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Report on the Peer Review Workshop on Revisions to the Exposure Factors Handbook

RISK ASSESSMENT FORUM

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REPORT ON THE PEER REVIEW WORKSHOP ON REVISIONS TO THE EXPOSURE FACTORS HANDBOOK

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Risk Assessment Forum
U.S. Environmental Protection Agency
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NOTICE

This report was prepared by Eastern Research Group, Inc. (ERG), an EPA contractor, as a general record of discussions during the Peer Review Workshop on Revisions to the Exposure Factor Handbook. As requested by EPA, this report captures the main points and highlights of discussions held during plenary sessions and includes brief summaries of the work group sessions. The report is not a complete record of all details discussed, nor does it embellish, interpret, or enlarge upon matters that were incomplete or unclear. In particular, each of the four work group summaries was prepared at the workshop by individual work group chairs based on the work group discussions held during the workshop. Thus, there may be slight differences between the four groups' recommendations. ERG did not attempt to harmonize all the recommendations.

CONTENTS

FOREWORD

This report includes information and materials from a peer review workshop organized by the U.S. Environmental Protection Agency's (EPA's) Risk Assessment Forum (RAF) and the National Center for Environmental Assessment. The meeting was held in Washington, DC, at the Doubletree Hotel Park Terrace on July 25-26, 1995. The subject of the peer review was the document entitled *Exposure Factors Handbook* (External Review Draft, EPA/600/P-95/002A, June 1995). A copy of this report was made available to the public through EPA's Office of Research and Development publications office, CERI, U.S. EPA, 26 West Martin Luther King Drive, Cincinnati, Ohio 45268 (703 487-4650). The expert technical reviewers were convened to independently comment on the draft document and make recommendations that will enhance the final Handbook.

Notice of the workshop was published in the *Federal Register* on July 13, 1995 (60 FR 36142). The notice invited members of the public to attend the workshop as observers and provided logistical information to enable observers to preregister. About 40 observers attended the workshop, including representatives from federal government, industry, environmental and health organizations, the press, trade organizations, and consulting firms.

A balanced group of expert peer reviewers were selected from academia, industry, and government. Selected reviewers provided scientific and technical expertise in the following disciplines: water ingestion, food ingestion, inhalation rates, soil ingestion, fish consumption, dermal contact, human activity patterns, residence characteristics, and survey statistics.

In outlining the scope of the peer review, EPA emphasized that peer involvement is a key component of the process of developing a useful Handbook. EPA explained that the intended audience for the Handbook includes members of the risk assessment community within and outside of the Agency involved in developing exposure assessments, scientists involved in studies for which exposure data are collected, and scientists conducting research on exposure assessment. EPA explained further that the comments and recommendations of outside experts will greatly benefit the development of the final Handbook. EPA asked the expert reviewers to concentrate their review on determining whether the data presented in the Handbook will be useful and support both point estimates and probabilistic analyses of exposure. EPA will use the expert reviewers' comments and recommendations drawn from this workshop in considering revisions to the draft Handbook.

The workshop report is organized as follows. The report opens with a brief introduction concerning the purpose of the workshop and the background of the Handbook (section 1). This is followed by the chairperson's summary (section 2) and then the four work group chairs' summaries (section 3). The last section of the report provides highlights of peer reviewers' preliminary comments, a summary of meeting deliberations, and observers' comments (section 4). Appendices to the workshop report include a list of reviewers, the reviewer's premeeting comments, the agenda, reviewer work group assignments, and a list of observers.

William Wood, Ph.D.
Executive Director
Risk Assessment Forum

SECTION ONE

INTRODUCTION

This report highlights issues and conclusions from a workshop convened to gather information from expert reviewers on the U.S. Environmental Protection Agency's (EPA's) *Exposure Factors Handbook* (the Handbook) (External Review Draft, EPA/600/P-95/002A) published in June 1995. This information will be used by EPA in further developing the Handbook. The workshop was sponsored by the EPA's Risk Assessment Forum and the National Center for Environmental Assessment (NCEA).

BACKGROUND

Seven years ago, in response to requests for guidance and information on how to select values for exposure factors, the Exposure Assessment Group of EPA's then Office of Health and Environmental Assessment issued the *Exposure Factors Handbook*. The Handbook addresses factors frequently relied on in exposure assessments and provides a common set of statistically based values (default values) suggested for use by EPA program and regional offices. The Handbook was intended to encourage consistency in exposure assessments, while allowing risk assessors the flexibility to tailor assessment approaches to specific situations.

The 1989 *Exposure Factors Handbook* is divided into two parts. Part I provides equations and data on factors used in assessing exposure by ingestion, inhalation, and dermal routes. Part I also provides values for other factors used for exposure calculations such as lifetime, body weight, and activity patterns. Part II presents standard exposure scenarios and a discussion concerning analysis of uncertainties. Standard exposure scenarios include, for instance, ingestion of recreationally caught fish/shellfish from large water bodies and inhalation of vapors outside residences. The scenarios provide basic equations for calculating exposures as well as default values that can be used when site-specific data on factors are not unavailable. Both qualitative and quantitative methods for assessing uncertainties associated with exposure assessment are presented.

Although originally developed as a support document in connection with EPA's 1986 Guidelines for Estimating Exposure (*Federal Register* 51:34042-34054) and 1988 Proposed Guidelines for Exposure-Related Measurements (*Federal Register* 53:48830-48853), the Handbook quickly became an extremely popular tool in conducting exposure assessments. Then in 1992, two events prompted efforts to revise the *Exposure Factors Handbook*: (1) EPA's Risk Assessment Council issued a memorandum on risk characterization that emphasized moving away from single-value risk assessments (i.e., in favor of assessments that consider both central tendency and high-end exposures); and (2) EPA published the revised Guidelines for Exposure Assessment (*Federal Register* 57:22888-22938). Moreover, risk assessors were using and seeking updated exposure factors.

As a first step toward revision, EPA initiated a survey of Agency exposure assessors to develop recommendations on what factors should be included in the updated Handbook. EPA's two-day peer involvement workshop held in July 1993 represented another step in planning the Handbook's revision. Subsequently, based on the results of the workshop and new data obtained for various factors, the Handbook was revised. For example, because experts at the meeting held diverse opinions on whether to include scenarios and default parameters, neither types of information were provided in the draft revision of the Handbook. The draft Handbook (the subject of this peer review workshop) presents a significant amount of new material over the original 1989 Handbook.

PEER REVIEW WORKSHOP

To involve outside scientific and technical experts in development of the Handbook, EPA's Risk Assessment Forum and NCEA sponsored a two-day workshop, which was held on July 25-26, 1995, at the Doubletree Hotel Park Terrace, Washington, DC. The meeting gathered 25 experts (see Appendix A for a list of expert reviewers) with the objective of ensuring that the Handbook is of sufficient scientific quality to distribute as an EPA publication.

Prior to the workshop, EPA provided each reviewer with a copy of the draft *Exposure Factors Handbook*. EPA asked workshop participants to review this material before the meeting and to prepare premeeting comments with the following issues in mind:

- EPA sought expert opinion on specific questions: Are the data presented in a way that is useful to exposure assessors? For example, the data presented in the home produced section have been broken out in various ways (e.g., by regions, urbanization, race, age groups). Is this the best way to present the data? Also, are the data presented in a way that will support both joint estimate and Monte Carlo assessments?

- The studies included have been grouped into key studies and other relevant studies based on the Agency's judgment about the adequacy of the data and their applicability to the exposure factors being evaluated. EPA sought reviewer comments on whether these groupings have been made appropriately.

- Recommendations are presented at the end of each section. These are based on the Agency's interpretation of the key studies. EPA sought opinions on whether this is the proper interpretation of the data and whether the limitations/uncertainties have been appropriately emphasized/described.

- EPA would like to develop a new chapter (or sections at the end of each chapter) that highlights data gaps and future research needs. EPA sought suggestions for this material.

Appendix B contains the reviewer's premeeting comments.

To begin the workshop, William Wood, Ph.D., Executive Director of the Risk Assessment Forum, and Michael Callahan, Director of the National Center for Environmental Assessment's Washington office, explained the need to revise the 1989 *Exposure Factors Handbook* and the process for producing a final document. They emphasized that the revision will be based on the results of the peer review workshop, discussions with EPA program offices, and a review by EPA's Science Advisory Board. Next, they reviewed the charge to reviewers (i.e., the four issues presented above) and emphasized the need for reviewers to address whether the data presented in the Handbook will be useful in supporting exposure analyses (e.g., site-specific and national exposure assessments).

P. Barry Ryan, Ph.D., a professor at the Rollins School of Public Health at Emory University, served as the chairperson of the workshop. In his introductory remarks, Dr. Ryan reviewed the agenda for the workshop (see Appendix C), providing an explanation of the format for work group sessions. Reviewers were divided into four work groups according to the following topic areas:

- food and beverage consumption;
- nondietary and dermal exposure factors;
- human activity patterns; and
- housing characteristics and indoor environments.

(See Appendix D for reviewer work group assignments.) To help focus the groups' efforts on addressing each question in the charge, Dr. Ryan reviewed the purpose and goals of the workshop. He reminded reviewers to focus on identifying and elucidating issues relevant to the draft Handbook, rather than attempting to reach a consensus on issues.

Dr. Ryan explained that whereas the 1989 Handbook provided guidance on exposure scenarios, the draft Handbook provides, to the degree possible, guidance on the distribution of exposure factors. Further, he noted that the broader purpose of the document is to present a compilation of scientific data that will facilitate consistency among exposure assessment presentations by providing recommended data for use in preliminary assessments.

SECTION TWO

CHAIRPERSON'S SUMMARY OF THE WORKSHOP

P. Barry Ryan
Rollins School of Public Health
Emory University
Atlanta, Georgia

This section of the report paraphrases general comments provided by the four work group chairs in their oral presentations on the draft *Exposure Factors Handbook*. Some of these comments reiterate or elaborate on comments provided by expert reviewers in their premeeting submissions (see section 4 for an overview of premeeting comments and Appendix B for the premeeting comments themselves). Written summaries of work group discussions provided by the four chairs are presented in the next section (section 3).

This section also summarizes comments from general discussions at the workshop concerning the adequacy of information on uncertainty analysis provided in the draft Handbook (i.e., in chapter 8) and highlights areas of general agreement among peer reviewers.

WORK GROUP ON FOOD AND BEVERAGE CONSUMPTION

Although this work group's presentation focused on exposure via fish consumption, many of the comments raised also are applicable to other areas of dietary exposure and exposure in general. Overall, this work group agreed with the basic approach taken for revising the document, referring to information included in the draft as sound.

Several comments raised by this work group concern the studies selected for the Handbook. The panel proposed including more recent studies that provide guidance on a site-specific basis. In particular, panel members suggested including new data based on geographic region or on the type of water from which fish are caught. This is an overarching theme, given that it applies by analogy to media for other exposures.

Other comments regarded the use of certain data sets that are not necessarily population based in place of those that are and the use of other available studies. Both of these issues arose in other work groups as well.

This work group ended its presentation by posing two questions for consideration: Are there differences in dietary exposures (and other exposures) that can be attributed to ethnic differences? What is the relationship between short-term measurements of dietary intake and long-term exposures through the diet?

The group could not cite studies in these areas and thus characterized the questions as indicative of data gaps.

WORK GROUP ON NONDIETARY AND DERMAL EXPOSURE FACTORS

This work group echoed several comments raised by other groups. In particular, group members emphasized the need for explaining short-term exposure measurements and long-term exposures. They also advocated for the inclusion of longer term studies.

Additionally, the panel urged reorganization of the literature reviews by type of study. Members suggested, for example, separating staged and unstaged studies. In general, studies should be organized such that surveys or population-based studies would not be viewed as equivalent to special studies on specific groups.

WORK GROUP ON HUMAN ACTIVITY PATTERNS

This work group's presentation focused primarily on general considerations rather than the specific topic of human activity patterns. One of the panel's suggestions was to present data in chapter 5 in graphical form where possible. The group noted that pie charts, bar graphs, and similar visual representations can make the presentation of data more immediate.

Panel members suggested beginning each section with an overview and including an index at the back of the Handbook. Each overview could include a summary of the information in the section, an explanation of the reason for including the information, and an outline showing the organization of the information provided. This would make the document considerably more user-friendly.

The work group also suggested that EPA conduct a more thorough literature search to identify more appropriate studies. This sentiment was echoed by all the work groups. In the panel's opinion, the studies presented discuss survey-related issues in an unsophisticated and inadequate fashion. Moreover, panel members found some of the data presented in the time/activity surveys to be obsolete.

WORK GROUP ON HOUSING CHARACTERISTICS AND INDOOR ENVIRONMENTS

Members of this work group concentrated their efforts on developing an outline for their proposed reorganization of the chapter. In their view, the chapter has all the appropriate information, but the pieces do not fit together well.

In regard to their charge, panel members advocated positioning reference residence exposure in the larger exposure context. Additionally, they suggested positioning the entire document within a single conceptual framework. The group developed such a framework for exposures experienced in residences and suggested that a single framework could be developed similarly for all aspects of exposure. In the panel's opinion, such a framework would provide a firm foundation for all discussions of exposure in the Handbook.

UNCERTAINTY ANALYSIS

Although none of the groups specifically addressed the treatment of uncertainty analysis in the Handbook (chapter 8), the workshop chairperson solicited comments on this topic. All peer reviewers agreed that the Handbook provides a useful introduction to uncertainty analysis, but that more information on this topic should be included. Reviewers suggested that if information in the chapter cannot be expanded upon, then the discussion on uncertainty analysis should be incorporated in the introductory chapter (chapter 1).

CONCLUSIONS

Based on comments made during workshop discussions and on work group presentations, peer reviewers generally agreed on the following:

- The revised Handbook will serve an important need.
- The Handbook should provide some method of evaluating the quality of the studies included.
- Although certain studies in the Handbook are "key" and "relevant," some studies are inappropriate or dated. Moreover, studies on specific populations should be eliminated or included with a strong caution about their use.
- Presentation of data is important, but could be enhanced with a graphical format.
- Available literature should be more thoroughly reviewed (studies seemed to have been selected without regard for their specific contribution to the exposure assessment field).

SECTION THREE

WORK GROUP SUMMARIES

Food and Beverage Consumption Work Group

Work Group Chair:	Barbara Petersen, Technical Assessment Systems, Inc.
Work Group Members:	J. Mark Fly, University of Tennessee Patricia Guenther, U.S. Department of Agriculture Mary Hama, U.S. Department of Agriculture Paul Price, ChemRisk John Risher, The Agency for Toxic Substances and Disease Registry Frances Vecchio, U.S. Department of Agriculture

INTENDED USES AND AUDIENCE

Information provided in the Handbook should be appropriate to meet the needs of the intended users of the data. Thus, the work group identified potential users for the chapter on food and beverage consumption:

- groups and individuals evaluating food additives/packaging (i.e., using the data as a shortcut to look at potential exposure through foods, though not for regulatory purposes);
- groups and individuals assessing indirect risk (e.g., from air pollution, sludge, material leaching from a large area of environmental media, multiple exposures over wide area of food crops);
- researchers; and
- state, federal, and local health departments.

The types of information that would be needed for such uses of the data include:

- data on the entire U.S. population and for subgroups;

- point estimates as well as distributions (i.e., high-end 90th or 95th percentile); and

- data with a variable level of precision depending on the application (user might be willing to make worse case assumptions instead of more accurate estimates).

Because some users of this information may have limited expertise, the chapter should provide more guidance on how to use the data. This guidance should be provided not as default values but as "reference" values, accompanied by explanations of appropriate use. In particular, more guidance is needed on how to use the fish consumption data. In the opinion of work group members, the addition of scenarios to the chapter would not be particularly useful to the reader.

MISSING DATA

In general, the work group found the data to be outdated and often incomplete. Thus, members recommended that the following data be added:

- data on all categories: USDA CSFII 1989-91 (available on data tapes;

- fish consumption data: Michigan Survey of Fish Consumption (1992) (currently available); and

- meat consumption data: USDA Ag. Econ. Ranching Survey; Home Slaughtering of Sheep and Beef Cattle (conducted on a national basis).

At the workshop, representatives of the U.S. Department of Agriculture (USDA) indicated that some data reports are available for the 1989-91 surveys and that these could be provided to EPA.

GUIDANCE ON MULTIPLE ANALYSES OF THE SAME DATA

The work group recommended the following on this topic:

- Fully inform the user that the Handbook includes multiple analyses of the same data.

- Provide complete documentation for tables, including, for instance, the source of the data and an indication of the form of the food (e.g., dry-weight basis, cooked, uncooked). (The work group strongly recommends this because panels often had difficulty matching text with accompanying tables.)
- Provide guidance on which estimates to use for which purpose, and note limitations.
- Include a column in each table that provides the source of the data and summarizes the data from each study.
- Include a chart that helps users identify which tables provide original data and which provide data that are the results of reanalyses. (The work group developed a flow chart for its own use in identifying the source of data used in the analyses reported in the food consumption chapter.)
- Ensure that the data presented in the table of water intakes for different activity levels does not conflict with whatever data are provided (if any) in other parts of the Handbook. (This group did not evaluate the water intake estimates, but did raise a concern about the consistency of data between chapters.)

PRECISION

The document should not imply precision beyond what the study authors produced. The group recognized, however, that EPA should not be asked to reassess the appropriate level of original data. Therefore, after much discussion, the group recommended that EPA not report more significant digits than the source data.

Moreover, an effort should be made to be consistent throughout the handbook. In particular, consistency may be a problem when per capita estimates are derived for infrequently consumed foods such as fish.

Additionally, the rules of rounding should apply to interpolated percentiles.

NUMBER OF SUBJECTS PER SUBGROUP

The group concluded that without a cell size of at least 30 observations, the cell should be left empty. Although the group did not recommend a specific number of observations, panelists felt that when distributions are to be generated the cell size should be more than 30.

SUBGROUPS

Does the Handbook present data for subgroups likely to be used by exposure assessors?

- For age and sex subgroups, the work group found the data to be adequate.
- For fish consumption, the work group recommended adding data on the following:
  - ethnic background subgroups;
  - subgroups relying on fishing for economic subsistence;
  - information by water bodies (river/stretch of the coast), marine vs. freshwater, nature of the fisheries;
  - Michigan study;
  - creel survey data; and
  - list of studies in Paul Price's comments.
- For meat consumption, the group recommended adding data on:
  - home-produced meat (USDA ranching survey).
- For game, deer, wild foul intake, the group recommended adding:
  - data available from USDA surveys (but few users);
  - data on how frequently these foods are consumed; and
  - data on total amounts consumed.
- For breast milk, the group noted the following:
  - some of the results of the studies included in the Handbook conflict. Thus, a comment should be added regarding these conflicts and guiding the user in the appropriate selection of data;
  - the Handbook should convey the level of uncertainty in these estimates, in both the text and in the degree of precision in the estimates; and

- estimates of intake are needed for specific age subgroups0 to 6 months, 6 to 12 months, greater than a year.

- In general: The group attempted to provide guidance for instances where observations are too few for a specific cell; thus, if too few people are in a cell:

  - combine foods (this would not necessarily be easy, and may depend on specific substance);

  - combine age/sex groups;

  - include information about how to obtain original data (it may be better for researchers to go back to the original data).

FOOD DISAPPEARANCE DATA

The food disappearance data are of extremely limited utility and should only be included when other sources of information are not available. Given the usefulness of data already included, the group recommended dropping the food disappearance data entirely. (See also Attachment A.)

SURVEY METHODOLOGY

The work group recommended the following on this topic:

- adding a checklist for every study, including reference period, sample size, and methodology (e.g., year, 3 days);

- if appropriate data are available, adding food frequency data for infrequently consumed foods; and

- providing guidance on the use of total population data; total population data may be too general for specific analyses (site specific, state specific), but useful for screening and preliminary analyses.

PRESENTATION

The work group recommended the following on this topic:

- add a discussion about how to obtain upper percentile estimates when the contaminant is present in more than one food (adding upper percentiles for individual foods is *not* the correct approach; user needs to be advised to go back to raw data);
- add a discussion on the use of per capita estimates and when per user estimates are more appropriate; and
- provide estimates of precision (standard deviations/standard errors/confidence intervals).

DERIVATION OF ESTIMATES FOR HOMEGROWN FOODS

On this topic the work group recommended adding a discussion on the limitations of estimates given as well as the methods/assumptions used to derive estimates.

Additionally, the group expressed interest in reviewing the analysis currently being conducted by Paul White. Some additional information from USDA is attached (see Attachments B and C).

ATTACHMENT A

United States
Department of
Agriculture

Food Consumption, Prices, and Expenditures, 1968-89

Judith Jones Putnam
Jane E. Allshouse

Like many time series, the data are more useful as indicators of trends over time than as measurements of absolute levels. In other words, this series provides an indication of whether or not Americans, on average, are consuming more or less of various foods over time. It is not a direct measure of actual consumption nor of the quantity ingested. The disappearance data for food have proved accurate enough to permit measurements of the average level of food consumption in the country as a whole, to show year-to-year changes in consumption of the major foods, to permit calculation of the approximate nutrient content of the food supply, to establish long-term trends, and to permit statistical analyses of effects of prices and incomes on consumption of the principal foods.

The food supply data series is the only data set that is consistent; that is, supply and total use must balance. It measures utilization of basic commodities without getting involved with identifying all end use products and the problems of decomposing compound foods back to commodity ingredients. It measures food supplies for consumption through all outlets, at-home and away from home. It is a long, continuous series, published first in 1941 and extended back to 1909 for most commodities. It is the only data set available for determining long-term trends in supply and consumption by major food groups.

The series covers the complete spectrum of primary foodstuffs. Hence, it can be used to measure interrelationships between foods and for measuring total food supply and apparent use. It is particularly useful for estimating complete demand systems that measure price and income elasticities of demand in a consistent way.

Limitations

Usually the food supply is a *residual* which makes the supply-utilization commodity table balance. The disappearance method of calculation relegates to the food supply all residual uses for which data are not available, such as miscellaneous nonfood uses, stock changes at retail and consumer levels, and sampling and measurement errors accumulated in the estimation of other components of the balance sheet. For example, an increasing proportion of the total chicken supply (especially backs, necks, and giblets) goes into pet foods. But since such use has yet to be officially estimated or entered as a nonfood-use component of the supply-utilization balance sheet, it is included in food disappearance. Thus, this report probably overstates chicken consumption. In contrast, the lack of reliable estimates of game fish supplies means that fish consumption is likely understated.

Food disappearance is often used as a proxy to estimate human consumption. Used in this manner, the food supply usually provides an upper bound on the amount of food available for consumption. Food disappearance estimates can overstate actual consumption because they include spoilage and waste accumulated through the marketing system and in the home. In general, food disappearance data serve more appropriately as indicators of trends in consumption over time than as measurements of absolute levels of food eaten. This is the case so long as changes in food production and marketing practices or consumer behavior over time do not alter the relative disparity between food disappearance and food actually eaten.

The food disappearance series may no longer be a reliable indicator of change over time in ingestion of food fats and oils. While food disappearance fairly accurately reflects trends in fats and oils sold for human food, it probably does not accurately measure trends in food eaten because the waste portion of food disappearance for fats and oils has increased during the past two decades with the growth in away-from-home eating places, especially fast-food places. Foodservice establishments that deep-fry foods can generate significant amounts of waste grease, referred to as "restaurant grease." A recent study by SRI, International indicates that the quantity of used frying fat disposed of by restaurants and processed by renderers for use in animal feeds, pet foods, industrial operations, and for export now annually amounts to about 6 pounds per capita, or nearly 10 percent of the 1989 disappearance of food fats and oils.

Food supply data are aggregates of food obtained from all sources. Retail-weight equivalents measure food availability as if all food were sold through retail foodstores. Much of this food, however, is consumed on farms where produced, or is sold through wholesale channels to restaurants, hotels, other away-from-home eating places, and to schools, camps, hospitals, and other institutions.

ATTACHMENT B

United States Department of Agriculture | Agricultural Research Service | Beltsville Area Beltsville Agricultural Research Center | Beltsville, Maryland 20705

The Continuing Survey of Food Intakes by Individuals and the Diet and Health Knowledge Survey, 1989-91

BACKGROUND: The Continuing Survey of Food Intakes by Individuals (CSFII), conducted as three separate 1-year surveys in 1989, 1990, and 1991, was designed to measure what Americans eat and drink. Information from the surveys is used to develop nutrition education programs, to assess dietary changes associated with participation in food programs, to develop food fortification and enrichment policies, to monitor the safety of the food supply, and to assess demand for agricultural products and marketing facilities.

The Diet and Health Knowledge Survey (DHKS), conducted as a telephone follow-up to the CSFII, is designed to improve our understanding of factors that affect food choices and to obtain information on people's knowledge and attitudes about the Dietary Guidelines for Americans. Together, the CSFII and the DHKS provide the first opportunity on a national scale to link an individual's knowledge and attitudes (from the DHKS) to his or her dietary behavior as indicated by food intake information collected from the same individual in the CSFII.

METHODS: Individuals who took part in the CSFII were asked to provide 3 consecutive days of dietary data. The first day's data were collected in a personal in-home interview using a 1-day dietary recall. The second and third days' data were collected using a self-administered 2-day dietary record. Individuals who were identified as the main meal planners/preparers in the CSFII were contacted by telephone, if possible, about 6 weeks after collection of the dietary data and were asked to answer a series of questions about knowledge and attitudes toward diet, health, and food safety.

DATA TAPES: Results from each year of data collection are available on data tape from the U.S. Department of Commerce, National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703-487-4650).

- "1989 Continuing Survey of Food Intakes by Individuals and1989 Diet and Health Knowledge Survey." Accession Number: PB93-500411.
- "1990 Continuing Survey of Food Intakes by Individuals and 1990 Diet and Health Knowledge Survey." Accession Number: PB93-504843.
- "1991 Continuing Survey of Food Intakes by Individuals and 1991 Diet and Health Knowledge Survey." Accession Number: PB94-500063.

REPORTS: Survey reports are in preparation. For information on availability, please write to [illegible] of Agriculture, Agricultural Research Service, Survey Systems/Food Consumption Laboratory, 4700 River Road, Riverdale, MD 20737. Phone: 301-734-8457.

September 1994

ATTACHMENT C

United States Department of Agriculture
Agricultural Research Service
Beltsville Area Beltsville Human Nutrition Research Center
Beltsville, Maryland 20705

ESTIMATION OF USUAL INTAKE DISTRIBUTIONS

ARS is sponsoring cooperative research with statisticians at Iowa State University to develop statistically defensible methods for estimating the distributions of usual food and nutrient intakes for populations and subpopulations. These distributions are required to determine the proportions of the population who are at risk for inadequate intake of essential nutrients or for excessive intake of undesirable dietary constituents, such as pesticide residues. This information is needed by regulatory and policy decision makers in both the nutrition and food safety arenas.

Our approach is based on the assumption that individuals can more accurately recall the types and amounts of foods they ate yesterday than they can recall intake over any longer period of time. When at least two days of dietary information are available for individuals in the sample, it is possible to develop a statistical method for estimation of long-term average intake by removing the within-person variation in intake, rather than by having the individuals come up with an estimate for their long-term intake.

Many statistical procedures are based the assumptions that the data under investigation are normally and identically distributed and come from a simple random sample. Dietary survey data typically do not meet these assumptions, and the method developed at Iowa State does not require them. Also, nuisance effects caused by seasonality, day of week effects, and sequence of survey day can be removed from the data with this method.

Software implementing the Iowa State method for estimating nutrient intake distributions is in the beta-testing stage. Beta-testers include researchers at other Federal agencies and universities.

Methods for estimating distributions of usual food intakes are under development. This problem is more difficult because of the high fraction of zero intakes in 1-day data. Research plans also include the development of software for implementing the usual food intake distribution methods.

April 1995

Nondietary and Dermal Exposure Factors Work Group

Work Group Chair:	John Kissel, University of Washington
Work Group Members:	Dennis Druck, U.S. Army Larry Gephart, Exxon Biomedical Sciences Peter Robinson, Procter & Gamble Company Brad Shurdut, DowElanco

INTRODUCTION

The Nondietary and Dermal Exposure Factors Work Group was given primary responsibility for reviewing draft Handbook sections 2.2 (Water Ingestion) and 2.8 (Soil Ingestion) and chapter 4 (Dermal Exposure), and the work group shared responsibility for chapter 8 (Analysis of Uncertainties).

WATER INGESTION (Handbook Section 2.2)

The revised Handbook cites eight studies of tap water ingestion. Good agreement among the studies is apparent and the prior recommended mean of 1.4 liters tap water/day is a reasonable interpretation of those studies. This finding is tempered somewhat by the fact that four of these studies (Pennington, 1983; U.S. EPA, 1984; Ershow and Cantor, 1987; Roseberry and Burmaster, 1992) are analyses of the same data, the 1977-78 U.S. Department of Agriculture (USDA) Food Consumption Survey (a fact that should be made more explicit in the commentary). Nevertheless, similar results are produced by the other studies. In addition, the number of individuals in these data sets is large compared to data sets available for many other exposure factors. The data are sufficient to produce a probability density function (PDF) for tap water ingestion; the work group recommends graphical presentation of such a result. Before a PDF is adopted or prepared, however, more recent U.S. Food and Drug Administration (FDA) figures should be examined to confirm similarities to the 1977-78 data.

Available data regarding regional variability suggest that differences are not important. Similarly, differences associated with pregnancy are small.

Some questions do remain regarding peak consumption rates associated with especially strenuous activity. These rates can be very high, although how long they are sustained is not clear.

Loss of volatiles before consumption due to heating is possible. For this reason, distinguishing between tap water that is heated before consumption and total tap water is desirable.

Incidental ingestion while swimming remains essentially unquantified.

SOIL INGESTION (Handbook Section 2.8)

General

The literature review provided in the Handbook stops at 1991. Because this topic is the subject of much ongoing speculation in the literature, references through 1995 must be included and reviewed (see premeeting comments of J. Kissel for list). Unfortunately, the recent literature on soil presents increasingly complex analyses that have the effect of adding to rather than reducing doubts about the adequacy of the available data.

Studies that represent hypotheses only and not actual data may be cited for completeness, but should not be represented in a way that suggests that they have the same weight as empirical studies.

Children

Recent improvements in the apparent consistency in results obtained with different tracers reflect a change in the assumed ingestion-to-excretion lag period from 12 to 23 hours. The validity using a constant lag period of any length has not been adequately demonstrated. Moreover, the fundamental assumption that these tracers are not bioavailable has not been justified.

The central tendency (mean) of the ingestion rate of children based on six tracers (Calabrese et al., 1995) is (to one significant figure) 100 mg/day. This value can be conditionally accepted as a point estimate but requires further validation.

Recently Calabrese and Stanek fit their (child) data to a log normal distribution and produced estimates of annual average soil ingestion rates that appear notably high relative to data from all but one subject. The extrapolation of short-term (4-day) studies to generate a distribution of annual ingestion rates is questionable. The work group is unwilling to accept the resulting distribution at face value.

In qualitative terms, the actual distribution of soil ingestion in children is likely to be quite skewed, with many persons at the low end and a few at the high end. Members of the work group, however, have little confidence in current quantitative knowledge about the shape of the distribution

The summary table on p. 2-410 of the Handbook should clearly distinguish the Davis et al. and Calabrese et al. studies from the other (nonbalance) studies. (It also should be given a table number and proofread.) Both old and new interpretations by Calabrese should be included. Additionally, explicit calculation of averages should be removed since methodologies were not equivalent.

Given that this is a particularly important pathway that often drives risk assessments, the current understanding of the available data is especially unsatisfactory. Multiple steps should be taken to alleviate this problem. These include:

- conduct independent reevaluation of the Davis et al. and Calabrese et al. data sets with respect to the signal vs. noise question;
- fund longer term studies that will provide a better evaluation of the fluctuation of excretion of relevant tracer compounds;

- identify data sets in which both body burdens and environmental (soil and dust) levels of tracers are known for purposes of dose reconstruction; and
- investigate the status of research by Calabrese, Bornschein, and others at Helena, Montana, that addresses soil ingestion.

Ultimately estimates of soil ingestion should correspond to observed exposures. A recent attempt at dose reconstruction based on arsenic exposure produced a median soil ingestion rate of 85 mg/day (Lee and Kissel, in press, Env. Geochem. Health). This value reflects assumptions that dermal absorption and inhalation exposures were negligible. Such a result requires corroboration by additional reconstructions.

Pica (Geophagia)

Current data are grossly inadequate. This is true for both the prevalence in the population of geophagia (which is of greater interest than the more generic pica) and for estimates of the related soil ingestion rate. Currently n=1 for this condition. Lasztity et al. (J. Anal. Atom. Spectrom. 4:737-742, 1989) should be checked as a possible second case (the work group has not reviewed this reference).

Adults

The current adult soil ingestion estimate is based on quite limited data (n = 6) from which it is not possible to justify generation of a PDF. The central tendency of the four tracers (i.e., aluminum, silicon, yttrium, and zirconium) designated as most reliable in Calabrese et al. (1990) is 28 mg/day (median of medians) to 39 mg/day (mean of means). Calabrese has disavowed his former recommended tracers for children, but apparently has not revisited the adult tracers. Thus, the work group was uncertain about how to interpret the adult data. A value of 50 mg/day for adult ingestion is conditionally acceptable as a point estimate, but requires validation.

DERMAL EXPOSURE (Handbook Chapter 4)

The emphasis in this chapter is on dermal contact with contaminated soil or water. Acknowledgment should be made that dermal exposure also can occur as a result of contact with surfaces such as floors, countertops, or carpets in the absence of soil or water phases.

Additional data are required concerning skin area actually exposed versus surface area of the body. Estimation techniques should be expanded to describe subareas of body surface associated with consumer product use. This discussion should be tied to chapter 6 (Consumer Products). Because this also has a behavioral component, a cross-reference in section 5.3 should be included (Activity Patterns).

Soil

Explicit mathematical formulations for dermal dose should be removed; however, relevant factors should be enumerated. Potential problems also should be cited with the use of a percent absorption fraction if loadings in the exposure scenario do not match loadings in the studies from which absorption efficiency is taken.

Soil adherence literature should be reorganized to reflect the type of study (staged vs. unstaged activity, direct vs. indirect measure of soil loading). Also, studies by Charney et al. (1980), Duggan et al. (1985), Gallacher et al. (1984), and Sheppard and Evenden (1992) should be included.

Description of the Kissel et al. data should be expanded to assist users in interpretation.

Since relevant activity patterns currently are not well understood, a PDF cannot be justified. A review of the Finley et al. paper, which presents a PDF, should be included. Also, the error in evaluation of the Que Hee et al. data should be noted. Moreover, equal weighting of dissimilar studies to produce the proposed PDF should be questioned.

Because adherence is a function of activity, the key question is how to apply data in the absence of adequate activity pattern data. The work group recommends use of multiple ranges with descriptions of representative activities. Other body-surface loadings can be estimated as fractions of hand loading by range or activity (and are likely to be lower than hand loading in most cases). The outcome for hand data would look something like the data in Table 1.

Table 1. Hypothetical Hand Data

Activity Range	Nominal Hand Loading (mg/cm^2)	Representative Activity
Background	0.01	Post-bathing, preactivity
Low contact	0.1	Soccer
Moderate contact	1	Rugby, farming
High contact	10	Children playing in mud

UNCERTAINTY ANALYSIS (Handbook Chapter 8)

The work group developed the following general recommendations:

- increase uniformity of summary statistics in various sections of the Handbook;
- provide more graphical representations of data;
- distinguish more explicitly among empirical and non-empirical data sources, key studies, and other studies;
- deemphasize "default" values wherever reasonable substitutes exist; and
- expand chapter 8 to be of practical use (this may warrant publication as a separate document).

OTHER

The work group also suggests adding a glossary to the Handbook.

Human Activity Patterns Work Group

Working Group Chair: Steve Colome, Integrated Environmental Services

Working Group Members: Ed Avol, University of Southern California
Neil Klepeis, Information Systems and Services
John Robinson, University of Maryland

INTRODUCTION

The Human Activity Patterns Work Group was asked to review sections of chapters 3,5,6, and 8 that involve issues of time use, microenvironmental occupancy, and activity patterns.

Exposure and risk assessment models require information and data on human activity patterns. A substantial amount of information is included in the current draft of the Handbook, but in the opinion of the work group that data will be lacking or limited for many exposure scenarios encountered by an exposure or risk assessor.

The Handbook covers a new and developing field and often relies on one or two studies to support an information need. New information is being produced rapidly in this field and some of that information will be more directed and of higher quality than the earlier studies cited in the Handbook. The panel recommends that the Handbook be considered one edition of a changing volume and that revisions be considered at intervals of 2 to 5 years.

A number of general recommendations were common to all of the chapters reviewed by this panel:

- It is important to recognize that the number of potential exposure scenarios is too large to present every possible combination of time, location, and activity for all major demographic groups. The current draft includes a large number of these scenarios, but for any particular risk assessment the scenario needed may not exist in the tables presented. The draft should acknowledge this limitation.

The panel recommends that key combinations of location (residence, work/school, outdoor) and activity (sleep, exercise, low activity) be presented graphically for purposes of illustration. Also, raw time activity data from the human activity pattern (HAP) studies should be included in the Handbook so that exposure and risk analysts can address time activity patterns directly for the scenarios particular to their assessments.

- The work group found it difficult to find information fitting many individual assessment scenarios. This difficulty might be unavoidable because the Handbook is an evolving document related to an emerging field of investigation.

  To increase the utility of the Handbook, the panel recommends starting each chapter with an index that indicates exactly what information can be found in the chapter and points out the role of that information in exposure assessment.

- Literature cited in some of the sections did not take full advantage of related fields and was too narrowly focused. For example, a rich literature is available on inhalation rates from the fields of sports medicine, occupational health, and pulmonary physiology. These fields were not explored in the chapter involving inhalation rates, and reference to such information would help develop a better understanding of the variability and uncertainty of this factor, which has an important influence on the dose of inhaled contaminants.

  The panel recommends that a full literature search of related fields be conducted for the topics of inhalation rate, consumer product use, exposure assessments using activity patterns, population mobility, lifetime, and body weight.

- All of the chapters lack a general introduction that identifies the role of the information provided in conducting exposure or risk assessments. Effectively positioning the information in each chapter would enhance the utility of the data and help to focus the authors of the Handbook in selecting the most useful tables and information.

  The panel recommends that each chapter open with a general introduction giving the reader a context for the information provided in the chapter and guidance on how data in the chapter is used in exposure and risk assessment.

- The Handbook would benefit from an introductory section to the document that presents a conceptual framework for the risk model showing the role of exposure assessment. The introduction should contain a flow chart of the interconnection of exposure components, with cross-references to sections of the Handbook where the particular information is addressed. Additionally, definitions could be established in the introduction. In particular, exposure should be distinguished from dose.

The panel recommends that an introductory chapter be written that establishes a conceptual framework for the Handbook. See figure 1 for the type of general diagram that would be helpful to orient the reader of the Handbook. The boxes in the figure could be used to identify specific chapters and sections of the Handbook that deal with the topics.

- Many of the data tables in the Handbook are based on social surveys and thus they are subject to several of the sources of limitation that affect all surveys. A major problem with the Handbook, however, is that it tends to treat all surveys as equal, when in fact they vary widely in sophistication and utility in terms of sample design, field quality control, question framing, and presentation of results.

  Because the description of survey methods for each of the surveys presented is inadequate and unsophisticated, the panel recommends incorporating a full description of survey methods into chapter 1 of the Handbook (see Attachment A).

INHALATION ROUTE (Handbook Chapter 3)

Introduction

This chapter presents a number of recent studies reporting on ventilation rates of children and adults over a range of age distributions and exertion levels. One additional study reported on the measured ventilation rates of California outdoor construction workers. Ten studies were discussed, ranging in study population size and description from nine nonsedentary adult volunteers aged 21 to 37 years on which direct measurements of ventilation were made, to several thousand households completing the USDA 1977-78 Nationwide Food Consumption Survey, for which ventilation rates were calculated based on metabolic relationships (i.e., oxygen consumption and associated energy expenditure for activities of varying duration).

General Recommendations

The discussion and recommendations drawn from this chapter are based on a limited cited data base of recently published work. A body of untapped work exists in the occupational and physical therapy, sports medicine, and exercise physiology literature that could provide improved estimates of ventilation rates for a range of exertion levels and life activities. The identification and

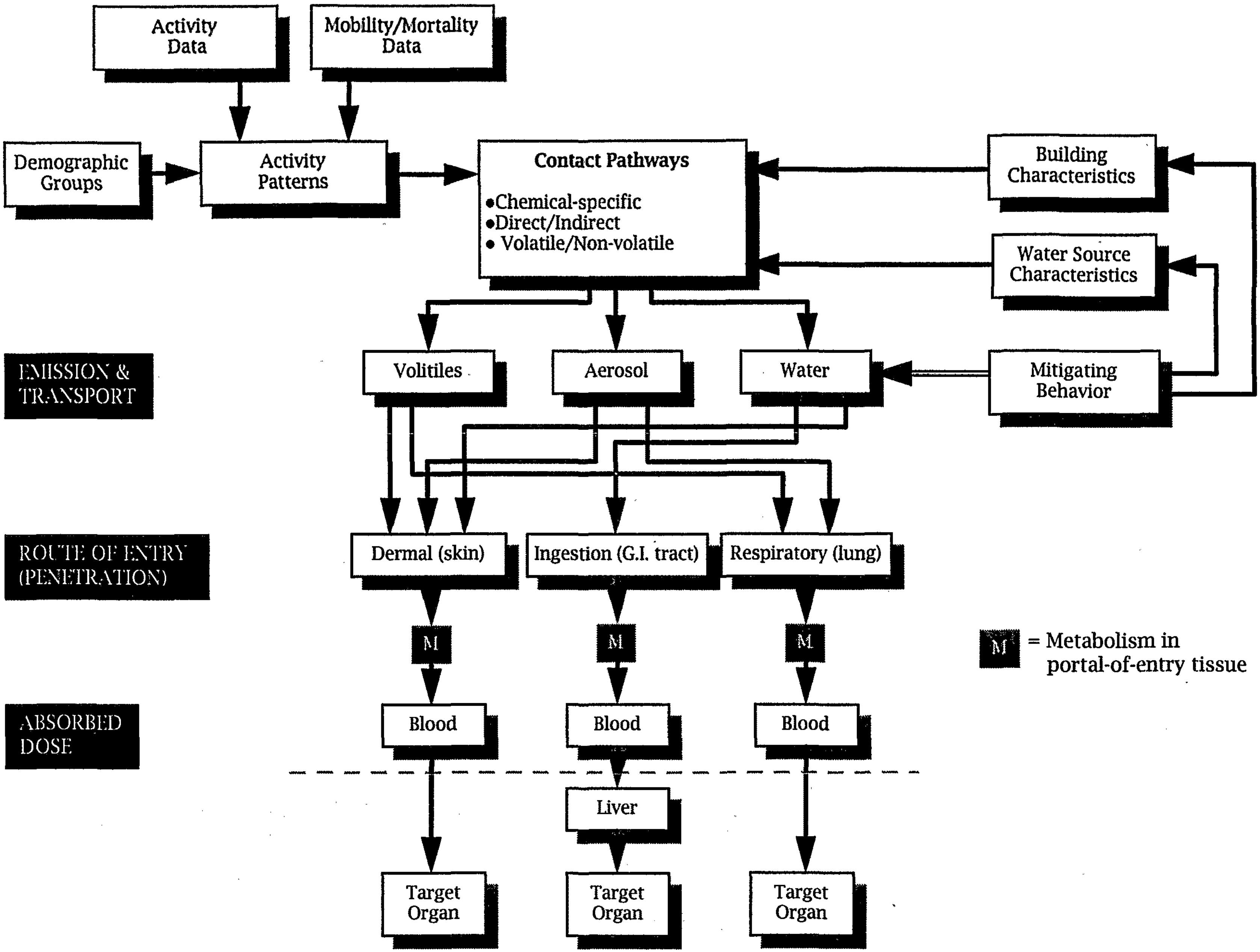

Figure 1. Exposure Assessment for Contaminants in Drinking Water.

review of additional published work in this area also would address panel concerns about day-to-day and subject-to-subject variability associated with the reported values and potentially expand and enhance the demographic nature of the cited data base.

A second stated concern of the review panel was the representativeness of the cited sample. The relatively small number of subjects participating in several of the reported studies (9 to 30 subjects) raised issues about applying these factors to larger populations of interest. The interesting (but limited) report on nine California outdoor construction workers left the panel wondering how applicable the activities and metabolic costs associated with outdoor construction in California are to construction workers in other parts of the country in other weather regimes.

Accordingly, the panel's primary recommendation is to undertake a search of literature on exercise physiology, occupational and physical therapy, and sports medicine to identify and include additional published and peer-reviewed information about ventilation rates over a range of life activities.

Several studies of varying size, scope, and focus were presented in the chapter; some of the cited work is research being performed for the purpose of acute respiratory assessment, while other studies are analyses of data initially collected for other purposes. The authors of the chapter made some attempts to identify perceived limitations or advantages associated with the studies being reviewed, but the evaluations made were inconsistent and occasionally superficial. The utility of the Handbook will depend on a critical assessment of the data that are included and, in that sense, endorsed as valid for subsequent use. Accordingly, the panel's second recommendation is to provide a uniform, objective, and critical review of the studies presented in the Handbook, with some judgment as to their value and applicability from the perspective of exposure assessment.

Specific Recommendations

The chapter on inhalation included a significant amount of information that will be of use to Handbook users. The following specific recommendations, however, should be considered:

- table 3-22 in the Handbook is a valuable source of information and should be moved to the front of the chapter to serve as a coherent summary and a guide to the information presented;
- the limitations and advantages presented in table 3-22 should be revised to provide a standardized summary of information with a critical judgment of the relative value of the data provided;
- the former reference inhalation rate of 20 m^3/day is too high; theoretical considerations and field data support a reduction—but not to the precision of 13.3 m^3/day; the data would seem to support values rounded at least to the nearest whole number (a range would be even better here); and
- the chapter should be corrected to differentiate between dose, which involves the delivery of a chemical species beyond a portal of entry to a target organ, and exposure, which involves the presence of a chemical species at a portal of entry.

OTHER FACTORS FOR EXPOSURE CALCULATION (Handbook Chapter 5)

Introduction

Chapter 5 of the Handbook (Other Factors for Exposure Calculation), is composed mostly of summaries of HAP studies (56 pages plus 32 pages in the appendix), with smaller sections on body weight (about 12 pages) and population mobility (15 pages plus 4 pages in the appendix) and only one paragraph on lifetimes. The introduction to the chapter is only a few sentences long and lacks elaboration on how the data presented in this chapter are to be used in exposure assessments. In particular, the data are not given a conceptual context. Several of the HAP studies (Robinson, 1965-75; Juster et al., 1975-81; Timmer et al., 1985) are outdated and not explicitly exposure relevant. Most of the HAP data are presented in terms of mean time spent instead of frequency distributions. In addition, little information on the percentage of time spent or the percentage of respondents in each location or activity category is provided. Also, no clear distinction is made between calculations involving doers (i.e., those actually experiencing a location or activity) and overall calculations (i.e., doers plus nondoers).

General Recommendations

The panel offers the following general recommendations:

- The number of possible human activity pattern analyses is very large (locations x activities x background activities x socioeconomic subgroups x geographic subgroups); thus, the Handbook should stress that users will not always be able to find the analyses they desire, even though chapter 5 and its appendix appear to be comprehensive (i.e., thick).

- Provide a general framework or context for the use of human activity patterns in human exposure assessment with citations from the literature.

- Since HAP studies are part of a relatively new field and they can be used in a variety of ways, examples should be given from the literature of past human exposure assessments that have used HAP studies.

- Most of the data in the Handbook are presented as means of time spent instead of frequency distributions and thus are not useful in probabilistic exposure assessments. Although many of the studies do not report frequency distributions, the kinds of frequency distributions that can be obtained from the raw data (e.g., locations, activities, demographic breakdowns) should be summarized.

- More clarification of the kinds of data presented from each study should be provided: Are the results for all respondents or do they represent the doers only (those who engaged in the microenvironments described)?

Specific Recommendations

The panel offers the following specific recommendations:

- Make it clear that the HAP studies presented represent (1) what location, activity, and demographic breakdowns were available, and (2) the authors' choice of which breakdowns are appropriate to analyze.

- Clarify the kinds of data that are available from each HAP data base and their utility in regard to human exposure assessment:

  - 24-hour minute-by-minute diaries (for accurate determinations of time spent in locations and activities); or

  - followup questions (for occurrences of specific kinds of exposure that respondents may overlook in their 24-hour diaries, e.g., going to a gas station on the way to work).

- Distinguish between the material presented by the authors in each study and the information available in the HAP raw data.

- Include a "usage table" that describes the kinds of data available in each study, the specific exposure-related categories the study uses in its analyses, the other kinds of analyses that may be possible with the raw data used in the study, and the study's usefulness in connection with exposure assessments.

- Since HAP studies represent a vast data resource that cannot possibly be adequately represented in the Handbook, consider making a version of the Handbook available on CD-ROM or over the Internet that contains the raw data from various studies.

- If the raw data are made available, then the Handbook needs to have a section summarizing its variables, breakdowns, and codes.

- Add the new 1992-1994 National Human Activity Pattern Survey (NHAPS) data to the Handbook (see examples in Attachment B).

- The Sexton/Ryan "study" should be moved into the introduction to the chapter.

- Old and outdated studies—both test and table—should be deleted from the Handbook (Robinson, Juster, and Tinner, pp. 5-14 to 5-30 and 5A15 to 5A21 in the appendix; Tarshis, pp. 5-60 to 5-62; Sell, pp. 5-64 to 5-66; and James and Knuiman, pp. 5-62), although they can be retained as references for those who may be interested in them.

- See the suggestion in John Robinson's premeeting comments to omit material.

- Mention ways to improve future HAP data collection efforts:

  - more specific exposure-related activities should be included (e.g., different categories of food preparation [baking and frying vs. sandwiches/salads] and cleaning [vacuuming, dusting, waxing the floor vs. general tidying]); and

  - more specific exposure variables should be included (e.g., smoker present, heat on, gas oven in use).

- Where appropriate, footnotes should be included at the bottom of each table explaining whether the calculations are for doers or both doers and nondoers.

- Some discussion should be provided on the concept of a microenvironment (a specific combination of a location and an exposure-related activity) with appropriate citations.

CONSUMER PRODUCTS (Handbook Chapter 6)

Introduction

This chapter attempts to present data on the specific usage of consumer products as it relates to potential exposure. The data come from one survey of particular consumer products conducted in 1987 by Westat. The only data presented appear to be in terms of minutes of exposure for those exposed for this restricted range of consumer products.

General Recommendations

The panel offers the following general recommendations:

- The title and range of potential exposures covered in this chapter need to be greatly expanded. The Westat data refer only to solvents and neglect the many other sources from consumer products, including "secondhand" exposure after the product has been used. This would include exposure to secondhand tobacco smoke, exhaust from gasoline engines, and usage of dishwashers by other household members. In addition, the list of potential pollutants include tap water, benzene, pesticides, and paints among many others.

- For many of these potential sources, more recent and generalizable data from the 1992-1994 MAPS (or NHAPS) data collection for EPA are readily available. The base data are provided by Robinson and Blair (1995) and several sample pages from this document are attached as examples of statistical information that could be directly reported in the Handbook. A list of all MAPS sources covered by their questions is shown in Attachment C (exhibits 1 and 2 and figures 2 and 3, and percent exposed data are given in tables 3-6 and 10; frequency distribution data for some of these questions are shown in table 7). An example of differences in percentages of the population exposed is shown in table 13, and parallel data are published in the report for the other pollution sources in tables 3-7. More detailed breakouts of data for environmental tobacco smoke exposure are shown in table 2, along with an analysis of differences by time of day in figure 1.

- In line with the wide variety of products covered and the primary/secondary usage split, the chapter needs to be retitled to "Exposure to Specific Potential Pollution Sources."

