

ExxonMobil Biomedical Sciences, Inc.
Clinton Township
P. O. Box 971, 1545 Route 22 East
Annandale, NJ 08801-0971
908-730-1199 Fax

Dennis J. Devlin, Ph.D.
Director
Toxicology & Environmental Sciences Division



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ExxonMobil Comments on the Review of the National Ambient Air Quality Standards for Ozone, Policy Assessment of Scientific and Technical Information OAQPS Staff Paper – First Draft, and Ozone Health Risk Assessment for Selected Urban Areas (FR Vol. 70, No. 221/Thursday, November, 2005, pages 69761-69763)

Via Electronic and First Class Mail

Attention: Docket I.D. #OAR-2005-0172

Air and Radiation Docket Center
Environmental Protection Agency
Mail Code 6102T
1200 Pennsylvania Avenue NW
Washington, DC 20460

Dear Dr. McKee:

Exxon Mobil Corporation is submitting comments on the Review of the National Ambient Air Quality Standards for Ozone, Policy Assessment of Scientific and Technical Information, OAQPS Staff Paper – First Draft, and accompanying Risk Assessment for Selected Urban Areas. These comments should be considered in light of those we provided on May 2, 2005, and November 30, 2005, with respect to drafts of the Criteria Document for Air Quality for Ozone and Related Photochemical Oxidants (CD). Our current comments on the draft Staff Paper are consistent with those provided by key members of the Clean Air Science Advisory Committee Ozone Review Panel (CASAC) in their recent (12/05) review of the CD and Staff Paper.

The following summarizes our major issues and concerns with the draft Ozone Staff Paper:

- **EPA has not adequately addressed the scientific deficiencies in the draft Ozone Criteria Document identified by CASAC. This has led to carry-over deficiencies in the draft Staff Paper** - As noted by CASAC at the December 8, 2005 public meetings to discuss the draft CD and Staff Paper, the existing scientific data are inadequate to establish a *causal* relationship between ambient ozone exposure and mortality. For this reason, CASAC suggested that any mortality estimates be qualified according to the likelihood that the epidemiologic-derived associations are causal. We agree with this recommendation. Further, until the confidence and qualification of causality is established, it is not appropriate for the Agency to present mortality estimates with the quantitative precision and confidence as done in the draft risk assessment and Staff Paper. CASAC and a number of public commenters expressed concern that the Agency has not addressed the key uncertainties in

the draft Staff Paper and risk assessment, as recommended by guidelines promulgated by OMB (OMB Circular A-4, Regulatory Analysis, 2003) and general risk assessments practices (National Research Council, Estimating the Public Health Benefits of Proposed Air Pollution Regulations, 2002). Specifically, CASAC recommended that the mortality estimates must reflect the underlying uncertainties.

CASAC, as well as a number of public commenters, also expressed serious concerns with the linear-no-threshold approach the Agency is proposing to quantify acute mortality. This approach is based on an inaccurate and biased interpretation of selective ecological epidemiology studies. Given the exposure misclassification problem with ozone time series studies, as documented by Brauer et al. (2002), it is not possible to determine thresholds in these studies. In our view, EPA is confusing the concept of "*it is not possible to determine thresholds*" with the concept of "*no thresholds have been reported*". Further, as discussed at the CASAC meeting, other lines of evidence, for example non significant results in ecologic studies when ozone levels are low, and clear No-Effect Levels in human clinical studies with potentially susceptible subgroups, support using a non-linear threshold-based approach to human health risk assessment for this pollutant. Finally, use of a linear no threshold approach to assess mortality is inconsistent with the approach the Agency is using to assess less serious morbidity endpoints such as moderate pulmonary function changes, which are not estimated below 50 ppb.

As a result of the discussions on this issue at the CASAC meeting, we understand that EPA has been directed to present the mortality estimates segmented according to ozone concentrations ranges. Further, EPA should qualify the mortality estimates associated with ozone concentrations below current ambient levels as *highly uncertain*. In addition, the key clinical experts on CASAC, as well as a number of public commenters, expressed serious concerns with the Agency's over-interpretation of the recent cardiac related studies on ozone. We understand from the discussions at the recent CASAC meeting that EPA has been directed to delete assertions appearing in both the draft CD and Staff paper that ozone is acting through cardiac related toxicological mechanisms, as well as assertions that the results of these studies provide plausibility and coherence to the epidemiology findings.

