UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

DATE

The Honorable Lisa P. Jackson
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Subject: SAB Review of EPA's *Approach for Developing Lead Dust Hazard Standards for Residences (November 2010 Draft)* and *Approach for Developing Lead Dust Hazard Standards for Public and Commercial Buildings (November 2010 Draft)*

Dear Administrator Jackson:

In 2001, EPA's Office of Pollution Prevention and Toxics (OPPT), under the Toxic Substances Control Act (TSCA), established lead dust hazard standards for residential buildings. The standards are used to identify the presence of lead hazards and are also used as clearance standards for lead abatement activities. OPPT is considering possible revision of the residential lead dust hazard standards as well as the development of lead dust hazard standards for public and commercial buildings. OPPT developed two draft documents entitled *Approach for Developing Lead Dust Hazard Standards for Residences (November 2010 Draft)* (hereafter referred to as the "Residential Document") and *Approach for Developing Lead Dust Hazard Standards for Public and Commercial Buildings (November 2010 Draft)* (hereafter referred to as the "Public and Commercial Document") which describe the technical approach for developing the standards. OPPT sought consultative advice from the SAB Lead Review Panel on early drafts of the documents and requested SAB peer review of the revised documents.

The technical approach in both documents is very similar and involves estimating blood lead levels resulting from candidate dust lead standards (using both empirical data and biokinetic modeling) and comparison against target blood lead concentrations that are associated with adverse health effects. In both documents, the candidate lead dust standards are intended to protect against IQ deficits in children. In the Public and Commercial Document additional candidate lead dust standards are intended to protect against hypertension in adults.

The SAB was asked to comment on the clarity and transparency of the documents, empirical modeling, biokinetic modeling, analyses of variability and uncertainty, and choice of models for developing the lead dust hazard standards. The SAB Lead Review Panel held a public meeting on December 6-7, 2010 to deliberate on the charge questions. The two documents utilize a very similar technical approach and the charge questions are nearly identical. Although the Panel discussed the two documents separately, the Panel's written response to the charge questions are applicable to both documents, except where noted in the report. For both documents, the SAB supports the overall modeling approaches and believes that they provide the best available means for establishing the quantitative relationship for predicting blood lead from dust lead levels. The SAB has a number of recommendations aimed at improving the application of several models discussed in the documents. The SAB responses to the EPA's charge questions are detailed in the report. The SAB major comments and recommendations for both documents are provided below.

- The SAB finds that the documents did not provide an adequate context for how the standards will be used. The clarity and transparency of the documents can be improved by establishing the context for how the standards will be used, e.g. to establish health protective guidelines for residential and public building lead dust loadings. The clarity and approachability of the documents can also be improved with the addition of executive summaries.

- The SAB supports EPA's reliance on the highly relevant and recent empirical findings from the National Health and Nutrition Examination Survey (NHANES) to establish the quantitative relationship between lead loading and blood lead concentrations. In EPA's reanalysis of the NHANES data, the lead concentration in dust was estimated from measured loading values. Since loading is a better predictor of blood-Pb, SAB recommends assessing the lead dust loading to blood lead level relationship directly, without converting dust lead loading to lead dust concentration.

- The SAB is concerned that the lower dust lead levels from the NHANES data were not included in establishing the relationship between dust lead and blood lead. The SAB recommends examining the full range of NHANES data including the lower dust lead loading levels. The SAB is concerned that EPA's reanalysis of the NHANES data does not reflect the importance of window sill contributions to blood lead and that EPA did not determine whether the NHANES data was representative of high risk exposures and the national housing stock. The SAB recommends comparing the results to other epidemiologic data to address these concerns.

- The SAB recommends including biokinetic modeling using the default input parameters used by EPA's Superfund Program. The SAB finds the predicted blood lead results from the biokinetic modeling associated with the candidate standards to be underestimated due to the selection of input parameters that differ from the defaults.

- The SAB recognizes that there is little to no empirical data related to lead dust exposures in public and commercial buildings and that using empirical data from residential settings introduces uncertainty.

- The SAB finds EPA's proposed use of an absolute target blood lead concentration requires the estimation of lead exposures from other media (including air, water, soil, and diet), which introduces considerable uncertainty. This uncertainty can be reduced by using an incremental risk assessment approach. The SAB strongly recommends the use of an incremental risk assessment approach which assesses how changes in *incremental* dust lead levels result in *incremental* changes in blood lead levels.

- The SAB is not able to provide a recommendation about model selection (charge question 2) without the benefit of the analyses described above.

The SAB appreciates the opportunity to provide EPA with advice. The SAB would be pleased to provide additional advice on this subject matter.

Sincerely,

Dr. Deborah L. Swackhamer	Dr. Timothy Buckley
Chair	Chair
EPA Science Advisory Board	SAB Lead Review Panel

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ACRONYMS

ALM	Adult Lead Methodology
EPA	United States Environmental Protection Agency
GM	Geometric Mean
GSD	Geometric Standard Deviation
HUD	United States Department of Housing and Urban Development
IEUBK	Integrated Exposure Uptake Biokinetic Model
NHANES	National Health and Nutrition Examination Survey
OPPT	EPA's Office of Pollution Prevention and Toxics
Pb	Lead
PbB	Blood lead
PbD	Dust lead
QL	Quasi-likelihood
SAB	Science Advisory Board

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1. EXECUTIVE SUMMARY

This report was prepared by the Science Advisory Board (SAB) Lead Review Panel (the "Panel") in response to a request by EPA's Office of Pollution Prevention and Toxics (OPPT) to review two documents entitled *Approach for Developing Lead Dust Hazard Standards for Residences (November 2010 Draft)* (hereafter referred to as the "Residential Document") and *Approach for Developing Lead Dust Hazard Standards for Public and Commercial Buildings (November 2010 Draft)* (hereafter referred to as the "Public and Commercial Buildings Document"). OPPT sought consultative advice from the SAB Lead Review Panel on early drafts of the documents (USEPA SAB Lead Review Panel, 2010) and sought SAB peer review of these documents. The SAB Lead Review Panel held a public meeting on December 6-7, 2010 and deliberated on the charge questions (see Appendix A). There were 5 charge questions for each document that focused on: the clarity and transparency of the document, empirical modeling, biokinetic modeling, analysis of variability and uncertainty, and choice of model. The two documents utilize a very similar technical approach and the charge questions are nearly identical. Although the Panel discussed the two documents separately, the Panel's written response to the charge questions are applicable to both documents, except where noted in the report. This Executive Summary highlights the Panel's major findings and recommendations.

<u>Overall Technical Approach</u>

EPA's Residential Document describes the methods that EPA proposes to develop candidate lead dust hazard standards for floors and windowsills in residences. Blood lead levels resulting from candidate lead dust standards are estimated using two different modeling approaches, i.e. empirical and biokinetic. The results are compared against a range of blood lead levels that offer differing levels of protection against IQ deficits in children.

EPA's Public and Commercial Document describes the methods that EPA proposes to develop candidate lead dust hazard standards for floors and windowsills in public and commercial buildings. The approach for estimating the impact of candidate lead dust hazard standards on children in public and commercial buildings is identical to the approach used in the Residential Document. The Public and Commercial Document also estimates adult blood lead levels associated with the candidate lead dust hazard standards using biokinetic models and are compared against a range of blood lead levels that offer differing levels of protection against hypertension in adults.

The SAB generally supports the overall modeling approaches described in both documents. The SAB also supports EPA's selection of target blood lead levels of 1 µg/dL and 2.5 µg/dL for children, but does not support the high blood lead value of 5 µg/dL due to recent studies indicating significant adverse health effects in children with blood lead levels well below 10 µg/dL.

The SAB finds EPA's proposed use of an absolute target blood lead concentration requires the estimation of lead exposures from other media (including air, water, soil, and diet), which introduces considerable uncertainty. This uncertainty can be reduced by using an incremental risk assessment approach. The SAB strongly recommends the use of an incremental risk assessment approach which assesses how changes in *incremental* dust lead levels result in *incremental* changes in blood lead levels.

With a few key exceptions, the SAB found both documents to be thoughtfully developed and well written. These documents provide important quantitative insights into the relationships among the variables and the value of different models for estimating blood lead levels from lead dust hazards. The general overall approaches discussed in the documents were clear. However, the overall clarity and transparency of both documents can be improved by including an executive summary, providing an adequate context for how the standards will be used, expanding the discussions on the degree of improvement in blood lead levels that differing candidate dust lead levels will achieve, and providing an analysis of the differences between the different approaches.

Empirical Models

Under the Agency's empirical modeling approach, the blood to dust lead relationship is derived from the National Health Nutrition Examination Survey (NHANES) data as described in Dixon et al. (2009). However, EPA deviated from the analysis provided by Dixon et al. (2009) due to concerns over their use of log-log regression model approach and other criticisms. The SAB did not find many of the criticisms of the Dixon model to be well-supported, lacking clarity and in some instances were inaccurate. The SAB expresses confidence in the Dixon model results and recommends that the Agency continue to include these results in comparisons between the various modeling approaches.

EPA also performed a reanalysis of the NHANES data using a quasi-likelihood generalized linear modeling methods (hereafter, the "NHANES QL model"). EPA's reanalysis using the NHANES QL model included a conversion from dust loading to dust concentration in order to compare the results with the results of the biokinetic modeling. The SAB expresses support for the NHANES QL model, but strongly recommends that EPA perform a direct analysis of the dust lead loading to blood lead relationship without converting dust loading to dust concentration. For comparison purposes, the SAB recommends that the dust loading to dust concentration conversion be performed on the biokinetic modeling. The SAB further recommends that EPA include data from other studies describing the relationship of lead loading to concentration to provide additional context.

