

01-09-12 Preliminary Draft Comments from Clean Air Scientific Advisory Committee (CASAC) Ozone Review Panel. These preliminary pre-meeting comments are from individual members of the Panel and do not represent CASAC consensus comments nor EPA policy. Do not cite or quote.

Preliminary Comments from Dr. H. Christopher Frey on

EPA's Integrated Science Assessment for Ozone and Related Photochemical Oxidants

(Second External Review Draft – September 2011)

Comments on the Preface, Preamble, Executive Summary (Chapter 1), and Integrative Summary (Chapter 2)

Preamble

The Preamble is a useful component of the report. It is helpful to have a section of the report that provides a methodological overview of the process for developing an Integrated Science Assessment. This Preamble will be useful to many stakeholders. For example, this would be a nice chapter to hand out to a class as an introduction to risk assessment methodology.

The preamble would be even better if it included one or more flow diagrams of the following:

- The ISA process
- The various steps by which scientific evidence were considered
- The framework for causal determination

The preamble is a good place to introduce key terminology and to clarify concepts. An example is to provide closure on the recent discussions between EPA and CASAC on the definition of 'vulnerable' and 'susceptible.'

The preamble lays out the main sources of evidence regarding hazard identification and quantification of dose-response relationships: controlled human (clinical) experiments, epidemiological studies, and toxicity studies. It would be helpful for the preamble to include perhaps a ½ page to a page on the implications of the source of the hazard identification and dose-response data with respect to the choice of whether exposure or some exposure surrogate is needed. For example, many epidemiological studies are not based on actual exposure, but use ambient concentration as a surrogate for exposure, which is subject to exposure measurement error. Exposure metrics also have implications for developing exposure management strategies. For example, on page lxiii (line 11), 'concentration-response or dose-response relationships' are mentioned, but the preamble does not adequately explain which one is used under what circumstance. It is not just the form of this function, but also the relevance of the exposure metric or surrogate to actual exposure that should be discussed. A discussion of exposure (contact of a chemical or agent with the outer boundary of the body), dose (amount of chemical or agent crossing a barrier into or within the body), concentration (e.g., ambient concentration, or exposure concentration based on time-weighted microenvironmental or personal monitoring concentrations), and their distinctions and implications would be helpful. This issue comes up again on page lxiii, lines 18-19, in the question regarding "What is the concentration-response, exposure-response, or dose-response relationship in the human population?" there has not been adequate explanation/motivation in the preamble as to the premise of why there are three alternatives mentioned here for exposure.

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Page lxiv uses the term ‘susceptibility’ (line 11), ‘susceptible’ (line 27), ‘vulnerable’ (line 27), and ‘sensitive’ (line 27). These terms should be carefully defined when first introduced.

Minor comments on Preamble

Page liii, lines 24-25: Give EPA (2005) not the title of the document, for consistency with other references cited here.

Page liv, lines 6-8: as written, this sentence is awkward. Explain what a ‘counter-factual claim’ is. Break this into two or more sentences.

Page lxi, footnote 4, delete ‘It should be noted that’ (‘It... that’ statements are passive and add no content).

Page lxvi, line 20, delete ‘It is important to recognize that’

Preface

The preface does a nice job of clearly explaining the statutory mandate for NAAQS and review of NAAQS. The history of the NAAQS for ozone is informative. However, the last paragraph of the history omits the disconnect between the range of levels of 0.060 to 0.070 ppm recommended by CASAC and the decision ultimately reached by the Administrator. The text might also describe the request for CASAC to reconsider its advice, and the subsequent decision by the Administrator to leave the current standard in place pending the current review.

Chapter 1 - Executive Summary

There were no page numbers or line numbers for this section, which makes identifying specific passages difficult.

An executive summary should convey the basic purpose, relevant context, methods, results, and conclusions.

Although this is relatively short at about 16 pages, the document is nonetheless a bit wordy in places. An executive summary should distill the key points, and leave more detailed discussions and justifications to the detailed text that follows in the report chapters.

