

**State of California
AIR RESOURCES BOARD**

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

**PUBLIC HEARING TO CONSIDER AMENDMENTS TO THE AMBIENT AIR QUALITY
STANDARDS FOR PARTICULATE MATTER AND SULFATES**

**Considered On: June 20, 2002
Agenda Item No: 02-5-01**

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I. INTRODUCTION

"The Initial Statement of Reasons for the Proposed Rulemaking—Public Hearing to Consider Amendments to the Ambient Air Quality Standards for Particulate Matter and Sulfates" (also referred to as the staff report) was released May 3, 2002, and made available to the public for at least 45 days prior to the public hearing. The staff report, which is incorporated by reference herein, provided a description of the rationale and necessity for the action proposed. The purpose of the regulation is to update California's ambient air quality standards for particulate matter and sulfates so that they accurately reflect the current body of peer-reviewed literature on related adverse health effects and provide adequate health protection for the citizenry of California—including that of infants and children as well as other sensitive sub-populations. The proposed action consisted of the adoption of new section 70100.1 and the amendment of sections 70100 and 70200, title 17, California Code of Regulations (CCR), concerning ambient air quality standards for particulate matter and sulfates.

On June 20, 2002, the Air Resources Board (ARB or Board) held a public hearing at which it received written and oral comments on the proposed regulation. At that time, the Board considered revised language that staff recommended to address issues raised during the preceding 48 days of the public comment period. At the conclusion of the public hearing, the Board adopted Resolution 02-24 and approved the proposed regulation with the proposed staff modifications. Resolution 02-24 is attached hereto and incorporated by reference herein. On August 15, 2002, ARB made available a "Notice of Public Availability of Modified Text," which provided the revised regulatory language for the required 15-day public comment period. During the public comment period, which lasted 16 days and expired on August 30, 2002, 5 comments were received. Additionally, on October 10, 2002 ARB made available a second "Notice of Public Availability of Modified Text", which provided the revised regulatory language for the required 15-day public comment period. During the public comment period, which lasted 16 days and expired on October 25, 2002, 1 comment was received.

As unanimously approved by the Board, the regulation modified several standards for particulate matter (PM). The newly adopted standards included:

- a PM10 annual-average standard of 20 micrograms per cubic meter ($\mu\text{g}/\text{m}^3$), not to be exceeded;
- a new PM2.5 annual-average standard of 12 micrograms per cubic meter ($\mu\text{g}/\text{m}^3$), not to be exceeded;

The Board further found that the 24-hour standard for sulfates should be retained at 25 micrograms per cubic meter ($\mu\text{g}/\text{m}^3$). In addition, the Board also adopted several recommendations to revise the monitoring methods for these standards.

II. MODIFICATIONS TO THE PROPOSED STATE REGULATION

A. Update of Information Contained in the Initial Statement of Reasons and Summary of Modifications to the Initial Regulatory Proposal

Prior to the Board's adoption of the proposed regulatory item, the public was given 48 days to review and submit comments on the proposed amendments. During this period, approximately 1,400 form letters or emails and 73 individual letters or emails were received. ARB staff also met with over 80 people at public workshops held throughout the state during December 2001 and June 2002, to discuss the regulatory proposals and to listen to their opinions. In addition, the Air Quality Advisory Committee (AQAC) held public meetings on the scientific basis of the proposed regulatory items in January and April 2002, which were attended by the public. The Board also heard testimony from 16 witnesses at the June 20, 2002 public hearing.

Comments in the letters and by the witnesses at the hearing raised the following issues: need for additional peer review; qualification of Air Quality Advisory Committee (AQAC) members; background PM concentration issues; basis for 24-hour standards recommendations; basis for all PM standards; need for clarification of sulfate health effects; need for collaboration between CARB and U.S. EPA; request for complete review of short-term standards by June, 2003; completion of 24-hour standards by end 2002; air pollution control issues; environmental justice concerns not adequately addressed; impacts of standards on the economy; inconsistent scientific basis for proposed standards; insufficient discussion of uncertainty; insufficient review time and request for delay of workshops and Board hearing; request for justification for California standards separate from U.S. EPA standards; lack of consistency among standards; issues relating to monitoring and air pollution control; belief that ARB refuses to collaborate with U.S. EPA; belief that standards are not stringent enough and request for an additional margin of safety; general support for protection of public health and the proposed PM and sulfate standards; and withdrawal of endorsement of short-term standards by AQAC. Staff developed revised text for several parts of the proposed regulation. Many of these comments were accommodated in the modifications to the proposed regulation; some were not, and the reasons are provided herein.

The proposed regulation was brought before the Board at the public hearing on June 20, 2002. After listening to public comments and deliberating the issues at the hearing, the Board approved the regulation with the modifications proposed by staff as described in Resolution 02-24. These changes to the initial proposal are summarized below.

In May 2002, staff discovered that the operation of the S-Plus statistical software package used by various researchers may have introduced a bias into the results of key studies that provided significant support to the justification for the proposed 24-hour PM_{2.5} standard. The degree of bias can only be determined following reanalysis of data in individual studies by the researchers. Therefore, staff decided that the establishment of a new 24-

hour standard for PM2.5 as proposed in 17 CCR section 70200 should be deferred, based on the need to review the reanalyses of epidemiological studies showing associations between short-term exposures to ambient PM2.5 levels and health effects, including mortality and morbidity resulting from cardiopulmonary causes. As a result, the Board directed the Executive Officer to review the key corrected research studies regarding the short-term PM standards when they become available, to report the results of the review to the Board, and to recommend appropriate recommendations for further review of the standards.

Currently the Health Effects Institute (HEI), a sponsor of several of the affected short-term studies, is working with U.S. EPA and the principle investigators on a review and reanalysis of many of the affected short-term studies. The review is intended to identify studies that used the statistical software in question, promote reanalysis of the data, and present a summary of reanalyzed findings in early 2003. ARB staff have been attending meetings on these activities and collaborating with HEI and U.S. EPA in order to ensure that results of these activities may be brought to the Board in the future.

In light of information learned after the May 3, 2002 release of the staff report, as described above, the ARB made available on August 15, 2002 a "Notice of Public Availability of Modified Text," which provided the necessary revised regulatory language to delete proposed text for a 24-hour PM2.5 standard in section 70200, title 17, CCR. Additionally, on October 10, 2002 ARB made available a second "Notice of Public Availability of Modified Text" to include additional samplers to section 70100.1, title 17, CCR, entitled "Methods, Samplers, and Instruments for Measuring Pollutants."

B. Availability of Modified Text and Additional Documents and Information

Pursuant to the Board's directions, the staff prepared modified regulatory language reflecting the changes approved by the Board. The modified regulation, with the changes to the originally proposed text clearly indicated as required by Government Code section 11346.7(a), were mailed in accordance with section 44, title 1, California Code of Regulations, on August 15, 2002 and October 10, 2002. Pursuant to Government Code 11347.1(b), these additional documents and all other documentation relied upon in the regulatory action were made available for inspection at the ARB's Public Information Office, Environmental Services Center, 1001 "I" Street, 1st Floor, Sacramento, California 95814. The comment periods ended August 30, 2002, and October 25, 2002, respectively.

A total of 5 comment letters or emails were received during the first noticed period (August 15-30, 2002). Comments were received on the following issues: urging the completion of the short-term, 24-hour standard reviews; how standards with concentrations that approach "background" levels may affect businesses and the economy of California; the need for harmonization of state and national standards and the difficulties that may arise due to fundamental differences in the approaches; the need for ARB to participate in the national review process; and the effects of software errors with the statistical models used in the

evaluation of short-term studies. Two of the commentors submitted comments that were deemed by staff to not be relevant to the proposed modification, including a request to add approved monitors for collection of data which were not included on the list of California approved monitors and information on emission reduction technology.

During the second noticed period (October 10-25, 2002) one comment letter (as email) was received. The comment received was deemed irrelevant to the proposed modification, as the subject focused on the need to control agricultural burning to reduce PM levels.

After considering the comments received in response to the Notice of Availability of Modified Text and Additional Documents and Information, the Executive Officer issued Executive Order G-02-079, dated April 14, 2003 adopting the publicly noticed regulations.

C. Environmental and Economic Impacts

As discussed in Chapter 2 of the staff report, the proposed ambient air quality standards will in and of themselves have no environmental or economic impacts. Section 39696(a)(2) of the Health and Safety Code authorizes the ARB to adopt standards for ambient air quality "in consideration of public health, safety, and welfare, including, but not limited to, health, illness, irritation to the senses, aesthetic value, interference with visibility, and effects on the economy." No comments were received identifying environmental issues pertaining to this item. The staff report identified no adverse environmental effects.

Once adopted, local air pollution control or air quality management districts will be responsible for the adoption of rules and regulations to control emissions from stationary sources that emit the subject pollutants to assure achievement and maintenance of the ambient standards. The Board is responsible for the adoption of emission standards for mobile sources. A number of different control measures are possible, and each will have its own environmental and economic impact. The environmental and economic impacts associated with the imposition of future control measures will be considered by the ARB or the air districts when specific measures are proposed.

D. Consideration of Alternatives

Pursuant to the APA [Government Code sec. 11346.7(b)(4)] the Board has further determined that no justifiable, adequately scientific-based alternative considered by the agency 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. In theory, a lower proposed standard would be more health protective, however, it would not be supported by the currently body of scientific literature and therefore not sufficiently justified.

III. SUMMARY OF COMMENTS AND AGENCY RESPONSES

A. Introduction

The Board received approximately 1,400 form letters and 73 individual letters from commentors during the 48-day public comment period prior to the June 20, 2002 hearing. The Board also heard testimony from 16 witnesses at the June 20, 2002 public hearing, whose corresponding written submissions were cross-checked with oral comments in meeting transcripts to ensure that all comments have been considered and addressed in this process. A list of commentors is set forth below with 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, with similar items grouped together. Each summary is followed by a response and explanation of how the proposed action has been changed to accommodate the objection or recommendation, or the reasons for making no change.

