Comments
on the

US Environmental Protection Agency's

Exposure Factors Handbook
SAB Review Draft
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Executive Summary

- Foundations of Exposure and Risk Assessment

Dictionaries define risk as the chance or probability of injury, damage, or loss (e.g., Webster's, 1970). Thus, flowing from the definition, probability and statistics are the basic language for analyzing and understanding risk. Given that mathematicians have developed powerful probabilistic tools over the last 300 years specifically for analyzing risks -- e.g., financial risks, military risks, engineering risks, and medical risks, to name a few -- it is surprising that health risk assessors have so long bypassed the probabilistic paradigm.

Even though risk assessment is by definition a probabilistic endeavor, most risk assessors working on projects under US EPA's regulations still use simple deterministic methods developed to approximate upperbounds for estimates. While these deterministic methods are adequate in a tiered risk assessment process, risk assessors and risk managers now realize that the probabilistic methods are better suited for more advanced and realistic analyses -- and for meeting the challenges of the 21st Century.

- Definitions of Variability and Uncertainty

Chapter 1 still lacks crisp definitions for variability and uncertainty as well as a discussion about why variability and uncertainty are important considerations in risk assessment and risk management. (See, for example, NCRP, 1996.) In particular, we recommend definitions along these lines for these two key terms:

> Variability represents true heterogeneity in the biochemistry or physiology (e.g., body weight) or behavior (e.g., time spent showering) in a population which cannot be reduced through further measurement or study (although such heterogeneity may be disaggregated into different components associated with different subgroups in the population). For example, different children in a population ingest different amounts of tap water each day. Thus variability is a fundamental property of the exposed population and or the exposure scenario(s) in the assessment. Variability in a population is best analyzed and

modeled in terms of a full probability distribution, usually a first-order parametric distribution with constant parameters.

Uncertainty represents ignorance -- or lack of perfect knowledge -- about a phenomenon for a population as a whole or for an individual in a population which may sometimes be reduced through further measurement or study. For example, although we may not know much about the issue now, we may learn more about certain people's ingestion of whole fish through suitable measurements or questionnaires. In contrast, through measurements today, we cannot now eliminate our uncertainty about the number of children who will play in a new park scheduled for construction in 2001. Thus, uncertainty is a property of the analyst performing the risk assessment. Uncertainty about the variability in a population can be well analyzed and modeled in terms of a full probability distribution, usually a second-order parametric distribution with nonconstant (distributional) parameters.

Uncertainty and variability have very different ramifications for decision making as discussed in Chapter 2.

- Parametric Distributions

For theoretical and practical reasons detailed later, we recommend that the Agency fund research at universities (via Cooperative Agreements) to fit parametric distributions to as many of the exposure variables in the Draft Handbook as soon as possible. As these fitted distributions become available, we ask the Agency to incorporate the results into the Exposure Factors Handbook and immediately post the results on the Web pages as discussed below.

- Prospects for the New Exposure Factors Handbook

The first Exposure Factors Handbook completely dominated US EPA's programs for the 8 years from its publication in 1989. When viewing this new Draft Handbook, we see it as a document that will affect all decisions made by the US EPA for many years to come.

We ask this Subcommittee and the full Science Advisory Board to speed the transition from the deterministic paradigm to the probabilistic paradigm by recommending that the Agency not wait 8 more years to revise the Draft Handbook again. We ask the Subcommittee to direct the Agency to make the Handbook a living document in the World Wide Web, continuously updated with results from newly completed research, newly measured data sets, and newly fitted parametric distributions.

- Access via the World Wide Web on the Internet

We recommend that the Agency publish the entire Handbook (and full data sets) in machine readable form on the Internet using the World Wide Web. We recommend that the Agency implement these Web pages so that:

+ users can search the entire contents (text and tables) using key words (with Boolean logic);

+ users can retrieve the full text of summary information;

+ users can download full data sets in machine-readable formats (for example, as comma-delimited files) that are easily imported into a spreadsheet program for analysis;

+ users can link to other Web pages;

+ the Agency can add new materials rapidly and frequently (as peer reviewed data become available) and can receive comments on draft guidance;

+ users can upload new analyses to US EPA for inclusion in the Web pages following peer review outside the Agency; and

+ the Agency create additional, linked Web pages where independent researchers can post peer-reviewed findings, especially parametric distributions fitted to data sets in the Handbook.

We ask this Subcommittee and the full Science Advisory Board to recommend that the Agency make the Exposure Factors Handbook into an "evergreen" document by

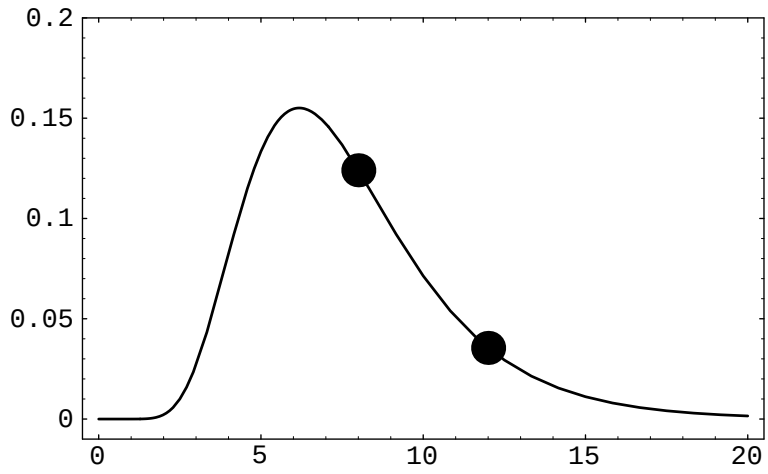
having the Agency post official updates on the Web every 30 to 60 days, much as the Agency already posts official updates to the IRIS system every 30 to 60 days.

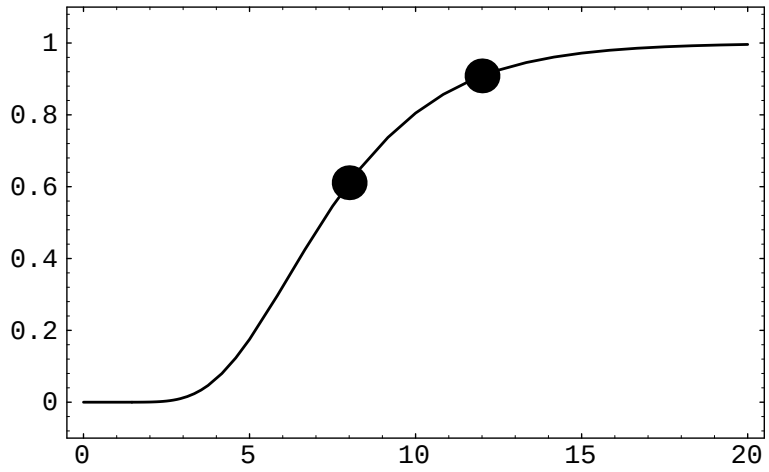
- Visualization

The 1989 version of the Handbook did a good job of including tables that were easy to find and use, and the 1995 and the 1996 Drafts of the Handbook are steps backwards in presentation. If a risk assessor submitted a report like the Draft Handbook to one of the Agency's Regional Offices concerning, say, a Superfund site, we think that the Agency would reject it as impenetrable -- too dense to read, a classic example of poor risk communication.

We recommend that the Agency add graphs and plots of many of the data sets and results for two reasons: (i) analysis and (ii) communications. There are now hundreds of books and reprints that stress the need to visualize data to understand them and communicate them to both technical and lay audiences (e.g., Pickover & Tewksbury, 1994; Wolff & Yaeger, 1993; Tufte, 1990; Tufte, 1983).

Data that are reported as percentiles in tables should be plotted using cumulative distribution functions (CDFs) to allow better visualization of the information. We believe that it would be very helpful to show graphically where the recommended values lie on the distributions. For example, here are the graphs for the PDF and the CDF for the distribution for the time spent showering (T_S ; min/d) fit by James and Knuiman (1987), with each abscissa measured in minutes per day. The black dots represent the point values recommended by the US EPA as the average (near T_S = 8 min/d) and the 95th percentile (near T_S = 12 min/d).





- Computational Strategy

We recommend that the Agency discuss the computational issues in the Handbook. We further suggest that the Agency should recommend the use of more distributions more of the time in exposure assessments.

We find no material in the report that discusses -- or gives reference to -- the essential topic of using these distributions in calculations or simulations. Having many measurements and summary statistics -- especially with several data sets reported for a particular phenomenon -- leaves open the question of how to combine values to estimate: (i) the full distribution (the most useful result), (ii) the average (much less useful), or (iii) any particular percentile of the distribution (also much less useful).

In Table 1-2 of the Handbook, the Agency summarizes its recommendations by giving the point estimates for each exposure factor top billing.

While this approach gives highest credence and priority to deterministic, upperbound calculations, it is worth remarking that there is no coherent computational strategy for combining a series of arithmetic means and high-end percentiles into a point estimate of exposure (or risk) with a known degree of conservatism.

Without a coherent computational strategy for combining point estimates, the Agency cannot know the degree of public health protection inherent in its calculations. We wonder why these observations alone have not convinced the Agency that the deterministic paradigm can only be used for screening calculations in a tiered approach as emphasized by the NRC (1994).

- Prioritize Research Needs Using the Value of Information (VOI)

This Draft Handbook provides a good overview of the available data and in some cases mentions additional data which would be worth collecting. We urge the Agency to go further in its efforts to highlight significant data gaps and research priorities.

We recommend that US EPA use VOI methods to prioritize research to fill data gaps when updating the EFH. In addition, as exposure and risk assessments using second-order random variables come to the fore, the studies will vastly increase our experience with the Value of Information Method.

Value of information techniques provide an analytical framework for addressing this dilemma (e.g., Morgan et al., 1978; Campbell et al., 1982; Evans et al., 1988; Lave et al., 1988; Reichard and Evans, 1989; Morgan and Henrion, 1990; Siegel et al., 1990; Hammitt and Cave, 1991; North et al., 1992; Taylor et al., 1993; Dakins et al., 1994; Dakins et al., 1996; Thompson and Evans, 1997). VOI methods provide estimates of the value that the decision maker would place on having improved information and consequently provide a sense of the amount of resources that could reasonably be spent to obtain better information.

- New Directions: Second-Order Random Variables

We note that the Draft Handbook makes no mention of new computational methods developed in the last 5 years for keeping variability and uncertainty separated throughout a computation.

Since we expect these methods will continue to grow in power and importance, we recommend that the Draft Handbook and new Web pages discuss them in detail.

- Notice Inside Front Cover of Each Volume

We recommend that the Agency print this Notice inside the front cover and inside the rear cover of each volume of the Final Handbook -- and on the first Web page housing the electronic version of the Handbook:

> This Handbook contains guidelines for use in probabilistic exposure assessments.
>
> Given the breadth and depth of probabilistic methods, and given the rapid development of new probabilistic methods, the Agency cannot list all the possible techniques that a risk assessor may use for a particular assessment.
>
> The US EPA emphatically encourages the development and application of new methods in exposure assessments, and nothing in this Handbook can or should be construed as limiting the development or application of new methods whose power and sophistication may exceed the guidelines contained in this Handbook.

General Comments

- Foundations of Exposure and Risk Assessment

Dictionaries define risk as the chance or probability of injury, damage, or loss (e.g., Webster's, 1970). Thus, flowing from the definition, probability and statistics are the basic language for analyzing and understanding risk. Given that mathematicians have developed powerful probabilistic tools over the last 300 years specifically for analyzing risks -- e.g., financial risks, military risks, engineering risks, and medical risks, to name a few -- it is surprising that health risk assessors have so long bypassed the probabilistic paradigm.

Even though risk assessment is by definition a probabilistic endeavor, most risk assessors working on projects under US EPA's regulations still use simple deterministic methods developed to approximate upperbounds for estimates. While these deterministic methods are adequate in a tiered risk assessment process, risk assessors and risk managers now realize that the probabilistic methods are better suited for more advanced and realistic analyses -- and for meeting the challenges of the 21st Century.

As 1996 comes to a close, we see risk assessment as part way along the transition from one overly simplified paradigm to a more powerful paradigm (that contains the simplified one as a sub-domain). In a few years, we think that risk assessors will view probabilistic methods as the fundamental techniques for studies, with simplification to the deterministic sub-domain appropriate in some circumstances.

Other professions have already made similar transitions. As described so clearly by Peter L. Bernstein in *Against the Gods: The Remarkable Story of Risk* (1996; Wiley and Sons, New York), no economist or portfolio manager working on Wall Street can view investment management except through probabilistic principles, techniques, and results. Similarly, communications engineers, transportation engineers, nuclear engineers, reliability engineers, water resource engineers, and mechanical engineers (to name but a few) who previously used deterministic methods have switched to probabilistic methods during the last 30 to 40 years. (The advent of Monte Carlo methods in 1946 made many of these transitions possible). Quantum physicists and chemists have always used probabilistic methods. We think health risk assessors are

now beginning to consider the probabilistic paradigm as the "standard paradigm," with the simplified deterministic methods reserved for use as screening techniques.

Since other professions in the science, engineering, and economics have already undergone the transition from the deterministic to the probabilistic paradigm, the National Academy of Sciences (NRC, 1994) and the Commission on Risk Assessment and Risk Management (CRARM, 1996) have highlighted the need to develop and implement the powerful probabilistic paradigm.

- Definitions of Variability and Uncertainty

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in a population can be well analyzed and modeled in terms of a full probability distribution, usually a second-order parametric distribution with nonconstant (distributional) parameters.

Uncertainty and variability have very different ramifications for decision making as discussed in Chapter 2. There is a logical disconnection associated with talking about variability but not uncertainty in Chapter 1. We recommend that the draft would be much improved by moving section 1.3.4. Characterizing variability and Table 1.3 to Chapter 2, and calling Chapter 2 Variability and Uncertainty. This new chapter could then discuss the differences between using point estimates and using distributions to characterize risk (or exposure) and the differences between risk descriptors, and it should provide guidance for determining when factors should be considered variable, uncertain, or both. Arguably, some of this guidance might be more appropriately placed in an US EPA guidance document on using probabilistic analysis which this draft could cite. Since such a document does not exist, we recommend that the US EPA include the information here. The draft also fails to cite guidance on risk characterization and to provide a description of computational methods which we believe should also appear in Chapter 2.

- Parametric Distributions

For all of the data, it is essential to show graphs demonstrating how the data are distributed. Looking through the report, we see many summary statistics reported by various researchers -- e.g., arithmetic means, standard deviations, geometric means, selected percentiles, minima, and maxima -- but we see few parametric distributions fit to the data. We believe there are more well-fit parametric distributions than mentioned in the report, and including them will aid risk assessors in efforts to fully characterize variability and uncertainty in risk. When available, parametric distributions should be given first billing, along with graphs of the fits and including plots of the residuals of the fits.

In discussions last year, some of the authors of the 1995 Draft Handbook argued that presenting a distribution as a series of empirical percentiles (e.g., the 1st, 5th, 10th, 15th, 25th, 50th, 75th, 85th, 90th, 95th, and 99th percentiles) is generally superior to fitting a parametric distribution to the data, even when a parametric distribution gives a good fit. We disagree on several grounds. First, on theoretical grounds: with a good fit,

parametric distributions (i) compress data sets into a parsimonious representation using a few parameters, (ii) facilitate comparisons among distributions, (iii) can, with care, extend results outside the measured range, and (iv) provide theoretical insight. As the adage reminds us, "The purpose of computation is insight."

Second, on practical grounds, with a good fit, parametric distributions (i) provide complete information on all percentiles and moments, (ii) speed computations and simulations (since the algorithms for generating pseudo random numbers from parametric distributions are much faster than the algorithms for generating pseudo random numbers by interpolation between tabulated percentiles), and (iii) facilitate probabilistic sensitivity analyses through the specification of alternate input distributions. These theoretical and practical advantages remain true even when it takes a (i) compound parametric distribution or (ii) a mixture of parametric distributions to achieve a good fit to a data set. (As an aside, the need for a mixture model to fit a data set gives theoretical insights as well.)

For these reasons, we recommend that the Agency fund research at universities (via Cooperative Agreements) and qualified consulting firms (via contracts) to fit parametric distributions to as many of the exposure variables in the Draft Handbook as soon as possible. As these fitted distributions become available, we ask the Agency to incorporate the results into the Exposure Factors Handbook and immediately post the results on the Web pages as discussed above.

- Prospects for the New Exposure Factors Handbook

The first Exposure Factors Handbook completely dominated US EPA's programs for the 8 years from its publication in 1989. When viewing this new Draft Handbook, we see it as a document that will affect all decisions made by the US EPA for many years to come.

When viewing this new Draft Handbook, we see it as a document that will affect all decisions made by the US EPA for many years to come. From that point of view, we think that the Draft Handbook is flawed because it does not place sufficient emphasis on fitted distributions.

Now the authors of the Draft Handbook will object to this criticism, arguing that this Draft does report percentiles of empirical distributions and fitted parametric distributions when they are available in the refereed literature. We acknowledge the point, but we think the advance is too uneven and too hesitant to make a practical difference during the expected long life of this key guidance document.

We ask this Subcommittee and the full Science Advisory Board to speed the transition from the deterministic paradigm to the probabilistic paradigm by recommending that the Agency not wait 8 more years to revise the Draft Handbook again. We ask the Subcommittee to direct the Agency to make the Handbook a living document in the World Wide Web, continuously updated with results from newly completed research, newly measured data sets, and newly fitted parametric distributions.

- Access via the World Wide Web on the Internet

We recommend that the Agency publish the entire Handbook (and full data sets) in machine readable form on the Internet using the World Wide Web. We recommend that the Agency implement these Web pages so that:

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+ users can upload new analyses to US EPA for inclusion in the Web pages following peer review outside the Agency; and

+ the Agency create additional, linked Web pages where independent researchers can post peer-reviewed findings, especially parametric distributions fitted to data sets in the Handbook.

Many years ago, the Agency created the Integrated Risk Information System (IRIS) as a dial-up information service to hold and distribute "chemical toxicity profiles" rapidly and concurrently to all interested parties. Recognizing the power and ubiquity of the Internet, we ask this Subcommittee and the full Science Advisory Board to recommend that the Agency distribute the full text and tables of the Exposure Factors Handbook (in machine readable form) via the World Wide Web.