Specific Recommendations

The panel offers the following specific recommendations:

- The list of potential pollutants extends far beyond those covered in MAPS, or in the Westat solvent study. Nor did MAPS cover specific brand names or products involved. These are potentially covered in market research data collected by Simmons, which are available through Pandian at the University of Nevada at Las Vegas. These data sources need to be cited at least; presumably, however, there is an EPA list of complete pollution sources that could be cited.

- The Westat data that are cited are too narrow. They should include at least percentages of the population who report using the product and their estimates for number of uses per year. The need for single-day validity data should be noted, given that estimate data typically involve overreports. The other measurement procedures/limitations of the study should be reported, particularly the response rate for the crucial mail-back portion of the study (not just the initial 73 percent telephone response rate) and information on the fairly cumbersome questionnaire respondents were asked to fill out.

ANALYSIS OF UNCERTAINTIES (Handbook Chapter 8)

Although this is a well-written and general summary, it provides little direct guidance to the risk assessor. The intent may be to force careful thinking with each assessment undertaken. If the other sections had been written with the same clarity, the rest of the document would have been easier to read.

ATTACHMENT A

GENERAL COMMENTS ABOUT SURVEY METHODS

Because many of the data tables in the Handbook are based on social surveys, they are subject to several sources of limitation that affect all such surveys. Thus, a major problem with the Handbook is that it tends to treat all surveys as equal, when in fact they vary widely in sophistication and utility in terms of sample design, field quality control, question framing, and presentation of results.

In general, a well-conducted survey of the public is expected to meet the following criteria:

1. A probabilistic sampling frame, in which *all* individuals have an equal (or at least known) chance of selection;

2. Sample sizes selected at random from the population that allow generalization to that larger population. (While statisticians argue about that sample size, it is the case that a random sample of 100 individuals has a sampling error of +/- 10 percent, which can be tolerable for some estimation purposes—if criteria #1 and #3 are met. Sample sizes below 20 or 30 individuals have 2 to 3 times that level of imprecision and are usually considered to be quite unreliable, particularly if the sample respondents are not chosen at random—as is usually the case.)

3. A high rate of response from those individuals chosen at random for the survey. (This is usually not a problem for surveys conducted by the U.S. Census Bureau with response rates above 90 percent, but it can be a serious problem for typical survey organizations that tolerate response rates of 60 percent or less. Few "consumer panel" surveys achieve response rates close to that level, if strict response rates are calculated. Unfortunately, the possibility of biased samples of respondents are high in such circumstances.)

4. Careful attention to the ways information and questions are framed to respondents. (Different ways of framing questions have been found to produce differences of 20 to 60 percentage points in estimates, compared to the 3 to 5 point error ranges associated with sampling error.)

Unfortunately, much less is known about these latter contributors to "nonsampling error" and so field procedures to overcome them are much less subject to control.

Some ways of asking behavioral questions are more generally accepted by survey practitioners than others, however. In general, the easier the reporting task expected of the respondent, the better. Thus, asking respondents to maintain accounts of what they are doing at the moment is easier and more reliable/understandable than asking what they do "regularly" or "typically." This approach also is preferable to long-term recall (e.g., "over the last six months"). Asking respondents to recall what they did yesterday, however, has not been found to generate serious recall difficulties (as is implied in several passages in the Handbook). A problem with "yesterday" behavior is that it provides only a limited view of the behavior of individual respondents; however, it can produce quite reliable data on what the population does on a particular day.

A major problem does arise, however, when these one-day data are used to model the long-term consequences of exposure for individuals. An individual can be exposed to an average carbon monoxide level per day at certain levels, but if the individual receives all of that dosage in a few minutes of a single day, it can be lethal. These long-term consequences at the individual level need to be considered. Thus, in general, the reader needs to take into account myriad factors before treating these data as factual or as scientific and free of mundane or naturally occurring sources or error. This should be done at the outset and in the context of each chapter, much as in the spirit of the current text, but more targeted on the most important sources of error.

Along the same lines, possibly each chapter could end with a call for needed measurement advances to produce the kind of statistical data that would be most appropriate for policy purposes.

A further problem arises from the lack of essential data for understanding the implications of the data that are presented. Thus, for drinking water or point application, what proportion of the population are involved in the activity for a day or a year? The percentile data appear virtually uninterpretible without such basic statistics, which should be readily available in the original source (if not, the original authors should be chided for omitting it). Many of these parameters are now available from our 1992-1994 MAPS study that should soon be published.

ATTACHMENT B

EXAMPLES OF ANALYSES DONE WITH THE NEW NHAPS 1992-1994 DATA

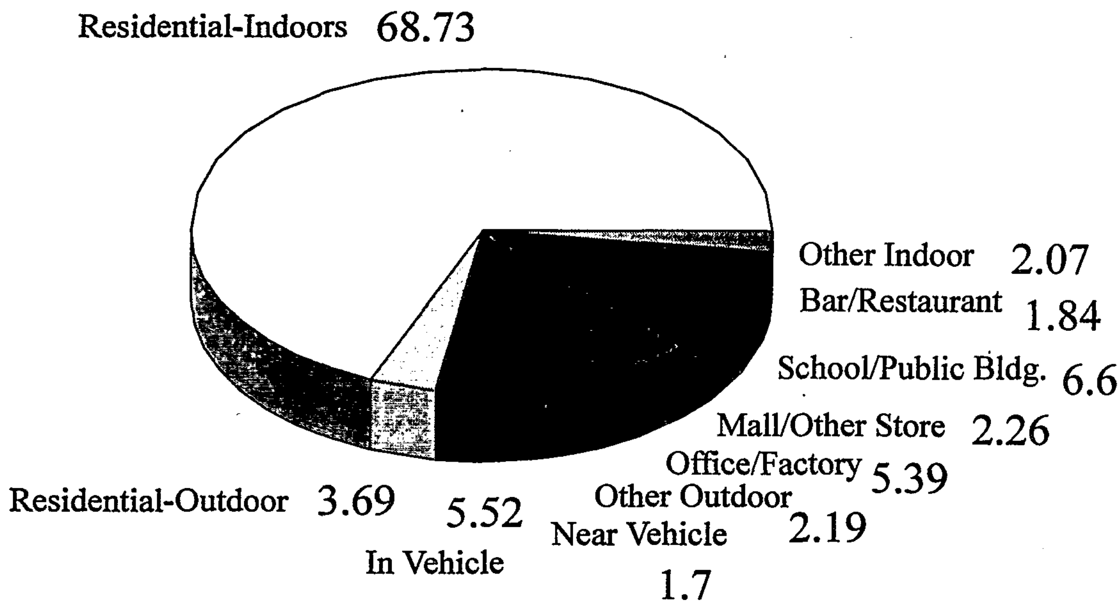

Figure 1. The overall weighted percentage of time spent by the respondents in each location. The total amount of time is 1,440 min x 9,196 respondents = 13,242,240 minutes.

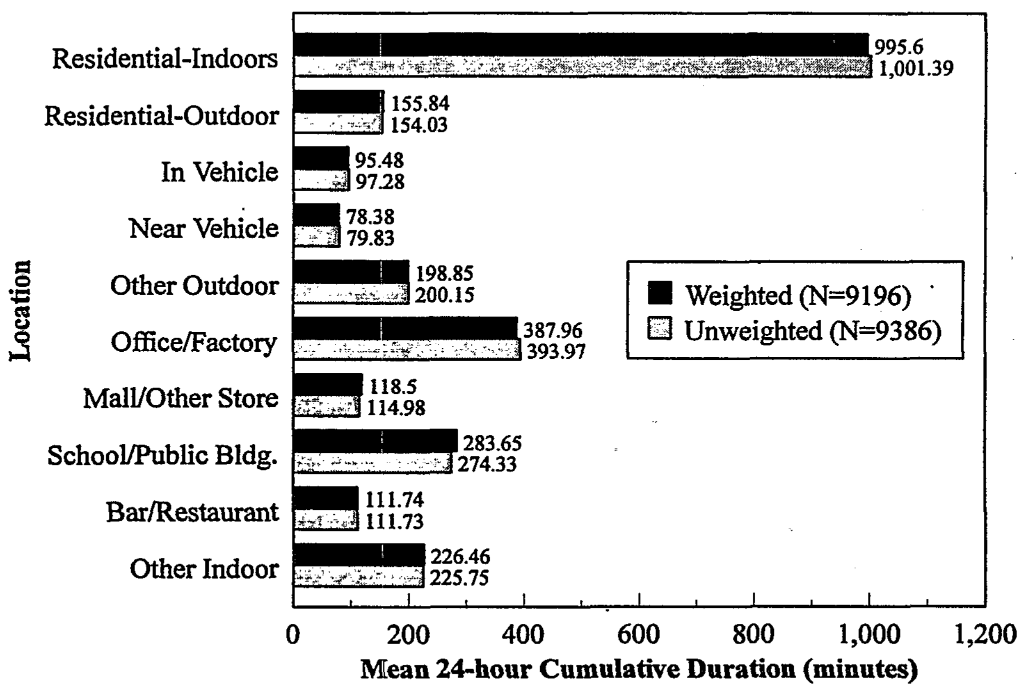

Figure 2. The overall weighted and unweighted mean 24-hour cumulative durations in each location (for doers only). In the weighted analyses, 190 respondents with missing age or gender values were excluded.

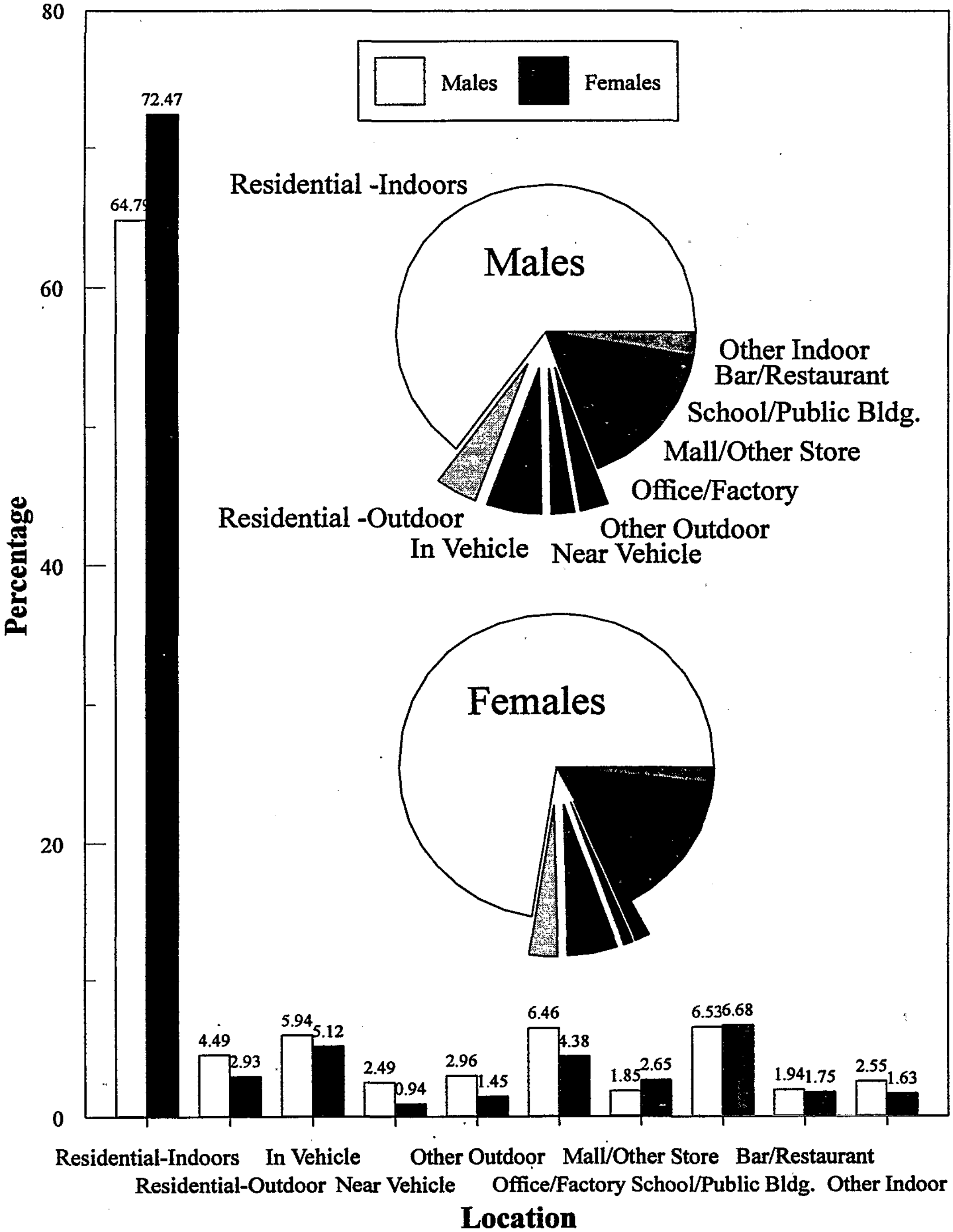

Figure 3. The weighted percentage of time spent in each location for males vs. females (doers plus non-doers).

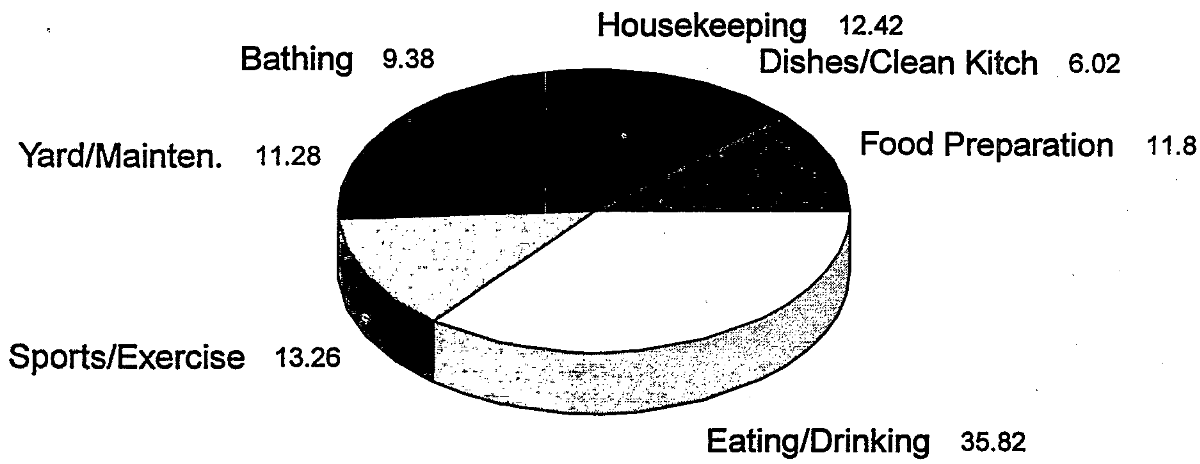

Figure 4. The overall weighted percentage of time spent by the respondents in each exposure activity -- excluding time spent in the No Exposure category. The total amount of time is 1,737,104 minutes = 1,440 min x 9,196 respondents (13,242,240 min) minus 11,505,136 min (the 86.88% spent in the No Exposure category, REGACT = 0).

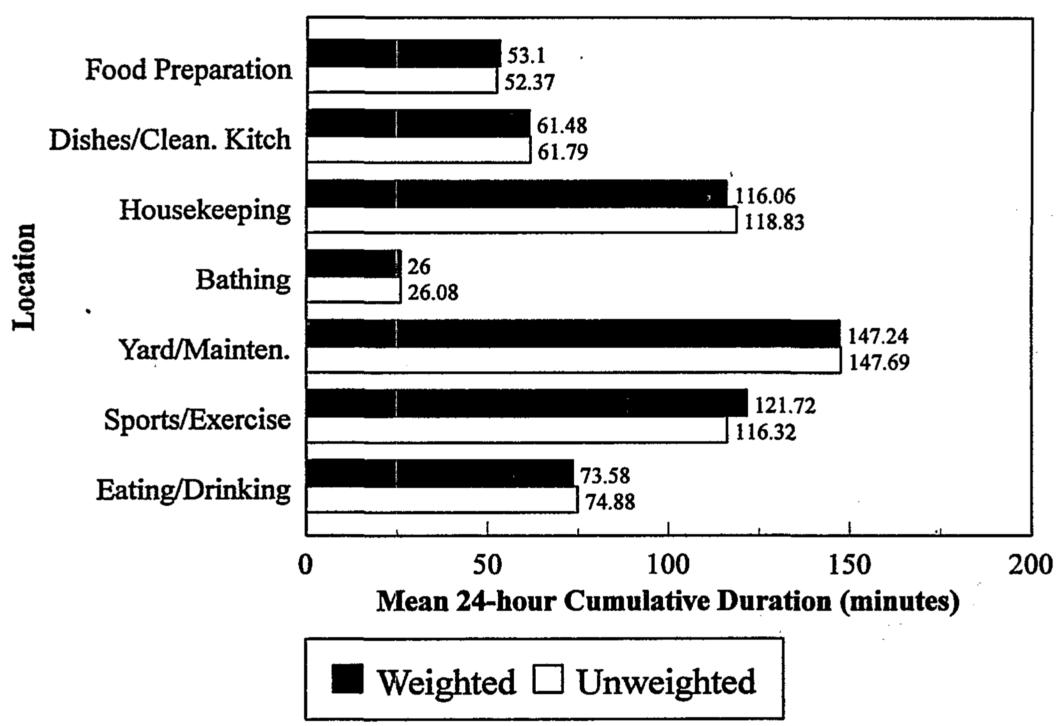

Figure 5. The overall weighted (N=9196) and unweighted (N=9386) mean 24-hour cumulative durations in each exposure activity. In the weighted analyses, 190 repondents with missing age or gender values were excluded. See Section 4 for a discussion of the weighting methodology.

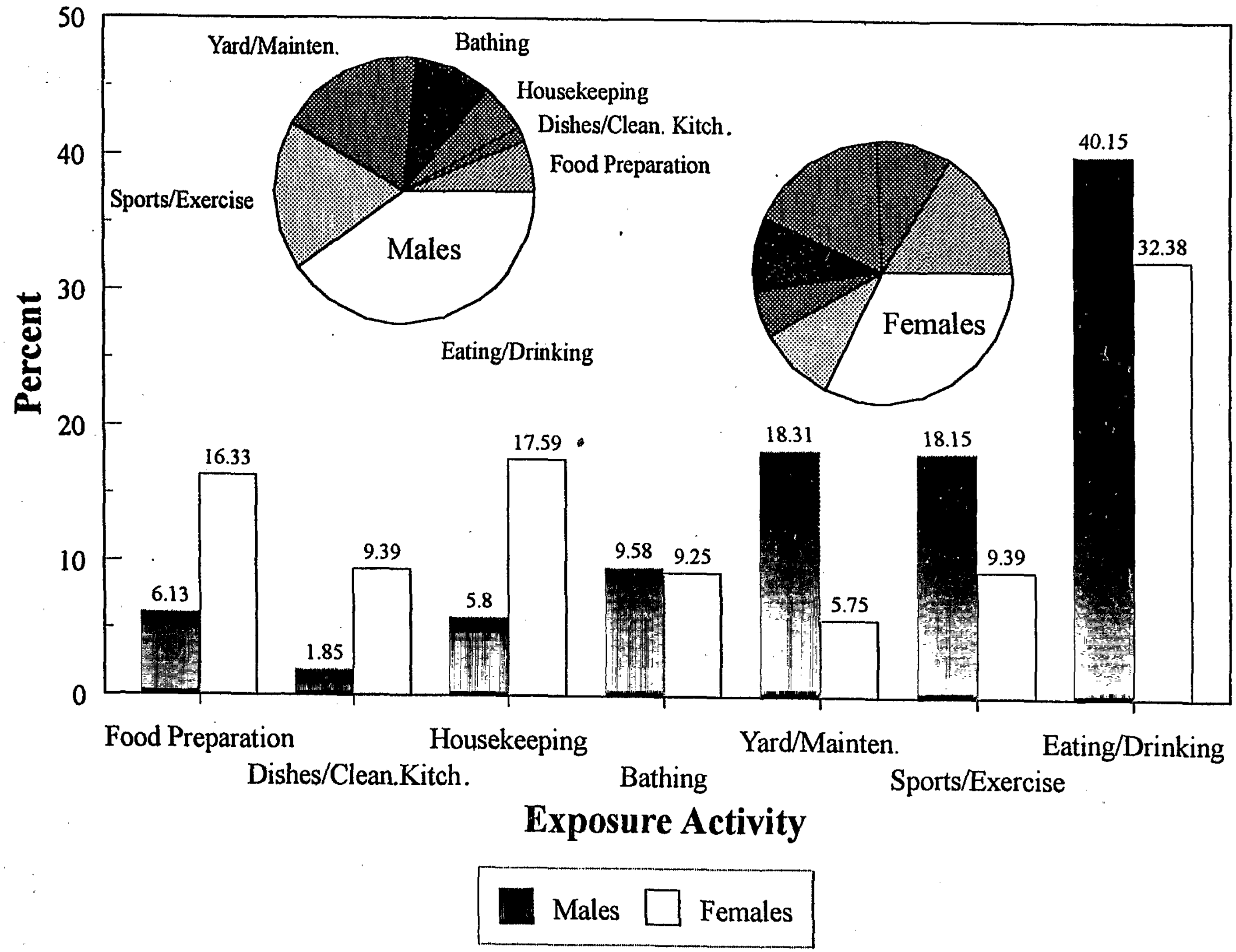

Figure 6. The weighted percentage of time spent in each exposure activity for males vs. females.

ATTACHMENT C

LIST OF ALL MAPS SOURCES

Exhibit 1: Chemicals/Pollutants Associated with Survey Questions (Form A)

	CO	NO_2	O_3	CHEMICAL VOCs	Benzene	PAHs	RFPs	SO_2	Lead	Pesticides	Chloroform	Other
1. a) Gasoline Storage				x	x							
b) Lawn Mowers				x	x							
c) Paint/Varnishes				x	x							
2. a) Mothballs												P-DCB 0 Naphtha
b) Stick-ups												P-DCB Limolene
c) Deodorizers												
d) Humidifiers							x					
3. a) Paints				x	x							
b) Fried food					x	x						
c) Open flames	x	x			x	x						
d) Glues				x								
e) Solvents				x	x							
f) Pesticides					x					x		
g) Floor wax				x	x							
h) Gas equipment				x	x	x						
i) Cleaning agent				x								
j) Dust							x					
k) Spot remover				x								
l) Nail polish				x								
m) Perfumes				x								
4. Smoking				x	x	x				x		Cadmium
5. Diary smoking				x	x	x						Cadmium
6. Gas station				x	x							
7. Gas range/pilot	x	x		x								
8. Shower/bath											x	
9. Dishwasher											x	
10.Washing machine											x	
11.Aerosol spray	x	x		x	x	x			x			
12.Heating				x	x							
13.Traffic/parking	x			x	x	x						
P11. Child floor											x	P6/Br Dust
P12. Child outside										x		

Exhibit 2: Chemicals/Pollutants Associated with Survey Questions (Form B)

	VOC	Benzene	Particles	Pesticides	Metals	Chloroform	PAHs	Other
1.a) Gasoline storage	x	x						
b) Lawn mowers	x	x						
c) Paint/varnishes	x	x						
2. Solvents, etc.	x	x						
3. Renovation	x	x	x					
4. Pesticide treatment				x				x
5. Floors swept	x					x		
6. Welcome mats	x	x	x					
7. Smoking	x	x	x	x		x		
11. Fish, eating					x			PC-B5
A1-5) Drinking/ Washing	x					x		Other trihalomethanes
A6) Humidifier								Biological aerosols (metals) bacteria, etc.
A7-11) Bathing, other							x	Thms

FIGURE 2

Implicit Model for EPA (MAPS Survey -- Form A)

Background Factor → **Outcome Variables**

Biological
40. Age
46-7. Race
ob. Gender

Status
41-4. Employment
98. Education

Role
kid1. Children
51. Other Adults
41-4. Work hour
a. evenings
b. outdoors

Geographic
45. ZIP-work
57. ZIP-home
54-8. Housing
59-65. Structure
Stories, rooms, carpet, basement, garage

Life-style
49-50. Health

POTENTIAL POLLUTANT EXPOSURE FORM --

Air | **Water** | **Ingestion**

Storage
1. Gas cans
2. Lawnmower
3. Paints
4. Mothball
6. Deodorz

Yesterday
8-9. Smoking
a. home/away
10. Others smoke
11. Paints
13. Open flame
14. Glues
15. Solvents
16. Pesticides
17. Floor wax
18. Gas equipment
19. Cleaning agents
20. Excessive dust
21. Stain removers
22. Perfumes
23. Nail polish
24. Gas stop
b. Pump gas
25. Gas stove
f. Microwave
29. Aerosol spray
30. Furnace
b. Fuel
d. Wood stove
e. Kerosene
f. Electric space
g. Fireplace
34. Heavy traffic
35. Road run/walk
36. Parking garage
37. Walk to car
38. Other outside
65a. Garage started car

Water
26. Shower/bath
27. Dishwasher
28. Wash machine

Ingestion
54-6. Kid<5

+Diary Variables
SMOKING
HARD BREATHING
OUTDOORS
TRAVEL
COOKING
ETC.

7. Humidifier
13. Windows open
32a. Doors open

FIGURE 3
Implicit Model for EPA (MAPS Survey -- Form B

Background Factors

Biological
- 40. Age
- 46-7. Race
- ob. Gender

Status
- 41-4. Employment
- 48. Education
- ? Income

Role
- kid1. Children
- 51. Other Adults
- 41-4. Work hour
  - a. evenings
  - b. outdoors

Geographic
- 45. ZIP-work
- 57. ZIP-home
- 54-8. Housing
- 59-65. Structure Stories, rooms, carpet, basement, garage

Life-style
- 49-50. Health

Outcome Variables

POTENTIAL POLLUTANT EXPOSURE FORM --

Air

Storage
1. Gas
2. Lawnmower
3. Paints
4. Solvent

Yesterday
- 8-9. Smoking
  - a. home/away
  - c. Other smoke
- 55. Car starts

Last 6 Months
- 5. Renovations
  - a. Paint
  - b. Floors
  - c. Addition
  - d. Carpets
  - e. Glues
  - f. Sleep elsewhere
- 6. Pesticides
  - c. Personal
- 7. Vacuum floors
- 8. Humidifier
- 56. Gas stove
- 57-8. Heat sources

+Diary Variables
- SMOKING
- HARD BREATHING
- OUTDOORS
- TRAVEL
- COOKING
- ETC.

Water / Ingestion
- 54-6. Kid <5
- 15-7. Shower/bath
- 18. Dishwasher
- 20. Wash machine
- 19. Dish washing
- 9. Water source
- 10. Bottled water
- 11. Tap water
- 12. Juices
- 13. Soft drinks

Last month
- 18. Pool swimming
- D17. Soil
- 24. Fish
- 25. Black

TABLE 3: EXPOSURE TO DIFFERENT AIR POLLUTANTS "YESTERDAY"

	ALL AGES	
		Median
	% Exposed	Minutes/(Times) Exposed/Exposure
Open paint	6%	60 Minutes
Fried/grilled food	24	17
Open flame	10	20
Glues/adhesives	7	17
Solvents/fumes	11	20
Pesticides	6	10
Floor wax	8	10
Gas equipment	10	60
Cleaning agents	19	10
Excessive dust	16	120+
Stain remover	3	5
Colognes/fragrance	50	1-2 Times
Nail polish	5	NA
Aerosol spray	32	1.6
Mothballs	13	NA
Air fresheners	65	NA
Toilet deodorizer	46	NA

TABLE 4

GENERAL EXPOSURE TO VARIOUS HOME SOURCES OF AIR POLLUTION

	% Reporting
Gasoline	20%
Lawnmowers	29
Paints	45
Solvents	28
In last 6 months:	
Renovate home	34%
Indoor painting	27
New flooring	5
Added room	4
Carpeting (with glue)	9 (1%)
Pesticides applied	43%
Indoors	16
Professionally	18
Personally	26
Vacuum floor (3+/week)	74%
Use Welcome mat	89
Work with soils	38%
Eat seafood	57%
Ate blackened food	25%
Used microwave	54% (5 minutes)
Smoking allowed in home	32%

TABLE 5

EXPOSURE TO GASOLINE AND OTHER PRODUCTS/EXHAUST "YESTERDAY"

	% Reporting	Time
At gas station	21%	10 Minutes
Pump gas	12%	NA
Others pump gas	6	
Drive in heavy traffic	25%	17
Walk/run near road	8	15
Indoor parking garage	6	5
Walk to car	72	5
Other time outdoors	27	30
Used gas oven	23	30
Used for heat	0.6	11 hours
Heated home	40	NA
with gas	19	
with furnace	30	
Used other heating	5	NA
Electric	3	
Coal	2	
Wood stove	3	
Kerosene	1	
Electric space heater	3	
Fireplace	2	
Other heating	4	
Window open	42	
Outside door open	84	6-9 times
Smoked at all	21	NA
Smoker in house	15	NA
Smoking by self at home	17	NA
Cigar	1	
Started auto in attached garage	22	1.4 Times

TABLE 6

WATER-RELATED EXPOSURES

Took bath or shower	91%
Shower	76
Bath	15
15+ minutes (Bath or Shower)	31
Swimming	8%
Drank tap water	72%
3+ glasses	41
Drank juice mix	61
3+ glasses	28
Drank sodas	54
3+ cans	15
Use bottled water	43
Get public water	80
Get well water	16
Washed dishes	84
Dishwasher used at home	23
Washing machine used at home	43
Use humidifier	24

TABLE 7
Frequency Distributions of Times Spent in Various Exposure Situations

Duration Minutes	(Mid-Point)	Paint	Fried Foods	Open Flames	Glues	Solvents	Pesticides	Floor Wax	Gas Equipment	Cleaning Agents	Dust	Stain Removers	Gas Station
None		93.9	76.0	90.2	92.9	89.3	94.2	92.4	90.4	80.8	84.1	97.3	78.7
0-2	(0)	.5	1.4	.8	1.2	1.5	1.6	.8	1.0	3.9	.4	.6	.9
3-7	(1)	.4	2.9	1.2	190	1.9	1.0	1.4	.8	4.4	1.3	.8	9.1
8-12	(5)	.5	3.4	1.0	.9	.8	.6	1.6	.7	2.9	.6	.3	6.3
13-17	(10)	.2	3.0	1.5	.6	.6	.1	.9	.6	2.0	.7	.2	1.7
18-24	(15)	.2	2.8	.8	.5	.4	.2	.4	.3	1.4	.4	*	.4
25-34	(21)	.3	4.4	1.5	.9	.7	.4	.8	.8	1.6	1.1	.2	.8
35-44	(30)	0	.2	.1	0	*	*	.1	.2	.1	.1	*	0
45-54	(40)	.3	.7	.2	.1	.1	.1	.1	.3	.2	.1	0	.1
55-64	(50)	.5	2.1	.7	.6	1.0	.4	.4	.7	.8	1.1	.1	.3
65-84	(60)	0	.1	0	*	.1	0	0	*	0	0	0	.1
85-120	(102)	.5	.8	.5	.1	.4	.1	.2	.8	.3	1.1 .6	.1	.2
121+		2.3	1.7	1.1	.7	2.9	1.1	.6	3.2	.9	8.2	.2	.3
TOTAL (n=)		275	1102	451	323	490	264	345	440	879	729	121	979
Median/Doer		60	17	15	10	21	8	12	60	8	140	5	5
Mean/Doer		71	34	38	38	49	38	28	67	18	85	24	14

* Less than 0.5%

TABLE 10
Means and Percentages of Selected Diary Exposure Variables

	Overall Mean	% Doing	Mean per Doer	Median per Doer
LOCATIONS:				
Travel	85 min/day	87	98 min/day	70 min/day
Vehicle Travel	77	82	93	69
Outdoors	110	59	187	120
Bar/Nightclub	6	3	176	145
Restaurant	20	21	97	60
Auto Repair	4	2	222	60
Dry Cleaners	0.4	0.3*	112	10
ACTIVITIES:				
Food preparation	23	43	54	40
Repair cars	2	1	111	60
Car repair shop	1	2	33	10
Play sports	21	16	129	95
Wash, shower etc.	15	63	24	20
EXPOSURE:				
Others' smoke (ETS)	167 min/day	44	382 min/day	320 min/day

TABLE 13
Differences in Exposure to Air and Other Pollutants by Background Factors

		Open Paints	Fried Foods	Open Flame	Glues	Solvents/ Fumes	Pesticides	Floor Wax	Gas Equipment	Cleaning Agents	Dust	Stain Remover	Perfume	Nail Polish	Aerosol	Mothball	Air Freshener	Toilet Deodorizer
TOTAL	(n=4701)	6%	24%	10%	7%	11%	6%	8%	10%	19%	16%	3%	50%	5%	33%	13%	65%	46%
GENDER																		
Male	(2123)	7	23	11	7	12	6	5	15	13	17	2	45	1	26	13	64	49
Female	(2576)	5	25	9	6	9	6	10	5	25	15	3	54	9	38	13	66	44
AGE																		
0-5	(235)	3	16	5	4	3	3	0	9	10	10	1	0	0	17	5	62	42
6-11	(355)	4	24	7	11	5	6	6	4	7	16	1	8	2	23	13	65	38
12-17	(261)	7	32	9	13	15	4	6	11	16	22	3	58	8	37	13	68	49
18-24	(404)	7	27	12	9	15	10	10	11	22	20	4	62	8	45	9	73	57
25-34	(811)	7	28	15	8	16	7	9	12	23	21	4	57	6	40	10	73	50
35-44	(772)	9	28	11	7	15	6	9	12	25	18	4	52	5	35	11	61	38
45-54	(590)	7	23	13	8	11	6	9	13	21	16	2	62	6	31	13	62	61
55-64	(489)	5	21	7	4	8	4	5	10	18	12	3	54	3	32	18	65	47
65-74	(419)	4	16	5	2	3	5	6	5	21	7	2	44	2	24	26	57	47
75+	(250)	2	13	5	1	2	3	5	4	18	4	1	35	4	24	23	55	53
RACE																		
White	(3887)	7+	24	10	7	11	5	8	11	19	16	3	49	5	33	12	64	42
Afro-American	(477)	3	24	5	6	9	8	6	4	21	13	2	54	6	27	20	71	64
Asian	(80)	3	22	4	5	6	3	4	12	12	10	4	42	9	25	19	58	45
Hispanic	(190)	6	23	9	6	12	11	8	3	14	16	5	69	7	36	12	69	60
Other	(86)	2	24	13	7	6	5	9	3	25	20	6	48	1	26	8	73	53
EDUCATION (18+)																		
< 12 yrs	(431)	3	26	9	2	10	5	9	10	19	15	1	47	3	32	16	59	59
H.S. grad	(1350)	6	25	10	6	12	7	9	12	23	17	4	57	6	41	13	71	49
Some College	(905)	9	24	10	8	14	6	8	11	24	16	3	55	5	36	12	67	43
College Grad	(597)	7	22	15	7	11	5	6	9	19	14	2	56	6	27	15	57	36
Post-Grad	(477)	7	19	11	7	12	7	6	7	22	16	4	52	5	25	18	56	40

		Open Paints	Fried Foods	Open Flame	Glues	Solvents/ Fumes	Pesticides	Floor Wax	Gas Equipment	Cleaning Agents	Dust	Stain Remover	Perfume	Nail Polish	Aerosol	Mothball	Air Freshener	Toilet Deoderizer
EMPLOYMENT																		
Full-time	(2070)	8	26	12	8	15	6	7	14	19	20	4	57	5	35	13	66	46
Part-time	(420)	6	25	12	7	13	6	9	9	25	16	2	60	6	37	16	67	46
Not employed	(1332)	4	21	8	3	7	6	8	6	25	10	2	48	5	33	15	63	49
DAY OF WEEK																		
Monday-Friday	(3145)	7	23	9	8	12	6	7	10	19	16	3	49	5	32	13	64	46
Saturday	(636)	4	24	9	5	10	4	9	9	21	17	4	51	6	32	11	67	48
Sunday	(920)	3	29	14	4	7	5	8	7	19	12	2	54	6	34	14	65	44
QUARTER																		
Sep-Dec '92	(355)	5	22	12	7	8	4	8	6	19	16	3	52	3	32	16	63	47
Jan-Mar '93	(631)	6	24	12	6	12	4	8	10	21	15	3	53	4	30	16	65	45
Apr-Jun '93	(634)	6	24	8	5	10	7	7	8	19	15	2	51	6	28	13	64	42
Jul-Sep '93	(616)	5	24	11	5	12	9	6	6	22	18	3	49	5	35	14	63	44
Sep-Dec '93	(587)	8	21	10	10	11	4	8	9	24	16	1	50	6	29	11	66	49
Jan-Mar '94	(626)	4	22	9	9	12	2	8	8	18	14	1	50	6	31	11	63	46
Apr-Jun '94	(615)	5	25	7	7	10	7	6	11	15	15	3	54	6	38	12	66	46
Jul-Sep '94	(637)	6	23	6	6	13	9	6	12	16	17	4	44	5	28	14	67	48
REGION																		
Northeast	(1023)	6	20	12	7	12	4	7	6	20	14	2	48	4	29	18	63	46
Central	(1064)	7	25	11	8	11	6	8	13	18	16	2	53	4	31	11	63	42
South	(1628)	6	26	8	6	9	7	9	11	21	15	3	52	5	38	16	69	52
West	(986)	6	22	9	8	11	6	6	7	24	18	3	46	7	28	7	62	40
HOUSING																		
Apartment	(944)	5	19	8	5	9	7	8	4	23	16	3	52	7	33	12	67	51
House	(3234)	7	24	10	7	11	6	7	11	20	16	2	50	5	32	14	64	45
Townhouse	(197)	6	28	13	11	16	7	11	5	26	15	4	54	4	40	11	68	42
Other	(272)	2	35	10	5	7	5	7	7	19	18	3	54	4	38	7	70	50

Table 2. Differences in the Average Duration of *MPE* by the Most Significant Predictors.

	n	Average Maximum Duration of Exposure to ETS (Minutes per Day) Unadjusted	Adjusted
TOTAL	1579	178	178
EDUCATION		Eta=.13	Beta=.11 **
Grammar School	(48)	169	201
High School Incomplete	(132)	193	209
High School Graduate	(488)	210	200
Some College	(471)	172	170
College Graduate	(267)	180	176
Graduate School	(154)	99	109
Not Reported	(18)	83	173
DAY		Eta=.09	Beta=.10 **
Sunday	(226)	172	209
Monday	(305)	149	146
Tuesday	(322)	167	163
Wednesday	(269)	182	170
Thursday	(30)	271	257
Friday	(201)	204	184
Saturday	(226)	200	208
EMPLOYMENT		Eta=.20	Beta=.06 (NS)
Working	(1066)	206	182
Looking for Work	(50)	202	190
Laid Off from Work	(14)	303	194
Retired	(202)	117	190
Going to School	(55)	68	109
Keeping House	(140)	85	156
Something Else	(52)	154	177
MARITAL STATUS		Eta=.13	Beta=.09 (NS)
Married	(918)	174	181
Living Together	(86)	282	247
Widowed	(75)	96	153
Separated	(25)	145	114
Divorced	(125)	193	176
Never Married	(334)	184	171
Refused	(16)	110	82

Table 2. Differences in the Average Duration of *MPE* by the Most Significant Predictors (Cont'd)

	n	Average Maximum Duration of Exposure to ETS (Minutes per Day) Unadjusted	Adjusted
NO. OF CIGARETTES SMOKED YESTERDAY		Eta=.34	Beta=.32 ***
None	(1230)	141	144
1-9	(91)	211	193
10-19	(102)	279	286
20-29	(103)	337	316
30-39	(24)	443	427
40 or more	(27)	565	568
Multiple R (Squared)			.46 (.21)

Note: ** - significant at $p < .01$; *** - significant at $p < .001$

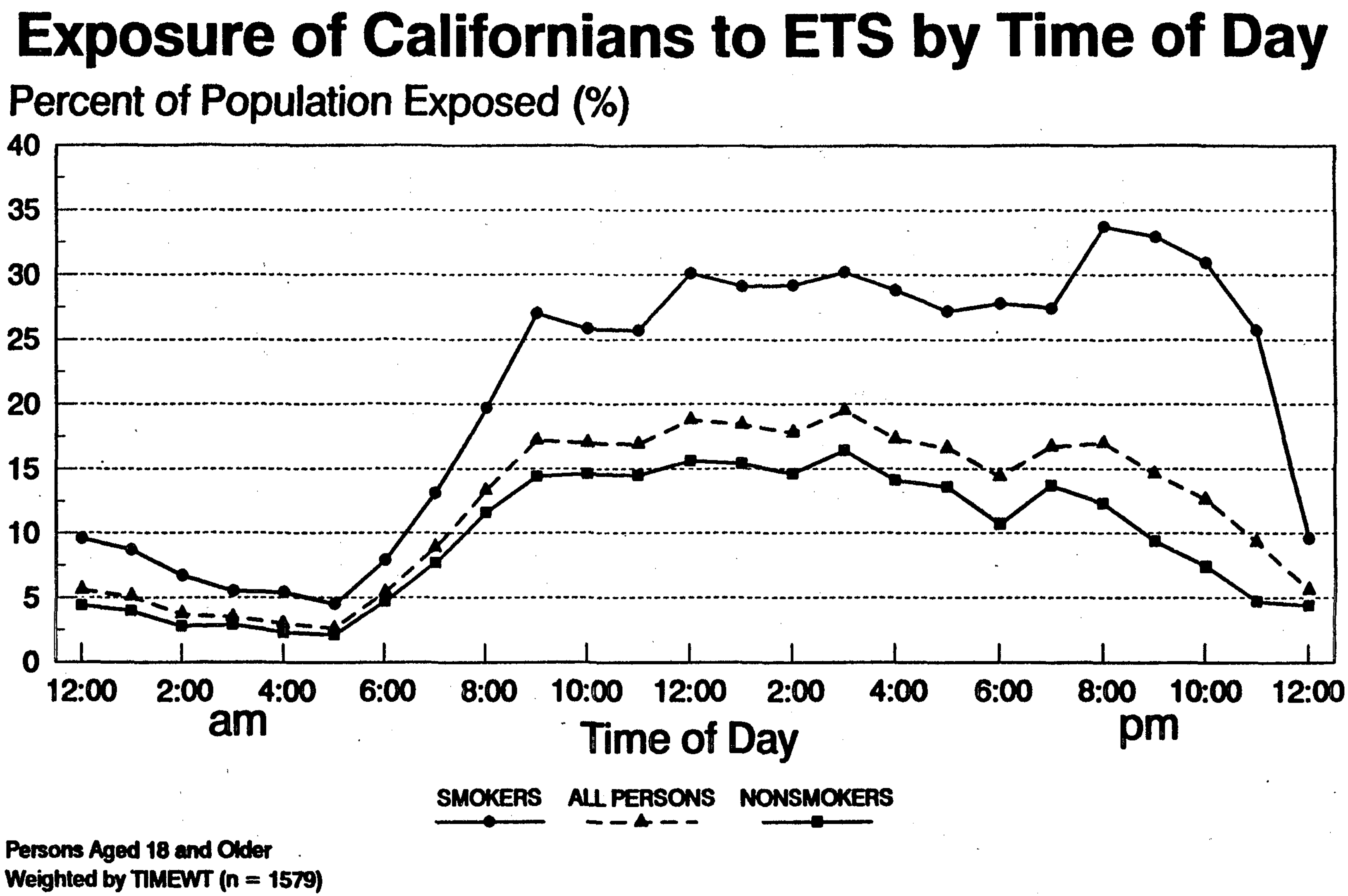

Figure 1. Percentage of the California population reporting "smokers present" by time of day for smokers, nonsmokers, and all persons.

Housing Characteristics and Indoor Environments Work Group

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INTRODUCTION

The Housing Characteristics and Indoor Environments Work Group focused its review on the draft Handbook's chapter 7 on reference residence, which was developed from input provided by the 1993 work group (panel) assigned to help develop this new chapter. The 1995 work group included five members of the 1993 work group. This summary report is organized as follows:

- review of 1993 workshop comments on what to include in the chapter;
- overview of the contents of the draft chapter reviewed by the 1995 work group;
- summary of the 1995 premeeting comments on the draft chapter;
- summary of discussions of the July 25-26, 1995 housing characteristics and indoor environments work group;
- the residential model proposed by the 1995 work group for this chapter;
- the 1995 work group's proposed outline for the chapter, based on premeeting comments, the July 25-26 work group's discussions, and the proposed model;
- the 1995 work group's guidance on what to include in the proposed sections of the revised chapter;
- data gaps and research needs noted by the 1995 work group, based on the July 25-26 discussions; and
- summary and recommendations.

REVIEW OF 1993 WORKSHOP COMMENTS ON WHAT TO INCLUDE IN THE CHAPTER

The 1993 work group's opinion was that the reference residence chapter should focus on inhalation, because of the relevance of this route to many indoor pollutants, and should cover the residential factors judged to have the greatest potential impact on these types of exposure assessments. The 1993 work group identified the following "high-priority" data and recommended that they be covered in the chapter:

- For single-zone assessments:
  - whole residence volume; and
  - air exchange rates.
- For multizone assessments:
  - room/zone volumes; and
  - room/zone air exchange rates.
- For "sink" terms for deposition and sorption:
  - surface areas for walls, floors, and ceilings; and
  - composition of walls, floors, and ceilings.
- For water-related assessments:
  - water usage for baths and showers;
  - water usage for appliances; and
  - water temperatures for appliances.

OVERVIEW OF THE CONTENTS OF THE DRAFT CHAPTER REVIEWED BY THE 1995 WORK GROUP

The input from the 1993 work group led to development by EPA and its contractor of the draft chapter provided to the 1995 work group for review and comments. The draft chapter reviewed by the 1995 work group was organized into the following sections:

7.1 Introduction
7.2 Indoor Volumes.
 7.2.1 Volumes of Residences
 7.2.2 Room Volumes and Surface Areas
7.3 Airflows
 7.3.1 Background
 7.3.2 Air Exchange
 7.3.3 Interzonal Airflows
 7.3.4 Variability Within Zones
7.4 Water Supply and Use
 7.4.1 Background
 7.4.2 Water Use
7.5 References for Chapter 7

SUMMARY OF THE 1995 PREMEETING COMMENTS ON THE DRAFT CHAPTER

The 1995 work group assigned to this chapter, and some members of the other 1995 work groups, provided extensive premeeting written comments about the draft chapter. Overall, the premeeting comments were favorable (e.g., "excellent material," "useful"). The premeeting comments discussed on July 25 and 26 by the 1995 work group are as follows:

- Modify the Introduction to help readers understand why this type of information on house and other residential volumes, air exchange rates, and water uses and volumes is important and how it can be used. The introduction could cite key publications to help readers understand use of the above information (e.g., McKone, T.E. Household exposure models. Toxicol. Lett. 49:321-329 (1989); Wilkes, C.R. et al.

Inhalation exposure model for volatile chemicals from indoor uses of water. Atmosp. Environ. 26A:2227-2236 (1992); and perhaps publications by Barry Ryan, Ken Sexton, and others).

- Add information on:
  - — modeling approaches (e.g., microscopic and macroscopic modeling) and computational tools; and
  - — sources of exposure (e.g., airborne, waterborne, dust and aerosol, and transport between source types).

- Make sure key new documents are included. For example, sections 7.2 and 7.3.2 state that no measurement surveys have been conducted to directly evaluate the range and distribution of residential volumes and residential air exchange rates. Some candidates for addition, however, include:
  - — Pandian, M. et al. Residential air exchange rates for use in indoor air and exposure modeling studies. J. Exposure Analysis Environ. Epidemiol. 3:407-416 (1993). (Residential air changeovers in different regions of the United States, different seasons, and different levels within the homes.)
  - — Murray, D.M., and Burmaster, D.E. Residential air exchange rates in the United States: Empirical and estimated parametric distributions by season and climatic region. Submitted for publication in Risk Analysis. (Residential air changeovers in different regions of the United States, different seasons, and as a function of "heating degree days.")
  - — Murray, D.M. Residential total house and zone volumes in the United States: Empirical and estimated parametric distributions by season and climatic region. Submitted for publication in Risk Analysis. (House volumes in the United States as a whole and for eight states. Results also presented for house zone volumes.)

- Add other products to those listed for wall coverings and floor surfaces.

- Add a listing of types of airborne contaminants likely to be emitted by wall covering and floor covering products.

- Add a discussion of the roles of season and temperature in affecting air exchange.

- Discuss the role of indoor versus outdoor influences and contributions.

- Discuss the possible impact of chemical and physical transformation.

- Discuss the possible impact of exposure from soil gas and ground water (e.g., via basement).

- Discuss changes in residential parameters such as ceiling height as a function of the year of construction of the residence.

- Add information on various residential surfaces that might be useful for dermal exposure assessments. This could include surface areas of various objects that might be handled.

- Expand indoor volumes section to become "Building Characteristics" (e.g., include configurations; surface areas of walls, floors, and ceilings; and characteristics of construction materials and furnishings).

- Discuss need to treat some materials as porous solids (e.g., include thickness, porosity, mass per unit volume, specific surface area).

- Discuss suburban versus urban and rural residences.

- Discuss possible relationships between house volumes and air exchange rates, and what might happen in individual rooms and zones.

- Discuss the best way(s) to present chapter 7's current and possible new information (e.g., format, key studies versus other studies, nature of the distributions).

- List the significant data gaps and research needs.

- Since this chapter and chapter 6 on consumer products are new, consider asking readers and others to help ensure that all potentially useful residential exposure data are included in future revisions of the Handbook. Consider establishing an EPA, or other, contact to receive data for possible inclusion in future revisions; perhaps listings of new data could be sent to known users of the Handbook, or the listings could be posted as an update file on the Internet (e.g., on a World Wide Web homepage).

SUMMARY OF THE JULY 25-26 DISCUSSIONS OF THE 1995 HOUSING CHARACTERISTICS AND INDOOR ENVIRONMENTS WORK GROUP

The 1995 work group discussed the following:

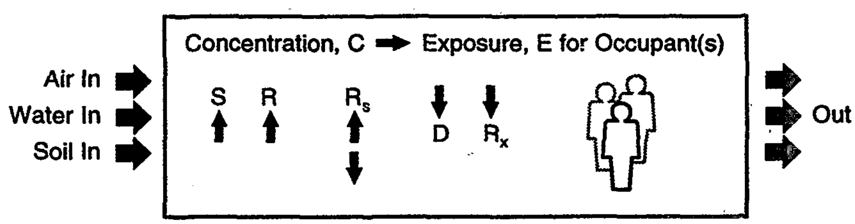
- The chapter should focus on information useful for single zone modeling, but this emphasis should be placed in the larger context of other modeling possibilities (e.g., multizone).

- The draft version of the chapter should be restructured. The group discussed possible sections, figures, and tables that could be modified or dropped, and, if dropped, how the key information could be captured elsewhere in the chapter. The work group examined the existing draft very carefully to assess how the information might be better organized and presented, what information should and should not be included, and what would be best for possible future revisions of the Handbook.
- The contents of the chapter need to go past inhalation as a route of exposure to include information useful for dermal assessments.
- The current references need to be updated to include new studies.
- Significant data gaps and research needs should be addressed, either in a new chapter or as a section at the end of the current chapter. The work group developed a listing of these gaps and needs.