The SAB is concerned that EPA's reanalysis underestimates the influence of window sill dust lead on children's blood lead and that EPA did not examine whether the dataset was representative of high risk environments and the national housing stock. The SAB recommends comparing and/or validating the results from EPA's modeling exercises against the relevant empirical data in the literature.

The SAB is concerned that EPA's reanalysis did not include dust lead levels below 5 $\mu g/ft^2$. This unnecessarily limits the models and reduces the document's transparency. The SAB recommends that these lower dust loading levels be included.

<u>Biokinetic Models</u>

In both documents, EPA used two biokinetic models, the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK) and the Leggett model, to estimate children's blood lead concentrations resulting from the candidate dust lead standards. The SAB finds that the results from the IEUBK model used in this approach are underestimated due to the selection of input parameters differing from the default input parameters recommended by EPA's Superfund Program. The SAB recommends including IEUBK modeling using the default input parameters. The SAB also recommends providing greater transparency in the rationale for the selection of input parameters differing from the defaults. The SAB does not support the use of the Leggett model for estimating children's blood lead concentrations and recommends that the results be moved to an appendix.

In the Public and Commercial Document, EPA used the Leggett model and the Adult Lead Methodology (ALM) to estimate adult blood lead levels resulting from the candidate lead dust standards. The SAB supports the use of the ALM because it produces more plausible results than the Leggett model, is simple to use, and is used extensively in EPA's Superfund Program.

<u>Analyses of Variability and Uncertainty</u>

EPA expressed the results of the biokinetic modeling as a lognormal distribution using a geometric standard deviation (GSD) as a way of representing variability. The SAB supports expressing variability for the biokinetic modeling in this manner. For the empirical modeling results, the SAB recommends estimating the variability in the predicted PbB distribution directly from the NHANES data.

The SAB acknowledges limited empirical data for relating dust lead to blood lead in public and commercial buildings. The NHANES data relates dust lead to blood lead in residential settings and application of this data set in establishing the dust lead to blood lead relationship in public and commercial buildings introduces uncertainty.

EPA's risk metric is based on an absolute blood lead concentration, which places a burden on the models to properly account for all major sources of lead exposure. The estimation of background exposure from non-dust sources (diet, air, soil, water) introduces many sources of uncertainty. The SAB recommends an incremental risk assessment approach which focuses on the slope of the blood lead (PbB) to dust lead (PbD) relationship. For the empirical models, the incremental PbB can be estimated directly from the partial regression plots and, possibly, from the standardized coefficients of the regression. For the biokinetic models, there is no need to estimate exposures from non-dust sources, thereby eliminating many sources of uncertainty.

The main concern with using the NHANES data to develop a dust loading hazard level is the structure of the database, which shows a large number of low dust lead levels and relatively low number of high blood lead levels. EPA has performed appropriate analyses to adjust for covariates. However, the overall model fit is weak-to-moderate (explaining less than 50% of variance) and it has a high non-zero intercept term. Clearly, there are many factors that contribute to the variance in PbB. Unmeasured variables effects, which are reflected in the intercept values of the regressions, require further consideration. Uncertainty in the intercept directly affects the baseline blood lead level and also increases the variance and uncertainty in the predicted values.

The input parameters used in the IEUBK model runs differ from those recommended in other Agency regulatory programs. For the child receptor, a range of geometric standard deviation (GSD) parameters are derived from NHANES survey results. Variability in measured PbBs reflects variability from multiple sources of exposure, including differences in dust lead loadings (and concentrations). This represents a departure from the concept underlying the use of the IEUBK model in which the distribution is intended to reflect variability in the population of children that may be exposed to the same media concentration. Further discussion of this difference in modeling approaches and the extent to which the risk metric is intended to reflect differences in dust lead loadings should be included. The SAB recommends running the biokinetic models in three ways: (1) using the standard Agency default parameters, (2) adjust the baseline input parameters to those values that best reflect the NHANES population, and (3) adjusting the baseline parameters to those values that best reflect the population to which the regulation will apply.

Agreement between the mean empirical estimates and the biokinetic modeling estimates would provide considerable comfort in using either, or both, to develop a standard. On the other hand, significant differences in the means or intercept values could suggest that the baseline PbBs are not adequately explained, or there are important input variables missing, or the NHANES database is not representative of the population of concern and the intercept includes significant unmeasured effects.

<u>Choice of Model for Hazard Standards</u>

For both documents, OPPT proposes to use the NHANES Quasi-Likelihood, Empirical Model to estimate children's blood lead levels from the candidate lead dust standards. As discussed in the empirical modeling section of this report, the SAB supports the use of the NHANES QL model. However, the documents do not provide an adequate scientific justification for the Agency's choice of the model. The SAB also expresses confidence in the results of the NHANES Dixon et al. (2009) log-log model. Moreover, the SAB expresses concern about the OPPT's implementation of the IEUBK model and judges it premature to reject the IEUBK approach.

The SAB recommends comparing the results obtained from the revised NHANES QL and IEUBK models to existing results of the Dixon model, using methods comparable to those employed in the approach document. Until then, the SAB is unable to conclude which modeling approach is most scientifically sound.

For the Public and Commercial Document, OPPT proposes to use the Adult Lead Methodology to estimate adult blood lead levels form the candidate lead dust standards. As discussed in the biokinetic modeling section of the report, the SAB supports the use of the ALM over the Leggett model for this analysis.

2. BACKGROUND

Human exposure to lead may cause a variety of adverse health effects, particularly in children. EPA's Office of Pollution Prevention and Toxics (OPPT) regulates toxic substances, such as lead, through the Toxic Substances Control Act (TSCA). Through TSCA, OPPT established lead dust hazard standards for residential buildings in 2001. Under these standards, lead is considered a hazard when equal to or exceeding 40 micrograms (µg) of lead in dust per square foot on floors and 250 micrograms of lead in dust per square foot on interior window sills. The standards are used to identify the presence of lead hazards and are also used as clearance standards for lead abatement activities. OPPT is considering possible revision of the residential lead dust hazard standards as well as the development of lead dust hazard standards for public and commercial buildings.

OPPT previously sought consultative advice from the SAB Lead Review Panel on early drafts of technical approach (August 2010 Consultation Report) and sought SAB peer review of two draft documents entitled *Approach for Developing Lead Dust Hazard Standards for Residences (November 2010 Draft)* (hereafter referred to as the "Residential Document") and *Approach for Developing Lead Dust Hazard Standards for Public and Commercial Buildings (November 2010 Draft)* (hereafter referred to as the "Public and Commercial Document") which describe the technical approach for developing the standards.

EPA's charge questions on these two documents are presented in Appendix A, and focus on the clarity and transparency of the document, empirical modeling, biokinetic modeling, analysis of variability and uncertainty, and choice of model. The SAB Lead Review Panel held a public meeting on December 6-7, 2010 to deliberate on the charge questions. The two documents utilize the same technical approach and the charge questions are nearly identical. Although the Panel discussed the two documents separately, the Panel's written response to the charge questions are applicable to both documents, except where noted in the report.

3. RESPONSE TO EPA CHARGE QUESTIONS

3.1. Charge Question 1 – Approach Document

OPPT has developed an Approach document for developing the hazard standards for floors and windowsills in residences and public and commercial buildings. This includes a description of the empirical and biokinetic approaches, as well as the resultant analyses used to estimate candidate lead dust hazard standards for residences. Please comment on the clarity and transparency of the document.

(The charge question for the Public and Commercial Document is very similar.)

This general charge question pertains to the overall approach and the clarity and transparency of the documents. EPA's Residential Document describes the approach EPA has taken to examine candidate lead dust hazard standards for floors and windowsills in residences. Blood lead levels resulting from candidate lead dust standards are estimated using two different modeling approaches, empirical and biokinetic. The results are compared against a range of blood lead levels that offer differing levels of protection against IQ deficits in children.

EPA's Public and Commercial Document describes the methods that EPA proposes to examine candidate lead dust hazard standards for floors and windowsills in public and commercial buildings. The approach for estimating the impact of candidate lead dust hazard standards on children in public and commercial buildings is identical to the approach used in the Residential Document. The Public and Commercial Document also estimates the impact of candidate lead dust hazard standards on adults in public and commercial buildings. Adult blood lead levels resulting from candidate lead dust hazard standards are estimated using the Adult Lead Methodology, which is used extensively in EPA's Superfund Program. The results are compared against a range of blood lead levels that offer differing levels of protection against hypertension in adults.

The SAB generally supports the overall modeling approaches described in both documents and supports EPA's selection of target blood lead levels of 1 and 2.5 µg/dL for children. The SAB believes that a blood lead level of 5 µg/dL for children would not offer sufficient public health protection, due to recent studies indicating significant adverse health effects in children with blood lead levels well below 10 µg/dL. That being said, the SAB believes the current approach of evaluating a dust lead level that *by itself* would achieve a given target blood lead level is flawed, because lead is a multi-media pollutant. This may simply be a function of how the data are presented. In any case, the SAB concludes that a simpler and more scientifically valid approach is to assess how changes in *incremental* dust lead levels result in *incremental* changes in blood lead levels, holding important covariates and other exposure inputs (i.e. air, water, soil, diet) at either zero and/or at national averages. This dynamic approach has been adopted by the Office of Environmental Health Hazard Assessment of the California Environmental Protection Agency (Carlisle and Dowling, 2007; Carlisle, 2009) and was also used in a pooled analysis of dust lead/blood lead studies (Lanphear et al., 1998). This approach requires a means of determining the incremental impact on blood lead resulting from exposure to both floor and sill lead dust. This can be achieved using both the biokinetic and empirical models and helps to alleviate uncertainty about the assumptions made for all other sources of lead exposure and the uncertainty about the absolute blood lead levels. This method will enable the Agency to focus on likely changes in blood lead from a decrement in dust lead levels, instead of the method in the Approach document, which seems to imply that little improvement is likely to occur, regardless of dust lead level, because current population blood lead levels are near the target blood lead level. Further details are presented in the response to Charge Question 4.

