APPENDIX B

COMMENTS ON THE U.S. ENVIRONMENTAL PROTECTION AGENCY'S PROPOSED NATIONAL AMBIENT AIR QUALITY STANDARD FOR OZONE

SUMMARY

The body of scientific studies that measured ozone exposure and response in humans indicate that the current one-hour federal standard of 0.12 parts per million (ppm) is not health protective -- people experience harmful effects at the level of the current standard and at lower levels with multi-hour exposures. California's own state standard for ozone of 0.09 ppm over one hour has been substantially more protective than the federal standard for the last ten years. The California standard continues to be supported by subsequent health studies. The science indicates that adequate health protection against both hourly and daily exposures can be achieved with either an appropriate one-hour standard or an appropriate eight-hour standard.

The U.S. Environmental Protection Agency (U.S. EPA) proposes to replace the current standard with an eight-hour standard set at 0.08 ppm. On the surface, the proposal may appear to be significantly more stringent than the current standard, but the eight-fold increase in exposure time combined with the relaxed form dilutes the effect. To satisfy the requirement in federal law to protect public health with a margin of safety, U.S. EPA must carefully consider how all of the elements of a standard affect the degree of health protection. The scientific evidence and extensive air quality monitoring data from California indicate that the proposed federal eight-hour standard for ozone of 0.08 ppm could offer protection close to that of the California one-hour standard if the most health-protective interpretation of the standard were used. The interpretation supported by the health studies would be a standard exceeded at a level of 0.081 ppm, with no more than one exceedance allowed per year, on average (or an equivalent statistical approach).

BACKGROUND

Both the State of California and U.S. EPA have established ambient air quality standards. State and national ambient air quality standards set legal maximum limits on the level of an air pollutant in the outdoor (ambient) air necessary to protect public health and the environment. The health-based national ambient air quality standards (NAAQS) are designed to protect public health and must include an adequate margin of safety. Health protection is the only legal basis for the selection of these standards.

The NAAQS are established through a carefully considered process that is designed to use the best scientific information available, with an opportunity for public input, as well as review by recognized independent scientific experts--the Clean Air Scientific Advisory Committee (CASAC). California's health-based state ambient air quality standards are set independently by the California Air Resources Board, also based solely on a review of the science. A comparison of the current and proposed federal ozone standards, and the current California standard, is presented in Table B-1.

Table B-1
Ozone Standards

Averaging Time	Level	Form
PROPOSED FEDERAL STANDARD		
8 hours	0.08 ppm	3-yr average of 3rd high value, highest monitor
CURRENT FEDERAL STANDARD		
1 hour	0.12 ppm	1 exceedance per year, on average, highest monitor
CALIFORNIA STANDARD		
1 hour	0.09 ppm	Statistical equivalent to 1 exceedance per year, on average, highest monitor

The level of a standard is expressed as the concentration of ozone in the ambient air, in parts per million. U.S. EPA proposes to change the averaging period from one hour to eight hours. The form represents the statistical expression of a given standard or the attainment test. The form of the current federal standard requires that an area not exceed the level of the standard more than once a year, on average, to be considered in attainment. The proposed form would replace the exceedance approach with a calculated average concentration that cannot exceed the level of the standard to be considered in attainment.

CURRENT FEDERAL STANDARD

Recent health studies support the conclusion that the current federal ozone standard of 0.12 ppm averaged over one hour is not protective of public health. Studies of both healthy people and asthmatics show adverse effects in the lung in response to one to three hour exposures to ozone at levels as low as 0.12 ppm. Numerous studies, completed since the last review, show transient changes in pulmonary function, respiratory symptoms, decreased exercise performance, and increased airway responsiveness. Community health (epidemiological) studies show an increase in symptoms, aggravation of asthma and increased hospital admissions for respiratory

illness consistent with the clinical studies. Some of the most significant short-term (one to three hours) exposure studies and results are cited below.

