State of California
AIR RESOURCES BOARD

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

PUBLIC HEARING TO CONSIDER AMENDMENTS TO THE AMBIENT AIR QUALITY STANDARD FOR OZONE

Considered On: April 28, 2005
Agenda Item No: 05-4-1

I. GENERAL

“The Initial Statement of Reasons for the Proposed Rulemaking—Review of the California Ambient Air Quality Standard for Ozone" (ISOR; also referred to as “the staff report”) was released March 11, 2005, 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, provides a description of the rationale and necessity for the action proposed. The purpose of the regulation is to update California’s ambient air quality standard for ozone so that it accurately reflects the current body of peer-reviewed literature on related adverse health effects and provides adequate health protection for the citizenry of California—including that of infants and children as well as other sensitive sub-populations. The action consisted of amendments to sections 70100, 70100.1 and 70200, title 17, California Code of Regulations (CCR) concerning ambient air quality standards for ozone, and the ARB document titled "Air Monitoring Quality Assurance Manual Volume IV”, which is incorporated by reference in section 70100.1.

On April 28, 2005, 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 to the ISOR/staff report that staff recommended to address issues raised during the preceding 45 days of the public comment period. At the conclusion of the public hearing, the Board adopted Resolution 05-31 and approved the regulation as originally proposed. On October 27, 2005, ARB made available a “Notice of Public Availability of Modified Text,” which provided the revised language to the ISOR/staff report for the required 15-day public comment period. During the public comment period no comments were received.

As unanimously approved by the Board, the regulation modifies the standard for ozone. The newly approved 8-hour average standard is 0.070 parts per million (ppm), not to be exceeded.

The Board further found that the existing 1-hour standard for ozone should be retained at 0.09 ppm. In addition, the Board retained the existing monitoring methods for these standards.

The Board also made conforming changes to the portions of section 70100 to remove the approved monitoring methods for particulate matter less than 10 (PM10) and less than 2.5 (PM2.5) microns in diameter, and to section 70100.1 to remove the list of approved samplers for PM10, PM2. Section 70100.1 was further modified to:

(1) Set forth the Federal Reference Method for the Determination of Particulate Matter as PM10 in the Atmosphere (40 CFR, Chapter 1, part 50, Appendix M, as published in 62 Fed. Reg., 38753, July 18, 1997) as that to be employed in California. California Approved Samplers for PM10

are set forth in "Air Monitoring Quality Assurance Manual Volume IV, Part A: Monitoring Methods for PM10," which is incorporated by reference.

(2) Set for the Federal Reference Method for the Determination of Particulate Matter as PM2.5 in the Atmosphere, 40 CFR, part 50, Appendix L, as published in 62 Fed. Reg., 38714, July 18, 1997 and as amended in 64 Fed. Reg., 19717, April 22, 1999 as that to be employed in California. The samplers listed in the Federal Reference Method must use either the WINS impactor or the U.S. EPA-approved very sharp cut cyclone (67 Fed. Reg., 15566, April 2, 2002) to separate PM2.5 from PM10. California Approved Samplers for PM2.5 are set forth in "Air Monitoring Quality Assurance Manual Volume IV, Part B: Monitoring Methods for PM2.5," which is incorporated by reference,

(3) The method for determining compliance with the ozone ambient air quality standard shall be the Federal Reference Method for the Determination of Ozone in the Atmosphere (40 CFR, part 53, as published in 62, Fed. Reg., July 18, 1997). California Approved Samplers for ozone are set forth in "Air Monitoring Quality Assurance Manual Volume IV, Part C: Monitoring Methods for Ozone", which is incorporated by reference.

The Board further approved modifications to Section 70100 (Definitions) and Section 70100.1 (Methods, Samplers, and Instruments for Measuring Pollutants), that delete lists of California Approved Samplers for PM10 and PM2.5, and replace these with reference to the California Air Resources Board's Air Monitoring Quality Assurance Manual, which lists monitoring methods. These changes will enable the Board to modify approved sampling methods separately from the consideration of future ambient air quality standards. The Board also approved a modification to Section 70200 (Table of Standards) to correct typographical errors for the PM10 standards that clarify that these standards are violated when concentrations exceed those set forth in the body of the regulation.

Update of Information Contained in the Initial Statement of Reasons and Summary of Modifications: During the 45 day public comment period on the proposed amendments, several letters or emails were received. The ARB staff also met with those persons attending public workshops held in Sacramento and El Monte during April 2005 to discuss the regulatory proposals. In addition, the Air Quality Advisory Committee (AQAC), which is the body that peer reviews ambient air quality standards, held public meetings on the scientific basis of the proposed regulatory items in January 2005.

After considering the written and oral comments, and deliberating the issues raised in public comments and at the hearing, the Board adopted Resolution 05-31, in which it approved the proposed amendments. The Board directed staff to develop revised text for several parts of the staff report/ISOR. All of the Board's directives were addressed in the revised text. While most of the

comments from the public were accommodated in the modifications to the staff report; several were not because they were deemed not relevant. Staff's reasons for not accommodating these comments are provided in the responses to comments contained in this document.

Availability of Modified Text and Additional Documents and Information: In response to comments received during the 45-day comment period, staff revised the assessment of the public health impacts associated with current levels of ozone compared to at attainment of the proposed standards in California from that presented in the ISOR/staff report, and presented the revised analysis to the Board at the public hearing on April 28, 2005. The commenters requested that staff present an analysis that compared the level of health protection provided by the federal ozone standard with the State one-hour standard and the proposed eight-hour standard. The Board directed staff to revise the staff report to incorporate the revised health impacts analysis, and make it available for a 15-day public comment period. The revised sections of the staff report were made available in a "Notice of Public Availability of Modified Text," dated October 27, 2005, which provided the revised health impacts analysis, and corresponding changes to the Executive Summary (Chapter 1), and Overview and Staff Recommendations (Chapter 2) of the staff report. Staff also corrected typographical and formatting errors in the staff report reference lists.

The modified text, with the changes to the originally published text clearly indicated, was mailed in accordance with section 44 of title 1, California Code of Regulations. The modified text was also posted on the ARB website. Pursuant to Government Code section 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 period ended November 11, 2005.

No comments were received during the 15-day comment period, and the Executive Officer issued Executive Order R-06-002 adopting the regulations as approved by the Board.

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 direct environmental or economic impacts. Section 39606(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 and air quality management districts are required to adopt 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, consumer products and several other categories of sources. A number of different control measures are possible, and each will have it own environmental and economic impact. The environmental and economic impacts associated with the implementation of future control measures will be considered by the ARB or the air districts when specific measures are proposed for adoption and public comment.

Mandate on Local Agencies or School Districts: The Board has determined that this regulatory action will not result in a mandate to any local agency or school district the costs of which are reimbursable by the state pursuant to part 7 (commencing with section 17500), division 4, title 2 of the Government Code.

Consideration of Alternatives: Pursuant to Government Code section 11346.7(b)(4), the Board has determined that no justifiable, scientifically-based alternative considered by the agency would be more effective in carrying out the purposes 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 current body of scientific literature and therefore is not sufficiently justified.

