer Products Rulemakings Considered on November 21, 1996. It should be noted that two separate rulemaking actions relating to consumer products were considered by the Board at the November 21, 1996 hearing. The rulemaking action addressed in this FSOR (i.e., the adoption of Method 310 and the related amendments to the regulatory test methods sections) was the first consumer products item considered at the hearing. The second, separately-noticed item made a number of amendments to the Regulation for Reducing VOC Emissions from Consumer Products (Title 17, CCR sections 94507-94517), and the Regulation for Reducing VOC Emissions from Aerosol Coating Products (Title 17, CCR, sections 94520-94528). This second item was submitted to the Office or Administrative Law for approval on the same day as the first item. To avoid confusion, it may be helpful to consider both items together--particularly since there is one CCR section (section 94515(a), Title 17, CCR) to which amendments were made by both the first and second rulemaking actions.

II. Modifications Made to the Original Proposal

In response to comments received during the 45-day comment period, the following modifications were made to the originally proposed language in Method 310 and the test methods sections of the California Consumer Products Regulations.

The test method sections of the California Consumer Products Regulations were modified by placing in the regulations the same language that appears in Sections 3.5 and 3.6 of Method 310. The description and rationale for this modification is described above in Part I (B) of this FSOR.

The text of Method 310 was modified to clarify that the current version of Method 310 does not apply to the determination of Low Vapor Pressure (LVP) compounds in products. Two references to LVP test methods were deleted in order to be consistent with this modification. In addition, section 6.0 (Method Precision and Accuracy) was modified to specify that the 95 percent confidence interval for Method 310 is 3.00 percent by weight, instead of 2.00 percent. This modification more accurately reflects the results of the consumer products round-robin testing program to determine the interlaboratory precision and accuracy of Method 310. (Documents relating to this round-robin were added to the rulemaking record, and made available for public comment, by the 15-day notice mailed on March 17, 1997). Finally, several other minor changes were made to Method 310 to improve clarity and readability.

III. Summary of Comments and Agency Responses

During the 45-day period before the November 21, 1997 hearing, the Board received six written comment letters on the proposed regulatory action. In addition, three individuals presented oral comments at the November 21, 1996 hearing. During the 15-day comment period, the Board received only one comment letter.

A list of the individuals who commented is set forth below, including the date and form of all comments that were timely filed. Following the list is a summary of each objection or recommendation made regarding the proposal, together with an explanation of the action taken to accommodate the objection or recommendation, or the reasons for making no change.

As discussed previously in this FSOR, two separate regulatory actions relating to consumer products were considered by the Board at the November 21, 1996 hearing. The comment letter from the Chemical Specialties Manufacturers Association (listed below) includes comments on both the regulatory action discussed in this FSOR (i.e., the adoption of Method 310 and the related amendments to the regulatory test methods sections), as well as comments on the separate consumer products regulatory action that was also considered by the Board at the November 21, 1996 hearing. This FSOR addresses only the comments relating to Method 310 and the test method sections. The comments related to the separate consumer products rulemaking are addressed in a separate FSOR for that rulemaking.

<u>List of Commenters Submitting Comments During the 45-day Comment Period</u>

Betty-Jane Kirwan
Attorney
Latham and Watkins, representing Exxon Chemical Company
Written Testimony: October 22, 1996 and November 20, 1996

Michael E. Thelen
Manager, Regulatory Affairs
Dow Corning Corporation
Written Testimony: October 25, 1996

Wayne L. Sorensen
Engineering Scientist
Condea Vista Company (Condea Vista)
Written Testimony: November 4 and 19, 1996

Ralph Engel
President
Chemical Specialties Manufacturers Association (CSMA)
Written Testimony: November 21, 1996

Laurie Nelson
Chemical Specialities Manufacturers (CSMA)
Oral Testimony: November 21, 1996

Robin Gentz
Clorox Corporation
Oral Testimony: November 21, 1996

Michele Stephens
Dial Corporation
Oral Testimony: November 21, 1996

List of Commenters Submitting Comments During the 15-day Comment Period

Wayne L. Sorensen
Engineering Scientist
Condea Vista Chemical
Written Testimony: March 31, 1997

A. Comments Received During the 45- Day Comment Period

1. Comment: We are in support of the need for most of the revisions to the existing regulations being proposed by CARB staff. The final problem, however, is one that is of upmost importance to our industry. It concerns the conditions under which results from Method 310 may be used to demonstrate that product formulation data submitted to CARB are inaccurate. We are urging CARB to make certain small but important further modifications to

the regulatory language related to Method 310, or to defer adoption of Method 310 until such time as it can be fully validated for use on the consumer products regulated by the existing regulations. (CSMA-Engel)