With a few key exceptions, both documents are well written. These analyses provide important quantitative insights into the relationships among the variables and the value of different models for predicting residential lead dust hazards for US children. The general overall approaches discussed in the documents were clear. However, there are several critical ways in which the overall clarity and transparency of both documents can be improved. Comments and recommendations on the clarity and transparency of specific assumptions and calculations of the empirical and biokinetic modeling are presented in the responses to those charge questions.

The documents would benefit from an executive summary, which currently is absent. The summary should explain the strengths and weaknesses of both the empirical and mechanistic modeling approaches in a way that can be grasped by practitioners. If indicated, the Executive Summary should conclude with recognition of the generally robust findings across different models and data sets, which serve to strengthen the confidence in the results.

The documents do not currently provide an adequate description of how the standards will be used. There are two principal uses for the standards. The first is as a means to identify a lead dust hazard (as a component of a “lead-based paint hazard”). The second is for “clearance,” i.e., to determine if dust lead levels following repairs or remedial action and cleanup in both market-rate and low-income federally assisted housing and other covered child-occupied facilities and public and commercial buildings has been adequate. For example, if dust lead levels remain at levels above the standard, then repeated cleanup and remedial action would be required until compliance is achieved. In addition, levels of lead dust greater than the standard would be disclosed to residents or buyers before they are obligated under a sales or lease contract, under existing EPA and HUD regulations.

The documents can be made more transparent by expanding the discussions on the degree of improvement in blood lead levels that differing candidate dust lead levels will achieve. The residential document states, “The results of the analyses…confirm that, under reasonable input assumptions, both the empirical and biokinetic models predict that large proportions (17–99 percent) of young children would have blood-lead levels above all three target levels, even if the standards were set at loading levels far less than the current values (40 µg/ft^2 for floor dust and 250 µg/ft^2 for window-sill dust). This general finding is robust across reasonable ranges of model inputs and exposure factor assumptions” (p.45). This seems to imply that no matter how low the standard is set, there will be little protection. Yet the incremental risk assessment approach recommended by the SAB is likely to provide a different conclusion. For example, if the residential floor dust lead standard were to be reduced from 40 µg/ft^2 (the current standard) to 10 µg/ft^2, the percentage of children with blood lead levels above 5 µg/dL would improve from 83% to 53% (using the NHANES quasi-likelihood model, holding window sill dust lead to 50 µg/ft^2). The Dixon log-log model results showed that the same reduction in dust lead levels would result in an improvement from 52% to 24% of children with blood lead levels greater than 5 µg/dL. These improvements are quite large, yet are not transparent in the documents.

The documents can also be made more transparent by showing the magnitude of the differences between the approaches. For example, the geometric mean blood lead levels at a floor dust lead level of 5 µg/ft^2 and window sill dust lead of 50 µg/ft^2 in the Dixon log-log model and the EPA quasi-likelihood (central tendency) model are 3.8 and 4.1 µg/dL, respectively, which does not appear to be a large difference. Similarly, the percent with blood lead levels above 5 µg/dL in both models is 33% and 38% respectively, again, not a large difference.

3.2. Charge Question 2 – Empirical Models

The empirical approach involves the estimation of blood-lead impacts based on analyses of empirical data from the 1999–2004 National Health and Nutrition Examination Survey (NHANES). Two analyses were used. First, the regression relationships among floor and windowsill dust, other covariates, and blood-lead concentrations that Dixon et al. (2009) derived were applied to predict blood-lead levels for the various hazard standards (combinations of floor and windowsill dust loadings). The second was an independent reanalysis of the NHANES data to derive alternate models for predicting blood-lead impacts; the variations from the Dixon et al. (2009) approach included changes to the form of the dust-loading variables and application of models that are inherently linear at low lead exposures, a relationship that is supported by a wide range of biokinetic data, and regression of blood-lead values against estimated dust concentrations, rather than dust loading. Please comment on the EPA reanalysis.

(The charge question for the Public and Commercial Document is very similar.)

The SAB commends the Agency for consideration of empirical data such as NHANES in developing the lead dust hazard standards. The Agency examined the Dixon et al. (2009) analysis of the NHANES data, which used a log-log regression model and also performed a reanalysis of the NHANES data using a quasi-likelihood generalized linear modeling methods (hereafter, the “NHANES QL model”).

<u>Dixon et al (2009) Analysis</u>

The Agency states that the Dixon analysis presents obstacles to its use for evaluating blood-lead impacts of floor and sill dust lead hazard standards. The SAB did not find many of the criticisms of the Dixon model to be well-supported, lacking clarity and in some instances inaccurate.

One of the Agency's main criticisms of the Dixon log-log regression model is that it "does not appear to be consistent with linear low-dose biokinetics (e.g., linear dependence of blood lead on lead dose under steady-state conditions), currently theorized to occur at low levels, that is supported by a large body of experimental and human data (USEPA 2006)" (p. 11 of the Residential Document; p. 22 of the Public and Commercial Document). The SAB does not believe that a linear relationship between low dose lead intake and blood lead in certain human biokinetic studies must constrain the development of an empirical model relating *lead dust loading* to blood lead. The SAB believes that, notwithstanding linear low dose toxicokinetics pertaining to lead ingestion, there can be multiple reasons that might result in a nonlinear relationship between interior dust lead and blood lead in optimized empirical models of the indoor residential environment. For example, these include differential confounding of dust lead by soil lead and nonlinear rates of transfer of dust to the hands and mouth.

EPA also seems to believe that the log-log Dixon analysis shows that blood lead decreases as floor dust lead increases at the upper tail of the empirical data distribution, which of course is not consistent with the idea that higher exposures should result in higher blood lead levels. The Dixon analysis used log transformation because that was the best fit to the empirical dataset. The SAB does not believe that it is correct to state that the log-log approach results in a decrease in blood lead as dust lead increases, because the Dixon model does not in fact show such a relationship. While blood lead levels do appear to level out or plateau at higher floor dust lead levels, none of the published (Lanphear et al., 1998; Lanphear et al., 2002; Dixon et al., 2009), data show the former declining at higher dust lead levels.

In several areas, EPA appears to have misinterpreted the Dixon log-log model. For example, EPA states, "the [Dixon analysis] floor-dust lead loading only enters into the model in the form of interaction terms, not as a main effect." It is not clear why EPA holds this view, because the Dixon analysis was clearly built with floor dust lead as a main effect. The transparency of the EPA documents can be improved if this is clarified.

EPA also states that the Dixon log-log approach introduces co-linearity in the method used to impute missing window sill dust lead loadings. Yet it appears EPA used other variables that are also likely to introduce some co-linearity. The documents' clarity can be improved by a more detailed description of the choice of methods used to impute missing window sill dust lead loadings. Because floor and window sill dust lead levels are so highly correlated, it is not clear why using floor dust lead values to impute missing window sill dust lead values is less valid than the EPA method of imputing missing values. Different imputation methods might best be explored further in the sensitivity analysis sections of documents. Another approach that could be examined for the imputation of missing dust lead loading values, developed specifically for imputing dust lead loading values below the detection limit, is that of Succop et al. (2004).

The SAB has confidence in the Dixon model results and recommends that the Agency continue to include these results in comparisons between the various modeling approaches.

NHANES QL Model

The SAB expresses support for the NHANES QL model used in EPA's reanalysis, but has several comments and recommendations to improve the modeling approach.

Conversion of Dust Loading to Dust Concentration

The QL model used a conversion from dust loading to dust concentration and a second conversion back to dust loading as the output. While it is clearly necessary to convert dust loading to dust concentration for the purposes of comparing the empirical and biokinetic modeling approaches, it is not clear that the dust loading/concentration conversion is needed for the quasi-likelihood empirical data analysis. If the loading/concentration regression is not used, the "noise" in the empirical models will likely be reduced, increasing the certainty in the results. The SAB strongly recommends that EPA perform the analysis using the QL model without the dust loading to dust concentration conversion. The SAB recommends that the dust loading/concentration conversion should take place in the biokinetic modeling.

Additionally, the EPA documents should include analyses of other data sets to determine if the estimated regression of dust lead loading with dust lead concentration is consistent. The estimated regression used by EPA uses data from a HUD National Survey from the 1990s, which used a blue nozzle vacuum dust collection method to compare with dust wipe sampling. There are other data sets, such as the Rochester Lead-In-Dust study (Lanphear et al., 1995) that can be used to assess the validity of the loading/concentration relationship. For example, the Lanphear et al. (1995) study evaluated a wipe sampling method, a cyclone vacuum method, and an open-faced filter cassette vacuum method in a side-by-side study design that assessed the relative predictive value of each method compared to children's blood lead level. It is possible that the different sampling methods capture different particle size distributions, which can in term affect the dust lead level.