We ask this Subcommittee and the full Science Advisory Board to recommend that the Agency make the Exposure Factors Handbook into an "evergreen" document by having the Agency post official updates on the Web every 30 to 60 days, much as the Agency already posts official updates to the IRIS system every 30 to 60 days.
We see remarkable progress in probabilistic methods each 12 to 18 months, so neither the Agency nor the regulated community can wait 8 years for the next update to this key guidance document.

In addition, we also ask this Subcommittee and the full Science Advisory Board to recommend that the Agency add supplemental pages to the Web site so that risk assessors who fit parametric distributions to data sets in the Handbook can post their results and conclusions (i.e., their fitted parametric distributions) directly on the supplemental pages. These supplemental Web pages must be electronically linked to the Web pages for the main text and tables of the official Handbook. With this innovation, mediated by the World Wide Web, the Exposure Factors Handbook will become an engine for innovation and research. We recommend that the Agency adopt an external peer review process, much like a peer-reviewed journal, for these postings.

- Visualization

The 1989 version of the Handbook did a good job of including tables that were easy to find and use, and the 1995 and the 1996 Drafts of the Handbook are steps backwards in presentation. If a risk assessor submitted a report like the Draft Handbook to one of the Agency's Regional Offices concerning, say, for a Superfund site, we think that the

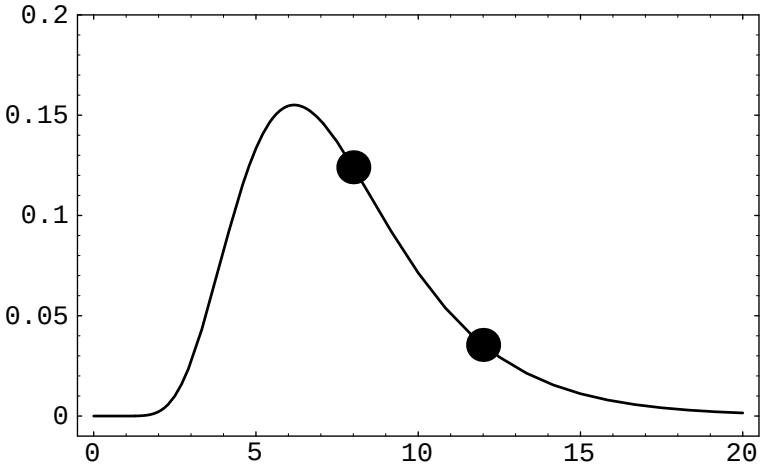
Agency would reject it as impenetrable -- too dense to read, a classic example of poor risk communication.

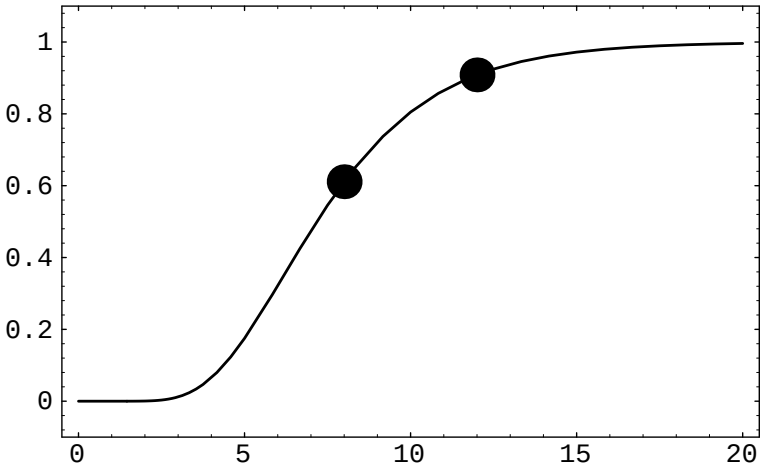
The current Draft Handbook presents oceans of tiny digits in black type. For example, Tables 12-50, 14-128, and 14B-1 undoubtedly contain interesting patterns that we cannot fathom.

After reading the report in detail, we see only a few graphs or plots. Of the Figures in this Draft Handbook, some convey low information and insight, while others convey high information and insight. For example, Figure 14-1 (a pie chart) conveys essentially no more information than could a compact table. As another example, Figures 10-1, 10-2, 6-1 and 6-2 (histograms) each give the reader much more information and insight than could a table of digits

We recommend that the Agency add graphs and plots of many of the data sets and results for two reasons: (i) analysis and (ii) communications. There are now hundreds of books and reprints that stress the need to visualize data to understand them and communicate them to both technical and lay audiences (e.g., Pickover & Tewksbury, 1994; Wolff & Yaeger, 1993; Tufte, 1990; Tufte, 1983). We recommend US EPA report summary statistics (which include the number of data and many percentiles) in both tabular and graphical form (see Principle 5 of Burmaster and Anderson, 1994).

Data that are reported as percentiles in tables should be plotted using cumulative distribution functions (CDFs) to allow better visualization of the information. We believe that it would be very helpful to show graphically where the recommended values lie on the distributions. For example, here are the graphs for the PDF and the CDF for the distribution for the time spent showering (T_S ; min/d) fit by James and Knuiman (1987), with each abscissa measured in minutes per day. The black dots represent the point values recommended by the US EPA as the average (near T_S = 8 min/d) and the 95th percentile (near T_S = 12 min/d).





- Computational Strategy

We recommend that the Agency discuss the computational issues in the Handbook. We further recommend that the Agency should recommend the use of more distributions more of the time in exposure assessments.

Discussion: We find no material in the report that discusses -- or gives reference to -- the essential topic of using these distributions in calculations or simulations. Having many measurements and summary statistics -- especially with several data sets reported for a particular phenomenon -- leaves open the question of how to combine

values to estimate: (i) the full distribution (the most useful result), (ii) the average (much less useful), or (iii) any particular percentile of the distribution (also much less useful).

In Table 1-2 of the Handbook, the Agency summarizes its recommendations by giving the point estimates for each exposure factor top billing. Often the Table starts with an average value, and then proceeds to a 90th, 95th, or 99th percentile. Only then does Table 1-2 mention qualitatively if an empirical distribution or a parametric distribution occurs in the body of the Handbook.

While this approach gives highest credence and priority to deterministic, upperbound calculations, it is worth remarking that there is no coherent computational strategy for combining a series arithmetic means and high-end percentiles into a point estimate of exposure (or risk) with a known degree of conservatism.

Let us consider a simple situation -- estimating the exposure dose to a population exposed to one chemical via one exposure pathway. In this simplified example, let us further agree that 7 exposure variables enter the dose equation, with 5 multiplicative factors in the numerator and 2 multiplicative factors in the denominator. Finally, let us assume that we know only (i) the arithmetic mean of the variability and (ii) either the 90th or 95th percentile for the variability for each of the 7 total exposure variables.

For this example, there is no coherent computational strategy to estimate the exposure dose with a known (or knowable) degree of conservatism.

+ If we use the average value for each input in the dose equation, we will, in general, not estimate the average exposure dose (Burmaster and Bloomfield, 1996), even if the exposure variables are uncorrelated. To the extent that the underlying distributions for some or all of the exposure variables are asymmetric with long tails to the right, the point estimate of dose thus computed may rise above the 80th percentile of the underlying distribution for dose.

+ If we use the high-end percentile values for each input in the dose equation, we will, in general, estimate a (very) high point value of dose, but we will not know its percentile in the underlying distribution of dose.

+ If we use the high-end percentile values for each input in the numerator of the dose equation and find some low-end percentile values for each input in the denominator of the dose equation, we will, in general, compute an even higher point estimate of dose, but we will not know its percentile in the underlying distribution of dose.

+ If we follow the Agency's informal guidance, we could use (i) average values for each exposure variable in the denominator, (ii) use high-end percentile values for two exposure variables in the numerator, and (iii) use average values for the other exposure variables in the numerator. In this computation, we will, in general, compute a point estimate of dose at some (very) high percentile of the underlying distribution of exposure dose, but we will not know its percentile in the underlying distribution. Worse still, if we change one or both of the exposure factors in the numerator for which we had taken high-end percentile values, we will compute a different point estimate of exposure dose, again at a (very) high but unknown percentile of the underlying distribution of dose.

Without a coherent computational strategy for combining point estimates, the Agency cannot know the degree of public health protection inherent in its calculations. We wonder why these observations alone have not convinced the Agency that the deterministic paradigm can only be used for screening calculations as emphasized by the NRC (1994).

- Treatment of Uncertainty

While the 1996 Draft Handbook addresses variability in many but not all exposure factors, it does not adequately address uncertainty in any of the exposure factors. Although there have been noticeable improvements since the 1995 Draft Handbook, for example in providing a sense of confidence in the recommendations (see Table 1-2), we recommend that the US EPA improve its assessment of uncertainty of the factors.

- Prioritize Research Needs Using the Value of Information (VOI)

This Draft Handbook provides a good overview of the available data and in some cases mentions additional data which would be worth collecting. We urge the Agency

to go further in its efforts to highlight significant data gaps and research priorities. We believe that a short discussion of the quality of the available data should include discussions of studies which could be performed to fill major data gaps.

Due to its poor treatment of uncertainty, the Draft Handbook fails to support efforts to prioritize research needs and assess the value of obtaining additional information about the factors. Further, the existence of the recommended values may lead people to believe that "knowledge base" about the exposure factors is sufficient when in fact it might be highly worthwhile to reduce our uncertainty about some or all of them. This Draft Handbook provides a good overview of the available data and in some cases mentions additional data which would be worth collecting. We recommend that the Agency go further in its efforts to highlight significant data gaps and research priorities.

Given the uncertainty inherent in risk assessment, a dilemma arises regarding the trade-off between making a decision immediately or waiting to consider improved information prior to taking action. Value of information techniques provide an analytical framework for addressing this dilemma (e.g., Morgan et al., 1978; Campbell et al., 1982; Evans et al., 1988; Lave et al., 1988; Reichard and Evans, 1989; Morgan and Henrion, 1990; Siegel et al., 1990; Hammitt and Cave, 1991; North et al., 1992; Taylor et al., 1993; Dakins et al., 1994; Dakins et al., 1996; Thompson and Evans, 1997). VOI methods provide estimates of the value that the decision maker would place on having improved information and consequently provide a sense of the amount of resources that could reasonably be spent to obtain better information. We believe that the ideal for the Final Handbook is to provide a list of the exposure factors data that US EPA would find valuable along with limits on the amounts that it is willing to spend. We believe that such a list would certainly stimulate more research in those areas.

We recommend that US EPA use VOI methods to prioritize research to fill data gaps when updating the EFH. In addition, as exposure and risk assessments using second-order random variables come to the fore, the studies will vastly increase our experience with the Value of Information Method.

- New Directions: Second-Order Random Variables

We note that the Draft Handbook makes no mention of new computational methods developed in the last 5 years for keeping variability and uncertainty separated throughout a computation.

In 1992, when he was an Intern at the US EPA in Washington, H. Christopher Frey wrote a manuscript -- later published by the AAAS (Frey, 1992). This report -- along with other pioneering research by Kenneth Bogen, Adam Finkel, and Owen Hoffman -- galvanized research on "second-order random variables" as a way to isolate variability from uncertainty throughout a computation. Since 1992, there may have been more than 50 publications and conference papers by various authors in the refereed literature that extend these methods and results (e.g., Macintosh et al, 1994; McKone, 1994; Frey & Rhodes, 1996; Hattis & Barlow, 1996; Cohen et al, 1996; Price et al, 1996). The National Council on Radiation Protection (NCRP, 1996) has just published a major report on the use of these methods in exposure assessment. Still in active growth and development, these "second-order" or "two-dimensional" methods have been used in practical computations and in regulatory decisions by some of US EPA's Regional Offices.

Since we expect these methods will continue to grow in power and importance, we recommend that the Draft Handbook and new Web pages discuss them in detail.

- Full Data Sets

For exposure factors that are so central to the Agency's mission and to all of its programs, we wonder why the Agency has adopted such a passive role. On Page 1-1 of this Draft Handbook, the Agency notes that the document summarizes data from other sources, with many data taken from refereed publications in the literature. In effect, the Agency sees itself as compiling research on exposure factors as done by others and as funded by others. We observe that a 'Gresham's Law' for exposure factors has held for too long -- that is, conservative policy *assumptions* have arrested the collection and analysis of new *measurements*.

As a first initiative to revitalize the study of exposure factors, we recommend that this Subcommittee and the full Science Advisory Board have the Agency contact all of the

primary researchers / authors of studies cited in the Draft Handbook for which the refereed literature contains only, say, an arithmetic mean and maybe a 90th, 95th, or 99th percentile. In our experience, primary researchers / authors are more than willing to provide their complete data set in response to a *bona fide* request for information and/or collaboration. We think that many researchers will cooperate and provide their full data sets for updating the Exposure Factors Handbook (and for publication on the Handbook's Web pages). While the initiative may take some time, it will greatly advance the coverage, quality, and usefulness of the Handbook.

- Notice Inside Front Cover of Each Volume

We recommend that the Agency print this Notice inside the front cover and inside the rear cover of each volume of the Final Handbook -- and on the first Web page housing the electronic version of the Handbook:

> This Handbook contains guidelines for use in probabilistic exposure assessments.
>
> Given the breadth and depth of probabilistic methods, and given the rapid development of new probabilistic methods, the Agency cannot list all the possible techniques that a risk assessor may use for a particular assessment.
>
> The US EPA emphatically encourages the development and application of new methods in exposure assessments, and nothing in this Handbook can or should be construed as limiting the development or application of new methods whose power and sophistication may exceed the guidelines contained in this Handbook.

- Data vs Interpretations and Synthesis of the Evidence

We recommend that US EPA sharpen the distinction between data and interpretations or models of data. We also recommend US EPA report raw data (in an Appendix if necessary). We believe it would also be very helpful if the Agency served as the

depository for exposure data, and facilitated dissemination of data via a variety of media (specifically, the World Wide Web).

We believe that the US EPA has done a fair job distinguishing between data and interpretations of data. However, we believe that it would be more useful to group the descriptions of the data and their interpretations by data instead of according to individual papers or reports. In other words, we believe that studies which provide another interpretation of the data than what was given in the original study should appear following the discussion of the original study. For example, in the soil ingestion chapter (Chapter 4), there are 5 studies that collected data that forms the basis for soil ingestion estimates for children (Binder et al., Calabrese et al., Clausing et al., Davis et al., and van Wijnen et al.) but it is hard to see this from the way the chapter is organized. In particular, Calabrese et al.'s 1995 revised interpretation of their 1989 study data appears as the first "key" study. This makes the later description of the 1989 study confusing since it sounds like a separate study. We believe that while the distinction of key vs. relevant is important, it may not be the best way to stratify and describe the existing literature. Instead, we believe that it would be much more useful to first provide a historical overview of when data have been collected (i.e., identify data sources) and then provide a description of each of the studies and their subsequent interpretations. Part of the problem of the key vs. relevant distinction is that older studies or interpretations are more likely to be outdated and therefore classified as "relevant" and therefore to appear later in the descriptions even though they occurred first and the "key" studies presumably represent improvements. We recommend that studies be described in a literature review format (more historical) and that the distinctions of "key" and "relevant" studies should be described just before the recommendations if at all. In addition, there should be a separate discussion of studies that synthesize and combine the information of different studies and provide an interpretation based on all of the evidence since this is really the goal of the review. This section should identify weaknesses of all of the studies (collectively and individually) and it should provide a good lead into the recommendations. This section should also highlight research that could or will reduce or eliminate some of the uncertainties and provide clear justification for the assignment of confidence levels.

- Extrapolation and Combining Data from Multiple Studies

We recommend that the US EPA develop and promulgate more explicit guidelines for interpreting and combining the study results.

Related to the use of defaults, the Draft EFH does not provide guidelines for extrapolating the information about exposure factors to smaller populations such as those potentially exposed at a specific site. Many of the studies US EPA reports suffer from substantial flaws and shortcomings. This is not surprising since most studies cited in the Draft EFH were not designed to provide bases for exposure factors. These shortcomings may jeopardize the usefulness of these studies for developing exposure factors as intended by US EPA. US EPA should explicitly evaluate the effects of these shortcomings and biases. For example, US EPA should discuss the issues related to the extent to which short sample durations (one-day produce consumption surveys, for example) affect summary statistics. We again recommend that discussions of these issues should appear in the draft and any guidance available should be provided.

US EPA combines the results of studies incorrectly by simply averaging estimated means across studies (see comments below in Chapters 10 and 13). This method of combining means is incorrect as it gives disproportionate weight to studies made up of fewer subjects. When combining studies, US EPA should combine raw data only, *and here with caution and attention to the initial study designs*. Techniques for combining data (e.g., meta analysis, Bayesian methods, and eliciting expert judgments based on all data) should be discussed.

- Principles for Use of and Deviation from “Default Options”

This draft gives the “recommended values” for risk assessments which may be treated by risk assessors as “defaults” in the spirit of the 1994 National Research Council’s report Science and Judgment in Risk Assessment. The report recommended that the US EPA provide formal criteria for departure from default options, “in order to give greater guidance to the public and to lessen the possibility of ad hoc, undocumented departures from default options that would undercut the scientific credibility of the agency’s risk assessments. At the same time, the agency should be aware of the undesirability of having its guidelines evolve into inflexible rules” (NRC, 1994: 8). The report further emphasizes the importance of peer review “to guarantee that [US EPA’s]

risk assessment decisions will have access to the best science available through a process that allows full public discussion and peer participation by the scientific community" (NRC, 1994: 8).

Thus far, US EPA has not produced guidelines for the use and deviation from defaults and to establish a mechanism for substantive peer review. The absence of such guidance undermines the utility of the EFH, and the US EPA should at a minimum include more guidance about the use and misuse of the recommendations in Table 1-2 of the draft. In addition, the US EPA should provide a description of the differences between using point estimates to characterize risk versus using distributions (see Thompson & Graham, 1996 for discussion of this) and justify its choice for providing defaults for point estimates but not for distributions.

- LogNormal Distributions

In our experience, LogNormal distributions appear again and again in exposure and risk assessments. As a practical matter, most risk assessors do not understand the power and ubiquity of LogNormal distributions, nor do most risk assessors understand (i) how to fit LogNormal distributions to data or (ii) how to manipulate LogNormal random variables in equations.

