External Peer Review of

Exposure Factors Handbook:

EPA Response to Peer-Review Comments

National Center for Environmental Assessment
Office of Research and Development
U.S. Environmental Protection Agency
Washington, DC 20460

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This report is a summary of discussion points made during the External Peer-Review Workshop of EPA's Draft Document *Exposure Factors Handbook*, held March 3−4, 2010 in Arlington, Virginia. This report captures the main points made by the external peer reviewers at the Workshop, and EPA's responses to the peer-reviewer comments. It is not a complete record of all details discussed, nor does it embellish, interpret, or enlarge upon matters that may have been incomplete or unclear. Statements represent the individual views of meeting participants.

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1. INTRODUCTION

The responses to comments from the Recommendations and Conclusions Section of the Final *Report on the External Peer-Review Workshop of EPA's Draft Document "Exposure Factors Handbook*" (EFH) are addressed in this document. The Peer-Review Workshop was held March 3−4, 2010, in Arlington, Virginia. This response to comments document is organized first by the charge questions provided to the peer reviewers and then by individual chapters, with the recommendations of the reviewers provided for each chapter. Following each comment is the response of the U.S. Environmental Protection Agency (EPA). Similar comments were grouped together with one response provided at the end to avoid repetition. Appendix A provides the responses to public comments. Comments that did not require a U.S. EPA response were placed in Appendix B.

2. RESPONSE TO PEER-REVIEW COMMENTS

2.1. Comments Related to Charge Question 1

Charge Question 1: Please comment on the organization of the Handbook. Does the EFH document present the information, including data provided in the tables, in a clear, easily understood, and usable format? What can be done to improve the format?

Comment: For the most part the organization of the Handbook is very clear and easily understood. However some improvements could be made to the tables. In particular tables that are longer than one page. Although it is clear on the second page that this table continues on from the previous page by the title on the second page of the table, it is not clear in the current format used throughout when you are looking at the first page that this table continues onto the next page. For example, it is not clear that Table 7-2 continues onto the next page. Something should be added to bottom of tables that continue onto other pages that differentiates them from tables that are only page long. Also consider including the superscripts and reference citations on each page of the table. It is cumbersome and confusing to the reader to have to look through three pages of a table to figure what the reference or superscript refers to. Also consider breaking up Table ES-1 into different tables by chapter or factor. The current table is very confusing as some factors are cut in two.

Response: *Tables that continue on the next page have the word "continued" on the headings of the following pages. The table in the executive summary was revised to add clarity, and footnotes were added after each chapter recommendations.*

Comment: In general, I believe that Chapter 1 has indeed covered the most important and relevant general guidance as well the primary developments in exposure science (note the preferred term exposure science rather than the more restrictive exposure assessment.) However, the organizational structure could be improved substantially. Let me offer the following suggestions. Sections 1.1 and 1.2 are appropriately placed in that it is necessary to state the Purpose and

Intended Audience right up front. Section 1.3 Background should indeed come next but the content of this section is not what I would expect to be. One should commence, as has been done, with a history of the document's development, but this history is much too brief and focuses on changes from an undescribed document, namely, the earlier versions of the Exposure Factors Handbook (EFH). A paragraph describing the previous document would be useful here. While some material is included in the Section 1.1 Purpose, a better description could be placed in a section called Background. As it is, the Background section is hard to follow. The bulleted point highlighting the revisions in the document could be much better developed in a Table with some descriptive text supplementing it. I am not at all sure why the sub-section entitled Variation Among Studies (note I think the word "among" should not be capitalized) is included in a Background section. It should receive its own discussion, and probably be a separate sub-section; it is not part of "Background." Further, the discussion of the selection of age-groupings is given under this heading, which seems inappropriate. My suggestion is a complete re-write of the Background section is warranted.

Response: *The entire chapter was revised. The history of the document was expanded. A new section on "scope" was added. The background was edited as suggested.*

Comment: Consider renaming Section 1.11 to "Organization of Handbook."

Response: *The section was revised as per comment.*

2.2. Comments Related to Charge Question 2

Charge Question 2: Please comment on whether the factors currently addressed in the EFH are those that are most needed to conduct exposure assessments?

Comment: The current factors included in the Handbook are the ones most commonly used. I don't know the distribution of the types of exposure assessments that either the EPA, other federal agencies or the broader exposure assessment community do most frequently, but suspect they are more likely local or focused than national in scope. The focus of the Handbook is to emphasize national population data and gives a premium to studies that are "general population" in scope. Whether that information is the most useful for more local or focused assessments is unclear.

Response: *This needs to be evaluated by the user of the Handbook on a case-by-case basis. Language was added in the Introduction to make the user aware of this issue.*

Comment: I believe the EFH addresses all of the major exposure factors that must be considered in the conduct of a household or environmental risk assessment. In a few instances (described in detail below), I think the document could expand somewhat in terms of how and when different factors should be

applied, although this may be beyond the scope of the EFH. This is particularly true for the fish ingestion exposure factors, where dozens of data summary tables are presented.

Response: *This is beyond the scope of the Handbook. More discussion on the use of the fish-consumption data was added.*

Comment: The one set of factors that is "missing" within the above-specified context should have to do with factors associated with microenvironments other than residential buildings. Of course, the EFH is not intended to support occupational exposure assessments; nevertheless, many "non-occupational" exposures (at least in the traditional sense of the term) take place indoors but in buildings that are not residential (e.g., schools and other public buildings, restaurants, movie theaters, stores and shopping malls, athletic facilities and clubs, hospitals, etc.) and these microenvironments need to be adequately characterized. In vehicle-exposures are also a major contributor to total exposure and the factors pertaining to relevant microenvironments (cars, buses, trains, etc.) also need to be properly characterized.

Response: *Chapter 19 was expanded and revised to include nonresidential buildings. Information about time spent in vehicles is provided in chapter 16.*

Comment: Furthermore, local outdoor conditions (roadways, intersections, street canyons, etc.) can modify the environmental conditions relevant to an "ambient background" level (e.g., the airborne contaminant values measured at a "central" monitor location) and appropriate factors that will help to quantify this modification need to be developed.

Response: *This is beyond the scope of the Handbook.*

Comment: I agree that these are the most used factors. In future, wondering if there will be a companion handbook of physiological factors for PBPK modeling?

Response: *A database on physiological factors is under development by the U.S. EPA.*

2.3. Comments Related to Charge Question 3

Charge Question 3: For the factors included in the EFH, are you aware of other data sources that have not been identified?

Comment: Two reviewers suggested adding a section that references other resources, databases (e.g., databases from the U.S. Geological Survey, the U.S. Food and Drug Administration [FDA], the U.S. Census Bureau), models, modeling frameworks, and tools that are standard in exposure assessment. One reviewer suggested that perhaps a table could be used to list the additional

references and denote the applicable exposure routes. An asterisk could be used for those that are in draft form or under development.

Response: *Other sources of information are mentioned throughout the Handbook when applicable. A separate effort aimed at providing tools and guidance to exposure assessors is under development by the U.S. EPA.*

Comment: Though the 2009 Update of the EFH is a very readable document, it however lacks visual elements (it has very few figures, charts, etc.) and its usability could be further enhanced through the addition of brief "Further Reading" recommendations at the end of each chapter, identifying standard literature sources (textbooks, handbooks, easily accessible reports, etc.) on the topic of the chapter, at "introductory," "intermediate," and "advanced" levels.

Response: *Although visual elements would improve the document's appearance, tables are the most effective way to present the data. The reader is referred to additional references where appropriate in the individual chapters (e.g., Chapter 2, Chapter 17, and Chapter 19).*

Comment: What a handbook user wants to know is whether it is worthwhile doing their own literature search and review because the Handbook only contains a small proportion of the available data sources or whether the authors did an exhaustive search and review and have included all the data that might be relevant for an assessor to use.

Response: *Literature searches were conducted for individual chapters. Additionally targeted searches and communications with researchers in the individual fields were conducted. Additional language was added to clarify.*

2.4. Comments Related to Charge Question 4

Charge Question 4: NCEA has grouped available studies in each chapter into "key" and "relevant studies." "Key studies" were the most useful for providing recommendations for the exposure factor of interest. For each individual chapter, please comment on the selection of studies that have been classified as "key."

Comment: It would be useful to explain why some chapters do not have key and recommended studies.

Comment: To increase confidence in the studies presented, the methods used to search for and identify key and relevant studies need to be better explained (mentioned by two reviewers).

Comment: Consider placing the description of the Key recommended studies, following the Confidence Tables of each Chapter, in order of how each scored (The Key study with the highest Confidence Rating described first) based on the Confidence Criteria, i.e., General Assessment Factors (GAFs). This would be

particularly useful for Chapter 15 (Human Milk Intake) and Chapter 19 (Residential Building Characteristics).

Comment: In general, the text of the EFH is clearly written—the introductory and summary parts more so than the review of the individual studies. One major deficiency, however, is that the recommended values are presented without a clear explanation of how, specifically, they were derived from the selected study/studies. I presume that there was a more or less formal approach that involved the weighting of the studies and the data within the key study/studies. However, this is not transparent. Furthermore, it is not clear how the studies designated as key studies relate to the studies used to derive the recommended values. For example, in chapter 4, the values given in Table 4-1 for hand-to-mouth frequency and object-to-mouth frequency are derived solely from Xue et al. 2007. However, there are 9 studies that are grouped in the text as key studies. The Introduction section to this chapter states that some of the key studies were included because they were used in the meta-analysis of Xue et al. What is the relationship of key studies to those used directly for the recommended values? What is the basis for the choice of the one recommended study in this case given the 8 other key studies? While the Xue et al. studies may be the most appropriate because they incorporate the best studies in their meta-analyses, this is not explicitly stated. Another deficiency is that, for the most part, the tables presenting the data from the individual studies are not self-explanatory, but generally require referring back to the details of the studies presented in the text in order to understand the nature of the data presented in the tables. This is also the case for some of the tables presented for the recommended values. For example, in chapter 4, the third section of the recommended values table (4-1) presents recommended values for "duration." Although this section is presented under the larger section entitled, "Object-to-mouth," reference to the description of the source studies indicates that some of those studies include only objects and not hands, while others include objects and hands. However, from table 4-1 alone, one cannot tell whether the frequency refers to objects-only or to objects and hands. This would be less of a problem if the tables were presented along with the text so that the reader could consult the table as the text is being read. However, presenting the tables in a separate section removes their context.

Comment: For the chapters I reviewed in depth, I would have to say that I am aware of other data sources not mentioned or discussed. Unfortunately it is impossible to know what studies the authors reviewed and rejected using their criteria. Nowhere is it mentioned how studies were identified, how many reviewed and culled to get the few used as "key" or of sufficient import to summarize. All we know is that supposedly reviews included publications into 2009.

Comment: In my four focus chapters (3, 6, 10, 15) the key studies appear to probably be the best available data. What is missing in either the introduction or in the individual chapters is a description of how the authors searched for studies to review (did they use key words in Google, in Pub med or Medline etc?). It

would be most useful to know how many studies they identified and reviewed and which were not included in the "relevant" listing and why. If there were thousands of papers reviewed, the reader needs to know that. Much time can be saved by Handbook users if they can be confident that the author team did an exhaustive review of the literature, systematically assessed and evaluated each study and what is in the Handbook are the best available and that the user would have little to gain by doing their own literature search. But as the Handbook currently stands, what or how the authors collected data is unclear. In all of these chapters, the confidence ratings are provided for the key study, but there are no ratings for the "relevant" studies described. These are not ranked in any way and it cannot be determined if they would be higher rated than the key study, if only for a more targeted population. So while the summaries of the relevant studies are informative, and there is some discussion of some of the evaluation criteria, it is up to the reader to decide for themselves. The "relevant" studies are listed in chronological publication order with the oldest listed first. I would suggest that ordering them in the reverse order, with the most current first would make more sense. Or order them by recommended rank.

Comment: In general the studies designated as key were appropriate, however it was difficult to determine sometimes why some studies were classified as relevant. It would be helpful at the end of each study to have a statement that qualifies their classification.

Comment: The initial definition of "Key" studies in Section 1.4 (Selection of Studies for the Handbook) is unclear, i.e., "Certain studies described in this Handbook are designated as "key", that is, the most useful for deriving exposure factors." Specifically, the term "most useful" is very unclear.

Comment: A key study is defined as the 'most useful for deriving exposure factors' (definition by EPA in Chapter 1). There is some amount of subjectivity in that definition. Currently, it is mostly based on the identified attributes and confidence ratings used to select studies. However, one more attribute to judge a study is how often the data is used to make exposure calculations in the exposure field. Of course this might require tracking down a lot more data, and usage of data. However, this is something to consider in the future.

> ***Response:*** *Studies were selected from literature searches conducted for individual chapters. Additionally targeted searches and communications with researchers in the individual fields were conducted. Additional language was added to clarify. It would be nearly impossible to list everything that has been reviewed for inclusion at one point or another since the first 1989 Exposure Factors Handbook was published. EPA agrees that the designation of "key" versus "relevant" is somewhat subjective. The definition of "key" was revised to say "the most up-to-date and scientifically sound for deriving recommendations for exposure factors." Exposure assessments are done for a variety of purposes and a study that may be applicable in one situation may not be applicable in others.*

Additional language was added to the Introduction to explain the differences between "key" and "relevant." Every attempt was made in the individual chapters to provide more clarity. For example, the strengths and limitations section was expanded to make it clear why a study was considered "relevant." Because of the subjective nature of the classification of "key" versus "relevant," it would not be possible to weigh studies within each category. With regard to the ordering of the studies, they were ordered in chronological order with the oldest studies listed first to show the evolution of the science. In chapter 4, the Xue et al. (2007) paper is a meta analysis of 8 studies in the literature. It presents the data in the format needed for the Handbook's purposes; it was used as the basis for the recommendation. The 8 studies are listed as "key" because they were used by Xue et al., (2007) in their analysis.

Comment: In the glossary (G-7), you define a key study as..."A study that is useful for deriving exposure factors". That fits the definition of a relevant study also. Consider expanding the definition for key study as defined in the main document.

Response: *The glossary was revised. The definition of "key" was revised to say "the most up-to-date and scientifically sound for deriving recommendations for exposure factors."*

2.5. Comments Related to Charge Question 5

Charge Question 5: Please comment on whether the confidence ratings used to select studies and rate factors provide a clear rationale and adequately reflect the advantages and/or limitations of the studies addressed in the document. Please provide suggestions for alternative approaches for addressing confidence ratings, if appropriate.

Comment: They do seem to provide a clear rationale. However, they do not seem to be applied similarly across studies or chapters. A more clearly defined rubric or numeric system may need to be developed to provide more consistency across factors.

Response: *U.S. EPA attempted to use a numeric system, but it was deemed inappropriate. Care was taken to use similar language in the confidence rating table and the same level of detail.*

Comment: For the most part the confidence ratings are clear. In the introduction, it is noted that the EPA does not weight each topic area equally and uses best scientific judgment when determining the overall rating. It would be nice if in a footnote below each confidence table if a sentence could be included that outlined the rational for the overall confidence rating.

Response: *U.S. EPA has tried to present the confidence rating tables with enough explanatory information to ensure their utility without introducing too much complexity. Discussions about data limitations are included*

throughout the text. The rationale for the overall rating is described in the summary paragraph for each recommendation.

Comment: In general the confidence ratings to select studies and rate factors provide a clear rationale and reflect the disadvantages and/or limitations of the studies. Please see comments on each study below. I feel in some cases, if resources allowed, EPA could contact some of the study authors to determine some factors necessary for improving the confidence ratings, such as quality assurance and methodologies used.

Response: *U.S. EPA appreciates the suggestion, but it would require additional resources. This is something that could be considered for future editions.*

Comment: The confidence ratings used to select studies and exposure rate factors reflect the advantages and/or limitations of the choices. Some consideration should be given to the use of confidence intervals for estimates of central tendency in order to indicate their precision for various studies.

Response: *Confidence intervals were not always available. They are presented where available.*

Comment: Given the general status of data specific to exposure factors, the current confidence ratings appear to be a reasonable approach. A quantitative characterization of confidence in specific exposure factors is not possible for the majority of currently available data sets. Incorporating recommendations for future collection of information that would allow calculation of specific quantitative confidence metrics, can enhance the design of new data collection studies.

Response: *Research needs are likely to vary depending on the user of the Handbook. Instead, the discussions about the data limitations provide the user with a sense of what additional information may be needed to reduce uncertainties.*

Comment: Consider renaming Table 1-2 from "Considerations used to rate confidence in recommended values" to "Criteria used to…." Additionally, associated with "Accessibility", consider rephrasing "The study data could be accessed." to "The study data is publicly available"

Response: *The section in Chapter 1 was revised as per comment.*

Comment: The column headers in "Table 1-2" could be more clearly stated. Instead of "Increasing Confidence", suggest "Factors that Increase Confidence" and likewise, instead of "Decreasing Confidence" suggest "Factors that Decrease Confidence.

Response: *The section was revised as per comment.*

Comment: The confidence ratings are explained adequately in the Introduction. However, I find their implementation a bit odd. In particular, the explanation states that even if all parts of the rating are deemed, say, "High" the overall rating may be lower due to the lack of applicability. This really needs to be clarified. I would guess that such a rating would apply if the data collected were for a different population, a non-representative population, or some such and that is appropriate. However, would this not affect the assessment of, say, variability (see below) and thus call the data into at least some question.

Response: *The section was revised as per comment.*

Comment: I did not find the categories used to generate the confidence ratings particularly useful. They seemed more geared to generating a ranking than to explaining the strengths and limitations of the data. Some of the categories were not really relevant to the data at hand. For example, in the Confidence summary for chapter 10 (Fish and Shellfish Consumption), the response to the "Currency" category was "The most current CSFIII 1994-98 data were used." The relevant fact here is not that the most recent CSFII data were used, but that the most recent data from the CSFII study is more than 12 years old. I think that a narrative discussing how the key studies addressed the intended use of the data would be more appropriate. EPA was trying to be consistent on the evaluation criteria.

Response: *The currency of the data is important for fish consumption too. If the data are old, this is noted in the confidence rating table. CSFII is no longer used as the basis for the recommendations. A more recent analysis of the 2003-2006 NHANES data set has been added. The intended use of the data could not be evaluated because exposure assessments are done for a variety of reasons. Data limitations are discussed within the text.*

Comment: In general the parameters considered to develop confidence ratings are appropriate. However, for some factors confidence in a study is assessed, but that does not necessarily correlate with the confidence in the data as presented. For example, some studies may have an adequate overall sample size, but when data are broken into smaller subcategories by age and gender, sample size may be very limited. The current approach does not adequately address these cases. For example, in Table 3-2 the drinking water ingestion study is rated medium to high, but in Table 3-1 there is a footnote that indicates sample size may be insufficient for some age groups.

Response: *To the extent possible, these caveats were noted. U.S. EPA has tried to is present the tables with enough explanatory information to ensure their utility without introducing too much complexity*

Comment: A suggestion is to provide a confidence rating both for the study and then for the data as used (so, for example, there may be medium overall confidence in a certain study but low confidence when the data are stratified into multiple age bands due to lower sample size per age band). Further, a

whole-picture approach is suggested for application of data. For example, where a "reality-check" suggests that the tails of a distribution may be biased, EPA should avoid recommendations based upon extremes of the tails and remain closer to 10th and 90th percentiles (as discussed under Chapter 6 comments).

Response: *It would be nearly impossible to account for all possible uses of the data. In general, for consistency, recommendations are based on the mean and 95th percentiles. Additional language was added to Chapter 1.*

2.6. Comments Related to Charge Question 6

Charge Question 6: Please comment on whether data variability has been adequately characterized and described.

Comment: On Page 1-4, in the section on "Variability in the Population", in addition to referring to Section 1.5.1, please refer to additional information on variability found in Chapter 2 of the EFH.

Response: *The section was revised as per comment.*

Comment: On Page 1-4: the section on "Uncertainty" is without a formal definition of Uncertainty. Consider including a definition and/or referring to Section 1.5 and Chapter 2 for further discussion on Uncertainty.

Response: *The definitions of variability and uncertainty are included in this section and in the Glossary.*

Comment: In Table 1-1, it is misleading to state that this table characterizes variability in all the listed exposure factors, considering that some of the exposure factors, such as soil adherence, time indoors, time outdoors, and life expectancy, only have average values from key studies checked. This table provides information on the descriptive statistics available from the key studies for each exposure factor. Consider including a column for whether the standard error or standard deviation is also provided/available. Also, consider including another column for "Lower percentile (s)" because it is misleading to have volume of resident and air exchange rate "checked" for "upper percentile", when only the lower percentile is provided.

Response: *The table title was changed to "Availability of Various Exposure Metrics in Exposure Factors Data." The "lower percentile" already has a footnote noting the comment.*

Comment: The approach to discussing and describing variability taken is appropriate and for the most part adequately provides the user with an understanding of variability and how to describe it. What to do about it is another issue all together. It would be helpful if the authors alerted the user to the factors or sub factors which display unusual variability. Otherwise it might easily be

overlooked. It would be useful to define what is the typical range of variability seen in a given chapter topic area.

> ***Response:*** *The difficulty with the approach suggested is that defining "usual variability" will be subjective. This is further complicated by the fact that there is variability with regard to age, gender, geographical location, etc. Providing such a refinement is unnecessary at this point.*

Comment: For the most part variability of parameters has been adequately described. It may be appropriate to also present median values in the recommendations, particularly for factors that might be skewed. For certain factors it may be important to include 5th percentiles for calculation of high exposure. For example body surface area is typically in the denominator for calculation of dermal exposure. Therefore individuals with the smallest surface areas would have the highest exposures and perhaps be the most at risk groups for dermal exposure, rather than the 95th percentile body surface area where the exposure would be averaged over a larger area.

> ***Response:*** *U.S. EPA has tried to present the tables with enough explanatory information to ensure their utility without introducing too much complexity. Detailed tables with other percentiles are provided at the end of each chapter and noted in the summary table. The surface area in the exposure/dose equation is in the numerator. See Chapter 7 for response to comments on dermal exposures.*

Comment: For the most part, yes. The summary of means and upper bounds for most exposure factors is very helpful. However, as noted below I believe there are instances where sufficient data exist to develop probability distributions (e.g., soil ingestion and dermal adherence).

> ***Response:*** *Comments were addressed in the individual chapters. U.S. EPA disagrees that the data on soil ingestion and dermal adherence are adequate to develop distributions. Data available in the literature are too limited to allow for the development of distributions.*

Comment: Values of the standard deviation provide a good measure of variability. For data that are approximately normally distributed, the estimate of the 95^{th} percentile is: (mean + 1.645 x standard deviation). Likewise, other percentiles can be estimated readily. For data that are approximately log-normally distributed, the standard deviation of the logarithms of the data provide a good measure of variability.

> ***Response:*** *Standard deviations and confidence intervals were provided when available.*

Comment: The discussion of the various issues of data variability in Chapter 2 captures the essential elementary concepts in an adequate manner (though the general discussion of "probabilistic" methods in Chapter 1 would probably

require some clarification. Indeed, a potentially novice user should not assume that a basic "distributional" calculation that aims to capture the (often critical) range of actual exposure outcomes based on known estimates of the variability of key parameters is somehow a challenging problem that involves advanced probability concepts.

Response: *The section was revised in Chapter 1 to refer the reader to Chapter 2.*

Comment: Data variability, in most instances, is adequately presented in terms of population distributions of the parameters. However, the underlying data used to produce these distributional characteristics, is perhaps inadequate to support some of the parameter estimates. If, for example, only a small number of non-representative individuals were used to generate an estimate, is it useful to present the distributional characteristics? What about a study that is statistically representative of some group, but that group is unique in some set of characteristics that makes it less useful as a big picture item?

Response: *The section was revised as per comment.*

Comment: It would clearly be very useful if the relevant data were presented in terms of percentiles so as to make the descriptions of variability useful in probabilistic/Mont Carlo analyses. Although for some of the individual (but not specifically key) studies the data are presented in an adequate array of percentiles, for the key studies (at least for those I reviewed), only a central tendency and upper percentile estimate were presented (and sometimes only a central tendency estimate) when the recommendations were presented. In many cases this reflects that fact that the key studies do not present sufficient (or sufficiently characterized) data to allow a detailed description of percentiles. However, this is not explicitly explained in the text that discusses the key studies. And, in at least one case, the CSFII data that serve as the key data for fish and shellfish consumption, percentiles are presented in the detailed discussion of the key study, but not in the recommendations. The rationale for this is not clear to me.

Response: *U.S. EPA has tried to present tables with enough explanatory information to ensure their utility without introducing too much complexity. The user is referred to tables at the end of the chapter with more percentile estimates.*

Comment: Chapter 1 provides a good summary of exposure assessment. However, in the discussion of uncertainty, I think there should at least be some mention of the concept of joint uncertainty and variability.

Response: *The section was revised as per comment.*

Comment: Page 1-4. Uncertainty. The statement—inherent variability in environmental and exposure-related parameters or possible measurement error—refer to variability, not uncertainty.

Response: *U.S. EPA agrees. The statement was deleted.*

Comment: Page 1-5. Section 1.5.3 (Variability, last sentence in Column 1). The average and median are measures of central tendency, not measures of variability. The variance, standard deviation, and inter-quartile range are measures of variability.

Response: *The sentence was revised to say that these are ways in which variability in a population was characterized.*

Comment: Also, as mentioned in the answer to Question 6, the discussion of "probabilistic" methods in Chapter 1 requires some clarification, so as not to deter someone from performing basic "distributional" calculations that aim to capture not only a point estimate but a distribution/range of actual exposure outcomes based on known estimates of the variability of key parameters.

Response: *The section was revised as per comment.*

2.7. Comments Related to Charge Question 7

Charge Question 7: Please comment on the usefulness of current data presentation (i.e., paper copy). Is this format appropriate and/or are there other formats that you would find useful (e.g., CDROM, Web-based, other)?

Comment: Several peer reviewers commented that Web-based access from the EPA web site is a must. The reviewers believed that this is the method most people will access such a large document. However, they indicated that CDROM and paper copy should be available by order.

Comment: Paper copy is probably easier and quicker to access than having to go on line to an EPA web site to get a pdf version of the Handbook. A searchable pdf version that can be downloaded to a user's computer so it is readily available is probably the easiest. The most useful format would be an on-line version that had an analytic engine behind it so the user could manipulate the data to get the value needed and not have to page through multiple tables to try and find the value. Such an interactive tool is probably well into the future, but such a goal for the program would be a good one and as research surveys are funded and completed, maintaining an eye for how the data could be made accessible for analysis would be important.

Thus an on line "Handbook" only improves on the paper copy if it takes advantage of what the internet and computer resources have to offer. Simply providing a pdf version on line, while useful does not advance utility very far. Being able to do word searches or key word searches would be very helpful and is not something that can be done with a paper copy.

Comment: I love paper copy formats. It is very useful to have one on your bookshelf that you can refer to as needed. However, it is also nice to be able to

access it via the web. That way it is always available when needed. On the web version it is useful to have both one complete document and one that breaks it up by sections to provide more flexibility for users needs.

Comment: Web based access from the EPA web-site is a must. I think this is the method most people will access such a large document. However CDROM and paper copy should be available to order for others to order at a reasonable cost.

Comment: I personally find it difficult to review the EFH in any format other than a hard copy paper version (due mainly to the volume of data summary tables). Others may prefer an electronic version (or some other format).

Comment: I prefer the paper copy.

Comment: USEPA should seriously consider an electronic, searchable version of EFH, along the lines of the FactorFinder computer program for the EFH. Indeed, in the past many users of EFH found FactorFinder extremely practical and, with advances in computer standards, a "modern multiplatorm version" (e.g., coded in Java, as the original FactorFinder, but with "more visual" options) would be a great resource (and a great advancement in terms of usability of format). Both self-standing and web-based versions of such applications would be useful (and relatively straightforward to develop).

Comment: Also, it is becoming less and less likely that a paper version of the EFH would be used in-lieu of a digital (e.g., CD) or web-based version. This is particularly the case given the searchability of the digital/web versions. In recent years, my references to the EFH have all been through the CD or web version. However, I suggest that for digital/web versions the pdf double column format not be used as it is extremely difficult to follow the text.

Comment: While I recognize the need for a paper copy, it is my least favored format. Ideally, a web-based document that included hyperlinks to the various other guidance, tools, etc. as referenced in the document would be most useful. This can be accessed from anywhere at anytime. The current PDF version with roadmap concept works well. It is a good compromise to be able to navigate an extensive document efficiently.

Comment: Paper copy is fine for many, but it should be available as well on CD-ROM and the EPA website.

Comment: I prefer a paper-copy and CDROM for review. But, for research purposes, find it preferable to view the document online and download the individual chapter and/or the entire document, and then to print, at my discretion, particular sections of the Handbook that I need for my research.

Comment: A hardcopy of this document would be completely unwieldy. At thousands of pages, it would take up a significant portion of a bookshelf. A downloadable electronic version is certainly preferable. EPA has excellent

experience in producing easily-downloadable pdf versions of various reports. This should be no exception. An even better solution would be a web-based query system such as that discussed above. Introductory material should be readily available in pdf format, but a better system for the useable data is needed. A searchable database with keyed elements offers a better approach. If I want to know the expected breathing rate of an exercising adult aged 40−60 years, I should be able to type such a query into the system and get the information out, including references to both primary and secondary data, estimates of the population distribution, etc. This would make the document (as a system) much more useful than thumbing through an enormous printed copy.

Comment: Web based access from the EPA web-site is a must. I think this is the method most people will access such a large document. However CDROM and paper copy should be available to order for others to order at a reasonable cost.

Comment: The current format is very useful. But I highly recommend a companion web-based format or even database type format (similar to that of ExpoFacts, the European Exposure Factors Database http://expofacts.jrc.ec.europa.eu/).

Comment: The paper format is a useful format. It should be made available on-line as well, with each chapter downloadable as a PDF.

Response: *U.S. EPA will provide the "highlights" report in hard copy. U.S. EPA plans to provide a thumb drive and Web version. In addition, a separate effort is underway to make the navigation through the web-based pdf easier to the user. Other formats will be considered in the future.*

2.8. Comments Related to Charge Question 8

Charge Question 8: The Introduction contains a summary of the latest guidance and developments in exposure assessment. Please comment on whether we have captured the most important and "relevant" guidance and developments in exposure assessment.

Comment: The answer to question 8 is "no" as the information provided is only marginally useful as an overview of variability and uncertainty and the information lacks accuracy and precision.

Response: *The chapter was edited to address the comments.*

Comment: The details of calculating exposure assessments for each route are not typically given. There are some general ideas on required factors for the assessment. However, the user is referred to other EPA documents that present quantitative methods for exposure assessments for each route. There are occasions where more examples or better explanations can be given. These are detailed below for each chapter in my set of reviews. Chapter 1 contains the bulk or most details for making the exposure calculations and the reader should always

review this chapter first. In fact each chapter should say "refer back to chapter one for guidelines on making exposure calculations".

Response: *Chapter 1 was expanded and revised. The type of guidance suggested by the reviewer is outside the scope of this document.*

Comment: The factors currently in the Handbook are useful but the approaches to actual exposure and risk assessment are either old or incomplete.

Response: *Chapter 1 was revised and updated with the most current Agency guidance.*

Comment: In Summary and in response to Question 8, the introduction does not provide the latest guidance and development nor capture the most important guidance and development in exposure assessment.

Response: *The Introduction was revised.*

Comment: It is useful to reference all the relevant EPA guidance documents that relate to exposure assessment and risk assessment. The listing appears quite extensive, but I am not familiar with all the EPA guidance. Going beyond EPA to include other developments probably is unwarranted as it is then difficult to know how comprehensive the discussion is and whether all perspectives have been included. It would be helpful if there are some new guidance documents that are under development or some that are undergoing revision to mention them. I think the critical information that helps exposure assessors is the reference to the EPA documents and how they can be retrieved. If mention can be made if any of them are specific to some of the factors, those links should be mentioned. Trying to capture the whole field is expecting too much.

Response: *U.S. EPA agrees with the reviewer. U.S. EPA is only providing U.S. EPA references at this point. There are other efforts underway to consolidate other tools.*

Comment: Yes, the Chapter does a very nice job of laying out the latest guidance and developments in exposure assessment. Under section 1.6, I would consider adding:

—US EPA (2005) Approaches for PBPK Models and Supporting Data in Risk Assessment

—EPA Standard Operating Procedures for Residential Exposure Assessments

Response: *This section was revised as per comment.*

Comment: Is there a manual for SHEDS or perhaps a list of EPA models that individuals may also like to consider using in conjunction with EFH to estimate exposure?

Response: *The SHEDs reference and a discussion were added to Sections 1.7 and 1.10.*

Comment: Consider also a discussion of aggregate exposures to complement the discussion of cumulative exposures.

Response: *Discussion about aggregate exposures was added.*

2.9. Comments Related to Charge Question 9

Charge Question 9: We acknowledge that there have been significant developments in the area of uncertainty analysis. Several new references have been added to the chapter on uncertainty and variability. Please comment on whether the information provided is useful as an overview of uncertainty and variability.

Comment: This is a complex area and it is difficult to do it justice in a short chapter. The Handbook is not a textbook or intended to be exhaustive. All that should be done is provide an overview and the conceptual framework. As elsewhere, the focus is upon EPA documents and perspective, which may not provide all the various perspectives seen in the literature. As a non-expert in this area, I found this chapter laid out what I would need to be aware of while doing an exposure assessment and what needs to be paid attention to. It points the reader to other references should it spark greater interest by the reader. For me the Handbook is a reference source for exposure factor numbers that have been vetted by the EPA. It is not a how-to guide or text book on all exposure and risk assessment issues.

Response: *U.S. EPA appreciates the comments.*

Comment: Chapter 2 provides an overview of variability and uncertainty. Since the field of statistics is focused on the study of variability and to a lesser extent uncertainty, it is strange that there is little or no discussion of appropriate statistical techniques.

Response: *The field of statistics is concerned with both variability and parameter uncertainty (i.e., standard errors). The chapter is largely dedicated to the conceptual issues of variability and uncertainty in the context of exposure assessments. The Exposure Factors Handbook reports largely on variability, while methods used to incorporate the variability into exposure assessments are treated elsewhere in the literature. The revised chapter does report on statistical techniques, i.e., Monte Carlo simulation, to treat uncertainty.*

2.10. Comments Related to Charge Question 10

Charge Question 10: Data on soil/dust ingestion are limited. Has NCEA done an adequate job in reviewing, presenting, and summarizing the available data? Is the differentiation between soil and dust ingestion clear?

Comment: The Agency has done a thorough job for most of the factors reported. I note a few missing data sources by chapter below. Chapter 5: Estimates of indoor dust based on number of hand to surface contacts and subsequent hand to mouth contacts. This work is being done within EPA through the SHEDS program.

Response: *The paper from Ozkaynak et al. (2010) that estimates soil and dust ingestion using hand-to-mouth contact information was added. A discussion about this methodology and how it is used in SHEDS was include and the recommendations were revised accordingly.*

Comment: One reviewer said that his main issue with Chapter 5 is the distinction between outdoor soil and indoor dust ingestion. The overlap of indoor soil-derived dust is not addressed. Soil can be tracked or blown into a house and mix with dust of indoor origin. Therefore, ingestion of indoor dust may also result in soil ingestion.

Response: *Definitions for soil and indoor and outdoor settled dust are provided in the introduction to Chapter 5. The distinction between outdoor soil and indoor dust ingestion is addressed in Section 5.1, in the definitions of "Soil" and "Indoor Settled Dust." The definition for "dust" has been amended to include "or blown" into a house. The issue of the ingestion of indoor dust resulting in soil ingestion is addressed in this definition: "These particles may include soil particles that have been tracked or blown into the indoor environment from outdoors as well as organic matter." In these definitions, the distinction between outdoor soil and indoor dust is the following: outdoor soil (or simply soil in these definitions) is soil located outdoors or used indoors in planters; indoor settled dust is indoor settled particles that may include tracked-in outdoor soil.*

2.11. Comments Related to Charge Question 11

Charge Question 11: Recreational marine fish intake rate data were only available for individuals >18 years of age. Recommended recreational marine fish intake rate values for children have been estimated based on the age-specific ratios of general population children's marine fish intake to general population adult marine fish intake, multiplied by the adult marine recreational fish intake rates. Please comment on this approach and, if "relevant," provide suggestions for alternatives, using the available data.

Comment: The method used by EPA (which consists of applying a ratio of children/adult marine fish ingestion rates in the general population x adult marine recreational fish ingestion rates) would seem to provide a reasonable approximation of recreational marine fish ingestion rates for children. However, I do have a few observations. First, the table which purports to summarize the recreational marine fish intake values (Table 10-3) has some formatting problems.

Response: *The formatting concerns have been addressed.*

Comment: Second, I was unable to locate any presentation of the method described above. Hence, while the approach appears to make sense conceptually, it is not possible to evaluate the specific values and factors considered by EPA in deriving the children ingestion rates. I believe this information should be summarized in an appropriate location in Chapter 10.

Response: *The text describing Table 10-3 has been clarified.*

Comment: This approach is based on the assumption that recreational fish intake follows non-recreational (i.e., store-bought) fish intake. Or, in other words, that fish consumers (including children) eat recreational marine fish instead of or identical to store-bought fish. This is an a priori reasonable assumption in the absence of evidence, but not an assumption whose validity is intuitively obvious. One approach to validating this assumption is to investigate whether adult recreational fish consumers who are high consumers of non-recreational fish are also high consumers of recreational fish. This comparison should be made in a population that has good access to store-bought fish rather than a subsistence fishing population that has minimal access or purchasing ability for store-bought fish.

Response: *While no change to the Handbook is necessary, the research suggested by the reviewer is a good idea. It will be considered in future efforts.*

Comment: The suggested approach seems like a reasonable approximation, but it should not be used to develop a recommendation. I have attached a file which contains estimates of the ratios utilized to develop Table 10-3, along with those for general population marine fish consumption in Table 10-1. This analysis indicates first, that the ratio for fish intake of a given age to that at age >18 is different for mean intake than for 95th percentiles. The analysis in Table 10-3 appears to use the mean ratio to generate both mean and 95th percentiles. Further, because this approach is just a general approximation, it should not be used in a recommendations table. It could be presented and discussed in the document. In addition, it is noted that the marine fish consumption recommendation in Table 10-3 are based upon 1993 data. There are a number of newer studies available, and a summary table of newer studies, similar to 10-5 and 10-6 but with the additional information indicated below under question 13, would assist in understanding how representative the 1993 data may be for the current population.

Response: *U.S. EPA has recalculated the 95th percentile, made the corrections to the table, and added a footnote to reflect the change. No newer data could be located that would have the information needed by regions.*

2.12. Comments Related to Charge Question 12

Charge Question 12: Relevant data on recreational marine fish intake presented in the chapter are limited to certain geographic areas and cannot be generalized to the U.S. population as a whole. Therefore, recommendations from these data could not be provided. Instead, the assessor has the flexibility to use data from these "relevant" studies that are more appropriate for their particular scenario or location. Please comment on this approach and, if appropriate, provide suggestions for alternative approaches, using the available data.

Comment: My experience bears out the conclusion of the EFH authors that patterns of recreational fish consumption are highly population and geographically specific. They depend on the cultural practices of local sub-populations, the specific types of freshwater fish available, the availability of these fish relative to seasonal weather and the ability of the population to access sites of freshwater fishing areas. In New Jersey, for example, recreational freshwater fishing is popular and there are several freshwater species that are popular for consumption elsewhere in the U.S. However, survey work we conducted in the 1990's indicated that freshwater fish consumption comprises only a very small percentage of total fish consumption. This is because the culture of recreational freshwater fishing in New Jersey is largely a catch-and-release culture (Stern et al., 1996 (see response to question #3). This appears to be in sharp contrast to the fishing culture in (e.g.) the Great Lakes recreational fishery.

Response: *U.S. EPA agrees that regional differences in fish consumption are important. U.S. EPA added material from Mahaffey et al. (2009), which used NHANES data to estimate regional differences in eating fish.*

Comment: I agree that it is not possible to develop a single set of freshwater or Native American fish ingestion rates that could be considered applicable to all scenarios that involve these angling populations, and I concur with EPA's decision to permit flexibility in choice of the most proper set of assumptions. I think the EFH does a good job in summarizing the available studies, particularly the tables at the end of the chapter. Hopefully, any fish ingestion scenario that must be addressed in a site-specific risk assessment can be "matched" to some degree with one of the studies summarized in this chapter. There are numerous "site-specific" factors that often must be addressed in a fish consumption risk assessment; some of these are discussed in detail in Chapter 10 and some are not. Since the updated EFH is eventually going to be employed as a resource document for risk assessors to use in evaluating fish ingestion scenarios, I think the following should be addressed in more detail at some point, possibly in Section 10.9

("Other Factors to Consider for Fish Consumption"):

—which consumption rates are most appropriate for family members who are consuming (but not catching) the fish; do angling and non-angling pregnant women need to be considered separately (with specific fish ingestion rates)?

—how does one best evaluate potential consumption of the "other" parts of the fish/shellfish that are not typically consumed by the general population but might be considered "delicacies" by some individuals? (e.g., fish skin, crab hepatopancreas); similarly, which consumption rates are most appropriate for "whole fish/shellfish" that might be included in some preparations (e.g., stews).

—the issue of "access" to fishing locations is an important factor that should be mentioned; quite often the risk assessor is faced with estimating fish ingestion rates for marine or freshwater locations that are highly industrialized and therefore have limited access. Which (if any) of the studies summarized in Chapter 10 best reflect a "limited access" scenario?

—should the presence of warnings or advisories be taken into account and if so, which studies best reflect their influence?

—the possibility of "subsistence" fish consumption is invariably raised in fish consumption risk assessments. Which, if any, of the consumption rates (marine or freshwater) in Chapter 10 are most representative of true subsistence rates? Does one simply use the 95%ile values of the "standard" rates or are there separate rates that apply only to subsistence anglers? (perhaps this is described in the Chapter and I just can't find it readily).

> ***Response:*** *The reviewer brings up valid issues that need to be considered when assessing exposure through the fish ingestion pathway. However, U.S. EPA believes that these are beyond the scope of this document and may be better addressed in a separate effort. Some of these questions are discussed in the literature summarized Chapter 10. For instance, subsistence fishing is addressed by Burger and Gochfeld (1991), Hudson River Sloop Clearwater (1993) and several studies of fish consumption by Native Americans.*

2.13. Comments Related to Charge Question 13

Charge Question 13: Recommended values for fish intake are not provided for recreational freshwater or Native American populations because the available data are limited to certain geographic areas and cannot be readily generalized to the U.S. population of freshwater recreational anglers or Native Americans as a whole. Instead, data from several relevant studies are provided in the chapter to give assessors the flexibility to choose data that are more appropriate for their particular scenario or location. Please comment on this approach and, if appropriate, provide suggestions for alternative approaches, using the available data

Comment: The lack of recommendations for recreational freshwater anglers is appropriate because site- specific factors will always be the predominate

determinant of fish consumption in the myriad types of freshwater bodies. Such factors include size of water body, climate, fishing regulations, availability of alternate fishable water bodies and water body productivity. Perhaps you could mention some of these factors in your justification.

Response: *Information on these factors has been added to the text.*

2.14. Comments Related to Charge Question 14

Charge Question 14: We are aware that food consumption data from the National Health and Nutrition Examination Survey (NHANES) "What We Eat in America" are available and NCEA is partnering with the U.S. EPA's Office of Pesticide Programs to get these data analyzed and incorporated into the final Handbook. This analysis is expected to be available in May 2010. Are you aware of other published data concerning food consumption that should also be considered?

Comment: Most reviewers agreed that it was important to incorporate the NHANES data into the EFH, and that the CSFII is dated. A reviewer noted that a reference to the FDA's Total Diet Study (TDS) should also be added to the EFH.

Response: *U.S. EPA agrees with the comment. The CFSII data was collected in 1994−1998. To update the Handbook, data and tables have been added from an analysis conducted by the U.S. EPA Office of Pesticide Programs of 2003−2006 NHANES data. The recommendations tables are now based upon that NHANES data with the exception of the recommendations on fat intake, which are based on CSFII. Although CFSII is not as current as the NHANES and is no longer the basis for the Handbook recommendations, it is still included as a "key" study because it contains regional, urban, and seasonal breakouts not found in NHANES. The FDA's Total Diet Study (TDS) is sometimes called the market basket survey. It is used to determine levels of various contaminants and nutrients in foods. The TDS uses data from USDA food consumption surveys including the 1987−88 Nationwide Food Consumption Survey (NFCS) and CSFII 94−96, 98 surveys. Referring to the TDS will not add any additional information to the Handbook since both the NFCS and CSFII are already included.*

Comment: There is an inherent disconnect between the speed of food intake data that are being generated from the NHANES surveillance program and the long and extensive period between revision/update of the EFH. At the current rate, new NHANES food intake data are being released every two years, while the frequency of updating the EFH is once every 10−12 yrs (last update was 1997). Given the time current time-lag, it is a challenge to maintain the currency of the dietary factors in the EFH. It may be more expedient to provide updated dietary factors for the EFH electronically via a web-based program. Also given the large number of data tables covering the wide range of food commodities in the US diet and the various exposure estimates (per capita, per user, per eating occasion, one-day, two day average, etc..), a web-based data-query system would be the

most effective and useful means of delivering the data to user. The USDA nutrient data query system (see USDA website: http://www.nal.usda.gov/fnic/foodcomp/search/) is an example of such a system.

> ***Response:*** *U.S. EPA is working on making at the food-intake updates more frequently.*

Comment: I am not aware of additional published food consumption data for the US. The following website might be useful for ancillary information:

http://www.iom.edu/About-IOM/Leadership-Staff/Boards/Food-and-Nutrition-Board.aspx

> ***Response:*** *The Web site did not appear to contain any nationwide nutritional survey results. Instead, the IOM provides good information regarding nutritional needs, food safety, obesity prevention, etc. Although this information is interesting, it is not within the scope of the report.*

Comment: There are some UK and European databases that might likewise provide ancillary information.

> ***Response:*** *U.S. EPA would welcome any specific suggestions with regard to data sources. However, consumption behavior in the UK and Europe might differ from the United States.*

Comment: I am not aware of other published data concerning food consumption. I believe that the "What We Eat in America" (WWEIA) data set is currently the most complete and representative data set available to assess a variety of food groups, and water, consumption by the US population. Will the Office of Pesticide Program's analysis be done on the NHANES 2003−2004 data set, or earlier, or later?

> ***Response:*** *U.S. EPA has added several new tables to the chapter based on U.S. EPA Office of Pesticide Program (OPP) analysis of the 2003−2006 NHANES data in addition to the CSFII data. The CFSII data is not as current, but it contains regional, urban, and seasonal breakouts not found in NHANES.*

Comment: FDA Total Diet Study (TDS)—The foods collected in the Total Diet Study (referred to as the TDS food list) represent the major components of the diet of the U.S. population. Currently, there are about 280 foods collected and analyzed in the TDS. The FDA has compiled the food consumption amounts for each TDS food have been compiled for the total US population and 14 age/sex subgroups (M/F 6−11 mos, M/F 2 yrs, M/F 6 yrs, M/F 10 yrs, F 14−16 yrs, M 14−16 yrs, F 25−30 yrs, M 25−30 yrs, F 40−45 yrs, M 40−45 yrs, F 60−65 yrs, M 60−65 yrs, F 70+ yrs, M 70+ yrs). These consumption amounts are collectively referred to as the TDS diets. The latest version of the TDS diets is TDS Diets, Version 3 (2003 food list + 1994−96, 1998 CSFII data) and can be downloaded

at:
http://www.fda.gov/downloads/Food/FoodSafety/FoodContaminantsAdulteration/TotalDietStudy/UCM184702. For completeness, a reference/link to this dataset should be added to the EFH.

Response: *These data are from CSFII, which is already reported in these chapters.*

Comment: The USDA website indicates more recent sources of food consumption data that should be considered within this document: http://www.ars.usda.gov/Services/docs.htm?docid=15044

Response: *The information in the USDA website provided by the reviewer is from NHANES, which is already presented in the Handbook. U.S. EPA has added several tables based upon 2003−2006 NHANES..*

2.15. Comments Related to Charge Question 15

Charge Question 15: Chapter 19 presents data on residential building characteristics that may be relevant for assessing human exposures in the residential setting. Please comment on whether there are any other data or factors, for which there are available data, that are important for inclusion in future revisions to this chapter?

Comment: The one set of factors that is "missing" within the above-specified context should have to do with factors associated with microenvironments other than residential buildings. Of course, the EFH is not intended to support occupational exposure assessments; nevertheless, many "non-occupational" exposures (at least in the traditional sense of the term) take place indoors but in buildings that are not residential (e.g., schools and other public buildings, restaurants, movie theaters, stores and shopping malls, athletic facilities and clubs, hospitals, etc.) and these microenvironments need to be adequately characterized. In vehicle-exposures are also a major contributor to total exposure and the factors pertaining to relevant microenvironments (cars, buses, trains, etc.) also need to be properly characterized.

Response: *Chapter 19 was expanded and revised to include nonresidential buildings. Information about time spent in vehicles is provided in chapter 16.*

Comment: I would like to describe one publicly available data source that may be useful, i.e., the California Statewide Residential Appliance Saturation Study (RASS) (CEC, 2004) may be a useful. The RASS may be a Relevant study to include data in future revisions to the EFH. The RASS was initiated in 2002 and surveyed nearly 22,000 respondents/households. I would not recommend it as a Key study because it is not representative of the US population and the low survey response rate (19% vs the expected 47% to the initial mail-solicitation; a non-response follow-up study conducted by telephone had a response rate of roughly 45%). Additionally, the selection of households was weighted to the

population represented by the sponsoring utilities. The RASS database includes linked data on the following residential and household characteristics that may be useful to describe and incorporate in Chap 16 (Activity factors), 17 (Consumer products), and 19 (Residential Building Characteristics) of future EFH revisions:

Length of time household living at current residence

Whether residence is "partial-year" or vacation home

Cooking frequency of household during week (breakfast, lunch, and dinner, and other separately)

Presence of swimming pool at residence

The Reference for the RASS is: CEC (2004). California Statewide Residential Appliance Saturation Study (RASS). Final Report, June 2004. Prepared by KEMA-XENERGY, Itron, and RoperASW under Contract No. 400-04-009 with the California Energy Commission (CEC). Report and data available for download at: http://www.energy.ca.gov/appliances/rass/. Additional Information on the RASS can be obtained by contacting Glen Sharp, the Project Manager at the California Energy Commission (CEC). His contact information is provided at the bottom of the RASS website (listed above)

Response: *The California Statewide Residential Appliance Saturation Study was reviewed, but the information provided in that report refers to energy consumption in California residences. This type of information may more suitable for a future update of U.S. EPA's Sociodemographic Data Used for Identifying Potentially Highly Exposed Populations (U.S. EPA, 1999).*

2.16. Comments Related to Charge Question 16

Charge Question 16: Are there any additional factors that need to be addressed in future revisions to the Handbook? Why are they of priority for EPA risk assessments? Are you aware of any sources of data for these new factors?

Comment: It would seem useful to do a survey and find out what the assessors like about the current Handbook and what they would like added or changed rather than rely on a few reviewers' experience. In some instances new factors may have been considered, but there may not have been adequate data. Did the authors identify factors that they would like to have included but could not because of lack of data? Has EPA received any unsolicited recommendations or requests?

Response: *NCEA receives feedback from U.S. EPA program offices and other users of the Handbook on a continuous basis. They have asked not necessarily for new factors, but for better or more up-to-date data on specific factors, such as soil ingestion rates, consumer product use.*

Comment: I agree that these are the most used factors. In future, wondering if there will be a companion handbook of physiological factors for PBPK modeling?

Response: *A database on physiological factors is under development by the U.S. EPA.*

Comment: Chapter 7 specifically limits its focus on the two areas of "measurements of body surface areas" and of "dermal adherence of solids to the skin." References are given for more comprehensive guidance relevant to dermal exposure assessments: these references are specifically USEPA reports from the early 1990s. In this reviewer's opinion, some of the additional exposure factors (other than the chemical-specific aspects, that are beyond the scope of the EFH), that are already mentioned on page 7-1 (variation of the thickness of the stratum corneum over different parts of the human body, variation of this thickness with age/gender, impact of exogenous and endogenous conditions that may effect absorption rates, etc) should, even briefly, addressed in Chapter 7. Specifically, it would be useful to incorporate in this Chapter:

Response: *Additional text has been added, as appropriate. Also, this chapter has been expanded to include information on film thickness, residue transfer, and the thickness of the stratum corneum.*

Comment: A discussion providing linkages with data on activities contributing to dermal exposure to liquids and gases (e.g., bathing, swimming, etc.).

Response: *This information is provided in the Introduction to this chapter.*

Comment: Representative data on changing skin surface thickness (for different body areas) with development and aging.

Response: *Information on the thickness of the stratum corneum has been added.*

Comment: Representative non-chemical specific data on dermal permeability transport rates for broad groups of compounds, focusing on the general mechanisms that dominate these rates and the exposure conditions that determine these mechanisms.