Window Sill Dust Lead Assumptions

The EPA reanalysis indicates that window sill dust lead was assumed to contribute only 1 percent of the total dust-lead intake, based on surface area of floors and sills. "When the empirical model was used, the coefficient for floor dust concentration was slightly more than 100 times that for window sill lead concentration. In the regression that used dust concentrations from the mechanistic model as its inputs, the coefficient for floor dust was approximately 700 times that for sill dust concentrations. These results provide additional support to the conclusion from previous studies and biokinetic modeling that <u>sill dust has relatively little influence</u> on children's blood-lead concentration" (p. 18 of the Residential Document; p. 29 of the Public and Commercial Document) (emphasis added).

The SAB believes that EPA may be underestimating the importance of window sill dust lead because empirical data clearly show that window dust lead is much more important than EPA suggests, especially if indirect routes of exposure are considered. For example, Dixon et al. (2009) found that floor PbD had a direct effect on children's PbB, whereas sill PbD had an indirect effect on children's PbB as mediated by floor PbD. Dixon et al. (2009) found that in their NHANES data analysis, floor PbD was more predictive of PbB than sill PbD (R^2 = 19.4% for floors; R^2 = 11.9% for sills; R^2 = 23.0% for floors and sills combined). These R^2 values are far different than the EPA 1% assumption, which, because it is based entirely on the difference between average floor and window sill surface areas, appears to ignore the well-documented fact that window sill dust lead loadings are far higher than floor dust lead levels (Jacobs et al. 2002).

The larger influence of window sills is also supported by a recent HUD-funded study, currently under review, which found that "twelve years after intervention, houses with all replacement windows had 41% lower interior floor dust lead, compared to non-replacement houses (p<0.001) and window sill dust lead was 51% lower (p=0.006). Houses with some windows replaced had interior floor and window sill dust lead loadings that were 28% (p=0.19) and 37% (p=0.07) lower, respectively, compared to non-replacement homes" (Dixon et al. 2010).

In another study, an increase in sill dust lead loading from 50 to 700 µg/ft^2 was associated with a doubling of the proportion of children who have a blood lead level greater than 10 µg/dL, from 10% to 20% (Lanphear, 2006).

In short, the EPA document appears to underestimate the influence of window sill dust lead on children's blood lead. Any results from the modeling exercises needs to be examined and compared or validated against relevant epidemiologic data.

NHANES Data Handling

The SAB has several comments and recommendations on how EPA handled the NHANES data in their reanalysis using the QL model, particularly related to truncation of results, detection limits, and flooring type.

The documents do not display the results of the different models when dust lead levels are below 5 µg/ft^2. This unnecessarily truncates the results and reduces the document's transparency. Greater transparency would be achieved if lower dust lead levels were also examined. For example, the Dixon et al. model displayed the results down to 0.25 µg/ft^2 (Dixon, et al. 2009). While there may be important analytical and feasibility constraints at such a level, the SAB believes that the scientific relationship between dust lead and blood lead should be considered below 5 µg/ft^2 to fully understand the relationship.

The documents lack clarity on exactly how window sill dust lead levels that were below the laboratory limit of detection were handled in the quasi-likelihood empirical data analysis of the NHANES dataset. The Centers for Disease Control (CDC) recommends using 1.41 µg as the detection limit for this dataset. For window sill dust lead samples, however, this detection limit should be divided by the surface area of each window sill sample in order to calculate the correct loading in µg/ft^2, because each window sill surface area will be different. This method would also make the approach more consistent with the Dixon log-log NHANES analysis, which would serve to make the two approaches more consistent and comparable.

The documents are not transparent in how floor surface types in the NHANES dataset are handled. This is important, because the Dixon analysis showed that for smooth and cleanable or carpeted floors, floor dust was associated with significantly higher blood lead levels at dust lead levels below 17 µg/ft^2. But for floors that were not smooth and cleanable and not carpeted, higher floor dust was associated with significantly higher blood lead only below 9 µg/ft^2. The SAB believes the documents should be more transparent in how floor surface types were included.

Comparison of NHANES data with other studies

The SAB concludes that the results of NHANES data modeling should be compared to other epidemiologic studies (see, for example Figure 1 in Dixon et al. 2009). The SAB concludes that the consistency of the slope of dust lead and blood lead levels observed in NHANES and these other epidemiologic studies, which measured soil lead and water lead, provides additional support for using NHANES, despite the limitations (e.g., confounding with soil lead concentrations) described in the documents.

The SAB believes that the documents would gain greater clarity if they were to examine the influence of higher dust lead loadings than those in the NHANES database, because this is likely to be more representative of higher risk environments and because higher dust lead loadings are likely to significantly influence the dust lead/blood lead slope at low levels. The SAB believes that any dust lead standard selected should help to ensure that populations with the highest exposures are adequately protected. Other high exposure data sets that EPA could examine include the Rochester Lead-In-Dust Study (Lanphear et al., 1995), the Evaluation of the HUD Lead Hazard Control Grant Program (NCHH and UC 2004) and the pooled dust analysis (Lanphear et al., 1998). All of these data sets have higher dust lead and blood lead values than the NHANES database.

The SAB believes the documents could be improved by examining how well the NHANES data represent the nation’s housing stock. This could easily be accomplished by comparing certain demographic information in the NHANES database with the American Housing Survey and Current Population Survey databases. Such an exercise was completed for the HUD National Survey of Lead and Allergens in Housing (NSLAH), which found that variables such as region, race and ethnicity, housing tenure and type, poverty-to-income ratio, urbanization and others were not significantly different (Jacobs et al., 2002) when comparing the smaller NSLAH data set to the larger data sets. If the NHANES data are representative of both the population and its housing, confidence and transparency will be increased.

3.2. Charge Question 3 – Biokinetic Models

Two biokinetic models were used to estimate children’s blood lead concentrations including EPA’s Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK), and the Leggett model. Information from the exposure scenarios is used to estimate relative contributions of exposures from different sources (soil, dust, air, diet, and water) and in

different microenvironments. Please comment on the use of these models and the inputs to these models.

(The charge question for the Public and Commercial Document is very similar and has the added statement, "The Leggett model and EPA's Adult Lead Methodology were used to estimate adult blood lead levels resulting from candidate floor and windowsill hazard standards.")

<u>Estimation of Children's Blood Lead Concentrations</u>

The SAB supports the use of the Integrated Exposure Uptake Biokinetic (IEUBK) Model for estimating children's blood lead concentrations for both residential and public and commercial settings, but has specific comments and recommendations for improving the model runs. Additionally, the SAB believes that the Leggett model is less trustworthy for estimating children's blood lead concentrations than the IEUBK model. The SAB therefore recommends moving the results from the Leggett model to an appendix.

The SAB believes that the results from the IEUBK model used in this approach were too low. The SAB believes that this is due to OPPT selecting certain input terms for the IEUBK model that are different from the default input parameters recommended by EPA's Superfund Program. The clarity and transparency of this modeling approach can be enhanced by providing a more complete description and justification for selection of input parameters.

For example, as discussed in more detail later in the section of this report pertaining to variability, the geometric standard deviation is a key parameter in the IEUBK model that requires careful selection, as it exerts considerable influence on the estimated number of children who might have a blood lead increment in excess of a targeted value. For the IEUBK model, the Approach document had used geometric standard deviations (GSDs) of 1.9, 2.1, and 2.3, all of which are in considerably in excess of the default GSD of 1.6 strongly recommended in the IEUBK Guidance Manual (EPA, 2007). The GSD of 1.6 is intended to depict the inherent variability in blood lead that has been found in children exposed to similar levels of lead in environmental media. EPA should utilize a GSD of 1.6, or provide a justification for deviating from this default value.

The SAB recommends providing greater transparency in how the input terms were selected and if they differ from EPA guidance, a discussion of why they selected a different value from the default. Additionally, for comparison purposes, the SAB recommends including IEUBK modeling using the default input parameters.

However, if EPA implements the incremental risk assessment approach as recommended by the SAB, this would obviate the need to specify input values (such as lead in food, water, or air) for all sources of lead other than that present in interior dust.

Estimation of Adult Blood Lead Concentrations

The Leggett model and EPA's Adult Lead Methodology were used to estimate adult blood lead levels resulting from candidate floor and windowsill hazard standards for public and commercial buildings. The SAB supports the use of the Adult Lead Methodology. The ALM is advantageous because it is a relatively simple and easily understood model and because the EPA has considerable experience using the approach. In addition, the ALM produced more plausible estimates of average population PbB concentrations than did the Leggett model. The SAB recommends that the Leggett modeling be moved to an appendix.

Incremental Risk Assessment

As stated previously and discussed in further detail in the response to Charge Question 4, EPA should conduct their modeling in a manner that provides a means to conduct an incremental risk assessment with respect to the relationship between dust and blood lead levels. This requires use of slope factors between blood lead and both floor lead and sill lead. This approach helps to alleviate uncertainty about the assumptions made for all other sources of lead exposure and the uncertainty about the absolute blood lead levels. To conduct the incremental risk assessment, all other exposure factors should be held constant, either at zero or at some baseline exposure level. Once this relationship is established, EPA can decide what incremental increase in blood lead levels should be tolerated (e.g., 1 μg/dL) and then easily decide what dust/sill concentration is associated with this target incremental increase in blood lead levels. A similar incremental approach was used by the State of California to set soil clean up guidelines (Carlise, 2009).