For example, the section on Scope could be cut in half or perhaps eliminated. It is not necessary to refer to other sections of the report for more details. It is not necessary to repeat basic ideas. For example, the first sentences of the first two paragraphs of the scope section are somewhat overlapping. The first three lines of the last paragraph on page 1 could be deleted. It doesn’t matter if the type of evidence varies by pollutant or assessment if the focus here is one pollutant and one assessment; thus, delete this clause on the 5th and 6th lines of this same paragraph. The idea that this assessment builds on previous assessments

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was mentioned in the prior paragraph. And so on. The point here is that there are many opportunities to tighten the text, so that points are made concisely without repetition.

Page 2 – probably do not need much explanation of the weight of evidence hierarchy – could delete a couple of lines in the first paragraph on this page.

For the executive summary, consider deleting Figure 1-1. This figure makes sense to a scientist, but probably not to the lay public that would read this summary. If the figure is deleted, then the last two lines on page 2 can be deleted.

Pages 3-4. The discussion of background is not very useful as written. First, explain what background is and why it is needed. Then, just state what definition was used here. The summary of ‘typically less than 50 ppb’ is, however, too terse. Variation in seasonal and geographic background should be mentioned... e.g., ‘background varies from X to Y ppb across regions of the continental U.S. in the summer’ would be more informative than an upper bound of the worst case at one location.

Page 4, the section on human exposure conveys concepts but what are the key findings, results, and conclusions?

Pages 4-5, section 1.5: “the amount of O₃ that is absorbed...” by what? E.g., the lower respiratory system? (something brief). The two paragraphs here are a bit wordy (especially the first) and repetitive (e.g., both start out referring to O₃ being inhaled).

Page 6, section 1.6. This is written in a sort of passive way as if the ISA is something different... whereas this can be written without repeated references to the ISA ... e.g., rather than state “The ISA evaluates and integrates...” state what was evaluated, and what was integrated in a more direct, declarative manner. Phrases such as ‘discussed in this ISA’, ‘details... are provided in the ISA,’ and (later) ‘discussion for all relevant welfare effects is provided in the ISA’ should be deleted. Although these may seem like minor wordsmithing comments, an executive summary needs to be as concise as possible, and anything that makes the summary unnecessarily long interferes with its mission of communicating main points to non-experts or extremely busy people who are not going to read anything else from this document.

Figure 1-2 is at an appropriate level of detail for an executive summary and is useful.

The subsections of section 1.6 should be reviewed carefully. For example, section 1.6.2 seems to boil down to a simple finding: “The last review concluded that available evidence was ‘highly suggestive’ that short-term exposure to ozone contributes to total non-accidental and cardiopulmonary mortality. More recent studies reviewed here support this conclusion. The current body of evidence supports the conclusion that there is likely to be a causal relationship between short-term O₃ exposure and mortality.” This paragraph might give some idea as to why the conclusion is ‘likely’ as opposed to simply ‘causal.’... i.e. what is the source of weakness in the available evidence?

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These are examples of the various opportunities for either making the executive summary more concise or more clear.

Chapter 2 – Integrative Summary

Overall, this chapter was very useful and provides a broad yet somewhat detailed overview of the various topics addressed in the ISA.

The discussion of the Continental North America (CNA) background concentration is useful. However, the text should do a better job of summarizing the key quantitative findings. It is confusing to state the lowest estimates in terms of ‘greater than XX ppb’... please provide numbers in terms of ‘less than XX ppb’ as with the highest estimates. For what averaging time are these numbers estimated? Later text summarizes currently air quality in terms of 24-hr, 8-hr, and 1-hr averages (page 2-11, lines 11-13). Can both the background and current air quality data be provided on a consistent basis to enable comparison?

Page 2-11, lines 16-20 – is the greater variability for LA because of topography? (e.g., mountains)

Page 2-11, line 29... are emissions in rural areas making a significant contribution to O₃ in those areas? The summary tends to make statements that are factually correct as written, but that may not be very informative because they tend to be laundry lists without any findings or conclusions regarding relative importance. Likewise, lines 31-33... which of these factors are important? Can they be listed in order of decreasing importance?

Page 2-12, lines 20-21. I could not figure out the transition from the prior text to this sentence. Perhaps leading off with ‘For example,’ would help.