Response: *Information on this topic has not been added; U.S. EPA is not addressing chemical-specific factors affecting dermal absorption in this chapter.*

Comment: A discussion of the influence of activity levels (i.e., of metabolic effects and of corresponding blood rates) on dermal absorption rates that can significantly influence uptakes through the dermal route.

Response: *Information on this topic has not been added; U.S. EPA is not addressing chemical-specific factors affecting dermal absorption in this chapter.*

Comment: A discussion of how the dermal absorption of contaminants could be underestimated or overestimated, if appropriate information for the above factors is not—or is not expected to become—available.

Response: *Information on this topic has not been added; U.S. EPA is not addressing dermal absorption in this chapter.*

Comment: Four reviewers noted that Chapter 7 is limited to two exposure factors—surface area and soil-skin adherence. They noted that many other factors (some from other chapters) are needed for the calculation of dermal exposure. They specifically mentioned the following:

—Soil loading per contact event (note the chapter does give soil loading on the skin mainly through activity events), residue transfer, immersion data, deposition, and removal rates (e.g., handwashing events, wipe events, rub events).

Response: *Information on exposure to liquids (film thickness approach) and residue transfer has been added to this chapter. Additional information on soil loading per event has been added as "relevant" studies.*

Comment: Soil properties and how long the different types of soil will adhere to the skin.

Response: *No papers were located that provide data on the amount of time that soil adheres to the skin. Some data on hand washing events after soil contact have been included in Chapter 16.*

Comment: Factors in Chapter 4 (Non-Dietary Ingestion Factors) and Chapter 16 (Activity Factors)

Response: *These other chapters are referenced as appropriate.*

Comment: Activities contributing to dermal exposure to liquids and gases (e.g., while bathing, swimming)

Response: *Activity factors are provided in Chapter 16.*

Comment: Changing skin surface thickness for different body areas.

Response: *Information on this topic has been added.*

Comment: One reviewer felt that Chapter 7 does not provide enough information for the user. Another reviewer suggested that, unless additional exposure factors

are added, the title of the chapter be changed to "Soil Adherence Factors" to more accurately represent the data presented.

Response: *Information on exposure to liquids (film thickness approach) and residue transfer has been added to this chapter.*

2.17. Comments Related to Charge Question 17

Charge Question 17: Please comment on any areas where future research could be conducted to fill data gaps?

Comment: The Exposure Factors Handbook generally presents the data in a clear, easily understood format (Question 1). I have no suggestions for improvement, except my suggestions for Chapter 2. The coverage of the literature is exhaustive and thorough. Some of it may be more of historical interest than of current value but it is difficult to develop criteria for excluding information, or to predict the varied uses for the data. Although, I do not think it is necessary to formally review exposure assessment guidance documents from the states, it might be useful to at least examine them for anything that might be useful. I would like to see a Recommendations for Future Research Section in each chapter.

Response: *U.S. EPA does not want to give the impression that resources have been committed to future research. Limitations and uncertainties have been listed.*

Comment: A future research need would be to obtain cosmetic and personal care products information for children and teenagers.

Response: *U.S. EPA agrees that further research regarding the use of cosmetic and personal care products by children and adolescents is warranted. However, no resources can be presently committed to conduct research in this area.*

Comment: For cosmetic and personal care products, there are no data for teenagers and children in the revised EFH. Also, the baby care data from Sathyanarayana et al (2008) are limited to % using and there is no information on amount/frequency use that are needed for a quantitative exposure assessment. Toothpaste/oral care, soap and detergent use data for the US population are not summarized in the revised EFH. Future research/update could consider these data gaps. The use data for cleaning products are also old and could be updated in the future.

Response: *U.S. EPA will consider suggestions for new references that contain such information in the next revision. No new references were located.*

2.18. Comments Related to Charge Question 18

Charge Question 18: Please comment on how you would like the U.S. EPA/NCEA to release future updates to the Handbook.

Comment: A section titled "Updates to this version of the EFH." This section could list a timetable of when updates for entire chapters (such as dermal exposure and building characteristics chapter) can be expected to be released (even just the year of expected release). This section would also contain information on how to get on the email notification list to receive information on updates of any exposure factor in a specific chapter, or updates to any portion of the EFH.

Response: *This suggestion will be considered for future revisions.*

Comment: One reviewer suggested the following ways to incorporate the NHANES data into the EFH on a more regular basis.

- Release a newer version of the EFH more frequently.
- Break the EFH into two parts—a section of factors that are updated on a regular basis (e.g., dietary factors) and a section of factors that are not updated regularly (e.g., dermal factors). Another reviewer supported this approach.
- A Web-based database may help with more frequent updates. Two reviewers supported this approach, especially because a great deal of data are available.

Response: *These are good suggestions that U.S. EPA will consider for future revisions to the Handbook.*

2.19. Comments Related to Charge Question 19

Charge Question 19: What additional information might be added in the future that would help the exposure assessment community better interpret and apply the data from the Handbook?

Comment: In general, one point to make clearer within the Handbook is that linkages between factors should be considered in their application. For example, skin surface area estimate have increased by about 10% from those in the current EFH, but these are calculated based upon body weight, which have increased by about 10%. So the updated skin surface area estimates are dependent upon and should be utilized with the updated body weight data. Brief discussion of the drivers for changes from the current EFH, such as this example would be helpful to the exposure assessor applying these updated recommendations.

Response: *Data from NHANES 2005−2006 were used to derive surface area. Considerations and caveats on the use of the data are discussed where appropriate throughout the Handbook.*

Comment: For the most part, the categories of factors used to are appropriate. There can be legitimate disagreement on the interpretation of the merit of a study

in any of these regards. For the food ingestion chapters that I reviewed, my particular concern was the rating of medium to high in some with the use of 12+ year old data that could have changed more recently. Also, while this dataset had a large population, when broken into individual age bins, these numbers decrease sometimes dramatically to the extent that they did not meet minimum requirements but were still used. My suggestion is to refrain from using data beyond its limits (even with footnoted caveats as these can often be ignored). A combination of quantitative and qualitative narrative should be used as appropriate.

Response: *U.S. EPA finds that providing the data even if they have limitations are useful, especially in studies where no other source of data is available. Limitations with the data are discussed.*

Comment: Any text or tables reporting data on mouthing of objects should clearly specify what is considered in the object category. This context is needed to appropriately interpret object-related data, as Xu et al., 2009 have suggested that study differences in the definition of "object" may be contributing to the statistically significant different in object-to-mouth behavior with regard to study.

Response: *U.S. EPA has tried to be as complete and accurate as possible when summarizing the data from the various studies. No further information on object categories was provided by the study authors.*

2.20. Comments Related to Charge Question 20

Charge Question 20: The Handbook addresses children as a susceptible population and includes data on older adults where available. So as to assist the Agency with planning for potential future projects, please comment on any other susceptible populations of interest that could be included in future updates to the Handbook, and suggest data sources for these populations.

Comment: We keep saying that that there is no guidance for age groups for presenting adult data, but the reader should be aware how activity patterns (e.g., time spent at home, time spent at work), really begins to change for the elderly. At that advanced stage, the human body becomes compromised due to the development of illnesses, chronic disease and, therefore, more susceptible to lower chemical concentrations. This should be considered in exposure assessments. I think EPA does address this further along in the chapter. It is worth repeating here.

Response: *The chapter already acknowledges the point made by the reviewer. No additional changes are necessary.*

2.21. Comments Pertaining to Multiple Chapters

Comment: For several of the chapters, it was noted by the reviewers that it was not clear why certain studies were deemed relevant rather than key.

Response: *The rationale for why specific studies were deemed "key" versus "relevant" is discussed in a number of places in each chapter; in the Introduction, in the introductory table discussing confidence ratings, and at the end of each study summary in the chapter (i.e., advantages and limitations of the study). Additional language was added to the Introduction of the Handbook to provide further clarity.*

Comment: A number of additional studies were suggested by the reviewers for inclusion in the chapters.

Response: *All of the additional references suggested by the reviewers were evaluated for inclusion in the Handbook. A number of new studies were added to various chapters as a result; other studies were not added for a variety of reasons (i.e., not "relevant" to the chapter, did not provide additional or more recent data, etc.).*

Comment: For a number of the chapters, there was some dispute by the reviewers regarding EPA's assignment of confidence ratings for the key studies.

Response: *Each of the comments regarding specific confidence ratings for the "key" studies was evaluated. U.S. EPA has supplied additional information for those chapters to further clarify the confidence rating.*

2.22. Chapter 1: Introduction

Comment: In the introduction "Background", it briefly indicates what areas have been updated or added to since the 1997 earlier Handbook. While useful information, what the reader would like is to know what the changes are or if they are significant or not and in what direction. This section indicates that soil ingestion and fish consumption are updated but the user would like to know did the ingestion rates go up or down or not change, was a different "key" data set used. Does the user need to spend time working through the chapter or is it only that the references have changed but the values have not? Since many of these factors are used regularly by assessors, many remember what they have been using. If that needs to change, it would be helpful to say so up front and not make the user page through looking and trying to remember what it used to be and what it is now. In each chapter intro it would be useful to say whether the "key" study has changed or not and whether the main table values have changed. Highlighting the tables with changes would be helpful.

Comment: A section on what's changed and why would be useful in the Introduction as well as at the start of each chapter. The recommendations in this document have been used for well over 10 years. A "simple" summary table or description of the context for the change would be useful for practitioners to help with decisions on the use of the new information (or not) given EPA's overall caveat that these are not legally binding values.

Response: *The Introduction has a list of what was updated. Although the suggestion about significant changes may be useful, it may be resource intensive. U.S. EPA has published a "highlights" report providing simple summaries of the recommendations.*

Comment: One reviewer thought that Chapter 1 should explain the concept of using micro, meso, and macro activity patterns when calculating exposure. This would determine the type of algorithm and exposure factor needed. Another reviewer said that new developments in exposure assessment, such as using biomarkers, should be explained better. A road map with links to existing and ongoing efforts in Chapter 1 might be a useful way to show new concepts and approaches to characterizing exposure. Another reviewer agreed that an interactive road map would be very beneficial.

Response: *Clarification about micro and macro activities was added. It is not clear what the reviewer meant by "meso activities." A road map and a schematic diagram were added to Chapter 1. A discussion about biomarkers was added.*

Comment: Two reviewers suggested adding a section that references other resources, databases (e.g., databases from the U.S. Geological Survey, the U.S. Food and Drug Administration [FDA], the U.S. Census Bureau), models, modeling frameworks, and tools that are standard in exposure assessment. One reviewer suggested that perhaps a table could be used to list the additional references and denote the applicable exposure routes. An asterisk could be used for those that are in draft form or under development.

Response: *Other sources of information are mentioned throughout the Handbook when applicable.*

Comment: Because exposure is part of a multidisciplinary approach, one reviewer suggested adding a road map to Chapter 1, similar to the one in the 1997 EFH, which shows the connections among chapters. Three reviewers agreed that a diagram would be beneficial. One reviewer said that there needs to be an explanation on how Chapter 19 (Residential Building Characteristics) and Chapter 17 (Consumer Products), specifically, fit into the exposure assessment. Two reviewers suggested adding a couple of paragraphs to describe each subsequent chapter.

Comment: To supplement the narrative, EPA should add a decision tree to guide the user toward selecting the most appropriate data for the assessment.

Comment: The addition of a few flowcharts clarifying relationships among concepts discussed in the text as well as "decision tree type" diagrams that would supplement the narrative in guiding the user towards the selection of the most appropriate data for her/his assessment.

Comment: EPA should add a diagram of an exposure pathway.

Comment: While a summary like documented in Table ES-1 is appropriate, the current version is too complicated and does not include the confidence rating. Instead, a version like the Roadmap Figure 1-2 of the 1997 version provides a much better presentation of this complicated information. While the need for a summary of percentiles is recognized, use of the roadmap format is much better suited to the range of information provided. It is likely more convenient to use this format for a PDF document with links than the paper version, in which case, the format (i.e., mean, upper percentile and confidence rating) of Table1-2 (of the 1997 version) is probably still relevant and sufficient for the ES. If current ES-1 format is retained, a lot more effort needs to be expended to make it correct, properly documented and easily understood.

Comment: The use of the roadmap concept (and word search) in the downloadable current PDF version should be retained. This feature allows for ease of moving through an extensive document even for the most knowledgeable users.

> ***Response:*** *A new schematic diagram relating pathways, factors, and routes has been added. The executive summary was revised. Table ES-1 was revised and updated.*

Comment: One reviewer felt strongly that Chapter 1 should contain caveats to explain the strengths and limitations of the EFH. He specifically mentioned that the following should be added to the end of Section 1.2:

"It does not supersede any standards or guidance provided by professional scientific societies involved more with exposure and/or risk assessments, statistics, or with specific organ systems (including the anatomy, physiology, immunology, biochemistry, etc. involved and the target organ exposure-dose-response relationships). The opinions of those bodies, NRC, WHO, UNEP, and other agencies should be respected as well."

This reviewer said that Section 1.9 should also contain caveats, particularly when evaluating exposure–dose-response relationships.

> ***Response:*** *A sentence similar to the one suggested by the reviewer was added.*

Comment: Because the analyses for some of the exposure factors are done on a different life-stage basis, Chapter 1 should explicitly state which chapters have the data presented in EPA's recommended age groups and which do not.

> ***Response:*** *This suggestion is not easily implemented because the many factors involved, especially in the food chapters. Further clarification was added.*

Comment: It would be useful to explain why some chapters do not have key and recommended studies.

Response: *The discussion about key versus relevant studies was revised to provide clarification.*

Comment: EPA should develop a separate document or appendix to the EFH to describe each of the handbooks listed in Chapter 1.

Response: *Budgeted resources were not sufficient to implement this suggestion at this time, but U.S. EPA will consider it in a separate effort currently underway. Links were provided in the references where available.*

Comment: It is important to describe in Chapter 1 the changes (especially involving key studies) between the 1997 EFH and this version (mentioned by three reviewers).

Response: *The main revisions were highlighted.*

Comment: To increase confidence in the studies presented, the methods used to identify key and relevant studies need to be better explained (mentioned by two reviewers).

Response: *A better description of "key" versus "relevant" is provided.*

Comment: The appendix to Chapter 1 in the 1997 EFH explaining dose calculations and providing examples should be updated and included in this version.

Comment: Appendix A1 of the 1997 version needs to be updated and included. This was a very useful primer on risk calculations and arguably is needed even more now with the inclusion of age bins which are not always consistently applied in this document with the CSEFH and are at odds with current RAGS "practice".

Response: *The appendix has been revised and updated.*

Comment: Chapter 1 should discuss where exposure factors fit into the overall risk assessment.

Response: *Additional discussion about the concepts in exposure assessments was added.*

Comment: In Chapter 1, clarify how the EFH fits into the hierarchy of other exposure factor documents, particularly EPA's *Child-Specific Exposure Factors Handbook.*

Response: *Additional text was added to clarify that the revised Handbook supersedes the information in the Child-Specific Exposure Factors Handbook.*

Comment: One reviewer said that while the majority of the reviewers felt that Chapter 1 makes an important contribution, most thought that substantial modifications are necessary. Problems to be addressed run the gamut from readability to improper relative emphasis to definitions that are not current. Most believe that Chapter 1 needs at least some work, and many believe an extensive rewrite is needed.

> ***Response:*** *The chapter has undergone substantial revisions. Definitions were updated, and a clear distinction between exposure and dose was made.*

Comment: The reviewers then had a discussion about the intended audience of the EFH. Several reviewers had the suggestion to provide additional explanation/background information on conducting an exposure assessment. One reviewer felt strongly that the EFH is a handbook for looking up factors, not a guide for conducting exposure assessment. He thought that users of the EFH should have at least a minimum level of expertise and that the EFH was not the appropriate venue for learning about exposure assessment. While agreeing that the EFH should not be a textbook on exposure, many felt that it is and should continue to be a useful resource of information for the educated lay person.

> ***Response:*** *Chapter 1 was revised to add discussion about exposure assessments methodologies and definitions.*

Comment: The reason for expanding the child age categories in the tables is described, but in reality few exposure assessments will utilize this detailed level of data. It will simply need to be aggregated. While providing the breakout may be useful and consistent with the referenced EPA guidance, it would probably be of greater utility if the initial tables provided an integrated value for the factor for children. This would make the tables less cluttered and allow further distributions to be provided in the same table. The details could be provided in subsequent tables.

> ***Response:*** *U.S. EPA believes the suggested change would defeat the purpose of Agency guidance promoting the use of age groups for assessing children exposures.*

Comment: For the most part the organization of the Handbook is very clear and easily understood. However some improvements could be made to the tables. In particular tables that are longer than one page. Although it is clear on the second page that this table continues on from the previous page by the title on the second page of the table, it is not clear in the current format used throughout when you are looking at the first page that this table continues onto the next page. For example, it is not clear that Table 7-2 continues onto the next page. Something should be added to bottom of tables that continue onto other pages that differentiates them from tables that are only page long. Also consider including the superscripts and reference citations on each page of the table. It is cumbersome and confusing to the reader to have to look through three pages of a

table to figure what the reference or superscript refers to. Also consider breaking up Table ES-1 into different tables by chapter or factor. The current table is very confusing as some factors are cut in two.

Response: *U.S. EPA believes that the changes suggested to the tables will not add to the Handbook's clarity. The table in the executive summary was revised.*

Comment: I would put all references at the end of chapters, after all the tables.

Response: *This will be inconsistent with NCEA document format.*

Comment: The reader should note, the EFH is not organized by exposure route necessarily, or the activity patterns specific for each route would be found in the related chapter and the principles for making the route calculation would be found also in that chapter. In other words, I do not think each chapter fully stands alone with all the necessary factors for making the exposure assessment for that route of exposure.

Response: *The schematic diagram that was added to help the user understand the linkages between exposure factors, routes, pathways and chapters.*

Comment: Though, as mentioned above, the 2009 Update of the EFH is a very readable document, it however lacks visual elements (it has very few figures, charts, etc.) and its usability could be further enhanced through:

—The addition of more "text boxes," (such as those appearing, e.g., on pages 1-1 and 2-2) with concise definitions of basic terms, summaries of critical information, critical recommendations or caveats, etc.

Response: *U.S. EPA weighed inclusion of explanatory textboxes versus the potential for distracting readers. In this edition, the Agency decided to err on the side of exclusion.*

Comment: The addition of selected charts that present the information contained in some of the tables in graphical form (i.e., in addition to maintaining the table with the numerical values), as a means of facilitating the comprehension of this information.

Response: *Although graphical representations may be visually more attractive and may be appropriate for oral presentations, U.S. EPA feels that exposure assessors need the information in tabular format. Values can be read more accurately from a table than from a graph or diagram. Tables are more accessible than graphics, thereby supporting Section 508 compliance for electronic format more strongly, which U.S. EPA is required to follow.*

Comment: The addition of a brief discussion of the general concept of microenvironments (indoor—residential and occupational, vehicular, outdoor) and of its critical significance in the proper assessment of exposures.

Response: *This type of information is included in the residential building characteristics chapter.*

Comment: The addition of brief "Further Reading" recommendations at the end of each chapter, identifying standard literature sources (textbooks, handbooks, easily accessible reports, etc.) on the topic of the chapter, at "introductory," "intermediate," and "advanced" levels.

Response: *The reader is referred to additional references where appropriate in the individual chapters (e.g., Chapter 2, Chapter 17, and Chapter 19).*

Comment: The "direct availability" of the information in the tables in electronic form (i.e., such as in spreadsheet or database form, in addition to the current pdf form) for direct input or linking with exposure models. Nevertheless, this probably relates to potential future versions of EFH with "enhanced interactivity and accessibility," that are discussed briefly in the answer to Questions 7 and 18.

Response: *U.S. EPA will consider this suggestion in future efforts.*

Comment: Much has changed with the inclusion of the child-specific exposure factors. While this may be appropriate, there are now two "current" documents with similar but not exactly the same information. Section 1.7 and to some extent Section 1.8 address the issues with children exposure and risk calculations. However, it is not entirely clear which of these two handbooks takes precedence. Maybe this is appropriate and obvious, based on a given factor. However, the topic seems worthy of a section on its own.

Response: *A statement was added to indicate that this version supersedes information in the Child-specific Exposure Factors Handbook.*

Comment: If not in the ES, then in the Introduction, there needs to be a better (recognize that an attempt was made to do this) discussion of the interplay between the major (if not all of the different) guidance/tools (such as the EFH, Child-specific Exposure Factors Handbook (CSEFH), Highly Exposed Population (HEP), Exposure Scenarios) exposure assessment. A figure (roadmap style) might be useful to achieve this. For example, the discussion above on the use of the two current documents that contain child-specific exposure factors could be more easily facilitated using such a figure.

Response: *U.S. EPA appreciates the suggestion and will consider it for future editions of the Handbook or as a separate effort. A statement was added to indicate that the Child-Specific Exposure Factors Handbook has been superseded by the 2011 edition of the Handbook. .*

Comment: The format is satisfactory, but the information in summary tables could be considered incomplete (see my comments on Chapter 6). Further, the explanations (e.g., as discussed below re: chapter 1 and in my comments for the other chapters I reviewed) are incomplete.

Response: *Responses are provided in the individual chapters.*

Comment: My suggestions for improving the clarity and usability of the EFH include the following:

In each Chapter, consider placing all figures after the tables. For example, in Chapter 19 the mix of figures and tables at the end of the chapter is confusing. If this structure changes, make note of this change in Chapter 1, under Section 1.11 (Organization), i.e., "All Figures are placed following the Tables at the end of the Chapter".

Response: *This change was noted in the "organization of the report" section. Figures were placed in the back of each chapter where appropriate.*

Comment: Consider placing the description of the Key recommended studies, following the Confidence Tables of each Chapter, in order of how each scored (The Key study with the highest Confidence Rating described first) based on the Confidence Criteria, i.e., General Assessment Factors (GAFs). This would be particularly useful for Chapter 15 (Human Milk Intake) and Chapter 19 (Residential Building Characteristics).

Response: *The studies were ordered in chronological order with older studies listed first to show the evolution of the science.*

Comment: The overall format is quite good with Introductory material followed by factor specific chapters. I find this to be the ideal method of presentation. I am concerned, however, that the data tables soon become overwhelming. I offer no solution for this at this time. The data must be presented and there are a lot of data. As Chair, however, I will solicit input from the general group on how best to make a presentation of the large amount of data. One possible solution is distribution of a database system that may allow queries to be done. One may, for example, perform a query for drinking water intake for a specific age group. The query would return the appropriate table. This may be necessary in light of the voluminous (now estimated at 3000 pages) report.

Response: *Other formats will be explored in future revisions.*

Comment: I have mentioned a few studies in my general comments on the specific chapters given below. I do have some concern that large-scale investigations such as NHANES, which gather at least some data on some factors, have not been a central focus. Further, I am concerned that some of the data used in developing the factors is now becoming a bit long in the tooth. Are intake

factors, body-size factors, etc., that were developed based on data from the late 1980s and early 1990s still valid in today's society? The growth in obesity in the American populace has accelerated substantially since then and should be reflected in any new Exposure Factors Handbook. However, such data may not be readily available at this point. If that is the case, readers and users should be cautioned somehow, perhaps in the Introduction, about the validity of such factors.

> ***Response:*** *Data from NHANES is now included in the Handbook. Trends about obesity are discussed in Chapter 8.*

Comment: In all the chapters the tables are focused upon age groups, which are dominated by narrow band child groups. It would be helpful in each chapter to mention what other characteristics significantly impact the values obtained, but are not included in the prime tables. Do males and females consume the same amount of water so gender does not need to be assessed or incorporated into the factors? The key study table would suggest that because gender is not included. In the water chapter it is not until table 29 that gender first appears and sporadically after that. If one wants gender information, it is quite a search effort.

> ***Response:*** *Data for various demographic groups were included where available, and the differences were noted. Summary tables were kept simple, but additional data are included in the tables at the end of the chapters.*

Comment: I did comment, and found their selection rather strange. Their methods of selection are doubtful and their characterizations of uncertainty lack a clear understanding of the literature. Further, they ignored some of the really best data and sources of information in those I reviewed, including some of those used by other components of EPA using similar general criteria.

> ***Response:*** *Without further specificity, U.S. EPA can't make revisions based on this comment.*

Comment: Additionally, I suggest appending Section 1.4.1 (General Assessment Factors) to Section 1.4. That is, describe General Assessment Factors as the basis for selecting "key" studies in Section 1.4 and renumber the subsequent section, i.e., Section 1.4.2 (Selection Criteria) as Section 1.4.1)

> ***Response:*** *The revisions suggested by the reviewer will result in a section with only one subsection. The redundancies were eliminated, but the section numbers were retained.*

Comment: This had been done below in the discussion relevant to each chapter for review. I will not repeat that discussion here. My comment on this focuses on the specific nature of several of the studies that are listed as "key." A study of one specific age group, a specific location, or exposures under a specific exposure profile, do not adequately represent population statistics. I was actually surprised

to see certain studies listed as key based on this concern. While such a study would certainly be key if the population for which the factors are needed matches well with the study at hand, it may not be key for another. For example, several of the "key" or "relevant" studies focus on a large-scale investigation- some 3000+ individuals- which is good, but the study looked only at children, obviously giving little insight into adult consumption levels. The study selected is excellent, but it is not "key" for an individual exploring the EFH for information on an elderly population consuming garden-grown vegetables in the shadow of a power plant, or an urban population of adults in general. Proper caveats should be placed on the selection criteria for key studies reflecting the focus of such a study.

> ***Response:*** *A sentence was added to say: "A study was classified as "key" based on its ability to represent the population for which the study was designed. The users of the Handbook need to evaluate the "key" studies' applicability to their population of interest."*

Comment: What was missing in the chapters that I reviewed in depth was a confidence rating for all the studies summarized. The only confidence rating provided was for the single "key" study. The confidence rating would be valuable if it can be used to compare multiple data sources, not simply describe the final selection. Were any of the other studies found to be stronger than the one study, but just not across the board? How many of the data sources were given ratings? Were the ratings used to select the "key" study and did that study stand out from the rest evaluated, or were there multiple studies with the same ratings and the one selected determined to be of broader applicability? Since most exposure assessments done are probably more local than "national" a regional or more local data set might have a higher overall confidence rating than the general population "key" study as long as the assessment is relevant to the area covered. Unfortunately, the confidence rating schema was not applied to all the "relevant" studies summarized. And there is no information on whether what is discussed as relevant includes all studies found or only those that met a certain threshold of confidence.

> ***Response:*** *The confidence rating applies to the overall recommendation. It could be based on one or multiple studies. More language was included in the Introduction to clarify.*

Comment: What a Handbook user wants to know is whether it is worthwhile doing their own literature search and review because the Handbook only contains a small proportion of the available data sources or whether the authors did an exhaustive search and review and have included all the data that might be relevant for an assessor to use.

> ***Response:*** *Literature searches were conducted for individual chapters. Additionally, targeted searches and communications with researchers in the individual fields were conducted. Additional language was added to clarify.*

Comment: [In reference to confidence ratings]They do seem to provide a clear rationale. However, they do not seem to be applied similarly across studies or chapters. A more clearly defined rubric or numeric system may need to be developed to provide more consistency across factors.

Comment: For the most part the confidence ratings are clear. In the introduction, it is noted that the EPA does not weight each topic area equally and uses best scientific judgment when determining the overall rating. It would be nice if in a footnote below each confidence table if a sentence could be included that outlined the rational for the overall confidence rating.

Comment: In general the confidence ratings to select studies and rate factors provide a clear rationale and reflect the disadvantages and/or limitations of the studies. Please see comments on each study below. I feel in some cases, if resources allowed, EPA could contact some of the study authors to determine some factors necessary for improving the confidence ratings, such as quality assurance and methodologies used.

Comment: The confidence ratings used to select studies and exposure rate factors reflect the advantages and/or limitations of the choices. Some consideration should be given to the use of confidence intervals for estimates of central tendency in order to indicate their precision for various studies.

> ***Response:*** *U.S. EPA attempted to use a numeric system, but it was deemed inappropriate. Care was taken to use similar language and the same level of detail in the confidence rating table. It will not be possible to summarize the rationale in just one sentence. Including confidence intervals is a good idea, but they were not always available. Confidence intervals are presented where available. Contacting original authors and obtaining additional information is a good suggestion but would require additional resources.*

Comment: Given the general status of data specific to exposure factors, the current confidence ratings appear to be a reasonable approach. A quantitative characterization of confidence in specific exposure factors is not possible for the majority of currently available data sets. Incorporating recommendations for future collection of information that would allow calculation of specific quantitative confidence metrics, can enhance the design of new data collection studies.

> ***Response:*** *Research needs are likely to vary depending on the user of the Handbook. Instead, the discussions about the data limitations provide the user with a sense of what additional information may be needed to reduce uncertainties.*

Comment: "Currency of information" on page 1-3 refers to studies that use the most recent practices or techniques to assess the exposure factor. Please consider

rephrasing “currency of information” to “Temporal Representativeness” Additionally, in Table 1-2, on page 1-19, under “Applicability and Utility,” I suggest the following changes:

- “Representativeness” to “Population Representativeness”
- “Currency” to “Temporal Representativeness”

Response: *No changes were made. The intent was to keep the tables as simple as possible.*

Comment: Section 1.5 is a description of the procedure used to assign recommendation for Key Studies. Therefore, “(2) Single versus Multiple Key Studies” should instead describe an action taken as part of the procedure, i.e., “(2) Selection of one or Multiple Studies”. Likewise, instead of “(3) Variability” consider replacing with “(3) Assess Variability” – “(4) Uncertainty” consider “(4) Assess Uncertainty” – “(5) Confidence Ratings” consider replacing with “(5) Assign Confidence Ratings”.

Response: *The section was revised as per comment.*

Comment: Consider renaming Table 1-2 from “Considerations used to rate confidence in recommended values” to “Criteria used to….” Additionally, associated with “Accessibility”, consider rephrasing “The study data could be accessed.” to “The study data is publicly available”

Response: *The section was revised as per comment.*

Comment: The column headers in “Table 1-2” could be more clearly stated. Instead of “Increasing Confidence,” suggest “Factors that Increase Confidence” and likewise, instead of “Decreasing Confidence” suggest “Factors that Decrease Confidence

Response: *The section was revised as per comment.*

Comment: The issue of correlation between variates is briefly discussed on page 1-12. It is desirable to express intake values such as drinking water or food intake in terms of L/kg BW-day or g/kg-BW both because it both takes correlations between body weight and intake values into account and the intake of a toxic chemical can be expressed in the most common expression of dose (mg/kg-BW). It might be better to state that long- term total caloric intake is correlated with BW but that individual food items such as strawberries may or may not be. You could mention that there is limited information at best on correlation between variates such as drinking water intake and breathing rates. Collecting longitutidinal data on multiple intake variates on the same individuals over time could help address this.

Response: *The reviewer does not provide a reference for the statement regarding limited information on correlations between variates. U.S. EPA*

will need to conduct some literature searches to support these statements. This could be considered in the future efforts.

Response: Comment: *It is good that the necessary guidance documents are listed. It can be overwhelming for the user to track down these documents and so it would have useful to highlight main recommendations from these guidance documents. I have already mentioned that the main updates (listed on Page 1-1) should be further explained with one of two sentences.*

Response: *Including the information suggested will be too overwhelming for the Introduction. It will be considered in a separate effort.*

Comment: Page 1-4, Paragraph 1: Here it says that 'recent studies are more likely to use state of art methodologies that reflect advances in the field'. I am not sure if EPA used the latest papers in the field….see comments on Chapter 7 for dermal factors.

Response: *U.S. EPA's aim was to include the most recent studies. The statement is still correct. Chapter 7 was revised and updated.*

Comment: Page 1-6, Last Paragraph, Column 1: This sections list the factors required for making an exposure assessment. Since the chapters do not give guidance on how to calculate exposure for a particular route (well, it is spotty and uneven), the beginning of each chapter sound point the reader back to this section and the various guidance documents. Also, for each chapter, the reader should be guided back to section 1.9 that talks about the fundamental principles of an exposure assessment.

Response: *This is a good suggestion, but it is outside the scope of this document.*

Comment: It is quite useful that EPA has created these life stages rather than subpopulations in terms of exposure factors. If we are calculating lifetime exposure, then we can sum exposures over life-stages. There are still occasions that we will make exposure calculations for subpopulations. There may be exposure only experienced by a subpopulation due to the nature of the chemical or the nature of activity patterns unique to a subpopulation. Through public comments and by EPA's own comments, we see that toxicological data is available or does not coincide with these new age groupings. Until this information catches up, or is collected in this manner, EPA should attempt to give some reasonable recommendations for overlapping the datasets. (For example, toxicological data for age group 1 through 5 should be used for age group 2 through 12, until further data is available).

Response: *Although the guidance suggested will be useful, it is outside the scope of this document. The most U.S. EPA can do at this time is to acknowledge the limitations.*

Comment: Page 1-1, Second Column: Under the background section, EPA talks about the main revisions to the EFH. However, it would be useful to say whether the change is minor or major and even briefly what the change is under this section. That may take only one added sentence for each of those 11 bulleted points, for easy reference.

Response: *. Highlights of the revisions are listed in section 1.4. U.S. EPA prefers to leave the decision of whether a change is major or minor to the users of the EFH.*

Comment: Page 1-2, Paragraph 2: Column 1: Minor change to first sentence: Switch the position of behavioral and physiological. Right after this first sentence you explain the behavioral differences and then the physiological difference. Just for consistency and flow.

Response: *The revision was made as per comment.*

Comment: Page 1-2, Paragraph 2: I am not clear what the EPA document's (i.e., 'Guidance on selecting age groups….') children age groups are based on, just from this section. Briefly mention whether it is based on developmental stages or physiological difference or some combination.

Response: *A statement was added to say "…based on behavioral and physiological changes throughout childhood."*

Comment: Some readings on children and exposure (may be useful to read/quote):

1) Moya, J.; Bearer, C. F.; Etzel, R. A. Children's behavior and physiology and how it affects exposure to environmental contaminants. Pediatrics. 2004, 113(4).
2) Thompson, K. M. Changes in children's exposure as a function of age and the relevance of age definitions for exposure and health risk assessment. Medscape Gen Med. 2004, 6(3), 1−37.

Response: *The first reference was added. The second reference did not have any new information. It provides a summary of the data available in the Child-Specific Exposure Factors Handbook.*

Comment: Page 1.10, Section 1.9: This is an 'Exposure Factors Handbook', and the approach in this section is to explain exposure from a dose perspective. So exposure is called External Dose. This section should be dedicated to having 3 simple exposure equations for inhalation exposure, ingestion exposure (dietary and non-dietary) and dermal exposure, if possible. Then there should be a focus on how exposure becomes dose, and the calculation of average daily dose. The reader can get confused between the two. It might require a discussion of picking an exposure boundary and defining the exposure in that manner and the dose a continuation of that with added factors. I realize ultimately we are interested in

that internal dose, but it is important here to makes these distinctions because we gather data according to exposure factors and dose factors and then wish to appropriately use them in physical representations.

Response: *The section was revised, and the distinction between exposure and dose was made.*

Comment: Page 1.10, Section 1.9.1 Paragraph 3, Column 2: In the sentence… "Factors presented in this Handbook that affect dermal exposure are skin surface area and estimates of the amount of soil that adheres to skin". I hope the reader does not confuse this sentence to mean that these are the only factors. Maybe follow-up with…"Other factors not covered in this Handbook are important in the calculation of dermal exposure." See comments for the dermal exposure chapter.

Response: *A sentence was added as suggested.*

Comment: Page 1-7, Last Paragraph, Column 2: We keep saying that that there is no guidance for age groups for presenting adult data, but the reader should be aware how activity patterns (e.g., time spent at home, time spent at work), really begins to change for the elderly. At that advanced stage, the human body becomes compromised due to the development of illnesses, chronic disease and, therefore, more susceptible to lower chemical concentrations. This should be considered in exposure assessments. I think EPA does address this further along in the chapter. It is worth repeating here.

Response: *A sentence was added to acknowledge the point made by the reviewer.*

Comment: Page 1-8, Second paragraph, Column 1: We are using the terms age bins and life-stages interchangeably? Also, for this section, EPA mentions that there were recommendations for EPA to consults with experts, and conduct long term research in the various fields in order to address the toxicokinetic and behavioral changes for children. Is this something EPA plans to do in order to improve the age bins/life-stages for the next version of the EFH?

Response: *A statement was added to make the distinction. Research in the area of toxicokinetics and behavioral changes throughout childhood and other life stages is ongoing in the Agency and elsewhere. Information will be incorporated as new data become available through periodic on line updates, as needed.*

Comment: Page 1-10, paragraph 3: In the equation, is the reader aware of what ADAF means? I do not see this term in the Glossary, although I do see ADD (Average Daily Dose) and others.

Response: *The term has been defined in the text and added to the glossary.*

Comment: Page 1-10, Paragraph 4, Column 1: "Once in the environment, the chemical……soil, dust, and diet." You could follow this sentence up by saying these fate and transport mechanisms result in various chemical concentration that the individual is exposed to.

Response: *A sentence was added as suggested.*

Comment: Page 1-3, Paragraph 4, Column 1: EPA talks about the selection criteria for judging a paper, one of which is whether the approaches to capture the exposure factor are direct or not. The nature of each exposure factor is unique. Sometimes, they cannot be judged by the same criteria. For example, a lifetime measure (i.e., how long people live, chapter 18) is an easier, more direct factor to obtain. Just follow past trends and gather death certificates on numerous people and there it is. But a factor such as soil loading on the skin, is by nature a more difficult factor to measure directly (and costly for substantial data-points). Sometimes we have to wait for the field to develop that more direct method of data collection. So, by nature it is going to receive a lower score under "soundness" or "adequacy". All is not even or fair in the world of exposure. This should be stated in the introduction chapter.

Response: *This is already acknowledged in Section 1.5 of the chapter. Clarification was added.*

Comment: Page 1-5. Section 1.5.2. (Single versus Multiple Key Studies). The midpoint of the range of upper percentiles across studies may provide a poor estimate, as the lowest and/or highest value that provides the range may be the result of a small or deviant study. A weighted average of upper percentiles across studies generally would provide a better value.

Response: *In a previous peer review of the Child-Specific Exposure Factors Handbook, reviewers discouraged U.S. EPA from taking an average of the upper percentiles. A statement was added to say: "It is recognized that the midpoint of the range of upper percentiles may not provide the best estimate, but in the absence of raw data, more sophisticated analysis cannot be performed."*

Comment: Page 1-5. Section 1.5.4. Uncertainty. Measurement error and sampling error that are quantifiable are measures of variance, not uncertainty.

Response: *U.S. EPA disagrees. Measurement error and sampling error also introduce biases in the calculations.*

Comment: Page 1-10. First full paragraph. Should be qualified as for mutagenic carcinogens.

Response: *A statement was added to clarify that it refers to mutagenic carcinogens.*

Comment: Page 1-18. Table 1-1. The average and median are measures of central tendency. The average or median in combination with upper percentiles provide an indication of variability.

Response: *The title was modified.*

Comment: Page 1-20. Table 1-3. Need to state that these age-dependent potency adjustment factors were developed for mutagenic carcinogens.

Response: *A statement was added to clarify that they refer to mutagenic carcinogens.*

Comment: The Introduction to the 2009 Update of the EFH indeed captures many essential developments in exposure assessment, especially the importance of the lifestages issue, and provides sufficient historical context for the reader who might be new to the subject. However, in this reviewer's opinion, the improved treatment of the lifestages issue is basically one positive step towards accepting the fact that "exposure biology" needs to be further incorporated in the "everyday practice" of exposure analysis and assessment, and it is hoped that future updates of the Handbook will indeed incorporate (actually in a manner consistent with the present discussion in Chapter 1) further information and exposure assessment relevant guidance related to issues such as the effects of aging, of genetic variability, of altered pathophysiological states, etc.

Response: *The suggestion will be considered in future updates as the information becomes available.*

Comment: Chapter 1 could benefit from additional contextual setting. It is not that the appropriate reference are included but rather how these complement each other and inform the assessment process seems to be lacking. The discussion on how to perform exposure assessment would be better earlier in the Chapter. Then, the context of how this document and others fit into the assessment would provide for more informative user handbook. I re-iterate that the Roadmap concept for the different documents would facilitate this objective. The inclusion of the factors from the CSEFH can cause some confusion. Demonstrating the nexus of the two by example would be helpful. Inclusion of an appendix on calculating risk, particularly with all the changes, would be helpful. Some form of summary of what has changed and why would likewise be useful.

Response: *Both a road map and a schematic diagram were included in Chapter 1. The Appendix 1A in Chapter 1 has been revised, updated, and added.*

Comment: 1.5 (5)—It should be stated that these factors of interest are discussed in each chapter.

Response: *A statement was added.*

Comment: 1.9—This section should be updated to reflect the advances in exposure assessment reflected in NRC/NAS documents, the Journal of Exposure Analysis/Science & EE, and the book "Exposure Assessment" edited by Ott, Steinemann & Wallace (Taylor & Francis, 2007).

Response: *Suggested references were added.*

Comment: 9.1—These equations are one approach only. At the end of the paragraph starting "The intake rate …" add after "soil" "and other media". The next paragraph starting with "The exposure duration …" is good policy/practice but is not followed well in other chapters (certainly not in Chapter 6 which I reviewed). Re: fourth complete paragraph on page1-11 (first column)—Do the authors really mean "potential dose" rather than calculated or estimated likely dose, and shouldn't it be in reference to specific end organs? Re: fifth complete paragraph on page 1-11 (first column)—This approach (or description) doesn't take into account the effect of acute massive exposures and doses on long-term responses as known to occur (e.g., asbestos, beryllium, etc.). The next two paragraphs reflect/highlight some of the problems I have with this EA approach—the dependence on body weight and not estimated end-organ dose derived from the exposure and likely independent of body weight, at least for several of the organ systems. For example, the respiratory system volumes of exposed pollutants reaching the system are height and age determined, as well as specific for gender, race and patho-physiology.

Response: *The section was revised. Comments on Chapter 6 are addressed later in this report.*

Comment: The first paragraph on page 1-12 doesn't reflect the more extensive statements and review in chapter 6. The last paragraph of sec. 1.9 indicates the simple generalized approach to RfDs—there aren't specific RfDs for children or for other susceptible and sensitive population groups. Yet, these populations are critical in setting standards (e.g., air quality standards). Thus, those actually evaluating exposure-dose-response relationships for standards use real data rather than models and focus on data collected on these susceptible and sensitive groups.

Response: *Appendix 1 was revised and added to discuss adjustments to dose response for other populations.*

Comment: 1.9.2—first suggestion—The exposure assessor should not use average values for a population unless no other data are available and if non-linear models can't be determined.

Response: *The determination to use average or some other metric is left to the user and may vary from program office to program office in U.S. EPA. The average was used as an example.*

Comment: 1.10—Cumulative and aggregate exposure assessment and risk assessment should be emphasized more and used more.

Response: *The discussion was expanded.*

Comment: Because the analysis of some of the Exposure Factors were done on a different life-stage basis (e.g., Chapter 9- Intake of Fruits and Vegetables, Chapter 12- Intake of Grain Products, and Chapter 13- Intake of Home-Produced Foods), and Chapter 15- Human Milk Intake, I suggest stating explicitly stating in the introduction (in Section 1.7 at the end of the Section, following the list of "recommended age groups"), which chapter have the data the recommended exposure factors presented in the EPA's recommended age groups, and which chapter do not. Additionally, please mention that when data was not analyzed in the recommended age group categories, the analyses were matched as close as possible to the recommended age group categories.

Response: *A statement was added about the age groups being matched as close as possible to the recommended age groups, but U.S. EPA does not feel it necessary to list for which factors data were available for the various age groups.*

Comment: Also, stating whether or not the "References for Chapter 1" are in Draft or Final Form would be helpful. Some Final reports are cited as such, but are there any other "draft" reports besides the US EPA (1994a) Estimating exposures to dioxin-like compounds? Or, are all the others either "interim final" or "final" reports?

Response: *U.S. EPA tried to cite only final reports. On occasions, external review drafts were cited, but these were noted as such.*

Comment: Section 1.4, Selection of Studies for the Handbook, is both necessary and, I think, well done. After an introductory section, it progresses from a discussion of General Factors influencing selection, and then details the Selection criteria. I am not a fan of the presentation of this section; the multiple indentation and set-offs, especially in light of the two-column presentation, makes reading difficult and individual indented sections with too few words per line. Yet the content is quite good. A simple re-formatting, without need for a re-write is in order here.

Response: *U.S. EPA understands the point made by the reviewer and did consider other formats, but did not find a more appropriate way to present the information. A table format was considered but was not deemed appropriate.*

Comment: One concern is criterion (2) Applicability and Utility. This asks if the information is relevant for the Agency's intended use. I have two problems with this. First, the Agency's intended use is not made clear. And second, this is a general document that will be used by other not in the Agency. Its use is more general that might be suggested by the comment. In the same section, under Representativeness of the Population, the last sentence reads: "… Higher

confidence ratings were given to exposure factors where the available data were representative of the population of interest.…" A fuller explanation is needed. For example, if the population of interest in the study used is not especially relevant, e.g., left handed mine workers in Kentucky, why should this have equal precedence with, for example, a much larger study descriptive of the population of New York City? Other criteria come into play here.

Response: *The language was taken directly from another U.S. EPA document. The explanation as to what it means is provided under (2). Additional clarification was provided.*

Comment: Section 1.5 is robust and well developed. Again, I think a reformatting would add to the presentation.

Response: *The section (see now Section 1.6) was edited.*

Comment: The first paragraph of Section 1.6 offers an excellent succinct summary of the steps needed to be performed in an exposure assessment. Why this little gem of a paragraph is tucked away six pages in is puzzling. Put it up front in the Background or Introductory section as it lays the framework for the entire document. This adds interest and a firm foundation for all that follows.

Response: *The information was moved as suggested.*

Comment: Section 1.6 is entitled "Suggested References for us in Conjunction with this Handbook." It is quite provincial to suggest only readings involving other EPA documents. Surely the authors have encountered an occasional piece not published by EPA that offers insight into exposure analysis. I offer a near-identical criticism of Section 1.12 References for Chapter 1 that lists a small number of non-EPA references, which one may argue are somewhat arbitrary in content. Of course these are discussed explicitly in the text, but the selection of these eight references to the exclusion of thousands of other peer-reviewed publications, book chapter, monographs, etc., on exposure science is just not warranted.

Response: *U.S. EPA appreciates the suggestion, but inclusion of guidance documents outside of EPA was outside the scope of this effort. U.S. EPA is currently directing a separate effort to provide a web-based toolbox for exposure assessors that will contain available resources for conducting exposure assessments.*

Comment: Sections 1.7 and 1.8 discuss age groupings. I do not think this belongs in an introductory chapter, but rather should be a separate chapter in itself. There is still a good deal of tension between age groupings suggested by behavioral specialists and those suggested by physiologists. Throwing exposure assessors into the mix would doubtless give rise to a different set of age groupings. This merits discussion. The reference to the 2000 meeting on this subjects may suggest to the reader that the matter is settled when in actuality these

is still a substantial amount of disagreement on what appropriate age groupings are. The National Children's Study, for example, is likely to choose a different final scheme for age groupings. Users of the Exposure Factors Handbook need to be aware of this lack of consensus and include such considerations in their uncertainty analyses.

Response: *U.S. EPA disagrees; the Agency has been using these age groups since 2005. A separate chapter would look out of place.*

Comment: In Section 1.9 confusion abounds. Dose and exposure are intertwined, sometimes considered the same thing, then substantially distinguished from one another. In fact, in Eqn. 1-2 we have the lead in clause: "… The exposure can be expressed as follows: " then the equation says "External Dose = …" What is it? External dose? Exposure? Potential Dose? Definitions are important and this must be cleaned up. Indeed this subsection, 1.9.1 Dose Equations starts off with the phrase "… Starting with a general integral equation for exposure…" followed by a reference, but no integral equation for exposure. What is a reader to think? But in a more fundamental sense, why is this in the Introduction anyway? Shouldn't there be a separate chapter laying all of these things out? Fundamentals of exposure, as the main section heading indicates, is an appropriate topic for the Introduction, but a detailed description of LADDs, ADDs, Dose, Exposure, etc., is better described elsewhere.

Response: *The entire section was revised.*

Comment: Section 1.10 Cumulative Exposure is a weakly developed add-on. There needs to be more discussion. One should start with the precipitating legislation, the Food Quality Protection Act of 1996, define route-specific exposure, aggregate exposure, and cumulative exposure in a clear fashion. Just putting in this brief discussion of Cumulative Exposure is confusing, misplaced, and does not give any insight into how the exposure assessment should be carried out.

Response: *The section was expanded, and discussion about aggregate "exposures" was added.*

Comment: Section 1.11 Organization offers little more than a Table of Contents, which is given elsewhere. Either more description is needed as to what is covered in each section- even a paragraph on each would help- or it should be left out as redundant with the Table of Contents.

Response: *A description of what is covered in each chapter was added.*

Comment: Along with the Executive Summary, the Introduction will doubtless be the most-read component of the Exposure Factors Handbook. Given this assumption, this should be the most readable as well. The two-column presentation does not lend itself well to the readability so desired. This is especially evident on the Page 1-1 that contains bulleted items, as well as a

text-box insert summarizing the purpose of the document. I found this to be distracting. New material added since the 1997 version could be better summarized in tabular form rather than in bullet form. Indeed bulleted forms and multiple levels of indenting are used extensively throughout the introductory chapter.

Response: *The report was originally done in a two column format in 1997 to improve readability in the printed version. Deleting the two-column format will be very time consuming for this version. It will be considered in the future.*

Comment: In general, chapter 1 is a good guide to the use of the EFH and to the general considerations involved in the recommendations in the individual sections. It is also a useful concise guide to exposure assessment. However, with respect to general guidance for exposure assessment, it should be noted that equation 1-2 supposedly gives the external dose. However, in discussing the relationship between exposure and dose, it is important to understand that dose is defined as the mass of a substance in contact with an interface divided by the body-weight. Equation 1-2 does not, however, yield a dose (as per this definition), but a mass of contaminant. In such a document it is important that this common misnomer not be promulgated.

Response: *The entire section was revised.*

Comment: Pg. 1-5, par. 4, line 4—Change “base” to “based”

Response: *The section was revised as per comment.*

Comment: Pg. 1-10, eq. 1-2—As noted previously, this equation is labeled as predicted ”dose” but in fact it predicts a mass. Dose is defined as mass/body wt. This also applies to the text on pg. 1-11, par. 3.

Response: *The equations were revised.*

Comment: Pg. 1-11, par. 4—The adjustment of the dose response parameter for differences between species in absorption across body barriers is carried out for inhalation exposures, but not generally for ingestion exposures. Ingestion is generally not specifically adjusted for species differences in absorption.

Response: *This is discussed in the appendix 1A.*

Comment: Pg. 1-13, first bullet, line 13 - Change “itself” to “themselves” (data is a plural word).

Response: *The section was revised as per comment.*

Comment: A useful guidance document to add is: Dermal Exposure Assessment: A Summary of EPA Approaches. EPA 600/R-07/040F.

Response: *The suggested reference was added to the Introduction and to Chapter 6.*

Comment: Also, in this section, the Child-Specific Exposure Factors Handbook is cited as a resource. Throughout this draft EFH, child-specific exposure factors are provided, and in some cases are based upon data more current than in the Child-Specific Exposure Factors Handbook (CSEFH). There are cases where the recommendations in this draft EFH differ from those in the CSEFH. While the effort to update materials is well-intentioned, these differences will lead to great confusion in application. Clear reference to the CSEFH and how the values in this draft EFH compare to CSEFH recommendations should be made any place in this document where child-specific data are given. Future editions of the CSEFH should do the same in reference to child-specific data contained in the EFH.

Response: *A statement was added to say that this Handbook supersedes the information presented in the CSEFH.*

Comment: Additional reference suggested: NAS Comm. on Advances in Assessing Human Exposure to Airborne Pollutants. NAS Press, 1991—Chapters 1 & 2.

Response: *The section was revised as per comment.*

Comment: Additional reference suggested: Ott et al., Exposure Analysis (Taylor & Francis, 2007)—Chapters 1 & 2

Response: *The section was revised as per comment.*

Comment: Additional reference suggested: Lioy P, Leaderer B, Graham J, Lebret E, Sheldon L, Needham L, Pellizzari E, Lebowitz MD. "The application of exposure assessment to environmental health science and public policy. J Expos Analysis & Environ Epidemiol. 15:121−22, 2005

Response: *The section was revised as per comment.*

Comment: Additional reference suggested: Lioy P, Lebret E, Spengler J, Brauer M, Buckley T, Freeman N, Jantunen M, Kissel J, Lebowitz MD, Maroni M, Moschandreas D, Nieuiwenhuijsen M, Seifert B, Zmirou-Navier D. "Defining Exposure Science." J Expos Analysis & Environ Epidemiol. 15:463, 2005.

Response: *Reviewed, but not "relevant."*

Comment: Additional reference suggested: Sexton, K., Kleffman, D.E., and Callahan, M. A. An introduction to the national human exposure assessment survey (NHEXAS) and related phase I field studies." J Exposure Analysis & Environ Epidemiol. (5):229−232, 1995.