Correction to Reference Title. There is one correction to the reference title in the ISOR. The correction concern the difference between the title of the reference copy, submitted with the ISOR, and the title cited in the ISOR reference lists. The correct title for reference #121 is as follows, with the corrections in **bold** type:

Wiley JA, Robinson JP, Cheng YT, Piazza T, Stork L, Pladsen K. 1991a. **Study of Children's Activity Patterns**. Final report, ARB contract A733-149.

II. SUMMARY OF COMMENTS AND AGENCY RESPONSES

Table 1: Summary List of Comments

Issue	Comment
1.	California does not meet the current federal or State ozone standards. Addition of a State 8-hour standard that is lower than the federal standard will lead to more standard exceedances. (Raised by commenter 1)
2.	The public health benefits of attaining the proposed standards are too small to justify the high economic costs that will be incurred to achieve attainment. (Raised by commenters 1, 2, 4, 6, 7, 8)
3.	The current statewide public health impacts of ozone exposure are not sufficiently large as to justify changing the current State ozone standard. (Raised by commenters 1, 2, 4, 8)
4.	The ARB has not considered the economic costs required to achieve attainment of the proposed standards as part of the ozone standard selection process. (Raised by commenters 1, 2, 6, 7, 9, 10, 12, 15, 16)
5.	The methodology used for assessing the public health benefits of attaining the proposed ozone standards is flawed because the biological mechanism(s) are unknown, and because the influence of other factors that are correlated with ozone levels (e.g., ambient temperature) can not be reliably separated from ozone-related effects. (Raised by commenter 1)
6.	Publication bias (the selective publishing of only studies with positive results) makes the epidemiologic database unreliable, and thus unsuitable for estimating the public health effects of ozone exposure. (Raised by commenter 1)
7.	Based on studies of personal exposure (the average concentration of a pollutant inhaled by a person integrated across the day, including both indoor and outdoor contributions), the average ozone concentration to which people are exposed is about half that of ambient levels. Standards should be based on personal exposure, not ambient levels. (Raised by commenter 1)
8.	Controlled human exposure studies should not use filtered air for the baseline comparison condition because no one is exposed to air that has no ozone in it. Instead, the baseline condition should be 0.04 ppm

ozone, since that is the background concentration put forward by ARB. (Raised by commenter 1)

9. Ground level ozone is beneficial to health, in that it protects against skin cancer and cataracts. Reducing ambient ozone through attainment of the proposed standards will lead to increases in these health endpoints. (Raised by commenter 1)

10. California Government Code 11346.3 requires that the ARB assess the potential of adverse impacts of proposed regulations on California businesses and individuals; however, the ARB did not present a cost-benefit analysis of the proposed ozone standard. (Raised by commenters 1, 2, 4, 6, 7, 9, 10, 12, 15)

11. The proposed ozone standards will damage health, welfare and quality of life because people will be made poorer due to increased costs required to attain the standards. (Raised by commenter 1)

12. The ARB should harmonize the State standards with the federal 8-hour average standard of 0.08 ppm. (Raised by commenter 1, 6)

13. Background ozone in the Central Valley of California is considerably higher than the 0.04 ppm value put forth by ARB; background ozone is at or above the level of the standards recommended. (Raised by commenter 1, 3)

14. The ARB has overstated the health effects of low-level ozone exposure by using a flawed methodology that uses an incorrect ratio to convert ozone concentrations between 1-, 8-, and 24-hour averaging times, and relies on data mining (selection of the statistical model that provides the answer wanted). Raised by commenter 1

15. The health benefits assessment presented in the staff report claims benefits for reducing ozone levels from current concentrations down to background (0.04 ppm). The ARB should not claim public health benefits for reducing ozone below the level of the standard, since ARB's definition of a standard is a "no effects" level. (Raised by commenter 1)

16. The staff report overstates the risk of children developing permanent lung function deficits with long-term ozone exposure in section 10.3.5 of the staff report. (Raised by commenter 1)

17. It is not biologically plausible that ozone exposure could increase the risk of developing asthma (section 10.3.6 of the staff report). **(**Raised by commenter 1)

18. The ARB used the wrong studies to estimate effects of ozone exposure on hospitalizations and emergency room visits because the studies were performed in areas with a different climate than California. The analysis should use studies from California or other places that have a similar climate as California. (Raised by commenter 1)

19. The Gent et al. (2003) analysis of respiratory symptoms attributable to ozone exposure suffers from publication and model-selection bias because the results are not biologically plausible, and the exposure assessment is flawed. (Raised by commenter 1)

20. The idea that ozone exposure could contribute to school absences is not biologically plausible. (Raised by commenter 1)

21. Controlled human exposure studies are not relevant because the ozone levels used are much higher than people's real personal ozone exposures. (Raised by commenter 1)

22. The incremental benefits of the proposed state standards should be compared to the federal standard and the current State standard, and should be presented in the staff report. (Raised by commenters 4, 6, 8, 9, 10, 11, 12, 13, 14, 15, 16)

23. The proposed standards are not attainable, and will require all human activity to cease. (Raised by commenter 6)

24. The health impacts assessment, based on epidemiology, should not form the basis for the 8-hour standard, and the epidemiologic findings should be removed from the list of scientific findings on which the standards were based (pgs. 1-5 and 11-29 of the staff report) because the epidemiologic literature is unreliable. (Raised by commenters 9, 10, 15, 16)

25. The ARB should schedule a public meeting to discuss the findings, assumptions, and methodology used for the new incremental benefits analysis. (Raised by commenters 17, 19)

26. The proposed standards are not adequately justified in the staff report. (Raised by commenter 8)

List of Commenters

Table 2 below contains the names and affiliations of persons who commented on the proposed staff report. The column labeled "Issue #" corresponds to the comment number set forth in Table 1, and 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. The form in which the comment was received by ARB is also listed in Table 2.

Table 2: Commenters on the Ozone ISOR

#	Comment Author	Issue(s) #	Written/Oral
1	Joel Schwartz, member of the public	1-21	Written
2	Paul Willhite, Smurfit-Stone	2, 4	Written
3	Thomas A. Cahill, member of the public	13	Written
4	Curtis Coleman, Southern California Air Quality Alliance	2, 10, 22	Written
5	Health Network for Clean Air (seven-member environmental coalition)	In favor	Written
6	Patrick Covert, Valero Energy Corp,	2, 4, 12, 22, 23	Written
7	Joseph Krkoska, Dow Chemical Co.	2, 4	Written
8	Sandy Galganski, Dow Chemical Co.	2, 22, 26	Written
9	Susan Smith, Plasti-Kote	4, 10, 22, 24	Written
10	Alliance of Automotive Manufacturers, et al. (endorsed by 19 trade associations)	4, 22, 24	Written
11	Shane Connolly, Smurfit-Stone	22	Written
12	Karen Jarrell, Smurfit-Stone	4, 22	Written
13	Douglas Raymond, National Aerosol Association	22	Written
14	Doug Dawson, Smurfit-Stone	22	Written
15	Madelyn Harding, Sherwin Williams	4, 22, 24	Written

16	Mary Metzner, Western Aerosol Information Bureau	4, 22, 24	Written
17	Steve Arita, Western States Petroleum Association	25	Oral
18	Stephen Ziman, Chevron Texaco	-	Passed on turn to speak
19	Steve Douglas, Alliance of Automobile Manufacturers	25	Oral
20	Charlie Peters, Clean Air Performance Professionals	Not related to regulation	Oral and written
21	Sujatha Jahagirdar, Environment California	In favor	Oral
22	Trisha Roth, MD, American Academy of Pediatrics	In favor	Oral and written
23	Jesse Marquez, Coalition for a Safe Environment	In favor	Oral
24	Diane Bailey, Natural Resources Defense Council	In favor	Oral and written
25	Bonnie Holmes-Gen, American Lung Association of California	In favor	Oral and written