In addition, comments received as a form letter have been grouped by subject and summarized as a "form letter" group. Several of these commentors expressed general support or disagreement with the proposed regulations, or certain aspects of it. While these comments were considered by the Board, most are not separately addressed in this Final Statement of Reasons because they were not objections or recommendations specifically directed at the proposed action or the procedures followed by the Board in proposing or adopting the proposed action. However, some of these comments have been included in those cases where they add additional information or perspective.

B. Summary of Comments Received During the 45-Day Comment Period (May 3, 2002 – June 20, 2002) and Oral Testimony at the Public Hearing held on June 20, 2002

List of Commentors

The list below contains the names of persons who commented on the proposed regulation, as individuals or as representatives of organizations. The comment reference is used to link the comment to the source for the comment-and-response section that follows in this document. Frequently, several persons commented on the same issue. A representative comment or a paraphrase of the comment(s) is used for each issue requiring a response. A commentor may have also raised different issues, whether as oral testimony (OT) or in writing during the 45-day comment period before the hearing (WC) or in a written submission (WS) at the hearing. The date on which the comment was received by ARB is also listed.

Table IIIa. List of Comments from 45-day period

Comment Code*	Commentor	Organization	Date Received
HAWKINS-WC1	Hawkins	Citizen	5/7/02
WINHOLTZ-WC2	Winholtz	Citizen	5/13/02
PETREE-WC3	Petree	Citizen	5/15/02
ROSESTONE-WC6	Rosestone	Solar Works, Inc.	5/15/02
WALKER-WC5	Walker	Environmental Working Group	5/15/02
BAGATTI-WC7	Bagatti	Citizen	5/16/02
BAGATTI-WC8	Bagatti	Citizen	5/20/02
HEANEY-WC9	Heaney	Citizen	5/20/02
SMITH-WC12	Smith	Citizen	5/20/02
FERRIS-WC11	Ferris	Citizen	5/22/02
TROUT-WC10	Trout	Citizen	5/22/02
ARUMUGHAM-WC16	Arumugham	Citizen	5/28/02
LOUGEE-WC15	Lougee	Citizen	5/28/02
MANDEL-WC13	Mandel	EMA	5/28/02
ROSEN-WC14	Rosen	Citizen	5/28/02
AL-WC17	Al	Citizen	5/29/02
BUNN-WC34	Bunn	International Truck & Engine	5/31/02
DASHE-WC35	Dashe	Citizen	5/31/02
ELLIOT-WC18	Elliot	Citizen	5/31/02
GARDNER-WC20	Gardner	Citizen	5/31/02
HARRISON-WC27	Harrison	Citizen	5/31/02
KERR-WC21	Kerr	Citizen	5/31/02
MODLIN-WC19	Modlin	DaimlerChrysler	5/31/02
Opp-Form Letter-WC	Form Letter	(4 Total)	May-June, 2002
Supp-Form Letter-WC	Form Letter	(Approx. 1,400 Total)	May-June, 2002
ANDARY-WC29	Andary	Alliance of Auto. Manufacturers	6/3/02
HAMMERQUIST-WC31	Hammerquist	Citizen	6/3/02
JENSEN-WC32	Jensen	Citizen	6/3/02
MILSTEAD-WC30	Milstead	John Deere	6/3/02
HACKER-WC25	Hacker	Citizen	6/4/02
HETTLER-SMITH-WC23	Hettler-Smith	Citizen	6/4/02

SMITH-WC22	Smith	Citizen	6/4/02
TAM-WC26	Tam	Sierra Club	6/4/02
WILLIAMS-WC47	Williams	CA Trucking Assoc.	6/4/02
CAIN-WC36	Cain	CA for Sound Fuel Strategy	6/5/02
KHALSA-WC46	Khalsa	Citizen	6/5/02
SCHNEIDER-WC43	Schneider	Citizen	6/5/02
SCRUGGS-WC48	Scruggs	Citizen	6/5/02
VERMEULEN-WC37	Vermeulen	Citizen	6/5/02
KRINOCK-WC45	Krinock	Citizen	6/6/02
ROHLFES-WC44	Rohlfes	CA Landscape Contractors Assoc.	6/6/02
ANDARY/FRENCH-WC38	Andary	Engine Manufacturer's Association (EMA)	6/7/02
BURNS-WC39	Burns	DaimlerChrysler	6/7/02
ALVIS-WC54	Alvis	Citizen	6/10/02
AUDERSON-WC51	Auderson	Citizen	6/10/02
BLOSE-WC49	Blose	Citizen	6/10/02
CRAIG-WC55	Craig	Citizen	6/10/02
EVANS-WC50	Evans	Citizen	6/10/02
LANDSHOFF-WC53	Landshoff	Citizen	6/10/02
SMITH-WC52	Smith	Citizen	6/10/02
MURRAY-WC56	Murray	California State Senator	6/11/02
AUKER-WC24	Auker	Citizen	6/13/02
NIKOLOFF-WC40	Nikoloff	Citizen	6/13/02
BORNSTEIN-WC42	Bornstein	Citizen	6/14/02
KLEINMAN-WC41	Kleinman	Air Quality Advisory Committee (AQAC)	6/14/02
CURNETT-WC58	Curnett	Citizen	6/17/02
MORRIS-WC57	Morris	Citizen	6/17/02
DERKSEN-WC61	Derksen	Citizen	6/18/02
MEANS-WC59	Means	Citizen	6/18/02
MILLER-WC62	Miller	Southern California Alliance of Publicly Owned Treatment Works (SCAP)	6/18/02
REYNOLDS-WC60	Reynolds	Lake County Air Quality Management District (AQMD)	6/18/02
BECK-WC69	Beck	Citizen	6/19/02
BERGEN-WC66	Bergen	American Lung Association & many other organizations	6/19/02
CORTEZ-WC63	Cortez	American Lung Assoc.- San Diego/Imperial County	6/19/02
HOLMES-GEN-WC70	Holmes-Gen	American Lung Association	6/19/02

		CA & many other organizations	
KLOC-WC72	Kloc	Golden Gate University & many other organizations	6/19/02
KUNECK-WC71	Kuneck	Citizen	6/19/02
LIFSON-WC64	Lifson	Asthma&Allergy Fndn. of America	6/19/02
PHALEN-WC73	Phalen	Citizen	6/19/02
SIEKMANN-WC65	Siekmann	Citizen	6/19/02
SODERBECK-WC68	Soderbeck	Citizen	6/19/02
STAHL-WC67	Stahl	LA County Sanitation Districts	6/19/02
ANDARY-WS3	Andary	Alliance of Auto. Manufacturers	6/20/02
CAIN-WS14	Cain	CA for Sound Fuel Strategy	6/20/02
CARMEAN-WS15	Carmean	Citizen	6/20/02
CORY-WS5	Cory	CA Farm Bureau Federation	6/20/02
GARVEY-WS6	Garvey	Bay Area Air Quality Management District (BAAQMD)	6/20/02
HEUSS-WS4	Heuss	Air Improvement Resources	6/20/02
HOLDEN/HARDISON-WS16	Holden	City of LA - City Council	6/20/02
HOLMES-GEN-WS11	Holmes-Gen	American Lung Association CA & many other organizations	6/20/02
LEE-WS9	Lee	Northern Sonoma County Air Pollution Control District (APCD)	6/20/02
LUI-WS2	Lui	South Coast Air Quality Management District (SCAQMD)	6/20/02
SHARP-WS10	Sharp	Environmental Working Group	6/20/02
SHARP-WS12	Sharp	Environmental Working Group	6/20/02
STERN-WS13	Stern	Citizen	6/20/02
STUART-OT	Stuart	Construction Industry Air Quality Coalition	6/20/02
SUCHECKI-WS8	Sucheck	EMA	6/20/02
WALLERSTEIN-WS1	Wallerstein	CA Air Pollution Control	6/20/02

		Officers Association	
WILLIAMS-WS7	Williams	CA Trucking Assoc.	6/20/02
LEE-WC33	Lee	Citizen	6/3/03

*Notes: WC = written comment(s) during 45-day period

WS/OT = written submission at hearing & corresponding Oral Testimony (see transcript)

OT = Oral Testimony (see transcript)

"Date Received" = refers to the stamped received date on hardcopy

"Comment Code" = refers to the last name of the commentor + associated comment type (WC, WS, or OT)
+ comment number as indicated on bottom of hardcopy

"Opp-Form Letter-WC" = Opposition form letters

Set forth below is a summary of each objection or recommendation regarding the proposed amendments, issues related to the particulate matter in general, the regulatory process in California or the procedures used by the ARB. These are presented together with an explanation of how the proposed action was changed to accommodate each objection or recommendation or the reasons for making no change. These comments, with responses, are arranged by topic and presented below.

Comments and Agency Response(s):

1. Peer Review

Comment: Recently discovered problems in a common statistical model used in analysis of epidemiology studies relied on for standards have been made public. The impacts of the statistical misapplication do have ramifications for the long-term, annual standards. However, staff decided that this is not the case. This decision requires peer review [by the Air Quality Advisory Committee (AQAC)]. In addition, the peer review committee (AQAC) may not be qualified and may be subject to influence. Commentors requested full background information on the qualifications of the committee members. (HEUSS-WS4; HAWKINS-WC1; SUCHECKI-WS8)

Agency Response: The recent issues associated with the misapplication of the statistical models used in the analysis of epidemiology studies have been evaluated by ARB and OEHHA staff for both the long-term and short-term epidemiology studies. Following a detailed review, staff has determined that the long-term studies used as the basis for the recommended annual standard levels for PM10 and PM2.5, as set forth on the staff report, were not affected by this misapplication. Since the recommendations for the long-term standards were reviewed and supported by the Air Quality Advisory Committee (AQAC) in January 2002, the staff's decision regarding the lack of impact of the statistical misapplication on the long-term standards does not require further review by the AQAC. The AQAC is comprised of a highly qualified group of experts on various aspects of PM, including measurement methods and health effects. Members are appointed to the AQAC by the University of California's Office of the President. Information on the members appointed to the Committee has been available at all public meetings, on the website at www.arb.ca.gov/research/aaqs/std-rs/aqac/aqac.htm, and upon request as of the November 2001 release of the draft staff report entitled "California Ambient Air Quality

Standards For Particulate Matter And Sulfates, Report To The Air Quality Advisory Committee.”