Response: *Reviewed, but not "relevant."*

Comment: Additional reference suggested: Lebowitz MD. "Exposure assessment needs in studies of acute health effects." J Sci Tot Environ 168:109−17, 1995.

Response: *The reference contains no new information. It refers to indoor and outdoor pollutants and the need to consider susceptible populations.*

Comment: Sect 1.3 (Background): cite "…Child-Specific Exposure Factors Handbook that was published in September 2008 (EPA, 2008)"

Response: *The section was revised as per comment.*

Comment: Sect 1.3 (Background), Page 1-2: change "racial" to "racial/ethnic"

Response: *The section was revised as per comment.*

Comment: I recommend a different way to organize the references listed in Section 1.6. My suggestions include: Include the program office or agency associated with each document; Include the web address for locating the document online; Include whether document is final or draft (e.g., "Estimating Exposures to Dioxin-like compounds" is a DRAFT document).

Response: *U.S. EPA believes that chronological order is more appropriate because it shows the evolution of the science; other information is provided in the reference section.*

Comment: Section 1.7, page 1-7, insert the citation (underlined here) in the following sentence: "This revision of the Handbook attempts to present data in a manner consistent with the US EPA's recommended set of age groupings for children (US EPA, 2008a).

Response: *The section was revised as per comment.*

Comment: Section 1.8, Page 1-10, insert the citation (underlined here) in the following sentence: "Table 1-3, along with Chapter 6 of the Supplemental Guidance report (EPA, 2005b) have been developed…

Response: *The section was revised as per comment.*

Comment: Section 1.9, page 1-10: Edit the following sentence : "Individuals become in contact with the chemical through inhalation, ingestion, or skin/eye contact." to "Individual come in contact with the chemical either through inhalation, ingestion, dermal, or eye contact."

Response: *The section was revised as per comment.*

Comment: Section 1.9.1, page 1-11 states that "…body weight is correlated with food consumption rates and inhalation rates." Insert the following (underlined) to

this sentence: "…body weight is correlated with food consumption rates and inhalation rates (for more information, see Chapter 6, Inhalation Rates)."

Response: *The section was revised as per comment.*

Comment: Why are the last paragraphs of Section 1.9.2, page 1-13, bulleted? I think leaving them as paragraphs would streamline the presentation. The dashes under the second bullet can remain, i.e.., with the following insertion: "If only a range of values is known for an exposure factor, the assessor has several options. These options include:"

Response: *The section was revised as per comment.*

Comment: Consider renaming Section 1.11 to "Organization of Handbook"

Response: *The section was revised as per comment.*

Comment: Consider removing the acronym definition in the ADAF column header from Table 1-3,

Response: *The section was revised as per comment.*

Comment: In Figure 1-1, consider changing "The text under the boxes indicates….characterize each box in the exposure-dose-effect continuum." to: "The text under the boxes indicates….characterize each step in the exposure-dose-effect continuum.

Response: *The section was revised as per comment.*

Comment: In general the Handbook is organized in a reasonable and clear format. Most tables are easily understood and usable to those performing exposure assessments. I may have specific comments on individual tables in each chapter. Each chapter begins with a description of the exposure route and most needed/obvious exposure factors. Then each chapter presents the main exposure factors in one or two tables that appear early on in the chapter, where the data comes mainly from the key studies. Following this, the key studies are presented in more details following by detailed tables from key studies and most relevant studies and their related tables. In this manner EPA is making the data from the key studies easily accessible. However, EPA does make the user aware of the other data tables that can be used in detailed or more specialized exposure assessments. Some tables can be improved by highlighting difference in tables or areas of emphasis.

Response: *U.S. EPA believes that the suggested revision can get too overwhelming to the user. It will require a lot of footnotes, and the tables can get overcrowded.*

Comment: I would put all references at the end of chapters, after all the tables.

Response: *This would be inconsistent with standard formatting for NCEA reports.*

Comment: The details of calculating exposure assessments for each route are not typically given. There are some general ideas on required factors for the assessment. However, the user is referred to other EPA documents that present quantitative methods for exposure assessments for each route. There are occasions where more examples or better explanations can be given. These are detailed below for each chapter in my set of reviews. Chapter 1 contains the bulk or most details for making the exposure calculations and the reader should always review this chapter first. In fact each chapter should say "refer back to chapter one for guidelines on making exposure calculations".

Response: *The chapter was revised to include much of this information.*

Comment: The reader should note, the EFH is not organized by exposure route necessarily, or the activity patterns specific for each route would be found in the related chapter and the principles for making the route calculation would be found also in that chapter. In other words, I do not think each chapter fully stands alone with all the necessary factors for making the exposure assessment for that route of exposure.

Response: *A new figure was created to assist the user in navigating through the document.*

Comment: Page 1-6, Last Paragraph, Column 1: This section lists the factors required for making an exposure assessment. Since the chapters do not give guidance on how to calculate exposure for a particular route (well, it is spotty and uneven), the beginning of each chapter sound point the reader back to this section and the various guidance documents. Also, for each chapter, the reader should be guided back to section 1.9 that talks about the fundamental principles of an exposure assessment.

Response: *The Introduction is meant to refer the reader to other sources of information that may be useful for conducting an exposure assessment. Some of these sources are repeated in the chapters as needed. Referring the reader back to Section 1.9 in each chapter was not deemed necessary.*

Comment: I suggest that the Introduction include the following sections (and in the suggested order): Purpose of the EFH; Intended Audience; A section on what the EFH includes, including a summary of what is included in the current handbook—with caveats. This section would refer to the "Background" Section for the main revisions to the 1997 EFH version as well as the new age groupings. I suggest explaining a little about the new standardized age bins based on the Guidance for Selecting Age Groups for Monitoring and Assessing Childhood Exposure to Environmental Contaminants (US EPA 2005), but explaining the detailed development of these new age-bins (i.e., 2000 Workshop and other

material on page 1-8 of the current EFH draft update) in the newly proposed Background Section. Also, mention in this new "What the EFH includes" section the availability of web-based databases for ingestion intake, if available.

Response: *The entire chapter was revised. A section on scope was added.*

Comment: Include a section on what is not in the EFH- i.e., which exposure factors (such as dermal exposure and residential and/or building characteristics) that will be incorporated to a much more fuller extent later. But, also stress that the EFH is continually striving to incorporate the variability in the exposure factors across the population, and as new data is collected and vetted, they will be considered for inclusion in future EFH updates.

Response: *The preface communicates this point.*

Comment: Include a Selection of Studies for the Handbook, including the universe from which the studies were selected, the database libraries (e.g., PubMed, Science Direct, etc) that were utilized.

Response: *A statement was added to reflect the comment.*

Comment: Include Fundamental Principles of Exposure Assessment. In addition to a proper and consistent definitions, and consistent use of exposure and dose, this section needs to include a Roadmap and additional figures that relate how various exposure factors can be combined to assess ingestion, inhalation, and dermal exposures, and cumulative exposures. I suggest that there be separate roadmaps for ingestion exposures (both direct and indirect), inhalation exposures, and dermal exposures. I would include a subsection on cumulative exposures within this section (the current Section 1.10 is suitable). In addition, I would include the following subsections:

- "Probabilistic Exposure Assessment" (a revision of Section 1.9.2)
- "Exposure factors for assessing risks and hazards" (currently material from Section 1.9 on page 1-11 to 1-12)
- "Considering Life Stages when Calculating Exposure and Risk" (Section 1.8 of the current EFH draft update).

Response: *The chapter was revised. A schematic diagram was added.*

Comment: I suggest the following table be inserted in the newly proposed Background section that would contain all the guidance documents (those currently listed in Chapter 1, pages 1-6 to 1-7). It would be useful to have this table in interactive form, i.e., one can just click on the specific report in a pdf version of the EFH, and then it would link to the report: Table ##. Supplementary US EPA reports that may be useful as guidance material for exposure assessment. An indication of whether the reports address indirect and direct exposures is also provided as well as the EPA Program Office that developed the report. Reports are listed in chronological order.

Response: *This suggestion will be considered under a separate effort.*

2.23. Chapter 2: Variability and Uncertainty

Comment: The reviewers' comments with regard to the adequacy of the variability presentation were diverse. Several thought the presentation was good for populations but not for individual groups. Others felt that the presentation of variability was inadequate, uneven, and sometimes non-existent.

Response: *Revisions were made to the chapter to discuss variability more thoroughly.*

Comment: Several reviewers commented on the confusion between variability and uncertainty. One reviewer said that Chapter 2 does not adequately define variability, nor does it explain the measures needed to describe variability. Because there are differences in quantitatively estimating and practically applying the results of variability and uncertainty, one reviewer suggested discussing each separately.

Response: *Variability and uncertainty were initially separated in parts of the chapter by dedicating specific sections to each. However, there were issues with variability and uncertainty not being carefully distinguished. An effort to address the confusion between uncertainty and variability was made throughout the revised chapter, in particular in Sections 2.1 and 2.6. A definition was provided for variability.*

Comment: One reviewer commented that the EFH provides good basic information, but he would like to see some additional topics, concepts, and methods referenced (specifics included in his pre-meeting comments). He does not expect to see a tutorial on variability and uncertainty but recommends adding a paragraph that tells the user where to go for further information. Acknowledging that the EFH should not be a statistics handbook, another reviewer suggested adding a brief discussion on sample size and estimates of central tendency. He thought it would also be beneficial to discuss how variability and uncertainty affect the final risk assessment. For example, bias is likely to be introduced if the population is not representative of the one about which you are concerned. One reviewer said that EPA's uncertainty and variability tool should be referenced in Chapter 2. Another reviewer agreed that there needs to be some discussion referring users to where they can get more information. One reviewer said that a good description will be helpful for those who need it.

Response: *Additions to the chapter were made with respect to topics, concepts, and methods. Recent U.S. EPA documents were cited as an initial reference for issues related to variability and uncertainty. A brief discussion of the effect of sample size on parameter uncertainty was added to Section 2.6. Central tendency, i.e., mean and median, are discussed in*

Section 2.3. The issue of bias from using unrepresentative samples is covered in Section 2.4b: use of surrogate data. A discussion of how variability and uncertainty affect the final risk assessment is addressed to some extent in Section 2.8.

Comment: One reviewer thought it was better to present variability and have less confidence than to not present the data at all. Another reviewer agreed it was important to present the data with appropriate caveats and let the health assessor decide whether the data are applicable. One reviewer said she liked it when multiple studies were combined to obtain a better distribution.

Response: *U.S. EPA agrees with the peer reviewers' comments and has chosen to present the data, with estimates of variability and uncertainty, provided it meets minimal statistical and scientific standards, as discussed in Chapter 1 (in general) and the other chapters (specific considerations).*

Comment: The discussion of variability and uncertainty is an extensive and thoughtful academic discussion. Variability analysis is well integrated into risk assessment practice, either with use of average and high-end estimates or Monte Carlo Analysis. There is an extensive literature on various distributions for exposure parameters. When point estimate approaches are used, knowledge of the variability in exposure parameters can be used to inform the selection of point estimates (e.g., the 90th or 95th percentiles for a high-end estimate). The limitations in assessment variability in risk assessment are the lack of data on variability and the lack of longitudinal data that would properly characterize interindividual variability. There is a particular dearth of information on variability in fate and transport model variates. It is therefore usually only possible to estimate a portion of the variability in a risk assessment. The path to better and more complete characterization of variability would involve more investment in research.

Response: *U.S. EPA agrees.*

Comment: In contrast, uncertainty analysis seems to be usually confined to a qualitative discussion, such as in the Exposure Factors Handbook. Quantitative approaches to uncertainty in actual risk assessments such as two- dimensional Monte Carlo Analysis seem to be rare. I would like to see an extension of the discussion to include the practical aspects of quantification of uncertainty in typical risk assessment applications, particularly in regulatory environments.

Response: *A section on practical considerations was added to Section 2.6.*

Comment: Actual examples, of how quantitative uncertainty analysis has been used in human risk assessment could be helpful. I would like to see a discussion of the relative uncertainty in exposure parameters, fate and transport, and dose response.

Response: *The peer reviewer's suggestions are excellent but are beyond the scope of the Exposure Factors Handbook.*

Comment: The dose response values in most site-specific risk assessment are the often most uncertain, followed by fate and transport (if used) and then by exposure parameters. Quantifying the uncertainty in exposure parameters will do little to quantify the overall uncertainty in a risk assessment if the majority of the uncertainty lies in the dose response (e.g., cancer potency factors) part of the assessment. Although, there is a literature on estimating uncertainty in dose-response, there does not appear to be any consensus on appropriate methods.

Response: *Discussion of this point was added in Section 2.1 in the example of lead poisoning.*

Comment: Uncertainty in many risk assessment applications is well understood and often could be addressed by allocation of more resources. Examples include soil sampling around a hazardous waste site instead of application of a fate and transport model, or collection of onsite meteorological data instead of meteorological data from the nearest airport to a facility.

Response: *The idea of additional resources to address uncertainty was treated in modifications to Section 2.5, Reducing Uncertainty.*

Comment: Risk assessment tools are often applied to situations as the least costly alternative and more as relative measure of risk between sites for the purpose of risk management resource allocation. The application of expert elicitation to attempt to quantify uncertainty in such situations would be costly and defeat the purpose of the using the risk assessment methods in the first place. I would suggest expanding the discussion to include such practical considerations.

Response: *This point was not discussed because risk management resource allocation is beyond the scope of this chapter. However, the discussion on reducing uncertainty has been expanded to include some of the points made by the reviewer.*

Comment: I would recommend separating the discussion of variability and uncertainty in Chapter 2. The methods used in quantitative estimation of uncertainty and variability are different. The integration of quantitative assessments of uncertainty and variability into the everyday practice of risk assessment is quite different. There is enough superficial resemblance (e.g., use of distributions) to cause confusion.

Response: *Variability and uncertainty were initially separated in parts of the chapter by dedicating specific sections to each. However, there were issues with variability and uncertainty not being carefully distinguished. An effort to address the confusion between uncertainty and variability was made throughout the revised chapter, in particular in Sections 2.1 and 2.6.*

Comment: The utility of quantitative information on variability to the risk manager seems straightforward. How quantitative uncertainty estimates fit into risk management decisions seems less clear.

> ***Response:*** *An effort was made to address the utility of uncertainty estimates by modifications to the Introduction. New references to U.S. EPA documents help motivate and describe the utility of quantitative uncertainty analysis.*

Comment: Chapter 2 provides an overview of variability and uncertainty. Since the field of statistics is focused on the study of variability and to a lesser extent uncertainty, it is strange that there is little or no discussion of appropriate statistical techniques.

> ***Response:*** *The field of statistics is concerned with both variability and parameter uncertainty (i.e., standard errors). The chapter is largely dedicated to the conceptual issues of variability and uncertainty in the context of exposure assessments. The Exposure Factors Handbook reports largely on variability, while methods used to incorporate the variability into exposure assessments are treated elsewhere in the literature. The revised chapter does report on statistical techniques, e.g., Monte Carlo simulation, to treat uncertainty.*

Comment: A short discussion should be added of the role of sample size on the estimation of the precision of measures of central tendency. The standard deviation of the mean is the standard deviation of measurements divided by the square root of the sample size. The uncertainty of the mean due to the variability of the measurements is provided by the statistical confidence limits, which are a function of the standard deviation of the mean.

> ***Response:*** *A discussion of the sample size as it relates to parameter uncertainty was added to Section 2.6.*

Comment: In addition, it should be noted that statistical tolerance limits place confidence limits on estimates of percentiles.

> ***Response:*** *Note that "statistical tolerance limits" and "confidence limits" seem to be one and the same in that they quantify parameter uncertainty of a percentile. Often exposure assessments are based on point estimates, which may include selected percentiles. Sometimes these assessments go so far as to calculate confidence intervals based on sample size, but often times they do not. It is unclear what is meant by confidence limits putting limits on percentiles, other than a statement of fact that confidence intervals are confidence limits. Clarification was added.*

Comment: For a calculation that depends on the sum of two or more factors, e.g., cumulative exposures, or the multiplication of two or more factors, it was noted that an estimate of an extreme should not be calculated by assigning extreme

values to all factors. Again, statistical techniques are available to estimate percentiles for the sum or multiplication of factors.

> ***Response:*** *It is reasonable to say that multiplication of two or more factors set at extreme levels would likely result in a very extreme, if not implausible outcome. For example, the product of the 95th percentiles of two variables is likely to be much larger than the 95th percentile of their product. When these factors belong to different families of distributions, e.g., normal and log normal, it is not a simple matter to describe the resultant outcome distribution when those factors are multiplied. There are statistical techniques to treat this issue, e.g., simulation or analytical solutions through parameterized distributions, but they are beyond the scope of the Handbook.*

Comment: It is surprising that there is no discussion of statistical sampling plans and the use of statistical analysis of variance techniques to estimate the size of the various components of variance (variability).

> ***Response:*** *The sample results and studies have been compiled by others. It is outside the scope of this chapter to describe techniques in designing a sample.*

Comment: Based on the items identified above, it is recommended that additional input should be solicited for statistical issues on variability and uncertainty. It should be indicated that estimates of variability based on the range depend upon the size of the sample. For example, with a sample size of 100 the smallest and largest values provide estimates of approximately the 1st and 99th percentiles; while the smallest and largest values from a sample size of 1000 provide estimates of approximately the 0.1st and 99.9th percentiles. Hence, the sample size should always be indicated for ranges.

> ***Response:*** *U.S. EPA agrees that sample sizes should be reported. However, note the challenge with reporting sample sizes when multiple studies (with differential weights) are used to calculate percentiles.*

Comment: Special attention should be given to the public comments on Chapter 2 provided by Dr. Kenneth T. Bogen.

> ***Response:*** *Bogen's comments were reviewed, and appropriate modifications were made to the chapter, taking into account his concerns.*

Comment: The treatment of variability and uncertainty constitutes a critical topic for exposure analysis and the 2009 Update has substantially advanced the guidance that is provided in the EFH. However, at a minimum, it would be very useful to include some additional references to the topic; as the journal-based literature on the subject is not only enormous but is rapidly expanding, with many new and potentially useful methods evolving constantly. In addition to the included reference to Cullen & Frey, 1999; references could be selected from available comprehensive USEPA reports and a from a few recent monographs and

textbooks (e.g., Bedford & Cooke, 2001; Isukapalli & Georgopoulos, 2001a; Ayyub & Klir, 2006).

Response: *Several references were added from U.S. EPA, along with Bedford and Cooke (2001). The abstract from Isukapalli and Georgopoulos (2001) was reviewed. This is a novel alternative to Monte Carlo simulation that has not found widespread use. The motivation for using this methodology comes in part from a claim that Monte Carlo simulation is computationally inefficient. It was not included because it is not clear that computational inefficiency is a prevalent problem in current risk assessments. Ayyub and Klir (2006 had an engineering and theoretical focus and was generally not a useful source of information for this chapter.*

Comment: It is of course beyond the scope of the EFH to provide a self-contained introduction to uncertainty analysis concepts and methods. Nevertheless, some brief but more specific comments on the increasing usability (software availability etc.) and application of Bayesian methods (mostly through the implementation of computationally efficient Markov Chain Monte Carlo algorithms like Metropolis-Hastings etc.) for the characterization of uncertainty in exposure/dose systems, should be added to the text of Chapter 2. (e.g., Gelman et al., 2003; Gilks et al., 1995; Robert & Casella, 2004).

Response: *A discussion of Bayesian approaches was added to Section 2.5 along with references.*

Comment: Some suggestions for other potentially useful references follow:

- [Isukapalli & Georgopoulos, 2001b] This is a USEPA report on computationally efficient uncertainty analysis methods and applications to environmental and biological models:—it also includes methods for different types of uncertainty characterization, uncertainty propagation, and uncertainty reduction.

Response: *This is the same reference as Isukapalli and Georgopoulos (2001a).*

- [Isukapalli et al., 2010—in press] An overview of recent developments in Uncertainty, Variability, and Sensitivity analyses.

Response: *This reference was not available at the time Chapter 2 was edited.*

- [Babendreier & Castleton, 2005] This a study that discusses uncertainty analyses in integrated multimedia environmental models

- [USEPA, 2008] Discusses key issues and case studies concerning uncertainty and variability in Physiologically-Based Pharmacokinetic (PBPK) models.

- [Xue et al., 2006] Presents exposure modeling focusing on two-stage Monte Carlo techniques for characterizing uncertainty and variability

- [Bois, 2009] It presents toolboxes for uncertainty reduction via Bayesian Markov Chain Monte Carlo (MCMC) method

- [Saltelli, 2008] This is a good primer on global sensitivity analysis with practical toolboxes for global sensitivity analysis. It should be noted that performing combined sensitivity and uncertainty analysis is generally needed in complex exposure systems, since it is possible that a parameter with low uncertainty can contribute substantially to overall uncertainty in model outputs if they are sensitive to this parameter while, conversely, high uncertainty and low sensitivity for a given parameter may mitigate each other.

- [Refsgaard et al., 2007] It includes reviews on multiple forms of uncertainty in integrated modeling.

Response: *These references were added to Chapter 2.*

- [Georgopoulos et al., 2009] This is a study that presents and compares methods for reducing uncertainty in exposure reconstruction and i interpretation through the use of exposure data at different levels of detail in combination with available biomonitoring data. —The abstract for this document was reviewed. Chapter 2 of the EFH is an introduction to issues of uncertainty and some of the accepted means of treating it. This study of physiologically-based pharmacokinetic (PBPK) modeling explores a new approach for highly specific issue (numerical reconstruction methods).

Response: *Because of the degree of specialization in this article, it was not discussed.*

Comment: There is some confusion in this chapter as to measures of variability and some distinct (not general) approaches to uncertainty. This uncertainty appears to include the usage of the standard deviation and non-parametric equivalents of statistical variation. (The use of averages, e.g., means vs. medians, and lesser discussion of non-linear models, appear to pervade this chapter and the Handbook.)

Response: *Additional discussion about variability and uncertainty was added to the chapter. A definition of variability, conforming to the definition in U.S. EPA's Guidelines for Exposure Assessment and Monitoring, was added to Section 2.1. Section 2.3, Addressing Variability, Section 2.4 Types of Uncertainty, 2.5 Reducing Uncertainty, and 2.6 Analyzing Variability and Uncertainty were edited. Additional references*

were added and discussed in Section 2.7 Literature Review of Variability and Uncertainty Analysis.

Comment: The chapter could use some editing and rewording. Real data examples would be useful—there certainly are plenty in the literature, even in just one journal (JESEE).

Response: *Much of the chapter has been edited. A useful example involving lead poisoning through the water consumption was added.*

Comment: Second paragraph: There is too much denigration of exposure assessment herein, especially considering that most risk assessments, as described in Chapter 1, don't utilize all the detailed quality data collected in exposure assessments. Further, it needs to be reworded as well because it doesn't reflect what this Handbook is all about nor what the EPA would like.

Response: *Second paragraph was removed.*

Comment: 2.1: It would be very important for the definition of variability to include the statistical definition (discussed above) as such statistical measures are necessary to understand variability in a set of data, and since some referral to it (whether correct or not) occurs in this chapter.

Response: *A statistical definition of variability was added.*

Comment: First paragraph, line 14: It may be inappropriate to state that variability cannot be reduced, as it can through sub-population analyses and through various statistical simulation methods. Actually, uncertainty in the form of biases are harder to reduce or correct. Further, one could state that even with such further analyses, "… variability may not be reduced in existing data sets, but could be with further data collection in the existing study population(s) or by replication of an exposure study with larger sample sizes, better statistical sampling techniques, and/or more precise measurements.

Response: *A statement was added to reflect the comment.*

Comment: One has ignored discussion of measurement variability herein, an important component of variability.

First paragraph, line 17: I would suggest adding, after "variability" the words "other than that due to sample size, inappropriate statistical sampling techniques or lack of precise measurements …". One could add a sentence as well that states "measurement variability could be due to the instrumentation and its precision, inter- and intra-observer/technician and subject variability, temporal and spatial variability in exposures not necessarily characterized well, and other factors discussed in the literature."

Comment: 2.2: Second line in first column on top of page 2-3, at end, I suggest adding "and variability due to measurements". I would also add two more bullets at the end of the next paragraph, i.e., "Variability in and between observers/technicians" and "Variability (precision) in measurements".

Comment: There have been extensive modifications to the first paragraph. As indicated in the previous comment and U.S. EPA response, treatment of variability due to measurements, i.e., measurement error, was brought into the revised edition of this chapter in Section 2.4.

Response: *Treatment of variability due to measurements, i.e., measurement error, was brought into the revised edition of this chapter in Section 2.4.*

Comment: First paragraph, last line: I would suggest adding at the end "and enogenous (e.g., genetic) factors.

Response: *Genetics was included among the endogenous factors.*

Comment: 2.1, paragraph 4 (in second column of page 2-2), Re: uncertainty—there are many reasons for uncertainty about a distribution, but they shouldn't include statistical measures of variability (e.g., standard deviation or other statistical measure appropriate to the best fitting distribution of data). One is further confusing the two terms by discussing these statistical measures under uncertainty!

Response: *This paragraph was removed.*

Comment: Paragraph on "Inter-individual variability", first paragraph, (1): after "age" add "gender, race, height," and after "body weight" add "(including any obesity), phenotypic genetic expression, and pathophysiological conditions".

Response: *These items were added to the section on interindividual variability.*

Comment: 2.3: The last sentence starting on the bottom of page 2-3 (2^{nd} column) is incorrect due to the increase in the proportion overweight, which also has a differential distribution by gender and race/ethnicity.

Response: *This paragraph was removed.*

Comment: Page 2-4, 1^{st} column, re third strategy. What "average" are they talking about here? It can't be the mean if the distribution is definitely non-Gaussian. Would they use a median? (see the "For example" in the paragraph on the top of the 2^{nd} column.)

Response: *This paragraph was removed.*

Comment: 2.4: Re: the classification of uncertainty, second paragraph. To (1) should be added "or biased" (not accurate). Somehow, the issues of biases are not incorporated well, including in Table 2-2, but they should be included. The discussion of uncertainty should be expanded to include this important area.

Response: *Section 2.4 was rewritten.*

Comment: 2.6—Figure 1 is misleading, even when using log AF, since these distributions appear to be Gaussian. They could well be gamma or negative binomial or Pearson types of distributions not characterized but likely. This needs to be discussed here.

Response: *Figure was removed.*

2.24. Chapter 3: Water Ingestion

Comment: In the water ingestion chapter 3, three key studies are used independently for general water, pregnant and lactating women water ingestion, and swimming water ingestion. These three scenarios are sufficiently discrete that deriving factors separately makes sense. While the publication date of the general water key study (2008) makes it seem current, in reality it is a reanalysis of data from 1994−96 and 1998, well more than a decade old. While water consumption is driven mostly by physiological need, the availability and marketing of bottled water has increased significantly over that time.

One reviewer said that there should be an introductory paragraph alerting the user to issues that might have an effect on the type of water people are drinking (e.g., the type of water people are drinking has changed in the last decade, as evidenced by the increase in bottled water consumption).

Comment: Another reviewer said that climactic variations have a big influence on water intake, and it would be useful to collect regional data to look at subpopulations. Another reviewer agreed that if the data are too broad, they may have limited use in a more specific risk assessment.

Response: *U.S. EPA agrees. To update the chapter, data and tables have been added from an analysis conducted by the U.S. EPA using data from the 2003−2006 NHANES data. The recommendations tables are now based upon the newer NHANES data for individuals ≥3 years of age. CSFII data were retained for children <3 years of age due to sample size limitations with NHANES for those age groups.*

Comment: I was a little confused by the presentation of "per capita" versus "consumer only" intake rates that appear separately in many of the tables, including the tables that contain the "recommended rates". It appears the "per capita" data represent the results of surveyed individuals whether or not they consumed any "source water" during the survey, while the "consumer only" data presumably represent intake rates of only those individuals who consumed source

water during the survey. Assuming this is true, I should note that neither of these "definitions" seems to appear in either the text (pages 3-1 and 3-2) or the tables (Tables 3-1 and 3-3) that describe the recommended ingestion rates for community water. The definition of these terms should appear in Section 3.2.

Comment: One reviewer said that per capita and consumer-only intake rates are not well defined and are confusing. More explanation should be given as to how the risk assessor is supposed to use the two separate recommended rates.

Comment: It is also unclear why these data (per capita vs. consumer) are presented separately as recommended rates. I didn't find any discussion as to the merits of one vs. the other. Since the "consumer only" rates are consistently higher than the "per capita" rates across all age groups, some discussion regarding this matter is warranted. It is unclear to me how a practicing risk assessor would/should make a distinction between these two rates, regardless of the site-specific conditions under evaluation. Since these are recall data, I would assume the "consumer only" rates are probably more accurate(?), yet the text in the "Recommendations" section (3.2) seems to emphasize the per capita rates.

> ***Response:*** *The definitions for" consumer-only" and "per capita" have been added to Section 3.3.1 and to Table 3-1 and Table 3-3, as suggested. Information on the use of "consumer-only" versus "per capita" has been added to Section 3.1.*

Comment: In several of the data tables, it is noted that, for select data, "Sample size does not meet minimum requirements as described in the Third Report on Nutrition Monitoring in the United States". The meaning and purpose of this notation, and how it is to be interpreted by the exposure assessor, is unclear to me.

> ***Response:*** *The text has been edited to explain the meaning of this notation. Estimates based on a smaller number of respondents may be less reliable statistically than estimates based on a larger number of respondents. The Third Report on Nutrition Monitoring in the United States suggests minimal reporting requirements.*

Comment: I did not see any estimates of private well water consumption rates. Risk assessors often must evaluate actual (current) or potential (future) exposures via well water. In those regions where the well water is potable, should the assessor simply assume the direct and indirect consumption rates that the EFH recommends for community water? Is there any reason to believe that well water consumption rates would be significantly different from those estimated for community water?

> ***Response:*** *Well water, together with spring, cisterns, and other sources not specified, is included in Other Sources water of the NHANES analysis. People obtaining their water from private wells would not be expected to drink a different amount than those getting their water elsewhere since the*

physiological need for water is the same regardless of the source. A statement was added in this chapter's intro about the majority of the U.S. population consuming public (i.e., community) water (about 15% of the U.S. population obtains their water from private (i.e., household) wells, cisterns, or springs (U.S. EPA, 2002). Also added the statement to indicate that, regardless of the source of the water, the physiological need for water should be similar.

Comment: I note that the EFH recommends consumption rates for water ingested while swimming. Does ingestion while showering occur to a degree that warrants consideration?

Response: *U.S. EPA is not aware of any studies that present data on water ingestion by showering.*

Comment: In the fish ingestion chapter, the EFH discusses the potential effects of cooking on contaminant loss/increase in fish tissue. In a situation where the tapwater contaminant is a volatile compound, should loss while cooking (and potential subsequent inhalation) be considered?

Response: *Information on the effects of cooking is provided in the fish ingestion chapter because uncooked and as-prepared fish intake rates (i.e., the exposure factor) may differ. Assessors must be aware of this so that they can use intake rates (cooked or uncooked) that "match" the basis of the contaminant concentration used (i.e., contaminant concentration in cooked or uncooked fish). This information is provided for the purpose of addressing the exposure factor (fish intake rates) and not to address adjustments to contaminant concentrations, which would be chemical-specific. Volatilization of chemicals from drinking water while cooking is a chemical-specific issue, rather than an exposure factor issue. Therefore, it is not appropriate for this chapter.*

Comment: In Chapter 3, the recommendations for water ingestion while swimming is based on one recent study. The confidence in the study is appropriately rated as low based on numerous uncertainties.

Response: *U.S. EPA agrees.*

Comment: Table 3-2 the drinking water ingestion study is rated medium to high, but in Table 3-1 there is a footnote that indicates sample size may be insufficient for some age groups. A suggestion is to provide a confidence rating both for the study and then for the data as used (so, for example, there may be medium overall confidence in a certain study but low confidence when the data are stratified into multiple age bands due to lower sample size per age band).

Response: *A note was added to the confidence rating table to alert the user about lower confidence for some age groups.*

Comment: Chapter 3 provides an excellent overview of studies on the ingestion of water and other select liquids. Overall the usability of the information provided could be enhanced through the addition of some graphical representations of the information contained in the tables. The list of the studies identified is quite exhaustive; some potential additions (especially useful in comparing US with foreign data) could be the following:

- [Kim, 2008] Provides original data on water consumption rates for Korean housewives in the winter and summer seasons to measure their exposures to volatile disinfection by-products (DBPs) in chlorinated tap water. Data were collected from visits to 60 households.

Response: *Not added; data are for Korean women and would not be representative, but we have nationally representative data for the United States.*

- [Schijven & Husman, 2006] Provides original data derived from answers to questionnaires given to occupational and sport divers in the Netherlands. Useful for exposure studies related to diving activity. Specifically, it lists the volume of water swallowed per dive)

Response: *Data from this study have been added.*

- [Riederer et al., 2006] Provides a distribution of (self-reported) water ingestion rates for 182 women aged between 15 and 49 from two communities in the Philippines.

Response: *This reference was not added; data are for Phillipino women and would not be representative, but we have nationally representative data for the United States.*

Comment: This revised draft EFH provides upper values based upon 95th percentiles, whereas previously recommendations were based upon 90th percentiles. Within Chapter 1, it is clearly indicated that the upper percentile refers to 90th percentiles and greater throughout this book. When a change has been made in the reference percentile selected to represent an upper bound, the basis for this change should be transparent.

Response: *U.S. EPA prefers to use the 95th percentile, when there are sufficient data to support reliable estimates of 95th percentiles. U.S. EPA revised Chapter 1 to ensure consistency with current preferences.*

Comment: It is unclear if the Dufour et al. study (p. 3-21) used to estimate ingestion during swimming considered tracer uptake from dermal exposure during swimming. This should be added to the discussion. Without this information, it can not be determined if the ingestion estimate represents ingestion alone.

Response: *Dufour et al. (2006) stated that dermal absorption of cyanuric acid has been shown to be negligible. A statement was added to reflect the comment.*

Comment: He also wondered whether there are data on the use of home filtration devices.

Response: *NHANES does not have a specific question or measurement to collect data on the use of home filtration devices.*

Comment: One reviewer thought that a question about filtration use is on the NHANES survey. He also noted that there may be regional differences that impact people's ingestion of water. Another reviewer agreed that a risk assessor must be aware of the caveats.

Response: *NHANES does not have a specific question or measurement to collect data on the use of home filtration devices. A question that contains relative information about home water filtration can be found in NHANES dietary interview for total nutrients. The question asks for "Total tap water drank yesterday including filtered tap water or water from a drinking fountain." However, this won't give a clear answer of the water consumption related to the use of filtration device only. U.S. EPA agrees that there may be regional differences in people's ingestion of water. However regional data from NHANES are not publicly available.*

Comment: One reviewer noted that smaller, more focused studies may provide more data. Their existence should at least be discussed, as the random sampling of the population does not apply to specific subpopulations (e.g., a roofer in Arizona who consumes more water than the average person).

Response: *Smaller studies that have been identified have already been included as "relevant" studies in this chapter.*

Comment: One reviewer noted that some of the studies list fairly recent publication dates; however, the newer publication is actually just a re-analysis of older survey data. This is particularly important because, as noted above, the type of water people are drinking has changed. Another reviewer noted the same thing and commented that newer data will be released soon.

Response: *U.S EPA agrees. To update the chapter, data and tables have been added from an analysis conducted by the U.S. EPA of the data from 2003−2006 NHANES data. The recommendations tables are now based upon this newer NHANES data for individuals ≥3 years old. CSFII was retained for children <3 years of age due to sample size limitations with the NHANES data for those age groups.*

Comment: One reviewer noted that from a contaminant perspective, bottled water may be even more contaminated than tap water, depending on the source of

the bottled water. Also, if filters are not changed in the filtration devices, they become a source of contamination.

> ***Response:*** *U.S. EPA agrees. It has been discussed in the text. It is assumed that bottled water is widely distributed and less likely to contain source-specific water. Data on the use of filtration devices are not available.*

Comment: To enhance the usability of this chapter, one reviewer said that a simple decision tree or road map may improve the overall application of these factors in the exposure assessment. This chapter is an example of where issues of variability are not easily represented in the tables. A diagram can help guide the user to the most appropriate factors. One reviewer commented that this idea of a decision tree could be applicable to all the factors.

> ***Response:*** *A schematic diagram is provided in Chapter 1. It is not clear what the reviewer means regarding issues of variability. To the extent that the data are available, distributions of water intake are provided in the tables to account for interindividual variability.*

2.25. Chapter 4: Non-Dietary Ingestion Factors

Comment: Page 4-5, Paragraph 1, Column 1; Is there supposed to be a table for the Zartarian et al., 1997a study? Why present it without giving some data. Is it still a relevant study then.

> ***Response:*** *The data from the Zartarian et al. (1997) study are presented within the text. Because the study only included four children, a table presenting the data was not deemed necessary. The Zartarian et al. (1997) study and several other "key" studies in this chapter were used by Xue et al. (2007) to conduct a meta-analysis. Because the Zartarian et al. (1997) study was used by Xue et al. (2007), U.S. EPA classified the Zartarian et al. (1997) study as "key." The data from this meta-analysis were then used for the recommended values presented in Table 4-1.*

Comment: Page 4-8, Paragraph 4, Column 1 One advantage of the Black et al. 2005 study was that it presented both survey responses and videotaped information of mouthing behavior. Can EPA mention whether these were in agreement or not?

> ***Response:*** *A sentence was added stating that parental survey reports were not strongly correlated with videotaped hand or object mouthing.*

Comment: Page 4-8, Paragraph 5, Column 1 For the Xue et al., 2007 study, 7 studies are mentioned. Can all be listed in this bracket? In general there are tables of data for the Xue et al. studies and they should list the included studies (e.g., table 4-10 and 4-11).

Response: *The studies that are included in the Xue et al. (2007 study are all listed in the text. The text was revised for clarity.*

Comment: This chapter gives no guidance on how to use duration and frequency of mouthing in order to calculate non-dietary exposure. Can EPA point to some guidance documents or study where reasonable calculations can be found for non-dietary ingestion exposure.

Response: *A statement was added to the text of the Introduction which discusses residue transfer from objects or skin to mouth.*

Comment: The first paragraph could more specifically say that when objects or the hands are mouthed, environmental contaminants on these objects or bodyparts are removed and enter the mouth. Sequence of events may be important, such as whether a handwashing event occurred after contact with soil and before the hand is placed in the mouth.

Response: *A statement was added to paragraph 1.*

Comment: EPA mentions on Page 1, paragraph 5 (column 2) that this Handbook does not address contaminant transfer from bodyparts or objects. This is a factor that is needed to make an exposure assessment for non-dietary ingestion exposure. The amount that transfers or the area of the object or bodypart mouthed is needed. It is possible that some of the videotaped studies presented could review existing videotapes to gather that data. EPA should consider funding such a study.

Response: *At this time, mouthing frequency, mouthing duration, and mouthing prevalence are included in this chapter, while the amount of contaminant transfer is beyond the scope of the Handbook.*

Comment: Page 4-2, Paragraph 3, Column 1; The sentence reads: "Recommendations for hand-to-mouth durations are not provided since those estimates may not be relevant to environmental exposure." It is unclear to me why these durations would not be relevant. Can EPA explain this further? Is it because all the contaminant is assumed to be removed immediately and so frequency, not duration matters.

Response: *Sentence has been rewritten to say that hand-to-mouth durations are not provided because the algorithm to estimate exposures from this pathway is not time dependent.*

Comment: To help clarify why certain studies were deemed relevant rather than key, one reviewer suggested organizing the chapter differently—present a study once with sections underneath for each of the four factors, noting whether it was considered key or relevant for each factor.

Response: *It seems clearer to group the "key" studies together followed by the "relevant" studies. Reorganizing the chapter as described in the*

comment would be unlikely to provide clarity on why specific studies were deemed "key" versus "relevant." Note that only the Zartarian et al., Beamer et al., and AuYeung et al. papers are repeated in both the frequency and duration sections of this chapter. The other 16 papers are only in either the frequency or duration section. Therefore, keeping the frequency and duration sections separate appears to be a reasonable approach.

2.26. Chapter 5: Soil Ingestion

Comment: Not clear why collection of excreta is mentioned twice in the first paragraph at the top of the second column on page 5-9.

Response: *Modified the paragraph so that the collection of fecal and urine samples is described only once in this paragraph.*

Comment: Could equation formatting be improved? For example, eq. 5-1 looks like the text was just underlined rather than created through an equation editor. Same for eq. 5-2. The underlining is distracting in trying to interpret the equation.

Response: *Recreated Equations 5-1 and 5-2 using Microsoft Equation Editor and inserted them into the text.*

Comment: Does Table 5-7 provide estimates of soil or dust ingestion? Not clear just from table.

Response: *The phrase "Soil Ingestion" was added to the table title to clarify that the data are for soil ingestion only. Note that this is now Table 5-6.*

Comment: The Agency has done a thorough job for most of the factors reported. I note a few missing data sources by chapter below. Chapter 5: Estimates of indoor dust based on number of hand to surface contacts and subsequent hand to mouth contacts. This work is being done within EPA through the SHEDS program.

Response: *The paper from Ozkaynak et al. (2010), which estimates soil and dust ingestion using hand-to-mouth contact information was added. Included discussion about this methodology and how it is used in SHEDS. The recommendations have been revised accordingly.*

Comment: Chapter 5—Table 5-1 does not indicate how the key studies were used to derive the recommended values.

Response: *A new section has been added to the chapter (see Section 5.6) entitled "Derivation of Recommended Soil and Dust Ingestion Values," which includes a detailed description of how both the central tendency and upper percentile (see Section 5.6.1 for soil-pica and Section 5.6.2 for geophagy) recommendations were derived from the "key" studies. Also,*

sources have been added to Table 5-1 (see comment below) to indicate which "key" studies are associated with the recommended soil ingestion values.

Comment: There is no citation for any of the individual values or of the recommendations as a whole.

Response: *Citations have been added to the text of the recommendations section to indicate the sources for the individual recommended values described in this section of the chapter. Sources ("key" studies) have also been added to the footnote section of Table 5-1 (Recommended Values table) to indicate which "key" studies are associated with the recommended soil and dust ingestion values. In addition, a new section has been added to the chapter (see Section 5.6) providing additional detail on how the recommendations were derived from the individual "key" studies in the chapter.*

Comment: Chapter 5: Rather than present variability for the general population, the authors include a central tendency of soil consumption for the general population and then include values for pica and geophagy. They state that these represent an unknown high percentile value. I think a bit more guidance could be given on how to use these values.

Response: *The central tendency recommendations now indicate that they refer to the general population. A new category referred to as "high end" is now provided. This category is subdivided into upper percentile, soil pica, and geophagy. The Handbook clarifies that the soil pica and geophagy recommendations are more appropriate for acute exposures.*

Comment: From reading the chapter, I get the sense that geophagy is quite rare, while it appears based on the study results that pica is much more common.

One reviewer suggested providing more guidance on what percent of the population exhibits pica behavior vs. geophagy. It should be made clear that geophagy is rare and an extreme behavior. Another reviewer agreed that there should be a general discussion of both behaviors and a data set with distributions. One reviewer noted that given the cloudy nature of the data, it is understandable that percentiles are not given. He also noted that from a policy standpoint, EPA has taken pica out of consideration for inadvertent soil ingestion, so to describe an upper percentile as a pica child would be inconsistent with how EPA uses the data.

Response: *Pica, in general, is the ingestion of nonnutritive substances, and has been more studied than geophagy. Information on prevalence of pica behavior from a new study has been added (Gravelis et al., 2010). A statement was added from ATSDR (2001) indicating that geophagy is an extremely rare behavior and that soil-pica, however, is a fairly common*

behavior among children.EPA has supplied additional information regarding what percent of the population exhibits pica behavior, and some information on distinctions between the two behaviors. Other text was also added to the Introduction to provide additional information about soil-pica and geophagy. Upper percentile recommendations for the general population have been added.

Comment: One reviewer said that his main issue with Chapter 5 is the distinction between outdoor soil and indoor dust ingestion. The overlap of indoor soil-derived dust is not addressed. Soil can be tracked or blown into a house and mix with dust of indoor origin. Therefore, ingestion of indoor dust may also result in soil ingestion.

Comment: The distinction between "indoor dust" and "soil" is clear and I agree that both ingestion pathways should be evaluated separately if possible. However, on page 5-1 it is stated that "it is not possible to distinguish between outdoor settled dust and soil because outdoor settled dust generally would be present on the uppermost surface layer of the soil". This seems to ignore the possibility of outdoor dust that has settled on non-soil surfaces where direct or indirect ingestion of the dust might occur (e.g., playground equipment, outdoor patio furniture, etc.). I am not aware of any studies that have attempted to distinguish "outdoor dust" vs. "outdoor soil" exposure pathways. Yet, one could envision an exposure scenario where contact with outdoor dust, but not soil, is a viable pathway (for example, a family living on a lawn-covered property that is near a contaminated site with exposed soils).

Comment: Given the limited data and the often confusing multiple re-analyses of the limited data, the EFH does a good job in presenting and summarizing the available data. However, with respect to soil and dust ingestion and the distinction between them, the discussion is confusing. This is particularly the case because the existence of indoor soil-derived dust is not directly addressed. Indoor soil ingestion is discussed, but it appears that this term is applied only to ingestion of soil deliberately brought indoors (e.g., potting soil for indoor plants). However, soil material can be transported into the house where it can mix with dust of indoor origin to produce a heterogeneous dust material. Ingestion of indoor dust, therefore, also results in soil ingestion. Also, the transport of soil indoors appears to be dealt with only with respect to material that is "tracked in." However, small size soil derived particulates can also be transported indoors by air, particularly with open windows.

Comment: Also, the relationship of soil and indoor dust and the overlap with respect to soil-derived indoor dust is not clearly defined.

Response: *Definitions for soil and indoor and outdoor settled dust are provided in the introduction to Chapter 5. The definition for outdoor settled dust has been modified and language was added to address the comment. The distinction between outdoor soil and indoor dust ingestion is addressed*

on page 5-2, in the definitions of "Soil" and "Indoor Settled Dust." The definition for "dust" has been amended to include "or blown" into a house. The issue of the ingestion of indoor dust resulting in soil ingestion is addressed in the definition. In these definitions, the distinction between outdoor soil and indoor dust is the following: outdoor soil (or simply soil in these definitions) is soil located outdoors or used indoors in planters; indoor settled dust is indoor settled particles that may include tracked-in outdoor soil. The reviewer is correct that ingestion of indoor dust may also result in soil ingestion, and the definition in the introduction of this chapter provides for that

Comment: Two reviewers commented that soil and dust ingestion data are sparse.

Response: *U.S. EPA agrees. Language is included in the chapter recognizing the fact that soil and dust ingestion data are sparse. The study from Ozkaynak et al. (2010) that provides dust ingestion information based on a modeling exercise is now included.*

Comment: One reviewer commented that it seems unlikely that adults ingest absolutely no dust at all. However, this reviewer mistakenly thought that a dash in a table represented zero rather than a lack of data. Therefore, a reviewer suggested explaining what the dash represents in the table.

Response: *It is assumed that these reviewers are commenting on Table 5−1. The second reviewer is correct that the dash in Table 5-1 indicates a lack of data, and not zero ingestion. U.S. EPA has revised the recommendations by calculating dust ingestion for adults using the same ratio of 45% soil and 55% dust.*

Comment: One reviewer said that there needs to be more explanation about why the key studies were chosen, especially because EPA is proposing a new approach and moving away from the well-known Calabrese studies. He said that he does not disagree with the new approach, but that EPA should provide more detail about the uncertainties and the choice of key studies.

Response: *Detailed information about the uncertainties and limitations associated with each of the studies is included in Section 5.4, Limitations of Key Study Methodologies. Many of the general assessment factors regarding the selection of the "key" studies (i.e., soundness, applicability, etc.) are shown in Table 5-2. Additional information on the derivation of recommendations was added.*

Comment: Another reviewer would also like additional information about how the Hogan et al. model was developed and validated. She was also curious about how the outcome would change if the default values for dust ingestion were changed to 70 mg/day or higher.

Comment: For the discussion of Hogan et al., 1998 on Page 5-13, how was the model developed? Or validated? Were parameters fitted independently? Was there a sensitivity analysis? How sensitive was the model to changes in soil and dust ingestion? As these are the value being proposed for EFH recommendations additional information here would be helpful. Does the outcome change significantly if the default value of dust ingestion is changed to 70 mg/day? How about 700 mg/day? Or at least over the range of values measured by the tracer studies?

Response: *U.S. EPA has added information on the model to both the Hogan et al. (1998) summary and to Section 5.4 describing limitations of the three methodologies used in the chapter. There was no extensive sensitivity analysis for two reasons. The calibration step used to fix model parameters (see previous response to comment) limits the degree that most parameters can reasonably be varied. The integrated exposure uptake biokinetic (IEUBK) model was not designed to predict blood lead levels greater than 25−30 μg/dL; there are few data to develop such predictions and less to validate them.*

Comment: Another reviewer said he was impressed with the approach using the integrated exposure uptake biokinetic (IEUBK) model for lead; however, he noted that the uncertainties and variabilities associated with that model were not well described. He thought the approach should be presented as a secondary method, though, and commented that gold would be a good tracer because it has no background and is nontoxic.

Response: *Additional information regarding the IEUBK model, including kinetic and intake parameters and sensitivity analyses, has been added to the chapter (see Section 5.3.3.2). The uncertainties and limitations of the IEUBK model are described in Section 5.3.1.2, Section 5.3.3.2, and Section 5.4.2. There are three methods for estimating soil and dust ingestion presented in the chapter, including the activity pattern method, which uses a modeling approach. U.S. EPA believes that these three methodologies complement each other and that they all have strengths and limitations. U.S. EPA agrees that a new methodology should be developed to get better estimates of soil and dust ingestion. At this point, no resources have been committed to develop such methodology.*

Comment: One reviewer commented that Chapter 5 uniquely combines environmental and biomarker data. He thought this approach could be introduced in other chapters as well, especially because using biomarker data in exposure assessments is an up-and-coming approach.

Response: *U.S. EPA has included biomarker approaches in places where such data are used to derive an exposure factor. One example is the estimation of inhalation rates based on doubly labeled water. It is unclear how biomarker data are applicable for some of the other factors of interest.*

Comment: As with Chapter 2, this is not my area of expertise or research, but the chapter seems adequate and these factors, especially the dust ingestion, has been receiving considerable attention as the indoor exposure to fire retardants via dust ingestion and dust inhalation have been shown to be important routes of exposure. The differentiation between soil and dust seems clear, although there is a clear overlap between the two. Soil contributes to the "dust" to a different degree, but not the other way around.

> ***Response:*** *U.S. EPA agrees with the reviewer. The definitions for soil and dust in Chapter 5 do include some overlap between the two. Soil may include particles that have settled onto outdoor objects and surfaces (outdoor settled dust), indoor settled dust may include soil particles that have been tracked or blown into the indoor environment from outdoors as well as organic matter, and outdoor settled dust may also include soil particles because outdoor settled dust generally would be present on the uppermost surface layer of soil.*

Comment: Estimation of soil/dust ingestion is difficult as there are no direct methods. Further clarification of the methods used would provide more transparency of the available data.

> ***Response:*** *Specific details of the methodologies used for each study in the chapter are described in the summaries for the individual studies. In addition, Section 5.3.1, Methodologies Used in Key Studies, provides a full discussion of the methods. Section 5.4 provides a detailed discussion of the limitations of each one of the methodologies.*

Comment: The analogy give on page 5-4 to fractions of a teaspoon by volume is difficult to picture. Perhaps consider comparing to something else. For example, your average aspirin is around 325 mg, so your daily soil or dust ingestion would be approximately equivalent to a 6th of an aspirin and the combined about would approximate a 3rd of an aspirin.

> ***Response:*** *The analogy has been rewritten to reflect the comment.*

Comment: It may be appropriate to list the size fractions of soil and dust that were analyzed for each of the studies. Where the same size fraction of soil used as for dust when dust concentration values were substituted into the algorithms? Studies have demonstrated that particles of soil and dust adhered to hands are generally < 63 microns in size (Choate et al., 2006; Yamamoto et al., 2006). Using concentration values for size fractions soil and dust that are not representative of what might actually be on the hands or ingested might affect the results and contribute to some of the negative values observed. For example in the differences observed in Calabrese et al. 1989 (page 5-9) may be related to different size fractions of soil and dust. Calabrese et al., 1996 (page 5-20) did report differences for some elements in comparing size fractions of <250 microns with those of <2 mm. However these particle sizes are still large relative to what

may actually adhere to hands. This was followed up by Stanek et al., 1999, on page 5-21, which indicates that the smaller size fraction of <100 microns had a lower concentration, which would result in increased soil ingestion rates according to their algorithm. Studies that measured tracers in soil and dust with size fraction of <63 microns should be considered separately if possible.