Agency Response: CSMA's written comment letter proposed a number of modifications to both the language of Method 310 and to section 94515,Title 17, CCR. These proposed modifications are individually discussed below in the responses to Comments No. 2 through 17. The response to Comment No. 7 specifically discusses CSMA's concern with "the conditions under which results from Method 310 may be used to demonstrate that product formulation data submitted to CARB are inaccurate." To address CSMA's concerns, section 3.6.2 of Method 310 was modified to specify that the Executive Officer will request a product manufacturer or responsible party to supply information to explain any discrepancy between Method 310 and a manufacturer's supplied formulation data. The test method sections of the California Consumer Products Regulations were also modified by placing in the regulations the same language that appears in Sections 3.5 and 3.6 of Method 310. Finally, Resolution 96-57 specified that the Executive Officer would provide periodic reports to the Board regarding the implementation and performance of Method 310. As a result of these changes, CSMA's representative Laurie Nelson testified at the Board hearing that, with these revisions, CSMA now supported the adoption of Method 310. CSMA's representative further testified that the revisions had resolved all of the concerns expressed in CSMA's written comment letter. (see Comment No. 27 and page 150 of the Board hearing transcript).

2. Comment: **Section 94515 Test Methods**: CSMA strongly objects to section 94515(b)(3), Title 17, CCR, which states: "if product records appear to demonstrate compliance with the VOC limits, but these records are contradicted by product testing performed using CARB Method 310, the results of CARB Method 310 shall take precedence over the product records and may be used to establish a violation of the requirements of this article." We also object to the similar language that appears in section 3.6.3 of Method 310. This language would appear to allow any result obtained using Method 310, whether valid or not, to take precedence over the formulation data supplied by the manufacturer, even if that data were perfectly valid in demonstrating that the consumer product was manufactured with a formula that was in compliance with the applicable VOC limit. This does not represent a justifiable use of Method 310. The "... shall take precedence..." language in these sections should be deleted. (CSMA-Engel)

Agency Response: It is not appropriate to modify the language as suggested by the commenter. The fundamental purpose of a regulatory test method is to provide a way for an agency to independently determine if regulatory standards have been complied with. Test methods are used for this purpose in hundreds of regulations adopted by the ARB, the U.S. EPA, and many other governmental agencies. The ARB must have a way to make such independent compliance determinations in order to adequately enforce the consumer products regulation. Regarding the formulation data supplied by a manufacturer, it is possible that such data may be inaccurate for some reason, such as a clerical error in entering the data, or a production error in which too much VOC was accidentally added to a particular batch of product. The only way to independently confirm whether the formulation data is valid for a particular product unit is to physically test the product. Method 310 was developed for this purpose.

In addition to the commenter's broad philosophical concern with how Method 310 may be used, the commenter also questions whether Method 310 is an accurate way to determine VOC content for consumer products. Method 310 is designed to test more than 28 product categories and thousands of individual consumer product formulations. Although the ARB staff has successfully used Method 310 to test a wide variety of product categories and formulations, it is of course impossible to verify Method 310 on every single formulation that may be manufactured. To insure that Method 310 yields accurate results, the method itself includes a process in which the ARB Executive Officer first determines a product's initial VOC content by testing. If the initial product testing indicates that a violation of the applicable standard may have occurred, the ARB Executive Officer must then request the product manufacturer to submit formulation data. If the submitted formulation data indicates compliance with the standard, the Executive Officer will conduct further testing to verify the formulation data. No enforcement action will be taken if the Executive Officer is able to verify formulation data showing that the product meets the standard. If the Executive Officer is unable to verify the data, however, he or she will ask the manufacturer for an explanation of the discrepancy. If the discrepancy still exists and cannot be resolved, it is only then that the Executive Officer will relay on the test results for a final determination of a product's VOC content. We believe that this process allows considerable input from the affected party, provides a mechanism to resolve discrepancies, and is a fair and equitable approach to enforce the regulations. Resolution 96-57 also requires the Executive Officer to report to the Board within six months (and annually thereafter for three years) on the implementation of Method 310. This will provide a further opportunity to identify and resolve any problems that may occur in the future with Method 310.