2. Technical Issues - Background Particulate Matter (PM) Levels

Comment: The proposed PM_{2.5} 24-hour standard may overlap with background PM levels and does not take into account natural variability and fluctuations of short-term levels. In addition, the proposed levels of the short-term and long-term standards are too close to background levels, which makes them impossible to attain, and may limit emissions for California businesses to essentially zero, with severe adverse economic impacts. (ANDARY-WC29; ANDARY/FRENCH-WC38; BECK-WC69; BUNN-WC34; CORY-WS5; HEUSS-WS4)

Agency Response: Ambient air quality standards are based solely on health and welfare effects. Therefore, staff is not required by law to evaluate control strategies, feasibility of controls, or costs of controls. These activities will occur in a separate public process with opportunities for all interested parties and stakeholders to provide input. However, based on information in the staff report, the proposed annual average of standards are at a level considerably above background levels of PM.

Recommendations for updating the 24-hour PM₁₀ standard and creating a new 24-hour PM_{2.5} standard have been deferred, since key short-term exposure PM studies are currently under review (see pages 2 and 3 of this document).

The staff report does provide information on PM₁₀ and PM_{2.5} background levels. Background monitoring sites are intended to quantify regionally representative PM concentrations in sites located upwind from populated areas and far from emission sources derived from human activities. However, depending on the season and meteorological conditions, even the monitoring sites located in pristine areas can be influenced by anthropogenic emissions and transport. For example, on certain days, Point Reyes, San Geronio, and Sequoia can be heavily affected by transported emissions from upwind urban areas and recirculation of emissions. This in turn may lead to higher annual average PM concentrations. Averaging PM measurements obtained at several sites located in the most pristine areas in California provides an upper-bound estimate of a value representative of PM background levels throughout the State. We estimated the 1996-1999 statewide annual average PM₁₀ and PM_{2.5} levels from data collected at seven sites (Lassen, Pinnacles, Point Reyes, Redwood, San Geronio, Sequoia, and Yosemite) from the Interagency Monitoring of Protected Visual Environments (IMPROVE) program. The annual average PM₁₀ and PM_{2.5} concentrations – aggregated over the 1996-1999 three-year period – for each of these sites are listed in Table 6.3 on page 6-12 of the staff report. The mean of the annual average PM₁₀ concentrations measured at these IMPROVE sites is 10.97 $\mu\text{g}/\text{m}^3$ (55 percent of the level of the new State annual PM₁₀ standard of 20 $\mu\text{g}/\text{m}^3$), while the PM_{2.5} mean is 4.87 $\mu\text{g}/\text{m}^3$ (41 percent of the level of the new State annual PM_{2.5} standard of 12 $\mu\text{g}/\text{m}^3$.)

The above approach provides an overall statewide estimate of background PM concentrations. It is also more appropriate to determine which monitoring sites are most representative of regional background conditions in California. Subsequent to the analysis presented in the staff report, data from several new background sites have become available. We have analyzed the characteristics of monitor location and PM concentrations collected at thirteen sites from the IMPROVE program and one site from the California Regional PM10/PM25 Air Quality Study (CRPAQS) for the year 2000. Three IMPROVE sites (Lava Beds, Lassen Volcanic National Park, and Bliss State Park) are the most appropriate background sites, as they are the least affected by anthropogenic emissions. At these sites, average PM10 concentrations range from 4.4-5.5 $\mu\text{g}/\text{m}^3$ (approximately one fourth of the level of the new State annual PM10 standard) and PM2.5 concentrations range from 2.6-3.2 $\mu\text{g}/\text{m}^3$ (approximately one fourth of the level of the new State annual PM2.5 standard). The Olancho site deployed during CRPAQS is also an appropriate PM2.5 background site with an annual average concentration of 3.7 $\mu\text{g}/\text{m}^3$ (about one third of the new annual PM2.5 standard).

Therefore, the levels representative of background for PM10 and PM2.5 are sufficiently below the proposed standards to allow for attainment activities that are capable of separating control of man-made versus background PM sources. Furthermore, control plans and related issues, while not the scope of this regulatory item, will take into account costs associated with attaining the proposed standards, as well as issues related to how background PM levels may affect attainment.

3. Technical Basis for the Proposed Standards

a. Comment: Recent statistical errors in studies using General Additive Models (GAM) need to be addressed by the ARB, including assessment of the significance of the association of adverse health effects due to PM exposure. This work should include the original study investigators, and the ARB should then revise, as necessary, conclusions and proposed standards based on corrected information. Until the scope of the problem is understood, no estimates of quantitative risks can be adequately relied upon. (ANDARY/FRENCH-WC38; CAIN-WS14; LUI-WS2; MANDEL-WC13; VERMEULEN-WC37; WILLIAMS-WC47; BUNN-WC34)

Agency Response: The ARB and OEHHA staff evaluated whether the problems with the GAM affected the results of the long-term (cohort) studies. Staff determined that these results were not affected by the software problem. These long-term studies formed the fundamental basis for the recommendations for the annual standards. However, the short-term effects studies may have been affected by the GAM problems. Therefore, the staff recommended and the Board concurred to defer any recommendations for the short-term PM10 and PM2.5 standards. The Health Effects Institute, in cooperation with the U.S. EPA, sponsored reanalyses of the key PM-related studies. Those reanalyses corroborated that the long-term studies were not affected. Both the Health Effects Institute and the U.S. EPA submitted letters describing the statistical software problem; the concerns they expressed were limited to the short-term

studies. While some of the latter used the software in question, many were conducted before the S-PLUS software program was widely used, and therefore their results were not affected. In addition, some of the principal investigators have already sent their reanalyses to journals for review and many new studies have been published or are ongoing. When the short-term PM standards are reviewed, all of this information will be included in the evaluation.

b. Comment: The ARB needs to explain what human control studies as well as control of co-pollutant studies have been performed at ambient levels that may support the proposed standards. (ANDARY/FRENCH-WC38; CAIN-WS14; LUI-WS2; MANDEL-WC13; VERMEULEN-WC37; WILLIAMS-WC47; BUNN-WC34)

Agency Response: To date, there have been few human control studies performed for PM₁₀ or PM_{2.5}. This is largely due to the complex nature of the particle mix in terms of sizes and chemical compositions. It is extremely difficult to design and characterize controlled human subject studies and ambient PM exposures because of this chemical and physical complexity. However, the staff report provides references for several controlled human studies based on exposure to concentrated ambient particles (CAPs) (Ghio et al., 2000), resuspended diesel particles (Nightingale et al., 2000; Salvi et al., 1999; Salvi et al., 2000), and radiolabelled carbon particles (Nemmar et al., 2001b). The results of these studies only provide information regarding the potential biological mechanisms by which exposure to PM harms human health.

In addition, there is substantial evidence from the available peer-reviewed literature that PM effects are, in general, not substantially affected by co-pollutants. In many of the time-series mortality studies, inclusion of additional pollutants into the regression model does not alter the estimated impact of PM. Samet et al. (2000a) provide a recent and comprehensive test of this theory using the data set consisting of 90 U.S. cities, as described earlier. The authors sequentially tested the estimated effect of PM₁₀ after gaseous pollutants (ozone, nitrogen dioxide, sulfur dioxide, and carbon monoxide) were each added to the regression model. The authors report minimal change in the estimated PM₁₀ coefficient after these inclusions. Similar results have been reported in most studies that have examined PM₁₀ and mortality, with few exceptions (e.g., Moolgavkar, 2000a). In a different approach to the issue, Schwartz (2000a) examined the sensitivity of the PM₁₀ coefficient to different amounts of co-pollutant covariation among 10 U.S. cities. Theoretically, if the PM₁₀ effect were really a result of confounding by another pollutant, the estimated PM₁₀ effect per $\mu\text{g}/\text{m}^3$ would be greater in those cities where PM₁₀ was highly correlated with other pollutants, indicating that PM₁₀ was taking on some of the explanatory power of the “true” causal co-pollutant. However, Schwartz (2000a) did not find any evidence consistent with this hypothesis, suggesting that confounding of the effects of PM₁₀ by other pollutants was unlikely. Similarly, in the study of 29 European cities, Katsouyanni et al. (2001) report no effect modification or confounding associated with either ozone or sulfur dioxide. PM effects were higher in cities with higher concentrations of nitrogen dioxide, but the effects of PM were not attenuated.

In addition, studies have reported effects of PM10 in areas where other pollutants such as ozone and sulfur dioxide were observed at both high and low concentrations. Therefore, it is unlikely that all of the associations reported with PM10 are due to co-pollutants.

4. Technical Issues – Clarification of PM Health Effects

Comment: I support the standards recommendations - , however, I would like additional information on the potential adverse health effects of sulfates and carbon added to the record, if any is available, in addition to that presented in the staff report. (SODERBECK-WC68)

Agency Response: The health effects of sulfates have been presented in several documents and public meetings, all of which are referenced in the public record for this regulatory item. Documents with discussions on either sulfates, “carbon,” or both include the following: 1) the December 7, 2000 staff report entitled "Adequacy of California Ambient Air Quality Standards: Children's Environmental Health Protection Act;" and 2) May 3, 2002 staff report entitled “Public Hearing to Consider Amendments to the Ambient Air Quality Standards for Particulate Matter and Sulfates.” In addition, transcripts from the January 23 and 24, 2002 public meeting of the Air Quality Advisory Committee meeting provide additional information on sulfates and are available at www.arb.ca.gov/research/aaqs/std-rs/aqac/aqac.htm.