> ***Response:*** *Size fractions for soil were listed in the summaries for the two studies where this information was available [Calabrese et al., (1996) and Stanek et al., (1999)]. No size fractions for dust were provided in any of the studies. Available information regarding the possible impact of size fraction on the adherence of soil to the hands, and on soil ingestion has been presented in the study summaries, as discussed by the reviewer in the above comment. Additional information [from Choate et al., (2006) and Yamamoto et al., (2006)] was added to the Introduction section regarding how soil particle size, organic matter content, moisture content, and other soil properties may affect the adherence of soil to the skin. Both of the studies that measured tracers in soil and dust and particle size have been presented in the chapter.*

Comment: The statement on page 5-8, that only one study (Lásztity et al., 1989) has published using the simultaneous equation method, does not coincide with the description of Barnes (1990) using the simultaneous equation method on page 5-9.

> ***Response:*** *Correction was made to include Barnes (1990) in the text on page 5-8.*

Comment: Have any studies been conducted to determine absorption rates of these tracer elements? This may help EFH users in selecting which tracer element to use.

> ***Response:*** *Some of the studies included in this chapter discussed the issue of absorption of the tracer elements, but there were some differences observed. For example, the authors of three of the studies appeared to agree that the presence of silicon in urine represented evidence that silicon was being absorbed from the gastrointestinal tract [Davis et al., (1990); Calabrese et al., (1989); Barnes, (1990); Davis and Mirick, (2006)]. There was some evidence of aluminum absorption in Calabrese et al., (1989) and Barnes (1990) while Davis and Mirick (2006) stated that aluminum and titanium did not appear to have been absorbed, based on low urinary levels. Davis et al., (1990) stated that silicon appears to have been absorbed to a greater degree than aluminum and titanium, based on urine concentrations. This is described in the chapter.*

Comment: Is there an explanation for the 2 in equation 5-1?

Response: *The "2" is included in Equation 5-1 to compensate for missing urine samples that were not collected during the study. This is described in the text.*

Comment: In Calabrese and Stanek (1995) on page 5-19, are any of the recovery rates mentioned for elements in soil or feces? For any of the other tracer studies? What digestion/extraction methods were used? Were the same used for soil and feces? Could the increased content of organic matter in feces influence the recovery rates? Depending upon what acid was used for soil digestion, different recovery rates could be obtained too. For example if a typical nitric acid digestion for soil was used that does not completely extract all elements, especially those within a silicon matrix, how does this compare to the treatment of the soil in the acidic environment of the stomach? Could the acids in the stomach mobilize more elements than the digestion methods used on the soil? It would important to assess the key studies based on these criteria too as this may also explain some of the negative values.

Response: *Calabrese and Stanek (1995) offered numerous possible reasons for both positive and negative bias in soil ingestion studies in this paper, which are presented in the summary of the study. The focus of this paper was on procedural factors contributing to positive and negative errors in soil ingestion estimates for children, and not on analytical sources of error, such as recovery rates. Many analytical factors may also influence soil ingestion values, as indicated in the comment above, but were not specifically addressed in the Calabrese and Stanek (1995) paper. Of the other "key" tracer element studies, only two included recovery values [(Calabrese et al., (1989) and Davis and Mirick, (2006)], and this information has been added to the summaries of these studies. Although not specific to this Calabrese and Stanek (1995) study, Chapter 5 does present discussions regarding the limitations of soil ingestion studies in general, including inaccuracies inherent in environmental sampling and laboratory analytical techniques, in Section 5.4, Limitations of Key Study Methodologies.*

Comment: Are there any reports for the particles in the 2 to <53 micron particle range for Stanek et al. (1999) on page 5-21?

Response: *No findings were reported for the soil particles in the 2 to <53 micron range in this paper. Clarification was added to the Stanek et al., (1999) section.*

Comment: Under the section for limitations of key studies: consider adding for tracer element studies that soil/dust size fractions, and digestion/extraction methods of sample analysis may be additional limitations. Limitations for the biokinetic model comparison methodology may be confidence in other model parameters and no discussion of a sensitivity analysis.

Response: *These limitations were added to the text.*

Comment: Choate et al. (2006). Dermally adhered soil: 1. Amount and particle-size distribution. Integr Environ Assess Manag, 2(4):375−384.

Response: *Information from this study was added to the Introduction regarding how soil particle size, organic matter content, moisture content, and other soil properties may affect the adherence of soil to the skin.*

Comment: Yamamoto et al. (2006). Size distributions of soil particles adhered to children's hands. Arch. Environ. Contam. Toxicol, 51(2): 157−63.

Response: *Information from this study was added to the Introduction regarding how soil particle size, organic matter content, moisture content and other soil properties may affect the adherence of soil to the skin.*

Comment: For the most part, NCEA has done a good job summarizing the data. There in one inconsistency with the definition of indoor dust. If the definition of indoor dust includes resuspention, inhalation, and subsequent swallowing of indoor particulate matter, it seems contradictory to assume there is no exposure to indoor dust for adults. Also, is inhalation of particulate matter then clearly excluded from the inhalation pathway?

Response: *This comment is assumed to refer to Table 5-1, where there are no recommended values for adult dust ingestion or adult soil-dust ingestion. The omission of these recommended values was not intended to suggest that there is no exposure to indoor dust for adults. A recommendation for dust ingestion for adults has been added using the same assumptions used for the IEUBK model (i.e., 45% soil; 55% dust). A sentence was added to reflect the comment.*

Comment: There is very little data available on ingestion of dust. I think the assumptions are adequate in terms on children's ingestion of dust. However, while children clearly have more hand to mouth activity than adults, it also seems unlikely that adults ingest absolutely no dust at all.

Response: *Language is included in the chapter recognizing the fact that both soil and dust ingestion data are sparse. For the comment regarding the fact that it seems unlikely that adults ingest no dust at all, it is assumed that this reviewer is commenting on Table 5-1. A recommendation for dust ingestion has now been added. The 50 mg/day recommendation was mislabeled as soil ingestion when in fact it is soil + dust ingestion. The correction has been made.*

Comment: Also, it does seem odd that there is not an increase in exposure in the age ranges that have the highest amount of hand to mouth activity, however, given the limited amount of data, it does not seem feasible to determine such differences.

Response: *U.S. EPA agrees with this comment. The data from a single study [Van Wijnen et al., (1990)], adjusted from the IEUBK default values provided by Hogan et al., (1998), are the basis for the soil (30 mg/day) and dust (30 mg/day) recommendations for children aged 6 weeks to 12 months. Unfortunately, the data are very limited, and they could not be broken out by fine age categories in order to observe those differences.*

Comment: The definition of pica and the assigned value seem to be contradictory. The definition states it is ingestion between 1000 and 5000 mg, yet the central tendency is assigned at 1000 mg.

Comment: Par. 5—"…due to the significant number of observations in the U.S. tracer element studies that are at or exceed that quantity, the recommended soil pica ingestion rate is 1,000 mg/day" This would seem to imply that 1,000 mg/day is an underestimate of the central tendency value for pica soil ingestion. Given that, I don't understand the basis for selecting 1,000 mg/day as the recommended value for this parameter.

Response: *Although the definition for pica, taken from the June 2000 ATSDR Workshop suggests that pica involves ingestion between 1,000 and 5,000 mg, other values in the literature are as low as 400 mg. Due to this, the lower value in the range from the ATSDR recommendation (i.e., 1,000 mg) was selected as the recommended value. This explanation is provided in Section 5.2 of the Handbook.*

Comment: In the section related to making the values more meaningful, it suggests that 50 mg it 7/1000 of a teaspoon. It might be more useful to reference something smaller, as it is hard to picture 7/1000 of a teaspoon. Additionally, it may make sense to reference the dimensions in terms of mm, rather than cm.

Response: *This section has been modified using an aspirin tablet as an analogy (see above response).*

Comment: On page 5-3, the "recommended" adult value of 50 mg soil/day is proposed (based on data from Davis and Mirick (2006), yet it is indicated that there are no published data for dust or soil+dust ingestion for adults and therefore no recommendations for these values are offered in the draft EFH. I would prefer to see some attempt to develop values for these ingestion rates from the available data. The Davis and Mirick values are clearly a combination of soil and dust exposure, not just soil (because the adults spent time indoors). Perhaps the Davis and Mirick value should be considered a combination of both, with some percentage assigned to soil ingestion and the remainder to dust ingestion (for a total soil+dust ingestion rate of 50 mg/day). Alternatively, perhaps one could simply assume the same dust and soil+dust ingestion rates as those that have been assigned to the 6-<21 year age group (60 and 100 mg/day, respectively).

Response: *The reviewer is correct in that the 50 mg/day recommendation is soil and dust combined and not just soil. The correction was made on the table. Soil and dust values were then derived using the IEUBK assumption of 45% soil and 55% dust.*

Comment: The second full paragraph on page 5-3 should be clarified. Specifically, the source study for the soil, dust, and soil+dust ingestion rates (presumably, Hogan et al 1998) should be cited here (as was done for the adult ingestion rates), as well as the fact that this is a biokinetic model study. This would make the reference to "blood lead levels" and other study details ("small number of study subjects") less confusing. Oddly, nowhere in Chapter 5 is the source study for the non-adult soil or dust ingestion rates clearly identified.

Response: *The reference for the Hogan et al., (1998) study has been added and the fact that it is a biokinetic model study. Additional citations have been added to the recommended values in the text and in Table 5-1 for clarity.*

Comment: On a more general level, the bases of the non-adult soil and dust ingestion rates could be explained more clearly or in more detail. Essentially, the EPA has decided to not rely on any of the numerous tracer element studies, instead focusing on the single "key" study that employed IEUBK blood lead modeling. At the very least, I think the EFH needs to explain how/why this study (Hogan et al 1998) is superior to all of the tracer element studies of children that have been published over the past 20 years (e.g., the numerous paper by Calabrese, Davis, and Stanek) and which form the basis of the recommended soil ingestion rates in the current EFH; many practicing exposure assessors are very familiar with these latter studies and have applied them in environmental risk assessments in the past. Pushing these studies aside to embrace Hogan will likely represent a "sea-change" to many. In the same vein, I believe it could be made more explicit that ALL of the non-adult values are ultimately derived in whole or in part from the data reported in the 1-6 year age group in Hogan et al (1998).

Response: *U.S. EPA is trying to make use of all the data that are available on soil ingestion. Hogan et al., (1998) is not the sole source of the recommendations. Three methodologies have been described in the chapter, and they all have strengths and limitations. The Hogan et al., (1998) and the other studies published are used as supporting evidence for providing recommendations on soil ingestion. Additional discussion was added providing further details on the derivation of recommendations.*

Comment: Regarding the EPA's interpretation of the Hogan et al (1998) study in more detail, I have a few observations. First, Hogan et al (1998) employed the default IEUBK value of 30% bioavailability. If this estimate is off by a significant percentage for these lead smelting settings, the soil and dust ingestion rate assumptions would similarly be incorrect. How confident is EPA that the

default IEUBK bioavailability values represented the true soil and dust lead bioavailabilities in these settings?

> ***Response:*** *U.S. EPA is confident that the 30% has been a reasonable value for most data sets/sites. Bioavailability has been assayed for soils similar to those in the calibration step and the empirical comparison data sets; 30% was used in the calibration step, and is, therefore, recommended for similar sites. The default provides a reasonable substitute when there are no specific data. Speciation of lead compounds for a particular exposure scenario could support adjusting bioavailability if they are known to differ strongly from 30%. In general, U.S. EPA supports using bioavailability rates determined for the particular soils of interest if available.*

Comment: Second, the text on page 5-3 indicates that the soil and dust ingestion rates for the age group 6 months-1 year (both are 30 mg/day) are based in part on the assumption that the relative proportions of soil and dust ingested in this age group are the same as the default values assumed in the IEUBK model for the 1-6 year age group (45% and 55% respectively). This suggests that: 1) the IEUBK model does not have separate dust and soil ingestion rate default values for the 6 month-1 year age group (but does for the 1-6 year age group), and 2) that Hogan et al (1998) estimated a total soil + dust ingestion value of approximately 60 mg/day in the 6 month-1 year age group and chose to apportion 30 mg/day to each pathway. If this is true, then it would be helpful if this was explained more directly; as currently written the reader is required to invest quite a bit of time to "put the pieces of the puzzle together". This could probably be remedied with just a few more line of text.

> ***Response:*** *Additional text has been added to the recommendations section to clarify the origin of the soil and dust ingestion values.*

Comment: Third, some commentary on the confidence (or lack thereof) in the 45%/55% assumption in the IEUBK model (for the 1-6 year age group) is warranted, since this directly affects the soil and dust ingestion rates recommended for the 6 month-1 year age group. More specifically, are these default percentages based on actual measurements in 1-6 year olds or are they simply "guesstimates"?

> ***Response:*** *U.S. EPA's confidence rating for this recommendation is low, as described in the recommendations section. The default percentages (45% soil, 55% dust) are based on U.S. EPA (1994a) and approximate the relative proportions of the Hogan et al., (1998) values for 1 to <6 year olds (i.e., 50 and 60 mg/day for soil and dust, respectively). The Hogan et al., (1998) values for 1 to <6 year olds were based on the IEUBK model.*

Comment: On page 5-3 of the document, the EPA indicates that there are insufficient data to support the development of a distribution for use in probabilistic risk assessment. I'm not sure I agree. Over 30 different analyses of

soil/dust ingestion rates, mostly in children, are described in the EFH. There are published probability distributions of soil ingestion rates that are likely outdated (e.g., Finley et al 1994) but which could provide a "road map" for developing a child soil ingestion rate distribution with or without the pica behavior included.

> ***Response:*** *This statement has been deleted. Although there may be several studies describing soil ingestion by children, many of them are reanalyses of previously published studies. Children are observed for a week or two weeks at a time, and developing distributions that would be reflective of long-term behavior may not be appropriate. Ozakaynak et al., (2010) provides a distribution of soil ingestion rates based on modeling assumptions.*

Comment: There is no discussion of soil particle size or organic content and the possible influence these factors might have on soil or dust ingestion rates. Since dermal contact with soil/dust has a direct influence on soil/dust ingestion rates, and because dermal adherence is governed in part by soil properties, such a discussion might be worthwhile. Perhaps this is beyond the scope of the EFH.

> ***Response:*** *Additional information was added to the Introduction section regarding how soil particle size, organic matter content, moisture content, and other soil properties may affect the adherence of soil to the skin.*

Comment: Presumably, the dust ingestion pathway is evaluated in order to ultimately understand the risks posed by outdoor soils. Exposures and risks associated with the soil + dust ingestion pathway often "drive" the risk at a contaminated property. In some instances, the dust ingestion pathway poses the highest risk because, although the dust and soil ingestion rates are similar, the indoor dust concentrations are much higher than those found in soil. But what if the indoor dust is comprised primarily of non-soil components? For example, consider a home where little soil is tracked into the house (because of little to no exposed soil around the home) but the home contains a fireplace that is used frequently and perhaps a significant degree of cigarette smoking occurs in the house. The indoor dusts might contain a relatively high concentration of polycyclic aromatic hydrocarbons and/or dioxins that are completely unrelated to soil contamination. How does one estimate or otherwise account for the levels of soil in indoor dust, which are certain to be very site-specific?

> ***Response:*** *This Handbook defines "dust" as particles in building interiors that may include soil particles that have been tracked in from outdoors. The definition for "dust" has been amended to include "or blown" into a house. At this time, U.S. EPA is unaware of any studies that estimate or otherwise account for the levels of soil in indoor dust. This is a limitation of the methodology.*

Comment: The nature of the soil and dust exposures that occurred in Hogan et al (1998) should be discussed briefly. For example, were these settings where the

children were consistently in contact with exposed soil? Or did relatively little direct contact occur? And does this need to be considered when using the EFH soil ingestion factors in a risk assessment?

> ***Response:*** *More information has been added to the Hogan et al., (1998) summary to reflect the comment.*

Comment: As described in Davis and Mirick (2006), consumption of unwashed garden produce (from a backyard garden) is a potential source of soil ingestion. Although Davis and Mirick (2006) indicated that there was no association between vegetable/fruit consumption and soil ingestion rate, they also acknowledge that the study design would not have detected an increase in soil ingestion via this pathway (because any soil on unwashed fruits/vegetables would have been analyzed and recorded as a food source). So, my question is whether this is a potential pathway that warrants consideration and if so, are there any soil ingestion rates that should be recommended?

> ***Response:*** *A statement has been added to the Davis and Mirick (2006) summary indicating that due to the study design, consuming unwashed fruits or vegetables would not have contributed to an increase in estimated soil ingestion for these participants. Although eating unwashed fruits or vegetables was not associated with soil ingestion in either children or adults in this study, it is a behavior that could lead to soil ingestion. The recommended soil + dust ingestion value for adults (50 mg/day) is based on the Davis and Mirick (2006) study.*

Comment: Swallowing of inhaled soil particles is accounted for in the "key studies" used to derive the recommended ingestion rates. I believe the EFH should make it clear that this pathway does not need to be considered separately in exposure assessments.

> ***Response:*** *A statement has been added to the text to clarify that the inhalation and subsequent swallowing of soil particles is accounted for in the recommended values; therefore, this pathway does not need to be considered separately.*

Comment: A clear description of how the recommended soil ingestion values were extracted from the various studies and analyses is lacking.

> ***Response:*** *A new section has been added to the chapter (see Section 5.6) entitled "Derivation of Recommended Soil and Dust Ingestion Values," which includes a detailed description of how both the central tendency and upper percentile (see Section 5.6.1 for soil-pica and Section 5.6.2 for geophagy) recommendations were derived from the "key" studies. Also, sources have been added to Table 5-1 (see comment below) to indicate which "key" studies are associated with the recommended soil ingestion values.*

Comment: Pg. 5-3, par. 3—The nature of the recommendation for "soil only" for outdoor or indoor sources or both needs clarification. As written, it seems to include exposure to outdoor soil while indoors (i.e., indoor soil-derived dust). In actuality, it probably refers to indoor soil (e.g., potting soil). The question of ingestion of indoor soil-derived dust needs to be addressed. Is this implicitly included in the 30 mg/day recommendation?

Response: *The sentence has been rewritten for clarity as follows: "if an estimate is needed for soil only, from soil derived from outdoor or indoor sources, or both outdoor and indoor sources, the recommendation is 30 mg/day." The issue of indoor soil-derived dust is addressed in the definition of "Indoor Settled Dust": Text was added to state that the definition includes soil particles that have been tracked or blown into the indoor environment from outdoors as well as organic matter. The recommended value of 30 mg/day for dust in Table 5-1 does include indoor settled dust, as indicated in footnote "b."*

Comment: Pg. 5-11, 5.3.2.5—This needs more discussion as the values are largely unclear.

Response: *Text was added for clarification.*

Comment: Pg. 5-13, par. 4—What does it mean that "exposures… had been collected?"

Response: *Replaced "collected" with "studied" to clarify.*

Comment: Par. 7—While the relatively close matches are consistent with the 50 mg/day estimate, the accuracy of the estimate depends on the slope of the relationship between soil Pb and blood Pb. If the slope is very shallow, then there may be a large uncertainty in the estimate.

Response: *The sentence was revised to reflect comment.*

Comment: Pg. 5-20, par. 5—More explanation is required to explain how the estimate of 31.3 percent of the weight of indoor dust comes from outdoor soil is derived from the parameters described in this paragraph. Also, the last two sentences in this paragraph are confusing and difficult to follow.

Response: *U.S. EPA agrees that much of the latter part of the summary is not clear, and as it does not substantially add to the main point, U.S. EPA has deleted it.*

Comment: Pg. 5-24, par. 3—This explanation is not clear.

Response: *The text refers to negative values resulting from the mass balance approach. Clarification was added to state that negative values*

result when the tracer amount in food and medicine is greater than that in urine/fecal matter.

Comment: Pg. 5-25, par. 2—"The second source of potential bias…" This explanation appears to fall under the general rubric of multiple compensating errors. It might be easier to describe it in those terms.

Response: *The existing discussion appears to be adequate, so no change was made.*

Comment: Pg. 5-26, par. 6—"…or outdoor soil tracked inside buildings by human or animal building occupants." Here and elsewhere in this chapter, soil-derived indoor dust is associated with tracking of soil into dwelling. There is no reason to discount the transport of soil derived particulates into dwellings as ambient airborne particulates.

Response: *The phrase "soil derived particulates transported into dwellings as ambient airborne particulates," was added to the paragraph. Pg. 5-27, par. 3—"The 64 children in the Calabrese et al. (1997a) study apparently were a stratified random sample…" This statement is not meaningful unless we are told on what basis the stratification was done.*

Response: *Text was added to clarify.*

Comment: Also, for section 5.4.4 as a whole a summary synthesis section is needed to evaluate the quality and applicability of the overall database.

Response: *Two summary paragraphs were added to the section to describe geographical location of the studies, climate, sex and age of the subjects, race, and socioeconomic status.*

Comment: Section 5.4x is only concerned with the limitations of the database. Given that values are derived and suggested for use a summary statement that is either overall positive or negative is warranted.

Response: *The confidence rating table is intended to serve as the overall "positive or negative" statement about the data.*

2.27. Chapter 6: Inhalation

Comment: Several reviewers said that it is important to include physiological data such as tidal volume in Chapter 6 (Inhalation Rates).

Response: *The physiology of the respiratory system is covered briefly in Chapter 6, but a detailed discussion or inclusion of physiological data such as tidal volume is beyond the scope of this Handbook. Some additional information has been added to the Introduction, as well as suggested references for additional reading.*

Comment: The increased appreciation of the differential sensitivity of children has led USEPA to use different age categories useful for estimating risk of appropriate age ranges of children. As the Handbook points out children have greater exposure than adults on a per kg body weight basis for inhalation. In order to properly assess the dose (mg/kg BW-day) for various age group the unit risk factor needs to be expressed as an inhalation cancer potency factor in IRIS. The Office of Environmental Health Hazard Assessment (OEHHA), California Environmental Protection Agency used a simple assumption of 20 m3 per day and a 70 kg body weight in order to convert unit risk factors to an inhalation cancer potency factor. A more sophisticated approach might be possible.

> ***Response:*** *The approach used by Cal EPA is different from the approach set forth in U.S. EPA guidance documents. In general, for inhalation exposures, U.S. EPA recommends the use of the concentration of the chemical in air as the exposure metric. As described in the introduction to the chapter, inhalation rates may be used in the estimation of the Human Equivalent Concentration (HEC). U.S. EPA (2008) Risk Assessment Guidance for Superfund: Volume I: Human Health Evaluation Manual (Part F, Supplemental Guidance for Inhalation Risk Assessment). Washington, DC: Office of Superfund Remediation and Technology Innovation. Peer-Review Draft. Prepared for U.S. EPA, Contract No. 68−W−01−05 discusses this issue and rationale for U.S. EPA's approach.*

Comment: The recommended breathing rates in Table 6.1 also need to be expressed in L/kg-BW-day. The information is available for the studies you recommend.

> ***Response:*** *Inhalation rates for these studies expressed on a body weight basis are provided later in the chapter. The recommended inhalation rates shown in Tables 6-1 and 6-2 at the beginning of the chapter are intended to provide the broadest summary of inhalation rates for users of the Handbook.*

Comment: One of the general weaknesses of the doubly labeled water studies compiled by Brochu et al. 2006 is that subjects are not representative of the general population. However, it seems intuitively obvious that the range of inter-individual variability is lower in the 0−2 age range and therefore there should be less concern that a particular group would be nonrepresentative, particularly in light of fairly large N of 76. The study also offers the rare advantage of repeated measures on the same individuals. This means that 95th percentile is more likely to represent interindividual variability. The method of Layton 1993 used by Arcus-Arth and Blaisdell 2007 has a greater likelihood of an overestimated 95^{th} percentile because the two days of intake data for each individual do not capture typical intake. In addition, caloric intake is not tightly coupled to breathing rate on any given day, only on the average.

Response: *U.S. EPA has used both Arcus-Arth (2007) and the Brochu et al., (2006) in the derivation of recommendations. U.S. EPA considers that both methodologies have advantages and limitations. Therefore, U.S. EPA deemed it appropriate to include both as the basis for recommendations. U.S. EPA's approach was to utilize as much data as possible so that the recommended inhalation rates were based on more individuals. The Arcus-Arth and Blaisdell (2007) study was selected as a "key" study because it was a national survey with a fairly large sample size.*

Comment: Table 6-1. Since means increased up to 16.3 m^3/day up to 21 years, it does not appear biologically credible that the mean for the 21 to <31 years group would drop to 15.7 m^3/day and then the mean for the 31 to <41 years group would again increase. Statistical smoothing techniques should be employed to provide recommendations that are biologically credible across age groups. Similarly, data smoothing should be employed for ages 21 to <61 for the 95th percentiles.

Response: *U.S. EPA statisticians reviewed the data and did not recommend data smoothing in this case. Data smoothing is used to reduce the effect of random variation. The variations between the 16 to 21 year and 21 to 31 year age group do not seem meaningful enough to question biological credibility. The mean and 95th percentile for the 21 to <31 year age group are not inconsistent with the other adult age groups, i.e., 31 to <61. If anything, the 16 to <21 year age group seems to be a bit different with regard to the mean and 95th percentile.*

Comment: As in the case of Chapter 3, Chapter 6 provides a rather thorough overview of studies on inhalation rates; again, the overall usability of the information provided could be enhanced through the addition of some graphical representations of the information contained in the tables.

Response: *For the purposes of this Handbook, it is believed that individuals accessing the Handbook are seeking specific numeric values, shown in tabular form throughout. The tabular form was retained.*

Comment: 6.2 Paragraph 2 and Table 6.1—why are averages of the inhalation rate data from the key studies used rather than showing the range and variability? Why were males and females combined?

Response: *Table 6-1 is the summary table for the chapter, showing the recommended inhalation rates. Additional tables later in the chapter provide inhalation rate distributions and separate male/female inhalation rates.*

Comment: 6.3.5—Averaging doesn't appear to use weighted averages or statistical methods of calculating combined distributions from which an average and percentiles could be derived. The differences in results from these studies are significant enough to question the notion of averaging per se.

Response: *In order to provide the recommended long-term inhalation rates shown in Table 6-1**,** data from the four "key" studies were combined. Mean and 95th percentile inhalation rate values for the four "key" studies are shown in Tables 6-20 and 6-21, respectively. The data from each study were averaged by sex and grouped according to the age groups selected for use in this Handbook, when possible. This information is described in the text of Chapter 6 (see Section 6.3.5, Key Studies Combined). The means for the combined "key" studies were not weighted because of unknown sample sizes in certain studies.*

Comment: 6.4: 6.4.1—ICRP, 1981—this approach is far better than those mentioned above. The sources of the inhalation raw data, supposedly being questioned herein as to their accuracy and validity and producing uncertainty in the minds of the authors of this chapter, were evaluated by the ICRP, and the authors of this chapter could have obtained that information from both the ICRP and the original data sources to remove such uncertainty. Some of the advantages of these ICRP estimates are: they account fairly well for time and activity and were gender specific.

Response: *ICRP compiled reference values from the literature. The data are limited in terms of the age groups provided and that assumptions were made with regard to activity patterns and their level of intensity during the day. These limitations were added to the discussion. Also added the age of the study as a limitation. Also, added a statement regarding the advantages of the study, as described above.*

Comment: 6.4.2—EPA, 1985—The data and results from this study could have been researched further to reduce the uncertainty in the authors of this chapter, as its approach is better than that of the studies presented in section 6.3.

Response: *This study was not considered a "key" study primarily due to its age (1985); many of the values used in the data compilation within the study were from early studies. These limitations are described in the chapter. The U.S. EPA does not feel that investing in the analysis of the U.S. EPA (1985) data would provide any added benefits.*

Comment: 6.4.3—6.4.7 & 6.4.10—Studies from the Hackney USC RLA lab**—**These are excellent studies with excellent physiological measurements from a group and lab that has had very high respect from the pulmonary and physiology professional community. Their methods were accurate and precise, and are considered valid and reliable. More attention should have been paid to the results of their studies for short-term inhalation rates even though their limited numbers of subjects are not necessarily representative of the general USA population. (I wonder if there aren't some similar data from the EPA—RTP HERL chamber studies and those from other similarly highly qualified applied physiologists referenced in the EPA AQGs.) It might be worth considering a "meta-analysis"

with appropriate sensitivity analyses, of such data sets and extension of short-term estimates to long-term estimates.

> ***Response:*** *These studies were not considered "key" studies for a variety of reasons—e.g., age of study, nonrepresentativeness of sample population, etc. Limitations of each study are described in the chapter. To the extent of U.S. EPA/NCEA's knowledge, chamber studies are used to research source, characterization, prevention, and control of indoor air pollution and not to estimate inhalation rates. Conducting a meta analysis will require obtaining raw data from studies that are over 20 years old. Availability of these data is unknown. Given the Agency's limited resources, the U.S. EPA feels that such an analysis would not result in any added benefit.*

Comment: 6.4.8—Adams, 1993—This study appears to have the potential to contribute a lot to the understanding and data base for short-term inhalation. This reviewer is not as well acquainted with this study as with those mentioned in the last paragraph and would have to review this gray literature report. However, if of high quality, then the comments would be similar to those made in the last paragraph.

> ***Response:*** *This study was not considered a "key" study primarily due to the study population not being representative of the general U.S. population. Additional limitations are described in the chapter. Briefly, Adams (1993) provided data for 160 adults and children. Age groups in this study were limited. In addition, activities were not classified in terms of the intensity level, which makes it hard to evaluate against data from other studies. Data for "running" scenarios are comparable to high intensity ventilation rates from the U.S. EPA (2009) analysis. The U.S. EPA does not feel that investing in the analysis of these data would provide any added benefits.*

Comment: 6.4.11—Rusconi et al., 1994—These data appear to be obtained with adequate attention to methods and QC and could be utilized in broader physiological analyses of inhalation rates. Comparisons to data in pediatric pulmonary physiology literature would have to be performed as well to compare these data obtained in Italians to that obtained in USA and other countries' infants and children. Spirometric data obtained in adults would indicate some differences between USA and Italian subjects.

> ***Response:*** *The data from Rusconi et al., (1994) were reviewed. Comparisons will be difficult because data are reported in breaths/minute for awake and asleep subjects. No activity pattern data are provided for the "awake" subjects in order to compare with the appropriate activity level. For these reasons, these data were considered "relevant" and were not used in making recommendations.*

Comment: 6.4.12—Price et al., 2003—These data obtained from modeling, not meant for the specific purpose of determining exposure or intake dose, need to be

validated against actual physiological data prior to being used for purposes other than that stipulated by Price et al.

> ***Response:*** *Text was added discussing the limitations of the Price et al., (2003) study.*

Comment: A detailed analysis of an earlier draft version of EPA 2009 was previously submitted during the review of the Child Specific Exposure Factors Handbook, and can be resubmitted. In this final EPA 2009 report, no changes were made in the analysis approach or the result tables, but an annex has been added that addresses comments received on the earlier draft report. The annex indicates that inhalation rates obtained with the study methodology are generally similar to those obtained with other methods. However, the annex analysis was done for individuals of normal body weight (EPA 2009, p. D-7: Figure D-2 compares ... for several age groupings of normal-weight individuals... Figure D-3 compares... for several age groupings of normal-weight individuals... Figure D-4 compares... for several age groupings of normal-weight individuals; and the same for Figures D-5 through D-7). The key factor leading to upward bias in the study estimates is that activity data from the Consolidated Human Activity Database were linked to gender and age but without the ability to link to body weight. Therefore, high physical activity levels can be associated with individuals of high body weight, leading to unrealistically high inhalation rates. This can be seen if you calculate out the breathing rates that would be need to be maintained to meet reach upper percentile inhalation rate estimates based upon typical lung volumes. These rates not only raise the upper distribution, but will increase the mean as well. As EPA's annex analysis only included normal weight individuals, this point has not been adequately addressed. Indeed, EPA 2009 acknowledges that upper percentile values are "more uncertain.... and are unlikely to represent an average individual."

> ***Response:*** *Additional language was included in the text to reflect the limitation noted by the reviewer. Comparisons were made using normal−weight individuals. Results may be different for overweight individuals. It should be noted that further examination of the data from Brochu et al. (2006a) for normal weight and overweight individuals revealed that differences in the mean inhalation rates between the normal weight and overweight individuals when normalized by body weight are not significant based on overlapping confidence intervals. Similar comparisons could not be done at the 95th percentile levels because of the lack of information on confidence intervals at the 95th percentile. The U.S. EPA believes that additional analysis would not change the recommendations significantly because results from U.S. EPA (2009) are averaged together with the results from Brochu et al. (2006) and Arcus-Arth and Blaisdell (2007). Although the values for children <11 years of age are slightly higher in U.S. EPA (2009) as compared to Brochu et al. (2006), they are fairly similar to values obtained by Arcus-Arth and Blaisdell (2007).*

Comment: It is unclear why Layton (1993), which serves as the basis for recommendations in the current EFH, is no longer considered. As indicated above, utilizing information across study methodologies is appropriate given the strengths and limitations of each one. The key references cited do not include any more recent studies for adults that utilize the approach taken by Layton (estimates based upon adult food consumption data). It is unclear why short-term recommendations are based upon a single study. Again, these should be averaged across studies given the strengths and limitations of each approach. In particular, short-term recommendations should not be based upon the EPA 2009 study for the reasons provided above. As indicated above, recommendations for children should not be based upon EPA 2009.

Response: *The U.S. EPA disagrees with the reviewer. Arcus-Arth and Blaisdell (2007), which is one of the studies used to derive recommendations, uses the same methodology as Layton (1993). The Layton (1993) study has been replaced with Arcus-Arth and Blaisdell (2007) because it updates the inhalation rates by using more recent food consumption data than the data used by Layton (1993). The U.S. EPA (2009) study was used as the only source for recommendations for the short-term inhalation rates because it provides the data for the age groups of interest, and it is representative of the U.S. population. The limitations with the U.S. EPA (2009) study do not apply to short-term inhalation rates.*

2.28. Chapter 7: Dermal Exposure Factors

Comment: In general, one point to make clearer within the Handbook is that linkages between factors should be considered in their application. For example, skin surface area estimate have increased by about 10% from those in the current EFH, but these are calculated based upon body weight, which have increased by about 10%. So the updated skin surface area estimates are dependent upon and should be utilized with the updated body weight data.

Response: *A statement was added to reflect comment.*

Comment: For Chapter 7, selection of the US EPA study on body surface area as the key study is appropriate. It provides a synthesis of many methods applied to a representative sample of the US population. Again it is not clear however, why certain studies were key and others relevant for Section 7.4. I could justify it, because the key studies were based on actual activities while the others were soil contact trials. However, this should be more explicit to the reader.

Response: *Some additional language was added to indicate why the "key" studies were chosen for the recommended values.*

Comment: There is relatively little discussion of soil properties and how they might influence the degree to which soil adheres to skin. Perhaps this is beyond the scope of the EFH. If not, then I think it would be helpful to discuss soil

particle size and organic content to the extent that it relates (or doesn't) to dermal adherence rates and how these factors should be considered (quantitatively) by the risk assessor.

> ***Response:*** *When particle size or organic content was evaluated in a study, it was also presented in this chapter.*

Comment: While it may be beyond the scope of the EFH, there is no discussion of what I will refer to as the "monolayer" question. Common sense dictates that more "mud" is likely to adhere to skin than "dry soil" (per unit area of skin), and this is indeed reflected in the results presented in Chapter 7. The question is how much of this solid matrix (in terms of thickness) is actually capable of delivering contaminants to the skin surface? For example, is it known whether any or all of the published adherence rates indicate total coverage of the skin? Are some of the higher adherence factors actually measuring soil that is in contact with an underlying film of more soil instead of skin? If so, would one expect the uppermost layer of soil particles to actually deliver contaminants to the skin surface?

> ***Response:*** *This is beyond the scope of the Handbook and is not addressed here.*

Comment: Similar to a comment I have on indoor dust ingestion rates: assuming the primary purpose of assessing indoor dust exposure is to determine the risks posed by contaminated soils outdoors, isn't it critical to understand how much of the indoor dust is actually comprised of soil? And if so, should this be taken into account (via a modification factor, perhaps) when using the indoor dust adherence rates recommended in this chapter?

> ***Response:*** *This is a policy consideration that would be taken into account by the assessor, but is not considered to be a "relevant exposure" factor for this chapter.*

Comment: On page 7-2, first full paragraph, it is noted that "soil can get under clothing" and that assessors should "consider this possibility for the scenario of concern and select skin areas that are judged appropriate". However, it is not clear whether any of the adherence rates presented in Chapter 7 reflect soil adherence measured on unexposed (clothed) skin. Presumably, less soil would adhere to clothed skin (?). It is also unclear whether the effects of "occlusion" (possibly increased dermal penetration by contaminants) should be considered for clothed skin. Some clarification would be helpful.

> ***Response:*** *The data are for exposed skin areas. Assessors are urged to select adherence data that matches the exposure scenario of concern, in terms of exposed body parts and activities, as closely as possible. The effects of increased dermal penetration are not addressed because chemical-specific absorption is beyond the scope of this chapter.*

Comment: On page 7-2, second full paragraph, it is noted that "insufficient data were available to develop distributions of probability functions for these values". I'm not sure I agree, and it is not clear whether any actual decision-making criteria have been applied to reach this conclusion. At the least, it would seem that there is more than sufficient data to develop distributions for age-specific skin surface areas. As noted on page 7-12, distributions have been published by Murray and Burmaster (1992) and Phillips et al (1993).

> ***Response:*** *The statement about insufficient data refers to soil adherence data, which is based on a small number of activity-specific observations for the available age groups. A paper by Finley et al. (1994) on soil−to−skin probability density functions (not activity specific) has been added as a "relevant" study to this chapter. The distributional data provided by Murray and Burmaster, and Phillips et al. are for skin surface area and not soil adherence.*

Comment: The first paragraph of Chapter 7 indicates that "this chapter focuses on adherence of solids to skin". Yet in a few places in this chapter reference is made to "liquids" in contact with the skin, such as the first full paragraph on page 7-2 ("Liquids may soak through clothing an contact covered areas of skin"). It is therefore unclear whether this chapter is intended to provide guidance on dermal contact with liquids or whether the critical information for doing so is presented elsewhere in the EFH.

> ***Response:*** *Additional information has been added to the chapter that addresses liquids.*

Comment: Still troubled by the fact that this is an Exposure Factor Handbook and yet the document still uses the word exposure and dose so interchangeably. Second paragraph of page 7-1, column 1 says…"These are only two of several parameters that influence dermal absorption." While this is technically true, these are only two factors that influence dermal exposure also. The book needs to first focus on exposure, then build up to express what is needed for dose (which is not covered in this book). What affects dose for dermal exposure is the exposure profile on the skin (time on skin and amount on skin), along with the skin and chemical properties (that influence that uptake rate).

> ***Response:*** *The terminology has been corrected to reflect that this chapter addresses dermal exposure and that factors related to absorbed dose are not included.*

Comment: Page 7-3, Only paragraph; It is mostly right to say that skin adherence values do not consider the influence of skin moisture on adherence. To some extent, we might see a similarity with results for soil moisture. Greater adherence to some maximum level might be expected. Also, humidity in the air (a type of moisture) can also affect adherence.

Response: *Information on factors (e.g., moisture) that may affect adherence has been added to this chapter.*

Comment: This chapter focuses on two exposure factors needed for the calculation of dermal exposure. Surface area of bodyparts for populations and soil loading. The dermal exposure route is a complex route of many mechanisms of exposure or loading of a chemical on the skin surface. There is soil loading, residue transfer, immersion and deposition. I think on Page 7-1 would could express dermal exposure in this manner more explicitly.

Response: *Information on exposure to liquids (film thickness approach) and residue transfer) has been added to this chapter.*

Comment: Surface area and soil loading are factors that are not chemical specific, as the EFH clearly says that it does not provide chemical-specific factors. Surface area exposure during contact with objects or surfaces is another non-chemical specific exposure factor needed for dermal exposure assessment and we should try and find some data for that factor.

Response: *Data from Au Yeung et al. (2008) on the fraction of the hand that comes into contact with objects has been added to this chapter.*

Comment: Chemical adherence to the skin is an important factor that should be given in the EFH in the future. Currently it is collected at a chemical specific level. We need to find a way to express this factor for a class of compounds or adherence specific scenario.

Response: *Information on residue transfer has been added to this chapter.*

Comment: Many models use data on the duration and frequency of contact with objects and surfaces in the environment for children, typically gathered through videotaping and video-translation methodologies. This type of activity patterns is very similar to the mouthing exposure factors presented in Chapter 4.

Response: *Information on the frequency of contact with surfaces or objects has been added; readers are referred to activity-specific information in Chapters 16 and 17.*

Comment: To some extent it is understandable why studies that show soil loading by activity have been chosen as key studies. For an easy, quick calculation, this simplifies into a one loading on the skin for the day, based on an exposure scenario. However, the field has advanced where we need for exposure models, data on a loading per contact event. Controlled studies that look at the data in that manner are quite useful. What gets defined as key and relevant may be subjective, but seems here to be divided along the lines of set activities as opposed micro-loadings or event loadings. But in fact the relevant studies are more controlled studies of adherence, and in terms of confidence ratings might score higher. EPA tends to call these ‘relevant’ dermal loading studies of “short

activity duration" but, again these are useful for models that look at individual contact events.

> ***Response:*** *Information has been added to Section 7.4 to address this. Why the activity-specific studies were chosen as the "key" studies for this chapter is explained.*

Comment: Use of data from Gehan and George (1970) and Boyd (1935) seems dated, and EPA should look to conducting newer measurements, given changes in US population average weights for all ages. Or maybe there can be an application of a factor increase on weight into surface calculations, based on newer CDC data on population weight changes. In light of that comment, Table 7-11 combines the U.S. EPA (1985) measurements (based on the older data) with the NHANES 2005−2006 study. How well did the weights and heights compare for the population?

> ***Response:*** *Although the direct measurement data are old, the new body weight and height data are used with the algorithms based on direct measurements to calculate surface areas.*

Comment: Table 7-3; For currency, it says that the age of data is not expected to affect its utility. If weight changes in the population are dramatic, surface area predictions based on weight may change.

> ***Response:*** *Clarification has been added to reflect comment.*

Comment: Tables 7-4, 7-5; It is to be noted that the Holmes, Kissel, and Shoaf studies come from the same lab. It has its advantages and disadvantages. This creates consistency in methodology, but not necessarily objectivity. This needs to be expressed in the confidence ratings. Also, I think EPA should contact these authors to find out more on quality control and include in document and even improve confidence rating.

> ***Response:*** *A statement has been added to the confidence in recommendations table reflecting this limitation.*

Comment: Chapter 7 specifically limits its focus on the two areas of "measurements of body surface areas" and of "dermal adherence of solids to the skin." References are given for more comprehensive guidance relevant to dermal exposure assessments: these references are specifically USEPA reports from the early 1990s. In this reviewer's opinion, some of the additional exposure factors (other than the chemical-specific aspects, that are beyond the scope of the EFH), that are already mentioned on page 7-1 (variation of the thickness of the stratum corneum over different parts of the human body, variation of this thickness with age/gender, impact of exogenous and endogenous conditions that may effect absorption rates, etc) should, even briefly, addressed in Chapter 7. Two reviewers suggested adding an explanation about the complexity of dermal exposure, noting

that a diagram may help. It might also be useful to include references for where the user can get more data.

> ***Response:*** *The following additions have been made to the chapter. Users are referred to: Guidelines for Exposure Assessment (U.S. EPA, 1992a), Dermal Exposure Assessment: Principles and Applications (U.S. EPA, 1992b), and Dermal Exposures Assessment: A Summary of U.S. EPA Approaches (U.S. EPA, 2007) for information on various methods used to estimate dermal exposure. They are also referred to: Risk Assessment Guidance for Superfund (RAGS) Part E (U.S. EPA, 2004), Standard Operating Procedures for Residential Pesticide Exposure Assessment, draft (U.S. EPA, 2009), and Methods for Assessing Exposure to Chemical Substances: Volume 7, Methods for Assessing Consumer Exposure to Chemical Substances (U.S. EPA, 1987) for additional scenario-specific information on dermal exposure assessment.*

Comment: One reviewer commented that more explanation is needed for why certain studies were classified as key. She also noted that determining which studies are key and which are relevant is subjective, depending on what model approach is used to estimate exposure. The macro activity approach seems to be the main approach in the chapter. There is no explanation of micro activity data and how they can be used in a model to calculate dermal exposure to chemicals in soils.

> ***Response:*** *The "key" studies are based on the macro activity approach as these are probably the most useful for exposure assessments based on specific activities. However, "relevant" data have been included that would allow exposure assessments to be conducted at the micro level. A statement has been added to Section 7.4 to clarify.*

2.29. Chapter 8: Body Weight Studies

Comment: One reviewer said that EPA should be commended for including the latest NHANES body-weight data in the EFH. However, the reference for the body mass index is older and should be replaced with the newer data. She recommended that EPA be more explicit about the purpose for presenting the older body-weight information.

> ***Response:*** *Included in Chapter 1 of the Handbook (Introduction) is a discussion of the purpose of including older data. Briefly, the purpose of including old data is to add perspective and provide information on trends. The analysis of more up-to-date BMI data was not located in the literature. The latest information on BMI currently in the Handbook comes from NHANES (2002).*

Comment: Several reviewers commented on the fact that the body weights are linked with several other exposure factors. They specifically mentioned that

dietary habits (fish vs. high calorie foods) and activity factors are related to body weight. Many felt that an interactive diagram (with active links) would be useful to show the interconnectedness of each chapter. It could be broken into routes of exposure and detail what is covered, what is not covered, and where to find the information in each chapter. Figure 1.2 in the 1997 EFH would be a good place to start.

Response: *U.S. EPA agrees. A new flowchart or map to the Handbook was added to Chapter 1.*

Comment: The increase in obesity is quite marked, and using older studies, might not be appropriate. Two reviewers debated whether the rise in obesity is nutritional (diet and habit) or hormonal. It is important to provide data specifically for pregnant women, not just women of child-bearing age, as such parameters are critical for addressing fetal exposures. In theory, heavier people are more protected from exposure. The one exception noted is obese people who may have higher inhalation rates and whose overall health is compromised.

Comment: Brainard and Burmaster (1992) and Burmaster and Crouch (1997) provided the statistics for the bivariate and lognormal distributions, respectively, for height and body weights for application in Monte Carlo simulation. These statistics were, however, derived based on very old body weight data—NHANES II (1967−80). New analysis with the NHANES 99−02 and 03−06 data should be conducted to update these statistics for use in Monte Carlo Simulation.

Response: *The "key" body weight study and the recommended values for body weight are based on analysis of recent NHANES 1999−2006 data. Also, a new "relevant" section has been added to address body weight for pregnant women using NHANES 1999−2006 data and another study found in the literature. The purpose of this chapter is to describe published studies on body weight in the general U.S. Discussions of obesity and related nutrition and physiological issues are outside the scope of the Handbook.*

Comment: Section 8.3.1. 4th paragraph. This paragraph on calculating percentiles would be much clearer if the weights are identified as sample weights as distinguished from body weights.

Response: *This clarification has been added as requested.*

Comment: Table 8-1. A mean body weight of 80 kg should not be used for all adults. Table 8-3 lists a mean value of 68.5 kg for adults over 80 years, a value 14% less than 80 kg. It is suggested that the recommended mean body weight for adults over 80 years should be listed as 68.5 kg.

Response: *The 80 kg listed in Table 8-1 is the mean body weight for all adults (men and women) 21 years and older, while the mean of 68.5 kg is for older people of 80 years and more.*

Comment: Odgen et al 2004 data are summarized in the revised EFH. The data in this analysis was based on NHANES I, II, II and 99−02. There is a later publication by Odgen et al (2008) reporting BMI for US children and adolescent using the NHANES 03−06 data. (JAMA (299):2401−2405)

Response: *The more recent Ogden et al. papers report new data on the prevalence of obesity among children and adolescents. Data are not provided for body weight or BMI.*

2.30. Chapter 9: Intake of Fruits and Vegetables; Chapter 11: Intake of Meats, Dairy and Fats; and Chapter 12: Intake of Grain Products

Comment: Most reviewers agreed that it was important to incorporate the NHANES data into the EFH. As a point of clarification, David Miller (EPA) explained that the NHANES data would be incorporated in the exact same format as the data currently included. A reviewer noted that a reference to the FDA's Total Diet Study (TDS) should also be added to the EFH.

Response: *U.S. EPA agrees with the comment. The Continuing Survey of Food Intakes by Individuals (CFSII) data was collected in 1994−1998. To update the chapter, data and tables have been added from an analysis conducted by the U.S. EPA Office of Pesticide Programs of 2003−2006 National Health and Nutrition Examination Survey (NHANES) data. The recommendations tables are now based upon that NHANES data with the exception of the recommendations on fat intake, which are based on CSFII. Although CFSII is not as current as the NHANES and is no longer the basis for the chapter's recommendations, it is still included because it contains regional, urban, and seasonal breakouts not found in NHANES. The FDA's Total Diet Study is sometimes called the market basket study. It is used to determine levels of various contaminants and nutrients in foods. The TDS uses data from USDA food consumption surveys including the 1987−88 Nationwide Food Consumption Survey (NFCS) and CSFII 94−96, 98 surveys. Referring to the TDS will not add any additional information to the chapter because both the NFCS and CSFII are already included in the chapter.*

Comment: One reviewer commented that the introductory text for Chapters 9, 11, and 12 is redundant. She suggested introducing the exposure metric and database in one area and then discussing the different factors. Another reviewer agreed that it would be useful to reduce the repetitiveness.

Response: *Although there is some repetitiveness among these three chapters, inclusion of similar introductory material is useful for consistency with other chapters in the Handbook. Including introductory material in these chapters allows the user to review the information they are most interested in without having to download other chapters.*

Comment: One reviewer suggested the following ways to incorporate the NHANES data into the EFH on a more regular basis:

- Release a newer version of the EFH more frequently.
- Break the EFH into two parts—a section of factors that are updated on a regular basis (e.g., dietary factors) and a section of factors that are not updated regularly (e.g., dermal factors). Another reviewer supported this approach.
- A Web-based database may help with more frequent updates. Two reviewers supported this approach, especially because a great deal of data are available.

Response: *These are good suggestions, which U.S. EPA will consider for future revisions to the Handbook.*

Comment: One reviewer wondered whether the updates would include fish intake. It might be useful to include the commercial sources of fish consumption in with the rest of the intake rates in Chapters 9, 11, and 12.

Response: *Fish and Shellfish shall remain a separate chapter for now, but U.S. EPA will consider the merits of restructuring the chapters in future revisions.*

Comment: One reviewer said that there could be better partitioning of the factors— maybe a chapter on "common" intakes and then separate chapters for sport fish and homegrown fruits and vegetables. These two reviewers talked about the benefit of conducting an exposure assessment on a probable composite diet, rather than combining all the 95^{th} percentiles. Another reviewer pointed out that the NHANES data are appropriate for intake of commercial fish; however, the recreational intakes are going to be highly variable by location and ethnic group. Another reviewer commented that NHANES is a national survey, and local or specific intakes would have to be compiled separately. One reviewer said that fish intake should be kept in a separate chapter because NHANES is only a small portion of all the fish data. One reviewer said a road map would help direct the user.

Response: *The fish intake chapter has been kept as a separate chapter. A road map is included in Chapter 1. Information on a probably composite diet is not available. However, Chapter 14 provides "relevant" information on the composition of the diet.*

Comment: One reviewer said she that she would like to know what has changed in these chapters in particular. For example, in terms of obesity, it is important in exposure modeling to know that serving sizes have increased. One reviewer suggested including a table at the beginning of each chapter to convey what has changed. Another reviewer suggested using an asterisk in the tables to denote a change. However, two reviewers said they are looking for more than just the

values; they would like a narrative that describes why some factors have changed. One reviewer said it might be worthwhile to include a simple trend analysis (e.g., a bar chart). One reviewer cautioned that some differences may be methodological and have nothing to do with trends.

> ***Response:*** *Adding a summary of revisions to each chapter's introduction has some distinct advantages, but would be difficult to implement for this revision. A brief discussion of the main updates to each chapter is included in Chapter 1. U.S. EPA will consider such a summary in each individual chapter for future revisions.*

Comment: One reviewer said that nutritionists look at the data differently than exposure assessors. He said that there should be an upfront discussion that talks about serving size and serving recommendations.

> ***Response:*** *This is outside of the scope of the current revisions. U.S. EPA will consider adding such a summary to future revisions.*

Comment: One reviewer noted the importance of being able to have access to regional data. Three reviewers discussed the logistics of disaggregating the NHANES data into regions. Mahaffey (2009) disaggregated the data into regional databases.

> ***Response:*** *In addition to the "key" study (i.e., NHANES), the Handbook includes the CSFII data, which offers some regional information and a number of additional studies that address at-risk populations, such as particular ethnic groups, or studies like Mahaffey et al., (2009) that look at regional differences.*

Comment: Several reviewers discussed the fact that different survey methods affect the results. They pointed to the following questions:

- Was the survey conducted on consecutive or nonconsecutive days?
- In what season was the survey was conducted (specifically related to homegrown produce)?
- Was the survey conducted on weekdays or weekends?

