

Preliminary Individual Comments. Do not cite or quote. These are preliminary individual comments from members of the Ozone Review Panel. They do not represent EPA policy or consensus CASAC advice. Updated 5-17-11.

## **Preliminary Comments on Ozone NAAQS: Scope and Methods Plan for Health Risk and Exposure Assessment (April 2011)**

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## Mr. George Allen

Preliminary Individual Comments for the CASAC Consultation on the Ozone NAAQS Scope and Methods Plan for Health Risk and Exposure Assessment, April 2011

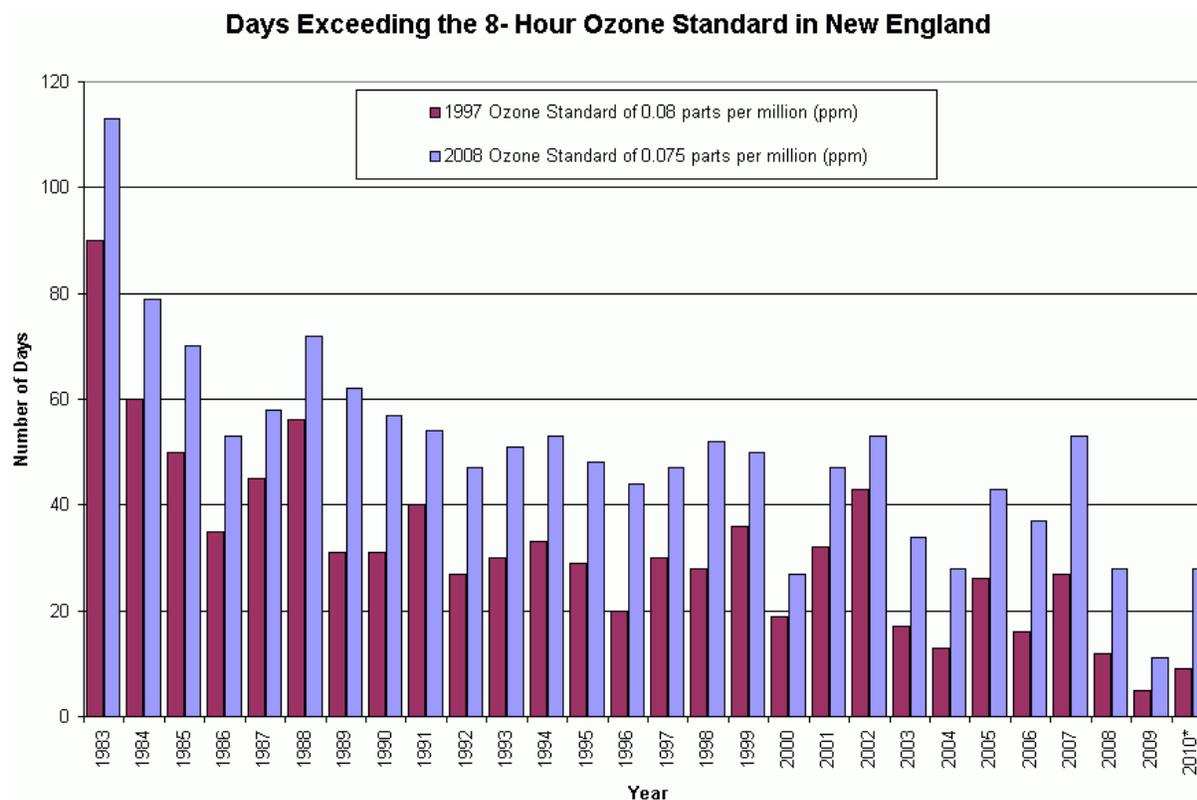
Section 2.2, Pg 2-1, line 26 and elsewhere throughout this document:

For many aspects of this analysis it is noted that the most recent three years of ambient ozone data (2008-2010) will be used. I assume three years are used since that's part of the form of the current NAAQS, and that will not be changed when the rule for the reconsideration of the 2008 O3 NAAQS is finalized late this July (hopefully). My concern here is that any one 3-year period may have unusual meteorological conditions in one or more of the years. In this case, 2009 was very notable for a cool and wet summer in much of the eastern US, resulting in distinctly lower seasonal ozone conditions. Region I posts trend analysis on their ozone web page at:

<http://www.epa.gov/region1/airquality/standard.html>. One example for all of New England is Figure 1, from: <http://www.epa.gov/region1/airquality/images/NE8HR.gif>:

Figure 1.