Pages 2-12, 2-13, on avoidance behavior. Page 2-12, lines 29-30 seems to state speculatively that there ‘may be changes’ in behavior to avoid O₃ exposure. The topic is then dropped but re-emerges two paragraphs later with a more definitive statement that ‘air quality alerts... induce reductions in outdoor activity...’ Thus, the degree of confidence in this finding seems to vary from one page to the next. It may be better to start with a lead paragraph for Section 2.4 that merely states what topics are addressed, and provide the evaluation, findings, and conclusions for each topic in a self-contained paragraph on that particular topic, to avoid confusion. The paragraph on page 2-13 seems to trail off with some highly jargon-laden text about ‘biased towards the null.’ This highly technical phrase raises a question – who is the audience for the integrative summary? Could this be stated without so much jargon?

Page 2-13 ... after reading this paragraph, I could not figure out what the finding or conclusion is. E.g., “To the extent that...” follows a statement that implies that the extent is not very great. Thus, what is the conclusion about whether the ambient monitor concentrations are ‘representative’?

Page 2-14... lines 6-8. Is wintertime exposure of significant interest? If not, why mention it in the integrative summary? This summary should focus on key points.

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Page 2-14, lines 15-24. Some mention should be made here to clarify what the typical exposure surrogate is in epi studies used here – i.e. fixed site monitor ambient concentration?

Page 2-14, line 25... after ‘inspiration’? ... does this refer to ‘inhalation’?

Table 2-1 ... are there clear statements of the conclusions for health outcomes such as “lung function”? What is given here is a lot of text but there is no statement as to which of the five-levels of the weight of evidence for causality fits here (e.g., inadequate to infer a causal relationship, not likely to be a causal relationship, suggestive of a causal relationship... etc.). Alternative, explain in a footnote as to why there is no reported level of weight of evidence for causality of many of the listed health outcomes.

Minor Comments on Executive Summary

Page 2-6, line 27: ‘similar’ rather than ‘the same’ ... arguable, some of the VOC species differ and there are differences in specific elementary process that are part of the chemical mechanism. However, there are also substantial similarities in the behavior of these mechanisms.

Page 2-7, lines 2-3: as written, the phrase ‘intensity and spectral distribution of sunlight’ is incomplete. Presumably, except for sun flares, the sun is producing some consistency in the intensity and spectral distribution of its emitted light. The intended meaning seems to be ‘intensity and spectral distribution of sunlight reaching the lower troposphere.’ Lines 4-5: ‘processing on cloud and aerosol particles’ is awkward.... Processing ‘on’? by what? Should be rewritten.

Page 2-8, line 31, insert ‘and’ at end of line

Page 2-10, lines 7-8... should rephrase as “Ozone monitoring is required at SLAMS sites...”

Page 2-26, lines 13-14: this sentence is awkward, but probably can be deleted.

Page 2-30, line 21 ‘studies also attempted...’ this is very awkward. A study is not an animate person, and thus cannot attempt anything. It is more appropriate to state ‘studies were conducted to...’ Similarly, next sentence, ‘These studies did so by conducting...’ should be ‘These studies involved...’

Page 2-31, lines 2-4... this is very awkward and doesn’t make sense as written. The intended meaning seems to be ‘Examination of at risk populations is useful information for assessing an adequate margin of safety when setting a NAAQS’ or something like this.

Page 2-31, line 7 ‘small number’ but ‘both’ ... is the number two? Would be less confusing to just say so.

Page 2-32, line 25... awkward, this text is not parallel.

Page 2-33. Lines 10-11... should be made clear as to what ‘concentration’ is being used – e.g., from fixed-site monitors, not personal exposures?

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Page 2-46, lines 8-12. This text is from the figure caption and should be deleted here.

General format comment

It is confusing to the reader when a figure appears in the middle of the page preceded by a horizontal line, yet followed by additional text. The horizontal lines are used to denote separation between sections, so when such a line appears before a figure, the reader may conclude that the text of that section has ended. Since the text that follows has no header, this raises doubts. A way to solve this is to put all figures at the top of the page on which they appear, so that no horizontal line is needed to separate them from the prior text. Also, avoid having only 2-3 lines of text at the bottom of the page under a figure – it is easy for the reader to think this is part of a caption.