Responses, by issue:

1. **California does not meet the current federal or State ozone standards. Addition of a State 8-hour standard that is lower than the federal standard will lead to more standard exceedances.** (Raised by commenter 1)

   Under California law, primary ambient air quality standards are health-based; thus attainability, and the number of likely standard exceedences, are not criteria for determining ambient air quality standards. Attainment of the standards, as well as implementation of control measures, is separate from the standard setting process. Standards define clean air (see Health and Safety Code 39014, which defines ambient air quality standards as "specified concentrations and durations of air pollutants which reflect the relationship between the intensity and composition of air pollution to undesirable effects established by the state board or, where applicable, by the federal government"). The health-based primary standards represent the State's clean air goal by defining maximum safe exposures. Thus, the number of exceedances is not relevant to determining whether or not a proposed standard is adequate to protect public health with an adequate margin of safety.

2. **The public health benefits of attaining the proposed standards are too small to justify the high economic costs that will be incurred to achieve attainment.** (Raised by commenters 1, 2, 4, 6, 7, 8)

   This comment is based on several incorrect assumptions. First, it is based on an incorrect understanding of what an ambient air quality standard is under California law. Standards define the maximum safe concentration for the selected averaging time, and thus represent clean air goals. State law does not authorize consideration of anything other than health and welfare effects in setting ambient air quality standards (health effects are addressed in "primary" ambient air quality standards; welfare effects are addressed in "secondary" ambient air quality standards). When the primary ambient standards are attained, adverse health effects are unlikely to occur below the levels of pollutant concentrations defined by the standard.

   Second, this comment assumes that the health impacts assessment in revised Appendix B of the ISOR was a factor in the standard setting process. The health impacts assessment presents sample information on the impact of current levels of ozone on several measures of human health. The point of the analysis is to show that ozone has public health impacts at current concentrations, and that the magnitude of these impacts would be expected to decrease once the proposed standards are attained. State law does not authorize consideration of whether or not the benefit of a proposed standard meets a minimum level, but simply requires the standard to protect public

health, including that of the most susceptible population subgroup. The assessment of the health impacts of the currently measured ozone levels, which was performed after the staff recommendations had been finalized, played no role in selection of the recommended standard.

Third, the comment assumes that risk management is part of the standard setting process. State law does not authorize consideration of the number of people who might be exposed to or adversely affected by exposure to air pollution, or the available measures and costs of control of the pollutant. Rather, California law specifies that primary ambient air quality standards are health-protective; that is, the identified adverse effects are unlikely to occur in anyone who is exposed to levels of the pollutant at or below the concentrations specified by the standard. This definition does not allow for a risk management approach to standard selection. Risk management occurs as part of the second stage of the process, during assessment and selection of proposed control measures.

Fourth, the comment assumes that cost-benefit analysis is part of the standard setting process. Because an ambient air quality standard under California law represents the maximum safe exposure to the pollutant, it is inappropriate to weigh the cost of attainment versus the public health benefits of the standard. When specific control measures are proposed, the economic costs versus the likely benefits of the proposed control measure will be evaluated. Federal law similarly requires a dual process that separates standard setting from standard implementation, (see, for example, Sections 108, 109, and 110 of the Clean Air Act).

3. **The statewide public health impacts of current levels of ozone exposure are not sufficiently large as to justify changing the State ozone standard. (**Raised by commenters 1, 2, 4, 8)

In the revised health impacts analysis, we have quantitatively estimated the health impacts of exposure to currently measured ozone concentrations for only a few of the known health effects of ozone exposure. These outcomes were selected to provide the public with concrete information regarding the magnitude of several adverse effects of current concentrations of ozone. Since this analysis does not include estimates for all known health impacts of ozone exposure (and does not address the effects of ozone on public welfare, i.e., non-health effects), it is an underestimate of the total impact of current ozone levels. Given this caveat, staff estimated that the annual impacts of public exposure to ozone at current levels, compared to ozone levels upon attainment of the proposed standards, for a few of the known impacts of ozone include:

- ~630 (310 – 950, probable range) premature deaths for all ages.
- ~4,200 (2,400 – 5,800, 95% confidence interval (CI)) hospitalizations due

to respiratory diseases for all ages.

- ~660 (400 – 920, 95% CI) emergency room visits for asthma for children under 18 years of age.
- ~3.7 million (470,000 – 6,800,000, 95% CI) school absences for children 5 to 17 years of age.
- ~3.1 million (1.3 million – 5.0 million, 95% CI) minor restricted activity days for adults above 18 years of age.

These are not "small" public health impacts. The analysis underscores the finding that current levels of ozone are associated with adverse public health effects. State law requires substantially better protection of public health.

The commenters assert that reductions in the adverse effects of the type and magnitude noted above are not large enough to warrant concern or action, and that the additional protection provided by the proposed state standards (compared to the federal ambient air quality standard for ozone of 0.08 ppm) is negligible, as well as unwarranted by the economic costs of attainment. This argument is based on an incorrect understanding of the definition of an ambient air quality standard under California law, and of factors that can be considered when recommending a standard. As explained in our responses to issues above, an ambient air quality standard represents the highest concentration of ozone for the specified averaging time that is unlikely to induce the specified health effects in people who undergo the defined exposure. Staff's revised health impacts analysis, presented in Appendix B to the ISOR, demonstrates that the public health impacts of ozone exposure would be substantially reduced with attainment of the proposed state standards compared to attainment of the federal standard, supporting the need for the standards proposed. The costs of attainment are reserved under State law for consideration when specific control measures are proposed. When control measures are proposed, a full cost-effectiveness analysis is performed for each measure to ensure that the benefit to public health justifies its economic cost.

4. **The ARB has not considered the economic costs required to achieve attainment of the proposed standards as part of the ozone standard selection process. (**Raised by commenters 1, 2, 6, 7, 9, 10, 12, 15, 16)

As stated above, under California law, setting health-based ambient air quality standards is a separate process from the adoption of source-specific emissions standards and other control measures to attain those standards. The proposed ambient air quality standards have no economic or fiscal impacts, in and of themselves, because no attainment plan is included in the standards themselves. Ambient air quality standards simply define clean air (see sections 39014 and 39606 of the Health and Safety Code). Once ambient standards are adopted by the ARB, local air pollution control and air quality management districts and the Board develop rules and regulations to

control air emissions from numerous source categories in order to attain the health-based ambient standards. A number of different emission standards and control measures are possible, and each will have its own economic or fiscal impact. These impacts must be evaluated when each control measure is proposed. Thus, any economic (and other)impacts associated with the implementation of future measures will be considered by the adopting regulatory agency in a public forum when specific measures are proposed.

