REVISION OF THE NATIONAL AMBIENT AIR QUALITY STANDARD FOR PHOTOCHEMICAL OXIDANTS

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STAFF SUMMARY PAPER

EXTERNAL REVIEW DRAFT

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Review of the National Ambient Air Quality Standard for Photochemical Oxidants

This paper discusses the nature and extent of changes which might be made to the existing air quality standard for photochemical oxidants. It was prepared by the staff of the Strategies and Air Standards Division, Office of Air and Waste Management, EPA, as part of the current review of the oxidant national ambient air quality standard. It has not yet been extensively reviewed within the Agency and therefore does not necessarily reflect Agency policy or an Agency position. However, it is being made available to solicit public review and comment which can be considered in the development of an Agency position on the revision of the oxidant standard.

We have classified the several decisions which must be made regarding the standard into two categories:

1. Those areas where the Strategies and Air Standards Division (SASD) has generated an informal staff position, and
2. Those areas where this office is still considering a range of alternatives.

Background

On April 30, 1971, the Environmental Protection Agency published in the Federal Register (36 FR 8186) National Ambient Air Quality Standards for photochemical oxidants. The scientific, technical, and medical basis for these standards is contained in the air quality criteria document for photochemical oxidants published by the U.S. Department of Health, Education, and Welfare in March, 1970. Pursuant to the provisions of Sections 108 and 109 of the Clean Air Act, as amended, EPA is now in the

process of reviewing, updating, and revising the AP-63 criteria document as well as reviewing the need for modification to the existing photochemical oxidant standard.

An external review draft of the oxidant criteria document was made available to the public in September and was reviewed by EPA's Science Advisory Board in a public meeting on November 10-11, 1977. Comments from this review and meeting are being incorporated into a final draft document scheduled for issuance in late February, 1978 (a second Science Advisory Board public meeting to critique this draft may be held in late January). At the time the revised criteria document is reissued, EPA will propose a revised air quality standard for photochemical oxidants or reaffirm the existing standard.

ISSUES WHERE EPA HAS DEVELOPED A STAFF POSITION

Several decisions must be made to explicitly define an ambient air quality standard. OAQPS has reached a preliminary position on several of these choices including: (1) designation of the chemical species for the standard, (2) averaging time of the standard, (3) a determination on the feasibility of promulgating a peroxyacetyl nitrate (PAN) standard, (4) a standard with a deterministic rather than a statistical form.

Designation of the Chemical Species for the Standard

The existing standard for photochemical oxidants was established for the entire class of this complex mix of compounds. Unfortunately, there are no satisfactory methods for accurately and reliably measuring this collective class of pollutants. The method used to estimate ambient

oxidant levels and to determine compliance measures only a single component of the oxidant mix--ozone. The weakness of this approach is that the chemical designation of the standard and the chemical composition of the pollutant measured to determine compliance are not consistent. Ambient ozone concentrations can range from approximately 65 percent to nearly 100 percent of the total photochemical oxidant concentration. Therefore, ozone may be a poor indicator of the quantity and composition of the non-ozone oxidant in the ambient air. Also of concern is that aside from PAN, which is an important constituent of the photochemical oxidant mix, the non-ozone oxidants remain essentially unidentified, cannot be measured, and have not been uniquely associated with adverse effects.

The inconsistencies cited above argue for moving away from a total photochemical oxidant standard to an ozone standard. Such a change also appears reasonable from a health standpoint. Evidence in the revised draft of the oxidant criteria document indicates that:

1. The majority of data presented in the revised criteria document is based on ozone exposures. Nearly all of the clinical and toxicological studies are based on effects from ozone.

2. Some more recent epidemiological studies associated adverse effects more closely with ozone than with total oxidants, and

3. Effects observed in clinical studies with ozone alone are similar to those effects observed in epidemiological studies where ozone occurs along with the complex mix of urban pollutants. These findings from the health data further suggest that health effects observed during periods of elevated photochemical oxidant concentrations are

reasonably attributable primarily to ozone in the ambient air.

Because it is desirable to designate a standard which is consistent with the material being measured to determine compliance, and the fact that good data exist on the adverse effects of ozone, we plan to propose to redesignate the photochemical oxidant standard as an ozone standard.

