

November 30, 1995

EPA-SAB-CASAC-LTR-96-002

Honorable Carol M. Browner
Administrator
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460

RE: CASAC Closure on the Primary Standard Portion of the Staff
Paper for Ozone

Dear Ms. Browner:

A Panel of the Clean Air Scientific Advisory Committee (CASAC) of EPA's Science Advisory Board (SAB) met on March 22, 1995, to review a draft of the primary standard part of the document entitled Review of National Ambient Air Quality Standards for Ozone Assessment of Scientific and Technical Information OAQPS Staff Paper. At that time, a draft of the secondary standard portion of the document was not completed. At the March meeting, the Panel made extensive recommendations for strengthening the document. In August 1995, a revised Staff Paper, which included a first draft of the secondary standard portion was sent to CASAC panel members for review. On September 19 and 20, 1995, the Panel met to complete this review. The Panel members' comments reflect their satisfaction with the improvements made in the scientific quality and completeness of the primary standard portion of the Staff Paper. The changes made in that portion of the document are consistent with CASAC's recommendations. However, the Panel Members provided additional comments to your staff at the meeting and subsequently in writing. Although the Panel would like to have these comments considered for incorporation in the Staff Paper, the Panel did not feel that it was necessary to review another revised version and came to closure on the primary standard portion. It was the consensus of the Panel that although our understanding of the health effects of ozone is far from complete, the document provides an adequate scientific basis for making regulatory decisions concerning a primary ozone standard.

The Panel could not come to closure, however, on the secondary standard

portion of the Staff Paper which was a first draft. To facilitate further development of this part of the Staff Paper, the Panel members have provided detailed comments to your staff. The Panel felt that the suggested revisions were extensive enough to warrant a review of the next draft.

I would like to summarize for you the Panel's recommendations concerning the primary standard. It was the consensus of the Panel that EPA's selection of ozone as the surrogate for controlling photochemical oxidants is correct. It was also the consensus of the Panel that an 8-hour standard was more appropriate for a human health-based standard than a 1-hour standard. The Panel was in unanimous agreement that the present 1-hour standard be eliminated and replaced with an 8-hour standard.

The Panel felt that the weight of the health effects evidence indicates that there is no threshold concentration for the onset of biological responses due to exposure to ozone above background concentrations. Based on information now available, it appears that ozone may elicit a continuum of biological responses down to background concentrations. This means that the paradigm of selecting a standard at the lowest-observable-effects-level and then providing an "adequate margin of safety" is no longer possible. It further means that EPA's risk assessments must play a central role in identifying an appropriate level.

To conduct the risk assessments, the Agency had to identify the population at risk and the physiological responses of concern, develop a model to estimate the exposure of this population to ozone, and develop a model to estimate the probability of an adverse physiological response to the exposure. The Panel agrees with EPA that the selection of "outdoor children" and "outdoor workers," particularly those with preexisting respiratory disease are the appropriate populations with the highest risks. After considerable debate, it was the consensus of the Panel that the Agency's criteria for the determination of an adverse physiological response was reasonable. Nevertheless, there was considerable concern that the criteria for grading physiological and clinical responses to ozone was confusing if not misleading. The Panel concurs, with the Agency that the models selected to estimate exposure and risk are appropriate models. However, because of the myriad of assumptions that are made to estimate population exposure and risk, large uncertainties exist in these estimates.

The results of two of the risk analyses are presented in Tables VI-1 and VI-2 in the Staff Paper and are reproduced in the attached tables. The ranges of the risk estimates across nine cities for outdoor children are presented in Table VI-1. Because of the large number of stochastic variables used in the exposure models, the exposure

estimates vary from run to run. However, the ranges are not reflective of all of the uncertainties associated with the numerous assumptions that were made to develop the estimates.