5. **The methodology used for assessing the public health benefits of attaining the proposed ozone standards is flawed because the biological mechanism(s) are unknown, and because the influence of other factors that are correlated with ozone levels (e.g., ambient temperature) can not be reliably separated from ozone-related effects. (**Raised by commenter 1)

   We have used a methodology in Appendix B of the ISOR that is similar to that used by U.S. EPA in the regulatory impact analyses (RIA) for the federal particulate matter and ozone standards. U.S. EPA also used a similar methodology in its report to Congress on the costs and benefits of the Clean Air Act (U.S. EPA, 1999). These efforts have undergone extensive peer review by several committees, including U.S. EPA's Scientific Advisory Board. Also, several articles using the methodology have been published in peer reviewed journals (Hubbell et al. 2005; Levy et al. 2001). This methodology has also been endorsed by California's Air Quality Advisory Committee (AQAC), an independent peer review panel that was appointed by the Office of the President of the University of California. Therefore, although the method has uncertainties, which we describe in the text, it is a reasonable model for describing the likely health impacts.

   Hubbell, BJ, Halberg A, McCubbin, DR, Post, E. 2005. Health-related benefits of attaining the 8-hr ozone standard. Environ Health Perspect 113:73-82.

   Levy JI, Carrothers TJ, Tuomisto JT, Hammitt JK, Evans JS. 2001. Assessing the public health benefits of reduced ozone concentrations. Environ Health Perspect 109:1215-26.

   U.S. Environmental Protection Agency. 1999. The benefits and costs of the clean air act 1990 to 2010: EPA report to Congress. Washington, D.C.: Office of Air and Radiation and Office of Policy. Report No.: EPA-410-R-99-001, November. (http://www.epa.gov/air/sect812/copy99.html).

6. **Publication bias (i.e., the selective publication of only studies with positive results) makes the epidemiologic database unreliable, and thus unsuitable for estimating the public health effects of ozone exposure.** (Raised by commenter 1)

The commenter alleged that the body of epidemiologic literature is skewed toward associating adverse health effects with ozone exposure. This concept, called "publication bias", embodies the view that studies that do not show associations between ozone exposure and adverse health effects are not submitted for publication, thus biasing the body of published literature toward positive findings.

Publication bias is unlikely to be an issue with the epidemiologic literature reviewed in the staff report. Almost all of it was originally designed to investigate PM effects, and any ozone results presented were part of the sensitivity analyses and investigation of potentially confounding factors relative to the main focus, PM. Consequently, there is little reason to suppose that negative findings have been suppressed. In fact, there is reason to suppose that any ozone related findings would be presented to show that the PM results were not influenced by ozone. In addition, a new analysis of the National Morbidity and Mortality Air Pollution Study (NMMAPS) data on ozone has been recently published[1]; this study inherently has no publication bias, and the authors reported results in the same range as previous studies. Finally, the World Health Organization (WHO)[2] has adjusted the methodology used in their estimates of the health impacts of ozone exposure to address the possibility of publication bias. WHO still reports a statistically significant association between ozone and both "all-cause" and cardiovascular mortality. Both of these studies (Anderson et al. and Bell et al.) were cited in the staff report, and have been considered in our review and findings.

We have not added the three new ozone mortality meta-analyses to our staff report, contrary to the commenter's assertion, because they were not available at the time the Board took action on the proposed amendments to the California ambient air quality standard for ozone. However, although the three groups used different criteria for selecting studies to include, and different statistical methodologies for their analyses, the results of the three analyses are very similar to each other and are in the same range as previously published studies that have investigated the relationship between ozone exposure and mortality. The three new studies add weight to the evidence that was available when the ISOR was drafted for the effect of ozone on mortality, and support the conclusions in the staff report.

7. Based on studies of personal exposure (the time-weighted average concentration of a pollutant across a day, including both indoor and outdoor contributions), the average ozone concentration to which

[1] Bell ML, McDermott A, Zeger SL, Samet JM, Dominici F. 2004. Ozone and short-term death in 95 US urban communities, 1987-2000. JAMA. 292(19):2372-8.

[2] Anderson HR, Atkinson RW, Peacock JL, Marston L, Konstantinou K. 2004. Meta-analysis of time-series and panel studies of particulate matter (PM) and ozone. Report of a WHO task group. World Health Organization.

people are exposed is about half of ambient levels. Standards should be based on personal exposure, not ambient concentrations. (Raised by commenter 1)

"Ambient air" refers to the air outside of buildings. Ambient air quality standards represent the maximum concentration of a pollutant for a given averaging time that is a safe outdoor exposure. People spend a significant portion of their time indoors, and central-site monitors do not, in general, accurately reflect personal exposure. There are few indoor ozone sources, and indoor ozone concentrations are considerably lower than those outdoors. Personal exposure includes components from both indoor and outdoor exposures. Most people spend more time indoors than outdoors, and when indoor and outdoor concentrations are averaged together, personal exposure concentrations are typically lower than outdoor concentrations. Nonetheless, ambient air quality standards are required by law to relate to outdoor exposures. Use of personal exposure to represent maximum safe outdoor exposure would not adequately protect people from adverse effects induced by outdoor exposure. Therefore, it is appropriate to use outdoor monitored values in the standard-setting process.

8. **Controlled human exposure studies should not use filtered air for the baseline comparison condition because no one is ever exposed to air that has no ozone in it. Instead, the baseline condition should be 0.04 ppm, since that is the background concentration put forward by ARB. (**Raised by commenter 1)

(The portion of ambient ozone concentrations that is not due to regulated emissions is often called "background" ozone.) The commenter asserts that the baseline for comparison of effects should be background (i.e., 0.04 ppm) rather than filtered air because the physiological responses measured are related to the change in ozone concentration, not to the concentration itself. This is erroneous because the biological responses caused by ozone are not linear functions, as the commenter apparently assumes, but rather are exponential. The human exposure data clearly indicate that responses to ozone exposure are proportional to the inhaled dose of ozone, which is the product of ozone concentration, breathing rate, and exposure duration, although concentration has the greatest contribution to observed effects.

Consequently, while numerous exposure scenarios can be postulated that would result in an inhaled dose that is likely to induce adverse responses, it appears, based on available evidence, that the effects of exposure to 0.04 ppm ozone would be equivalent to those observed with filtered air exposure. The available controlled exposure study data also point to a threshold ozone concentration, particularly on the individual level, above 0.04 ppm, and below 0.12 ppm, for 1 to 3 hour exposures, in heavily exercising subjects, and below 0.08 ppm is for 6.6 hour exposures, in moderately exercising subjects. Since

0.04 ppm is below the apparent effects threshold, use of 0.04 instead of filtered air for the baseline for calculating responses to ozone exposure is unlikely to change the conclusions reached as to the magnitude of the effects of ozone exposure.

9. **Ground level ozone is beneficial to health, because it protects against skin cancer and cataracts. Reducing ambient ozone through attainment of the proposed standards will lead to increases in these endpoints. (**Raised by commenter 1)

   The only references supporting this comment is a document[3] that has been discredited by U.S. EPA on the grounds that it has not appeared in the peer reviewed literature, and it does not include sufficient detail as to the methods employed to allow for independent evaluation of the conclusions.

   It is currently not possible to scientifically test the hypothesis that UVB absorption by boundary layer will offset health risk ozone (reduced skin cancer) from inhalation. Setting aside concerns about the behavioral problems in estimating radiation doses, calculating a spatially resolved estimate of the ground level radiation impact of projected small changes in ozone concentration is technically impossible from the sparse and "noisy" UV radiation data available. Moreover, the radiant change would probably be dwarfed by the uncertainty due to effects of clouds, aerosols, time of day and season of peak ozone dosage shift, and even small changes in stratospheric ozone concentrations.