THE RESIDENTIAL MODEL PROPOSED BY THE 1995 WORK GROUP FOR THIS CHAPTER

The 1995 work group proposed the following for use in a revised figure 7-1, Elements of Residential Exposure:

- Air exchange, leakage
- Sources:
  - — direct emission (S)
  - — transport from outdoors (air, water, soil)
  - — re-emission, re-suspension (R)
- Sinks and loss mechanisms:
  - — deposition (D)
  - — transport out
  - — reaction (R_x)
  - — reversible Sinks (R_s)



THE 1995 WORK GROUP's PROPOSED OUTLINE FOR THE CHAPTER, BASED ON PREMEETING COMMENTS, THE JULY 25-26 DISCUSSIONS, AND THE PROPOSED MODEL (SHOWN ABOVE)

The 1995 work group proposed the following outline for the revised chapter:

7.1 Introduction

7.2 Building Characteristics

- 7.2.1 Volumes and Surface Areas of Residences
- 7.2.2 Volumes and Surface Areas of Rooms
- 7.2.3 Mechanical System Configurations
- 7.2.4 Building Materials and Furnishings
- 7.2.5 Basement and Crawl Spaces

7.3 Transport Rates

- 7.3.1 Airflow Rates
  - Air Exchange Data
  - Lawrence Berkeley Laboratory Model
  - Mechanical Systems (Kitchen, Bathroom, and Newer Mechanical Ventilation Systems)
- 7.3.2 Deposition and Filtration
- 7.3.3 Interzonal Airflow
- 7.3.4 Water Supply
- 7.3.5 Water Filtration
- 7.3.6 Soil Tracking
- 7.3.7 Soil Removal/Resuspension
- 7.3.8 Wind and Outdoor Temperature (for Predictive Models)

7.4 Sources

- 7.4.1 Airborne Sources (Outdoor Air Concentrations and Indoor Airborne Sources)
- 7.4.2 Waterborne Sources
- 7.4.3 Soil and House Dust Sources

THE 1995 WORK GROUP's GUIDANCE ON WHAT TO INCLUDE IN THE PROPOSED SECTIONS OF THE REVISED CHAPTER

The 1995 work group offered the following guidance on revising the chapter:

7.1 Introduction

The initial two paragraphs should discuss the general framework for residential exposure analysis (e.g., how data such as building characteristics, transport rates, and sources and reversible sinks are used in a "residential model" to develop estimates of concentration[s]), followed by use of other information such as human activity patterns to develop the assessment of exposure(s).

The next two paragraphs should discuss residential modeling approaches (can use information from pages 7-1, 7-2, and 7-3 of the draft chapter). This would include a more complete classification and discussion of macro- and micro-contaminant dispersal, flow, and integrated analyses and should also include a presentation of a simple single zone "case study" along with citation to one or more key reviews (e.g., McKone, T.E. Household exposure models. Toxicol. Lett. 49:321-329 [1989]). Also, these paragraphs should inform readers about multizone and microcomputational analyses as well as the tools available for advanced/complex studies.

The last paragraphs in the section should outline the rest of the chapter, set the emphasis on simple single zone analyses, and identify limitations. For example, these paragraphs could include statements about the known accuracy of some of the data (e.g., those for transport rates).

7.2 Building Characteristics

7.2.1 Volumes and Surface Areas of Residences. Use information from section 7.2.1 of the draft chapter. Also, the current section 7.2.1 on this topic includes table 7-2, Residential Volumes in Relation to Household Size and Year of Construction. The work group recommends that an attempt be made to include representative building configurations in this table (e.g., single family detached and attached, multifamily units, and mobile homes as noted in table 7-1).

7.2.2 Volumes and Surface Areas of Rooms. Use information from section 7.2.2 of the draft chapter and provide some text on how to use information presented in table 7-4, Examples of Products and Materials Associated with Floor and Wall Surfaces in Residences (Tucker, 1991, citation). Some work group members recommended removing table 7-3 (Room Volumes and Surface Areas from Energy Conservation and Indoor Air Quality Research Homes) and table 7-4 from the chapter, and attempting to replace them with tables containing better data.

7.2.3 Mechanical System Configurations. Identify as a data gap?

7.2.4 Building Materials and Furnishings. Identify as a data gap? Need information on surface areas, compositions, and porosities of materials and furnishings.

7.2.5 Basement, Crawl Spaces, and Other Possible House Areas/Units to Consider

7.3 Transport Rates

7.3.1 Airflow Rates

- Air Exchange Data. Use some of the information from sections 7.3.1 and 7.3.2 of the draft chapter, along with other possible studies. The work group recommends that the format for presentation be carefully examined, with the data perhaps best presented in both "visual" (figures) and tabular form. The work group also recommends that "the net be broadened" in an attempt to ensure that all useful studies are included. Also, the work group recommends that statements be included to address small sample sizes in some of the data sets, the type of study (e.g., 12-hours or 1 week in duration), and the need to assess the applicability of the data for particular assessments (e.g., exposure assessors should try to use representative data for a particular region of interest; also, can some of the data shown in table 7-5, such as the 23.32 air changes per hour value, be considered as very extreme and beyond what might reasonably be considered as possibly occurring?).

- Lawrence Berkeley Laboratory Infiltration Model.

- Mechanical System (Identify as a data gap? Need information on kitchen, bathroom, and newer mechanical ventilation systems).

The work group noted the usefulness of the ASHRAE (1993) "Fundamentals" handbook as a publication readers of this section and chapter could be directed to for additional information.

7.3.2 Deposition and Filtration

7.3.3 Interzonal Airflow. The current section 7.3.3 on this topic includes figure 7-2, Residential Configurations. The work group recommends that an attempt be made to include other representative building configurations (e.g., multifamily units and mobile homes as noted in table 7-1).

7.3.4 Water Supply. Use information from section 7.4 of the draft chapter, try to include some appliance use data, and point to other references such as the University of Pittsburgh work performed by Julian Andelman and others.

7.3.5 Water Filtration

7.3.6 Soil Tracking. Include work by John Roberts and others.

7.3.7 Soil Removal/Resuspension. The work group recommended including work by David Layton on surface areas for resuspension, and discussing "the effective surface area" of furniture and other residential surfaces for helping to determine the amount of dermal exposure that can occur.

7.3.8 Use of Wind and Outdoor Temperature Information (for Predictive Models)

7.4 Sources

This section could be immense in size; however, an attempt should be made to keep it to about two pages while discussing types of sources and referring to key publications for further information.

7.4.1 Airborne Sources. (Outdoor Air Concentrations and Indoor Airborne Sources.)

7.4.2 Waterborne Sources

7.4.3 Soil and House Dust Sources

7.5 Complications

This section could use information from section 7.3.4 of the draft chapter for the new 7.5.1.

7.5.1 Personal Versus Micro Environmental Exposures

7.5.2 Reversible Sinks

7.6 References

DATA GAPS AND RESEARCH NEEDS NOTED BY THE 1995 WORK GROUP, BASED ON JULY 25-26 DISCUSSIONS

The 1995 work group identified the following data gaps and research needs (not listed in order of recommended importance):

- source emissions;
- urban versus suburban versus rural housing characteristics;
- ceiling height as a function of the year of construction and location (urban versus suburban versus rural) (*Note:* The work group noted that variations in ceiling height affect data on house volumes, including the information presented in table 7-1, and that a footnote could be added to that table to note this along with noting it as a data gap and research need);
- single versus multifamily residences, including representative building plans;
- ensuring all useful air exchange data sets are covered;
- appliance characteristics (temperatures and volumes);
- building materials and furnishings;
- mechanical system configurations and rates;
- transport (e.g., soil tracking); and
- need for reality checks of exposure assessments, including factor values used, and the need for validation of models.

SUMMARY AND RECOMMENDATIONS

The 1995 work group assigned to this chapter provided extensive comments that should make chapter 7 easier to follow and use, with the aim of having the revised proposed chapter provide key exposure factor information needed for assessments of indoor environments. It is recommended that EPA and its contractor review the above summary for suggested changes to the current draft of the chapter.

SECTION FOUR

OVERVIEW

REVIEWERS' PRELIMINARY COMMENTS

Prior to the workshop, each expert reviewer was asked to read the draft *Exposure Factors Handbook* and provide written comments. (Appendix B presents the reviewers' premeeting comments.) Relying on their technical knowledge and best professional judgment, reviewers responded with comments on:

- the usefulness of presented data in support of both joint estimates and Monte Carlo exposure assessments;
- the Agency's grouping of key studies and other relevant studies based on judgments about the adequacy of the data and their applicability to the exposure factors being evaluated;
- the adequacy of interpretations of the data and the appropriateness of the limitations/uncertainties emphasized/described in the Handbook's recommendations; and
- the usefulness of developing a new chapter (or sections at the end of each chapter) that highlights data gaps and future research needs.

In his introductory remarks, Dr. Ryan, the workshop chairperson, summarized several recurrent observations from reviewers in their preliminary, general comments on the Handbook:

- Overall the document is not "user-friendly" because of its size, nongraphical data presentations, inconsistent referencing, and inconsistent formatting of footnotes, tables, and references.
- Terms are undefined or poorly defined (e.g., upper percentile, default values). Also, the use of significant figures varies across factors.
- Terminology is inconsistent (e.g., geometric mean versus arithmetic standard deviations).

- Studies and distributions are presented without explanation of their strengths and weaknesses. Further research is needed on identifying the "best" surveys or studies.

- No distinctions are apparent between primary and secondary studies or in defining "key" studies and "relevant" studies. Because the details of survey design are lacking, the document assumes all studies are equal.

- The chapter on uncertainty analysis (i.e., chapter 8) is incomplete. It presents tools but describes no methods or procedures. The chapter should be either expanded or abandoned. Also, the discussion in this chapter might be more appropriately placed at the beginning of the document.

- Some old data are used for areas in which newer and better data are available.

- A Handbook needs to present a condensed summary of ranges.

- The document should be made available on the Internet via EPA's homepage and on CD-ROM.

Overall, the comments raised a number of issues for consideration at the workshop.

Comments on Food and Beverage Consumption

Barbara Petersen, Ph.D., of Technical Assessment Systems, Inc., reviewed the premeeting comments that focused on exposure factors dealing with food and beverage consumption. Dr. Petersen identified several major themes in reviewers' comments:

- A list of resource people needs to be developed and included in the Handbook, as well as a list of training programs.

- Although the Handbook focuses on five major types of food and beverages, people consume many different types of food. It is important to estimate precise and realistic consumption values for whole diets to avoid errors in food consumption distribution rates.

- The results of the USDA National Survey for 1989 through 1991 are not provided in the Handbook. At a minimum, references for this data should be provided.

- Better guidance is needed on selecting appropriate exposure data for specific types of studies, including the advantages and limitations of these data.

- Categories of food (e.g., cooking) and types of data (e.g., data on meal size and daily intake needed to assess acute exposures) are missing.

Dr. Petersen presented an array of comments on the treatment of data in the Handbook. For example, it was felt that some statistical interpretations are not justified (e.g., presenting percents for small sample sizes and using data on one individual to develop a range); the inconsistent use of significant figures throughout the Handbook can effect the precision of assessment results; expanded footnotes are needed to facilitate moving between tables and text. Also, reviewers expressed the opinion that equal consideration was given to both primary and secondary data, and it was suggested that the Agency look at interpersonal variations in data where point estimates and Monte Carlo simulations can and cannot be used. Other comments included the need for the Agency to:

- conduct systematic peer review of new data;
- provide a second source of information;
- adequately present study results to illustrate intake rates;
- review study results to ensure that accurate information is presented (e.g., cooked vs. uncooked; dry vs. wet weight);
- clarify how household food is assigned to individuals;
- update Eleanor Pao's USDA data;
- clarify the terminology and methods used in studies to describe different types of food (e.g., sources of water); and
- provide more information on total infant intake (breast milk and formula).

Comments on Nondietary and Dermal Exposure Factors

John Kissel, Ph.D., of the University of Washington, presented a summary of the premeeting comments on water ingestion, soil ingestion, and the dermal route. He identified the two major issues concerning water ingestion as (1) the presence of volatile organic compounds (VOCs) in water and (2) the effect of showering and the use of heat in the preparation of food and incidental ingestion of water while swimming and bathing. All of the studies on water ingestion were found to be relatively consistent.

Dr. Kissel noted several comments regarding soil ingestion. For example, it is felt that the Handbook provided a good review of the soil ingestion literature up to 1991. Data on adult ingestion of soil as well as on the pica child, however, was found to be inadequate. Although multiple studies are available on ingestion of soil by children, reviewers view the mean child ingestion rate of 180 mg/day as conditional because of their low confidence in the studies. Issues in regard to the studies include the validity/sufficiency of input/output studies, the methods used for short-term versus long-term studies, and the lack of confidence in the Calabrese study's probability density function of annual averages generated from 4-day data. Given the importance of this exposure pathway, reviewers suggested conducting the following and including the results in future revisions of the Handbook:

- new longer term studies;
- interim dose reconstructions; and
- independent reevaluation of existing data.

Issues in regard to the dermal route and its presentation in the Handbook include:

- The lack of data on individual behaviors that can affect a determination on what skin surfaces are exposed limits the probability density function of related exposure factors. Historically, exposure assessors assumed that people wore shorts and t-shirts. Data on more specific surface areas are needed.
- The lack of nonsoil and nonwater dermal exposures.
- The literature review should be reorganized by type of study (e.g., direct v. indirect).
- More data by Kissel should be presented to put the discussion in context.
- Although soil adherence is a function of activity, the data do not reflect this association. For example, in an episodic dermal exposure to soil, information on the time between contact and showering is needed.

- Current protocols are not consistent for different routes of exposure. For example, percent absorbed is used to calculate dermal exposures to contaminants in soil, whereas mass transfer coefficients are used to calculate dermal exposures to contaminants in water. The protocol for dermal exposure should be the same for all media.

Comments on Human Activity Patterns

Steven Colome, Ph.D., of Integrated Environmental Services, presented the following summary of reviewers preliminary comments:

- No major conflicts exist among reviewers.
- The information assembled in the Handbook is useful.
- More information is needed to orient the exposure assessor on why this information is required and on how the information can be applied.
- More effective and critical evaluation of the adequacy and quality of information is needed.
- The relationship between time-activity data and data applications needs to be made clearer.
- The Handbook as written reflects the multiple authors (e.g., uneven editing, incomplete or selective referencing).

Many of the reviewers' specific comments on chapter 3 (Inhalation Route) were of an editorial nature. In addition, however, reviewers noted that inconsistent definitions are used and in some cases overly precise, but not fully justified, recommendations are made (e.g., 13.3 mg^3/day). Also, study evaluations were found to be not particularly useful without the overall summary of the full body of information. Also, it was felt that the small size of some studies may not be representative.

Reviewer's commented that the information presented in chapter 5 (Other Factors for Exposure Calculations) was not well synthesized. Also, the 1992-1994 NHAPS study will replace many of the earlier, outdated studies. Reviewer's identified the need to distinguish data needs for dose and exposure.

There was general agreement among reviewers that limited data are available on consumer products (chapter 6). They also contended that the tables containing the Westat data are not integrated and it is unclear how this information would be used in an exposure assessment. Thus, some suggested that a critical evaluation of data quality and information should be conducted.

All reviewers commented on the lack of direction and lack of information in chapter 8 (Analysis of Uncertainties). Several reviewers suggested that the information might be better used as part of the introduction to the Handbook.

Comments on Housing Characteristics and Indoor Environments

Based on the results of the 1993 peer involvement workshop, chapter 7 (Reference Residences) was added to the Handbook. P.J. Hakkinen, Ph.D., of the Proctor and Gamble Company, summarized reviewers comments on housing characteristics and indoor environments. Overall, most reviewers found that the chapter contained useful material. It was suggested that the introduction be modified to help readers understand why this type of information is important and how it can be used. It also was suggested that information be added on:

- modeling approaches (e.g., microscopic and macroscopic modeling) and computational tools;
- sources of exposure (e.g., airborne, waterborne, dust and aerosol, and transport between source types); and
- key new documents.

Reviewers noted that sections 7.2 and 7.3.2 currently state that no measurement surveys have been conducted to directly evaluate the range and distribution of residential volumes and residential air exchange rates. Some pointed out, however, that a great deal of published information, as well as information submitted for publication, from various studies could be added to this chapter. Also, it was suggested that the publications currently cited in chapter 7 on air exchange rates need to be verified to ensure that they have been corrected for a known data coding problem.

Reviewers suggested that information on the following be added to the chapter:

- other wall covering and floor surface products;
- types of airborne contaminants likely to be emitted by wall covering and floor covering products;
- the role of season and temperature in affecting air exchange;
- the role and contribution of indoor versus outdoor influences;
- the possible impact of chemical and physical transformation;
- the possible impact of exposure from soil gas and ground water (e.g., via the basement);
- changes in residential parameters (e.g., ceiling height as a function of the age of the residence); and
- sizes and other relevant information for various residential surfaces (e.g., for possible use in dermal exposure assessments).

Moreover, reviewers suggested that the section on reference residence:

- expand the "Indoor Volumes" section to become "Building Characteristics" (addressing configurations; surface areas of walls, floors, and ceilings; and characteristics of construction materials and furnishings);
- discuss the need to treat some materials as porous solids (e.g., include thickness, porosity, mass per unit volume, specific surface area);
- discuss suburban versus urban versus rural residences;
- discuss possible relationships between house volumes and air exchange rates, and what might happen in individual rooms and zones;
- discuss the best way(s) to present chapter 7's current and possible new information (i.e., format, key studies versus other studies, nature of distributions); and
- discuss the significant data gaps and research needs.

Dr. Hakkinen explained that as with chapter 6 on consumer products, chapter 7 is a recent addition to the Handbook. Based on this, it was suggested that the Agency:

- ask readers and others to help ensure that all potentially useful residential exposure data are included in future revisions of the Handbook;
- establish a contact to receive data for possible inclusion in future revisions; and
- send updates of new data to known users of the Handbook, or post an update file on an Internet World Wide Web homepage.

Reviewers in this work group concurred with other workshop reviewers that chapter 8 (Analysis of Uncertainties) needs extensive expansion and thought. Reviewers also suggested that this chapter might benefit from some examples.

SUMMARY OF WORKSHOP DELIBERATIONS

The workshop provided a forum for the expert reviewers to discuss the scientific aspects, thoroughness, and completeness of the draft Handbook. Workshop participants contributed useful and substantive suggestions and recommendations for improving the Handbook. Section 3 of this report provides summaries and recommendations as reported by the chairpersons of the four work groups.

All workshop reviewers acknowledged the frequent use of the Handbook by diverse groups within the public and private sectors and commended EPA's efforts in updating and expanding the contents of the Handbook. Reviewers recommended that EPA provide an overview discussion on how all of the exposure factors provided in the Handbook can be integrated (e.g., why is it important to understand activity patterns and indoor environments?) and provide conceptual frameworks for each chapter.

Food and Beverage Consumption

Considerable discussion among reviewers focused on data that are missing from the Handbook. Although data are available from the USDA Continuing Survey of Food Intake by Individuals (CSFII) from 1989 to 1991 and the Michigan study on fish consumption from 1992, the results have not been included in the Handbook. The results of a survey conducted by the USDA on ranching activities (i.e., cattle and sheep slaughtered for home consumption) have never been evaluated regarding the distribution and frequency of consumption. Reviewers also noted that the bioavailability issue is missing from any discussions in the Handbook on homegrown foods.

Several reviewers commented on the multiple analysis and use of the same data in different sections of the document. Reviewers recommended that a genealogy (flow chart) of the data be provided so that readers can follow the chronology and relationship between different studies and their uses. Reviewers also suggested that expanded footnotes be provided in tables that indicate where the data came from, note any analyses conducted, and explain uses for the data. Reviewers expressed the opinion that the tables should provide sufficient documentation to enable them to stand alone (e.g., intake rates should specify whether the observation was on an as-eaten or a dry-weight basis; household or individual basis). One reviewer asked whether multiple sources of data are needed to determine consistency.

Considerable discussion focused on the level of precision throughout the Handbook. Reviewers cautioned that the Handbook should not create false precision when using existing data.. Most reviewers considered the use of one significant figure sufficient for data on food consumption. The use of rounding was also found applicable for interpolation and percentages. Reviewers also discussed criteria for the number of observations or subjects/cell necessary to calculate central tendency versus percentiles. They considered $n = 30$ acceptable for distributions, $n \geq 30$ acceptable for central tendency, and $n > 30$ acceptable for percentiles.

Reviewers emphasized the importance of identifying subpopulations and providing for an appropriate level in disaggregation (e.g., data on fish consumption by ethnic group). They expressed the opinion that food disappearance data may not be useful because values can be overestimated.

Reviewers discussed the limitations of studies used in the Handbook, including survey designs (i.e., 1-year recall versus 3-day) and criteria for including distributions. They recommended that for each study the survey methodology and its limitations be addressed. For example, one reviewer noted that taking national data and applying it to a site-specific situation is problematic. Reviewers recommended adding a discussion on how per capita estimates can be used when "per user" data would be more appropriate. A discussion on how to compute high-end exposures in situations where more than one contaminated commodity is present also was recommended. Reviewers did state that national data could be used for screening purposes.

Several reviewers addressed recreational fish consumption (self caught) and found the basic approach for freshwater anglers to be sound. Exposure assessors should not rely on defaults but rather should look at available studies and present distributions for the relevant studies. Reviewers made several recommendations for revisions to the Handbook regarding exposures from recreational fish consumption:

- new studies need to be added;
- criteria for selecting key or recommended studies need to be presented;
- guidance on selection of relevant studies based on the type of water body, regional variation, etc. is needed; and
- creel and mail survey results should be separated to avoid the potential for bias.

Regarding Native Americans, reviewers recommended that new studies be added and that data on Native Americans in surveys of recreational anglers be evaluated. Reviewers also recommended that subsistence anglers be discussed in the Handbook and criteria be developed for determining the presence or absence of such populations at individual water bodies.

Reviewers in this work group also discussed the need for consistency within tables and chapters and between chapters.

Nondietary and Dermal Exposure Factors

Members of the nondietary and dermal exposure factors work group concurred that there was good agreement between the results of prior studies conducted on water ingestion. Large data sets are available from which distributions can be recommended.

Reviewers expressed the opinion that the even the best data on soil ingestion by children were difficult to interpret. Reviewers held little confidence in the results of the Calabrese study or his interpretations, which were based on 4 days of data. They could not justify a distribution based on the Calabrese data or other data, but felt a central tendency and upper confidence could be recommended. The value of 100 mg/day was viewed as conditional by the reviewers. Reviewers questioned the validity of available studies and the issue of values based on short-term exposures versus exposures for longer periods.

Similarly for a pica child, reviewers contended that the data sets were too small (n = 1 or 2) and the uncertainty too high to interpret, and they recommend a distribution based on the data. Reviewers also considered the data on adult ingestion of soil to be inadequate.

Reviewers provided recommendations on how to improve the exposure factors associated with soil ingestion:

- conduct longer term studies to validate the 4-day study;
- as an interim measure, initiate dose reconstruction efforts; and
- sponsor (i.e., EPA) an independent reevaluation of existing data.

The work group reviewers addressed how the dermal route discussion in the Handbook could be improved:

- add nonwater and nonsoil routes for dermal exposures, and relate this discussion to exposure to consumer products (e.g., carpets);
- add more specific skin surface areas;

- remove equations in the text;
- reorganize the literature review by type of study;
- present more Kissel data to put the dermal route discussion in context;
- add behavioral data that would permit probability density functions; and
- generate activity ranges rather than calculating probability density functions (see the Nondietary and Dermal Exposure Factors Work Group summary in section 3).

The reviewers also made several general recommendations for improving the Handbook, including:

- add a glossary;
- separate data more explicitly by quality (high confidence versus low confidence); and
- reference data by source (i.e., original data versus manipulated data).

Human Activity Patterns

The human activity patterns work group reviewed chapters 3, 5, and 6 of the Handbook. Reviewers expressed the opinion that data included in chapter 3 (Inhalation Route) are limited and that the chapter would benefit from a broader literature search that sought information from the sports medicine and occupational fields. Reviewers discussed the role of variability (i.e., day-to-day variability and variability in demographic groups) and the selection of a representative sample in developing inhalation rates. They agreed that the theoretical and field data support a reduction in the daily inhalation rate from 20 m^3/day, but did not support the precision of the 13.3 m^3/day rate. Another area of discussion was the need to distinguish the difference between dose and exposure.

Reviewers found that the few distributions presented in chapter 5 (Other Factors for Exposure Calculations) would be difficult to use in probabilistic estimates. They expressed the opinion that the human activity patterns area remains a confusing field of study that lacks a strong consensus within the scientific community. Because the data can be arranged in many ways and the

Handbook could not present all the distributions for each situation listed in the tables, the reviewers suggested that a structure for using human activity patterns data in exposure assessments and applications for the data be established. In addition, reviewers suggested that the chapter could be reduced in size.

Although the Westat results are from an established study, reviewers recommended that the survey and measurement procedures be described in the text of chapter 6 (Consumer Products). Reviewers also suggested that the chapter would benefit from the addition of citations obtained from available literature. For example, information is needed on either the proportion of users of consumer products or exposure to environmental tobacco smoke.

The human activity patterns work group made the following recommendations:

- information should be presented graphically wherever possible, given that illustrations can present information more comprehensively than text;
- raw time-activity data from the HAP studies should be made available in the Handbook to facilitate site or situation-specific exposure assessments;
- a short introduction or index should be added to the beginning of each chapter to increase the useability of the Handbook (the introduction could describe the context of the information presented in the chapter, explain what the information can be used for, and note where the information can be found);
- a comprehensive literature search of related fields should be conducted on inhalation rate, consumer product use, exposure assessments using activity patterns, population mobility, lifetime, and body weight;
- a full description of survey methods should be incorporated into chapter 1; and
- a conceptual framework for the information provided in the Handbook should be developed and presented in an introductory chapter.

Housing Characteristics and Indoor Environments

Considerable discussion took place among members of the housing characteristics and indoor environments work group on restructuring chapter 7 (Reference Residence) and developing a revised outline (which is provided in the work group chairperson's summary in section 3 of this report). The proposed outline includes all of the sections in the current draft Handbook except the one on interzonal mixing.

Reviewers agreed that the focus of this chapter should be on single zone modeling; however, they expressed the opinion that this model also should be placed in a larger context. Information should be made available for Handbook users who want to know more about multizones. Reviewers suggested that the chapter also move beyond inhalation to include some discussion on indoor exposures due to soil tracking and dermal contact with surfaces. In addition, reviewers recommended that a discussion on modeling approaches (computational tools) be added to the introduction of the chapter and that the references be updated to include new studies.

Reviewers described a residential model with direct emissions; transport of air, water, and soil from the outdoors; and reemission and resuspension as sources to the indoor environment. The model would account for air exchanges and leakage, as well as sinks and loss mechanisms due to deposition, transport out of the residence, reactions, and reversible sinks.

Reviewers identified future data needs and existing data gaps related to housing characteristics and indoor environments. In their view, information is needed on:

- source emissions;
- ceiling height as a function of construction year;
- suburban versus rural versus urban housing characteristics;
- single versus multifamily housing characteristics, including representative building plans;
- all useful air change per hour data sets;
- appliance characteristics (e.g., wash water temperature);
- building materials and furnishings;
- mechanical system configurations and rates;

- validated models; and
- transport (e.g., soil tracking).

OBSERVERS' COMMENTS

The workshop agenda included an opportunity for observers to make public statements during the morning plenary session on Tuesday, July 25, and the afternoon plenary session on Wednesday, July 26. Observers were asked to sign up if they intended to make a statement. At the discretion of each work group chair, observers also were provided an opportunity during work group sessions to participate in discussions.

Only one observer, Annette Guiseppi-Elie, Ph.D., of Mobil Oil Corporation and Chair of the American Industrial Health Council's Environmental Health Risk Assessment Subcommittee, made a statement during the plenary sessions. Dr. Guiseppi-Elie commended EPA for expanding the Handbook to include considerable new data and for sponsoring the peer review workshop. She stated that her initial observations are consistent with comments made previously by each of the four work group chairs. She expressed disappointment that single point distributions were used (chapter 4) and that the equivocal presentation of data made it difficult to generate distributions. She said the data presented in chapter 6 is incomplete and chapter 8 needs to be substantially expanded to include a discussion of the advantages and disadvantages of different methods of conducting uncertainty analyses. Dr. Guiseppi-Elie suggested that peer reviewers and the public be given adequate time to digest and comment on the Handbook. She concluded by suggesting the following revisions to the Handbook:

- With the many intended uses of the Handbook, the document is primarily a compilation of data. As such, the Agency should critically review relevant studies and avoid the use of default or reference values. Exposure assessors should have access to all available data, and the data should be presented in an appropriate format. Nevertheless, the Handbook should explain that in some instances—for example, screening analyses—reference values are useful.

- An extensive discussion on exposure assessment methodology is not needed. This subject is covered in other documents and the Handbook is not intended to be a guidance manual. For newer exposure assessment areas (e.g., consumer products),some guidance in the form of examples might be appropriate.

- The most up-to-date data should be provided in the Handbook.

- Data should be presented in a user-friendly manner.

- Because limited data are available on exposure parameters for soil ingestion and this pathway drives most risk assessments, the Agency should hold a smaller peer review meeting with experts in this field to address the issues associated with ingestion of soil by children and adults.

- The revised Handbook should be made available to the public before it is finalized.

- Chapter 8 should be either eliminated as it currently exists in the Handbook or expanded, improved, and peer reviewed.

APPENDIX A

REVIEWER LIST

United States
Environmental Protection Agency

Peer Review Workshop on Revisions to the Exposure Factors Handbook

Doubletree Hotel Park Terrace
Washington, DC
July 25-26, 1995

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APPENDIX B

PREMEETING COMMENTS

U.S. Environmental Protection Agency

Peer Review Workshop on Revisions to the Exposure Factors Handbook

Washington, DC
July 25-26, 1995

PREMEETING COMMENTS

Work Group #1

Food and beverage consumption

Barbara Petersen

COMMENTS ON THE EPA's Risk Assessment Forum

General comments:

The authors have attempted to include a wide variety of different data sources. It appears that the authors had little personal knowledge of the national food consumption surveys and the other data presented in the tables.

Equal weight was given to secondary analyses of original data (and even to secondary analyses of summary data) without adequate explanation as to the reason for reliance of secondary analyses. Prior to publication, the data tables must be carefully evaluated by experienced statisticians with specific knowledge of the original surveys designs, data reporting, etc. This will ensure that the data are not misused. The data need to be evaluated rather than simply summarized.

It is also important that each table be revised to address the following issues: (1) correct expression of the precision of the results, e.g. appropriate rounding of numbers, (2) presentation of the uncertainty of each data point, and (3) expansion of the footnotes to adequately explain data sources and manipulations as well as characteristics of the food categories, collapsing of foods into categories, etc.

In the time available, I have reviewed many of the tables and identified some issues. Although I have summarized some of these below, I am concerned that I may have missed some very important issues. Nonetheless, I wanted to provide a general indication of the types of issues that are of concern.

Water Intake:

- Needs an additional reference to the new USDA Continuing Survey of Food Intakes and the ability to estimate tap intake from this survey. (It is possible to use the factors developed by Ershow and Canter with the newer USDA surveys with minor additional considerations)

  Also needs a comment about the control of water intake. It seems highly unlikely that individuals continue over the long run to require 6-11 liters water/day (as noted on page 2-43). Such amounts are more likely to reflect short-term intakes before the body's homeostatic mechanisms can initiate water conservation. A factor for lengths of time individuals can be expected to maintain such high levels should be included.

- In the past few years, the quantities of commercial beverages and bottled water have increased and a source of such information should be included.

Food Intake Studies - Section 2.3.2:

This section is seriously out-of-date. In addition, there are several reanalyses of the same data that do not appear to provide potential users with any unique information but do appear to introduce significant sources for potential misuse of the data. The information that seems to be required should be obtained by directly analyzing the original survey and presenting those results along with references so that users can obtain the raw data for additional analyses.

USDA is now conducting a continue survey on an annual basis, called the Continuing Survey of Food Intakes by

Individuals (CSFII). This data is much more recent than the survey cited in this chapter. Data about food consumption in the United States are now available (on CD-ROM) through 1991-92. Three years can be combined to provide sample sizes of greater than 10,000 individuals (almost 30,000 days of food intake data).

The 1987-88 survey had methodological issues which should be noted in this chapter if data are included from that survey.

The tables that were developed by EPA's Office of Pesticide Programs and are presented in detail should be regarded as historical data. Similar tables should be generated using current (1989-1992) food consumption data or the user should be referred to these databases and provided with methodology to permit the user to compute similar estimates. Dietary patterns have changed substantially since 1977-78.

Likewise, the reference by Pao et al. (1982) is based on data which is almost 20 years old and should be updated using the more recent food consumption information. It should also be noted in the text that the categories used by Pao et al. (1982) do not necessarily capture all of the consumption of the item since foods in many mixed dishes were not included. For example, broccoli consumption includes only those dishes that are primarily broccoli and would miss the broccoli consumed in mixed dishes. Nor are all categories of foods included in the report.

The data in table 2-27 is useful for trend analyses but the user will require similar estimates to be derived from the 1989-92 CSFII. If this is not possible, a reference should be included to direct the user to the relevant data sources. These data are particularly useful because it includes foods consumed as part of mixed dishes (which represent a significant percentage of U.S. fruit and vegetable consumption).

It appears that the data in Table 2-28, 2-29, 2-30 and 2-32 also do not include fruits and vegetables consumed as part of a mixed dish. If this is correct, a footnote should be added.

On page 2-64, there is a presentation of an analysis by EPA using USDA NFCS food categories which are presented in Appendix 2-A. It is unclear whether the analysis was conducted using the USDA household data or the individual data. This needs to be carefully explained. If the household data are used, there needs to be a justification for why - when individual data are available. While this appears to include foods that are in "mixed dishes" it is very likely that this only includes those foods where the fruit or vegetable is the major component and that it also includes the quantities of components that are not intended to be included, e.g. grams of beef in a beef-vegetable stew. The EPA DRES approach is much more suitable for this type of an analysis. It is quite simple to combine EPA DRES individual fruits/vegetables into categories if that is the additional information that is being obtained through this approach.

There are significant differences in the estimates of intake which are obtained using the USDA household data and those from the individual intake and the user should be made aware of these differences. Furthermore, it is not a simple matter to apportion intake among members of the household - it requires careful development of factors reflecting the differing ages, activities, etc. This is particularly difficult when the results are then used to create distributes of intake and there is a significant likelihood of distorting the results.

The information presented in Tables 2-32 through 2-73 will certainly be misused without additional explanation of how the data were generated and the degree of uncertainty; the treatment of individuals within the households, the handling of mixed dishes, etc. etc. This data has been adjusted by body weight and, again, the handling of this key statistic within a household and the assignment of food intake/unit body weight needs to be explained. This analysis should have been done with the individual data rather than the household data (it may be that the data were generated using the individual data and that this is inadequately described in the accompanying text). In sum, Tables 2-32 through 2-73 should either be revised and fully explained or deleted from the handbook. (Note that there are similar tables obtained by the same analysis in other sections of this chapter and these comments apply to those Tables as well.)

2.3.2.3.:

These analyses are based on the out-of-date 1977-78 USDA survey. Similar methodology could readily be applied to the newer data and the user should be so instructed.

Page 2-110:

Canadian Department of National Health and Welfare Canada Survey.

Newer data are now available for many Canadian provinces.

Page 2-111:

A footnote should be added indicating that these are on a dry-weight basis. While this is clear in the text, it is extremely easy for such a table to be misused and it is worth the extra effort to associate this fact with the data.

Page 2-114 through 2-177:

The references for this information are entirely inadequate. Handbook 8 contains multiple entries for each of these foods and the procedure for extracting such estimates needs to be documented and accompanied with the associated uncertainty of the estimates. This table implies precision to two digits to the right of the decimal point - when, in fact, the precision is probably no more than ± 5% for most of the commodities listed. Presumably, this information is to be used in combination with the FDA Total Diet Study data - yet the data are presented for different categories of foods.

Table 2-79:

It needs to be reiterated that the data presented in Pao, et al. do not include all fruit and vegetable consumption.

The "traditional definition" needs to be carefully defined.

Page 2-121:

"Upper percentile per capita rates may be calculated using the consumer only distribution data in Tables 2-32 through 2-73 and the survey size data presented in Section

2.7. I do not believe this is correct. Before this statement is included, survey statisticians who have worked with the design and analysis of the USDA data (preferably at the USDA) should be consulted to ensure that the results are correctly presented and that the user is given appropriate guidance in correct use. The surveys have complex statistical designs and care must be taken to avoid misinterpreting the findings.

2.4.1 Intake Studies:

The same comments noted above apply here - the more recent surveys need to be included.

Likewise, the comments above apply to the information presented in Table 2-82 through 2-103.

Tables 2-103 through 2-105 reflect disappearance data. Waste and cooking losses need to be added to these estimates or the user fully informed as to the potential extent of these differences. This is particularly important for animal fats. The degree of precision implied in the estimates (2 significant digits to the right of the decimal) is unjustified.

Table 2-107. I do not understand the significance of the footnotes, e.g. composition of household. Also, it is not clear whether the amounts of consumption defined the categories or vice versa.

Table 2-108 would be more appropriate if it were taken from the nutrient data that accompanies the USDA survey results, e.g. for the same categories of food as are reflected as consumed in the survey and which are used for many of the other tables in this chapter. The degree of precision in this table is, again, unjustified; estimates of uncertainty should be included. These do not appear to match the levels of "trim" that were developed by USDA for use with the most recent surveys.

Page 2-165:

National Health and Nutrition Examination Survey III (NHANES III) is apparently mentioned for the first time in conjunction with food consumption information. A full description of the survey needs to be added along with references and a notation of the dates the information was collected. Also, the response rate needs to be defined more appropriately, e.g. I believe this only applies to the response of those individuals who otherwise completed the NHANES survey (clinical component, etc). The NHANES surveys provide another useful source of information and results from these surveys could be included in the handbook.

2.4.4. Recommendations:

Indicates that all results were based on USDA NFCS data. This is generally true, but it should be noted that data are included from other sources as well. Also, there have been many significant modifications of the USDA data - some with quite surprising impact on estimates of intake.

Also, I note in several places the statement, "the recommended average intake rates"..... I do not believe that USDA recommends an amount of intake of any specific food... Is the writer, rather suggesting that the "recommended value to use as an estimate of the average intake???

Table 2-111:

Since contaminant residues will be quite different for different sources of fat, I wonder what the utility of this table would be. I would recommend deleting it.

Breast Milk:

I do not feel qualified to accurately comment on this section. However, given my comments above and the importance of this information to EPA assessments, I strongly recommend that this chapter be submitted to a formal peer review ... by individuals experienced in the measurement of breast milk intake.

Fish and Shellfish:

On page 2-218, there is a presentation of an analysis by EPA using USDA NFCS food categories which are presented in Appendix 2-A. It is unclear whether the analysis was conducted using the USDA household data or the individual data. This needs to be carefully explained. If the household data are used, there needs to be a justification for why - when individual data are available. While this appears to include foods that are in "mixed dishes," it is very likely that this only includes those foods where the fish/shellfish is the major component and that it also includes the quantities of components that are not intended to be included, e.g. grams of fish in a vegetable/fish dish, etc. The EPA DRES approach is much more suitable for this type of an analysis. It is quite simple to combine EPA DRES individual fruits/vegetables into categories if that is the additional information that is being obtained through this approach.

There are significant differences in the estimates of intake which are obtained using the USDA household data and those from the individual intake and the user should be made aware of these differences. Furthermore, it is not a simple matter to apportion intake among members of the household -- it requires careful development of factors reflecting the differing ages, activities, etc.

The information presented in Tables 2-141 through 2-145 will certainly be misused without additional explanation of how the data were generated and the degree of uncertainty; the treatment of individuals within the households, the handling of mixed dishes, etc. etc. This data has been adjusted by body weight and, again, the handling of this key statistic within a household and the assignment of food intake/unit body weight needs to be explained. This analysis should have been done with the individual data rather than the household data (it may be that the data were generated using the individual data and that this is inadequately described in the accompanying text).

Table 2-137 and 2-138:

It seems highly unlikely that the degree of precision is justified given the conversion from lb/year.

Table 2-151:

It seems highly unlikely that the degree of precision is justified.

The reader should be given guidance as to the relevance of commencement Bay to other U.S. waters or to selected populations, etc.

Page 2-237:

The study that is referenced in the first full paragraph is unclear, e.g. "These values are much higher than the values obtained in this study...?" Is the study that is referenced U.S. EPA, 1993. According to this paragraph the U.S. EPA 1993 study is a reanalysis of the pierce data - is that correct? If so, the discrepancy needs to be explained.

Table 2-155:

The degree of precision expressed is unwarranted given the methodology, e.g. the balsa fish wood model.

Page 2-277:

Are the results expressed on a raw or cooked basis?

Page 2-292. First paragraph:

The conclusion confuses the Pao report with the original USDA data. Upper percentiles can certainly be obtained from any of the USDA surveys.

Table 2-181:

Implies far more precision than can be justified by the underlying data source.

Page 2-303:

Confuses the source of the information about homegrown food usage. Although there is a detailed description of the individual component of the USDA survey, that does not appear to be the source of information about homegrown vegetables. USDA collects substantially more information about the farm use of many commodities and EPA should make arrangements to obtain and use that data.

Tables 2-185 through 2-249:

The estimates of the intake of homegrown food will probably be one of the more important uses of the handbook. The selection of categories and the handling of the data need to be carefully evaluated. I have particular concern about the generation of percentile for subgroups, particularly age groups, which were derived from household data. Table 2-186 is a good example of the undue level of precision that is applied in these estimates.

The division of the population into regions and then into ages, seasons, etc. provides extremely small sample sizes. For example, in Table 2-189, a total of 3 < 01 from the south region. Yet these data were somehow used to generate percentiles!!!! I question whether even the mean is a useful value. Similarly in Table 2-207, percentiles were generated for Age 06-11 based on a single individual!!!!. (It should be noted that the intake estimates are the same at all the percentiles -- thus, a user would erroneously be estimating intakes). It is also extremely important that the user not combine intake of different foods at the upper percentiles.

The values do not appear to be reasonable estimates of intake from homegrown sources and should be carefully evaluated. An independent validation using data from another source is absolutely essential. At a minimum, these tables need to be edited and all values that have inadequate sample numbers be removed.

There is a reference to "homegrown exposed fruits" several places within the chapter. I did not find a list of the fruits that are included in this category. It is also important to ensure that the categories are consistently used in all estimates for exposed fruits, etc.

Soil:

I will defer to other peer reviewers who have worked on these types of estimates for their comments on this topic.

Paul Price

Comments on the June 1995 External Review Draft of the Exposure Factors Handbook

The 1995 revision of the Exposure Factors Handbook (Handbook) represents a substantial expansion of the basis on which exposure factors are derived. The Environmental Protection Agency (EPA) needs to be commended for the level of effort expended in preparing this draft. The topics critical to performing exposure analyses have been addressed and, in general, the Agency has done an reasonable job of summarizing the available literature on these key exposure factors.

The comments included in this document are divided into two sections. The first section presents general comments on the overall document and provides suggestions for how the document may be improved. The second section presents comments by chapter including general comments for the chapter and specific recommendations for revisions of the Handbook. In cases where important information was absent from a section, suggestions are made regarding additional references or the need for additional research.

GENERAL COMMENTS ON THE DOCUMENT

1. Providing Support for Standard or "Default" Distributions for Exposure Factors

A major issue of discussion at the 1992 workshop on the Exposure Factors Handbook was the extent to which the revised Handbook would provide support for statistical techniques such as Monte Carlo Analysis. Specifically, the discussion focused on whether the new Handbook should provide recommended or default distributions, in addition to the recommended point estimates for the typical and high percentile individuals. A consensus was not reached at the workshop on this issue.

The current document reflects this ambiguity. The Handbook provides detailed information on interindividual variation in factor values as presented in key studies; however, no default distributions for any of the factors are specified. Typically, the information is presented as a table of values (consumption rates, duration periods, etc.) for selected percentiles of the surveyed population. In addition, the document discusses many of the papers by Dr. David Burmaster and various coauthors, that present distributions of interindividual variation in exposure factors, as well as the 1992 Guidelines for Performing Exposure Assessment, that emphasizes the importance of characterizing interindividual variation in exposure. However as stated earlier, the current draft does not specify a default distribution for any of the factors. For certain factors, such as tapwater consumption, the Handbook does make a recommendation for using a particular distribution. However, for other factors such as fish intake, no distribution is recommended.

Not providing a distribution on interindividual variation presents a fundamental contradiction for EPA because the data required to document values for a typical individual (represented by the average or median individual) and the high-end individual (represented by a value for an individual in the top 10 percent of the population) will also be adequate to justify a distribution. For certain factors EPA may find that there are insufficient data to recommend either a distribution or values for point estimates for the typical or high-end individual. In such cases, the Agency should acknowledge the lack of data and simply put forward the results of available studies. However, the Agency cannot maintain that data are available to specify the point estimates, but not for describing a distribution.

An appropriate way for the Exposure Factors Handbook to address the issue of distributions of interpersonal variation would be to identify three data availability categories as a means to classify data on each of the various factors. The first category would represent those factors with sufficient data to allow the development of both point estimates for the typical and high-end individual and a sufficient number of other percentiles of the distribution to allow Monte Carlo and other statistical techniques to be used. The second category would include those parameters that had enough data that EPA was able to specify point estimates for the typical and high-end individual. Parameters in this category might have some uncertainty; however the uncertainty would fall within a sufficiently narrow range that the point estimate would still have meaning, although data would be insufficient to allow the development of a distribution. Finally, a third category would contain parameters that the Agency is unable to specify either point estimates or distributions.

Guidance for developing distributions for factors can be found in Finley et al. (1994) and in the draft versions of "Developing Distributions for Use in Probabilistic Exposure Assessment" by Cullen and Frey (draft version expected late 1995).

2. Discussion of Scenario-Based Exposures

The Exposure Factors Handbook of 1989 and the revised draft version provide risk assessors using scenario-based exposure estimate techniques with default or general guidance on values of exposure parameters. However, neither document clearly identifies the role of the Handbook in developing scenario-based exposure assessment techniques. To this end, it is recommended that the introduction be expanded to clearly identify that the Handbook is intended to provide guidance for scenario-based exposure assessments. In addition, the introduction should discuss the strengths and limitations of scenario-based estimates of exposure.

Issues that should be discussed in an expanded introduction include: impacts of simplifying assumptions in exposure scenarios, uncertainty in the applicability of exposure scenarios to specific sites of environmental contamination, and the use of scenario-based exposure assessments in models of interindividual dose rate variations. Although some of these issues are discussed in the current chapter on uncertainty, they should be mentioned earlier in order to provide a context for decisions concerning the development of specific factors.

3. Research Needs

While the purpose of the Exposure Factors Handbook is not to present new research findings, but rather, to summarize the information in the published literature, in several instances relatively simple analyses on existing data could be conducted to produce distributions of point estimate exposure factors that will be greatly superior to the information currently available in the published literature. EPA should give serious consideration to providing support to short-term data analysis projects which would improve the basis for many exposure factors. Specific examples of such research needs will be provided in the following sections.

4. Need to Differentiate Between Different Types of Studies

In many of the chapters, EPA apparently used a single format for summarizing the results of published studies. This single format did not differentiate between studies that generated new data (surveys) and studies which analyzed the existing data. This approach obscured the significance of many studies. In the chapter specific section, recommendations are made for reorganizing the relevant studies into various categories.

5. Additional References

Attached are several references to studies that warrant consideration for inclusion in the Handbook.

6. Discussion of Uncertainty in the Studies

Throughout the Handbook a paragraph is included at the end of each study that dutifully tolls a list of potential limitations and biases. While such a list may be helpful for individuals looking up an individual study in the Handbook to obtain a brief overview of the study and its findings, the list of potential biases is presented without any indication of how the use of the study would be affected by the individual biases. A more helpful approach would be to group similar types of studies and discuss the overall implications of the biases common to that particular group.

A larger problem with the listing is that the information on uncertainty is not used in any objective way in the selection of the recommended point estimate values. EPA should discuss how the limitations of each study (biases, uncertainties, etc) were taken into consideration in the selection of recommended values.

7. Significant Figures

All recommendations on point estimates should be limited to the appropriate number of significant figures. For example four significant figures are given for the typical breast milk ingestion rate and three figures for inhalation rate.

CHAPTER SPECIFIC COMMENTS

CHAPTER 1 INTRODUCTION

Specific Comments

- On page 1-2 EPA provides guidance for eliminating Part II of the 1989 Handbook. This decision is a proper one; however, it should be recognized that by proposing specific equations for scenarios, EPA is still defining a specific method for deriving toxicological relevant doses for various exposure pathways. Although useful, these methods should not preclude the use of more sophisticated techniques for modeling, when warranted.

- In the last paragraph on page 1-3, the text lists steps for performing exposure assessments. The first step, determining pathways of exposure, should include steps 2 and 5. Defining a pathway of exposure requires identification of the source media by which the contaminant is transmitted to an exposured population as well as a characterization of the exposed population.

- EPA states on page 1-6, that the averaging time period for chronic noncancer effects is the actual period of exposure. This is not an appropriate assumption and is inconsistent with the following sentence that states that the averaging time should express the dose that is comparable to the dose response relationship of the effect being evaluated. Many RfDs are based upon reproductive or systemic effects that occur as a result of exposure over a few months or years. Where the periods of exposure are significantly longer than the duration of exposure associated with the adverse effect, the use of an exposure duration will underestimate the potential for risk. This issue is not important for estimates of chronic exposure that do not consider temporal variations in exposure parameters; however, it can be critical in the evaluation of time-varying sources of contamination.

- On page 1-8, the last sentence in Section 1.2 should be rewritten to read:

  "since a different person could be exposed during each of seven sequential 10-year periods."

CHAPTER 2 INGESTION ROUTE

2.1 Dose Equation for Ingestion

- No comments

2.2 Drinking Water Consumption

Specific Comments

- On page 2-15, EPA lists Rosemary and Burmaster (1992) as another study of tapwater intake that produced raw data. As discussed above, studies which reanalyze existing data should be evaluated differently than those which present raw data. Specifically, EPA should indicate whether the new analysis is more useful (than the original study) for characterizing the values for exposure factors.

- The EPA provides data on page 2-26, on the consumption of raw tapwater from USEPA (1984d). In certain instances where the chemicals of concern include highly volatile chemicals such as radon or vinyl chloride, the potential for exposure from tapwater in coffee, tea, or reconstituted soups and beverages may not be relevant to the exposure assessment. During the process of beverage or food preparation, such chemicals are likely to be volatilized from tapwater. In these cases, information on the amount of water consumed directly (and likely to have the highest potential of retaining the volatile compounds) is most relevant.

- In Section 2.2.2.5., High Activity Levels/High Climates, EPA reviews a series of studies on the impact of ambient temperature on tapwater consumption rate. This section should be expanded to consider the information on seasonal and geographic variation in tapwater consumption rate in the general population as presented by Ershow and Cantor (1989) as well as other studies based upon the Pennington data. These studies demonstrate that regional and seasonal differences have almost no effect on the distribution of tapwater consumption rates for any age group in the general population. This suggests that the vast majority of the U.S. population deals with high external temperatures by spending more time in climate controlled areas or by reducing activity, not by drinking more water.

  The finding from Ershow and Cantor (1989) is not inconsistent with other individual studies that documented increased needs for fluid intakes under a combination of high levels of activity and high temperatures. However, it is important to note that high levels of activity in high temperatures do not typically occur in the general population. Therefore, only scenarios that specifically assume that the high levels of activity will occur during times of high temperature should consider the potential for increased fluid intake. In all other cases, there appears to be little need for deriving seasonal or geographic-specific estimates of tapwater consumption for the general population. This point is not well made in the current document.

- On page 2-41, EPA proposes an estimate for the typical and upper percentile drinking water consumption rates for adults. In the last sentence, the Handbook also indicates that the distribution generated by Roseberry and Burmaster (1992) may be used. Is the Agency endorsing the results of this study as default distribution for tapwater consumption rate? If so, then why have similar studies not been endorsed for other parameters? Assuming EPA wishes to endorse a distribution for tapwater consumption rates, EPA should also acknowledge that the interindividual variation in tapwater consumption rates could be characterized using the percentiles presented by Ershow and Cantor (1989).

- On page 2-43, EPA presents its recommendations for high activity/hot climates. The recommendations should be modified to reflect previous comments. It is not appropriate to recommend that the value of 6-11 liters per day be used to characterize tapwater consumption rate for the portion of the general population not specifically involved in high levels of activities.