In the literature, there are three common ways to parameterize LogNormal distributions: (i) arithmetic mean and standard deviation of the log-transformed variables, (ii) geometric mean and standard deviation of the non-transformed variables, and (iii) arithmetic mean and standard deviation of the non-transformed variables. The three methods contain identical information (for the ideal distribution or in the asymptotic limit of large sample sizes), but few risk assessors seem to know the algebra for making the interchange, and fewer risk assessors understand when and how to use LogNormal probability plots. Even the new Draft Handbook does not use a single, consistent convention for presenting LogNormal variables -- a situation that will lead, we think, to serious misinterpretations. (As but one example of many in the Handbook, Table 3-11 and Table 4-6 use different parameterizations for the LogNormal distribution.)

Since LogNormal distributions have such a central role in exposure and risk assessment, we recommend that the Agency will (i) adopt a single method for

presenting LogNormal distributions in the Final Handbook and (ii) reprint the attached article by Burmaster and Hull (1996; in press) as an Appendix to the Final Handbook.

- Organization

While this Draft Handbook represents an improvement over the previous one in terms of its organization, there are still organizational problems.

First, we believe that there should be separate chapters for all of the identified factors in Table 1-2. In particular, we believe Chapter 5 should be titled “Inhalation Rate” instead of “Inhalation Route” and Chapter 6 should be divided into two chapters titled “Surface Area” and “Soil Adherence.”

Second, we believe that since Chapters 9, 11, and 12 are all based on the same studies that these should appear together and Chapter 10 should be moved to follow them. The current arrangement of inserting Chapter 10 between Chapters 9 and 11 disrupts the flow and logic of the document.

Third, we believe that the presentation of studies according to their status as “key” or “relevant” makes the chapters read poorly, since key studies are more likely to be recent studies that improved on earlier designs. We recommend that chapters be reorganized to present the logical progression that has occurred in the research because it is both easier to follow and it more clearly shows the level of progress that has or has not been made. This approach lends itself much better to a discussion of the strengths and weaknesses of the available data than the current format. Thus, we recommend that each chapter give an introduction/overview, then describe the sources of data and their subsequent interpretations, then provide some synthesis of the information and discuss the limitations, and finally give recommendations. The designation of studies as “key” or “relevant” should appear in the tables that summarize the available data, but it should not be used to group the studies.

- Glossary

We recommend that the Agency mention and discuss the Glossary early in Chapter 1.

We also recommend that the US EPA expand the Glossary with 50 to 100 new terms. It would also help to have the glossary include definitions of distributions that are discussed in the report so that the unfamiliar reader has some help and to avoid the reference to distributions as in the "@RISK format." For example, since the document discusses several different parameterizations for LogNormal distributions, it would be helpful to detail these and the relationships among them. Alternatively, if the US EPA elects to standardize the definitions so that they all use the same parameterizations, the Glossary is a natural place to define these. Abbreviations and acronyms should also appear in the Glossary.

Detailed Comments

Chapter 1 Introduction

- Section 1.1 Purpose

Issue: The Draft Handbook states: "The purpose of the Exposure Factors Handbook is to: (1) summarize data on human behaviors and characteristics which affect exposure to environmental contaminants, and (2) recommend values for use for these factors."

Comment: The Agency has defined the Handbook's purpose narrowly -- so narrowly, we think, that it cramps and distorts the true nature of exposure assessment. Since no two people -- much less all the people in an exposed population -- have the same physiology or the same behavior, it is essential to start with the understanding that peoples' behaviors and physiology are necessarily described and modeled by ranges or distributions of values. we recommend that the best way "to summarize data" is as (i) parametric distributions, or, if none fit the data adequately, as (ii) empirical distributions (i.e., lists of percentiles (at least the 1st, 5th, 10th, 15th, 25th, 50th, 75th, 85th, 90th, 95th, and 99th percentiles)).

The second purpose stated by US EPA contradicts the first. Since the data originate from distributions for the variability in a population, and since the data are properly summarized in terms of a distribution fitted to the data for variability, it makes little sense to reduce these distributions to a single point value or even two point values. This is a fundamental point. The selection of any single point value from a distribution destroys enormous amounts of information in the distribution -- regardless of whether the single point value chosen is the arithmetic mean, the median, or some preferred percentile.

However, if, upon suitable analysis, a particular family of parametric distributions fits the data well, then it is meaningful to describe the full data set with the one or two (or more) parameters for the distribution without loss of information.

- Page 1-1, para 1

Issue: The last statement in the paragraph indicates that the Handbook provides a consistent framework for calculating dose, but it fails to define the term "dose."

Recommendation: As described in the Guidelines for Exposure Assessment, there are many types of dose and we believe it is important to reiterate these definitions and to provide them in a glossary.

- Chapter 1, Page 1-3, last full paragraph on page

Issue: The statement “Each factor is described by a specific term, such as lognormal, normal, ...” is poorly worded.

Comment: The statement implies that the American Industrial Health Council (AIHC) came up with “terms” to describe data when in fact these “terms” are well-characterized mathematical functions. This is a great place to refer to the Glossary where the different distributions are defined.

- Chapter 1, Page 1-5, Section 1.3.4

Issues: Move section 1.3.4 to Chapter 2. Also, second sentence of section should define variability.

Comment: As a mathematical theorem, Burmaster and Bloomfield (1996) show that the average exposure dose does <u>not</u> equal the multiplication and division of the average value of each input variable, even for a exposure to a single chemical by a single pathway. This result surprises many people.

- Page 1-10, continuation of section 1.3.4

Issue: This section needs a lot of work and we reiterate that it should be moved to Chapter 2 Variability and Uncertainty. Why is it more appropriate to look at a range of data and use judgment to assert certainty (i.e., pick one point) than to assert uncertainty and use judgment to pick a distribution?

Comment: We recommend that the US EPA use distributions to describe and quantify variability and uncertainty, i.e., when their use is the most appropriate. Further, the idea of asking experts should come in here as well as the idea of collecting more data. The choice between the various options should depend on a number of factors including the importance and cost of the information and this section needs to provide more guidance to risk assessors on how to deal with this problem.

- Page 1-10, Section 1.4

Comment: The first sentence reads better as follows: “In the Exposure Assessment Guidelines, exposure is defined as....” The issues of adjusting for relative bioavailability should be discussed in this section.

- Page 1-10

Issue: The Agency has not responded to the NRC's recommendations concerning susceptibility.

Comment: In 1994, the National Research Council's report titled *Science and Judgment in Risk Assessment*" concluded that the US EPA does not account for person-to-person variations in susceptibility to cancer, but instead treats all humans as identical in this respect in its risk calculations (NRC, 1994, p. 219). The NRC also asserted that "... [i]n light of the biochemical and epidemiological data [it reviewed] it is currently not scientifically plausible that the US population is strictly homogeneous in susceptibility to cancer induction by cancer-causing chemicals ..." (NRC, 1994, p.207) Consequently, the NRC charged the Agency with including consideration of susceptibility in its risk assessments and indicated a preference for the Agency to develop a "default distribution" of susceptibility (NRC, p. 219). We recommend that the Agency review Chapter 10 of the NRC report and contact researchers, like Dr. Dale Hattis at Clark University, who are currently exploring ways to characterize susceptibility with distributions.

- Page 1-12, Section 1.5

Issue: The section on research needs should be expanded and made consistent.

Comment: Several of the issues are written as if they are recommended by US EPA as areas for research, while the ones starting with “reviewers recommended...” sound like US EPA does not agree. Since these are key findings of this exercise, they need to be expanded and discussed more.

- Page 1-1 Variation Among Studies

Issue: The report states: "This Handbook is a compilation of available data from a variety of sources. ..." .

Comment: We agree, but we note that the US EPA has funded few if any of the studies cited in the 1,000 pages that follow. Since this document is so central to the mission of the Agency, we recommend that the Agency fund research to measure new exposure data and to fit parametric distributions for publication on the World Wide Web.

- Page 1-3

Issue: The Draft Handbook states: "... The AIHC Sourcebook summarizes and evaluates statistical data for various exposure factors used in risk assessments. Probability distributions for specific exposure factors were derived from the available scientific literature ..... "

Comment: Published in 1994, the AIHC Sourcebook is an exemplary document for thinking about exposure factors using the appropriate concepts -- parametric distributions, or failing an adequate fit, empirical distributions. We recommend that the Agency follow this methodology in this Draft Handbook.

- Section 1.3.3 Approach Used to Develop Recommendations

Issue: In five numbered points, the Agency discusses the selection of key studies and other issues.

Comment: The Agency does not discuss the selection of one or two point values to represent the distribution (variability) inherent in the exposed population.

- Page 1-5

Issue: The Draft Handbook states: " .... Analyses to fit standard parametric or distributions .... to the exposure data have not been performed by the authors of this Handbook, but have been reproduced in this document wherever they were found in the literature. ... "

Comment 1: Since many people on various review committees have recommended that the Agency fit parametric distributions to the data, we recommend that the Agency do so.

Comment 2: We recommend that the Agency add the material to honor this statement. Here are two obvious examples where the Draft Handbook does not contain fitted parametric distributions readily available in the literature: (i) The Draft does not publish the bivariate parametric distributions fit by Brainard and Burmaster (1992) to data for body height and body weight. (ii) The Draft does not publish the parametric distributions fit by James and Knuiman (1987) to data for the length of time spent showering.

- Page 1-5

Issue: The Draft Handbook states: " .....Even if these distributions are known, it may not be necessary to apply this technique. For example, if only average exposure values are needed, these can often be computed accurately by using average values for each of the input parameters. .... "

Comment: As a mathematical theorem, Burmaster and Bloomfield (1996) show that the average exposure dose does not equal the multiplication and division of the average value of each input variable, even for a exposure to a single chemical by a single pathway. We recommend that the Agency add materials to discuss this important issue.

- Page 1-5

Issue: The Draft Handbook states: " .....Distribution functions to be used in Monte Carlo analysis may be derived by fitting an appropriate function to empirical data. In

doing this, it should be recognized that in the lower and upper tails of the distribution the data are scarce, so that several functions, with radically different shapes in the extreme tails, may be consistent with the data. To avoid introducing errors into the analysis by the arbitrary choice of an inappropriate function, several techniques can be used. One way is to avoid the problem by using the empirical data itself rather than an analytic function."

Comment 1: We recommend that the Agency add a discussion of the fundamental principle that "Processes -- meaning, physical, chemical, biological, and/or statistical processes -- create distributions" (Hattis & Burmaster, 1995). For example, under the conditions of the central limit theorem, additive processes tend to create Normal distributions, while multiplicative processes tend to create LogNormal distributions. Fracture processes tend to create LogNormal distributions, while "pure death" processes common in reliability analyses tend to create Exponential, Gompertz, and related distributions. "Inter-arrival" processes tend to produce Poisson, Exponential, and Gamma distributions. In situations when several families of distributions seem to fit a data set adequately, the analyst can use knowledge about the process to discriminate among the contending distributions to select one for use.

Comment 2: The use of the data themselves in the situation discussed is not a solution to the problem identified for the lower tail and the upper tail. In a small data set, the tails are not present -- so using the data alone does not fill in the tails. Instead, bootstrap sampling from a small data set is akin to truncating a parametric distribution at the smallest datum and at the largest datum. This may be an appropriate strategy in some circumstances.

- Table 1-2 Summary of Recommendations

Comment: Since variability is a fact of Nature, we ask the Agency to re-formulate each entry in this Table (i) to list the parametric distribution(s) first, and, if such are not available, (ii) to list the empirical percentiles for the distribution(s) second, i.e, specify the distribution by listing these empirical percentiles: 1st, 5th, 10th, 15th, 25th, 50th, 75th, 85th, 90th, 95th, and 99th. In situations where neither a parametric distribution nor an empirical distribution is available, then the Table could -- as a last resort -- list whatever pair of point estimates are available, e.g., the arithmetic mean and the 90th percentile as are published for drinking water intake.

- Chapter 1, Minor corrections

Page 1-6, Table 1-1: Spacing of low confidence response rates are shifted by one line.

Page 1-10, Eqn. 1-2, IR = Intake Rate and ED = Exposure Duration are missing.

Chapter 2 Analysis of Uncertainty

General Comment: Throughout this chapter, the Agency discusses uncertainty first and variability second.

Recommendation: Since variability is a fundamental property of Nature and of exposed populations, we think it deserves first discussion in each section of this chapter and in each chapter in the Draft Handbook. Variability has always existed and will always exist, regardless of the number of measurements completed. Further, variability in this Draft Handbook is a measure of what we do know, so, we think, it is appropriate to discuss variability (what we know) before uncertainty (what we do not know).

Uncertainty, on the other hand, is not a fundamental property of Nature nor of an exposed population. It is a property of the risk assessor who may, through further study, decrease his or her uncertainty (i.e., improve his or her knowledge) through appropriate measurements or investigations. In fact, a key use of uncertainty analysis -- in the form of the Value of Information (VOI) analysis -- is to elucidate the most cost-effective topics for future research. Again, starting from what we know (variability), we can decide how to fund research to quantify and then reduce uncertainty.

For some exposure variables, the range of variability may be far larger than the range of uncertainty. For example, the range of variability in adult body weights far exceeds the range of uncertainty in adult body weights. For the majority of the exposure variables in the Draft Handbook, we think that the variability exceeds the uncertainty, so placing variability first makes sense for this reason as well. Of course, for some exposure variables, variability and uncertainty may have comparable ranges. For a few exposure variables in this Handbook, the range of uncertainty may exceed the range of variability pending appropriate research.

These issues go to the heart of all the discussions in this chapter.

- Section 2.2 Definitions of Variability and Uncertainty

Issue: The Draft Handbook states: " While some authors have treated variability as a specific type or component of uncertainty, the US EPA (1995) has advised the risk assessor (and, by analogy, the exposure assessor) to distinguish between uncertainty and variability. Uncertainty represents a lack of knowledge about factors affecting exposure or risk, whereas variability arises from true heterogeneity across people, places or time. In other words, uncertainty can lead to inaccurate or biased estimates, whereas variability can affect the precision of the estimates and the degree to which they can be generalized."

Comment: We think these definitions for variability and uncertainty are inadequate for exposure assessment. In particular, we recommend definitions along these lines for these two key terms:

> Variability represents true heterogeneity in the biochemistry or physiology (e.g., body weight) or behavior (e.g., time spent showering) in a population which cannot be reduced through further measurement or study (although such heterogeneity may be disaggregated into different components associated with different subgroups in the population). For example, different children in a population ingest different amounts of tap water each day. Thus variability is a fundamental property of the exposed population and or the exposure scenario(s) in the assessment. Variability in a population is best analyzed and modeled in terms of a full probability distribution, usually a first-order parametric distribution with constant parameters.
>
> Uncertainty represents ignorance -- or lack of perfect knowledge -- about a phenomenon for a population as a whole or for an individual in a population which may sometimes be reduced through further measurement or study. For example, although we may not know much about the issue now, we may learn more about certain people's ingestion of whole fish through suitable measurements or questionnaires. In contrast, through measurements today, we cannot now eliminate our uncertainty about the number of children who will play

in a new park scheduled for construction in 2001. Thus, uncertainty is a property of the analyst performing the risk assessment. Uncertainty about the variability in a population can be well analyzed and modeled in terms of a full probability distribution, usually a second-order parametric distribution with nonconstant (distributional) parameters.

Variability and Uncertainty are deeply intertwined. When analyzing a population, body weight -- for example -- exhibits variability across the population. But when analyzing a single individual from that population (who has a single, unknown value of body weight) then the variability in the body weights in the population may represent uncertainty in the body weight of the individual In some cases, consideration of intra-individual variability may be important (i.e., people's body weights are not exactly the same day-to-day).

Of course, spatial variability and temporal variability exist, but neither of these terms must necessarily have a probabilistic component.

- Chapter 2, Overall

Issue: The chapter would be much improved if it discussed both variability and uncertainty and their implications as given above in the general comments.

Comment: Uncertainty and variability have very different ramifications for decision making as discussed in Chapter 2. There is a logical disconnection associated with talking about variability but not uncertainty in Chapter 1. We believe that the draft would be much improved by moving section 1.3.4. Characterizing variability and Table 1.3 to Chapter 2, and calling Chapter 2 Variability and Uncertainty. This new chapter could then discuss the differences between using point estimates and using distributions to characterize risk (or exposure) and the differences between risk descriptors, and it should provide guidance for determining when factors should be considered variable, uncertain, or both. Arguably, some of this guidance might be more appropriately placed in an US EPA guidance document on using probabilistic analysis which this draft could cite, but since such a document does not exist the information must be included here. The draft also fails to cite guidance on risk characterization and to provide a description of computational methods which we believe should also appear in Chapter 2. This Chapter 2 would also be the logical

place to describe US EPA's policies on when to use or not use the defaults and when and how to extrapolate and/or combine data.

While the draft report adequately addresses variability in a number of exposure factors, it does not adequately address uncertainty. Although there have been noticeable improvements since the previous draft, for example in providing a sense of confidence in the recommendations (see Table 1-2), we recommend that the US EPA do better in its assessment of the uncertainty of the factors in the Handbook.

- Section 2.2 Examples of Variability and Uncertainty

Issue: The Draft Handbook states: "Uncertainty and variability can complement or confound one another. An instructive analogy has been drawn by National Research Council (NRC 1994, Chapter 10), based on the objective of estimating the distance between the earth and the moon. Prior to fairly recent technology developments, it was difficult to make accurate measurements of this distance, resulting in measurement uncertainty. Because the moon's orbit is elliptical, the distance is a variable quantity. If only a few measurements were to be taken without knowledge of the elliptical pattern, then either of the following incorrect conclusions might be reached: ..."

Comment: While this example may work for physicists who want to measure a single quantity that changes with time in a deterministic trajectory, we think this example is misleading to discuss in a Handbook regarding exposure assessment conducted by and for the US Environmental Protection Agency.

Recommendation: Most, if not all, exposure assessments conducted by or for the US EPA concern people in a population. None of these people have the same behaviors or the same physiology. Thus, even with perfect knowledge, probability distributions are the natural language for a risk assessor to understand, quantify, and model the variability in the population. In situations without perfect knowledge (the usual case), second-order probability distributions (Burmaster and Wilson, 1996) are the natural language for a risk assessor to understand, quantify, and model the uncertainty in the variability in the population.