   Nonetheless, we would argue qualitatively that any such effect would be very small because the change in UVB absorption would be restricted to a very short path length (solar beam transit of the shallow surface boundary layer during extreme ozone episodes) - typically a few hundred meters. The limited literature on this topic does not support the commenter's contention. As an example of the relationship between surface ozone and UVB intensity, consider these plots for UVB and ozone from a relatively unpolluted site (thus simulating ozone concentrations in the range expected as we approach attainment of the ozone standard):

[3] Department of Energy (1995). *EPA Docket A-95-54, IV-D-2694, Appendix B-9.* Washington DC. (March 21).

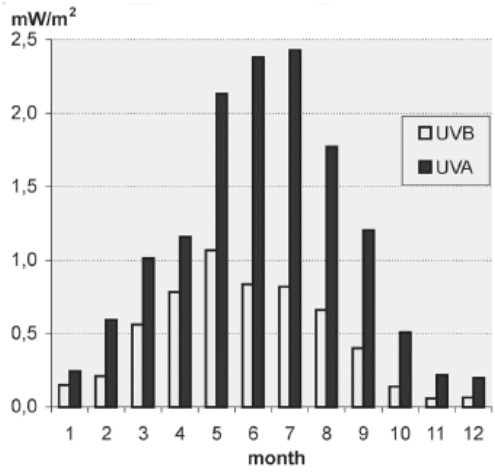

Fig 8. Average values of UVA and UVB radiation in 2002 (UVB radiation values multiplied by 10)

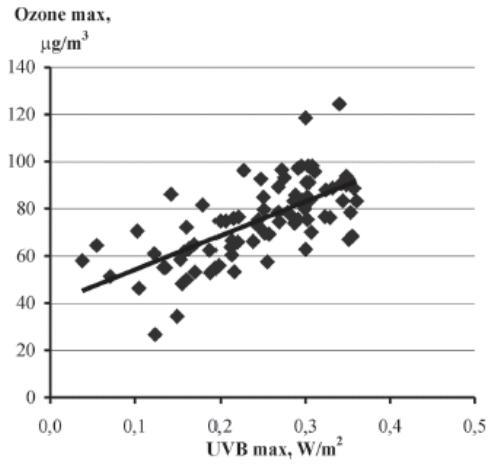

Fig 9. Scatter chart of ozone and UVB radiation data

Figure 1: Annual cycle of UV radiation and UV-O_3 scattergram for a low-ozone mid-latitude site (Chadysiene, R., et al., 2005[4]).

Not only is the scatter large (+- 20 ppbv), but the linkage between strong UV flux and ozone formation is a positive correlation, contrary to the implicit assumption in the commenter's argument. Based on these considerations, staff believes the commenter's assertion to be unsupported, and we have not relied on this information in putting forward the proposed standards.

10. The ARB has not presented a cost-benefit analysis of the proposed ozone standards as required by Government Code section 11346.3. (Raised by commenters 1, 2, 4, 6, 7, 8, 9, 10, 12, 15)

The proposed ambient air quality standards have no economic or fiscal impacts; they simply define clean air (see sections 39606 and 39014 of the Health and Safety Code). The determination of a health-based ambient air quality standard for ozone does not in itself have any economic impacts. As explained above, under California law, setting health-based ambient air quality standards is a separate process from the adoption of source-specific emissions standards and other control measures that will be necessary to attain them.

Once ambient standards are adopted by the ARB, local air pollution control and air quality management districts and the Board develop rules and regulations to control air emissions from numerous source categories in order

[4] Renata Chadysiene, Rasele Girgzdiene, Aloyzas Girgzdys, Ultraviolet Radiation and Ground-Level Ozone Variation in Lithuania, Journal of Environmental Engineering and Landscape Management, 2005, Vol XIII, No. 1, p.3136.

to attain the health-based ambient standards. A number of different emission standards and control measures are possible, and each will have its own economic (and other) impacts. These impacts must be evaluated when each control measure is proposed. Any economic or other impacts associated with the implementation of future control measures will be considered by the adopting regulatory agency in a public forum when specific measures are proposed.

11. The proposed ozone standards will damage health, welfare and quality of life because people will be made poorer due to increased costs required to attain the standards. (Raised by commenter 1)

The basis for this comment is that economic resources, both on a personal and societal level, will be diverted away from effective health improving policies and actions, and toward air pollution control policies and actions that will ultimately harm health as a result of spending public funds to attain the ozone standards.

As we have discussed above (see responses to comments 4 and 10), ambient air quality standards represent maximum safe exposures to the pollutant under consideration, and only the health consequences of air pollution exposure can be considered in setting the primary ambient air quality standards (Health and Safety Code section 39606(a)). Issues related to the costs of potential attainment strategies are considered when specific control measures are proposed. This process compares the costs and benefits of various control measures to insure that the selected measures are technologically and economically feasible, and cost-effective.

(We parenthetically observe that higher income on an individual level does not necessarily guarantee better health, welfare and quality of life. For example, according to recent statements from the US Government and news accounts, a national epidemic of obesity penetrates all socioeconomic levels, with corresponding adverse health impacts.)

12. The ARB should harmonize the State standards with the federal 8-hour standard of 0.08 ppm. (Raised by commenter 1, 6)

Under both the federal Clean Air Act and State law, California is authorized to set its own ambient air quality standards, in consideration of statewide concerns, and the Board's judgment regarding scientific health effects data. There is no requirement that the State and federal standards be the same.

There are several differences between California law and federal law regarding the standard review process that may clarify for the commenter why California and the U.S. EPA review the same literature and may arrive at different recommended standards. California law requires that the standards

protect the most sensitive subgroup of the population. This requires that we consider the range of individual responses to different exposure protocols to understand the range of variability in the population as a whole, and then to base our recommendations on the most sensitive sub-group, such as children and people with asthma. In contrast, U.S. EPA primarily considers group mean responses, with little consideration of the variability among individuals.

Second, California standards are based solely on health considerations, without consideration of risk analysis. As noted above, State law requires the Board to determine a concentration of the pollutant that, when measured over a specified averaging time, is unlikely to induce the adverse effects associated with that pollutant in anyone who experiences the specified exposure pattern. The exposure patterns selected are based on a combination of pollutant concentrations identified by ambient air quality monitoring and likely outdoor activity patterns. The likelihood of undergoing the exposure patterns defined by the standards is not a factor in California standard setting, while the U.S. EPA does consider this to some extent. (See sections 108 and 109 of the Clean Air Act (42 USC 7408 and 7409) for a description of the federal standard-setting process.)

Third, when EPA last considered the ozone standard in 1996/1997, there were far fewer epidemiologic studies showing serious outcomes associated with ozone exposure than there are today. Finally, interpretations fo the same data often differ, based upon the individuals making the decision, the regulatory environment, and the like. California standards are often more health-protective than corresponding federal standards.

