



AN SAB ADVISORY ON THE USEPA'S DRAFT CASE STUDY ANALYSIS OF THE RESIDUAL RISK OF SECONDARY LEAD SMELTERS

**Prepared by the Residual Risk
Subcommittee of the Science
Advisory Board**

May 19, 2000

EPA-SAB-EC-ADV-00-005

Honorable Carol M. Browner
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue
Washington, DC 20460

RE: Advisory on the USEPA's Draft Case Study Analysis of the Residual Risk
of Secondary Lead Smelters

Dear Ms. Browner:

On March 1-2, 2000, the Science Advisory Board's (SAB's) Residual Risk Subcommittee of the SAB Executive Committee conducted a peer review of an Agency case study of the residual risk assessment methodology, described in its Report to Congress (USEPA, 1999), as applied to the secondary lead smelter source category (USEPA, 2000). The review of the seven-volume set of material focused on eight specific questions that are addressed in detail in the accompanying SAB report.

In short, the Subcommittee concludes that the Agency has developed a useful, self-described "work-in progress". The methodology used in this interim workproduct, as far as it currently goes, is consistent with the methodology described in the Report to Congress. Further, the assumptions used are consistent with current methods and practice. The case study provides a valuable example of how the approach presented in the Report is going to be implemented.

However, because the Subcommittee has not yet seen a full residual risk analysis and, thus, is unable to comment on the complete process, a number of important concerns were identified that should be addressed. Specifically, this interim analysis does not include the following important elements: an ecosystem risk assessment; a health risk assessment that includes population risks; a full analysis of uncertainty and variability; a computer model for assessing multimedia transport and fate that has been adequately evaluated; nor a clear description of the process and how the assessments link to the eventual risk management decisions. The attached consensus report contains a discussion of a number of additional issues related to the specific approaches taken in the interim analysis.

Looking to the future and the 173 other source categories to be addressed in the residual risk program, the Subcommittee is concerned about the data gaps that are likely to be even more of a

problem than they are in the case of secondary lead smelters. Both the Agency and the Congress need to recognize this problem in order to ensure that there is an adequate data base to support the residual risk analysis program.

During the review by the Executive Committee, a number of important concerns were raised that will be the subject of a subsequent SAB Commentary. In addition, the Health and Environmental Effects Subcommittee (HEES) of the SAB's Council on Clean Air Act Compliance Analysis (COUNCIL) and the Agency will host a June, 2000 workshop on dealing with hazardous air pollutants (HAPs). The workshop and its outcomes could prove useful insights that are applicable to the implementing of the Residual Risk Program.

We appreciate the opportunity to provide advice on this effort. The Agency staff was open, collegial, cognizant of shortcomings in the document, and accepting of the Subcommittee's suggestions. Given the incomplete state of the document at this time and the precedent-setting nature of this -- the first of 174 -- residual risk analyses, we conclude that a peer review of the final Agency Report on secondary lead smelters is in order. We look forward to your response.

Sincerely,

/s/

Dr. Morton Lippmann, Interim Chair
Science Advisory Board

/s/

Dr. Philip Hopke, Chair
Residual Risk Subcommittee
Science Advisory Board

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- a. SAB Members: Experts appointed by the Administrator to two-year terms to serve on one of the 10 SAB Standing Committees.
- b. SAB Consultants: Experts appointed by the SAB Staff Director to a one-year term to serve on ad hoc Panels formed to address a particular issue; in this case, the application of the Agency's Residual Risk Policy to the case of secondary lead smelters.

TABLE OF CONTENTS

1.0 EXECUTIVE SUMMARY	1
2.0 INTRODUCTION	4
2.1 Background	4
2.2 Charge	4
2.3 SAB Review Process	5
3.0 RESPONSES TO SPECIFIC CHARGE QUESTIONS	6
3.1 Charge Question 1: Overall	
<i>Is the methodology that the Agency applied in this risk assessment consistent with the risk assessment approach and methodology presented in the Report to Congress (EPA-453/R-99-001)? Are the assumptions used in this risk assessment consistent with current methods and practices?</i>	6
3.2 Charge Question 2: Model Inputs	
<i>Are the methods used to estimate emission rates, and the method used to estimate species at the stack appropriate and clearly described?</i>	8
3.2.1 Inhalation Screening	8
3.2.2 Multipathway Risk Assessment	9
3.3 Charge Question 3: Models	
<i>Does the risk assessment use appropriate currently available dispersion models both at the screening level and at the more refined level of analysis? Are the models applied correctly? Given the state of the science, does the risk assessment use an appropriate multi-pathway model? The assessment uses the IEM-2M model, with some modifications. Is the IEM-2M model appropriate for use in this regulatory context? With regard to the modification and application of the model, did the EPA appropriately modify the model for use in this risk assessment, and did the Agency apply the model correctly? Is there another model or another approach that is available at this time that EPA should consider?</i>	10
3.3.1 Does the risk assessment use appropriate currently available dispersion models both at the screening level and at the more refined level of analysis?	10
3.3.2 Are the models applied correctly?	10

3.3.3	Given the state of the science, does the risk assessment use an appropriate multipathway model? The assessment uses the IEM-2M model with some modifications. Is the IEM-2M appropriate for use in this regulatory context? .	11
3.3.4	With regard to the modification and application of the model, did the EPA appropriately modify the model for use in this risk assessment, and did the Agency apply the model correctly?	13
3.4	Charge Question 4: Choice of Receptors <i>The Agency identifies the home gardener as the appropriate receptor to estimate risks to the residential population and the farmer to embody high end risks. Are these receptors appropriate for this task?</i>	13
3.5	Charge Question 5: Ecological Risk Assessment <i>Given currently available methods, are the models used for the ecological assessment appropriate? Are they applied correctly? Are the ecological benchmarks appropriate?</i>	14
3.5.1	General Statement	14
3.5.2	Given currently available methods, are the for the ecological assessment appropriate?	14
3.5.3	Are they (the models) applied correctly?	16
3.5.4.	Are the ecological benchmarks appropriate?	16
3.6	Charge Question 6: Health Risk Assessment <i>Section 3.4.1 of the Report to Congress identifies several data sources that the Agency would draw upon for choosing dose-response assessments to be used in residual risk assessments. The Report also states that EPA will develop a hierarchy for using such sources. Given available dose-response information, is the hierarchy presented in this assessment appropriate (see especially footnote #6, section 2.2.1)? For each chemical included in the assessment, is the choice of dose-response assessment appropriate? Are the dose-response assessments appropriately incorporated into the assessment?</i>	17
3.7	Charge Question 7: Uncertainty and Variability Assessment <i>Did the assessment use appropriate currently available methods to identify the variables and pathways to address the uncertainty and variability assessment? Are the methods used to quantify variability and uncertainty acceptable? Are there other, more appropriate methods available for consideration?</i>	20
3.8	Charge Question 8: Presentation of Results <i>Does the Agency's document clearly present and interpret the risk results? Does it provide the appropriate level of information? Do</i>	

<i>the figures and tables adequately present the data? Do the formats provide for a clear understanding of the material?</i>	22
3.8.1 Initial Screening Analysis	22
3.8.2 Multipathway Analysis	24
3.8.3 Uncertainty and Variability Analysis	25
3.8.4 Risk Characterization	26
3.8.5 Summary and Discussion	26
4.0 REFERENCES	R-1

APPENDIX A

WRITTEN COMMENTS OF SUBCOMMITTEE MEMBERS

1. Dr. Gregory Biddinger	A-2
2. Dr. Stephen L. Brown	A-7
3. Dr. Deborah Cory-Slechta	A-14
4. Dr. Thomas J. Gentile	A-17
5. Dr. Dale Hattis	A-27
6. Dr. Michael J. McFarland	A-34
7. Dr. Paulette Middleton	A-39
8. Dr. George E. Taylor	A-42
9. Dr. Rae Zimmerman	A-48

APPENDIX B

A MORE DETAILED DESCRIPTION OF THE SAB PROCESS	B-1
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APPENDIX C

GLOSSARY	C-1
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1. EXECUTIVE SUMMARY

On March 1-2, 2000, the Science Advisory Board's (SAB's) Residual Risk Subcommittee of the SAB Executive Committee conducted a peer review of an Agency draft case study of the residual risk assessment methodology, as described in its Report to Congress (USEPA, 1999), as applied to the secondary lead smelter source category (USEPA, 2000). The SAB understands that the Agency plans another iteration, including additional data collection and analysis before the results are considered for use in a regulatory contexts. The review of the seven-volume set of material focused on eight specific questions that are addressed in detail in the accompanying SAB report.

In short, the Subcommittee concludes that the Agency has developed a useful, self-described "work-in progress". The methodology used in this interim workproduct, as far as it currently goes, is consistent with the methodology described in the Report to Congress. Further, the assumptions used are consistent with current methods and practice. The case study provides a valuable example of how the approach presented in the Report is going to be implemented.

However, because the Subcommittee has not yet seen a full residual risk analysis and, thus, is unable to comment on the complete process, a number of important concerns were identified that should be addressed. Specifically, this interim analysis does not include the following important elements: an ecosystem risk assessment; a health risk assessment that includes population risks; a full analysis of uncertainty and variability; a computer model for assessing multimedia transport and fate that has been adequately evaluated; nor a clear description of the process and how the assessments link to the eventual risk management decisions. With respect to the specific approaches taken in the interim analysis, a number of questions are discussed in detail in the attached consensus report.

One of the greatest shortcomings of the case study in its incomplete state is that only the first stage screening analysis has been done for the ecological risk assessment. While the Office of Air Quality Planning and Standards (OAQPS) recognizes that a full risk assessment is needed, the Subcommittee is disappointed at the pace at which the assessment is being developed and implemented for ecology and natural resources. It would appear that a more concerted and scientifically sound analysis is needed in order to meet the mandate of the Clean Air Act Amendments (CAAA).

Regarding the health risk assessment portion of the case study, the Subcommittee finds that, within the limitations of data and resources, the approaches employed by the Agency were able to qualitatively identify potentially high human health risk situations. However, the Subcommittee also concluded that the currently available science is insufficient to be comfortable with the quantitative values estimated by these models. In particular, the analysis calls into question the ability of the model to reliably quantify the amount of the deposited contaminant that is transferred to the food chain. In addition, the current risk assessment will have to be further developed in order to include population risks if it is to meet the needs of the Agency.

The lack of a more rigorous treatment of uncertainty and variability may lend an aura of precision to the risk estimates in the case study that may not be warranted and could, thereby, be misleading for Agency decision makers. In particular, the uncertainty analysis does not consider the propagation of uncertainties of the model parameters throughout the analysis.

In the case of multimedia computer models, the Subcommittee is concerned about the extent to which such models were applied without due consideration of the plausibility of the assumptions and the physical meaning of the results. There should be an iterative process in which implausible results flag problem areas, so that the Agency can make appropriate revisions in the model and/or its inputs, and the model run again. A number of plausibility checks were described by the Subcommittee and in public comments that would provide checkpoints in the analysis and, thereby, indicate the need for alternative assumptions and recalculation. Inclusion of these checkpoints would be helpful to both the Agency and the reader.

Finally, an overarching comment is that the case study should provide more details of what was done, how it was accomplished, and how the results link to the eventual risk management decisions. It is critical that the process be described as clearly as possible, especially articulating why particular choices were made at various decision points in the risk analysis. The current document is lacking in this regard.

Moving beyond the strictly technical aspects of the document on which the SAB has been asked to provide advice, the Subcommittee would like to comment on what it understands is the Agency's intention to make decisions based on these results. Specifically, the Agency is mandated under Section 112(f) of the Clean Air Act to conduct the residual risk assessment and to make a decision about whether or not further regulation is necessary in order to protect public health and the environment. In particular, as stated in the Agency's response to the previous SAB review of the Report To Congress (SAB-EC-98-013), "the decision made with the results of the screening analysis is [either] no further action or refine the analysis, while the decision made with the results of the more refined analysis is [either] no further action or consider additional emissions control." As discussed above, the Subcommittee concludes that, as the currently presented, the results of the refined analysis provide the same answer as the initial screening analysis; that is, they will not suffice as a basis for risk-based rulemaking, and, therefore, an even more refined analysis is needed. Therefore, the case study, at this stage, has not achieved its decision objective, and another level of analysis or iteration is needed. A better-informed decision will be possible if the results of the case study more fully reflect the inability to define the risks more precisely.

Outside the bounds of this particular analysis, the Subcommittee expressed two broader concerns regarding future assessments. First, the present source category, secondary lead smelters, is relatively data-rich. Because of the existence of the lead National Ambient Air Quality Standard (NAAQS) and the concern for blood lead levels in children, there are more data in the vicinity of facilities of this source category than are likely to be available for other HAPs from other types of sources. For many or most other source categories, the number of HAPs and the number of source types, coupled with the limited

data on emissions and quantitative information on health and ecological effects, makes the residual risk task substantial.

Second, while the basic Congressional approach of imposing controls and assessing residual risk of remaining HAPs emissions makes sense, in concept, it appears that there have not been sufficient resources provided to collect and assess all of the pertinent data from state/local air quality and public health agencies that could be fruitfully brought to bear on this problem. There are certainly not sufficient resources to permit the testing of specific HAPs for their toxicity if those dose-response data are not already available. In the case of secondary lead smelters, only seven of the 50 identified HAPs were excluded from the residual risk assessment due to the lack of dose-response data. However, lack of data will likely pose much greater problems when other source categories are addressed in the future. Such data gaps could lead to the omission of compounds from the assessment, resulting in a subsequent underestimation of the residual risk. Appropriate recognition of this problem is needed by both Congress and the Agency in order to develop an adequate data base to support the residual risk analysis program.

2. INTRODUCTION

2.1 Background

Section 112(f)(1) of the Clean Air Act (CAA), as amended, directs EPA to prepare a Residual Risk Report to Congress (RTC) that describes the methods to be used in assessing the risk remaining, (i.e., the residual risk) after maximum achievable control technology (MACT) standards, applicable to emissions sources of hazardous air pollutants (HAPs), have been promulgated under Section 112(d). The RTC was intended to present EPA's proposed strategy for dealing with the issue of residual risk and reflected consideration of technical recommendations in reports by the National Research Council ["Science and Judgment"] (NRC, 1994) and the Commission on Risk Assessment and Risk Management (CRARM, 1997). As a strategy document, the Agency's RTC described general directions, rather than prescribed procedures. The announced intent was to provide a clear indication of the Agency's plans, while retaining sufficient flexibility that the program can incorporate changes in risk assessment methodologies that will evolve during the 10-year lifetime of the residual risk program.

In 1998, the SAB conducted a formal review (SAB, 1998b) of the draft RTC (USEPA, 1998) and its proposed methodology. In their review, the SAB noted that it was difficult to assess the Agency's methodology without first seeing it applied to a specific case.

In the summer of 1999, the Agency asked the SAB to provide advice on the application of the residual risk methodology to the specific case of lead smelters. This source category was selected since it was relatively small (fewer than 30 facilities nationwide) and data rich.

2.2 Charge

In the months leading up to the SAB meeting, the Agency and the Board negotiated a Charge consisting of the eight questions below.

a) Overall -- *Is the methodology that the Agency applied in this risk assessment consistent with the risk assessment approach and methodology presented in the Report to Congress? (EPA-453/R-99-001)? Are the assumptions used in this risk assessment consistent with current methods and practices?*

b) Model Inputs -- *Are the methods used to estimate emission rates, and the method used to estimate species at the stack appropriate and clearly described?*

c) Models -- *Does the risk assessment use appropriate currently available dispersion models both at the screening level and at the more refined level of analysis? Are the models applied correctly? Given the state of the science, does the risk assessment use an appropriate multi-pathway model? The assessment uses the IEM-2M model, with some modifications. Is the IEM-2M model appropriate for use in this regulatory context? With regard to the modification*

and application of the model, did the EPA appropriately modify the model for use in this risk assessment, and did the Agency apply the model correctly? Is there another model or another approach that is available at this time that EPA should consider?

d) Choice of Receptors -- *The Agency identifies the home gardener as the appropriate receptor to estimate risks to the residential population and the farmer to embody high end risks. Are these receptors appropriate for this task?*

e) Ecological Risk Assessment -- *Given currently available methods, are the models used for the ecological assessment appropriate? Are they applied correctly? Are the ecological benchmarks appropriate?*

f) Health Risk Assessment -- *Section 3.4.1 of the Report to Congress identifies several data sources that the Agency would draw upon for choosing dose-response assessments to be used in residual risk assessments. The Report also states that EPA will develop a hierarchy for using such sources. Given available dose-response information, is the hierarchy presented in this assessment appropriate (see especially footnote #6, section 2.2.1)? For each chemical included in the assessment, is the choice of dose-response assessment appropriate? Are the dose-response assessments appropriately incorporated into the assessment?*

g) Uncertainty and Variability Assessment -- *Did the assessment use appropriate currently available methods to identify the variables and pathways to address the uncertainty and variability assessment? Are the methods used to quantify variability and uncertainty acceptable? Are there other, more appropriate methods available for consideration?*

h) Presentation of Results -- *Does the Agency's document clearly present and interpret the risk results? Does it provide the appropriate level of information? Do the figures and tables adequately present the data? Do the formats provide for a clear understanding of the material?*

The Charge guides an SAB review, but it does not constrain the range of comments that the Subcommittee members can legitimately offer.

2.3 SAB Review Process

The SAB Subcommittee was recruited following nominations received from SAB Members and Consultants, the Agency, and outside organizations. The group met in public session on March 1-2, 2000 at the main auditorium of the USEPA Environmental Research Center in Research Triangle Park, NC. Written comments prepared before and after the meeting by Subcommittee members, and made available at the meeting, form the basis for this report. Individual comments are included in Appendix A for the edification of the Agency as an illustration of the issues identified by the Subcommittee members and of the range of views expressed. Those comments are not a part of the consensus report. A more detailed description of the SAB process for this review can be found in Appendix B.

3. RESPONSES TO SPECIFIC CHARGE QUESTIONS

3.1 Charge Question 1: Overall

Is the methodology that the Agency applied in this risk assessment consistent with the risk assessment approach and methodology presented in the Report to Congress (EPA-453/R-99-001)? Are the assumptions used in this risk assessment consistent with current methods and practices?

The methodology presented in this report is consistent with the Report to Congress, as far as it currently goes, and many of the assumptions are consistent with current methods and practice. However, the Subcommittee has not yet seen a full residual risk analysis and is unable to comment on the complete analysis process. More specifically, this was an interim analysis that did not include such important elements as an ecosystem risk assessment, a health risk assessment that includes population risks, a full uncertainty and variability (U&V) analysis, a computer model for assessing multimedia transport and fate that has been adequately evaluated, nor a clear description of the process and how the assessments link to the eventual risk management decisions. At this interim stage, it looks only at four of the 23 sources from the secondary lead smelters category. Nonetheless, the report does provide a valuable indication of how the approach presented in the Report to Congress is going to be implemented in practice. With respect to the specific approaches used in the case study, there are a number of questions that are discussed in detail in response to the specific charge questions below.

A general comment is that the case study should provide more details of what was done and how it was accomplished. It is critical that the process be as clear and fully articulated as possible. More details are needed on how each model has been modified from prior use. For example, it is not clear how the IEM-2M model was modified from its prior use in the mercury assessment in order to be used for the secondary lead smelter emissions. The interested and knowledgeable reader should be able to follow what changes were made and understand why such modifications were made.

There is clearly a significant problem with how fugitive emissions are being treated. In this analysis, much of the residual risk results from fugitive dust emissions. However, there is little direct information in the Agency's document on how these emission rates were modeled. In the Agency presentations at the meeting, four approaches to modifying the fugitive emissions were provided.

It should be possible to utilize existing data to help refine the emissions estimates. At many or most of these facilities, there are ambient monitors generating data to determine compliance with the lead (Pb) National Ambient Air Quality Standard (NAAQS). These data should provide an opportunity to estimate the routine emissions around the plant and potentially observe the differences in concentrations before and after whatever steps were implemented to comply with the fugitive part of the MACT standard. Information on the frequency and extent of upset conditions at these plants could be used to supplement monitoring data from routine operations. Anytime data are available to provide ground truth,

the Agency should compare those data to the model results. This feedback approach would mitigate against the generation of results that appear unreasonable.

A number of concerns were raised about the manner in which the models appear to have been applied without adequate consideration of the plausibility of the assumptions or the physical meaning of the results. An iterative process is needed in which, even in the absence of external comparison data, when implausible results are obtained, the model inputs can be appropriately revised and the model run again. For example, when excessively high blood lead levels are estimated (e.g., 200 µg/dL), the analyst should reexamine the model inputs and make appropriate modifications. Similarly, where excessively low breast milk contaminant levels were estimated, the analyst should also reexamine the models. A number of such plausibility checks were described by the Subcommittee or in public comments that can provide checkpoints in the analysis to indicate the need for alternative assumptions and recalculation. The resulting discussion of these implausible results and the changes made to the calculation would be a useful modification to the current approach.