Averaging Time of the Standard and Exposure Durations of Concern

Clinical studies clearly show impairment of lung function in moderately exercising healthy subjects exposed to ozone for two hours. Since the impact of ozone is related to the total dose delivered to the respiratory tract and since more intense exercise would shorten the time required to deliver an equivalent dose, exposure durations of less than two hours are of concern for protection of individuals engaged in intense exercise. A recent clinical study published this year by DeLucia, and not available for inclusion in the current draft of the criteria document, appears to confirm this thesis as it shows lung function changes in exercising subjects after one hour exposure to relatively low ozone levels. Based on these considerations, OAQPS does not propose a change in the current one hour averaging time of the standard.

Promulgation of a Primary Standard for PAN

Ozone and PAN are the primary chemical species in the oxidant mix for which health effects data have been documented. The key effect associated with exposure to PAN is eye irritation. However, at the present time the health data upon which to base a separate PAN standard is inadequate and routine PAN measurement methods are not available. Most of the studies which have documented the effects of

PAN have used ozone or total oxidants as a surrogate for the material causing the adverse effect.

Ozone is not a reliable indicator of PAN. Recorded data shows ozone/PAN ratios ranging from 3 to 150. This variation in the ratio of ozone to PAN makes it extremely difficult to correlate the eye irritation effects of PAN with specific ozone values. However, it has been shown that at ozone levels of about 0.1 parts per million (ppm), PAN concentrations will be at a level below those associated with perceptible eye irritation effects. This is true even for pessimistic (low ozone/PAN ratios) assumptions regarding the ozone/PAN ratios.

Despite the lack of a separate PAN standard, those measures taken to reduce oxidant/ozone precursor emissions will also reduce PAN levels. In fact, the revised draft criteria document reports that smog chamber studies show control of oxidant precursor emissions have a greater impact on PAN levels than on ozone/oxidant levels.

A Standard with a Deterministic vs. Statistical Form

The current oxidant standard is stated in a deterministic form, that is, a standard violation is determined by the second highest ambient concentration as measured by a single ambient monitor. A similar standard expressed in a statistical form would allow the expected number of exceedances of the standard to be one. The original purpose of permitting a single exceedance of the existing standard was to allow for unusual meteorological conditions that were unrepresentative of air quality in a given area. Unfortunately, this objective is not achieved by the current standard since the once-a-year approach

specifies in effect that there be zero probability that the second high concentration measured in a year exceed a given value. That is, when a single exceedance of the standard is permitted, a second or third exceedance is also likely to occur. If this probability is zero, then pollutant emissions must be sufficiently low to prevent the standard concentration from being exceeded even in years in which very rare adverse weather conditions occur.

Another fundamental problem with the current deterministic standard is that it focuses on a single measured value, the second high observation. This value is subject to instrument error, is not a stable statistic, and also will vary in any given area over a period of time. Use of such a random statistic to determine compliance and levels of control can lead to values that are unrepresentative of the true air quality problems in an area.

An approach to avoiding the problems of a deterministic air quality standard is to redefine the standard in a way that does not require us to rely on a single measured value. This can be done, while maintaining the focus of the standard on peak concentrations, by defining the standard in terms of probability distributions or expected values. For example, the standard could read 0.08 ppm one hour average with an expected number of exceedances of one per year. We plan to propose a change from the current deterministic standard to one stated in statistical terms.

ISSUES WHERE EPA IS CONSIDERING A RANGE OF ALTERNATIVES

Preliminary reviews of the health evidence presented in the draft revised criteria document suggest that the standard level be set somewhere below 0.15 ppm and that the choice within that range be based on the level and nature of health risk tolerated. At this time, we are not prepared to accept recommendations made to us to set a standard at a higher level, but we are ready to listen to these and other proposals during the public review process. Recommendations which we are not prepared to accept at this time include: (1) Ford Motor Company's recommendation for a 0.24 ppm max one hour concentration not to be exceeded more than once in a 90 day period. (2) The recommendation of the city of Houston, Texas for a standard in the range of 0.2 ppm to 0.4 ppm and, (3) The Manufacturing Chemists Association recommendation of a 0.25 ppm 4 hour average standard. We are also in disagreement with several other groups (American Petroleum Institute, General Motors Co., and Shell Oil Co.) who fell short of recommending a specific standard level but concluded that there are no significant effects due to ozone at levels below the 0.25 - 0.37 ppm range. We disagree with the estimated effects level suggested by these proposals (particularly for sensitive segments of the population) and with the implication that a standard should be set at a relatively high level.