> ***Response:*** *These are important differences. It is our intention that the summary of each study describes such differences in survey methods.*

Comment: In Table 9-2, page 9-4, the Rating for "Variability and Uncertainty" GAF should be "low- for individual fruits and vegetables" and "High- for total fruits and vegetables". This is due to the fact that full distributions were provided for total fruits and vegetables, but it appears that only the means were given for individual fruits and vegetables. This doesn't change the "Overall rating" however, of the recommendation based on the EPA analysis of the CSFII 1994−96, 1998.

Response: *The text was modified as requested.*

Comment: It is not clear why the age-groups in Table 9-7 through 9-11, based on US EPA's analyses of the 1994−96 CSFII, differ from the age groups of Tables 9-3 to 9-6 (based on US EPA's analyses of the 1994−96, 1998 CSFII). An explanation for why the age groups differ should be provided in Section 9.3.1.1.

Comment: In the future, I suggest that the total fruit and vegetable intake (Chapter 9) be revised to conform to the EPA's life-stages and assess the variability by the age distribution of the population.

Comment: In the future, I suggest that the total grain intake (Chapter 12) be revised to conform to the EPA's life-stages and assess the variability by the age distribution of the population.

Response: *The age distribution presented was as provided by the source document. In the future, U.S. EPA intends to provide the underlying data as they become available from NHANES so that the user can do their own analysis with the age groups of interest.*

Comment: NCEA needs to contact each of the federal agencies who have supported the development of the data bases utilized and learn what they have under development, if any. Another source of data on children may well be the National Children's Study. EPA is already supporting this activity. So as it gets underway, the data being collected should be assessed for its potential utility for exposure factors.

Response: *The reviewer is correct. U.S. EPA expects that the National Children's Study will be an excellent source of exposure data on the intake of meat, fruit, grains, and fish, as well as other parameters. By the time the Handbook is revised again, such data should become available.*

Comment: Section 11.3.2 mentions data from the 1987−88 in Table 11-8, yet this survey is not mentioned in the title or elsewhere. If memory serves, I believe the results from this survey were criticized in a GAO report because a nonresponse bias test was not performed. A minor point, these data are pretty old anyway.

Response: *These data are considered "relevant" and not "key", in part, for the reasons noted by the reviewer.*

Comment: If you are planning to analyze the more recent NHANES data as mentioned in Chapter 9, and resources permit, perhaps it would be good to obtain the meats, dairy products and fats.

Response: *U.S. EPA/OPP has conducted an extensive analysis of the NHANES data, and U.S. EPA has added several tables based upon these data.*

Comment: I would suggest reviewing the literature on the percentage of total consumption that is home raised for site-specific risk assessment (e.g., airborne emissions from stationary sources.)

Response: *The only data that U.S. EPA is aware of are the data included currently in Chapter 13 on home produced foods. An additional analysis based on the same data set provides "per capita" intake rates.*

Comment: I am not aware of other published data concerning food consumption. I believe that the "What We Eat in America" (WWEIA) data set is currently the most complete and representative data set available to assess a variety of food groups, and water, consumption by the US population. Will the Office of Pesticide Program's analysis be done on the NHANES 2003−2004 data set, or earlier, or later?

Response: *U.S. EPA has added several new tables to the chapter based on the U.S. EPA OPP analysis of the 2003−2006 NHANES data in addition to the CSFII data. The CFSII data are not as current, but contain regional, urban, and seasonal breakouts not found in NHANES.*

Comment: In Section 9.3.1.1, page 9-6, it is not clear how the individual fruits and vegetables were selected for assessing their intake. A description or the criteria used for assessing intake of individual fruits and vegetables would be helpful.

Response: *The list of fruits and vegetables were selected based on number of households (>30) reporting consumption in Chapter 13 (home produced). Other food chapters were made consistent with the selections made in Chapter 13. All fruits and vegetables were included in the estimation of total fruits and vegetables. A sentence was added for clarification.*

Comment: General Response to Chapters 9, 11, 12, 13, and 14: The primary studies on dietary intake include those outlined in the presentations here. These are large-scale investigations. However, many of the large studies, e.g., CSFII, USDA studies, etc., are now quite old- representing eating habits common in the mid-to-late 1990s, now upwards of 15 years ago. Eating habits have changed as have contaminant levels likely found in the foods. Even total caloric intake has modified during that time period. Further, obesity is becoming endemic in the United States. Bearing all of these comments in mind, it may be useful to look at even more of the smaller-scale investigations, and individual studies to determine likely intakes of all food substances. It may be possible, for example, to use these small-scale investigations to "scale" the factors from these earlier studies to reflect current trends. This of course applies equally well to Chapters 9, 11, 12, 13, 14.

Response: *Newer data from NHANES 2003−2006 have been added to the food chapters.*

Comment: The NHEXAS investigations, now also about 15 years old and thus perhaps no longer as relevant as newer studies, also gathered a good deal of data on dietary intakes of these foodstuffs using multiple methods ranging from duplicate diets, through food diaries, and even dietary checklists. These data are readily available and could be used in these contexts. All three of the investigations offered statistical representativeness of specific areas. One offers some insight as to the variability of such intakes over an annual time period. The data are readily available from EPA, yet none of the studies is mentioned. The NHANES investigations took data on intake of certain foods and might add useful information to these studies.

> ***Response:*** *U.S. EPA agrees that the 1994−1998 CSFII data are becoming dated. The 1996−1997 NHEXAS data is getting old as well. U.S. EPA has added several new tables based upon 2003−2006 NHANES data.*

Comment: The majority of the studies selected as key in Chapter 9, were for very specific populations and had modest sample sizes. For example, the Vitolins, et al., investigation looked only are older rural adults. The Fox, et al., Ponza, et al., and Menella, et al., investigation had a large sample size, but was a study of infants and toddlers only. While certainly relevant for this group, the population as a whole was not represented.

> ***Response:*** *U.S. EPA agrees that several of the studies cited were not representative of the population as a whole and presented them as "relevant" (not "key") studies. The recommended values presented in Table 9-1 were based upon U.S. EPA's analysis of the 2003−2006 NHANES data which are representative of the U.S. population.*

Comment: The studies listed as "key" in this Chapter [11] are the same as those listed for Chapter 9, hence the same comments apply. They are repeated here for easy transfer. The majority of the studies selected as key in Chapter 11, were for very specific populations and had modest sample sizes. For example, the Vitolins, et al., investigation looked only are older rural adults. The Fox, et al., Ponza, et al., and Menella, et al., investigation had a large sample size, but was a study of infants and toddlers only. While certainly relevant for this group, the population as a whole was not represented.

> ***Response:*** *U.S. EPA agrees that several of the studies cited were not representative of the population as a whole and presented them as "relevant" (not "key") studies. The recommended values presented in Table 11-1 were based upon U.S. EPA's analysis of the 2003−2006 NHANES data, which are representative of the U.S. population.*

Comment: The studies listed as "key" in this Chapter [12] are the same as those listed for Chapter 9 (and 11), hence the same comments apply. They are repeated here for easy transfer. The majority of the studies selected as key in Chapter 12, were for very specific populations and had modest sample sizes. For example, the

Vitolins, et al., investigation looked only are older rural adults. The Fox, et al., Ponza, et al., and Menella, et al., investigation had a large sample size, but was a study of infants and toddlers only. While certainly relevant for this group, the population as a whole was not represented.

> ***Response:*** *U.S. EPA agrees that several of the studies cited were not representative of the population as a whole and presented them as "relevant" (not "key") studies. The recommended values presented in Table 12-1 were based upon U.S. EPA's analysis of the 2003−2006 NHANES data, which are representative of the U.S. population.*

Comment: In the introduction of each chapter [9, 11, 12 and 14], it is indicated that the relevant data are provided in addition to the key data/recommendation to provide reader with added perspective on the current state-of-knowledge pertaining to various food intakes. However, a number of the "relevant data" provided in the revised EFH are based on dated food consumption surveys (NFCS 1977−78, 87−88, CSFII 94−95, ERS 1970−90) and clearly do not provide users with current state-of-knowledge of the US diet. These old data should be removed and replaced with more current/relevant information (see specific comments below). Section 9.3.2.2—USDA (1993)—Food Consumption, Prices, and Expenditure: The USDA Economic Research Service (ERS) data presented in this section are based on annual food supply/availability. While they may be useful in screening assessment, since they do not account for food waste/spoilage, these estimates are conservative/high end intake estimates. Further, the ERS data presented in this section are old (1970−92). More recent data are available from ERS. A more thorough search of the USDA-ERS website (http://www.ers.usda.gov/Data/FoodConsumption/) will yield more current consumption data based on production statistics than what is currently in the EFH. At this website, query and exporting of data tables can be conducted to generate output needed for the EFH. Below is a citation of a typical and more recent report from ERS. A copy is also attached to these comments…

[Similar comments were provided on sections 9.3.2.4, 11.3.2.2, 11.3.2.3, 12.3.2.1, 12.3.2.3, and 12.3.2.4].

> ***Response:*** *U.S. EPA agrees that the data provided by 1994−1998 CSFII are somewhat dated. U.S. EPA has revised the Handbook to include tables based upon 2003−2006 NHANES data but have retained the CSFII data as a "relevant" study because it provides some data not found in NHANES (regional, urban, and seasonal breakouts, plus the race/ethnicity categories are very different). U.S. EPA has retained CSFII as a "key" study for fat intake because is the only analysis available on fat intake.*

2.31. Chapter 10: Intake of Fish and Shellfish

Comment: Several peer reviewers commented that the CFSII data, upon which the Chapter's recommendations are based, was old and needed to be replaced with more current data.

> ***Response:*** *U.S. EPA agrees. The Continuing Survey of Food Intakes by Individuals (CFSII) data was collected in 1994−1998. To update the chapter, data and tables have been added from an analysis conducted by the U.S. EPA Office of Pesticide Programs of 2003−2006 National Health and Nutrition Examination Survey (NHANES) data. The recommendations found in Table 10-1 are now based upon that NHANES data. CFSII data are included as a "relevant" study and include intake data on fish habitat, regional, urban, and seasonal breakouts not found in the more recent NHANES.*

Comment: I commend your decision to analyze and incorporate the NHANES data for Chapters 9, 11 and 12. I would suggest analyzing general fish consumption for Chapter 10 from the same data. I would provide best-fit parametric models for Monte Carlo from the NHANES data.

> ***Response:*** *U.S. EPA has added text and tables from its analysis of 2003−2006 NHANES data. Distributions are provided that can be used in Monte Carlo analyses.*

Comment: I believe that there are relevant data sources available for Chapter 10 (Intake of Fish and Shellfish) that have not been cited and discussed:

1. Stern AH et al., (1996). Estimation of fish consumption and methylmercury intake in the New Jersey population. J Exposure Assessment Environ Epidemiol. 6:503−525.
2. Mahaffey KR et al. (2009). Adult women's blood mercury concentrations vary regionally in the United States: association with patterns of fish consumption (NHANES 1999−2004). Environ Health Perspect 117(1):47−53.

Stern et al. (1996) provides data on frequency of fish consumption and portion size in the general population in New Jersey based on a telephone survey of 1,000 households. In addition to asking species-specific information on fish consumption over the previous 7 days, the survey also asked about the usual frequency of fish consumption. This allowed for the identification of infrequent (and frequent) consumers and thus, statistical re-weighting of the data to account for the under-representation of the consumption patterns of infrequent consumers. Mahaffey et al. (2009) provides data from the NHANES study of regional patterns of fish consumption. These data would be very useful to exposure assessors for refining the overall national estimates provided in the summary recommendations of the EFH.

Response: *A summary of Mahaffey et al., (2009) and a figure showing regional fish consumption frequency have been added to the chapter. Most of the information in Mahaffey et al., (2009) refers to mercury "exposure," and it is not "relevant" to the chapter. A summary of Stern's et al. (1996) New Jersey fish consumption study was added as well as four tables.*

Comment: Chapter 10, fish intake uses data from the 1994−96, 98 study, which is outdated. While there are many "relevant" studies mentioned and summarized, it does not appear that any current studies have been considered. I believe there have been some recent publications using the NHANES data that might be considered. There are also many studies that include fish consumption correlation with specific human chemical biomarker data. So much is known about contaminants in fish, that a general consumption rate is a poor indicator of many exposures, which are what the exposure assessor is using—combining consumption with contamination. While the early study is probably adequate for general information, much has changed, even though it does not appear that overall total fish and shellfish consumption changed over the years they reviewed. The species of fish consumed has changed especially since the rapid growth of farmed fish and shellfish. It would be helpful if the annual commercial sales of fish were provided so commercial distribution can be appreciated as well as the increasing amount. The general fish consumption tables provided are probably not very useful to the exposure assessor as combining wild caught fin fish with farmed fish, with shell fish and then implying specific contaminant or even nutrient exposure is pretty gross as shrimp and squid are quite different from swordfish, tuna or farmed catfish.

Response: *To update the chapter, data and tables have been added from an analysis conducted by the U.S. EPA Office of Pesticide Programs of 2003−2006 National Health and Nutrition Examination Survey (NHANES) data. The recommendations found in Table 10-1 are now based upon that NHANES data. Although annual commercial sales of fish may be useful, they could not be equated to consumption. This information will not be "key" and, therefore, not very useful for deriving recommendations on intake rates.*

Comment: The use of the CSFII data as the basis for the recommended values for general population fish intake is questionable. This is a 2-day survey and, as such, over-represents the consumption patterns of frequent consumers and under-represents the patterns of infrequent consumers. There are no data internal to that database that can be used to re-weight the data to compensate for this. Furthermore, the CSFII data are up to 15 years old. Although the text states, on the basis of comparison of the 1994−96 CSFII to CSFII data from the 1970's, that fish consumption did not appear to change significantly over that period, there is reason to believe that both fish consumption advisories and information on the beneficial effects of fish consumption may have significantly changed fish consumption patterns in the intervening 15 years.

Response: *U.S. EPA conducted an analysis of 2003−2006 NHANES data for use in this chapter. These data are the basis of the recommendations.*

Comment: Table 10-1 (the recommended values for general population fish consumption) does not provide the source of the data for those recommendations. The reader has to consult Table 10-2 to get that information.

Response: *Table 10-1 includes the source of the recommendations: U.S. EPA analysis of NHANES 2003−2006 data.*

Comment: First a few general comments on this chapter. The introduction needs to make the point that while fish are exposed to all the pollutants in sediments and the water, fish only become a significant exposure source for those chemicals they bioaccumulate through the food chain. Thus, the contaminants of concern are more limited than the universe of chemicals in the environment. It should also distinguish between the lipophilic chemicals and other chemicals since the lipophylic chemicals like PCB are in the fish fat while other chemicals like mercury or arsenic are in the meat portion and can't be removed by cleaning.

Response: *The text has been modified.*

Comment: The mention that there can be an increase in the concentration of chemicals from cooking is not completely correct.

Response: *The comment is referring to the following text: "Assuming that cooking results in some reductions in weight (e.g., loss of moisture), and the mass of the contaminant in the fish tissue remains constant, then the contaminant concentration in the cooked fish tissue will increase." The statement is correct.*

Comment: To be useful to an exposure assessor or risk assessor the consumption has to be converted to a dose. Concentration times weight equals dose. It is good to warn the exposure assessor that you can't use the raw fish concentration and a cooked weight to estimate the dose, because concentration may vary in each. You have to have like measures. The paragraphs on page 10-3 are confusing and could be simplified.

Response: *The text has been modified.*

Comment: The major problem with this chapter is that contaminants vary greatly in fish and shellfish as do consumption preferences. That needs to be taken into consideration in the exposure assessment and simply assigning a "fish consumption" rate is inadequate to translate into a specific exposure.

Response: *Ingestion of pollutants from fish varies greatly due to differences in consumption rates, cooking, and preparation and species consumed. Chapter 10 presents data on all three parameters.*

Comment: Most commercial fish are marine and often come from the same waters as the recreational marine fish. It is valuable to describe in an exposure assessment the proportion of recreational fishers in an area along with the fish they target and consume. Most studies suggest that they consume more total fish than non anglers and are likely to target a more limited set of species that are local and of course contaminant concentrations can also be local. Not only do anglers eat personally caught fish, but they also consume commercial fish, and do so at higher rates. It is hard to not come to the conclusion that local recreational fish consumption rates are of much higher value to the assessor than the uncertainty in applying a national estimate. … In a population I would suggest that the proportion of recreational anglers in the population will have a greater influence on the average child consumption than meal frequency distribution differences.

Response: *U.S. EPA agrees with the observation made by the reviewer. However, no specific change to the chapter was suggested.*

Comment: It is stated on page 10-3 that the CSFII data on which the general population recommendations are based are short-term survey data and should not be used to estimate the distribution over the long term. This statement should be modified to read that the CSFII data has serious limitations when the distribution is applied to estimate risk from long-term exposure to chemicals in fish. Distributions from short-term survey data is commonly used long-term exposure. It is true that fish is less frequently consumed food and thus short-term data is less likely to capture typical intake and thus overestimate the upper percentiles in particular. However, the use of short-term data is common practice when assessing long-term exposure because appropriate longitudinal data are simply not available. There is a similar statement on page 10-26 that should also be modified.

Response: *A discussion was added in the introduction to the chapter to address the use of short-term and long-term data as well as the use of "per capita" versus "consumers–only" data.*

Comment: The lack of a recommendations for recreational freshwater anglers is appropriate because site- specific factors will always be the predominate determinant of fish consumption in the myriad types of freshwater bodies. Such factors include size of water boy, climate, fishing regulations, availability of alternate fishable water bodies and water body productivity. Perhaps you could mention some of these factors in your justification.

Response: *Information on these factors has been added to the text.*

Comment: It is pointed out on the age groupings from the CSFII data analysis did not match the USEPA's Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposure to Environmental Contaminants because the analysis of the CSFII data predated the recommendation. USEPA is planning to analyze the most recent NHANES data. Perhaps the fish consumption data from

the NHANES dietary database could be compiled for the appropriate age ranges and replace the use of the older CSFII data.

Response: *EPA's most recent analysis of NHANES data uses age groups that are very similar to those recommended in U.S. EPA, 2005.*

Comment: On page 10-22, the Santa Monica Bay Restoration Project, 1994−Seafood Consumption Habits of Recreational Anglers in Santa Monica Bay, Los Angeles is discussed. It should be mentioned that this study was not adjusted for avidity bias. The OEHHA adjusted the distribution of fish consumption for avidity bias and other factors in the Air Toxics Hot Spots Program Risk Assessment Guidelines Part IV: Exposure Assessment and Stochastic Analysis Technical Support Document available at www.oehha.ca.gov. Although this study is dated, you may want to include the avidity bias and other adjustments to the distribution in The Exposure Factors Handbook, if you concur with our analysis.

Response: *The Handbook has been revised to indicate that this study was not adjusted for avidity bias and that adjusted data are available from OEHHA in the document mentioned.*

Comment: The method used by EPA (which consists of applying a ratio of children/adult marine fish ingestion rates in the general population x adult marine recreational fish ingestion rates) would seem to provide a reasonable approximation of recreational marine fish ingestion rates for children. However, I do have a few observations. First, the table which purports to summarize the recreational marine fish intake values (Table 10-3) has some formatting problems.

Response: *The formatting problems have been corrected.*

Comment: Second, I was unable to locate any presentation of the method described above. Hence, while the approach appears to make sense conceptually, it is not possible to evaluate the specific values and factors considered by EPA in deriving the children ingestion rates. I believe this information should be summarized in an appropriate location in Chapter 10.

Response: *The text describing Table 10-3 has been clarified.*

Comment: I would suggest that assigning recreational marine fish consumption as a national rate ignores the local issue as much as the freshwater recreational fish if not more. Every state has a freshwater recreational fishery, but only a few have marine recreational fisheries. Recreational marine fish species on the West coast are quite different from the East Coast as well. Not a large marine recreational fishery in the plains states. In general I think the agency needs to rethink the narrow emphasis on providing national estimates when there is so much regional variability. The same issue holds for using national rates for ethnic groups. The fish consumption chapter probably is the one where national estimates are the least useful and have greater uncertainty and an emphasis on

local and regional as well as ethnic information is certainly legitimate. Providing regional or state proportions of the population who are recreational anglers would be very useful. The recent study by Kate Mahaffey 2008 based on the NHANES data shows considerable differences in regional fish consumption and the resulting differences in methyl mercury distribution. I would suggest that trying to develop national estimates (one size fits all) for recreational fish consumption is counterproductive and exposure assessors need to be told to seek and utilize regional and local information. Concentrations of contaminants very greatly and that is the critical second step in the assessment process combining consumption with concentration.

> ***Response:*** *The Handbook contained three separate sets of recommended recreational intake values for Atlantic, Gulf, and Pacific areas and not a national rate.*

Comment: Probably more than any other chapter, it would be important for the authors to indicate the process they used to identify studies to report. Studies listed are mostly quite old. My knowledge of the literature suggests there are many more current studies of regional or local utility. I don't see the biomonitoring studies or some of the surveys that gathered "meal" information and converted using an estimated meal size. What was the search protocol and how many studies were reviewed and rejected. If these were reviewed and rejected, that needs to be indicated. This is a very long chapter because of all the regional studies summarized and converted to tables, so the perception is that the authors have gleaned all the studies. As mentioned earlier I would think the NHANES data could be used. We also published two Great Lakes Basin consumption studies that generated population rates for sport fish consumption. Perhaps these were rejected, which I could understand, but it would be good to know that all these types of studies underwent evaluation. Were only studies done on US populations considered? More attention needs to be paid to how the studies used and summarized got selected.

> ***Response:*** *With regard to identifying studies to include in the Handbook, see responses under charge question #3. With regard to study methodologies, to be considered "key", a study should be representative of the population of interest, recent, and sufficiently large. "Relevant" studies may provide useful data that provide additional information or perspective on the actor of interest. Both "key" and "relevant" studies were based upon U.S. populations, if possible. A literature search was initially used to identify articles, but revisions to the Handbook have relied primarily upon U.S. EPA staff and peer reviewers to identify "key" and "relevant" research. Additional language was added to Chapter 1 to explain how studies were identified and classified.*

Comment: I agree that it is not possible to develop a single set of freshwater or Native American fish ingestion rates that could be considered applicable to all scenarios that involve these angling populations, and I concur with EPA's

decision to permit flexibility in choice of the most proper set of assumptions. I think the EFH does a good job in summarizing the available studies, particularly the tables at the end of the chapter. Hopefully, any fish ingestion scenario that must be addressed in a site-specific risk assessment can be "matched" to some degree with one of the studies summarized in this chapter.

Response: *U.S. EPA agrees with the comment.*

Comment: ("Other Factors to Consider for Fish Consumption"):

—which consumption rates are most appropriate for family members who are consuming (but not catching) the fish; do angling and non-angling pregnant women need to be considered separately (with specific fish ingestion rates)?

—how does one best evaluate potential consumption of the "other" parts of the fish/shellfish that are not typically consumed by the general population but might be considered "delicacies" by some individuals? (e.g., fish skin, crab hepatopancreas); similarly, which consumption rates are most appropriate for "whole fish/shellfish" that might be included in some preparations (e.g., stews).

—the issue of "access" to fishing locations is an important factor that should be mentioned; quite often the risk assessor is faced with estimating fish ingestion rates for marine or freshwater locations that are highly industrialized and therefore have limited access. Which (if any) of the studies summarized in Chapter 10 best reflect a "limited access" scenario?

—should the presence of warnings or advisories be taken into account and if so, which studies best reflect their influence?

—the possibility of "subsistence" fish consumption is invariably raised in fish consumption risk assessments. Which, if any, of the consumption rates (marine or freshwater) in Chapter 10 are most representative of true subsistence rates? Does one simply use the 95%ile values of the "standard" rates or are there separate rates that apply only to subsistence anglers? (perhaps this is described in the Chapter and I just can't find it readily).

Response: *There are numerous considerations that often must be addressed in a fish consumption risk assessment; some of these are discussed in detail in Chapter 10, and some are not. The chapter is not meant to provide comprehensive guidance on how to select specific values to be used in an exposure assessment. Providing this type of guidance is beyond the scope of the report.*

Comment: There are some fairly recent papers that describe the results of a year-long intercept survey on a stretch of the Passaic River in New Jersey:

Ray, R., V. Craven, M. Bingham, J. Kinnell, E. Hastings, and B. Finley. 2007. Human health exposure factor estimates based upon a creel/angler survey

of the lower Passaic River (Part 3). J Toxicol Environ Health A. 70(6):512−528.
Ray, R., V. Craven, J. Kinnell, M. Bingham, M. Freeman, and B. Finley. 2007. A statistical method for analyzing data collected by a creel/angler survey (Part 2). J Toxicol Environ Health A. 70(6):496−511.
Kinnell, J: M. Bingham; E. Hastings; R. Ray;V. Craven; M. Freeman. 2007. Survey Methodology for Collecting Fish Consumption Data in Urban and Industrial Water Bodies (Part 1). J Toxicol Environ Health A. 70(6); 477−495

I believe these should be included (and summarized) in Chapter 10.

Response: *The Handbook typically discusses studies that either are representative of the national population or focus on a specific at-risk population, such as Native Americans. This 3-part New Jersey study is local, based upon a very small number of anglers consuming fish, and may contain an error (the mean is greater than the 95th percentile for carp). For these reasons, they have not been added to the Handbook.*

Comment: My experience bears out the conclusion of the EFH authors that patterns of recreational fish consumption are highly population and geographically specific. They depend on the cultural practices of local sub-populations, the specific types of freshwater fish available, the availability of these fish relative to seasonal weather and the ability of the population to access sites of freshwater fishing areas. In New Jersey, for example, recreational freshwater fishing is popular and there are several freshwater species that are popular for consumption elsewhere in the U.S. However, survey work we conducted in the 1990's indicated that freshwater fish consumption comprises only a very small percentage of total fish consumption. This is because the culture of recreational freshwater fishing in New Jersey is largely a catch-and-release culture (Stern et al., 1996 (see response to question #3). This appears to be in sharp contrast to the fishing culture in (e.g.) the Great Lakes recreational fishery.

Response: *U.S. EPA agrees that regional differences in fish consumption are important. U.S. EPA added material from Mahaffey et al. (2009), which used NHANES data to estimate regional differences in eating fish and Stern et al. (2006).*

Comment: Pg. 10-3, par. 5—There is another and perhaps stronger justification for using uncooked intakes and concentrations. Consumers purchase and catch fish relative to the purchase and catch weights. They do not weight fish after cooking. Reported weights are more likely to reflect uncooked weight and interpretation of advisories are likely to be in terms of uncooked weights.

Response: *The text was changed to reflect the suggestion.*

Comment: Pg. 10-6, Applicability and Utility-Currency—The fact that the most recent CSFII data (i.e., 1994−96, 1998) were used, does not mean that those data were, in fact, current. They are not.

Response: *To update the chapter, data and tables have been added from an analysis conducted by the U.S. EPA Office of Pesticide Programs of 2003−2006 National Health and Nutrition Examination Survey (NHANES) data. The recommendations found in Table 10-1 are now based upon that NHANES data.*

Comment: Pg. 10-7—Although the use of the term "per capita" is clarified in the footnotes, this term is somewhat misleading since per-capita implies that the values apply to the entire population when, in fact, only consumers are included. This should be relabeled as "consumers only." The unclear use of "per-capita" appears throughout this chapter. This terminology should be used only to refer to values that apply to the entire population.

Response: *The text has been revised to make it clear that these data represent neither "per capita" nor "consumer-only" intake as previously defined. A clear definition of what these intake rates do represent has been added.*

Comment: Pg. 10-15, par. 2—The use of "per-capita" here is inconsistent with previous uses in this chapter. Previously, it was used to mean per-individual within the group of consumers. Here, it is used to mean individual average consumption for the entire population regardless of consumption status. This is confusing.

Response: *In this case "per capita" was used correctly, but the text describing its use was indeed confusing. It has been clarified.*

Comment: Pg. 10-54—Since "per capita" has been used to mean different things in this document, its use here should be clarified. Does "per capita" here mean the entire population—whether or not they consume fish?

Response: *According to the source document, "per capita" in this case does indeed refer to the entire U.S. population. The text has been clarified.*

Comment: Pg. 10-11, 10.3.1—This discussion provides no indication of the under-representation of the patterns of infrequent consumers inherent in the use of a 2-day sampling study such as the CSFII

Response: *A discussion was added regarding the use of "per capita" and "consumer-only" data from 2-day sampling study such as the CSFII.*

Comment: Pg. 10-14, par. 8—In the context of this database, does "home produced fish" mean self-caught? If so, that should be made clear.

Response: *The term "home produced fish" means self-caught. The text has been clarified.*

Comment: Pg. 10-16, par. 1—However, if, as noted, the estimate does not include processed or canned fish, it excludes most tuna intake. Tuna is consistently reported as the most or second most popular fish. Thus, if canned tuna is not included in this estimate, the cited value is, in fact, a significant underestimate

Response: *Actually, there is no underestimate. Consumption is estimated as number of servings times average serving size. The average number of servings per month includes tuna, and the average serving size excluding canned tuna is 170 grams. A typical can of tuna contains about 5 oz or 142 grams. The two averages do not substantially differ from each other.*

Comment: Pg. 10-18, par. 8—No evidence is provided to support the statement here that "this figure is somewhat conservative…"

Response: *The text has been clarified to indicate that it is assumed to be a conservative assumption.*

Comment: Par. 9—Add "marine" before the last word in the paragraph.

Response: *The text was modified as suggested.*

Comment: Pg. 10-27, par. 5—"U.S.EPA estimated the annual frequency…" Since it was stated immediately prior that the survey did not obtain information on fish obtained from recreational sources, it is not clear from where the frequency of recreationally caught fish referred to here was taken.

Response: *The text states that "The usual frequency component of the survey asked about the frequency of fish meals during each of the four seasons and requested respondents to give the overall percentage of household fish meals that came from recreational sources." These data were used in calculating recreational fish intake.*

Comment: Pg. 10-29, par. 5—"…an assumption that the average success and consumption rates for the individual angler during the trips already taken would continue through future trips." This does not appear to me to be a conservative assumption as stated. It is the standard statistical assumption that future frequencies can be predicted from existing data. It strikes me as a relevant assumption. Furthermore, stating that this is a "conservative" assumption implies that it is biased (in this case, biased high). While future success may differ from that reported, there doesn't appear to me to be any a priori reason to assume that future success will be less than past success.

Response: *The text was modified such that it no longer referrers to the assumptions as conservative.*

Comment: Also, the assumption that "Over reporting appears to be correlated with skill level… it is likely that the higher consumption rates may be substantially overstated" is highly speculative and not supported by the data presented. Since "consumption," not "catch" is being reported, there is no a priori reason to assume a performance bias in reporting.

Response: *The text of concern has been deleted.*

Comment: Pg. 10-34. par. 8—"First, there was some interdependence within households…" The meaning of this sentence is not clear.

Response: *The text has been revised to address this concern.*

Comment: Pg. 10-38, par. 2**—**"…and then dividing by the total number of household members in the household sample." This gives average consumption by household member, but this is misleading as (e.g.) children will have a significantly lower intake than average adults.

Response: *The text has been revised to reflect this concern.*

Comment: Pg. 10-39, par. 5**—**"…the study was designed to give nearly equal sample size to each tribe." Ensuring equal sample sizes among tribes does not ensure adequate sample size for any individual tribe.

Response: *The text of concern has been deleted.*

Comment: Pg. 10-41, 10.6.5—The relevance of the controls to the consumption estimates of the study population and the basis for selection of the controls is not clear.

Response: *The text has been revised to reflect the controls used in the study.*

Comment: Pg. 10-46, par. 2—"Therefore, extrapolation of data to other ethnic groups should be used with caution." The caution necessary in extrapolating these data to other ethnic groups does not specifically result from the small number of respondents in each group. Rather, this caution is a function of the potentially significant culturally-based patterns among ethnic groups.

Response: *The text has been revised to address the concern.*

Comment: Pg. 10-47, eq. 10-5—Assuming that 'C' in equation 10-5 corresponds to concentration, the equation is correct. However, if 'C' corresponds to intake as per the definition of the variables in the text, then the equation is incorrect.

Response: *The text has been revised to address the concern.*

Comment: 10.9.2—The text should provide some guidance as to when lipid adjustment is appropriate.

Response: *The text has been revised to address the concern.*

Comment: I agree with the need to have population specific information and for the flexibility of the assessor to determine this, and so foregoing a recommendation table. A useful addition, however, would be to include some additional general statistics from the available data sets in Table 10-5, such as reported intake ranges and average across studies by age on a kg body weight basis, as well as additional discussion, if possible, of factors that may be associated with study differences. This would better indicate the relative magnitude of interpopulation variability and factors for the exposure assessor to consider in selecting a study that may be most representative of a population of interest.

Response: *The requested data are in the tables later in the chapter. U.S. EPA prefers to keep the summary tables as simple as possible with more detailed information in the body of the chapter.*

Comment: Other sources of information:

- The USDA website indicates more recent sources of food consumption data, which should include fish consumption data that should be considered within this document: http://www.ars.usda.gov/Services/docs.htm?docid=15044
- Mayfield et al., 2007. Survey of fish consumption patterns of King County (Washington) recreational anglers. Journal of Exposure Science and Environmental Epidemiology 17:604−612.

Response: *The USDA Web site refers to data from What We Eat in America from NHANES, which is now included in the chapter. The Mayfield et al. (2007) study has been added to the Handbook.*

Comment: Section 10.3.2.1—as indicated on page 10-13, this study is over thirty years old; suggest discussion could be cut much shorter than the current 2 pages.

Response: *The text has been edited to less than half the original length.*

Comment: In general, for this section, where recommendations are based upon the CSFII two non-consecutive day survey, if possible some discussion as to if there was any relationship between weekday vs. weekend fish consumption and seasonal consumption (for example, near shore resort areas, does fish consumption increase during weekend recreation? does fish consumption increase during fishing season and decrease when availability of fresh fish is lower? and if so, how is this considered in the annual average?).

Response: *This analysis would be helpful, but not enough resources are available to conduct the suggested analysis. It may be considered in future versions of the Handbook.*

Comment: Suggestions for new references.

- Mayfield et al., 2007. Survey of fish consumption patterns of King County (Washington) recreational anglers. Journal of Exposure Science and Environmental Epidemiology 17:604−612.
- The USDA website indicates more recent sources of food consumption data, which should include fish consumption data that should be considered within this document: http://www.ars.usda.gov/Services/docs.htm?docid=15044
- Ray, R., V. Craven, M. Bingham, J. Kinnell, E. Hastings, and B. Finley. 2007. Human health exposure factor estimates based upon a creel/angler survey of the lower Passaic River (Part 3). J Toxicol Environ Health A. 70(6):512−528.
- Ray, R., V. Craven, J. Kinnell, M. Bingham, M. Freeman, and B. Finley. 2007. A statistical method for analyzing data collected by a creel/angler survey (Part 2). J Toxicol Environ Health A. 70(6):496−511.
- Kinnell, J: M. Bingham; E. Hastings; R. Ray;V. Craven; M. Freeman. 2007. Survey Methodology for Collecting Fish Consumption Data in Urban and Industrial Water Bodies (Part 1). J Toxicol Environ Health A. 70(6); 477−495
- Air Toxics Hot Spots Program Risk Assessment Guidelines Part IV: Exposure Assessment and Stochastic Analysis Technical Support Document available at www.oehha.ca.gov.
- Mahaffey, KR; Clickner, RP; Jeffries, RA. (2009) Adult women's blood mercury concentrations vary regionally in the United States: Association with patterns of fish consumption (NHANES 1999−2004. Environ Health Perspect 117(1): 1−7.
- Stern, AH; Korn, LR; Ruppel, BE. (1996) Estimation of fish consumption and methylmercury intake in the New Jersey population. J Expos Anal Environ Epidemiol 6(4):503−525.
- Great Lakes Basin consumption studies

Response: *The 9 new references suggested for Chapter 10 were reviewed. Those by Mahaffey et al. (2009), Mayfield (2007), and Stern et al. (1996) contained data considered to be a valuable addition to the Handbook. Summaries of these studies were added to the Handbook as well as new tables. The other studies were not added for various reasons (e.g., based upon a small geographic area, did not address at-risk populations, did not provide consumption data, or were based upon older data).*

2.32. Chapter 13: Intake of Home-Produced Foods

Comment: Several reviewers noted the utility of these factors but lamented the fact that surveys of homegrown food intake are sporadic. One reviewer said it might be helpful if EPA could fund a survey of homegrown food intake on a semiregular basis.

Response: *U.S. EPA does not plan to conduct a homegrown food intake survey at this time.*

Comment: One reviewer suggested obtaining additional information from an urban gardener association, seeing that urban gardening has increased dramatically both demographically and regionally.

Response: *Additional data from the National Gardening Association have been added. This information includes data on the average yield of fresh produce per square foot of garden area, the size of home gardens, and total yield.*

Comment: It would also be useful to include existing intake data on consumption of locally produced farmer's market foods.

Response: *No data on intake of farmer's market foods were located.*

Comment: Two reviewers noted that it is important to consider seasonal vs. year-long averages and that these data are usually collected based on recall. Hence, appropriate caveats are needed in the discussion, as well as recommendations for these parameters.

Response: *Additional language was included in the Introduction to caution users regarding the use of short-term data to represent long-term intake rates. This limitation is also reflected in the confidence rating given in Table 13-2. Seasonally Adjusted Consumer-Only Homegrown Intake rates are provided in Table 13-30 of this chapter.*

Comment: The US EPA's analysis of the NFCS 1987−1988 is the Key study provided for the intake of home-produced foods. However, the data from the 1987−1988 National Food Consumption Survey (NFCS) are over 20 years old and are dated for assessing current intake of home-produced foods. In Section 13.3.1, page 13-7, the EFH states that "intake rates of home-produced foods are higher among populations in non-metropolitan and suburban areas and lowest in central city areas". However, this geographical trend in home-produced foods has likely shifted somewhat, or at least become more prevalent in central-city areas, since the 1987−1988 NFCS was conducted. The 2009 National Gardening Association Report on The Impact of home and Community Gardening states that "43 million US households plan to grow their own fruits, vegetables, berries and herbs in 2009− …up 19% from 36 million households in 2008."Although the National Gardening Association (2009) Survey, conducted in 2008, is much more recent, but unfortunately it does not contain any homegrown food intake values. It is useful as a Relevant study, however. I think that including additional characteristics (in addition to those listed in Table 13-70) of food gardeners would be helpful, including collecting data on the prevalence of food gardening by Urbanization, and ethnicity. Data is available on the prevalence of home-gardening by US Census Region in the 2009 National Gardening

Association report, but the following information is not currently included in Table 13-70 of the EFH:

Response: *Additional information from the National Gardening Association survey, has been added, as suggested.*

2.33. Chapter 14: Total Food Intake

Comment: There is only one Key study- the US EPA's analysis of the CSFII 1994−96, 1998. No relevant studies are provided for total food intake. Unfortunately, this data source is 11−15 years, and therefore the total food intake values may not represent the current trends in food intake (e.g., food intake patterns resulting in the prevalence of obesity). Unfortunately, there is no information on variability within the general population on any factor besides age. Inclusion or re-analysis of the data based on other factors that may describe total food intake of specific food categories, would be useful (such as by the "region", "urbanization", and "ethnicity" factors that are provided in Chapter 9 Intake of Fruit and Vegetables and Chapter 12 Intake of grain products). Because the data source is the 1994−96, 1998 CSFII which was also used to estimate total fruit and vegetable intake (Chapter 9) and total grain intake (Chapter 12), the total per-capita food intake may also be re-analyzed and reported based on additional spatial and demographic variables. In the future, I suggest that the analysis of total food intake (Chapter 14) be re-analyzed to conform to the US EPA's life-stages (i.e., new childhood age categories).

Response: *U.S. EPA appreciates the suggestion for reanalysis and could consider it in the future. Newer data on total food intake from NHANES 2003−2006 have been added, but the data on diet composition are still from the 1994−96, 1998 CSFII.*

Comment: The dietary factors include in chapters 9, 11, 12 and 14 are useful food commodity factors for assessing exposure to environmental contaminants that may be present at the commodity levels (e.g., spinach, pork, etc). However, if contaminants are present at the "food as consumed" level, e.g., in canned soup, the dietary factors in these chapters are of limited utility.

Response: *U.S. EPA evaluates foods at the commodity level or as total foods in certain categories. Therefore, the focus of this chapter is on foods at the commodity level or broad categories of foods (total vegetables, total fruits, etc.). However, some limited information on other food categories is provided in Chapters 9, 11, and 12.*

Comment: The CSFII 94−96, 98 is the key data source for the dietary factors in chapters 9, 11, 12 and 14. It is recognized that EPA is in the process of but has not completed updating its food commodity intake database (FCID) for the more recent NHANES data release (i.e., NHANES 03−06); therefore, it cannot yet analyze the more current NHANES data to develop food intake at the commodity

level for purpose of updating the EFH. For this reason, the previous analysis of the older consumption dataset, mainly the CSFII 94−96, 98, is included in the current EFH update. However, it should be noted that not only there has been changes in food pattern/intake rates since the CSFII 94−96, 98, but there has also been significant changes in the types of food products available in the marketplace and consumed today than from a decade ago. This is evident by the fact that there are more than 700 new food codes in the NHANES 03−06 database that were not in the CSFII 94−96, 98. Hence relying on the more than 10 yr old consumption data has limitations. Further, it is noted in the charge to this peer review that the EPA FCID update will be available in May 2010. Thus, by the time the EFH update is peer-reviewed/finalized, the recommended dietary factors based on the CSFII 94−96, 98 as presented in the current revision of the EFH would be completely outdated.

> ***Response:*** *Data in the other food chapters will be updated based on the most recent NHANES data available. However, U.S. EPA has no plans for updating the diet composition analysis at this time. Data on total food intake are now based on NHANES 2003−2006.*

Comment: The key study for the dietary factors in chapters 9, 11, 12, and 14 are the CSFII 94−96, 98. It may be more appropriate to rate the "applicability and utility" factor as low rather than medium due to the age of the data (1994−96) and per the above comment.

> ***Response:*** *Currency is only one factor considered under "applicability and utility." While this would be rated as low, other factors, such as "representativeness" and relationship to the "exposure factor of interest" would be considered to be high. Therefore, the overall rating for "applicability and utility" was considered to be medium.*

Comment: For the "variability and uncertainty" factor: in the discussion of the data from Smiciklas-Wright et al 2002, it was noted that recipes not provided by respondents of CSFII 94−96 for mixed foods and that standard recipes were used to determine the components of mixed foods and thus there is uncertainty associated with component food intake rates from this study. This source of uncertainty (recipe uncertainty) is also true with the translation from 8-digit food codes to food commodity ingredient level (e.g., deriving the beef portion in a beef stew). This is a source of uncertainty that should be noted in the confidence/data quality summary table.

> ***Response:*** *This additional type of uncertainty has been added to the confidence rating table.*

Comment: This chapter provides overall intake rates by major food groups (dairy, meats, fish, eggs, grains, vegetables, fruits, fats). Nuts/legumes intakes were omitted. Nuts/legumes intake data are available and should be incorporated.

Response: *U.S. EPA has no plans for reanalyzing the data at this time. A note has been added to the tables that present total food intake and to the recommendations and confidence rating tables to indicate that an uncertainty related to the analysis is the exclusion of these food groups.*

Comment: The intake rates are based from same source CFSII 94−96, 98 and analyzed by EPA in 2007. The data from tables 12-3, 11-3 and 9-3 are the same as data presented in table 14-5. However, it is noted that the age bins in this chapter are different from those in chapters 9, 11 and 12. It is not clear why this inconsistency exists.

Comment: One reviewer wondered why the age bins in Chapter 14 are different than those in Chapters 9, 11, and 12. There are some age groups where the sample sizes are too small to accurately estimate upper percentiles. She recommends not presenting the upper percentiles in those cases.

Response: *The inconsistencies result from the fact that the analysis was conducted before U.S. EPA published the guidance entitled Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants [U.S. EPA (2005)]. In order to conform to the standard age categories for children each of the tables from U.S. EPA (2007) was modified by reanalyzing the source data and applying the new childhood age categories.*

Comment: For some specific age groups in table 14-4 and 14-5 (very young children < 1yr), for some food groups, the sample sizes are too small to estimate upper percentiles. These upper percentiles are not accurate and should be noted or not presented at all.

Response: *U.S. EPA agrees. As noted in the footnote on these tables, data are not reported where the number of consumers was less than 20.*

Comment: Total food intake in tables 14-3, 14-4 and 14-5 should have footnotes as in text indicating that it is sub-total of diet (no beverages, nuts, sugars/candy/sweets included).

Response: *Footnotes have been added to these and other tables as suggested.*

Comment: Several reviewers said that Chapter 14 should also include nuts/legumes and beverage intakes.

Response: *U.S. EPA appreciates the suggestion for reanalysis and may consider it in the future.*

Comment: One reviewer said that there is no information on variability within the general population on any factor besides age. It would be useful to reanalyze

the data based on other factors—such as region, urbanization, and ethnicity—that may describe total food intake of specific food categories.

Response: *U.S. EPA appreciates the suggestion for reanalysis and may consider it in the future.*

Comment: Two reviewers commented on the currency of the data.

Response: *The data used in this diet composition analysis are based on the 1994−94, 98 CSFII. U.S. EPA has no plans for updating this analysis at this time. Data from NHANES 2003−2006 were used for the total food intake.*

Comment: Two reviewers commented that the tables should stand on their own and include footnotes, even when carried through into the Executive Summary.

Response: *Footnotes from the recommendation table for this chapter (and others) will be added to the Table of Recommendations in the Executive Summary of the Exposure Factors Handbook.*

2.34. Chapter 15: Intake of Human Milk, Lipids, and Formula

Comment: Chapter 15, Human milk consumption combines several different studies into the table for breastfed infants. This chapter is a challenge because of the paucity of data. But it is valuable to include. I am not familiar with this literature, but it appears that nearly all the data used is quite old, some of it over 30 years. Since so many different studies are utilized, it is difficult to assess the confidence in each study. Was a minimum threshold needed to include a study in the composite? It would be very hard for a user to duplicate the data in the tables from the source documents. More method detail description is needed. Additional language was included in the introduction describing why studies were selected as key. Although data are old, infants' nutritional needs are not expected to have changed with time.

Response: *The overall confidence in the recommended values for human milk intake is described in Table 15-2; limitations and advantages of individual studies are described in the text summarizing each study. Because quite a few different studies were used in developing the recommended values, Tables 15-3 and 15-4 were provided to show how the values were derived for milk intake, and Tables 15-5 and 15-6 were provided to show how the values were derived for lipid intake. If desired, the user can use these tables to duplicate the recommended values shown in Table 15-1.*

Comment: There is a lot of data and information provided in this chapter related to human milk intake, but most of the Key studies, with the exception of Arcus-Arth et al (2005) and Butte et al (2000), are nearly, or in most cases more than, 20 years old. Additionally, the fact that Arcus-Arth et al. (2005) included

populations from Sweden and Finland makes their data less representative of average daily milk and lipid intake by infants in the US population. I think that these two factors (not entirely representative of the US infant population and dated studies) makes the "Applicability and Utility" of the key studies closer to a "Low" rating than a "Medium" Rating.

> ***Response:*** *These limitations are noted in Table 15-2 and were taken into consideration when developing the confidence rating of "medium". Additional language was included in the Introduction describing why studies were selected as "key." Infants' nutritional needs are not expected to change with time or geographically.*

Comment: Additionally, because the Mitoulas et al. (2002) and Mitoulas et al. (2003) data were collected in Australia, I think it is questionable in terms of representatives to the US population to include these data in Section 15.4.2 and 15.4.3, respectively. Consider placing these in Section 15.5.1- Relevant Studies on Lipid Intake from Human Milk", instead. Consider including baby formula intake here too (in addition to Chapter 3- "Ingestion of Water and Other Select Liquids") so that all infant food intake would be in one succinct chapter. If this is done in future revision, than I suggest changing the title of Chapter 15 from "Human Milk Intake" to "Infant Intake of Human Milk, Lipids, and Formula." In any case the latter title is more descriptive of all the exposure factor information contained in this chapter currently, even without inclusion of the additional formula information from Chapter 3.

> ***Response:*** *The Mitoulas et al. (2002) and Mitoulas et al. (2003) studies have been moved to "relevant" not because the data are from Australia, but because the focus of the studies was on on milk production and composition and not intake. The title of the chapter was retained for simplicity. Available data on formula intake from the "key" and "relevant" studies were added.*

Comment: Lastly, I think it is worth considering placing Chapter 15 solely in the Child Specific EFH and not in the EFH and noting in Chapter 14 (Total Food Intake) that the infant diet in terms of human milk, lipids and formula is included as Chapter 15 of the EPA's CSEFH (2008). If Chapter 15 remains in the EFH it is still worth noting that the infant diet, in terms of human milk, lipids and formula is presented in Chapter 15 (of the EFH).

> ***Response:*** *U.S. EPA anticipates that eventually there will be just one Handbook in which all of the information is contained.*

Comment: In Chapter 15, the variability in breast milk intake is well documented in the key studies. I think the SE, or standard deviation would be useful to include in Tables 15-3 to 15-6 (the recommended value tables).

Response: *Standard deviations are shown later in the chapter in the tables for individual studies. The recommended value tables referred to are composites where a number of studies were combined. The purpose of the summary tables is to keep them simple.*

Comment: I think that inclusion of additional data on partially breast-fed infants would also be useful to include to characterize the variability in the infant diet. To the extent that the data on partially breast-fed were available, they were included.

Response: *U.S. EPA has included some data on partially breast-fed infants [Pao et al. (1980)] and will include additional data if they become available.*

Comment: Two reviewers thought that human milk intake would be better in the Child-Specific Exposure Factors Handbook. EPA could remove it from this EFH and include a reference to the factor in the Child-Specific Exposure Factors Handbook, perhaps in the Total Food Intake chapter (Chapter 14). Three other reviewers thought that the information should be provided in both places. All four felt that if presented in both places, the sections should be similar.

Response: *U.S. EPA agrees with the reviewers who thought that the information should be provided in both handbooks. Every update results in some differences between the two handbooks, but the goal is to have the chapters be similar, and that eventually, there will be one handbook.*

Comment: One reviewer noted that some of the referenced studies were more than 20 years old. The proportion of women who are breastfeeding has been increasing in recent years. She also wondered about the applicability of the studies from Australia. Another reviewer agreed that the extent of breastfeeding may have changed.

Response: *Although prevalence of breast feeding has changed, the nutritional needs of infants have not. The nutritional needs are also not expected to change with time. Data on prevalence of breast feeding from other countries are provided for an added perspective.*

Comment: Two reviewers thought it would be useful to have more data on the breastfeeding population, such as ethnic, racial, and socioeconomic differences. Another reviewer noted that the studies included were on a relatively homogeneous population of breastfeeding women. Maternal age and parity are useful factors for determining contaminant intake.

Response: *No other data on breast feeding were found in the literature that could provide more information in this area.*

Comment: One reviewer suggested changing the focus of the chapter to be "Infant Intake" to encompass everything (e.g., breastmilk and formula) in an infant's diet.

Response: *The title of the chapter was retained for simplicity.*

2.35. Chapter 16: Activity Factors

Comment: Although some of the activity factors described in Chapter 16 could be used to assess dermal exposure from bathing/showering and swimming, they do not provide frequency of contact and duration with other objects that may contain contaminants.

Response: *As the reviewer has stated, the activity factors in Chapter 16 do not include frequency and duration data for contact with objects. Frequency and duration data for mouthing behavior, which includes all activities in which objects, including fingers, are touched by the mouth or put into the mouth except for eating and drinking, is described in Chapter 4, while Chapter 7 provides data for dermal (hand) contact with objects and surfaces. Language was added in the Introduction to direct the reader to these chapters.*

Comment: I would like to describe one publicly available data source that may be useful, i.e., the California Statewide Residential Appliance Saturation Study (RASS) (CEC, 2004) may be a useful. The RASS may be a Relevant study to include data in future revisions to the EFH. The RASS was initiated in 2002 and surveyed nearly 22,000 respondents/households. I would not recommend it as a Key study because it is not representative of the US population and the low survey response rate (19% vs the expected 47% to the initial mail-solicitation; a non-response follow-up study conducted by telephone had a response rate of roughly 45%). Additionally, the selection of households was weighted to the population represented by the sponsoring utilities. The RASS database includes linked data on the following residential and household characteristics that may be useful to describe and incorporate in Chap 16 (Activity factors), 17 (Consumer products), and 19 (Residential Building Characteristics) of future EFH revisions:

−Length of time household living at current residence

−Whether residence is "partial-year" or vacation home

−Cooking frequency of household during week

−Presence of swimming pool at residence

The Reference for the RASS is: CEC (2004). California Statewide Residential Appliance Saturation Study (RASS). Final Report, June 2004. Prepared by KEMA-XENERGY, Itron, and RoperASW under Contract No. 400-04-009 with the California Energy Commission (CEC). Report and data available for

download at: http://www.energy.ca.gov/appliances/rass/. Additional Information on the RASS can be obtained by contacting Glen Sharp, the Project Manager at the California Energy Commission (CEC). His contact information is provided at the bottom of the RASS website (listed above)

Response: *The California Statewide Residential Appliance Saturation Study was reviewed, but the information provided in that report refers to energy consumption in California residences. This type of information may be more suitable for a future update of U.S. EPA's Sociodemographic Data Used for Identifying Potentially Highly Exposed Populations [U.S. EPA (1999)].*

Comment: Videotaping can also be used as a method to capture human activity factors, especially the details of contact activities for dermal contact with surfaces and objects and mouthing activities for non-dietary exposure. Now technically the mouthing behavior given in chapter 4 is really another set off activity factors and could have been organized in this chapter or at least mentioned in this chapter. Handwashing events from relevant studies are covered in the activity chapter (16-67), but is useful for both dermal exposure, dietary and non-dietary exposure calculations. Not sure if we being consistent in how the exposure factors are being presented. The types of exposure factors needed for a calculation/estimate really depends on the type of exposure model/calculation.