3. Comment: **Method 310**: The purpose of the test method is to provide an estimate of the contents of the consumer product container that inherently either meets the standard or does not based on the actual contents of the container, not the response of those contents in a given test procedure. (CSMA-Engel)

Agency Response: We do not agree with CSMA's characterization of the purpose of the test method. As discussed in more detail in the response to the previous comment, the purpose of the test method is to specify a procedure that the Executive Officer can use to independently determine if a consumer product complies with the applicable standard.

4. Comment: **Section 94515 Test Method:** Method 310 has not been sufficiently validated regarding either precision or accuracy to justify that it automatically "shall take precedence over product records." (CSMA-Engel)

Agency Response: Since the consumer product regulations cover thousands of individual products, it is virtually impossible to test every single product formulation in order to validate the method. However, ARB staff has conducted testing on a wide range of products, and we believe that Method 310 is an accurate, effective way to measure VOC content. To provide additional reassurance of the method's accuracy, a process was included in Method 310 to allow a manufacturer with the opportunity to present information showing that the product complies with the regulations. Additional discussion of these issues is contained in the response to Comment No. 2.

5. Comment: **Section 94515 Test Method:** Several of our members' companies assisted in an inter-laboratory "round robin" testing program to begin validation of the precision and accuracy of Method 310. Even with this simple study problems with both precision (ability to produce the same result on the same product) and accuracy (the ability to predict the true value) was noted. In all cases this rudimentary evaluation shows that Method 310 is not sufficiently reliable to be given automatic precedence over formulation data. (CSMA-Engel)

Agency Response: As mentioned by the commenter, the ARB conducted inter-laboratory "round robin" testing to establish the precision and accuracy of Method 310. ARB staff recognizes the limitations of the "round robin" testing and the difficulties in testing every consumer product formulation. However, the round-robin samples were formulated as much as possible to represent real worlds products, such as hair sprays and air fresheners. Staff went so far as to include a low vapor pressure compound, glycerine, resulting in a slight deviation from the calculated VOC. Pre-round-robin analysis at the ARB laboratory of VOC content with known concentrations indicated a precision and accuracy of about 3% of the expected result over the range of 5-80% VOC. In the interlaboratory round-robin analysis, prepared as a representative of the VOC content expected, the overall standard deviation for the final percent VOC was 1.27. Therefore, the 95% confidence level (defined as ± 1.96 x standard deviation) is expected to be less that ± 2.5% VOC. This was rounded to 3.0% to obtain the variability of the method.

6. Comment: **Section 94515 Test Method:** There have been no inter-laboratory studies whatsoever to evaluate the precision and accuracy of Method 310 using any commercial products subject to these regulations. This total lack of validation cannot justify its results taking precedence over the actual contents of the consumer product as manufactured. (CSMA-Engel)

Agency Response: As mentioned in the response to the previous comment, inter-laboratory "round robin" testing was used to establish the precision and accuracy of Method 310. Interlaboratory precision and accuracy determinations using actual commercial products were not made for Method 310 because of the difficulty in obtaining commercial products where the ingredients are known accurately. Most commercial products are produced by combining various ingredients where the constituent amounts are known generally, but not to a high degree of accuracy. In addition, as explained in the Response to Comment No. 2, Method 310 test results will only take precedence over formulation data if the Executive Officer is unable to verify the formulation data, and the manufacturer is not able to provide a satisfactory explanation for the discrepancy between the formulation data and test results.

7. Comment: **Section 94515 Test Method:** CSMA does not believe that Method 310 is sufficiently flexible for skilled ARB analysts to validate compliance or demonstrate a noncompliance of a product. We therefore support the adoption of Method 310 only if section 94515(b)(3) is modified to read: "If the Executive Officer is able to demonstrate the inaccuracy of the supplied formulation data, then the Executive Officer will take appropriate enforcement action." This language would require a reasonable burden of proof before CARB could act against manufacturers in situations where the results of Method 310 differ from the supplied

formulation data. (CSMA-Engel)

Agency Response: We believe Method 310 is sufficiently flexible for ARB analysts to determine compliance or non-compliance with the regulatory standards. In addition, we believe that the commenter's proposed language is extremely inappropriate for use in a test method such as Method 310. The proposed language would require the Executive Officer to demonstrate the inaccuracy of a manufacturer's formulation data before Method 310 could be used to determine whether a product has violated the regulatory standards. The language would place an almost insurmountable burden of proof on the ARB to affirmatively prove that information supplied by a manufacturer is incorrect. Such a demonstration would be nearly impossible to make in most situations. After all, in most situations the only practical way to demonstrate the inaccuracy of formulation data for a particular product is to physically test the product (i.e., use Method 310). Accepting the proposed language would make Method 310 virtually worthless as a way to make independent compliance determinations, and would severely hamper enforcement of the California Consumer Products Regulations.