Primary Standard Level, Risk, and Margin of Safety

The Clean Air Act requires that the EPA Administrator establish ambient air quality standards that protect sensitive segments of the population, with an adequate margin of safety, from the adverse effects

of specified pollutants. This is an extremely difficult task and requires that health judgments be made as well as reasoned assessments of health criteria and information. Uncertainties exist with regard to the way studies were performed, the lack of experimental data for sensitive individuals, the synergistic and exacerbating effects of other pollutants in the ambient air, and the lack of conclusive experimental or epidemiological evidence to support an exact effects level. In an attempt to deal with these uncertainties in a reasonable and logical way for arriving at a decision on the standard, two complementary approaches were used to assess the significance of the health effects information presented in the oxidant criteria document. One is a qualitative consensus judgment of leading health experts regarding effects levels, risks, and safety factors. The second approach is more quantitative and separates effects judgment from risk judgments, but also calls upon health experts for health related judgments.

Qualitative Approach

This input to the standard setting process provided an in-depth interpretation by a panel of leading health experts of the effects data provided in the criteria document. Experts were selected based on their contribution to the key health effects studies cited in the criteria document and their general medical background. Included in the group were both those researchers who had performed these studies as well as those EPA health experts responsible for preparation of the criteria document. At a two-day meeting on June 7 and 8, 1977, panel members addressed issues regarding effects level, margins of

safety, risks, sensitive population, seriousness of effects, exposure durations, and the technical merit of individual studies.* Key findings from these discussions are summarized below.

With regard to health studies, the panel reached consensus that short-term exposure to ozone in the range of 0.15 ppm to 0.25 ppm may impair mechanical function of the lung, and may induce respiratory and related symptoms in sensitive segments of the population. These symptoms and effects will be more readily induced in exercising subjects, particularly in a complex urban atmosphere environment in which ozone can interact with other pollutants.

The panel judged that the occurence of respiratory symptoms and alterations of mechanical function of the lung have important public health implications, particularly for the developing lungs of young children. Although such effects appear to be reversible in exposed young adults, they represent a potentially serious risk for asthmatics and other individuals with ariway disease. In the population of individuals with varying states of biological adaptability, exposures which produced the above, described effects may at times overwhelm the biological defense of some persons. Thus, the reversibility of effects in experimentally exposed healthy subjects should not be generalized to the entire population.

In reviewing the Schoettlin and Landau asthma study used to support the original standard, the panel agreed that evidence supports the statement that a portion of asthmatics will be affected by maximum

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*Panel report available as part of support material for this paper.

hourly concentrations of 0.2 ppm* and that this effect is likely to occur at concentrations in the range of 0.15 to 0.25 ppm in some asthmatics or other persons with sensitive airways. More recent Japanese epidemiological studies by Kagawa and Toyama were also cited as showing a decrease in ventilatory function of school children at ambient ozone concentrations from 0.1 to 0.3 ppm. The panel concluded that these studies further supported the evidence for an increased health risk from ozone exposure over the range of 0.15 to 0.25 ppm and that a likelihood of lesser but real health risks exists at even lower concentrations.

Of key importance in the animal studies are findings of increased susceptibility to bacterial infection following ozone exposures of 0.1 ppm. The panel agreed that these studies have definite human health implications. Although an exposure level associated with such effects in humans may be different, these reactions in laboratory animals represent basic biological responses to infectious agents, and there is no reason to believe that the pollutant induced alterations of basic defense mechanisms in experimental animals would not occur in similarly exposed and challenged humans. However, the panel was not aware of any epidemiological evidence that susceptibility to infection increases in persons exposed to ozone and other photochemical materials. The panel also agreed that the margin of difference between ozone concentrations that produce serious toxicological effects in animals (as

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*This number is at variance with the draft criteria document value of 0.25 ppm since the panel estimate represents a medical judgment of the most likely effect level for this study and not simply the concentration recorded by investigators.

well as symptomatic and lung function changes in humans) and ambient levels of ozone is much smaller than for any other atmospheric pollutant.