5. Technical Request -- Collaboration

a. Comment: The ARB recognizes that the U.S. EPA is involved in a national standard setting process, but chooses to make a final decision without input from the U.S. EPA or from the Clean Air Scientific Advisory Committee (CASAC). The ARB should work with other technical agencies or organizations such as the U.S. EPA or Health Effects Institute (HEI). The ARB refuses to collaborate with the nation’s top scientists who actually conducted the studies on which the standards have been based. (ANDARY-WS3; ANDARY-WC29; CAIN-WS14; BUNN-WC34; SUCHECKI-WS8; WILLIAMS-WS7)

Agency Response: The ARB is aware that U.S. EPA is promulgating national ambient air quality standards for particulate matter (PM). In completing its review of the scientific literature for these PM standards, ARB and OEHHA staff relied on information in the U.S. EPA PM standards draft criteria document. During the process to complete the staff report and develop recommendations to amend the PM standards, ARB and OEHHA staff were in regular contact with key U.S. EPA staff regarding federal efforts to revise the national PM standards. The ARB and OEHHA have consistently worked with the top scientific experts throughout the standard review process. A collaborative approach with experts has always been part of the ARB’s regulatory process, and in this particular case began formally with the December 7, 2000 staff report entitled "Adequacy of California Ambient Air Quality Standards: Children's Environmental Health Protection Act." As part of that review, nationally recognized experts provided reports, based on available literature, to

ARB on each of the State's ambient air quality standards, including evaluations with respect to the protection of children. In addition, ARB and OEHHA staff have been in contact with scientific experts throughout the standard review process who are from national and international technical agencies such as HEI and the U.S. EPA. Finally, the ARB has the authority based on state law (Health and Safety Code 39606(b)) to establish state ambient air quality standards independent of the U.S. EPA.

As part of our ongoing efforts to collaborate with the U.S. EPA in all aspects of air pollution control, including standard setting, ARB and OEHHA staff continue to be in regular contact with key U.S. EPA staff. Staff attend pertinent meetings and symposia in order to harmonize state and national efforts. The ARB has and will continue to work with the U.S. EPA in order to harmonize our actions on PM standards. This harmonization process includes informing the U.S. EPA of ARB actions to establish health protective PM standards and encouraging the U.S. EPA to establish equally protective PM standards.

b. Comment: The standard setting process performed by the ARB is in direct conflict with Executive Order W-137-96b, requiring consistency with the federal government when using risk-based approaches. (CORY-WS5; WILLIAMS-WS7; CAIN-WS14)

Agency Response: The ambient air standard setting process is not required by state law to follow Executive Order W-137-96b and is not required to be a risk-based approach. Standards are required by state law (Health and Safety Code Section 39606(a)(2)) to be adopted "in consideration of public health, safety, and welfare, including, but not limited to, health, illness, irritation to the senses, aesthetic value, interference with visibility, and effects on the economy". The process for adopting these standards was not a risk-based approach. Rather, it was an approach based on identifying level(s) staff deemed protective of public health based on peer-reviewed scientific literature and reviewed and endorsed by the Air Quality Advisory Committee.

6. Short-term Standard Review and Recommendations

Comment: The review of the short-term (24-hour) standards for PM, including subsequent standard recommendations, should be completed as soon as possible, with a time frame set for completion and hopefully brought before the Board by the end of 2002 or by June 2003. (LEE-WS9; BERGEN-WC66; HOLMES-GEN-WC70; HOLMES-GEN-WS11; LIFSON-WC64; SHARP-WS10)

Agency Response: The ARB staff recommendations for short-term PM standards were deferred until issues related to the misapplication of statistical models are resolved. The ARB and OEHHA staff are in the process of monitoring the activities associated with the reanalysis of key epidemiology study results that may have been affected by the misapplication of statistical software. A proposal by ARB for any new short-term standard or review of any existing short-term standard is linked to these reanalyses, which is occurring at the national level. The U.S. EPA sponsored a workshop in November 2002 where researchers of key PM health studies presented and discussed the results of their

reanalysis efforts. Information presented at this meeting will be peer-reviewed by a committee coordinated by the Health Effects Institute at the request of the U.S. EPA. A final report is due in the spring of 2003. At that point ARB staff will review the reported findings and reassess a plan for a short-term standard review. However, any staff recommendations for short-term PM standards will occur after a public review process that includes the development of a new PM staff report, public comment periods, peer review by the Air Quality Advisory Committee, and a release of staff recommendations prior to a formal Board hearing.

7. Air Pollution Control and Economic Issues

a. Comment: Why does section 39606(a)(2) of the Health and Safety Code mention that the standard setting process must consider the effects on the economy, yet the staff report states that there is no economic impact of the proposed standards? The ARB must balance public health protection and the welfare of all Californians by establishing standards that are both scientifically and technically viable, and by taking into consideration the costs of implementing controls. The health benefits and economic impacts and a feasibility analysis need to be included. In addition, there needs to be a description of the regulatory efforts required to achieve the proposed standards, as well as a discussion on how new emission reduction rules, which may not be justified, may harm California's economy, especially at levels near background. (ANDARY-WC29; ANDARY/FRENCH-WC38; BURNS-WC39; CAIN-WS4; CARMEAN-WS15; CORY-WS5; MANDEL-WC13; MILLER-WC62; MILSTEAD-WC30; CAIN-WS14; Opp-Form Letter-WC; WILLIAMS-WC47; STAHL-WC67; VERMEULEN-WC37)

Agency Response: The 1984 California Supreme Court decision (208 Cal. Rptr.850) in *Western Oil And Gas Association (WOGA) v. ARB*, clarifies the language in the Health and Safety Code §39606(a)(2) regarding effects on the economy. The Supreme Court held that the language directs the ARB to adopt air quality standards in consideration of several factors, including the effects of air pollution on the economy, not the effects of air quality standards on the economy. The Legislature intended local and regional authorities, rather than the Board, to consider the economic consequences of the stationary source rules they adopt for compliance with the air quality standards.

In the process of setting the PM standards, the ARB has based the standards on the best available information in an effort to protect public health. The law requires the standards to be based on health and welfare effects, not potential economic impacts. Thus, the staff report does not evaluate emissions standards and other control measures and planning strategies, including an evaluation of their economic costs. These activities will occur in a separate public process when the air districts and, for mobile and specified area sources, the ARB propose rules that apply to sources of PM. Thus, the adoption of health-based ambient standards is separate from the control of sources that limit the pollutants that the standards address.

b. Comment: The ARB should establish a close working relationship with the City of Los Angeles and local air districts in order to ensure that development of any control and implementation strategies are reasonable, protective of public health, feasible, and cost effective. In addition, the local districts urge the Board to direct staff to work with the local air districts and with the U.S. EPA prior to implementing any comprehensive changes to the monitoring network, including the use of continuous monitors. (HOLDEN-HARDISON-WS16; LEE-WS9)

Agency Response: It is the intention and commitment of the ARB to work closely with the City of Los Angeles as well as local air districts during the control measure development process. The adoption of strategies to control sources of PM will involve input from all interested parties. Staff recommendations that will result in changes to the PM monitoring network, were done to align state and federal methods.

8. Request for Delay in Public Workshops and June 29, 2002, Board Hearing

a. Comment: The ARB should delay or postpone the public workshops and the June 20, 2002 Board Hearing due to insufficient review time and the need to address the issues associated with statistical errors that have recently arisen. The ARB should wait until the U.S.EPA and its external peer review committee, the Clean Air Science Advisory Committee (CASAC), have considered how the statistical issue may affect both national and state PM standards. By not allowing sufficient review time, the ARB has effectively limited meaningful comments. The decision on the state standards should wait until after the CASAC PM Review Panel meeting in July 2002, where these statistical issues will be further discussed. (ANDARY-WC29; ANDARY/FRENCH-WC38; ANDARY-WS3; BUNN-WC34; BURNS-WC39; CAIN-WC36; CORY-WS5; Opp-Form Letter-WC; MANDEL-WC13; MANDEL-WC13; MILLER-WC62; MILSTEAD-WC30; MODLIN-WC19; MURRAY-WC56; ROHLFES-WC44; STAHL-WC67; SUCHECKI-WS8; VERMEULEN-WC37; WILLIAMS-WC47; WILLIAMS-WS7)

Agency Response: ARB has made a conscious effort to ensure adequate public participation at every major step in the standard review process, in accordance with applicable legal requirements and ARB policy. Public outreach included dissemination of information through public meetings, workshop presentations, electronic "list-serv" notification systems, traditional mailing lists, and various web pages. Public notice of the availability of the original draft staff report, including the schedule for public meetings and workshops, was published on November 30, 2001. Subsequent public workshops were held in December 2001 in Oakland, Sacramento, Bakersfield, Mira Loma, El Monte, and Huntington Park. In addition, public meetings of the Air Quality Advisory Committee (AQAC) were held in Berkeley on January 23 and 24, 2002 and in Oakland on April 3, 2002. The public was invited to submit comments to the Committee before and during these meetings. The May 3, 2002 staff report formally opened the 45-day public comment period for this regulatory item and was followed by public workshops in June in Sacramento and El Monte. Public comments were accepted up to the June 20, 2002 Board Meeting, as well as by testimony during the meeting.

Staff decided not to postpone the workshops after initial review of the information regarding the statistical software problems. The workshops allowed staff to discuss with stakeholders the issues surrounding the software problem and their conclusions regarding why the annual standards recommendations were not affected. After further review, staff concluded the annual standards recommendations were not affected, but the short-term standard recommendations should be deferred. Based on these conclusions, staff decided postponement of the Board Hearing was not warranted. These issues were thoroughly discussed at the June 2002 Board Hearing. Ultimately, the U.S. EPA came to the same conclusion that the long-term cohort studies were unaffected.