8. Comment: **Section 94515 Test Method**: The accusation that a company supplied inaccurate data is serious and should be subject to reasonable burdens of proof. Invalidated results of an invalidated test method must not automatically be used to bring enforcement action. If CARB is unwilling at this time to adopt this language and establish a fair and reasonable burden of proof for this finding, then we urge the Board to defer approval of Method 310 until such time as it can be validated for all currently regulated products and forms. (CSMA-Engel)

Agency Response: As discuss in the response to Comment No. 2, Method 310 contains a detailed process designed to insure that supplied formulation data is fully and carefully evaluated before the results of Method 310 would be used as a basis for an enforcement action. In the event that the ARB ultimately determines that supplied formulation data is not accurate for a particular product sample, this determination by itself would not be an "accusation" against a company. Formulation data might be inaccurate in a particular case for many reasons, such as simple clerical, labeling, or production errors. Finally, the response to the previous comment explains why it is not appropriate for a "burden of proof" to be imposed on the ARB in Method 310.

9. Comment: **Method 310 Section 1.0**: Method 310 currently has no mechanism to provide estimates of the exempted LVP-VOC content of a consumer product, or any standard procedure to confirm the LVP-VOC status of an ingredient for use in consumer products, and is incapable of measuring the fragrance content that is subject to the 2 percent fragrance exemption. We ask that Section 1.3 state that "Method 310 does not apply to the determination of the composition or concentration of fragrance components or LVP-VOCs in products." CARB staff has agreed to this modification. (CSMA-Engel)

Agency Response: As requested by the commenter, section 1.3 of Method 310 was modified to explicitly state that the method does not apply to the determination of the composition or concentration of fragrance components or LVP-VOC compounds in products. However, Method 310 may be modified in a future regulatory action to include test methods applicable to these compounds.

10. Comment: **Method 310, Section 2.0**: We request that two procedures potentially relevant to estimating LVP-VOC content and status, 2.5 (ASTM D2887-93) and 2.7 (ASTM E1131-86) be deleted, and included with the isoteniscope procedure in our project next year to develop and evaluate LVP-VOC methods for inclusion in Method 310. CARB has agreed to delete these methods. (CSMA-Engel)

Agency Response: As requested by the commenter, references to ASTM D2887-93 and ASTM E1131-86 were deleted from the list of test procedures referenced in Method 310, section 2.0.

11. Comment: **Method 310, Section 3.0**: We request that the language of Section 3.5.1 be changed from "may perform testing to confirm" to "shall perform additional testing to evaluate." CARB staff has agreed to this change. (CSMA-Engel)

Agency Response: ARB staff did not agree to change. The suggested change is inappropriate because the Executive Officer should have the discretion to decide on a case-by-case if additional testing is necessary for the initial determination of a product's VOC content, which is what section 3.5 is concerned with. There are instances where the measured levels in a product are so high or so low that additional testing to confirm the initial results is not necessary. It would be a waste of resources to require such testing in every instance. Furthermore, the additional procedures required by sections 3.5.2 to 3.6.3 provide ample safeguards to insure that the final determination of a product's VOC content is accurate.

12. Comment: **Method 310, Section 3.0**: Subsection 3.6.2 of Method 310 should be modified to read: "If the Executive Officer is unable to verify the accuracy of the supplied formulation data, then the Executive Officer will request the product manufacturer or responsible party to supply information to explain the discrepancy." (CSMA-Engel)

Agency Response: Section 3.6.2 was modified as requested by the commenter. We agree that the proposed language more clearly describes the action that should be taken by the Executive Officer at this point in Method 310. The language clarifies that the manufacturer will be given a chance to explain a discrepancy before enforcement action will be taken.

13. Comment: **Method 310, Section 5.0**: We believe that it should be made clear that 2 percent precision estimate is absolute percent, not relative percent. (CSMA-Engel)

Agency Response: The 3.0 percent is an absolute percent of the VOC content. This is the accepted meaning of the term "percent" when used in this context. A revision to the language of section 5.0 is not necessary.