In reviewing the body of evidence on health effects, the health panel concluded that there is no reason to suggest a change from the concentration defined by the existing primary air quality standard, namely, 0.08 ppm. This conclusion was based upon the panel consensus that a variety of adverse effects are likely to occur in some segments of the population from short-term ozone exposures of 0.15 to 0.25 ppm and upon other evidence that suggests, though less conclusively, a possibility of effects at concentrations as low as 0.1 ppm.* The panel recognized that this standard provides a very small margin of safety, as noted above. The issues of how many times the 0.08 ppm one-hour level could be exceeded without increased health risks was also addressed. The panel agreed that the level of health risks increased: (1) in proportion to the hourly concentration above 0.08 ppm, (2) in proportion to the number of hours in one day above 0.08 ppm, and (3) in proportion to the frequency of days in which hourly averages exceed 0.08 ppm, though the latter conclusion was recognized to be quite judgmental and generally lacking in confirmatory studies. Nevertheless, the panel could not cite a medical reason to suggest that an exceedance of the standard were witohut health risks.

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*While we respect the opinion of the panel members, we do not necessarily agree that: (1) inadequate data exist to select a standard level (be it the same or different from the existing standard), (2) that any possible decision to reaffirm the existing standard be based on a lack of data. Conversely, such a choice should be based on health criteria and evidence in the criteria document.

Quantitative Approach

In an attempt to provide a more rigorous approach to the standard setting process, we have developed a new methodology for systematically collecting and assessing the data important for a standard setting decision. This methodology has the following characteristics: 1) it considers all available data and where critical data is lacking, the best possible judgment of medical experts is used, 2) the uncertainty associated with the judgment of medical experts is quantified, and 3) quantitative decision analysis techniques are used to calculate the risks associated with alternative options regarding the standard. The output of this approach estimates the risk that sensitive segments of the population will be subjected to identified adverse health impacts at various alternative standard levels.

The preliminary step in the quantitative approach is to develop numerical estimates regarding the judgments of medical experts on their confidence that an effect level exists at a specified pollutant concentration. A number of such estimates were developed through the cooperation of medical experts with substantial recognition in the area of oxidant/ozone effects research. These individuals include Drs. Timothy Crocker, Jack Hackney, Bernard Goldstein, David Bates, Richard Ehrlich, and Carl Shy. The key effects categories identified by these investigators to describe the health impact of ozone and photochemical oxidants are: 1) alteration of pulmonary function, 2) cough and chest discomfort, 3) reduced resistance to bacterial infection in man, and 4) aggravation of asthma, emphysema and chronic bronchitis.

Risk values were generated by combining the judgment on effects levels by medical experts with our best assessment of the expected distribution of peak ozone values at various standard levels. Preliminary results from this analysis suggest that health effects can be observed in selected populations at standard levels of about 0.1 ppm ozone. For example, the risk that at least a small percentage of individuals in sensitive segments of the population will suffer any one or a combination of the above mentioned effects is in the range of 70 percent to 90 percent for an ozone standard of 0.1 ppm.

Number of Exceedances of the Standard

The existing standard permits a single exceedance of the standard level each year. The rationale for providing this flexibility was not based on health criteria but on the need to allow for unusual meteorological conditions. A move to an increased number of exceedances of the standard cannot be supported based on existing health data. Rather, the health data indicate that the insult to the respiratory tract is related to the total dose of ozone delivered, i.e., it is related to the exposure concentration, frequency of exposure and duration of exposures. Thus, the health risk to an individual increases not only with the ozone concentration but also with the number of exposures. Furthermore, while healthy individuals may not be at serious risk from a single one-hour exposure to ozone, similar exposures of sensitive persons such as asthmatics may induce a serious health effect, and repeated exposures of even healthy persons may lead to increased risks of respiratory impairment. Consequently, we question whether it is prudent to significantly modify the number of exceedances (or expected exceedances) of the standard.

Because of our concerns regarding unusual meteorological events, we are considering changing the form of the standard to allow one (or more) days in which the hourly standard is exceeded. Permitting a day of hourly values above the standard would more reasonably account for rare meteorological events. Unusual weather conditions are likely to result in two or three consecutive hours of high ozone values. A standard which allows a full day of hourly exceedances would permit the unusual day (with several high ozone values) to occur an average of once a year; the present standard would have registered a violation for this day. Unfortunately, this approach has the same limitation as the existing rule for exceedances (one hour per year permitted) in that it cannot be based on health criteria. There will undoubtly be some finite increase in health risk associated with moving from a single hourly exceedance to a single day of hourly exceedance(s). We are not prepared at this time to estimate that incremental risk or make a judgment on whether such an incremental risk would be acceptable. Our staff position on this issue is open and we welcome comment on how to best account for meteorological concerns without impairing health protection when defining allowable exceedances of the standard.