- Healthy subjects experience decrements in pulmonary function while intermittently exercising during short-term exposures to ozone levels as low as 0.12 ppm. Symptoms of cough and respiratory irritation also occur. (McDonnell et al., 1983; Kulle et al., 1985; Seal et al., 1993). In addition, exposure to 0.12 ppm ozone results in decreased athletic exercise performance (Linder et al., 1988). Furthermore, studies of healthy children at summer camp support the association between increased ambient ozone exposures and decreased lung function (Spektor et al., 1988, 1991; Spektor and Lippmann, 1991; Raizenne et al., 1987, 1989; Higgins et al., 1990; Gross et al., 1991; Avol et al., 1990, 1991).

- Individuals with asthma are also adversely affected by exposure to 0.12 ppm ozone. Exposure to 0.12 ppm ozone sensitizes adolescent asthmatics to a subsequent respiratory challenge (Koenig et al., 1990). In addition, various tests of lung function and capacity show adverse effects of 0.12 ppm ozone exposure on adolescent asthmatics (Koenig et al., 1985; Koenig et al., 1987; Koenig et al.,1988). Furthermore, some adult asthmatics also experience an increase in bronchial responsiveness following exposure to 0.12 ppm for one hour at rest (Molfino et al., 1991).

- Studies of hospital admissions for respiratory causes indicate that admissions increase as ambient ozone levels increase for both asthmatics and the elderly (Thurston et al., 1992; Thurston et al., 1994; Burnett et al., 1994; Delfino et al., 1994; Schwartz 1994a, b, c).

- Hundreds of studies of laboratory animals confirm that actual cellular and tissue damage occur in the respiratory tract after low-level ozone exposure (U.S. EPA, 1996a, b). Some of these studies indicate that repeated exposure to ozone, such as occurs under ambient conditions, can lead to chronic structural changes in the lungs (Chang et al., 1992; 1995; Harkema et al., 1993; Tyler et al., 1988). Such studies suggest that similar phenomena occur in humans.

These studies support the finding of CASAC that the current federal one-hour standard of 0.12 ppm is not sufficiently health protective.

PROPOSED FEDERAL OZONE STANDARD

In addition to the evidence showing effects after short-term ozone exposure at the level of the current federal standard, recent studies demonstrate adverse effects from 6.6 hours of ozone exposure at lower levels. Multi-hour (four to 6.6 hours) ozone exposures cause decreased pulmonary function, increased respiratory symptoms and inflammation, decreased exercise performance, and increased airway responsiveness. The evidence that prolonged ozone exposure

is harmful is the basis for the proposal to replace the current one-hour federal standard with an eight-hour standard. This shift would offer significant benefits to areas of the country (especially the eastern U.S.) which experience prolonged exposure to ozone at levels below the current federal standard.

The science indicates that concerns about multi-hour ozone exposures are important, but addressing prolonged exposure does not eliminate the need to consider the well-documented history of adverse effects from peak, one-hour ozone exposures. California's cities generally experience more pronounced peak ozone levels, with downwind rural areas subject to the prolonged, lower exposures typical in the East. To provide adequate public health protection on a national basis, the federal standard must address both harmful one-hour and multi-hour ozone exposures.

U.S. EPA proposes to use a new approach for the "form" of the health-based ozone standard. The form of a standard defines how attainment is determined and affects the amount of air quality improvement needed. All elements of an ambient air quality standard -- the level, the averaging time, the form, and the exceedance level -- are important in determining the degree of protection provided by a standard. The form of the current federal standard requires that an area not exceed the level of the standard more than once a year, on average, to be considered in attainment. The proposed form would replace the exceedance approach with a calculated, average concentration that cannot exceed the level of the standard to be considered in attainment. Specifically, U.S. EPA proposes to use the three-year average of the third highest concentrations measured each year at the highest monitor. This concentration-based value would then be compared to the standard of 0.085 ppm to determine each area's attainment status. The proposed form would essentially allow multiple exceedances of the standard to be excused each year.