14. Comment: **Method 310, Section 5.0**: Section 5.0 of Method 310 should note that the estimate of the method's precision and accuracy could increase as additional procedures, such as the LVP-VOCs methods, are added and assessed for precision. We urge that a statement regarding method accuracy be added to note that the existence of either fragrance material or LVP-VOCs in the product will affect the accuracy of the method. (CSMA-Engel)

Agency Response: It is not necessary to add this statement. Addressing precision for

LVP-VOC is premature at this point since Method 310 does not apply to the determination of LVP-VOC. If a future rulemaking action adds a procedure for measuring LVP-VOCs and this results in a change in the overall precision or accuracy of Method 310, the change will be addressed in the rulemaking action which adds this procedure. This is also true for any other future additions to Method 310 that may be made.

15. Comment: **Method 310 Section 5.0**: We also requested that the significance of the precision estimate be explained in terms of CARB procedures in determining noncompliance. (CSMA-Engel)

Agency Response: The Board's policy on method precision is explained on Page 4 of the ISOR. As explained there, the Board will take enforcement action based on test results only if the results are outside of the range of the method's precision. For example, the ARB would not use the test results to take enforcement action in a situation where the standard is 60%, the measured VOC content is 63%, and the method precision is ±3.0%. However the ARB would take appropriate enforcement action if the measured VOC content is 64%. The ARB has consistently followed this general enforcement policy for many years in enforcing ARB regulations. We also believe that it is not appropriate to articulate this enforcement policy within an ARB test method, since test methods deal primarily with technical testing procedures. None of the numerous other test methods adopted by the ARB has ever included the information requested by the commenter, and we do not believe that it is appropriate to do so in Method 310.

16. Comment: **Method 310, Section 5.0**: We ask that an outline of Compliance Division procedures be included as an appendix to this method, or separately to show the course of events after a determination is made in Method 310 that "the Executive Officer will take appropriate enforcement action" in Section 3.5.3 and 3.6.2, or in handling failures to provide requested data in Section 3.5.4. (CSMA-Engel)

Agency Response: We believe the process described in Sections 3.5 and 3.6 is quite detailed in describing the steps that will be taken by the Executive Officer in using Method 310 to establish a violation of the California Consumer Products Regulations. Regarding the specific Method 310 sections cited by the commenter, section 3.6.2 was modified as requested by the commenter. For sections 3.5.3 and 3.5.4, however, we do not believe that additional modifications are appropriate. The basic purpose of Method 310 is to establish whether or not a violation of the regulatory standards has occurred. Once it has been established that a violation has occurred, the exact sequence of enforcement actions that may be taken is a case-by-case decision that depends on many factors, such as the magnitude of the violation, the length of time over which it has occurred, the conduct and intent of the parties involved, etc. Including any additional specificity about the ARB's possible enforcement actions is inappropriate within a test method because it would unreasonably interfere with the agency's enforcement discretion.

17. Comment: **Use of ASTM D-2887 in Method 310**: We concur with CARB that dropping both ASTM D-2887(GC/FID) and the isoteniscope vapor pressure test from Method 310 is appropriate at this time to reduce confusion in the understanding of these regulations. (Condea Vista-Sorensen (11/19/96))

Agency Response: As mentioned in the response to Comment No. 10, references to these two test methods have been deleted.

18. Comment: **Method 310 Confidence Limits**: We believe there is an error in the calculation of Method 310 confidence limits. We also believe that CARB should give some consideration to raising the confidence limits from the current level of 95 percent. At the current confidence level, there is on average, one analysis out of twenty when a compliant product (at the legal VOC limit for that product) will be flagged as being in non-compliance with the requirements. Given the possibility of large penalties, the cost of product recalls, and the legal costs involved, there is sufficient justification for raising these confidence limits. (Condea Vista-Sorensen (11/19/96))

Agency Response: We have reviewed our calculation methodology and found that the originally proposed confidence interval of ± 2.00 percent is incorrect. The confidence interval should be ± 3.00 percent, and section 5.0 of Method 310 has been revised accordingly. The commenter is also requesting that the 95% confidence level be raised to some higher level. The 95% confidence level is currently used in the enforcement of other ARB programs, such as the Cleaner Burning Gasoline program. The 95% confidence level was selected to be consistent with the ARB's long-accepted practice of balancing the need to minimize the variability of the method to achieve an effective enforcement program, while providing manufacturers with reasonable manufacturing tolerances. Raising the confidence level would increase the method variability to a level where more noncomplying products would be incorrectly deemed to be compliant, and would reduce the incentive for manufacturers to implement reasonable quality control procedures to ensure that products are meeting the VOC limits. Finally, raising the confidence level is not appropriate because it would encourage the sale of products with true VOC levels above the regulatory limits, thereby reducing the air quality benefits of the California Consumer Products Regulations.