Conversion of Dust Loading to Dust Concentration

As noted previously, the SAB believes that converting dust lead loading to dust lead concentration in the empirical modeling is not favorable. The SAB appreciates the need to make results consistent between the empirical models and biokinetic models. The SAB prefers to use the conversion in reverse to put the biokinetic model results in context. Therefore, for the biokinetic model results, EPA should convert the modeling results from blood lead concentration versus dust lead concentration to blood lead concentration versus dust lead loading.

Steady-State Exposures

It was noted by the SAB that use of IEUBK and the ALM necessitates that EPA only consider chronic, steady-state exposures, which is appropriate for setting the dust lead hazard standards. However, neither of these approaches is scientifically defensible for acute exposures. Furthermore, use of an incremental risk assessment approach also necessitates an assessment of chronic, steady-state exposures to lead.

Other Biokinetic Modeling Issues

Air entrainment of lead from dust are not considered in the biokinetic models. EPA should consider this potential and assess the degree to which current biokinetic modeling results under-predict the effect dust loading has on blood lead predictions. Could this issue partly explain any discrepancies between predictions using the empirical vs. biokinetic models?

The impact lead in soil has on lead concentrations/loading in indoor dust was not adequately addressed in the assessment. The mechanistic model for indoor dust generation (Figure 3-5. Figure E-1 and elsewhere) designates the tracked in material as "soil". This name of this term needs to be expanded to also include exterior dust. The material that is tracked in is derived from a number of locations including the surface of the soil, sidewalks, roadways, porch and entryways etc. This material generally comes from the surfaces of these areas. Soil lead measurements are usually determined for cores of soil, most often about one inch in depth. Mielke et al. (2007) have developed a method (PLOPS) to obtain a sample from the surface of soil areas. Data using such a method would more likely represent tracked in particles than soil core concentrations. A surface scraping method, applied to hard packed soil areas and other hard surfaces such as entryways), was used in the environmental sampling phase of the Cincinnati Longitudinal Children's Study. The ratio of the geometric mean lead concentration of surface scrapings to that of the soil cores ranged from 1.7 to 8.1 depending upon housing type (Clark et al., 1991). In the HUD Evaluation, the geometric mean lead concentration of exterior entry dust (determined by a vacuum method) has been found to be more than 50% higher than that of the soil lead of the same dwellings (Clark et al., 2004). Exterior dust is therefore likely a more accurate measure of the contribution of particulates that are tracked into houses. (There are a number of other locations in the two Approach documents being reviewed where similar comments apply.) Terms such as "Outdoor Soil" and "outdoor soil particles" would be more accurately characterized by "outdoor soil and dust particles". In locations in the various models and other analyses in these two Approach documents where values have been assigned to soil lead concentration, consideration should be given to increasing these concentrations to more accurately reflect the material that is likely to be tracked into the housing and other buildings.

3.3. Charge Question 4 – Analyses of Variability and Uncertainty

Monte Carlo methodology was not used to evaluate the impacts of variability and uncertainty in model parameters on blood-lead estimates as insufficient data exist concerning the potential variability in many key model variables to support informative Monte Carlo modeling. Instead, point estimates of central tendency (geometric mean) blood-lead concentrations in children are derived utilizing statistical models based on empirical data and on biokinetic models of blood lead, coupled with assumptions regarding distributions of highly uncertain variables. The sensitivity of the deterministic relationships between dust lead and blood lead to changes in key variables and covariates is explored through sensitivity analyses. The modeling inputs and assumptions that most strongly affect the predicted blood-lead distributions associated with candidate lead-dust hazard standards have been identified, based on the measures of statistical uncertainty from the empirical analyses and sensitivity analyses of the biokinetic models. Please comment on the characterization of variability and uncertainty.

(The charge question for the Public and Commercial document is very similar.)

The SAB has several comments and recommendations regarding EPA's characterization of variability and uncertainty in both the empirical modeling and biokinetic modeling (i.e., both the IEUBK model and the ALM [slope factor] models). In general, the SAB agrees with the decision to move away from the use of Monte Carlo analysis (MCA) as a means of propagating variability and uncertainty in the biokinetic model for purposes of estimating a probability distribution of blood lead concentrations (PbBs). Instead, a two-parameter lognormal distribution is used whereby the central tendency parameter is quantified and the variance (represented by the geometric standard deviation [GSD]) is specified. This approach is consistent with historical applications of the IEUBK and ALM models and is a reasonable simplification given the uncertainties in defining input distributions needed to support MCA.

The lognormal model is also applied to the empirical modeling approach as a means of specifying a probability distribution of PbBs so that threshold exceedance probabilities can be estimated. It is intuitively appealing to use the same expressions of variability in the empirical and biokinetic models as this simplifies the model specification and reduces the burden of comparing and contrasting alternative modeling approaches. The GSD parameter becomes the single lumping term for all sources of variability, and the choice of a lognormal model has a long history of use in environmental data analysis and lead risk assessment. However, the SAB concludes that the use of the lognormal model in the empirical approach misses an opportunity to capitalize on a strength of the empirical approach – namely, the fact that a statistical analysis of the NHANES data set presumably allows for a direct measure of the extent to which variance in PbB can be associated with changes in dust lead loading (or concentration).

The SAB recommends that EPA adopt a weight of evidence framework that allows for a more direct comparison of estimates of variability and uncertainty in the empirical and biokinetic models. For the empirical models, variability in the predicted PbB distribution can be estimated directly from the data rather than by imposing the lognormal distribution model with an assumed GSD. EPA should explore the use of $100 \times (1 - \alpha)\%$ prediction intervals on the regression as well as partial regression plots that relate dust lead loading to changes in PbB as a means of estimating the slope (i.e., delta PbB associated with the delta dust lead) within the range of the anticipated candidate standard levels. Results from the NHANES data analysis should be presented both graphically and in tables. Intervals for the original Dixon et al. estimates would be interesting, if obtainable, as well. Note that the prediction interval is preferred over the confidence interval because the prediction interval is analogous to percentiles of the PbB distribution at a given dust lead, whereas confidence intervals would provide a measure of the uncertainty in the mean PbB at a given dust lead. To the extent that the prediction interval from the empirical model overlaps with the distribution obtained by the biokinetic model, this provides greater certainty in using either approach to establish a relationship between a dust lead standard and a corresponding reduction in exposure and risk.

<u>Incremental Risk Assessment Approach</u>

The SAB discussed two approaches to using empirical and biokinetic models to establish dust standards, both of which are amenable to a weight of evidence analysis. One approach, which is largely reflected by the analysis conducted by EPA, is to focus on using the models to estimate blood lead concentrations that may be associated with alternative threshold blood levels of concern. When a risk metric is based on an absolute blood lead concentration, a burden is placed on the models to properly account for all major sources of lead exposure – not just dust lead. At very high blood lead levels and relatively high dust lead standards, uncertainty in specifications of non-dust sources (e.g., diet, air, drinking water) are unlikely to contribute substantially to uncertainty in the relationship between dust lead and blood lead. However, as the proportion of the total average daily exposure attributable to dust lead reduces, the importance of the uncertainties in the non-dust exposure pathways increases. This is true for both the empirical models for which limited data are available from NHANES within the range of dust lead standards of interest, and the biokinetic models for which low target blood lead levels may be exceeded by non-dust sources alone.

The SAB strongly recommends that OPPT consider a second approach that focuses on the slope of the blood lead / dust lead relationship (incremental risk assessment approach). Specific advantages of the incremental risk assessment approach include:

1. For the empirical models, incremental PbB can be estimated directly from the partial regression plots and, possibly, from the standardized coefficients of the regression (depending on the magnitude of co-variance with other factors).
2. For the biokinetic models, there is no need to estimate exposures from non-dust ingestion pathways (diet, air, soil, and water), thereby eliminating many sources of uncertainty.
3. The method facilitates risk management policy decisions regarding a target incremental PbB by providing a simple and clear presentation of the relationship between delta dust lead and delta PbB, as well as the key factors that contribute to variability and uncertainty.

The incremental risk assessment approach does require specific decisions and assumptions, including:

1. Percentile of the PbB distribution that is the basis for the target risk level. For example, a delta PbB of 1 or 2 µg/dL at the 90th percentile.
2. Whether or not the dust lead standard is intended to reflect the mass contribution of lead to dust from all sources (including non-residential sources) or more specifically lead sources associated with the residence (i.e., paint). If the standard is intended to control levels from any source, then the "baseline" dust lead loading is 0 µg/ft2; if the standard applies only to paint lead contributions, then some non-zero baseline dust lead loading should be considered.

Other model constructs, including assumptions of linearity in the low-dose region, time-activity patterns (proportion of dust exposure allocated to the primary residence), and a probability model with an assumed measure of variance (i.e., GSD term) are still needed.

Empirical Modeling

The SAB acknowledges limited empirical data for relating dust lead to blood lead in public and commercial buildings. The NHANES data relates dust lead to blood lead in residential settings and application of this data set in establishing the dust lead to blood lead relationship in public and commercial buildings introduces uncertainty.