Protection against multi-hour exposures. The 6.6 hour health studies show evidence of harmful effects when people are exposed to ozone concentrations as low as 0.08 ppm. Since adverse effects were demonstrated after 6.6 hours of exposure or less, setting an eight-hour standard at the same level of exposure lessens the protection. With health effects at the level of the proposed standard, seemingly small details about how the standard would be interpreted and applied become important. These details include the level at which the standard would be exceeded and the specific form of the standard.

Protection against peak, one-hour exposures. To evaluate the protection against peak, one-hour exposures, we looked at how the proposed eight-hour standard compares to a one-hour level. Analyses of California monitoring data for ozone, from all sites statewide between 1993 and 1995, show that U.S. EPA's proposed eight-hour standard is roughly equivalent to a one-hour value of 0.114 ppm -- just below the current federal standard. This comparison provides a general indication of how the one- and eight-hour values relate to each other on a statewide basis. Analysis of each individual monitoring site (or air basin) would produce a slightly different result, as would any analysis based on other years of data.

A form of the standard that allows multiple exceedances each year to be excused is not consistent with the health evidence. Repeated exposure to ozone can cause inflammation of the lung and carry an attendant risk of long-term effects. U.S. EPA recognizes the potential effects of repeated inflammation of the lungs, yet the agency dismisses the effects by stating "most, if not all, of these effects begin to resolve in most individuals within 24 hours if the exposure to ozone is not repeated." This statement does not reflect the reality of ozone episodes in California where levels can be high for several days in a row under stagnant weather conditions.

The scientific evidence can support an eight-hour ozone standard of 0.08 ppm, with a more protective interpretation of two of the proposed details. First, retaining the current form, expressed as one exceedance per year (or the statistical equivalent), would significantly improve the health protection offered by the proposed eight-hour standard. Second, tightening the level at which the standard is exceeded -- from the current rounding convention of 0.085 ppm to 0.081 ppm -- would provide additional protection against peak one-hour exposures. This change would better align the standard with the lowest concentrations observed to produce adverse effects.

An eight-hour federal ozone standard of 0.08 ppm, exceeded at 0.081 and based on a single exceedance per year would provide adequate protection against both short-term, one-hour exposures and prolonged multi-hour exposures. Such a federal standard would be comparable to the current California ozone standard.

U.S. EPA'S ALTERNATIVE PROPOSALS FOR OZONE

U.S. EPA has also requested comments on the suitability of an eight-hour averaged standard set at 0.09 ppm. Although U.S. EPA characterized the relative protection afforded by a standard of 0.08 versus 0.09 as fairly close, analyses of the limitations of the risk assessment and the air quality data indicate important differences between the two levels.

First, like most risk assessment models, those used by U.S. EPA may not capture the upper or lower ends of the distributions of exposure or response very well. The likely underrepresentation of the individuals at risk for repeated high exposures will to tend to represent the 0.08 and 0.09 ppm standards as conferring more health protection than would actually occur. Second, in a variety of clinical and field studies, there is often a substantial minority (5 to 30 percent) of subjects who tend to be substantially more susceptible to the acute effects of ozone than others. In most such individuals, the responsiveness to ozone appears to be an intrinsic characteristic and is reproducible on repeated exposures separated by weeks to months. U.S. EPA's risk assessment methodology tends to dilute the potential responses of this group and would tend to underestimate the effects likely to occur in response to attainment of the alternative standards.

Finally, analysis of California air quality data shows that an alternative eight-hour standard set at 0.09 ppm is less protective than the current one-hour federal standard.

SUPPORTING TECHNICAL ANALYSES

This section describes our analyses of California air quality data to understand the impacts of U.S. EPA's proposal. To understand the effect of an eight-hour ozone standard on one-hour peaks, we examined the peak levels that would exist if an eight-hour standard is achieved.