19. Comment: **Incorporating Product Efficacy with Reactivity Data**: I recommend that product efficacy be considered when looking at reactivity values. Product efficacy affects the use or dose level of the product. If two applications are necessary for a low-VOC product to provide the same effect as one of a higher VOC product, the ozone-forming potential may be the same. In this case the extra costs for reformulation and enforcement testing do not provide any benefit to the consumer. (Condea Vista-Sorensen (11/19/96))

Agency Response: Issues related to product efficacy and reactivity have been extensively discussed in the past rulemakings which adopted the VOC regulatory standards in the California Consumer Products Regulations. These issues are not relevant to this present rulemaking action, since Method 310 is a test method designed to measure compliance with the VOC regulatory standards that have already been adopted. It is beyond the scope of this rulemaking to further address the air quality benefits and rationale for these regulatory standards.

20. Comment: **Acceptability of Outside Laboratory Results**: We believe Method 310 could be used by a business to ensure its products are in compliance, but we are not sure whether CARB would recognize Method 310 results obtained by outside labs or in-house laboratories since the tests are standard ASTM, EPA, and NIOSH methods. (Condea Vista-

Sorensen (11/19/97))

Agency Response: Results or data from outside or in-house laboratories would be acceptable, assuming that the Executive Officer is satisfied that these laboratories have correctly followed the procedures specified in Method 310. If ARB staff used Method 310 to test a product sample, and an outside laboratory tested a similar sample and obtained very different results, ARB staff would make every reasonable effort to understand why different results were obtained. If the Executive Officer is confident that Method 310 was properly followed by ARB staff, of course, the Executive Officer would ultimately rely on ARB testing results rather than the results from an outside laboratory which could not be independently confirmed.

21. Comment: **Regulatory Costs**: While Method 310 is seen by CARB as an enforcement tool, we believe that a prudent business would view Method 310 as a quality control tool and would use Method 310 to ensure that its products were in compliance. The business costs of using Method 310 were not considered in the economic impact analysis that CARB performed for the regulation. (Condea Vista-Sorensen (11/19/97))

Agency Response: The economic impacts of Method 310 are discussed on pages 9 and 10 of the IS0R. This analysis points out that manufacturers are already required to comply with the VOC regulatory standards, which will not be changed by the adoption of Method 310, and that this regulatory action will impose no additional requirements on any person to do any act or refrain from doing any act. Therefore, no additional costs will be imposed on the regulated community. It is of course true that individual businesses may voluntarily choose to use Method 310 as a component of whatever program they currently use to insure that their products comply with the applicable regulatory standards. For example, a manufacturer may currently use an in-house proprietary test method as a quality control and compliance tool. A manufacturer may choose to replace the currently used method with Method 310, or may choose to run some tests using Method 310 to determine how the results from the current method correlate with Method 310 results. None of these actions is required by this regulatory action, and therefore no costs are imposed. In actual fact, many manufacturers may choose not to use Method 310 and to instead rely on their formulation procedures to insure that the correct amount of VOC is present in their products. Even for those manufacturers who do choose to use Method 310, it is unlikely that this choice would result in any significant additional expense.

22. Comment: **Method 310 Section 5. Method Precision and Accuracy**: We believe that the statistical calculations using the results of the round robin were done incorrectly, producing confidence levels that are too narrow for Method 310. My calculations of the confidence limits indicates that the correct number should be ±2.40. Should CARB choose to be conservative by doubling the confidence interval range, the precision of the test should actually be twice the 2.40 value or 4.8%. (Condea-Vista-Sorensen (11/04/97))

Agency Response: As explained in the response to Comment 18, Method 310 was modified to specify a confidence interval of ± 3.00 percent. We believe that this confidence interval provides an ample “margin of safety” for VOC determinations. We do not believe that it is necessary or appropriate to have a higher confidence interval of ± 4.8 percent. A

confidence interval of ± 4.8 percent would make it to difficult to enforce the VOC standards for many product categories and would compromise the air quality benefits of the California Consumer Products Regulations.

