

April 29, 2005

Mr. Fred Butterfield  
Designated Federal Officer  
EPA Science Advisory Board [1400F]  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460

Re: Comments on EPA's Ozone Health Assessment Plan: Scope and Methods for Exposure Analysis and Risk Assessment, 70 *Fed. Reg.* 10544, April 20, 2005

Dear Mr. Butterfield:

The American Petroleum Institute (API) is pleased to comment on the U.S. Environmental Protection Agency's (EPA's) Ozone Health Assessment Plan: Scope and Methods for Exposure Analysis and Risk Assessment (the 'Plan'). API is a national trade association with over 400 member companies involved in all aspects of the oil and natural gas industry. As API members' facilities and products both factor heavily into ozone (O<sub>3</sub>) attainment strategies, our members have a significant interest in the review of the O<sub>3</sub> National Ambient Air Quality Standards (NAAQS).

General Comments:

**We object to the extremely short notice provided for public comment.**

The Plan was published on April 20, 2005. EPA requests that public comments be received by April 28, 2005 for Clean Air Scientific Advisory Committee (CASAC) review. Although EPA will accept public comments as late as May 5, 2005, the day of the CASAC review, such later comments are unlikely to be considered during the scheduled CASAC review. Since the risk assessment is perhaps the most critical document used to decide whether to revise an existing ozone standard and since the ozone NAAQS revision schedule is under a consent decree, additional time for critical public review of proposed Agency assessment Plan now, before expenditure of considerable time and Agency resources, is warranted both on efficiency and regulatory policy grounds. Accordingly, we request that Office of Air Quality Planning and Standards (OAQPS) staff and CASAC members delay implementation of the proposed assessments until the Plan has been fleshed out according to comments below and time has been provided for a thorough review by CASAC and the public.

**Preliminary API analysis indicates that many proposed assessment approaches are flawed.**

The Plan indicates that many of the approaches used in the 1996 ozone risk assessment will be incorporated by OAQPS into their 2005 effort. For example, pulmonary function and symptoms will be used as endpoints in the chamber-based risk assessment and dose-response functions will be formulated from the same three Agency chamber studies used in the last rulemaking. Similarly, young adult male dose-response functions will be used to estimate responses of

children and older adults even though research indicates these cohorts to be several-fold less responsive.

Given the similarity between the 1996 and 2005 chamber-based risk assessments, it is appropriate for CASAC and the Agency to consider the findings of our critical review and sensitivity testing of assumptions and risk assessment models used in the 1996 rulemaking. A summary of our results is attached as Appendix A. We call EPA's and CASAC's attention specifically to comments reviewing questionable assumption and approaches employed in the 1996 exposure (pp 15-20) and risk models (pp 20-34). The proposed 2005 Plan needs to specify the 'lessons learned' from the last NAAQS review and to address the improvements anticipated from the subsequent ten years of additional research available.

Specific Comments (Plan page/paragraph/line):

*2/4/1 – The planned exposure analysis and health risk assessment described in the Scope and Method Plan build upon the methodology and lessons learned from the exposure and risk work conducted for the last review. We are gratified that OAQPS has chosen to modify some approaches taken in the 1996 risk assessment but are distressed that many of the core assumptions and practices discussed below reflect little change from this earlier flawed approach.*

*3/4/1 – In order to conduct exposure and risk analyses...staff will adjust the air quality data to simulate just meeting the current and alternative standards. The adjustment of air quality data will be based on three years of data (2002-2004). Staff is currently considering various approaches to making such adjustments, including the quadratic air quality adjustment approach that was evaluated and used in the last review. Staff's rationale for using only 2002-2004 data, rather than more widely spaced hi-lo years to validate their adjustment algorithms is unclear. Differences in ozone air quality over such short periods will surely more reflect changes in meteorology than emissions reductions. As EPA has not proposed to control the weather as a means of achieving standards compliance, we encourage staff to consider calibrating proposed adjustment approaches over longer (10-20 year) periods where hi-lo years would better reflect changes in precursor emissions. We also suggest that the hi-lo years be selected from years with normal meteorology to remove the effects of atypical weather patterns.*

*3/5/10 – In particular, the results of the global tropospheric O<sub>3</sub> model GEOS-CHEM will be used to estimate monthly average background O<sub>3</sub> levels for different geographic regions across the U.S. As noted in earlier API comments on the January draft ozone Air Quality Criteria Document (AQCD), case-study results from more highly spatially resolved models than the GEOS-CHEM model exercised by Fiore et al. (2003) provide contradictory findings, reporting a larger degree of stratospheric O<sub>3</sub> contribution at elevated sites (e.g., Yellowstone). The failure of the Fiore model to correctly quantify ozone sources for seasons at locations where such non-anthropogenic signals should be the highest calls into question its reliability at lower elevations less optimal for modeling. Use of a monthly average background level is an improvement over the 7-month seasonal average used in the 1996 assessment; however, we continue to believe that comparable statistics should be compared. Since compliance is determined from the 3-year average of the 4<sup>th</sup> highest daily maximum 8-hour values (the approximate 98-99<sup>th</sup> percentile of the annual distribution of daily maximum 8-hour average ozone values), a similar statistic for background fluctuations should be estimated for comparisons to ozone standards.*