13. **Background ozone in the Central Valley of California is considerably higher than the 0.04 ppm value put forth by ARB; background ozone is at or above the level of the standards proposed, and so they cannot be met. (**Raised by commenter 1, 3)

(The comment submitted was extensive and wide ranging, and much was not relevant to the matter at hand. The staff response is limited to the relevant portions of the comment: those that concern the levels and sources of background ozone in the Central Valley of California.) The comment included an analysis of background ozone concentrations in the Central Valley, which the commenter asserted indicates that the proposed ozone standards are at or below the regional background level, and thus are not reasonable or justifiable, because they cannot be met. However, the commenter's analysis of ambient ozone levels, and especially background ozone levels, is not directly pertinent to the standard setting process.. While the relationship between the level of standard and the level of background ozone can be a significant issue concerning efforts to attain the standard and selection of control measures, the standard itself reflects relationships between ozone levels and adverse health effects.

Even so, the staff considered the comment, and offers the following response. The commenter states in the opening summary that peak (8-hour) ozone levels at Fresno in 2002 reached about 0.13 ppm, of which he attributes approximately 0.06 to 0.07 ppm to background ozone, approximately 0.04 ppm to NOx emissions from Bay Area refineries and power plants, and the remaining approximately 0.03 ppm to other emissions in the Bay Area and the San Joaquin Valley. Unfortunately, the analyses offered in support of this conclusion are generally ambiguous, and the interpretations presented for some of the analyses are highly doubtful.

Substantial amounts of ozone can be present at daybreak, even reaching 0.06 to 0.10 ppm on high ozone days. However, this ozone does not represent "background" (defined below). Instead, it mostly represents residual ozone from human activity on the preceding day or days. Although ground level measurements in Fresno decrease to approximately 0.01 ppm by early morning, the air above ground level typically contains a large reservoir of residual ozone left over from the previous day. Data collected atop the Sutter Buttes in the middle of the Sacramento Valley show this phenomenon clearly. The figure below shows hour by hour averages of 30 daily profiles.

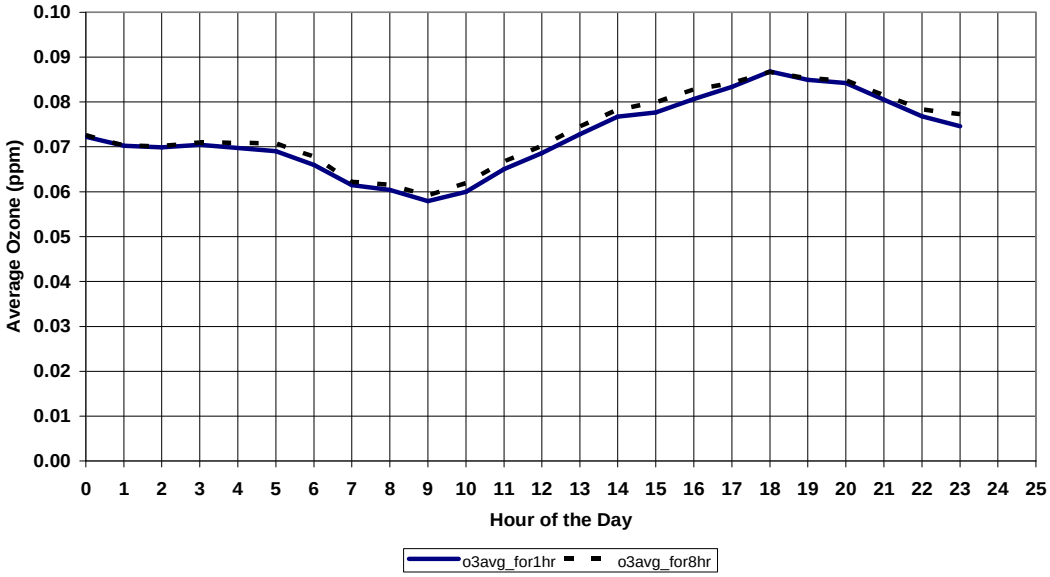

Figure 2. Diurnal profiles for top 30 1-hr and 8-hr ozone days in Sutter Butters for the years 2000-2002.

Residual ozone in the Central Valley (and in other areas of the state) that carries over from one day to the next is attributable to emissions from human activity; therefore, the residual ozone is not appropriately thought of as "background" ozone. In addition, high ozone concentrations caused by NO_X emissions from the Bay Area, that mix with biogenic VOCs in the Sierra

Foothills are the result of the phenomenon called “transport.” Transported pollution is subject to California regulatory control (i.e., the upwind district is charged with reducing its emissions so as not to cause exceedances of ambient air quality standards in downwind areas; see sections 39610 and 40912 of the Health and Safety Code), and is thus not background as defined in the staff report. The following quotation from page 4-1 of the staff report defines background ozone for the purposes of this regulatory action:

“From a regulatory perspective, the important distinction is not between “natural” and “anthropogenic” ozone, but between ozone produced by controllable emissions and ozone due to emissions beyond the reach of regulation. In a policy context, anthropogenic ozone produced outside the jurisdiction of an agency and transported into a control region is functionally indistinguishable from that due to natural processes. Within the range of concentrations due to such external or uncontrollable sources, those concentrations that may impact determinations of compliance with air quality standards or limit the potential air quality improvements due to control programs are the “policy-relevant background.”” The key distinction here is that ozone and ozone precursors that derive from human activity (whether local activity or from activity in upwind areas within California) do <u>not</u> constitute “background” the next day or in downwind areas.

The staff finds little indication in the material provided by the commenter that “background” ozone, as defined for the purposes of the standard setting process, reaches levels much above the 0.04 ppm used by the staff to characterize background ozone levels in the state.

14. The ARB has overstated the health effects of low-level ozone exposure by using a flawed methodology that uses an incorrect ratio to convert between 8-hour and 1-hour levels, and relies on “data mining” (selection of the statistical model that provides the answer wanted). (Raised by commenter 1)

Epidemiologic studies of ozone health effects have examined the relationships between 1-, 8-, and 24-hour average ozone concentrations and various health endpoints. Because there is a very high correlation among these three averaging times, they can be mathematically converted to other time bases to facilitate comparisons between studies that use different averaging times. We used a ratio of 1.33 for converting between 8-hour and 1-hour ozone levels, which is the same national ratio used by leading air pollution epidemiologists, including Drs. Levy and Schwartz from the Harvard School of Public Health. In addition, we found that the ratio of 1.33 between 8- and 1- hour ozone levels was valid for California based on our analysis of monitored ozone data from the South Coast Air Basin and the San Francisco Bay Air Basin that is presented in Appendix B of the staff report.

"Data mining" refers to selecting the statistical analysis model that provides the answer wanted. The commenter asserts that ARB has pre-determined the results of its health impacts analysis. The commenter claims that application of the Bayesian approach applied by Koop and Tole (2004)[5] will provide a more unbiased estimate of the effect of ozone on mortality than the available time series literature staff relied on, and will prevent data mining. Koop and Tole proposed an approach that is purely statistical, and that includes every possible variable, and all possible interactions of these variables. Unfortunately, they also include variables and interactions that have been shown by physiological research to have no biological plausibility. There is no reason to include variables in the models that can be excluded *a priori* on physiological grounds. Inclusion of such variables complicates the models, leads to computational difficulties, increases standard errors, and confuses interpretation of the results.