ARB and OEHHA staff based their recommendations on the best available science and on peer-reviewed scientific literature. In addition, there has been ample opportunity for public participation and comment, which has played a critical role in refining the recommendations. The decision to approve the recommendations presented to the Board at the June 20, 2002 meeting was not made in haste, but rather with careful review and consideration. In addition, the ARB is in communication with the U.S. EPA regarding the progress of the review of the national PM standards in order to facilitate an equivalent degree of health protectiveness.

b. Comment: The ongoing research on PM and health effects must unfold before action is taken to regulate PM. (PHALEN-WC73)

Agency Response: Research will always be ongoing; meanwhile, there have been hundreds of studies associating PM exposure with adverse health effects including many studies demonstrating adverse health effects at levels below the PM standards set in 1982. There is a significant cost to public health from further delays in updating this standard, which has not been reviewed since the early 1980s. Prudent public health policy dictates that these new standards be promulgated based on all available scientific evidence.

9. Environmental Justice

a. Comment: ARB cavalierly dispensed with commentor's environmental justice concerns by making generic claims that better standards are good for everyone. This shifts the responsibility to address environmental justice to the implementation phase of the pollution control process. (KLOC-WC72)

Agency Response: The commentor correctly pointed out that the ARB's approach, by law, is to separate the standard-setting process from the pollution management process. Only health-related scientific literature is considered when setting the ambient air quality standards. In this way, the standard-setting process is not unduly influenced by the feasibility of attaining the standards; the standards represent "healthy air." As presented in the health section of the staff report, staff reviewed studies which attempted to identify differential health effects of PM for different ethnic or socioeconomic groups. No studies were found that indicate any differential health effects.

During the development of control measures for the attainment of the standards, the ARB and the air districts will consider and address any disparate impacts of the proposed measures among different communities. The public will be notified of the rule development and adoption proceedings and invited to participate.

b. Comment: Staff's proposed PM standards failed to adequately incorporate ARB's environmental justice policy. (KLOC-WC72)

Agency Response: State law defines environmental justice as the fair treatment of people of all races, cultures, and incomes with respect to the development, adoption, implementation, and enforcement of environmental laws, regulations, and policies (Senate Bill 115, Solis; Stats 1999, Ch. 690; Government Code 65040.12(c)). The ARB recently developed policies consistent with the directives of State Law. Because ambient air quality standards define clean air, all individuals exposed to unhealthful levels of PM, regardless of ethnicity or income, would benefit from the proposed standards as progress is made towards attainment. Furthermore, determining the extent to which various communities within the state are exposed to PM, as well as development of strategies to address specific community exposures, will be considered when specific control measures are developed. As part of the ARB's commitment to achieving environmental justice and implementing its principles and policies, the process involving the development of implementation and control measures for the attainment of the standards includes an environmental justice component, which will be a detailed, public process involving all stakeholders and interested parties and which will further address related issues.

c. Comment: ARB dismissed commentor's environmental concerns by incorrectly characterizing the PM standards as "simply defining clean air," and that "all of California's communities will benefit from the proposed health-based standards..." (KLOC-WC72)

Agency Response: State law defines ambient air quality standards as specified concentrations and durations of air pollutants which reflect the relationship between the intensity and composition of pollution to undesirable effects (title 17 California Code of Regulations, section 70100). Hence, these standards define the upper limit of exposure to which there are no observable adverse health effects. All individuals that may be exposed to a higher level of PM10 or PM2.5 than those defined in the recommended standards in the staff report would benefit as progress is made toward attainment of these standards.

d. Comment: ARB and OEHHA staff should note that past modes of environmental regulation impose significant burdens on minorities. People of color and low-income communities are disproportionately exposed to air pollutants and so face disproportionately higher health risks. Thus, health protective standards should take this into account. (KLOC-WC72)

Agency Response: The ARB does recognize that current modes of regulation shall ensure that a disproportionate burden not exist for any individual regardless of race, culture, or

income. However, the ARB does not consider pollution management issues during the standard-setting process. Only the health-related scientific literature is considered and evaluated when setting the ambient air quality standards. The extent to which various populations within the state are exposed to PM will be considered when specific control measures are developed, including strategies and plans to reduce those exposures.

e. Comment: ARB disregarded its own risk assessment calculations, which showed that the proposed standards would still allow many deaths and serious illness. (KLOC-WC72)

Agency Response: Staff did not disregard its risk assessment calculations when it recommended the new levels of the PM standards. This comment refers to the estimates of health benefits from future PM air pollution reductions as presented in the tables in Chapter 9 of the staff report. These health benefit estimates are based on the quantitative results from major health studies that found associations between PM exposure and human health effects (morbidity and mortality). These same studies were the basis for choosing the level of the new proposed PM standards. Table 9-4 reflects estimated health benefits from attaining the new PM_{2.5} standard. Table 9-5 reflects total estimated health benefits based on reducing PM levels below the new proposed standards, down to background PM levels (or near background levels for PM mortality). Estimated health benefits in Table 9-5 are based on the mathematical dose-response for PM effects obtained from the major PM health studies and on the theoretical concept that there may not be a threshold for PM effects (an ambient PM level below which there would be no risk of a significant adverse health outcome). As discussed in section 7.3.5 of the staff report, many researchers have attempted to conduct analyses explicitly to determine thresholds but have failed to detect any. However, no epidemiological health study has found statistically significant health outcomes at levels below the new proposed standards. This, of course, was the basis for recommending the new proposed levels for PM standards. Therefore, these estimates of health benefits at levels below the new proposed levels of the standards are highly uncertain and cannot be the basis of the standards proposed. Staff based their recommendations on the best available science and believes the proposed levels adequately protect public health.

10. Public Outreach

Comment: Previous comments submitted to the ARB received only limited acknowledgement or no consideration. In addition, there has been limited public outreach and only two public workshops. An outreach and implementation plan should be developed, and should include Board hearings and public meetings throughout the state in order to receive public input and to allow sufficient time for consideration prior to the Board hearing. In addition, the ARB must include public outreach to educate citizens on the potential effects on their livelihoods after adopting the proposed standards. (ANDARY/FRENCH-WC38; BURNS-WC39; MODLIN-WC19; Opp-Form Letter-WC; SUCHECKI-WS8)

Agency Response: Comments that have been submitted to the ARB or OEHHA have been addressed at public meetings (e.g. AQAC meeting), workshops, or at the June 20, 2002 Board Hearing. In addition, public comments pertaining to the PM standard review have been thoroughly reviewed by staff, and where necessary and deemed appropriate, have resulted in modifications or changes to the staff report and PM recommendations presented to the Board. Therefore, staff does not believe that comments have received only limited acknowledgement or no consideration.

The standard review setting process has interwoven a well-developed plan and conscious effort into the ARB public outreach framework to ensure adequate public participation. Public outreach has involved dissemination of information through various outlets, including public meetings, workshop presentations, electronic "list-serv" notification systems, traditional mailing lists, and various web pages. Notification of the original draft staff report, including the schedule for public meetings and workshops, occurred on November 30, 2001. Subsequent public workshops were held in December 2001 in Oakland, Sacramento, Bakersfield, Mira Loma, El Monte, and Huntington Park, where the public was encouraged to participate through comments and discussion with ARB and OEHHA staff. In addition, public meetings of the Air Quality Advisory Committee (AQAC) were held in Berkeley on January 23 and 24, 2002, in Oakland on April 3, 2002. The public was invited to submit comments to the committee before and during these meetings. In addition, publication of the notice of the Board meeting and the staff report (ISOR) on May 3, 2002 opened the 45-day public comment period for this regulatory item and was followed by public workshops in June in Sacramento and El Monte. Public comments were accepted up to the June 20, 2002 Board Meeting, as well as by testimony during the meeting.

11. State Standards versus National Standards

a. Comment: Since both the State of California and U.S.EPA standards are based on the same body of literature, how can the ARB defend creating a different set of standards, and why are the standards so much more stringent? (ANDARY-WS3; ANDARY/FRENCH-WC38; MANDEL-WC13; CORY-WS5; WILLIAMS-WS7)

Agency Response: The standards are based on the ARB and OEHHA staff's review of the best scientific literature and evidence available. Overall, the same body of scientific literature is used in setting the national ambient air quality standards for PM. However, one important distinction between the state versus the national process is that the state process uses an approach based on the inclusion of an additional margin of safety in order to ensure public health protection for sensitive sub-populations such as children, the elderly, or those individuals with pre-existing illness. In addition, when constructing the rationale for a health-based standard, ARB and OEHHA focus on exposure and health information most relevant to California, which may differ from the focus of the broader national standard review program. In the sciences, as with many other disciplines, reasonable minds may derive somewhat different conclusions from the same data. The U.S. EPA has not yet proposed recommendations for new PM standards.

b. Comment: There is a lack of concordance between the PM10 and PM2.5 standards. Since it was shown that the proposed national PM10 and PM2.5 standards overlap and were found to be arbitrary and unlawful, why is ARB proposing such standards and continuing down this path? The ARB should work to harmonize the California and national PM standards, as well as consider a coarse particle standard (PM10-PM2.5) in place of the current PM10 standard to ensure that compatible and legal standards are established. (ANDARY/FRENCH-WC38; MANDEL-WC13; SUCHECKI-WS8; WILLIAMS-WS7)

Agency Response: The ARB adopted separate standards for PM10 and PM2.5 because adverse health effects have been observed for both pollutant mixtures. The fine particle component of PM10 (particles 2.5 microns in aerodynamic diameter and smaller) was selected for special consideration due to the adverse health effects attributed to the rates of penetration and lung deposition which differ from those of PM10. In both cases, the “specified concentrations” of either PM10 or PM2.5 reflect a relationship between the “intensity and composition” of the pollutants to identified “undesirable effects,” as required by sections 39606 and 29014 of the Health and Safety Code.

While PM10 by definition contains some particles of 2.5 microns or less, the percentages of the components in PM10 vary, and adverse health effects are associated with the composite range of particles. Since exposure to particles from 10 microns down to less than 0.1 micron can result in adverse health effects, it is appropriate to adopt an ambient standard for the entire PM10 size range. Likewise, since specific “undesirable effects” result from exposures to the subset of PM particles signified as PM2.5, it is appropriate to single these out for a separate health-protective ambient standard.