*4/1/8 – This choice of population groups includes a strong emphasis on children, which reflects the results of the last review in which children, especially those who are active outdoors, were identified as the most important at-risk group. As noted in Appendix A (pp. 17-18), this 1996*

result likely resulted from the faulty approach used then both to characterize the behaviors of 'outdoor children' and the proportion of children who might be expected to maintain this lifestyle. Given the likely impact of this error on the projected magnitude of outdoor children's exposure and the subsequent compounding error of applying adult dose-response functions to children's exposure (discussed at 12/2/6 below), the Agency should seriously consider whether another group, such as the outdoor construction workers, might actually be the most at-risk population.

*4/3/1 – The EPA has developed APEX [the Air Pollutants Exposure model] as a tool for estimating human population exposure to criteria and air toxic pollutants. We congratulate OAQPS staff in maintaining and improving the regulatory exposure models over the last three decades in a progression from the original NAAQS Exposure Model (NEM) to the probabilistic NEM (pNEM) to APEX. We look forward to the opportunity to test and exercise APEX when it is finally available for public use and anticipate that it will continue to remain at the cutting edge of regulatory models, as did its predecessors during their day.*

*4/4/4 – The population demographics are from the 2000 Census at the tract level, and a national commuting database based on 2000 census data provides home-to-work commuting flows between tracts. While we appreciate and support inclusion of worker commuting patterns, the Agency makes clear that the risk assessment will place a 'strong emphasis' on children. The lack of a similar home-to-school commuting pattern for the school-age children that EPA will model is a distinct liability. API has researched this area and reported its findings to the Agency and its contractors<sup>1</sup>. We are disappointed that EPA has not chosen to correct this deficiency given available research. We encourage the Agency to include such home-to-school commuting patterns into APEX.*

*5/6/3 – Hourly O<sub>3</sub> concentration measurements from the fixed-site monitoring data maintained in EPA's Air Quality System and surface temperatures from the National Weather Service will be spatially interpolated for each study area for input to APEX. It is unclear in the Plan how the Agency will define the impact areas of individual monitors. The Plan should offer some description of the extent of geographical extrapolation and interpolation and the role of topographical impediments.*

*6/1/2 – Exposure modeling will also be performed based on policy-relevant background [PRB] concentration levels alone, in order to be able to assess health risks due to O<sub>3</sub> concentrations in excess of background. We support the Agency's decision to estimate risks that may be controlled by regulation, although we differ on the appropriate form and level of PRB as noted in PRB comments submitted earlier by Dr. Allen S. Lefohn on the AQCD.*

*6/2/10 – Staff, in conjunction with staff from NERL [National Exposure Research Laboratory], is developing a methodology for constructing longitudinal diaries from the CHAD [Consolidated Human Activity Database] data which will be used in the O<sub>3</sub> exposure analysis. This method will be described in the exposure analysis technical support document. A brief conceptual discussion of the methodology under consideration should be provided in the Plan. CASAC and the public are not being given adequate information to assess the Agency's methodology even from a conceptual framework, let alone on the basis of detailed information.*

*7/1/4 – In this analysis, exposure indicators will include daily maximum 1- and 8-hour average O<sub>3</sub> exposures, stratified by equivalent ventilation rates (i.e., ventilation normalized by body*

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<sup>1</sup> API, (1999), "A Home-to-School Commuting Model for Use in Population Exposure Assessments", API HESD Pub. No. FR 5, American Petroleum Institute, Washington, DC, April.

*surface area*). Although initially we were hopeful that the above description indicated that the 2005 risk assessment would take into account the effects of equivalent ventilation rates (EVR) on Forced Expiratory Volume (FEV) decrements, we understand from staff that it will not. As noted in Appendix A (pp. 32-34), a failure to incorporate breathing rate effects into the dose-response function results in a large overestimation of projected ozone effects. In 1996, EPA deemed all responses at a given O<sub>3</sub> concentration in the EVR range of 13-27 liters per minute (lpm)/m<sup>2</sup> of body surface area to be equivalent. By arbitrarily refusing in 1996 to consider responses reported for prolonged chamber studies other than its own, the Agency ignored findings from exposures conducted at 30 lpm to compare to its studies at 40 lpm, information that would have allowed them to quantify EVR effects on response<sup>2</sup>. EPA should correct this error in its 2005 assessment. Furthermore, contemporary<sup>3</sup> and recent<sup>4</sup> studies exploring realistic diurnal exposure patterns, as contrasted to the flat, 'square-wave' exposures used in the EPA studies, indicate the importance of accounting for variations in O<sub>3</sub> level during prolonged exposures in predicting population response. The Agency should incorporate such new understanding into its 2005 assessment.