Only the first stage screening for potential hazard was available for consideration of the ecological risk. It is recognized by OAQPS that a full assessment of ecological risk is needed, but the rate of progress in this direction has been slow. The methods and supporting assumptions made are general, at best, and would need to be more definitively treated in a refined ecological risk assessment (See Charge Question 5 for more details). The Agency should devote sufficient effort and resources to insure a credible ecological risk assessment for this prototypic case study.

One of the critical problems for future residual risk analyses will be the availability of data. Secondary lead smelters emit lead and other HAPs. Emissions and related ambient monitoring data for lead are generally available. Data on the other HAPs are less available, making future assessments of residual risk associated with these other HAPs more of a challenge. Even when data are available, the data will need to be evaluated to determine their appropriateness for ground-truthing risk estimates. In addition, there is a significant question about how available are the critical input data needed to credibly characterize the residual risks from the other 173 source categories. In the present analysis, missing information, such as the toxicity of a number of HAPs, led to those compounds being excluded from the analysis. There may be molecular modeling approaches (e.g., Quantitative Structure-Activity Relationships (QSAR)) that would permit estimation of relative toxicity of the organic HAP compounds for which data are not available and a screening analysis of their likely effect on the overall risks could possibly be developed.

The Subcommittee felt that, within the limitations of data and resources, the approaches adopted were able to identify potential high human health risk situations. However, they also felt that the science is insufficient to be fully confident in the quantitative values estimated by these models. There are significant concerns regarding the nature of the full ecological risk assessment because a complete analysis has not yet been presented. There is concern that the apparent precision of the resulting risk estimates may be overstated and that more effort is needed to present results that better reflect the uncertainties and variability in the analysis. The review material did not give a clear picture of how the results of the

analysis would be used in the risk management process. Such information would have helped the Subcommittee to comment more precisely on the adequacy of the analytic results to support the decision making process.

In any event, it is recognized that at some point management decisions will have to be made based on results stemming from analyses of this type. The Agency is mandated under Section 112(f) to conduct the residual risk assessment and to make a decision to implement further regulation or to make a decision that no further regulation is needed. In response to the previous SAB review (SAB, 1998b) of the Report to Congress, the Agency responded that, "the decision made with the results of the screening analysis is [either] no further action or refine the analysis, while the decision made with the results of the more refined analysis is [either] no further action or consider additional emissions control." As discussed above, the results of the more refined analysis provides the same answer as the initial inhalation screen; that is, an even more refined analysis is needed. Therefore, the case study, in its current state, has not achieved the decision objective, and another level of analysis or iteration would be needed. The case study needs better quality input data/estimates on fugitive emissions, a more in-depth and refined analysis, a clearer presentation of the steps taken in the analysis and the results produced, and a more serious effort to fully integrate uncertainty and variability into the analysis. In summary, a better-informed decision will be possible if the results of the case study more fully reflect the inability to define the risks precisely.

3.2 Charge Question 2: Model Inputs

Are the methods used to estimate emission rates, and the method used to estimate species at the stack appropriate and clearly described?

3.2.1 Inhalation Screening

The fundamental equations used by the Agency to estimate the specific inorganic and organic hazardous air pollutant (HAP) emission rates for process and process fugitive emissions are described by Equations 1 and 2, respectively. These equations provide a technically sound methodology for estimating specific HAP emission rates based on the metal HAP and hydrocarbon emissions data provided in the Background Information Document (BID) (USEPA, 1994). Although the Subcommittee can support the Agency's initial decision to employ the AP-42 based fugitive HAP emissions estimates in the inhalation screening study, the combined effect of using these conservative data with a conservative air pollution concentration model has clearly resulted in an overestimation of ambient HAP air concentrations. On the other hand, "upset" conditions were not assessed with any data in this assessment, and considerable lead may be emitted from these facilities under such circumstances. This could lead to an underestimation of ambient HAP air concentrations. To ensure that the use of SCREEN3 will result in realistic predictions of ambient air pollutant concentrations, the Agency should evaluate the underlying assumptions adopted in the area source emissions algorithm, as well as the quality of emissions data, to determine if they warrant further refinement.

Although the Agency should be commended for its creative and resourceful use of existing data to estimate specific HAP emission rates, the Subcommittee identified several opportunities for the Agency to improve its general description and use of the reported data sets. First, the Agency should provide a better and more complete description of the data elements contained in Tables B.1.1 and B.1.2. A reviewer of these tables would find it difficult to discern what statistical measurement is actually being reported; i.e., mean, median, or upper confidence limit (UCL). Secondly, the Agency should explore using means as inputs to the HAPs emission rate estimate methodology, since the means of these likely skewed distributions would provide a quick screening tool that is more conservative than the median and less conservative than the 95th percentile upper confidence limit (UCL). The concern is that simply using of the 95th percentile UCL would screen out very few, if any, sources. Countering this concern, of course, is the unknown impact of upset conditions, as noted above, whose analysis also needs attention. Finally, to provide a reviewer of the methodology an opportunity to reproduce any or all of the emission rate estimates, the Subcommittee recommends that the Agency provide an example within the document that illustrates the proper use of Equations 1 and 2.

As noted in the response to Charge Question 7 below, the Subcommittee found that the analysis of uncertainty and variability was incomplete in several respects, thereby depriving the risk manager of important information when making these important decisions.

3.2.2 Multipathway Risk Assessment

To estimate the specific HAP emission rates from both the process and process fugitive emission sources, the Agency employed site-specific HAP emissions information from facility compliance reports, as well as information from the BID database, where necessary, in the multipathway risk assessment. Although the Subcommittee commends the Agency for demonstrating resourcefulness in employing the best available site-specific data to generate HAP emission rates, there is concern over the general approach used by the Agency in employing secondary data to estimate site-specific HAP emission rates in the multipathway risk assessment.

To improve the scientific defensibility of both the stack and fugitive HAP emission estimates for the multipathway risk assessment, the Subcommittee developed several recommendations for consideration by the Agency. First, prior to using secondary data for site-specific emission estimates, the Agency needs to evaluate the quality of the individual data sets using a clear, easy-to-follow, and well-documented methodology. Development and implementation of a technically sound data quality evaluation methodology will provide the Agency with a framework for establishing the minimum data quality criteria for use in residual risk estimates. Secondly, to leverage limited time and resources, the Agency should collaborate with its industrial partners to identify and collect additional site-specific monitoring data for use in estimating process and process fugitive HAP emission rates. Third, because of its relative importance in characterizing human health and ecological risk, existing air monitoring data, where available, should be employed by the Agency for the groundtruthing of site-specific fugitive HAP emission estimates. Information on the frequency and extent of non-routine, or upset, conditions must be considered. Finally, to assist a reviewer in reproducing any or all of the final risk assessment numbers, the

Agency should present a detailed example illustrating the basic process by which a data element contained in a NESHAP secondary lead smelter compliance report is used to generate final human health and ecological risk estimates.

3.3 Charge Question 3: Models

Does the risk assessment use appropriate currently available dispersion models both at the screening level and at the more refined level of analysis? Are the models applied correctly? Given the state of the science, does the risk assessment use an appropriate multi-pathway model? The assessment uses the IEM-2M model, with some modifications. Is the IEM-2M model appropriate for use in this regulatory context? With regard to the modification and application of the model, did the EPA appropriately modify the model for use in this risk assessment, and did the Agency apply the model correctly? Is there another model or another approach that is available at this time that EPA should consider?

3.3.1 Does the risk assessment use appropriate currently available dispersion models both at the screening level and at the more refined level of analysis?

Both the SCREEN3 and Industrial Source Complex Short Term 3 (ISCST3) models have become widely accepted tools-of-the-trade and probably are the most suited for this point source category. However, there are minor shortcomings in the models that need to be clearly articulated. The conservative screening nature of SCREEN3 is designed to "capture" all facilities that may need further investigation. As a result, the output should result in many false positives which may reduce the credibility of the model.

In the current assessment, the Agency uses the IEM-2M model for its multipathway analysis. Although it is the only multipathway modeling tool that the Agency has readily available for use, there are a number of concerns regarding the model that are discussed elsewhere in this Advisory. In the meantime, it should be noted that OAQPS is in the process of developing the Total Risk Integrated Model (TRIM) as a flexible, state-of-the-art model for evaluating multimedia chemical fate, transport, and risk of HAPs. A recent review of this effort by SAB's Environmental Models Subcommittee found TRIM to be promising and innovative, while providing a number of recommendations for further improvement (SAB, 2000). When TRIM becomes available, it should provide an improvement over the modeling framework used in the current report.

While understanding the need for the Agency to move ahead with the Residual Risk Program, the Subcommittee is concerned that the IEM-2M model, as currently employed, is not able to provide the level of technical information that is needed for making scientifically sound regulatory decisions. Conceptually, the TRIM model is a significant improvement over IEM-2M. However, TRIM faces development challenges of its own that will require resources to address. Therefore, the Agency faces the difficult near-term choice of trying to improve an inferior model or committing to complete a superior model. The Agency needs to develop a plan for how and when they will use these models and how they will effect a transition from one to the other.

3.3.2 Are the models applied correctly?

A number of assumptions in model execution can affect the outputs. For example, it was assumed that all emissions come from the center of the facility, when, in fact, the exact location of emission source -- currently unknown -- should have a strong influence on predicted downwind exposure levels. Locations of stacks in relation to buildings and building sizes can also result in an incorrect estimation of exposure rate. Also, using meteorological data from the nearest reporting meteorological station is an approximation commonly employed. However, risk assessors and risk managers need to be aware of the suitability of this approximation in some locales, such as those with complex terrain and/or long distances between the facilities and the station..

A major issue which must be addressed is how to consider historical lead and other persistent chemical contamination at the site which was deposited prior to the promulgation of the MACT standard but which may nonetheless substantially contribute to on-going exposures post-MACT. A residual risk analysis that does not add exposures to baseline contamination to the estimates of on-going contamination may vastly underestimate the hazard quotient at the site and incorrectly conclude that the on-going releases pose risks at less than threshold levels.

The Agency chose four cases with relatively high projected risks as illustrative examples, including both urban and rural settings. The Subcommittee understands that the terrain in each of these four cases was unremarkable, and, consequently, it was reasonable to model them in that way. In the final residual risk assessment for this source category, all of the facilities in the category will be modeled individually, and complex terrain, downwash, and other model adjustments will need to be incorporated into that analysis, as appropriate.

Other issues raise questions that should be addressed in subsequent reports. For instance, classification of metals as persistent, bioaccumulative toxicants (PBTs) is problematic, since their environmental fate and transport cannot be adequately described using models for organic contaminants. Also, hazard indices for the ingestion pathway were developed separately from those for inhalation, and the impact of this strategy on the non-cancer results is unknown.

3.3.3 Given the state of the science, does the risk assessment use an appropriate multipathway model? The assessment uses the IEM-2M model with some modifications. Is the IEM-2M appropriate for use in this regulatory context?

The IEM-2M modeling was performed as a set of linked Excel spreadsheets. Although pertinent equations were given in Appendices, the implementation of the modeling effort needs to be carefully examined. The spreadsheets were not provided to the Subcommittee in time for substantive review by the members, and implementation of complex spreadsheet models can often lead to unsuspected errors. Therefore, the Subcommittee was unable to verify the figures and can only encourage the Agency to carefully examine the quality control applied in the construction of the spreadsheets. Further, the spreadsheets should be available to the public.

The Subcommittee understands that use of the IEM-2M model for the case of mercury (Hg) has benefitted from some limited peer review. However, adaptation of the model to address HAPs other

than Hg does not appear to have been rigorously evaluated (Rimer, 2000). In view of the unique environmental chemistry of mercury, extrapolation of the model to other metals must be made with extreme caution.

Through application of the model to a number of source categories and a number of pollutants with different behaviors, the Agency will have the opportunity to evaluate the model, at least in part. While human exposure data are rare, data on environmental concentrations of pollutants in various media are more widely available. In many cases, simply knowing that the model estimates are within an order of magnitude of measured environmental concentrations would provide much greater confidence in the model as an analytic tool. In particular, it would be important for the Agency to show that the multipathway model produces approximately correct estimates results for the concentrations in food of dioxins/furans and mercury, two important and difficult to model pollutants. If the evaluation exercises indicate that the model is at variance with reality, the model will have to be revised and previous results may need to be recalculated.

At the same time, the Subcommittee recognizes that the Agency is moving toward final development and implementation of the TRIM computer model, which would replace the IEM-2M model. Therefore, the Agency will have to balance the competing needs of making significant improvements to the old model vs. completing development and evaluation of the next generation model.

In its present form, the model can be used to show that there may be a relationship between atmospherically deposited HAP and the total burden of the particular contaminant in a target ecosystem. It cannot reliably quantify the amount of deposited HAP expected to be transferred to the human food chain. While some of the problem could arguably be related to an overestimate of fugitive emissions, it is clear that missing process considerations in the model severely limit its ability to simulate the movement of materials in the environment. For example, the transfer coefficients have been estimated without considering the effects of biogeochemical processes on contaminant reaction rates, speciation, and bioavailability. By ignoring the physical and chemical drivers, the IEM-2M model may have yielded grossly unrealistic concentrations of some contaminants in environmental contaminants. Table 6.8 (p. 160, Vol. I) provides an excellent example of the model inadequacy. The calculated concentrations of lead in surface water near a secondary lead smelter is reported as 103 to 106 ug/L, which is a high enough concentration of lead to sterilize the water. These unrealistic estimates should be identified as such, and appropriate adjustments made. In real life, most of the deposited lead would be adsorbed onto particulates and removed to the sediment. This scavenging removal could readily reduce the dissolved lead concentration to the measured value of 0.002-2.0 ug/L. Exaggerated concentrations, as well as unrealistic risks that have been reported for other contaminants, might likewise be traced to model deficiencies. This is an example of how the results of the model can be compared with what can be reasonably assumed about the functioning of a water system. The consequence of this comparison should be a reevaluation of the results so that the estimated concentrations are brought into line with what would be reasonably observed in real ecosystems. A simple re-scaling of the fugitive emissions estimates, alone, is not likely to solve some of these obvious problems.

The IEM-2M has a number of limitations of which the decisionmakers need to be aware. The model does not differentiate between natural and anthropogenic fractions of a contaminant in a given environmental medium. It estimates the incremental levels/effects without considering the levels/effects of the contaminant that have already been built up in the environmental medium. The Subcommittee suggests that the Agency discuss how inclusion of baseline concentrations (that is, contributions from natural plus anthropogenic sources other than the post-MACT facility) would affect estimated total and attributable risks. The model does not insure mass balance, nor does it account for feedback mechanisms between environmental media. While the IEM-2M can be used to estimate individual excess risk, it is not at all clear from the documentation that it can provide the spatial and temporal distributions of exposure that will be needed to provide the link to distributed populations. Therefore, additional refinement made be needed so that the model can be used to estimate the population risk.

Uncertainty analysis, a critical adjunct to risk analysis, is not included in the IEM-2M model. In view of the uncertainties and assumptions in the model, ground-truthing should be an essential aspect of the model analysis.

3.3.4 With regard to the modification and application of the model, did the EPA appropriately modify the model for use in this risk assessment, and did the Agency apply the model correctly?

The IEM-2M model should be regarded, at best, as a work-in-progress. The Subcommittee understands that the IEM-2M will be replaced by the TRIM model, referenced above, once the latter has been sufficiently well-developed. In the meantime, in light of the limitations noted about the IEM-2M, its results must be regarded with informed caution.

3.4 Charge Question 4: Choice of Receptors

The Agency identifies the home gardener as the appropriate receptor to estimate risks to the residential population and the farmer to embody high end risks. Are these receptors appropriate for this task?

The home gardener and the farmer are acceptable receptors for this task, but their assumed exposure scenarios need to be modified in order to provide a more realistic estimate of the risks to typical members of the local community. Specifically, the input assumptions for both scenarios may be unrealistically high compared to the real exposures of the local residential and farm communities, particularly regarding inhalation and food preparation activities. The inhalation exposures assume that the receptor is exposed to outdoor concentrations 24 hours per day. The food ingestion pathway assumes that home-grown produce is not washed. The risk model results are very sensitive to these assumptions. Moreover, these exposure assumptions make it especially difficult to check the model results through comparison with data. Existing and potential data on human exposure levels are likely to be from people in nearby communities who do not have these high-end exposure behaviors. For these reasons, the Subcommittee recommends that the Agency also model the exposure of home gardeners who are not outside all the time and who do wash their home-grown produce.

Further, the case study assumes continuous exposure over a lifetime for inhaled HAPs but exposure over shorter periods for ingestion of soil, water, and produce containing HAPs; i.e., 12 years for a home gardener and 17 years for a farmer. The reason for this apparent inconsistency should be made clear.

The overall characterization of the risks to the local community needs to be clarified when the population exposure assessment is completed.

3.5 Charge Question 5: Ecological Risk Assessment

Given currently available methods, are the models used for the ecological assessment appropriate? Are they applied correctly? Are the ecological benchmarks appropriate?

3.5.1 General Statement

In the previous SAB review of the residual risk issue (SAB, 1998b), the Subcommittee strongly encouraged the Agency to elevate the prominence of ecological risk and to establish a commitment to ecological concern that was more nearly co-equal to that of human health. The recommendation was driven by the neglect of ecological and natural resources considerations in the draft Report to Congress (USEPA, 1999).

At the March 1 briefing, the Agency stated that the risk to ecological and natural resources will not be addressed at this time in other than a screening level analysis; i.e., a hazard assessment, rather than a risk assessment. This position is unfortunate, even for a document that is admittedly a work-in-progress, since this shortcoming was strongly identified in the Board's earlier report (SAB, 1998). Such a position would be unacceptable in the final document in that it would ignore the legal mandate to avoid "an adverse environmental impact" that is "significant" and "widespread" and likely to result in the "degradation of environmental quality over broad areas" (CAAA Section 112(a)(7)). By pursuing a hazard assessment for secondary lead smelters rather than a risk assessment, the Agency will likely generate a large number of "false positives" that will make the task of the risk manager more difficult. It could also have the unwarranted effect of setting a precedent for using hazard assessment for ecological and natural resources analysis in lieu of a risk assessment for future residual risk analyses.

3.5.2 Given currently available methods, are the for the ecological assessment appropriate?

As a matter of first importance, the document should indicate whether the ecological risk assessment presented here is being developed in accordance with the Agency's Ecological Risk Assessment Guidelines (EPA, 1998). These guidelines have been developed over several years, have involved many experts from the ecological science community, and have been endorsed by the SAB (SAB, 1997).

The ecological risk screen is underpinned by five concatenated models, with the term "model" used loosely to include both formally constructed code, as well as more simple spreadsheets. The

source, dispersion, deposition, and multipathway models are the same as those used to conduct the human health characterization. The fifth and last model -- and the one unique to ecology and natural resources -- is the spreadsheet to screen for ecological effects using the Hazard Quotient (HQ) and Hazard Index (HI) methodologies. The only two models that are specifically relevant to ecology and natural resources are the multipathway and ecological effects models.

- a) Multipathway Models - The multipathway model is appropriate for the task of characterization of exposure and supporting a risk assessment. The model has the necessary features to handle the transport, transformation, and fate of organic and inorganic compounds in multiple media; i.e., soil, water, air and biota. In light of the results from both human health and ecology analyses, the "screened risks" appear to result from a few critical parts of the code, most notably soil-to-plant uptake, atmosphere-to-plant deposition and accumulation, bioaccumulation in the food chain, and transport in aquatic environments. Because these processes are so instrumental in the overall risk analysis and because the model's validity was repeatedly questioned, it is recommended that these critical subcodes be peer-reviewed to assure that the mathematical formulation is reasonable, current, and scientifically defensible. However, as noted above in Section 3.3.3, the Agency needs to balance efforts to improve the IEM-2M model against the need to develop and implement the next generation models, such as TRIM.

Although multipathway methods are more than adequate for the task of screening and are certainly the appropriate method for a risk assessment, it is not necessary to use multipathway models in the initial screening assessment. Traditionally, multipathway models are reserved for those compounds that are persistent and bioaccumulative toxicants (PBTs). Unless the entire list of HAPs is made up of PBT chemicals, it would be more efficient to screen using simple fate and direct exposure models. If a PBT compound were to pass the toxicity screen ($HQ < 1.0$), the hazard of direct contact would likely be insignificant, and the Agency could decide if the compound warrants a review of higher trophic considerations based on size and spatial distribution of the industry source category, plus the dispersion potential of the HAP. If the sources were many, large, and widely distributed, it might pass the test of being "widespread" and likely to result in "degradation in environmental quality over broad areas". Otherwise, only compounds with $HQ > 1.0$ would be the subject of the multipathway analysis.

- b) Ecological Risk Screening (i.e. Hazard) Model - The Agency provides a rudimentary hazard ranking or screening process for culling through the HAPs associated with secondary lead smelters source category. The method is based on the generation of Hazard Quotients (HQs) which are simple ratios of environmental concentrations to effects-based environmental benchmarks. The benchmark is a concentration level in a medium at which little or no potential exists for an hazard. As a screening tool, this approach is valid, although it necessarily results in a high number of "false positives". Screening ecological hazards with this approach is well-established for use in ranking and prioritizing hazards associated with chemicals; e.g., new product design and approval,

risk-based corrective actions at contaminated sites, and prioritization of resources in regulatory programs.