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Note that 2009 is the lowest since 1983, and that at the 75ppb threshold, 2009 had fewer than half the number of days than the next lowest year. This chart also shows 2003-2004 as “clean years” and 2007 as a “not clean” year. Both 2008 and 2010 were normal to cleaner than normal years. In cleaner areas like VT (<http://www.epa.gov/region1/airquality/images/VT8HR.gif>) both 2009 and 2010 (preliminary data) had no days over the 75ppb standard; the only other year with no days was 2006.

Thus, a three-year metric for 2008-2010 may have an unusual low bias in the eastern US due primarily to meteorological conditions. A more through analysis than that presented here should be done of course.

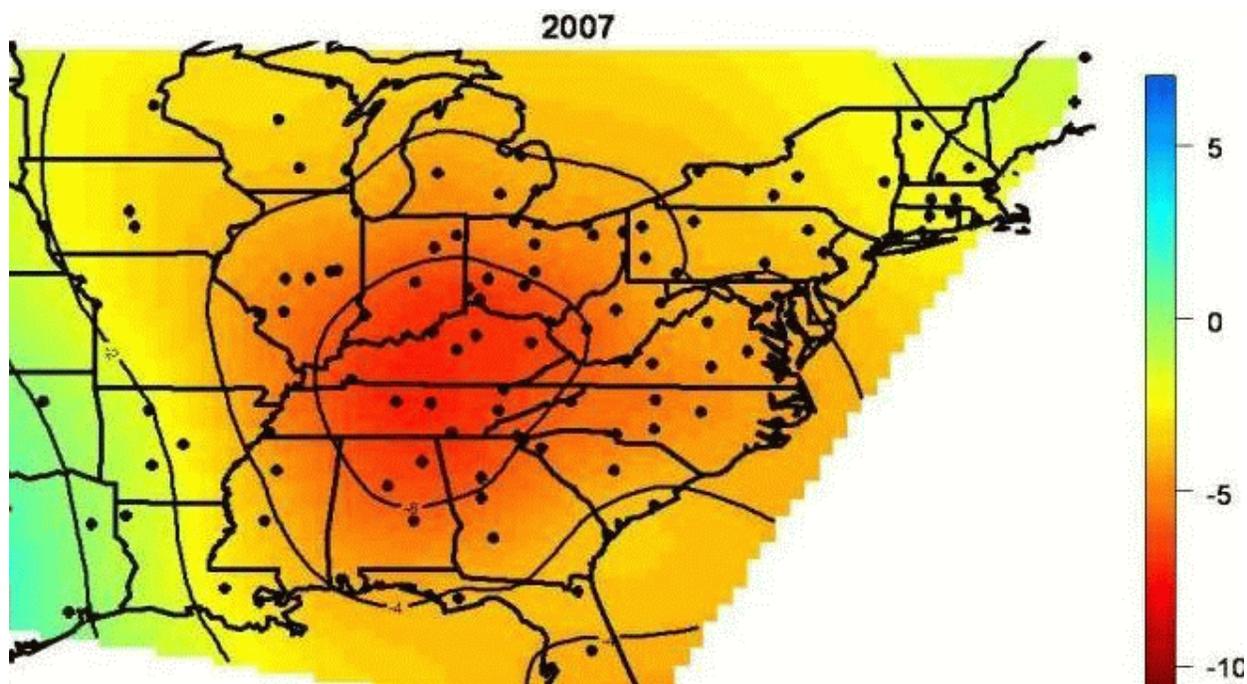
When EPA does ozone trend analysis, a meteorological correction is applied to minimize the effect of unusual years on the trend (Camalier et al., 2007). There is substantial year to year variation in various ozone metrics in many areas of the US, but it is a reasonable assumption that sources (ozone precursors) do not change much from year to year, and if they do it’s usually a monotonic downward trend as various control strategies are implemented. Figure 2 shows the adjustment to the ozone trend for 2007, a year with

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higher than usual ozone levels over much of the eastern US. A similar figure but with the opposite correction is at:

[http://www.epa.gov/airtrends/weather/adj\\_2003\\_map.jpeg](http://www.epa.gov/airtrends/weather/adj_2003_map.jpeg)

Figure 2 (source: <http://www.epa.gov/airtrends/weather.html>).



These two years (2003 and 2007) have a correction range of more than 10 ppb. Unusual years like these can influence a 3-year ozone metric.