*8/2/8 – Children will be characterized as active if their median daily [Physical Activity Index] PAI over the period modeled is 1.75 or higher, a level characterized by exercise physiologists as being 'moderately active' or 'active'. The relationship between PAI and nominal EVR is not simple. The Plan should provide an approximate PAI-EVR equivalence table to facilitate comparisons of the available chamber exertion levels used to quantify pulmonary function decrements.*

*10/3/10 – For the current health risk assessment, staff plans to use the probabilistic exposure-response relationships developed during the last review, which was based on analysis of individual data that describes the relationship between a measure of personal exposure to O<sub>3</sub> and the measure(s) of lung function recorded in the study. This statement confirms our concerns in the above comment that EVR effects will be neglected the 2005 study.*

*12/2/1 – In the last review, the health risk assessment estimated both lung function decrements ( $\geq 10$ ,  $\geq 15$ ,  $\geq 20\%$  changes in FEV<sub>1</sub>) and respiratory symptoms in children 6-18 years old associated with 1-hour exposures at moderate and heavy exertion and 8-hour exposures at moderate exertion. As noted in Appendix A (p.29), 6-hour exposures at quasi-continuous breathing rates of 40 lpm are deemed by EPA chamber study authors and the 1996 AQCD as 'severe manual labor' and 'strenuous work or play', not moderate exertion. The Plan does not specify how it will determine how representative such prolonged exertion is to normally encountered work or play. As noted in Appendix A (p. 30), it is doubtful whether such prolonged continuous exertion is currently experienced by significant numbers of individuals.*

*12/2/6 – As discussed in the 1996 Staff Paper and AQCD, findings from other chamber studies for children 8-11 years old and summer camp field studies in at least six different locations in the United States and Canada found lung function changes in healthy children similar to those observed in health adults exposed to O<sub>3</sub> under controlled chamber conditions. Staff intends to use the same approach in this assessment [citations omitted and emphasis added]. As noted in Appendix A (pp. 31-32), use of the word 'similar' in this context must incorporate children's*

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<sup>2</sup> Linn, W.S., D.A. Shamoo, K.R. Anderson, R-C. Peng, E.L. Avol, J.D. Hackney. Effects of prolonged, repeated exposure to ozone, sulfuric acid, and the combination in health and asthmatic volunteers. *Am J Respir Crit Care Med* 150: 431-40 (1994).

<sup>3</sup> Hazucha, M.J., L.J. Folinsbee, E. Seal, Jr. Effects of steady-state and variable ozone concentration profiles on pulmonary function. *Am J Respir Crit Care Med* 146: 1487-93 (1992).

<sup>4</sup> Adams, W.C. Comparison of chamber and facemask 6.6-hour exposure to 0.08 ppm ozone via square-wave and triangular profiles on pulmonary responses. *Inhalation Tox* 15: 265-81 (2003).

responses 2-3 fold lower than those measured for young male adults. The Agency should correct this 1996 oversimplification in its 2005 risk assessment and incorporate the lessened responses of younger and older individuals rather than equating them to responses reported for the 18-25 year old group.

12/3/4 - ...staff plans to include only the 8-hour moderate exertion exposures in the current risk assessment for this [lung function] endpoint. We agree with this focus on responses connected to the current 8-hour NAAQS.

12/5/5 – *The data from these controlled human exposure studies are corrected for the effect of exercise in clean air to remove any systematic bias that might be present in the data attributable to an exercise effect. Generally, this correction for exercise in clean air is small relative to the total effects measures in the O<sub>3</sub>-exposed cases.* The Agency ignores a positive bias created by this approach that results from normalizing O<sub>3</sub>-exposed responses to zero ozone exposure. This correction is inconsistent with EPA's decision to compare estimated risks to background O<sub>3</sub> exposure risks, not controllable under foreseeable Agency regulation. Accordingly, chamber responses should be corrected against background ozone level responses, rather than zero O<sub>3</sub> levels at exercise.

13/2/5 – *The mean number of occurrences [of FEV decrements  $\geq 15\%$  or  $20\%$ ] per child also will be calculated to provide an indicator of the average number of time that a responder would experience the specified effect during an O<sub>3</sub> season.* As noted in Appendix A (pp. 13-14), how EPA treats the issue of 'responders' greatly affects its estimates of individual occurrences. The Plan should specify how this issue will be addressed in the 2005 assessment. We encourage the agency to present its current understanding of this issue in the Plan for CASAC consideration and public comment.

We look forward to presenting supplementary comments to CASAC during its May 5<sup>th</sup> review.

API would welcome the opportunity to discuss these comments in greater detail. Please feel free to contact Will Ollison (202-682-8262; ollisonw@api.org) or me with any questions regarding these comments.

Sincerely,



for HJF

cc: H. Richmond