Response: *Videotaping has been added to the paragraph as an additional method that can be used to capture human activity factors. In addition, a sentence has been added to the paragraph referring to mouthing behavior in Chapter 4. Although it is an activity, mouthing behavior was placed in a separate chapter because of the importance of this pathway in assessing children's exposures. Other factors necessary to characterize an exposure scenario were cross referenced in the chapters and indicated above.*

Comment: Frequency and duration of contact with surfaces and objects for dermal exposure is not covered in this chapter. In fact, on Page 16-1, Paragraph 4, when Hubal et al., 2000 (author also talks about this in a later paper and the utility of different type of activity patterns, micro vs. macro) talks about children's wider distribution of activities being more challenging, dermal activity patterns is a consideration. This could be covered in this activity chapter or in the dermal exposure chapter to complement the soil loading factors, and surface area of body part.

Response: *As the reviewer has stated, the activity factors in Chapter 16 do not include frequency and duration data for contact with objects. Frequency and duration data for mouthing behavior, which includes all activities in which objects, including fingers, are touched by the mouth or put into the mouth except for eating and drinking, is described in Chapter 4, while Chapter 7 provides frequency and duration data for dermal (hand) contact.*

Comment: How does the CHADS database of activities fit into this activity factors chapter? The CHAD database is referenced here under the Hubal et al., 2000 paper (Page 16-16), but are any studies that were included in CHAD also referenced separately here in this activity chapter. That overlap should be made clear. The Graham and McCurdy, 2004 analysis is based also on the CHAD database (Page 16-17).

> ***Response:*** *As stated in the chapter, Hubal et al. (2000) reviewed available data from the Consolidated Human Activity Database (CHAD), including activity pattern data. In addition, activity pattern data from CHAD were used in the analysis by Graham and McCurdy (2004). Data from twelve activity pattern studies conducted at the city, state, and national levels, as well as the two "key" studies in this chapter are included in CHAD. To make this clearer in the chapter, the following sentence has been added to the summaries for Hubal et al. (2000) and Graham and McCurdy (2004): "Data from the two "key" studies in this chapter [Wiley et al.(1991) and U.S. EPA (1996)] are included in CHAD."*

Comment: The Wiley study and the NHAPS study are the key studies used for activity patterns. They are both substantial studies with a wealth of data, with medium to high confidence ratings. The Carey study 1988 and the US Bureau of the Census (2008b) are also key studies for occupational and population mobility. The Graham and McCurdy study also appears to be substantial with a large N especially for certain age groups (21 to 44, 6 to 10) that it should also be evaluated as a key study for certain activity patterns. I realize though it is based on the CHADS database of varying studies and such issues as quality assurance and consistency might be hard to assess.

> ***Response:*** *The CHAD database is comprised of 12 separate studies, and as noted by the reviewer, issues such as quality assurance and consistency between the studies are difficult to assess. In addition, current human activity pattern surveys do not collect data on microactivities that are important to understanding "exposures," especially for children, nor do they discriminate sufficiently among activities important to developing energy expenditure estimates. These limitations have been added to the chapter.*

Comment: The statements in 16.1 are good and govern what is presented. The key studies are good, but there are other key studies, including some that are considered only relevant herein. EPA has funded studies of sufficient magnitude to give valid and reliable data on time-activity patterns for representative populations in different regions, including the NHEXAS studies (whose data are on the EPA website), and STAR studies of children's activities in relation to exposures (especially related to ingestion), such as by the Univ. of Minnesota group, O'Rourke et al., Fenske et al., and Freeman et al. (The NHEXAS data show significant differences by region of the country.) They should be considered as well.

Response: *The focus of the published analyses done on the NHEXAS data has been on chemical-specific exposures, which are outside of the scope of the Handbook. Analysis of activities data from the NHEXAS can be conducted, but it is not clear that this will result in any additional information due to the age of the data set and the fact that these were pilot studies in few areas of the country and, therefore, not representative of the entire United States. Publications from the STAR studies are included in Chapters 4 and 7.*

Comment: Mean and 95th percentiles appear to be those recommended, but it would be wiser to use median and 90th percentiles, since the distributions are non-Gaussian. Examples of median data presented are in earlier tables in this chapter.

Response: *As noted by the reviewer, the recommended values selected for each of the chapters in the Handbook are the mean and 95th percentile values. This has been done for consistency throughout the Handbook. Distributions are provided in additional tables later in the chapter, and users of the Handbook may wish to select values from these tables for specific exposure assessments.*

Comment: 16.2.2—As shown, median tenures vary entirely by age group within gender, and should be stated as such.

Response: *U.S. EPA agrees with the reviewer that occupational tenures vary by age and gender. A statement was added to reflect comment.*

Comment: Comparisons should be made between relevant studies conducted previously and more recent data to determine if the data actually show a change in time-activity patterns in subsequent years/decades. (The Wiley study is also "old" by the criteria used to judge these "relevant" studies, and the NHAPS data are now 14 years old as well.) Further, just because they were conducted only in one state should rule them out, especially if California or if data from other states/regions are available in relevant studies. Thus, I don't think confining these good studies to the relevant category is appropriate. Presenting data on occupational tenure and on mobility are good. It's unfortunate one doesn't have more complete data on how each occupational category spends its time—it varies widely based on occupational exposure studies. Presenting all these tables is very good and useful. Present more, so that risk assessors can choose as to which data are most relevant to their purpose.

Response: *The rationale for why specific studies were deemed "key" versus "relevant" is discussed in a number of places in the chapter; in the Introduction, Tables 16-2, 16-4, and 16-6 (discussion of confidence ratings), and at the end of each study summary in the chapter. U.S. EPA agrees with the reviewer that more complete data on how each occupational category spends its time would enhance the chapter on activity factors. As new*

studies become available, the data will be added to the Exposure Factors Handbook. In terms of presenting numerous tables, U.S. EPA has summarized the data from "key" studies for each chapter in the tables providing recommended values, but has then provided additional data later in the chapter. The general rule has been to include most, if not all, of the data from individual studies for use by exposure assessors.

Comment: Two reviewers specifically noted that additional discussion about the Consolidated Human Activity Database (CHAD) should be included in Chapter 16.

Response: *The Consolidated Human Activity Database (CHAD) is currently discussed in Section 16.3.2.5 where Hubal et al., (2000) reviewed available data from CHAD, including activity pattern data, to characterize and assess environmental "exposures" to children and in Section 16.3.2.7 where activity pattern data from CHAD, containing 30 or more records per day, were used in an analysis. Advantages and limitations of the CHAD database are included in these sections. In addition, data from CHAD are presented in Table 16-60 (Number of Person-Days/Individuals for Children Less than 12 Years in the CHAD Database), Table 16-70 (Time Spent Outdoors Based on CHAD Data), Table 16-72 (Time Spent Indoors Based on CHAD Data), and Table 16-73 (Time Spent in Motor Vehicles Based on CHAD Data).*

Comment: One reviewer said that the American Time Use Survey (ATUS) should be used more.

Response: *U.S. EPA agrees that the American Time Use Survey provides useful information, especially considering the large sample size, the representativeness of the sample, and the currency of the data. In addition to the summary of the ATUS provided in Section 16.3.2.10, Table 16-78 provides information on the average amount of time spent in 12 major time use categories by gender, age, race/ethnicity, marital status, and educational level. Estimates of time use in subcategories of these 12 major categories are presented in Table 16-79. Table 16-80 provides estimates of time use for all children ages 15 to 19 years by gender. It also provides a more detailed breakdown of the Leisure and Sports category for all children, ages 15 to 19 years old.*

Comment: One reviewer suggested adding information about activity pattern trends to the introductory text.

Response: *Additional information about activity pattern, occupational mobility and population mobility trends was added to the Introduction of the chapter.*

Comment: A few reviewers commented on the numerous tables. One reviewer suggested that they might be easier to navigate if the EFH were Web based. Another said that EPA could spend some time reducing the number of tables to those that are really key but then provide all the tables in an Appendix or on a Web site. Several reviewers thought this was a good idea.

> ***Response:*** *These are helpful suggestions, and U.S. EPA will consider making these changes in subsequent versions of the Handbook.*

Comment: A few reviewers were surprised to see occupational mobility information included in Chapter 16. One reviewer said it was good to include these data—even "critical" for determining lifetime exposure risk. The reviewer said that more data could be provided and that information on time spent in each occupational category can be sought. Another reviewer said that assessors in California use the occupational data to evaluate people who are exposed as members of the public (i.e., not on the job). Providing such an example in Chapter 16 would be useful.

> ***Response:*** *At this time, occupational mobility is included in Chapter 16 to provide information on the length of time (tenure) spent in an occupation, by age and gender. Exposures to chemicals outside the job need to be evaluated separately and are scenario specific.*

Comment: Since the studies used for activity patterns were based on memory recall, the confidence ratings should have been lower.

> ***Response:*** *Although some measurement or recording error may have occurred since the diaries were based on 24-hour recall, U.S. EPA believes that a confidence rating of medium is appropriate for the activity pattern studies based on a number of other factors, including representativeness and other methodological factors.*

Comment: The mean and 95^{th} percentiles were presented as the recommended values. However, since the distributions are non-Gaussian, one reviewer suggests using median and 90^{th} percentiles.

> ***Response:*** *As noted by the reviewer, the recommended values selected for each of the chapters in the Handbook are the mean and 95^{th} percentile values. This has been done for consistency throughout the Handbook. Distributions are provided in additional tables later in the chapter, and users of the Handbook may wish to select values from these tables for specific exposure assessments.*

Comment: EPA should compare relevant studies conducted previously with more recent data to determine if the data actually show a change in time-activity patterns in subsequent years/decades.

Response: *A discussion about trends in activity patterns was added to the introduction of the chapter.*

Comment: Two reviewers recommended explaining the overlap in activity patterns to help avoid overestimating exposure. It would also be helpful to have more guidance about which studies are recommended.

Response: *Guidance on how to use the data from the Handbook, although useful, is outside the scope of this document. The use of the data is scenario specific.*

2.36. Chapter 17: Consumer Products

Comment: One reviewer said that the information provided in Chapter 17 is too general. Additional detail on the specific product type being included in each category should be presented. Also, additional product usage information such as location (e.g., indoors or outdoors) is important to know when estimating potential consumer exposure. Finally, the data should be presented by gender and age to account for the differences in consumer product use patterns.

Response: *U.S. EPA agrees that additional information on location, gender, and age would be useful, however, U.S. EPA is not aware of references that provide these breakouts systematically. U.S. EPA will consider suggestions for new references that contain such information in the next revision.*

Comment: One reviewer suggested reorganizing the chapter into sections and data tables by types of consumer product categories—cosmetics/personal care, cleaning products, and pesticides. As currently presented, it is difficult for the user to go through all the tables to decide which factors to use.

Response: *The chapter tables currently address product categories. A reorganization as proposed could be confusing for users interested in addressing multiple product categories.*

Comment: One reviewer was uncomfortable with the personal care product data being estimated by the company rather than from a participant survey. This is only mentioned in a footnote to a table, and it should be discussed in the text.

Response: *This information has been added to the text.*

Comment: Another reviewer said that some data are collected and released by consortia or trade organizations, and the data are limited.

Response: *This has been noted in the text.*

Comment: One reviewer said that the CTFA 1983 data are very old and unreliable. She questioned the rationale for even including the data in Chapter 17.

Several reviewers then discussed the use of older data in retrospective exposure assessments and the need for access to the older data. One reviewer said that older data could be obtained from previous versions of the EFH. Another said that there are "really old" data collected under FDA contracts that could be used to conduct a retrospective exposure assessment.

> ***Response:*** *The summary of the results of surveys of the amount and frequency of use of cosmetic products by women has not been updated since it was published in 1983, but it contains valuable frequency, duration, and amount data. U.S. EPA contacted CTFA to see if they have published anything new on the topic, but they only cited the Loretz et al., (2005, 2006, and 2008) papers already in the Handbook.*

Comment: The types of products are changing. An example is pesticide products for pets. There are no data on the top spot application … The addition of one pesticide study in Chapter 17 seems incomplete given the significant number of studies on pesticide use.

> ***Response:*** *Many studies conducted on pesticide usage lack the exposure frequency, duration, and amount data vital for inclusion in this chapter. U.S. EPA will consider suggestions for new references that contain such information in the next revision.*

Comment: A future research need would be to obtain cosmetic and personal care products information for children and teenagers.

> ***Response:*** *U.S. EPA agrees that further research regarding the use of cosmetic and personal care products by children and adolescents is warranted.*

Comment: In the discussion of the CTFA study in section 17.3.1, I think is important that it is noted that the mass of product used was estimated by the companies. This can be found as a footnote to Table 17-3, but there is no information on how the companies estimated these values or anything to give us any idea of the degree of confidence in these values.

> ***Response:*** *The text has been amended to note that values reported in Table 17-3 were provided by cosmetic companies, associations, or market research firms. The methodology used to develop these estimates could not be specified since it is not included in the source documents.*

Comment: Five new studies on cosmetic and personal care products (Weegels et al, 2001; Loretz et al 2005, 2006 and 2008; and Hall et al 2007), one on new household pesticide use (Bass et al 2001), and one on baby care products (Sathyanarayana et al 2008) were added to the consumer products chapter. These new data add strength to the information in this chapter. However, with the expansion of information, there is a need to better organize this chapter into sections and data tables by types of consumer product categories, i.e.,

cosmetics/personal care, cleaning products, paints, pesticides, etc… As presented some of the studies have use data on multiple product types and users would have to go through all tables to decide which factor to use. Also, the products included under the household maintenance products (table 17.1) cover a wide range of consumer products ranging from cleaning products to laundry detergents to fertilizers. This product category should be re-organized into several product categories.

> ***Response:*** *Data tables are organized by type of product for each individual study. U.S. EPA will consider suggestions for new references that contain such information in the next revision.*

Comment: For cosmetic/personal care products, the provided factors amount/frequency) are adequate for screening level exposure assessments (with default assumption of 100% retained/absorbed, etc…). For cleaning product scenarios, use amount, frequency and duration data are available from the Westat 1987 and Abt 1992 dataset allowing for screening level assessments.

> ***Response:*** *U.S. EPA agrees.*

Comment: Since there is no key study/data recommendation, it would be helpful to include an overall summary table of the studies indicating strength, limitations and relevance given the age of each study cited in this chapter. It is noted that some of the use rates in table 17-3 (based on CTFA 1983 survey) is lower than the use rates in the more current CTFA surveys (e.g., shampoo uses).

> ***Response:*** *Adding a confidence rating table would be inconsistent with the Handbook's definition of "key" studies. Data limitations are discussed within each study presented.*

Comment: This raises questions on the relevancy of the old CTFA data when assessing today's consumers' exposures.

> ***Response:*** *The text has been amended to note that the values reported in Table 17-3 were provided by cosmetic companies, associations, or market research firms. The methodology used to develop these estimates could not be specified because it is not known.*

Comment: Both amount use and frequency of use data are available from the Hall et al. and Loretz et al cosmetic/personal care data; mean and percentile estimates are also available and useful for exposure assessment. The older dataset (Westat 1987, Abt 1992, and EPA 1996) also provided useful percentile estimates. The baby care products dataset (Sathvanarayana et al 2008) is limited to % using and of limited utility.

> ***Response:*** *U.S. EPA agrees.*

Comment: For cosmetic and personal care products, there are no data for teenagers and children in the revised EFH. Also, the baby care data from Sathyanarayana et al (2008) are limited to % using and there is no information on amount/frequency use that are needed for a quantitative exposure assessment. Toothpaste/oral care, soap and detergent use data for the US population are not summarized in the revised EFH. Future research/update could consider these data gaps. The use data for cleaning products are also old and could be updated in the future.

> ***Response:*** *U.S. EPA could consider suggestions for new references that contain such information in the next revision.*

Comment: On p. 17, section 17-1 mentions 2 information sources on consumer products (Household Products Database and the Source Ranking Database) but recognizes that they do not provide exposure factors information. While these may be useful resources, it is unclear why they are included in the Exposure Factors Handbook.

> ***Response:*** *The paragraphs discussing these two references have been deleted.*

Comment: Much of the information in this chapter is summarized in a general manner. Additional detail on the specific product types that are included in each category should be presented within the document. This type of information is needed to enable the data to be applied appropriately. For example, in Table 17-4, it is unclear which products fall under the category water repellants/protectors, which may include liquids or sprays. It is likely that use amounts and patterns differ for each. Also, the WESTAT 1987a document contains additional useful information as to where product usage occurs (indoors or outdoors, garage, etc.) and if ventilation is used. This information is very important to estimating potential consumer exposure, in conjunction with the use amount, duration, and frequency. If possible, re-analysis that evaluated the potential relationship between use amount, location, and ventilation would be very valuable.

> ***Response:*** *The report did not appear to define "water repellants" so its use probably differed among respondents. The type of information suggested by the reviewer would be more appropriate for a future update of U.S. EPA's Sociodemographic Data Used for Identifying Potentially Highly Exposed Populations [U.S. EPA (1999)].*

Comment: Consumer product use patterns vary based upon age, gender, and multiple other factors. Therefore, the study population should be clearly described for each table included in this chapter (for ex. NHAPS is a US National study, Bass was 107 households with children in Arizona, etc.). On p. 17-6, additional information should be provided as to the population of the Weegels and van Veen (2001) study (in what geographic region was this done?).

Response: *To the extent that this information is provided in the studies, it was included in the study summaries in the Handbook. The study population in the Weegels and van Veen (2001) study was added.*

Comment: Other sources of information not mentioned include:

- the European Commission's Joint Research Center EIS-Chemrisks website http://web.jrc.ec.europa.eu/esi-chemrisks/
- RIVM (National Institute for Public Health and the Environment, the Netherlands) Fact Sheets http://www.rivm.nl/en/healthanddisease/productsafety/ConsExpo.jsp#tcm:13-42823
- Human and Environmental Risk Assessment on Ingredients of Household Cleaning Products Guidance Document Methodology include information on EU consumer habits and practices: http://www.heraproject.com/files/HERA%20TGD%20February%2020005.pdf

Response: *U.S. EPA is open to the suggestion of any specific exposure factor data (e.g., frequency, duration, amount). However, it is not clear what information is being suggested in these sources. Also, some of the links provided are no longer functioning.*

Comment: Additional references suggested by peer reviewers:

- Adgate J.L., Kukowski A., Stroebel C., Shubat P.J., Morrell S., Quackenboss J.J., Whitmore R.W., and Sexton K. Pesticide storage and use patterns in Minnesota households with children. *J Expo Anal Env Epid* 2000: 10(2): 159−167
- Davis J.R., Brownson R.C., and Garcia R. Family Pesticide Use in the Home, Garden, Orchard, and Yard. *Arch Environ Con Tox* 1992: 22(3): 260−266.
- Flint M.L. Residential Pesticide Use in California: A Report of Surveys taken in the Sacramento (Arcade Creek), Stockton (Five-Mile Slough) and San Francisco Bay Areas with Comparisons to the San Diego Creek Watershed of Orange County, California. *University of California Statewide IPM Program* 2003: CA DPR contract 01-0219C.
- Savage E.P., Keefe T.J., Wheeler H.W., Mounce L., Helwic L., Applehans F., Goes E., Goes T., Mihlan G., Rench J., and Taylor D.K. Household Pesticide Usage in the United-States. *Arch Environ Health* 1981: 36(6): 304−309.
- van der Jagt K.E. Residential exposure should be considered in appropriate terms - Summary of discussions. *Ann Occup Hyg* 2001: 45: S167−S170.
- Whitmore R.W., Immerman F.W., Camann D.E., Bond A.E., Lewis R.G., and Schaum J.L. Non-Occupational Exposures to Pesticides for Residents of 2 US Cities. *Arch* Environ *Con Tox* 1994: 26(1): 47−59.

Response: *All these references were reviewed, but they do not contain adequately detailed product exposure frequency, duration, and/or mass data.*

2.37. Chapter 18: Lifetime

Comment: One reviewer said that it might be useful to describe population characteristics that impact an exposure evaluation, such as population mobility. He specifically mentioned incorporating information on immigration and military service. Another reviewer said that stage in life is another function of mobility. One reviewer said that if this kind of information is included in Chapter 18, the title should be changed. One reviewer commented that Chapter 18 could be useful for assessing carcinogenic risk. He recommends adding the following information to the chapter:

- Information about lifetime radiation exposures (e.g., radon) and the methods used to obtain such estimates.
- Methods to incorporate long-term exposures using activity patterns, including specific occupational tenures and mobility found in Chapter 16.
- Methods for extending short-term to long-term exposures.

Response: *U.S. EPA agrees that there are many important factors that affect life expectancy, and the leveling off of life expectancy increases is important. The purpose of the Lifetime chapter, however, is to address life expectancy itself, not the factors that impact it or to explain why increases in life expectancy have leveled off. Some factors raised by reviewers, such as activity patterns, are already addressed elsewhere in the Handbook.*

Other factors raised by reviewers, such as radiation exposures, smoking, and population mobility, and how life expectancy varies with these factors may be of interest, but data on life expectancy stratified by these factors could not be located. The following reports were found in the literature, but did not contain "relevant" information.

- *Pleis JR, Lucas JW, Ward BW. Summary health statistics for U.S. adults: National Health Interview Survey, 2008. National Center for Health Statistics. Vital Health Stat 10(242). 2009.—This report only contained information on frequency of selected diseases in the in U.S. population. The report does not contain information on life expectancy.*

- *U.S. National Research Council. Health risks from exposure to low levels of ionizing radiation: BEIR VII, Phase 2. Washington, DC: National Academies Press. 2006.—This report only contains information on health effects of radiation exposure and not life expectancy.*

Comment: Provide an explanation for how EPA's Integrated Risk Information System (IRIS) calculates the cancer slope factor such that the relationship to lifetime can be established.

Response: *The requested text is beyond the scope of the Handbook. However, an appendix to Chapter 1 containing discussions about exposure factors and using information from IRIS has been added and references to IRIS provided.*

Comment: Variance is not presented for Chapter 18. This should be explained.

Response: *The available literature published on variance in life expectancy is limited. Oosse (2003) published some analysis of variance based upon a literature review. She reported variance over time by region, providing coefficients of variation by region and state, but not within state/region estimates of life expectancy. Interquartile ranges typically varied by no more than 1 year between males and females born in 1960, 1970, 1980, and 1990. Thus, the paper did not seem to provide variance data that would be useful to an exposure assessment.*

Oosse, Monique. Variations in state mortality from 1960 to 1990. U.S. Census Bureau. Population Division Working Paper Series No. 49. May 2003.

Comment: Because there is variability for races in this set of exposure factors, it would be useful to have data presented for Latinos, given the rapid growth of this group.

Response: *It would be useful to present similar data for Latinos as blacks and whites. Unfortunately, the source for Table 18-3, Xu et al., 2010 does not present these detailed data for Latinos. Life expectancy data for Latinos in a more limited form has been added to the Handbook based upon census data at http://www.census.gov/population/www/projections/methodstatement.html.*

Comment: Smoking or exposure to environmental tobacco smoke is a major factor that affects longevity. Should this information be provided in the EFH? At least provide a reference to where the user can obtain pertinent information.

Response: *Life expectancy information for individuals who smoke or have existing health conditions or diseases could not be easily located in the literature. The life insurance industry may collect this type of information, but it is likely to be proprietary data. More targeted efforts to locate such data can be further explored in future revisions.*

Comment: The insurance industry could be a good source for life expectancy data.

Response: *U.S. EPA agrees that the insurance industry may be a good source of data, but it is likely to have proprietary information. U.S. EPA conducted a limited search on this topic, and it revealed that the insurance industry relies heavily on the data from the U.S. Census, supplemented by their own data collection. Further research in this area will require additional resources.*

Comment: Longevity varies between the northern and southern states.

Response: *Life expectancy varies by many factors such as geographic area (country, region, urban versus rural), occupation, education, income, and diet. Unfortunately, the U.S. Census does not stratify the data by state. A report was recently published (June 15, 2011) that contains life expectancy by state. However, the data are presented for each individual county within each state. It is unlikely that an exposure assessment will require this level of detail. Some effort will be required to aggregate the county data and estimate a state value for all counties combined. This can be further explored in future revisions.*

Sandeep C Kulkarni, Alison Levin-Rector, Majid Ezzati, Christopher JL Murray. 2011. Falling behind: life expectancy in U.S. counties from 2000 to 2007 in an international context. Population Health Metrics 2011, 9:16

Comment: In the last paragraph of section 18.2, the document discusses the fact that IRIS does not use a 70 year lifetime in the calculation of the cancer slope factors. There should be a statement explaining how IRIS calculates the slope factors to provide clarity to the reader.

Response: *The requested paragraph is beyond the scope of the Handbook. Some discussion about toxicity values from IRIS and exposure factors is provided in appendix 1A.*

Comment: Page 18-1, Paragraph 4. Why is 70 used for U.S EPA risk assessment? Is this based on old data? And if this is the case, how does the user integrate the toxicity data based on 70 years, with exposure data now based on 78 year averages for lifetime.

Response: *Cancer slope factors, typically based on a 2-year rodent study, are assumed to approximately reflect the extra cancer risk from a lifetime exposure of the rodent. In physiological terms, the risk associated with the two years of adult rodent exposure is assumed to approximate that of a human. However, the cancer slope factors derived from rodent bioassays are independent of any finely tuned value assumed for a human lifetime. The use of 70 year continues to be a methodological choice due to the fact that there is no evidence to suggest that cancer risk per year of exposure has decreased due to an increased life expectancy that largely is due to reduced mortality from noncancer causes of death such as cardiac disease.*

Therefore, no adjustments to slope factors are necessary due to increased life expectancy at birth. Risk estimation will continue to use 70 years as the averaging lifetime for purposes of calculating a "lifetime average daily dose" to be used with cancer slope factors to estimate potential human cancer risk.

Comment: Table 18-2. Do you know if this ACS publication considers obesity trends and its effects on longevity into the projections for 2020?

Response: *Reference to the ACS publication was deleted because it did not contain information on life expectancy. All the information and tables on life expectancy were obtained from Xu et al., (2010) and the U.S. Census Bureau*
http://www.census.gov/population/www/projections/methodstatement.html
There is no discussion about obesity or any other health status and how they may affect longevity on the referenced web site.

Comment: Table 18-3. EPA may want to highlight how expectation of Life at Birth has increased from 1970 to 2005, but some leveling has occurred from 2000 to 2005. What is this due to? Is there just a limitation to how much we can extend life through medical treatment/advances or are we beginning to see the effects of obesity and even stress aspects in our communities?

Response: *The references used in this chapter do not discuss this type of trend analysis. It is beyond the scope of the Handbook to conduct this analysis.*

Comment: Page 18-4, Paragraph. EPA could add a comment on how the data in Table 18-19 is derived. Is it simply the life expectancy minus a particular age?

Response: *Additional language was added describing the methodology. It is not simply life expectancy at birth minus current age.*

Comment: This is one chapter or set of exposure factors that we do see variability for races (i.e., black and white) and sexes. It is a pity that the Latino community is not represented in this exposure factor. Many states (e.g., Florida and California) have a sizable Latino community (this will continue to grow rapidly, also in other states). Hopefully, the U.S., National Center for Health Statistics will collect this data going forward. EPA should however look for another source of data.

Response: *A report was recently published (June 15, 2011) that contains state-specific data. Some effort will be required to conduct further analysis of these data. It would be useful to present the same data for Latinos as blacks and whites. Unfortunately, the source for Table 18-3, Xu et al., (2010) does not present these detailed data for Latinos. Life expectancy data for Latinos in a more limited form has been added to the Handbook*

based upon census data at
http://www.census.gov/population/www/projections/methodstatement.html

Comment: Section 18.1. 2nd sentence: This statement is mathematically incorrect. Hence, the sentence is not true and should be deleted. For example, suppose the weighted average lifetime dose = d_o over a lifetime of L_o years. Now, suppose the lifetime is extended by an additional L_e years and the weighted average dose during the extended period is d_e. Therefore, the weighted average lifetime dose (d) over ($L_o + L_e$) years is

$$d = (d_o L_o + d_e L_e)/(L_o + L_e)$$

Hence, $d \geq d_o$ when:

$$(d_o L_o + d_e L_e)/(L_o + L_e) \geq d_o$$

$$(d_o L_o + d_e L_e) \geq d_o (L_o + L_e)$$

$$d_e L_e \geq d_o L_e$$

$$d_e \geq d_o .$$

That is, the weighted average dose over the longer lifetime will be ≥ the average dose over the shorter lifetime when the average dose during the extended period (d_e) is greater than the average dose during the shorter lifetime (d_o).

Conversely, $d \leq d_o$ when $d_e \leq d_o$.

Response: *The sentence has been deleted.*

Comment: This is an adequate Chapter and useful for risk assessors for carcinogenic risk. In such applications, the research into radiation exposures, such as that for radon, would be a useful addition to indicate how exposure and risk assessment could be performed for lifetime exposures. It would be useful for exposure assessment, and thus for risk assessment, of non-carcinogenic agents if it included methods to incorporate long-term exposures to such agents, including indoor, ambient and occupational exposures. Such methods could incorporate activity patterns, including specific occupational tenures and mobility found in Chapter 16. Estimates of lifetime exposures have been performed in various studies, including those in the radon studies, and in the Adventist Cohorts (cf., Abbey's group's work) for non-carcinogenic agents. Exposure estimates for long-term occupational exposures have been conducted and/or reviewed by NIOSH for several agents of interest to EPA, and less detailed exposure-response relationships in the general population have been conducted by several, including the author (Environ Res. 14:56−67, 1977). Methods have been evaluated as well for extending short-term to long-term exposures and these reports in the literature should be explored.

Response: *U. S. EPA agrees that the collection of information on how life expectancy varies in relation to specific exposures or health status would be useful. An NRC report was found on "exposures" to ionizing radiation, but it does not contain information on life expectancy, only health effects and risks.*

U.S. National Research Council. Health risks from exposure to low levels of ionizing radiation: BEIR VII, Phase 2. Washington, DC: National Academies Press. 2006.

2.38. Chapter 19: Residential Building Characteristics

Comment: Several reviewers thought that Chapter 19 needed a lot more updating. They suggested adding several additional parameters. The loss of outdoor particles as they move through the building shell or losses from infiltration should be added to the deposition and filtration section. This is critical for evaluating the impact of outdoor particles on indoor levels.

Response: *Text has been added to describe the general mechanisms by which outdoor particles infiltrate a building's shell and enter indoor environments.*

Comment: Air exchange between different rooms or regions within a building should be discussed. For example, an attached garage will have different sources of air contamination.

Response: *A discussion of air exchange between dwelling area and attached garage and within apartment buildings has been added.*

Comment: There should be some discussion of multi-unit dwellings and the fact that air can flow from one unit to another, thereby transferring pollutant sources from one unit to another. One reviewer replied that there is a residential appliance study conducted by the California Energy Commission that would provide a lot of relevant information, such as year built, number of bedrooms, etc.

Response: *A discussion of air exchange in multiunit buildings was added to the section on residential exchanges rates as well as a new section on nonresidential building exchange rates.*

Comment: The chapter also should present summary information on the distribution of house sizes, sample volumes, ages, and materials.

Response: *This information is already in the chapter.*

Comment: The issue of embedded dust (i.e., dust not easily removed with a conventional vacuum cleaner) should be mentioned, as it provides a reservoir for organic compounds.

Response: *A brief discussion about embedded dust has been added to the section on House Dust and Soil Loadings.*

Comment: A key pathway for consideration is vapor intrusion (i.e., factors on how soil gas enters buildings). There should be reference to other guidance being developed by EPA on this issue.

Response: *U.S. EPA is aware that vapor intrusion is a topic discussed in the current literature. Unfortunately, none of the 113 references suggested by peer reviewers appeared to address vapor intrusion or soil gas specifically. U.S. EPA will consider adding this topic in a future revision of the Handbook where appropriate.*

Comment: The chapter presents a small subsection of possible indoor settings. There are many other areas where people spend time indoors (e.g., school, mall, movie theater).

Response: *This topic is addressed in Chapter 16—Activity Factors and by the addition of data on nonresidential buildings.*

Comment: It would be useful to include information about ventilation (whether the windows are open or closed) in the tables with air exchange rates.

Response: *While it would be helpful if air exchange rate tables contained information about ventilation, this would be difficult to abstract from the hundreds of buildings and measurements captured by the studies in the Handbook.*

Comment: Two reviewers commented on the currency of the data. One found it striking that only eight of the references were published after 1996. The other said that even the newer references were updates to continuing studies. Several reviewers said that there are many more references that should be included in the chapter. One reviewer specifically mentioned including more recently collected data on air exchange rates and particle deposition. Another specifically mentioned studies that can be included in the resuspension section.

Response: *With regard to the currency of the data, if a new reference is found that is strong and provides data in the format needed for an exposure assessment, the old reference would be replaced or moved to the "relevant" section. However, at this time, even the oldest references offer useful data to the building characteristics section, and so they have been retained. With regard to adding information, several new entries and tables have been added to the revised Handbook including a new deposition rate table. No new data on air exchange rates or resuspension were found. Specific suggestions for new sections, or tables, to add or replace existing data could be considered for future updates.*

Comment: It is not clear why air deposition is included in Chapter 19.

Response: *Air deposition is "relevant" to air transport studies in general. It seemed best to include it with building characteristics, rather than place it in another chapter or make air transport studies its own chapter.*

Comment: The basis for the assumption of an 8-foot ceiling height should be discussed.

Response: *The basis was added to the text as well as a note about the conclusion by Murray (1996) that, based upon his sensitivity analysis, the effect of the 8 ft ceiling height assumption is insignificant.*

Comment: Two reviewers mentioned including a diagram of building characteristics.

Response: *A diagram might be useful. The U.S. EPA would consider developing diagrams in future revisions.*

Comment: Two reviewers commented that Chapter 19 has high variability in the housing volume data and high uncertainty in the air exchange rates due to methodological issues.

Response: *U.S. EPA agrees. When future studies with low uncertainty become available, it is likely they would replace studies with high uncertainty in future revisions.*

Comment: The chapter identifies models that can be used to evaluate the microenvironment. However, there are <u>many more approaches, formulations, and models that should at least be</u> <u>mentioned</u> [emphasis add].

Response: *The chapter was updated with new references provided by the peer reviewers. One of the references provided on models is not published in the peer-review literature and, therefore, could not be included at this time.*

Comment: Central air use varies regionally.

Response: *Central air heating and cooling does vary regionally. New text and tables have been added with regard to regional differences in cooling and heating.*

Comment: Several reviewers discussed options for this chapter. All felt that the draft was not ready for release but that the information was important and should be included in some form. They offered several different options for how EPA could proceed, but all felt that the re-working of Chapter 19 should not delay the release of the EFH.

- Present the data in a way that will allow the exposure assessor to relate the factors to a specific population, geographic area, or temperature.

- Release Chapter 19 as a general chapter that introduces the context for residential exposures. It could even reference where to find additional information. Then release a different document that goes into more detail on each of the parameters or release an update to this chapter at a later date. If a separate document is released, it might be useful to have it provide more contaminant-specific information.
- Seeing that the EFH is supposed to present values, if the chapter cannot supply useful, reasonable, accurate values, then it might be best to remove it altogether.
- Because many of the newer references are just updates to the continuing studies, perhaps the 1997 version of Chapter 19 should be included as a placeholder so that people are not misled into think that new information is being presented.
- A placeholder "glossary" could be included that describes what indoor factors need to be explored. This way, risk assessors would know what is important to consider without providing misleading values.
- Keep the chapter in draft form and replace it with a "General Building Characteristics" chapter years from now, after it has been peer reviewed.
- One reviewer commented that any substantial revisions to the draft chapter should be peer reviewed by at least a small committee.

Response: *U.S. EPA agrees that the Building Chapter would benefit from an extensive updating. The chapter has been revised in accordance with the major comments received in this round. The chapter has been expanded to include commercial buildings. .*

Response: Comment: *I would like to describe one publicly available data source that may be useful, i.e., the California Statewide Residential Appliance Saturation Study (RASS) (CEC, 2004) may be a useful. The RASS may be a Relevant study to include data in future revisions to the EFH. The RASS was initiated in 2002 and surveyed nearly 22,000 respondents/households. I would not recommend it as a Key study because it is not representative of the US population and the low survey response rate (19% vs the expected 47% to the initial mail-solicitation; a non-response follow-up study conducted by telephone had a response rate of roughly 45%). Additionally, the selection of households was weighted to the population represented by the sponsoring utilities.*

The RASS database includes linked data on the following residential and household characteristics that may be useful to describe and incorporate in Chap 16 (Activity factors), 17 (Consumer products), and 19 (Residential Building Characteristics) of future EFH revisions.

- Type of building (Single family detached home and number of stories, Townhouse/Duplex/row house, apartment or condominium (2−4 units), apartment or condominium (5+ units), mobile home, and other)

- Year residence built
- Bedrooms in home
- Square feet of living space (including bathrooms, foyers, and hallways)
- Whether exterior walls are insulated
- Whether home's attic/ceiling insulated
- Presence of Double and/or single pane windows
- Household occupancy and age of household occupants
- Whether natural gas line or hook-up to any part of home
- Type of heating system used in home
- Presence of pilot light if natural gas used for fuel,
- Type of fuel used for cooking appliances (cooktops/stovetops/range, or oven, or outdoor barbeque) and age of appliance
- Additionally, the following Household information is included for each household/residence in RASS, including:

    - Highest level of education by any head of household
    - Primary language spoken in home
    - Any occupants that are permanently disabled
    - Ethnic groups represented by head of household
    - Household's total annual income

Response: *While the RASS database does provide an excellent source of building information for California, the U.S. EPA agrees that it is not representative of the United States. In addition, the information provided may be more suitable for a future update of U.S. EPA's Sociodemographic Data Used for Identifying Potentially Highly Exposed Populations [U.S. EPA (1999)]. Therefore, it was not included.*

Comment: There are no explicitly "Key" studies, only four recommended studies for characterizing the volume of residence and four studies describing the air exchange rate. Are these "Key" Studies? If they are, then they should be referred to as such in future revisions of the EFH.

Response: *The chapter has been revised to identify "key" studies.*

Comment: The recommended value for House volume is provided by the 2005 RECS survey data (US DOE, 2005), and the recommended central estimate value for housing volume was based on the 2007 American Housing Survey (US BoC, 2008). But the PFT database (Versar, 1990) contains potentially outdated (1982−1987) measurements, and there has been an increase in housing volume since the data were collected, so the "currency" of the PFT database is questionable. Fortunately, the "Applicability and Utility" GAF takes this into account, and a "Medium" rating is provided. Also, please include under "Currency" that data from the 2007 American Housing Survey was used. Additionally, in Table 19-2, associated with the "Uncertainty" GAF for "House Volume", the Rationale states: "Some measurement error may exist since surface

areas were estimated using the assumption of 8 ft. ceiling height" but, this appears to contradict the Rationale under the "Adequacy of Approach" that states :

"For the RECS survey, volumes were estimated assuming an 8 ft ceiling height. The effect of this assumption has been tested by Murray (1996) and found to be insignificant."

Therefore, I suggest changing the Rating for the "Variability and Uncertainty" GAF to High.

> ***Response:*** *Despite the finding by Murray that the effect of the 8 foot residential ceiling assumption is insignificant, there are other limitations with the data. U.S. EPA, therefore, changed the rating for variability and uncertainty from "low" to "medium." For nonresidential buildings, U.S. EPA classified the uncertainty as "low" because of large variations in ceiling height between building types.*

Comment: In Table 19-3: I believe that the confidence rating for the "Soundness" and "Applicability and Utility" GAFs on the Air Exchange Recommendations should be "Low". The reasons for this are as follows:

1) The "Adequacy of the Approach" had major limitations (uniform mixing assumption) and the residences were not selected at random.
2) The residences in the PFT were not representative of residences in the US and included homes that were not randomly selected.
3) The measurement in the PFT database were taken over 20 years ago and only short term data were collected

> ***Response:*** *The table has been changed accordingly.*

Comment: Additionally, in Table 19-3: The "Rationale" associated with the "Variability in Population" GAF should be moved to the "Rationale" associated with the "Representativeness" GAF, i.e., append "because some of the sample sizes for the subcategories were small and not representative of the US, the utility is limited" to "Representativeness" rationale, and restate the Rationale for "Variability in the Population" to: "Distributions are presented by US Census Regions, seasons, and climatic regions, but some of the sample sizes for the subcategories were small."

> ***Response:*** *The table has been changed accordingly.*

Comment: Also, In Table 19-3, I suggest including the following as part of the "Rationale" for characterizing the Uncertainty GAF: "Some measurement error may exist. Additionally, PFT has been found to underpredict seasonal average air exchange by 20 to 30 percent (Sherman, 1989)."

> ***Response:*** *The table has been changed accordingly.*

Comment: Lastly, in terms of presentation, I suggest moving Section 19.3.1.4 US Census Bureau, 2008—AHS for the US 2007 as Section 19.3.1.1 instead. The AHS is the most current study and the basis for the recommended volume of residences (in Table 19-1). Additionally, move Section 19.3.1.3US DOE, 2005—RECS description second (as Section 19.3.1.2) because it is the second most current study, and also because the Murray (1996) study (currently Section 19.3.1.2) reference the RECS study.

> ***Response:*** *Such a change would be inconsistent with established Handbook norms which include discussing studies in chronological order rather than reverse chronological order.*

Comment: It would seem that information on schools and day care indoor environments would be a good addition to the residential environment. I don't know where such data exists, but it may be available and if not it might be able to add to other data collection instruments.

> ***Response:*** *U.S. EPA agrees that a new subsection on nonresidential building characteristics would be beneficial to the Handbook, so one has been added to the 2011 revision. The data source is DOE's Commercial Buildings Energy Consumption Survey (CBECS), which provides info on building size, purpose, age, heating, and cooling for a wide range of building types including schools, offices, churches, warehouses, and hotels. It does not, however, address building substructure or materials.*

Comment: There are a number of areas where the Handbook could benefit from additional parameters. I have grouped the comments into general subject areas.

Air Flow within Compartments of Buildings

It should be specified throughout the chapter which factors are related to single family homes. There should be some discussion on multi-unit dwellings and the fact that air can flow from one unit to another, thereby transferring pollutant sources from one unit to another. Sax *et al.* suggested concentrations of some VOCs within apartment units unaccounted for by known activities within the apartment are from pathways within the building (Sax, *et al.*, 2004). Diamond and colleagues reviewed several apartment building ventilation studies, which showed that air flow between apartment units via the common apartment hallway may be substantial but that these rates tend to be fairly specific to building type, occupant behaviors, unit location, and meteorological conditions (Diamond R.C., *et al.*, 1996). Dodson and collected limited measurements (Dodson 2008). Data on this phenomena are limited and therefore specific factors are unlikely to be able to be recommended, but it would still be worthwhile to include a discussion.

Diamond, R. C., et al. 1996. Ventilation and infiltration in high-rise apartment buildings. Lawrence Berkeley Laboratory. Berkeley

Dodson, R. E., Levy, J. I., Shine, J. P., Spengler, J. D. and Bennett, D. H., 2007. Multi-zonal air flow rates in residences in Boston, Massachusetts. Atmospheric Environment 41, 3722−3727.

Sax, S. N., Bennett, D. H., Chillrud, S. N., Kinney, P. L. and Spengler, J. D., 2004. Differences in source emission rates of volatile organic compounds in inner-city residences of New York City and Los Angeles. J Expo Anal Environ Epidemiol 14 Suppl 1, S95−109.

Response: *A summary of the conclusions presented by Diamond et al., (1996) was added to the text. Sax et al., (2004) provides chemical-specific data, which is outside the scope of the Handbook. The other reference was reviewed, but was not included because of the limited number of houses included in the study and the limited amount of monitoring time which make it difficult to make generalizations.*

Comment: When discussing air flows through a home, air flows from the garage to the home need to be included. In addition to automobiles, people often store gasoline, oil, paints, lacquers, and yard and garden supplies in garages, which can be a source of VOCs such as benzene, toluene, ethylbenzene, m,p-xylene and o-xylene (BTEX), both from evaporative emissions and start-up/shut-down emissions (Batterman, et al., 2006a). As a result, some studies have found elevated indoor VOC concentrations in residences with attached garages compared to those without attached garages. (Adgate, et al., 2004, Gordon, et al., 1999, Graham, et al., 1999, Lansari, et al., 1996, Thomas, et al., 1993, Wallace, 1991). For example, available studies estimated that over 50% of benzene concentrations in a home may be attributable to the garage (Dodson et al. 2008, Batterman, et al., 2007, Furtaw, et al., 1993, Noseworthy and Graham, 1999). Air flow rates between a garage and a residence have been reviewed (Emmerich S., et al., 2004) and estimated in several studies (Dodson et al 2007, Batterman S., et al., 2006b, Batterman S., et al., 2006 Batterman S., et al., 2006, Graham L., et al., 1999, Graham L., et al., 2004,Tsai and Weisel 2000, Isbell M.A., et al., 2005). While there have not been any large scale studies, there have been quite a few smaller studies such that the EPA may be able to produce a recommended value.

Adgate, J. L., Church, T. R., Ryan, A. D., Ramachandran, G., Fredrickson, A. L., Stock, T. H., Morandi, M. T. and Sexton, K., 2004. Outdoor, indoor, and personal exposure to VOCs in children. Environ Health Perspect 112, 1386−92.

Batterman, S., Hatzvasilis, G. and Jia, C. R., 2006a. Concentrations and emissions of gasoline and other vapors from residential vehicle garages. Atmospheric Environment 40, 1828−1844.

Batterman, S., Jia, C. R., Hatzivasilis, G. and Godwin, C., 2006b. Simultaneous measurement of ventilation using tracer gas techniques and VOC concentrations in homes, garages and vehicles. Journal of Environmental Monitoring 8, 249−256.

Batterman, S., Jia, C. R. and Hatzivasilis, G., 2007. Migration of volatile organic compounds from attached garages to residences: A major exposure source. Environmental Research 104, 224−240.

Dodson RE, Levy JI, Shine JP, Spengler JD, Bennett DH. Multi-zonal Air Flow Rates in Residences in Boston, Massachusetts. Atmos Environ, 2007; 41 (17): 3722−3727.

Dodson, R.E., J.I. Levy, J.D. Spengler, J.P. Shine, and D.H. Bennett. Influence of Basements, Garages, and Common Hallways on Indoor Residential Volatile Organic Compound Concentrations. Atmospheric Environment. 2008, 42(7):1569−1581.

Emmerich, S., et al. 2004. Air and pollutant transport from attached garages to residential living spaces - literature review and field tests. International Journal of Ventilation. 2. 265−276

Gordon, S., Callahan, P., Nishioka, M., Brinkman, M., O'Rourke, M., Lebowitz, M. and Moschandreas, D., 1999. Residential environmental measures in the National Human Exposure Assessment Survey (NHEXAS) pilot study in Arizona: preliminary results for pesticides and VOCs. Journal of Exposure Analysis and Environmental Epidemiology 9, 456−470.

Graham, L., O'Leary, K. and Noseworthy, L. 1999. Indoor air sampling for infiltration of vehicle emissions to the house from the attached garage. Environment Canada. ERMD Report #99−26768−2

Graham, L. A., Noseworthy, L., Fugler, D., O'Leary, K., Karman, D. and Grande, C., 2004. Contribution of vehicle emissions from an attached garage to residential indoor air pollution levels. Journal of the Air & Waste Management Association 54, 563−584.

Isbell, M. A., Stolzberg, R. J. and Duffy, L. K., 2005. Indoor climate in interior Alaska: simultaneous measurement of ventilation, benzene and toluene in residential indoor air of two homes. Science of the Total Environment 345, 31−40.

Lansari, A., Streicher, J. J., Huber, A. H., Crescenti, G. H., Zweidinger, R. B., Duncan, J. W., Weisel, C. P. and Burton, R. M., 1996. Dispersion of automotive alternative fuel vapors within a residence and its attached garage. Indoor Air-International Journal of Indoor Air Quality and Climate 6, 118−126.

Noseworthy, L. and Graham, L. 1999. Chemical mass balance analysis of vehicle emissions in residential houses from attached garages. Environment Canada. ERMD Report #99−26768−3

Thomas, K. W., Pellizzari, E. D., Clayton, C. A., Perritt, R. L., Dietz, R. N., Goodrich, R. W., Nelson, W. C. and Wallace, L. A., 1993. Temporal variability of benzene exposures for residents in several New-Jersey homes with attached garages or tobacco-smoke. Journal of Exposure Analysis and Environmental Epidemiology 3, 49−73.

Tsai, P. Y. and Weisel, C. P., 2000. Penetration of evaporative emissions into a home from an M85-fueled vehicle parked in an attached garage. Journal of the Air & Waste Management Association V50, 371−377.

Wallace, L. A., 1991. Comparison of risks from outdoor and indoor exposure to toxic chemicals. Environmental Health Perspectives V95, 7−13.

Response: *Text has been added to address the issue of attached garages on indoor air quality. General findings from Emmerich (2004) were added, as well data from Graham's 2004 study of 16 homes with attached garages. These other references were reviewed, but were not included because they were either chemical-specific data, which is outside the scope of Handbook, or the information had limited applicability.*

Comment: When discussing air flows within a home, the manuscript states that most homes have some kind of central heating and air conditioning system. I think that there should be a note that this does vary regionally, with many of the older cities not have central heating that transfers air, but rather radiant heating. For example, central heat is very uncommon in many parts of the northeast.

Response: *Text and three tables have been added using RECS data to show the types of heating and cooling used by U.S. residences and how they vary regionally and by urban/rural location.*

Comment: In the deposition and filtration section, there is no mention of the loss of outdoor particles as they move through the building shell, or losses from infiltration. This is critical for evaluating the impact of outdoor particles on indoor levels. The document states at the end of section 19.4.5 that particles smaller than 10 µm can penetrate the building shell. Numerous studies have shown losses through the building shell. Particles of outdoor origin enter the home through purposeful openings such as doors and windows, as well as cracks and crevices in the building envelope. As particles travel through the cracks, they can be removed by impaction, diffusion, or interception mechanisms. The penetration efficiency (P), the fraction of particles of a specific diameter that pass through the building envelope, is dependent on the number and geometry of the cracks as well as the velocity of the air passing through the cracks, which is a function of the air exchange rate (Liu and Nazaroff 2001, 2003). The roughness and shape of the crack are also influential (Jeng et al. 2006, 2007, Tian 2008). It is expected that particle loses vary by home, due to differences in home characteristics, suggesting the need for taking measurements on a wide range of homes. Particle losses also vary temporally due to changes in air exchange rates, wind velocities, relative humidity, and temperature differences, suggesting the need for modeling results dynamically and understanding the impact of these factors. The penetration efficiency also depends on the particle size, with lower efficiencies for small particle sizes (<0.1 µm) due to Brownian deposition and for larger particles (>1.5 µm) due to impaction, interception and gravitational loses. Therefore, the different particle size fractions of the regulated fine and coarse particle mass are not expected to exhibit the same penetration factors.

Once in the home, particles are deposited onto indoor surfaces [deposition rate (k)]. Again, this process is strongly influenced by particle size. The deposition

rates have been found to vary between homes due in part to differences in air flow velocities within the home, the quantity and surface of furnishings in the home, the interior surface-to-volume ratio, and the difference in temperature differential between the air and surfaces and particle roughness (Lai and Nazaroff 2000; Thatcher, Lai, Moreno-Jackson et al. 2002, Lai 2006).

Due to penetration and deposition losses indoors, particle concentrations are lower relative to outdoor concentrations in the absence of indoor sources. The infiltration factor (F_{inf}) has been defined as the fraction of outdoor particles that penetrate indoors and remain suspended (Wilson and Suh 1997; Wilson, Mage and Grant 2000). Therefore, determining infiltration efficiency and understanding its relationship to the different parameters such as home characteristics, air exchange rates, temperature, etc. is very important in our efforts to assess individual and population exposures to particles of outdoor origin. Studies have also determined this factor by determining the indoor outdoor ratio of particles of outdoor origin (Meng et al. 2007).