The following discussion uses some terminology and notation that we must define before proceeding. Our analyses involve what we call "design values" for alternative standards. We apply the term "design value" according to one of its common meanings: a value that is based on the prevailing air quality data and calculated using the specified form of a standard; the design value can then be compared to the level of the standard to indicate whether the air quality data "attain" the standard for an individual site or a region. In many cases, the regional attainment status would not be determined site-by-site but by the site with the highest design value.

Some additional notation reflects the terminology used in U.S. EPA's Staff Paper concerning the ozone NAAQS review. In the Staff Paper, U.S. EPA distinguishes between "expected exceedance" and "concentration-based" forms for standards. For example, U.S. EPA identifies the present one-hour NAAQS as an expected exceedance form, denoted as ExEx1 -- the 1 indicates that the standard is attained when the expected number of exceedances is less than or equal to one per year. For the ExEx1 standard, the design value for a site is the fourth highest daily maximum one-hour ozone concentration for all three years combined.

In contrast, U.S. EPA identifies the proposed eight-hour ozone NAAQS as a concentration-based form which we refer to as CB3. The CB3 form is the average over three years of the annual 3rd highest daily-maximum eight-hour ozone concentrations. U.S. EPA is also considering CBx forms other than the CB3 form. The alternatives discussed in the Staff Paper are the three-year average of the annual 1st, 2nd, 4th, and 5th highest daily maximum eight-hour concentrations. For each of the CBx alternatives, we use the CBx statistic as the associated "design value".

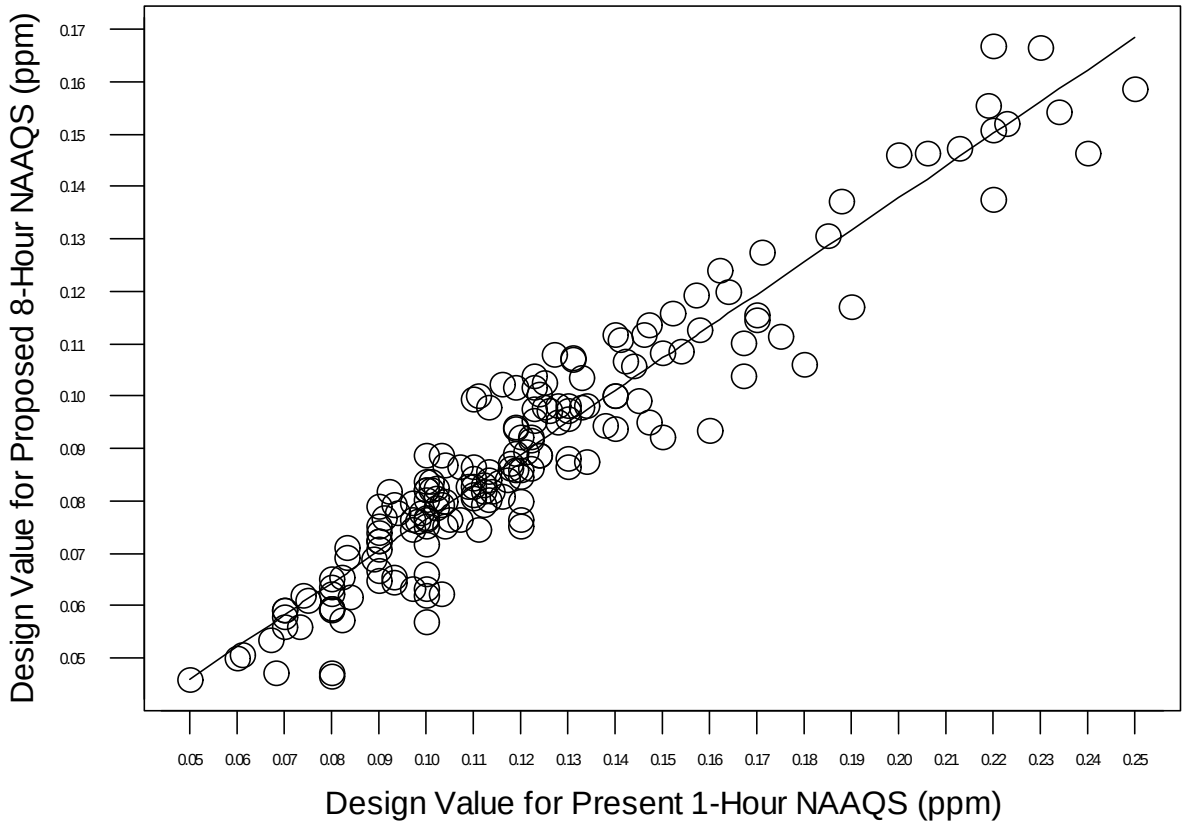
To compare the ExEx1 and CBx standards, we considered all of the ozone air quality data at monitoring sites in California for the three-year period, 1993-1995. For each site where the data met the required completeness criteria, we calculated the respective design values for the alternative standards. As a general rule, the various design values tracked one another.