- Page 2-1, para 6

Issue: The Draft Handbook should be aware that the term “best estimate” has different meaning to different people in addition to the issue of accuracy.

Comment: Different people have different statistics in mind when the talk about “best estimates” or “central tendencies” and these all have different implications for decision making. For example, some people think about the expected value (or arithmetic mean), while others talk about the mode or median. These terms should all be defined in the glossary.

- Page 2-2, para 7

Issue: This paragraph should cite NRC, 1994.

Comment: Since the last sentence is almost a direct quote from NRC, 1994, it should be cited more sufficiently than simply saying the National Research Council. To someone unfamiliar with NRC, 1994, this statement begs the question: Which National Research Council report? Which page?

- Page 2-4, para 5, last sentence

Issue: This sentence violates the basic concepts of value of information.

Comment: Consider the situation where one properly uses surrogate data (due to a lack of existing data) only to realize that no matter what value is used that data is irrelevant compared to other portions of the risk assessment. In this case, it is easy to see that surrogate data are adequate and it would be a waste of money to collect more data on this irrelevant factor. In general, data should be sought when it seems that the uncertainty in the factor is significantly affecting the uncertainty in risk and in the decision such that the value of the missing information exceeds the cost of the research needed. The US EPA should also consider which factors contribute substantially to all risk assessments to highlight research that would improve many risk assessments collectively even though the value of information from one study alone would not offset the costs.

- Page 2-6, para 3

Issue: The use of expert judgment should be discussed fully along with recent references (e.g., Cooke, 1991).

Comment: Studies of experts have shown a number of errors in judgment which are relevant to the area of exposure assessment and these should be discussed. This section should also note that to date there are not many models in the literature for eliciting judgments from exposure assessors (see Hawkins and Evans, 1988 for one of the few) and research in this area is needed.

- Page 2-7 through 2-9

Comment: We recommend that the Agency determine effective ways to present information about variability and uncertainty in risks to decision makers (we know only of the study by Bloom, Byrne, and Andresen, 1993).

- Section 2.7 References for Chapter 2

Recommendation: We recommend that the Agency update the key references for this chapter by adding the many publications and conference proceedings since 1993.

Comment: In addition, Ronald L. Iman's last name is spelled incorrectly as "Inman." Also, “Seller” should be “Seiler.” We recommend that the references be checked throughout the document.

Chapter 3 Drinking Water Intake

- The Chapter

Recommendation: We recommend that the Agency add current information on the large increase in the amount of bottled water and bottled fruit juices in the diets of many people.

- Section 3.2 Selection of Key Studies

Comment: While we generally agree that the Agency has selected the appropriate studies as the basis for this chapter, we disagree strongly that the study by the Canadian Ministry of Health and Welfare (1981) is the first study to present or that it is the most reliable study.

In our judgment, the various studies completed by Abby G. Ershow and Kenneth P. Cantor (sometimes with additional authors) form a far stronger basis for setting science policy. First, the studies by Ershow and Cantor consider behaviors in the US, not Canada. Second, the studies by Ershow and Cantor tend to rely on the USDA's NFCS with its larger and more diverse population, especially in terms of climatic region, socio-economic status, and race. Third, the studies by Ershow and Cantor report more robust summary statistics, generally in two sets of units: ml/d and ml/(kg•d). Overall, we think that the Agency errs in placing first reliance on the Canadian studies instead of the studies by Ershow and Cantor.

- Page 3-1, Full Paragraph 2 in Right Column

Issue: In this paragraph, quoted in full, the Agency states: "The distribution of water intakes is usually, but not always, lognormal Instead of presenting only the lognormal parameters, the actual percentile distributions are presented in this Handbook, usually with a comment on whether or not it is lognormal To facilitate comparisons between studies, the mean and the 90th percentiles are given for all studies where the distribution data are available. With these two parameters, along with information about which distribution is being followed, one can calculate, using standard formulas, the geometric mean and geometric standard deviation and hence any desired percentile of the distribution. Before doing such a calculation, one must be sure that one of these distributions adequately fit the data."

Comment 1: We recommend that the Agency add material along these lines: While no data set ever follows a LogNormal distribution perfectly, many exposure variables follow LogNormal distributions to within a tight tolerance -- that is the deviations from perfection are negligible in the overall calculations that follow.

Comment 2: Most of the time, the Agency follows the precept that parametric distributions must undergo careful scrutiny before a risk assessor may use the best-fitting one in a simulation of variability in the population. In the sentences in the latter portions of this paragraph, the Agency adopts a relaxed attitude -- indeed, a cavalier and unjustified attitude -- about fitting a LogNormal distribution to a data set by using the "... mean and the 90th percentiles ..." (emphasis added) and by using "... standard formulas....". We think that the Agency misstates the underlying mathematics. Given the median (not the mean!) and the 90th percentile of a data set known to follow a LogNormal distribution, one may easily calculate the geometric mean and the geometric standard deviation.

- Page 3-5

Issue: The Handbook states: "Ershow and Cantor (1989) also measured total water intake for the same age groups.....". (emphasis added)

Comment: Ershow and Cantor tabulated and analyzed data collected by the US Department of Agriculture; they did not measure any water consumption rates.

- Table 3-11

Issue: Neither the table nor the associated text describe the probability model and the units of measurement for the LogNormal parameters reported in the table.

Comment: Without the model and the associated units, the results in the table are useless. We ask the Agency to add this information, where IR is the ingestion rate:

$$\ln[\,IR\,] \sim Normal[\,\mu, \sigma\,] \quad ; \quad IR \text{ in ml/d}$$

which is equivalent to

$$IR \sim \exp[\,Normal[\,\mu, \sigma\,]\,] \quad ; \quad IR \text{ in ml/d}$$

The text most closely associated with this table discusses some of the results in units of "L/day" -- that is, units which do not apply to the model used to construct Table 3-11.

- Section 3.4

Issue: In discussing the results of Ershow et al. (1991), the Agency states: "...The tapwater distributions are neither normal nor lognormal ....."

Comment: Ershow et al. (1991) did not arrive at this conclusion; to the best of our knowledge, Ershow et al. are silent on the issue in that they only report percentiles of the data without attempting a parametric fit. This statement by the Agency seems to contradict its policy of not attempting to fit parametric distributions to data. If the Agency concludes that neither Normal nor LogNormal distributions can fit the data, the Agency must present two types of evidence supporting its conclusion: (i) goodness-of-fit statistics and (ii) probability plots showing the nature and the extent of the deviations.

- Page 3-28

Issue: The report states: " The average of the 90th percentile values from the same two studies (2.35 L/d) is recommended as the appropriate upper limit..... " (emphasis added).

Comment: We disagree with the statistical method used. Taking the average of the 90th percentiles from two different studies is not an acceptable method to pool the results from the two studies. This sentence misleads the reader into thinking it is statistically meaningful to pool results from different studies by adding (or averaging) upper percentiles. There are, of course, valid methods to address this issue, including Bayesian methods and meta-analysis.

- Page 3-28

Issue: The report states: "....The simulated balanced population distribution of intakes generated by Roseberry and Burmaster is not recommended for use in the post-1997 time frame, since it corrects the 1978 data only for the differences in the age structure of the US population between 1978 and 1988."

Comment: Roseberry and Burmaster (1992) make no claim that the results from their simulated balanced population could or should apply to any year later than 1988, the year simulated. More importantly, the Agency completely misses the larger point -- that

simulation is the right tool for combining component distributions for different (age) groups to generate a distribution for a particular mixed (or balanced) population at some other date or location. We recommend that the Agency add material on how to use the information in the chapter to simulate the distribution for a balanced population at different points in time.

- The Chapter, Overall

Issue: In presenting and comparing the studies, the Agency uses only text and tables.

Comment: We recommend that the Agency re-write this chapter to present, compare, and analyze the data using many graphs and plots.

- The Chapter

Comment 1: We recommend that the Agency add a discussion about water consumption by infants consuming formula instead of or in addition to breast milk.

Comment 2: We recommend that the Agency add cross-references to information about water intake while swimming and showering.

Comment 3: The discussion about the dietary fraction variable is inadequate - are there data for this (i.e., are there data describing percent of water consumed at home, percent of water which is bottled, and percent of water consumed in other important microenvironments)? In addition, for some contaminants (e.g., volatile organic compounds), total tap water consumption (including water used in beverages and food preparation) may lead to overestimates of exposure if the contaminants are released during processing and are not ingested. In contrast, it is also possible that some contaminants (e.g., metals) will be concentrated during processing.

Comment 4: This chapter does not indicate that people are likely to consume very large amounts of water for only short durations or for only a few days, e.g., during a few days or weeks of high athletic activity in warm weather. For example, a particular survey may report that some people drink very large amounts of water during the 3- or 5-day period of record. While some of those people may really drink such large

amounts of water every day, others simply may not. Thus, the upper percentiles from a short-term survey may well over estimate long-term exposures.

- Page 3-28

Issue: The Draft Handbook indicates that the LogNormal distributions fit to Ershow's and Cantor's data by Roseberry and Burmaster (1992) may be useful.

Comment: This is a rare place in the Draft Handbook which promotes the use of distributions. We recommend that statements like this be placed throughout the document when distributions are available.

Chapter 4 Soil Ingestion and Pica

- The Chapter

Issue: The organization of this chapter makes it confusing and it would be more useful to group the descriptions of the data and their interpretations by data instead of according “key” and “relevant” individual papers or reports. The studies which provide another interpretation of the data than what was given in the original study should appear following the discussion of the original study.

Comment: In this chapter on soil ingestion there are five studies that collected data that form the basis for soil ingestion estimates for children (Binder et al., 1986; Clausing et al., 1987; Calabrese et al., 1989; Davis et al., 1990; and van Wijnen et al., 1990) but it is hard to see this from the way the chapter is laid out. In particular, Calabrese et al.’s 1995 revised interpretation of their 1989 study data appears as the first “key” study, even though it is a re-analysis of the 1989 study data.

Consistent with our general comment about organization above, we recommend that the Chapter be re-organized as follows:

4.1 Introduction - In the second paragraph, add appropriate citations to “early studies” in the second sentence and to “soil intake studies” in the third paragraph. The different methods of estimating should be described here along with their limitations. This is more efficient than talking about the method-related limitations which now appear

along with the descriptions of each of the studies using the method (e.g., all of the mass balance studies are short term and local populations). The issue of method validation should be discussed here. We suggest that the mass-balance method has not been adequately validated, in part because Calabrese et al. used the data instead to estimate soil ingestion for adults.

4.2 Incidental soil intake among children -
4.2.1 Mass-balance studies - Start with Binder et al. section (since it occurred first) and include text of section now starting with "Thompson and Burmaster" in the Binder et al. section without a new heading. Then, go to sections with headings for Clausing et al., Calabrese et al., van Wijnen et al., and Davis et al. The section with Calabrese et al. should start with the 1989 study and then review all of the subsequent interpretations which Calabrese and Stanek et al. have issued plus the AIHC (1994) distribution. (As it is currently written, this section fails to show why Calabrese and Stanek have changed their interpretations and it looks as if there is more data than what really exists. With this presentation format, it will be more obvious that Calabrese et al. and Davis et al. set out to improve the work of Binder et al. and Clausing et al. by including consideration of food intake and presence of trace elements in urine.)
4.2.2 Observational studies - Section including Lepow which includes later interpretations by Hawley, followed by section about Day et al., and section about Duggan and Williams. This section should be short to emphasize the relative unimportance of these studies.
4.2.3 Synthesis and reviews of the evidence - Sedman and Mahmood, most recent Stanek and Calabrese which combines their data with Davis et al. data, and Sheppard paper. Also, this section should mention any previous US EPA guidance and limitations associated with the data and interpretations

4.3 Incidental soil intake among adults
4.3.1 Mass-balance studies - Only Calabrese et al.
4.3.2 Observational studies - Only Hawley. (We believe that Krablin, 1989 does not meet the minimum criteria for inclusion since it is not widely available or peer-reviewed)
4.3.3 Synthesis and reviews of the evidence - Sedman and Mahmood, any previous US EPA guidance and limitations associated with the data and interpretations

4.4 Studies of deliberate soil intake -
4.4.1 Prevalence of pica (now section 4.5)
4.4.2 Evidence (now section 4.6).

4.5 Recommendations - This section should also include some assessment of research needs and the value of improved information.

- Page 4-1, para 3

Issue: The discussion of the sampling done by Calabrese et al. is very confusing.

Comment: Assuming that the text is reorganized so that the 1989 study is described first, this part should be moved and made more clear. Some obvious problems with the text include the statement “day 1 of the fecal sample corresponded to the 24 hour period from midnight on Monday to noon on Tuesday.” This is either a typo and 24 should be 36, or something else is not right. It is difficult to understand how a study can assume that the mass balances when inputs were collected for 3 days (Monday morning - Wednesday night according to Calabrese et al., 1989) and outputs were collected for 4 days (Monday afternoon - Friday morning). In general, the whole issue of a lag period deserves more comment and critical review. It is useful to keep in mind that Binder et al. got the idea of doing this type of study from previous studies on cows, and that cows differ from humans in that they tend to eat the soil and grass from only one area (they have little variability in their diet) and they eat a relatively much higher quantity of soil. Binder et al., Clausing, and van Wijnen did not use a “lag period” because they did not measure ingestion of food. Calabrese et al. reportedly used a 28 hour period, while Davis et al. used a 24 hour period. The discrepancy between choices of lag period is troubling. In addition, a number of factors suggest that there might be problems underlying the method. Overall, the draft correctly summarizes the information given in the original sources, but it fails to synthesize the information over studies or as a whole.

- Page 4-2, para 2

Issue: The draft correctly asserts that use of daily soil ingestion estimates is subject to larger errors than are weekly averages, but it otherwise fails to challenge the validation of these studies and analyses.

Comment: Given that the lag time problem becomes acute when one tries to estimate soil ingestion daily and it seems more reasonable to assume that a mass balance will close over 3 days for an individual's inputs and outputs than it will over the course of 1 day, it might be useful to consider the estimates obtained by averaging over the week. Unfortunately Calabrese et al. do not report their estimates averaged over the week or study period so this information may not be available. The fact that Calabrese et al. end up screening a large number of their data out on the argument that they are "less consistent" is also troubling. In reality, each person ingests a true but unknown amount of soil every day which can be averaged over any time period (e.g., exposure assessors typically would like to know the daily estimate averaged over a year.)

Although none of the studies discussed have chosen this approach, another way to view the estimates for different tracers is as duplicate measures of the same unknown quantity. Consequently, one indication of a reliable method would be that the different tracers give similar estimates for a given individual for a day or over the study period. From the very limited data given in Stanek and Calabrese (1995a) and from the wide ranges reported in the Davis et al. data, it appears that the intra-individual variability in estimates for the given tracers could be so high that it may exceed the variability in estimates among individuals and that the mass-balance approach may not be a very reliable method. Also note that the results of Sedman and Mahmood (described on page 4-14, para 2) suggest that some trace elements should be dropped from consideration (i.e., Ba, Mn, and Zr) because they yield statistically significant differences in soil ingestion estimates than other tracers.

- Page 4-2, last sentence

Issue: The Draft's assertion that mean estimates are more reliable than any available distribution needs more explanation.

Comment: We do not understand the argument behind this statement. Instead, we believe that sufficient uncertainty exists about soil ingestion and that our imperfect knowledge might best be characterized using a distribution.

- Pages 4-3 and 4-4

Issue: Binder et al., Clausing et al., and van Wijnen may not be appropriate for inclusion as "key studies."

Comment: While Binder et al. and Clausing et al., are important because they performed the initial studies, they did not use a complete mass balance approach. Thus, the estimates they produce are likely to be biased high since trace elements which are ingested are also included. The recommended reorganization above eliminates the problem.

- Pages 4-7 and 4-8

Issue: The description of the Davis et al. study is incomplete and Eqn 4-2 is incorrect.

Comment: Some features of the study that are not mentioned include the lag period issue, the assumed collection of only half of the urine output (and thus the basis for multiplying E_U in Eqn 4-2 by a factor of 2), and the fact that the data collection continued throughout the summer and did not occur for all subjects during a particular week. In fact, the later sentence on page 4-8, para 2 that says "The study was conducted over a one-week period during the summer" further implies all of the subjects were sampled at the same time even though they were not. Also, Eqn 4-2 is missing some key parentheses, one "(" in the front of the numerator, and a ")" after the E_f (see Davis et al., 1990: 115).

- Page 4-9, para 1

Issue: Discussion of the study on adults should not be included here.

Comment: This section is related to soil ingestion rates for children. The section on the Calabrese et al. adult study should be moved to the section on adults and only referred to here.

- Page 4-10, para 1

Issue: The statement that the method was validated is too strong.

Comment: The small adult validation study contained few individuals (n=6) and the results only consider averaging over weeks, not over days. In addition, the mass balances did not close and this led Calabrese et al. (1990) to use the study as a basis for estimating soil ingestion by adults. The validation study also fails to describe how it resolves the imbalance of collecting output for 4 days and input for only 3 days. If not corrected, this imbalance would tend to increase soil ingestion estimates by increasing the relative amounts of outputs to inputs. In short, the EFH should include a comment to the effect that the trace element method for assessing soil ingestion has not been adequately validated. It seems reasonable that it would be worthwhile to perform another adult validation study. It might be very helpful to have the study volunteers flush out their bodies prior to the collection of any samples and at the completion of the study so that the time lag problem is reduced. Even though this approach might not be acceptable for children, if we are unable to validate the method under ideal conditions for adults, then it is difficult to imagine ever validating it for children.

- Page 4-10, para 2

Issue: The discussion of Stanek and Calabrese (1996) is incomplete and it should discuss the issues associated with throwing out a large number of data as "outliers."

Comment: Stanek and Calabrese (1996a) devise a function to determine which estimates are considered to be outliers. However, their assumption that "large errors" occur and outliers arise due to "... some other source of trace-element ingestion apart from food or soil ..." is troubling and again begs the question of validation.

- Page 4-11, para 1 and 2

Issue: These paragraphs synthesize information from two studies; they should be moved to an appropriate section.