For long time periods, e.g., a few hours, with reasonably constant outdoor concentrations and air exchange rates, in the absence of indoor sources, the infiltration factor can be determined using a steady state model and is defined as the ratio of the indoor to outdoor concentrations. Several studies have determined infiltration ratios during periods when contributions of indoor sources are negligible (e.g., night-time periods). During these periods, infiltration factors were determined for various size fractions using regression techniques assuming steady state conditions (Abt, Suh, Catalano et al. 2000; Long, Suh, Catalano et al. 2001). The assumption of steady state neglects changes in outdoor concentrations and air exchange with time. Furthermore, infiltration ratios were determined using a random component superposition model (Ott, Wallace and Mage 2000). According to this approach the infiltration ratio equals the slope of the regression of indoor on outdoor concentrations, again neglecting the impact of temporal changes. The authors suggest that over long time periods the average infiltration rate is the same for all homes (Wallace, Mitchekk, O'Connor et al. 2003).

Studies have also calculated P and k values separately, in some cases by controlling environmental conditions such as particle levels and ventilation conditions. For example, penetration and deposition rates were determined for 6 homes in Hong Kong by raising indoor particle concentrations, which was achieved by opening windows and doors (Chao, Wan and Cheng 2003). Subsequently, the windows and doors were closed and the decay of particles indoors was measured. Thatcher et al. (Thatcher, Lunden, Revzan et al. 2003) determined P and k values in two test homes in California using a dynamic model. For these tests, particle concentrations were uniformly raised throughout the home, and then were allowed to decline to determine k. It is important to note that they were able to bring achieve well mixed conditions prior to determining k, as reductions in particle concentration from mixing of particles through the home are mathematically indistinguishable from reductions due to particle deposition. The investigators then determined penetration efficiencies by reducing indoor

concentrations using pressurized filtered air and then allowing concentrations to increase through natural home ventilation to determine P. Schneider et al. determined penetration values for an uninhabited apartment using a dynamic model (Schneider, Jensen, Clausen et al. 2004). A small slit was made in the apartment through which there was assumed to be no penetration loss. Deposition loss rates were taken from Thatcher et al. (Thatcher, Lunden, Revzan et al. 2003). Using the measured particle penetration, the ratio between predicted and measured concentration values was analyzed with air-exchange and meteorological conditions to determine a correction factor, which was based on the wind velocity, outdoor relative humidity, and air-exchange rate (Schneider, Jensen, Clausen et al. 2004).

While altering the environmental conditions is an effective way for determining house-specific penetration efficiencies and deposition rates, it is not practical to conduct these experiments in a significant number of homes, especially over an extended time period. Long et al. (2001) used a steady-state model during nighttime non-source periods (when residents were asleep eliminating the possibility for sources) to obtain average estimates for P and k for a group of nine homes in Boston, but not for individual homes. An infiltration factor was calculated using a dynamic model for these homes by Bennett and Koutrakis (2006). Allen et al. (Allen, Larson, Sheppard et al. 2003) determined the air exchange rate, penetration efficiency, and deposition velocities for 44 homes in the Seattle area, using particle light scattering measurement data. Other efforts to evaluate infiltration include Mosley et al. (2001) and Thornburg et al. (2001).

Some mention of this large body of work should be mentioned in the residential section:

Abt, E., Suh, H. H., Catalano, P. J. and Koutrakis, P. (2000). Relative contribution of outdoor and indoor particle sources to indoor concentrations. *Environmental Science & Technology*, 34, 3579−3587.

Allen, R., Larson, T., Sheppard, L., Wallace, L. A. and Liu, L. J. S. (2003). Use of real-time light scattering data to estimate the contribution of infiltrated and indoor-generated particles to indoor air. *Environmental Science & Technology*, 37, 3484−3492.

Bennett DH and Koutrakis, P. Determining the Infiltration of Outdoor Particles in the Indoor Environment Using a Dynamic Model. *Journal of Aerosol Science*, 2006, 37:766−785.

Chao, C. Y. H., Wan, M. P. and Cheng, E. C. K. (2003). Penetration coefficient and deposition rate as a function of particle size in non-smoking naturally ventilated residences. *Atmospheric Environment*, 37, 4233−4241.

Jeng, CJ; Kindzierski, WB; Smith, DW (2007) Particle penetration through inclined and L-shaped cracks *Journal Of Environmental Engineering-ASCE* 133 (331−339)

Jeng, CJ; Kindzierski, WB; Smith, DW (2006) Particle penetration through rectangular-shaped cracks. *Journal Of Environmental Engineering and Science* 5 (S111−S119).

Lai, A. C. K. and Nazaroff, W. W. (2000). Modeling indoor particle deposition from turbulent flow onto smooth surfaces. *Journal of Aerosol Science*, 31, 463−476.

Lai, ACK,(2006) Particle deposition and decay in a chamber and the implications to exposure assessment. *Water Air and Soil Pollution* 175 (323−334)

Liu, D. L. and Nazaroff, W. W. (2001). Modeling pollutant penetration across building envelopes. *Atmospheric Environment*, 35, 4451−4462.

Liu, D. L. and Nazaroff, W. W. (2003). Particle Penetration Through Building Cracks. *Aerosol Science and Technology*, 37, 565−573.

Liwei Tian; Guoqiang Zhang; Jinghua Yu, et al. (2008) Impact of surface roughness on particle penetration through building envelope leakage. International Journal of Energy Technology and Policy, Pages: 534−42 Published: 2008

Long, C. M., Suh, H. H., Catalano, P. J. and Koutrakis, P. (2001). Using Time-and Size-Resolved Particulate Data to Quantify Intoor Penetration and Deposition Behavior. *Environmental Science & Technology*, 35, 2089−2099.

Meng, QY; Turpin, BJ; Lee, JH, et al.(2007) How does infiltration behavior modify the composition of ambient PM2.5 in indoor spaces? An analysis of RIOPA data. *Environmental Science & Technology* 41(7315−7321).

Mosley, R. B., Greenwell, D. J., Sparks, L. E., Guo, Z., Tucker, W. G., Fortmann, R. and Whitfield, C. (2001). Penetration of ambient fine particles into the indoor environment. *Aerosol Science and Technology*, 34, 127−136.

Ott, W., Wallace, L. A. and Mage, D. (2000). Predicting particulate (PM10) personal exposure distributions using a random component superposition statistical model. *Journal of the Air & Waste Management Association*, 50, 1390−1406.

Schneider, T., Jensen, K. A., Clausen, P. A., Afshari, A., Gunnarsen, L., Wahlin, P., Glasius, M., Palmgren, F., Nielsen, O. J. and Fogh, C. L. (2004). Penetration of indoor concentration of 0.5−4 mm particles of outdoor origin in an uninhabited apartment. *Atmospheric Environment*, 38, 6349−6359.

Thatcher, T. L., Lai, A. C. K., Moreno-Jackson, R., Sextro, R. G. and Nazaroff, W. W. (2002). Effect of room furnishings and air speed on particle deposition rates indoors. *Atmospheric Environment*, 36, 1811−1819.

Thatcher, T. L., Lunden, M. M., Revzan, K. L., Sextro, R. G. and Brown, N. J. (2003). A concentration rebound method for measuring particle penetration and deposition in the indoor environment. *Aerosol Science and Technology*, 37, 847−864.

Thornburg, J., Ensor, D. S., Rodes, C. E., Lawless, P. A., Sparks, L. E. and Mosley, R. B. (2001). Penetration of Particles into Buildings and Associated Physical Factors. Part 1: Model Development and Computer Simulations. *Aerosol Science and Technology*, 34, 284−296.

Wallace, L. A., Mitchekk, H., O'Connor, G. T., Neas, L. M., Lippmann, M., Kattan, M., Koenig, J., Stout, J. W., Vaughn, B. J., Wallace, D., Walter, M., Adams, K. and Liu, L. J. S. (2003). Particle Concentrations in

Inner-City Homes of Children with Asthma: The Effect of Smoking, Cooking, and Outdoor Pollution. *Environment Health Perspectives*, 111, 263−272.

Wilson, W. E., Mage, D. T. and Grant, L. D. (2000). Estimating separately personal exposure to ambient and nonambient particulate matter for epidemiology and risk assessment: Why and how. *Journal of the Air & Waste Management Association*, 50, 1167−1183.

Wilson, W. E. and Suh, H. H. (1997). Fine particles and coarse particles: Concentration relationships relevant to epidemiologic studies. *Journal of the Air & Waste Management Association*, 47, 1238−1249

Response: *The section on deposition has been expanded to include discussions of the general mechanisms by which outdoor particles infiltrate a building's shell and enter indoor environment. Thatcher et al. 2002 was included. Other studies were reviewed, but are not "relevant" due to specificity of location and/or contaminant.*

Comment: In addition to the dust that is easily sampled, there is an additional loading of dust that is not easily removed. Fortune, et al. investigated the mass of dust obtained from vacuuming and vacuuming with a beater-bar machine to remove deeply embedded dust in eight homes (Fortune, et al. 2000). The results indicated that the actual dust loading in carpet was approximately ten times the amount removed by conventional vacuuming. This dust needs to be accounted for in the model, as it is a potential reservoir for pesticide storage and it needs to be included in the fugacity capacity of the carpet.

Fortune CR, Blanchard FT, et al. 2000. Analysis of aged in-home carpeting to determine the distribution of pesticide residues between dust, carpet, and pad compartments. RTP, NC: EPA-NERL.

Response: *A brief summary of Fortune's et al., (2000) findings was added to the section on House Dust and Soil Loadings.*

Comment: Chapter 19 potentially provides a strong link with indoor air modeling; in fact, by taking an approach that is not generally followed in this Handbook, this Chapter identifies a specific set of available software models for indoor air modeling (on page 19-3). However, the selection of these particular software implementations (described in the text of page 19-3 as "Leading examples of indoor air models") omits a wide range of available—and increasingly popular—approaches and formulations, including Computational Fluid Dynamics (CFD) models. Numerous indoor air quality modeling approaches have been reported in the literature; however, depending on the modeling scenario, only few of them address—typically a limited subset of—physical and chemical processes that affect complex air pollution mixtures (e.g., photochemical oxidants) indoors [Freijer & Bloemen, 2000; Hayes, 1989, 1991; Nazaroff & Cass, 1986]. It would be beyond the scope of EFH to present in detail the current status of indoor air modeling methods. However, it could

briefly state the fact that existing indoor air concentration models are available as a wide range of empirical regression relationships, parameterized mass balance models (that can be either "single-zone"—that is, single well-mixed room—or "multi-zone" models), and CFD-based models. Various studies have compared the different formulations of zonal models and of more complex, CFD, models [Teshome & Haghighat, 2004]. Some indoor air models have also considered atmospheric chemistry, that can be especially important in the presence of indoor sources such as gas stoves, etc. [Georgopoulos et al., 1997], while others considered potential limitations of uniform mixing assumptions [Sorensen & Weschler, 2002]. These can be important issues when calculating personal exposures and need to be addressed in conjunction with developing and evaluating indoor emission inventories for specific contaminants. It should be noted that the focus of this Chapter is specifically on residential settings: as mentioned earlier, it is hoped that in the future consideration of other indoor microenvironments (schools, offices, restaurants, shopping malls, etc.) will be incorporated in the EFH (please also see answer to Question 16, below). Some selected references to useful recent studies follow:

- [Dodson et al., 2007] Interzonal air flow for indoor air quality assessment
- [Grøntoft & Raychaudhuri, 2004] Tables of surface deposition velocities for common indoor pollutants.
- [He *et al.*, 2005] Table 1 gives a summary of the experimental conditions of the residential house studies on particle deposition rates
- [Meng *et al.*, 2009] Table 1 provides AER for different fan/AC operations and building age/type
- [Wallace *et al.*, 2004] Deposition rates based on central fans and in-duct filters
- [Yamamoto *et al.*, 2009] AER based on Relationship among Indoor, Outdoor and Personal Air (RIOPA) study
- [Hellweg *et al.*, 2009]

An essential reference that can be useful in relation to indoor air modeling in general (but not listed in the Handbook, probably due to its primary focus on occupational exposures) is the corresponding AIHA Guidance [AIHA, 2000]. This document contains valuable information that could, however, be equally useful in characterizing residential microenvironments (note that a 2009 update of the AIHA Guidance is now available).

It would be useful—since specific software for indoor models is listed in this chapter anyway, to at least include some references to major available CFD platforms and to specific indoor air models and a brief discussion of the type of information these models (a) require as inputs and (b) produce from their calculations in the context of an exposure analysis. To facilitate selection of references relevant to CFD modeling for future updates of EFH, a set of tables is included here (from Georgopoulos *et al.*, 2007), listing available CFD modeling

software as well as sets of CFD studies of both airflow and contaminant dispersion in various indoor microenvironments.

Response: *The Handbook is not meant to provide a comprehensive review of computational fluid dynamics. Only limited information on this topic is provided in the chapter.*

Comment: This Chapter presents a number of factors that are relevant for residential buildings but does so primarily in a qualitative manner. Even the two parameters for which recommendations are provided, the information is limited, dated and recommendations come with low confidence ratings. EPA should consider the factors currently identified in the chapter an area for concerted effort. A key pathway for consideration is the vapor intrusion. Currently, guidance is provided via the modeling efforts associated with the Johnson and Ettinger model. A number of the factors identified in the Chapter are relevant to this pathway including air exchange rates and building dimensions.

Response: *A number of changes and additions to the chapter have occurred in response to peer-review comments that collectively should address the reviewer's comment. Among these changes is the addition of a subsection on Vapor Intrusion that addresses the Johnson and Ettinger model. A number of new residential transport studies have been added, some published as recently as 2010, and the chapter now address nonresidential buildings.*

Comment: In Section 19.2, page 19-3, the citations for the "leading" indoor air models are essentially all for Price et al. (2003), with the exception of CONTAM, MCCEM, and THERdbASE. Please include the specific references pertaining to the Technical documentation and/or Model Development of each of these indoor air models. For example, MIAQ was developed at the California Institute of Technology by Nazaroff and Cass (1989) and is described in the following peer-reviewed publication: Nazaroff WW and GR Cass (1989). Mathematical modeling of indoor aerosol dynamics. Environmental Science and Technology 23: 157−166. Additionally, consider providing the web address for where the indoor air models currently listed can be downloaded (or if not available, then the contact person or EPA agency to contact for more information) as part of the citation in the references. I think that most (all?) of these Indoor Air models should be publicly available/accessible. Also, in the References, I suggest including a website for downloading or accessing the VERSAR (1990) PFT database.

Response: *The text covering mathematical models has been greatly expanded.*

Comment: Of the 76 or so references cited in Section 19.7 References for Chapter 19, most are >= 15 years old. I think there needs to be a more current literature review and data analysis using more recent data on housing stock,

included in any future EFH Revisions including the Building Characteristics Chapter. Only the following eight references are from 1996 or later: Murray (1996), Price (2001), Price (2003), Sherman and Dickerhoff (1996), US BoC (2008), US DOE (2005), US EPA (2000), and Wallace (1996).

> ***Response:*** *U.S. EPA agrees that many of the references in this chapter are old and have low confidence ratings; however, they are included because existing chapter tables cannot be replicated using data from any recent references known to us. For this reason, U.S. EPA has decided to retain old references until better data sources become available and the data can be incorporated into the chapter tables. Many new references suggested by the reviewers were added.*

Comment: Because the housing stock has changed rather dramatically since many of the air exchange rate studies reported in Chapter 19 were conducted, I suggest including more recently collected data analysis and models on air exchange processes. Specifically, I suggest the following additional data and/or analysis from Sherman and Matson (2002), Chan et al (2003) and Chan et al (2005), and Yamamoto et al (2010) and Price et al (2006) for consideration to be included in future revisions of the EFH (possibly described after the second paragraph of page 19-2 and/or in Section 19.4.2 Infiltration Models on page 19−2):

Sherman and Matson (2002)._Air tightness of new U.S. houses: A preliminary report. Technical Report, Lawrence Berkeley National Laboratory, Berkeley, CA. March 2002.LBNL-48671. In the second paragraph of page 19-2, in Section 19-1 and/or Section 19.4.2 Infiltration Models. on page 19-2,, suggest inserting newer air leakage analysis by Sherman and Matson (2002) on the Air Tightness of New US Houses. Their analysis found that "newer" construction is "significantly tighter than the housing stock as a whole" and that the "air tightness of new construction is no longer improving." The Sherman and Matson (2002) analysis was based on a database of over 70,000 air leakage entries from numerous (over 30) energy efficient and conservation programs throughout the US. Chief among the air leakage data contributors are the Ohio Weatherization Program (nearly 80% of measurements), AKWarm (in the state of Alaska, with over 10% of measurements), and the Wisconsin Energy Conservation Corporation (approximately 5% of all measurements). The following three figures (Figures 3, 4, and 6 of Sherman and Matson's (2002) report) are show their results of the trends of normalized leakage (i.e., total leakage cm2 normalized by square footage of the home m2) in "new houses" and "new conventional houses" (those that were not built as part of any energy efficiency program), and "energy efficient" homes (mostly built as part of the "Energy Star of Building America programs") and "new" is defined as home construction b/w 1993−2000):

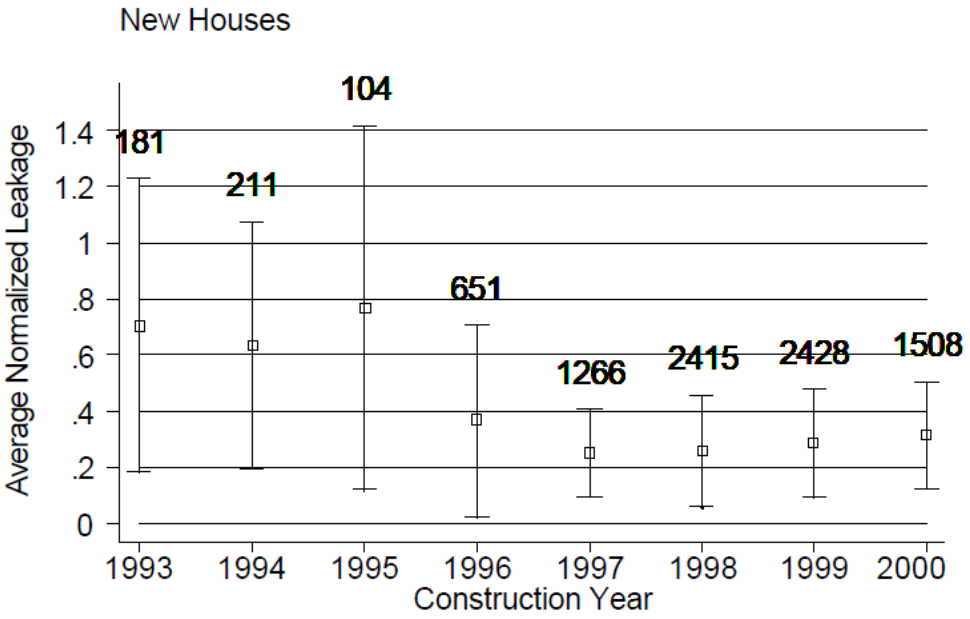

Figure 3 from Sherman and Matson (2002). This figure shows the "Normalized leakage for new houses by year of construction. Size bars indicate the standard deviation of the sample for each year and Numbers above bars indicate sample size."

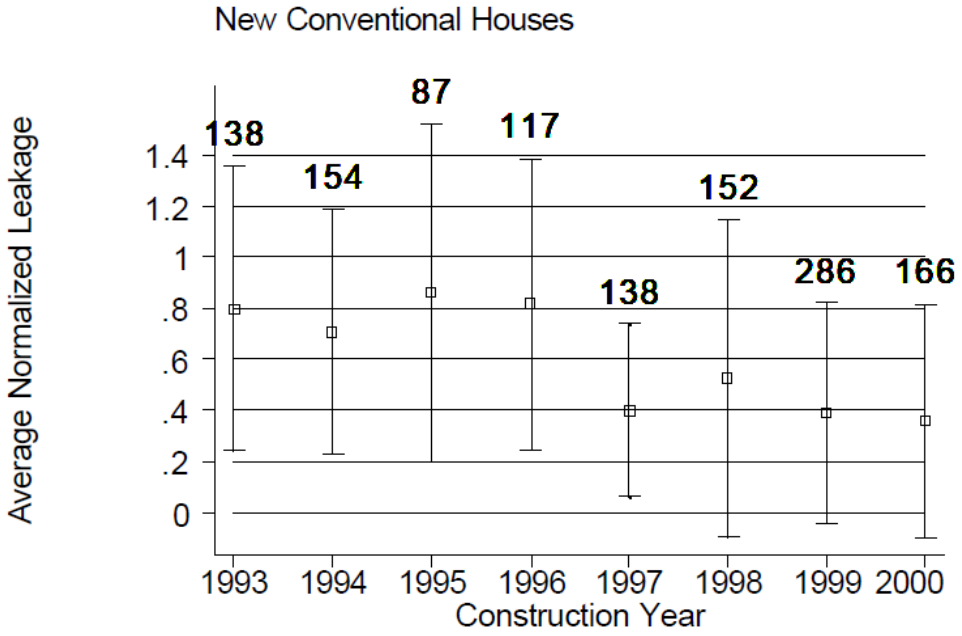

Figure 4 from Sherman and Matson (2002). This figures shows the "Normalized leakage for conventional houses by year of construction. Size of bars indicates the standard deviation of the sample for each year. Numbers above the bars indicate sample size."

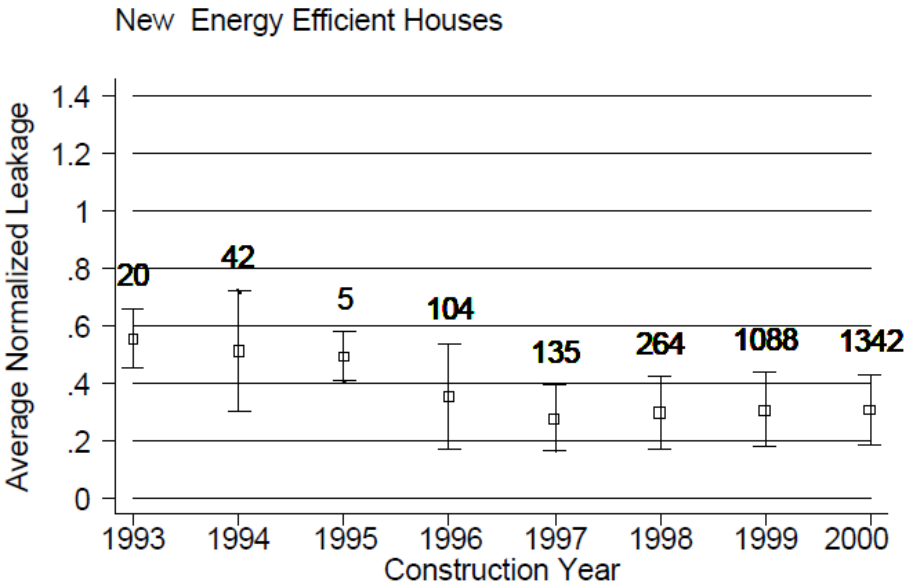

Figure 6 from Sherman and Matson (2002). This figure shows the "Normalized leakage for new, energy efficient homes by year of construction. Size of bars indicates the standard deviation of the sample for each year. Numbers above the bars indicate sample size."

Response: *A paragraph has been added that summarizes the findings of Sherman and Matson (2002) regarding air leakage and newer homes.*

Comment: Chan, WR, PN Price, MD Sohn et al (2003). Analysis of US Residential Air Leakage Database Lawrence Berkeley National Laboratory, January 2003. LBNL Report Number 53367.

and

Chan, WR, WW Nazaroff, PN Price et al (2005). Analyzing a database of residential air leakage in the United States. Atmospheric Environment 39:3445−3455.

Chan et al (2003 and 2005) found that normalized leakage (air leakage normalized by floor area) for single-family detached residences is a function of the years since home built and floor area. Therefore, "older and smaller home are more likely to have higher normalized leakage areas than newer and larger ones." They present the following equation (Equation 11 of Chan et al., 2005) for estimating ACH: based on normalized leakage (dimensionless), height (H, m), and a scaling factor, F (dimensionless, and varying typically b/w 10−30 with F= 16 giving best fit for national data)

$$= 48\left(\frac{2.5\,\mathrm{m}}{H}\right)^{0.3}\frac{\mathrm{NL}}{H\,F}[\mathrm{h}^{-1}],$$

Equation 11 of Chan et al. (2005)

The following Table (Table 3 from Chan et al., 2005) "summarizes the normalized leakage distribution weighted for all dwellings in the US".

Table 3
Statistics of estimated normalized leakage distribution weighted for all dwellings in US

House type	Estimated normalized leakage percentiles							Estimated	
	5th	10th	25th	50th	75th	90th	95th	GM	GSD
Low income	0.30	0.39	0.62	0.98	1.5	2.2	2.7	0.92	1.9
Conventional	0.17	0.21	0.31	0.48	0.75	1.1	1.4	0.49	1.9
Whole US	0.17	0.22	0.33	0.52	0.84	1.3	1.7	0.54	2.0

Table 3 from Chan et al. (2005)

The following figure (Figure 8) copied from Chan et al.(2005) compares the best-fit AER estimated in their analysis with other AER analysis.

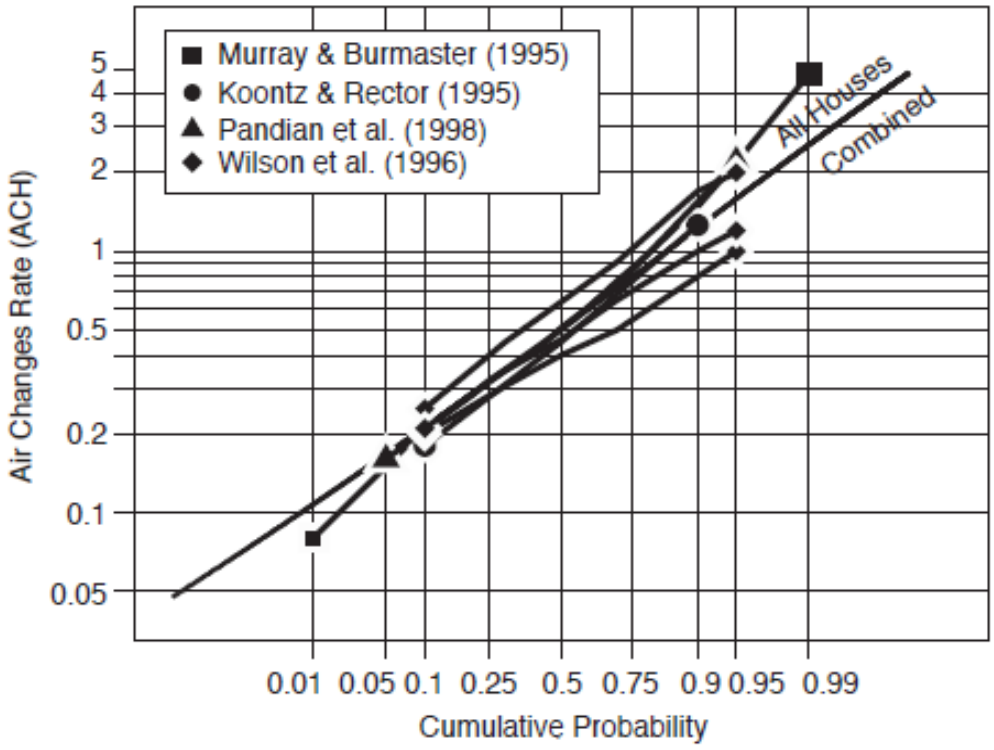

Figure 8 of Chan et al (2005) and attached caption. "Comparison of best-fit air exchange rates estimated from linear regression models obtained in this analysis, and values found in EPA Exposure Factors Handbook (US EPA, 1997). The distributions reported by Pandian et al. (1998) are inclusive of all the studies listed. In Wilson et al. (1996) all residences measured are located in California (three distributions are shown: measurements from Los Angeles being most leaky, followed by San Diego and Northern California). The other references analyze collections of multiple projects. Koontz and Rector (1995) assigned weights to the results to compensate for geographic imbalance of measurements. Murray and Burmaster (1995) presented results as functions of weather using the degree-day metric."

Response: *Additional text was added to the Handbook summarizing the findings of Chan et al., (2005). In addition, a new table was added reflecting their normalized leakage distributions. Additional information from Sherman and Matson (2002) was also added.*

Comment: Yamamoto, N, DG Shendell, AM Winter and J Zhang (2010). Residential air exchange rates in three US metropolitan areas: results from the Relationship among Indoor, outdoor, and Personal Air Study 1999−2001. Indoor Air 20: 85−90.

New Residential Air Exchange Rates (AER) have been reported from analysis of the Relationship Among Indoor, Outdoor, and Personal Air Study (RIOPA) 1999−2001 study by Yamamoto et al. (2010) and I suggest that it be incorporated in future revisions of the EFH (within the AER section, currently 19.4.1). The abstract of Yamamoto et al (2010) is copied here:

"We report approximately 500 indoor–outdoor air exchange rate (AER) calculations based on measurements conducted in residences in three US metropolitan areas in 1999−2001: Elizabeth, New Jersey; Houston, Texas; and Los Angeles County, California. Overall, a median AER across these urban areas and seasons was 0.71 air changes per hour (ACH, or per hour; n = 509) while median AERs measured in California (n = 182), New Jersey (n = 163), and Texas (n = 164) were 0.87, 0.88, and 0.47 ACH, respectively. In Texas, the measured AERs were lower in the summer cooling season (median = 0.37 ACH) than in the winter heating season (median = 0.63 ACH), likely because of the reported use of room air conditioners as Houston is typically hot and humid during the summer. The measured AERs in California were higher in summer (median = 1.13 ACH) than in winter (median = 0.61 ACH). Because the summer cooling season in Los Angeles County is less humid than in New Jersey or Texas, natural ventilation through open windows and screened doors likely increased measured AER in California study homes. In New Jersey, AER were similar across heating and cooling seasons, although the median AER was relatively lower during the spring."

In addition, Yamamoto et al (2010) also assessed intra-home variability as two measurements were taken in each household during different seasons.

Response: *Text summarizing Yamamoto et al., (2010) has been added.*

Comment: Price, PN., A. Shehabi, and R. Chan. 2006. Indoor-Outdoor Air Leakage of Apartments and Commercial Buildings. California Energy Commission, PIER Energy-Related Environmental Research Program. CEC−500−2006−111. Report can be downloaded at: http://www.energy.ca.gov/2006publications/CEC−500−2006−111/CEC−500−2006−111.PDF

This report compiles data on AERs collected from 14 different studies on apartment buildings in the US and Canada. The authors acknowledge that the air leakage data of apartment building are very scarce. Nevertheless, they found that the "observed air change rates, mostly from 0.5 to 2 ACH, are higher than data from single-family houses in weather conditions such as these: typical air exchange rates in houses in these conditions would be of the order of 0.2 to 1 ACH (Pandian et al., 1998; Wilson et al, 1996)."

Response: *Text summarizing Price et al., (2006) has been added.*

Comment: Additionally, I suggest the following additional studies/analysis on Residential Air Exchange research for inclusion in future EFH revisions:

- Pandian, MD, JV Behar, WR Ott et al (1998). Correcting errors in the nationwide data base of residential air exchange rates. *Journal of Exposure Analysis and Environmetnal Epidemiology* 8(4): 577−586.
- Wilson, AL, SD Colome, Y Tian et al (1996). California residential air exchange rates and residential volumes. *Journal of Exposure Analysis and Environmental Epidmiology* 6(3): 311−326.

Response: *Summaries of these two papers were not added to the Handbook, although they are referred to in the text. Pandian et al. pointed out errors in the PFT database. Wilson et al. discusses the merits of a survey of air exchange rates in residential structures in California. While the study is interesting, it is not representative of the nation overall.*

Comment: In Section 19.4.5, for particle deposition please consider including the data and analysis contained in the following two references:

Comment: Thatcher, TL, AC Lai, R Moreno-Jacksona, RG Sextro, WW Nazaroff (2002). Effects of room furnishings and air speed on particle deposition rates indoors. Atmospheric Environment 36 (2002) 1811−1819. They Measured deposition loss rate coefficients (h−1) for particles of different median diameter (ranging between 0.55−8.66 mm), and with fans on or off and at different mean airspeed's (varied by means of changing the voltage to four small, instrument-cooling fans within a room). The deposition loss rate was characterized in three types of experimental rooms: (1) bare room surfaces (unfurnished with metal floor), (2) carpeted room (unfurnished) ,and (3) a fully furnished room (including carpeting, chairs, table bookcase and curtains). The following table (Table 2 of Thatcher et al., 2002) presents their measurement results of the deposition loss rate:

Table 2
Measured deposition loss rate coefficients (h^{-1})[a]

Median particle diameter (μm)	Fans off			$V = 5.4$ cm/s			$V = 14.2$ cm/s			$V = 19.1$ cm/s		
	B	C	F	B	C	F	B	C	F	B	C	F
0.55	0.10	0.12	0.20	0.10	0.13	0.23	0.09	0.18	0.23	0.14	0.16	0.27
0.65	0.10	0.12	0.20	0.10	0.13	0.23	0.10	0.19	0.24	0.14	0.17	0.28
0.81	0.10	0.11	0.19	0.10	0.15	0.24	0.11	0.19	0.27	0.15	0.19	0.30
1.00	0.13	0.12	0.21	0.12	0.20	0.28	0.15	0.23	0.33	0.20	0.25	0.38
1.24	0.20	0.18	0.29	0.18	0.28	0.38	0.25	0.34	0.47	0.33	0.38	0.53
1.54	0.32	0.28	0.42	0.27	0.39	0.54	0.39	0.51	0.67	0.51	0.59	0.77
1.91	0.49	0.44	0.61	0.42	0.58	0.75	0.61	0.78	0.93	0.80	0.89	1.11
2.37	0.78	0.70	0.93	0.64	0.84	1.07	0.92	1.17	1.32	1.27	1.45	1.60
2.94	1.24	1.02	1.30	0.92	1.17	1.46	1.45	1.78	1.93	2.12	2.27	2.89
3.65	1.81	1.37	1.93	1.28	1.58	1.93	2.54	2.64	3.39	3.28	3.13	3.88
4.53	2.83	2.13	2.64	1.95	2.41	2.95	3.79	4.11	4.71	4.55	4.60	5.46
5.62	4.41	2.92	3.43	3.01	3.17	3.51	4.88	5.19	5.73	6.65	5.79	6.59
6.98	5.33	3.97	4.12	4.29	4.06	4.47	6.48	6.73	7.78	10.6	8.33	8.89
8.66	6.79	4.92	5.45	6.72	5.55	5.77	8.84	8.83	10.5	12.6	11.6	11.6

Table 2 of Thatcher et al. (2002)

V represents mean airspeed in room core; B implies bare room surfaces; C indicates carpeted room; F indicates fully furnished.

Response: *Text summarizing Thatcher et al., (2002) has been added to the Handbook as well as the table above.*

Comment: He, C., L Morawska, and D Gilbert (2005). Particle deposition rates in residential houses. Atmospheric Environment 39(21): 3891−3899. He et al (2005) found that the "lowest deposition rates were found for particles in the size range from 0.2 to 0.3 μm for both minimum (air exchange rate: 0.61±0.45 h−1) and normal (air exchange rate: 3.00±1.23 h−1) ventilation conditions. The results of statistical analysis indicated that ventilation condition (measured in terms of air exchange rate) was an important factor affecting deposition rates for particles in the size range from 0.08 to 1.0 μm, but not for particles smaller than 0.08 μm or larger than 1.0 μm."

Response: *Text summarizing He et al., (2005) has been added to the Handbook.*

Comment: This Chapter is not organized as clearly as other chapters in the EFH. There is no section header for Key Studies and Relevant Studies for house volume and air exchange rate.

Response: *Chapter 19 was reorganized identifying "key" and "relevant" studies.*

Comment: Table 19-1: suggest that it be indicated in footnote "a" that this is the median value across all single family detached and mobile housing units" Actually, the value of 401 m3 is the median , not the average as is presently in Table 19-1 (as currently stated in Table 19-7). Therefore my suggestion for footnote "a" is the following: "a Median value presented in Table 19-7

recommended for use as a central estimate for all single-detached homes, including mobile homes."

Response: *The change was made, as suggested.*

Comment: Table 19-1: footnote "b" "Mean of two 25th percentile values (Table 19-4)—recommended to be used as a lower percentile estimate" should be corrected (underlined portion) as: "Mean of two….(Figure 19-2b) recommended to…"

Response: *The change was made, as suggested.*

Comment: Table 19-1, footnote "c": consider clarifying the region the central estimate applies, by adding the following text (underlined): "Median value recommended to be used as a central estimate based across all US Census Regions (Table 19-14)"

Response: *The change was made, as suggested.*

Comment: Section 19-1, page 19-1: Remove "code-intensive" from the following sentence: "Nazaroff and Cass (1986) and Wilkes et al. (1992) have used code-intensive computer programs feature…"

Response: *The change was made, as suggested.*

Comment: Section 19-1, page 19-1: provide Citations for the Indoor Air Quality Building and Assessment Model (I-BEAM) and for the Multi-Chamber Concentration and Exposure Model (MCCEM)

Response: *The change was made, as suggested.*

Comment: Section 19-1, page 19-1: Table 19-1, footnote "d": consider clarifying the region the lower percentile applies, by adding the following text (underlined): "10th percentile value (across all US Census Regions) recommended to be used as a lower percentile value (Table 19-14)."

Response: *The change was made, as suggested.*

Comment: Section 19.3.1.1, page 19-6: The sentence "These data were compared to the results of the residential volume distributions form the 1995 Residential Energy Consumption Survey (RECS) (Thompson, 1995)" should be correct to: "These data were compared…from the 1993 Residential Energy Consumption Survey (RECS) (Thompson, 1995)." Further, the Thomspon, 1995 reference is actually a personal communication. Since the 1993 RECS is over 15 years old, suggest updating the comparison, using the 2005 RECS data. This would also give insight as to how relevant the PFT database is to characterize current residential volumes.

Response: *The change was made, as suggested. The 2005 RECS data will be used where ever possible and appropriate.*

Comment: Section 19.3.3, page 19-6: Consider moving the text in footnote "a" of Table 19-5 and Table 19-6 (both have same information provided in footnote "a") to the text of Section 19.3.3, i.e., move the following from footnote "a" to Section 19.3.3, page 19-6: "The total average square footage per housing unit for the 2001 RECS was reported as 1975 square feet. This figure….The only available figures that permit comparison….in all housing units—for 2001 the total square footage was 2,005 and for 2005 the total was 2,029 square feet."

Response: *The change was made, as suggested.*

Comment: Section 19.3.2.1, page 19-7: Consider removing the last two sentences and stating instead the conversion factor (0.0293 m^3/ft^3 or 3.3 ft per m). Additionally, instead of the last two sentences, consider mentioning and citing Table 19-8 in this section for characterizing the dimensional quantities for residential rooms because it is directly related to converting b/w ft and m units.

Response: *The text was retained. The suggested change will not add more clarity.*

Comment: Section 19.3.2.2 Surface Areas should be renamed "Surface-to-volume (loading Ratios)"and placed after Section 19.3.2.3 Products and Materials. Consider deleting the sentence "Table 19-8 provides the basis for calculating loading ratios for typical-sized rooms." (refer instead to Table 19-8 in Section 19.3.2.1 Room Volume) and replace with "Loading ratios are calculated based on typical sized rooms, presented in Table 19-8."

Response: *The change was made, as suggested.*

Comment: In Section 19.3.2.3 Products and Material, consider specifying which type of residences are "typical", i.e., which residence type does the following statement refer to: "surface area are based on typical values for residences…" Additionally, please specify in Footnote "a" of Table 19-9 the type of residence (single family detached (including mobile home), single-family attached (townhome or duplex) or multifamily (apartment building) residence that the values refer to).

Response: *The clarification would be helpful; unfortunately, the source document does not elaborate on the type of residence.*

Comment: In Section 19.3.3, on page 19-8: I believe that the insertion/clarification (underlined) should be made to the following sentence: "Three types of mechanical systems are: (1) systems associated with heating, ventilating, and air conditioning (HVAC); (2)…"

Response: *The change was made, as suggested.*

Comment: In Section 19.3.4.2: Modify the last sentence to read "Table 19-11 defines the four Census Regions"

Response: *The change was made, as suggested.*

Comment: In Section 19.4.1.4 , page 19-11: Move the following sentence from this section, to a footnote in Table 19-15 associated with column header "Climate Region": "The coldest region was defined as having 7,000 or more heating degree days, the colder region as 5,500−6,999 degree days, the warmer region as 2,500−5,499 degree days, and the warmest region as fewer than 2,500 days."

Response: *The change was made, as suggested.*

Comment: In Section 19.4.2, page 19-11, Eqn 19-1 is identical to Eqn 19-2. I believe the correct equation needs to be inserted for Eqn 19-1 (Eqn 19-2 is correct).

Response: *Equation 19-1 has been corrected.*

Comment: In Section 19.4.3.1.2, page 19-12: please insert the units for "overall particle deposition rates", i.e., [h^{-1}].

Response: *The change was made, as suggested.*

Comment: In Section 19.4.4, page 19-13, I suggest including some examples of interzonal airflow models

Response: *The change was made, as suggested.*

Comment: In Section 19.4.5.2, page 19-13, Please insert the following underlined text: "Mass loading of floor surfaces (Table 19-20) was measured in the study of Thatcher and Layton (1995) by thoroughly cleaning the house and sampling accumulated dust, after one week of normal habitation and no vacuuming."

Response: *The change was made, as suggested.*

Comment: In Section 19.5, page 19-14, suggest including some basic concepts and exposure factors related to assessing residential radon gas exposures as well as for assessing mold or spore exposures indoors, in addition to the airborne contaminants, waterborne contaminants and soil/house dust indoor sources.

Response: *The purpose of this chapter is not to address specific exposures, but rather to describe building characteristics that affect exposures.*

Comment: In Section 19.5.1, on page 19-14, suggest replacing "direct discharge sources" with "direct emission sources". Generally, suggest that "discharge" be replaced with "emission" throughout Section 195.1.

Response: *The change was made, as suggested.*

Comment: In Section 19.5.1, on page 19-14, suggest inserting other references besides Reiwani et al (1986) for "Emissions factors for combustion products of general concern (e.g., CO, Nox) have been measured for a number of combustion appliances using room-sized chambers (Reiwani et al. + insert additional references)

Response: *U.S. EPA could consider adding additional references in future updates. The reviewer did not provide specific references.*

Comment: In Section 19.5.1, on page 19-14, replace "Table 19-32" with "Table 19-21" in the first sentence of the second paragraph of the right hand column.

Response: *The change was made, as suggested.*

Comment: In Section 19.5.1, on page 19-14 and 19-15. The section on the "exponential formulation" is confusing. For one, shouldn't the exponent in Eqn 19-3 be negative, i.e., Ec/Eo exp $(-k_s t_c)$, and likewise for Mc/M exp $(-k_s t_c)$, to represent a exponential decay? Also, it is not clear how to solve the relationships to estimate k_s , the decay factor. Third, I think that Eqn 19-4 is incorrectly presented, what is the term "Eo/ks" on the far right of the equation? I think Eqn 19-4 is actually estimating the total amount (mass) released, M, and needs to be clarified and correct. Lastly, neither Eqn 19-3 nor Eqn 19-4 are cited in the text.

Response: *The equation contained an error. Errors were corrected.*

Comment: In Section 19.5.1, on page 19-15. Consider changing the last sentence of Section 19.5.1 from "…but this concept is best considered using the multiple-zone model" to "…but this concept is best considered using multi-zone models (see Section 19.4.4).

Response: *The change was made, as suggested.*

Comment: In Section 19.5.2—Source Descriptions for Waterborne Contaminants on page 19-15: edit the first sentence from "Residential water supplies may convey chemicals…" to "Residential water supplies may be a route for exposure to chemicals through ingestion, dermal contact, or inhalation."

Response: *The change was made, as suggested.*

Comment: In Section 19.5.2-On page 19-15: edit the following sentence from "The exposure potential for a given situation will depend on the source of the water, …" to "The exposure potential for a given chemical will depend on…"

Response: *The change was made, as suggested.*

Comment: In Section 19.5.2-On page 19-15, "Primary types of residential water use (summarized in Section 19.4.5)…" These are not summarized in Section 19.4.5 (House Dust and Soil Loadings Section).

Response: *The parenthetical note was deleted.*

Comment: In Section 19.5.2-On page 19-15, please specify the underlined portion in the sentence "Release rates (S) are formulated as:…"

Response: *The change was made, as suggested.*

Comment: In Section 19.5.2—I think something is missing in Equation 19-5, as the units on the right hand side of the equation don't work out to [g/h], i.e., the units of S.

Response: *These have been corrected.*

Comment: The "K" (whether K_{LI} or K_{GI}) needs to be specified on the left hand side of Equation 19-6.

Response: *These have been corrected.*

Comment: In Section 19.5.3—Soil and House Dust Sources on page 19-16, the following portion (underlined) of the first sentence of this section should be corrected "The rate process descriptions compiled for soil and house dust in Section 19.5.3…" It is not clear what section this is intended to refer to.

Response: *The text has been corrected.*

Comment: In Figure 19-1: recommend changing "Removal" to "Deposition"

Response: *Unfortunately, the source document for the graphic used "removal."*

Comment: In Figure 19-2: cite the DOE survey and PFT Database in the legend

Response: *The figure did not come from the Versar PFT reference.*

Comment: In Table 19-7: include "(m^3)" as units after "…by Volume" in table caption. Also, on the row titled "Median" state instead "Median Volume (m^3)". Additionally, it is confusing as to what the "Total" column under Year-round refers to. The sum of the "owner occupied" and "renter occupied" do not add up to this "Total".

Response: *The change was made, as suggested. In addition, we updated the source data from AHS (2007) to AHS (2009).*

Comment: In Table 19-14, please correct the column header. Is "North Central Region" supposed to be "Midwest"? There are only 4 Census Regions (Northeast,

Midwest, South, and West). "North Central Region" is actually one of the Census Divisions.

Response: *The change was made, as suggested. The error was in the source document.*

Comment: In Table 19-17: remove h^{-1} from values and place units in column header, i.e., "Deposition Rate (h^{-1})"

Response: *The change was made, as suggested.*

Comment: In Table 19-18: it would be useful to indicate on this table that all homes were single-family detached residences, and indicate (with a footnote) which two were mobile homes. Additionally, it would be useful to include a footnote, indicating which houses did not use a vacuum cleaner for housecleaning (i.e., the two that exhibited the highest dust loadings—33.7 g/m^2 and 812.7 g/m^2)

Response: *The table now indicates that the two houses with the highest dust loadings were mobile homes, seven of the houses were single family detached homes, and two were mobile homes. It also indicates that the source did not indicate which two were mobile homes.*

Comment: Table 19-21: Suggest changing the following:

- "Direct Discharge" to "Direct Emission Rate"
- "Combustion" to "Combustion emission rate"
- "Volume Discharge" to "Volume Emission rate"
- "Mass discharge" to "Mass emission rate"
- "Diffusion limited" to "Diffusion limited emission rate"
- "Exponential" to "Exponential emission rate"

Response: *The changes above were made as suggested.*

Comment: It is not clear in Table 19-21 what is referred to by "Transport" and the subcategories of "Description" and the "components" do not seem to clarify what processes are involved.

Response: *The original source did not provide any additional clarification.*

Comment: I am not aware of any additional research that would reasonably supplement the data presented in chapter 19. However, I am not convinced that, given the very high variability inherent in these data, it is reasonable to refine these estimates in a way that would be meaningful and useful. Rather, it would be more useful to gather or generate data on residential volume and air exchange rates relative to factors such as age of the housing stock, population density, annual average temperature, and average winter temperature. Data stratified in this way could not only potentially lead to more specific and more useful data, but would also allow exposure assessors to estimate population-specific parameters.

Response: *U.S. EPA is limited by the type of data available. A number of improvements have been made to the chapter to make it more useful for exposure assessment. U.S. EPA may consider additional data in future additions.*

Comment: Section 19.3, Building characteristics Studies is an informative monograph, but not really part of an EFH database.

Response: *The text has been modified.*

Comment: The basis for the assumption of 8 ft ceilings should be discussed.

Response: *The text has been modified, as suggested.*

Comment: It would seem that housing volume and ACH would be negatively correlated. This is not mentioned.

Response: *The text has been modified, as suggested.*

Comment: Pg. 19-7, par. 4—Define "loading rations"

Response: *The text has been modified.*

Comment: Pg. 19-11, eq. 19-1—The definition of the variables does not correspond to the equation. Equation 19-2 is identical to equation 19-1. Pg. 19−14, eq. 19-3—I think that the correct term is e^{-kt}. As written, there is no minus sign. Pg. 19-16, eq. 19-7—The 'd' subscript is not defined.

Response: *The equations have been corrected.*

Comment: Pg. 19-12, 19.4.3.1—It is not clear why this section has been placed here. It would not likely be looked for in this section of the EFH and it is not clear that it is relevant to an EFH

Response: *Deposition and filtration were placed in the Building Characteristics chapter because they are related to transport of contaminants within in a building.*

Comment: Pg. 19-13, 19.4.5—This section could reasonably be moved to the soil/dust ingestion chapter.

Response: *For this version of the Handbook,U.S. EPA has decided to keep the section in Chapter 19.*

Comment: Suggestions for new references.

Response: *The following is a list of the new articles mentioned by peer reviewers. Those that are shown in bold were added to the chapter. Those that are underlined were not added due to their specificity on computational*

fluid dynamics. Only limited information on this topic is provided in the chapter. Also, added to the chapter were CBECS data, U.S. EPA (2010), and Turk (1989). The other references were reviewed but were not included because Handbook typically includes studies that either are representative of the national population or focus on a specific at-risk population and not from specific geographical locations.

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2.39. Glossary

Comment: The expansion of the Glossary to include terms and concepts that are quite common in exposure analyses (even in cases where the Handbook does not focus particularly on them). For example, the Glossary does not currently contain terms such as "Aggregate Exposure," "Bayesian Analysis or Bayesian Statistics," "Geographic Information Systems (GIS)," "Microenvironment," or "Physiologically Based Pharmacokinetic—or Toxicokinetic—Model," etc. (It should be noted that Bayesian methods are mentioned repeatedly in the narrative of Chapter 2 and PBPK models in the narrative of Chapter 6; however, GIS do not seem to me mentioned in the Handbook). It is realized, of course, that the Handbook is not a dictionary or encyclopedia of exposure analysis methods, but

without doubt, it will be used by individuals new to this field, who would benefit by an expanded Glossary. Even basic concepts such as e.g., "Biomarker" deserve their own entry (currently they are only partially addressed in existing entries, such as "Biokinetic model comparison" and "Biomarker model comparison" that, however do not address in any way the possible range of available biomarkers of exposure—and, even more, their potential relationship to biomarkers of susceptibility and biomarkers of effect).

Response: *The glossary was revised.*

APPENDIX A. RESPONSE TO PUBLIC COMMENTS

Note: No comments were received from the public on Chapters 8 and 18.

A.1. Chapter 1 (Introduction)

A.1.1. Comments from the Tri-Service Environmental Risk Assessment Work Group

Comment: Section 1.1: The second paragraph, first sentence is confusing in its emphasis on "…life stages rather than as subpopulations…" Rewrite the first sentence to clarify its meaning. Additionally the paragraph should explain what the document means by life stages and subpopulations.

Response: *The definition was added.*

Comment: Section 1.3: Here and throughout the Chapter, a critical point that is not articulated is that there are virtually no toxicological data to correspond to the age ranges for which exposure data might (now) exist. Clarify how the age-specific exposure factors may be used with existing information. It would also make the document more useful if it clarified the following points:—In what circumstances would it be appropriate to quantitatively assess chemical exposure risk in 3 to 6 year olds?—Where would there be an occasion to carry out such an assessment?—How sizable a population would there be in a given instance? And would there be enough to justify assembling such exposure data?

Response: *Providing specific guidance on how to use the data for every possible exposure scenario is beyond the scope of this Handbook. The circumstances where specific age groups need to be assessed will not only depend on exposure parameters, but also on the chemical of interest. The decision on how much data are necessary to reliably estimate exposure depends on many factors including the type of assessment needed (e.g., screening), the problem formulation, and the amount of certainty needed to make environmental decisions.*

Comment: Section 1.4: 1st paragraph. The text stated that studies were chosen that were seen as useful and appropriate for estimating exposure factors for adults and children. In the next paragraph two terms, key and relevant, are used to explain the meaning of useful and appropriate. Introducing these terms initially allows for a smooth transition into the explanation of the terms when identifying useful and appropriate studies. Rewrite the sentence to introduce the terms "key" and "relevant" when referring to useful and appropriate studies that were chosen. For instance, "Studies were chosen that were seen as useful (i.e., key studies) and appropriate (i.e., relevant studies) for estimating exposure factors…"

Response: *The section was rewritten, and the definition of "key" has changed slightly. More discussion was added clarifying differences between "key" and "relevant" studies.*

Comment: Section 1.4.2: This Section would be much more complete if it included some discussion on any and all of the following: the number and kinds of searches conducted; the keywords used when searching; the number of databases used; a simple summarization of the degree of change in the exposure factors (e.g., which factors changed a lot [relatively]; the degree of change; direction of change; anticipated changes for the future, and when there may again be a reevaluation of the subject matter). Update the text to provide more information as described.