23. Comment: **Use of ASTM D2887 in Method 310**: Exxon Chemical is concerned that adoption of Method 310 would result in confusion to Exxon Chemical's customers and expose them and Exxon Chemical to enforcement for violation of a CARB regulation. Exxon Chemical would not be able to use the isoteniscope method or its initial boiling point-vapor pressure method to show that its product qualifies as an LVP material. This is because the proposed amendments to section 94515, Title 17, CCR, mean that Exxon Chemical's test procedures can no longer be used. We do not believe that this result was intended by ARB staff in proposing Method 310. Under the circumstances, we suggest two options: (1) withdraw from the Board's agenda adoption of any method to certify LVP-VOC, namely ASTM D2887, until the isoteniscope method is included in Method 310, or (2) add the following language to the end of Section 94515:

> "Notwithstanding the above, a manufacturer of solvents used in consumer products may determine compliance with the requirements of this article using the isoteniscope procedure or other generally accepted procedure for determining vapor pressure until Method 310 is revised to include an isoteniscope procedure."

(Latham and Watkins-Kirwan (10/22/97))

Agency Response: As mentioned previously in the response to Comment No. 10, Method 310 was modified by deleting ASTM D2887 and ASTM E-11341-86 (which are used to test for LVP compounds) from the list of test methods referenced in Method 310. Method 310 was also modified to specifically state that it does not apply to the determination of LVP compounds in products. These modifications fully address the issue raised by the commenter. The language proposed by the commenter is therefore unnecessary.

24: Comment: **Use of ASTM D2887 in Method 310**: Betty-Jane Kirwan of Latham and Watkins sent a letter thanking ARB staff for their prompt response in revising Method 310 to clarify that it does not apply to the determination of LVP compounds in products, and that therefore Method 310 does not preclude Exxon Chemical from using its own method to qualify solvents for the LVP exemption until the ARB adopts a test procedure for determining LVP compounds. (Latham and Watkins-Kirwan (11/20/97))

Agency Response: Comment Noted.

25. Comment: **Method 310: Section 2.0**: ASTM D859, a calorimetric analysis for total Silica, is not suitable for determining volatile methylsiloxanes (VMS) content in antiperspirants, consumer products, and aerosol coatings. This calorimetric method will not distinguish between volatile and non-volatile methylsiloxanes, thereby creating the potential for an inaccurate measure of the VMS content in the test material. Gas chromatography is the preferred method to determine VMS content in antiperspirants, consumer products, and aerosol coatings. Dow Corning suggests that the Bay Area Air Quality Management District

(BAAQMD) Method 43 be used for determining VMS content. (Dow Corning Corporation-Thelen)

Agency Response: The reason for incorporating ASTM D859 in Method 310 is that a general method for determining silicone is needed in the event manufacturers wish to replace partial hydrocarbon solvents with polymethylsiloxane-200 mixtures. The commenter is correct that gas chromatography is an appropriate method to quantify individual VMS compounds. It is also possible that VMS may not be detected during the initial determination of VOC content under Method 310. This type of situation is one reason why Method 310 specifies that, if the initial VOC content determination indicates that a product does not meet the applicable VOC standards, then the Executive Officer will request product formulation data. If the formulation data indicates that the product contains VMS, Method 310 allows the Executive Officer to use test methods such as BAAQMD Method 43 or gas chromatography to verify the presence and quantity of VMS.

26. Comment: **Regulations and Method 310**: Our written statements express some concerns related to Method 310 that have since been resolved. CSMA now supports the revisions to Method 310. The additional modifications proposed at the public hearing and status report will allow the performance of Method 310 and the effectiveness of the procedures be monitored and addressed if problems occur. (CSMA-Nelson)

Agency Response: Comment Noted.

27. Comment: **Regulations and Method 310**: Dial supports the adoption of Method 310, with staff's suggested modifications. My original testimony regarding Method 310 was prepared prior to the ARB's latest modifications. Our main concern with Method 310 was that additional validation is necessary before it can be used as the sole enforcement tool. The modifications suggested by staff incorporate steps for manufacturers to submit formulation data and to discuss the discrepancies between Method 310 results and formulation data. With these modifications, Dial can support the method. We strongly urge the ARB to continue validation of these procedures using representative consumer product formulations. We hope that, if warranted, further modifications will be made to the Method as additional validation is completed. (Dial-Stephens)

Agency Response: The ARB staff is conducting an ongoing program to insure that Method 310 is providing valid data, and has committed to provide periodic reports to the Board regarding the implementation and performance of Method 310. If future information indicates that Method 310 should be modified, appropriate modifications will be proposed in a future regulatory action. As mentioned by the representative from Dial Corporation, Dial now supports Method 310 with the modifications proposed at the Board hearing. The following two comments summarize Dial's earlier testimony that was prepared before Dial decided to support the modified regulations.