The main concern with using the NHANES data to develop a dust loading hazard level is the structure of the database, which shows a large number of low dust lead levels and relatively low number of high blood lead levels. Most of the loading values are below levels of interest for establishing standards. Of the approximately 2,000 paired results, only about n=100 reflect floor dust lead loadings greater than 4 µg/ft^2, so logically even fewer results inform the PbB vs PbD relationship at loadings in the range of greatest interest (i.e., 10 – 40 µg/ft^2). The baseline regression models were developed to reflect subsets of demographic characteristics including race/ethnicity, country of birth, floor surface condition, smoker status, and home/apartment type. Therefore, the corresponding sample size that informs the relationship is very small indeed. In addition, several of the high blood lead levels are paired with the low dust loading observations. The latter data points could be due to the distribution of individual responses; or to confounding variables (both measured and unmeasured), such as other sources or exposure co-factors. To support using these equations for predictive analyses, it is important to know whether these discordant observations reflect response variance or the effects of unmeasured source variables. This is particularly critical because the NHANES data suggest that most residences have lead loadings well below both the current and proposed alternative standards, yet PbBs exceed target risk thresholds.

EPA has performed appropriate analyses to correct for the measured variables. However, the overall model fit is weak-to-moderate (explaining less than 50% of variance) and a high non-zero intercept term. Clearly, there are many factors that contribute to the variance in PbB. The effects of unmeasured variables, which are reflected in the intercept values of the regressions, require further consideration. Uncertainty in the intercept directly affects the baseline blood lead level and also increases the variance and uncertainty in the predicted values. These effects could combine to inflate the estimated percentage of children to exceed target blood lead levels due to factors unrelated to dust loading. In this case, use of the QL or Dixon models to estimate the hazard level required to effect blood lead goals could, in effect, attribute blood lead reductions to the hazard level that, in fact, are due to unrelated sources and would not be manifested in the real world. This effect would diminish the effectiveness of any standard based on these equations.

A key issue addressed in the documents is the conversion of dust concentrations to dust loadings. Interestingly, empirical models based on NHANES do not appear to favor dust loading over dust concentration as a predictor variable. Nevertheless, biokinetic models require concentration terms and the hazard standards are defined in loading terms, so a conversion is required. Uncertainty in the regression equation (p. 16 of the Residential Document and p. 27 of the Public and Commercial Document) should be presented by way of confidence intervals on the regression line.

NHANES QL model predictions are expected values (arithmetic mean PbB), and yet EPA elected to interpret these as geometric mean (GM) values. The rationale for this is unclear, and the consequence is to overestimate the true GM values. EPA should consider converting model predictions to true GM values based on (weighted) estimates of variance.

The empirical models use regression techniques to associate dust lead loading for floors and sills with PbB. The biokinetic models assume that sill loadings are a minor contribution to the total dose. The apparent insensitivity of PbBs to sill lead raises a question as to the utility of various sill Pb standards as a tool for reducing lead risks. This point is inferred by the summary tables and discussion in the report, but should be more fully developed.

Biokinetic Modeling

The input parameters used in the IEUBK model runs vary significantly from those recommended in other Agency regulatory programs. For the child receptor, a range of GSD parameters is evaluated with values based on NHANES survey results. Variability in measured PbBs reflects variability from multiple sources of exposure, including differences in dust lead loadings (and concentrations). This represents a departure from the concept underlying the use of the IEUBK model in which the distribution is intended to reflect variability in the population of children that may be exposed to the same media concentration. Further discussion of this discrepancy and the extent to which the risk metric is intended to reflect differences in dust lead loadings should be included.

The SAB recommends using the default GSD of 1.6 for which the IEUBK model was verified. The GSD should be adjusted upward from the guidance recommendation, only if EPA has justification to assume that the variance in the input exposure parameters is larger than that anticipated in the guidance recommendations. To some extent, this selection can be informed by the variance noted in QL analyses. These adjustments and attendant results should then be discussed in terms of exposure and biological plausibility. A direct comparison of the models can then made in terms of the predicted dust loading values necessary to protect 95% of the childhood population.

Three applications or multiple runs of the IEUBK are then suggested. The proposed procedure is consistent with the Agency's review of IEUBK submittals required in Superfund risk assessments. Specific guidance documents issued by EPA's Superfund Program are available regarding default IEUBK runs. Generally, that policy is to require an initial run using the default parameters recommended in the guidance. That can be followed by site-specific (in this case a population-specific or database-specific) application modifying select parameters. EPA's Superfund guidance generally requires that any modification of the default exposure parameters be justified with scientific references or empirical data. These justifications should be cited in this document. The following runs of the IEUBK are recommended:

1. The first run should use the default parameters currently recommended in the model guidance documents and EPA advisories. The default soil/dust concentration should be varied by substituting the dust concentration from the loading conversion

equations into the dust portion of the soil/dust partition, and determining a weighted average for the soil/dust input concentration. The soil portion of the weighted average should remain constant at the default value. The results can be plotted against dust loading to show change in estimated mean blood lead levels and percent to exceed criteria.

2. A second run should adjust the baseline input parameters to those values, in EPA's judgment, that best reflect the NHHANES population that was addressed in the QL and Dixon analyses. The dust concentration should be varied, the soil concentration held constant. The results should be plotted in the same manner. Particular care should be taken in selecting the soil concentration value. The soil value used in the current document, taken from the National Allergens Survey, may not be reflective of the NHANES database, or the population to be regulated. This run should be compared the Dixon and QL models. Particular attention should be paid to the intercept and slope comparisons.

3. A third run should then be accomplished adjusting the baseline parameters to those values that, in EPA's judgment, best reflect the population to which the regulation will apply. Again selection of the central-tendency soil lead concentration should be given special attention and be justified accordingly.

<u>Comparison of Empirical and Biokinetic Modeling Approaches</u>

The decision to establish a risk metric based upon either an absolute PbB distribution or an incremental blood lead level may be made after addressing some of the SAB's concerns noted above. Agreement between the mean empirical estimates biokinetic modeling estimates would provide considerable comfort in using either, or both, to develop a standard. On the other hand, significant differences in the means or intercept values could suggest that the baseline PbBs are not adequately explained, or there are important input variables missing, or the NHANES database is not representative of the population of concern and the intercept includes significant unmeasured effects. In this case, EPA may observe that, while it is logical to expect reductions in lead levels in dust will result in some reduction in total lead exposure and corresponding PbBs in children, it may not be possible to discern the relative contribution of dust lead exposures at this low level on a national scale. It may become clear that a health protective standard aimed at achieving a low probability of exceeding a low PbB level cannot be calculated directly from empirical models alone. Consequently, the SAB would urge EPA to revisit the definition of the risk metric and how we establish a link between changes in dust lead exposure to expected changes in PbB. Focusing on the delta PbB may prove to be a more viable option.

A decision to use an incremental risk assessment approach may also be informed by comparing the slopes (and confidence intervals on the slopes). Note that estimates of the slopes will be more informative if differences in the intercepts can be reconciled. Differences in the slopes should be explored through sensitivity analyses, and attempt to quantify each of the key sources of uncertainty, including dust loading to concentration conversions, baseline soil concentrations, the soil to dust partition coefficients, and the floor to sill ratios.

3.4. Charge Question 5 – Choice of Model for Hazard Standards

The document presents two empirical models and two biokinetics models. OPPT proposes to use the NHANES Quasi-Likelihood, Empirical Model for the estimation of the residential hazard standards. Please comment on this proposed choice.

(The charge question for the Public and Commercial Document reads, "The document presents empirical models and biokinetic models. OPPT proposes to use the NHANES QL, Empirical Model and the ALM model for the estimation of the hazard standards for floors and windowsills for children and adults, respectively. Please comment on this proposed choice.")

The SAB did not find that the documents provided adequate justification for the Agency's choice in models to use for the development of the dust lead hazard standards. The SAB recommends greater clarity and transparency in the justification of the Agency's choice of models.

<u>Choice of Model for Children</u>

As discussed in further detail in the empirical modeling section of this report, the SAB supports the use of the NHANES QL model, but concludes that the documents did not provide adequate justification for EPA's choice. The SAB also expresses confidence in the results of the NHANES Dixon et al. (2009) log-log model and is concerned that EPA's presentation and critique of that model lacks clarity and, on certain key points, is likely inaccurate. Moreover, the SAB expresses concern about the OPPT's implementation of the IEUBK model and judges it premature to reject the IEUBK approach.

In this report the SAB has made specific recommendations for revising the NHANES QL and IEUBK models so that their products can be more meaningfully compared to the Dixon et al. (2009) results. Most notably, the SAB recommends (1) that results for all models be presented using an incremental approach that describes how changes in PbD affect changes in children's PbB concentrations, while holding constant all other sources of Pb exposure and relevant covariates; (2) that a more transparent comparison be made between the NHANES QL and the Dixon log-log model by revising the NHANES QL model to use PbD loadings directly, rather than convert loadings to concentrations; (3) that results be presented for the .25 $\mu g/ft^2$ – 40 $\mu g/ft^2$ range of PbD loadings, with attention to the need for clarity in describing and displaying results in the range below 5-10 $\mu g/ft^2$; and (4) that the current implementation of the IEUBK model be reviewed to ensure that appropriate default values have been used and that their primary data sources have been fully documented.

The SAB urges EPA to compare the results obtained from the revised NHANES QL and IEUBK models to existing results of the Dixon et al. model, using methods comparable to those employed in the approach document. Until then, the SAB is unable to conclude which modeling approach is most scientifically sound.

<u>Choice of Model for Adults</u>

The SAB acknowledges the lack of an empirical data base for estimating the blood lead impacts of adult exposure to floor and window sill dust in public and commercial buildings, necessitating the use of a mathematical model. In agreement with OPPT, the SAB supports the use of the Adult Lead Methodology (ALM) adapted to accept dust lead exposures. The advantages of using the ALM include it being a relatively simple and easily understood model and considerable use and application of the ALM in EPA's Superfund Program. In addition, the adapted ALM produced more plausible estimates of average population PbB concentrations than the Leggett model produced.