> ***Response:*** *The section was rewritten to add more clarification about selection of studies and the main revisions done to each chapter. A discussion about the degree of change or direction of the change and anticipated changes was deemed too complicated given the number of factors involved.*

Comment: Section 1.6: It would be helpful if the document, perhaps here, identified the specific program(s) for which the exposure factors might be relevant. A sizeable number of the listed USEPA guidance documents stem from the Superfund program, but our familiarity with that program tells us that most of the newly assembled exposure data would not be of service in that context. There are several reasons why this is so. First, there is not a need to assess a group or cohort of children over a specific 3- or 6-month period. Second, "credible distribution data (or ranges) for exposure factors" are often lacking. Update the text to discuss which programs the exposure factors might be relevant.

> ***Response:*** *It would be nearly impossible to determine all the factors that are used by each individual program office and other users of the Handbook. Program offices have their own regulatory constraints that in many cases dictate what age groups and point in the distribution they need to assess. The Handbook is not meant to be prescriptive, but rather provide all the data available and their limitations so that users can make their own determinations as to what data to use based on their specific needs.*

Comment: Section 1.7: 1st paragraph The implication from the text is that child development is a series of discrete events occurring along a continuum. If, by way of example, a two year old was to be assessed for his/her entire life until that point, a more accurate representation than simply evaluating the two-year stretch as a single block of time, would have assessors (citing here from page 1-9) "summing age-specific exposures across time", as well as "integrating age-specific exposures with age-specific differences in toxic potency". The great attention given to acknowledging the discrete exposure events in one's life is commendable, but it overshadows the reality that there are no toxicological data to support fragmented assessments. It would be advisable for this document to acknowledge that there is a lack of appropriate toxicity factors (cancer slope factors, reference doses, etc.) to support fragmented assessments.

Response: *Language was added acknowledging the lack of toxicity factors for some life stages.*

Comment: Section 1.9.1: The section uses terms "exposure", "average exposure", "average dose", "potential dose", and "external dose" as if they are interchangeable. Rewrite this section to make clear what is meant by dose and exposure.

Response: *The section was rewritten, and differences between exposure and dose clarified.*

Comment: Section 1.9.1: 2nd paragraph The paragraph mentions calculating risks by integrating exposures throughout all life stages and it is unclear as to what that actually means. An example will enhance readers' understanding of the methodology. Include a simple example of what the document means by "risks should be calculated by integrating exposures throughout all life stages."

Response: *This type of example would be more appropriate for the U.S. EPA Guidelines for Exposure Assessment currently under revision.*

A.1.2. Comments from the American Chemistry Council

Comment: Within Chapter 1, EPA indicates that the upper percentile refers to 90th percentiles and greater throughout this Handbook. In the case of drinking water ingestion, this draft recommends use of the 95th percentiles as high end values whereas in the current EFH recommendations are based upon 90th percentiles. Further explanation and scientific policy justification as to this change in approach is warranted. Specifically for inhalation, while newer information allows for the development of high end percentiles, it is unclear why the draft recommendations are based upon 95th percentile values when it is acknowledged that "all of the 95th percentiles listed in Table 6-1 represent unusually high inhalation rates for long-term exposures, even for the upper end of the distribution." A 90th or other upper percentile that may be a physiologically feasible upper value would be a more useful recommendation. Given the weight that these recommendations carry for future inhalation exposure and risk estimates, this is a matter that should be addressed.

Response: *Language was added indicating that the 95th percentile was used to represent the high end because it is the middle of the range between the 90th and the 99th percentiles.*

Comment: We support the practice of keeping the EFH as complete and current as possible. However, this can lead to the case where there are differences in recommendations between the EFH and child Specific EFH (CSEFH). For example, such differences are apparent in Tables 6.1, 6.17 and 6.19 of both documents. We suggest that there be some mechanism in place to avoid future confusion. The EFH should add text within the recommendations discussion that indicates the basis of the difference (for the example cited, it was due to

regrouping data into child specific age groups; while indicated in a footnote, it would be useful to have this clearly stated within the text).

Response: *Language was added indicating that this revision supersedes the 2008 Child-Specific Exposure Factors Handbook. In the future these may be consolidated into one life stage Handbook. Chapter 2 (Variability and Uncertainty)*

A.1.3. Comments from the Tri-Service Environmental Risk Assessment Work Group

Comment: General Chap. 2: This chapter is nearly identical to Chapter 2 of the first volume of the 1997 EPA Exposure Factors Handbook (EPA/600P-95/002Fa). Almost all of the paragraphs are taken verbatim from the 1997 document. To the extent that other chapters of this revision are also very similar to the 1997 version of the document, thought should be given to instead producing a "supplement" to the 1997 document. Text at the start of the supplement could indicate that there have been only minor wording changes since the last version. The supplement could list out those changes from the previous document, most of which are very minor (e.g., a name change for a chapter subsection).

Response: *Chapter 2 has been revised and updated. A considerable number of changes have been made to the Handbook in both content and format. This warrants a new revised edition instead of a supplement as suggested.*

Comment: Section 2.7: 6th paragraph. This paragraph is confusing. It starts by using the term "descriptors" that seem to relate to exposure scenarios. Later it uses descriptors as terms to define risk levels. It refers to "these definitions" but it is unclear what definitions the paragraph is referencing. Recommend the paragraph be rewritten to clearly and concisely make the central point of the paragraph.

Response: *The paragraph was revised to improve clarity.*

A.1.4. Comments from Kenneth T. Bogen

Comment: Chapter 2 ("Variability and Uncertainty") of the 2009 U.S. EPA Exposure Factors Handbook Update (External Review Draft) is conceptually weak, at points reflects poor scholarship by improperly characterizing and/or omitting certain key references, and contains statements that are inaccurate and/or confusing.

Response: *The chapter has been revised and updated. Several new references have been added.*

Comment: Chapter 2 begins with clear statement that "Accounting for variability and uncertainty is fundamental to exposure assessment and risk analysis.

Properly addressing variability and uncertainty will increase the likelihood that results of an assessment or analysis will be used in an appropriate manner." However, conceptual weakness of the chapter follows by its failure to clearly articulate just after this statement why these initial assertions are true, or at least where in the following chapter text answers to this fundamental question of "why" may be found. A more clear presentation of the utility of uncertainty/variability analysis in the specific context of environmental exposure assessment can be found in the recent publication:

Bogen KT, Cullen AC, Frey HC, Price PS. Probabilistic exposure analysis for chemical risk characterization. Toxicol Sci 2009; 109(1):4−17; doi: 10.1093/toxsci/kfp0 (online publication; print version in press). This paper (not cited in the 2009 U.S. EPA external review draft Handbook) details conceptual history, utility, and methodologies bearing on uncertainty (U) analysis, variability (V) analysis, and analysis of joint uncertainty and variability (JUV) in the specific context of environmental exposure assessment. This paper provides conceptual clarity by focusing first on sets of specific purposes that are facilitated by U, V and JUV analysis (only some of which will concern a regulatory agency like the U.S. EPA), and by then clearly summarizing why these types of analyses may facilitate those corresponding sets of goals. In particular, discussion of the central conceptual relationship between U, V and JUV analysis of risk per se, to that of exposure per se, discussed by Bogen et al. (2009), is not addressed in any detail in the Draft Handbook. In contrast, e.g., Section 2.1 ("Variability Versus Uncertainty") of the Draft Handbook begins by stating "the U.S. EPA (1995) has advised the risk assessor (and, by analogy, the exposure assessor) to distinguish between variability and uncertainty," but then fails to describe specific purposes served by this recommendation. Only after a meandering "example" concerning a calculation of average daily dose (ADD) is it revealed that the National Research Council (NRC, 1994) "noted" that "the realms of variability and uncertainty have fundamentally different ramifications for science and judgment." Handbook readers are not informed that the 1995 U.S. EPA recommendation had followed a specific recommendation in the 1994 NRC report that the U.S. EPA ought to adopt a policy "to distinguish between variability and uncertainty", for specific reasons described in the NRC report, which report contained specific chapters on Variability, Uncertainty, and Aggregation, including reasons for, and methods for, aggregating variability and uncertainty in exposure and/or risk assessment—none of which is summarized in any systematic way for Handbook readers. Even in the ADD example, it is not explained (as it is by Bogen et al. 2009) that the choice of whether or how to characterize U, V, and/or JUV in an ADD estimate will often hinge on the dose-response function likely to used in dose-response assessment for risk characterization into which exposure assessment typically feeds; e.g., for a linear no-threshold dose-response model, variability in dose-rate over time tends to be irrelevant insofar as time-weighted average values of individual ADD are fully sufficient to characterize corresponding individual risks. The same is generally not true whenever risk is nonlinearly related to exposure. For example, acute risk may proportional to a biologically effective dose (toxic load, L) that, in turn, is nonlinearly related to ambient concentration (C) and duration (T)

according to a generalized Haber's Law relationship: L = k C*n* T, which is substantially nonlinear whenever the "toxic load exponent" (*n*) in this relationship differs markedly from 1, as it is estimated to do for acutely toxic gases such as hydrogen sulfide and hydrogen cyanide (see: Bogen KT. Risk analysis for environmental health triage. Risk Anal 2005; 25:1085−1095). In this case, failure (as do commonly used atmospheric dispersion models such as the USEPA ALOHA model) to account jointly for temporal variability in C, and in spatial heterogeneity in time-integral values of C actually realized within a defined geographic region, have been estimated to yield large (e.g., up to 20-fold) under-estimates of the area of zones potentially affected by a specified level of toxic severity (see: Bogen KT, Gouveia FJ. Impact of spatiotemporal fluctuations in airborne chemical concentration on toxic hazard assessment. J Hazard Mater A 2008; 152(1):228−240). Incidentally, parameters governing the magnitude of expected spatiotemporal variability in C, e.g., in urban vs. rural areas, are not discussed in the Draft Handbook.

> ***Response:*** *A new section was added to discuss a literature review of variability and uncertainty. Numerous new references were cited and discussed in this section and throughout the chapter. Bogen et al., (2009) was added as a reference.*

Comment: Poor scholarship in Chapter 2 of the Draft Handbook is indicated by its heavy, at points egregious, citation of NRC (2009) as a reference source for numerous ideas about uncertainty/variability analysis in the specific context of environmental exposure and risk assessment discussed in the text, despite the fact that these ideas have received much greater detailed treatment in earlier reports and publications. This pattern begins with the third sentence of Chapter 2: "Characterizing and communicating uncertainty and variability should be done throughout all the components of the risk assessment process (NRC, 2009)." This pattern fails to give proper credit to the fact, noted above, that a previous NRC (1994) report had 15 years earlier focused on just this specific issue in great detail, as to a lesser extent did the later U.S. EPA (1995) report, and as have several previous publications in peer-reviewed scientific journal publications. This occurs repeatedly throughout Chapter 2. As one specific example, in Section 2.6 ("Analyzing Variability and Uncertainty"), the NRC (2009) is repeatedly cited as a source of information on this subtopic, whereas calculation methods specific to "analyzing uncertainty and variability" are mentioned most directly (and rather inexplicably) only earlier in Section 2.3 (called "Coping with Variability"), at the sentence: "Techniques for characterizing both uncertainty and variability are available, and generally require two-dimensional Monte Carlo analysis (U.S. EPA, 2001)." This citation fails to provide any details of these techniques, and fails to alert readers that such specific information on joint uncertainty/variability analysis−critical to the topic of Section 2.6 and to Chapter 2 in general−are discussed in great detail in Chapter 11 and Appendix I-3 of NRC (1994), which drew heavily on−and so cited as key conceptual sources—two references, Bogen and Spear (1987) and Bogen (1990), that only are cited

elsewhere in the Draft Handbook, at places not logically related to the specific focus of these references on joint analysis of variability and uncertainty in environmental exposure and risk assessment: (Bogen, K.T.; Spear, R.C. (1987). Integrating uncertainty and interindividual variability in environmental risk assessment. Risk Analysis. 7(4):427−436, and Bogen, K.T. (1990) Uncertainty in environmental health risk assessment. Garland Publishing, New York, NY.) The Draft Handbook fails entirely to cite or discuss a highly related later publication that again focused joint analysis of variability and uncertainty in assessment of environmental exposure as well as risk (Bogen KT. Methods to approximate joint uncertainty and variability in risk. Risk Anal 1995; 15:411−419). The earliest of these publications, Bogen and Spear (1987), was indeed the first publication in a peer-reviewed scientific journal to focus specifically on the topic of joint analysis variability and uncertainty in assessment of environmental exposure as well as risk, and was the first such publication to derive and present fundamental mathematical relationships linking joint uncertainty and inter-individual variability in exposure and associated individual risks, to uncertainty in corresponding estimated population risk. In view of the fact that Section 2.7 ("Presenting Results of Variability and Uncertainty Analysis") highlights that "The risk descriptors in the Exposure Guidelines include those for individual and population risk," one would think that the Handbook should (e.g., most appropriately in Section 2.6) at least mention the specific topic, and perhaps even give some mathematical details, concerning the mathematical linkage between these risk descriptors−as first described by Bogen and Spear (1987)−and how this linkage becomes impossible to characterize whenever no distinction is made between uncertainty and variability in exposure as well as in risk−again as first pointed out by Bogen and Spear (1987). Not only does the Draft Handbook fail to do this, but it totally mischaracterizes the nature of the paper by Bogen and Spear (1987), in particular mischaracterizes and dilutes its general significance and relationship to the topic covered by Section 2.6 that addresses both uncertainty and variability, by the following incongruous and inaccurate statement: "Uncertainties associated with the model need to be evaluated (NRC, 2009). Reviews of these methods are available in Bogen and Spear (1987), ..." It is completely inaccurate to relegate Bogen and Spear (1987) to a mere "review", and to totally mischaracterize its focus as being only on methods to address "model uncertainty," when in fact this was a seminal peer-reviewed journal publication that developed nomenclature, developed fundamental mathematical relationships, and illustrated their application to joint uncertainty and variability analysis for environmental exposure and risk assessment using two-dimensional ("Nested") Monte Carlo analysis, as clearly recognized and properly cited by NRC (1994) and by Bogen et al. (2009). To cite merely U.S. EPA (2001) as a basis or source or reference for ideas fundamental to joint analysis of uncertainty and variability in environmental exposure and risk assessment is misleading and indicates poor scholarship.

Response: *The chapter was revised. "Relevant" references were added. Chapter 11 and Appendix I-3 of NRC (1994) and Bogen et al., (1990) are*

now cited. However, the chapter is not intended to provide a comprehensive guidance on uncertainty analysis. A literature review section was added to refer the reader to other, more in-depth publications.

Comment: Section 2.4 of Chapter 2 distinguishes three categories of uncertainty: scenario, parameter, and model. An important point omitted on this topic is the fact noted on page 197 (footnote 4) of NRC (1994) that "some ... model choices can be safely recast as parameter uncertainties," i.e., that the distinction between non-parameter and parameter uncertainties is arbitrary to the extent that all "non-parameter" uncertainties can be represented as parameter uncertainties of a more broadly defined model.

Response: *The section on parameter and model uncertainty has been expanded.*

Comment: Section 2.6 states "Price, et al. (1999) review the history of the inter-individual (or intra-species) uncertainty factor, as well as the relative merits of the sensitive as well as the relative merits of the sensitive population conceptual model versus the finite sample size model in determining the magnitude of the uncertainty factor. They found that both models represent different sources of uncertainty and that both should be considered when developing inter-individual uncertainty factors. Uncertainties related to inter-individual and inter-species variability are treated in Hattis (1997) and Meek (2001), respectively." By using the dated phrases "uncertainty factor" and "inter-individual uncertainty factor" in this specific text, this statement is confusing to the reader in view of the careful distinction made earlier between variability and uncertainty. In keeping with the distinction made earlier in the Chapter, the factor at issue is more properly referred to as a "variability factor" or "inter-individual variability factor", among the various adjustment factors (pertaining to, e.g., animal-to-human-extrapolation scaling and/or its uncertainty, uncertainty due to data gaps, or to inter-individual variability in susceptibility) used in deriving a reference dose or concentration for a classical toxicity endpoint.

Response: *The paragraph was revised to say "…interindividual variability factor."*

A.2. Chapter 3 (Water Ingestion)

A.2.1. Comments from the Tri-Service Environmental Risk Assessment Work Group

Comment: Section 3.1: 5th paragraph. This paragraph includes the following sentence, "The recommendations and confidence ratings for general water ingestion ingestion among pregnant and lactating women, and ingestion while swimming are found in Section 3.2." Delete the second "ingestion" so the

sentence reads, “The recommendations and confidence ratings for general water ingestion among pregnant and lactating women…”

Response: *The section was revised as per comment.*

Comment: Section 3.3.2.1: It is not clear how the Body water content report derived the values. Most of the report descriptions give a brief summary of how values were derived. This section provides no information to let the reader determine the validity of the Body water content report. Rather than saying “about 77%” or “about 60%” a mean and confidence interval should be provided.

Response: *This type of information is not available in the source document.*

Comment: Section 3.3.2.7: This section contains the following sentence: “The chief limitation of the study is that the data were collected in 1978 and do not reflect the expected increase in the U.S. consumption of soft drinks and bottled water or changes in the diet within the last two decades.” 1978 was 31 years ago, which is three decades. Recommendation: Replace “two” with “three.”

Response: *The section was revised as per comment.*

A.2.2. Comments from the American Chemistry Council

Comment: A newly available study by Dufour is used to estimate water ingestion while swimming using cyanuric acid as a tracer. As written, it was not clear if the ingestion rate could be overestimated due to including tracer uptake from dermal or maybe even inhalation exposure during swimming as well. The text should include discussion concerning dermal exposure, i.e., whether there was any need to correct for dermal absorption of the tracer, and if so, indicate how this was done.

Response: *The Dufour study indicated that dermal absorption is negligible. This has been added to the text.*

Comment: Also, it would be helpful to point out within the recommendation table that these values are for a 45 minute event as per experimental design, and may need to be adjusted if used with swimming time recommendations reported elsewhere in the EFH.

Response: *The table includes both intake per event and intake per hour and includes a footnote to indicate that an event was 45 minutes. The hourly rate has been adjusted from 45 minutes to 1 hour.*

A.3. Chapter 4 (Non-Dietary Ingestion Factors)

A.3.1. Comments from the American Chemistry Council

Comment: Xu *et al.,* 2009 indicated that there was a statistically significant difference in object-to-mouth behavior with regard to study as well as location and age group. The authors suggest that this may be due to differences in the definition of "object" categories across studies. EPA should include this information within the EFH. To enhance transparency and further address this issue, Table 4-1 should include footnotes as to which items were included in the object category for each of the studies used in the analysis.

Response: *The object categories varied depending on the study authors. Because Xu et al., (2009) is a meta analysis of various studies, object categories are those defined by the original authors. Tables indicate the items that were considered "objects." Footnotes were added where appropriate.*

A.4. Chapter 5 (Soil Ingestion)

A.4.1. Comments from the Tri-Service Environmental Risk Assessment Work Group

Comment: Sections 5.1 and 5.2: As presented in the text it is not clear whether soilpica and geophagy are distinct behaviors from one another. Since upper percentile recommendations for soil ingestion are based upon soil-pica and geophagy and are presented for both separately it is important that the differences between these behaviors be understood. Recommend that a clear definition of geophagy be presented in the text. If geophagy cannot be distinguished from soil-pica the use of separate terms should be reconsidered.

Response: *The ATSDR definitions have been retained; however, additional text has been added to Section 5.2 to help clarify the distinction between soil-pica and geophagy.*

Comment: Definitions are presented for soil and dust, but size fraction differences are not presented. The differences between the two would be clearer if this information were presented as part of the definition, and would also enhance the usability of the information presented in this chapter. Please present size fraction information for soil, indoor dust and outdoor dust as part of their definition in the text.

Response: *Information on soil and dust size fractions have been added to the Introduction of the chapter.*

Comment: Section 5.3.2: Studies which rely upon self-reported data are known to not be as reliable as studies that collect empirical data. The Vermeer and Frate study which relies upon self reporting behaviors should not be considered a

reliable source of quantitative data and would be more appropriately categorized as a supporting or secondary analysis study. There is nothing presented in the summary of the study suggesting that it is appropriate to assume the same ingestion rate for children as for adults. The status of Vermeer and Frate should be reconsidered as a primary study. We strongly recommend that the study be reconsidered as a source of recommended soil ingestion parameters. If retained, the application of 50 mg/day needs to be justified for children.

Response: *The Vermeer and Frate study was included as a "key" study because it was the only source for a quantitative soil ingestion estimate for the practice of geophagy (50 g/day for both adults and children). The 50 mg/day soil ingestion value for children, discussed above, was based on the study by Hogan et al. (1998), while the 50 mg/day soil ingestion value for adults was based on the study by Davis and Mirick (2006). Data limitations do not permit further refinements on the recommendations. U.S. EPA is trying to make use of all the data available.*

Comment: Section 5.4.3: This section should discuss the relative strengths/weaknesses of survey response data to quantify exposures. Please include discussion of the limitations of survey responses for quantifying exposures.

Response: *This section was expanded to include discussion of the "activity pattern" methodology. The limitations of the survey responses are included in this discussion.*

A.5. Chapter 6 (Inhalation)

A.5.1. Comments from the Tri-Service Environmental Risk Assessment Work Group

Comment: General Chap. 6: The bulk of Chapter 6 is comprised of lengthy, detailed descriptions of the essential studies that gave rise to the new sets of inhalation rates that are reported in the revised Exposure Factors Handbook. It would seem that a helpful addition to the chapter would be to present a table (matrix) that condenses the multi-page discussion by culling the essential elements of each study. Information to be presented in columns would be such things as age(s) of populations studied, activity patterns studied, mean inhalation rates, adequacy of data (in terms of size of the dataset), advantages of the dataset/study, and limitations of the dataset/study.

Response: *Numerous summary tables were provided in the chapter in an effort to condense the large amount of data into a more manageable format. In addition to Tables 6-1 and 6-2, which provide summaries of recommended inhalation rates at the beginning of the chapter, Table 6-3 presents a summary of the limitations/advantages of the "key" studies, and Tables 6-20 and 6-21 condense the mean and 95th percentile inhalation*

values for the "key" studies and show how recommendations were arrived by combining the data from the various studies. In addition, Table 6-25 provides a concordance of age groupings for the "key" studies used. The U.S. EPA believes that adding more information to these tables (e.g., elements of each study, limitations) will make the summary tables more complicated and difficult to read.

Comment: Section 6.2: Table 6-3: From the title of this table (Table 6-3) it is not clear to the reader if it refers to long-term or short-term exposures. Note that the titles of Tables 6-1 and 6-2 specifically indicate the type of exposure. Recommend renaming this table so that it is clear to the reader if this applies to long-term, short-term or both exposure periods.

Response: *The phrase "Long- and Short-Term" was added to the title for Table 6-3. The title has been edited to read: "Confidence in Recommendations for Long- and Short-Term Inhalation Rates."*

Comment: Section 6.3.1: The first sentence of this Section's last paragraph lists an advantage of the study as the fact that I provides inhalation rate data for age groups of less than one year of age. However the lack of toxicity data to coincide with exposures for age groups of less than one year old raises concerns about the proper use of these values. We recommend that this document acknowledges that there is a lack of appropriate toxicity factors (cancer slope factors, reference doses, etc.) to support assessments for this age group.

Response: *Although the U.S. EPA agrees that the lack of toxicity data for the various age groups is a pitfall when doing risk assessment for susceptible lifestages, it is not a limitation of the exposure factors data. Adding such a statement is outside the scope of the Handbook.*

Comment: Section 6.3.3: An advantage of this study is given as the narrow age ranges. We recommend that this document acknowledges that there is a lack of appropriate toxicity factors (cancer slope factors, reference doses, etc.) to support assessments for this age group.

Response: *See previous response.*

Comment: Section 6.4.1: 1st paragraph What might constitute occupational vs. nonoccupational activities for children is not readily understood and could use clarification. Briefly explain if light activities for children were divided between occupational and nonoccupational activities as in adults. If so, define what that means for children.

Response: *The study summary was revised to clarify that the time periods for "rest" and "light activities" apply to both adults and children, while occupational activities refer only to adults.*

Comment: Section 6.4.3: 1st paragraph Shamoo et al. (1990) cited a "macho effect" as an explanation for an observation in their study. The term is not a common term. It would be helpful to have this term defined as in the study in order to understand the impact this effect had on the study.

Response: *Additional text was added to the Shamoo et al. (1990) summary to clarify the term "macho effect," as used by the study authors. It refers to the fact that the younger male subjects were reluctant to report "very heavy" exercise even when it was obvious to an observer, because they considered it an admission of poor physical condition.*

A.5.2. Comments from the American Chemistry Council

Comment: We reiterate the comment made earlier indicating other percentiles are more appropriate than the 95th percentile as an upper bound. This applies to both long- and short-term recommendations. Similar to the information provided in the text on caloric intake needed to maintain this level, food consumption data and human respiratory physiology parameters should be used to substantiate the recommended levels. Further, if the upper values of the distribution are not representative of inhalation rates that could be maintained long term, it is very likely that the average values of the distribution are biased upward. If so, the text should recognize the conservative nature of the average values in discussion.

Response: *These issues are discussed in the Recommendations section.*

Comment: ACC had previously commented on the public comment draft of Lordo et al., 2006, which is now final as the EPA 2009 report included in the inhalation analysis. The EPA 2009 inhalation rate values remain the same as in the earlier draft, indicating there was no adjustment in the analysis in response to these comments. A copy of our earlier comments is attached as an appendix. The approach used leads to upper rates that are unrealistically high likely due to the inability to link body weight with time activity patterns. The limitations description on p. 6-8 should include this point.

Response: *The limitations described by the reviewer have been added to the discussion in Chapter 6. There is no scientific method to make the adjustments this reviewer is suggesting.*

Comment: As inhalation rates vary by gender, previous long-term recommendations were presented by gender. Only combined gender recommendations are included in the current document. The reason for this should be addressed within the document.

Response: *The recommended inhalation rates shown in Table 6-1 at the beginning of the chapter are intended to provide the broadest summary of inhalation rates for users of the Handbook. Gender- and age-specific inhalation rates from the studies used for the recommendations, including those expressed on a body-weight basis, are provided later in the chapter.*

Comment: Layton (1993) which served as the basis for previous recommendations should remain as one of the key studies. None of the current key studies include estimates based upon food intake data for adults, which is included in the Layton study.

Response: *The U.S. EPA disagrees with the reviewer. Arcus-Arth and Blaisdell (2007) used the same methodology as Layton (1993), but updated the data based on more up-to-date food consumption data. The Arcus-Arth and Blaisdell (2007) study was used to replace Layton (1993) in the recommendations.*

Comment: Short-term recommendations should be made based upon data from multiple studies cited within the document, not a single study.

Response: *The U.S. EPA (2009) study was used as the sole source for recommendations for short-term inhalation rates because it provided data for the age groups of interest, and it is representative of the U.S. population. Other studies available are limited in terms of sample size and lifestages.*

A.6. Chapter 7 (Dermal Exposure Factors)

A.6.1. Comments from the Tri-Service Environmental Risk Assessment Work Group

Comment: Section 7.1: 2nd paragraph. The sentence is listing factors that influence dermal absorption. The amount of chemical delivered to the organ is the result of the integration of these factors. Recommend deleting "and the amount of chemical delivered to the target organ"

Response: *The section was revised as per comment.*

A.7. Chapter 9 (Intake of Fruits and Vegetables)

A.7.1. Comments from the Tri-Service Environmental Risk Assessment Work Group

Comment: Table 9-1: It is confusing for users when the age groups overlap. In reference to 16 to<21 years and 20 to <50 years; which age group would a reader chose if they wanted the consumer only 95th percentile for total fruits for 20 year olds, 3.7 g/kg-d or 4.4 g/kg-d? If the recommended values for the age groups were identical it probably would not matter if the age groups overlapped. However, different values are provided for the age groups. Although the slightly different age groups have to be used based on guidance and age groups used in studies, it would be preferable if they did not overlap.

Response: *The section was revised as per comment.*

A.8. Chapter 10 (Intake of Fish and Shellfish)

A.8.1. Comments from the Tri-Service Environmental Risk Assessment Work Group

Comment: Section 10.2.1 and Table 10-1: Since the recommended values are broken out by fish groups and there are numerous types of fish, it would help to have examples of the different fish in each group. Letting the readers know that there is a table that includes the fish types in each groups will save time. Add a sentence that states that examples of freshwater, estuarine and marine fish can be found in Table 10-8.

Response: *The section was revised as per comment.*

Comment: Section 10.2.1: EPA conducted a "key" 2002 analysis regarding fish intake from data sourced from USDA data 1994−1996, & 1998.We recommend providing more recent data for a key EPA study/analysis. Data from 1994/96/98 may reflect inaccurate confidence ratings. We recommend addressing this uncertainty.

Response: *The chapter was updated to include data from NHANES 2003−2006.*

Comment: Section 10.2.1: Recommended values were not available for children less than 3 years old or 18 to < 21. Values for these age ranges should be part of the study.

Response: *Data for these age groups cannot be provided because they were not part of the analysis of the data in the study.*

Comment: Section 10.2.1: The 1994−1996, 1998 CSFII data, may not reflect accurate confidence ratings for fish intake for 3 to 18 years old. Is there new data (post 1998) supporting accurate confidence rating for fish intake relative to children ages 3 to 18. If more recent data are available we recommend considering them for inclusion. Otherwise, ensure that the uncertainty associated with the use of these data is adequately discussed.

Response: *The chapter was updated to include data from NHANES 2003−2006.*

Comment: Table 10-1: Based on the key study used data values were not presented for children < 3 years and18 to <21 years, but Table 10-1 provides a recommended value for >18 years (this would include 18 to <21 years). What is the rationale for including the 18 to <21 years without data and not including values for < 3 years? Although some children under 3 probably eat fish, recommended values for this age group was not included. Rationale is because data were not presented in the key study used. However, data were not presented

for 18 to <21, but there are recommended values that include that age group. Please explain.

Response: *The chapter was updated to include data from NHANES 2003−2006. The recommendations are now based on these data.*

Comment: Table 10-2 and 10-4: Why are the overall ratings rationales different? For General Population fish intake the overall rating rationale (Table 10-2) is based on the mean and long-term upper percentiles. The Recreational Marine fish intake overall rating rationale (Table 10-4) is for adults and children.

Response: *The rationales are different because of the different types of data sets used.*

A.8.2. Comments from Exponent

Comment: We were encouraged to see so many creel-angler surveys added to Chapter 10, Intake of Fish and Shellfish, of the Exposure Factors Handbook 2009 Update compared to the 1997 version. Of particular interest to us were those related to freshwater and marine recreational creel-angler surveys. The 2009 Update encompasses surveys from varying time periods, regions, and waterbody types, and the survey designs vary. In addition, we were encouraged to see EPA recognize and embrace the benefit of applying the data that are most relevant to the scenarios and locations being assessed, including site-specific data. Following these themes, we would appreciate EPA's consideration of including in the 2009 Update a creel-angler survey that we performed on the Lower Passaic River. The onsite survey was performed during 143 days over the course of a year and included two components: survey personnel in a roving boat assigned to enumerate and capture demographic and fishing or crabbing characteristics of every angler or crabber observed, and an intercept team that interviewed anglers and crabbers at sites throughout the study area. In short, this survey is the most comprehensive survey of which we are aware for the purpose of exposure assessment. The methodology used allowed us to accurately characterize fishing and crabbing habits and consumption for a highly urban and industrialized estuary with limited fishing access. The results of the survey are testament to EPA's view on site-specific data, given that such data better reflect actual consumption from the waterbody than application of general fish consumption values. The details of the survey, and the results, are clearly laid out in a series of published articles:

• Kinnell J, Bingham M, Hastings E, Ray R, Craven V, Freeman M. A survey methodology for collecting fish consumption data in urban and industrial water bodies (Part 1). Journal of Toxicology and Environmental Health, Part A, 2007; 70:477−495.

Response: *This paper provides information on the methods used but does not provide any "relevant" information on intake.*

• Ray R, Craven V, Kinnell J, Bingham M, Freeman M, Finley B. A statistical method for analyzing data collected by a creel/angler survey (Part 2). Journal of Toxicology and Environmental Health, Part A, 2007; 70:496−511.

Response: *This paper provides data on statistical methods but no real intake data that could be provided as "relevant" data for this chapter.*

• Ray R, Craven V, Bingham M, Kinnell J, Hastings E, Finley B. Human health exposure factor estimates based upon a creel/angler survey of the Lower Passaic River (Part 3). Journal of Toxicology and Environmental Health, Part A, 2007; 70:512−528.

In addition, the study design and analysis underwent extensive peer review, the results of which are also captured in a published article:

Response: *This paper provides some information on cooking methods and species caught. However, it has not been included in the chapter because the information is specific to only a 6-mile stretch of the Lower Passaic River that was highly contaminated and only includes intake data for a small number of individuals from that specific study area. The information may be too site-specific to be of interest more broadly.*

• Finley BL, Iannuzzi TJ, Wilson ND, Kinnell JC, Craven VA, Lemeshow S, Teaf CM, Calabrese EJ, Kostecki PT. The Passaic River creel/angler survey: Expert panel review, findings, and recommendations. Human and Ecological Risk Assessment 2003; 9(3):829−855.

Response: *This paper provides some information on intake. However, it has not been included in the chapter because the information is specific to only a 6-mile stretch of the Passaic River that was highly contaminated and only includes intake data for a small number of individuals from that specific study area. The information may be too site-specific to be of interest more broadly.*

A.8.3. Comments from the Penobscot Indian Nation

Comment: Our comments specifically address Table 10-6: Summary of Relevant Studies on Native American Subsistence Fish Intake. We are greatly concerned that the information provided in the table from the ChemRisk 1992 study is inaccurately being referenced and described as a study of Native American subsistence fish intake. The referenced study is not a survey of subsistence fish intake rates of Maine tribes, but is a mail survey of recreational fishermen holding state of Maine fishing licenses….Because the 10 g/day rate provided in this proposed update is not a subsistence rate, we request that it be removed from Table 10-6.

Response: *The ChemRisk 1992 study has been removed from Table 10-6 and from the section on Native American intake studies.*

Comment: We believe that the Penobscot Nation subsistence fish rates are more in line with the 142.4 g/day rate for protection of subsistence fishers that are recommended in the EPA's "Revisions to the Methodology for Deriving Ambient Water Quality Criteria for Protection of Human Health" (2000) EPA 822-B-00-004. We believe the updated Exposure Factors Handbook should include and refer to EPA's own recommended subsistence default rate. In developing this default rate, EPA went through a thorough process of examining many consumption surveys, from many locations, from many tribes across the country. The rate is based on defensible, credible science and is designed to be protective of highly exposed populations of subsistence fishers.

Response: *Chapter 10 has been revised, and a paragraph was added describing subsistence behaviors. A few references were added regarding subsistence fishing. Values on subsistence fishing found in the literature were generally based on anecdotal information. The value of 142.4 g/day cited in U.S. EPA (2000) is based on the 90th percentile consumption fresh/estuarine finfish and shellfish for the general population obtained from the CSFII 1994−96 survey. It does not come from a survey of subsistence fishing population. Office of Water adopted this value as a policy decision. The goal of the Handbook is to present the available data. Policy decisions as to what values to adopt are left with the program offices and other users of the Handbook.*

A.9. Chapter 11 (Intake of Meats, Dairy Products, and Fats)

A.9.1. Comments from the Tri-Service Environmental Risk Assessment Work Group

Comment: Section 11.1: 2nd paragraph. A terminal period is missing between "population" and "In" approximately half way down the paragraph. Edit sentences so they read, "Per capita intake rates are generated by averaging consumer only intakes over the entire population. In general…"

Response: *The section was revised as per comment.*

Comment: Section 11.1: 3rd paragraph. The cooking losses in chapter 13 are not directly findable in chapter 13's table of contents. Section 13.3 should be specifically referenced, where the cooking losses are explained. "For more information on cooking losses and conversions necessary to account for such losses, the reader is referred to Chapter 13 Section 3 of this Handbook."

Response: *U.S. EPA does not believe that this is necessary because the text in Chapter 13 is not lengthy.*

Comment: Section 11.3.2: Five of the reports listed are about children. There is redundant use of the same data set, multiple reports use FITS data. It would increase the document's transparency and clarity if this potential limitation were clearly stated.

Response: *The text clearly states that these studies all use data from FITS. While the data originate from the same study, each report provides different information or sets of data.*

A.10. Chapter 12 (Intake of Grain Products)

A.10.1. Comments from the Tri-Service Environmental Risk Assessment Work Group

Comment: Section 12.2: 2nd paragraph. The U.S. EPA used outdated analysis of data from the 1994−96 and 1998 Continuing Survey of Food Intake by Individuals (CSFII) in selecting recommended intake rates. Recent data enhances confidence ratings for grain intake; we recommend using more recent data if available.

Response: *The chapter was updated to include data from NHANES 2003−2006. The recommendations are now based on these data.*

A.11. Chapter 13 (Intake of Home-Produced Foods)

A.11.1. Comments from the Tri-Service Environmental Risk Assessment Work Group

Comment: Section 13: The current table of contents provides very little information for the content of the subsections. For example, cooking losses are referenced in other chapters. We recommend including important subsections such as "cooking losses" in the table of contents.

Response: *U.S. EPA does not believe that this is necessary because the text in Chapter 13 is not lengthy.*

Comment: Section 13.3.1 has information relevant to other parts of the Handbook, but as it is currently organized to find 1 page worth of information the reader need to look at 5 pages. Section 13.3.1 is 5 pages long. Important topics are covered in it, if it was broken down into several sub portions, finding relevant information would be easier.

Response: *U.S. EPA does not believe that this is necessary because the text in Chapter 13 is not lengthy. Also, this reorganization would be inconsistent with other chapters.*

A.12. Chapter 14 (Total Food Intake)

A.12.1. Comments from the Tri-Service Environmental Risk Assessment Work Group

Comment: Table 14-1: The recommended values for children and adults are overlapping. What if a reader wanted to know the total food intake for 20 year

olds? Which recommended value should they use, 16 to <21 years or 20 to <40 years? Although the slightly different age groups have to be used based on guidance and age groups used in studies, it would be preferable that they do not overlap.

Response: *The section was revised as per comment.*

A.13. Chapter 15 (Intake of Human Milk, Lipids, and Formula)

A.13.1. Comments from the Tri-Service Environmental Risk Assessment Work Group

Comment: Section 15.3.1: Provide a reference or why the density of human milk was assumed to be 1.03 g/ml. Include reference.

Response: *The NAS (1991) reference has been provided for the human milk density.*

A.14. Chapter 16 (Activity Factors)

A.14.1. Comments from the Tri-Service Environmental Risk Assessment Work Group

Comment: Section 16.2.2: 1st paragraph Sentence contains a typographical error, "…the occupational mobility recommendations are presented in Table 16-4. It should be noted that…" Replace underlined with "Table 16-4. It should". Correction for typographical error (lack of sentence punctuation).

Response: *The section was revised as per comment.*

Comment: Section 16.5.2: The summaries of Israeli and Nelson (1992), National Association of Realtors (1993) and the U.S. Bureau of the Census (2008b) do not provide limitations of the studies. Understanding the possible limitations of the studies will help to weigh the strength of the studies' findings. Please include the limitations or note that no limitations existed.

Response: *The section was revised as per comment.*

A.15. Chapter 17 (Consumer Products)

A.15.1. Comments from the American Chemistry Council

Comment: The chapter contains much additional information in a concise manner. Categories of consumer products can be quite varied, for example adhesives may include glue sticks, hobby glue, aerosol sprays, floor and tile adhesives; similarly, wood stains, varnishes and finishes may include aerosol and liquid products. Where references provide further description of the range of products that were included in a given category, this information should be provided. For example, a companion table to Table 17-5, that summarizes the

definitions and/or products included in each category of the Westat study, would help to ensure appropriate application of these data.

Response: *The Exposure Factors Handbook presents data as they are shown in the original papers. Additional detail is not available.*

A.16. Chapter 19 (Residential Building Characteristics)

A.16.1. Comments from the Tri-Service Environmental Risk Assessment Work Group

Comment: Section 19.4.2: Currently equations 19-1 and 19-2 are identical, which does not make sense. Moreover, the variables cited for 19-1 are not even present in the equation. Equation 19-1 needs to be corrected.

Response: *The section was revised as per comment.*

Comment: Section 19.5.1: The reference to Table 19-32 is incorrect since this section only includes 21 tables. Update the reference to this table.

Response: *The section was revised as per comment. It is now Table 19−35.*

Comment: Section 19.5.12: The reference to Section 19.4.5 seems to be in error. Correct the reference to this section.

Response: *The section was revised as per comment.*

Comment: Eqn 19-6: The label for the equation should be moved to a different line from the equation, either above or below it. The label of Eqn 19-6 is difficult to read since it is up against the column boundary.

Response: *The section was revised as per comment.*

A.17. Glossary

A.17.1. Comments from the Tri-Service Environmental Risk Assessment Work Group

Comment: Glossary G-3: A slight but critical distinction needs to be made here. It is the *intent* of the benchmark dose (or concentration) to track changes in the response rates of adverse effects. Nevertheless, in the great majority of cases, it is not known if it is an adverse effect that is under study. By way of example, if a liver enzyme is being under-produced, this is not an adverse effect unless it is definitively known that the underproduction (itself, and in that specifically measured degree) leads to a compromised health condition. Update text as appropriate to clarify this distinction.

Response: *The section was revised as per comment.*

APPENDIX B. COMMENTS THAT NEEDED NO RESPONSE

The following comments necessitated no response.

B.1. Comments Related to Charge Question 1

Charge Question 1: Please comment on the organization of the Handbook. Does the EFH document present the information, including data provided in the tables, in a clear, easily understood, and usable format? What can be done to improve the format?

Comment: The organization of the Handbook is appropriate. In general, the data presented in tables are clear and usable in the current format.

Comment: The organization is very good. The up-front summary of all recommendations is very useful and easy to find. Starting each chapter also with the recommendations really helps with quickly locating the key information.

B.2. Comments Related to Charge Question 2

Charge Question 2: Please comment on whether the factors currently addressed in the EFH are those that are most needed to conduct exposure assessments?

Comment: The factors that are addressed in the Draft Exposure Factors Handbook are the most needed for exposure assessment, although I did suggest that data on percent of total consumption for homegrown produce and meats be reviewed. The selection of the key studies seems appropriate for the chapters I reviewed, except for the 0−2 age range for breathing rates. The NHANES data when USEPA finishes its analysis should probably replace the CSFII data in most cases. The confidence ratings for the Chapters that I reviewed seemed appropriate. The only other source of data that I identified was for Chapter 10.

Response: *Responses to individual chapter comments are provided in the response to comments on those chapters.*

Comment: In terms of the topic areas selected, the Handbook includes the most important factors. Within the residential section, I do see some factors missing but I include those with my answers to question 15.

Comment: The factors addressed in the EFH are relevant and generally adequate to conduct exposure assessments for subsequent risk assessments.

Comment: The factors currently addressed in the 2009 Update of the EFH should be generally adequate in the context of most exposure analyses that this Handbook is intended to support, i.e., excluding "exposure assessments involving physiologically-based pharmacokinetic (PBPK) modeling" (as per statement on page 1-1) or, in general, analyses that would not attempt to incorporate other levels (i.e., beyond pharmacokinetic) of biological information in their methods.

Comment: The document appears to strike a reasonable balance of exposure factors considered including both general and specific factors (e.g., food ingestion and activity patterns). While there may be several other specific "pathways" and, hence, factors that are worthy of review and recommendations, the current focus of the EFH appears appropriate.

Comment: I believe the most important factors are presented in the document and, where appropriate are sub-divided by age group.

B.3. Comments Related to Charge Question 5

Charge Question 5: Please comment on whether the confidence ratings used to select studies and rate factors provide a clear rationale and adequately reflect the advantages and/or limitations of the studies addressed in the document. Please provide suggestions for alternative approaches for addressing confidence ratings, if appropriate.

Comment: Considerable attention is given to the confidence rating methodology in the introduction and elsewhere. And it is hard to disagree with the selected variables. These are all valuable components of confidence in the data. But in reality applying the final construct is left to "expert opinion" and judgment of the authors.

Comment: The confidence ratings are fairly subjective but I find that the EFH does a very thorough job of delineating how and why the confidence ratings were assigned. While I find the explanations informative, I think it is unlikely that the confidence ratings will have much impact on the choice of exposure factors.

B.4. Comments Related to Charge Question 6

Charge Question 6: Please comment on whether data variability has been adequately characterized and described.

Comment: The variability has been adequately described; however, you could determine best-fit parametric models for the NHANES data for Monte Carlo Analyses (Question 6). The Exposure Factors Handbook should be available in all the formats mentioned (Question 7).

Comment: Data variability is best described for age groups and sexes throughout the document where studies provide. Data variability is not well described for races or socioeconomic status for most factors (Activity factors have the most expression in variability in the chapters I was assigned). This is mostly due the lack of studies focused on these differences. However, on this issue I have specific comments below for the chapters reviewed.

Response: *Comments are addressed in the individual chapters.*

Comment: In general, data variability is addressed appropriately.

B.5. Comments Related to Charge Question 8

Charge Question 8: The Introduction contains a summary of the latest guidance and developments in exposure assessment. Please comment on whether we have captured the most important and "relevant" guidance and developments in exposure assessment.

Comment: In response to Question 8, the most important latest guidance and developments in exposure assessment have been addressed.

B.6. Chapter 1: Introduction

Comment: The Handbook is appropriately organized and generally presents the data in a logical sequence from general to specific. Having the summary table that includes all factors in the front is very useful and serves as a quick reference for the user. Generally the tables are described adequately in their titles so an assessor who is looking for a specific set of data can find it fairly easily. However it is likely that the user will need to work through a whole chapter rather than be able to go directly to what they need. The greatest difficultly is finding what you need. The layout of the tables is consistent across most of the factors and therefore once you find the needed table, where to look in the table is pretty self-explanatory.

Comment: The factors that are addressed in the Draft Exposure Factors Handbook are the most needed for exposure assessment, although I did suggest that data on percent of total consumption for homegrown produce and meats be reviewed (Question 2). The selection of the key studies seems to appropriate for the chapters I reviewed (Question 3), except for the 0−2 age range for breathing rates. The NHANES data when USEPA finishes its analysis should probably replace the CSFII data in most cases. The confidence ratings for the Chapters that I reviewed seemed appropriate (Question 4). The only other source of data that I identified was for Chapter 10 (see below).

Response: *Responses to individual chapter comments are provided in the response to comments on those chapters.*

Comment: In general the Handbook is organized in a reasonable and clear format. Most tables are easily understood and usable to those performing exposure assessments. I may have specific comments on individual tables in each chapter. Each chapter begins with a description of the exposure route and most needed/obvious exposure factors. Then each chapter presents the main exposure factors in one or two tables that appear early on in the chapter, where the data comes mainly from the key studies. Following this, the key studies are presented in more details following by detailed tables from key studies and most relevant studies and their related tables. In this manner EPA is making the data from the key studies easily accessible. However, EPA does make the user aware of the other data tables that can be used in detailed or more specialized exposure assessments. Some tables can be improved by highlighting difference in tables or areas of emphasis.

Comment: With a few exceptions delineated in my comments below, I find the format to be very "user-friendly" and do not recommend any changes in presentation of the material.

Comment: The organization of the Handbook is appropriate. In general, the data presented in tables are clear and usable in the current format.

Comment: The 2009 Update to the USEPA Exposure Factors Handbook provides a most valuable resource that summarizes a wealth of information covering a diverse range of topics and improves substantially and effectively the previous version. The information, in both narrative and tabular form, is, in general, clearly presented, and one could state that the whole document is highly readable and usable (though, of course, some improvements are possible and some are suggested in the following). As long as the updated Handbook is used within the context for which it was prepared, and the user keeps in mind that it is neither a textbook (either introductory or advanced) nor an encyclopedia of the field of exposure analysis, it can be an excellent tool for supporting basic exposure assessments that indeed could help improve standard practices in the field. The multidisciplinary teams that developed reviewed, and quality-assured this Update should definitely be commended for their effort and the overall quality of this effort's outcome.

Comment: I think the Handbook contains much-needed data on exposure factors and is an extremely valuable resource to the exposure assessment community. The Handbook includes exposure factors needed to assess inhalation, dermal, and direct and indirect ingestion exposures. Having used it in the past to assess inhalation and ingestion exposures, I can attest to its usefulness and am very glad to see that it is being considered for revision, with more recent data and analysis, where available.

Comment: I commend EPA for the level of work and resources directed to preparing this very important exposure assessment reference. This Handbook is a much-consulted resource not only in the US but also internationally, speaking to the value of the information it holds. I also appreciate the privilege of being a member of the peer-review panel.

Comment: Substantial effort has been spent both in updating references and in providing, when available, distributional data to support probabilistic analyses. These efforts will be of great use to the exposure assessment community.

Comment: The organization is very good. The up-front summary of all recommendations is very useful and easy to find. Starting each chapter also with the recommendations really helps with quickly locating the key information.

Comment: The current draft EFH provides very useful data in a systematic manner for an enormous number of factors that are needed to conduct a wide variety of exposure assessments. These exposure factors are probably the ones

that are needed most frequently, and are appropriate or inclusion in the Handbook. Some additional ones for consideration are provided below.

Comment: In terms of the topic areas selected, the Handbook includes the most important factors. Within the residential section, I do see some factors missing but I include those with my answers to question 15.

Comment: The factors addressed in the EFH are relevant and generally adequate to conduct exposure assessments for subsequent risk assessments.

Comment: The factors currently addressed in the 2009 Update of the EFH should be generally adequate in the context of most exposure analyses that this Handbook is intended to support, i.e., excluding "exposure assessments involving physiologically based pharmacokinetic (PBPK) modeling" (as per statement on page 1-1) or, in general, analyses that would not attempt to incorporate other levels (i.e., beyond pharmacokinetic) of biological information in their methods.

Comment: The document appears to strike a reasonable balance of exposure factors considered including both general and specific factors (e.g., food ingestion and activity patterns). While there may be several other specific "pathways" and, hence, factors that are worthy of review and recommendations, the current focus of the EFH appears appropriate.

Comment: Yes, I think that the EFH contains important information on what data and analysis is available on exposure factors to assess inhalation, ingestion, and dermal exposures.

Comment: I believe the most important factors are presented in the document and, where appropriate are sub-divided by age group.

Comment: It appears that the appropriate general topics necessary for conducting exposure assessments have been addressed.

Comment: With the exception of some creel/angler studies for the fish ingestion factors (described in detail below), it appears to me that the EFH has captured most or all of the critical studies for each exposure factor.

Comment: I am not aware of other usable data sources.

Comment: Most of the major data sources for the factors that are currently included in the EFH have been identified (or are in the process of being added, as per the material provided for performing the review). Of course there are various studies that provide some additional "supporting" or "related" information, that could potentially be mentioned in the Handbook; though most of them should not be considered critical. Some specific suggestions regarding such studies are given in the responses for individual chapters.

Comment: [Referring to Question 3 on other data sources.]Yes, many, as I provided and inferred in my reviews of other chapters; also see response in the next paragraph.

Comment: [Referring to Question 3 on other data sources.]See response to question 14.

Comment: When aware of additional data sources, these are pointed out under chapter specific information.

Comment: Answers are given in responses for individual chapters; it can be stated, however, that the selection of "key" studies has been generally appropriate.

Comment: Considerable attention is given to the confidence rating methodology in the introduction and elsewhere. And it is hard to disagree with the selected variables. These are all valuable components of confidence in the data. But in reality applying the final construct is left to "expert opinion" and judgment of the authors.

Comment: The confidence ratings are fairly subjective but I find that the EFH does a very thorough job of delineating how and why the confidence ratings were assigned. While I find the explanations informative, I think it is unlikely that the confidence ratings will have much impact on the choice of exposure factors.

Comment: My comments are focused on the description of the Confidence Ratings in Section 1.4.2—Selection Criteria (page 1-3 to 1-4) and Section 1.5—Approach Used to Develop Recommendations for Exposure Factors (p 1-5 to 1-6). I offer these suggestions to make the confidence ratings more clear. I think that the Table at the beginning of each chapter summarizing the Confidence in the Key studies, by GAF, is helpful and succinctly summarizes the important criteria of all the key studies for assessing specific exposures to the population and sub-populations.

Comment: The main change seems to be these life-stages over subpopulations and the grouping of exposure factors where possible into these life stages for especially children. This is commendable given distinguishable changes in activity patterns and physiology. I think the field will as a result drift to calculating/measuring/observing exposure factors in this manner, and eventually toxicological data to match.

Comment: The reader should be aware that some of these recommendations from guidance documents are later covered in Sections 1.9.

Comment: The more important and relevant guidance and developments in exposure assessment have been included in the Exposure Factors Handbook (EFH). Specific comments follow.

Comment: 1.7 (bottom of first column on page 1-8)—One could not agree with this more—it is very obvious that this is needed.

Comment: 1.8—There are many good statements in this section and reinforce the need just mentioned.

B.7. Chapter 5: Soil Ingestion

Comment: Chapter 5: I agree with the key studies.

Comment: With a few exceptions (described in subsequent comments), I found that the key and relevant studies were adequately summarized. The format of the data presentations in Tables 5-1 through 5-20 is very helpful.