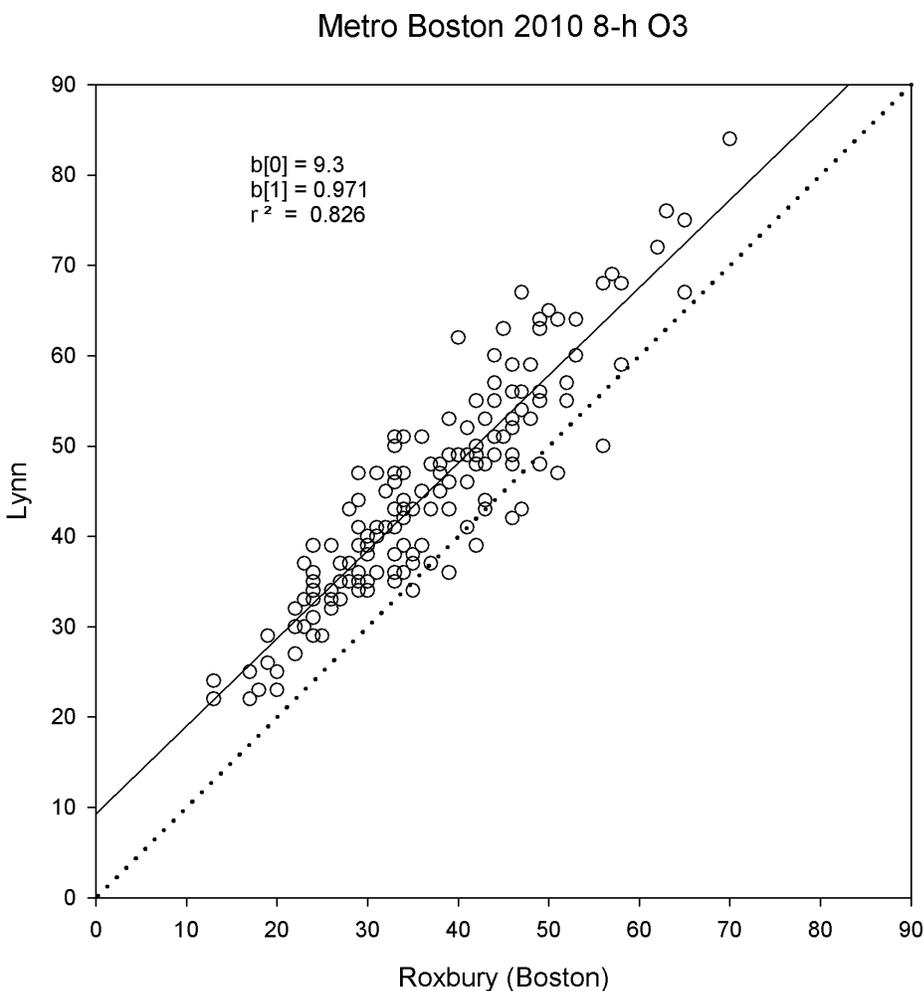
This document does not mention if the 2008-2010 ozone data will be corrected for meteorology or not. While one can make the case either way, it is likely that metrics for these three years will be lower than expected in parts of the country due to meteorological conditions. EPA should include this discussion in their Plan, and state why or why not these kinds of corrections should be made to the ambient ozone data that will be used in the analysis.

Section 5 discusses issues related to spatial heterogeneity of ozone across urban study areas (Pg 5-9, lines 17 and 19; Pg 5-10, line 6) . With the existing urban data available, many cities do not have sufficient monitoring sites to properly address this issue directly. Boston, one of the candidate cities for this analysis, only has one site in the urban core

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(Roxbury). There are two other sites that may be relevant (Long Island in Boston Harbor, and Lynn ~12 miles NE of downtown), but neither site can be considered to reflect ozone within ~3-5 miles of the core area of Boston. These other 2 sites are very similar for 8-hour ozone data, and both somewhat different from Roxbury. Notably, there is a ~9 ppb intercept in the regression of Lynn vs. Roxbury for 2010 data. This likely reflects the impact of NO titration at the Roxbury site that is minimal at the Lynn site. Figure 3 shows a scatter plot of Lynn vs. Roxbury.

Figure 3. Preliminary Metro Boston Ozone, May-September.



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Note that as expected, ozone at the suburban Lynn site is generally higher than Roxbury, and never significantly lower. This document discusses the need for reasonable spatial correlations across an urban study area, but does not discuss cases like this where correlation and slope can be good but with a substantial offset across sites. The question would be: does this Boston scenario influence the kinds of analysis approaches discussed in Chapter 5.