As is well-stated in the case study, this conservative methodology is only used either to remove chemicals from further risk management consideration (i.e. the risk is acceptable) or to indicate that there is a need for further analysis. The HQ approach with such conservative effects benchmarks is really aimed at protecting all individuals in the ecosystem and, by inference, to protecting the structure and function of the ecosystem in which that individual lives.

3.5.3 Are they (the models) applied correctly?

Given that this analysis is a screening exercise (i.e., hazard assessment) and not a risk assessment, the models are applied correctly, with the exception of the summation of HQs, as discussed below. There are several key aspects of the application for a screening exercise that warrant the Agency's attention:

- a) Top Carnivores - This functional group is omitted from the model in terrestrial ecosystems; yet it is likely to be the most responsive functional group for PBTs. The rationale for not including this functional group (i.e., "Data are not available") is contrary to what can be done in a screening exercise.
- b) Background Concentration - For ecological systems, the inclusion of geochemical background concentrations is more important than for human health, particularly for those chemicals that have a natural source; e.g., manganese, mercury, and nickel. The natural background issue should be re-evaluated in order to address the risk to ecological and natural resources.
- c) Summation of HQs - Generating an HI by summation of HQs for chemicals in different classes (e.g., metals and organics) or for obviously different organics (e.g. phthalates and PAHs) goes beyond current good practice in screening ecological risks. The resulting HI is possibly misleading. Summation of HQs should be limited to chemicals that operate via the same mode of action on the same target organ or system.

3.5.4. Are the ecological benchmarks appropriate?

It is not possible to completely answer this question from the information given. The selected benchmarks represent the current state of the practice for screening assessments, many of which have been developed for use at contaminated sites as a means of focusing management action on only the chemicals of greatest concern. For some of these situations, especially those involving water and sediment, there may be different benchmarks for freshwater and marine systems, and it is not clear which was used in this case.

What is clear is that these numbers should not be used in a sophisticated risk assessment. The data behind these criteria may support a risk assessment, but the final "criteria value" can only be used to eliminate chemicals of concern. As HQs are refined, the exposure estimate should be refined to reflect site-specific conditions, and the characterization of effects should also advance from a general benchmark to an estimate of a toxic threshold, based on dose-response data for a representative or surrogate species.

3.6 Charge Question 6: Health Risk Assessment

Section 3.4.1 of the Report to Congress identifies several data sources that the Agency would draw upon for choosing dose-response assessments to be used in residual risk assessments. The Report also states that EPA will develop a hierarchy for using such sources. Given available dose-response information, is the hierarchy presented in this assessment appropriate (see especially footnote #6, section 2.2.1)? For each chemical included in the assessment, is the choice of dose-response assessment appropriate? Are the dose-response assessments appropriately incorporated into the assessment?

The Agency has used a reasonable approach to summarize the toxic effects and the dose-response values for the HAPs included in the multipathway analysis. The document succinctly summarizes a tremendous body of information and accurately describes the endpoints upon which reference doses are derived. The important information related to each is adequately summarized.

The toxic effects and dose-response analysis information are derived from multiple sources according to the following hierarchical structure: Integrated Risk Information System (IRIS), Agency for Toxic Substances and Disease Registry (ATSDR) toxicology profiles, Health Effects Assessment Summary Tables (HEAST) and State of California Environmental Protection Agency (CalEPA) values. However, the document does not provide the rationale for the specific ranking. The clarification provided at the March 1 meeting should be a part of the document, including the intent to make chemical-by-chemical decisions about which database to use and the often higher quality of information in the CalEPA database (CalEPA, 19...) than is found in the older HEAST compendium (USEPA, 1994).

The residual risk exercise emphasizes, once again, the importance of having accurate, current information in the Agency's IRIS database. As it has been stated in the past (NRC, 1994; USEPA, 1999), the SAB continues to encourage the Agency to create and maintain a credible set of data in IRIS. Another SAB panel will review a Congressional-directed study of IRIS later this year.

While the case study has employed methods that are routinely used at the Agency, the Subcommittee has some concerns. The approach appears to utilize the default assumption that all health effects described are of comparable severity and concern. For example, risk estimates derived for some of the HAPs compounds are based on rather vague endpoints, such as body weight loss, which are not explicitly associated with any disease process; whereas, in other cases, the assessment may center on effects, such as pulmonary or neurotoxicological effects, that are of a more grave character. This

approach is another example of the conservative stance taken through much of the analysis. However, the risk assessor and the risk manager need to recognize and appreciate these differences in potential severity of health effects when comparing and combining the results of the analysis.

Another supposition which may ultimately prove problematic is the assumption that effects of mixed exposures are additive. In reality, mixtures may produce effects that are additive, synergistic (potentiated), or even attenuated. The current default assumption is necessitated by the absence of any information with which to more precisely model such effects and, therefore, represents a conservative approach.

A related point is the difference in confidence with respect to cancer potencies calculated from human vs. experimental animal data. Unit risk estimates based on human data are generally maximum likelihood estimates calculated from studies that, if anything, have biases towards underestimating human incidence of carcinogenicity because they are usually based on worker populations, not children, who are arguably more susceptible. Exposure estimates in this case usually have substantial uncertainties that tend to bias comparisons of more vs. less exposed workers towards the null and, therefore, towards lower estimates. On the other hand, animal-based unit risk estimates include a number of procedural assumptions that are thought to usually lead to overestimates of risk, such as the use of 95% confidence limits, choice of the most sensitive species for projection to humans, etc.

The Subcommittee is concerned about the potential problems associated with a residual risk assessment that must omit HAPs in assessments of the risk of noncancer endpoints due to the fact that there are no dose-response data on these compounds currently available and that Agency policy dictates against using probabilistic values. For example, in the case of secondary lead smelters dioxins/furans are omitted from consideration as a non-cancer risk due to the lack of data. While the Agency indicated at the March 1 meeting that dioxins/furans would be included in the next iteration of the process, other compounds are, and presumably would continue to be, omitted due to the lack of data. The document needs to address this limitation directly and indicate how the decision making process will take these vulnerabilities into account. As one possible way to address the problem, the Subcommittee recommends that the Agency explore the use of quantitative structure-activity relationships (QSAR) to assess whether any of the organic HAPs with insufficient dose-response information might, in fact, be a significant concern that is currently being overlooked. While QSAR would not play a definitive role in the analysis, it could identify potential problem compounds that are otherwise ignored entirely in the current case study.

The Subcommittee understands that the Residual Risk Program is following current Agency guidance by calculating hazard quotients (HQs) for non-carcinogens, with the implicit assumption of a threshold in the dose-response curve. However, the HQ approach is not a true risk assessment (i.e., a probabilistic estimate of the likelihood of harm), is not based on a biologically compelling foundation, and does not explicitly address the possibility of low-dose effects above or below the reference dose (RfD), even for highly non-linear dose-response relationships. As a part of its overall effort, the Agency should continue work on developing and implementing a more scientifically based risk assessment procedure for

non-carcinogens that would lead to improved risk assessments. For example, some reports now suggest that the slope defining Pb effects is actually steeper at blood lead levels below 10 ug/dL than above it.

As noted above, the Subcommittee is concerned about how some of the results of this analysis will be treated. In particular, while the generation of hazard index (HI) values can be useful, despite its implicit limiting assumptions (e.g., additivity of all effects), there is no indication in the document of how these values will be used in the final decision making process. Without some indication of how they will be used and for what purpose, the Subcommittee is unable to comment effectively on the appropriateness of HIs in this case.

Also, as discussed above, it is clear that the residual risk analysis results in an estimate of incremental exposure and, in the case of cancer, incremental risk of disease. However, it is not clear how the Agency plans to use the incremental exposure estimates in the case of non-cancer effects, when these additional exposures (that is, in addition to already existing exposures from other sources) might subject some elements of the population to a "level-of-concern"; e.g., $HI > 1$.

Two examples are included in the document that relate the derived HQs to anticipated consequences of human exposures: the cases of lead and dioxins/furans. The lead case allows some type of human health risk assessment, since blood lead levels associated with specific human health effects have been well documented. However, in both cases, the outcome suggests problems with the models. Specifically, the derived blood lead values are so high that they would be associated with gross toxicity; e.g., acute encephalopathy and even mortality. If such effects are real, it is quite likely that the problem would have already been discovered by the local medical community. Therefore, these derived blood lead values are a clear indication that the multipathway model has problems and needs to be revised.

As noted above, the Agency indicates that some of these problems may not be problems of the model per se, but rather problems associated with overestimates of fugitive emissions. While the Subcommittee agrees that overestimates of fugitive emissions may play a role here, there is no indication of the extent of that role. On the other hand, it is quite clear that the model fails to consider biophysical chemical processes that definitely play an important role and that the model has not benefitted from a rigorous peer review. (The model was not a major focus of the SAB review of mercury (SAB, 1998a).) In fact, some consideration should be given to using the TRIM model in its incomplete version rather than continuing to use IEM-2M. A more integrated and complete uncertainty and variability analysis would help to clarify these matters.

Additionally, Table 6.9 compares modeled concentrations of dioxins/furans in human milk with measured concentrations in human breast milk. It shows that modeled concentrations are notably lower than those measured in human milk. These findings are interpreted as indicating that emissions of dioxins/furans from secondary lead smelters are a minor contributor to overall dioxins/furans nationwide. An alternative interpretation (namely, that dioxin is not adequately modeled in the residual risk assessment paradigm) is not even considered, which clearly seems to be an oversight.

Finally, at this stage in the of development of the assessment, the Agency has not generated any population risk estimates. The Subcommittee would like to emphasize the fundamental importance of generating such estimates in the final document. Currently, there is little discussion of how this critical step will be taken.

3.7 Charge Question 7: Uncertainty and Variability Assessment

Did the assessment use appropriate currently available methods to identify the variables and pathways to address the uncertainty and variability assessment? Are the methods used to quantify variability and uncertainty acceptable? Are there other, more appropriate methods available for consideration?

In short, the uncertainty and variability (U&V) assessment is one of the weakest parts in the draft case study and appears to be a rather peripheral afterthought to a main analysis, rather than an example in which U&V considerations are fully integrated into a project. As noted above, this concern was mentioned prominently in connection with the multipathway exposure model results.

The fact is that U&V analysis has advanced significantly over the past ten years. The combining of traditional point-estimates of parameters, together with their separate ranges of uncertainty, hardly qualifies as even a "quick-and-dirty" analysis these days. Instead, readily available computing power and increased experience with distributions for various quantities (e.g., EPA Exposure Factors Handbook (USEPA, 1997) have combined to made distributional analysis of U&V, even simple Monte-Carlo analysis, much more the standard expectation for the field. These techniques have by no means reached the level of being "cookbook manipulations". Rather, they do require skilled, knowledgeable judgments on a case-specific bases. However, they are being applied with much greater frequency, providing the basis for much more informed decisions, particularly in significant decision making contexts, such as the residual risk program under discussion here (Cullen and Frey, 1999; Thompson, 1999; Hattis and Froines, 1992; Hattis and Burmaster, 1994; Hattis et al, 1999).

In the first instance, the terms "uncertainty" and "variability" need to be clearly defined and consistently used. Variability refers to real differences in things or people that would be seen even with perfect measurement or estimation techniques; e.g., the differences in the body weights of the individuals in an exposed population around a lead smelter. Uncertainty, by contrast, refers to the imperfection in our knowledge of the values of a specific parameter; e.g., characteristics of the throughput of material at a particular lead smelter. Generally, uncertainty can be reduced by gathering better information, but real variability will be unchanged, although it can be better characterized by better information.

The failure to distinguish variability from uncertainty in the present analysis almost guarantees confusion. Variability and uncertainty are different things and require different techniques for estimation. For example, soil type may vary from facility to facility, but it may be relatively uniform at any one facility. If the soil type is not known at a particular facility, the distribution that describes variability among facilities where soil type is known can be used to construct an uncertainty distribution for the particular facility.

Without understanding the distinction between uncertainty and variability, a risk manager cannot make a fully informed decision based on the results of the U&V analysis. A properly prepared analysis of uncertainty and variability analysis should help a risk manager to answer the question, "What actions must I take in order to assure that no more than Y percent of the population exposed incurs a risk greater than X, with confidence Z?" In other words, the risk manager should be able to understand not only how risk might vary from person to person, as described by X and Y, but also how sure we are about our estimates, as described by Z (cf., Hattis and Anderson (1999), and Hattis and Minkowitz (1996)). That kind of goal for the U&V analysis is not made explicit in the Agency's case study.

Although it is challenging to carry out an analysis that fully separates considerations of uncertainty and variability, and although it is sometimes a matter of perspective whether a given distribution describes uncertainty or variability, the Subcommittee did not find the Agency's justification for combining the two in its analysis convincing. For example, consumption rates of water and food really do vary from person to person, and the corresponding calculated risks due to any specific smelter's emissions would also vary accordingly. On the other hand, the distribution used for the annual average emissions of the smelter is dominated by uncertainty, since so few data are available from post-MACT facilities. However, there is little expectation that annual average emissions (in g/sec) would vary substantially from year to year.

The Agency chose to use distributions for emissions and for some elements of the exposure analysis, but not for the parameters of the fate and transport models or of the toxicity analysis. While the Subcommittee understands that it is currently Agency policy not to undertake distributional analyses of toxicity information, the Agency should reconsider this policy. Some members of the Subcommittee believe that omitting the uncertainties in the toxicity data from the assessment vitiate much of the benefit of performing the U&V analysis, and that the literature does contain early illustrative efforts to estimate uncertainty and variability for risks of both cancer and non-cancer endpoints (Hattis et al. (1999); Hattis and Barlow (1996); Crouch (1996)). Moreover, omitting any distributional treatment of the transport and fate module makes any conclusions from the U&V analysis suspect. Although the Subcommittee agrees that iterative calculations using the full ISCST-3 and IEM-2M models would be computationally intractable, it does not seem unreasonable to introduce some overall uncertainty distribution to represent the uncertainties in risk introduced by all of the assumptions and parameter choices embedded in those models. The governing notion is that the while distributions based on data are certainly preferred, the use of subjective distributions -- fairly (unbiased) developed, technically rationalized, and clearly presented -- can provide useful and valuable insights that can credibly inform the decision making process.

In this case, the Subcommittee also found that the description of how some of the distributions were derived to be incomplete, even for the parameters that were included in the analysis. Although in many cases the Agency simply took distributions that had already been described for other Agency purposes (e.g., the Exposure Factors Handbook (USEPA, 1997)), in others it seemed to arrive at a distribution with very little evident rationale. For example, the document states, "we assumed that annual lead emissions follow a log-normal distribution, with the emission rate falling within two orders of magnitude of the value given in the compliance report 95% of the time" (later corrected to 99% of the time). Although the document is far from clear on this point, in oral presentations EPA representatives

indicated that this assumption was based on some analysis of emissions observations by a knowledgeable contractor, Dr. Christopher Frey -- which was useful, reassuring information. In the next iteration of the document, this analysis should be presented in detail and, to the degree possible, the analysts should consider the need for adjustments in observed emissions data across plants to account for differences in throughput characteristics, among other relevant factors. To the degree that day-to-day and/or plant-to-plant variations in emissions can be explained on the basis of factors such as throughput, the estimate of uncertainty in annual average emissions may be reduced.

Another major problem is that the current analysis does not follow existing EPA guidance on the documentation and presentation of distributional analysis (USEPA, 1997). Specifically, that guidance emphasizes that the model itself and derivations of distributions used in the analysis must be transparently presented in sufficient detail that a reviewer can reproduce them. Therefore, the case study itself should have included, as an appendix, both the extensive display of results for each stack, as well as the spreadsheet model equations and the mathematical form of the distributional assumptions that were used. The Subcommittee believes that any report of the results of a U&V model must include documentation of the model spreadsheet itself, the dependencies among parameters that are or (in the case of independence assumptions) are not built into the model, and the precise mathematical form of the distributional assumptions. For example, from the current presentation it is not clear if correlations have been built into the emissions of lead and other HAPs from different stacks that might reflect different processing rates on different days, or whether these are considered as independent.

Finally, the Agency's treatment of "upset conditions" is not clear. While there is a description of the assumptions made to account for such occurrences, the explanation/justification of the assumptions is lacking. Since emissions associated with upset conditions can, in some cases, outweigh the impact of emissions during normal operation, it is especially important that this situation be directly addressed and clearly explained.

In summary, the Subcommittee was unconvinced by the rationale for the selection of variables and pathways to address in the U&V assessment and found the methods for quantifying the U&V suspect in at least some respects. The Subcommittee recommends that the Agency redo the analysis starting with a clearly stated management objective, incorporating a better degree of separation of variability from uncertainty, and generating a more comprehensive treatment of the most important sources of uncertainty and variability.

3.8 Charge Question 8: Presentation of Results

Does the Agency's document clearly present and interpret the risk results? Does it provide the appropriate level of information? Do the figures and tables adequately present the data? Do the formats provide for a clear understanding of the material?

This Charge Question addresses the important issues of a) risk characterization, which goes beyond numerical presentations of results to qualifications and discussions of uncertainty and data

limitations (USEPA, 1999, p. 70), and b) risk communication, which conveys those results in easily accessible terms to interested and affected parties. The focus of the discussion here is on the presentation of the results. The majority of Subcommittee views on the various aspects of the results themselves are found in response to the earlier Charge Questions.

3.8.1 Initial Screening Analysis

According to EPA, the screening analysis is designed to obtain preliminary inhalation risk estimates for the 23 facilities and 50 HAPs. In the course of the analysis, many other simplifications and conservative assumptions are made, such as generic assumptions about releases of HAPs from smelter facilities. The default release characteristics used in the SCREEN3 modeling are clearly presented in Table 2.2. The Agency has indicated that all of the assumptions used in the initial screening analysis are not conservative and that best estimates (simplifying defaults) are used. A sensitivity analysis or other qualitative discussion of the effect of these selections on the results should be included in order to give the reader a better appreciation of the robustness and the conservativeness of the initial screening analysis.

In some cases, the report identifies areas in which information was not available, e.g., housekeeping procedures for fugitive emissions. During the Agency presentation at the meeting, four possible approaches to estimating fugitive emissions were presented: back calculating from lead monitoring data, theoretical modeling, extrapolating from another source that has conducted fugitive emission testing, and direct measurement. These approaches should be identified in the report, along with general methods for dealing with missing data, to help the reader understand what would be required to gather this information.

The discussion of the screening (Section 2.2.4) portrays easily readable risk results for each HAP for cancer/non-cancer risk. It presents maximum and minimum risk values for each individual organic and metal HAP. The table should include an explanation of the maximum and minimum values; i.e., they are simply the range of estimates determined for all of the facilities. The text discussion clearly indicates the bottom line (risks above one-in-a-million) and the fact that some of the HAPs are associated with higher values. Procedures for arriving at the risk estimates and identifying where overestimates occurred are clearly presented.

Uncertainty estimates are not presented in the tables, nor are they discussed in this section. This should be explained in the results section. The text should expand on the potential impact of the discussion in footnote 8 concerning the lack of dose-response values for the ten HAPs that have not been considered in the case study due to a lack of available dose-response information.

The form in which numbers are presented in Tables 2.3 and 2.4 (i.e., as exponents) is not easily communicated to the public, and perhaps an alternative means should be considered. The Agency should keep this form for the Tables, but should consider using consistent cancer risk expressions in the narrative of the case study, avoiding the use of different expressions for cancer risk. For example, the use of the expression 8-in-10,000 should be changed to 800-in-a-million. This will allow the lay reader to place the

results into the common context of the less than one-in-a-million expression which appears in the CAAA and throughout the case study.

Section 2.2.4.2 identifies a large set of defaults and assumptions, without providing an explanation or rationale. More discussion of these defaults and assumptions is warranted, including statements about how they affect the final result. If the effects of the assumptions are unknown (as identified in this section), some discussion of why this is the case should be included.

The conclusion section for the initial inhalation screening analysis (parts of Section 2.2.4.3), are troublesome because of their lack of specificity with respect to the chemicals being discussed and the sources. For example, in the statement "Metal HAP risk results exceed these levels", the identity of the metal HAP is unclear. Furthermore, any conclusions for this section are questionable since, as is pointed out in the report, the largest source is fugitive dust emissions which are very uncertain due to uncertainties in emission rates and the failure of the estimates to agree with NAAQS measurements made in the vicinity of these facilities.