Consistent with its recommendations for all other models, the SAB urges the EPA to use an incremental risk assessment approach when implementing and presenting the results of the adapted ALM. In addition, because the model also requires a conversion of PbD concentration to PbD loading it is important to implement any changes made to that conversion algorithm based on the SAB's comments in previous sections of this report.

4. REFERENCES

Carlisle J, Dowling K 2007. Child-specific benchmark change in blood lead concentration for school site risk assessment. California Environmental Protection Agency: Sacramento, CA. April.

Carlisle J 2009. Revised California human health screening levels for lead. California Environmental Protection Agency: Sacramento, CA. September.

Clark S, Bornschein R, Succop P, Roda S, Peace B 1991. Urban Lead Exposures of Children in Cincinnati, Ohio. Chemical Speciation and Bioavailability 3(3/4):163-171.

Clark S, Menrath W, Chen M, Succop P, Bornschein R, Galke W, Wilson J 2004. The Influence of Exterior Dust and Soil Lead on Interior Dust Lead Levels in Housing Which Had Undergone Lead-Based Paint Hazard Control, Journal Occupational and Environmental Hygiene 1:273-282.

Dixon SL, Gaitens JM, Jacobs DE, Strauss W, Nagaraja J, Pivetz T, Wilson JW, Ashley PJ 2009. U.S. Children's Exposure to Residential Dust Lead, 1999-2004: II. The Contribution of Lead-contaminated Dust to Children's Blood Lead Levels, Env Health Perspect 117:468-474.

Dixon S, Jacobs DE, Wilson J, Akoto J, Clark CS 2010. Window Replacement and Residential Lead Paint Hazard Control 12 Years Later. (in review)

Gaitens JM, Dixon SL, Jacobs DE, Nagaraja J, Strauss W, Wilson JW, Ashley PJ 2009. U.S. Children's Exposure to Residential Dust Lead, 1999-2004: I. Housing and Demographic Factors Associated with Lead-contaminated Dust, Env Health Perspect 117:461-467.

Jacobs DE, Clickner RL, Zhou JL, Viet SM, Marker DA, Rogers JW, et al. 2002. The prevalence of lead-based paint hazards in U.S. housing Environ Health Perspect 110: A599–A606.

Lanphear BP, Emond E, Weitzman M, Jacobs DE, Tanner M, Winter N, Yakir B, Eberly S 1995. A Side-By-Side Comparison of Dust Collection Methods for Sampling Lead-Contaminated House Dust, Environ Res 68, 114-123.

Lanphear BP, Matte TD, Rogers J et al. 1998. The contribution of lead-contaminated house dust and residential soil to children's blood lead levels. A pooled analysis of 12 epidemiological studies. Environ Res, Section A 79:51-68.

Lanphear BP, Hornung R, Ho M, Howard CR, Eberley S, and Knauf K 2002. Environmental lead exposure during early childhood. Journal of Pediatrics 140: 40-47.

Mielke HW, Powell ET, Gonzales CR, Mielke PW Jr. 2007. Potential lead on play surfaces: Evaluation of the "PLOPS" sampler as a new tool for primary lead prevention, Environ Res; 103: 154–9.

National Center for Healthy Housing (NCHH) and University of Cincinnati (UC) Department of Environmental Health, 2004. Evaluation of the HUD Lead-based Paint Hazard Control Grant Program. Final Report, Washington, DC.

Succop P, Clark CS, Chen M, Galke W 2004. Imputation of Data Values that are Less Than a Detection Limit, Journal Occupational and Environmental Hygiene 1:436-441.

United States Envrionmental Protection Agency Science Advisory Board Lead Review Panel 2010. Consultation on EPA's Proposed Approach for Developing Lead Dust Hazard Standards for Residential Buildings and Commercial and Public Buildings, EPA-SAB-10-011, Washington, DC. August. Available at: http://yosemite.epa.gov/sab/sabproduct.nsf/F8DA254881FEC6898525778F004C789A/$File/EPA-SAB-10-011-unsigned.pdf

APPENDIX A – CHARGE QUESTIONS

Charge Questions for the Approach for Developing Lead Dust Hazard Standards for Residences

Background

TSCA section 403 directs EPA to promulgate regulations that identify, for the purposes of Title X and Title IV of TSCA, dangerous levels of lead in paint, dust, and soil. EPA promulgated regulations pursuant to TSCA section 403 on January 5, 2001, and codified them at 40 CFR part 745, subpart D (USEPA, 2001a). These hazard standards identify dangerous levels of lead in paint, dust, and soil and provide benchmarks on which to base remedial actions taken to safeguard children and the public from the dangers of lead. Lead-based paint hazards in target housing and child-occupied facilities are defined in these standards as paint-lead, dust-lead, and soil-lead hazards. A paint-lead hazard is defined as any damaged or deteriorated lead-based paint, any chewable lead-based painted surface with evidence of teeth marks, or any lead-based paint on a friction surface if lead dust levels underneath the friction surface exceed the dust-lead hazard standards. A dust-lead hazard is surface dust that contains a mass-per-area concentration of lead equal to or exceeding 40 micrograms per square foot ($\mu g/ft^2$) on floors or 250 $\mu g/ft^2$ on interior windowsills based on wipe samples. A soil-lead hazard is bare soil that contains total lead equal to or exceeding 400 parts per million (ppm) in a play area or average of 1,200 ppm of bare soil in the rest of the yard based on soil samples.

On August 10, 2009, EPA received a petition from several environmental and public health advocacy groups requesting that the EPA amend regulations issued under Title IV of TSCA (Sierra Club et al., 2009). Specifically, the petitioners requested that EPA lower the Agency's dust-lead hazard standards issued pursuant to section 403 of TSCA from 40 $\mu g/ft^2$ to 10 $\mu g/ft^2$ or less for floors and from 250 $\mu g/ft^2$ to 100 $\mu g/ft^2$ or less for window sills. On October 22, 2009, EPA granted this petition under section 553(e) of the Administrative Procedures Act, 5 U.S.C. 553(e) (USEPA, 2009a). In granting this petition, EPA agreed to commence the appropriate proceeding, but did not commit to a particular schedule or to a particular outcome.

In June 2010, EPA issued a Proposed Approach for Developing Lead Dust Hazard Standards for Residences and submitted the document to the Science Advisory Board (SAB) Lead Review Panel for a consultation. The SAB Panel met July 6–7, 2010 and provided comments on the Proposed Approach to EPA on August 20, 2010.

The current document entitled "Approach for Developing Lead Dust Hazard Standards for Residences" describes the methods that EPA proposes to examine candidate hazard standards for floors and windowsills in residences. This document takes the SAB comments from the July, 2010 consultation into consideration in developing several candidate standards for residences.

Charge Question 1 - Approach Document

OPPT has developed an Approach document for developing the hazard standards for floors and windowsills in residences. This includes a description of the empirical and biokinetic approaches, as well as the resultant analyses used to estimate candidate lead dust hazard standards for residences.

1. Please comment on the clarity and transparency of the document.

Charge Question 2 - Empirical Models

The empirical approach involves the estimation of blood-lead impacts based on analyses of empirical data from the 1999–2004 National Health and Nutrition Examination Survey (NHANES). Two analyses were used. First, the regression relationships among floor and windowsill dust, other covariates, and blood-lead concentrations that Dixon et al. (2009) derived were applied to predict blood-lead levels for the various hazard standards (combinations of floor and windowsill dust loadings). The second was an independent reanalysis of the NHANES data to derive alternate models for predicting blood-lead impacts; the variations from the Dixon et al. (2009) approach included changes to the form of the dust-loading variables and application of models that are inherently linear at low lead exposures, a relationship that is supported by a wide range of biokinetic data, and regression of blood-lead values against estimated dust concentrations, rather than dust loading.

2. Please comment on the EPA reanalysis.

Charge Question 3 - Biokinetic Models

Two biokinetic models were used to estimate children's blood lead concentrations including EPA's Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK), and the Leggett model. Information from the exposure scenarios is used to estimate relative contributions of exposures from different sources (soil, dust, air, diet, and water) and in different microenvironments.

3. Please comment on the use of the biokinetic models and the inputs to the models.

Charge Question 4 - Analyses of Variability and Uncertainty

Monte Carlo methodology was not used to evaluate the impacts of variability and uncertainty in model parameters on blood-lead estimates as insufficient data exist concerning the potential variability in many key model variables to support informative Monte Carlo modeling. Instead, point estimates of central tendency (geometric mean) blood-lead concentrations in children are derived utilizing statistical models based on empirical data and on biokinetic models of blood lead, coupled with assumptions regarding distributions of highly uncertain variables. The sensitivity of the deterministic relationships between dust lead and blood lead to changes in key variables and covariates is explored through sensitivity analyses. As presented in Section 6, the modeling inputs and assumptions that most strongly affect the predicted blood-lead distributions associated with candidate lead-dust hazard standards have been identified, based on the measures of statistical uncertainty from the empirical analyses and sensitivity analyses of the biokinetic models.

4. Please comment on the characterization of variability and uncertainty.

Charge Question 5 - Choice of Model for Residential Hazard Standards

The document presents two empirical models and two biokinetics models. OPPT proposes to use the NHANES Quasi-Likelihood, Empirical Model for the estimation of the residential hazard standards.