#### References.

Camalier, Louise; William Cox, and Pat Dolwick (2007). The effects of meteorology on ozone in urban areas and their use in assessing ozone trends. *Atmospheric Environment* Volume 41, Issue 33, October 2007, Pages 7127-7137  
doi:10.1016/j.atmosenv.2007.04.061

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Dr. John Bailar

## OZONE NATIONAL AIR QUALITY STANDARDS: SCOPE AND METHODS PLAN FOR **HEALTH** RISK AND EXPOSURE ASSESSMENT

Throughout, this document frequently says, “we may”, “we are considering” and the like, but rarely says *how* EPA will decide whether to go ahead or not. This seems to me to be a serious gap.

Page 1-7. The list of goals is cast in terms of all-or-none. This is appropriate for mortality and some other endpoints, but not for quantitative matters such as pulmonary function. Maybe you have no way to deal with degree of impairment (including exacerbation of lung damage not due to ozone) but the matter should at least be addressed here and elsewhere in the document. (It appears that lines 5-14 on the next page do not cover this.)

EPA is well aware that short-term lab studies cannot inform us about long-term responses, but this should be acknowledged on pages 1-9/10

I simply do not understand the bullet that begins at the bottom of page 1-10. The third bullet is also unclear. In general, these four bullets may be correct, but they need substantial re-writing.

The statement in lines 5-7 on page 1-1. Not specific? Volunteers are generally drawn from local residents, and they may therefore carry the effects of any prior exposures with them. I would be pretty cautious about assuming that a person with past exposures to substantial levels of ozone or other pollutants would respond just like a person without that exposure, and I would not want to guess which direction such an effect, if any, might go.

Page 2-1, line 5. How is (1) different from (2) and (3)? Aren't they to be evidence-based to the extent possible?

Top page 2-3. Spatial and temporal heterogeneity within an area raises issues quite different from such heterogeneity across areas. This could use some discussion.

Page 2-5, lines 9-18. How were these grid sizes chosen?

Page 3-, lines 8-13. Please say more about how the areas will be selected, or insert a cross-reference to Section 5.3.2.

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Sections 3-2 to 3-5 say a lot about what APEX *can* do, but Section 3-6 does not say enough about what will in fact be done with it.

Table 3-2 could usefully include a column that says how the study participants were selected. I am a little concerned about possible bias. The first bullet on page 3-16 does not really address the problem of non-representativeness *within* specific categories or demographic descriptors, but survey statisticians quite broadly recognize that anything short of a random sample with a high response rate may be seriously biased.

Averting behavior (page 3-17) is, in my view, less a scientific issue and more a philosophical/political issue. There should be at least brief mention of the tension centered on questions of how much sensitive (or other) persons should have to change their behavior to mitigate a hazard. (Similar questions have arisen in other situations, e.g. the broad agreement that it is inappropriate, and even illegal, to refuse employment to potentially sensitive persons such as women of childbearing age.) See also the top of page 5-16. One issue is how to accommodate the costs (broadly defined) of present averting behavior vs. the benefits (and costs) of future adoptions of averting behavior.

Several activities will be undertaken “if sufficient resources are available”. But what is the priority ranking of these, if you can do some but not others? This seems to require some thought now, rather than later.

Page 3-19, line 7 refers to the joint distributions of parameters, but there is also reason to be concerned about the joint distribution of effects – i.e. synergy. This might be mentioned here.

I enthusiastically support the last paragraph on page 3-19.

Section 5.3.2 is an important aid in understanding this proposal, but I remain concerned about the use of 12 urban areas to represent the entire (urban?) population of the US. These 12 should be examined separately and compared. Only if they are in pretty good agreement should they be combined into a national figure, but I do not see a description of this critical comparison, including criteria for judging whether they are sufficiently similar to provide a reliable combined estimate. If they are not sufficiently similar, reasons for differences should be sought and, to the extent possible, the effects of differences should be estimated. This could be in the form of a sensitivity analysis, or perhaps by allocating each US city to a category that closely matches one or more of the 12 areas.

The totals on page 3-15 are a bit silly given the vast differences in quality and depth of information, and the fact that bias will surely be a bigger threat to conclusions than variance.

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Equation 4-1. Using interval midpoints is appropriate only when the midpoint fairly represents the whole interval. In regions of a curve that are flat or changing evenly this may be OK, but it can lead to errors in categories near a point of inflection. This can be remedied by using sufficiently fine intervals, or by using a point a bit toward one side or the other within a broader interval (toward the higher side if the curve is bending downward, toward the lower side if it is bending up). A quadratic fit might also work.

Page 4-5, line 18. Children under 8 may present special problems. Do you recommend research to fill this gap the next time around?