The ARB does not agree that the retention of a more stringent PM10 standard simultaneously with an adoption of a new PM2.5 standard results in “double regulation” despite a finding to that effect by the District of Columbia Court of Appeals in American Trucking Association v. U.S. EPA (1999) 175 F.3d 1027. First, the adoption of ambient air quality standards is an indicator of how much of a given pollutant can be considered unhealthy; it is not a regulation that, like an emission standard or limitation, requires any entity to limit its pollution. When control measures are adopted to address each standard, to the extent where there is synergy between the pollutants that are regulated, there will similarly be synergy between the emission reductions that are realized. Thus, for example, sources will not need to reduce NOx emissions (as particulate precursor) “twice,” since any reduction will benefit both PM10 and PM2.5 levels, though to different extents, depending upon such variables as the source of the particles (i.e., combustion source emissions are comprised largely of PM2.5 compared to, say, agricultural feedlot emissions).

The strategies that will reduce emissions of one pollutant mixture will be beneficial also on reducing emissions of the other. Rather than resulting in “double regulation,” the reductions will act synergistically to reduce ambient concentrations of both pollutants, and at the same time control measures can be tailored to address one or the other pollutant mix as the top priority. Without a separate PM2.5 standard, reductions in emissions sufficient to attain the PM10 standard would not necessarily be sufficient to reduce PM2.5 to the extent

necessary to prevent adverse health effects. Conversely, reductions sufficient to allow PM_{2.5} concentrations to fall within the ambient standard level may not result in sufficient reductions in health-harmful PM₁₀. While the ARB could have chosen to establish a PM_{10-2.5} “coarse” standard along with the PM_{2.5} standard, we do not believe we were required to follow this approach.

Second, individual components of generic pollutants are often separated out for additional or more specific control once enough is known about their health risks, physiochemical patterns, biological mechanisms and activity, and the like. Thus, certain metallic particles that compromise PM are also identified as toxic air contaminants, such as antimony, inorganic arsenic, and chromium VI, and nickel for example. While generic PM control measures will reduce concentrations of these particles to some extent, and vice versa, their unique characteristics justify separate treatment from a public health standpoint. Similarly, the large category of “reactive organic gases” (ROG) is subject to an ambient air quality standard because it is an ozone precursor. Nevertheless, even though reduction in ROG yield some reductions in volatile gases which happen to be separately listed as toxic air contaminants, the unique and serious health consequences of these individual toxic ROGs highlight the need to regulate these specifically. The fact that reducing these TACS also reduces total ROG does not mean regulation of both is “double regulation.” Rather, it means that the control strategies may be synergetic as well as ultimately reducing each TAC and total ROG below the scientifically-determined acceptable risk threshold.

12. Technical Issue – Stringency of Standards

Comment: The recommended standard levels are not stringent enough, and ignore studies that the levels should be set lower than those recommended. The standards should be reconsidered and revised downward. Consequently, we request that the ARB promulgate standards that contain a margin of safety in addition to those already considered and recommended by the staff, and at levels that protects all individuals. It would be better to promulgate overly stringent criteria and then adjust them upward five years hence, in the event that the new scientific data support a more relaxed standard. (KLOC-WC72)

Agency Response:

An “adequate margin of safety” in standard-setting is understood to account and compensate for scientific uncertainty, as well as the lack of precise predictions regarding the health impacts of air pollutants on potentially susceptible subpopulations. Some of the relevant uncertainties in this instance would include potential health hazards that have not been identified, factors determining variability in response to PM among susceptible subpopulations, microenvironmental variability in PM exposure related to indoor penetration of PM, activity patterns, and geographic proximity to point and area sources. The incorporation of a safety margin has been recognized by the California Supreme Court

as integral to the process of promulgating ambient air quality standards [See *Western Oil and Gas Association v. Air Resources Board*, 37 Cal.3d, 502 (1984)].

Using the current epidemiological data and analytic techniques, researchers have been unable to detect a level of PM exposure below which no adverse health effects would ever be expected to occur, which creates substantial uncertainties in the prediction of health impacts of low-level PM exposure. To the extent that health effects associated with ambient PM have occurred at relatively low levels of exposure, and that there is substantial inter-individual variability in response to environmental insults, it is difficult to promulgate any PM standard that will provide universal protection for every individual against all possible PM-related effects.

Nevertheless, taking into account the current knowledge regarding the health impacts of PM, the limitations of the scientific data and the methods available to analyze this data, as well as variability in real-world exposures and human responses to PM, we have applied the concept of an adequate margin of safety by recommending multiple standards that, in combination, should protect nearly all of the California population, including infants and children, against PM-associated effects throughout the year. We have reviewed the available scientific literature and proposed standards that, when attained, will avoid exposures that have been reported to produce health effects in scientific peer reviewed published studies.

It should be noted that standards are defined by law to “adequately protect” (Health and Safety Code 39606(a)(1)) public health, and do not require an absolute zero level of risk. Staff based their recommendations on the best available science and believes the proposed levels adequately protect public health. Recommendations were limited to the annual standards, which staff believe allow for an adequate margin of safety. Furthermore, multiple health-protective standards (e.g. the PM10 annual and the current PM10 24-hr; the annual PM2.5) should provide an additional layer to the margin of safety, ensuring adequate protection against both acute and chronic effects for the vast majority of the population, including susceptible subgroups. As substantial pertinent new scientific data become available, the standards will be reevaluated as required by title 17, California Code of Regulation, section 70101.

13. Comments in Support of Proposed Regulations

Comment: We support the standard levels recommended by staff in the May 3, 2002 report because they will ensure public health protection across the State. We also support the enforcement of any new standards approved by the Board. Therefore, we urge the Board at the June 20, 2002 meeting to adopt the proposed standards. (Supp-Form Letter-WC; ALVIS-WC54; ARUMUGHAM-WC16; AUDERSON-WC51; AUKER-WC24; BAGATTI-WC7; BAGATTI-WC8; BERGEN-WC66; BLOSE-WC49; BORNSTEIN-WC42; CORTEZ-WC63; CRAIG-WC55; CURNETT-WC58; DASHE-WC35; DERKSEN-WC61; ELLIOT-WC18; EVANS-WC50; FERRIS-WC11; Supp-Form Letter-WC; GARDNER-

WC20; GARVEY-WS6; HACKER-WC25; HAMMERQUIST-WC31; HARRISON-WC27; HEANEY-WC9; HETTLER-SMITH-WC23; HOLMES-GEN-WC70; JENSEN-WC32; KERR-WC21; KHALSA-WC46; KRINOCK-WC45; KUNECK-WC71; LANDSHOFF-WC53; LEE-WC33; LEE-WS9; LIFSON-WC64; LUI-WS2; LOUGEE-WC15; MEANS-WC59; NIKOLOFF-WC40; PETREE-WC3; ROSEN-WC14; ROSESTONE-WC6; SCHNEIDER-WC43; SCRUGGS-WC48; SHARP-WS12; SIEKMANN-WC65; SMITH-WC12; SMITH-WC22; SMITH-WC52; SODERBECK-WC68; STERN-WS13; TAM-WC26; TROUT-WC10; WALKER-WC5; WALLERSTEIN-WS1; WINHOLTZ-WC2)

Agency Response: Thank you for your comments. The ARB and OEHHA have worked diligently and will continue to do so in order to ensure that the standards remain protective of public health.

14. Withdrawal of Support for Short-Term (24-hour) PM Standards

Comment: Recent findings reported by the Health Effects Institute (HEI) on statistical issues associated with short-term, time series studies and their analyses, have demonstrated that some published results were erroneous. The source of the error was misapplication of statistical software in some, but not all, of the relevant time series studies. This error would not have affected the analyses of studies of health effects from long-term PM exposure, which were used in establishing annual average standards. The Air Quality Advisory Committee (AQAC) withdraws its endorsement of the new short-term standards until the short-term studies are reanalyzed and evaluated. (KLEINMAN-WC41)

Agency Response: Thank you for your comment. The ARB and OEHHA appreciates the work and effort undertaken by the AQAC during the standards review process. As a result of these recent findings and staff's evaluation of these findings, as well as the withdrawal of AQAC support of the short-term standards, there was a change in the scope of the proposal at the June 20, 2002 public hearing.

Specifically, staff withdrew their proposal to establish a 24-hour-average PM_{2.5} standard, and this was not considered at the public hearing. The associated proposed regulatory text that was also removed from consideration in this process was the level for the PM_{2.5} short-term standard. The removal of this text was made available and referenced in the 15 day "Notice of Public Availability of Modified text for Ambient Air Quality Standards for Suspended Particulate Matter and Sulfates. Currently, staff is monitoring the re-evaluation process of the affected short-term studies, and any staff recommendations on short-term PM standards will be brought before the AQAC for peer-review.

15. Insufficient or Inconsistent Scientific Basis

a. Comment: The proper air metric, or measurement basis, for health effects associated with particulate matter is unknown. (PHALEN- WC73)

Agency Response: The consistency of results among scores of epidemiological studies provides substantial evidentiary support for causality. The ranges of risk estimated in all these studies have been remarkably similar, despite the different PM source mixtures and size distributions, co-pollutant distributions, weather patterns, and population characteristics (see Section 7.3 of the May 3, 2002 staff report, for example). Daily mortality and morbidity have been linked with different measures of PM as well, including TSP, PM10, PM2.5, the coarse fraction (PM10-PM2.5), black smoke, and ultrafine particles. It can be seen in Table 7.1 and Sections 7.3 through 7.6 that, with very few exceptions, point estimates of relative risk are consistently greater than unity. If these findings were due to chance, one would expect a more nearly equal distribution of point estimates of risk above and below unity. In general, consistency of results across scores of investigations offers one of the strongest arguments favoring a causal relationship for different measures of particles.