Section 2.4 (Overall Summary of the Initial Screening Analysis) is very brief and would benefit from a description of the organization of the initial screening analysis and how it leads to the multipathway screening analysis. The selection of facilities for the refined analysis needs to be placed into some type of risk management framework. These facilities were obviously selected since they represented the highest risk (e.g. cancer risk > 9000-in-a-million and HQ > 70). However, a defined process is needed for selecting which facilities will be included in the refined analysis. For example, if the 100-in-a-million cancer risk value were used only two of the 23 facilities would pass the screening criteria. The use of this cancer risk range would be consistent with the benzene decision and the Commission of Risk Assessment and Risk Management (CRARM) recommendations by having the total cancer risk from the facility being in the range of less than one to one hundred in a million for the screening assessment. In addition, if a hazard quotient of 10 is used as an action level for the screening assessment, as recommended by CRARM, then a decision to eliminate facilities 6, 9, 12, 20, 25 and 29 for further analysis of noncancer health effects can be made. A section entitled 2.X Initial Screening Analysis: Selection of Facilities for Refined Multipathway Analysis should be added in the Chapter 2 results section in order to present this rationale more clearly.

Section 2 needs to provide a better description of the 23 facilities that have undergone the initial screening analysis. This information would include a general physical description of the facility size, location (urban, suburban, rural or industrial) and terrain, the annual amount of material throughput, the degree of facility enclosures (total or partial enclosure of fugitive sources), and, perhaps most importantly, the current HAP emission inventories for these facilities. The inventory information could be obtained from the 1996 or more current National Air Toxics Assessment (NATA) project that the Agency is working on or HAP emission statements filed with State environmental agencies. Some of this information is readily available from the "Locating and Estimating Air Emissions from Sources of Lead and Lead Compounds" (USEPA, 1998). This information would be very useful for the risk manager when evaluating the initial screen inputs and results and would serve as a check on those facilities which

would be selected for further refined analysis. The brief discussion contained in the case study is inadequate.

3.8.2 Multipathway Analysis

Section 3.3 (Results and Key Issues of the Multipathway Analysis), is much too long for a results and issues section. The heart of this material is on pp. 94-96, so a reorganization of this portion of the report would be in order.

The Subcommittee found a need for a discussion about a few key issues, in addition to those already listed in Section 3.3.2. Specifically, these are the lack of consideration of background concentrations in the risk analysis and the effects of the adjustment of the nickel inhalation unit risk estimate which reduces the conservatism of the cancer risk estimates.

The Report to Congress (USEPA, 1999) discusses the need to include background risk and the difficulty associated with this specific issue. The case study does not address background risk issues around any of the 23 facilities in the human health and ecological risk assessment. This is serious omission from the case-study, and the Agency should address this issue at a minimum from a qualitative/quantitative point of view, well beyond the comparisons made in Chapter 6. The absence of an assessment of background risk seriously impacts statements about the conservative nature of the refined screening assessment.

The use of only 25% of the inhalation unit risk estimate for nickel subsulfide needs to be explained in greater detail, since it will have a large impact on the total cancer risk estimates in the case study.

Some Subcommittee members thought the tables and figures were clear and comprehensible; others felt they could be clarified. For example, the plots and bar charts presented as a part of the Agency's briefing on March 1 were very helpful and could be added to the document.

HAPs that were not included in non-cancer endpoints should be clearly identified, together with an explanation of why they were omitted.

3.8.3 Uncertainty and Variability Analysis

As indicated in Section 3.7 above, the Subcommittee had serious concerns about the handling of the U&V assessment. The comments below pertain primarily to the format and presentation, rather than the adequacy or completeness, of the underlying analysis. In short, the Subcommittee finds that the presentations (e.g., graphical and tabular displays) are conceptually sound and effective. However, many of the procedures used in the assessment are not as well-laid out as they need to be.

The tables and figures used throughout Section 4 provide a concise and well-thought out approach for the presentation of variability for each scenario evaluated. They allow the reader to

evaluate the broad spectrum of risk and the impacts of the various exposure parameters used in the refined multipathway risk assessment. These tables and figures significantly enhance the comprehensibility of the variability assessment results. For example, the use of a 13.3 m³ inhalation rate in the multipathway analysis (Table 4.3), when cross-referenced with Table 4.4, indicates that the inhalation value used is between the 25th and 50th percentile and is really not that much of an extreme conservative assumption. When the inhalation rate is coupled with the 70-year duration of exposure and the fraction of the day at home, the final risk estimate falls into the 95 percentile for inhalation risk. This is consistent with the recommendations contained in the NRC (NRC, 1994) and the CRARM (CRARM, 1997) reports and the language in the 1990 CAAA to estimate risk for "...the individual most exposed to emissions from a source....." This presentation format allowed the reader to understand in a rather simplistic manner the amount of conservatism that was used in the refined multipathway risk analysis for each exposure parameter. So, if the risk manager wanted to observe the impact of setting each parameter (maximum inhalation rate, maximum exposure duration, maximum ingestion rate, maximum time spent outdoors, etc.) and the impact it has on the risk estimates, it can be done rather quickly.

The inclusion of the point estimates in Tables 4.5 and 4.6 is an excellent way to concisely present information to the risk manager. The use of a large circle to identify the final cancer risk estimates on the probability figures (Figures 4.2a - 4.7b) that would be used by the Agency to characterize the risk for the final risk management decision would significantly enhance the presentation of the results and make them easier to interpret. The tables and figures provide the risk manager with the ability to view the broad spectrum of risk predictions, which includes risks to the average exposed individual (AEI), the maximum individual risk (MIR) and the maximum exposed individual (MEI).

The use of distributional analysis is unclear. The technique was used for some steps in the risk assessment, but not all. For example, the distributional analysis was clearly used for exposure estimates, because data from the Agency's Exposure Factors Handbook (USEPA, 1997) were used. However, it is not clear whether the same data source was used for the emission estimates.

As noted in 4.8.7 above, the selection of variables and methods of quantifying variability and the distinction between uncertainty and variability is not clear. Such a discussion should be firmly grounded in the Agency's risk management goals and a clear understanding of how these results will be used to help achieve those goals.

3.8.4 Risk Characterization

In Section 5.7 the focus is whether the HQ values are above or below 1. The Agency should consider the robustness of such "bright line" decisions in light of the uncertainties involved. Section 5.8 was clear and acceptable to the group.

3.8.5 Summary and Discussion

Keeping in mind the limitations and problems identified with the methodology above, this section presents a good summary of results. Tables 6.1 and 6.2 provide a good overview summary of the final results for the refined multipathway risk assessments. The presentation of results could be greatly enhanced with the addition of more site-specific information to the case study. The collection of additional data should not be an overwhelming task. The Agency should consider the importance of such a refinement before the case study becomes a public document.

The discussion in Section 6.2.1.1 should be expanded. The pre-NESHAP monitoring data from New York indicates that the NAAQS for lead can be exceeded and that the stringent control of fugitives can result in a dramatic lowering of ambient concentrations of lead and probably other metal HAPs in the vicinity of secondary lead smelters.

Section 6.2.1.5 needs to be expanded since it provides information on an excellent biomarker for potential exposure; i.e., blood lead levels. The inclusion of this type of information would greatly enhance the case study. The Center for Disease Control and Prevention (CDC) and State Health Departments should be consulted to find out if there is any other information on blood lead levels in children who reside in communities that are in close proximity to secondary lead smelters.

Table 6.7 should be modified by including the distance to the monitors, as well as a brief discussion of siting issues (e.g., predominant downwind or upwind monitoring locations) before any comparisons are made. The same point can be made for the comparisons of the surface water concentrations. However, the Agency does appropriately acknowledge that the comparisons in Table 6.8 are not meaningful.

In summary, the information in the report is generally well-presented in some instances and could be significantly improved in others, as noted above. However, it is important to gather and evaluate more site-specific information, using the risk assessment tools presented in the case study, before any final risk management decisions are made for this source category.

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APPENDIX A

WRITTEN COMMENTS OF SUBCOMMITTEE MEMBERS

Each member of the SAB's Residual Risk Subcommittee prepared written comments, centered on the Charge Questions. These materials were available at the meeting March 1-2, 2000. As a result of the public meeting, some of the Members altered their original drafts and asked that the revised versions be included in an Appendix to the Subcommittee's consensus Advisory. Other Members chose not to submit their comments for inclusion in the document.

Therefore, this Appendix contains the final written comments from those Subcommittee Members who chose to submit them for this purpose. These materials are included in this SAB document so that the Agency and the public can a) benefit from the specific comments and b) appreciate the range of views represented on the Subcommittee.

While all of these statements are commended to the Agency for careful consideration, unless a comment is addressed explicitly in the body of this SAB Advisory, it should be viewed as a statement from an informed individual, not as the collective view of the Subcommittee.

The comments are including in the following order:

1. Dr. Biddinger
2. Dr. Brown
3. Dr. Cory-Slechta
4. Mr. Gentile
5. Dr. Hattis
6. Dr. McFarland
7. Dr. Middleton
8. Dr. Taylor
9. Dr. Zimmerman

1. Dr. Gregory Biddinger

Exxon-Mobil Company
Fairfax, VA

General Comments

1. A Risk Assessment strategy should be designed in alignment with a risk management process.

Although this may seem like an obvious and generic point, I feel it is very relevant to make at the onset of these comments. It became clear during the review of this case study that the linkage between the ecological risk assessment (ERA) and risk management process is weak and this weakness is likely due to a lack of clear definition on how the risk management process will proceed. I believe this lack of clarity as to how the ERA will be used to support any risk management decision makes it difficult to either design an ERA process that goes beyond a screening step or to define what are the *Next Steps* for ERA in this specific case study.

Recommendation: The footnote on Page 34 of Volume 1 indicates that OAQPS is working on developing a risk management decision framework for the residual risk program. That framework should be presented to the SAB review group to evaluate alignment between the risk assessments and the risk management process. If the strategy is not final, revisions to the case study should be deferred until the framework is available.

2. With regards to Ecological Risk assessment, the Agency needs to define what is meant by the management goal of ensuring that HAP emissions do not result in "*an adverse environmental effect*".

In order to evaluate the Questions associated with Charge 5, which is fundamentally, were the appropriate models used correctly, it is essential to understand what environmental attributes are being protected and at what spatial scale. In section 5.2.1 the agency cites Section 112(a)(7) of the Clean Air Act Amendments (CAAA) to say it is "*any significant and widespread adverse effect, which may reasonable be anticipated to ... or significant degradation of environmental quality over broad areas*". The key and operative terms in these statements, which require clarification, include 1) *significant*, 2) *widespread* 3) *adverse* 4) *environmental quality* and 5) *broad areas*. Without a clear definition of what the agency believes is the intent of these words in the CAAA, it is not possible to assess the correctness of the agencies actions. Based on an assessment strategy that uses hazard Quotients (HQ's) and conservative ecotoxicological screening benchmarks, I would have to assume the Agency's goal is to protect individuals in all populations and in all places.

Recommendation: The Agency needs to provide the appropriate clarifying discussion in Section 5 of Volume 1 or through the development of a technical policy statement which can be cited in this section.

This exercise should not be viewed as a philosophical exercise. In developing this clarifying analysis the Agency should identify some practical rules or decision logic which can reasonably be used to eliminate source categories from ecological risk. Some (but not the only) possible rules for not doing an ERA include:

- a) Source categories with a few small facilities in different regions
- b) Source categories with a few large facilities but no persistent or bioaccumulative HAP's.
- c) Facilities in source categories where the primary releases (e.g. downwash, etc) are contained to the site

3. The Ecological Risk Assessment provided is a screening risk assessment and clearly is not intended to be used for risk management decisions other than "No Action " or Further Analysis". But the recommendation(s) of the assessors for any follow-up options are missing.

The Agency is to be commended for so clearly stating in a number of places in the case study that the environmental hazard assessment undertaking is not adequate for making a final risk management decision that would require controls or other actions to mitigate ecological risks. This reviewer is left with the question "What will the Risk manager be able to do with this analysis?" If the assessors felt that more sophisticated or detailed analysis was necessary than they should have at least said so, even if they believed performing that analysis was not in the scope at this point in the analysis. The case study is incomplete with the ERA as provided because the next steps are not clear. It would not at all be a breach of the risk assessor and risk manager roles for the assessors to provide some further definition of what they could do to explore the significance of some of the High HQ's for various aspects of exposure to key metals (e.g. Antimony) from the Fugitive emissions at facilities 3,4 and 13.

Recommendations: The case study needs to include a section on Next step options with recommendations for the risk manager to consider.

4. The sources of uncertainty in the ERA are understated.

In section 5.7.3 the report reviews the sources of uncertainty associated with the screening level risk assessment. This review on uncertainty doesn't completely account for the uncertainty associated with the exposure estimates. Although it does identify inclusion of assumption of bioavailability and the exclusion of some pathway it does not account or refer back to any analysis of the uncertainty associated with the dispersion and fate. The uncertainty reviewed in section 4 associated with emission rates, dispersion, environmental fate and pathway analysis could easily overwhelm the uncertainty described in section 5.7.3.

Recommendation: Section 5.7.3 should recognize the uncertainty passed through from the dispersion, fate and pathway models.

Charge Question 5: Ecological Risk Assessment

1. Given Currently Available Methods, Are the models used for the ecological assessment appropriate?

In addressing this question it is important to consider my general comments listed above. The method of using Hazard Quotients (HQ's) and their summation, Hazard Indices (HI's) to screen ecological hazards is well established for use in ranking and prioritizing hazards associated with chemicals. The method has had significant use in new product design and approval, Risk-Based Corrective Actions at contaminated sites and prioritization of resources in regulatory programs. As is well stated in the document such a conservative technique is only used to remove chemicals from further risk management consideration (i.e. the risk is acceptable) or to indicate that there is a need for further analysis. What this case study does not do is take or even identify the next steps to refine the analysis of those chemicals that fall above an HQ or HI of 1.0. One would have expected that some refinement of the exposure and effects characterization for metals with the highest HQ's would have been explored. If only to see if less conservative or site-specific modifications to the exposure characterization or full use of dose-response data for relevant surrogate species might have brought the HI exceedances into acceptable ranges. As it stands now we are left with some significantly high HQ's implying to an unsophisticated audience that a serious problem exists but without any framing of an approach to validate or refute such an implication. As a risk assessor, I recognize that this is only the first step and that these HQ's can drop orders of magnitude when they are refined, but any lay audience reading this review and seeing HQ's of 400 with no action recommended is likely to be alarmed.

Recommendation: The Agency needs to have a process that goes beyond the initial step of ecological risk assessment that is taken in this draft case study and either a) refines the hazard screening process by improving the estimates of exposure and selecting more appropriate Toxicity Reference Values (TRVs) or b) moves into a risk assessment process that is based on more complete and relevant profiles of exposure and effects

2. Are the (available methods) applied correctly?

For the most part yes but one particular aspects of the application of the HQ approach goes beyond current good practice, that is the summing of HQ across all chemicals. Summation of hazards for chemicals which are operating with the same mode of action on the same target organ or system may be acceptable. But summarizing across an array of benchmarks which are based on a variety of endpoints, some of which are NOAELs and some are LOAEL's is not conservative it is misleading. I can't see any way that metals and organics could be considered additive to either the individual or at the population.

The only classes of chemicals in this case study which might allow such a summing technique would be the summation of HQ's for Dioxin/furan congeners and the summation of PAH's. But for

PAH's it would still be necessary to break the summations into high and low molecular weight categories. If this were being done for assessment of acute hazards I would be more accepting but with chronic toxicity criteria the endpoints could vary across growth, development, reproduction and survivorship

3. Are the ecological benchmarks appropriate?

It is not really possible to completely answer this question from the information given. The benchmarks that were selected represent the current state of the practice for screening benchmarks. Many of these benchmarks were developed for use at contaminated sites to focus management action on only the serious chemicals of concern. For some of these lists especially the water and sediment benchmark series there may be different benchmarks for freshwater and marine systems. Which were used? The lower of the two? Which ever was available? For screening purposes this is not likely going to be a problem or certainly any error of application could be caught in the next round of refinements.

What is clear is that these numbers should not be used for any sophisticated risk assessment. The data behind these criteria may well support a risk assessment but the final "criteria value" can only be used for what has been done here which is to eliminate chemicals of concern. As HQ's are refined not only should the exposure estimate be refined to reflect site specific conditions, but also the characterization of effects should advance from a general benchmark to an estimate of a toxic threshold based on dose-response data for a representative or surrogate species.

Recommendation: If the Agency is going to do 174 source categories, it is worth the effort to develop a matrix of Toxicity Reference Values (TRV's) for various receptors and endpoints for each of the HAPs that could be used as screening values. If the complete dose-response relationships are available, then the same data could be used for a) screening (NOAELs), and b) first risk approximations (EC10 or EC20) and c) complete risk distributions (Slope of the dose-response curve). Although this is not a small task, such a front-loaded effort could stream-line much of the subsequent source category analyses. If the Agency were to embark on such a task, I recommend leveraging this effort with interested industry coalitions.

Section Specific Comments.

Section 5.1

The language in paragraph 1 of page 130 is confusing. Suggest discussing hazard potential rather than potential risks.

Are all of the cited EPA documents available to the public? Is EPA 1999d available? If not should it be cited?

Section 5.2.1

As previously stated in general recommendation #2, this section should be expanded to give the

agencies interpretation of the management goal from the CAAA. This would require defining such terms as:

- 1) *Significant*,
- 2) *Widespread*
- 3) *Adverse*
- 4) *Environmental Quality* and
- 5) *Broad Areas*.

Section 5.3

This section is weak because of the lack of interpretation of the management goal in section 5.2.1. It should be more clearly stated that the assessment endpoint is No or limited adverse effects to individual members of sensitive populations. There is no real consideration of impacts to structure or function. It is only a simple extrapolation to suggest that if no individual is adversely affected than neither will the service of its population or the structure and function of communities and ecosystem it lives in be affected. This assessment is being done in a fashion to protect individuals; there is nothing wrong with this if that is the agency's interpretation of adverse environmental effects. I would suggest it is a bit stringent but for a screening assessment not atypical. But ultimately the assessment of residual risk should be at a level of population or higher.

Table 5.1

Citations for Suter et.al. and Will, M.E. et.al. are in conflict with the reference list.

Section 5.7.2

The discussion incorrectly states that all facilities had HQ's >1 for metals. Facility 2 was not reported in section 5.7.1.1 or in appendix E to have HQ's > 1 with or without fugitives emissions. This inconsistency needs to be corrected.

Section 5.8

As stated previously, this section should address recommendations to the manager about the need for follow-up actions.

Sec. 2.3 The use of lists to identify Persistent and Bioaccumulative compounds is inappropriate.

Recommendation: The Agency needs to specifically design or adapt a process to support a Residual Risk process.

2. Dr. Stephen L. Brown

Risks of Radiation Chemical Compounds (R2C2)
Oakland, CA

These comments are submitted to alert the Subcommittee members to some issues I will want to discuss in our meeting on points OTHER than on my main assignment--the uncertainty and variability analysis. Along with my co-discussant, Dale Hattis, I will be submitting a formal, although preliminary, writeup on that subject.

Overall Effort

Overall, I have mixed feelings about the case study. On the one hand, its overall structure and components are similar to those in many of the risk assessments conducted in the past few years by or for USEPA and other environmental agencies such as the California EPA. It features some standard and generally well accepted models such as ISCST-3 as well as a detailed multipathway model, IEM-2M. It uses values for many of the needed parameters that can be found in standard sources such as the IRIS data base of toxicity information and the Exposure Factors Handbook. It features a screening level analysis prior to the main analysis that is designed to help the latter focus on the most important HAPs and facilities. It includes a variability/uncertainty analysis and a risk characterization section that are both recommended in recent EPA guidance on the conduct and presentation of risk assessments. Many of its assumptions are similar to those in other EPA risk assessments and therefore consistent with them.

On the other hand, it shares most of the deficiencies of those same comparison risk assessments and seems to introduce a few of its own. The conservative assumptions inherent in most Agency risk assessments are repeated here, and are not adequately balanced by the supposedly less biased uncertainty analysis. Many of the case-specific assumptions are inadequately described, let alone well justified, in the text supplied to the Subcommittee. Some of the predictions of the assessment are truly astounding (e.g., the blood lead levels calculated when fugitive dust emissions are included in the assessment), yet there seems to have been little attempt to identify and correct the problems that might have led to such conclusions. Even though the case study is not supposed to be a final assessment for the secondary lead smelter category, it should have included more thorough quality control to demonstrate how such an activity would be included in a final assessment.

In reviewing the assessment, I was struck by how similar the structure was to assessments conducted under AB2588, the California statute titled the Air Toxics Hot Spots Act. That act is specifically designed to evaluate the risks from emissions to air by stationary sources in California. In that case, the risk assessments are conducted by the facility itself using guidance provided by the State, and the assessments are reviewed by the local air district for conformity with that guidance and accuracy of inputs and outputs. The facility may submit an alternative assessment with more site-specific information and less conservative assumptions, including a distributional analysis in some cases, but the local authority is not obligated to review those assessments. The standard assessment is usually conducted with the aid of a computer model such as ACE2588 or HRA96 that was designed to follow the guidance precisely.