- **EPA has not presented appropriate scientific support for numerous conclusions in the draft Staff Paper** - ExxonMobil previously expressed its significant concerns associated with the advocacy and definitive (i.e. 'strong associations') tone of the draft CD, based on conflicting new information and analysis subsequent to the 1997 review. However, the Agency's current Staff Paper actually goes beyond many of the more qualified positions in the CD, offering a more conclusive and overly biased tone in describing health impact areas such as emergency department visits, hospital admissions, cardiovascular mortality, lack of threshold response, and lung function decrement in children. The Agency ultimately uses three of these areas- lung function decrement in children, hospital admissions and mortality- in the risk estimate calculations to address the current NAAQS standard and possible need for alternative standards. ExxonMobil and other stakeholders have submitted the following technical concerns with the strength of evidence utilized by EPA to demonstrate the health impacts that form the basis of the risk assessment.
 1. EPA asserts that there is clear and unambiguous evidence of lung function decrements from children exposed to ambient levels of ozone. However, the premier study of the largest cohort of highest exposed children (Children's Health Study-California) concluded there is *no evidence* for an association between long-term ozone exposure and lung function in children (CD, p. 7-106).

2. EPA asserts there is clear and substantive cardiorespiratory mortality at levels of 0.5-2.5% for multi-city studies and 0.5-5% for single city studies (Staff Paper, p. 3-28). However, this conclusion is based on the weak and often non-significant results reported in these studies and the 2005 meta-analysis publications that offer a "best" estimate of 0.4% when corrected for publication bias and city heterogeneity.
3. EPA presents precise estimates of hospital admissions in their draft risk assessment. However, these estimates are based on the data presented in the draft CD (page 8-48) wherein they state "Many other studies reported less consistent or no associations between increases in ozone concentrations and hospital admissions. A few other studies raise questions and concerns about other factors in this relationship." Further, the cardiovascular hospitalization data shown in Fig. 8-5 essentially supports no association for this endpoint.

ExxonMobil and other stakeholders have also indicated a serious concern with the Agency's use of Policy Relevant Background (PRB) values generated solely from the GEOS-CHEM model (0.015 to 0.035 ppm) when other empirical data and evaluations suggest higher values (e.g. 47 and 50+ ppb). As mentioned above, the approach of extrapolating mortality down to PRB is not supported by the lack of significant mortality risks observed in winter when ozone levels are lower, and findings from human clinical and toxicology studies. The approach the Agency is using biases the final risk evaluations in a substantial manner.

Finally, given the above caveats and issues, it is significantly troubling that Agency concludes in the summary "These initial analyses suggest that meeting the current 8-hour standard would likely result in substantial reductions in exposures of concern and associated risks of serious health effects above a level of 0.08 ppm ozone", yet then speculates that further analysis should be done to generate alternative standards to provide more health protection beyond the current ozone primary standard (pg 6-14). This indicates a level of certainty in the Agency's position with the current data and risk evaluation that cause them to recommend further 'uncertainty' risk evaluations. As stated earlier, CASAC recommended that staff conduct a more detailed 'uncertainty' analysis of the key base data discussed in the CD.

- **The Agency has not addressed the uncertainty related to exposure misclassification or the use of highly heterogeneous results in ozone time-series studies.** As described by Dr. Harvey Richmond in his presentation to CASAC in December, a critical factor to the validity of the EPA risk assessment is the assumption that measurements from ambient monitors provide reliable estimates of aggregate personal exposure to ozone. The data presented by EPA at the CASAC meeting clearly did not support this assumption. A very poor correlation has been reported in Baltimore and Boston and the poor correlations reported by EPA are consistent with the general literature, which indicate that ambient measurements are *not* a valid surrogate for aggregate ozone exposure.

EPA must also address the uncertainty introduced by using widely different results for individual cities as reported by different authors. In particular, for most cities, the results from Schwartz *et al.* are inexplicably higher than those reported by other authors. Further, EPA must address the uncertainty introduced when using highly heterogeneous results across cities, including how model specification factors such as treatment of meteorology and seasonality, lag time, air conditioning, and other factors impact the risk estimates. EPA must discuss how confounding factors that have not been fully evaluated, such as fine particulate matter (PM), may impact the results, including the issue of double-counting of fine PM and ozone acute mortality.

Detailed comments that support the key points mentioned above are attached. If you have questions concerning our comments, please contact me or Mr. Larry Gephart of my staff at 908-730-3417.

Sincerely,

Dennis J. Devlin

Attachment: Detailed ExxonMobil Comments on the 1st Draft Staff Paper for Ozone and Accompanying Risk Assessment