2.3 Consumption of Fruits and Vegetables

Specific Comments

- In Section 2.3, it would be helpful to provide the distribution of total root crops and total above ground surface crops that are consumed. Such estimates would be relevant when evaluating the different exposure pathways that may affect food crops.

2.4 Consumption of Meat, Poultry, and Dairy Products

Specific comments

- On page 2-152, information collected by the USDA's economic research service is discussed. The USDA also collects information on cattle and other livestock beef that is slaughtered for home consumption. This information can be used to derive consumption rates for beef and other types of meat for ranchers and their families, an important subpopulation for risk assessment. The data is collected as part of the yearly agricultural survey performed on the nation's farms and ranches, although it is not reported in the USDA annual report on food consumption prices and expenditures. A copy of the survey can be provided to EPA, if requested. Adjustments to account for home grown beef consumption from this data would be very useful, because they are based upon annual reports and would provide a measure of long-term beef consumption.

- The expansion of the Handbook to consider poultry products is commendable.

2.5 Breast Milk Intake

Based upon the data presented by EPA in the Handbook, the mean and upper percentile breast milk and lipid uptake rates for infants calculated by EPA appear to be reasonable and based on the most current science. The available data on this parameter appears to be sufficiently adequate to warrant including the full distribution of consumption rates in the recommendations. Providing all the relevant data will enable risk assessors to develop probability distributions for evaluating uncertainty and to complete probabilistic exposure analyses. Of equal importance, EPA should provide an interpretive discussion of the recommended values for the breast milk related factors, including the limitations and uncertainties associated with each, for evaluating infant exposures to chemicals that have accumulated in breast milk.

Specific Comments

- The Handbook would be greatly improved by providing more comprehensive information on the distribution of breast milk intake rates for different breast feeding intervals as well as distributions for time-weighted averages. In addition, the Handbook should identify distributions for exposure duration, that is, the length of time that infants are breast-fed.

- Exposure duration data should cover not only cover the general population, but should also be stratified by applicable demographic factors such as geographic location, race, and socioeconomic status.

- A significant short coming of the draft guidelines is the lack of any discussion regarding the use of recommended factors to estimate exposure to infants from breast feeding. Such a discussion is critical to assure that risk assessors use the recommended exposure factors appropriately and have a clear understanding of the limitations and uncertainties associated with the data.

- On page 2-185, EPA again treats the Maxwell and Burmaster study (1993)as a study that presents new data, even though the study is a reanalysis of Duey et al. (1991).

- On page 5-195, the recommendations for breast milk intake should not be given to four significant figures. Rather, the numbers should be rounded to 700 and 1000 milliliters per day for the two point estimates.

2.6 Intake of Fish and Shellfish

General Comments

Overall, Section 2.6 has been greatly expanded over the 1989 Handbook. The expanded section reflects the fact that fish and shellfish consumption has been the subject of many studies since the late 1980s.

Unfortunately, the current section reads like a compendium with little synthesis or interpretation. Because the body of research is now reasonably large, for any particular application there are likely to be several potentially applicable studies to serve as basis for fish consumption rate estimates. EPA should provide guidance on which studies are the most relevant for various scenarios. In addition, judgment as to quality or applicability of studies for exposure assessment is confined to classifying a study as either "key" or "relevant" and to including a brief advantages/limitations paragraph in summarizing each study. The reason for classifying any one study as "key" vs. "relevant" is not given. In addition, the advantages/limitations comments are not directly comparable across studies to assist in understanding the key vs. relevant classifications. This is a major flaw in the current document.

Specific comments

- A more useful format than the existing Table 2-180 for evaluating the studies for applicability on a site-specific basis might be a matrix classifying studies by (1) population type (anglers, general population); (2) survey type (creel, mail, telephone); (3) water body type and size (marine/estuarine, freshwater, single waterbody, regional coverage); (4) recall period (length, seasonal coverage); (5) available data (summary statistics only vs. full distributions, groupings of rates by demographic categories) and some qualitative ratings for key quality evaluation criteria; (6) design relevance; (7) sample size; (8) response rate; and (9) representativeness).

- The term "fishermen" should be replaced with the more general term "anglers" throughout.

- The distinction between fish consumption measurement/estimation studies and reanalyses of measurement/estimation studies published by others should be clearly stated. The latter can be used for interpreting and applying the former. For example, the Price et al. (1994) study should be discussed in the section with the Puffer et al. (1981) and Pierce et al. (1981) studies, and the Ruffle et al. (1994) study should be discussed with the Javitz (1980) and Rupp et al. (1980) studies. This approach will provide commentary on whether the reanalyzed study or the original study provides the best basis for deriving parameter values and distributions.

- Potentially useful information missing from the present draft is a compilation and summary of the published information on fish/shellfish meal size. Meal sizes ranging from approximately 120 to more than 250 grams have been used both in measurement/estimation studies and subsequent risk assessments. While annualized fish consumption rates sometimes negate the need for meal size estimates, there are often occasions where meal size is a relevant exposure factor or interpretive tool.

- The discussion of other factors to consider in selecting and using fish/shellfish consumption rates (e.g., edible parts/portion, preparation methods, losses due to cooking, lipid normalization, dry to wet weight conversions) should be moved out of the recommendations section (2.6.9) and into its own section.

- The issue of cooking loss should be discussed in the Handbook. While the degree of cooking loss is chemical-specific, the frequency of use of cooking methods is not. The frequency of cooking method is a key issue in evaluating cooking loss and should be presented in the handbook. Data on relative frequencies of various cooking methods are available in a number of studies (Connelly, et al. 1990, 1992; Chemrisk , 1991).

- On page 2-201, the last paragraph on this page appears to be incorrect. Individuals at or above the 90th percentile of fishing frequency are by definition frequent fisherman. As such, they would be expected to contribute more than 10% of the overall fishing effort from the total population of anglers. The same applies to the median intakes.

- On page 2-273, in EPA's discussion of the Pierce et al. (1981) study, the Agency confuses the finding of Pierce et al. (1981) with those of USEPA (1993). Pierce did not attempt to develop estimates of fish consumption for individual anglers. EPA developed estimates in the original Exposure Factors Handbook and in EPA (1993).

- The discussion on page 2-242 of Price et al. (1994) is difficult to follow and fails to highlight the essential finding of the paper (i.e., that all creel surveys have the potential to overestimate consumption rates). This finding is glossed over and the study is treated as a survey of fish consumption rates. Instead, the results of Price et al. (1994) should be included with the discussion of the Puffer et al. and Pierce et al. case studies and a discussion of the importance of the bias inherent in the use of creel surveys in developing recommendations for point estimates for fish consumption rates should be added.

- On page 2-291, EPA's recommendations for marine anglers is inappropriate. As demonstrated in Price et al. (1994), the values reported by Puffer and Pierce do not accurately reflect the distributions of consumption rates in the population of anglers. Rather, they are biased towards reporting the results for anglers that have a high frequency of using the surveyed bodies of water. As a result, the estimate of the mean or median, as well as the upper percentiles of the distribution dose rate, overestimate the true values by one to two orders of magnitude for the median and upper percentiles. Although, this point is made on page 201, it is not carried through to the recommendations section. Similarly, while Price et al. (1994) did not evaluate the results from the Santa Monica survey, the same potential for bias also exists.

  Therefore, EPA is encouraged to perform a reanalysis of the Santa Monica survey using the methodology outlined in Price et al. (1994). A reanalysis will allow the development of adjusted estimates of the median and 90th (or 95th) percentile, that can be used as the basis of the typical and upper percentile fish consumption rate. The results of the three creel studies (Puffer et al., Pierce et al., and Santa Monica) after adjustment would be appropriate guidance for evaluating consumption rates for marine anglers fishing in highly productive waters. In addition, because the methodology and the survey results produce a full distribution of fish consumption rates, the entire distribution can be recommended as a distribution for probabilistic analysis.

- The basis for the selection of studies included in the recreational freshwater anglers is unclear. Several studies which surveyed a larger number of anglers and had a higher response rate were not included in the list. At a minimum, EPA should provide a clear rationale for including certain recreational angler studies and excluding others.

- On page 2-292, the basis for the Native American freshwater angler estimates do not include other studies which indicate that other Native American populations consume lower fish consumption rates. These studies (cited in attached reference list) should also be discussed and evaluated as a potential consumption rate estimate for Native American anglers.

- On page 2-293, EPA provides an equation for developing estimates of the consumption of fat from fish meals. Fish consumption rates in most surveys do not take into account the reduction in fish size that occurs during trimming or cooking. Therefore, the use of fish consumption rates in conjunction with levels of fat that reflect as consumed can lead to poor estimates of the total amount of fat consumed in fish meals. Since Table 2-181 presents many species where the total percent of fat is reported based upon cooked or prepared fish, there is a significant potential for error.

Section 2.7 Intake Rates for Various Home Produced Food Items

The homegrown intake studies in Section 2.7 are based on a U.S. Department of Agriculture Nationwide Food Consumption Survey (NFCSs) from 1987-88. These data were used over earlier NFCS studies because they are believed to be more reflective of current eating patterns in the US. Using these data, EPA has developed a series of equations that result in homegrown intake rates for fruits, vegetables, meats, poultry, and dairy products in different regions and for specific ethnic groups.

Specific Comments

- It is unclear why EPA is assuming that the NFCS surveys should be the only source for determining homegrown intake rates. In the 1989 Handbook, a variety of studies were referenced to derive a homegrown percentage for intake rates. The NFCS derivation may be more definitive, but a comparison to alternative derivations would also be useful. In addition, the real usefulness of this information is somewhat questionable.

- For adults, the fish consumption mean is about 70 g/day, which is very high in comparison to mean rates reported in Section 2.6.

- The conclusions to Sections 2.7, as well as 2.3 and 2.4 are quite disappointing. Instead, it would be more helpful if EPA presented total intake rates in the text similar to the 1989 version. Without these conclusions, the reader must wade through the myriads of tables to determine total intake of poultry or other food items.

2.8 Soil Ingestion and Pica

Overall, the 1995 Handbook bases its estimates upon a considerably more robust data set than was available in 1989.

Specific Comments

- In deriving soil ingestion estimates for children, EPA focuses on mean values as measures of central tendency. However, each of the five data sets that EPA cites in its presentation of the range of soil ingestion rates is characterized by considerable variability. In such cases, the median is the more appropriate measure of central tendency, as it is less likely to be influenced by extreme values in the data set.

- EPA should be commended for its recognition of the extreme value presented by the pica child in the Calabrese (1989) data set, and the variability of the titanium tracer in all of the cited studies, as a justification for recommending a soil ingestion estimate of 100 mg/day.

- A conspicuous absence is Calabrese (1992), "What Proportion of Household Dust is Derived from Outdoor soil?". This paper estimated the amount of outdoor soil in indoor dust in the Calabrese et al. (1989) study. Based upon the results of this study, Calabrese et al. (1989) recommend that the median outdoor soil ingestion rate be reduced by 35%, stating that 'for the three most reliable tracers, the median soil ingestion estimates would be reduced from 29 to 19 mg/day for Al, 55 to 36 mg/day for Ti, and 16 to 190 mg/day for Zr."

- Several investigators have shown that mouthing behavior declines after the age of three (Hawley, 1985; LaGoy, 1987; Sedman, 1989). This would lead to reduction in soil ingestion among children aged 3 to 6. There is no mention of these studies in the soil ingestion chapter.

- It is unreasonable to base the recommended abnormal soil ingestion estimate of 10-14 g/day upon data provided by a single child (the pica child in the Calabrese study). Additional abnormal soil ingestion data should be reviewed in order to derive a more accurate estimate for pica children.

CHAPTER 3 INHALATION ROUTE

General Comments

This section presents a useful segregation of available studies into those which evaluated short-term inhalation rates and those which evaluated chronic inhalation rates. EPA has correctly determined estimates of long-term inhalation rates using the stoichiometric approach to estimating oxygen needs presented in Layton (1993).

Specific Comments

- On page 3-46, EPA inappropriately recommends using a value of 13.3 cubic meters per day based upon a simple arithmetic mean of the recent approaches presented in Layton (1993). Instead, EPA should determine which of the three approaches used by Layton will provide the most accurate estimate and use that approach to derive a recommended value. In addition, providing three significant figures for a "typical" inhalation rate is inappropriate.

- The recommendations for the upper end of inhalation rates and the inhalation rates for children are better estimated by using the relationship between body weight and inhalation rate developed by Layton to calculate the distribution of inhalation rates in the human population (see Finley et al., 1994). The result of this approach is a series of age-specific distributions for inhalation rates which can be used to select both the typical and high percentile inhalation rate.

- To be consistent, the value for the ventilation rate during heavy exercise given on page 3-2, paragraph 1 should be in the units of liters/minute.

- Footnote C in Section 3.2.2, Table 3-12 incorrectly refers to Tables 3-8 and 3-9. The tables that should be referred to are Tables 3-11 and 3-10.

- In Section 3.2.2, Table 3-13, the "Age" column and the "Adult Male" category are incorrectly footnoted. The correct footnote is k, not d. In this same table under column labeled "moderate", the value corresponding to the adult female is either incorrectly footnoted or the value should not be in the table.

- The footnote "h" in Table 3-14 shows moderate activity for males as "moving." The text, however, states that the males are "mowing." These should be consistent.

- The units in Table 3-15 for VR should read m^3/hr, not M^3/hr.

- The footnotes a and b in Table 3-16 should be switched.

- It appears as if the conclusions on page 3-33 to the Shamoo et al., study are omitted from the text. Since the purpose of this study was to demonstrate the accuracy of self estimating ventilation rates, a discussion regarding the accuracy of self estimating ventilation should be provided.

- On page 3-36, paragraph 1, the text directs the reader to Table 3-18 for a presentation of inhalation rates by age, gender, and activity level. However, this is not the data that is shown in Table 3-18. It appears as if a table is missing from the main body of text. If this is the case, this table should be included.

- The statement made on page 3-45, paragraph 2, comparing the activity of the 13-17 year old age group to that of the older adults is subjective and should be deleted.

- No backup information is provided on page 3-46 of the Handbook regarding the justification of the 20 m^3/day value from the EPA Ambient Water Quality Criteria Document. The studies used to derive the 20 m^3/day inhalation rate for the EPA Water Quality document should be summarized in either sections 3.2.2 or 3.2.4, with a reference provided in the text.

- The reference to Table 3-11 on page 3-47 should be deleted from the summary table.

- No upper percentile value is provided for infants or children on page 3-47.

- The inhalation rate values for the outdoor worker/athlete for the slow and medium categories given in Section 3.2.4, page 3-48, paragraph 2 (1.1 m^3/hr and 1.5 m^3/hr, respectively) are low when compared with the values for these categories in Tables 3-7 and 3-9. In Table 3-7, the inhalation rate for outdoor workers at a slow and medium pace are 1.26 m^3/hr and 1.50 m^3/hr, respectively. Similarly, the average of all subjects at a slow and medium pace as summarized in Table 3-9 are 1.44 m^3/hr and 1.86 m^3/hr, respectively. If the lower values are given as exposure factors, further explanation of their derivation should be provided.

CHAPTER 4 DERMAL ROUTE

Specific Comments

- The study by Phillips et al. (1993) indicated that due to the strong correlation (0.986) between surface area and body weight the use of surface area to body weight ratios in exposure assessments is more appropriate than treating each as an independent variable in the equation. This point is important for Monte Carlo analyses of risk and less important for point estimates. The Handbook should make note of this fact in its discussion of the study advantages and disadvantages.

- . The revised Handbook gives little attention to the issue of fraction of surface area exposed. In drawing upon EPA (1992), the Handbook does note that clothing cannot always be assumed to protect against dermal exposures to contaminants carried on fine dust or in liquid suspension (e.g., some pesticides). With respect to soil exposures, the Handbook continues to assume that clothing limits exposure to contaminants in soil.

- The allowance for modifications to the estimates based on climate considerations appear to be reasonable. Assumptions of 5% for winter, 10% for spring and fall, and 25% for summer are appropriate defaults in the absence of site-specific information.

- The Handbook should indicate that the fraction of skin exposed is highly dependent on site- or exposure scenario-specific assumptions and that the proposed values should not be take as absolute values.

- The section on dermal adherence of soil should include the paper by Finley et al.(1994).

- Due to the comprehensive nature of the study by Kissel et al. (1995), and the fact that it provides data on actual field conditions, the revised Handbook recommends that this study serve as the basis for dermal adherence assumptions. While dermal adherence factors for most activities and body parts were well within the range originally identified by EPA (1992) (0.2 - 1.0 mg/cm^2), the activity termed "kids-in-mud" resulted in adherence values between 35 and 58 mg/cm^2.

- Risks from dermal exposure are directly proportional to the dermal adherence factor; thus, risk estimates resulting from the use of the Kissel et al. (1995) study would be greater by at least a factor of 35 up to a factor of almost 300 than those estimated with the EPA (1992) range for activities of this type. While the reported values appear to be plausible for the scenario described. The use of their values in the equation provided in this section may not result in plausible estimates of dermal exposure. Particularly when a fraction of contaminant approach is used to characterize the dose rate (see page 4-3). In many instances, assumptions about the fraction of contaminant that is absorbed is based upon a scenario of a thin layer of dirt which comes in direct contact with the stratum corneum, in the absence of an intervening barrier of water. In such situations, nonpolar compounds can directly defuse from the organic portion of the soil into the stratum corneum and be available for absorption. This scenario is not appropriate for thick layers of mud. Under these circumstances, the vast majority of the material would not come in direct contact with the skin and would not be available for absorption. In addition, where sufficient water is present a significant barrier may prevent the transport of lipophilic compounds from soils particles to the stratum corneum. The current document should provide a warning on the use of such high values for dermal adherence.

CHAPTER 5 OTHER FACTORS FOR EXPOSURE CALCULATIONS

5.1. Lifetime

Specific Comments

- The current text inappropriately suggests that gender- and race-related differences in lifespan may be incorporated in the estimate of the LADD. This may not be appropriate. Lifetime, is used as a factor in the derivation of the lifetime average daily dose (LADD). In this equation, the factor serves as a metric for extrapolating the impact of duration in toxicological testing across species. As such, the impact of variation in lifespan in different subpopulations or in individuals is unclear. To the extent that the variation in a subpopulation reflects genetic-specific differences in lifespan and not differences in socioeconomic behavior, an argument could be made for use of slightly different lifespans for different subpopulations (such as men, women, racial groups). However, differences in lifespan that are due to other factors such as elevated death rates from accidents or other non-health related factors should not be considered. In addition, the actual age when an individual dies should not be considered in deriving the LADD. The Exposure Factors Handbook should include this discussion to avoid errors when placing distributions of lifetimes in Monte Carlo models of LADDs.

5.2 Body Weight Studies

No comments

5.3. Activity Patterns

Specific comments

- The factor for occupational mobility is inappropriately grouped in the activity pattern section. It should be placed in a separate section, similar to population mobility. Additional information on occupational tenure is available from studies by the Department of Labor. Specific references can be provided, if requested. In addition, a simulation of occupational tenure was developed in Price et al. (1991).

5.4. Population Mobility

General Comments

- Section 5.4 is insufficient in that EPA has failed to provide any analysis or evaluation of the studies presented. To improve the usefulness of this section, EPA should include insight on how the study results should be used in calculating duration for residentially-related exposures.

Specific Comments

- Section 5.4 would benefit from an additional discussion of how residential duration, as determined by population mobility, influences various scenarios and how information on changing residence, changing counties, and changing states, can be use in different exposure scenarios. For example, where a source of contamination is related to a specific home or a specific location, any change in housing location can be assumed to remove the exposure. As a result, duration is determined by the residential occupancy period. In contrast, where a source of contamination affects an entire county (such as a wide-spread air pollution, or the use of a local body of water for fishing) moves that do not result in the individual leaving a community or area will not result in the ending of exposure.

- Population mobility information from the IRS is available for any county in the U.S. and should be identified as an additional source of information.

- The use of residential occupancy in determining doses presents a number of complexities which warrant discussion in Section 5.4. For example, if the purpose of an exposure assessment is to characterize future doses to a population currently living at an affected site then a distribution of residential duration should only reflect the future residency starting from the present. If the scenario assumes that an individual will be exposed during his or her entire duration of residence the distribution should be based on the period of total residency. A third distribution should be used if the assessor was interested in characterizing historical exposures to a population currently living at a site. This distribution should be based on the number of years in the past individuals have lived in their current houses.

- This section also fails to provide any guidance for selecting either point estimates or distributions of duration.

CHAPTER 6 CONSUMER PRODUCTS

No comments

CHAPTER 7 REFERENCE RESIDENCE

General Comments

Referencing of research papers and reports in Chapter 7 is not consistent with other sections of the Handbook.

Specific Comments

- Latex and oil based paints should be added as common wall coverings on page 7-8. In addition, carpeting, waxes, and acrylic floor finish should be added as common products used for floor surfaces.

- A column should be added to Table 7-4 describing the types of airborne contaminants likely to be emitted by each of the common products associated with wall and floor coverings. This information may aide the analyst in determining the potential sources and source contribution of indoor air pollution.

- The last sentence in paragraph 2 on page 7-10 regarding the strength of stack forces during the warming season versus the cooling season generalizes that the cooling season indoor-outdoor temperature differences are not pronounced. This is dependent on what part of the country is being studied. However, where there is a pronounced indoor-outdoor temperature difference (i.e., in the higher latitudes), it is likely that the stack effect will be minimized due to the restricted air flow caused by closed windows perhaps affixed with additional storm windows and closed doors.

- It should be noted that the exception to diluting indoor air pollution with outdoor occurs when the outdoor air is the source of the indoor air pollution. If this is the case, increased mixing of indoor air with outdoor air will not necessarily result in the dilution of contamination in indoor air (page 7-11, paragraph 1).

- Values for air exchange rates given in the "Earlier Studies" subsection on page 7-12 are reported as the geometric mean of the sample population. This indicates that the data in that population were lognormally distributed. Air exchange rates given in Table 7-5 are expressed as both the arithmetic and geometric mean of the sample population. It should be made clear to the reader which value, the arithmetic or the geometric mean, should be used in assessing the potential air exchange rates within a household.

- An extra open parenthesis is found just prior to the word "volume" on page 7-17, paragraph 1. This parenthesis should be deleted.

- The variable, V, representing the household volume is expressed as both lower and upper case. This should be made consistent throughout Section 7.3.3.

- In the example given on page 7-18, the resulting air exchange rate shown as 27.0 m^3 should be 27.0 $m^3 h^{-1}$.

CHAPTER 8 ANALYSIS OF UNCERTAINTIES

General Comments

This chapter addresses an important topic that is the focus of much recent research. While the existing sections provide a discussion of several important aspects, they do not address many of the issues included in the March 1995 memorandum on risk communication issued by Carol Browner and the recent literature on methods and applications of uncertainty analysis within exposure assessment. Recent volumes of *Risk Analysis* and the *Journal of Exposure Analysis and Environmental Epidemiology* provide relevant material as well as the 1990 text *Uncertainty* by Morgan and Henrion (1990).

EPA should revise and expand Chapter 8. A suggested outline for the chapter is attached.

Specific Comments

- The @Risk software package (Palisades Corp.) identified on page 8-6, can perform sensitivity analysis within the probabilistic analysis setting. In addition, analyses that incorporate dependencies among parameters can be constructed relatively easily either directly or by age- or gender-stratification. In addition, Monte Carlo analysis offers an extremely powerful tool for evaluation of nonlinear relationships between factors and dose rates. Scatterplots of matched pairs of inputs for selected factors and the dose results for individual iterations of a Monte Carlo model provide a very useful description of the interrelationship between any given factor and the dose estimates.

- Monte Carlo analysis can also incorporate information on interdependence in exposure factors. In addition, intelligent design of distribution selection can allow the effective modeling of the parameter interaction (see for example Phillips et al. (1993)).

Additional References for Use in the Preliminary Draft Exposure Factors Handbook

2.4 CONSUMPTION OF MEAT, POULTRY AND DAIRY PRODUCTS

Texas Agricultural Statistics Service. 1994. *Agricultural Survey: January 1, 1994.* Texas Agricultural Statistics Service, Austin, TX.

2.6 INTAKE OF FISH AND SHELLFISH

ATSDR. 1995. *Final Report: Exposure to PCBs from Hazardous Waste Among Mohawk Women and Infants at Akwesasne.* Prepared by the Bureau of Environmental and Occupational Epidemiology, New York State Department of Health and Health Research, Inc. for the U.S. Department of Health and Human Services, Atlanta, Georgia. PB95-159935. January.

ATSDR. 1995. *Final Report: Health Study to Assess the Human Health Effects of Mercury Exposure to Fish Consumed from the Everglades.* Prepared by the Division of Environmental Epidemiology, Florida Department of Health and Rehabilitative Services, Tallahassee, Florida for the U.S. Department of Health and Human Services, Atlanta, Georgia. PB95-167276. January.

Connelly, N.A. and T.L. Brown. 1995. Use of angler diaries to examine biases associated with 12-month recall on mail questionnaires. *Trans. Am. Fish. Soc.* 124:413-422.

Connelly, N.A., B.A. Knuth, and C.A. Bisogni. 1992. *Effects of the Health Advisory Changes on Fishing Habits and Fish Consumption in New York Sport Fisheries.* Human Dimension Research Unit, Department of Natural Resources, New York State College of Agriculture and Life Sciences, Fernow Hall, Cornell University, Ithaca, NY. Report for the New York Sea Grant Institute Project No. R/FHD-2-PD. September.

Degner, R.L., C.M. Adams, S.D. Moss, and S.K. Mack. 1994. *Per Capita Fish and Shellfish Consumption in Florida.* Prepared by Florida Agricultural Market Research Center a part of the Food and Resource Economics Department Institute of Food and Agricultural Sciences, University of Florida, Gainesville, FL for the Florida Department of Environmental Protection. August 31.

Ebert, E.S., S.H. Su, T.J. Barry, M.N. Gray, and N.W. Harrington. 1995. Estimated rates of fish consumption by anglers participating in the Connecticut Housatonic River creel survey. *N. Am. J. Fish. Management* (In press)

Finley, B., D. Proctor, P. Scott, N. Harrington, D. Paustenbach, and P. Price. 1994. Recommended distributions for exposure factors frequently used in health risk assessment. *Risk Anal.* 14(4):533-553.

Fitzgerald, E., S.A. Hwang, K.A. Briz, B. Bush, K. Cook, and P. Worswick. 1995. Fish PCB concentrations and consumption patterns among Mohawk women at Akwesasne. *J. Exp. Anal. Environ. Epid.* 5(1):1-19.

West, P.C., J.M. Fly, R. Marans, F. Larkin, and D. Rosenblatt. 1993. *1991-92 Michigan Sport Anglers Fish Consumption Study.* Prepared by the University of Michigan, School of Natural Resources for the Michigan Department of Natural Resources. Technical Report No. 6. May.

2.8 SOIL INGESTION AND PICA

Calabrese, E.J. and E.J. Stanek. 1992. What proportion of household dust is derived from outdoor soil? *J. Soil. Contam.* 1(3):253-263.

Hawley, J.K. 1985. Assessment of health risk from exposure to contaminated soil. *Risk Anal.* 5(4):289-302.

LaGoy, P.K. 1987. Estimated soil ingestion rates for use in risk assessment. *Risk Anal.* 7(3):355-359.

Sedman, R.M. 1989. The development of applied action levels for soil contact: A scenario for the exposure of humans to soil in a residential setting. *Environ. Health Perspect.* 79:291-313.

3.2 INHALATION RATE

Finley, B., D. Proctor, P. Scott, N. Harrington, D. Paustenbach, and P. Price. 1994. Recommended distributions for exposure factors frequently used in health risk assessment. *Risk Anal.*. 14(4):533-553.

4.3 DERMAL ADHERENCE OF SOIL

Finley, B.L., P.K. Scott, and D.A. Mayhall. 1994. Development of a standard soil-to-skin adherence probability density function for use in monte carlo analyses of dermal exposure. *Risk Anal.* 14(4):555-571.

5.3 ACTIVITY PATTERN

Price, P.S., J. Sample, and R. Strieter. 1991. PSEM-A model of long-term exposures to emissions from point sources. In: *Proceedings of the 84th Annual Meeting and Exhibition of the Air & Waste Management Association.* Vancouver, British Columbia.

5.4 POPULATION MOBILITY

Price, P.S., J. Sample, and R. Strieter. 1992. Determination of less-than-lifetime exposures to point sources emissions. *Risk Anal.* 12(3):367-382.

Suggested Outline for Chapter 8

I. Introduction
   A. Uncertainty in exposure assessment is a key issue
      1. Uncertainty is a critical component in the exposure assessment process
      2. Uncertainty must be characterized in a form that enables decision makers to evaluate the uncertainty in risk findings.
   B. Management of uncertainty in different types of exposure assessments (e.g., screening vs. refined assessments).

II. Presentation of a taxonomy of uncertainty in exposure assessment
   A. Definitions for uncertainty and variation
   B. Uncertainty in data related to exposure assessment (Section III)
   C. Uncertainty in exposure factors used in exposure scenarios (Section IV)
   D. Uncertainty in estimates of dose rates derived from scenarios (Section V)

III. Data collection and evaluation
   A. Characterization of the quality and/or limitations of data used in residential exposure assessment
      1. Sources of uncertainty
         a. Random and systematic errors
         b. Measurement errors
         c. Analytical limitations
         d. Limitations of survey design
         e. Dependence and correlation
      2. Uncertainty in characterizations of variation
      3. Statistical evaluation of data
         a. Parametric techniques
            (1) Common distributions
            (2) Summary statistics
            (3) Distribution fitting
            (4) Probability plots
         b. Non-parametric techniques

IV. Key issues in evaluation of exposure factors
   A. Is the factor dominated by variation or uncertainty
   B. Time-scale of data and implications for the exposure factor
   C. Certainty of factor values at the upper and lower limits of the reported values
   D. Choice of parametric or empirical descriptions of uncertainty
   E. Uncertainty in distributions of variability
   F. Applicability of factors to populations that differ from the sampled population

V. Uncertainty in modeling dose rates
   A. Types of models used in exposure assessment
      1. Screening assessments
      2. Refined assessment
   B. Key issues
      1. Differences between modeling uncertainty and addressing uncertainty in data
      2. Model structure

3. Errors due to extrapolation of models
4. Disagreement between models

C. Techniques for managing modeling uncertainty
1. Model validation
   a. Complete data
   b. Incomplete data
   c. Use of multiple models
2. Attribution of uncertainty in models
   a. Sensitivity analysis
   b. Scatter plots
   c. Linear regression
   d. Probabilistic techniques

VI. Propagation of uncertainty in models

A. Available techniques
1. Analytical methods
2. Simulation methods
   a. Factorial design
   b. Discrete probability distribution (DPD) arithmetic
   c. Monte Carlo
   d. Latin Hypercube
   e. Fuzzy arithmetic

B. Software

C. Examples

VII. Presentation of uncertainty

A. Summary Statistics
1. Variance/Standard Deviation
2. Range
3. Interquartile Range

B. Graphical techniques
1. PDFs
2. CDFs
3. Box plots
4. Two dimensional plots of uncertainty and variation

C. The role of uncertainty in risk and exposure descriptors

J. Mark Fly

These comments are concerned primarily with section 2.6 "Intake of Fish and Shellfish" of Chapter 2 "Ingestion Route" since these topics are most closely tied to my background and experience. The comments, however, may be generalizable to other sections of the handbook. The comments correspond with the issues outlined by Dr. Wood in his review directive.

1. Are the data presented in a way that is useful to exposure assessors? Obviously it will be very useful for exposure assessors to have available in one document a summary of the existing literature and data on fish and shellfish consumption in the U.S. This will save a lot of time and effort by eliminating the need for assessors to start their efforts with a literature review and possibly additional data analysis. The data are also presented in a reasonable fashion. If I place myself in the imagined role of an exposure assessor, however, I wonder how I would ever use these data to make specific recommendations or to set standards for pollution or fish consumption that could reasonably be defended in the public arena or in court and to not appear quite arbitrary. For these reasons, Chapter 8 (Analysis of Uncertainties) may be the most important chapter of all and appears to serve its purpose quite well although I am no expert on uncertainty and exposure or risk assessment. If expertise on uncertainty is rather limited across the country, then it may be helpful to local and state government, federal agencies, non-governmental organizations and industry to develop a list of resource people that could be called upon for consultation. Training programs may be needed to expand this expertise in the U.S. If it does not already exist, there appears to be a need for a professional organization with accepted standards of practice for dealing with uncertainty in exposure assessment. The purpose of these standard procedures would be to reduce the opportunity for administrative or legal challenges to decisions made related to exposure rates. This would be similar to standard procedures of medical practice or for playground safety, for example. Such procedures would help remove the feelings of neurotic helplessness and consequent indecisiveness that most decision makers in this arena must face.

Regardless of how the data are presented or the recommendations made, the handbook should emphasize that the primary consideration needs to be on those segments of the population who are most at risk. Examples would be anglers rather than the general population, fish consumers as opposed to non-consumers, and those who studies indicate consume considerably more fish than the average person, such as the elderly, Native and African Americans, and people who fish for subsistence.

2. Have the division of key studies and other relevant studies been made appropriately? Given the limited number of fish consumption studies available, one can understand how the division between key studies and other relevant studies was made. My greatest concern about the key studies for recreational freshwater fish is that four of the five studies used a one year recall period. Current research in survey methodology on autobiographical memory raises considerable question about the validity of one year recall data. The general tendency is for respondents to overestimate their participation rates, particularly in recreation related activities. People like to believe that they do more of their favorite activities than they really do. However, we cannot assume that recall of fish consumption would err in the same direction. For these reasons, the National Hunting and Fishing Survey has dropped their one year recall approach and instituted alternative methods. The survey is conducted every five years by the U.S. Fish and Wildlife Service and the U.S. Census Bureau. Of the key studies, that leaves only one study (West et al., 1989) with a shorter recall period (7 days).

3. Do the recommendations represent proper interpretation of the data? On page 2-285 under recommendations for Chapter 2.6 Intake of Fish and Shellfish, the report states: "Recommendations for consumption rates were classified into the following categories: General Population - Per Capita;" etc. What is actually presented in the report, however, does not appear to be recommendations as much as purely results from the key and related studies. Perhaps these results could be interpreted by exposure assessors as guidelines. Clearly, the report avoids making recommendations because of the confounding factors affecting any particular situation, such as locale and differences in rate and type of consumption by sub-populations.

Should the report go beyond merely summarizing study results and make suggestions on how these results might be used? For example, the report might describe hypothetical scenarios and indicate what recommendations would be made based on available data. If we could map out the key scenarios that might occur across the country and provide recommendations for each scenario, then we would be closer to actually having recommendations of practical use.

The greatest problem, however, is that the mean values seem to be so wide ranging. By merely presenting these results, along with their limitations, the assessors are likely to throw up their hands in frustration.

4. Are there suggestions for data gaps and future research needs? There is a need for more data on the consumption of recreational freshwater fish using a much shorter recall period than one year. It would be helpful to convene a panel of experts to develop survey methodology guidelines for determining fish consumption that would avoid as many of the limitations as possible that have been noted in the handbook. It would be more difficult for future studies that followed the guidelines to be discredited in terms of their application to exposure assessment.

Peter Robinson

Preliminary comments on EPA *Exposure Factors Handbook*

Section 1: Introduction

- Some discussion and a listing of software available (both within EPA and elsewhere) to help in exposure assessment would be very valuable, either here in the introduction or at the end of the document. Example software may include:
  - CONSEXPO (RIVM)
  - THERdbASE (EPA)
- Ordering of sections: perhaps it wouldbe preferable to have *Breast Milk Intake* following shellfish and home-produced sections?

Section 2, 2.1: Dose Equation for Ingestion

Section 2.3: Consumption of Fruits and Vegetables

- p. 2.49. 5 lines from end: (**e.g.** some items... 1992)).

Section 2.4: Consumption of Meat...

Section 2.5: Breast Milk Intake

- Would exposure to infant formula also be a separate issue for the handbook?

Section 2.6: Intake of Fish and Shellfish

Section 2.7: Intake Rates for Various Homeproduced Food Items

Section 8: Analysis of Uncertainty

- p. 8.5: 4 lines from end: This is true only in linear systems (think of averages of fractions compared with ratio of averages of numerator and denominator)
- p. 8.6, 8.7: The criteria for the selection of models are reasonable, but they should be applied to the recommended models in the document itself. I'm not sure that this is done. For example, in the dermal absorption section (Section 4), the "nonsteady state approach" is recommended for estimating the dermally absorbed dose for organics without any discussion of its validation and verification status, of how well it represents the situation being addressed, and without any discussion of plausible alternatives. I am aware of some discussion within the scientific community of the applicability of this particular model in this case. (I present more detailed comments on Section 4 separately).
- The American Industrial Health Council Exposure Factors Sourcebook is an invaluable resource that emphasises parameter distributions, and should be mentioned here.

Preliminary comments on EPA *Exposure Factors Handbook*

Dermal Route

- p. 4.2: The "nonsteady-state approach" should be explained. In particular, ot is not mentioned what kinds of information and parameters are required to apply this model in a realistic manner. I think a referral to the EPA dermal exposure document is not sufficient to give the reader an idea of what is involved in applying this model. Some discussion of the current validation status of this model should also be made. Perhaps a discussion of alternative approaches that may be more useful when certain kinds of data are (or are not) available would also be most useful.
- Section 4.1 should, I think, be expanded. For example, it would greatly benefit from some discussion of factors that may affect dermal absorption. These should at least be mentioned as "watch-outs" that may affect dermal exposure. Examples may include:
    - vehicle effects
    - compromised skin
    - skin hydration
    - absorption of compounds from thin film on the skin (the film thickness may be an important parameter)
    - role of the stratum corneum (and other skin components)
- Many of these factors may have a much more important effect on dermal exposure than some of the nuances of the "nonsteady-state approach".

Patricia Guenther
Mary Hama
Frances Vecchio

In response to the request for review of the draft Exposure Factors Handbook, we submit the following comments, organized into two sections: (1) General Comments, which pertain to large sections of the Handbook and which address the four questions listed in Dr. Wood's memo dated July 5, 1995, and (2) Specific Comments, which are presented by section and page number. We focused our comments on sections relevant to USDA's NFCS data.

GENERAL COMMENTS

DATA PRESENTATION

- o We are pleased that Section II has been dropped from the Handbook.
- o An overall description of the major USDA surveys should be provided in one place.

Data from USDA's Nationwide Food Consumption Survey (NFCS) 1977-78 and NFCS 1987-88 and related data sources (e.g. Pao et al. in "Foods Commonly Eaten by Individuals"; DRES) are described in several sections of the Handbook. Perhaps a more efficient organization would be to have one section or chapter that includes a complete description of each survey or data source, including the descriptive information now found in the text, and the differences among them. The reader could be referred to that section/chapter as needed. This would eliminate any discrepancies among repeated survey descriptions, response rates, and so on. (For example, the NFCS 1987-88 sample size of 4,300 households on page 2-303, paragraph 1 differs from the value of 4,500 households mentioned in an earlier description of the survey.)

This survey description section/chapter should include a description of the two distinct components of both the NFCS 1977-78 and NFCS 1987-88: (1) household food use during a 7-day period --about 4,500 households with a response rate of 37 percent, and (2) individual food intakes by household members for a 3-day period--8,468 individuals, with an estimated response rate of 68 percent of participating households; 10,172 individuals completed a Day 1 recall, an estimated response rate of 81 percent of participating households. This section/chapter should also include a description of the data presented by Pao et al., namely the estimated distributions of mean daily intakes for individuals who consumed the specified food at least once during any given 3-day period. Other survey-based data (e.g. the DRES data) should be described here also.

- o We recommend the use of "household members" throughout, rather than "family members."

- o "Response to questionnaire" in the tables for home-grown food and caught fish refers to activities undertaken the previous year on a household basis rather than on an individual basis (tables 2-141 through 2-145, table 2-184, and tables 2-185 through 2-231).

- o It should be mentioned that the body weights of individuals were self-reported (not "actual").

- o "Complex foods" should be defined or a few examples given when the term is introduced.

- o Detailed descriptions on how the survey data were used should be provided.

Detailed information should be provided on what data were used in the Handbook and how they were used, including the assumptions made. When the NFCS data are referenced, it must be made clear whether the reference is to the household food use data or the individual intake data. This is especially necessary when the NFCS 1987-

88 household data were used to estimate individual intakes. In reality, household food is not evenly distributed among household members so assumptions made for these calculations should be clearly stated.

For example, the source of the data in tables 2-141 through 2-145 is unclear, particularly since the household food use component of the NFCS 1987-88 is not referenced prior to this section in the present draft. It should be clarified that the data were collected during a week-long period and then converted to, and reported as, g/kg/day. As another example, the derivation of daily intake of home-grown foods (described on pages 2-303 through 2-309) is not a simple activity. We recommend the inclusion of a short outline of the data variables used and the steps taken in the calculations. For example, how was the serving size (q_i) for an individual within the age and sex category derived?

Every time food data are described it must be made clear if complex foods were disaggregated or not. This has not been done consistently. Inclusion of the definitions of food groups in the Appendix might also be useful.

- o Provide an overall description of the data strengths and limitations for use in exposure assessment.

The report adequately pulls together the food intake resources that are available for exposure assessment. However, the general strengths and limitations of these data for use in exposure assessment should be made clearer to the readers, particularly if specific intake levels are included in the Handbook with the intent that a researcher can use the data to link to substance concentration data. The following types of information might be useful to include:

a. The information required from food intake data depends on the substance being measured (i.e., what the food intake data are being linked to) and the degree of accuracy required by the researcher. For example, for some substances an accurate exposure estimate may require knowing the specific type of fruit, the source of the fruit (e.g., home-grown or commercial), the degree of processing and cooking, the storage conditions, etc., while for other substances some of this information may not be needed. For some substances, the accuracy of a specific exposure estimate may be decreased if default recipes are used rather than coding the specific ingredients reported, or if ingredients from complex foods are not categorized into their respective food groups, while these factors may have less of an effect on other substances.

b. To estimate chronic exposure, the distribution of long-term food intakes is desired.

c. Error [both variable (random) error and bias (nonrandom) error] is introduced into food intake estimates through nonobservation (i.e. coverage error, nonresponse error, and sampling error) and observation error (i.e. during data collection and data processing).

d. Similar sources of error exist in substance concentration data.

e. The food intake-substance linkage should take into account that both food intake data and substance concentration data are better represented by a distribution of values, rather than a mean value; i.e., the distribution of exposures can be better estimated by convoluting the two distributions.

f. Error is often introduced into the linkage process when assumptions are made about the data sources, or when one or both of the sources are modified so that they are compatible. The food intake data may have been measured at a greater level of detail, regarding ingredients or preparation methods, than that of the substance data, so that the researcher is forced to ignore some information in the food intake database. Alternatively, the food intake data may be less detailed than that of the substance data, so that the researcher may need to choose between items in the substance database or use a combination of items.

g. The error in the final exposure distribution will reflect errors in both the food intake and substance distributions, as well as from the process of linking the data.

h. Factors that increase the variance of the linked food intake-substance data beyond the true variance are likely to bias estimates of upper centiles towards higher values than the true values, and factors that decrease the variance of the data may bias estimates of upper centiles downward. For example, food intake data collected for only several days will likely result in an overestimate of the prevalence of high intakes unless adjusted statistically to correct for intra-individual variability.

i. Some researchers believe that risk is affected not only by lifetime substance exposure, but also by the combination of foods eaten or the pattern of food intake over time. These issues cannot be addressed easily, but should be considered in conducting exposure assessment.

If this type of information is considered beyond the scope of this Handbook, the readers could be provided with a reference instead, such as:

> Life Sciences Research Office, Federation of American Societies for Experimental Biology. 1988. S. A. Anderson (ed.) Estimation of Exposure to Substances in the Food Supply.

The specific discussions of the strengths and limitations of the NFCS 1977-78 and NFCS 1987-88 are repeated several times throughout the Handbook. Again, a more efficient organization might be to provide one section/chapter on the general data strengths and limitations, and refer the reader to this as needed.

Where applicable, notations should be included on the tables to indicate the degree of reliability of the data. For example, each table should alert readers of values based on samples of less than specific cell counts. Cells with unacceptably low cell counts should be suppressed. Otherwise, values with small cell sizes are misleading.

DESIGNATION OF KEY STUDIES

We agree with the designation of USDA's Nationwide Food Consumption Surveys as key studies in this Handbook. Individuals or organizations interested in doing their own analyses should be referred to the primary data. (References for the NFCS 1987-88 Datasets are listed under "References for Chapter 2.") More recent food intake data are available from USDA's Continuing Survey of Food Intakes by Individuals (CSFII) 1989-91:

> U. S. Department of Agriculture. (1994) Dataset: 1991 Continuing Survey of Food Intakes by Individuals and 1991 Diet and Health Knowledge Survey. U.S. Dept. of Commerce, National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22161. Accession No. PB94-500063.
>
> U. S. Department of Agriculture. (1993) Dataset: 1990 Continuing Survey of Food Intakes by Individuals and 1990 Diet and Health Knowledge Survey. U.S. Dept. of Commerce, National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22161. Accession No. PB93-504843.
>
> U. S. Department of Agriculture. (1993) Dataset: 1989 Continuing Survey of Food Intakes by Individuals and 1989 Diet and Health Knowledge Survey. U.S. Dept. of Commerce, National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22161. Accession No. PB93-500411.

Weights for the combined CSFII 1989-1991 sample are on the CSFII 1991 data tape.

PRESENTATION OF KEY STUDIES

As described under "Data Presentation," the strengths and limitations of the data sources should be spelled out, preferably before the Recommendations section.

RESEARCH NEEDS

Distributions of 1-day food intakes would be an additional analysis useful for assessing acute exposure.

Research is needed to develop improved statistical methods for conducting risk analyses. To estimate chronic exposure, the distribution of long-term food intakes or other behaviors is desired. However, it is not possible to observe long-term behavior directly with an acceptable degree of accuracy. Thus, research must be conducted to develop scientifically sound statistical methods for estimating long-term distributions from short-term observations.

SPECIFIC COMMENTS

SECTION 1.1: BACKGROUND

Page 1-7, paragraph 3, last sentence: This combination of low body weight and high consumption is likely in the case of some foods.

SECTION 2.2: DRINKING WATER CONSUMPTION

"Water" and related terms (e.g. "drinking water," "tapwater," "source-specific drinking water") are used inconsistently throughout this section. Although these terms are used differently by different authors, it would be helpful to the reader if EPA would use these terms consistently, with clarification on the specific terms and meanings used by different authors. Definitions could be as follows:

Tapwater:	Water from the tap, whether filtered or not.
Other sources of water:	Bottled, spring, etc.
Drinking water:	Water that is drunk alone; it may be tapwater or other sources of water.
Source-specific water	Drinking water and water added to foods, such as in reconstituting juices, coffee, and soups; it may be tapwater or other sources of water.

For example, the following uses of these terms seem inconsistent:

Page 2-2, paragraph 4: "These rates include drinking water consumed in the form of juices and other beverages containing tapwater (e.g. coffee)." -- "Drinking water" as used includes some food sources of added water. Does this include reconstituted juices only? Are beverages containing bottled water included?

Page 2-3, paragraph 2: "However, for the purposes of exposure assessments involving contaminated drinking water, intake rates based on total tapwater are more representative of source-specific tapwater intake." -- Are non-tapwater sources of water included in "drinking water?"

Page 2-4, paragraph 1: "Tapwater used in cooking foods" -- Does this phrase refer to water used to reconstitute foods, water used for boiling, etc., or both?

Page 2-10, paragraph 3: Describe how drinking water intake was estimated.

Page 2-37, paragraph 2: The Recommendations section is lacking recommendations.

SECTION 2.3 CONSUMPTION OF FRUITS AND VEGETABLES

Page 2-44, paragraph 1: There is no botanical definition of a "vegetable." Delete "not the botanical definition."

Page 2-47: Are white potatoes correctly listed under raw vegetables?

2.6 INTAKE OF FISH AND SHELLFISH

Page 2-219 Footnote (a) in Table 2-140: The correct reference is USDA Nationwide Food Consumption Survey 1987-88.

Pages 2-279 through 2-282, table bottom: Should SW be SE (standard error)?

Page 2-279: The last piece of the Source (".pd < (95th) < 194 gpd") seems to be misplaced.

2.7 INTAKE RATES FOR VARIOUS HOME-PRODUCED FOOD ITEMS

Page 2-303, paragraph 1: Does the sample include only those households that provided only 1 day of diary data?

Page 2-303 through 2-309: All assumptions should be described. For example, the estimates assume that regardless of the sex or age, each household member used home-grown foods in proportion to the number of meals eaten from the household. A standard serving size for all individuals within any sex/age category was used.

Page 2-305: How the serving size (q_i) for an individual within an age and sex category was derived should be described. Also, an explanation is needed of the values reported for infant intakes of asparagus and onions, or these values should be suppressed.

Page 2-306: The source reference should be such that it can stand alone. We recommend citing the survey as follows: USDA Nationwide Food Consumption Survey 1987-88 or, more appropriately, citing the publication.

Page 2-309, paragraph 1: This statement is incorrect; the intake of home-grown dairy products is not highest for individuals in the South. Suggest instead: "Results of the regional analyses indicate that intake rates of home-grown fruits, vegetables, and meat are generally higher for individuals in the Midwest and South than in the Northeast regions of the United States. Intake rate of home-grown dairy products was also higher in the Midwest than in the Northeast."

SECTION 2.9 REFERENCES FOR CHAPTER 2

Pages 2-421 and 2-422: The following are corrections to USDA references:

- The references listed as USDA (1966) and USDA (1972) are for the same publication. The correct citation is:

  USDA. (1972) U.S. Department of Agriculture. Food Consumption: Households in the United States, Seasons and Year, 1965-66, HFCS Rept. No. 12.

  USDA. (1979-1992) U.S. Department of Agriculture. Composition of Foods...Raw, Processed, Prepared. Agriculture Handbook No. 8-1 through 8-21.

USDA. (1983) U.S. Department of Agriculture. Food Consumption: Households in the United States, Seasons and Year, 1977-78, NFCS Rept. No. H-6.

U. S. Department of Agriculture. (1991) Dataset: Nationwide Food Consumption Survey 1987-88 Household Use of Food. U.S. Dept. of Commerce, National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22161. Accession No. PB92-500016.

A citation is also needed for the NFCS 1987-88 Individual Intake database: U. S. Department of Agriculture. (1990) Dataset: Nationwide Food Consumption Survey 1987-88 Individual Intake. U.S. Dept. of Commerce, National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22161. Accession No. PB90-504044.

USDA. (1992a) (References should be listed by author.) Lutz, S.M; Smallwood, D.M.; Blaylock, J.R.; Hama, M.Y.

USDA. (1992b) and (1993a) refer to the same publication.

USDA. (1993a) (This citation is listed twice; the second reference should be USDA (1993b).)

APPENDIX 2A

Cover: The title is incorrect; it should read:

Food Codes and Definitions Used in Analysis of the NFCS 1987-88 Data

SECTION 8.1 TYPES OF UNCERTAINTY

Page 8-5, paragraph 2 and page 8-6, paragraphs 2 & 3: Suggest adding "Dietary intake data, for example, are not normally distributed and have heterogenous variances."

Work Group #2

Nondietary and dermal exposure factors

John Kissel

FOOD INGESTION

2.6 Intake of Fish and Shellfish

Recent literature - Toy et al. reported a study of fish consumption among native Americans at the 2nd International Congress on Health Effects of Hazardous Waste in Atlanta in June 1995. A copy of the abstract is appended to this review.

ACTIVITY PATTERNS

5.3 Activity Patterns

Data gap - No links between physical activity that might lead to soil contact, clothing worn, and subsequent bathing are available in the existing data. Exposure event duration in the dermal soil contact pathway is therefore undefined. Current EPA cooperative agreement CR 824065-01-0 includes some relevant information gathering.

Comment - Unless the underlying source of figures obtained from Tarshis (1981) can be identified and validated, that source should be dropped (p. 5-60).