The single estimates presented in Table VI-2 do not reflect any of the uncertainties associated with these estimates. (Table VI-2 contains only the estimated hospital admissions due to asthma which account for over 85% of the estimated total hospital admissions due to ozone exposure). These uncertainties need to be explicitly articulated in order to put the estimates in proper perspective. Nevertheless, based on the results presented in these and other similar tables presented in the Staff Paper, the Panel concluded that there is no “bright line” which distinguishes any of the proposed standards (either the level or the number of allowable exceedences) as being significantly more protective of public health. For example, the differences in the percent of outdoor children (Table VI-1) responding between the present standard and the most stringent proposal (8H1EX at 0.07 ppm) are small and their ranges overlap for all health endpoints. In Table VI-2, the estimates in row 1, which appeared in the draft Staff Paper, suggest considerable differences between the several options. However, when ozone-aggravated asthma admissions are compared to total asthma admissions (rows 5 and 6), the differences between the various options are small. Consequently, the selection of a specific level and number of allowable exceedences is a policy judgment. Although it was the consensus of the Panel that the ranges of concentrations and allowable exceedences proposed by the Agency were appropriate, a number of Panel members expressed “personal” preferences for the level and number of allowable exceedences. Of the ten panel members who expressed their opinions, all ten favored multiple allowable exceedences, three favored a level of 0.08 ppm, one favored the mid to upper range (0.08 - 0.09 ppm), three favored the upper range (0.09 ppm), one favored a 0.009 - 0.10 ppm range with health advisories issued when the 8-hour ozone concentration was forecasted to exceed 0.007 ppm, and two just endorsed the range presented by the Agency as appropriate and stated that the selection should be a policy decision. The members who favored the lower numbers expressed concern over the evidence for chronic deep lung inflammation from the controlled human and animal exposure studies and the observations of pain on deep inspiration in some subjects.

Because there is no apparent threshold for responses and no “bright line” in the risk assessment, a number of panel members recommended that an expanded air pollution warning system be initiated so that sensitive individuals can take appropriate “exposure avoidance” behavior. Since many areas of the country already have an infrastructure in place to designate “ozone action days” when voluntary emission

reduction measures are put in place, this idea may be fairly easy to implement.

It was also the consensus of the Panel that the form of the 8-hr standard be more robust than the present 1-hour standard. The present standard is based on an extreme value statistic which is significantly dependent on stochastic processes such as extreme meteorological conditions. The result is that areas which are near attainment will randomly flip in and out of compliance. A more robust, concentration-based form will minimize the “flip-flops,” and provide some insulation from the impacts of extreme meteorological events. The Panel also endorses the staff recommendation for creating a “too close to call” category.

Since the last ozone NAAQS review, the scientific community has made great strides in their understanding of the health effects of ozone exposure because of ongoing research programs. Panel members were very impressed with how much more we understand now as compared to the prior round. Nevertheless, there are still many gaps in our knowledge and large uncertainties in many of the assessments. For example, there is little information available on the frequency of human activity patterns involving outdoor physical exercise. Little is also known about the possible chronic health impacts of ozone exposure over a period of many years. In addition, there is no clear understanding of the significance of the inflammatory response inferred from the broncholavage data. Panel members stated, however, that the scientific community is now in a position to frame the questions that need to be better resolved so the uncertainties can be reduced before the next ozone review in 5 years. For this reason, it is important that research efforts on the health and ecological effects of ozone not be reduced because we have come to closure on this review.

CASAC would appreciate being kept informed of progress on establishing a revised or new ozone standard, and plans for research on ozone effects. Please do not hesitate to contact me if CASAC can be of further assistance in this matter. We look forward to receiving the revisions of the secondary standard portion of the Staff Paper.

Sincerely,

/signed/

Dr. George T. Wolff, Chair
Clean Air Scientific Advisory Committee

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**Table VI-2 (revised)
ESTIMATED HOSPITAL ADMISSIONS FOR ASTHMATICS IN THE NEW YORK CITY AREA**

	1H1EX 0.12	1H1EX 0.10	8H1EX 0.10	8H1EX 0.09	8H1EX 0.08	8H1EX 0.07	8H5EX 0.09	8H5EX 0.08	AS IS
Excess Admissions ^a	210	130	240	180	110	60	180	120	=385 ^d
% ^ from present std	0%	-38%	+14%	-14%	-48%	-71%	-14%	-42%	+83%
Excess + background ^b	890	810	920	860	790	740	860	800	1065 ^e
% ^ from present std	0%	-9%	+3%	-3%	-11%	-17%	-3%	-10%	+20%
All asthma admissions ^c	28,295	28,215	28,325	28,265	28,195	28,145	28,265	28,205	28,470 ^f
% ^ from present std	0%	-0.3%	+0.1%	-0.1%	-0.4%	-0.5%	-0.1%	-0.3%	+0.6%

a - excess asthma admissions attributed to ozone levels exceeding a background concentration of 0.04 ppm; from Table VI-2, page 155 in the August 1995 OAQPS Draft Staff Paper
b - asthma admissions included in (a) plus those due to background ozone concentrations; admissions due to background = 1065^e - 385^d = 680
c - asthma admissions due to all causes = 28,470^f - 385^d - Excess Admissions from row 1
d - estimated from Figure V-15, page 125 in the August 1995 OAQPS Draft Staff Paper
e - from page 127, line 13 in the August 1995 OAQPS Draft Staff Paper
f - total admissions from asthma = total asthmatics (365,000 - from page 126, line 24) x hospitalization rate (78/1000 asthmatics - from page 126, line 29)

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