In the equations on pages 4-4/4-5, are all of the betas constants to be estimated from the data?

Page 5-1, last line. Is the inequality reversed?

Page 5-2. I do not understand where the footnote is pointing because it is already in section 5-1.

Page 5-3, top. It is not clear how you will select the “modeling elements” to be taken as core vs. those for sensitivity analysis. If you will make the selection after you look at results, say so, with some comment on how you will choose; otherwise give the reader some guidance about your choices prior to analysis. The paragraph on page 5-4 helps, but does not go far enough given the criticality of this phase of the analysis.

Footnote 5-1 belongs in the main text.

Page 5-8, figure. My copy of the draft document does not include color, but I infer that “Incidence and Prevalence Rates” is an input to “Adverse Health Effects”. This seems backwards, unless “Incidence and Prevalence” refers to background rather than the effects of ozone. Please clarify. Also, I would give this figure a figure number.

Page 5-9, line 4. Can you possibly put these critical details in the next version of this document?

The paragraph at the bottom of page 5-11 is quite hard to follow, but it is worth noting that the evidence for a broad effect (e.g. total mortality) must be rated as being at least as strong as the evidence for any component effect (e.g. respiratory mortality) unless you admit the possibility of countervailing benefits in some other component. In short, if you decide that there is an effect on respiratory mortality,

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you will almost have to conclude that there is an effect on total mortality, whether that can be established independently or not.

Page 5-13, line 25. A finding that two or more effects in a multi-pollutant model are non-significant (not “insignificant”, please) should be followed by computations that omit one, two, ... pollutants to see whether they remain non-significant. When two pollutants are highly correlated in occurrence, the data may just be saying that one (or possibly both) is having an effect, but the data cannot tell which one it is. Please do not pass over a pollutant just because it is non-significant in a multi-pollutant model; there may be an important effect that is masked by the correlations.

Pages 5-22/23. I am not a fan of the WHO Tier classification because it gives zero guidance to the analyst. The words in the WHO descriptors of tiers are subject to a vast range of interpretations and distortions, and there are no sharp divisions among the tiers anyway. It is useful only for describing what was done after the fact. This bit should be deleted or replaced with a more informative statement.

Page 5-26, bullet 4. Surely nature does not provide D-R relationships that follow any simple mathematical formula for any heterogeneous population. The goal is purely empirical -- to find some curve that fits pretty well and is mathematically tractable. For example, a small, unrecognized sub-population of acutely sensitive persons will produce a distinct blip in the toe of the D-R curve such that low-dose risks estimated by a linear model are substantially underestimated. A specific, well-known example is vinyl chloride. Or, an unknown physiologic mechanism may bend the low-dose curve in unexpected ways (e.g., for vinyl chloride). (See Bailar et al., One-Hit Models of Carcinogenesis: Conservative or Not? Risk Analysis 8: 485-497, 1988.)

Page 5-31, line 17. Please expand on “subset”.

Section 6. I would like to see some discussion of the level of detail (especially geographic detail) that will be published at the end of the analysis. National only? By state? by county? By SMSA? Other?

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## Dr. David Chock

The Scope and Methods Plan is quite comprehensive. The EPA should be commended for this thorough effort.

### Exposure Analysis:

The Plan intends to cover three or more of the 12 urban areas for exposure analysis. The methodology of Air Pollutants Exposure (APEX) model is sound. The details involved as described in Figure 3-1 of the Plan is quite comprehensive. One concern I have is the input data, especially those from the Consolidated Human Activity Database (CHAD). Many of the database as described in Table 3-2 is quite old, some as old as the 1980s. The RTI NSAS database for eight cities is the most current (2009) but the sample size is relatively small on a per-city basis. Perhaps one can still lean toward enabling the use of these most up-to-date data in the selection of the urban areas.

The list of population groups selected for exposure estimates is adequate, so long as the exposure data are available for each of the selected groups.

The use of a two-dimensional Monte Carlo sampling approach to study both uncertainty and variability of exposure is an excellent idea. The authors point out the differences between model parameter uncertainty and model formulation uncertainty. Indeed, the latter is more critical for model evaluation, but is more difficult to characterize.

### Health Risk Assessment:

From the description of the controlled exposure studies in the Plan, the model of McDonnell, et al. (2010) for  $FEV_1$  seems to cover the full range of ozone exposure concentration. Accordingly, the EPA's proposed approach to estimate the probabilistic lung-function decrement risks is justified.