Users are allowed to use some site-specific information, such as stack characteristics and the location of actual water bodies used as drinking water sources. The models include not only direct inhalation exposures via concentrations calculated by ISCST-3 but also via multimedia pathways similar to those in IEM-2M (although IEM-2M features a more detailed water partitioning model because it was designed specifically for mercury). Another similar multimedia risk assessment model designed for emissions to air is TRUE, developed by the Electric Power Research Institute for assessing fossil fuel power plants. TRUE includes a mercury model similar in design to IEM-2M. TRUE is generally less conservative than the AB2588 models, but is still described as conservative by its authors.

I will now provide comments by Section of the Case Study, more or less in page order.

Introduction

I was disappointed not to see a clearly articulated description of the decision that this type of risk assessment is to serve. Although the obvious application is to the residual risk requirements of the CAAA, it is not clear that EPA knows how it will interpret those requirements in evaluating the outputs of the risk assessments. For example, how will risks to highly exposed individuals be weighted in comparison to the population risks for the whole exposed population? How will a highly exposed individual be defined? Some fixed percentile of a distribution? A qualitative representation of such a percentile, such as the RME? A hypothetical maximally exposed individual or MEI? What are the quantitative criteria that will trigger further risk reduction actions? Will those actions be applied to only those facilities whose calculated risks are above the criteria, or will the whole category be affected? What level of assurance will be demanded that the criterion is met in order to state that the residual risk requirement is met? Without knowing rather well what questions will be asked, the Agency may not provide useful answers.

In the Introduction, the concepts of the unit risk estimate (URE) and the reference concentration (RfC) are introduced for inhalation risks. Although it is clear that both of these numbers are applicable to continuous lifetime exposure to a constant concentration in air, it is not clear that calculated concentrations may need to be adjusted for exposure duration before being used to determine risk using the URE or RfC. This lack of clarity is not entirely dispelled in the later section on Dose Response. One stakeholder commenter believes that the duration adjustment was appropriately made for ingestion exposures but not for inhalation exposures. More generally, the document could use considerable improvement in the exposition of what was actually done in the risk assessment.

Initial Screening Level Residual Risk Analysis

The idea of screening level analyses to focus further risk analysis on the facilities and HAPs most likely to violate the residual risk limits is sensible. In fact, multi-level screens may be appropriate, not just one initial screen. However, the screening analysis as designed could be improved. First, screening on only inhalation exposures may give a false sense of security about some facilities or chemicals if other pathways are in fact substantial contributors to risk. For some HAPs emitted to air, pathways other than

inhalation may be orders of magnitude more important to risk, particularly if the fate parameters are such that concentrations in soil will build up over a long time before plateauing as removal processes become effective. It may be necessary to build in some HAP-specific screening-level multipliers for multimedia effects into the inhalation risk calculations. On the other hand, it appears that the screen for secondary lead smelters may have been too conservative in that all facilities and many of the individual HAPs exceeded the screening criteria when fugitive dust emissions are included. If a screen does not screen out anything, it is not very effective.

I am also not particularly impressed with the rationale for selecting the HAPs to take forward into the multipathway analysis. The occurrence on a list of “PBT” (persistent, bioaccumulative, toxic) substances is, in my view, a weak substitute for a more quantitative classification. The actual risk posed by a substance depends on all three attributes, and others, in a complex way dependent on the actual conditions of fate, transport, and exposure. It is possible to examine complex multimedia models and create simplified models that reproduce their results in a crude fashion, preserving how the effects of half-life, BAF/BCF, and toxicity interact. I again recommend an effort to create HAP-specific multipliers for screening purposes to help identify the HAPs that should enter the multimedia assessment.

Multipathway Residual Risk Analysis

As stated in my overall impressions, in many ways the multipathway analysis is equivalent to or better than other regulatory-responsive risk assessment models, featuring a widely accepted air dispersion model along with a highly detailed multimedia transport and fate model. My reservations have more to do with implementation than with overall concept.

Perhaps my foremost reservation is about the emissions estimates. As I understand it, no facility has more than one set of tests (e.g., a one- to three-day measurement protocol) subsequent to achieving MACT. Furthermore, there is no evident attempt to correlate the emissions testing results with any explanatory input such as lead throughput during that period, type of operation, or type of emission control equipment. (The latter two factors do seem to be used as a guide to extrapolations from one set of measured results to a different facility, however.) The document does not discuss any inherent temporal variability, such as variation in throughput, that might make a snapshot of emissions inappropriate for calculating an annual average. Perhaps these points are all discussed in the underlying data sources, but they do not appear in the current document. As stated in my preliminary comments on uncertainty, the variability seen in the lead emissions estimates may be more representative of day-to-day variations than to annual average variability. There is no evident test of correlations between lead emission rates and HAP-to-lead emission ratios, that might occur, for example, if lead emissions followed lead throughput but some other source (e.g., refractory brick) were the source of a different metal. The Agency clearly has little confidence in the fugitive dust emissions estimates--all derived from pre-MACT data, as I understand it--but still presents risk results as some sort of upper bound on risk. I contend that such an upper bound is probably not reasonable, given the failure of monitoring data to confirm the concentrations

of lead or other HAPs offsite.¹ Unless the Agency is prepared to undertake empirical studies of fugitive dust emissions from secondary lead smelters, it might be better advised not to do any quantitative analysis, simply stating that risks might be higher had fugitive dust been included. I suspect the same may be true for other source categories.

Another major concern is the seeming inconsistency between the very detailed multimedia modeling, which includes such abstruse topics as sediment-water partitioning with BCF and BAF adjustments to fish concentrations side-by-side with an inability to locate stacks in relation to facility boundaries or the assumption of home garden consumption at a nearby residence. It would seem to entail little work to telephone the facility for information or make a site visit in comparison to developing all the inputs for the IEM-2M model, yet such inexpensive efforts could improve confidence in the risk estimates greatly.

I generally agree with the hierarchy of choice for selecting toxicity values to be used in the model. Some commenters have questioned the use of CalEPA values as one of the possibilities, but as a member of the Risk Assessment Advisory Committee, I have examined that Agency's methods and believe them, on balance, to be as good or superior to USEPA's. I therefore cannot fault OAR for using the IRIS values when available and ATSDR, CalEPA, and HEAST values when IRIS is silent. Nevertheless, some of the toxicity numbers appear to affect the results markedly and should be viewed with caution. I am especially concerned about the values for antimony and for manganese. The antimony RfC is based on irritation, for which application of standard uncertainty factors may not be appropriate. The antimony RfD is based on toxicity endpoints that include blood glucose and cholesterol, not clinical illness. The manganese RfC is based on "impairment of neurobehavioral function," an endpoint that is probably to some extent subjective and less severe than endpoints used to define other toxicity values. I recommend that EPA's Risk Assessment Forum explore ways to make the IRIS data base more consistent (perhaps by explicitly considering severity of endpoint) and to verify any values that seem to drive risk assessments.

I note the importance of particle size distributions in defining deposition velocities and other parameters for dry and wet deposition, which can greatly influence the overall deposition rates and risks for the same estimated air concentration. I understand that the distribution for stack and controlled fugitive emissions was assumed to be similar to those observed in emissions from baghouses, and generally ranges downward from 10 microns. However, I did not find this assumption to be stated in the

¹I am not as sanguine about the virtues of "model validation" for the multimedia model as some of the other reviewers of the Case Study. The model is designed to estimate media concentrations averaged over some vaguely specified future time period after continuous operations at MACT conditions with no prior operation. Measurements of media concentrations that can be conducted in the present, however, will not capture the effect of future emissions, so might be underestimates, and will capture the effect of higher pre-MACT emissions, so might be overestimates, of the desired validation quantity. Moreover, the proper temporal and spatial averaging techniques to make model predictions and measured concentrations strictly comparable are not easy to specify. Perhaps the best we can hope for is the identification of gross inconsistencies.

document, nor did I find information on the assumed distribution for fugitive dust emissions or how the particle size distributions were translated to deposition velocities. Generally speaking, reductions in particle size tend to spread deposition over a greater area but reduce peak deposition at the RME location. However, if the particle size distribution is dominated by particles so large that they deposit on-site, reducing the particle size may actually increase the RME deposition.

Although the actual model inputs include a provision for chemical degradation after deposition, this mechanism of HAP removal from soil and water is not mentioned in the text. It should be. I also understand that the locations of actual water bodies were used for the drinking water and fish concentration calculations, not some hypothetical water body co-located with the RME, but again this procedure was not described in the text. I also am not sure whether these water bodies are actual, or only potential, sources of drinking water for the local community. The text is also unclear about the fraction of all produce consumed that is assumed to be contaminated by the smelter. In some cases, it appears that a 100% assumption was used, whereas elsewhere, it appears that some standard EPA assumptions less than 100% were used. I am particularly concerned that any significant part of “grain” consumption is assumed to be locally produced, at least for home gardeners.

Non-cancer risks are represented by the hazard quotient/ hazard index structure that, with all its limitations, is the standard Agency method for the so-called “threshold” toxicants.² The averaging period for exposures to be used in non-cancer risk assessments is generally taken to be one year in Agency assessments, and that practice seems to have been followed here. On the other hand, the averaging period for exposure to carcinogens is taken to be a lifetime, at least for all carcinogens treated as having linear dose-response relationships with no threshold. That assumption implies that cancer risk varies linearly with duration of exposure if daily exposure is held constant. Although it is reasonably clear that the Agency has taken duration into account in exposure averaging for the ingestion routes of exposure, one of the stakeholder commenters has alleged that the Agency did not do so for the inhalation route, thereby overestimating risk by the ratio of a lifetime to the assumed duration of exposure. If true, this error should be corrected. If not, explanatory text should be added.

I would have expected that lead would be the most important risk from a secondary lead smelter. cursory inspection of Tables 3.13-3.16 might suggest to the unwary that it is not, because no hazard quotients are presented for the ingestion routes, and the hazard quotients for inhalation are not as high as for some other HAPs. However, this impression is due to two facts that are not as emphasized as they might be. First, the inhalation hazard quotient is calculated from the primary NAAQS for lead, which is not purely a health-based number. Second, the ingestion hazard quotient is not calculated at all, because the Agency refuses to promulgate an RfD because of the asserted non-threshold nature of lead.

²The Agency views lead as a non-cancer risk that nevertheless has no identifiable threshold, and treats it with the IEUBK model. In reality, toxicity data rarely if ever identify a true threshold and the RfD or RfC is set as the practical equivalent of no risk. Probably more at issue is the assumption that risk of cancer is more likely to vary linearly with exposure at low exposure than is the risk of non-cancer effects.

Therefore, the significant analysis for lead is accomplished through the IEUBK modeling procedure described in Section 3.3.1.4. From Table 3.23, it can be seen that predicted blood lead levels can be quite high, especially for the fugitive dust scenario. Although some discussion of the lack of conformance of these predictions with observed blood lead values is presented, I think that the magnitude of these values casts grave doubts about the validity of the modeling. See, however, Footnote 1 on the difficulties of making comparisons of model predictions with measurements.

Initial Ecological Screening Analysis

Although my expertise is not on the ecological side, this section struck me as more straightforward, polished and easier to understand than most of the health risk assessment sections. I note that it is screening-level in terms of the evaluation of the significance of media concentrations, but is more-than-screening-level in terms of the calculation of media concentrations, as it uses the same ISCST-3/IEM-2M outputs as does the multimedia health assessment. The text suggests that some organics and acid gases might be included in a more detailed assessment, but was not clear what reasons would induce the Agency to include them.

The text states that single point estimates are used to evaluate media concentrations, but does not state at what geographic location. I infer that they are probably the RME locations used for the health assessment, but the location should be made explicit. Averages over some reasonable range for the organisms assessed might be more reasonable.

Summary and Discussion of Results

In general, the summary is a reasonable representation of the procedures and findings from the preceding sections. It also attempts to discuss a number of issues that might be troubling to a reader, including the comparison of modeled concentrations with measured ones. However, my overall impression is that the risk characterization is more optimistic about the quality of the analysis than is justified. For example, in Section 6.4, the Agency states: "For any particular pollutant, pathway and exposure scenario the resulting distributions can be used to identify the confidence or probability that risks will be below or above specific risk levels (e.g., acceptable risk)." Given the deficiencies in the uncertainty analysis, let alone those in the deterministic assessment, I think that is a gross overstatement. Nor do I think that the uncertainty analysis in any way validated the deterministic assessment, although that is also suggested here.

I also found the section on children's health gratuitous, unconnected to the main analysis, and full of overstatement. For example, the description of newborns having a "weaker immune system" omits the temporary carryover immunity from the mother. Although children eat more food per unit body weight than adults for some foods, they eat less for others (e.g., fish). And those differences are already captured in the exposure analysis by age. The fact that cancer risks, even if due to early-life exposures, are expressed later in life is not mentioned, and the reader is left with the impression of a potential epidemic of children's cancer due to lead smelters.

Finally, I want to share one procedure that I always followed when preparing AB2588 assessments. Because I was usually contracted to a facility owner, I wanted to be sure that the results were not overstated through error, even if overstated through mandated assumptions. I therefore always traced back the dominant risk drivers by pollutant, exposure pathway, and source. I often found simple errors to be responsible, such as entering a number that was expressed in different units than needed, or even copying errors. Sometimes the problem was more subtle, such as including a route of exposure that was actually not possible for the specific facility. I am not convinced from reading the Case Study that the Agency took similar efforts to assure quality, and I recommend it do so. My experience can be extended for those who are worried about risks being understated by looking at pollutants that were expected to show higher risks but did not.

3. Dr. Deborah Cory-Slechta

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1. There are two major but related aspects of the residual risk analysis which are disconcerting. The first is the extensive degree of uncertainty in the models that have been developed and the total or cumulative uncertainty of the overall risk analysis. To the credit of its authors, the models are well thought out progressions that go from an initial identification of what may be the major contaminants from the smelters to a multiple pathway analysis that includes multiple sources of exposures as well as multiple types of receptors. Models for each component of these pathways feed into the overall derivation of the resulting HI values. The logic and inclusiveness of this progression is a major strength of the approach. In addition, the multiple pathway analysis approach includes consideration of different age groups, at least early age groups. However, the actual derivation of the HQ and HI values is almost totally dependent upon substituted values rather than upon actual data and these are propagated through the process. Thus, there is really no validation of the model that has been attempted to date. Certainly no systematic attempt to validate the model was undertaken; but even the assessment against some known entities is not considered. The outcome is really presented in the abstract. While there is repeated discussion of the uncertainties of the analyses, there is no discussion following either Chapters 3 or 4 of Volume I as to the realities and or the limitations of the findings. This represents a major weakness of the approach, recognizing what may be difficulties in obtaining data for the most relevant parameters of the models.

2. Also with respect to issues of validating and understanding the model, there is little indication of how the actual default assumptions used alter the outcomes and any tests to look at how modifying these assumptions changes the outcomes, or drives the outcomes. Its not clear how the validity of the model can be established without understanding how its components work and influence outcomes.

3. The uncertainty analysis does little to provide additional reassurance with respect to the validity of the model. The description of the outcome of this analysis is presented but with little attention to its conclusions and to how these conclusions relate to the validity of the residual risk model, particularly the multipathway analysis. For example, the plots presented with respect to outcome are somewhat difficult to comprehend and do not provide a straightforward assessment of uncertainty. The analyses presented in Chapter 5 of Volume I are plotted in a manner that is not intuitively obvious and must be extracted. It is indicated, almost as an aside, that the range predicted for each cancer or non-cancer effect spans at least two orders of magnitude. How acceptable is this range? What would typically be an acceptable range of values from such an analysis?

4. Some of the predicted values from the residual risk assessment suggest problems with the default assumptions. For example, the residual risk assessment predicts blood lead values from Facilities 3, 4 and 13 for infant blood lead levels of over 200 ug/dL. These are extraordinarily high, likely much higher than even encountered in an occupational context these days. Surely, if such blood lead values were being generated, they would result in obvious toxic effects and even lethality in infants and would be evident.

5. Similarly, the residual risk assessment derives exposure values for dioxins and furans were found to be considerably lower than those reported in breast milk in all of the facilities. The residual risk assessment concludes that this means that emissions of dioxins/furans from secondary lead smelters are a minor contributor to overall dioxin/furan emissions nationwide. Not considered here is the alternative explanation that dioxins/furans may be inadequately modeled. The comments summarized in #s 3 and 4 above suggest that by the simple potential mechanisms of validating the model, it does not work well.

6. Two major assumptions upon which the residual risk assessment is based are not adequately justified nor explained. The assumption that cancer as an endpoint has no threshold, whereas non-cancer endpoints do exhibit thresholds has no obvious biological basis. It also is not well supported by more recent reanalyses of data suggesting that Pb exposures below 10 ug/dL (a value used as a type of risk threshold) may actually produce larger effects than those above 10 ug/dl. It is also notably inconsistent with the rest of the document, since this is certainly not the most conservative approach. If this assumption is to remain in the residual risk assessment, then some type of rationale for it should be provided.

7. Another assumption that is problematic is that the effects of HAPs are considered to be additive. This may need to be a default assumption given the relative absence of a data base from which to conclude otherwise. Assumptions of synergistic or potentiated effects may be overly conservative and thus not appropriate in this case. Again, however, some rationale for the reliance on this assumption should be provided.

8. The focus on dioxin as a cancer risk really fails to embrace the fact that these compounds have marked effects on the immune system, the reproductive system, and perhaps the nervous system as well. This component of dioxin/furan effects should be included in the non-cancer effects.

9. Some of the distinctions between the subsistence farmer and the home gardener seem somewhat arbitrary. For example, why wouldn't the home gardener also be ingesting animal products, in fact those grown on the subsistence farm; local processing and distribution of these products certainly occurs.

10. One major component of the document that seems to be missing is any real discussion of the outcomes of the multipathway analysis with respect to known values as determined from other sources for emissions of the various metals and organics chosen as well as any exposure data for these compounds in smelter workers and or groups living around smelters. How do values computed relate to any known emission or exposure data?

11. A related point is that the document does not really put the risks generated into an adequate public health context. What do these derived risk estimates mean with respect to public health? The values generated are presented without really providing any discussion of their relationship to known toxicity levels for these compounds.

12. A minor point, but wouldn't chicken be a better choice than pork with respect to total human consumption in the category of animal product ingestion?

4. Dr. Thomas J. Gentile

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Science Advisory Board Review (March 1 -2, 2000)

1. Overall: Is the methodology that the Agency applied in this risk assessment consistent with the risk assessment approach and methodology presented in the Report to Congress? Are the assumptions used in this risk assessment consistent with current methods and practices?

The risk assessment methodology presented in the case study is consistent with the framework described in the Report to Congress (RTC) with some significant exceptions. Overall, the case-study approaches incorporates the iterative approach (e.g. refine the risk assessment by reducing the conservatism by including site-specific detail). It carefully identifies the assumptions and impacts of the assumptions on the risk estimates presented. In addition, the public health risk assessment is consistent with current methods and practices. Although I have some concerns about the adequacy of the ecological assessment, these concerns may be due to my unfamiliarity with the current state of the science about ecological risk assessment practices.

However, the case study does not go far enough in providing site-specific information to make the important risk management decisions concerning the adequacy of the NESHAP to protect public health and the environment. There was an attempt to incorporate some site-specific information (e.g. facility compliance stack test, state stack test, receptor locations, ambient measurements and local blood lead levels), but more site specific information (e.g. the degree of partial or total fugitive emissions enclosures, specific terrain information for receptor modeling, soil sampling results for metals in the local areas) needs to be obtained by working with State and Local Public Health and Environmental Agencies and industry. This point is evident when a comparison is made between the screen and refined risk estimates for inhalation only exposure (Table 1).

Table 1. A comparison between the refined and screen inhalation cancer risk estimates for the facilities selected for refined analysis. (All risk estimates are cases per million)

Facility	Initial Screen	Refined Screen w/o fugitives	Refined Screen w/ fugitives	Risk Reduction w/o fugitives	Risk Reduction w/fugitives
2	6000	10	52	600	115
3	9000	5	2240	1800	4
4	6000	268	6950	22	risk increases
13	10000	16	130	625	7

The increase in risk for facility 4 as a result of the refined modeling raises concerns, which may go beyond the lack of refinement of the fugitive dust emission estimates in the refined analysis. This needs to be explored in greater detail in the case-study. The obvious differences which impact the risk assessment between facility 4 and the others is the size of the facility as determined by the number of emission points (n=13), the furnace type and the closer receptor impacts (Table 3.7 in case-study). However, the most troubling aspect is that Facility 4 had stack test data reported for all of the HAPs which were assessed in the refined screening exercise. It also had the smallest incremental reduction in risk (22 times) when just the process and process fugitive emissions impacts from inhalation exposure are considered. The other issue is that Facility 3 also had stack test data reported for all of the HAPs which were assessed in the refined screening analysis and had the largest incremental reduction in risk (1800 times). An in depth analysis of these large differences in risk reductions (1800 versus 22) needs to be examined more closely in the case study. In addition, they have probably been subject to stringent state air toxics requirements under the California Air Toxics Hot Spots Program. Is there a State Air Toxics Hot Spot Risk Assessment for these facilities? If it is available has OAQPS conducted an independent evaluation of the results and actions which were taken to reduce risk?