Recent literature - Zartarian et al. (J. Expos. Assess. & Environ. Epid., 5(1):21-34, 1995) presented a videotaping study that raises doubts about the accuracy of questionnaire data.

NONDIETARY AND DERMAL

2.8 Soil Ingestion and Pica

Recent Literature - The reference list in the handbook seems to stop in 1991 on this topic. The literature is dense and contradictory, but the pathway is too important to to be treated casually. Calabrese et al. (Human & Exp. Tox., 10:245-249, 1991) is referenced in the text, but cited incorrectly in the reference list. Papers that are not referenced, but should be, include: two 1991 Calabrese and Stanek papers (Reg. Tox. & Pharm., 13:263-277, 278-292) which provided an alternative (but temporary) interpretation that differs from the 1989 paper; Calabrese and Stanek (Reg. Tox. & Pharm., 15:83-85, 1992) which deals with relative contribution of outdoor soil vs. indoor dust; two 1994 papers that deal with detection limits (Stanek and Calabrese, J. Soil Contam., 3(2):183-189; 3(3):265-270); yet another interpretation of the Amherst mass balance studies (Calabrese and Stanek, Environ. Health Prespec., 103(5):454-457, 1995) in which mean ingestion rates for children are estimated to range from 97 to 208 mg/day for all six tracers and from 97 to 136 mg/day for the three tracers deemed most reliable; a paper (Stanek and Calabrese, Environ. Health Perspec., 103(3):276-285, 1995) that fits ingestion estimates to a lognormal distribution which produces very large values in the upper tail: a review paper Sheppard (Environ. Monitoring. & Assess, 34:27-44, 1995) that includes arguments based on dermal loadings and hand-to-mouth contact and soil residues on edible plants; and another review paper (Sedman and Mamood, J. AWMA, 44:141-144, 1994). In a paper that has not yet appeared, Lee and Kissel (Environ. Geochem. & Health, in press) back calculated soil ingestion rates necessary to explain observed urinary As concentrations in 2-6 year old children (n=73) living in the vicinity of a smelter using assumptions regarding background exposures and neglecing dermal and inhalation exposures. The resulting estimated median soil ingestion rate was 85 mg/day (mean, 261 mg/day). Use of the Davis et al. data (median, 31 mg/day) resulted in signficant underprediction of observed urinary levels.

4.1 <u>Equation for Dermal Dose</u>

Comment - The units of equation 4-1 do not make sense as written because of confusion over EV and EF.

$$ADD\ [\frac{mg}{kg \cdot day}] \neq \frac{DA_{event}\ [\frac{mg}{cm^2 \cdot event}] \cdot EV\ [\frac{events}{yr}] \cdot ED\ [yrs] \cdot EF\ [\frac{days}{yr}] \cdot SA\ [cm^2]}{BW\ [kg] \cdot AT\ [days]}$$

Both EV and EF are defined as event frequency on p. 4-2, but assigned different units. EF is *exposure* frequency [days/yr]. EV (the true *event* frequency) should have units of [events/day], not [events/yr]. Redefinition of EF as (effectively) EV·EF for the soil case is confusing. EF [days/yr] (water case) should be distinguished from EF [events/yr] (soil case) by calling the latter EF' or EVF.

Comment - Recommendation of the "absorption fraction" approach for dermal absorption from soil should be abandoned. Percent absorbed is a function of soil loading (Duff and Kissel, *J. Tox. & Environ. Health*, in press). Computational requirements associated with extrapolation of the fraction absorbed from experimental to actual conditions are not simpler than computation of apparent permeability coefficients (which can be generated from existing data and are therefore no less available than percent absorbed data). Use of percent absorption has frequently led (erroneously) to direct transfer of laboratory data to field conditions. Consistent treatment of aqueous and soil media would reduce confusion and be an improvement. Also, in the dermal case, event duration is not constant and bioavailability is likely to vary with time of exposure. Careless use of the term bioavailability in a manner that suggests it is a constant should be avoided.

4.2 Surface area

Data gap - None of the existing surface area models distinguish face and neck from total head area. Situations arise in which the more limited surface area is the one of interest.

4.3 Dermal Adherence of Soil

General comments - Some reorganization of the literature is required. Studies should be more clearly distinguished with respect to nature of activity (real or staged) and measure of soil loading (direct or indirect).

Roels et al. data. - Roels et al. reported lead mass and lead concentration in soil, not soil mass. The average 159 mg figure was generated by Sedman (1989) by dividing lead recovered by lead concentration in soil, not by Roels et al. It refers to boys only, and reflects equal weighting of four study populations of somewhat different sizes. The corresponding average that can be produced from the girls' data is 88 mg, and the overall average is 123 mg. Those figures are not corrected for lead recovery efficiency. Roels et al. did not report any measure of efficiency. Que Hee et al. (1985) reported that the absolute efficiency of a single dilute HNO_3 rinse, using a method that involved the entire hand, was 45 percent. Roels et al.'s rinse protocol (rinsing *with*, not rinsing *in* 500 ml dilute HNO_3) could not be expected to clean the entire hand. The overall lead recovery efficiency used to calculate total soil load on the Roels et al. subjects should therefore be less than 45 percent. A reasonable interpretation of the entire Roels et al. data set might be as follows:

$$\frac{123 \text{ mg}}{375 \text{ cm}^2} \cdot \frac{1}{0.45} \cdot \frac{1}{0.8} = 0.9 \text{ mg/cm}^2$$

This result is the same as that generated by Sedman using the boys only data, an overall recovery of 60 percent, and a slightly lower hand area. A more recent intepretation of the

Roels et al. data by Finley et al. (*Risk Analysis* 14(4):555-569, 1994) produced mean and median values that appear too low and cannot be reproduced using stated assumptions.

Que Hee et al. data. - The protocol did not include shaking of hands (and was limited to one hand). The data were obtained in experiments in which a subject (described as a small adult) pressed a hand onto a petri dish containing house dust and then inverted and reinverted both hand and dish over weighing paper. Mass adhering to the palm was determined as net mass loss from the dish and paper. Prior interpretation of this data by Sedman employed an incorrect contact area and is too low. As a result Sedman's lumped estimate (0.5 mg/cm^2) of the Roels et al., Lepow et al., and Que Hee et al. data is about half what it should be.

Driver et al. data - (Discussion of particle size effects) Preferential adherence of finer soil fractions has also been shown by Duggan et al. (Sci. Tot. Environ., 44:65-79, 1985) and Sheppard and Evenden (J. Environ. Qual., 23:604-613, 1994) and Kissel et al. (unpublished). Only the Que Hee et al. data do not show this effect. Those data represent house dust rather than soil, were limited to a total of six points, and included no replicates. Selection of finer particles is very likely. The key here is not that some persons will be exposed to fine soils and will experience greater mass loadings. Size distributions in real soils are heterogeneous. The important point is that adhering particles are likely to have different properties (such as greater surface area to volume ratios) than bulk soils. This has implications for both contaminant concentration and desorption kinetics.

Yang et al. data - The first sentence under section 4.3.4 on p. 4-28 says that the Yang data was not included, but the data appears in the summary (Table 4-14). The *in vitro* estimate of mass required to produce a monolayer was apparently determined visually (and presumably without aid of microscope). Nine mg/cm^2 appears too high in light of electronmicrographs (also of sub-150 µm soil) and calculations presented by Duff and Kissel (J. Tox. & Environ. Health, in press). In addition, my interpretation of the paper is that the *in vivo* tests were done at the same loading for consistency, not that a second and corroborating measurement of monolayer mass loading was generated.

Kissel et al. data - Three components should be distinguished more clearly. Hand press experiments were similar to Driver et al.'s work, but include evidence of positive effect of moisture on adherence and post-adherence soil fractionation. Greenhouse experiments demonstrated that coverage is uneven and very incomplete on surfaces other than hands. Field studies demonstrate that loadings vary substantially with activity (so activity pattern data is needed), that average loadings on hands exceed average loadings on other body parts within given activity, but that hand loadings are not conservative predictors across activities. Measures of central tendency in figures in Table 4-12 should be identified.

Other data - Papers by Charney et al. (Pediatrics, 65(2):226-231, 1980), Gallacher et al. (Arch. Dis. Child., 59:40-44, 1984) (mentioned but not discussed or referenced), Duggan et al. (Sci. Tot. Environ., 44:65-79, 1985), and Sheppard and Evenden (J. Environ. Qual., 23:604-613, 1994) can also be used to generate soil adherence estimates.

Recent literature - Finley et al. (*Risk Analysis* 14(4):555-569, 1994) have proposed a probability density function for soil adherence based on Monte Carlo sampling of six distributions generated from data from the prior literature. The published version includes a very significant misinterpretation of the Que Hee et al. data. Many additional questions are raised by an implausible claim of universal applicability, failure to support conclusions with appropriate statistical tests, failure to justify equal weighting of dissimilar data sets, understatement of uncertainty by inclusion of point estimates, and use of arguments regarding monolayer loadings that show no familiarity with relevant loading ranges.

4.4 Recommendations

Comments on Table 4-14 - The Lepow et al. entry should read > 0.5 mg/cm^2 since recovery was undoubtedly less than 100 percent, but was not taken into account because it wasn't quantified. Schaum's interpretation of the Roel's et al. data (1.5 mg/cm^2) is presented, but not explained in the text. The number of subjects and number of replicates should be added. Add notation that all figures except Kissel et al. (and Yang et al. if retained) represent hand data only. It is reasonable to assume that average loadings on non-hand surfaces are less than hand loadings.

Comment - Final notation (p. 4-35) that more research is needed to deal with interpretation of specific acitivity loading data could include mention that CR 824065-01-0 is addressing this question.

A Fish-Consumption Survey of the Tulalip and Squaxin Island Tribes

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The Environmental Protection Agency (EPA) has adopted criteria for toxic pollutants to protect human health. These criteria are based on a fish-consumption rate of 6.5 grams per day. This default value was obtained through a 1973 nationwide survey and did not recognize regional or cultural consumption patterns. To protect the health of all populations, criteria must be based on sound scientific rationale.

This survey was conducted to determine the fish-consumption rates of two Puget Sound tribes. Interviews were conducted between February and May of 1994. A total of 263 tribal members, age 18 years and older, were surveyed. Data were also collected for 77 children from birth to 5 years of age. Information was obtained for species consumed, fish parts consumed, preparation methods, source of fish, and children's consumption rates. Consumption rates were estimated by age, sex, income, and species groups. Species groups (anadromous, bottom fish, pelagic, and shellfish) were defined by life history and distribution in the water column. Fish consumed were primarily from Puget Sound. The mean consumption for both tribes was found to be 10-12 times higher than EPA's default value.

INTERNATIONAL CONGRESS ON HAZARDOUS WASTE:

IMPACT ON HUMAN AND ECOLOGICAL HEALTH

ABSTRACTS

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Marriott Marquis Hotel
Atlanta, Georgia

U.S. Department of Health and Human Services
Public Health Service
Agency for Toxic Substances and Disease Registry

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13 July 1995

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Overall Comments:

First, a disclaimer. I have not had a chance to read all the sections on nondietary and dermal exposure factors as assigned to our work group, much less the whole document. Notwithstanding that limitation, I have these preliminary comments.

1. LogNormal Distributions

In my 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.

Dee Hull and I anticipated this need. Last fall, with the Exposure Factors Handbook in mind, we drafted two essays to fill this perceived gap (copies attached). The first attachment discusses the three common parameterizations for LogNormal distributions, and the second one shows how anyone with a spreadsheet can make LogNormal probability plots, Dee and I hope that US EPA will reprint these essays as appendices to the main Exposure Factors Handbook.

2. Visualization

Wow! this report is dense, dense, dense with digits in black type. Thumbing through the report now, I do not see a single graph, plot, or picture -- just oceans of black type! (Oops, I just found one pie-chart and one histogram.)

I strongly urge the Agency and its contractor to 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. As appropriate, I can supply many references in this direction.

If an external risk assessor submitted a report like this to one of the Agency's Regional Offices concerning, say, for a Superfund site, I dare say the Agency would reject it as impenetrable -- too dense to read, a classic example of poor risk communications.

3. Parametric Distributions

Looking through the report, I see many summary statistics reported by various researchers -- e.g., arithmetic means, standard deviations, geometric means, selected percentiles, minima, and maxima -- but I see very few parametric distributions fit to the data. At first blush, I believe there are more well-fit parametric distributions than mentioned in the report. For the ones known, certainly, it is essential to show graphs of the fits, including plots of the residuals of the fits. I plan to study this issue further in preparation for the meeting in Washington.

4. Constraints and Dependencies

In the section on food, I see no mention of constraints or dependencies among the distributions conveyed as tables of digits. For example, given the Agency's fondness for choosing near-maximum values for many if not all exposure factors simultaneously, I do not think it is possible for a person to eat all the foods listed at the 95th percentile of each foods intake rate. For example, I strongly doubt that a person who eats bread at the 95th percentile of dietary rate also eats rice, beans, and corn at the 95th percentile of dietary rate as well. After all, there is a constraint operating on the intakes -- the total calorific intake and its distribution across the population.

5. Variability vs Uncertainty

At first reading, I do not see sufficient distinction between variability and uncertainty in the report.

As a practical matter, most risk assessors agree that all the variables in an exposure or risk assessment contain both (i) variability [representing knowledge of heterogeneity in a well-characterized population, which is usually not reducible through further measurement or study] and/or (ii) uncertainty [representing ignorance about a poorly characterized phenomenon or model, which is sometimes reducible through further measurement or study]. Thus, variability describes the diversity found in nature, while uncertainty describes our states of knowledge or ignorance.

I will bring more material on these issues to the meeting in Washington.

6. Computational Issues

So far, I have found no material in the report that discusses -- or gives reference to -- the essential topic of using these distributions in calculations. Having lots of 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). At the Workshop, I will raise this question.

I attach a copy manuscript that demonstrates that the average risk is usually not equal to the function of the average value of the input variables.

7. Section 8 - Analysis of Uncertainties

This section is completely inadequate.

It also perpetuates the false statement that Monte Carlo simulations cannot deal with input variables that have correlations or dependencies among them. The reverse is true -- Monte Carlo simulation is often the only way to work with input variables that have correlations or dependencies among themselves.

• • • • • • •

That's all for now...... See you at the Workshop.

Dave

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A Tutorial on LogNormal Probability Plots

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1.0 Introduction

This presentation supplements a companion piece titled "A Tutorial on the LogNormal Distribution" (Burmaster & Hull, 1994).

Statisticians have designed "probability plots" for many kinds of probability distributions, e.g., normal, lognormal, and exponential distributions, but no probability plots exist for some distributions, e.g, gamma distributions. For a general discussion of probability plots, see, e.g., Chapter 1 in *Goodness-of-Fit Techniques* (D'Agostino & Stephens, 1986).

LogNormal probability plots have many, many uses in probabilistic risk assessments precisely because LogNormal distributions occur naturally and are ubiquitous in probabilistic risk assessments. Figure 1 shows a typical LogNormal probability plot.

By definition, a probability plot is any 2D graph (with special or transformed axes) on which values realized from the corresponding probability distribution plot in a straight line (Benjamin & Cornell, 1970). For example, a set of values that are randomly sampled from an exponential distribution will plot in a straight line on an exponential probability plot (or in an almost straight line, given the randomness of the sample). As another example, data measured from many physical, chemical, or biological processes follow LogNormal distributions in theory and in practice (Hattis & Burmaster, 1994).

In this presentation, we teach the reader how to create a LogNormal probability plot using only a spreadsheet program. As a practical matter, we think all risk assessors need to know how to plot their own probability plot for three reasons. First, it teaches important skills. Second, it allows the risk assessor to extend the technique to develop and plot data on related graphs, e.g., a CubeRoot probability plot. Third, it gives the risk assessor a way to correct a flaw in many commercial statistics programs (e.g., Systat, 1992) that reverse (or transpose) the axes.

In this presentation, we do not consider making a LogNormal probability plot for a set of values or data that include censored or truncated entries, e.g., chemical concentrations reported as BDL (below the detection limit), although such plots are sometimes easily accomplished if only a few values are truncated or censored (see, e.g., Travis & Land, 1990).

2.0 The Functions p(z) and z(p)

2.1 The Function p(z)

Most introductory books on probability or statistics introduce the "standard" or "unit" Normal distribution with a mean $\mu = 0$ and a standard deviation $\sigma = 1$. Here, we write the unit Normal distribution as N(0, 1).

For this section, let us assume that the random variable $\underline{\underline{Z}}$ is distributed as a unit Normal distribution: $\underline{\underline{Z}} \sim N(0, 1)$. The probability density function (PDF) for this random variable is (Feller, 1968 & 1971; Stuart & Ord, 1987 & 1991) :

$$f(z) = \frac{1}{\sqrt{2\pi}} \cdot \exp[-\frac{z^2}{2}] \qquad \text{Eqn 1}$$

for $-\infty \leq z \leq +\infty$. This is the familiar bell-shaped curve.

The cumulative distribution function (CDF) for this unit Normal distribution is often written (Feller, 1968 & 1971; Stuart & Ord, 1987 & 1991):

$$p(z) = \Phi(z) = \int_{-\infty}^{z} f(x)\ dx \qquad \text{Eqn 2}$$

with x as the dummy variable of integration. Figure 2 shows a plot of Eqn 2. Almost every introductory text on probability and statistics includes a table of this integral (Benjamin & Cornell, 1970). The function $\Phi(z)$ ranges from a minimum of 0 at $z = -\infty$ to a maximum of 1 at $z = +\infty$. Some easily memorized values are $\Phi(-2) = 0.023$, $\Phi(-1) = 0.159$, $\Phi(0) = 0.50$, $\Phi(+1) = 0.841$, and $\Phi(+2) = 0.977$.

In this Tutorial, we interpret $100 \cdot \Phi(z)$ as computing the percentile of the unit Normal distribution associated with a particular z value for $-\infty \leq z \leq +\infty$. Under this interpretation, we see that the $z = -1$ corresponds to the 16th percentile, $z = 0$ corresponds to the 50th percentile (the median), and $z = +1$ corresponds to the 84th percentile. Thus, we can use Eqn 2 to compute the percentiles for a unit Normal distribution.

2.2 The Function z(p)

To make a LogNormal probability plot, we need the function z(p), the inverse function for p(z). In this framework, $z(p) = z^{-1}(p) = \Phi^{-1}(p)$.

This new function, z(p) -- the inverse of p(z) -- allows us to compute the variable z associated with each percentile of a unit Normal distribution. With this inverse function, we want to recover the value $z = -1$ as corresponding to the 16th percentile, $z = 0$ as corresponding to the 50th percentile (the median), and $z = +1$ as corresponding to the 84th percentile.

Happily, the function z(p) is well defined because the function $\Phi(z)$ has a well defined inverse function (Feller, 1968 & 1971; Stuart & Ord, 1987 & 1991). Figure 3 shows a plot of the inverse function, $\Phi^{-1}(p)$ for most of the domain $0 \leq p \leq 1$. As expected, over this domain, the inverse function $\Phi^{-1}(p)$ has a range from $-\infty$ to $+\infty$. Note that the inverse function $\Phi^{-1}(p)$ is an odd function:

$$\Phi^{-1}(p) = -\Phi^{-1}(-p) \qquad \text{Eqn 3}$$

3.0 Computing the Function z(p)

To make a LogNormal probability plot, the goal of this Tutorial, we need values for the function z(p) evaluated at each of the sampled or measured values. There are generally two ways to do this.

First, from standard tables. It is easy but tedious to read standard tables p(z) backwards, i.e., to read values for z(p) from tables of p(z) (e.g., Benjamin & Cornell, 1970).

Second, by computation. Many commercial spreadsheet products and many other commercial software packages calculate the function z(p). For example, in Microsoft Excel™ 5.0 for the Macintosh and for Windows (Microsoft, 1994), the built-in function called NORMSINV(probability) computes z(p) for $-\infty < p < +\infty$. In Mathematica™ (Wolfram, 1991), the user may define a function z(p) in terms of functions built into the software:

z[p_] := Sqrt[2] InverseErf[2 p - 1] Eqn 4

With the basic mathematical formulae available in standard mathematical handbooks (e.g, Abramowitz & Stegun, 1964), the analyst can evaluate the function z(p) by knowing the right built-in function or by writing a short subroutine. Also, Kenneth Bogen (1993) has published a fast intermediate-precision approximation for z(p).

4.0 Plotting a LogNormal Probability Plot

In this Tutorial, we use the symbols $x_1, x_2, \ldots, x_n, \ldots, x_N$ to denote a set of N values sampled (or realized or measured) from a random variable $\underline{\underline{X}}$. We want to see if these x_n values come from a LogNormal distribution. Even though $\underline{\underline{X}}$ is a random variable, each of the N realizations from it, denoted x_n (for $n = 1, \ldots, N$), is a point value.

We recommend a 6-step process to make a LogNormal probability plot to visualize a set of N values $x_1, x_2, \ldots, x_N$.

Step 1: Sort the N values from the smallest to the largest, so that $x_1 \leq x_2 \leq \ldots \leq x_N$. This presentation allows for some ties among the N values. In the rest of this algorithm for LogNormal probability plots, we assume that the N values are sorted from the smallest to the largest.

Step 2: Check to see if each of the values $x_n > 0$ for $n = 1, \ldots, N$. If some values are zero or negative, Stop, because a 2-parameter LogNormal distribution cannot fit the data. If all x_n are positive, Go to Step 3, because a 2-parameter LogNormal distribution may fit the data.

Step 3: Take the natural logarithms of the x_n values for $n = 1, \ldots, N$. Work "in logarithmic space" with the $\ln[x_n]$ values in all of the remaining steps in this fitting process. Go to Step 4. [EndNote 1}

Step 4: For each of the N data points, compute an empirical cumulative probability as:

$$p_n = \frac{n - 0.5}{N} \qquad \text{for } n = 1, 2, \ldots, N. \qquad \text{Eqn 5}$$

This simple formula works well in most cases, but the statistical literature contains discussions of other formulae for computing the empirical cumulative probability for use in probability plots.

Step 5: Compute $z(p_n)$ for $n = 1, 2, \ldots, N$. [EndNote 2]

Step 6: Plot the points with coordinates $\{z(p_n), \ln[x_n]\}$ for $n = 1, 2, \ldots, N$ on a LogNormal probability plot with $z(p_n)$ on the abscissa and $\ln[x_n]$ on the ordinate. If the N points plot in a curved line on these axes, Stop, because a 2-parameter LogNormal distribution cannot fit the data [EndNote 3]. If the N points plot in an approximately straight line on these axes, Continue, because a 2-parameter LogNormal distribution will fit the data. Include this graph in your final report. Some authors (e.g., D'Agostino & Stephens, 1986) and some commercial software packages (e.g., Systat, 1992) transpose the axes by plotting $\ln[x_n]$ on the abscissa and $z(p_n)$ on the ordinate.

Next Steps: Complete the additional steps discussed in the companion piece titled "A Tutorial on the LogNormal Distribution."

5.0 Discussion

LogNormal probability plots are a powerful technique because they allow the analyst to see all the data in comparison to a full LogNormal distribution. Data points falling in a straight line on a LogNormal probability plot imply that a LogNormal distribution will fit the data with high fidelity (e.g., Figure 1). In such a situation, the analyst may estimate the two parameters of the best-fit LogNormal distribution by using ordinary least squares to fit a straight line to the data and to compute the regression coefficients.

With a LogNormal probability plot, the analyst can see the nature and the quality of the fit over the whole distribution, and she or he can use any systematic departures from a fit to investigate other models for the data (D'Agostino et al, 1990). For example, Figure 4 in Brainard and Burmaster (1992) shows how a systematic curvature of data points plotted on a LogNormal probability plot led to a new understanding of the distribution of women's body weights.

Traditional GoF tests do not let the analyst visualize the data. With a traditional GoF test, one or two errant data points may lead to a conclusion that a LogNormal distribution does not fit the data, but a LogNormal probability plot may show that the fit is excellent over the range of primary interest.

EndNotes

1. Some authors (e.g., Hattis & Burmaster, 1994) use common logarithms (to the base 10) in making LogNormal probability plots. This convention is internally consistent, but any parameters estimated by linear regression on such a plot require conversion if the rest of the analysis uses Napierian logarithms.
2. Given that z(p) is an odd function, $z(p_1) = -z(p_N)$ when $p_n = \frac{n - 0.5}{N}$ for n = 1, 2, ..., N.
3. If the points tend to follow a smooth, nonlinear curve on a LogNormal probability plot, D'Agostino & Stephens (1986) suggest other types of probability plots to consider. For example, the data may plot in a straight line on a Normal probability plot, a CubeRoot probability plot, or another PowerTransformed probability plot.

Acknowledgments

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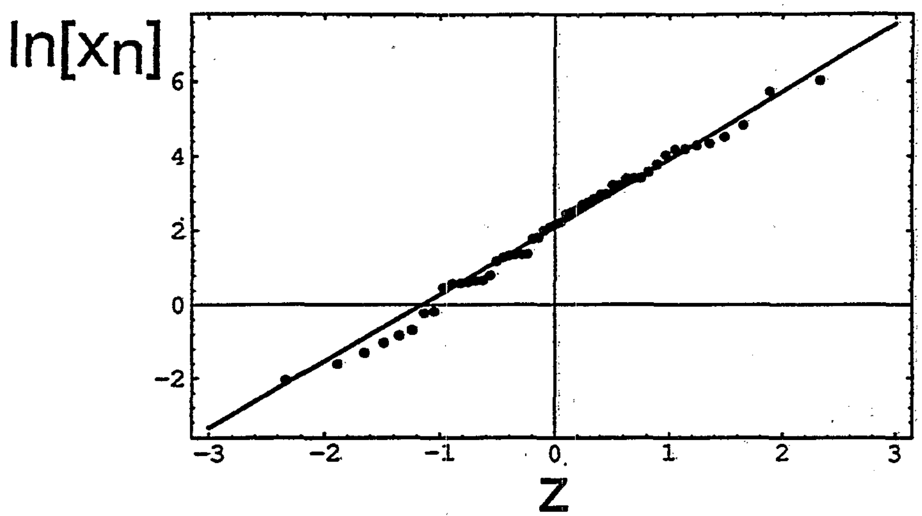

Figure 1
A LogNormal Probability Plot
for 51 Random Samples from
$\underline{\underline{X}}$ ~ exp[N(2, 2)]

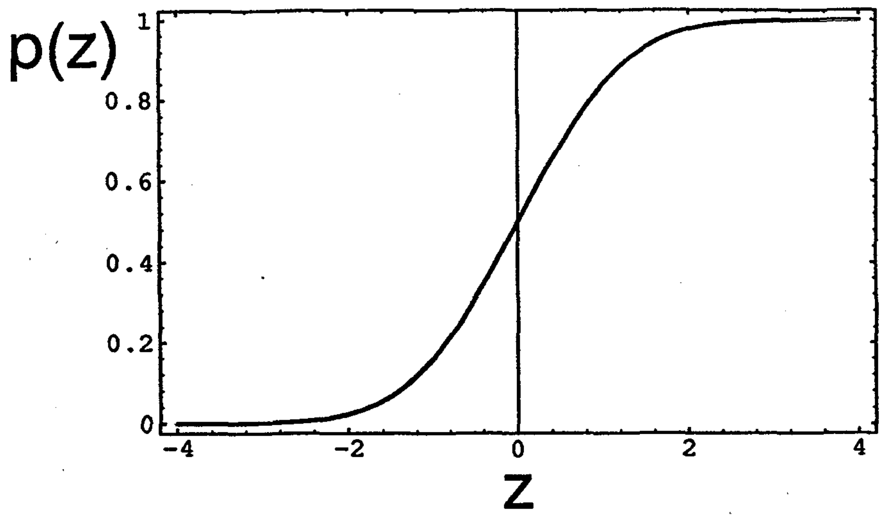

Figure 2
A Plot of p(z)

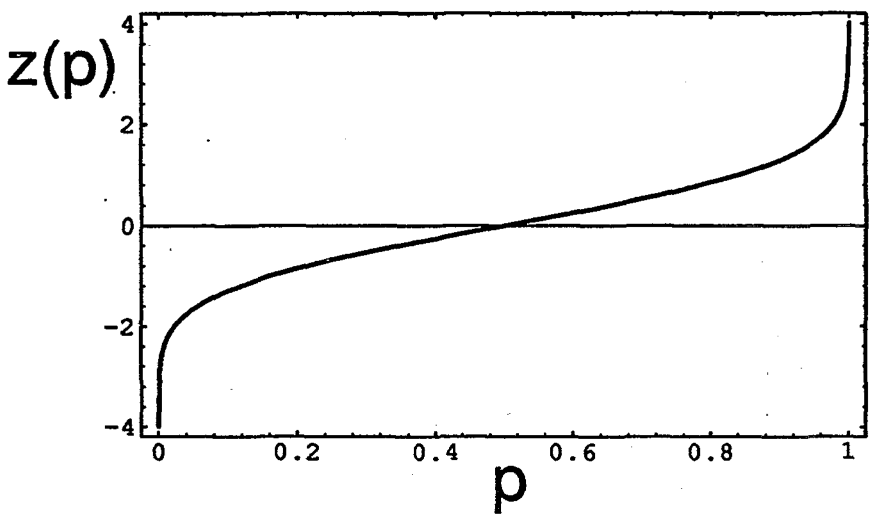

Figure 3
A Plot of z(p)

A Tutorial on the LogNormal Distribution

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1.0 Introduction

The lognormal distribution (with two parameters) has a central role in human and ecological risk assessment for at least three reasons. First, many physical, chemical, biological, and statistical processes tend to create random variables that follow LogNormal distributions (Hattis & Burmaster, 1994). For example, the physical mixing and dilution of one material (say, a miscible or soluble contaminant) into another material (say, surface water in a bay) tends to create non equilibrium concentrations which are LogNormal in character (Ott, 1990). Second, the mathematical process of multiplying a series of random variables will produce a new random variable (the product) which is LogNormal in character, regardless of the distributions from which the input variables arise (Benjamin & Cornell, 1970). Finally, LogNormal distributions are self-replicating under multiplication and division, i.e., products and quotients of lognormally distributed random variables are themselves distributed lognormally (Crow & Shimizu, 1988), a result often exploited in back-of-the-envelope calculations.

2.0 Concepts and Notations for Random Variables

In this appendix, we use the symbol $\underline{\underline{V}}$ to denote a positive random variable, i.e., a variable in an equation that can take any value greater than zero. Here, the double underscores indicate that $\underline{\underline{V}}$ is a random variable. The relative frequency of values sampled (or "realized") from the distribution is governed by a mathematical function called a probability distribution. We use random variables described by probability distributions to represent the variability and/or the uncertainty inherent in a quantity.

3.0 Symbolic Approach

In this Tutorial, we do not manipulate the probability density function (PDF) or the cumulative distribution function (CDF) for any distributions (Feller, 1968 & 1971; Stuart & Ord, 1987 & 1991). Instead, we demonstrate an alternative symbolism, complete with its own algebra, that makes the concepts and the calculations easier to understand (Springer, 1979). This abstract symbolism is, of course, not what a computer does in a numerical simulation with Monte Carlo or Latin Hypercube sampling. Computer algorithms are beyond the scope of this Tutorial (see, e.g., Knuth, 1981).

4.0 The Two-Parameter Lognormal Distribution

The 2-parameter lognormal distribution takes its name from the fundamental property that the logarithm of the random variable is distributed according to a Normal or Gaussian distribution (Evans et al, 1993):

$$\ln[\underline{\underline{X}}] \sim N(\mu, \sigma) \qquad \text{Eqn 1}$$

where ln[•] denotes the natural or Napierian logarithm function (base e) and N(•, •) denotes a Normal or Gaussian distribution with two parameters, the mean μ and the standard deviation σ (with $\sigma > 0$). In Eqn 1, $\underline{\underline{X}}$ is a lognormal random variable, and $\ln[\underline{\underline{X}}]$ is a normal random variable. In Eqn 1, μ is the mean and σ is the standard deviation of the distribution for the normal random variable $\ln[\underline{\underline{X}}]$, not the lognormal random variable $\underline{\underline{X}}$. Although sometimes confusing, μ is also the median of the normal random variable $\ln[\underline{\underline{X}}]$ because μ is the median of $N(\mu, \sigma)$. Many people say that Eqn 1 represents the lognormal random variable $\underline{\underline{X}}$ "in logarithmic space." As can be seen in Eqn 1, the random variable $\ln(\underline{\underline{X}})$ is distributed normally, but the random variable $\underline{\underline{X}}$ is distributed lognormally.

Figure 1 shows graphs for both the PDF and the CDF for an illustrative Normal distribution, $N(\mu, \sigma) = N(2, 1)$. In Figure 1, the three dotted vertical lines show the values of the distribution at $x = \mu$ and $x = \mu \pm \sigma$. As for every Normal distribution, some 68 percent of the area under the PDF occurs between $x = \mu - \sigma$ and $x = \mu + \sigma$.

The information coded in Eqn 1 is identical to the information coded in Eqn 2:

$$\underline{\underline{X}} \sim \exp[\, N(\mu, \sigma)\,] \qquad \text{Eqn 2}$$

where exp[•] denotes the exponential function and N(•, •) again denotes the same Normal or Gaussian distribution with the same two parameters, mean μ and the standard deviation σ (with $\sigma > 0$) as above. In Eqn 2, $\underline{\underline{X}}$ is a lognormal random variable. As earlier, μ is the mean and σ is the standard deviation of the normal random variable ln[$\underline{\underline{X}}$], not the lognormal random variable $\underline{\underline{X}}$. Many people say that Eqn 2 represents the lognormal random variable $\underline{\underline{X}}$ "in linear space." When working with Eqn 2 as the representation for a lognormal random variable $\underline{\underline{X}}$, many people refer to N(μ, σ) as the "underlying Normal distribution" or "the Normal distribution in logarithmic space" as a way to remember its origins.

Figure 2 shows graphs for both the PDF and the CDF for the LogNormal distribution, exp[N(μ, σ)] = exp[N(2, 1)], i.e., the LogNormal distribution for which the Normal distribution in Figure 1 is the underlying Normal distribution. In Figure 2, the dotted vertical lines show the values of the LogNormal distribution at x = exp[μ] and x = exp[$\mu \pm \sigma$]. As for every LogNormal distribution, some 68 percent of the area under the PDF occurs between x = exp[μ-σ] and x = exp[μ+σ].

Of course, these two alternate representations for a lognormal random variable -- Eqn 1 and Eqn 2 -- contain identical information. For a particular lognormal distribution, the normal or Gaussian distributions N(μ, σ) in Eqn 1 and Eqn 2 have numerically identical parameters. The graphs in Figures 1 and 2, then, show two ways to visualize a particular LogNormal distribution, exp[N(2, 1)]. Figure 1 shows the Normal distribution ("in logarithmic space") underlying the LogNormal distribution ("in linear space") in Figure 2.

5.0 Percentiles of Random Variables ln[$\underline{\underline{X}}$] and $\underline{\underline{X}}$

The two random variables ln[$\underline{\underline{X}}$] and $\underline{\underline{X}}$ are related intimately to each other by a common transformation -- either ln[•] or exp[•] -- depending on the direction of the transformation. In either the direction, the transformation is 1:1 and monotonic, so the percentiles are closely related by the same transforms. For example, the 95th percentile for $\underline{\underline{X}}$ is the exponential of the 95th percentile for ln[$\underline{\underline{X}}$], and, in the other direction, the 95th percentile of ln[X] is the natural logarithm of the 95th percentile of X.

$$\{X\}_{0.95} = \exp[\,\{\ln[X]\}_{0.95}\,] \qquad \text{Eqn 3}$$

Similarly, the median (or 50th percentile) of X is the exponential of the median of ln[X], and, in the other direction, the median of ln[X] is the natural logarithm of the median of X:

$$\{X\}_{0.50} = \exp[\,\{\ln[X]\}_{0.50}\,] \qquad \text{Eqn 4}$$

For example, if the 95th percentile of ln[X] is 4 (i.e., in logarithmic space), then the 95th percentile of X is exp(4) or 54.60 (i.e., when the distribution is converted to linear space).

More generally, for a Normal distribution, the $(100 \bullet p)^{th}$ percentile $(0 < p < 1)$ occurs at a z(p), where z(p) is the inverse of the cumulative distribution function of the standard (or unit) normal distribution. Values for the function z(p) are widely available in most text books on statistics as tables of the cumulative distribution function for the standard (or unit) normal distribution (e.g., Benjamin & Cornell, 1970). For example, here are three values frequently used and easily remembered: z(0.16) = -1, z(0.50) = 0, and z(0.84) = +1.

The $(100 \bullet p)^{th}$ percentile for the underlying Normal distribution may be calculated as:

$$\begin{aligned} \{\ln[X]\}_p &= \{N(\mu, \sigma)\}_p \qquad \text{Eqn 5} \\ &= \mu + (z(p) \bullet \sigma) \end{aligned}$$

By extension, the $(100 \bullet p)^{th}$ percentile for the LogNormal distribution may be calculated as:

$$\begin{aligned} \{X\}_p &= \{\exp[\,N(\mu, \sigma)\,]\}_p \qquad \text{Eqn 6} \\ &= \exp[\,\{N(\mu, \sigma)\}_p\,] \\ &= \exp[\,\mu + (z(p) \bullet \sigma)\,] \end{aligned}$$

This last result is particularly pleasing.

Figures 1 and 2 graph a particular Normal distribution, N(2, 1), underlying a particular LogNormal distribution, exp[N(2, 1)]. The median (or 50th percentile where $z = 0$) in Figure 1 is $\mu = 2$, and the median in Figure 2 is exp[2] = 7.39. We know that z(0.16) = -1, so, by Eqns 5 and 6, the 16th percentile of the underlying Normal distribution occurs at μ-σ = 1 and the 16th percentile of the LogNormal distribution occurs at exp[μ-σ] = exp[1] = 2.72. We also know that z(0.84) = +1, so, by Eqns 5 and 6, the 84th percentile of the underlying Normal distribution occurs at μ+σ = 3 and the 84th percentile of the LogNormal distribution occurs at exp[μ+σ] = exp[3] = 20.09. In addition, we know that z(0.95) = 1.645, so, again by Eqns 5 and 6, the 95th percentile of the underlying Normal distribution occurs at μ+(1.645•σ) = 3.645 and the 95th percentile of the LogNormal distribution occurs at exp[μ+(1.645•σ)] = exp[3.645] = 38.28. Thus, Figures 1 and 2 show two alternative ways to visualize the same LogNormal distribution.

6.0 Arithmetic Central Moments of Random Variables ln[X] and X

The first two arithmetic central moments for the Normal random variable ln[X] are straightforward:

AMean[ln[X]]	=	AMean[N(μ, σ)]	Eqn 7
	=	μ	
AStdDev[ln[X]]	=	AStdDev[N(μ, σ)]	Eqn 8
	=	σ	

Here, the notation AMean[•] refers to the arithmetic mean of a random variable, more properly the expected value calculated by the expectation operator, E[•]. The notation AStdDev[•] refers to the arithmetic standard deviation of the random variable.

The first two central moments for the LogNormal random variable X are more complicated and not easily derived. They are:

AMean[X]	=	AMean[exp[N(μ, σ)]]	Eqn 9

$$= \exp[\ \mu + ((1/2) \cdot \sigma^2)\ ]$$

$$\text{AStdDev}[\ \underline{\underline{X}}\ ] = \text{AStdDev}[\ \exp[\ N(\mu, \sigma)\ ]\ ]$$

$$= \exp[\ \mu\ ] \cdot \sqrt{\exp[\ \sigma^2\ ] \cdot (\ \exp[\ \sigma^2\ ] - 1)} \qquad \text{Eqn 10}$$

For the LogNormal distribution shown in Figure 2, the arithmetic mean is 12.18 and the arithmetic standard deviation is 15.97.

7.0 Geometric Moments of Random Variable $\underline{\underline{X}}$

The first two geometric moments of a positive random variable $\underline{\underline{V}}$ are defined as:

$$\text{GMean}[\ \underline{\underline{V}}\ ] = \exp[\ \text{AMean}[\ \ln[\underline{\underline{V}}]\ ]\ ] \qquad \text{Eqn 11}$$

$$\text{GStdDev}[\ \underline{\underline{V}}\ ] = \exp[\ \text{AStdDev}[\ \ln[\underline{\underline{V}}]\ ]\ ] \qquad \text{Eqn 12}$$

where GMean[•] denotes the geometric mean of a positive random variable and GStdDev[•] denotes the geometric standard deviation of a positive random variable.

When applied to Eqn 2, these formulae yield:

$$\text{GMean}[\ \underline{\underline{X}}\ ] = \exp[\mu] \qquad \text{Eqn 13}$$

$$\text{GStdDev}[\ \underline{\underline{X}}\ ] = \exp[\sigma] \qquad \text{Eqn 14}$$

Thus, for LogNormal distributions, the median of $\underline{\underline{X}}$ equals the geometric mean of $\underline{\underline{X}}$. Note that the arithmetic mean of a LogNormal distribution is always greater than the geometric mean of the distribution.

8.0 Different Ways to Parameterize the LogNormal Distribution

Fundamentally, it takes two and only two parameters to describe a particular LogNormal distribution. There are an infinite number of ways to pick the two values. First, the analyst could pick two parameters in "logarithmic space," two parameters in "linear space," or one in each. Second, the two parameters chosen could be two arithmetic moments, two geometric moments, two percentiles, or one of each of two types. With some effort, it is generally possible to convert one representation of a particular lognormal distribution to another representation for the same distribution. After all, the particular lognormal distribution remains the same, only the parameterization changes from one representation to another. We have seen many different parameterizations in the literature, and we have seen some authors use several different parameterizations in the same article. Given the infinite number of representations for just one lognormal distribution, the possibilities for confusion and misunderstanding and mistakes are boundless.

In this Tutorial, we emphasize the central importance of μ and σ, the mean and standard deviation of the Normal or Gaussian distributions in "logarithmic space," as a consistent and powerful way to parameterize a lognormal distribution for $\underline{\underline{X}}$. We recommend this practice to you.

However, in writing articles in the refereed literature, many other authors often choose different parameterizations. Many authors prefer to parameterize a lognormal distribution for $\underline{\underline{X}}$ in terms of its geometric mean and its geometric standard deviation, or equivalently, in terms of its median and its geometric standard deviation.

Fewer authors parameterize a lognormal distribution for $\underline{\underline{X}}$ in terms of its arithmetic mean and arithmetic standard deviation. We find this usage particular confusing and prone to error because the arithmetic mean of $\underline{\underline{X}}$ and arithmetic standard deviation of $\underline{\underline{X}}$ are numerically unstable when working with data or simulations.

Given the formulae in the earlier sections, the reader may solve the equations pairwise to convert one parameterization to another.

At the risk of causing great confusion, we must mention that some authors prefer to use common logarithms (base 10) in the fundamental representations:

$$\log_{10}[\underline{\underline{X}}] \sim N(\mu_{10}, \sigma_{10}) \qquad \text{Eqn 1'}$$

which is equivalent to:

$$\underline{\underline{X}} \sim 10\text{^}[\, N(\mu_{10}, \sigma_{10})\,] \qquad \text{Eqn 2'}$$

where $\log_{10}[\bullet]$ denotes the common logarithm function (base 10), $10\text{^}[\bullet]$ indicates the number 10 raised to a power, and $N(\bullet, \bullet)$ denotes a Normal or Gaussian distribution with two parameters, the mean μ_{10} and the standard deviation σ_{10}. The information coded in Eqn 1' is identical to the information coded in Eqn 2'. In Eqns 1' and 2', we have used subscripts on the parameters to indicate the use of common logarithms.

The fact that some authors use common logarithms (instead of Napierian logarithms) introduces another dimension of confusion. Without giving the full derivations, there are some convenient formulae to convert from the parameterization in common logarithms to Napierian logarithms:

$$\mu = \ln[10] \bullet \mu_{10} \qquad \text{Eqn 15}$$

$$\sigma = \ln[10] \bullet \sigma_{10} \qquad \text{Eqn 16}$$

$$\text{GMean}[\underline{\underline{X}}] = 10\text{^}[\, \mu_{10}\,] \qquad \text{Eqn 17}$$

$$\text{GStdDev}[\underline{\underline{X}}] = 10\text{^}[\, \sigma_{10}\,] \qquad \text{Eqn 18}$$

With these conversions in place, the reader may now convert among the four most common but different parameterizations of a particular lognormal distribution.

9.0 A Constant Times a LogNormal Distribution

In many human or ecological risk assessments done in a probabilistic framework, the risk assessor must multiply a lognormal distribution $\underline{\underline{X}}$ by a constant c, say, for example, to convert from one set of units to another. To begin, we set $c' = \ln[c]$. Then

$$c \bullet \underline{\underline{X}} \sim c \bullet \exp[\, N(\mu, \sigma)\,] \qquad \text{Eqn 19}$$

$$\sim \exp[\, c'\,] \bullet \exp[\, N(\mu, \sigma)\,]$$

$$\sim \quad \exp[\, c' + N(\mu, \sigma) \,]$$
$$\sim \quad \exp[\, N(\mu + c', \sigma) \,]$$

Thus, in this symbolism, the multiplication of a LogNormal distribution by a constant shifts the mean μ of the underlying Normal distribution by $c' = \ln[c]$, but the operation does not change the standard deviation σ of the underlying Normal distribution.

For example, Brainard & Burmaster (1992) fit a LogNormal distribution to data for the body weight (in pounds) of adult males as $\underline{\underline{BW}}_{lb} \sim \exp[\, N(5.14, 0.17) \,]$. We want to convert this distribution to body weight in kilograms, and we know that there are 2.2 pounds in a kilogram. So

$$\underline{\underline{BW}}_{kg} \sim (1/2.2) \bullet \underline{\underline{BW}}_{lb}$$
$$\sim (1/2.2) \bullet \exp[\, N(5.14, 0.17) \,]$$
$$\sim \exp[\, -0.79 + N(5.14, 0.17) \,]$$
$$\sim \exp[\, N(5.14 - 0.79, 0.17) \,]$$
$$\sim \exp[\, N(4.35, 0.17) \,]$$

Of course, as expected,

$$\text{AMean}[c \bullet \underline{\underline{X}}] = c \bullet \text{AMean}[\underline{\underline{X}}] \qquad \text{Eqn 20}$$

$$\text{AStdDev}[c \bullet \underline{\underline{X}}] = c \bullet \text{AStdDev}[\underline{\underline{X}}] \qquad \text{Eqn 21}$$

10.0 Products and Quotients of LogNormal Distributions

In many human and ecological risk assessments done in a probabilistic framework, the risk assessor often uses a simple equation with products and quotients of variables to estimate a distribution of risk $\underline{\underline{R}}$:

$$\underline{\underline{R}} = \frac{\prod_{i=1}^{I} \underline{\underline{X}}_i}{\prod_{j=1}^{J} \underline{\underline{Y}}_j} \qquad \text{Eqn 22}$$

where all inputs are positive random variables, $\underline{\underline{X}}_i$ (for i = 1, ..., I) and $\underline{\underline{Y}}_j$ (for j = 1, ..., J).

In the special case in which all the $\underline{\underline{X}}_i$ and $\underline{\underline{Y}}_j$ are *independent* LogNormal random variables, $\underline{\underline{R}}$ is also a lognormal random variable:

$$\underline{\underline{R}} \quad \sim \quad \exp[N(\mu_R, \sigma_R)] \qquad \text{Eqn 23}$$

with

$$\mu_R \quad = \quad \Sigma\, \mu_{Xi} - \Sigma\, \mu_{Yj} \qquad \text{Eqn 24}$$

$$\sigma^2_R \quad = \quad \Sigma\, \sigma^2_{Xi} + \Sigma\, \sigma^2_{Yj} \qquad \text{Eqn 25}$$

This theorem demonstrates both a fundamental property of independent LogNormal distributions and the felicity of parameterizing the distributions in terms of the mean and standard deviation of the underlying Normal distribution. In the first equation for μ_R, the contribution from the variables in the denominator enter preceded by a minus sign, but, in the second equation for σ^2_R, the contribution from the variables in the denominator enter preceded by a plus sign.

11.0 Fitting Lognormal Distributions to Data

In this Tutorial, we use the symbols $x_1, x_2, ..., x_n, ... , x_N$ to denote a set of N values sampled or realized from the random variable $\underline{\underline{X}}$. Even though $\underline{\underline{X}}$ is a random variable, each of the N realizations from it, denoted x_n (for n = 1, ..., N), is a point value.

First, before beginning a formal fitting process below, use exploratory data analysis and visualization to plot the data in many different ways on many different axes (Tukey, 1977; Cleveland, 1993; Cleveland, 1994). Modern commercial software (e.g., Systat, 1992) running on a desktop computer makes this exploratory data analysis fast, fun, and indispensable.

When it comes time to fit a LogNormal distribution to a set of data $x_1, ..., x_N$, we recommend an 8-step process. In this presentation, we do not consider fitting a distribution to a data set with censored or truncated values, e.g., chemical concentrations reported as BDL (below the detection limit), although such fits are sometimes easily accomplished.

Step 1: Check to see if each of the values $x_n > 0$ for $n = 1, \ldots, N$. If some values are zero or negative, Stop, because a 2-parameter LogNormal distribution cannot fit the data. If all x_n are positive, Go to Step 2, because a 2-parameter LogNormal distribution may fit the data.

Step 2: Take the natural logarithms of the x_n values for $n = 1, \ldots, N$. Work "in logarithmic space" with the $\ln[x_n]$ values in all of the remaining steps in this fitting process. Go to Step 3.

Step 3: Plot a histogram of the $\ln[x_n]$ values. If the histogram of the $\ln[x_n]$ values is asymmetric by having a long tail to the left or the right, Stop, because a 2-parameter LogNormal distribution cannot fit the data. If the histogram of the $\ln[x_n]$ values is symmetric, Go to Step 4, because a 2-parameter LogNormal distribution may fit the data.

Step 4: Plot a LogNormal probability plot with z(p) on the abscissa and $\ln[x_n]$ on the ordinate. If the N points plot in a curved line on these axes, Stop, because a 2-parameter LogNormal distribution cannot fit the data. If the N points plot in an approximately straight line on these axes, Go to Step 5, because a 2-parameter LogNormal distribution will fit the data. Include this graph in your final report. Some authors (e.g., D'Agostino & Stephens, 1986) and some commercial software packages (e.g., Systat, 1992) transpose the axes by plotting $\ln[x_n]$ on the abscissa and z(p) on the ordinate.

Step 5: Using ordinary least-squares regression, fit a straight line to the data plotted on the LogNormal probability plot with z(p) on the abscissa and $\ln[x_n]$ on the ordinate. The line will have this functional form, with z as the independent variable in the regression:

$$\text{line} = a + (b \cdot z) \qquad \text{Eqn 26}$$

where a is the intercept of the fitted line when z = 0 and b is the slope of the fitted line. Include this graph in your final report, along with all the goodness of fit statistics for the regression. Then, $\hat{\mu}$ = a is a good estimate for the parameter μ in Eqns 1 and 2 and $\hat{\sigma}$ = b is a good estimate for σ in Eqns 1 and 2. Usually the regression package will report confidence internals for a and b. Go to Step 6. In this Step 5, a regression line fit to the transposed LogNormal probability plot with $\ln[x_n]$ on the abscissa and z(p) on the ordinate will not give correct estimates for $\hat{\mu}$ and $\hat{\sigma}$ because the regression does not have the proper independent variable.

Step 6: Calculate the values of these two estimators to obtain alternate estimates of parameters μ and σ:

$$\overline{\ln[x]} = \frac{\Sigma \ln[x_n]}{N} \qquad \text{Eqn 27}$$

$$s = \sqrt{\frac{\Sigma(\ln[x_n] - \overline{\ln[x]})^2}{N-1}} \qquad \text{Eqn 28}$$

Then, $\hat{\mu} = \overline{\ln[x]}$ is an alternate good estimate for the parameter μ in Eqns 1 and 2 and $\hat{\sigma}$ = s is an alternate good estimate for σ in Eqns 1 and 2. If the alternative estimates of $\hat{\mu}$ from Steps 5 and 6 are numerically close to each other, AND if the alternative estimates for $\hat{\sigma}$ from Steps 5 and 6 are numerically close to each other, go to Step 7.