Section 2.3.2 of the Plans describes the intention to re-evaluate the quadratic rollback approach for the portion of ozone concentration that exceeds the policy-relevant background. This is helpful, especially if the evaluation could involve some stress tests with photochemical modeling, since ozone formation depends on many factors, and the levels and locations of peak ozone can change depending on changes of the precursor emissions and of the relevant atmospheric environment. As extreme weather becomes more commonplace, there is a concern that even the policy-relevant background cannot be assumed to be stable.

It is reasonable to favor the use of distributed lags over direct multiple lags in short-term risk analyses to reduce multicollinearity of the lag coefficients.

The ISA does not seem to indicate the presence of thresholds for short-term risks, including lung-function decrements based on control studies. It appears reasonable to assume no threshold provided that the health endpoint risk increment estimates and associated uncertainties are always extrapolated from the actual baseline

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studies, both upward and downward in exposure concentrations. This should be the case even when alternative, more stringent standards are considered relative to the current standards. The description on page 5-19, lines 20 to 24 needs to be revised so that two  $\Delta x$ 's, one based on the current standard and one on the alternative standard, need to be determined, both with the same reference point from the baseline studies. Because the model is nonlinear, use of the current standard levels as reference point is inappropriate, especially when the population number is large. For long-term risks, the Plan intends to use a range of thresholds including none. Again, this is reasonable provided that the associated uncertainties are also indicated.

The Plan describes a very comprehensive uncertainty and variability approach in risk assessment. This is commendable. One concern is that there may not be sufficient amount of reliable information to adequately characterize the uncertainty for each of the range of variability to be considered.

In the description of single vs. multi-pollutant models (page 5-13, lines 23 to 28), it should be noted that if the co-pollutants and ozone are all causal variables to the health endpoint, then their inclusion in the model is necessary, and the model based exclusively on ozone would actually be a misfit especially when the ozone correlation with one or more of the causal co-pollutants is large. In fact, multi-pollutant models are a safer choice since non-causal covariates would not impact the coefficients of the causal covariates.

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Dr. Judy Graham

## **GRAHAM COMMENTS ON PLAN FOR HEALTH RISK AND EXPOSURE ASSESSMENT DRAFT APRIL 2011**

### **General Comments**

1. OAQPS has a stellar history of developing excellent Exposure Assessments (EA) and Health Risk Assessments (HRA). Based on my reading of the plan, this new effort will rise to that historical standard. With appropriate resources, I expect that this effort will even exceed their previous quality. A few specific comments follow, but they do not detract from the general excellence of the plan.
2. I take note that the Plan adheres to most (and perhaps all) of the major recommendations of the NRC on “Models in Environmental Regulatory Decision Making” (2007 [http://www.nap.edu/catalog.php?record\\_id=11972](http://www.nap.edu/catalog.php?record_id=11972)). Chief among them are (1) involving the policy user in setting the goals for the development of a scientifically robust model for the regulatory purpose (in this case a NAAQS), (2) having peer and public reviews of the plan as well as the models during the life cycle of the model, (3) quantifying and communicating uncertainty, (4) evaluating the model throughout its life-cycle, (5) providing leadership for model advancement with an interaction of models and measurements, and (6) using models that are publically available. I recommend that the Plan include a short discussion of the relationship of their proposed use of models to the NRC recommendations. This will add strength to the plan and its eventual results.
3. The situation of resources limiting the EA and HRA may be real, at present, but it is *totally unacceptable*. O<sub>3</sub> is one of the very very few pollutants for which ambient exposures cause adverse health effects in a large number of people. Hence, the need for a scientifically robust EA and HRA to enable regulatory decisions to fulfill the requirements of the CAA. Because the NAAQS is already at the third decimal place (0.075 ppm), evaluating its adequacy and the need for revision call for a higher degree of accuracy, which in turn requires a thorough analysis. Thus, addressing all high priority EA and HRA needs is essential and must be of highest priority.