Koop and Tole also propose investigating an unlimited number of multi-day lag times to further investigate relationships between health outcomes and air pollution levels. However, selection of lag times needs to be physiologically informed. Contrary to the commenter's assertion, including a large number of lags and a physiologically uninformed selection of variables is "data mining," the very thing that the commenter asserts ARB has done. The Bayesian approach can be useful, and has been applied by several recent papers, including one of the recently published meta-analyses. However, the authors of that paper have used known relationships to limit model inputs to those that have biological plausibility.

15. The health benefits assessment presented in the staff report claims benefits for reducing ozone levels from current concentrations down to background (0.04 ppm). The ARB should not claim public health benefits for reducing ozone below the level of the standard, since ARB's definition of a standard is a "no effects" level. (Raised by commenter 1)

This comment refers to the estimates of health impacts of current ozone concentrations compared to health impacts at attainment of the proposed standards, as presented in Tables B-3, B-4, and B-5 of Appendix B of the staff report. We do not claim that the proposed standards are "no effects" levels (see explanation of "no effects" in the following paragraph), contrary to the commenter's assertion. Rather, based on the available scientific evidence, we believe that adverse effects are unlikely to result from exposures equivalent to those defined by the standards proposed.

The estimates of health impacts at levels below the levels of the proposed standards are highly uncertain and thus cannot be the basis for the

[5] G. Koop and L. Tole, "Measuring the Health Effects on Air Pollution: To What Extent Can We Really Say that People Are Dying from Bad Air?" *Journal of Environmental Economics and Mangement* 47 (2004): 30-54.

standards. Because of this, we used the controlled human exposure (chamber) studies for determining the proposed standards, since epidemiologic studies do not allow determination of the precise concentration and averaging time responsible for observed health effects. However, the epidemiologic studies are useful in showing impacts on health from changes in ozone concentrations in a general population. Staff based their recommendations on the best available science and believes the proposed levels adequately protect public health, although we cannot say with certainty that each and every individual is protected by the proposed standards. Consequently, the standards should not be considered to be "no effects" levels.

The health impacts estimates are based on the quantitative results from major health studies that found associations between ozone exposure and human health effects (morbidity, i.e., sickness; and mortality, i.e., death). Tables B-3, B-4, and B-5 reflect total estimated health benefits based on comparing ozone levels at the new proposed standards, down to the assumed ozone background level of 0.04 ppm. We have included concentrations down to background because the epidemiologic studies used for the impacts assessment include concentrations below the levels studied in chamber studies, down to background.

The estimated health impacts in Tables B-3, B-4, and B-5 are based on the mathematical dose-response for ozone effects obtained from major ozone health studies based on the theoretical concept that there may not be a threshold for ozone effects (i.e., an ambient ozone level below which there would be no risk of a significant adverse health outcome).

As discussed in sections 10.2.3, 11.6.3.2, and 11.6.3.3 of the staff report, only a few studies, all investigating emergency room visits for asthma, have conducted analyses to explicitly evaluate the potential for population health effects thresholds. While these emergency room studies are suggestive that there might be a population level threshold in the range of the ozone standards proposed, they are by no means conclusive and probably would not apply to individuals.

16. **The staff report overstates the risk of children developing permanent lung function deficits with long-term ozone exposure in section 10.3.5 of the staff report. (**Raised by commenter 1)

The commenter is incorrect in stating that the Children's Health Study (CHS) found no association between long-term ozone exposure and lung function. Peters et al. (1999) and Gauderman et al. (2002) both reported a significant reduction in the growth rate of peak expiratory flow rate (PEFR), which is a measure of lung function. In addition, these two papers are based on different cohorts from the CHS, giving greater weight to their findings.

Studies by Galizia and Kinney (1999), Kinney et al. (1998), Tager et al. (1998) and Kunzli et al. (1997) also report smaller attained lung function in young adults who grew up in areas with high, compared to those who grew up in areas with lower, ozone concentrations.

17. **It is not biologically plausible that ozone exposure could increase the risk of developing asthma (section 10.3.6 of the staff report). (**Raised by commenter 1)

Staff did not state that ozone causes asthma. Because there are a few studies that have investigated the subject we did discuss the issue in the staff report, and offered an assessment of the strength of the evidence. We concluded that the evidence was inconclusive and that more investigation into the topic was required before a conclusion could be reached.

The commenter misrepresents the statement on page 10-58 of the staff report, claiming that we stated that asthma was "not higher" in high ozone communities. In fact, the full statement is that asthma risk was not higher. In context, the paragraph was meant to convey that the relative risk of developing asthma in the higher ozone communities was not higher than in the low ozone communities, except for children in the high ozone communities who played three or more team sports. This statement is in accord with McConnell et al. (2002).

The commenter makes factual errors in his discussion of results from McConnell et al. (2002). His statement is incorrect that the higher relative risk of developing incident asthma in very active children in high ozone areas was based on a comparison with medium and low concentration areas. The communities for this analysis were divided into only two groups of six communities, not three groups of four communities. The commenter next argues from McConnell et al.'s initial analysis (without inclusion of activity level) that the finding of no significant differences among the 12 communities in cases of new asthma suggests that ozone is not a factor in development of new asthma. While little is known about how ozone may induce incident asthma, the observation that the effect was only observed in the children who presumably had the greatest ozone exposure (played three team sports in the high ozone communities), does allow for the possibility that ozone could be involved in some way for that sub-set of the population of children. The observation that the effect was not evident in less active children who would have had less ozone exposure, or in low ozone communities does not negate the paper's conclusions. True, ozone levels have generally gone down statewide over the past 20 years, but applying these results to all children ignores the issue of differential exposure that was a key point in the McConnell et al. paper.

Figure 5 from the comment's submission on the trend in overall asthma prevalence versus ozone levels does not take inhaled dose into account. The results from McConnell et al. (2002) suggest that increased inhaled dose may be the relevant factor, in that the effect was observed only in very active children in the higher ozone communities.

18. **The ARB used the wrong studies to estimate effects of ozone exposure on hospitalizations and emergency room visits because the studies were performed in areas with a different climate than California. The analysis should use studies from California or other places that have a similar climate as California. (**Raised by commenter 1)

    The staff report reviews a large number of studies on hospital admissions and emergency room visits. The report includes considerable discussion as to weaknesses in study design, statistical power, and other factors that could influence the conclusions to be drawn from the studies. Greater weight was given to multi-city studies, and to those that included longer time series because they have greater statistical power. We selected studies for the impacts analysis that we judged to be the most technically sound. It is true that the Thurston and Ito study (1999) used only data from areas with "cold climates," meaning the eastern U.S. However, the areas included in the study have a similar ozone season as California, and there is no reason to suppose that the population of the northeast U.S differs significantly from that of California. The Thurston and Ito (1999) study also has considerably greater statistical power than the single city study (Birmingham, AL) the commenter recommends. Impacts analyses usually are based on multi-city studies because they have greater statistical power and are considered to be more representative of diverse populations.

    The California studies the commenter referred to were not used for the impacts analysis because are all short time series (less than 5 years), have small sample sizes, and used a method (coadjustment method) of adjusting for parameters such as weather and other air pollutants that have been shown to lead to biased air pollution effects estimates where both outcome under study and air pollution have strong seasonal cycles (Burnett et al. 2001). Issues related to the coadjustment method, and why studies that use this method are less reliable, are discussed on page 10-25 of the staff report. The van den Eeden (2003) report the commenter refers to is not a peer-reviewed publication, which eliminates it as a basis for the impacts assessment.