This is extremely important since the refined analysis for facilities 3 and 4 was based more site specific emissions information. The increased risk observed for facility 4 in the refined analysis indicates that the initial screening assumptions may not be overly conservative in all cases. The only way to check this would be to obtain some basic site-specific information to insure that the parameters used in the initial screen are always going to be conservative for all facilities.

In summary, a detailed site specific description of the four facilities selected for the refined analysis should be summarized and included in volume 1. The brief discussion in section 3.1.1 is inadequate and should be expanded. This qualitative expansion should include cross references to other sections where site specific data is used in the refined analysis. For example, the use of actual stack characteristics for the refined analysis which is found in Table 3.3, the use of local met data which is found in Table 3.4 and the use of actual receptor locations which is found in Table 3.7. This would place all site specific or cross references to site-specific information into one important place and would help the reader conceptualize the differences between the facilities under evaluation.

In context of the framework presented in the RTC, it appears that the refined analysis can not answer the question: Is human health risk acceptable? The fugitive emissions issue (e.g. lack of refinement) and the lack of site-specific information clearly result in negative answer to the question: Are information and analysis sufficient to evaluate management options? This answer indicates that a further refinement of the case-study or another iterative step is needed before an evaluation of the risk management options can be considered.

The Agency is mandated under Section 112(f) to conduct the residual risk assessment and make a decision to implement further regulation or to make a decision that no further regulation is needed. In response to the previous SAB review of the RTC, the Agency responded that, “the decision made with the results of the screening analysis is no further action or refine the analysis, while the decision made with the results of the more refined analysis is no further action or consider additional emissions control.”

As discussed above, the results of the refined analysis provides the same answer as the initial inhalation screen, that a more refined analysis is needed. Therefore, the case study has not achieved the ultimate decision objective and another level of analysis or iteration is required. The case study should do a more in-depth refined analysis or an additional step-wise iteration to improve the case study for risk management decision making.

An examination of the initial screen results indicates that it has provided important information about which hazardous air pollutants (HAPs) need to be considered in the multipathway and refined analysis. However, the results from the above Table are disconcerting. How can the refinement and the removal of conservative assumptions and HAPs from consideration result in an increased inhalation risk for receptors around facility 4? It is important to narrow the scope and refine the residual risk analysis in the first step, however, extreme caution must be exercised when eliminating HAPs and facilities from consideration as a result of the initial screening. It is clear that the use of post NESHAP emission rates in the initial screen would provide a better starting point for the case study.

The impact of consolidating emission points into a centroid emission point needs to be carefully considered and analyzed. The Office of Air Quality Planning and Standards (OAQPS) should evaluate the work that has been conducted with the Office of Pollution Prevention and Toxics (OPPT) on the Risk Screening Indicators Model concerning the use of centroid emissions locations versus the use of facility specific stack and location parameters. An analysis conducted by OPPT found that the impacts in the area close to the facility fence lines was underestimated by a factor of three to seven when the centroid was used to estimate emission impacts. As distance from the facility increased the centroid modeling provided more consistent predictions when compared with the model using actual stack emission parameters and location characteristics. Therefore, some of the conservatism of the initial screening and the refined screening exercises may be questionable if receptors are in close proximity to the facility fencelines.

The selection of facilities for the refined analysis needs to be placed into some type of risk management framework. These facilities were obviously selected since they represented the highest risk (e.g. cancer risk > 9000 in a million and HQ > 70). However, a defined process is needed for selecting which facilities will be included in the refined analysis. For example, if the 100 in a million cancer risk value was used only 2 of the 29 facilities would pass the screening criteria. The use of this cancer risk range would be consistent with the benzene decision and the Commission of Risk Assessment and Risk Management (CRARM) recommendations by having the total cancer risk from the facility being in the range of less than one to one hundred in a million for the screening assessment. In addition, if a hazard quotient of 10 is used as an action level for the screening assessment as recommended by CRARM, then a decision to eliminate facilities 6, 9, 12, 20, 25 and 29 for further analysis of noncancer health effects can be made. One can construe from the selection of only four facilities that a decision of no further action may be made for the other 19 facilities based on the initial screening assessment.

In summary, there is a need to gather more site specific information for the initial and refined analyses than what was gathered and presented in the case-study.

The RTC discusses the need for including background risk and discusses the difficulty associated with this specific issue. The case study does not address background risk issues around any of the 23 facilities in the human health risk assessment. This is serious omission from the case-study and there is a need to attempt to address this issue at a minimum from a qualitative and quantitative point of view, well beyond the comparisons made in Chapter 6. No assessment of background risk seriously impacts statements about the conservative nature of the refined screening assessment.

I disagree with the statement on page 134 of the case-study that any attempt to include background concentrations in the ecological assessment “.... were beyond the scope of this assessment.” This is a critical part of the ecological risk assessment since these facilities have been probably impacting the local ecosystems for a long time prior to the addition of NESHAP controls. An assessment of background risk in addition to the screening level assessment is absolutely necessary before any decisions can be made about the significance or conservativeness of the ecological risk assessment.

The RTC also discusses the assessment of acute effects from short-term HAP exposure. The case study contains no discussion or assessment of acute effects from HAP emissions for this source category.

2. Model Inputs: Are the methods used to estimate emission rates, and the method used to estimate species at the stack appropriate and clearly described?

The methods used to estimate emission rates for the initial screen and refined analysis are clearly described. However, there is a concern that the emission rates used for the lead to metal HAP ratios in the initial screen are biased low based on the actual stack test results from facilities 3 and 4. A comparison of the lead/HAP metal ratios used in the initial screen and refined analysis are presented in Table 2.

Table 2. A comparison of the lead to HAP metal ratios used in the initial and refined screening analysis.

Metal HAP	Initial Screen (Process)	Refined (Process)	Initial Screen Process Fugitive	Refined Process Fugitive
Arsenic	0.09	0.31	0.03	0.035 - 0.098
Chromium	0.05 ⁽¹⁾	0.00048	0.01	.00013 - 0.0014
Cadmium	0.02	0.031	0.01	0.02 - 0.045
Nickel	0.08	0.179	0.06	0.13 - 1.99

(1) - The ratio for the initial screen is total chromium and for the refined analysis it is hexavalent chromium. An adjustment of the initial screen total chromium values using the 1% assumption as hexavalent provides almost the same value used for the refined process and process fugitive emissions.

The differences between the arsenic and nickel ratio values used in the initial screening analysis and the refined screen analysis clearly undermines the conservativeness of the initial screen risk results presented in Tables 2.4a and 2.4b. If the stack test results from facilities 3 and 4 are post NESHAP, then a decision should have been made to use those results in the initial screen versus the median values estimated from Background Information Document (Table B1.3 - Appendix B).

The Agency should consider requesting stack emissions test for process and process fugitive at some of the facilities in order to obtain better emission estimates for use in the screening assessment case-study.

The Agency carefully needs to reevaluate the fugitive emissions rates since the modeled annual concentrations of lead with fugitives in Appendix C are unrealistically high for facilities 3 and 4. There is a need for site specific information on the effectiveness of fugitive emissions control after the implementation of the NESHAP housekeeping standards. Fugitive emissions from this source category are an issue and need to be carefully evaluated. In 1987, there were two exceedances of the National Ambient Air Quality Standard (NAAQS) for lead (1.5 ug/m³) in the vicinity of a secondary lead smelter. The elevated lead concentrations (2.46 and 1.61 ug/m³) at the monitor were the result of malfunctioning emissions control equipment and fugitive emissions from the plant. Monitoring of lead around the plant was increased by the addition of two downwind monitors. The plant upgraded the process emission controls, but the concentrations of lead were still elevated, but below the NAAQS when compared to other monitoring sites in the State. Further investigations concluded that fugitive emissions from the plant were a problem that needed to be addressed. The entire facility was enclosed and placed under negative pressure. HEPA filters were installed on all air exchange units and other housekeeping practices were required. This facility currently has 16 emission points. The annual geometric mean of lead at one monitoring site dropped from a high of 0.71 ug/m³ (1987) to 0.06 ug/m³ (1993) after all of the facility upgrades were in place. The highest quarterly average measured at the two remaining monitoring site in 1996 were 0.06 ug/m³. These two monitors are located 275 meters from the facility fence line. The third site was shutdown at the end of 1995.

The incorporation of this type of information into the case study and the refined screening analysis will result in a more informed risk management decision for this source category.

3. Models: Does the risk assessment use appropriate currently available dispersion models at the screening level and at the more refined level of analysis? Are the models applied correctly? Given the state of the science, does the risk assessment use an appropriate multipathway model? The assessment uses the IEM-2M model, with some modifications. Is the IEM-2M model appropriate for use in this regulatory context? With regard to the modification and application of the model, did EPA appropriately modify the model for use in this risk assessment, and did the Agency apply the model correctly? Is there another model or another approach, that is available at this time that EPA should consider?

The decision to use facilities 2,3,4, 13 because these represented facilities with the highest excess cancer rate and highest hazard index based on the initial screening produced a situation where only simple terrain would be used in the refined analysis. This process could have biased the modeling results to underestimate impacts at other facilities, with complex terrain, which were not designated for refined analysis. The Agency should reevaluate if any of the 29 facilities are in areas of complex terrain.

The exposure inputs into the IEM-2M and IEUBK model are conservative which is clearly acknowledged by the Agency throughout the case study. The Agency should continue refine the risk assessment using site specific information as discussed in many of my other comments. There is a strong need for another iteration to refine the case study which is acknowledged by the Agency in section 6.7. The case study should remain a Pre-Decisional Document until the next iterative refinement is conducted. OAQPS should work diligently with State and Local Health and Environmental Departments, the Agency for Toxics Substances and Disease Registry, Industry and the EPA Regions to further refine the case study. This step is absolutely necessary before any decision about unacceptable risk is made for the majority of the facilities identified in the case-study. The uncertainties associated with the fugitive emission parameters are the driver for a more detailed risk assessment within the source category. This need is discussed by CRARM on page 23 of the RTC.

4. Choice of Receptors: The Agency identifies the home gardener as the appropriate receptor to estimate risk to the residential population and the farmer to embody high end risk estimates. Are these receptors appropriate for this task?

The receptors identified by the Agency are appropriate and adequately represent the maximum individual risk (MIR) concept which is discussed in the RTC.

5. Ecological Risk Assessment: given the currently available methods, are the models used for the ecological assessment appropriate? Are they applied correctly? Are the ecological benchmarks appropriate?

The case study does not include a discussion of other ecological stressors (e.g. criteria pollutants) which may have an impact on the surrounding ecosystem. The effect of this omission on reducing the conservativeness of the ecological risk screen is mentioned on page 147. However, any refined analysis of ecological risk is going to have to account for these additional ecosystem stressors, especially the effects on terrestrial plants exposed via direct contact with criteria pollutants (in this case sulfur oxides) in the ambient air.

6. Health Risk Assessment: Given available dose-response information, is the hierarchy presented in the assessment appropriate (see especially footnote #6, section 2.21)?

The hierarchy presented in the assessment is appropriate. I agree with the use California Environmental Protection Agency values over HEAST values for all of the reasons outlined in footnote #6.

For each chemical included in the assessment is the choice of dose response assessment appropriate?

Overall, the choice of the available dose-response data used in the case study is appropriate. I have concerns about the elimination of HAPs from consideration in the case study if they have no available cancer or noncancer public health values. Seven organic HAPs are eliminated from consideration in the case study. It is difficult to assess the impact of the elimination of these organic HAPs from the case study. However, the effect may be negligible since emission rates in Appendix B for the organic HAP emissions omitted from consideration are low. The Agency should consider the development of default or surrogate values based on the available toxicity information or structure activity relationships with other HAPs which have dose response data. .

Why is propanol identified as a HAP in the case study? I can not locate it on the list of 188 HAPs identified by the Clean Air Act.

The application of the use of risk ranges for benzene and 1,3-butadiene in the initial screen needs to be discussed. Do the cancer risk results presented in Table 2.3 use the high or low end of the range?

The use of only 25% of the inhalation unit risk estimate for nickel subsulfide needs to be explained in greater detail, since it will have a large impact on the total cancer risk estimates in the case-study.

Are the dose response assessments appropriately incorporated into the assessment?

Yes, the available dose response assessments are appropriately incorporated into the assessment, with a few exceptions as noted above.

7. Uncertainty and Variability Assessment: Did the assessment use the appropriate currently available methods to identify the variables and pathways to address the uncertainty and variability assessment? Are the methods used to quantify variability and uncertainty acceptable? Are there other, more appropriate methods available for consideration?

**8. Results Presentation: Does the document clearly present and interpret the risk results?
Does it provide the appropriate level of information?
Do the figures and tables adequately present the data?
Do the formats provide for a clear understanding of the material?**

It is very difficult to present such a large amount of information in a clear and concise manner. The case study does a good job of presenting and interpreting the risk results. The discussion of the initial inhalation screening results should include a discussion of how the maximum and minimum risk values presented in Table 2.3 were defined. The Agency should indicate that they are simply the range of estimates determined for all 29 facilities.

The Agency should consider using a consistent cancer risk expressions in the narrative of the case study. The lay reader will be confused by the constant interchangeable expressions of cancer risk. For example, the use of the expression eight in a ten thousand should be changed to 800 in a million. This will allow the lay reader to place the results into the context of the less than one in one million expression which appears in the Act and throughout the case study.

The identification of the key issues and assumptions are clearly identified in the result sections of the the initial inhalation screen, the refined multipathway screen , the variability and uncertainty analysis, and the ecological screening assessment. The addition of a discussion about a few key issues concerning the lack of a background risk analysis and the effects of the adjustment of the nickel inhalation unit risk estimate could be added to the key issues identified in Section 3.3.2.

The tables and figures used throughout Section 4 provide a concise and well thought out approach for the presentation of variability and uncertainty for each scenario evaluated. They allow the reader to evaluate the broad spectrum of risk and the impacts of the various exposure parameters used in the refined multipathway risk assessment. These tables and figures significantly enhance the comprehensibility of the variability and uncertainty assessment results. The inclusion of the point estimates in Tables 4.5 and 4.6 is an excellent way to concisely present information to the risk manager. The tables and figures provide the risk manager with the ability to view the broad spectrum of risk predictions, which includes the average exposed individual (AEI), the adjusted maximum individual risk and the maximum exposed individual (MEI).

Tables 6.1 and 6.2 provide a good overview summary of the final results for the refined multipathway risk assessment. I have some concerns about Section 6.2.1 Comparison of Modeled Concentrations with Measured Environmental Concentrations. As discussed through out my comments this section can be greatly enhanced and another iterative refined multipathway risk assessment step which relies on more site specific information should be added to the case study.

The effort which will be needed to gather the relevant information for this next step should not be considered overwhelming or beyond the scope of the case study. It should be considered as a necessary refinement which needs to be conducted before the case study becomes a public document. The

discussion in section 6.2.1.1 needs to be expanded. The pre-NESHAP monitoring data from New York indicates that the NAAQS for lead can be exceeded and that the stringent control of fugitives can result in a dramatic lowering of ambient concentrations of lead and probably other metal HAPs in the vicinity of secondary lead smelters. Table 6.7 should be modified by locating the distance to the monitors and include a brief discussion of siting issues (e.g. predominate downwind or upwind monitoring location) before any comparisons are made. The same point can be made for the comparisons of the surface waters concentrations. However, the Agency does appropriately acknowledge that the comparisons in Table 6.8 are not meaningful.

Section 6.2.1.5 needs to be expanded since it provides information on an excellent biomarker for potential exposure (e.g blood lead levels). The inclusion of this type of information would greatly enhance the case study. The CDC and State Health Departments should be consulted to find out if there is any other information on blood lead levels in children who reside in communities that are in close proximity to secondary lead smelters.

In summary, there is a strong need to gather and evaluate more site specific information using the risk assessment tools presented in the case study before any final risk management decisions can be made for this source category. The case study should undergo another iteration before being released to the public.

Editorial Notes:

The overview presented in section one the case study is very good

Section 2.2 needs to include the chemical abstract service registry numbers and the identity of the chemicals as they are primarily identified in Section 112 (b) of the Clean Air Act (e.g. 2 -methyl phenol is identified by 112 (b) as o-cresol, iodomethane should be identified as methyl iodide, etc.)

Table 6.8 - the units (ug/l) are missing.

5. Dr. Dale Hattis

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Below are my updated responses (following discussion at the meeting) to the questions posed to the Secondary Lead residual risk review Subcommittee:

Charge Question 1. Overall--Is the methodology that the Agency applied in this risk assessment consistent with the risk assessment approach and methodology presented in the Report to Congress? (EPA-453/R-99-001)? Are the assumptions used in this risk assessment consistent with current methods and practices?

I have very considerable difficulty making an appropriate response to the first part of this question. I was not provided with a copy of the Report to Congress that is specifically referred to. Fairly recently, I was sent a copy of a substantial earlier SAB review of that document from which I can make some inferences about the risk assessment approach and methodology that was presented in the Report to Congress. However there does seem to be very significant commentary in the SAB review of the need to “validate” models, and to conduct appropriate analyses of the population variability of regulated risks and give a fair estimation of the uncertainty in the variable risk distributions. The current document, though very extensive in many ways, does not seem to reflect a serious effort to assemble and analyze a substantial body of post-MACT emissions and exposure (e.g., community blood lead) information that could be juxtaposed with the emissions estimates made in the early 1990’s when the MACT standards were set. The documents do not appear to describe a systematic search for such information, do not present the specific emissions information that was collected, and do not document in nearly adequate detail the specific analyses that were done with the emissions information. There is no visible attempt to juxtapose model projections of either emissions or exposures (e.g., for blood lead) with such data and to form the bases for an updated set of distributional exposure and risk projections.

There is a great deal of discussion in the SAB review, and in the EPA residual risk assessment, of the need to conserve scarce EPA resources by limiting the analysis in various ways (by structuring the analysis in a series of tiers beginning with generic conservative assumptions, restricting the HAPs covered, the facilities examined in detail, etc.). Sadly the implementation of this approach does not seem to have lead to an economical analysis that can be said to have succeeded in producing meaningful insights into the likely level of risk posed to real people in the immediate vicinity of these facilities. There is no more expensive analysis than an analysis that does not produce results that can meaningfully inform public policy choices. The screening level analysis as it stands probably is adequate to focuses EPA’s attention on lead and a few metallic HAP’s, and away from the great majority of organic HAP’s, but that result probably could have been foreseen with considerably less work than appears to have been devoted to this project. Certainly something is seriously amiss when the document can show projections of essentially lethal blood lead levels (200 ug/dL and above) for the case where fugitive emissions are included—and very significant blood lead levels (68 ug/dL) even without fugitives for one of four modeled facilities—without that leading to some attempt to pursue the issue with blood lead observations or some

deeper conclusion than that the fugitive emissions estimates are probably “conservative”. Maybe they are “conservative”, but then to blithely exclude both the fugitive emissions and all exposures to lead entirely from the “variability/uncertainty analysis” without further reappraisal of the source of the apparent estimation problem seems to turn the screening results on their head. Any “tiered” analysis procedure that leads the investigators to exclude such a major source of concern as lead from important parts of the secondary lead smelter analysis has a serious fundamental problem, at least as implemented here. This is particularly true in the light of the fact that emissions of the other HAP’s that are included in the variability/uncertainty analysis are estimated as ratios to lead.

The context of this residual risk analysis is a long term possible consideration of the need for emissions control measures that go beyond the available control technology-based standards that were mandated in the first round of controls following the passage of the 1990 iteration of the Clean Air Act. Almost by definition, when you are building the informational basis for considering the need for technology-forcing measures, you need to have data that would be sufficient to support decisions that might involve very substantial technical and economic restructuring of an industry. At the same time, the context also involves considering the possibility that appreciable residual risks remain for people in communities surrounding these facilities that mean that the promise of the 1990 Act to provide an ample margin of safety for health protection is still not being fulfilled ten years after the promise was made. This context demands that EPA take the time and devote the resources needed to fairly assess the current public health problem posed by these facilities. Otherwise no actions based on such an analysis are likely to survive Congressional and Judicial oversight.

Charge Question 2. Model Inputs--Are the methods used to estimate emission rates, and the method used to estimate species at the stack appropriate and clearly described?

Briefly, no. The primary data should be provided in the document and the detailed analysis steps should be given in sufficient detail to allow an informed reader to reproduce the analysis. My understanding from the extra documents that have been provided to me in the context of the variability/uncertainty analysis is that the existing data base is not extensive—consisting apparently of three “runs” (of undetermined duration) measuring Lead, Arsenic, Cadmium, and Nickel emissions from various stacks at two different facilities—constituting in all about 168 separate measurements if I have counted correctly. For a large number of other HAP’s and other facilities my understanding is that there is some additional information available from recent (post 1990) measurements for four facilities, but that the primary sources of estimates of emissions is the 1994 Background Information Document for setting the MACT standards. The bases of these estimates and their applicability to current conditions is not discussed.