Figure B-1 shows a scatter plot of the CB3 design value (y-axis) versus the ExEx1 design value (x-axis), where each point represents a monitoring site. Two characteristics of this scatter plot are noteworthy. First, the general relationship between the two design values appears to be linear. Second, the points cluster closely around the best fitting line ($r^2 = 0.91$). These two characteristics indicate that a stable, approximately proportional relationship between the two design values may persist across a wide range of pollution levels (the y-intercept for the line is close to zero).

Figure B-1.

Relationship Between the Proposed 8-Hour Ozone NAAQS and the Present 1-Hour Ozone NAAQS

(All California sites with qualifying data for 1993-1995)



The design value for the proposed NAAQS is the annual 3rd highest daily maximum concentration averaged over three years. The design value for the present NAAQS is the 4th highest daily maximum concentration within three years.

Figure B-2 shows regression lines that relate design values for the five CBx alternatives -- CB1, CB2, CB3, CB4, and CB5 -- to the ExEx1 design value. The x and y coordinates of a point on a line represent approximately equivalent levels for the forms of their respective one-hour and eight-hour standards. For example, the CB3 line on the graph has a point for which the x-axis is close to 0.130 ppm and the y-axis is close to 0.095 ppm, which indicates that these two levels are approximately equivalent for the CB3 eight-hour and the ExEx1 one-hour forms of a standard.

According to Figure B-2, the proposed eight-hour standard (CB3 at 0.085 ppm) is approximately equivalent to a one-hour ExEx1 standard at a level of 0.114 ppm. In other words, the proposed eight-hour standard seems to be somewhat stronger than the present one-hour NAAQS at the level of 0.125 ppm.