Comment: It would be very helpful for the draft to consider the whole of the evidence and attempt to synthesize all of the information.

- Page 4-14, box with unnumbered equation

Issue: Giving the equation alone is insufficient because it is unintuitive and it requires explanation.

Comment: Sedman and Mahmood asserted that soil ingestion rates should be a function of age and they created this equation to include age dependence in their estimates. This draft needs to describe the basis for their assumption, the method they used to derive this relationship, and the implications for the results. Also, give the interpretation of x and the value used by Sedman and Mahmood.

- Page 4-17

Issue: The only quantitative adult study of soil ingestion (performed by Calabrese et al., 1990) was intended to be a validation of the method.

Comment: The adult soil ingestion estimates should be used carefully since they are based on data from so few individuals (n=6). In addition, the Draft EFH should include a comment to the effect that the trace element method for assessing soil ingestion has not been adequately validated. Further, the reference to Calabrese et al. (1987) needs to be updated in the reference section (which indicates that the paper is "In press" even though it was presumably published almost 10 years ago). We have not seen this paper.

- Page 4-19

Issue: Calabrese et al., 1989 appear to have sampled one child exhibiting pica.

Comment: The Agency correctly recognized that this data would increase the expected value of soil ingestion estimates based on Calabrese and Stanek's paper. We believe the single observed child serves as an inadequate source of information on amounts consumed during pica. It would be helpful to know whether or not the supervising adults observed any soil eating behavior for this child. The draft implies that these observations were made in the statement “In the study, a 3.5-yr old female exhibited extremely high soil ingestion behavior during one of the two weeks of observation.” However, we believe that the original studies (Calabrese et al., 1989; 1991) did not

note observing the child's behavior but instead reached their conclusions based on the high estimates. We believe that it is very important to know whether the child actually exhibited pica (i.e., ate dirt), or if instead the child ate unwashed fruits or vegetables that escaped collection in the duplicate meals which we would not characterize as pica.

Also the heading of Calabrese et al. 1994 does not match with the Calabrese et al. 1991 reference. One of these 2 lines needs to be fixed. Stanek and Calabrese (1996a) also make a troubling finding that children may exhibit highly variable daily soil ingestion rates and that pica may be more prevalent in the population (i.e., that children may exhibit very high rates over the period of a couple of days). The implications of this finding should be discussed, as well as its speculative nature. In particular, it seems possible that these high daily rates may be artifacts arising from the true mismatch between inputs and outputs (i.e., Stanek and Calabrese have made large and unvalidated assumptions in the derivation of these results). We believe that the statement on page 4-23 that "It is plausible that many children may exhibit pica (over short periods) if studied for longer periods of time" needs to be weakened by noting the above limitations.

- Page 4-20, end of first full paragraph

Issue: The text asserts that "Exposure during [winter months], although lower than in the summer months, would not be zero because some portion of the house dust comes from outdoor soil." This opens up the sticky issue of what these estimates of soil ingestion represent.

Comment: The text needs to grapple with the issue of soil and dust versus soil ingestion rates only. In particular, house dust contains outdoor soil brought into the house from all members of the family (which is one reason why para-occupational exposure to lead may be a problem - see Knishkowy and Baker, 1986). Thus, ingestion of tracers and contaminants from dust may come from locations other than the one under consideration. How should risk assessors deal with this problem? What does it mean for risk management? For example, if one believes that a large portion of soil ingestion comes from indoors instead of active outdoor play for children (as might be implied by this statement), then risk managers should consider strategies to inform parents of the need to keep their homes free of dust.

- Page 4-21 and 4-22, Table 4-20

Issue: Reorganize Table 4-20 so that it follows the chapter organization (i.e., first children, then adults, then pica) and identify studies as “key” or “relevant” in a separate column.

Comment: As it is currently organized, the table fails to separate data for adults from children, so it is difficult to see that relatively fewer data exist for adults.

- Page 4-24, Table at top of page

Issue: The text is incomplete with respect to this unnumbered and untitled table.

Comment: This table is useful and it should remain, but it needs to be discussed in the text. Arguably, the results for Ti should not be included since the studies that did not include intake are likely to be biased high for this element (and at a minimum the table should note this). In addition, the table should be more specific about the term “upper percentile” since some people may interpret this to mean a 90th percentile, while others will think of a 95th, or 99th percentile.

- Table 4-22

Issue: Table 4-22 should not include a recommended mean value for pica. The notes in the table also need work.

Comment: We believe that the single data point is insufficient to support a recommendation. In general, better information about mouthing behaviors could greatly improve this chapter. In addition, note "a" of the table implies that the estimate of 100 mg/d is not “conservative” and it is unjustified and should be removed. Instead, note "b" which applies to all of the numbers should be attached to all of the numbers. The table also needs to note that recommendations are not given for pica or for an upper percentile of adults due to the inadequacy of the data base. We believe that the recommendations themselves should also be the subject of peer review (in the spirit of the NRC’s 1994 report Science and Judgment in Risk Assessment.)

- Page 4-19 to 4-24, Recommendations

Issue: This section is poorly written and needs to be reorganized.

Comment: The limitations of the Calabrese et al. (1990) study should also include “(3) the method needs to be further validated” (page 4-24, para 2) and this limitation should also be given for the child studies.

- Chapter 4, Omissions and Corrections

This chapter suffers severely from the lack of distinction between variability and uncertainty. Clearly, soil ingestion studies suggest that these rates are variable within the population, but our confidence in the studies is low and a large amount of uncertainty surrounds these estimates. All of the recommendations suffer from trying to boil down the uncertainty and variability into a single number, and this is an area where probabilistic analysis and/or expert judgment might be very helpful.

Page 4-24, typos in text “wre” instead of “were,” “hve” instead of “have,” and the double adverb “clearly highly” which should probably just be “highly.”

Also, there should be a period instead of a comma between “conjectural” and “Krabin.” Finally, there is a subject-verb agreement problem in the sentence “The study protocols are not well described and has not been formally published.” (We reiterate our above concern that the Krablin reference does not meet the minimum inclusion criteria for this draft.)

Chapter 5 Inhalation

- Section 5

Issue: This Chapter/Section should be titled Inhalation Rate, not Inhalation Route.

- Section 5.2.2 and 5.2.3 (misnumbered) Selection of Key Studies

Comment: We agree that the Agency has selected the appropriate studies as the basis for this chapter. However, Beals et al. (1996) have just published important new results

in a paper titled "Quantifying the Distribution of Inhalation Exposure in Human Populations: Distribution of Minute Volumes in Adults and Children." in addition, we understand that Beals and her co-authors have also prepared another important manuscript that fits parametric distributions to the data in the paper already published. We think that these results are so important that we recommend that the US EPA add these results and findings to the EFH just as soon as possible by making them the first update on the World Wide Web.

- The Chapter

Issue: The chapter repeats many pages of tables filled with tiny type.

Comment: By deciding not to show any graphs or plots for any of the data reported in the chapter, the Agency misses the major generalization of the results. To wit, that many of the variables tabulated in this chapter follow LogNormal distributions.

For example, in his Figures 2 and 3, Layton (1993) shows that (i) Oxygen Uptake Rate and (ii) Ventilatory Equivalents, respectively, follow LogNormal distributions. We do not understand how the Agency could rely on Layton's manuscript so extensively and yet fail to report two of his main graphs and two of his most powerful and generalizable conclusions.

- Table 5-5 and Related Text

Issue: In Table 5-5, the Agency presents Layton's results (1993) for the inhalation rates associated with different short-term exposures.

Comment: We suggest that the Agency also add information of the abilities of different people to sustain different inhalation rates for stated durations. For example, various Regional Offices of the US EPA have stated in the past that some categories of workers can sustain "heavy work" inhaling 4 m^3/hr for 8 hr/d for weeks on end. Not even the winner of the Boston Marathon can sustain that inhalation rate for more than a few hours during a race. From this, we conclude that the Agency needs to supplement the chapter with additional information on typical durations for high inhalation rates (i.e, for breathing rates above, say, those for "light activity").

- Table 5-7

Comment: An arithmetic mean and 99th percentile are difficult to use in an exposure assessment? Can the Agency contact the original authors to obtain other percentiles of the data, say, 1st, 5th, 10th, 25th, 50th, 75th, 90th, and 95th percentiles? With these additional percentiles and the arithmetic mean, a risk assessor can easily see if a LogNormal or other parametric distribution may fit the data (or use an approximate empirical distribution).

- The Chapter

Comment: For a future edition of the Handbook, we suggest that the Agency add material that will allow the exposure assessor to differentiate the $IR_{outdoors}$ from the $IR_{indoors}$. Since indoor and outdoor air qualities usually differ, this information would be useful in many contexts.

- Table 5A-1

Comment: We cannot deduce the units for the BMR equation.

- Table 5A-2

Comment: What are the units for age and HR Range?

- Table 5A-7

Comment: What are the abbreviations used in the "Subject" column?

Chapter 6 Dermal

- Page 6-1

Issue: Overall, the chapter needs re-organization. The format of this chapter differs in that the Tables and Figures all appear at the end instead of throughout the Chapter.

Comment: The Tables and Figures should be interspersed with the text for consistency. General discussions about equations to calculate dose should appear in Chapter 1. We believe that Chapter 6 is more logically divided into two or three shorter chapters; there is no advantage to lumping them into a single chapter on the “dermal route.”

- Page 6-1, Section 6.1

Issue: In its current form, this section is confusing. Does it address water or soil dose? The section relies too much on the reader having to refer to US EPA, 1992.

Comment: It is not clear why Equation 6-1 differs from Equation 6-2, that is, why do we care about multiple events per day for water but not soil? Also, the text is messy and confusing on whether Eqns. 6-1 and 6-2 are for the ADD only or also for the LADD. (We know that they represent LADDs or ADDs depending on the AT, but this may not be obvious to other readers). More importantly, while it is obvious from Eqns. 6-1 and 6-2 where the data about SA fits in, it is hard to see where the dermal adherence part of the chapter comes into play or why it is relevant. We reiterate that this chapter is most logically divided into two separate chapters: one on surface area and one on dermal adherence.

An example of the extensive reliance on US EPA, 1992 appears in the 3rd paragraph of the section which refers to "the nonsteady-state approach" and "traditional steady-state approach" but does not describe them. At a minimum, these terms should be defined in the glossary. These terms have no meaning without some description and simply referring to other US EPA documents does not provide enough information about inputs required to use the models or underlying assumptions. How well have these models been verified and validated? Under what conditions do recommendations change and should alternatives be sought? Are there conditions about which assessors should be particularly concerned?

- Page 6-2, last sentence

Issue: The chapter suffers from organizational problems.

Comment: The information given in Appendix 6A is very relevant background information for one trying to understand the available surface area data. This text should appear first in the chapter (since it describes the original source data studies) and it should be followed by the other studies which are re-analyses. It is very difficult to understand why one would be interested in Eqn. 6-3 without the context gained from reading the appendix.

- Page 6-3, para 7

Issue: This section is not emphasized enough with respect to the correlation between BW and SA.

Comment: The sentence “They studied the effect of using these factors as independent variables in the LADD equation” is not helpful. First of all, the AT is irrelevant in this discussion, so even though Philips et al. looked at the LADD, their results are equally valid and important for the ADD. Second, this discussion does not emphasize enough the importance of being consistent in accounting for the correlation between BW and SA in risk assessments and it fails to help risk assessors that endeavor to do so.

- Page 6-4, line 5

Issue: What is D'Agostino's test?

Comment: We believe this is an uncommon test and a citation should be given to a good book, e.g., Madansky (1988).

- Page 6-4, para about AIHC

Issue: The recommendations here may lead to problems for readers using this source.

Comment 1: Overall, we read this paragraph as a very favorable review of this part of the AIHC Sourcebook. In particular, the last sentence says “As such, it is clearly relevant as an alternative information source on body surface area as well as other exposure factors.” While we strongly agree with what the statement says, we suggest that it could lead to problems if risk assessors who use the Sourcebook are criticized because they are not using the EFH. In our opinion, the real issue here is one of

getting distributions into the EFH, not having the EFH send users elsewhere to find them. This is an issue that we hope will be discussed at length when the US EPA's Science Advisory Board reviews this draft.

Comment 2: Whatever the resolution of this issue, we think that it is inappropriate for the US EPA to implicitly recommend a commercial software package (@Risk from Palisades, Inc.). In addition, the mathematical notations use by the @Risk program are generally non standard and confusing -- so the US EPA ought not endorse either the software or the confusing notation. We recommend that the Agency use standard mathematical notation for parametric distributions; in particular, we recommend that the Agency adopt the notations in Evans et al. (1993) and in Burmaster and Hull (1996; attached).

- Page 6-5, para 2 and Table 6-15

Issue: The recommended central estimate of 2 m^2 for adult skin area is high given the data presented in Table 6-4. (If changed it should also be changed in Table 1-2.) More importantly, the recommended upper percentile of adult body surface area lies above the maximum value for women and is inappropriate for over 51 percent of the population. In addition, the recommendations should not be presented in different units than were discussed throughout the chapter, instead conversion factors should appear in the glossary.

Comment: The chapter reports all data in m^2 so it is confusing to see recommendations in cm^2. The minimum surface area for women is actually 14,500 cm^2 (not 17,000) which yields central estimate of approximately 18,000 cm^2 (not 20,000). It may be helpful to provide separate estimates for men and women given the differences that exist. For men, the recommended 2 m^2 is in the middle of the range (1.7 m^2 to 2.3 m^2). For women, the recommended 2 m^2 is at the high end of the range (1.45 m^2 to 2.1 m^2). The adult body surface area recommendations should be reconsidered since they are likely to be inappropriate for women.

- Page 6-5, para 5

Issue: The text uses speculation (i) to provide policy recommendations for exposure to soil. and (ii) to modify soil contact estimates according to climates.

Comment: The assumption used is that 25 percent of the total body surface area will be exposed to soil. Clearly this amount may vary considerably for different exposure scenarios, different activities, different seasons, and different climates. We wonder if these recommendations are really needed (i.e., are they valid and useful)? While the assumptions about adjustments for climate seem reasonable, the bases for them are not given. The entire discussion of dealing with clothing is not helpful since it fails to provide references to other sources and it fails to reach clear conclusions.

Since the Agency has no empirical data on these phenomena, this section amounts to speculation. As such, this section contradicts the opening statement for the volume (Page 1-1, para 1): "The purpose of the Exposure Factors Handbook is to: (1) summarize data on human behaviors and characteristics which affect exposure to environmental contaminants, ...".

- Page 6-5 and 6-6, para spanning both pages

Issue: This discussion of the two methods is unclear and out of place.

Comment: For example, the 1st complete sentence on page 6-6 says “No reduction of body part area is made for clothing coverage using this approach” but the reference to which approach is ambiguous. In particular, we believe that this statement applies to the approach described in section 6.3, but it appears at the end of section 6.2. This paragraph should be rewritten and should appear in the introduction section of a new chapter devoted only to soil adherence.

- Page 6-6, description of Kissel et al. (and first bullet point on page 6-9)

Issue: The reader would benefit from more context than is given here.

Comment: For example, how do the Seattle soil samples compare to other soil types (i.e., are there soils that are richer and differ significantly in clay or organic carbon content or do these samples reflect the full range of soil types?) This type of information is needed for the reader to buy into the generalization given at the end of the paragraph that “soil adherence to hands could be directly correlated with moisture content, inversely correlated with particle size, and independent of clay content and

organic carbon content." What does the phrase "adjusted loading, averaged over fluorescing areas only" mean? Also, the data for indoor environments are completely inadequate. A greenhouse is arguably a covered outdoor environment, leaving only tae kwon do-karate as a studied indoor activity. Given this major limitation, we believe that this method should only be used for outdoor activities at the current time unless one is interested in the particular indoor activity of tae kwon do-karate. Further, more guidance is needed to make choices between the limited number of options given in Tables 6-12 and 6-13 and for differences in clothing, particularly given the strong recommendation to use this method given in the third and fourth paragraphs on page 6-9.

- Page 6-8, para 1

Issue: What is the basis for the statement that the representativeness of the data is somewhat limited by lack of consideration of race or gender? What about the small sample size and the fact that the data are very old?

Comment: While it is hard to see this from the presentation in the text, the measurements reported in the text were made in the population alive prior to 1935. Thus, the recommendations are based on the implicit assumption that today's population is similar to the population in the early 1900s. We suspect that the current population may be both taller and heavier than the one sampled and we believe that it would be worthwhile to test the implied assumption of similarity between the populations. In addition, sampling 401 people out of hundreds of millions is actually a small sample. On the other hand, we do not understand the concern about gender and race since information about gender has been considered and we are unaware of evidence to suggest differences between races.

- Page 6-8, para 2 and "Lack of bias" entry in Table 6-16

Issue: This paragraph is confusing in the way it refers to the 401 measurements collected by Boyd (1935).

Comment: Since all of the analyses are based on the same underlying data, they should all give similar results. This section fails to clearly point out that it is comparing apples to apples. In addition, we do not understand the justification for the assertion

that the analysis done by Murray and Burmaster (1992) cannot be applied to children. Since all of the analyses are based on the same data, concluding that the “results were reproduced by others with different methods” is weak support for assigning high confidence to a lack of bias in the study design. Based on our reading, we would probably have given and overall rating of “medium” instead of “high.”

- Page 6-8, untitled and unnumbered table

Issue: This section of the text should refer to Table 6-15 instead of showing the existing untitled and unnumbered table.

Comment: This is one place it is clear that the tables and figures should be interspersed in the text. Table 6-15 is more informative than the table now appearing with the text. We reiterate here our previous objections to the recommendations given in the table.