In addition, the authors should take a more creative approach to assembling other types of data relevant to emissions than they have apparently considered. For example, to estimate fugitive emissions, one clue might be air exposure levels measured for workers in this industry by OSHA industrial hygienists. [Some helpful background on the history of air and blood lead levels in the industry can be found in a couple of past reports I helped do for the Office of Technology Assessment—Goble et al., (1995, 1983)]. Such air levels, when combined with general ventilation assumptions and baghouse

capture efficiencies, should provide some basis for new estimates of at least some process fugitive emissions, as should air measurements from environmental monitoring conducted near the facilities, and children's blood lead measurements that are routinely collected by agencies in several states, and which may therefore be available for communities near the facilities under study. In addition, it should allow some estimation of fugitive emissions from other parts of the process than the battery breaking and materials handling steps that are presently included as contributing fugitives in the current process flow diagram. What happens to the air around the workers working at other steps than the first two? Is it captured and treated to remove some dust? With what efficiency? Additionally, it would seem sensible to make systematic comparisons of observed community air levels with those predicted from the dispersion models.

Charge Question 3. Models--Does the risk assessment use appropriate currently available dispersion models both at the screening level and at the more refined level of analysis? Are the models applied correctly? Given the state of the science, does the risk assessment use an appropriate multipathway model? The assessment uses the IEM-2M model, with some modifications. Is the IEM-2M model appropriate for use in this regulatory context? With regard to the modification and application of the model, did the EPA appropriately modify the model for use in this risk assessment, and did the Agency apply the model correctly? Is there another model or another approach, that is available at this time that EPA should consider?

These questions cannot be fairly answered from the information provided. There was just not a sufficient presentation of the assumptions inherent in the IEM-2M model for me to evaluate it. I was provided with very large spreadsheets of the model, but without a great deal more time and appropriate documentation of the structure and assumptions built in to the model it is just impossible for me to make a sensible evaluation. I don't know and cannot easily infer, for example, how it differs from other multimedia models that are available, such as CALTOX.

Charge Question 4. Choice of Receptors --The Agency identifies the home gardener as the appropriate receptor to estimate risks to the residential population and the farmer to embody high end risks. Are these receptors appropriate for this task?

I'm not at all convinced of this. My impression is that the chief pathway responsible for transferring gasoline air lead to children when gasoline lead was still allowed was a dust-hand-mouth pathway. It seems to me that this pathway, together with more recent information on the efficacy of community soil cleanups in reducing blood lead levels, needs to be evaluated as part of any fuller analysis of the issue. I understand EPA's desire to exercise its IEM-2M models, and this should certainly be one part of the analysis, but key issues need to be addressed, such as the persistence of dust contaminated with lead and other metallic HAP's in neighboring communities, rates of exchange between outdoor dust and indoor dust, and the magnitude and duration of exposures that result from emissions and deposition of indestructible metallic compounds in urban and other communities.

Charge Question 5. Ecological Risk Assessment Given currently available methods, are the models used for the ecological assessment appropriate? Are they applied correctly? Are the ecological benchmarks appropriate?

This is not my area of expertise, and I have not evaluated this portion of the document.

Charge Question 6. Health Risk Assessment--Section 3.4.1 of the Report to Congress identifies several data sources that the Agency would draw upon for choosing dose response assessments to be used in residual risk assessments. The Report also states that EPA will develop a hierarchy for using such sources. Given available dose-response information, is the hierarchy presented in this assessment appropriate (see especially footnote #6, section 2.2.1)? For each chemical included in the assessment, is the choice of dose response assessment appropriate? Are the dose response assessments appropriately incorporated into the assessment?

I do not have the cited Report to Congress, and I have not thoroughly evaluated this aspect of the document. However I would suggest that at least for lead, where there are quantitative estimates of relationships between children's blood lead levels and IQ, that the results be taken to estimate likely individual and population aggregate impacts in quantitative terms—how much relative deficit for how many kids. Additionally, I believe that cancer impacts can and should be evaluated in population aggregate terms as well as in terms of risks to particular percentiles of the estimated exposure distributions. This would allow decision makers in Congress and EPA to assess the public health productivity of investments made under the residual risk provisions of the Clean Air Act.

Charge Question 7. Uncertainty and variability assessment--Did the assessment use appropriate currently available methods to identify the variables and pathways to address in the uncertainty and variability assessment? Are the methods used to quantify variability and uncertainty acceptable? Are there other, more appropriate methods available for consideration?

Although there are some glimmers of creative analysis of data in the uncertainty/variability portion of the effort (e.g. the attempt to calculate metal HAP/lead ratios over a longer time period than covered by the directly observations), the current analysis is very disappointing in numerous ways. First, the scope and objectives of the analysis fall far short of what any sensible decision maker will wish to have in order to make informed choices under the residual risk mandate of the 1990 Clean Air Act. To fulfill the mandate of the Clean Air Act, EPA needs to not only be confident that it has addressed the most significant hazards posed by the industry under study, but to define what it means by an “ample” or “adequate margin of safety” in distributional terms, (e.g. X level of probability of harm of a particular type or severity for the Yth percentile of the exposed population with Z degree of confidence—See for example Hattis and Anderson, 1999; Hattis and Minkowitz, 1996). EPA then needs to develop an analysis that addresses the likely real variability and fairly appraised uncertainty for at least the HAP's and exposure pathways that are thought to pose the greatest potential for public health harm for the industries studied. In the present context, omission of the variability and uncertainty of lead exposures and risks, and

omission of some analysis of the uncertainty in fugitive dust emissions and exposures means that the analysis is substantially irrelevant to some of the most important concerns that arise from the earlier screening and multipathway efforts.

The failure to distinguish variability from uncertainty in the present analysis almost guarantees confusion. Variability and uncertainty are different things and require different techniques for estimation. It is a shame that the individual variability in estimated exposures is essentially completely neglected even though existing dispersion modeling techniques, combined with data on the population distributions around the studied facilities, could readily produce such information. This information would seem central to the required analysis. The fact that it is not undertaken, at least at this stage in the development of the project, suggests that the current variability/uncertainty analysis is largely a placeholder for some later effort that, it is hoped, will be planned as a more central part of some future analysis.

A second major problem is that the current analysis does not follow existing EPA guidelines on the documentation and presentation of distributional analysis. Those guidelines, drawn up in part at workshops that I attended, emphasize that the model itself and derivations of distributions used in the analysis must be transparently presented in sufficient detail that a reviewer can reproduce them. I have recently received several spreadsheets that contain portions of the model, but in the very limited time available I have not been able to get them running sufficiently to even examine the model structure, distributional assumptions, and correlation/dependency assumptions made. The document itself should have included as an appendix not the endless display of results for each stack, but the spreadsheet model equations, and the mathematical form of the distributional assumptions that were used.

In summary, in the present effort, the uncertainty/variability analysis appears to have been an afterthought, perhaps undertaken at a late stage in the development of the principal results. Unless analyses of variability and uncertainty are undertaken integrated into the warp and woof of the primary study, they will likely continue to be unsuccessful and unsatisfactory in illuminating the major issues involved in the evaluation of the real choices facing EPA decision makers, Congress, and the public.

Some more technical suggestions can be made for pursuing the probabilistic analysis in future work:

- a) In assessing the distribution of metal HAP to lead ratios, the analysts should explore the possibility that some air exhaust streams might be systematically different than others. In particular arsenic, which is more volatile than the lead and most other inorganic HAP's may appear in larger concentrations relative to lead in some air streams than others depending on the temperature of the process and exiting gas. The data should be examined to see if such mechanism-based expectations are borne out in the available observations. If so, then some metal HAP to lead ratios could be varied across process streams (and perhaps across facilities) to reflect the mechanism-based associations.
- b) In representing the interindividual variability of exposure factors such as consumption of different kinds of produce and fish, the analysts should seek data to quantify variability

observed on different time scales than the 1-3 days that are typical for direct dietary studies. Some downward adjustment clearly needs to be made to calculate variability over longer time scales from shorter term data. However, because some dietary preferences are likely to be relatively consistent characteristics for individual people, it is not reasonable to estimate long term dietary exposure variability either by simply assuming that each separate 1 or 3-day period is a random draw from an observed population distribution of consumption. Some data bearing on the difference in effective variability in fish consumption inferred for longer- vs shorter time frames is reviewed in Hattis et al. (1999).

- c) In Section 4.4 the document should clearly explain the implications of the assumptions that are being made. For example, the statement is made on p. 127 that because of data insufficiency, no analysis of correlation among emission parameters and exposure factors was undertaken. The statement should be clarified to say that the correlation could not be undertaken because the data wasn't available for it.

Charge Question 8. Results Presentation--Does the Agency's document clearly present and interpret the risk results? Does it provide the appropriate level of information? Do the figures and tables adequately present the data? Do the formats provide for a clear understanding of the material?

As discussed above, the presentation of the basic inputs and methodology is very far from being adequate to provide a document that is even transparent enough for a thorough review, let alone a document that appropriately assess the uncertainty and variability for decision-maker and the dependence of the results on key sets of assumptions. Without documentation of the derivation of the results and their uncertainties, the results cannot be appropriately conveyed to decision makers and the public. Moreover the neglect of real population variability in both exposures and risks deprives the reader of important information that is needed to arrive at risk management judgments.

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6. Dr. Michael J. McFarland

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Residual Risk Assessment
Secondary Lead Smelter Source Category

SAB Charge Question # 1:

Are the methods used to estimate emission rates and the method used to estimate species at the stack appropriate and clearly described?

Initial Inhalation Risk Screening

FINDINGS

The method used to estimate the HAP emission rates involve the use of several data sets from the Background Information Document from which the MACT standards were initially derived. The first data set (Table B.1.1) includes estimate emission rates (in metric tons/year) for each of the three emission sources including: 1) process stack emissions (both organic and metal HAPs), 2) process fugitive stack emissions and 3) fugitive emissions. The second data set (Table B.1.2) includes ratios of specific organic HAP emissions to total hydrocarbon emissions from the stacks of three (3) types of secondary lead smelter furnace types.

The final data set includes the median metal specific HAP to lead ratios (Table B.1.3) as well as the total metal HAP to lead ratio for each of the three emission sources that include: 1) process stack emissions, 2) process fugitive stack emissions and 3) fugitive emissions.

Although Table B.1.3 indicated that the reported data were the median metal (total and specific) HAP to lead ratios, it is unclear whether Tables B.1.1 or B.1.2 were also reporting median values or another statistical measure (*e.g.*, mean or average) of the sampling data. Moreover, since the purpose of the initial inhalation screening analysis was to employ a lower tier conservative approach to screen those HAPs that did not pose a significant human health risk, it would seem more appropriate to use the upper limit of a confidence interval (*e.g.*, 95%) of the HAP ratios for estimating emission rates rather than mean (or median) values to estimate inhalation risk. Given the wide range in HAP ratios found in the data tables, use of an upper confidence limit would provide greater protection from deletion of species that may, in fact, represent a significant human health and/or ecological risk. The same argument can be applied to the use of a mean or median total HAP emission rate (Table B.1.1) for estimating specific HAP emission rates. The large range in reported data suggests that a more defensible risk screening evaluation would be achieved by selecting an upper limit of a prescribed confidence interval of emission rates for input into the general inhalation risk model rather than the use of an average emission rate.

Another concern regarding the inhalation risk model inputs was the specific management of the acid gas data. Both chlorine (Cl₂) and hydrogen chloride (HCl) emissions were included in Table B.1.2 and treated as organic HAPs in the emission rate calculations. The concern with regard to the acid gas data stems not only from the placing of the inorganic acid gas emissions in the table for organic HAPs (*i.e.*, Table B.1.2) but, it is also unclear as to whether the total organic HAP process emission rate data (Table B.1.1) includes the contribution from the acid gases.

Although there are some concerns regarding the input data quality for the initial inhalation risk screening, the mathematical equations used to estimate the specific HAP emission rates are fundamentally sound. The specific metal HAP emission rates (E_{HAP}) from each of the three emission sources (*i.e.*, process stack emissions, process fugitive stack emissions and fugitive emissions) were estimated by substituting the estimated total metal HAP emission rates (metric tons/yr) for each emission sources (E_{TMH} - Table B.1.1), the median metal HAP to lead ratio (R_{HAP} - Table B.1.3) and the total metal HAP to lead ratio (R_{TMH} - Table B.1.3) into Equation 1.

$$E_{\text{HAP}} = (E_{\text{TMH}}/R_{\text{TMH}}) (R_{\text{HAP}}) \quad \text{Eq. 1}$$

where

E_{HAP} = Individual metal HAP emissions (*i.e.*, antimony)

E_{TMH} = Total metal HEP emissions

R_{TMH} = Ratio of total metal HAP emissions to lead emissions

R_{HAP} = Ratio of individual metal HAP emissions from lead emissions.

The specific organic HAP emission rate (E_{VOC}) from the process stack emission source was estimated by substituting the estimated total hydrocarbon emission rate (metric tons/yr) from Table B.1.1 (E_{THC}) and the ratio of specific organic HAP to hydrocarbon emissions (R_{VOC} - Table B.1.2) into Equation 2.

$$E_{\text{VOC}} = (E_{\text{THC}})(R_{\text{VOC}}) \quad \text{Eq. 2}$$

where

E_{VOC} = Individual organ HAP emissions

E_{THC} = Total hydrocarbon emissions

R_{VOC} = Ratio of individual organic HAP emissions to total hydrocarbon emissions.

RECOMMENDATIONS

Although the data input descriptions were, in general, well written, there are several areas where significant improvement could be made. The specific recommendations for this section of the review include the following:

The data in Tables, B.1.1 and B.1.2 can be improved by explicitly stating the statistical measurement parameter being reported.

Consideration should be given to the use of upper confidence limits (of the HAP ratios) as inputs to the inhalation risk model.

The text should provide greater clarity as to how the acid gas data are being managed.

To provide clarity in the use of the mathematical relationships, quantitative examples should be inserted into the text that illustrate the use of Equations 1 and 2.

An example should be provided (perhaps in an appendix) illustrating how raw emission data from each emission source (*i.e.*, process stack emissions, process fugitive stack emissions and fugitive emissions) is managed to generate final risk numbers.

Multipathway Analysis

FINDINGS

The method used to estimate emission rates for the multipathway analysis included the use of compliance reports from stack tests for specific facilities (*i.e.*, Facilities 2, 3, 4 and 13 – Table C.1.1) as well as the EPA database developed in the Background Information Document (BID). The MACT standards require that facilities report, at a minimum, both the total lead and total hydrocarbon emission rates. For Facilities 3 and 4, additional compliance testing was conducted that allowed specific organic and metal HAP emissions to be estimated. These facility-specific emission estimates were then used to generate specific emission ratios including: 1) organic HAP to total hydrocarbon ratio and 2) metal HAP to total lead ratio.

To estimate specific organic HAP emissions for Facility 2, the organic HAP to total hydrocarbon ratio generated from Facility 3 data was multiplied by the total hydrocarbon emission rate from Facility 2. Similarly, to estimate specific organic HAP emissions for Facility 13, the organic HAP to total hydrocarbon ratio generated from Facility 3 data was multiplied by the total hydrocarbon emission rate from Facility 13. Since diethylhexyl phthalate and naphthalene were not measured in Facility 3-stack test, EPA database information was used to generate the organic HAP to total hydrocarbon ratio for these species for Facility 2 and 13.

To estimate specific organic HAP emissions for Facility 3 and 4, averages from three (3) stack test measurements for each facility were reported (adjusted for nondetects). Since diethylhexyl phthalate and naphthalene were not measured in Facility 3-stack test, EPA database information was used to generate the organic HAP to total hydrocarbon ratio for these species. It was not possible to estimate diethylhexyl phthalate and naphthalene emissions in Facility 4 since the MACT standards do not require total hydrocarbon measurements for reveratory furnaces.

To estimate specific metal HAPs for process emissions for Facility 2, the metal HAP to total lead ratio developed for Facility 3 was multiplied by the lead emission rate found in the Facility 2 compliance report. Similarly, for Facility 13, the metal HAP to total lead ratio developed for Facility 3 was multiplied by the lead emission rate found in the Facility 13 compliance report. Facilities 3 and 4 reported specific metal HAP emission rates for process emissions. It should be noted that Facility 3 did not test for antimony and Facility 4 did not test for manganese or mercury. The emissions of these metal species were estimated using EPA database information to develop the metal to lead ratio, which was then multiplied by the lead emission

rate from the facility compliance report.

To estimate specific metal HAPs for process fugitive emissions for Facility 2, the average of the fugitive metal HAP emissions to total lead ratio developed for Facility 3 and 4 was multiplied by the lead emission rate found in the Facility 2 compliance report. Similarly, for Facility 13, the average of the fugitive metal HAP emissions to total lead ratio developed for Facility 3 and 4 was multiplied by the lead emission rate found in the Facility 13 compliance report. Facilities 3 and 4 reported specific metal HAP emission rates for fugitive process emissions. Finally, the Background Information Document (BID) estimates for fugitive emissions used in the initial inhalation screening were employed in the multipathway analysis.

With regard to metal speciation, 99% of the chromium emissions is assumed to be Chrome (III). This assumption was based on one furnace measurement and the fact that the secondary lead smelters operate under a reducing environment. For mercury speciation, it was assumed that all of the evaluated mercury was in the form of divalent particulate mercury (HgO).

Although the multipathway analysis employs site-specific data, it is unclear whether the comparability of the data been evaluated. In other words, in many cases, EPA database information is used in conjunction with site specific data to generate specific HAP emission rates with no verification that the data sets contain elements of equivalent or similar quality. The absence of data quality evaluation leads to several fundamental questions that are summarized as follows:

What criteria were used to determine when Facility 3 data should be used for estimating organic HAP emissions from Facility 2 and 13 versus EPA database information?

Are emission estimates provided in Table C.1.1 averages, median or upper limits of a confidence interval?

How many samples comprise the emission values reported in Table C.1.1? Can ranges or standard deviations be given?

Do the state compliance stack permits specify the number of samples to be taken? In other words, are all data of a known quality?

Descriptions of Facility 3 and 4 stack tests indicate that three stack test were conducted to estimate organic HAP emissions. Does this mean three samples?

It is unclear as to why the average of Facility 3 and 4 process fugitive metal HAP emissions were used to derive a specific metal HAP to total lead ratio for Facility 2 and 13.

RECOMMENDATIONS

Since HAP emission rates were generated using various facility data sets as well as the EPA database, the most important general recommendation is that the Agency verifies the comparability of the

data. In other words, use of data of varying quality in the risk assessment models would generate final risk numbers of questionable value. Therefore, the quality of each data set should be compared and documented prior to having its elements used in the risk assessment. Secondly, since there is no specific protocol employed for estimating the HAP emissions from each of the four facilities, it is strongly recommended that quantitative examples be inserted into the text that illustrate each unique approach. Finally, additional recommendations regarding data inputs to the multipathway model include the following:

- a. Specify the type of statistical measurement being reported in Table C.1.1 (*i.e.*, means, median, upper confidence limits, etc.).
- b. Specify the number of samples that comprise the emission values reported in Table C.1.1 and provide both ranges and standard deviations.
- c. Provide an explanation as to why the average of Facility 3 and 4 process fugitive metal HAP emissions were used to derive a specific metal HAP to total lead ratio for Facility 2 and 13 rather than some other statistical measurement.

7. Dr. Paulette Middleton
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1. Links to Other Key EPA Activities Dealing with HAPs

Other EPA activities that have direct bearing on the residual risk assessments should be noted in the document. These activities demonstrate that EPA is actively improving on the current framework. While the current approaches used in the document under review here are acceptable in the current timeframe, many of their shortcomings may be addressed as a result of these other ongoing efforts. Acknowledgment of this could be done upfront in the introduction where discussion of model appropriateness and future assessments are mentioned. They also could be placed at the end of the report where next steps are sited and where it is noted that SAB comments will be considered in next steps.

2. TRIM

In particular, it should be noted that EPA/OAQPS is developing TRIM as a flexible, state-of-the-art system for evaluating multimedia chemical fate, transport, exposure and risk of HAPs. The recent SAB/Environmental Models Subcommittee review of this effort found it to be effective and innovative and outlined a number of recommendations for improvement. When TRIM becomes available, it should provide an improvement over the modeling framework used in the current report.

3. SAB/EPA Workshops on the Benefits of Reductions in Exposure to Hazardous Air Pollutants

As stated in the description of these up and coming workshops, "HAPs have been the focus of a number of EPA regulatory actions, which have resulted in significant reductions in emissions of HAPs. EPA has been unable to adequately assess the economic benefits associated with health improvements from these HAP reductions due to a lack of best estimate dose-response functions for health endpoints associated with exposure to HAPs and also due to a lack of adequate air quality and exposure models for HAPs. EPA is conducting two workshops to develop a proposed methodology to generate estimates of the quantified and monetized benefits of reductions in exposure to HAPs. The first workshop will focus on developing best estimates of dose-response functions that relate changes in HAP exposure to changes in health outcomes. The second workshop will focus on (1) integrating these dose-response functions with appropriate models of HAP concentrations and human exposure and (2) translating these into economic benefits that would estimate changes in health risks resulting from regulations that reduce HAP emissions." The results of these workshop discussions, in particular the reviews of models and methods, could well provide additional valuable input to this ongoing evaluation of the residual risk review and development of next steps.