28. Comment: Method 310 has not been adequately validated for consumer products. The round-robin conducted by the ARB was very limited, and the results do not demonstrate the validity of Method 310. More complex formulas will yield higher errors than the simple formulas tested in the round-robin, and Method 310 has not been tested with aerosols.

Further evaluation is necessary to determine the precision and accuracy of Method 310. The adoption of Method 310 should be postponed until it has been adequately validated. Adequate validation would require that all product forms and categories subject to present and future regulations should be validated prior to use of these procedures. (Dial-Stephens)

Agency Response: Although the Interlaboratory round-robin testing was somewhat limited, during the development of Method 310 ARB staff conducted hundreds of tests on a wide variety of consumer product formulations, including aerosol formulations. We are confident that Method 310 will yield valid results when the procedures are correctly followed. The issues raised by Dial in this comment are discussed in more detail in the responses to Comments No. 2, 4, 5, and 6.

29. Comment: Without adequate validation of Method 310 to insure the procedure will properly identify VOC content in a typical consumer product, it is inappropriate to allow the results of Method 310 to take precedence over manufacturing and formulation records, as provided in section 3.6.4 of Method 310. Section 3.6.4 should be deleted, and section 3.6.2 should be revised to read: "If the Executive Officer is able to demonstrate the inaccuracy of supplied formulation data, then the Executive Officer will take appropriate enforcement action. (Dial-Stephens)

Agency Response: The issues raised in this comment are discussed in the response to Comment No. 7.

30. Comment: **Regulations and Method 310**: Clorox supports the adoption of Method 310. We have submitted written comments for the public record, which were prepared prior to the modifications presented by CARB staff today. Chlorox encourages the Board to perform additional validation testing and offers assistance with testing efforts. (Clorox-Gentz)

Agency Response: As discussed in the response to Comment No. 27 , ARB staff has an ongoing testing program to ensure the validity of Method 310. As stated by their representative, Clorox now supports Method 310 with the modifications proposed at the Board hearing. The following comment summarizes Clorox's earlier testimony that was prepared before Clorox decided to support the modified regulations.

31. Comment: Clorox requests that the ARB defer adoption of Method 310 until such time as further validation of the test method's precision and accuracy can be made. The round-robin conducted by the ARB was very limited, and the results do not adequately demonstrate the validity of Method 310. Only two of the six tests comprising Method 310 have been validated, and testing was conducted on simple, lab-prepared products that are not representative of the diversity of the products in the marketplace. In addition, a method error of two percent may not apply to all products, particularly low-VOC products. For a number of technical reasons, further validation is needed to ensure that the two percent error calculated for Method 310 is applicable to all products. (Clorox-Gentz)

Agency Response: The issues raised in this comment are discussed in more detail in the responses to Comments No. 2, 4, 5, 6, and 28.

B. Comments Received During the 15-Day Comment Period

32. Comment: Section 5 .0 of Method 310 states in part "... the 95 percent confidence level for Method 310 is ±3.00 percent by weight ..." I believe that this is a misleading statement for the following two reasons: (1) It should be explicitly stated in the method that the confidence interval was calculated based on the average of two measurements or replicates of the same sample. Currently the phrasing would imply that by doing the test once, the result would be accurate to within three weight percentage units when in fact the method must be done twice and averaged to get the precision required. (2) The confidence interval is not 3 percent but ±3.00 percent. The statement in the method seems to imply that the entire interval is three percentage units or a 1.5 percent range on either side of the method value. I feel a more accurate and less confusing statement would be similar to the following "...the 95% confidence interval for Method 310 is ±3% by weight (W.T./W.T.%) on the average of two (2) replicates." (Condea-Vista-Sorensen (3/31/97))

Agency Response: We believe that the current language "... the 95 percent confidence level for Method 310 is ±3.00 percent by weight ..." is a clear, straightforward statement that should be left alone. In fact, we believe that the commenter's proposed language is considerably more confusing than the current language. Regarding the more specific points made by the commenter, it is not necessary within the language of the test method to go into extensive detail about exactly how the confidence level was calculated. This information is of limited interest compared to the more relevant information of the actual numerical value of the confidence level. We also do not believe that the regulated public will be confused by the absence of a "±" sign in front of the 3.0 percent number. Since the purpose of Method 310 is to determine whether a product complies with the applicable VOC standard, it is obvious that the issue of concern is the "plus" sign of the equation (i.e., whether the product contains more VOC than allowed by the regulations). A test result of "minus 3%" (i.e., indicating that the product contains less VOC than the maximum it is legally allowed to contain) is irrelevant to the enforcement process.