- Chapter 6 - Omissions and minor corrections

The chapter does not discuss additional data which may be of value (e.g., a breakdown of surface area data for face only and better information about variability in skin permeability for different individuals, conditions, and regions of the body).

page 6-2, last sentence is missing the verb “used” between “formulae” and “to determine.”
page 6-3, last sentence of para 6 is way too long and confusing.
page 6-4, para 4, “AICH” should be “AIHC” also “Brainard and Burmaster et al. (1991)” should be “Brainard and Burmaster (1992)”
page 6-8, para 2, we believe the phrase “generally accepted measurements that enjoy widespread usage” should be “widely used and generally accepted measurements.”
page 6-12, Table 6-1. Column headings “W^{a1}” and “H^{a2}” should be simply “a1” and “a2” since these numbers presumably represent the values of the coefficients alone. We also could not find the reference to note "a" in the table.
page 6-13, Tables 6-2 and 6-3 have different spacing between the lines for no apparent reason.

page 6-14, Table 6-4, to be more clear, the line for TOTAL should appear under a separate set of column headings. Also the accompanying text should explain why the median and standard error are reported for the TOTAL.
pages 6-17, 6-20, and 6-21 - Tables 6-11, 6-12, and 6-13 references to Kissel et al., 1995 and Kissel et al., 1996 are inconsistent with citations in the references
page 6-22, typo in last 2 lines of table “Costaff” should be “Costeff” and “Based on height weight data...” should probably be “Based on height and weight data....”

Chapter 7 Body Weight Studies

- Section 7.1 Selection of Key Studies

Comment: We agree that the Agency has selected the appropriate studies as the basis for this chapter.

- Tables 7-1 and 7-2

Issue: In Tables 7-1 and 7-2, the Agency repeats arithmetic mean and arithmetic standard deviations for the body weight (kg) of adults and children as originally reported by NCHS.

Comment: We do not dispute the facts in these tables (or in the NCHS sources), but we think the presentation will mislead people into thinking that body weights follow Normal distributions. They do not. To avoid misleading the readers, we recommend that the Agency simply delete Tables 7-1 and 7-2. The tables, as presented, only serve to perpetuate the widely believed fallacy that body weights are properly modeled with Normal distributions (instead of LogNormal distributions). In addition to misleading the reader, these tables are also redundant with information presented (in a richer format) in Tables 7-3, 7-4, 7-5, and 7-6, next.

- Tables 7-3, 7-4, 7-5, and 7-6

Issue: In these four tables, the Agency repeats arithmetic means and widely spaced percentiles for the body weights (kg) of adult males, adult females, boys, and girls as originally reported by NCHS.

Comment: These tables present the empirical data well. First, they correctly present the data as empirical distributions for different ages of males and females. Second, even a cursory visual examination of the data in the tables shows that (i) each arithmetic mean exceeds each median and that (ii) the percentiles of body weight are asymmetric about the median. These are indisputable signs that body weights do not follow Normal distributions because they have longer right tails than left tails.

- Tables 7-7 and 7-8 in Section 7.2

Issue: The Agency does not state the probability model that underlies the table.

Comment: Without a statement of the probability model and the units of measurement, the results in the two tables are useless. We recommend that the Agency publish these formulae with body weights measured in kilograms for each age group:

$$\ln[\,BW\,] \sim Normal[\,\mu, \sigma], \quad ; \quad BW \text{ in kg}$$

which is equivalent to:

$$BW \sim \exp[\,Normal[\,\mu, \sigma\,]\,] \quad ; \quad BW \text{ in kg}$$

- Tables 7-7 and 7-8 in Section 7.2

Issue: The Agency quotes results from a manuscript by Burmaster, Lloyd, and Crouch (1994) for boys and girls, ages 6 mon to 20 yr.

Comment: While the results quoted in these two tables are correct, Burmaster and Crouch (1996; copy attached) have re-analyzed the same data for children along with additional data for adults. The new, integrated results include parametric LogNormal distributions as a continuous function of age from 6 mon through 74 yr. We urge the Agency to re-write the Tables 7-7 and 7-8 based on these newer results. These new tables should include both the new results for adults and also the parametric equations.

- Chapter 7

Issue: The chapter includes no figures or graphs.

Comment: The distributions of body weights change systematically as a function of age -- that is, LogNormal distributions fit the data well for each one-year age interval and for both genders, but the parameters of the LogNormal distributions change with age. In an age of inexpensive and powerful computer graphics, we suggest that the Agency include plots that visualize the numbers in key tables (Pickover & Tewksbury, 1994; Wolff & Yaeger, 1993).

- Section 7.2 Study by Brainard and Burmaster (1992)

Issue: The Agency reports the results of this study without stating the probability model used and without showing the graphical evidence supporting the conclusion.

Comment: By eliminating the mathematical statement of the probability model (for continuous LogNormal distributions for body weight of adult men and women) and by not including the graphical evidence that makes the results understandable to a wide audience, the Agency has effectively eliminated any chance that the readers will learn the key generalization of all our knowledge about distributions of body weight -- that body weights follow LogNormal distributions for all ages and both genders. If ever there were a huge data base consistently supporting the use of a full probability distribution for the variability in the population, this is the case!

- Pages 7-6 and 7-7, Discussion of Bivariate Distributions for Height and Weight of Men and Women

Issue: This section summarizes a publication by Brainard and Burmaster (1992; copy enclosed) that fit bivariate distributions to NCHS data for the heights and weights of men and women.

Comments: We think the study by Brainard and Burmaster is sound and appropriate, but the Agency misinterprets and then incorrectly summarizes its results.

First, the summary repeatedly uses the phrase " height and lognormal weight ... (follow) a normal distribution...." This phrasing garbles the results in the original publication and it makes no sense as re-written. (Note: We discussed this error in comments sent to the Agency 12 months ago, but the errors were not corrected.)

Second, the summary does not report the statistical model used. In this case, Brainard and Burmaster used a bivariate Normal distribution of this form:

$$\text{Normal}\ (\ \mu_{Ht},\ \sigma_{Ht},\ \mu_{lnWt},\ \sigma_{lnWt},\ \rho\ )$$

where

μ_{Ht} = arithmetic mean of height in inches,

σ_{Ht} = arithmetic std dev of height in inches,

μ_{lnWt} = arithmetic mean of natural logarithm of weight in pounds,

σ_{lnWt} = arithmetic std dev of natural logarithm of weight in pounds, and

ρ = correlation coefficient for the stated units.

Third, the summary does not report the values of the best-fit parameters, the key ingredients for Monte Carlo simulation.

Fourth, the summary does not report ρ, the correlation coefficient. We find this omission particularly disturbing since the Agency frequently castigates risk assessors for omitting correlations! This correlation has practical importance in Section 6.2 when estimating distributions of total skin surface area. In particular, standard regression formulae present total skin area as a function two variables -- body weight and body height. Since these two variables are correlated to a non negligible degree ($0.40 \leq \hat{\rho} \leq 0.46$).

(Note: We discussed these same points in comments sent to the Agency 12 months ago, but the errors and omissions were not corrected.)

- Section 7.3

Issue: The Agency recommends the use of point estimates.

Comments: We strongly recommend that the Agency include the statistical models mentioned above so that risk assessors may use the fitted parameters to simulate full distributions in Monte Carlo analyses

- The Chapter

Issue: The Agency needs to adopt a new statistical model for body weight as a function of age -- from 6 mon through 74 yr.

Comment: Using Maximum Likelihood techniques, Burmaster and Crouch (1996; copy attached) have developed and had accepted for publication a new statistical model for distributions of body weight as a function of age from birth to death. We strongly urge the Agency to include this new model in revisions to the Draft Handbook. We hope the Agency will include this new model.

Chapter 8 Lifetime

- Page 8-1

Issue: The discussion of lifetime brings up the issue of altering potency numbers obtained from IRIS to account for a longer average lifetime than was previously used (i.e., 75 years instead of 70 years)

Comment: Since IRIS serves as the authority on Cancer Slope Factors (CSFs), the US EPA should consider adjusting all of the CSFs on IRIS to reflect the changes suggested by this Handbook. If the Agency fails to do this, then risk managers will not have a consistent source against which they can check toxicity numbers that are given in risk assessments. We strongly recommend that the US EPA consider this issue.

Chapter 9 Intake of Fruits and Vegetables

- Page 9-1

Issue: This section provides a sufficient summary of the background of studies designed to evaluate the ingestion rates of fruits and vegetables. However, it does not address a key issue: the estimation of ingestion rates for site-specific risk assessments. Since all of the studies reported focus on ingestion rates for relatively large regions and populations, the question of estimating ingestion rates for smaller regions and local populations remains unanswered.

Comment: The issue of developing site-specific exposure factors is one which confronts many risk assessors and we therefore recommend that US EPA develop and promulgate more explicit guidelines for developing site-specific exposure factors.

The data reported in this section represent total ingestion rates. However, when performing site-specific risk assessments, it is usually the case that exposure is only possible via food produced in the vicinity of the site. The fraction of fruits and vegetables that are homegrown has been characterized by US EPA (1989). The fraction of fresh, canned, and frozen vegetables that are homegrown is estimated to be 0.596 for rural farmers, 0.267 for rural non-farmers, and 0.051 for urban dwellers. Even for regional-scale risk assessments, it is unlikely that all produce consumed is produced locally. Therefore, some fraction less than one should be used for most exposure assessments.

- Page 9-1

Issue: Most intake studies are based on data collected as part of the US Department of Agriculture National Food Consumption Survey (NFCS).

Comment: We recognize the NFCS is the most comprehensive survey of food consumption in the US. However, we have several concerns about its use:

First, dietary patterns have changed considerably since USDA (1977-78) and Pao et al. (1982) studies and consequently reliance on these data may be problematic. The

Agency should attempt to use data which are more recent such as the USDA's Continuing Study of Food Intake (CSFII) by Individuals which also has the advantage of including mixed dishes (e.g., vegetables and meats).

Second, the NFCS was not designed to develop exposure factors for use in assessment of risks to human health. The survey suffers from a fundamental shortcoming: the survey period is limited to one and three days. We believe that relying on a 3-day survey period may introduce a substantial bias into the estimation of ingestion rates. Individuals who fail to consume a food on any of the three days of the survey, may erroneously be assumed to consume none of that food year-round. Conversely, as US EPA acknowledges, individuals who happen to consume food on all three days would be assumed to consume the food 365 days each year. As a result of these uncertainties, ingestion rates of lower and upper percentile consumers may be substantially under- and overestimated, respectively. Such a bias may affect estimates of the mean as well. Since sampling bias could significantly affect estimates of ingestion rates (in either direction) for a large fraction of the US population, we recommend that the US EPA evaluate its impact and take appropriate measures to account for it in the derivation of exposure factors.

- Page 9-1, para 5

Issue: Sentence: "... vegetables that are grown below ground may be more likely to be contaminated by soil pollutants."

Comment: Ground water irrigation is also a source which should be mentioned.

- Page 9-2 and 9-3

Issue: The study *US EPA Analysis of 1987/88 USDA NFCS Data* relies on the 1987/88 NFCS 7-day recall data.

Comment: The 1987/88 USDA NFCS data set is probably more representative of current ingestion rates than earlier NFCS studies. In addition, reliance on a 7-day recall period probably results in a substantial reduction of the uncertainty caused by using shorter survey periods. We believe that the Draft should discuss in more detail why these data are used to a lesser degree than the 1977-78 data (i.e., is it simply that

the sample size was greatly reduced for the later survey or is there more to it?). Also, more discussion of consumption trends which appeared to have changed between the surveys is necessary than simply referring to tables.

- Page 9-6, para 4

Issue: The discussion of dietary risk of pesticide exposure based on NFCS (USDA 1977-78) intake rates is incomplete.

Comment: The text sets an arbitrary value of 0.000001 g/kg-day for some food items, but does not explain how, and what assumptions were used. This information should be presented clearly in the Draft EFH, with appropriate footnotes added to Table 9-9. (Simply citing an unavailable document does not help.)

- Page 9-6, middle of right column

Issue: The statement referring to the ADD equation is not accompanied by an ADD equation.

Comment: Reference to the ADD equation here is unnecessary.

- Page 9-7

Issue: The US EPA Office of Radiation Programs and Office of Science and Technology estimated ingestion rates based on NFCS data. The *Canadian Department of National Health and Welfare Nutrition Canada Survey* relies on a Canadian study which is analogous to the USDA NFCS. 24-hour recall was used.

Comment: These studies suffer from shortcomings identical to the studies discussed above.

- Page 9-8, Eqn 9-1 and 9-2

Issue: The same mathematical function appears in both Eqn 9-1 and in 9-2.

Comment: Only 1 equation here is necessary, anyone using the Handbook should be able to figure out the relationship.

- Tables in Chapter 9 (and in 11 and 12)

Issue: Tables should be readable and carry sufficient warnings about appropriate and inappropriate uses of the data.

Comment: We recommend the data be presented in conformance with a standard rule such as Principle 5 of Burmaster and Anderson (1994) (see comment in "General Comments section). In addition, limitations and assumptions should be added to these tables as footnotes. For example, Tables should include a footnote to the effect: "Data for individual food items should not be summed for the purpose of total food group intake in exposure assessments." In addition, Table footnotes should mention the problems associated with multiplying by a single body weight as discussed in the text. All of the tables imply a high degree of precision (usually more than two decimal points!!) which is unjustified by the quality of the data and this should at a minimum be pointed out in appropriate footnotes. We recommend graphical presentation of these data to facilitate evaluation and comparison of the data.

- Chapter 9 - Omissions and minor corrections

Other data include Hoffman and Baes (1979).
page 9-6, para 2 "member of the US population " should be "members..."
page 9-7, para 2, typo "radio nuclides" instead of "radionuclides"
page 9-9, sentence before last paragraph should refer to Chapter 12, not Chapter 4.
page 9-20, Table 9-7, title typo "Rott" should be "Root"

Chapter 10 Intake of Fish and Shellfish

- Chapter 10

Issue: This section provides an overview of the background of studies designed to evaluate the ingestion rates of fish and shellfish. The data presented in this section appear to be relatively inconsistent and consequently, this section suffers badly from a lack of synthesis of the data. As it stands, it provides little guidance for an assessor,

largely because it attempts to reduce the complex variability and uncertainty in fish intake to single recommended point estimates.

Comment: Given the current presentation, it is difficult to follow the text, compare the results of different studies qualitatively and quantitatively, and assess which data to use as the basis of a site-specific analysis. This in part arises from the "key" vs. "relevant" distinction problem we have discussed above, although it is arguably better than some of the other chapters because it at least starts with a discussion of different types of studies. We believe a big issue here is in deciding how to best represent the intermittent exposures of the multiple different subpopulations that could be of interest to risk assessors and risk managers. We believe that the current presentation loses a great deal of information by not maintaining information about the intermittent nature of fish consumption (frequency) and meal size.

- The Chapter

Issue: US EPA acknowledges some of the biases of the studies, such as an overemphasis on male adults.

Comment: Such acknowledgment is both relevant and appropriate as it better informs the risk assessor of the limitations of the data. In general, we recommend that the US EPA be more critical of the studies it adopts and include more comments such as these.

- Page 10-4, para 3

Issue: The reference to the methods used by Ruffle et al. is insufficient.

Comment: Since most readers will not have a good idea what the three methods are, the EFH should do a much better job explaining it.

- Page 10-7, para 2

Issue: The study reported by Javitz (1980) fails to distinguish between self-caught fish and fish obtained from other sources. In addition, as-purchased weights are used, which may include portions of the fish not eaten by most consumers. Furthermore, the

recall period is relatively short (one month) and probably results in the underestimation of fish ingestion rates for infrequent fish consumers.

Comment: The Javitz (1980) study suffers from many flaws of general population studies. Since the methods used to estimate population-wide fish ingestion rates under-represent infrequent consumers of fish and overestimate the quantities eaten, it is likely that ingestion rates are overestimated for the general population. Indeed, the estimated mean intake (14.3 g/day) reported in Javitz (1980) exceeds some means estimated for the sub-population of freshwater anglers as reported in Table 10-29. Clearly there is some inconsistency. While recognizing the broad scope of Javitz (1980), we recommend more warnings and guidance about its use.

- Page 10-16

Issue: Studies based on data collected as part of the National Food Consumption Survey suffer from the bias introduced by the short recall period of 3 days. This bias is probably larger when estimating ingestion rates of foods eaten less frequently, such as fish, than for more frequently eaten foods.

Comment: As in the Javitz (1980) study, estimated mean fish ingestion rates are quite high, exceeding analogous estimates for anglers. This is probably a result of the sampling bias introduced by the 3-day recall period. We recommend caution in using these data.

- Page 10-18

Issue: The implications of the assumptions about intended fish consumers (= 2.5) and the edible fraction (= 0.5) should be analyzed more carefully.

Comment: We believe that this chapter would be greatly improved by using distributions to represent uncertainty and variability in fish intake. Since numerous target populations can be of interest, we believe that the assessment should be as clear and transparent as possible, and it has a long way to go in this chapter. When reading the chapter it is difficult to get a sense of the relative magnitudes of uncertainty and variability.

- Page 10-22

Issue: The study *Intake Rates of Potentially Hazardous Marine Fish Caught in the Metropolitan Los Angeles Area* is flawed in several respects, including (i) failure to interview during January, February, and March, (ii) limitation to successful anglers, and (iii) the assumption that the catch at the time of interview is equivalent to the catch at the end of the day.

Comment: It is unclear what bias is introduced, if any, to the study by excluding winter months from the analysis. By sampling only a successful sub-population of anglers, fish ingestion rates for the population of anglers are overestimated. (Perhaps a per capita estimate should be included to account for those who do not catch fish -- i.e., do not eat fish -- as part of the total population.) By assuming the catch at the time of the interview is equivalent to the catch at the end of the day, ingestion rates are underestimated. It is unclear what aggregate effect these uncertainties would have on the study results. We recommend US EPA re-evaluate the usefulness of this study to evaluate the biases introduced. If necessary, the study should be excluded from the Draft EFH.

- Page 10-29

Issue: The *Michigan Sport Anglers Fish Consumption Survey* assumes non-response for 7-day recall is equivalent to not eating fish. It reports estimated mean and 95th percentile intakes for two data sets, one which includes non-responses (assumed to be zero) and one which excludes non-responses.

Comment: This is incorrect and will grossly underestimate consumption. Non-response can be caused by a variety of factors, only one of which is not eating fish. Neither approach is correct. Excluding non-responses probably results in overestimation of mean and lower percentiles. Including non-responses as zero probably results in underestimation of the mean and lower percentiles. A more appropriate approach (based on the same study), which distinguishes between those who did and did not eat fish during the recall period is reported in Murray and Burmaster (1994). We recommend US EPA adopt a similar approach when interpreting data such as those reported in the *Michigan Sport Anglers Fish Consumption Survey*.