4. Questions and comments on the current study

a. Missing HAPs

Have all of the potential important HAPs been included in the screening analysis? Can understanding of the processes be used to better substantiate the list of HAPs considered for screening?

Why are the acid gases not included in the analysis?

Organics are not considered beyond the screening. Can this screening result be better substantiated?

b. Emission rates

The development of emission rates for individual HAPs needs to be more clearly described. Here are some outstanding questions that need to be answered before providing a reasonable evaluation of appropriateness of the emissions estimates used in the modeling (both screening and multi-pathway).

What exactly was measured at the representative sites and how were the measurements done? How valid are the extrapolations of representative measurements to annual averages?
How valid are the extrapolations to other facilities?

Are the processes leading to the emissions fairly constant throughout the year?
How variable are the fugitive emissions at a given site?

5. Modeling

The model choices have been defended reasonably well. However, as noted above, improvements are needed and may be forthcoming with TRIM. Models seem to have been applied appropriately. However, several concerns are noted below regarding the assumptions in the modeling that could have an impact on the overall analyses.

6. Screening

There needs to be more convincing discussion of the representativeness of the building and meteorology general parameters chosen.

Are the facilities being considered reasonably represented by the general building and stack configurations assumed? Stack height and building heights are particularly important variables.

Is the meteorology of the sites being screened adequately represented by the standard worst case meteorology? Wind speeds and directions relative to the selected receptor sites are particularly important variables.

7. Multi-pathway

Again, are the assumptions about standard building parameters reasonable? The assumptions about building parameters are retained in the multi-pathway analysis. This is probably reasonable provided the actual facilities are similar in construction.

What particle parameters and sizes are assumed in the modeling? This is very important to clarify since the ISCST3 does show different results for assumptions about larger particle sizes. If all of the particles considered are assumed to be less than 10 microns, then I doubt there is any difference in deposition and concentration patterns from those for the gases. This needs to be clarified since the exposures are sensitive to assumptions about particle size and particle versus gas.

8. Receptors

A suggestion. The ISCST3 can produce patterns of concentrations and deposition at regular distances from the source. It might be helpful to provide these patterns as well as analysis at specific receptors. Patterns help provide an assessment of where risks might be important in the future. Is this type of analysis thought to be beneficial to the overall residual risk assessment?

9. Model/measurement comparisons

The results presented seem to be reasonable for the air models. However, the other comparisons are difficult to understand and are being discounted. The way that these comparisons are being presented detracts from the work and tends to make one more skeptical of the findings.

10. Uncertainty

It would be helpful to even more explicitly tie uncertainties to well-defined next steps.

8. Dr. George E. Taylor

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General Comments

G.E. Taylor, Jr.

A Case Study Residual Risk Assessment Secondary Lead Smelter Source Category

The SAB review of the draft *Residual Risk Report to Congress* was a challenge in light of the report being framed in very general way. In my participation of that review, I was uneasy about the review solely because I was unable to see the trajectory for the analysis in a quantitative sense.

The *Secondary Lead Smelter Source Category* analysis is a giant step forward and helps me be more confident that the analyses will be quantitatively based and linked to the literature on human health and ecology. The Agency is commended for pursuing that tack.

There are a number of general issues that are of concern however in the draft document and the presentations at the meeting. These general issues are outlined. Collectively, these suggest to me that the current draft is well short of being scientifically defensible with respect to natural resources and ecology.

1. Attention to Ecology and Natural Resources

The attention to ecology and natural resources was a major concern in the *Residual Risk Report to Congress*, and I strongly encouraged the Agency to place ecology at parity with human health in this effort. Some assurances were made in that review exercise that ecology would be given more attention.

In the case of the *Secondary Smelters*, the case for ecology and natural resources is again diminished by the Agency. The effort is clearly well behind the analysis being conducted for human health and is not at a stage where this reviewer can be comfortable with a positive review. In short, while we have made some progress, there is insufficient analysis conducted to meet the legal mandate of the CAA.

This issue is a major one and warrants high visibility. My recommendation is for the committee to exhort the Agency to be more forthcoming with resources in order to get the task done in a scientifically sound manner.

2. Not a Risk Assessment But a Risk/Hazard Characterization

The title of the Agency's report is *A Case Study Residual Risk Assessment: Secondary Lead Smelter Source Category. Risk Characterization*. Following the original review of the draft *Residual Risk Report to Congress*, this reviewer was expecting an analysis that was more nearly a

risk assessment. What was presented was a hazard characterization for ecology and natural resources, and the analysis was preliminary at best. Moreover, the Agency stated that no further work toward a risk assessment would be conducted for ecology and natural resources.

As a consequence, the current analysis does not meet the legal mandate of the CAA.

3. If this is the final product for this source category...

Because this report establishes a methodology for analyzing 179 source categories, it is very important that this report be done right. In light of the Agency's commitment to a preliminary hazard characterization *in lieu* of what is the legal mandate, I am concerned that this document will establish a precedent for all subsequent analyses so that ecology and natural resources are poorly addressed. As it now stands, the methodology produces a high number of false positives and fails to incorporate some pathways and receptors that are the most sensitive ones in an ecosystem with respect to persistent and bioaccumulated chemicals.

The proposed methodology is not likely to be of value in assessing the residual risk to ecology and natural resources and is likely to leave the risk manager with a formidable problem in handling the purported risks.

4. Linkage to Risk Manager

The shortcomings of the current report are presented above and are worthy of attention. Above and beyond these shortcomings is the linkage of the risk assessment to the task of the risk manager. There is no discussion of how the risk manager is likely to use this assessment.

It is recommended that a framework for the risk management be made a part of this report. The same recommendation was made for the previous report (*Residual Risk Report to Congress*) by the SAB.

5. Conclusion That the Analysis is Conservative

This assertion is stated throughout the report, and I am not in full agreement with that distinction with respect to ecology and natural resources. My rationale is twofold. Most importantly, the omission of fish eating birds (top carnivores) removes one of the top predators in terrestrial/aquatic systems and one of the receptors that is highly valued (charismatic megafauna). In my analysis of the report, mercury would easily have been identified as a risk had this trophic level been included; it probably would have been the dominant risk. The argument that predatory fish are included does not suffice since predatory birds consume predatory fish, so there is an additional trophic level for bioaccumulation. The argument that data do not exist to evaluate this receptor is not accurate.

The second point is more tangential. The analysis for ecology identified a number of HAPs with concern in the screening exercise. Most, if not all, of these are likely to be "false positives". For

example, antimony is screened as a risk, but I have never read a paper dealing with ecotoxicology to plants of antimony. The citation for the benchmark is an old paper published in an agricultural setting. The point is the false positives are almost to the point of being “silly” and can be easily discounted by the risk manager. This “silliness” might establish a precedent for ecology and natural resources that would permeate all 179 analyses.

I would much prefer to see a screening exercise that covers the potential serious risks (e.g., bioaccumulated HAPs in top carnivores) than marginal risks, and I think that is the objective of the legal mandate.

6. HAPs That are Persistent and Bioaccumulated

The tenet is stated that any HAPs that is persistent and bioaccumulated is automatically carried to the next level (multipathway not refined analysis?). I think those terms are confusing (e.g., if it is bioaccumulated, by definition it is persistent; some persistent HAPs may not be bioaccumulated). I am not certain what this statement means.

Most HAPs by definition are persistent. Lead, Ni, Hg, etc...are elements and by definition are persistent. Most of the HAPs are also accumulated to some extent simply because many are lipophilic either as elements or in the complexes they form. So, there must be a threshold for bioaccumulation. Does that have to be a trophic enhancement factor of 2?

7. Background Concentrations

This issue was raised in the previous review and I encourage the Agency to re-think its position. While there may be some rationale for assuming a zero background concentration in the screening exercise, there are some major liabilities even at this level for pursuing this line of reasoning.

Even more difficult is the next level of analysis in which exposure-response functions might be generated. Given that many of the HAPs are elements and are common geochemical constituents in the crust, not addressing this issue is likely to undercut the conclusions significantly from a scientific basis.

Specific Comments

This review supplements the forgoing analysis, which is more general. The comments herein are more specific and either supportive of the above or individualistic.

1. More refined analysis. The argument is presented often about the next iteration, which is a refined analysis. The structure and refinements to be done in that analysis are not presented. Is this to be a full risk assessment?
2. Screening for chronic effects protects for acute effects. While I can appreciate why shortcuts are used, I am not certain that this position is true. I can think of several cases where chronic

exposures would not protect against acute exposures. For example, if you had a fugitive emission of a toxic chemical with a high 1 hour exposure, over the course of the season that exposure would not be significant but may very well compromise some receptors (e.g., radiochemicals, ozone). Can you provide a citation that supports the position?

3. Background concentration. This issue was raised in the previous review, and I am not in favor of the position being taken in the report. While the screening exercise may opt to assume that the background concentration is zero, this is NOT a conservative decision. In fact, it may significantly negate many HAPs (particularly those that are elements common in the earth's crust) from ever accumulating enough to exceed a threshold.

I recommend that the Agency re-consider its position on background exposures, particularly as one moves on to more refined analyses. From my perspective, this omission negates the Agency's position that the analysis is conservative. Moreover, I do not think you can conduct a more refined analysis without including a background exposure for either human health or ecology. But, in the case of the latter, it is clearly critical.

4. Modifications to the multipathway model. It is noted that the analysis used the multipathway model in the *Mercury Report to Congress* for this modeling effort but that the model was modified on a HAPs-specific basis. Those modifications are important to state since they could underpin the analysis.
5. Dispersion modeling. The report uses a dispersion model (Gaussian) to handle the off-site transport of HAPs. The guts of the model are not presented and key aspects are missing that might help skeptics relate to the code. Is deposition velocity (Vg) the operative parameters for driving deposition? If so, what nonlinear relationship is being used? Is particle size a part of the emission data? If not, then Vg cannot be used.
6. Figure 3.1 is missing but discussed in the text.
7. Plant Characteristics. Plants appear to be one of the critical parts of the model as the exposure to humans is preceded by deposition to leafy vegetable. This part of the code needs to be reviewed for such features as leaf area index, Vg, seasonality of phenology, yield, foliar leaching, etc. My suspicion is that none of these factors are part of the model, so it is unclear that the model handles the atmosphere-leaf transfer very well.
8. Figure 3.3. It is customary in compartment model diagrams to show compartments/state variables as boxes and transfers as ovals or some other geometric shape. They mean very different things. Also, is the half-life (T1/2) part of the model for HAPs? If so, a table of T1/2's should be published. This is an important parameter.
9. The argument is presented that the mercury concentration in fish is a function of the mercury concentration in water. Is that true? I do not see how this could be coded into an aquatic model with multiple trophic levels? The mercury concentration in water must be processed through several intervening trophic levels before it gets to fish and thereafter it is bioaccumulated as a function of the trophic level.
10. The summary for all sections is not a summary. The summaries relate the methodology but not the summary of using the mythology for this exercise on lead smelters.
11. What are the endpoints in ecology and natural resources? In human health it is the farmer and his family. Clearly state the endpoints for this hazard characterization.
12. It is stated that the structure and function of the ecosystems is an endpoint. I have difficulty with

that position.

13. It is stated that rare and endangered species are an endpoint. Again, I have trouble with that position.
14. Are receptors the same as assessment endpoints?
15. Why are carnivorous terrestrial wildlife omitted? These are likely to be the “charismatic megafauna” of most interest and the ones at greatest risk from HAPs that are bioaccumulated.
16. EC50 derivation. The argument is presented to derive some benchmarks from EC50's by dividing by a factor of 10. I am not certain that is justified. I would prefer to simply leave the benchmarks as stated in the literature rather than deriving some. This will eliminate a number of false positives and will help add credibility.
17. Summing HQ's. As noted above, this approach needs to be done with extreme caution.
18. Bioaccumulation. It is stated that bioaccumulation is assumed to be 100%. I am not sure what that means. Does that mean 100% of the HAP in the system is bioaccumulated to the next trophic level? If so, what BAF is used?
19. All chemicals without data are analyzed further. This is difficult to imagine. But, if there are insufficient data to conduct a screening analysis, how could there possibly be enough data to do a more refined analysis?
20. Fugitive Emissions. While I understand that fugitive emissions can be important, I am skeptical of the methodology that shows the entire assessment being driven by fugitive emissions. From my knowledge of ecology and human health, that simply does not compute.
21. False positives for ecology. This is where I think the methodology suffers, and I recommend that some remediation is in order. The ecology risk section concludes that several HAPs –antimony, chromium, and nickel- are a significant enough risk to warrant further study. I am not aware of any report for antimony in plants that would warrant that conclusion and probably the same for chromium and lead and nickel. The creation of many false positions that are unrealistic will be self defeating in the long run.
22. False negatives for ecology. In contrast to the above concern, there are some HAPs that are missing for methodological reasons. The most notable is mercury, which can be traced to the absence of top carnivores in terrestrial ecosystems.
23. Appendix F, Table F.2. The equation for calculating dry deposition simply does not work as portrayed. The units do not cancel out to arrive at the correct units.
24. Appendix E. The hazards with fugitive emissions are an order of magnitude higher than those without fugitive emissions. This seems inordinately high.
25. Distance for dispersion. The distance used for dispersion and assessment needs to be defined. Clearly it is not the distance traveled by the HAPs after emission, which for some of these (e.g., mercury) is global.
26. Air stagnation events. How are air stagnation events handled in the model?
27. Criteria pollutants. While I understand some of the legal mandate for this analysis, I suspect that some of the most significant residual risk from these categories will be the impact of the criteria pollutants, notably ozone and PM2.5. This liability is best presented up front so the caveats are well articulated.

9. Dr. Rae Zimmerman

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Basis for Case Study selection

The rationale for the choice of secondary lead smelters as a case that will become a prototype is only briefly described and should be expanded. Why is it significant and prototypical? Is it like other industrial emission sources?

The change in capacity or use of these smelters might be one reason for their being a significant case. The discussion on p. 5 alludes to a reduction in the number of lead smelters nationwide in 1999 over 1993-1994 levels. Capacity is really key, however. Has the capacity of the remaining smelters increased? Is the need for them changing, i.e., what is the quantity of lead-acid batteries needing recycling?

One very strong reason for its selection is that it is central to the debate over electric cars (see debate in Science, 1995). The contribution of lead smelters to air pollution in the course of recycling lead-acid batteries is part of the overall assessment of the relative environmental impact of electric cars over the conventional automobile. Thus, the relative risk associated with secondary lead smelters addresses a much broader health debate.

Methodological Issues

A number of methodological issues need greater explanation or some references to justify methodological approaches and choices.

- a. p. 6 – the expediency of using a surrogate standard for all metals is clear, but why was lead selected?
- b. p. 9 – what is the justification for using inhalation analysis for all HAPs rather than the ingestion route also, e.g., via soil deposition and subsequent entrainment in exposure areas? p. 14 also notes that inhalation pathway is the most important route of exposure, which needs a short explanation.
- c. Decisions are made throughout the analysis, and should be explained. For example:
- d. p. 9 How is the subset of facilities selected – just high emission rate rather than mix of HAPs? In other words a facility with a high emission rate may have low concentrations of HAPs.
- e. p. 10 Receptor locations chosen as the point of maximum air concentration – was this regardless of the number and type of HAPs?
- f. p. 10 How were the three HAPs and three pathways selected for the variability and uncertainty analyses?
- g. Is there any way of identifying which of the HAPs present in the emission stream are likely to react with one another to increase or reduce residual risk?
- h. The rationale behind the use of very numerous assumptions/defaults at any given point in the assessment is difficult to evaluate, e.g., p. 24, 32. On p. 24, for example, there are

numerous simplifying assumptions for the inhalation screening analysis. How do these assumptions interact with one another and affect the results?

i. In areas where information is not known, can't the Agency undertake some scenario building to at least identify some of the boundaries? For example:

1) Geographic differences in the location of the smelters and the effects of this variation on exposure are not included, but need to be factored in somehow into the analyses. For example, p. 24-25 the building downwash or terrain options for SCREEN3 were not used because site specific information was not available. This is important, however, since the report specifically identifies that the use of such options can result in higher values for air pollutants. What about using locational scenarios?

2) Where information on d/r for HAPs was not available the HAPs were excluded from the analysis (p. 33) – Does the uncertainty analysis at least include the fact that “HAPs for which quantitative d/r assessments are not available” were excluded from the quantitative analysis?

j. p. 30 The technique for aggregating cancer risks is additivity. The drawbacks of this yet the need should be clearly stated, as well as how additivity is likely to affect the results.

APPENDIX B

A MORE DETAILED DESCRIPTION OF THE SAB PROCESS

The SAB Staff recruited Dr. Philip Hopke, Chair of the Chemistry Department at Clarkson University, to serve as Chair of the Subcommittee. Working with the Chair, other SAB Members and Consultants, Agency Staff, and submissions from the American Industrial Health Council (AIHC) and the Natural Resources Defense Council (NRDC), the SAB Staff compiled a list of over 30 scientists and engineers who were subsequently surveyed for their interest in and availability for participating in the review. The Chair and SAB Staff made the final selections for membership on the Subcommittee and assigned different members lead and associate responsibilities for each of the Charge Elements.

The Agency transmitted review materials to the Subcommittee members in late January. In mid-February SAB Staff convened a conference call with Agency staff to identify gaps in the information sent to the Subcommittee and to identify areas that the Agency should be prepared to clarify at the face-to-face meeting.

In addition, public comments were received from the follow parties and distributed to the Subcommittee Members before the meeting:

- a. Association of Battery Recyclers and the Lead Industries Association:
 - Robert Steinsurtzel and Michael Wigmore – Swidler Berlin Shereff Friedman (Counsel for Association of Battery Recyclers)
 - Jane Luxton and Cynthia A.M. Stroman -- King and Spalding (Counsel for Lead Industries Association, Inc.)
 - Dr. Teresa S. Bowers -- Gradient Corporation
 - Russell S. Kemp -- Lake Engineering
- b. Cambridge Environmental Inc:
 - Dr. Edmund Crouch and Dr. Stephen Zemba
- c. Indiana Department of Environmental Management
 - Mr. Michael Brooks
- d. Residual risk Coalition:
 - Dr. Elizabeth Anderson -- Sciences International, Inc.
- e. Sanders Lead Company, Inc:
 - Mr. Billy Nichols, Dames & Moore

On March 1-2, 2000 the Subcommittee convened in the Main Auditorium of Environmental Research Center at the USEPA laboratory in Research Triangle Park, NC. Minutes of the meeting are available. Each member of the Subcommittee submitted written comments on the Charge questions for which he/she had lead responsibility. Two members of the public (Dr. Elizabeth Anderson and Dr. Teresa Bowers, see a and d above) provided comments on the technical issues under discussion. Following a full day of discussion, Subcommittee members drafted and reviewed responses to the Charge questions.

The Subcommittee members were given the opportunity to refine their pre-meeting comments for their inclusion in the Appendix A to the Advisory. These written materials formed the basis of this Subcommittee Advisory that was drafted by the Chair and the SAB Staff and subsequently modified/approved by the Subcommittee. [An SAB "Advisory" is a term-of-art used to denote review of an Agency document that is still undergoing development, in contrast to an SAB "Review" of a final Agency product.] The Subcommittee-approved draft was sent to the SAB Executive Committee (EC) for action during a publicly accessible conference call on May 1, 2000. At that meeting the EC approved the Advisory, subject to final approval by designated vettors, Dr. Kenneth Cummins and Dr. Linda Greer.

APPENDIX C

GLOSSARY

AEI	Average exposed individual
ATSDR	Agency for Toxic Substances and Disease Registry
BID	Background Information Document
CalEPA	California Environmental Protection Agency
CAAA	Clean Air Acts Amendments of 1990
CDC	Centers for Disease Control and Prevention
CRARM	Commission on Risk Assessment and Risk Management
HAPs	Hazardous air pollutants
HEAST	Health Effects Assessment Summary Tables
HI	Hazard index
HQ	Hazard quotient
IEM-2M	Indirect Exposure Methodology
IRIS	Integrated Risk Information System
ISCST3	Industrial Source Complex Short Term model
MACT	Maximum achievable control technology
MEI	Maximum exposed individual
MIR	Maximum individual risk
NAAQS	National Ambient Air Quality Standard
NATA	National Air Toxics Assessment
NESHAP	National Emission Standards for Hazardous Air Pollutants
NRC	National Research Council
OAQPS	Office Air Quality Planning and Standards
PAHs	Polyaromatic hydrocarbons
QSAR	Quantitative Structure-Activity Relationships
PBTs	Persistent bioaccumulative toxicants
RfD	Reference Dose
RTC	Agency's 1998 Report to Congress
SAB	Science Advisory Board
TRIM	Total Risk Integration Model
TRVs	Toxicity Reference Values
U&V	Uncertainty and variability
USEPA	United States Environmental Protection Agency