In the absence of a full understanding of the biological mechanisms of particle-associated health effects, it is not possible to designate which physico-chemical characteristics of particle subclasses would be the most important to regulate. However, it is abundantly clear that PM10 and PM2.5 have been linked with morbidity and mortality in many different settings. Recognizing that these size fractions are of variable composition, with some sub-fractions likely to be more important toxicologically than others, there is nevertheless more than enough evidence that reducing exposures to these PM classes will result in major health benefits in California. Future research may provide a basis for focusing on one or more different PM metrics; however, to refrain from action waiting for a speculative “optimal” PM regulatory metric would represent abandonment of the goal of protecting the public against well-established exposures.

b. Comment: The scientific database supporting the proposed air quality standards is exceptionally weak and inconsistent and therefore it is not possible to draw rigorous or defensible conclusions from it. In addition, there are studies that show no associations between PM exposure and mortality in California. (PHALEN-WC73; HEUSS-WS4)

Agency Response: The proposed standards have undergone rigorous peer review by AQAC (see comment 1), a blue-ribbon panel of academic experts recommended by the Office of the President of the University of California. While different reviewers may give differential weighting to the scientific evidence, the commentor’s observations are at variance with those of the AQAC, which endorsed the staff recommendations for ambient air quality standards after a thorough review of the scientific foundation.

The most consistent aspect of the acute epidemiology results is the identification of statistically significant PM effects on mortality in a large number of studies conducted in over 100 cities in the U.S. as well as many in other countries. Not surprisingly, risk coefficients reported from different locations vary somewhat. This may relate to variations in pollutant mixes, population characteristics, and analytic methodologies across the wide range of studies reported to date. As a group however, the acute mortality studies and, to a lesser extent, the morbidity studies present a consistent picture regarding the effects of

PM on health. The consistency of results among scores of epidemiological studies provides substantial evidentiary support for causality. Several hundred studies, conducted among different populations on five continents over multiple time periods, have reported small, but consistently elevated risks of daily mortality and diverse measures of morbidity (such as hospital admissions and emergency department visits for cardiac and respiratory causes, exacerbation of asthma, increased respiratory symptoms, restricted activity days, school absenteeism, and decreased lung function). Though the principal study design has been time-series analysis, modeling approaches have differed substantially among investigators. Moreover, similar estimates of effect have been obtained with other study designs, including case-crossover and panel studies.

With regard to studies showing no associations between PM exposure and mortality in California, risk coefficients reported from different locations vary, which may be due to variations in pollutant mixes, population characteristics, relative exposure misclassification, and analytic methodologies across the wide range of studies reported to date. As a group, however, the acute mortality studies and, to a lesser extent, the morbidity studies present a consistent picture regarding the effects of PM on health. We have summarized the studies in the staff report and have indicated that not all have reported statistically significant associations. It should be noted, however, that at least a half-dozen time-series and panel studies in California have reported statistically significant associations between one or more PM metrics and adverse health outcomes. We believe it is important to be health-conservative when recommending safe levels of air pollution.

c. Comment: The staff report does not provide a thorough scientific evaluation or sufficient justification for the levels selected. In addition, there is considerable concern with the scientific basis of the standards as reiterated by Dr. Phelan's comments in item 15a, above, that the data supporting the standards are weak. Furthermore, there is a minimal discussion of uncertainties as well as the presence of contrary evidence in the staff report. (ANDARY-WC29; HEUSS-WS4; MANDEL-WC13; STAHL-WC67)

Agency Response: The ARB acknowledges your concerns. However, the recommended standards are based on the review and evaluation conducted by OEHHA and ARB staff of the best scientific evidence available. This evaluation was both thorough and complete, with a detailed scientific evaluation presented in the May 3, 2002 staff report. Furthermore, the findings and their scientific bases were reviewed by AQAC (see comment 1), the external peer review advisory committee, in two public meetings. The findings of the committee were made available to the public and were incorporated into the May 3, 2002 staff report to ensure that the proposed recommendations are based on sound scientific evidence and protect public health.

Although the preponderance of evidence in the published literature supports an association between exposure to PM and adverse health effects, contrary evidence (null studies) exist and were included in our review of the evidence. Our aim was not to generate an exhaustive review of all of the literature (as provided in U.S. EPA's Criteria Document). Rather, we aimed to provide a focused review that would capture a sense of the weight of

evidence. We also attempted to provide the scientific reviewers and the public with a sense of what were the key uncertainties. For example, we discussed the lack of a clear understanding of the biologic mechanisms and the lack of clear epidemiologic evidence about ultrafine particles and other components of the PM mix.

In addition, the ARB, as well as other agencies and institutions are focusing their research efforts on characterizing and identifying which specific components of PM may be significant from a health standpoint. During the next standard review, new information will be reviewed and incorporated into the process.

d. Comment: ARB should focus its research program on identifying which specific components of PM need to be further reduced. (HEUSS-WS4)

Agency Response: There is an ongoing debate over whether toxicity is more related to particle size, mass, number and specific constituents. More research is clearly necessary. Any new information on this issue will be incorporated into ARB policy and standards development over time. However, it is generally accepted among researchers that combustion-related particles (e.g., diesel) are toxic. Among the lines of scientific evidence supporting this observation include: (i) PM₁₀ and PM_{2.5} deposit throughout the lung and are retained in large quantities, though the fractional deposition and retention differ by size, chemical composition, hygroscopicity, electrostatic charge, as well as by individuals' breathing patterns, pulmonary anatomy, pre-existing lung disease, and other factors; (ii) they are linked in controlled exposure studies with lung inflammation; (iii) they can penetrate into residences and other buildings in which people spend most of their time; (iv) there are many epidemiological studies demonstrating associations with daily morbidity and mortality.

e. Comment: Regional differences in PM effects should be evaluated prior to setting standard. (HEUSS-WS4)

Agency Response: From the prospective cohort studies, on which the annual standards are based, there are not sufficient data from California alone to effectively test for state-specific effects. The region classified as "West" included cities in the Northwest (which included Northern California), Southern California, Southwest, and upper Midwest. Therefore, the ACS reanalysis does not supply information on a California-specific result. Results for California from Abbey et al (1991, 1999) and McDonnell et al (2000), however, do support an association between long-term exposure to PM and increased mortality.

f. Comment: The ACS study shows stronger health effects associated with SO₂ than PM—how is this accounted for? (HEUSS-WS4)

Agency Response: While the PM_{2.5} risk estimate was decreased in the Krewski et al. (2000) sensitivity models that also included SO₂, this should not be interpreted as necessarily signifying that the PM_{2.5} effects are actually smaller than the single-pollutant models indicate. The inclusion of correlated variables in a regression at the same time,

such as SO₂ and PM_{2.5} in the case of the Krewski et al. sensitivity analysis, violates one of the basic assumptions underlying regression models -- i.e., that the predictor (x) variables are independent, so the effect estimates are biased by the inter-correlation among the "independent" variables. The likely reason that SO₂ and PM_{2.5} are so correlated spatially is that they both are predominantly derived from a common source: fossil fuel combustion. This largely shared-source aspect of PM_{2.5} and SO₂ in the U.S. makes it very difficult for simultaneous regressions (e.g., those conducted by Krewski et al., 2000) to "partition" their respective effects. Thus, finding that the PM_{2.5} effect estimates change with the inclusion in the model of a correlated variable such as SO₂ would not be unexpected. The new estimate based on the multi-pollutant model is not necessarily more accurate. Having two correlated variables in the model at the same time violates the underlying regression model assumption of independent (i.e., uncorrelated) predictor variables, which almost certainly biases the effect estimates in relation to the true magnitudes of effect.

Indeed, in the HEI Report (Krewski et al., 2000), the original research authors note (on page 275) that: "We understand the inappropriateness of estimating many alternative statistical models that use many combinations of often correlated variables while searching for a preferred result or a statistical explanation for a disavowed result. We know that the Reanalysis Team, Expert Panel, Advisory Board, and Review Panel also understand the inappropriateness of such an approach. But, of course, it is hard to know when to stop. A systematic and skillful estimation of dozens (maybe even hundreds) of alternative statistical models with different variables and combinations of variables, even when it is done in the name of sensitivity analyses, will ultimately produce spurious associations."

It should also be noted that in two-pollutant sensitivity models, the relative risk estimates for PM_{2.5} by Krewski et al. (2000) still fell within the 95% confidence intervals of the single-pollutant model estimates. As these estimates were still greater than 1.0, the PM_{2.5} effect estimates, though diminished for statistical reasons as discussed above, were not significantly changed by the addition of SO₂.

Overall, the statistical importance of SO₂ in the Krewski et al. (2000) sensitivity results seems unlikely to represent a direct effect of SO₂ per se. Rather, it is likely that SO₂ is an indicator for fossil fuel combustion-related pollutants. In fact, the HEI Report (Krewski et al., 2000) notes (on page 233) that "The absence of a plausible toxicological mechanism by which sulfur dioxide could lead to increased mortality further suggests that it might be acting as a marker for other mortality-associated pollutants". In addition, as we discussed in the recommendations, Sarnat et al. (2001) has shown that there is little association between ambient measurements of SO₂ and subsequent personal exposure.

g. Comment: As you may know, the Health Effects Institute (HEI) released a study containing various inaccuracies due to an error contained in the HEI's National Morbidity, Mortality and Air Pollution Study (NMMAPS). In light of the inaccuracies found in NMMAPS, I urge you to remove the agenda item from the June 20, 2002 meeting. Further complicating the matter is the uncertainty of the federal standards and CARB's failure to provide and economic analysis. Should CARB move forward as planned. California could

be held to a more stringent PM 2.5 standards than the federal standard. Clearly, at a minimum, the NMMAPS discrepancy must be resolved before taking further action. Again, I urge you to postpone the subject matter until the study is corrected and a complete economic impact study are provided.

Agency Response: Chairman Alan Lloyd responded fully to the commentor in a letter dated June 12, 2002, which is set forth as Appendix A.