### **Specific Comments**

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1. 1-9 L8. This is the first of several areas where the extent of the effort “will depend on the available resources.” As I mentioned above, this is unacceptable. I suggest that OAQPS expand their prioritization here and elsewhere and discuss the value of more completeness to the quality of the NAAQS review. For example, on this page, what is the value of modeling exposure in 3, 6, 9, or 12 urban areas? The Plan discusses good criteria for selection of the urban areas, but are there 3 urban areas that fulfill all these criteria? If not, this would be important to state to clearly identify the need for adequate resources.
2. 1-9 L22. I presume you mean “Quantitative” health endpoints. If so, say so.
3. 3-6 Table 3-1. This lists the microenvironments to be modeled. Which of these scenarios represents “near home”? Also, collectively what percentage of an individual’s activities is represented here? For example, is 100% of a child’s time accounted for? An outdoor worker’s time? Etc.
4. 3-12 L8 This says OAQPS is considering modeling indoor sources of O3. Given the inadequate resources, are there sufficient sources to make this worthwhile? Will you be doing a sensitivity analysis to determine its priority?
5. 3-12 L18. CHAD will be used. It is superb and has been extremely useful for many analyses from the research level to the regulatory level. However, activity patterns are changing, especially for children in this day of sitting in front of the TV or computer, to say nothing of sitting in a chair texting. Thus, please consider the validity of using activity pattern data on children that were conducted prior to 1990, for example. I say “for example” because there might be a more accurate cut point. Since children often fall into the susceptibility class because of their greater amount of time outdoors with exercise, choosing the most appropriate cut point becomes important.
6. 3-16 L20. I strongly recommend incorporating the ATUS data files into the analysis, assuming OAQPS does a professional evaluation of the quality of ATUS (for example, does it have metadata and has it been subjected to extensive QA?). Because of the importance of activity patterns to the EA outcome and the question about the older activity pattern surveys, using the ATUS data would be a very high priority.
7. 3-17 L7. Again, the “if sufficient resources are available”. Is this possible to do with current databases? If so, do it.
8. 3-19 L18. Are the exposure data and metadata publically available from DEARS. Has the exposure data been subjected to QA? If not, how do you intend to deal with this?

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9. 4-1 L23. I agree that selecting FEV1 is a good choice to estimate exposure-response relationships. Some other endpoints do not have as robust exposure-response curves, but they are quite important (e.g., inflammatory markers, airway responsiveness). Given the statements in the text, I am expecting to see a high quality discussion of this that clearly lays out the risks that are likely at low levels, but can't be quantified. I further expect that this discussion will include the concordance of animal toxicology studies since that adds scientific strength to understanding the whole possible array of effects and their severity.
10. 4-4 L6ff. Since the NAAQS rests heavily on analyses of human clinical pulmonary function studies, it is essential to find the resources to see if a computational improvement is possible. It is also important to use *all* of the high quality data available. If not, the quantitative HRA results will be vulnerable to charges of bias from only using the older studies and not incorporating as much science as possible.
11. PRBs are discussed in several places and are defined well. However, it is still not clear how OAQPS will relate the science of thresholds/no thresholds and PRB. This is even more difficult because, as described in the plan, backgrounds are increasing due to global factors.

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Dr. Daniel Jacob

**Air Quality Considerations in the Health REA document (chapter 2 and chapter 3)**

This chapter of the REA document does its job in providing the atmospheric basis for the exposure analyses. I just have two comments.

2-5, line 4: proper reference is Wang et al., AE2009, instead of Bey et al.

2-6, lines 26-28: according to the IPCC AR5 RCP scenarios methane is not projected to further increase in the future. These scenarios may turn out to be wrong, but one cannot just assume that methane will continue to increase.

3-17, lines 23-30: I'm surprised that not more attention is paid to near-roadway exposure. The report states that ozone would be lower because of titration by NO to NO<sub>2</sub>, which an uneducated reader might assume would reduce exposure, but in fact ppb for ppb NO<sub>2</sub> is no better than ozone.

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Dr. Fred J. Miller

**Ozone NAAQS: Scope and Methods Plan for Health Risk and Exposure Assessment**

**General Comments**

The document was written with enough detail that a reviewer could see what is planned at the “30,000 foot level”. Rather than responding to the list of topics provided by OAQPS for the Exposure Analysis and Health Risk Assessment, I will provide a set of specific comments that collectively cover most of the areas about which OAQPS staff requested that the Ozone Review Committee provide consultative advice. Thus, if I do not cover an area, one can assume that I agree with OAQPS’s proposed course of action.

Too many places in the document, the statement is made “ we will do this if there are enough resources”. Given the uncertainty of EPA budgets, does OAQPS have a strategic priority list that identifies the base things that will be done and then which additional analyses will sequentially be added if the monies are made available? If such a list does not currently exist, one needs to be developed.