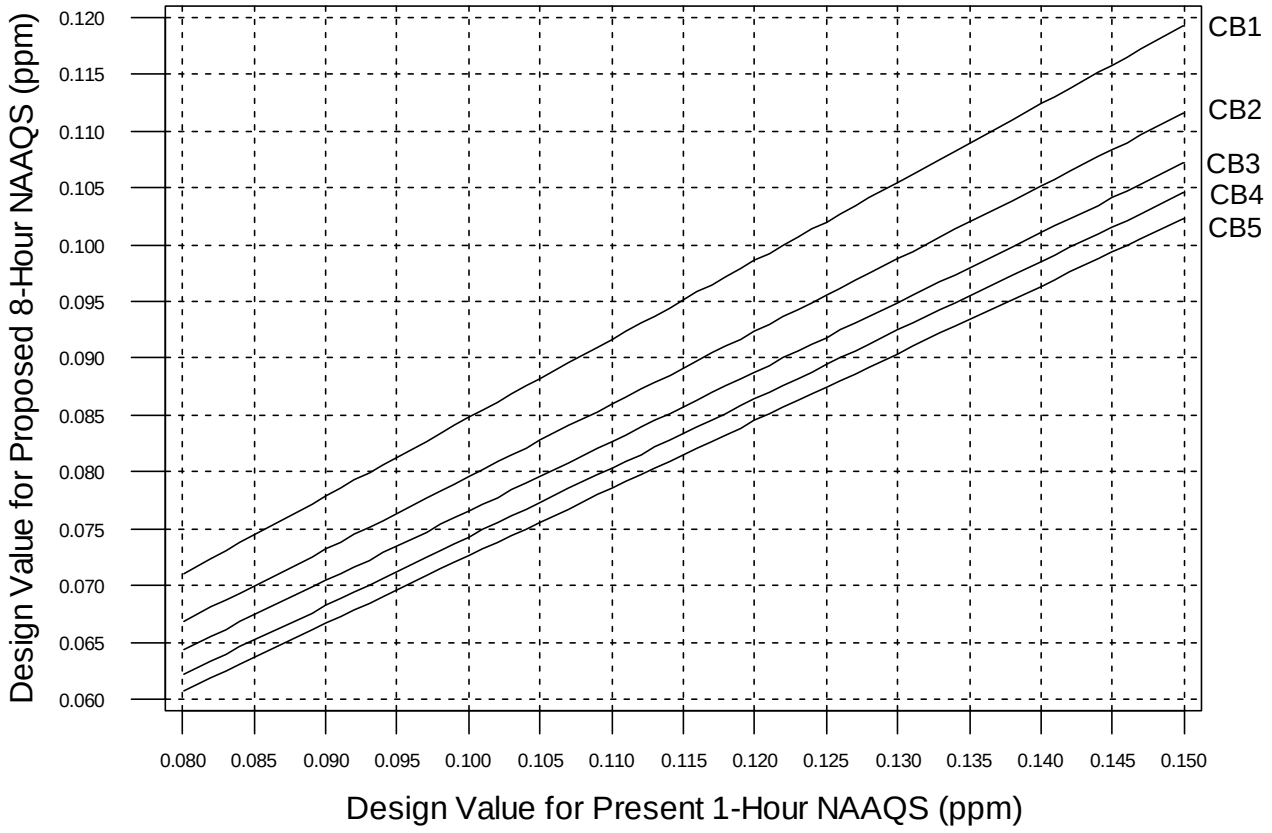
Figures B-1 and B-2 are snapshots in time for all California sites with complete monitoring data. The precise "equivalency" of one-hour and eight-hour values will vary from individual site to site, as will analyses run against a different set of data years. However, analyses for each individual monitoring site and for a wider range of years confirm that the relationship between the daily maximum eight-hour and one-hour average ozone concentrations remains highly correlated and linear. This relationship implies that the same factors that lead to high one-hour maxima also lead to high eight-hour maxima.

Setting the CB3 level to 0.081 ppm (an alternative U.S. EPA is considering) would be like setting the level for a one-hour ExEx1 standard to 0.107 ppm. As expected, an eight-hour standard at 0.081 ppm would be more protective than an eight-hour standard at 0.085 ppm. In each of these cases, the nominal level of the standard is 0.08 ppm, and the difference arises in the number of significant digits and the "rounding convention" to be used when comparing measured air quality data to the standard.

The precision of ozone air quality data appears to be sufficient to support a standard of 0.080 ppm (that is, with the third decimal digit "significant"). In addition, an eight-hour average would have better precision than a single hourly average, further supporting the use of the third decimal digit. There is no technical reason to limit the level of an eight-hour standard to two significant figures. Therefore, both 0.085 ppm and 0.081 ppm seem to be legitimate options for the level of an eight-hour ozone standard.

Figure B-2

Relationship Between Alternative Forms of an 8-Hour Ozone NAAQS and the Present 1-Hour Ozone NAAQS



The design value for each CBx alternative is the annual Xth highest daily maximum concentration averaged over three years. The design value for the present NAAQS is the 4th highest daily maximum concentration within three years.

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