- Page 10-50

Issue: Ruffle et al. recommended adjusting upward by 25 percent (see page 10-7), but the adjustment is 50 percent on page 10-50.

Comment: The 50 percent adjustment needs to be justified. Also note that page 10-7 correctly uses natural logs ("ln"), but page 10-50 indicates common logs ("log," meaning to the base 10). Which is correct?

- Page 10-51

Issue: The method of combining estimated means is incorrect.

Comment: Averaging summary statistics in this manner gives disproportionate weight to studies with few subjects. It might be better here to combine the raw data or to use expert judgment or meta analysis to deal with the apparent inconsistencies.

- Page 10-50 through 10-52, Tables

Issue: The tables in the recommendations need titles, numbers, warnings, and reformatting.

Comment: The recommendations for fresh water anglers should consider the results of Murray and Burmaster (1994) in addition to West et al., 1993. The table showing recommendations for Native American Subsistence Populations is poorly formatted. It should not list the minimum and maximum values for the Alaskan Communities under the left-hand column because it is misleading. Also, the table should contain warnings about the limited nature of the data and warnings about whether the numbers are based on edible portions or whole fish.

- Chapter 10, Omissions

Issue: Estimates of percentiles reported for different studies span approximately an order of magnitude, but it is difficult to find this since the results are not presented well. In particular, Tables that were helpful for demonstrating this in the previous draft are

now gone (e.g., see Former Table 2-166) and in this respect, the current draft represents a step backwards. The range of these estimates suggests a high degree of uncertainty, variability between populations, incompatibility of studies, or other deficiencies in their estimation.

Comment: We feel it is inappropriate for US EPA to report such apparently disparate results without further comment or analysis. US EPA should explicitly recommend appropriate uses for such estimates (e.g., data collected in the Tittabawassee River basin should only be applied to populations in the basin). Failing to provide relevant guidelines can only encourage the misuse and abuse of such data summaries.

- Chapter 10 - Minor corrections

page 10-2, 1st sentence of 1st full para - should say "they used data" instead of "he used data" since it refers to Price et al.
page 10-16, 3rd full para - extra "." after ?"
page 10-17, 9th line from bottom, sounds funny to say "NMFS in deriving their" it should probably be "NMFS investigators in deriving their"
page 10-18, 1st full paragraph, does "continental US" include Alaska and Hawaii?
page 10-23, last line of left column, "Price et al. was" should be "Price et al. were"
page 10-26, para 1, "members of their households or other household" should have "households" at the end
page 10-26, last para, Eliminate the following "The 50th, or more generally" and start the sentence with "The pth"
page 10-28, para 3, the sentence containing the phrase "is calculated by taking 20 percent (i.e., 100 percent - 80 percent)" is too wordy

Chapter 11 Intake of Meat and Dairy Products

- Page 11-1 and 11-2

Issue: This section provides a sufficient summary of the background of studies designed to evaluate the ingestion rates of meat, poultry, and dairy products. However, it does not address a key issue: the estimation of ingestion rates for site-specific risk assessments. Since all of the studies reported in the Draft EFH focus on ingestion

rates across relatively large regions and populations, the question of estimating ingestion rates on a local level remains unanswered.

Comment: The issue of developing site-specific exposure factors is one which confronts many risk assessors. We recommend US EPA develop and promulgate more explicit guidelines for developing site-specific exposure factors.

The data reported in this section represent total ingestion rates. However, when performing site-specific risk assessments, it is usually the case that exposure is only possible via food produced in the vicinity of the site. The fraction of beef and milk that is produced at home has been characterized by US EPA (1989 and 1990). Even for regional-scale risk assessments, it is unlikely that all meat and dairy products consumed are produced locally. Therefore, some fraction less than one should be used for most exposure assessments.

- Page 11-2

Issue: Most intake studies are based on data collected as part of the US Department of Agriculture National Food Consumption Survey (NFCS). The use of the NFCS for meat, poultry, and dairy products suffers from the same shortcomings discussed for fruits and vegetables above.

Comment: See comments above. More recent data are available and they should be considered. Also, the example of "total vegetables" on the 7th line should probably be for "total meat."

- Page 11-6

Issue: As noted above, only 1 equation is needed to show the relationship between "dry weight" and "as consumed." Also, there is a spacing error next to the W.

- Tables in Chapter 9, 11, and 12

Issue: Tables should be readable and carry sufficient warnings about appropriate and inappropriate uses of the data.

Comment: We recommend the data be presented in conformance with a standard rule such as Principle 5 of Burmaster and Anderson (1994) (see comment in "General Comments section). In addition, limitations and assumptions should be added to these tables as footnotes. For example, Tables should include a footnote to the effect: "Data for individual food items should not be summed for the purpose of total food group intake in exposure assessments." In addition, Table footnotes should mention the problems associated with multiplying by a single body weight as discussed in the text. All of the tables imply a high degree of precision (usually more than two decimal points!!) which is unjustified by the quality of the data and this should at a minimum be pointed out in appropriate footnotes. We recommend graphical presentation of these data to facilitate evaluation and comparison of the data.

- Chapter 11- Minor corrections

Page 11-7, typo in the citation Finley, B.L. and Paustenbach, D.L. reference. The second author is Dennis L. Paustenbach so his initials should be "D.L." and not "B.L." Page 11-13, Table 11-5, there sure are a lot of significant figures in this table (!!) and this table should note that an update is pending.

Chapter 12 Intake Rates for Various Home Produced Food Items

- Page 12-2

Issue: Estimates of intake rates in Chapter 12 are based on the National Food Consumption Survey (NFCS).

Comment: As noted above, we believe using data from the NFCS for developing exposure factors may be inappropriate, especially for foods eaten infrequently. It is unclear what is the impact of the bias introduced by the NFCS survey methods in the case of home-produced food items. We recommend that alternative approaches and data be considered to estimate exposure factors for homegrown produce.

- Page 12-5

Issue: The discussion of disaggregation of household data to find individual consumption rates requires more clarification.

Comment: It is unclear if the disaggregation was done accurately with the data as analyzed due to the body weight of respondent limitation and the "average serving size for the specific age group." This disaggregation should be discussed more thoroughly and clearly indicate whether individual or household data are being used.

- Page 12-5, last sentence

Issue: The reference to "other food chapters" should be more specific.

Comment: It is more clear to say "Chapters 9 and 11."

- Tables in Chapter 9, 11, and 12

Issue: Tables should be readable and carry sufficient warnings about appropriate and inappropriate uses of the data.

Comment: We recommend the data be presented in conformance with a standard rule such as Principle 5 of Burmaster and Anderson (1994) (see comment in "General Comments section). In addition, limitations and assumptions should be added to these tables as footnotes. For example, Tables should include a footnote to the effect: "Data for individual food items should not be summed for the purpose of total food group intake in exposure assessments." In addition, Table footnotes should mention the problems associated with multiplying by a single body weight as discussed in the text. All of the tables imply a high degree of precision (usually more than two decimal points!!) which is unjustified by the quality of the data and this should at a minimum be pointed out in appropriate footnotes. We recommend graphical presentation of these data to facilitate evaluation and comparison of the data.

Tables 12-8 through 12-71 are very difficult to read. The font size needs to be increased at the expense of reducing the spacing between columns!

Chapter 13 Breast Milk Intake

- Sections 13.2, 13.3, and 13.4

Comment: We think that the Agency has not evaluated all the appropriate studies as the basis for this chapter. Other studies which have been conducted to evaluate breast milk intake rates include: Pluim et al. (1993) and Whitehead and Paul (1981). Lipid content data have also been reported by Pluim et al. (1993).

- The Chapter

Issue: The Agency downplays key information about the fraction of mothers breast feeding their newborn infants.

Comment: Maxwell and Burmaster (1993), using information from Ryan (1991) highlight two key issues. It is not possible to estimate the exposures -- much less the variability or uncertainty of exposures -- in the general population without this additional information.

First, not all mothers breast feed their newborns, even at the time of discharge from the hospital For example, for the years 1985 through 1989, only 52 to 58 percent of new mothers nursed their newborns at the time of discharge from the hospital (see Ryan, 1991; see also Table 1 and Figure 1 in Maxwell & Burmaster, 1993).

Second, the fraction of mothers nursing their newborns decreases exponentially from the date of birth. For example, from 1985 through 1989, the fraction of mothers breast feeding their infants decreases from 52 to 58 percent (at the time of discharge from the hospital) to 18 to 22 percent (at age 6 mon) to 6 to 7 percent (at age 12 mon) (see Ryan, 1991; see also Table 1 and Figure 1 in Maxwell & Burmaster, 1993). In this case, a graph of the results conveys much more information than the table alone.

- The Chapter

Issue: The Agency also downplays key information about temporal trends in breast feeding.

Comment: Over the last 30 years, the fraction of mothers breast feeding their newborn infants has increased and decreased markedly. For example, from 1985 through 1989, Ryan (1991) reports a decline of 6 percentage points (from 56.4 percent to 50.6 percent) in the fraction of mothers breast feeding their newborns just one week after birth. While we have not compiled more recent data on temporal trends in the fraction of mothers breast feeding their infants, we suggest that the Agency do so.

- The Chapter

Issue: The Agency also downplays socioeconomic information and trends in breast feeding.

Comment: We know from discussions with researchers in the field (Dr. Alan Ryan, Ross Laboratories; Prof. Kathryn Dewey, University of California, Davis) that socioeconomic factors (e.g., education, income, work outside home) strongly influence (i) the fraction of mothers who initiate breast feeding immediately after giving birth and (ii) the fraction of mothers who continue to breast feed at age 1 mon, 2 mon, etc. As long as the Agency excludes this information from the Handbook, it will be difficult if not impossible for risk assessors to do site specific risk assessments.

- The Chapter

Issue: All of the studies of breast milk intake reported in this section report data for a subset of the US infant population: infants of well-educated, middle and upper middle class and predominantly white mothers.

Comment: We agree with US EPA that the literature concerning breast milk intake studies suggests few data are available for infants that do not fall in this category. We recommend US EPA recognize that exposure assessments must include representative populations of US infants and provide guidance for extrapolating the available data to include infants from different ethnic and socio-economic backgrounds.

- Table 13-2

Issue: The study conducted by Butte et al. (1984) reports breast milk ingestion rates for only a single 24-hr period.

Comment: The short sampling duration does not take into account day-to-day variability of breast milk ingestion rates. We recommend that day-to-day variability be discussed re the estimated ingestion rates.

- Page 13-10

Issue: The analysis of lipid content data reported by Maxwell and Burmaster (1993) is included in this section.

Comment: Maxwell and Burmaster (1993) analyzed data collected by others. Although they estimate useful parameters for describing the probability distribution of lipid content in breast milk, their simulation study should not be considered "data." To refer to the hypothetical population of 5000 infants as "data" or as "those observed" is entirely inappropriate. The study conducted by Maxwell and Burmaster (1993) should be placed in a different category than studies which collect actual data. We believe that asking the authors of the original studies to review applicable sections of the Handbook would help to identify inappropriate representations, uses, and interpretations of the data.

- Page 13-10

Issue: The Draft Handbook provides recommendations for breast milk intake rates for babies which are only breast fed and fails to recommend values for the fraction of mothers breast feeding their infants or for mothers supplementing their babies' diets with formula.

Comment: These estimated breast milk intake rates are not representative of the US population. To be representative, US EPA should, at a minimum, report the fraction of women breast feeding their infants at an age of six months. We recommend that US EPA strive to characterize the population of infants that is both breast and bottle fed at various points in the first year of life and beyond.

Chapter 14 Activity Factors

General Comments: The 1996 Draft Handbook shows improvement in the quantity of reviewed literature. The chapter contains a larger collection of results and a good review of the literature. One of the primary problems with the 1995 Draft Handbook was the reliance on older field studies. The revised draft contains many more recent studies. In general, however, we believe the discussion needs a bit more sharpening to provide the user with a road map and a method to implement the findings. Some of the discussion mentions literature that contain distributions which might be used in Monte Carlo analyses. Furthermore, we believe that distributions should have been provided when available. We recognize that the chapter is already quite large, but selected distributions would add to the discussion and certainly mention of their existence is essential Finally, we hope that the Agency will reformat the tables to be more readable. Many contain too small of a font size such as Tables 14-6 to 14-10. The Tsang and Klepeis Tables, 14-19 through 14-139 appear to be poorly photocopied from original tables, making them difficult to decipher.

- Page 14-1

Issue: The introduction to Activity Patterns fails to mention the difficulty of combining information from disparate studies.

Comments: We urge the Agency to include a statement on the difficulty of combining data from different studies and a warning that when combining, a risk assessor may not choose activities that add to more than 24 hr in a day.

- Page 14-2 to 14-4 and Tables 14-4 to 14-16

Comments: The studies by Robinson and Thomas (1991) and the California Air Resources Board (CARB, 1991) provide good data on activity patterns and mean time spent in those activities. The Handbook has correctly identified some of the limitations of these studies, but we would like to see an indication of the availability of primary data that might be used to establish distributions. In addition, the California studies are less general than US EPA suggests. While we generally support the several CARB studies, we note that US EPA's summaries fail to make two caveats. First, many

Californians live in weather and climate atypical of most other population centers. Many people have documented that Californians spend a large amount of time outdoors and driving compared to other regions, so extrapolations from the CARB data require care. Second, the demographics of California differ from other regions of the US. Californians are younger than residents of most other states, and certainly differ from people in retirement communities in, say, south Florida.

- Pages 14-4 and 14-5 and Table 14-18

Issue: The Draft Handbook cites the study by James and Knuiman (1987) as the source of cumulative frequency for the duration of showers.

Comment: We recommend that the Agency add the parametric distribution -- a LogNormal distribution -- fit by James and Knuiman to their data using Bayesian techniques. We strongly urge the Agency to include (i) a statement of the statistical model and (ii) a summary of the best-fit parameters in the Draft Handbook.

After converting the results in the paper by James and Knuiman (1987) to more common notation, the distribution for time in a shower, T_S, is:

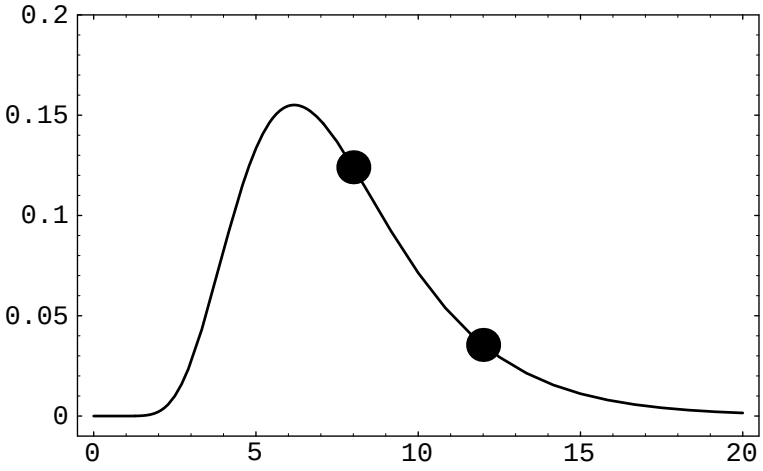
$$\ln[T_S] \quad \sim \quad \text{Normal}[\mu, \sigma] \quad ; \quad T_S \text{ in min/d}$$

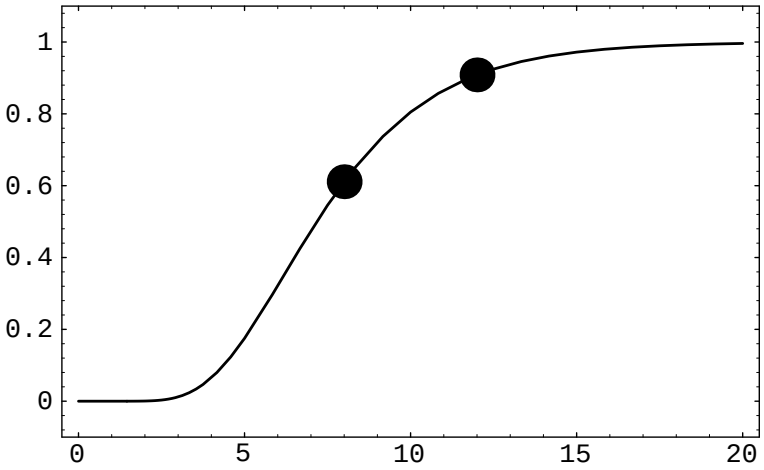
which is equivalent to

$$\ln[T_S] \quad \sim \quad \exp[\text{Normal}[\mu, \sigma]] \quad ; \quad T_S \text{ in min/d}$$

with $\mu = 1.97048$ and $\sigma = 0.386378$ for T_S in min/d. The arithmetic mean of this LogNormal distribution is approximately 7.73 min/d, a value above the 60th percentile of the distribution.

Here are the graphs for the PDF and the CDF, with each abscissa measured in minutes per day. The black dots represent the point values recommended by US EPA as the average (near $T_S = 8$ min/d) and the 95th percentile (near $T_S = 12$ min/d).





- Pages 14-5 and 14-6 and Tables 14-19 to 14-139

Comments: The results of the Tsang and Klepeis (1996) study have clearly added a wealth of findings to the Handbook. The tables in their current form are discouraging to use and need to be cleaned up or reformatted. The Agency should make the tables and primary data available so that a analyst may more easily incorporate the tabulations into a risk assessment, or even estimate distributions from the primary data for use in Monte Carlo risk assessments.

- Pages 14-6 to 14-7 and Tables 14-140 to 14-143

Comments: The review of the Robinson study (1977) correctly identifies many of the limitations of this useful but severely aging study. Given that it is approximately 20 years old, it might be wise to further downplay its relevance to current applications.

- Pages 14-10 to 14-11 and Tables 14-149 to 14-153

Issue 1: The Agency summarizes results from Carey (1988, 1990) and others on occupational tenure, employer tenure, and occupational mobility.

Comment 1: While we agree that the supplemental data to the January 1987 Current Population Survey (CPS) is a good source of information, the US Bureau of Labor Statistics reports much more detailed information than the crude summary statistics repeated in the Draft Handbook. We recommend:

First, at a bare minimum, the Agency give better descriptions of and pointers to the riches of data available from the CPS and subsequent publications.