**Specific Comments**

Page, line	Comment
1-9, 4	The document states that EPA plans to model population exposures in three or more of the 12 urban areas listed here. This is too vague. If only 3 are done, they should probably represent cities in each of 3 geographically varied regions and the city in the region with the dirtiest air and the highest population used. If 6 were done. One might do the 3 regions together with the cleanest and dirtiest cities. And the list goes on. OAQPS needs to establish criteria for city selection that are based on defined goals and issues.
2-1, 26	Can a portion of the analyses use a 3-year moving average? Suppose one city is picked and risk estimates are derived using the moving average of O <sub>3</sub> levels in that area between 2000 and 2010. This would really establish how dependent the risk analysis estimates are on the air quality, and it would show if risk has been reduced or increased over time.
3-3	The figure legend has an oval as representing a simulation step but the figure contains no ovals.
3-7, 24	Breathing rate is not ventilation rate. Minute volume is the product of breathing rate and tidal volume. Ventilation rate can be minute volume

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	or it can be the inspiratory flow rate.
3-8, 6	Conflation always has been a problem. One occurrence for 10 people must involve less risk than 10 occurrences for 1 person. Isn't there a way around this? Draw from a sampled pool where each entry has a unique identifier, and then tract the identity of those selected?
3-10, 14	How is the proximity factor, $P_{FR}$ , estimated?
3-11	In equation 12, one can hardly read the + and - signs.
3-14	CHAD has only one reference beyond 2005. With the advent of computer games, etc., I imagine that activity patterns have changed since most data in CHAD were collected. Thus, it seems critical to get the ATUX data into CHAD or even to replace the current CHAD data.
3-17, 11	Staff plan to examine averting behavior if resources are available. My view is that it should not be examined because people should not have to change their activity pattern due to pollution - more later.
4-1, 5	Figure 2 is really Figure 4-1.
4-1, 18	Where will OAQPS get the data to develop lung function risk estimates for asthmatic school children?
4-2, 4	To the data being considered for exposure-response relationships, you now also have the data at 60 ppb from Kim et al. (2011).
4-5, 7	For the piecewise linear fit, why not let the data determine the joining points rather than forcing them because of the data set intervals. This would involve isotonic regression (see Gaines and Rice. Amer. Nat. 135:310-317, 1990).
4-5, 16	While true that no ozone exposure data exist for children < 8 years of age, why not use the data baseline data for children less than that age (say 3 - 6 years) and assume the same kinds of drops with ozone seen with children > 8? Is there any reason to think these changes would not follow the same slope as for those > 8 years old? (See, for example, Piccioni et al. (2007). Reference values of forced expiratory volumes and pulmonary flows in 3 -6 year children: a cross-sectional study. Resp. Res. 8:14. ( <a href="http://respiratory-research.com/content/8/1/14">http://respiratory-research.com/content/8/1/14</a> ).
5-2, 2	You have enough to do; do not expand to include additional health categories beyond those already identified. The picture is far from clear on birth weight and long-term exposure mortality.
5-6, 4	What is meant by "First, once we have properly specified the BENMAP software, ...."?
5-11, 20	Long-term exposure mortality seems to be a disconnection. Saying it is a type of respiratory health effect (likely causal) but also a mortality endpoint that is only suggestive of causal is trying to have it both ways. Maybe the CASAC Ozone Review Panel deliberations on these endpoints discussed in the ISA will clarify this.
5-14, 13	I agree with placing greater weight on using C-R relationships that reflect adjusted single-city estimates obtained form multi-city studies.

Preliminary Individual Comments. Do not cite or quote. These are preliminary individual comments from members of the Ozone Review Panel. They do not represent EPA policy or consensus CASAC advice. Updated 5-16-11. [Type text]

	It represents the best of both worlds.
5-15, 18	I have a problem with no thresholds. Please clarify how you handle risk below PRB levels. Certainly, there are effective biological thresholds for these endpoints. You are basically making a policy judgment when it should be a scientific one.
5-16, 1	Now the more later. I don't agree here. Risk aversion behavior is a negative. Suppose you take risk aversion to its ultimate point. Then you are left with letting pollution increase, and we simply will have to stay indoors all the time, use respirators, etc. EPA should be about clean air that doesn't require persons to have to use avoidance to mitigate risks from the air they breathe.
5-18, 2	It is tremendously important that you be able to map ICD-9 to ICD-10 codes. Suggest you draw in the main players at CDC that redid the code, and make it their contribution. <b>START NOW!</b>
5-18, 3	Please clarify cause-specific admissions and ER visits. What about an ER visit or a hospital admission for pneumonia but it is really aspiration pneumonia due to swallowing dysplasia from a stroke?
5-19, 25	Don't you have sufficient sample size to use asymptotic variance estimates?
5-22, 16	Can you fix the values for those model elements that don't have enough data and then incorporate the probabilistic assessment for those elements having sufficient information to assign probabilities? If I go by what is written here, one never would be able to do a probabilistic assessment because a universe of data would be needed.