Step 7: Do one or more goodness of fit (GoF) tests (Madansky, 1988; D'Agostino & Stephens, 1986) on the $\ln[x_n]$ values to see if they do or do not fit a Normal distribution. Even though these methods do not visualize the data and are not as robust as the probability plot above, discuss the results of these tests in your final report. Go to Step 8.

Step 8: Discuss the adequacy of the fit compared to the use of the LogNormal distribution in a narrative in your final report. Note any outliers, problems, or issues. State the conditions and circumstances in which the results apply; also state the conditions and circumstances in which the results do not apply. Discuss alternative fits and conduct numerical experiments to see if use of an alternative fit would lead to a different decision in the real world.

Discussion:

After the initial exploratory data analysis and data visualization, we recommend an 8-step process for fitting a LogNormal distribution to data. First, we recommend that the analyst work with the $\ln[x_n]$ values to fit the parameters μ and σ of the underlying Normal distribution -- precisely because working with the untransformed x_n values is numerically unstable in most cases. Second, we recommend that the analyst complete all 8 steps in entirety -- precisely because we have seen egregious mistakes when an analyst ignores a particular step. Third, visualize! visualize!! visualize!!! in each step in the procedure. These 8 steps form the framework of many publications in the refereed literature (e.g., Roseberry & Burmaster, 1992; Murray & Burmaster, 1992)

Although we have found that these 8 steps work well for many univariate data sets and for the marginal distributions of many multivariate data sets, the methods will not work to fit a multivariate distribution to multivariate data that may include non negligible correlations and/or dependencies. Finally, although this recommended 8-step process rests on powerful and recognized statistical techniques with long pedigrees -- i.e., probability plots, the method of moments, and the method of maximum likelihood -- there are other powerful and accepted techniques not included -- e.g., maximum entropy methods (Kapur & Kesavan, 1992) and model-free curve estimation (Tarter & Lock, 1993).

12.0 Numerical Simulations with LogNormal Variables

When a person is first starting a numerical simulation with LogNormal random variables, we recommend a two-step process.

First, generate or simulate values for $\ln[\underline{\underline{X}}]$ by drawing values from the underlying Normal distribution $N(\mu, \sigma)$ in logarithmic space. Second, exponentiate those values for $\ln[\underline{\underline{X}}]$ to obtain values for $\underline{\underline{X}}$ from the LogNormal distribution $\exp[N(\mu, \sigma)]$ in linear space.

This two-step process basically reverses the 8-step fitting process just presented in Section 11.0 above. For example, when using a commercial software product such as Crystal Ball™ (Decisioneering, 1992) or @Risk™ (Palisade, 1992) in conjunction with a spreadsheet on a desktop computer, the analyst would simulate the underlying Normal distribution, N(μ, σ), in one cell and then exponentiate it in an adjacent cell. This two-step process gives the analyst much more control of the simulation at a negligible penalty in speed. It also helps the reviewer, e.g., a reviewer at a regulatory agency, check for errors.

Many commercial software packages, [e.g., Demos™ (Lumina, 1993), RiskQ™ (Bogen, 1992; Murray & Burmaster, 1993), Crystal Ball™, @Risk™] offer pre-programmed routines or functions that sample a LogNormal distribution in one step instead of two. We recommend that an analyst not use these features until she or he is seasoned and highly experienced in the pitfalls of simulation.

Why not use such tempting features? In our experience, each different software package uses a different parameterization for the LogNormal distribution. This in itself is not necessarily bad, only confusing, especially when the Users Manuals are often less than clear on the chosen parameterization. If a neophyte analyst misinterprets the User Manual -- say by specifying the geometric mean of a distribution when the software expects the arithmetic mean of the distribution as an input -- the overall simulation may be wrong by an order of magnitude or more. Moreover, a reviewer would have an extremely difficult time catching this fundamental error. GIGO [EndNote 1] happens all too often in numerical simulations because the analyst does not understand the tools in use and does not use numerical experiments or the algebra of random variables (Springer, 1979) to check the first set of simulations.

Once an analyst has months of experience with the two-step process recommended here, she or he may want to experiment with the built-in features of her or his chosen software package. Caveat emptor! as always.

<u>EndNotes</u>

1. In earlier days, GIGO stood for the phrase "Garbage In, Garbage Out." Today, GIGO too often stands for the phrase "Garbage In, Gospel Out."

Acknowledgments and Dedication

Alceon Corporation supported this work.

We dedicate this Tutorial in memory of Jerome Bert Wiesner.

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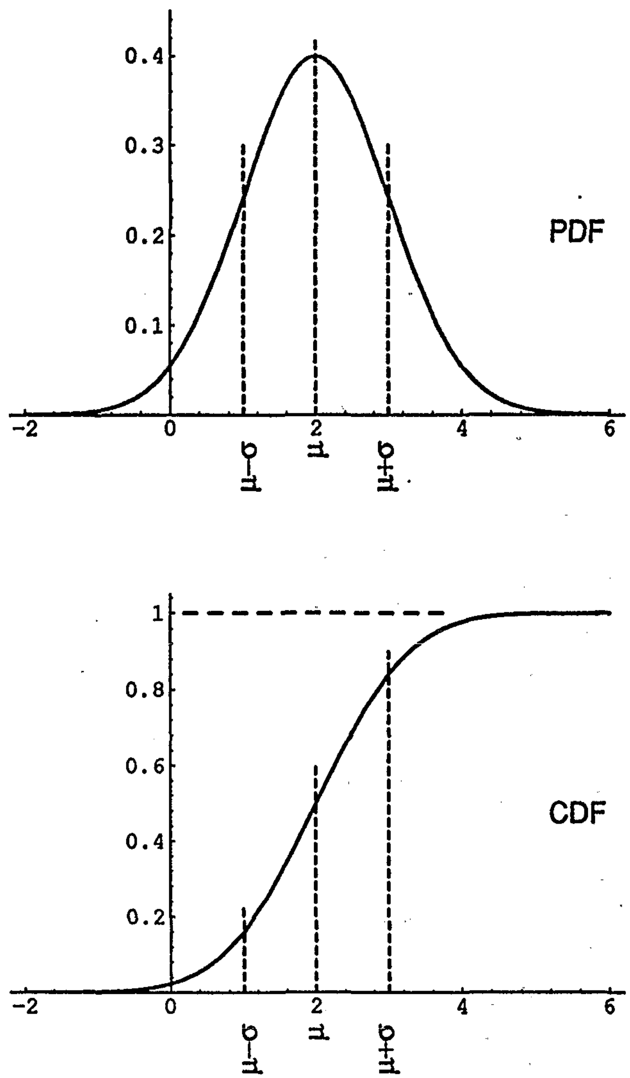

Figure 1
PDF and CDF for the Normal Distribution
$N(\mu, \sigma) = N(2, 1)$

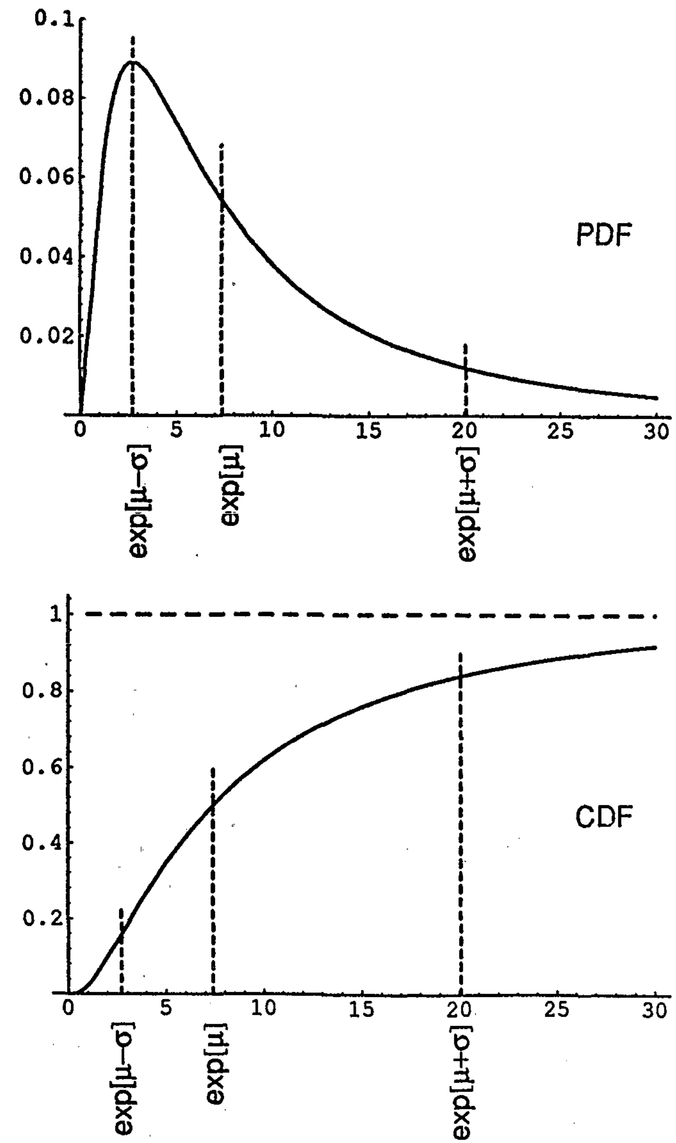

Figure 2
PDF and CDF for the LogNormal Distribution
$\exp[N(\mu, \sigma)] = \exp[N(2, 1)]$

Larry Gephart

General Comments

EPA should be commended for efforts the agency has undertaken to update the Exposure Factors Handbook. The new draft Handbook contains significant new information on exposure factors. Also, both new and old data are presented in a manner which allows for better use of the data in exposure assessments.

To assist users of the handbook, it is recommended that for all exposure factors, central tendency values (e.g., medians), defined upper percentile values (e.g., 90th percentiles), and where possible, distributions should be presented. This would allow exposure assessors to tailor the use of exposure factor data in specific risk assessments.

It is recommended that EPA consider removing the policy concept of "default" from the Exposure Factors Handbook. For most exposure factors, data are sufficient to define a central tendency and an upper percentile value. However, reference to "default" values still receives favorable attention in the draft revised handbook. For example, current data support changing the default child soil ingestion rate of 200 mg/day to a central tendency value of 50-100 mg/day, the default adult soil ingestion rate of 100 mg/day to a central tendency value of 25-50 mg/day, the default adult daily inhalation rate of 20 m^3/d to a central tendency value of 13 m^3/d, and the adult life expectancy from 70 years to 75 years.

Section Specific Comments

Section 2.2 - Drinking Water Consumption

1. Are data presented in a way that is useful to exposure assessors?

In general, data are presented in way that will facilitate their use in exposure assessments. For example, data from table 2-7 will allow for preparation of exposure distributions. Data from other tables will allow for exposure assessments for certain unique situations (e.g., as a function of physical activity, sex, or geographical area).

It is recommended that section 2-2 should not begin with a statement concerning the drinking water consumption value currently used by EPA (pg 2-3). The term "default" value should be deleted, or, at least defined.

Drinking water intake rate and tapwater intake rate are used to define the same exposure factor. This is potentially confusing to the reader. It is recommended that the latter term be used, since it better meats the definition provided.

For purposes of risk assessment, it is useful to maintain separate figures for tapwater intake, which is defined to include food and beverages reconstituted with tapwater, and for total fluid intake, which is defined to include consumption of commercial products. However, the final recommendations do not maintain this separation.

It is not clear what is meant by "upper percentile tap water intake" on pg 2-3 (i.e., is this a 95, 99 percentile value?). Similarly, on pg 2-3, it is not clear what is meant by the statement "the data tend to support EPA's use of 2 L/day for upper percentile tapwater intake."

2. Have the key studies been identified?

The key studies have been identified and emphasis has been placed on making recommendations from the key studies (Cantor et al., Ershow and Cantor).

3. Are the interpretations of the studies and recommendations appropriate?

The final recommendations are appropriate. However, some minor re-wording is needed. As clearly supported in the studies by Ershow and Cantor and Cantor et al., and confirmed by other studies, the average drinking water consumption rate is 1.4-1.5 L/day. Therefore, as stated on pg 2-41, a value of 1.4 L/day is appropriate to recommended as the average drinking water rate for adults. However, it is not clear why later in the same paragraph, values of 2 L/day and 2.27 L/day, which are the 82th and 90th percentile values from the study by Ershow and Cantor, are recommended for "chronic" and "acute" exposure assessments, respectively. The methods used by Ershow and Cantor and Cantor et al. do not indicate a systemic bias towards lower intake rates. Rather, the data collected by various investigators indicates consistency around 1.4 L/day and 2.0 L/day values as central and upper percentile estimates, respectively. The implication is that only the upper percentile values should be used in exposure assessments, and use of central tendency values should be discouraged. This is inconsistent with the goals stated in the preface to the handbook. Perhaps including the statement "for use in chronic exposure assessments" to the sentence describing the average value would help clarify this issue.

4. What are the significant data gaps?

There is apparent agreement amongst studies on total fluid intake rates. However, as described in the June 1994 Exposure Factors Handbook Workshop, more data are needs on the portions of total water consumption: 1) ingested directly from the tap; 2) ingested after heating or after treatment; 3) used in commercial beverages and 4) used as an ingredient in home prepared beverages. Consumption rates for specific sub-populations (e.g., infants, athletes, pregnant women) are lacking. Data are also needed for incidental water ingestion which occurs during swimming.

Section 2.8 - Soil Ingestion and Pica

1. Are data presented in way that is useful to exposure assessors?

In general, the technical summaries of the studies effectively bring out the strengths and weakness of the various study designs. However, as described below, there are a number of technical issues on individual studies that need of resolution. A summary table providing the final conclusions of the various authors from the published papers would be useful. Most importantly, given the extreme differences in quality of the studies and how much confidence there is in the quantitative estimates of soil ingestion rates derived from the individual studies, it is not clear if data from multiple studies should be used to derive a mean composite estimate of soil ingestion for children (pg 2-410). Is such a composite is deemed useful, as described below, the information in the table contains a number of errors which should be corrected.

There are also a number of publications available which are not cited in the text or reference section which should be added.

In the background section, I suggest changing "toxics" to chemicals and "dirt" to soil.

In the study by Calabrese et al. (1990), based on percentage recoveries, the authors clearly indicated a higher level of confidence in the data for the tracer substances Al, Si, Y and Zr. Similarly, in the study by Calabrese et al. (1989), the authors indicate higher confidence in the data for Al, Si, and Y. These differences should be noted in the study summaries and data for these tracers, plus data for the tracer Zr (see text below) should be included in the summary table on pg. 2-410.

There are a number of important papers on soil ingestion detection limits not included section 2.8. For example, in a paper by Stanek and Calabrese (Reg. Tox Pharmacol. 13, 263-277, 1991; Stanek and Calabrese Reg. Tox. Pharmacol. 13, 263-177, 1991), the authors indicate that the studies by Binder et al (1986) and Van Wijnen et al (1990), which did not employ a mass balance approach and did not therefore adequately account for intake of tracer materials though the diet or medicines, do not provide quantitative estimates of soil ingestion. In addition, with the exception of data for the single tracer Zr from the study by Calabrese et al. (1989), data from the other studies do not provide quantifiable estimates of soil ingestion. More recent reports by these investigators, which are not cited in this section, indicate that Al, Si, and Y are may be the most reliable tracers for soil ingestion in children (Calabrese and Stanek Env. Hlth. Persp. 103 (5), 454-4457, 1995; Stanek and Calabrese Env Hlth Persp. 103:276-285, 1995; Stank and Calabrese J. Soil Cont. 3(2), 183-189, 1994). While this subject is controversial and still under review, it raises the question concerning the validity of producing a composite soil ingestion rate using data from multiple studies of differing design (pg 2-410).

A summary of a paper on methods to distinguish outdoor soil ingestion from indoor dust ingestion in a soil pica child by Calabrese and Stanek (1992) should be included in this section (Reg Toxicol. Pharmcol 15, 83-85, 1992).

In the table on page 2-410, there are a number of errors. Both data points from the study by Clausing et al. are not corrected for control (hospitalized children) values. The corrected value for Al should be 176 mg/day (232 mg/day - 56 mg/day). A footnote should be included noting the unavailability of control data for the AIR data. Similarly, the corrected values from study by Van Wijnen et al range from 69-120 mg/day instead of 162-313 mg/day. The mean soil ingestion rate for Al in the study by Davis et al. was 39 mg/day rather than 3 mg/day. As described above, for the study by Calabrese et. al (1989), the data for Zr should included, since data for this tracer may in fact be the most reliable. Using the corrected values from the studies by Clausing et al. and Van Wijnen et al, and higher confidence data points from the study by Calabrese, the mean composite value should be recalculated. To decrease the impact of extreme values, considerations should be given to calculating a median instead of or in addition to a mean composite value. Notation to the method used to account for ingestion of tracers in food should be added. Finally, using all the data cited in the table, it is not possible to calculate a separate mean for soil ingestion versus soil/dust ingestion, as indicated. In the studies by Binder et al and Van Wijnen et al, no distinction was made for intake of housedust and soil. Therefore, only the data on soil and dust combined should be included in the table and the composite value should be designated as representing intake of soil plus household dust. Data for Zr should be included in calculating the composite value. A revised sample table is presented below.

Estimated Daily Soil and Dust Ingestion Rate in Children[a]

(mg/kg)

Soil Tracer Substance					Reference
Al	Si	AIR	Yi	Zr	
121[b]		136[b]			Binder
175[b]		129[c]			Clausing
52[d]	112[d]				Davis
30[d]	49[d]		11[d]	11[d]	Calabrese
69-120[a,e]					Van Wijnen

[a] all values represent medians except where noted

[b] value is corrected for ingestion of food using a hospital control group

[c] value is not corrected for ingestion of food due to detection limit considerations

[d] value is corrected for ingestion of food using mass balance methodology

[e] values are geometric means since medians were not available

Concerning adult soil ingestion, in the summary of the study by Calabrese et al. (1990) it should be mentioned that due to recovery considerations, Al, SI, Y, and Zr were considered the most reliable tracers. For this reason, the summary table on pg. 2-411 should include information for Zr rather than Ti. Also, it is recommended that this table list median rather than mean values, or list both mean and median values. The mean values listed in the study summary on pg 2-402 were taken from week 1 data alone (table 7 of the study) and are not representative of the whole data set. The more appropriate values, as listed by the authors, are taken from table 8. For example, for Al, Si, Y, and Zr, the correct values are 77, 5, 53, and 22 for Al, Si, Y, and Zr, respectively, instead of 110, 30, 63, and 134 mg/day. Finally, the value of 480 mg/d as an "upper percentile" taken from the Hawley paper should be deleted from the summary table and from the discussion following the table. This value was obtained from an exposure reconstruction rather than from an actual study. The recommended revised table appears as below.

Estimated Soil and Dust Ingestion Rate In Adults[a]

(mg/day)

	Soil Tracer Substance			
	Al	Si	Y	Zr
Mean	77	5	53	22
Median	57	1	65	-4

mean of mean = 39 mg/day

median of median = 28 mg/day

[a] Data are from Calabrese et al. (1990)

2. Have the key studies been identified?

The text correctly indicates that higher consideration should be given to placing less emphasis on studies with serious design limitation (e.g., Binder et al. and Clausing et al.) and more emphasis on the studies which have fewer study design weaknesses (Calabrese et al, Davis et al., Van Wijnen et al.). However, due to design limitations, consideration should be given to not including the studies by Binder et al. and Clausing et al. in the key study section.

Similarly, in the section on adult soil ingestion, the papers by Hawley et al. (1985) and Krablin (1989) do not provide actual quantitative information on soil ingestion rates. Rather, they were exposure reconstructions which attempted to estimate soil ingestion. Therefore, it is recommended that these data should not be included as key studies but as "other information on soil intake among adult." The only actual quantitative study is by Calabrese et al (1990).

3. Are the interpretations of the studies and recommendations appropriate?

On pg 2-411, the discussion is inappropriately worded in a way to support the current EPA "default" values of 200 and 100 mg/day for children and adults, respectively. For the soil intake rate in children, the text appropriately indicates that more weight should be given to data from studies which were corrected for dietary intake of tracer substances. These studies were conducted subsequent to when the 200 mg/day value was recommended. However, as described above, the values in the summary table for the Wijnen study are not corrected for background. Once the corrected values are included and presented as medians, the data clearly indicate that the average rate lies in the range of 11-112 mg/day and the 100 mg/day value is towards the upper end of this range. Therefore, the statement concerning the 200 mg/day value being a "conservative mean average" should be deleted.

For adults, the only quantitative data available indicates that the average soil intake value lies in the range of 25-50 mg/day. (see table above). The statement on the bottom of pg 2-411 starting with "This set of values is consistent with the 50 mg/day range often used by program offices" should be deleted. No information is cited to verify the statement and such recommendations may change over time. In fact, an adult soil intake rate of 100 mg/day is the often recommended value (e.g.,m EPA RAGS I, 540.1-89/002). If 50 mg/day is chosen, the text should indicate that this value if towards the upper end of the average range based on limited available data.

4. What are the significant data gaps?

There is only one published study on soil ingestion rates for adults and only 6 data points were included in the study. Clearly, more data are needed on adult soil ingestion. Much of the published data on soil ingestion rates for children are of questionable reliability. Therefore, much more data are needed for this critical exposure factor. Data on the frequency of pica and ingestion rates for children exhibiting pica are needed.

Section 3 - Inhalation Route

1. Are data presented in a way that is useful to exposure assessors?

Much of the data are presented in a format useful for exposure assessors. It is apparent that many of the original references did not provide all of the data required for a complete exposure assessment. For example, the Linn et al (1993) study presented statistics on the hourly inhalation rate for different activity levels but failed to include the time spent at each activity. Additionally, arithmetic means of breathing rate are presented, not median values. In some instances, (e.g., Shamoo et al., 1991) data are presented in such a way that distributions can be made of ventilation rate which may then be coupled to the appropriate time at each activity level.

2. Have the key studies been identified?

Yes

3. Are the interpretations of the studies and recommendations appropriate?

All of the key studies have been summarized in adequate detail to give the exposure assessor the necessary information. The advantages and disadvantages of each study have been clearly expressed. Based on the information provided in the Handbook, it is clear that there is only one study that represents the general U.S. population: Layton, 1993. All other studies were limited to the Los Angeles area and may be biased. For long-term exposures Layton presents arithmetic means of daily inhalation rates for different cohorts (age, sex) and considers both active and inactive periods. Other studies (Spier et al, 1992) present daily inhalation rates for active periods only, which will significantly overestimate daily inhalation rate.

The recommended average daily inhalation rate for adults for continuous exposures where activity patterns are not known of 13.3 m^3/day (based on the Layton studies) is an appropriate recommendation. However, the recommended upper percentile value of 20 m^3/day is not supported by the key studies. This value is an upper percentile for active periods (supported in Layton, 1993) but is not a representative upper percentile which considers both active and inactive periods. The recommended upper percentile should not be higher than 17 m^3/day, which is the maximum reported value from Layton (1993) in all three approaches.

Breakdown of time spent at each activity are relatively consistent among the studies. The recommended time spent at each activity seem appropriate.

4. What are the significant data gaps.

Only one study is representative of the general U.S. population. Additional information on general U.S. trends to support Layton 1993 would be beneficial. Also, complete statistics on breathing rates within a cohort (to create distributions) would assist in performing cohort specific exposure assessments.

Section 4 - Dermal Route

1. Are data presented in a way that is useful to exposure assessors?

Much of the data, particularly the tables, are presented in a way that will facilitate the use of the data by exposure assessors.

2. Have the key studies been identified?

Yes, the new studies by Kissel et al. on soil adherence, and the available studies on surface area have been identified.

3. Are the interpretations of the studies and recommendations appropriate?

Overall, the recommendation to use data summarized in table 4-4 on surface area is appropriate. This table presents mean and 90th percentile values for specific body parts which allows the risk assessors flexibility in performing assessments. The data set which forms the basis of this table, while dated, is perhaps the best available. In addition, other assessments do not reveal marked inconsistencies.

The recommendation on pg 4-23 concerning default total body area should be revisited. It is stated that the total adult body surface area can vary from 17,000 cm^2 to 23,000 cm^2 (with reference to table 4-4). Based on this range, a value of 20,000 cm^2 (central estimate) is recommended for use in exposure assessments. However, the values presented in table 4-4 actually range from 14,500 cm^2 (minimum for women) to 23,000 cm^2 (maximum for men), with a central estimate of 18,750 cm^2. Also, the mean of the values for men and women combined is 18,150 cm^2. Therefore, 18,000 cm^2 should be recommended as the central tendency value for use in exposure assessments, in lieu of using age or sex specific values.

On soil adherence, the recommendation to use the high quality data from the study by Kissel et al. (1995) is appropriate. The data presented in table 4-12 will allow the risk assessor to perform activity specific assessments with consideration for exposure to specific body areas. This approach is very superior to the approach recommended in the previous handbook, which assumed a constant upper bound soil adherence rate for all body areas.

4. What are the significant data gaps?

As described in the previous exposure factors workshop, many of the serious data gaps lie in the area of skin exposed under various exposure scenario (soil contact, use of various commercial products, seasonal impacts, etc.).

Section 5.3 - Activity Patterns

1. Are data presented in such a way that are useful for exposure assessors?

Data on some of the important time activity patterns (e.g., residence time, shower duration) are presented in a way that will facilitate their use in exposure assessments, including preparation of exposure distributions. Data on other factors, for example, occupational tenure, are presented in a way that will help exposure assessors prepare assessments for selected occupational, ethnic, and age groups. However, the data on occupational tenure are not presented in a way which allows for preparation of exposure distributions. All of the data collected by Robinson et al. (tables 5-28 to 5-30) do not allow for preparation of distributions.

2. Have the key studies been identified?

The two comprehensive compilations of time activity patterns (Robinson et al., 1991 and CARB 1991) are cited. Also, the key studies for occupational tenure (Carey, 1987/1988), residence time (Isralei, 1992 and Cappel, 1992), and shower duration (James and Knuiman, 1987) are cited. However, none of these studies are clearly identified as "key" studies.

3. Are the interpretation of the studies and recommendations appropriate?

The recommendations on a number of important time activity patterns are not clearly stated. For example, for residence time, summaries of the 3 primary studies (Nelson and Isralei and Nelson, 1992; Johnson and Cappel, 1992; and U.S. Bureau of census, 1993) and some of the limitations of the studies are provided. However, it is recommended that the text include a summary paragraph which provides guidance on preference for which data set to use, based on technical considerations. An example is given below.

In the study by the U.S. Bureau of Census, the assumption of even distributions within ranges for which the data were collected, severely limits the usefulness of the study. The approaches for estimating a distribution of the average total residence time used by Isralei and Nelson (1992) and Johnson and Cappel (1992) were fundamentally different in two significant areas. First, the Israeli and Nelson study took survey data to determine the desired distribution for households. Johnson and Cappel centered their model around individuals. Second, their data sources and data manipulation differed greatly. Israeli and Nelson took current residence time data and performed rigorous probability calculations to determine a moving rate and then a total residence time, whereas Johnson and Cappel utilized available data on mobility to do simple calculations for probabilities of moving and then ran these probabilities through as simulation to arrive at their final distribution. Because of the above differences and the fact that Johnson and Cappel used the more current data of the two, the data by Johnson and Cappel (tables 5-49 and 5-50) are recommended for use in exposure assessments (e.g., 50th and 90th percentile values of 9 and 26 years, respectively).

4. What are the significant data gaps?

Much of the data available on activity patterns do not allow for preparation of exposure distributions.

Section 8 - Analysis of Uncertainties

1. Are data presented in a way that is useful to exposure assessors?

This section differs from the other sections in that it presents methods rather than data. It's specified goal is to discuss "methods that can be used to evaluate and present the uncertainty associated with exposure estimates". However, it deals more with characterizing "types of uncertainty" than with methods to evaluate and present uncertainty. In some cases, the descriptions of the types of uncertainty are vague or confusing. In most cases, the description of methods for evaluating uncertainty is not made clear.

A recommendation is to specifically highlight the methods, either by bold type, by numbering, or by putting them into a section of their own. My reading of this section uncovers (by careful highlighting) the following 18 specific methods recommended:

1. Classify uncertainty into one or more types, e.g., scenario, parameter or model.

2. Identify sources of uncertainty for each type, e.g., professional judgment for scenario selection.

3. Describe rationale for professional judgment.

4. Characterize uncertainty as high, medium or low.

5. Do sensitivity analysis to set credible upper limit.

6. Avoid surrogate data.

7. Use bounding estimates.

8. Use a "best" estimate.

9. Use a probabilistic distribution based on data for a parameter that "profoundly influences" the exposure estimates.

10. Use expert judgment to generate subjective probability representation.

11. Do a sensitivity analysis by using upper and lower limits.

12. Use "analytical uncertainty propagation".

13. Use probabilistic uncertainty analysis.

14. Use statistical methods.

15. Describe rationale for selection of models.

16. Use different models to establish a range of modeled estimates.

17. Confirm modeled computer code output.

18. Compare performance of model to actual observed data similar to scenario.

It is obvious that the above items are not presented in a way that is useful to an exposure assessor. Aside from being hidden within the text, the methods are not described well, nor are there any examples which would more clearly illustrate their use.

2. Are the data presented in a way that will support both point estimate and Monte Carlo assessments?

No. On the contrary, the recommendations in Section 8 argue against Monte Carlo assessment by providing a laundry list of disadvantages with limited advantages (general applicability, no restriction on form of input distributions, and straightforward computations). The list of "do not use" reasons includes:

- only use when there are credible distribution data for most key variables
- don't use if you only need average exposure values
- don't use if you only need a bounding estimate
- sensitivity analysis is difficult to do and doesn't work.
- assumption of independent distributions is a problem

It appears that the writer wants to discourage Monte Carlo analysis and has a great deal of uncertainty about its usefulness. This is especially apparent in the statements regarding sensitivity analysis. The need to rerun the entire calculation several hundreds or thousands of times is not a disadvantage since the software and hardware available to do this is practical and quick (seconds to minutes). Secondly, a check on the shape of the resultant exposure distribution against the shapes of the input distributions is a quick way to pinpoint potential sensitive or "driving" distributions.

The alternatives to Monte Carlo analysis are to use "analytical uncertainty propagation" and "classical statistics". The document does not describe the first with any degree of clarity, and the second, of course, is desired but often not possible due to lack of data. The result is that the reader is left with one choice: use sensitivity analysis. Worse yet, the recommended method for doing a sensitivity analysis is incomplete: only use the upper and lower bound. More complete use of sensitivity analysis is to alter the parameters by a constant percentage to test the sensitivity of the mathematical model.

3. Are there data gaps?

One major issue is actually identified but then left with no recommendation: how should

DEPARTMENT OF THE ARMY
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REPLY TO ATTENTION OF

July 14, 1995

Health Risk Assessment and Risk
Communication Program

SUBJECT: Review of the Draft Exposure Factors Handbook

Ms. Helen Murray
Eastern Research Group, Incorporated (ERG)
110 Hartwell Avenue
Lexington, Massachusetts 02173-3198

Dear Ms. Murray:

Thank you for the opportunity to review the Draft Exposure Factors Handbook. Dr. Jack M. Heller and Mr. Dennis E. Druck of the Health Risk Assessment and Risk Communication Program reviewed the subject handbook with special emphasis on the sections pertaining to water and soil ingestion and dermal contact. The presentation of the data and recommendations is organized in a manner which should be useful to exposure assessors. Overall, the handbook is well done and provides information that should improve the exposure assessment process.

Our only recommendation is that the Background Section of the Introduction includes an expanded discussion of the importance of using site-specific exposure factors in lieu of default values when such information is available. Our point of contact is Dr. Heller at commercial (410) 671-2953.

Sincerely,

Arthur P. Lee

Arthur P. Lee, P.E.
Major, U.S. Army
Program Manager, Health Risk
Assessment and Risk
Communication

Copies Furnished:

Headquarters, Office of The Surgeon General
Commander, U.S. Army Medical Command

Readiness thru Health

Brad Shurdut

Comment for Draft *Exposure Factors Handbook* Non-Dietary and Dermal Exposures

I. General:

The additions to the Drinking Water Ingestion, Soil Ingestion, and Dermal Exposure sections have significantly bolstered the utility of the book. The presentation of material in this book does provide the reader with a fairly objective listing of pertinent studies from which exposure factors have been derived and forces the user to use his discretion as to the factors which he deems most appropriate. Although previous input has suggested that the development of standard scenarios will not be pursued, the use of a brief and simple example which either precedes or follows the textual discussion of the exposure parameters would certainly clarify the utility of the data presented.

Should the authors or sponsors of this book promote the use of some results more than others to ensure the consistency or validity of exposure assessments? Stronger suggestion rather than a recommendation may achieve this end. I think the utility of this book is two-fold: (1) to present a compilation of credible scientific data and studies to be used to facilitate and enhance the development of exposure assessments and (2) to improve the consistency of the data used in exposure assessment by suggesting 'recommended' data to be used for assessments. One of the greater utilities of exposure and risk assessments is the use of the work product within the regulatory framework of the EPA. In my interactions with the EPA, especially in the area of pesticide human exposure assessment, one of the larger problems faced by myself and others in industry is the inconsistent use of exposure data and values by the assessor and the EPA scientist. It seems to me that the Exposure Factors Handbook presents an opportunity to sift through the pertinent studies and highly recommend the data sets and methodologies that *should be used* in assessments in concert with other EPA generated guidelines. This can be more easily achieved by a table at the end of each section or chapter summarizing the recommended values or point estimates for describing each variable.

Although this format provides a rich source of information for the exposure assessor from which he can choose appropriate factors for his assessment, the data (and data tables) may confuse rather assist the assessor. For those data sets that have gained greater levels of acceptance within either the scientific or regulatory communities, a notation should be provided. This may in fact be done by the classification of studies as either 'key' or 'other relevant studies'.

II. Water Ingestion:

Usefulness of Data Presentation:
The 'Drinking Water Consumption' chapter would be easier to follow if the chapter sections were presented in a manner which paralleled the variables within the dose equation. For instance, the section entitled 'Key General Population Studies' could be re-titled as 'Ingestion Rate (IR): Key Studies' . For those variables, such as body weight and exposure duration, which are discussed in other parts of the book can be referenced to applicable sections. In addition, those variables, such as concentration (C), diet fraction (DF), and averaging time (AT), which are either not applicable for drinking water consumption or specific to a chemical and/or event can be briefly touched upon before the primary analysis of water consumption rates.

The 'Ingestion Rate' discussion could be organized into sub-categories. For instance, there are several factors of interest that potentially affect the rate of intake. These may include, but are not limited to, geographic regions living and activity level. Therefore, the data may be presented by category rather than exclusively by author. The effect of activity pattern on consumption rates, for example, is discussed in the Ershow results and then in the Mcnall and Schlegel results. Consolidation would more efficiently direct the exposure assessor to a section of the chapter and preclude the need to comb the entire chapter. Another suggestion may be to first present the capsule summaries of each study included in the chapter and then to group the tables at the end of each section.

A summary of the factors presented would be useful to include at the end of the drinking water section. This would boil down the studies into a 'quick' reference form. Each factor and/or study describing the parameters could be accompanied by a 'high', 'medium', or 'low' ranking based on the strength and accuracy of the study reporting the data.

Means and standard deviations should be included in drinking water tables. This would facilitate the use of point estimates if desired by the assessor (Tables 2.2 and 2.3).

Data contained in the National Food Consumption Survey was collected in 1977-78 which was used in the Ershow analysis. Not only is this database slightly outdated which may effect the consumption values, but the data contained therein refers to commodities regardless of the mode of preparation. As a result, the water content of commodities may significantly change following the consumer's preparation.

Water consumption is a function of the ingestion of water over the course of a day from many sources. Most of the water consumption data are aggregate results. When concerned about source-specific exposure it is necessary to estimate potential water consumed at one location versus another- not total water ingested from a variety of sources over the course of a day (restaurants, place of employment, etc.). A percentage breakdown of the source of ingested water needs to be split out of the general discussion and presented in a distinct section describing the dietary fraction (DF) variable.

Another source of water for ingestion, although not easily quantified, results from swimming in potentially contaminated bodies of water and during the taking of showers. Although these routes of exposure can be considered minimal, they should be acknowledged.

The use of arithmetic and geometric means are not clearly identified. As on page 2-41, use of a 'mean' heading does not sufficiently describe the measure of central tendency used.

Gaps/Future Research needs:

EPA is currently considering the use of more recent consumption databases for DRES (Dietary Risk Analysis). There is a need to use more up-to-date consumption data than the NFCS upon which many of the studies are based. Consumption data is underestimated by approximately 15-20% compared to the more recent databases. In addition, dietary patterns may be quite different today than those reported within studies from 1976. Today there is an increased emphasis on eating healthy which may also affect consumption patterns.

There is a need to additionally refine some of the ingestion data. Source specific and location-specific data would be useful to assess water ingestion exposures resulting from distinct sources (home vs. other sources) and the source of tap water whether the source be from a well or reservoir, etc.

III. DERMAL ROUTE OF EXPOSURE

The organization of this chapter does present and develop the data well. Since only body surface area studies are presented in the general dermal exposure section of this chapter, the reader should initially be directed to other applicable sections of the book to find some of the other exposure factors, i.e. exposure/activity frequency, event duration. In addition, the section dealing with dermal adherence of soil has not been broken down into 'key' and 'other' studies. Since some of the studies contain empirical data while others like the Sedmán study presents mere re-calculations of other previously reported data, clearly some results are more key than others. The studies by Lepow and Driver may arguably be more reliable than the other studies provided in this section, but less reliable than the Kissel study contained in the 'New Soil Adherence Research' section.

Other factors which may be required for dermal exposure assessment are measures of the frequency of dermal contact with a surface and the size of the surface dermally contacted. The data to answer these questions are most likely presented in the 'Reference House' of 'Activity Patterns' sections within the book. The user should be directed to these areas in the sections briefly describing each exposure parameter in the dermal exposure assessment equation. In addition, ranges for transfer factors reflecting the amount of a material capable of being dislodged from a surface need to be developed. Studies using pesticides have shown that generally less than 1% of the material applied to a carpet matrix is actually removed from the carpet onto the skin. These factors have been demonstrated using both dislodgeable residue techniques with dosimeters and biological monitoring performed in concert with human activity on the treated surfaces.

Since the surface area data is of primary importance to the determination of dermal exposure, the data must be coupled with the estimated area of skin exposed while conducting various tasks. A section may be added that summarizes these results which further supplements Table 4-11. Several publications have presented this data (USEPA, 1992; Hawley, 1985).

The authors are correct in saying that contrary to initial perceptions, clothing does not eliminate dermal contact with a chemical. However, depending on the chemical potentially exposed to, clothing is generally an effective barrier against chemical penetration and greatly reduces the amount of pesticide contacting the skin. Studies conducted to evaluate exposures to pesticide workers demonstrate that generally less than 10% of a pesticide contacting the outer surface of clothing penetrates through the clothing with a majority of the results being much less than 10%. Secondary dermal exposure may also be a consideration. Some chemicals may be trapped in clothing materials which are subsequently transferred to the skin over time especially as the clothing becomes wet with perspiration.

The soil adherence studies presented in the Dermal Exposure section, except for the Kissel study, are very limited. It is generally regarded that the amount of soil found adhering to exposed skin regions are highly dependent on the type of activity performed. Many of the studies do not specifically look at this variability when performing different tasks. However, the Kissel study does attempt to describe this variability which occurs in the real world by documenting soil-skin adherence for several tasks and for all exposed skin regions.

Recommendations:
The recommendations presented are appropriate for this section.

Data Gaps:

There is a need to include additional data regarding site-specific absorption differences for different regions of the body (variability of skin permeability). Maibach has discussed this issue and documented this regional variation in percutaneous penetration. Penetration indices for regions of the body have been developed by comparing penetration of a challenge compound to the penetration of a chemical through the forearm. The penetration indices were specifically derived from hydrocortisone skin penetration data and from absorption results using the pesticides, malathion and parathion (Guy and Maibach, 1984).

Another need is for a description of regions of the body that may be potentially exposed during the conduct of various activities. In addition, the size of an area contacted by an individual performing a certain task directly influences his potential exposure. Therefore, dermal exposure is not only a function of the surface area of the body part being exposed but the number of times that the area will be exposed to the contaminated media (i.e. exposure when walking barefoot on contaminated grass or soil is dependent on the surface area of the receptor (the foot) contacting the grass and the either the amount of the total lawn walked upon or number of times contacted).

There exists a need to develop additional soil adherence numbers for certain tasks or activities conducted in various types of soils (sand, loam, or silt with varying moisture contents). Furthermore, there is a need to investigate the potential relationship between residence time on the skin and absorption, and the relationship between loading levels (greater than a monolayer) on the skin and subsequent dermal absorption. The general relationship between dermal adherence, exposure to solvents and particulates in or on the soil, and subsequent dose needs to be more fully investigated before recommendations for the use of this data can be encouraged.

In order to measure potential exposure and extrapolate dermally absorbed dose additional factors should be considered in the analysis:

- Permeability differences between skin of child/adult
- Permeability differences of hydrated vs. dry skin.

IV. Soil Ingestion and Pica:

The organization of the chapter is good. However, since a majority of the studies deal with ingestion rates discrete time period, the Hawley study describes results for each season. Since seasonality could be considered a significant factor for the amount of soil ingested, this data set should be distinguished.

The soil ingestion studies (Clausing) using trace analysis from outdoor soil which is subsequently correlated with fecal levels of the trace material may potentially overestimate soil ingestion quantities. These studies do not delineate between potential exposure to trace elements from either indoor or dietary sources. It is possible and likely that the trace elements are present within the home in dusts, etc., especially following tracking in of soil into the home, which subsequently leads to potential exposures following contact with contaminated surfaces. Furthermore, the control population consisting of hospitalized children, are quite different than the studied population in terms of types of activities performed over the course of a day and the limited indoor environment to which he is exposed. As a result, both the Calabrese and Davis studies yield more reliable results than the preceding studies.

Data Gaps:

All the studies are lacking in the apparent documentation of a child's activity and the amount of soil ingested. Soil ingestion would intuitively be activity-dependent and characterization by level of activity would be more useful for the exposure assessor. By doing this, it would also facilitate the use of the data to re-create exposure scenarios in different regions and under different climatic conditions.

Little work has been presented as to a child's 'mouthing behavior'. The number of times that a child sucks his thumb, touches his food (especially a sticky lollipop) with his hands can have a strong impact on the final amount of soil ingested. Data as to activity patterns, 'mouthing behavior', removal efficiency of soil by saliva, and soil loading on the hands (Kissel and Lepow studies) may present an equally predictive method for estimating soil ingestion.

Analysis of Uncertainties:

Good general overview of uncertainty analysis. It does briefly summarize the uncertainties that one must be aware of when conducting exposure assessments. It also presents the limitations of potentially using point estimates in contrast to probabilistic estimates using Monte Carlo simulations.

Work Group #3

Human activity patterns

Steven Colome

Review of:

EXPOSURE FACTORS HANDBOOK

External Review Draft
June 1995

EPA/600/P-95/002A

The National Center for Environmental Assessment published the first edition of the Exposure Factors Handbook in 1989. Availability of newer data on human exposures and further development of approaches to the craft of risk assessment led to the drafting of this second edition. Sections have been added on the use of consumer products and the reference house. Content has been updated throughout the text.

This reviewer did not participate in the 1993 workshop and comes to this task with a fresh perspective. My review concentrated on sections of the draft that relate to activity patterns including portions of Chapters 3, 5, 6, and 8. These were the subject of my assigned review. In addition, I scanned the section of Chapter 7 dealing with air exchange rates.

Overall, the document presents information that may be useful to the risk assessor. The task of compiling the exposure literature relevant for risk assessment was accomplished in the Handbook. Of greater use to the risk assessor, there was some screening of the literature for pertinence to the task of risk assessment. Individual studies have been evaluated for strengths and weaknesses relative to risk assessment objectives and not necessarily to the stated objectives of the investigators and the original purposes of the studies. A substantial amount of raw and summary data are provided in the Chapters and Appendices that may be used by the risk assessor for background information or modeling.

Still, the Handbook was not particularly easy reading, and reviewing the assigned sections of the document left me with the feeling that something was still missing. I tried to approach this document as a risk assessor faced with a specific project. This is the person who might turn first to this document for information.

The chapters I reviewed were generally weak on interpretation and evaluation of the available studies. Many of the individual study evaluations read like the study-by-study evaluations of the Criteria Documents. Those documents have legal status that requires attempts at full and balanced evaluation. It seems so me that the Handbook could take more latitude by skipping weaker studies, using what can be gleaned from available studies, and directly identifying the data gaps and weaknesses. To assist in interpretation and qualitative estimation of uncertainty, the Handbook could address biases and the their potential magnitude. This directness was generally avoided and the authors opted to point out limitations without discussion of the potential influence of those limitations on the results of risk assessments. I would also have liked to see an attempt at more integration of information across studies. How are the studies similar and how do they differ? Can we learn something from the differences?

Detailed comments follow:

CHAPTER 3

Page 3-1, 1st paragraph. The word should either be *particulate matter* or *particles*. You should not use "particulates" as a noun.

Page 3-1, equation 3-1. It may be useful to add a conversion from ppm to $\mu g/m^3$. Gaseous measurements may be expressed in ppm.

Page 3-2, paragraph 1. The reference to "Heart" watches should be dropped. There are a variety of techniques for monitoring heart rates and the apparent endorsement of a product should be avoided.

Page 3-6, Table 3-2. The footnote should correspond more directly to the referenced headings. This table is difficult to read and needs additional editing.

Page 3-9, paragraph 2. It is unclear from the presentation whether the time/activity survey of 2126 Californians was conducted by Layton or by another investigator. The discussion is deficient in evaluation of the quality of the exertion distributions, which are based on recall. Since this study is heavily relied upon to provide summary information on breathing rates, this omission is significant. It is also stated that this study is representative of the general US population even though the participants are all drawn from California. In other sections, regional studies are often said to be nonrepresentative because subjects are drawn only from the region of the survey. I would tend to be more accepting of regional studies when they provide the only available information. The Handbook, however, needs to have consistency across chapters in its evaluation criteria.

Page 3-13, last paragraph. This is an example of the type of evaluative comment made about a study. Chapter 8 indicates that this information can be used by the risk assessor to establish qualitative uncertainty estimates for data drawn from the studies. However, I am at a loss as to how a risk assessor can constructively use the information presented in this paragraph in order to assist a decision-maker to interpret uncertainty in a quantitative risk assessment. More to the point, we need to know the quality of information for the parameter presented. Are the results likely to be biased. If so, what is the direction and potential magnitude of any bias. What are the likely results from a study being nonrepresentative? Should we proceed to use the data distributions for lack of more general data? The evaluative paragraphs are too general and inconsistent now to be of much use.

Page 3-2, paragraph 1. I suspect the heart rates were regressed with log VR and not "lognormal" VR. The distribution of VR may be approximately lognormal but the manipulation of data takes the log of the value. This error appeared earlier in reference to the Linn or Layton papers but I could not find it while looking back.

Page 3-22, Table 3-11. The number of students studied (EL=17; HS=19) should appear on this table. It would be a good practice to provide numbers of subjects on all tables since this helps in estimating variability and may be necessary for certain models. Also, tables have a way of being reproduced absent the accompanying text.

Page 3-27, paragraph 2. Why does this California study fail to represent the US population while the Layton study, also conducted in California, is interpreted as providing generalizable information. The criteria used to evaluate studies needs to be consistent.

Page 3-28, last paragraph. Why is the lack of heat stress information used as a limitation of this study alone? I do not believe that any of the cited studies included consideration of heat stress. There are a large number of demographic groups and health considerations for which it would be useful to have additional information. The need for risk assessment is to set priorities on this information and focus on factors that have the highest individual or aggregate population risk.

Page 3-30, paragraph 2. Lognormal is again used incorrectly. Also, regression lines are not "fed to" unless we have developed a new strain of equation-eating bacteria. Also, discuss whether classification by the categories of essential vs. nonessential activities was productive. It appears from Table 3-16 to be insignificant. If 'essentialness' of an activity is not an important classifier, then it should be dropped from consideration in risk assessments. Let the Handbook be a guide to where risk assessments may constructively apply our limited efforts. We are still at a stage of development in this field of risk assessment where information needs to be filtered.

Page 3-33, last paragraph. It is meaningless to discuss the "distribution of the data set" for a sample of 9 people. The useful comparison is whether this small data set falls generally in line with observations from larger studies. If the study merits presentation in this handbook you should be able to discuss the added understanding derived from the effort. Studies for special populations such as people with certain diseases, occupations or health status, may be useful when the sample size is small. The values derived from these special studies can be compared with those derived from population studies to determine whether parameter estimates need adjustment for the population subgroups. I do not see this type of evaluation here.

Page 3-37, Table 3-18. This table is difficult to interpret and will therefore be difficult to use. How would a risk assessor apply the percentage of correct assessments of ventilation range to a questionnaire of self-assessed activity? I suggest that the table be made more self-explanatory or else that it be dropped and the relevant information summarized in the text.

Page 3-36. Something is lacking in the transition between the first and second paragraphs under the section on "US EPA". This needs an appropriate segue between ventilation rates and percent time spent indoors.

Page 3-46, first paragraph. The recommendation of 13.3 m^3/day is far too exact for our level of understanding. By using a false sense of precision, risk assessments often portray greater certainty than exists. I recommend presenting a range of values and listing characteristics such as gender that influence inhalation rates. Since the recommended value differs substantially from the previously used ICRP value of 20, I think it is essential that the rationale be more tightly constructed.

Page 3-46, paragraph 2. It is stated that 20 m^3/day represents "an upper percentile estimate". What is meant by this? I suspect this means the upper 1% value. However, this would be arbitrary and the phrasing could mean upper 1, 5, 10 or 25% value. In general, the recommendations made for this section are not convincing and have not been presented in a manner that would be of great use in a risk assessment.

Page 3A-5. If Table 3A-5 is essential it should be retyped for clearer presentation.

CHAPTER 5

Pages 5(16-20). It may be useful to collapse this table since many of the categories of activities are not needed in exposure studies. How, for example, would a risk assessor use family time or free time spent in social life? These extra categories are present because the original studies were not conducted to assist the risk assessment enterprise; instead they had a clear purpose to address social behavior. Your task is something like putting a round peg in a square hole - you'll need to trim the edges to make it fit.

Page 5-23, paragraph 2. The "limitation" that time-use relevant to exposure questions is missing is not a design limitation. As stated above, these studies were conducted for other purposes. It is useful to keep this in mind while evaluating exposure applications of data from these studies. It would be useful here to point out the need and utility of conducting time-use studies with exposure-related objectives.

Page 5-24, last paragraph. What evidence is there that the activity patterns of children have changed significantly since 1981? Unless these is some direct evidence of this, the age of the study should not be listed as a limitation. It would be valid to state that there are questions regarding the current application of exposure models due to possible changes in the activity patterns of children over the past 15 years. Even with a general comment like that it would be useful to think through which behaviors might have changed that would alter exposure patterns. This could serve the further use of this

Handbook, which is to point the way to additional studies that will assist in reducing uncertainty in risk assessments.

Page 5-(40 to 45). This study is useful in part because it makes direct comparisons between groups (i.e., Californians and the US as a whole) on exposure-relevant activities.

Page 5-45, paragraph 3. The CARB study and the national studies were **not** conducted independently. John Robinson was a common factor and principal in both efforts. Because of this, the study designs and methods were similar.

Page 5-62. I would classify the paper by Sexton and Ryan as a review and concept-setting piece, and not as a study. The Handbook treats this like a data presentation study. The summary of this paper more appropriately belongs in the introduction to this chapter where it can provide some orientation and direction for the detailed studies that follow.