19. **The Gent et al. (2003) analysis of respiratory symptoms attributable to ozone exposure suffers from publication and model-selection bias because the results are not biologically plausible, and the exposure assessment is flawed. (**Raised by commenter 1)

The commenter asserts that the finding that asthmatic subjects on medications exhibited larger ozone effects than those not on medications is not biologically plausible (Gent et al., 2003). On the contrary, the children taking regular medications would be more severe asthmatics than those not taking medications regularly, and it is not surprising that they might have more effects. While the exposure assessment was done somewhat differently than in many other studies, ozone is a regional pollutant in the area where the study was performed, and a different method of assessing exposure likely would not have made a significant difference in the results. One would expect a larger effect related to peak one-hour ozone concentrations compared to eight-hour average concentrations, as Gent et al. reported, based on findings from controlled human exposure studies indicating that ozone concentration drives the observed effects, compared to exposure duration. The statement referred to on page 10-7 was meant to indicate that the children reported the same symptoms with exposure to both one-hour and eight-hour ozone levels, not that the relative risk estimate was the same.

20. The idea that ozone exposure could contribute to school absences is not biologically plausible. (Raised by commenter 1)

The commenter has several issues with the staff report conclusions regarding the influence of ozone on school absences. The ARB disagrees with the commenter's assertion that it is biologically implausible that ozone has an influence on school absences for illness. Toxicological data show that exposure to ozone increases infectivity potential of microorganisms (see page G-25, et. seq. of the staff report). The significant association between time outdoors and reduced school absences is plausible from the standpoint that, while time outdoors would likely increase ozone exposure, increased time outdoors would also be expected to reduce risk of exposure to infectious agents. The issue of the relatively long lag time between ozone exposure and respiratory illness also makes sense, contrary to the commenter's claim, because infectious organisms have an incubation period before illness becomes apparent, and this can be as long as 1.5 to 2 weeks, in agreement with the study results.

Berhane and Thomas (2002) and Rondeau et al. (2005) analyzed the same data sets, but they had somewhat different objectives. The Berhane study used the data set for development of a new statistical methodology, while the Rondeau study included individual-level risk factors, and also used the data set for methods development. The methodologies for the Berhane and Rondeau studies are relatively new, and have not been widely used in air pollution epidemiology. As we noted in our staff report, the number of studies on school absences is small, and more work needs to be done on this topic in a larger number of communities. However, we believe that the analysis we

presented estimating the potential impact of ozone on school absences is valid and supported by the available studies.

21. **Controlled human exposure studies are not relevant because the ozone levels used are much higher than people's real personal ozone exposures. (**Raised by commenter 1)

    As we discussed in our response to issue number 7, basing ambient air quality standards on personal exposure, which includes contributions from both indoor and outdoor air, would not adequately protect the public from outdoor exposures. Ambient air quality standards by design represent the maximum concentration for a given averaging time that is a safe outdoor exposure.

    As we have also noted, ambient air quality standards identify our best scientific estimate of safe exposures. Controlled human studies are particularly relevant to standard setting because they clearly demonstrate the relationship between a defined exposure (ozone concentration and exposure duration) and health outcomes. Because both the exposure duration and ozone concentration can be varied, this type of study is particularly relevant for investigating exposure/response relationships, and for identifying exposures that have no effects. Consequently, these studies provide key data for identifying safe exposures.

22. **The incremental benefits of the proposed state standards should be compared to the federal standard and to the current state standard, and should be presented in the staff report. (**Raised by commenters 4, 6, 8, 9, 10, 11, 12, 13, 14, 15, 16)

    Several commenters asked that the health benefits (impacts) analysis be presented in such a way as to illustrate the proportion of total benefits that would accrue with attainment of the federal 8-hour ozone standard of 0.08 ppm, the State 1-hour standard of 0.09 ppm and the proposed State 8-hour standard of 0.070 ppm, in order of stringency. Staff has performed this analysis, and the results are presented in the revised Appendix B of the staff report that was released on October 27, 2005, for a 15 Day Public Comment Period.

23. **The proposed standards are not attainable, and will require all human activity to cease. (**Raised by commenter 6)

    Staff recognizes that attainment of the proposed standards is not likely in the near term. However, State law requires ambient air quality standards to be based solely on public health considerations. As such, standards represent clean air goals that define the maximum safe concentration for the selected averaging time. Under State law, standard setting can not include

consideration of attainability, or any factor other than public health. Consequently, whether or not the proposed standards are attainable in the near-term is irrelevant to selection of health-based standards.

24. **The health impacts assessment, based on epidemiology, should not form the basis for the 8-hour standard, and the epidemiologic findings should be removed from the list of scientific findings on which the standards were based (pgs. 1-5 and 11-29 of the staff report) because the epidemiologic literature is unreliable. (**Raised by commenters: 9, 10, 15, 16)

    Several commenters asserted that epidemiology should not be the basis for the proposed 8-hour ozone standard because the data are too uncertain, and requested that findings from the epidemiology literature review be removed from the list of findings in the staff report on pages 1-5, and 11-29. The staff report (section 11.6.3.3 on pg. 11-25) clearly states that the controlled human studies literature, not the epidemiologic literature, formed the primary basis for the proposed 8-hour standard. The findings of the review of the epidemiologic literature were considered in development of the margin of safety, which is required by State law to be reflected in the recommended standards. Staff believes that the findings of the health literature review listed in the staff report accurately reflect the conclusions that can be drawn from the available literature.

    The commenters may have misunderstood the staff report, and incorrectly believed that the analysis of the health impacts of current ozone concentrations, which is based on epidemiologic studies, was the basis for the recommended 8-hour average standard. As explained above, this assessment was performed after the staff recommendations had been finalized, and it played no role in selection of the recommended standard. The purpose of the assessment was to present sample information on the impacts of current levels of ozone on several measures of human health. The analysis showed that ozone has substantial public health impacts at current concentrations, and that the magnitude of these impacts would be expected to decrease with attainment of the proposed standards.

    In addition, the endpoints used in the health impacts analysis were not used as the basis for the recommended standards. The standard recommendations were based primarily on controlled human exposure studies, which do not evaluate population-level effects.

25. **The ARB should schedule a public meeting to discuss the findings, assumptions, and methodology used for the new incremental benefits analysis.** (Raised by commenters 17, 19)

Two commenters at the Board hearing thanked staff for performing the incremental benefits analysis that stakeholders had previously requested staff to perform. Since the results of the analysis were presented for the first time at the Board hearing, both speakers requested that staff hold a public meeting to discuss the methodology, assumptions, and results of the new analysis. Staff held the requested meeting on July 25, 2005, and 8 people representing the organizations who requested the meeting attended the discussion. In addition, staff published a 15-day notice of revised text to receive public comments on the revised staff report text describing the incremental benefits analysis; no comments were received in response to the 15-Day Notice.

26. The proposed standards are not adequately justified in the staff report. (Raised by commenter 8)

The proposed standards are based on a critical review of approximately 1000 scientific publications b OEHHA and the ARB, and have undergone rigorous peer review by the Air Quality Advisory Committee (AQAC), an independent peer review panel that was appointed by the Office of the President of the University of California. AQAC unanimously endorsed the scientific findings presented in the staff report, as well as the proposed standards. Thus, we disagree with the commenter that the proposed standards are not adequately justified in the staff report.