16. Comments Not Germane to This Regulatory Item

a. Attainment and Control Issues:

Comment: The staff report should include a discussion of attainment issues, and the implications of setting non-attainable standards. In addition, ARB policy should be revised with regard to consideration of abnormal events and their role in determining attainment under the new standards. Several districts request a review of the current statistical method the ARB uses for determining attainment and year-to-year violations, including a review of ARB policy on consideration of abnormal events data. (ANDARY/FRENCH-WC38; LEE-WC62; REYNOLDS-WC60)

Agency Response: The standards are based on health and welfare effects, and while the staff report does include the potential health benefits attributable to attaining the proposed standards, it does not evaluate attainment, control and planning strategies. These activities will occur in a separate public process with input from all interested parties and stakeholders. The staff report does define the basic “form” of the proposed standards including the recommended concentration, the monitoring method used in order to measure the pollutant, the averaging period (for example annual arithmetic mean), and the description of “not to be exceeded” which gives a sense as to what will be needed in order to determine attainment. For example, the annual PM10 standard is defined. Valid concentrations, based on current definitions, that may be affected by unusual or abnormal events but that are below the level of the 24-hour State standard, will be considered as data of record. However, the impact of these unusual or abnormal events will be taken into consideration when the data are used in any regulatory process such as designations or control strategy development.

b. General Comments

Comment: I am very much in favor of reducing gas, oil, and coal consumption and would like to help. In addition, staff should find corroborative data for the benefits that recycling will have on reduction of all pollution (air pollution implied) (TAM-WC26).

Comment: Commentor performed research on the removal of sulfur from gasoline and the addition of ethanol and is willing to do further research on fuel oxygenates. (MORRIS-WC57)

Comment: Standards, including the PM standards, will not be effective unless the ARB deals with sport utility vehicles (SUVs), old cars, and better public transportation. (AL-WC17)

Agency response for previous three comments: Ambient air quality standards simply define acceptable levels of air pollution. Possible ways to achieve the proposed air quality standards will be considered at subsequent Board meetings and by the air districts.

Comment: The ARB should increase the level of monitoring, emission control measures, and enforcement of the standards, particularly in poor and non-anglo neighborhoods. (SHARP-WS12)

Agency Response: As part of the ARB's commitment to achieve environmental justice and to implement its principles and policies, the control measures development process for the attainment of the standards will include an environmental justice component, which will involve all stakeholders and interested parties. As part of that process, monitoring, control, and enforcement of the standards will be discussed and implemented.

**C. Summary of Comments Received During the 15-Day Comment Periods
August 15-29, 2002 and October 9-25, 2002**

Table IIIb. Comments from 15-day periods

Comment Code*	Commentor	Organization	Date Received
CORTEZ-15D-WC1	Cortez	American Lung Assoc.- San Diego/Imperial County	8/22/2002
CORTEZ-15D-WC2	Cortez	American Lung Assoc.- San Diego/Imperial County	8/28/2002
STENBERG-15D-WC3	Stenberg	Citizen	8/29/2002
ANDARY & DOUGLAS-15D-WC4	Andary & Douglas	Alliance of Auto. Manufacturers	8/30/2002
LANANE-15D-WC5	Lanane	Great Basin Unified APCD	8/30/2002
HENDRY-15D2-WC1	Hendry	Citizen	10/15/02

*Notes:

15D = first 15-day notice comment period (August 15-30, 2002)

15D2 = second 15-day notice comment period (October 10-25, 2002)

WC = written comment(s) during 15-day periods

On August 15, 2002 the ARB made available a “Notice of Public Availability of Modified Text,” which provided the necessary revised regulatory language to delete proposed text for a 24-hour PM_{2.5} standard in section 70200, title 17, CCR. Additionally, on October 10, 2002 ARB made available a second “Notice of Public Availability of Modified Text” to include additional samplers to section 70100.1, title 17, CCR, entitled “Methods, Samplers, and Instruments for Measuring Pollutants.” The comment periods ended August 30, 2002, and October 25, 2002, respectively.

The ARB received a total of 6 comments during the two noticed periods, which are as listed in Table IIIb, above. Comments were received on the following issues: urging the completion of the short-term, 24-hour standard reviews; the effect of standards concentrations that approach “background” levels; the need for harmonization of state and national standards and the difficulties that may arise due to fundamental differences in the approaches; the need for ARB to participate in the national review process; and the effects of recent issues with the statistical models used in the evaluation of short-term studies.

These comments, with ARB responses, are arranged by topic. Also note that comments received from three of the individuals listed above (LANANE-15D-WC5; HENDRY-15D2-WC1; STENBERG-15D-WC3) were deemed by staff to be not relevant to the proposed modifications as identified in the notices and were therefore not addressed.

Comments and Agency Response(s):

1. Clarification of Standards

Comment: Is it true that the ARB’s modified text to Attachment B meant that there would not be a 24-hour PM_{2.5} standard of 25 µg/m³? Is it true that the only ARB standard proposed is a 12 µg/m³ PM_{2.5} annual arithmetic mean standard? (CORTEZ-15D-WC2)

Agency Response: Correct. No 24-hour PM_{2.5} standard of 25 µg/m³ was considered by the Board because the results of the key short-term studies may be affected by the misapplication of statistical software. The 12 µg/m³ PM_{2.5} annual arithmetic mean standard was the only new standard proposed. However, the ARB also approved a modification to the concentration and form for the PM₁₀ annual standard of 20 µg/m³ not to be exceeded, as well as modifications to the monitoring methods for PM₁₀ and sulfates.

2. Background Levels

Comment: The Board asked for a discussion of background PM levels, which relate to the attainability of the standard. A follow-up report to the Board should compare the form of the standard and attainment test. (ANDARY & DOUGLAS-15D-WC4 a)

Agency Response: This comment does not pertain to the subject matter in the 15-day public notice. Regarding a follow-up report to the Board, staff will provide information on background PM_{2.5} and PM₁₀ levels to the Board at a future time. However, state law

defines an ambient air quality standard as a specified concentration and duration of an air pollutant which reflects the relationship between the intensity and composition of the pollutant to undesirable effects (title 17 California Code of Regulations, section 70100). Attainment of the standards is addressed in a separate process.

3. Harmonization of State and National Standards

Comment: A federal court ruled that national PM2.5 and PM10 standards overlap. Harmonization between the California and national PM standards will not be possible due to federal court decisions, unless California considers revisions. In effect, U.S. EPA is prohibited from harmonizing with California by adopting the State's PM10 standards, and attempts at harmonization – without California considering revisions – will not be successful. (ANDARY & DOUGLAS-15D-WC4, b)

Agency Response: This comment does not pertain to the subject matter in the 15-day public notice. In response to the issue of overlapping standards as well as harmonization with the national process, please refer to the agency response to comment 11b (Section IIIB). The ARB does not believe it was required to follow the approach taken by the national standard setting process where a separate coarse (PM10-PM2.5) and fine (PM2.5) standard are being considered (although not yet proposed). However, the Air Resources Board staff attempts to harmonize national and state air quality standards to the extent possible. If complete harmonization is not possible, the Board is still required to take action to protect public health. Such action, however, does include input from the public, the Air Quality Advisory Committee, and the U.S. EPA, as well as other interested parties, to ensure that the bases are founded on sound science and adequate public health protection.

4. California's Coordination with CASAC and Statistical Issue Review

Comment: Supports the effort to coordinate with other interested parties as well as update the Board on the results of the CASAC proceedings. The ARB should coordinate its review of the impact of the statistical issues with the U.S. EPA and CASAC before establishing additional PM standards. This will also maximize the likelihood of harmonizing health-protective state and national standards. (ANDARY & DOUGLAS-15D-WC4, c)

Agency Response: This comment does not pertain to the subject matter in the 15-day public notice. However, the ARB and OEHHA staff have been consulting with U.S. EPA regarding activities by their staff and the CASAC regarding any significant issues, including but not limited to the mentioned statistical issues, in an attempt to harmonize standards to the extent possible. However, if harmonization is not possible, the Board is still required to take action to protect public health.

5. PM2.5 Standards

Comment: The proposed annual PM2.5 standard will be more protective of public health than the national PM2.5 standard, especially for sensitive populations such as asthmatic children. The ARB should approve the 24-hour PM2.5 standard at the 25 µg/m³ level, in order to protect citizens from unhealthy acute exposures. (CORTEZ-15D-WC1)

Agency Response: The Board approved the annual PM2.5 standard. The Board deferred consideration of the 24-hour PM2.5 standard, due to statistical issues that emerged shortly before the Board hearing. In 2003, the ARB staff intends to update the Board on the status of a possible review of 24-hour standards for PM2.5 and PM10 in light of recent issues.

6. No Response Needed

a. Comment: The May 3 staff report recommended adoption of the Federal Reference Methods (FRM) for PM10 as the monitoring method for California, allowing for alignment of State and Federal methods for PM monitoring with all federal samplers. However, the proposed new section 70100.1 does not include all Federal methods for PM10 monitoring. The District requests the ARB reconsider the list of approved methods for PM10 and PM2.5 particulate monitoring and allow the use of any FRM monitor/sampler for collection of PM data to meet the requirements of the State of California PM standard. (LANANE-15D-WC5)

Agency Response: This comment was in response to the first modification, which was noticed on August 15, 2002, pertaining to the deletion of the proposed 24-hour PM2.5 standard. ARB's notice stated that only comments relating to the proposed modified text (section 70200) would be considered. This comment concerns another section of the proposed modified text (section 70100.1), and so cannot be considered.

b. Comment: Based on the statistical issues that influence the PM time-series studies, support was expressed for the decision to delete the proposed 24-hr PM2.5 standard. (ANDARY & DOUGLAS-15D-WC4, d)

Agency Response: Thank you for your comment.

c. Comment: The ARB should consider a solution to the poor quality of our air. KLEENAIR SYSTEMS, Inc. of southern California has a product that eliminates up to 75% of emissions from automobiles, trucks and buses. The ARB should also consider control or ending of agricultural waste burning as a means to lower PM levels. (STENBERG-15D-WC3; HENDRY-15D2-WC1)

Agency Response: Ambient air quality standards simply define acceptable levels of air pollution. Possible ways to achieve the proposed air quality standards may be considered at subsequent Board meetings.

APPENDICES

- A. Response to The Honorable Kevin Murray from Chairman Alan C. Lloyd**
- B. Resolution 02-24**

APPENDIX A

APPENDIX B