5. Please comment on this proposed choice.

Charge Questions for the Approach for Developing Lead Dust Hazard Standards for Public and Commercial Buildings

Background

Section 402(c)(3) of TSCA directs EPA to revise the regulations promulgated under TSCA section 402(a), *i.e.*, the Lead-based Paint Activities Regulations, to apply to renovation or remodeling activities in target housing, public buildings constructed before 1978, and commercial buildings that create lead-based paint hazards. In April 2008, EPA issued the final Renovation, Repair and Painting Rule (RRP Rule) under the authority of section 402(c)(3) of TSCA to address lead-based paint hazards created by renovation, repair, and painting activities that disturb lead-based paint in target housing and child-occupied facilities (USEPA, 2008a). The term ''target housing'' is defined in TSCA section 401 as any housing constructed before 1978, except housing for the elderly or persons with disabilities (unless any child under age 6 resides or is expected to reside in such housing) or any 0- bedroom dwelling. Under the RRP Rule, a child-occupied facility is a building, or a portion of a building, constructed prior to 1978, visited regularly by the same child, under 6 years of age, on at least two different days within any week (Sunday through Saturday period), provided that each day's visit lasts at least 3 hours and the combined weekly visits last at least 6 hours, and the combined annual visits last at least 60 hours. The RRP Rule establishes requirements for training renovators, other renovation workers, and dust sampling technicians; for certifying renovators, dust sampling technicians, and renovation firms; for accrediting providers of renovation and dust sampling technician training; for renovation work practices; and for recordkeeping. Interested States, Territories, and Indian Tribes may apply for and receive authorization to administer and enforce all of the elements of the RRP Rule.

Shortly after the RRP Rule was published, several petitions were filed challenging the rule. These petitions were consolidated in the Circuit Court of Appeals for the District of Columbia Circuit. On August 24, 2009, EPA entered into an agreement with the environmental and children's health advocacy groups in settlement of their petitions (USEPA, 2009a). In this agreement, EPA committed to propose several changes to the RRP Rule. EPA also agreed to commence rulemaking to address renovations in public and commercial buildings, other than child-occupied facilities, to the extent those renovations create lead-based paint hazards. For these buildings, EPA agreed, at a minimum, to do the following:

- Issue a proposal to regulate renovations on the exteriors of public and commercial buildings other than child-occupied facilities by December 15, 2011 and to take final action on that proposal by July 15, 2013.
- Consult with EPA's Science Advisory Board by September 30, 2011, on a methodology for evaluating the risk posed by renovations in the interiors of public and commercial buildings other than child-occupied facilities.
- Eighteen months after receipt of the Science Advisory Board's report, either issue a proposal to regulate renovations on the interiors of public and commercial buildings other than child-occupied facilities or conclude that such renovations do not create lead-based paint hazards.

In order to evaluate the potential risks associated with lead exposure due to renovations in public and commercial buildings, and the potential need for regulations on these activities, it is first necessary to develop the hazard standards for lead dust on window sills and floors in public and commercial buildings; these become the standards to help inform the impact of renovation activities. These standards will identify dangerous levels of lead in paint and dust, and provide benchmarks on which to base remedial actions taken to safeguard children and the public from the dangers of lead.

In June 2010, EPA issued a document entitled **"**Proposed Approach for Developing Lead Dust Hazard Standards for Public and Commercial Buildings" and submitted the document to the Science Advisory Board (SAB) Lead Review Panel for a consultation. The SAB Panel met July 6–7, 2010 and provided comments on the Proposed Approach to EPA on August 20, 2010.

The current document entitled "Approach for Developing Lead Dust Hazard Standards for Public and Commercial Buildings" describes the methods that EPA proposes to examine candidate hazard standards for floors and windowsills in public and commercial buildings. This document takes the SAB comments from the July, 2010 consultation into consideration in developing several candidate standards for public and commercial buildings.

Charge Question 1 - Approach Document

OPPT has developed an Approach document for developing the hazard standards for floors and windowsills in public and commercial buildings. This includes a description of the empirical and biokinetic approaches, as well as the resultant analyses used to estimate candidate lead dust hazard standards for public and commercial buildings.

1. Please comment on the clarity and transparency of the document.

Charge Question 2 - Empirical Models

The empirical approach involves the estimation of blood-lead impacts based on analyses of empirical data from the 1999–2004 National Health and Nutrition Examination Survey (NHANES). Two analyses were used. First, the regression relationships among floor and windowsill dust, other covariates, and blood-lead concentrations that Dixon et al. (2009) derived were applied to predict blood-lead levels for the various hazard standards (combinations of floor and windowsill dust loadings). The second was an independent reanalysis of the NHANES data to derive alternate models for predicting blood-lead impacts; the variations from the Dixon et al. (2009) approach included changes to the form of the dust-loading variables and application of models that are inherently linear at low lead exposures, a relationship that is supported by a wide range of biokinetic data, and regression of blood-lead values against estimated dust concentrations, rather than dust loading.

2. Please comment on the EPA reanalysis.

Charge Question 3 - Biokinetic Models

Two biokinetic models were used to estimate children's blood lead concentrations including EPA's Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK), and the Leggett model. Information from the exposure scenarios is used to estimate relative contributions of exposures from different sources (soil, dust, air, diet, and water) and in different microenvironments.

The Leggett model and EPA's Adult Lead Methodology were used to estimate adult blood lead levels resulting from candidate floor and windowsill hazard standards.

3. Please comment on the use of these models and the inputs to these models.

Charge Question 4 - Analyses of Variability and Uncertainty

Monte Carlo methodology was not used to evaluate the impacts of variability and uncertainty in model parameters on blood-lead estimates as insufficient data exist concerning the potential variability in many key model variables to support informative Monte Carlo modeling. Instead, point estimates of central tendency (geometric mean) blood-lead concentrations in children are derived utilizing statistical models based on empirical data and on biokinetic models of blood lead, coupled with assumptions regarding distributions of highly uncertain variables. The sensitivity of the deterministic relationships between dust lead and blood lead to changes in key variables and covariates is explored through sensitivity analyses. The modeling inputs and assumptions that most strongly affect the predicted blood-lead distributions associated with candidate lead-dust hazard standards have been identified, based on the measures of statistical uncertainty from the empirical analyses and sensitivity analyses of the biokinetic models.

4. Please comment on the characterization of variability and uncertainty.

Charge Question 5 - Choice of Model for Public and Commercial Building Hazard Standards

The document presents empirical and biokinetic models. OPPT proposes to use the NHANES QL, Empirical Model and the ALM model for the estimation of the hazard standards for floors and windowsills for children and adults, respectively.

5. Please comment on these proposed choices.

APPENDIX B – EDITORIAL COMMENTS

Correction of certain typographical and unit of measure errors in the Residential Document (also applies to the respective portions of the Public and Commercial Document):

Pages 21 and 31 Figures 3-8 and 4-2: Both of these scatter plots show the raw data, being the unadjusted raw NHANES data as the dots and the model predictions as the several curves. The figure key of 3-8 says "raw data" which is clear enough, but 4-2 did not. Also, using the word "predicted" in the vertical axis is unclear, since it was also for raw data.

Page 32, Figure 5-1 - This figure has 9 curves. The clarity of the document would be improved if the figure presented only central tendencies (6 curves), which would make the figure less cluttered. Figure 5-2 shows only those curves, which is clearer. The upper and lower bounds can be presented with error bars about a few points on the central tendency data points.

Pg 6 footnote * insert "and for blood lead" after "…measurements,"
Pg 23 2nd para, 3rd line from bottom "data that are"
Pg 27 4.1.5 1st and 2nd lines "Soil" does not appear to be needed in both lines.
Pg 28 Table 4-3 and elsewhere: The units of air concentration and blood lead involve "µg" and not "mg".
Pg 29 The "proposed standards" should be "current standards"
Page 38, Table 4-4 - The units for lead should be checked (mg vs. µg). Similarly in table 7-2, also page 72. So, table 7-3 with elasticity, the units may be correct or not?
Pg. 40 6.1 2nd line Change "dust" to "blood"
Pg 41 3rd line from bottom Change "flood" to "floor."
Page 45, 7.1 - The meaning of the phrase "support for a key input" is not clear
Page 44, line 4: change "76 percent" to "24 percent".
Page 56, Figure 6-3: in the caption, change "Greater than 5.0" to "Greater than 2.5"
Page 72, Table 7-2: Many of the units in the first column that are labeled "mg" (milligram) should be changed to "µg" (microgram). Also, the last column should be labeled as applying only to the Leggett model.
Page 74, Table 7-4: in the second column, third row, change 0.011 to 0.11.

In the fifth row, the proportion of time that a child spends at home is listed as 0.76, in contrast to the information on page 35, which indicates a value of 0.83.

In the last row of the table, the upper bound and lower bound estimate entries appear to be reversed.

Page 74, Table 7-5: The narrative indicates this table is intended to apply to adults, but the caption refers to children. The contents and caption should be checked. For example, the dust lead absorption fraction of 0.5 applies to children, but the soil lead absorption fraction applies to adults.

Pg. E-20 The title for Table E-9 appears to have been inadvertently used for Table E-10 also.

The inhalation rate of the exposed individual is typically described as the "ventilation rate." This can be confusing to the reader because ventilation rate is often used to describe the rate of air volume movement through residential or commercial room spaces. It is suggested that the term "inhalation" rate or "breathing" rate be used to describe physiological ventilation of the lungs.

A summary table of variables in the NHANES database should be presented to improve clarity.