Second, we urge the Agency to present and discuss the models and the new results just finalized by Shaw and Burmaster (1996, copy attached). In this manuscript, the authors develop and fit parametric probability distributions to employment data for women and men in key occupations and industries. The results clearly show that surveys of current tenure have two major flaws that distort the record: (i) they under-sample the number of short jobs that a person has in a life of working, and, of course, (ii) they under-sample the full duration of the current job. A standard statistical model can correct for both of these distortions in surveys of current employment. When both distortions are removed, the authors find that the first distortion is numerically larger than the second. That is, after suitable analyses, the data from the Bureau of Labor Statistics show that (i) surveys of current tenure over-state the arithmetic mean duration of employment and that (ii) all of the percentiles of the duration of actual employment are shorter than the same percentiles of the duration of current employment.

Third, of all the Tables in Shaw and Burmaster, we recommend the Agency publish Table 5, and then Tables 2 and 4.

Fourth, we note that the methods used by Shaw and Burmaster are completely general and could be applied by other analysts to other data for tenure in other occupations or industries.

Issue 2: The Agency confuses occupational tenure with job tenure (or employer tenure). To determine how these data may be applied to risk assessment, the Agency should recognize and understand the subtle differences between these terms and the behavior that they measure.

Comment 2: Occupational tenure is the total number of years that a person has worked in his or her current occupation regardless of the number of employers, interruptions in employment, or time spent in other occupations (Carey, 1988); it is the total time that a worker has accumulated in an occupation (Monthly Labor Review, 1989). Job tenure (often referred to as employer tenure) is the length of time a person has been employed continuously with a present employer (or as self-employed) except for interruptions for vacation, temporary illness, labor-management dispute, short-term layoff (less than 30 days), and other temporary reasons (US Department of Labor, Bureau of Labor Statistics, 1987).

Stated more simply, occupational tenure measures the cumulative number of years worked in a current occupation, while job tenure measures the cumulative number of years that a person has worked with the same employer. So, say for example, that the CPS is conducted in 1987 and we collect data on both occupational tenure and job tenure. Worker A is a teacher in New Mexico from 1979 to 1983, a real estate agent in Texas from 1983 to 1985, and a teacher in Maine from 1985 to 1987. Worker A would report his or her occupational tenure in a current occupation (in this case, as a teacher) as 6 years. However, Worker A's tenure with a current employer (i.e., job tenure) would be 2 years.

The occupational tenure data presented by Carey (1988) merely indicate how long workers are employed in a current occupation by (1) age and sex, (2) race and sex, (3) full-time versus part-time status, (4) age and occupational group. Occupational tenure is a measure of cumulative time worked in an occupation; therefore, these data do not

indicate the number of companies/organizations that a worker has been employed by in a particular occupation. Although a change in occupation implies, in most cases, a change in employer (and work location), since occupational tenure is a measure of cumulative time worked in occupation, these data cannot be used to identify a change of employer.

While job tenure data do not provide an indication of a worker's total job tenure with a current employer, they do measure how long someone has been employed with a company/organization up to the time of the survey.

If the Agency is looking for data that would provide some estimate of the amount of time that a person may work at a particular location (to support an estimate of exposure duration), job tenure rather than occupational tenure data should be used as the basis for this estimate.

Issue 3: Carey (1988) does not present information on the design of the January 1987 Current Population Survey.

Comment 3: The Current Population Survey (CPS) is conducted by the Bureau of the Census on a monthly basis (data collected are used by the US Department of Labor, Bureau of Labor Statistics (BLS) to determine the unemployment rate). Periodically, BLS issues a special supplement to the CPS to collect data on occupational mobility, job training, and length of employment at a current job. Information regarding the CPS such as the population coverage of the survey and the types of questions asked by interviewers, and the raw data gathered on occupational mobility, job training, and length of employment at a current job is available through BLS.

A special supplement to the CPS with questions on tenure and mobility was most recently conducted in January 1991. According to BLS staff, the next special supplement on tenure and mobility will be conducted in February 1996.

- Pages 14-11 through 14-13, Tables 14-154 and 14-155

Issue: The Agency summarizes the results for distributions and expected residence times for US households as published by Israeli and Nelson (1992).

Comments: Israeli and Nelson (then employed by the US EPA) developed and fit parametric probability distributions for (i) current and (ii) total residence times for households in the US. Using survey data collected in 1985 and 1987 by the Bureau of the Census, Israeli and Nelson used standard techniques from "survival analysis" to model duration of residency in a novel way. The Agency's summary of this pioneering work is flawed and insufficient.

First, the results presented out of context in Table 14-154 will likely mislead most risk assessors into thinking that total residence time and current residence time each follow Normal distributions with the stated means and standard deviations. Nothing could be further from the truth! -- and the Agency should go to pains to make sure no one could possibly make such a false interpretation of Israeli and Nelson's results.

Second, although the tabulation of selected values from R(t) in Table 14-155 start to present the fullness and usefulness of the overall findings, we think a graphical presentation of these and related results would be far more useful. Throughout this Draft Handbook, the Agency has systematically excluded graphs from the original authors' work in favor of tables of digits in black type. This study by Israeli and Nelson is but one crisp example where "a picture is worth a thousand words" -- and then some.

Third, if the Agency does not present Israeli and Nelson's fitted parametric results, we urge the Agency to include numerical breakpoints for the fitted distributions in the Draft Handbook. While such numerical breakpoints as the only summary of James and Knuiman's results were inappropriate alone (because the underlying LogNormal model is well within the reach of most risk assessors), we think tabulated breakpoints over the entire distributions fitted by Israeli and Nelson are appropriate here (because the underlying statistical model is well outside the reach of most risk assessors).

Fourth, the Draft Handbook glosses over a point that Israeli and Nelson make forcefully and thoroughly: Surveys of current residency time (i) under-sample previous behavior and (ii) under-sample future behavior. Israeli and Nelson show how the tools of survival analysis can lead to a deeper and richer

understanding of the true behavior which cannot be measured by a current survey, no matter how well designed and executed.

Fifth, the Draft Handbook fails to conclude that risk assessors should pay more attention to the fitted distributions of total residence time (than to the fitted distributions of current residence time) because it is the proper measure of behavior for assessing exposures in a population.

Sixth, the Agency should stress, as do Israeli and Nelson, that the distribution of total residence time is always less than the distribution of current residence time at corresponding distributions of the cumulative distributions. (In mathematics, this well-known and powerful property is called "first-order stochastic dominance of one distribution by a second." (Clemen, 1991))

- Pages 14-13 and Tables 14-158 and 14-159

Issue: The Agency summarizes some of the key features of a Monte Carlo model for simulating residential occupancy periods as prepared by Johnson and Capel.

Comments: We urge the Agency to note how readers of the Draft Handbook can obtain working copies of the source code for these subroutines.

- Pages 14-13 through 14-14 and Tables 14-160 through 14-162

Issue: The Agency summarizes results from 1,763 usable responses from a survey of home buyers conducted by the National Association of Realtors (NAR) in December 1993.

Comments: These are interesting data. They clearly present the results as empirical distributions. But the Agency fails to include information on the socio-economic status of the surveyed population -- except to say that they are among an advantaged minority of the overall population that owns a house.

- Page 14-18, Table 14-1

Comment: The table numbering appears to be in error.

Chapter 15 Consumer Products

- Chapter 15

Comment: This chapter contains essentially all new materials. We applaud its inclusion.

Recommendation: We recommend that the US EPA add a statement like this early in the chapter: "The user of this Handbook can locate additional information on many of the consumer products discussed in this chapter by contacting the appropriate trade association, e.g., the Soap and Detergent Association. These can be identified by key word searches (e.g., "detergents" or "cosmetics") of organizational directories such as the Encyclopedia of Associations CD-ROM (published by Gale Research, Inc.) available as a part of the SilverPlatter series (telephone 800-521-0574) and other sources."

- Section 15.1 Background

Issue: The chapter and this section often focus on consumer products as sources of chemicals in indoor air.

Comment: We urge the Agency to broaden the discussion. Certainly other sources, e.g., wood stoves, kerosene heaters, and gas ranges in the kitchen, cause as much or more exposure to certain chemicals indoors. Radon and volatile organic compounds introduced into a house via soil gas or household water supply can cause concerns. We encourage the Agency to broaden this Section to include a paragraph or two on these other key issues and to give references to other parts of the Handbook or to other literature on these issues.

- Section 15.4 Recommendations

Comment: We agree with the Agency's conclusion that "it is not feasible to specify recommended exposure values as has been done for other chapters in this Handbook."

- Section 15.5 References

Issue: Four of the seven references are dated 1987 or earlier.

Comment: We encourage the Agency to mention the limitations of such old data and to encourage the collection of current data for the issues in this chapter. Based on anecdotal evidence, we think that usage patterns for many consumer products have changed greatly in the last decade.

- Tables 15-2, -3, -4, -5, -12, -13, -14, 15, -16, -17, and -18

Issue: These tables do not report the number of persons responding.

Comment: We ask the Agency to add the size of the sample in each table.

- Table 15-20

Issue: This table does not include key information: the number of people responding, the volume of the can or bottle of beverage consumed, and the time interval for which the numbers apply.

Comment: We ask the Agency to state the number of the respondents and the volume(s) of the bottles or cans of beverage. Also, do the numbers apply to a day or a week or some other time interval?

- Tables 15-22, -23, -32, -33, -34, -37, -38, -39, -40, and -41

Comment: We ask the Agency to add information to these tables concerning the time interval to which the statistics apply. Do the numbers refer to events per day? events per week? events per year? some other duration? We think that the statistics in the different tables may be based on different time intervals.

- Tables 15-24, -26, -27, -28, -29, and -30

Comment: Can the Agency clarify whether these statistics apply to uses at home? at work? both? other locations?

- Table 15-42

Issue: This table includes information on the average and the 90th percentile of the frequency of use for various products.

Comment: How many people are included in this survey? Does the original research report contain other percentiles as well? If so, we ask the Agency to include the values for all the other percentiles available in the original reports.

- Omissions from Chapter 15

Comment: None of the tables in this chapter report information on possible correlations among the different activities, nor do they discuss possible differences in exposures between women and men.

Chapter 16 Reference Residence

General Comments: The 1996 Draft Handbook contains important improvements from the previous draft, most notably more complete discussion of the technical aspects, more complete discussion of pertinent literature and reference to it, and inclusion of some percentiles for a few distributions. We see the need for three essential improvements:

- Include distribution parameters when available from the literature, e.g., for house volumes and whole house air changes per hour. The Handbook could easily include reliable distributions, both empirical and parametric that would make it possible to perform probabilistic risk assessments and therefore estimate full distributions of risk. Many distributions are currently available in the literature.

- Either replace the tables for air changes per hour by census region with tables by climate and season or add the latter.

- Remove the numbers from the presentation on air flow rates for two-zone homes or clearly label it as a sample calculation. The discussion and results

provided appear to be based on erroneous assumptions about the database that was used. Use of these results could seriously flaw the outcome.

Specific Comments

- Page 16-2 to 16-4

Issue: The Handbook needs to provide more details on distributions of house volumes.

Comments: Section 16.2.1 should clarify throughout the text and tables that the volumes discussed are heated house volumes, not whole house volumes. Tables 16-1 through 16-3 should give specific sample sizes. We believe that the RECS volumes and percentiles in these tables are slightly in error and must be double checked. For comparison, see Murray (1996; copy attached). One explanation of the difference may be that Murray classified a third value of the own/rent variable "occupied without payment of rent" as "rental" whereas the Handbook appears to have placed these households into the "owner-occupied category".

We believe that it would be superior to revise these tables to include distributions (empirical and/or parametric) for heated house volumes. These distributions are currently available based on both the PFT and RECS databases. We attach a copy of "Residential Total House and Zone Volumes in the United States: Empirical and Estimated Parametric Distributions" (Murray, 1996). The Handbook does refer to this paper, but neither includes any of the distributions nor refers to the existence of the distributions in the paper. We feel that the distributions in the Murray manuscript are valuable and of high quality and should be included in the Handbook.

- Page 16-5

Issue: Distributions of Room Volumes

Comment: In the first full paragraph, reference is made to Murray (1996). We suggest that the data be put into table form, hopefully with the addition of some distribution parameters. More note should be made that these data are based on limited and unrepresentative sampling, and that the zones are as described in the original data collection, but may not truly represent such zones in a typical home. Two typographical

errors have been noted and the last sentence in the paragraph should read ".. . for the first floor, and 223 ± 111 m^3 for the second floor."

- Page 16-9

Comment: Delete these maps. The text does not refer to them and the one table that lists data by Census Region should be replaced (see below).

- Pages 16-10 to 16-12

Issue: Air exchange rates specified by Census Region only are marginally useful.

Comments: We agree that the PFT database is by far the best source of data available to estimate air exchange rates. It is true that it is not statistically representative of all areas of the country, but we believe it is satisfactory if used properly. There are two issues of concern with Table 16-9. First, there is great difficulty in applying the statistics specified to an actual risk assessment given that the table does not differentiate between seasons of the year and because the choice of census regions as a means of segmenting the data into subsets is inappropriate. Second, there is a lack of sufficient statistics to conduct a probabilistic risk assessment.

With regard to the first issue, it is our understanding that it is essential to examine the data with consideration for weather conditions. Air changes per hour (ACH) are strongly dependent upon the indoor/outdoor temperature differential and wind (Murray and Burmaster, 1995). Segmenting the data by census regions only is not useful because no consideration is made for the substantial difference in ACHs between summer and winter and the widely differing climate conditions contained within each census region. Since such differences exist, it does not make sense to use either the national or regional (census) statistics in Table 16-9 for an actual risk assessment.

With regard to the second issue, we believe that the quantity and quality of the PFT database is more than sufficient to provide valid distributions that can be used in probabilistic risk assessments. These distributions are currently available in the literature (Murray and Burmaster, 1995). A copy of this paper has been attached. Not only does the paper provide both empirical and parametric distributions, but also the distributions are segmented by season and climatic region. Table 16-10 does contain

some of the data from Table II of Murray and Burmaster (1995), but we strongly recommend that Table II and Table III from the above paper be included in their entirety. An analyst faced with an actual deterministic or probabilistic risk assessment will find these tables both reliable and easy to use. Table II contains complete statistics specifying the underlying empirical distributions. Table III contains estimated parametric distributions. Many analysts may find the latter to be easier to use, especially if a closed form solution is a possibility.

- Page 16-3

Comment: Equations 16-1 and 16-2 should be enlarged so that the subscripts and superscripts are readable.

- Pages 16-16 to 16-17

Issue: The analysis is based on seriously flawed data.

While the discussion here is interesting, unfortunately it appears that the data on which the analysis is based were not properly utilized. The analysis used the PFT database in which zone volumes, airflows, and descriptions are given for each zone of each house. Zones are typically labeled as "bedroom", "kitchen", "living room", "basement", etc. In the database there are approximately 1,450 zones labeled as "kitchen", approximately 1,300 zones labeled as "bedroom", and 550 zones labeled as "basement". It is very tempting to assume that these labels are correct and to proceed to analyze zone volumes and interzonal airflows. However, after extensive contact with many of the individuals involved with the original data collection, Murray (1996) found that a vast majority of the zones contained larger areas of the house than the label indicated, i.e., "bedroom" zones contained all bedrooms and the associated hallway, "kitchen" zones contained the kitchen and associated areas such as pantries, utility rooms, dining area, and even living areas. For example, the largest set of data is from southern California. Each house was split into only two zones, bedroom and kitchen, and all areas of the house were assigned to one of these two zones. Thus none of the California data can be used in an analysis of interzonal airflows for bedrooms or kitchens. Murray did not feel that there were sufficient sample sizes for any room, bedroom, kitchen, etc., to produce reliable distributions. We strongly question that there could be anywhere near 1000 cases that could be used in an analysis as

mentioned in the Handbook. While the nature of the discussion in this section may be of interest, we believe that the actual calculations and their reference to kitchen and bedroom interzonal airflows and ACHs should be removed. It is very unfortunate that there is not sufficient data to produce the kind of information suggested in this section. We suggest the discussion and equations (enlarged to be readable) remain, but that there be no numerical coefficients in the equations and that Figure 16-7 be removed.

One other item that should be added to the Handbook is the important finding in the Murray paper that there is very little correlation between total house volume and the total house air exchange rate. This finding should be included for use in probabilistic risk assessments.

- Page 16-19

Comment: Add sample sizes to Table 16-15.

- Page 16-20

Comment: In Table 16-19, the unweighted mean has been taken for three items which do not appear to be comparable. No mean is specified for Tables 16-20 to 16-22.

- Pages 16-22 to 16-24

Comment: Enlarge Table 16-27 and equations 16-5 to 16-8 to be readable.

- Page 16-25

Comment: The Recommendations section should be modified in keeping with the changes suggested above.

- Page 16-27

Comment: The following changes should be made to two references:

> Murray, D.M. (1996) . . . Accepted for publication in *Risk Analysis*, In Final Revision.
>
> Murray, D.M.; Burmaster, D.E. (1995) . . . *Risk Analysis*, 15(4):459-465.

- Page 16-30

Comment: For the Murray, 1996 study, two corrections are needed. Under "Areas Surveyed", the description should read "RECS - Nationwide (random sample); PFT (not random sample) - large fraction in California". Under "Comments", add "Contains numerous empirical and parametric distributions of volume".

- Page 16-31

Comment: For the Murray and Burmaster (1995) study, add the following under "Comments": "Contains numerous empirical and parametric distributions of air exchange rates."

- Table 16-20

Issue: These data are increasingly out of date and misleading.

Comment: After 1994, dishwashers must have maximum total water consumption of 9.5 gallons per load. Leading designs are now down to 6 to 6.5 gallons per load. Dishwashers now use much less water overall, so the mass of chemicals volatilized from the water is greatly reduced. We recommend that the US EPA contact the Association of Home Appliance Manufacturers (AHAM) to obtain current data for the use of water in home appliances.

- Table 16-22

Issue: Again there are data supporting the fact that much less water is being used.

Comment: With water conservation built into the design, machines use much less water overall. Thus the mass of chemicals volatilized from the water is greatly reduced. We again recommend that the US EPA contact the Association of Home Appliance Manufacturers (AHAM) to obtain current data for the use of water in home appliances. With reductions running 10 percent to 20 percent and higher, the reductions in exposures are significant.

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