CHAPTER 6

Pages 6-3 to 10. The tables on these pages present the mean value for minutes spent in use of various consumer products to the hundredth of a minute. Since the standard deviations are typically express in tens of minutes to hours, the precision of the means is silly and implies greater accuracy than exists. The means should be rounded to the nearest minute. Also, you should more critically evaluate the quality of the use data since they are based on one-year recall of product use. That information may be so inaccurate as to be virtually worthless. The issue of data value should be more directly addressed in this section.

Page 6-21. The recommendation section here is very good and should be a model for Chapters 3 and 5. The summary addresses which information is needed in order to estimate exposure. It proceeds to indicate which of these data are available in the chapter and what data must be gathered from other sources or otherwise estimated.

CHAPTER 7

I also reviewed the section on building ventilation presented in this chapter. Very little guidance is given in this section to the risk assessor on how they might use the information provided on building ventilation. Further, there is no reference to the joint distribution of volume and ventilation and how a risk assessor might merge the distributions for these two variables. Ventilation and building volume are the two most critical factors affecting building exposures once the source strength in an enclosed space is known.

This section also does not spend much effort describing the role of season and temperature in affecting air exchange. For example, while colder temperatures in winter will lead to tightening of the structure to minimize heat loss, thereby reducing ventilation rates, the higher driving force associated with the temperature difference between the inside and outside will tend to increase ventilation rates. The same is true for the air conditioning periods of summer. It is in the transitions that great differences can be observed between two adjacent homes while one uses cross ventilation to cool the residence, a neighbor may have tightened up the home to efficiently use air conditioning. These differences have a significant influence on ventilation and may have a significant influence on exposure. I get no sense of these relationships in reading this section.

This section should also cite the M. Pandian et al., paper published in J. Exposure Assessment and Environ. Epidemiology in 1994. This manuscript used the VERSAR ventilation data base. Following publication, it was found that the VERSAR data base was incorrect for the western states due to errors in the coded data provided by Brookhaven and misinterpretation of the data flags. These errors were corrected in errata published by the same journal.

The Koontz & Rector manuscript from 1993 would have used the incorrect VERSAR data base while the Koontz & Rector 1995 manuscript is not listed in the references and I do not know for certain whether this version uses the correct data. Based on the values presented in Table 7-5, I suspect these values are corrected. It would be useful to cite the Pandian manuscript, however, especially since it was published as an aid to conducting exposure and risk assessments.

CHAPTER 8

This is a well written and general summary. However, it provides little direct guidance to the risk assessor. This may be purposive in order to force careful thinking with each assessment encountered. If the other sections had been written with the same clarity, the rest of the document would have been easier to read.

Edward Avol

Comments on Chapters 3, 5, 6, and 8 (Activity Patterns Panel):

CHAPTER 3, INHALATION ROUTE

p.3-1, sec 3.1, equation definitions - There is an inconsistency in the definition and professed use of Equation 3-1; In the text, the claim is made that ADD is to be used for non-carcinogenic non-chronic effects, but in the equation definitions, AT is defined for carcinogenic as well as non-carcinogenic effects. Since the LADD is used for carcinogenic-related calculations, either correct Eqn 3-1 so that AT is replaced by ED, or add another equation for LADD with AT appropriately defined.

p.3-1, sec 3.1, para 2, second to last sentence - If exposure duration is defined with respect to a particular location, ADD would need to be a summation of multiple location-based exposures, would it not?

p.3-1, sec 3.2.1, first sentence - health risk is also a function of the chemical species, not just concentration, duration, and inhalation rate; for example, exposure to hexavalent chromium at a given concentration, duration, and inhalation rate should result in a different health risk assignment than exposure to sodium chloride at the same concentration, duration, and inhalation rate.

p.3-2, sec3.2.1, para2 - Most discussions of ventilation rates and minute volumes are framed in units of liters per minute; this practice is begun in the paragraph, then discontinued, but it would be more valuable to users of the handbook to present the discussion in commonly used units (liters per minute) than to have readers continually have to back calculate from cubic meters per hour. Also, the reference for the Ozone Criteria Document should be EPA, not CARB.

p.3-4 - general editing comment - having the tables interspersed with the text made it difficult to read and follow...is it possible to put tables and figures at the end of each chapter, as is done with references?

p.3-3, sec3.2.2, Layton discussion - the text discusses the three approaches but only addresses the potential advantages and limitations of the third approach; in any event, it is a little difficult to follow the discussion - would it be possible to add a summary table comparing the three approaches with regard to limitation, advantages, and results?

p. 3-42, Table 3-22 - Layton reference should be 1993, not 1992.

p.3-45, Summary table of inhalation rates -
(a) The presentation, in the paragraph leading to this table, begins,"...for purposes of this recommendation,...", and then the summary table is presented. The presented values are misleading to potential readers in that only after reading the text following the summary table doe it become clear that the summary values in the table are not the recommended values for use; it would be more direct and of more use to the reader to summarize recommended values, and then explain them, if need be (i.e., re-work this summary table and use the

surrounding paragraph of text as justification/explanation of what the table says; otherwise, there is a risk that a reader may just use the values in the table, without ever reading that the Spier value for upper percentile inhalation rate was too high for continuous exposure assessment estimates. Perhaps a good compromise would be to add another line to each of these summary tables, called "recommended value"...
(b) The title is misleading, and should include the word "adult" or "age 13-65+yrs" or some other identifier, since the table on p3-47 is also summary of long-term exposure data (but for children less than 12yrs).

p.3-46, Summary table of short-term exposure inhalation rates - title problem; no specification of appropriate age range for use, but it appears in the section marked adult (yet CARB studies cited included children)...? Again, another line with "recommended values" would be most helpful.

Chapter 3 Issue Review:
1. The data is presented in a way that could be useful to assessors, if the recommendations above are incorporated. In terms of the <u>best</u> way to present the data, my personal reference might have been to more clearly identify key studies, supporting studies, limitations, advantages, and recommended values as numbered sub-headings so the reader/user could quickly turn to the critical passage for technical support (since it is my expectation that all potential users will not work their way through the text to find the qualifiers and considerations that could have been more clearly identified.

2. The studies seem to have been appropriately grouped and fairly presented; clearer identification, as described in the previous comment above, would help.

3. As Issue Review Comment #1 above suggests, the recommendations could be more clearly presented in the tables; possible specific suggestions are presented above in comments on summary tables.

4. A useful chapter here would include shortfalls in applicable activity pattern information for ventilation rates of workers in a variety of field occupations (indoor and outdoor), reproducibility of ventilation rates (perhaps the ranges we see reported are reflective of real-world variability and not shortcomings of experimental design).

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CHAPTER 5, OTHER FACTORS FOR EXPOSURE CALCULATIONS

p 5-1, sec 5.1, middle of para - should read "...Black females (75.6 years)."

p 5-1, sec5.1 , last sentence - Given concern for environmental justice and the observation that minorities may be in locations of exposure to toxics, what is known from Census about life expectancy of Asians? Hispanics?...in California, for example, these sectors of the population are on their way to becoming larger in number than the white sector.

p.5-10, sec5.2.2 - Burmaster et al article submitted 2/1/94 for publication - is this a published reference now?

p.5-13, sec 5.2.2, para 2 - heights and weights here are presented in inches and pounds, but everywhere else in this section, in metric units.

p5-13, sec 5.2.3 - A summary table of recommended values would be useful for readers.

p.5-29, Table 5-17 - Saturday time duration sum is 2440 instead of 1440 - should social entertainment be 114 instead of 1114 minutes?

p. 5-41, first sentence - It is unclear what a "tomorrow" approach is; a sentence description would clarify the discussion.

p. 5-51, para 1, line 9 - "One child was randomly selected from an English-speaking household" suggests that all the rest were from non-English speaking households! Please rephrase so that it is clear that only English-speaking households were eligible for survey and in any selected home, a child was randomly chosen (regardless of age) to participate in the study.

p. 5-52, Table 5-31, note c - wording is incorrect; column totals may differ from 1440 due to rounding error.

p.5-66 - There should be some sort of conclusion or recommendation here, after covering so much time/activity data. Recommendations for use?

p. 5-82 - Again, there needs to be some closing thought here - a recommendation or something...It just sort of stops...

Chapter 5 Issue Review:
1) A great deal of information was presented in this chapter, but it was not really synthesized into a usable body of data. When so much data is provided, it is often difficult to recommend what values should be used, but at least, recommendations of study data sets, for explicitly listed reasons, could be made. In this section, there did not seem to be any.

The presentation could have been better focused; in the face of so many tables and so much overlapping data, it was difficult to see where any filtering, editing, or judgement about the quality of the inherent data had taken place; a summary recommendation, similar to that proposed in the Chapter 3 review above, would help here.

2) Rationale for why one set of study data was chosen to be emphasized over another similar data set might be useful, but ultimately, a clear summary of what was persuasive for each study considered would help the reader.

3) (See comments in Chapter 5 Issue Review, #1 above).

4) Suggestions for the discussion of data gaps in the activity pattern area include the following: how have changes in the economy (shifting to service driven work force with less

industrial base) and work force (male/female) affected distributions of exposure (the presented work is generally from the '70s and '80s); have mobility patterns changed (do grown children stay and live with their parents longer, resulting in longer and different exposures)? How does one quantify the residential history pattern of off-spring, as opposed to homeowner?

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CHAPTER 6, CONSUMER PRODUCTS

p.6-7, Table 6-3 - The amount of home solvent product used annually, in mean ounces per year, presumably is determined on sales information and not based on the percentage of active ingredient in each of the home products. If it is reasonable to suggest that some home products have a greater percentage of ingredients of exposure interest, would it be useful to have a table of percentage of active ingredients (the text prefaced the tables by specifying methylene chloride or its substitutes)? Would this change apparent perspectives on potential exposures?

p.6-22, References - Is any other information available, or is Westat the only source of data?

Chapter 6 Issue Review:

1. The data is presented in a useful manner. As suggested in the first comment above for Chapter 6, some re-ordering of potential exposures, based on active ingredients, might also be helpful (although it may admittedly be out of the scope of typically available information).

2. Only three studies, all performed by Westat for EPA in 1987, were presented. These may be the best information available, or the only information available. That being the case, these are certainly relevant and appropriate for inclusion.

3. This chapter had a recommendation section that could be of great value to the intended reader. However, given that only a few studies were available to draw from (and all were performed by one agency), it would seem especially appropriate to summarize the limitations and uncertainties of the reported work in the final section.

4. The dearth of reportable studies in this area in and of itself are a dat gap for future research. In addition, it would be useful to learn more about what percent of the ingredients in the products being tracked are of potential health concern (and order exposure by that criteria); it would be useful to learn more about the exposure pattern of the actual end user - it may be that a given product is only used for 10 minutes per event, but how often is the same person (such as in an occupational setting for a janitor, or aircraft maintenance, or home cleaning woman) exposed?

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CHAPTER 8, ANALYSIS OF UNCERTAINTIES

p.8-3, sec 8.1.2, para 2, line3 - should read "...such as consumer product preference surveys or..."

p. 8-8, sec 8.2. - this section is a valuable introduction and overview of how the entire document should be interpreted and used; it ought to be an overview comment at the front end of the book, so that potential users read this section and keep this perspective in mind as they seek information in the document.

Chapter 8 Issue Review:

1. The types of uncertainties in analyses are presented, one after the other, without example or much discussion; in that sense, this chapter is much more abstract and different from the previous chapters. Better sub-section identification of discussion points (such as 8.1.2.1 Sensitivity analysis, 8.1.2.2 analytical uncertainty propagation, 8.1.2.3 probabilistic analysis, 8.1.2.4 classical statistical methods...

2. Key and relevant studies don't apply in the same sense here as in earlier chapters; still, several studies are appropriately cited for obtaining additional information.

3. Uncertainties have been fairly discussed, but no specific or general recommendations are given at the end of discussion.

4. (no suggestions to offer on this point)

John Robinson

TO: HELEN MURRAY 617-674-2906

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From: John Robinson

GENERAL COMMENTS ABOUT SURVEY METHODS

Many of the data tables in the handbook are based on social surveys. As such they are subject to several sources of limitation that affect all surveys. A major problem with the handbook is that it tends to treat all surveys as equal, w--- in fact they vary widely in sophistication and utility in terms of sample design, field qualit -ol, question framing and presentation of results.

In general, a well-conducted survey of the public is expected to meet the following criteria:

1) A probabilistic sampling frame, in which ALL individuals have an equal (or at least known chance of selection)

2) Sample sizes selected at random from that population that allow generalization to that larger population. While statisticians argue about that sample size, it is the case that a random sample of 100 individuals has a sampling error of +/- 10%, which can be tolerable for some estimation purposes -- if conditions #1 and #3 are met. Sample sizes below 20 or 30 individuals have 2 to 3 times that level of imprecision and are are usually considered to be quite unreliable, particularly if the sample respondents are not chosen at random (as is usually the case)

3) A high rate of response from those individuals chosen at random into the survey. This is usually not a problem for surveys conducted by the U.S. Census Bureau with response rates above 90%, but can be a serious problem for typical survey organizations that tolerate response rates of 60% or less. Few "consumer panel" surveys achieve response rates close to that level, if strict response rates are calculated. The possibility of biased samples of respondents are unfortunately high in such circumstances.

4) Careful attention to the ways information and questions are framed to respondents. Different ways of framing questions have been found to produce diffferences of 20 to 60 percentage points in estimates, compared to the 3 to 5 point error ranges associated with sampling error.

Unfortunately, much less is known about these latter contributors to "non-sampling error" and so field procedures to overcome them are much less subject to control.

Some ways of asking behavioral questions are more generally accepted by survey practitioners than others, however. In general, the easier the reporting task expected of the respondent the better. That means that asking respondents to keep accounts of what they are doing at the moment is easier and more reliable/understandable than asking what they do "regularly" or "typically". It is also preferable to long-term recall, such as "over the last six months". However, asking respondents to recall what they did yesterday has not been found to generate serious recalll difficulties (as is implied in several passages in the handbook). There is the problem that "yesterday" behavior does provide only a limited view of the behavior of individual respondents, but it can produce quite reliable data on what the population does ON A PARTICULAR DAY.

A major problem does arise, however, when we attempt to use these one-day data to model the long-term consequences of exposure for individuals. An individual can be exposed to an average carbon monoxide levels per day at a certain levels, but if they receive all of that dosage in a few minutes of a single day, it can be lethal. These long-term consequences at the individual level need to be considered.

In general, then, there are myriad factors that the reader needs to take into account before treating them as factual or scientific error free of mundane or naturally-occurring sources of error. This should be done at the outset AND in the context of each chapter, much as in the spirit of the current text, but more targeted on the most important sources of error.

Along the same vein, it would not seem difficult to end each chapter with a call for needed measurement advances to produce the kind of statistical data that would be most appropriate for policy purposes.

A further problem arises from the lack of essential data to understand the implications of what are presented. Thus if we look at drinking water or paint application, what proportion of the population are involved in the activity for a day or a year. The percentile data appear virtualy uninterpretible without such basic statistics that should be easily available in the original source (if not the original authors should be chided for omitting it). Many of these parameters are now available from our 1992-94 MAPS study that should soon be published -- copies to be sent with with the hard copy of these comments.

Additional background information needed in the introduction to the book include:

1) More detail for the initiate on terms like "default values", exposure scenarios" and "site-specific situations" (page 1-2)

2) The difference between Part I and Part II estimates (best noted for all tables throughout the handbook)

3) Greater discussion of the page 1-5 model and how the page 1-8 examples can be interpreted and considered for policy terms. Would it be possible to provide a graphic display of this model and how it works for a well-measured exposure phenomenon, or for the best understood example.

SOME SPECIFIC COMMENTS ON CHAPTER 3:

The above comments on sample and field weaknesses apply very clearly to the various studies described in Chapter 3. Not only are these based on small samples, but more importantly on highly unrepresentative groups, like athletes and construction workers, or people living in California. The applicability to any other population is almost absurd, perhaps even to construction workers in other parts of the country. (This does not mean that the data are totally wothless, only that their limitations should be clearly noted. If we could show the proportion of the population in construction, or other at risk, populations that could also be useful in understanding the import of the data. These data could also be used with diary data for these groups to show how divergent a group they are in terms of their activity patterns).

On the other hand, a good deal of irrelevant data are reported, such as on the estimate data of Shamoo, appear in the text. If it is important, the reader needs to know why. Why show Tables 3-45,3-47 which have only one entry. Where are the "healthy adults" in Table 3-13?

SUGGESTIONS ON CHAPTER 5:

It is probably too early to include the 1992-94 MAPS (NHAPS) data in this chapter, but at least it should be cited as being available soon, along with (we hope) user-friendly instructions. Can someone call Bill Nelson (919-541-3184) to get permission to use and cite the report at our meeting?

I would argue that the data and studies on pages 5-14 to 5-30 can be eliminated, given the more recent and risk-focused data from Robinson and Thomas (1991). At most, these earlier data could be cited in the Appendix or referenced in the earlier handbook. The Robinson-Thomas could be moved into the main text as a substitute for the excluded material. Note that I am suggesting killing my own data, which are now both obsolete and too imprecise for exposure assessment.
The Carey data on occupational tenure should be in another separate section. MORE TO COME BY 3PM!

TO: HELEN MURRAY 617-674-2906

P3

More Specifiacally:

-Why not show some data in pounds, as well as kilos for us metric retards? p5-4, 5-5.

-What is "Gaussian" p5-13, and how do you get there from regression?

-Data in Tables 5-14,5-15 do not add to 1440 minutes, another reason to drop them

-p5-23 and elsewhere refer to "respondents that" rather than "respondents who"

-Is voluntary mobility useful when involuntary mobility has the same exposure implications?

-p5-45 limitations do not seem that serious given the final sentence in the paragraph.

-p5-55 limitations are not serious

-Tarshis data are from very poor and ancient surveys; MAPS data are available and far superior -- also contain estimates to compare with Table 5-39

-Table 5-40 data are ancient -- put in Appendix at best (can be inferred from Robinson-Thomas also)

-Drop Sell data on kids time, as CARB data are far superior

-Section 5.4.2 Drop NAR data -- ?sampling frame & awful response rate: Census data are definitive, p 5-79 line 14 "demographic" (drop s)

-Who says 100% of people move, ever? My neighbor has lived here for almost 60 years. Data are confusing at best.

-Tables 5A-2 to 5A4 can be dropped, in line with text drops

COMMENTS ON SECTION 6:

-p 6-1 discusion confuses sampling and data collection and needs to describe the specific (difficult) questions asked of respondents. p 6-2 line 4 middle paragraph says "will" implying new data.

-Biggest question in Table 6.1 -- What % use the product at all and how many times for them?

-Why only 208 painters & again what % of those contacted?

-Somehow it seems that these details of the WESTAT study do not give an integrated picture and could be readily retabulated to give far more useful data

COMMENTS ON SECTION 7:

-Don't the detailed Table 7-3 data refer to less than 20% of housing units in the US?

-Why are the California data in Table 7-6 so much higher (93,67,70)?

-Why can't fuller data be obtained from utility companies?

P4

COMMENTS ON SECTION 8:

This should be given in the Introduction, with a brief example

COMMENTS ON SECTION 2:

The data on page 2-14 ARE convergent, despite disparate sources. Mention should be made of this at the outset. Same for the rich data (apparently) in Tables 2-26 to 2-31.

In contrast, the fish data seem all over the map.

COMMENTS ON SECTION 3:

Data from activity pattern studies are needed here. SEE EARLIER COMMENTS.

— P3-13 line 13, except rather than expect

COMMENTS ON SECTION 4:

Whole body data more appropriate for showers and baths than for soil/pesticide exposure.

IN GENERAL:

For each section, some comments at the beginning on data needs and how adequate the current are would help greatly, along with their relation to models and government policy guidelines, would be most helpful to non-insiders.

Neil Klepeis

Neil Klepeis - 7/14/95

REVIEW OF THE EPA's *EXPOSURE FACTORS HANDBOOK* -Activity Patterns-

Contents:

1. Comments on the Human Activity Patterns (HAP's) material in the Introduction and Chapter 5 of the handbook
2. Suggested new material on general exposure assessments that make use of HAP studies
3. Examples of HAP analyses from the recent national study by EPA (9,386 respondents nationwide)

Note: The Exposure Factors Handbook is referred to as the *handbook* below.

Comments on the Introduction, pp. 1-1 to 1-10:

- Much of the introduction is devoted to a discussion of dose, which should be clearly distinguished from a discussion of exposure.
- A crucial parameter in the dose equation is exposure duration, which can only be obtained from human activity pattern studies (HAP's)
- Likewise, contaminant concentrations can only be obtained from microenvironmental monitoring/measurement studies
- Some more discussion is needed in the introduction on how to use exposure durations and contaminant concentrations to estimate population exposures
- The handbook should contain more background material on exposure -- including a complete definition of exposure as it is distinguished from dose, how exposure fits into the complete risk model, which exposure factors are most crucial in making accurate population exposure assessments, definitions of terms and techniques used in exposure assessment, and descriptions of different exposure monitoring (*e.g.* the Total Exposure Assessment Methodology (TEAM) studies by EPA) and modeling efforts (see references 12-17 below).

For example:

- The complete risk model can be viewed as a sequence of dependent events: Pollutant Sources -> Movement of Pollutants -> Exposure to Pollutants -> Dose -> Health Effects
- In this model total human exposure (THE) is defined as when a person is present in some location at some time and the concentration of a pollutant is present at the same location at the same time. In this way a pollutant concentration can come into contact with a person via the air (lungs, skin), water (gut, skin), soil (gut, skin), or food (gut) pathways at any given instant. The emphasis in THE assessment is on human beings and the sources of chemical toxins in their immediate surroundings (environmental tobacco smoke, household goods/services, etc.)
- There can be multiple routes of exposure for different chemical pollutants, *e.g.*, chloroform via both air and water
- Predictions of dose require knowledge of metabolism, absorption, etc., which can be based on body weight, inhalation rate, etc.
- Predictions of exposure require the study of factors leading up to the exposure event (Pollutant Sources and Movement of Pollutants): chemicals emitted or present, emission rates, air exchange rates, deposition rates, chemical reactions, reaction rates, etc.
- Modeling human exposure to air pollution requires the concentrations of pollutants at specific locations (from monitoring/measurement studies), and the times that people spend there (from activity patterns)

References on total human exposure concepts:

1. Ott, W., (1985), "Total Human Exposure: An emerging science focuses on humans as receptors of environmental pollution", Feature Article, *Environmental Science and Technology*, Vol. 19, pp. 880-885.
2. Ott, W., (1990) "Total Human Exposure: Basic Concepts, EPA Field Studies, and Future Research Needs," *Journal of Air & Waste Management Association*, Vol. 40, No. 7, pp. 966-975.
4. M. Fugas, (1975) "Assessment of Total Exposure to Air Pollution," in *Proceedings of the International Conference on Environmental Sensing and Assessment*, Las Vegas, NV, Paper No. 38-5, Vol. 2, IEEE #75-CH1004-1 ICESA.
5. N. Duan, (1982) "Microenvironment Types: A Model for Human Exposure to Air Pollution," *Environment International*, Vol. 8, pp. 305-309.
6. Ott, W., (1982), "Concepts of Human Exposure to Air Pollution", *Environment International*, Vol. 7, pp. 179-196.

Comments on Chapter 5, pp. 5-1 to 5-86:

- Quantities such as body weight, inhalation rates, etc. are relevant for **dose** or health risk assessments, but not for **exposure** assessments. Quantities directly related to exposure assessment are microenvironment duration (related to life expectancy), averaging time, and use of consumer products. Exposure is simply the confluence of a pollutant concentration and a person in time and space, whereas dose is the amount that enters the person's system, *i.e.*, blood stream. These ideas should be clarified in the introduction to Chapter 5.
- The introduction to Section 5.3 should be expanded to include more discussion of the use of human activity patterns in total human exposure assessment (see detailed suggestions below).
- In addition to those studies described in Section 5.3, the handbook should include several analyses of the California Air Resource Board's 1987-88 California Activity Pattern study on exposure to environmental tobacco smoke (ETS), and by time-of-day (see references below).
- Human exposure is highly correlated with time-of-day, and recent HAP studies are very well suited for analyses by time-of-day since the data is collected in 24-hour diaries with minute resolution (see reference 10 below)
- Analysis of the recent national human activity pattern study by EPA should be included in the handbook pending its completion (reference 11)
- In a section on future work, the handbook should include suggestions for improved human activity pattern studies including:
  - ⇒ better exposure-relevant activity categories in 24-hour diaries
  - ⇒ inclusion of only those follow-up questions that have been shown to have a high response rate in the past
- There does not appear to much data on the fraction of time spent in microenvironments, which is useful to determine their relative significance to the entire population
- Usefulness to Exposure Assessors: Most of the data presented is in terms of mean microenvironment durations or total minutes of time spent in different microenvironments (mins/day). These data will be useful for point estimates of exposure. However, to conduct probabilistic exposure assessments that produce frequency distributions of exposure, it is necessary to have as input into the model either: (1) frequency distributions of the time spent in microenvironments, or (2) the raw data. It is impractical for reports on HAP studies to include all the desired frequency distributions for all possible exposure assessments. Thus, more

emphasis in the handbook should be placed on how to use the raw HAP data in probabilistic exposure assessments, than on comprehensive data listings. See suggestions below.

Other Activity Pattern Analyses:

3. Jenkins, P. L., Phillips, T. J., Mulberg E. J., and Hui, S.P., (1992) "Activity Patterns of Californians: Use of and Proximity to Indoor Pollutant Sources", *Atmospheric Environment*, Vol 26A, No. 12, pp. 2141-2148.
4. J. Wiley, J. Robinson, T. Piazza, K. Garrett, K. Cirksena, U. Cheng and G. Martin, (1991) "Activity Patterns of California Residents", Final Report Under Contract No. A6-177-33, California Air Resources Board, Sacramento, CA.
5. J. Wiley, J. Robinson, T. Piazza, L. Stork and K. Pladsen, (1991) "Study of Children's Activity Patterns", Final Report Under Contract No. A733-149, California Air Resources Board, Sacramento, CA.
6. Robinson, J.P. and Blaire, J., (1995) "Estimating Exposure to Pollutants Through Human Activity Pattern Data: The National Microenvironmental Activity Pattern Survey", Annual Report, Survey Research Center, University of Maryland.
7. J. P. Robinson, P. Switzer, W.R. Ott, (1994) "Smoking Activities and Exposure to Environemental Tobacco Smoke (ETS) in California: A Multivariate Analysis", Report No. 1 for the California Activity Pattern Survey, Department of Statistics, Stanford University, Stanford, CA.
8. J. P. Robinson, P. Switzer, W.R. Ott, (1994) "Exposure to Environmental Tobacco Smoke (ETS) Among Smokers and Nonsmokers", Report No. 2 for the California Activity Pattern Survey, Department of Statistics, Stanford University, Stanford, CA.
9. J. P. Robinson, P. Switzer, W.R. Ott,, (1994) "Microenvironmental Factors Related to Californians' Potential Exposures to Environmental Tobacco Smoke (ETS)", Report No. 3 for the California Activity Pattern Survey, Department of Statistics, Stanford University, Stanford, CA.
10. W.R. Ott, P. Switzer, J. P. Robinson, (1994) "Exposures of Californians to Environmental Tobacco Smoke (ETS) by Time-of-Day: A Computer Methodology for Analyzing Activity Pattern Data", Report No. 4 for the California Activity Pattern Survey, Department of Statistics, Stanford University, Stanford, CA.
11. Klepeis, N., and Tsang, A. (1995) "Analysis of the National Human Activity Pattern Study from a Viewpoint of Human Exposure Assessment", EPA Report in Preparation, EMSL, Las Vegas, NV.

Additional Material/Clarifications to Include:

The handbook should contain a guide to *conducting exposure assessments with human activity pattern (HAP) studies* including examples of studies that have been done (see list of references below). Some or all of the following ideas should be considered for expanded discussion in the handbook:

- By providing microenvironment durations, HAP studies are useful to compare relative potential exposures between segments of the population without ever knowing the exposure magnitudes. It is necessary to assume that the mean pollutant concentrations in each microenvironment are approximately the same across different subgroups (region, age, gender, etc.), *i.e.,* the exposure mechanisms (source strengths, air exchange rates, deposition rates, etc.) do not change appreciably for different socio-economic or geographical groups.
- HAP's are probably most useful for comparisons of relative potential exposures from **air** pollutants since these exposures are approximately proportional to the duration of time spent in a microenvironment
- Dermal, ingestion, etc. exposures require more complicated assessments (surface area, volume eaten/applied, concentrations of toxins, etc.); and actual exposures may vary greatly between subgroups due to unspecified factors even though the exposure durations are comparable. HAP's may not be useful to model these exposures unless they also collect data (or are combined with data from other studies) on the amount of material that is being ingested or coming into contact with skin during the appropriate microenvironments
- HAP's can be used for a complete population exposure assessment (giving either point estimates or frequency distributions of exposure) by combining measurements of the magnitude of air exposures in microenvironments for specific segments of the population with the amount of time people spend being exposed -- as obtained from HAP studies.
- For a complete and accurate weighting of microenvironmental exposures by the amount of time spent in each microenvironment, the population should be divided into subgroups that have been shown to have different exposure magnitudes. If deterministic models, *i.e.,* the mass balance equation (see references below), are being used, then different parameters need to be determined for each different subgroup.
- Point estimates of population exposure to air pollutants can be made by multiplying the mean microenvironmental exposure experienced by each subgroup by the fraction of time spent in the microenvironment by that subgroup (*i.e.* weighting each microenvironmental exposure by the fraction of time spent there), and summing over each of these contributions to obtain the overall exposure.
- In a probabilistic exposure assessment, frequency distributions of microenvironmental exposure magnitude and exposure duration are Monte-Carlo sampled to predict population exposure. When deterministic submodels (air exchange, source strength, etc.) are used to

predict exposure magnitudes, some model parameters may be correlated and a joint frequency distribution should be calculated (as discussed in Chapter 8 of the handbook).

Some references for past or ongoing population exposure assessments:

12. Ott, W., (1984) "Exposure Estimates Based on Computer Generated Activity Patterns," *Journal of Toxicology: Clinical Toxicology,* Vol. 21, , pp. 97-128.
13. Ott W., J. Thomas, D. Mage, and L.Wallace, (1988) "Validation of the Simulation of Human Activity and Pollutant Exposure (SHAPE) Model Using Paired Days from the Denver, CO, Carbon Monoxide Field Study," *Atmospheric Environment,* Vol. 22, No. 10, pp. 2101-2113.
14. Ott W., Mage, D., and Thomas, J., (1992) "Comparison of Microenvironmental CO Concentrations in Two Cities for Human Exposure Modeling," *Journal of Exposure Analysis and Environmental Epidemiology,* Vol. 2, No. 2, , pp. 249-267.
15. Lurmann, F. W. and Korc, M. E. (1994) "Characterization of Human Exposure to Ozone and PM-10 in the San Francisco Bay Area", Final Report STI-93150-1416 FR, for the BAAQMD, San Francisco, CA.
16. Behar, J.V., Thomas, J., and Pandian, M.D., "Estimation of the Exposure to Benzene of Selected Populations in the State of Texas Using the Benzene Exposure Assessment Model (BEAM)", EPA 600/X-93/002, Environmental Monitoring Systems Laboratory, U.S. Environmental Protection Agency, Las Vegas, NV, January 1993.
17. Klepeis N. E., Ott W., and Switzer P., (1994) "A Total Human Exposure Model (THEM) for Respirable Suspended Particles (RSP)", National Technical Information Service (NTIS) No. PB94-197415, Presented at the 87th annual meeting of the A&WMA meeting in Cincinnatti, OH.

List of references on deterministic submodels for predicting microenvironmental exposures to environmental tobacco smoke (ETS):

18. Switzer, P., and Ott, W. (1992) "Derivation of an Indoor Air Averaging Time Model from the Mass Balance Equation for the Case of Independent Source Inputs and Fixed Air Exchange Rates," *Journal of Exposure Analysis and Environmental Epidemiology,* Vol. 2, Suppl. 2, pp. 113-135.
19. Ott, W., Langan, L., and Switzer, P. (1992) "A Time Series Model for Cigarette Smoking Activity Patterns: Model Validation for Carbon Monoxide and Respirable Particles in an Chamber and an Automobile," *Journal of Exposure Analysis and Environmental Epidemiology,* Vol 2, Suppl. 2, pp. 175-200.
20. Klepeis, N., Ott, W., Switzer, P, (1995) "Modeling the Time Series of Carbon Monoxide and Respirable Suspended Particles from Multiple Smokers: Validation in Two Public Smoking Lounges", presented at the 88th Annual Meeting and Exhibition of the A&WMA, San Antonio, TX, June 1995.
21. Ott, W., Klepeis, N., and Switzer, P., (1995) "Modeling Environmental Tobacco Smoke in the Home Using Transfer Functions", presented at the 88th Annual Meeting of the A&WMA, San Antonio, TX, June 1995.

The following is a list of ideas that are important when analyzing HAP's. They might be included in the introduction or in a subsection of Chapter 5.

- In using HAP studies to estimate relative exposures via the air pathway, the significance of a microenvironment is determined by the amount of time spent experiencing them, *i.e.* their duration. These significances are best compared for similar microenvironments since sources (exposure magnitudes) vary from micro. to micro.
- Exposure magnitudes (obtained from monitoring/measurement studies) must be used in conjunction with exposure durations to obtain accurate population exposures.
- The proportion of respondents in microenvironments, proportion of time spent in microenvironments, frequency of occurrence of microenvironments, and mean durations of microenvironments are used to approximate the **relative** significance of microenvironmental exposure (assuming exposure depends mostly on duration) and to compare exposures between subgroups (gender, age, race, region, etc.).
- Analysis over all respondents (the doers -- those experiencing each microenvironment -- plus non-doers) indicates the significance of each microenvironment to the population as a whole. Analysis of only the doers indicates the significance of each microenvironment to the pool of respondents that are being exposed (see Table 1). See examples using the recent national study presented below.
- When analyzing HAP studies, it is usually appropriate to weight each subgroup according to the proportion of respondents in the "true" population, *e.g.*, to compensate for oversampling.

Examples from the Recent EPA National Human Activity Pattern Survey:

Figures 1 to 4 contain some of the recent results of the national human activity pattern study by EPA (reference 11): time-of-day analysis by location, percentage of time spent in each location x activity microenvironment (over all respondents), percentage of respondents experiencing a given microenvironment on the diary day, and the 24-hour mean duration of microenvironments (doers only). The most significant microenvironments over the 24-hour diary days of the entire population (besides those involving non-exposure activities like sleeping) are Eating/Drinking, Food Preparation, Housekeeping, and Bathing -- all in the Residential-Indoor location (Figure 2). These microenvironments are also among those that have the highest number of respondents experiencing them on the diary day (Figure 3). Since its 24-hour duration (Figure 4) is one of the smallest (25 min), we can see that the overall significance of the Residential-Indoor-Bathing microenvironment is due more to the number of respondents engaging in it than to the amount of time it takes up. In addition, Housekeeping has about the same overall percentage of time as Food Preparation, but it has a smaller fraction of respondents experiencing it. Thus, its relative significance arises from its larger mean 24-hour duration.

Table 1. How Each Microenvironmental Quantity (HAP Calculation or Experiment) Is Used to Estimate Exposure

	Microenvironmental Quantity	HAP Variable	Doers or Non-Doers + Doers	Purpose/Comment
1	Percentage of Time Spent	**Duration, D**	Doers + Non-Doers	Assigns significance of microenvironments based on the number of people being exposed and the length of the exposures; large percentages could result from long exposure durations or from large numbers of people experiencing the exposures
2	Percentage of Respondents	**Sample Size, N**	Doers + Non-Doers	Assigns significance of microenvironments based on the number of people being exposed; confirms that large percentages of time spent are resulting from large numbers of people experiencing a microenvironment and not a small number of people experiencing long exposure durations; also used to analyze the movement of respondents through microenvironments over the diary day in fixed time frames (1 minute, 3-hours, etc.)
3	Percentage of Time Spent	**Duration, D**	Doers	Assigns significance of microenvironments based on the length of exposures of those exposed; can be compared with the percentage of time spent for doers and non-doers combined to estimate number of people experiencing each microenvironment as provided by the percentage of respondents (#2)
4	Mean 24-Hour Durations	**Duration, D**	Doers	Assigns significance of microenvironments based on the length of exposures of those exposed
5	Percentage of Microenvironment Occurrences	**Microenviron. Occurrences, O**	Doers + Non-Doers	Assigns relative significance of microenvironments during a given time frame (1 minute, 3-hours, 24-hours, etc.); equal to the proportion of respondents at the time resolution of the study
6	Mean 24-Hour Frequency of Occurrence	**Microenviron. Occurrences, O**	Doers	Indicates significance of microenvironments based on how often exposures occur during the day for those that are exposed
7	*Exposure Magnitude (Means, Standard Deviation, Percentiles)	**Monitoring or Modeling**	Doers	Determines microenvironments that may pose a significant exposure risk based on magnitudes of exposures, *e.g.*, average pollutant concentrations; cannot assign significance of exposure across a population since this requires population exposure durations; can be combined with HAP studies to estimate exposure magnitudes across populations

Note: Magnitudes of exposures are determined from factors "unkown" in HAP studies alone such as air exchange rates, source strengths, or from actual monitoring studies. The *significance* of a microenvironment for a given population is defined by how much it poses a serious exposure risk for that population. HAP studies can assign significance based on the time spent in microenvironments as determined from: the duration of microenvironments **D**, the number of respondents in each microenvironment N, and the number of times the microenvironment occurs **O**. A microenvironment may not be significant for the population as a whole but can pose a very serious exposure risk for the members of the population that experience it (small numbers of people with large durations). Alternatively, microenvironments that appear to be significant for the whole population may be experienced by large numbers of respondents, but they may not have very large durations. * = not obtained from HAP studies

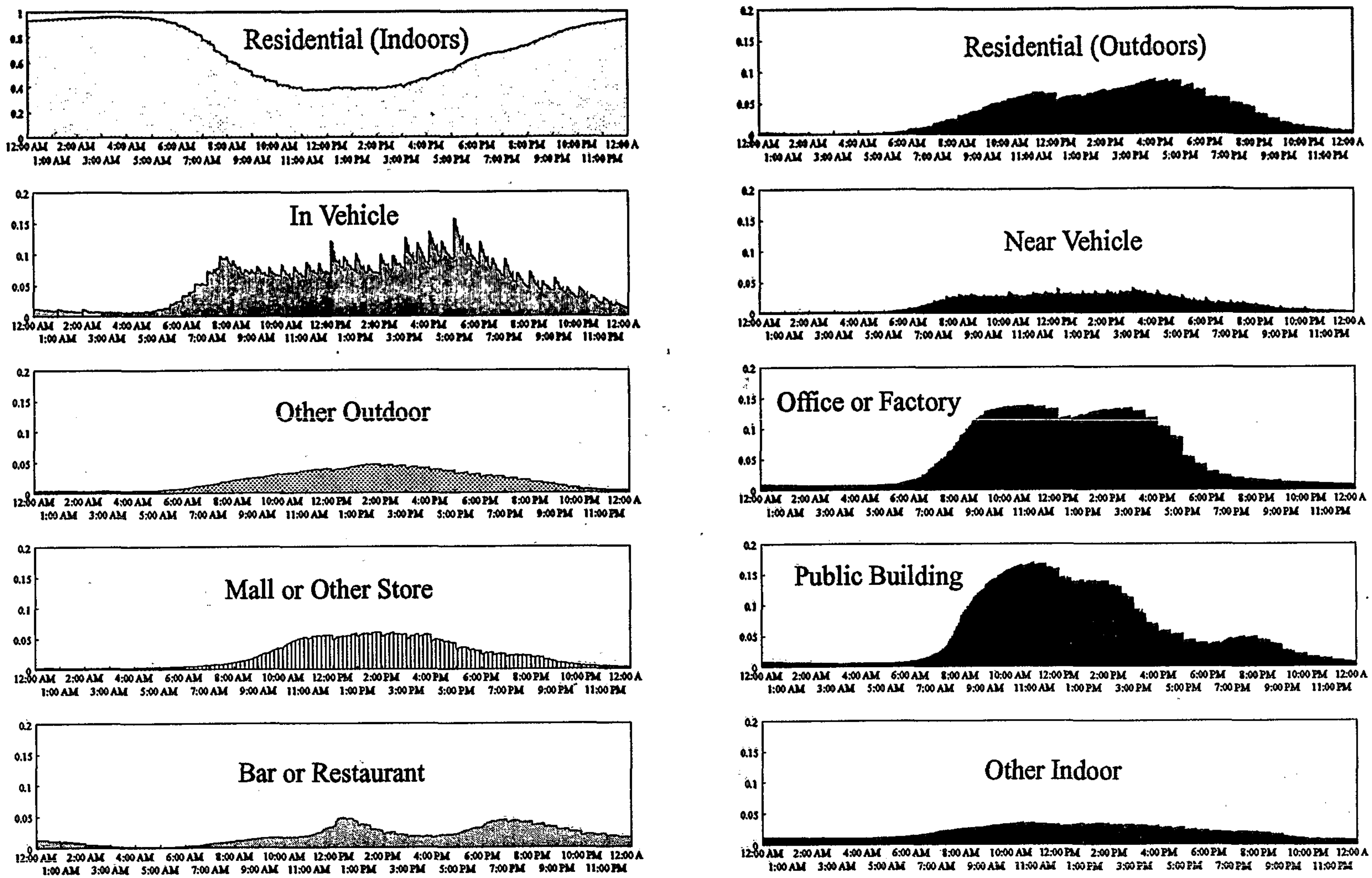

Figure 1. Example of a HAP time-of-day analysis by location from the recent EPA national study (reference 11): the fraction of respondents in each location for each minute of the diary day. Human exposures are highly correlated by the time-of-day. During the 24-hour diary day between 60 and 100% of the respondents were in the Residential-Indoor location.

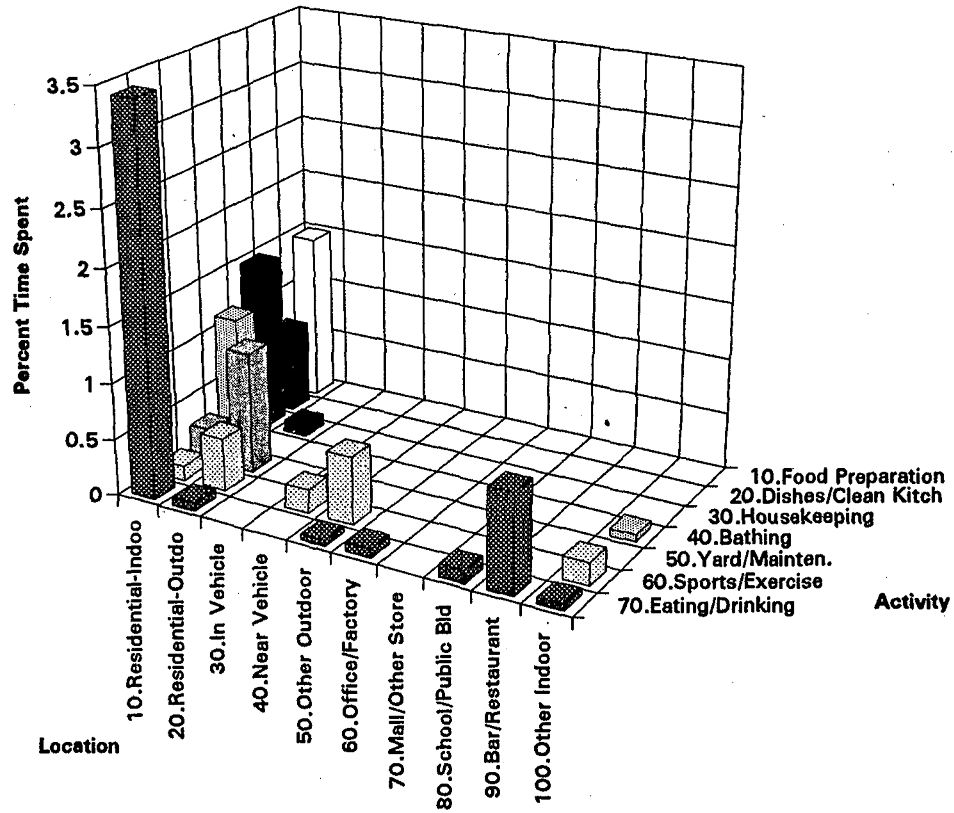

Figure 2. 3-D plot of the overall weighted percentage of time spent in 21 out of 70 location x activity microenvironments. The missing microenvironments had less than 100 occurrences over the diary days of all the respondents. The most significant microenvironments for the population (besides those for non-exposure events like sleeping) were for Eating/Drinking, Food Preparation, Housekeeping, and Bathing in the Residential-Indoor location. Source: the recent national human activity pattern study by EPA (reference 11).

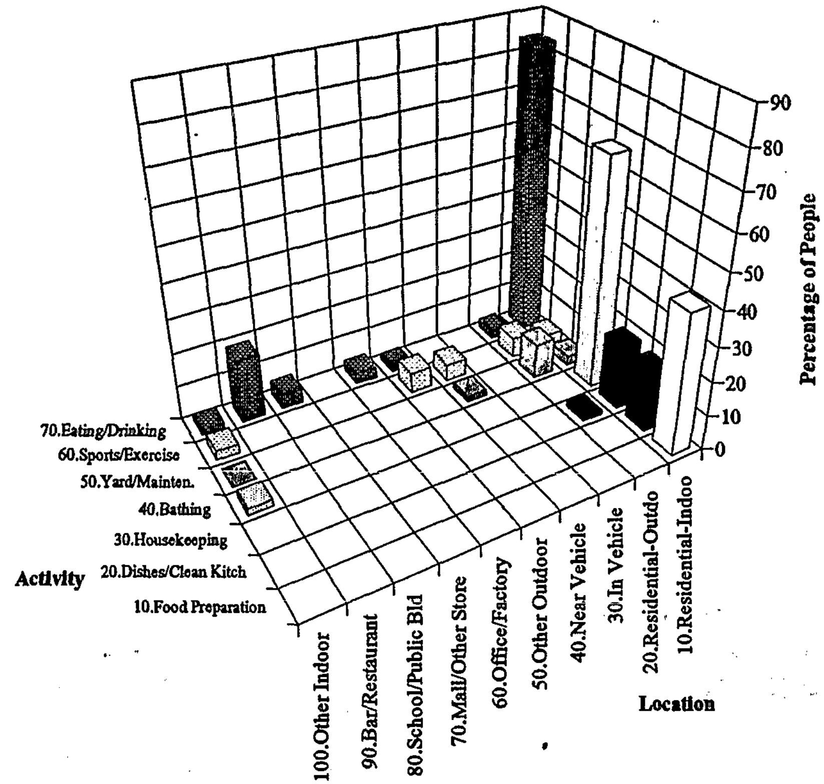

Figure 3. 3-D plot of the overall weighted percentage of doers (people experiencing a microenvironment on the diary day) in 21 out of 70 location x activity microenvironments. The missing 49 microenvironments had less than 100 occurrences over the diary days of all the respondents. It is confirmed that the Residential-Indoor activities are the most significant overall (from Figure 2), except the large percentage of time spent Bathing appears to be more due to the large proportion of people in this microenvironment on the diary day, than on large durations (see Figure 4). Source: the recent national human activity pattern study by EPA (reference 11).

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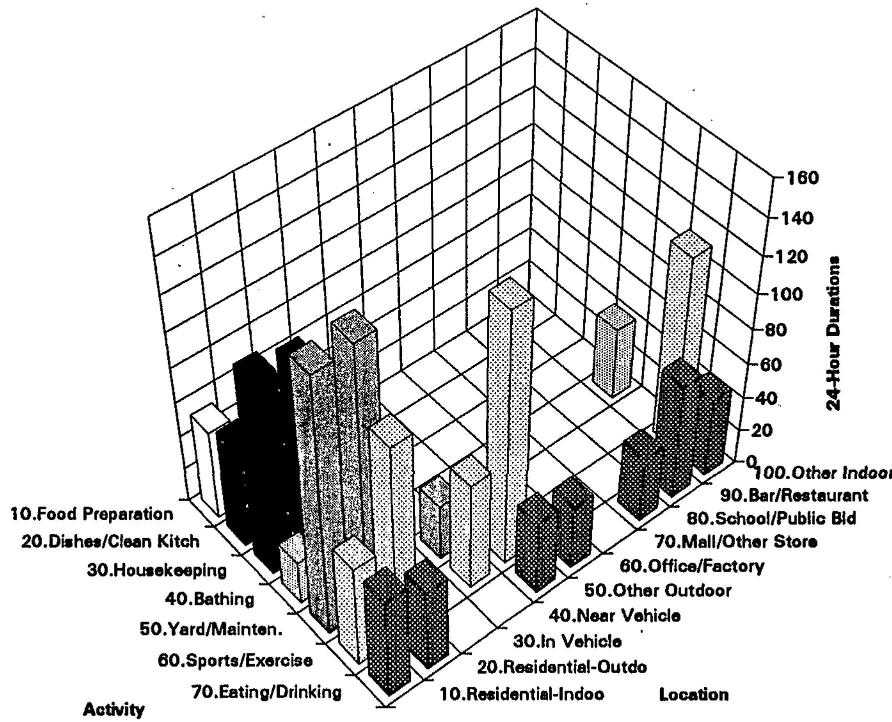

Figure 4. 3-D plot of the overall weighted mean 24-hour duration (for the doers) in 21 out of 70 location x activity microenvironments. The missing 49 microenvironments had less than 100 occurrences over the diary days of all the respondents. These durations are useful to estimate the exposure of persons experiencing the microenvironments rather than the overall significance to the population. Since the Bathing activity has small durations, its overall significance arises more from the number of people experiencing it (see Figure 3). Source: the recent national human activity pattern study by EPA (reference 11).

Val Schaeffer

U.S. CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, D.C. 20207

August 21, 1995

Helen Murray
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Re: Comments on June 1995 Draft of the Exposure Factors Handbook

Dear Ms. Murray:

Thank you for the opportunity to comment on the updated draft of the EPA Exposure Factors Handbook (EFH). Since neither Lori Saltzman or I could participate in the peer review workshop held on July 25 and 26, 1995, I am submitting post-meeting comments as we discussed. My review is restricted to Chapters 3, 5, 6, and 8 since Lori was assigned to the workshop's Activity Patterns panel. In general, Chapters 3 and 5 provide comprehensive and exhaustive reviews of multiple studies but the information needs to be better organized and presented. On the other hand, Chapters 6 and 8 provide information in a succinct and organized manner, but treat the subject matter in a cursory fashion. Specific comments by chapter are as follows.

Chapter 3 - Inhalation Route

This chapter is a superior review of ten studies that determine inhalation rates by a number of methods in a variety of populations under a range of activity levels. Eight of the ten studies were reported since the last edition (1989) of the EFH and represent a sizable new data base. The studies grouped as "key studies" and the recommended inhalation rate values are appropriately chosen. The limitations of the various studies are adequately stated. The summary table (3-22) is particularly helpful. Unfortunately, the data is not presented in a user-friendly way. The most useful data are the recommended long-term and short-term inhalation rates for children and adults found at the end of the chapter on pages 3-40 to 3-48. This means the interested reader has to go through 40 pages of study descriptions and 21 tables of often conflicting data before reaching the critical information. I would suggest that the recommended inhalation rates be presented early in the chapter followed by a briefer discussion of studies that contributed to the values and an explanation of why the revised recommended breathing rates are superior to those advocated in the 1989 EFH. The more detailed data tables and study descriptions can be incorporated in an appendix.

Chapter 5 - Other Factors for Exposure Calculations

Many of the comments to Chapter 3 also apply to Chapter 5. This chapter covers lifetime, body weight, activity patterns, and population mobility. The first two topics are relatively straightforward and well treated. The available data on human activity patterns is more varied and complex. While the key studies are identified, there was little attempt to group the data and present it in a way that would be useful. Eleven studies are described and 35 data tables are introduced but no clear guidance is provided as to the most appropriate data to use. Recommended values or data sets for activity patterns by age, sex, race, employment status, weekday/weekend, and season need to be clearly stated early in section 5.3. The same comments apply to the five studies and nine data tables presented on population mobility.

Chapter 6 - Consumer Products

This chapter is restricted to usage data presented from three national surveys of selected consumer product categories performed by Westat in the mid 1980's for the EPA Office of Pollution, Prevention, and Toxics (OPPT). Abt Associates conducted a follow-up 1991 consumer use survey, under contract with CPSC, for three of the product categories; paint strippers, aerosol spray paints, and adhesive removers. The telephone survey of nearly 5000 respondents was modeled after the 1987 Westat usage survey of household solvent products using the random digit-dialing technique. The pertinent data tables from the CPSC survey are enclosed. They can be used to update tables 6-1 through 6-4 for the three product categories. The source document is entitled *Methylene Chloride Consumer Use Study - Final Report, Abt Associates, December 1991.* It can be obtained from the CPSC Directorate for Economic Analysis by contacting Charles Smith (301-504-0962 x1325) or Bill Zamula (301-504-0962 x1331). The document title and CPSC contacts were previously provided to the Office of Health and Environmental Assessment (OHEA) at the 1993 EFH workshop.

The Westat and Abt surveys also supplied usage information on the location (outside, garage, living room, etc.) and the indoor ventilation conditions (windows, doors open/closed) in which the product categories were used. This information is necessary in order to characterize exposure and should be either presented in the chapter or its availability acknowledged in the study descriptions. Table 6-3 on the amounts of various household products used would be more useful if the data were presented as ounces <u>per use</u> rather than ounces per year.

It is disappointing that OHEA chose not to pursue the recommendations of the Activity Patterns panel of the 1993 workshop for the presentation of consumer product-related exposure factors. This included providing data on chemical composition and chemical emission factors as well as usage information for a limited number of reasonably well-studied consumer product categories. There is an ever-increasing amount of formulation and emission rate information being gathered by various EPA offices. This includes OPPT through its use cluster projects, the Indoor Air Division through its indoor air source ranking data base, the Air Pollution Prevention and Control Division through its product emissions testing, and the Office of Air Quality Planning and Standards through its study of volatile organic compound emissions from consumer and commercial products. The EFH could be used as a vehicle to provide some of this exposure-critical data in a structured and organized manner. Paints might be a good product candidate to try this approach since data has been gathered on this category in the above EPA efforts.

Another recommendation of the 1993 workshop panel was to provide some general guidance on how the different consumer product-related factors would be used to assess consumer exposure. The current chapter does not reflect this advice and EPA is encouraged to include this. At a minimum, other documents (e.g. *Standard Scenarios for Estimating Exposure to Chemical Substances During Use of Consumer Products*, EPA Contract No. 68-02-3968, 1986) should be cited as references.

Chapter 8 - Analysis of Uncertainties

This chapter is a satisfactory introductory description of the terms and general principles involved in uncertainty analysis. If feasible, it should be augmented by providing a framework and some approaches to conducting an assessment of uncertainty. The chapter needs to more clearly distinguish between characterizing exposure variability, that is the heterogeneity in exposure received by a population of individuals and characterizing exposure uncertainty, which is the lack of knowledge of the true value of a particular exposure estimate. It should state early-on that the two topics should be treated separately, and variability is sometimes erroneously included in the analysis of uncertainty.

The discussion of the Monte Carlo technique could be more positive. While there are certainly cautions that must be exercised when using this method, it is a reasonable way to characterize exposure variability and uncertainty provided sufficient information is known about the frequency and probability distributions of the different exposure parameters and the dependencies among them. The Monte Carlo technique is not cumbersome in terms of assessing sensitivity since modern day software can run large numbers of simulations quickly and the method does not assume parameter independence. Finally, the quantitative alternatives to Monte Carlo analysis are usually more difficult to compute and generally more problematic.

If there are questions regarding the comments or if further assistance is needed, I can be reached at 301-504-0994 x1390/fax 301-504-0025.

Sincerely,

Val Schaeffer

Val Schaeffer, Ph.D.
Directorate for Epidemiology and Health Sciences

Enclosures:

cc: William Wood, EPA Risk Assessment Forum (letter only)

Table 2-4: Number of Times of Use of Paint Removers/Strippers Within the Last 12 Months - Recent Users[a]

	Current Study (Unweighted N=316)	1986 Study (Unweighted N=761)
Mean	3.54	3.68
Standard deviation	7.32	9.10
Minimum	1.00	0.03
1st Percentile	1.00	0.03
5th Percentile	1.00	0.23
10th Percentile	1.00	0.69
25th Percentile	1.00	4.0[b]
Median Value	2.00	2.00
75th Percentile	3.00	3.00
90th Percentile	6.00	6.00
95th Percentile	12.00	11.80
99th Percentile	50.00	44.56
Maximum Value	70.00	100.00

[a]Recent users are those who have used the product in the last year and purchased the product in the past two years.

[b]Values are inconsistent with other values in this column.

Table 2-5: Minutes Spent Using Paint Removers/Strippers Last Time Used — Recent Users[a]

	Current Study (Unweighted N=390)	1986 Study (Unweighted N=752)
Mean	144.59	125.57
Standard deviation	175.54	286.59
Minimum Value	2.00	0.02
1st Percentile	5.00	0.38
5th Percentile	15.00	5.00
10th Percentile	20.00	5.00
25th Percentile	45.00	20.00
Median Value	120.00	60.00
75th Percentile	180.00	120.00
90th Percentile	360.00	240.00
95th Percentile	480.00	420.00
99th Percentile	720.00	1200.00
Maximum Value	1440.00	4320.00

[a]Recent users are those who have used the product in the last year and purchased the product in the past two years.

Table 2-6: **Minutes Spent in the Room After Last Use of Paint Remover/Stripper — Recent Users[a]**

Including those who did not spend any time in room after use	Current Study (Unweighted N=309)	1986 Study (Unweighted N=748)
Mean	12.96**	31.38
Standard deviation	85.07	103.07
Minimum Value	0.00	0.00
1st Percentile	0.00	0.00
5th Percentile	0.00	0.00
10th Percentile	0.00	0.00
25th Percentile	0.00	0.00
Median Value	0.00	0.00
75th Percentile	0.00	20.00
90th Percentile	10.00	60.00
95th Percentile	60.00	180.00
99th Percentile	180.00	541.20
Maximum Value	1440.00	1440.00

Including only those who spent time in the room	(Unweighted N=39)	(Unweighted N=340)
Mean	93.88	NA
Standard deviation	211.71	NA
Minimum Value	1.00	1.00
1st Percentile	1.00	1.00
5th Percentile	1.00	1.00
10th Percentile	3.00	3.10
25th Percentile	10.00	10.00
Median Value	60.00	30.00
75th Percentile	120.00	60.00
90th Percentile	180.00	180.00
95th Percentile	420.00	240.00
99th Percentile	1440.00	826.20
Maximum Value	1440.00	1440.00

*Statistically significant at the .05 level
**Statistically significant at the .01 level
[a]Recent users are those who have used the product in the last year and purchased the product in the past two years.

Table 2-7: **Amount of Paint Remover/Stripper Used — Recent Users[a]**

Fluid Ounces of Paint Remover/Stripper used in the past year		
	Current Study (Unweighted N=307)	1986 Study (Unweighted N=737)
Mean	142.05**	63.73
Standard deviation	321.73	144.33
Minimum Value	15.00	0.64
1st Percentile	15.00	1.50
5th Percentile	16.00	4.00
10th Percentile	16.00	8.00
25th Percentile	32.00	16.00
Median Value	64.00	32.00
75th Percentile	128.00	64.00
90th Percentile	256.00	128.00
95th Percentile	384.00	256.00
99th Percentile	1920.00	512.00
Maximum Value	3200.00	2560.00
Fluid Ounces per use of Paint Removers/Strippers		
	(Unweighted N=307)	(Unweighted N=735)
Mean	64.84**	29.84
Standard Deviation	157.50	50.28
Minimum Value	.35	0.23
1st Percentile	2.67	0.651
5th Percentile	8.00	1.60
10th Percentile	10.67	2.67
25th Percentile	16.00	7.15
Median Value	32.00	16.00
75th Percentile	64.00	32.00
90th Percentile	128.00	64.00
95th Percentile	192.00	128.00
99th Percentile	320.00	256.00
Maximum Value	2560.00	512.00

*Statistically significant at the .05 level
**Statistically significant at the .01 level
[a]Recent users are those who have used the product in the last year and purchased the product in the past two years.

Table 3-4 Number of Times of Use of Spray Paint Within the Last 12 Months - Recent Users[a]

	Current Study (Unweighted N=775)	1986 Study (Unweighted N=1178)
Mean	8.23**	4.22
Standard deviation	31.98	15.59
Minimum Value	1.00	1.00
1st Percentile	1.00	1.00
5th Percentile	1.00	1.00
10th Percentile	1.00	1.00
25th Percentile	1.00	1.00
Median Value	2.00	2.00
75th Percentile	4.00	4.00
90th Percentile	11.00	6.10
95th Percentile	20.00	12.00
99th Percentile	104.00	31.05
Maximum Value	365.00	365.00

*Statistically significant at the .05 level.
**Statistically significant at the .01 level.
[a]Recent users are those who have used the product in the last year and purchased the product in the past two years.

Table 3-5: Minutes Spent Using Spray Paint Last Time Used — Recent Users[a]

	Current Study (Unweighted N=786)	1986 Study (Unweighted N=NA)
Mean	40.87	39.54
Standard deviation	71.71	87.79
Minimum Value	1.00	2.00[b]
1st Percentile	1.00	0.17[b]
5th Percentile	3.00	2.00
10th Percentile	5.00	5.00
25th Percentile	10.00	10.00
Median Value	20.00	20.00
75th Percentile	45.00	45.00
90th Percentile	90.00	60.00
95th Percentile	120.00	120.00
99th Percentile	360.00	300.00
Maximum Value	960.00	1800.00

[a]Recent users are those who have used the product in the last year and purchased the product in the past two years.
[b]Values are inconsistent with other values in this column.

Table 3-6: Minutes Spent in the Room After Last Use of Spray Paint — Recent Users[a]

Including those who did not spend any time in room after use		
	Current Study (Unweighted N=791)	1986 Study (Unweighted N=1158)
Mean	3.55**	12.70
Standard deviation	22.03	62.80
Minimum Value	0.00	0.00
1st Percentile	0.00	0.00
5th Percentile	0.00	0.00
10th Percentile	0.00	0.00
25th Percentile	0.00	0.00
Median Value	0.00	0.00
75th Percentile	0.00	1.00
90th Percentile	0.00	30.00
95th Percentile	0.00	60.00
99th Percentile	120.00	260.50
Maximum Value	300.00	1440.00
Including only those who spent time in the room		
	(Unweighted N=35)	(Unweighted N=305)
Mean	65.06	NA
Standard deviation	70.02	NA
Minimum Value	1.00	1.00
1st Percentile	1.00	1.00
5th Percentile	1.00	1.00
10th Percentile	10.00	2.00
25th Percentile	15.00	5.00
Median Value	30.00	15.00
75th Percentile	60.00	60.00
90th Percentile	120.00	120.00
95th Percentile	120.00	222.00
99th Percentile	300.00	480.00
Maximum Value	300.00	1444.00

*Statistically significant at the .05 level.
**Statistically significant at the .01 level.
[a]Recent users are those who have used the product in the last year and purchased the product in the past two years.

Table 3-7: Amount of Spray Paint Used — Recent Users[a]

Fluid Ounces of Spray Paint used in the past year		
	Current Study (Unweighted N=778)	1986 Study (Unweighted N=1121)
Mean	83.92**	30.75
Standard deviation	175.32	52.84
Minimum Value	13.00	0.02
1st Percentile	13.00	0.75
5th Percentile	13.00	2.01
10th Percentile	13.00	3.25
25th Percentile	13.00	7.00
Median Value	26.00	13.00
75th Percentile	65.00	32.00
90th Percentile	156.00	65.00
95th Percentile	260.00	104.00
99th Percentile	1170.00	240.00
Maximum Value	1664.00	1053.00
Fluid Ounces per use of Spray Paint		
	(Unweighted N=778)	(Unweighted N=1118)
Mean	19.04**	13.80
Standard Deviation	25.34	24.40
Minimum Value	0.36	0.01
1st Percentile	0.36	0.19
5th Percentile	3.47	0.80
10th Percentile	6.50	1.50
25th Percentile	9.75	3.50
Median Value	13.00	8.00
75th Percentile	21.67	16.00
90th Percentile	36.11	26.00
95th Percentile	52.00	39.00
99th Percentile	104.00	96.00
Maximum Value	312.00	526.50

*Statistically significant at the .05 level.
**Statistically significant at the .01 level.
[a]Recent users are those who have used the product in the last year and purchased the product in the past two years.

Table 4-4: Number of Times of Use of Adhesive Removers Within the Last 12 Months - Recent Users[a]

	Current Study (Unweighted N=58)	1986 Study (Unweighted N=167)
Mean	1.66**	4.22
Standard deviation	1.67	12.30
Minimum Value	1.00	1.00
1st Percentile	1.00	1.00
5th Percentile	1.00	1.00
10th Percentile	1.00	1.00
25th Percentile	1.00	1.00
Median Value	1.00	1.00
75th Percentile	2.00	3.00
90th Percentile	3.00	6.00
95th Percentile	5.00	16.80
99th Percentile	12.00	100.00
Maximum Value	12.00	100.00

*Statistically significant at the .05 level.
**Statistically significant at the .01 level.
[a]Recent users are those who have used the product in the last year and purchased the product in the past two years.

Table 4-5: Minutes Spent Using Adhesive Removers Last Time Used -- Recent Users[a]

	Current Study (Unweighted N=52)	1986 Study (Unweighted N=168)
Mean	172.87	121.20
Standard deviation	304.50	171.63
Minimum Value	5.00	0.03
1st Percentile	5.00	0.03
5th Percentile	10.00	1.45
10th Percentile	15.00	3.00
25th Percentile	29.50	15.00
Median Value	120.00	60.00
75th Percentile	240.00	120.00
90th Percentile	480.00	246.00
95th Percentile	1440.00	480.00
99th Percentile	1440.00	960.00
Maximum Value	1440.00	960.00

[a]Recent users are those who have used the product in the last year and purchased the product in the past two years.

Table 4-6 **Minutes Spent in the Room After Last Use of Adhesive Remover — Recent Users[a]**

Including those who did not spend any time in room after use		
	Current Study (Unweighted N=51)	1986 Study (Unweighted N=166)
Mean	13.79**	94.12
Standard deviation	67.40	157.69
Minimum Value	0.00	0.00
1st Percentile	0.00	0.00
5th Percentile	0.00	0.00
10th Percentile	0.00	0.00
25th Percentile	0.00	1.75
Median Value	0.00	20.00
75th Percentile	0:00	120.00
90th Percentile	0.00	360.00
95th Percentile	120.00	480.00
99th Percentile	420.00	720.00
Maximum Value	420.00	720.00
Including only those who spent time in the room		
	(Unweighted N=5)	(Unweighted N=131)
Mean	143.37	119.3
Standard deviation	169.31	NA
Minimum Value	5.00	1.00
1st Percentile	5.00	1.00
5th Percentile	5.00	1.60
10th Percentile	5.00	4.00
25th Percentile	20.00	10.00
Median Value	120.00	60.00
75th Percentile	420.00	120.00
90th Percentile	420.00	420.00
95th Percentile	420.00	504.00
99th Percentile	420.00	720.00
Maximum Value	1440.00	720.00

*Statistically significant at the .05 level.
**Statistically significant at the .01 level.
[a]Recent users are those who have used the product in the last year and purchased the product in the past two years.

Table 4-7: Amount of Adhesive Remover Used — Recent Users[a]

Fluid Ounces of Adhesive Remover used in the past year		
	Current Study (Unweighted N=51)	1986 Study (Unweighted N=155)
Mean	96.95*	34.46
Standard deviation	213.20	96.60
Minimum Value	13.00	0.25
1st Percentile	13.00	0.29
5th Percentile	13.00	1.22
10th Percentile	16.00	2.80
25th Percentile	16.00	6.00
Median Value	32.00	10.88
75th Percentile	96.00	32.00
90th Percentile	128.00	64.00
95th Percentile	384.00	138.70
99th Percentile	1280.00	665.60
Maximum Value	1280.00	1024.00
Fluid Ounces per use of Adhesive Removers		
	(Unweighted N=51)	(Unweighted N=153)
Mean	81.84*	22.04
Standard Deviation	210.44	85.44
Minimum Value	5.20	0.04
1st Percentile	5.20	0.06
5th Percentile	6.50	0.33
10th Percentile	10.67	0.67
25th Percentile	16.00	3.00
Median Value	26.00	8.00
75th Percentile	64.00	16.00
90th Percentile	128.00	32.00
95th Percentile	192.00	64.00
99th Percentile	1280.00	574.72
Maximum Value	1280.00	1024.00

*Statistically significant at the .05 level.
**Statistically significant at the .01 level.
[a]Recent users are those who have used the product in the last year and purchased the product in the past two years.

Work Group #4

Housing characteristics and indoor environments

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Comments About June 1995 External Review Draft of EPA/600/P-95/002A "Exposure Factors Handbook" Update

This contains my comments as a reviewer of the above document. As assigned, I have focused my review and comments on the housing characteristics and indoor environments portions of this document, but have also commented on other sections. As requested by EPA, my comments have kept the following issues in mind:

- Are the data presented in a way that is useful to exposure assessors?
- Are the data presented in the best way?
- Are the data presented in a way that will support both point estimate and Monte Carlo assessments?
- Have the studies been appropriately grouped into key studies and other relevant studies?
- Are the recommendations at the end of the sections based on a proper interpretation of the key studies, and have the limitations/uncertainties been appropriately emphasized/described?
- What can be suggested about data gaps and research needs for each section?

As noted below in the comments about Sections 6 and 7, a broad recommendation would be to ask readers to help ensure that all potentially useful exposure data are included in future revisions of the Exposure Factors Handbook. A similar message could be sent to various trade associations, key academicians, and others. Could someone in EPA be designated in the handbook as a possible contact to receive data for possible inclusion in future revisions? If done in this way, perhaps periodic updates listing new data for the various sections could be sent to known users of the Exposure Factors Handbook, or even posted as an update file accessible via EPA's Internet World Wide Web "home page." These updates could include a statement that the data are, as yet, unreviewed for final inclusion in upcoming editions of the handbook.

Building on the above comments, I also feel that serious consideration be given to making the entire handbook available on-line via EPA's Internet World Wide Web home page, and/or putting it on a searchable CD (similar to how encyclopedias are now available and searchable as CDs). The current about 1,000 pages is not very user friendly to store, search, and transport, and the technology exists to make it much more user friendly and accessible to exposure assessors. If accessible via an Internet "home page," that means could also be used by EPA to receive comments and information for consideration and possible inclusion in future revisions.

Another general comment is that the American Industrial Health Council's Exposure Factors Sourcebook should be carefully reviewed to see if any of its contents should be added to the revised Exposure Factors Handbook. Also, the various ways data are presented in the AIHC document are user friendly, and perhaps could be added to the revised Exposure Factors Handbook, e.g., the AIHC document has very nice figures showing adult body weight distributions based on information in tables from the original Exposure Factors Handbook.

The following additional comments are organized in the same order as the contents of the handbook.

Section 1. Introduction

Page 1-2. After reviewing this document, I recommend that thought be given to returning to a two part handbook, with the second part containing standard (or commonly applied) scenarios. A key reason for this recommendation is the largely increased size of the handbook which makes it intimidating and more difficult to find relevant information. A second part containing standard scenarios would enable users to quickly find and understand the types of exposure assessments that are commonly performed, and the variety of data and assumptions needed for the assessments. Adequate cross-referencing and warnings about the need to consider the uniqueness of site-specific situations would help encourage exposure assessors to apply data and assumptions focused on their particular exposure assessment needs without the need for separate guidance and support documents. A "key words" master index would also help readers use the document more easily.

Section 2. Ingestion Route

No comments.

Section 3. Inhalation Route

The following are potentially useful publications on respiratory volume as a function of the month of pregnancy:

- Spatling, L. et al. The Variability of Cardiopulmonary Adaptation to Pregnancy at Rest and During Exercise. BRITISH JOURNAL OF OBSTETRICS AND GYNAECOLOGY 99, Supplement 8: 1-40 (1992). *Has respiratory minute volume and other related information as a function of the month of pregnancy.* .

- Clapp, J. F. et al. Maternal Adaptations to Early Human Pregnancy. AMERICAN JOURNAL OF OBSTETRICS AND GYNECOLOGY 159: 1456-60 (1988). *Has data similar to the Spatling publication.*

- Pernoll, M. L. et al. Ventilation During Rest and Exercise in Pregnancy and Postpartum. RESPIRATION PHYSIOLOGY 25: 295-310 (1975). *Has data similar to the above two publications.*

Section 4. Dermal Route

For the sake of accuracy, the following publication may be worth noting in this section:

> Slone, T. H.
> Letter to the Editor on "Body Surface Area Misconceptions."
> RISK ANALYSIS. 13: 375-377 (1993).
> *"Clearly the skin's surface is heterogeneous; it consist of numerous desquamating scales, sweat pores, follicular orifices, and follicles with hairs... One would obtain different values depending on whether one is examining nearly flat nonfolllicular areas or the three-dimensional follicles... There is insufficient evidence that surface area has ever been measured accurately..."*

The following is a potentially useful publication on how much of a skin-applied treatment is needed to cover the surface area of an adult:

> Sherertz, E. F.
> Pharmacology. I. Topical Therapy in Dermatology.
> JOURNAL OF THE AMERICAN ACADEMY OF DERMATOLOGY 21: 108-114 (1989).
> *"Approximately 30 grams of topical medication is needed to cover the body surface of an adult in a thin layer." (If the medication is has a specific gravity of 1 gram per cm^3 and the adult total body surface area is 18,000 cm^2, the film thickness can be calculated to be 0.0017 cm.)*

The following is a potentially useful publication on the capacity of human skin to hold a liquid product:

> Rutledge, L. C.
> Some Corrections to the Record on Insect Repellents and Attractants.
> JOURNAL OF THE AMERICAN MOSQUITO CONTROL ASSOCIATION 4: 414-425 (1988).
> *Most persons applying a liquid repellent ad libitum will apply it at a rate of about 2 mg/cm². Although it is possible to apply more than this intentionally, a limit is eventually imposed by the inception of runoff from the skin. For most repellents, this limit is about 4 mg/cm².*

Section 5. Other Factors for Exposure Calculations

See Section 6 comments for possible additions to Section 5.

Section 6. Consumer Products

Key Comments:

All three Westat studies forming the basis of this section were based on the recall of the subjects. As noted on Page 6-2, "Participants were asked to recall product usage data from the previous 12 months. This may degrade the response accuracy of the participants." Did this happen? Not currently shown in Section 6 is evidence suggesting that this did occur in at least with the Westat 1987b study.

A 50 person subset of the original 193 person phone survey participated in a four-week diary study of eight of the 14 cleaning tasks originally studied. The key finding of the diary study was that much less time per day was spent on performing six of the eight tasks when the diary study data were used. For example, wiping-off counters with a light-duty liquid decreased from a 50th percentile value of 54.75 hours in the phone recall survey to just 18.45 hours in the diary study (= 33.4% of the recall study value).

While the text of Westat 1987b suggests seasonal differences in product usage as playing the key role in the above observed differences, the diary data could at least be included for perspective, and to serve at least as a lower, perhaps more accurate set of data. If similar follow-up diary studies were performed as part of Westat 1987a and Westat 1987c; I would make the same comments and suggestions. The Hakkinen and Hakkinen et al., publications noted below contain discussions about phone recall and diary studies that might be useful to note in the paragraphs discussing the Westat studies in the Exposure Factors Handbook.

Other Comments:
I will bring copies of the following potentially useful publications to the workshop. To make this section as user friendly as possible, I suggest considering adding a master table listing all the various types of consumer products (over 70 if the following publications are included), and showing which publications contain potentially useful information for a particular product type. Also, some published tables, such as those in the Cosmetic, Toiletry, and Fragrance Association document noted below could be added in their entirety:

- Cosmetic, Toiletry, and Fragrance Association, Inc., Summary of the Results of Surveys of the Amount and Frequency of Use of Cosmetic Products by Women. *Contains usage amount and frequency of use data for lotions, creams, mascara, sunscreen, hair sprays, shampoos, toothpastes, underarm deodorants, etc. The frequency of use data are from several sources, and are shown as average and upper 90th percentile values.*

- Curry, K. K. et al. (P&G-sponsored). Personal Exposures... During Use of Nail Lacquers..." JOURNAL OF EXPOSURE ANALYSIS AND ENVIRONMENTAL EPIDEMIOLOGY 4: 443-456 (1994). *Contains consumer use data for nail lacquer products, i.e., nail polishes, basecoats, and topcoats.*

- European Centre for Ecotoxicology and Toxicology of Chemicals. Technical Report No. 58. Assessment of Non-Occupational Exposure to Chemicals (1994). *Contains usage amount and frequency of use data for lotions, shampoos, toothpastes, mouthwashes, etc. (in all, 15 "cosmetic" product types). The frequency of use data are shown as "normal use" and "extensive use" levels. Table 3 summarizes the data, and could be used "as is" in the Exposure Factors Handbook as European data for direct use and comparison to U.S. values.*

  Also, this publication contains task usage amount and task frequency data for various types of laundry detergents, hand dish washing liquids, automatic dish washing products, and fabric conditioners (in all, ten "laundry and cleaning" product types). Table 4 summarizes the data, and could be used "as is" in the Exposure Factors Handbook as European data for direct use and comparison to U.S. values.

  Various other types of products are also discussed at least briefly in the above document.

- Hakkinen, P. J. et al. (P&G). Exposure Assessments of Consumer Products: Human Body Weights and Total Body Surface Areas to Use, and Sources of Data for Specific Products. VETERINARY AND HUMAN TOXICOLOGY 33: 61-65 (1991). *This review discusses sources of exposure-related data for specific product types needed for exposure assessments. The review also contains a discussion of the importance of statistical characterization of the consumer data, and the importance of examining these data for correlative interactions.*

- Hakkinen, P. J. (P&G). Cleaning and Laundry Products, Human Exposure Assessments. HANDBOOK OF HAZARDOUS MATERIALS 145-151 (1993). *Includes some exposure information for assessing consumer exposures to cleaning and laundry products, along with discussion of the topics covered in the 1991 P&G publication.*

- International Sanitary Supply Association. Cleaning Time Estimator. *Contains estimates of times required to conduct various cleaning tasks, e.g., cleaning a shower stall, sinks, toilet, stairways, windows, etc. In all, over 50 estimated task durations are noted. Note that this information could also be a possible addition to the "Activity Patterns" portion of Section 5 of the Exposure Factors Handbook.*

- Vermeire, T. G. et al. Estimation of Consumer Exposure to Chemicals: Application of Simple Models. THE SCIENCE OF THE TOTAL ENVIRONMENT 136: 155-176 (1993). *Includes some exposure information for assessing consumer exposures to detergents, deodorants/antiperspirants, spray cleaners, etc.*

- Wooley, J. et al. Release of Ethanol to the Atmosphere During Use of Consumer Cleaning Products. JOURNAL OF THE AIR & WASTE MANAGEMENT ASSOCIATION 40: 1114-1120 (1990). *Includes some exposure information for assessing consumer exposures to liquid hand dish washing and laundry products.*

The current section only contains information from the Westat data. A broad recommendation would be to ask readers to help ensure that all potentially useful consumer product data are included in future revisions of the Exposure Factors Handbook. A similar message could be sent to various trade associations. Could someone in EPA be designated in the handbook as a possible contact to receive data for possible inclusion in future revisions? If done in this way, perhaps periodic updates listing new data could be sent to known users of the Exposure Factors Handbook, or even posted as an update file in EPA's Internet World Wide Web "home page."

Section 7. Reference Residence

The introduction to this section could use citation of one or more key publications readers could consult to get an overview of how residential inhalation exposure assessments are performed, why specific residential factors are needed, how the residential factors potentially relate to each other, and the potential relative importance of residential inhalation exposure to other exposures, e.g., drinking or ingestion exposures to volatile contaminants in tap water. A very good publication that covers the above is:

McKone, T. E. Household Exposure Models. TOXICOLOGY LETTERS 49: 321-329 (1989). *"There are 4 types of input data required by the indoor model: (1) house and room volumes, (2) residence times for air in each household volume, (3) water use by category, and (4) amount of time individuals spend in the shower, bathroom,, and remaining house..." This publication's Table IV also provides information from two other publications on ranges of water use per person per day for toilets, showers, baths, laundry, dishwater, kitchen and sinks, and cleaning. Other portions of the text provide information on house and room volumes, and shower stall volumes.*

Another overall perspective and information on various residential parameters, e.g., water consumption, is available in:

Wilkes, C. R. et al. Inhalation Exposure Model for Volatile Chemicals from Indoor Uses of Water. ATMOSPHERIC ENVIRONMENT 26A: 2227-2236 (1992).

Section 7.2 starts by stating that no measurement surveys have been conducted to directly evaluate the range and distribution of residential volumes. Likewise, Section 7.3.2 states that no measurement surveys have been conducted to directly evaluate the range and distribution of residential air exchange rates. A key comment about these statements is that some of the following publications address these key needs. As discussed below, a great deal of potentially very useful published and submitted for publication information from various studies could be added to this section. These studies include:

- Finley, B. L. et al. Evaluating the Adequacy of Maximum Contaminant Levels as Health-Protective Cleanup Goals: An Analysis Based on Monte Carlo Techniques. REGULATORY TOXICOLOGY AND PHARMACOLOGY 18: 438-455 (1993).

Portions of Table 2 and Table 3 may be worth using "as is" for the revised Exposure Factors Handbook. including cited (when all were available or assumed) distribution type, mean, standard deviation, minimum and maximum values for shower exposure time, shower and house water use rates, shower, bathroom, and house air exchange rates, shower, bathroom, and house exposure times, and transfer efficiencies from water to shower air and household air (shown are transfer efficiencies based on perchloroethylene).

- McKone, T. E. and Bogen, K. T. Uncertainties in Health-Risk Assessment: An Integrated Case Study based on Tetrachloroethylene in California Groundwater. REGULATORY TOXICOLOGY AND PHARMACOLOGY 15: 86-103 (1992). *Like the Finley et al publication noted above, this contains a useful table (Table 1) containing distribution type, arithmetic mean, and standard deviations for shower duration, shower and total house water use per person, exposure times in the bathroom and house, bathroom and house ventilation rates, and transfer efficiency from water to shower air and water to household air (shown are transfer efficiencies estimated for tetrachloroethylene). This publication also notes assumptions for representative shower, bathroom, and house volumes and air changeovers for these locations.*

- Pandian, M. et al. Residential Air Exchange rates for Use in Indoor Air and Exposure Modeling Studies. JOURNAL OF EXPOSURE ANALYSIS AND ENVIRONMENTAL EPIDEMIOLOGY 3: 407-416 (1993). *Includes data from numerous studies and generates frequency distributions and summary statistics for residential air changeovers in different regions of the United States, different seasons, and different levels within the homes. The summary statistics (Table 1) and cumulative frequency plots (Figures 1-3) should be considered for addition "as is" to the Exposure Factors Handbook.*

- Murray, D. M. and Burmaster, D. E. Residential Air Exchange Rates in the United States: Empirical and Estimated Parametric Distributions by Season and Climatic Region. Submitted for publication in RISK ANALYSIS. *Includes data from several key studies and generates frequency distributions and summary statistics for residential air changeovers in different regions of the United States, different seasons, and as a function of "heating degree days." In all, 25 frequency distributions are provided. The summary statistics (Tables I, II, and III) should be considered for addition "as is" to the Exposure Factors Handbook.*

- Murray, D. M. Residential Total House and Zone Volumes in the United States: Empirical and Estimated Parametric Distributions by Season and Climatic Region. Submitted for publication in RISK ANALYSIS. *Includes data from several key studies and generates frequency distributions and summary statistics for house volumes in the United States as a whole and for eight states. Similar results are also presented for zone volumes for different areas of the house. Also noteworthy is that the possible correlation between house volume and air changeovers per hour was found to be very weak. The summary statistics (Tables I and II) should be considered for addition "as is" to the Exposure Factors Handbook.*

- Anonymous. What is the average house in Northeastern U.S? A University of Maine 100-home study cited in SCIENCE NEWS (October 15, 1988, Page 254). *This study found the average home to be "A home with 2,000 square feet of floor space, eight-foot ceilings, 250 gallons of water use per day and a total venting of indoor air about once every 1.2 hours." Calculating the house volume from some of these data gives a volume of 458,300 liters.*

- Brambley, M. R. and Gorfien, M. Radon and Lung Cancer: Incremental Risks Associated with Residential Weatherization. ENERGY 6: 589-605 (1986). *"A number of studies have involved measurement of air infiltration rates for both conventional and energy-efficient homes. In a survey by Diamond and Grimsrud of 312 recently constructed homes throughout the U.S. and Canada, the mean measured infiltration rate during the months of November through March was 0.63 air changeovers per hour (ACPH). In a re-evaluation of existing data, Nero estimates average infiltration rates in the U.S. to be 0.7-0.8 ACPH. Although rare, air-exchange rates as great as 4.0 and lower than 0.25 ACPH have been measured. Generally, an infiltration rate of 0.5 ACPH is considered by McNall as representative of recently, well-sealed homes."*

The U.S. Department of Energy has in years past apparently received various appliance-type exposure information from the Association of Home Appliance Manufacturers (20 North Wacker Drive, Chicago, Illinois 60606). This potentially very useful information included water volume per appliance load, frequencies of appliance use, etc.

Like the previous section on consumer products, the current section is new. A broad recommendation would be to ask readers to help ensure that all potentially useful residential exposure data are included in future revisions of the Exposure Factors Handbook. A similar message could be sent to various trade associations and key academicians. Could someone in EPA be designated in the handbook as a possible contact to receive data for possible inclusion in future revisions? If done in this way, perhaps periodic updates listing new data could be sent to known users of the Exposure Factors Handbook, or even posted as an update file in EPA's Internet World Wide Web "home page."

Section 8. Analysis of Uncertainties

Two related reviews on human exposure assessment uncertainties that could be noted in this section are:

Whitmyre, G. K. et al. Human Exposure Assessment I: Understanding the Uncertainties. TOXICOLOGY AND INDUSTRIAL HEALTH 8: 297-320 (1992).

Whitmyre, G. K. et al. Human Exposure Assessment II: Quantifying and Reducing the Uncertainties. TOXICOLOGY AND INDUSTRIAL HEALTH 8: 321-342 (1992).

Other Comments:

Finally, since one of the charges to reviewers was to identify data gaps and research needs for each section, it should be noted that the following two recent publications in particular have discussed ways to improve the science of exposure assessment. I don't necessarily recommend noting all of the following in the revised Exposure Factors Handbook; however, some of the areas for improvement and research needs are related to exposure factors and the use of exposure factors, and seem worthy of highlighting in the appropriate section(s).

Whitmyre, G. K. et al. Human Exposure Assessment II: Quantifying and Reducing the Uncertainties. TOXICOLOGY AND INDUSTRIAL HEALTH 8: 321-342 (1992).

Potential improvements to human exposure assessment that were discussed in the above publication included:

(1) Use of more appropriate exposure default values...;

(2) Incorporation of time-activity data...;

(3) The use of reasonable exposure scenarios...;

(4) The use of stochastic approaches...;

(5) Use of bivariate analysis...;

(6) Use of less than lifetime exposure...; and

(7) Incorporation of physiological considerations relevant to absorbed dose estimation...

The above publication also discussed other ways to improve the exposure assessment process, and identified the following key research needs (see Pages 339-340 of original publication for full text):

(1) Exposure Parameters. *Collecting statistical distribution data on parameters for which data are incomplete or absent.*

(2) Methods for Calculating Joint Probabilities. *More information on the inter-relationships of exposure parameters is needed.*

(3) Pharmacokinetic Modeling. *Pharmacokinetic parameter data, such as blood flow rates and tissue volumes, need to be developed on key chemicals of interest. PBPK model uncertainties should be examined in more depth using Monte Carlo and other stochastic methods. New models need to be validated. Chemical-specific factors such as partitioning ratios and metabolic rate constants need to be developed.*

(4) Indirect Pathways. *More research is needed in this area.*

(5) Personal Monitoring and Human Activity Patterns. *Total human exposure monitors that measure personal exposures in a reproducible way need to be developed for a variety of chemicals. More effort is needed in developing and improving human activity models and databases. Further understanding of microenvironments is needed, as is the need for further studies to define the relative contributions of various routes, pathways, and microenvironments to exposures to many types of compounds for various subpopulations and regions.*

Paustenbach, D. J. The Practice of Health Risk Assessment in the United States (1975-1995): How the U.S. and Other Countries Can Benefit from that Experience. HUMAN AND ECOLOGICAL RISK ASSESSMENT 1: 29-79 (1995).

The above publication by Paustenbach presented several "lessons learned" in the United States about how to improve exposure assessments. They include:

(1) Don't put too much emphasis on risk estimates for the maximally exposed individual (MEI);

(2) Evaluate the uptake (absorbed dose) for both the 50% and 95% persons;

(3) Do not repeatedly use conservative or worst-case assumptions. Incorporate Monte Carlo techniques whenever possible;

(4) Ensure a proper statistical analysis of environmental data;

(5) Conduct sensitivity analysis to understand fragility of dose estimates;

(6) Understand the role of environmental fate when estimating exposure;

(7) Validate the reasonableness of the exposure estimates;

(8) Consider using biological monitoring to confirm exposure estimates; and

(9) Consider all indirect pathways of exposure.

Please feel free to contact me if you have any questions about my comments. Thank you again for asking me to participate in the review of this document.

Very truly yours,

The Procter & Gamble Company

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James Axley

Review Comments

Housing Characteristics and Indoor Environments (Chapter 7. Reference Residence)

submitted by
James W. Axley
Yale School of Architecture

General Comments

The authors of Chapter 7 have taken on a very difficult challenge and have done a very admirable job establishing a reasonable framework and first draft for the description of a *Reference Residence* for exposure analysis. They have been extremely careful to make sure the data is presented in a form that is useful to exposure assessors; to discuss studies that support the analytical approaches presented; and to present recommendations for use of the data.

The general suggestions put forward below are largely proposals to expand the scope of the chapter rather than offer corrections – adding, it is hoped, to the excellent material presently included in this chapter.

- *Organization:* The general organization of the Chapter – 7.1 Introduction; 7.2 Indoor Volumes; 7.3 Airflows; 7.4 Water Supply and Use – could be expanded to include sections on modeling approaches, sources, and analysis and the Indoor Volumes section could be generalized to "Building Characteristics" to allow inclusion of a more complete characterization of residential buildings as:

  7.1 Introduction

  7.2 Modeling Approaches

  To include a general discussion of the approaches to modeling making the distinction between microscopic and macroscopic modeling and establishing the classes of data needed for analysis.

  7.3 Building Characteristics (formerly Indoor Volumes)

  To include building configurations; room volumes, wall, floor and ceiling surface areas; construction material characteristics, furnishing characteristics

  7.4 Airflows

  7.5 Water Supply and Use

  7.6 Sources

  7.6.1 Airborne Sources

  7.6.2 Waterborne Sources

  7.6.3 Dust and Aerosol Sources (e.g. tracking of soil into homes)

  7.6.4 Transport Between Source Types

  7.7 Analysis

To include general formulations of single-zone and two-zone formulations of the contaminant dispersal problem with steady-state solutions and dynamic solutions for representative cases and an introduction to computational tools for multizone analysis.

- *Suburban Bias*: The discussion of building configurations and room volumes, wall, floor and ceiling surface areas appears to be biased toward suburban residences. There is a clear need to consider urban residential environments and, possibly, rural residences as well.

- *Geomet Bias*: As noted in the specific comments below, much of the discussion is related to research completed at Geomet. While this Geomet research has been consistently of the highest quality, it would be best to tie the discussion to a broader array of studies. Furthermore, at this point in time, the studies have not been explicitly classified into "key" and "other relevant" as mandated by EPA.

- *Data Gaps and Future Research Needs*: Some are noted below in the specific suggestions and many could be enumerated, but at this time it would be best to address this issue during the workshop.

Specific Comments and Suggestions

Page 7-2

Figure 7-1 should include chemical and physical transformation (i.e., in addition to indoor sources, reversible sinks, and decomposition and deposition). Examples include gaseous chemical reactions such as $O_3 + NO \rightarrow NO_2 + O_2$ and physical transformations such as condensation or coagulation of aerosols.

Page 7-4 to 6

The use of an assumed ceiling height of 8 feet to estimate residential volumes and surface areas may introduce significant error. Historically, it is likely that the trend of ceiling heights in detached single family homes and many urban attached single-family homes ranged from below 8' before circa 1850 to above 10' by the great depression then, influenced strongly by the code minimum of 7' 6" remained close to 8' until recent building trends have revived higher ceiling heights. Urban neighborhoods not only tend to be dominated by these older residences, a significant portion of these residences have been transformed to multi-unit residential configurations. As a result, one might expect the tabulated volume and, importantly, surface estimates (i.e., from a lead paint exposure point of view) to significantly underestimate urban residential dwellings.

Page 7-5

It is not immediately clear whether the estimated volumes reported in Table 7-1 are whole-building volumes or residential unit volumes. The magnitudes indicate, however, that the volumes are residential unit volumes. This should be clarified.

Page 7-8 Table 7-4

Due to past beliefs regarding the nature of "surface" emissions "surface" materials have been characterized by their surface area alone. More contemporary, and physically consistent, views of the nature of "surface" emissions and sorption phenomena now recognize the importance of treating most of these materials as porous solids and providing more complete physical characterization of them (e.g., thickness, porosity, mass per unit volume, specific surface area, etc.). For example, the ubiquitous gypsum board is very porous, from the perspective of gas molecules, and has an extremely high specific surface area ($> 500\ m^2/g$) – characteristics far more significant than the surface covered.

Additional research is needed to provide more complete and more relevant characterization of building materials in general and especially those building materials used in the construction of room surfaces.

Page 7-10 ¶2

A small technical point: The second sentence of the second paragraph of this page should be altered to read:

"The forces causing the airflows are *due to* temperature differences, the actions of wind, and mechanical ventilation systems."

Page 7-10 ¶3

This paragraph presents a macroscopic view of air circulation in buildings. From a microscopic point of view, the circulation in a building with "free communication between floors or stories" may be (is likely to be) far more complex than that described. It would not be unreasonable to expect a complex overlay of recirculation loops at each level with smaller flow loops or eddy-like flow structures here and there throughout a building. A revision of this paragraph should be considered.

Page 7-11

Regarding the use of PFT air exchange data. It is an established fact that the application of a constant injection tracer technique based on average tracer concentration measurements, such as the conventional PFT technique, may be expected to consistently underestimate air exchange rates. The problem results from the fact that air exchange rates vary with time while the theory upon which these methods are based presumed constant air exchange rates. The underestimation error that may result may be expected to be larger with longer averaging times. Furthermore, the PFT database while large contains, I suspect, many measurements taken by nonexperts that may, therefore, be suspect.

This problem should be noted and ideally the uncertainty associated with it quantified. It is significant that the Grot & Clark study and the Grimsrud studies noted on page 7-12 report means significantly greater than that extracted from the PFT database for, I believe, these two earlier studies were not based on data collected using the conventional PFT method.

Page 7-14

The background discussion is biased in two respects regarding characteristic residential configurations is, I believe, biased toward single-family residences found primarily in suburban areas. This should be noted and, if possible, urban and, possibly, rural (i.e., both farm and upscale residential dwellings that tend to be more complex or exceptional in configuration) configurations should be discussed.

Page 7-14

The heuristic relationship between internal airflows and house volume and air exchange is novel and, as such, interesting, but it does not in any way represent a consensus view of researchers in the field. In fact, I suspect few researchers in the field even know of this approach. From my perspective it suffers from the following flaws:

- It is based on the tacit assumption that whole-house air exchange rate is distributed to zones in proportion to volume. This is not likely to be the case. Among other factors, rooms associated with entries and exits might be expected to experience proportionately greater air exchange, room exposure must be expected to be important, and occupant behavior will result in significant day-time, night-time, and seasonal differences.
- As noted interzonal airflows are presumed to be "symmetrical" between two zones. Air exchange is due to wind, buoyancy, and/or mechanical devices that, by their nature, must be expected to result in a net transport from zone to zone. Thus "symmetrical" flows must be expected to be the exception rather than the rule.
- Again the PFT database has been assembled from a variety of sources. Some data has most certainly been collected by investigators not familiar with the many pitfalls of multi-zone tracer gas measurements. Multi-zone tracer gas measurement is in many (most) cases an ill-conditioned problem – i.e., sensitivity to measurement error can be pathologically extreme – passive sampler-PFT techniques must be expected to especially susceptible in this regard. (In this regard, multi-zone PFT airflow data including negative values should be rejected out-of-hand.)

The heuristic method proposed certainly has the advantage of simplicity, but correctness must be held as more important and this method should not be put forward as standard practice.

Page 7-18

The first paragraph of section **7.3.4 Variability Within Zones** refers to the very interesting and rigorous work of Baughman et al., but does not properly establish the context of the research discussed. From Baughman et al.'s Abstract:

> "... This experimental study characterizes quantitatively the rate at which smoke from a cigarette disperses within an unoccupied, 31 m^3, low air-exchange rate room [0.03-0.08 ACH] under natural convection flow conditions. Sidestream smoke ... was simulated with ... SF_6 ...[at] 41 locations within the room ... Duplicate runs were conducted under three conditions: nearly isothermal surfaces, convection from a 500 watt heater; and convection from incoming solar radiation. Characteristic mixing times ranged from 7-10 minutes for the solar radiation case to 80-100 minutes for the nearly isothermal case." (Baughman, A.V., A.J. Gadgil, and W.W. Nazaroff, *Mixing of a Point Source Pollutant by Natural Convection Flow within a Room*. Indoor Air, 1994. **1994**(4): pp. 114-122.)

Importantly, these studies were conducted at extremely low air exchange rates – not at all characteristic of airflows found in residences.

Furthermore, the statement in section **7.3.4** that "Similar finding might be expected for a continuously emitting area source ..." is technically off the mark. Even molecular diffusion from a point source will differ substantially from that from a planar source.

More to the point, are the consistent findings that microenvironmental monitors consistently underestimate dose/exposure when compared to personal environmental monitors. Charles Rodes provides a very useful review of these findings and establishes a reasoned position relative to their importance to exposure modeling:

> " In a less-than-ideal mixed situation, contaminant concentration gradients may be large in close proximity to the source, even though the general area concentration at some distance away may change insignificantly. ... Thus, the application of integrated exposure models, using activity pattern information and compartmental average concentration data, may give results that are unacceptably inaccurate and produce [exposure] estimates that are often biased low." (Rodes, C.E., R.M. Kamens, and R.W. Wiener, The Significance and Characteristics of the Personal Activity Cloud on Exposure Assessment Measurements for Indoor Contaminants. Indoor Air: International Journal of Indoor Air Quality and Climate, 1991. **Vol. 2**: p. pp. 123-145.)

In this paper, Rodes discusses the importance of the so-called "proximity effect" and his investigations of the "personal cloud" that appears to be central to this effect.

The second and third paragraphs of this section address this issue more appropriately, but the research reported is limited to two studies. This section should be revised using a broader collection of studies. The work reviewed by Rodes should go a long way toward achieving this objective.

P. Barry Ryan

Comments on Chapter 7- Reference Residence

The Reference Residence is an important concept in modeling of exposures experienced in indoor environments. As a large fraction of total time is spent in such locations, a proper understanding of the environment is warranted. This Chapter presents field data and suggestion for parameters to use in modeling of residential exposure.

The chapter is, by and large, a useful one. The compendium of data is unique and the reference list at the end very valuable. I have several specific comments given below.

Introduction- The Introduction does not touch upon any soil gas contamination processes, e.g., radon which show variable impact depending upon the characteristics of the residence- basement condition, tightness, etc.

Tables 7-1 - 7-3 represent extremely useful data for indoor air quality modelers. They (particularly 7-1 and 7-2) would be even more useful if the variability were described either by presenting percentiles of distributions or even standard deviations.

The arguments on page 7-8 relating size of test homes to national average is very strained. The test homes should be viewed as such without a lot of effort designed to that they are, somehow, represented of trends in all homes.

Again on page 7-8 the discussion of surface-to-volume ratio (S/V) is important. This parameter is crucial in modeling deposition of particles and gases. The discussion is couched in extremely confusing language related to S/V ratios for floors and walls. I was confused into trying to figure out what the volume of a wall or floor might be. Specifically state the relationship- the ratio of wall surface area to total volume and similarly for total wall surface area to total volume. Then it becomes clear.

On page 7-10, there is an unqualified assertion the I/O temperature differences are smaller in cooling seasons than in heating seasons. This is not categorically true; in Arizona, Nevada, and doubtless many other locations, such differences may indeed be greater in cooling seasons. There is no need to be so assertive.

In Table 7-5, perhaps as a footnote, the nature of the distributions should be described. Are the distributions essentially normal, lognormal, etc.? Skewness, boundedness etc. are all useful parameters for modelers.

On page 7-12 the text states theat "... Statistical techniques were applied to compensate for some of these imbalances (is seasonal and geographical coverage) ..." What techniques were applied and how? This should be discussed.

Page 7-12ff discusses air exchange rates. The listings for air exchange rates, a critical parameter in any modeling exercise, report this parameter as mean $\pm$ geometric standard deviation ACH. This is odd. First, it is not clear whether the deviation is geometric or arithmetic. If it is arithmetic, the units are fine but there is an apples and oranges mix of parameters. If it is geometric, the variability is multiplicative and, thus, has no units. Given the expected skewness in theses data (NB max for west is 23.82) the reported values could be either. Also, given what I know about the technique, I would be highly suspect of any measurement above about 8.0 ACH. For air exchange rates higher than this, the measured tracer level is probably below detection limits.

On page 7-17, equations are given relating interzonal flows, Q_z with air exchange rate. In that this appears to be a statistical regression model, it would be very useful to know the qulaity of the fit. For example, what is the expected error in this fit, the R^2, etc. Further, a discussion of conditions resulting in failure of this model would be beneficial. Also, again with knowledge of the technique used to gather the basic data, caution should be exercised in using this regression model. An improper assumption regarding the location of zones can result in non-physical interzonal flows. These may or may not be included in the data set used to derive these relationships.

Section 7.3.4 reads differently than the other sections. It is more a description of a research experiment without really putting it into perspective for the exposure factors handbook.

Table 7-6 makes use of several data sets. The idea of using the mean or median of these investigations is flawed as it gives each study identical weight. As I am not familiar with each investigation, I cannot estimate the effect. I can speculate that some studies may have been geared toward specific populations which may use one or more of these categories to a greater or lesser extent than others. Although these may be the best data available, extreme caution should be urged in their use.

In the overview documents we received, it was stated that a set of recommendations would be presented at the end of each section. No such recommendations were found at the end of Section 7.

Comments on Chapter 8- Analysis of Uncertainties

Chapter 8 is a brief compilation of terms and ideas from the references (in particular, USEPA, 1992). This in and of itself is quite useful and will supply the potential user with some knowledge of the nomenclature associated with the study of uncertainty. What is not supplied, however, is a mechanism for implementing this information. Much of the section is devoted to expanding on the three brief definitions given at the beginning regarding uncertainty in scenarios, parameters, and models. Some approaches to investigating such uncertainties are suggested but without sufficient detail to afford the unschooled practitioner to make any headway. In this, there is a severe failing. The final subsection discusses methods of presenting the data. Such issues are like apple pie and motherhood; who can object to a goal of clear presentation? On the other hand, there is little information on how to present. Detailed examples are found below.

In summary, I found this chapter to be sorely lacking. It is an excellent introduction to a chapter on uncertainty estimates. If this handbook is to serve in the manner needed, this section needs to be greatly expanded. I would urge the presentation of a series of worked examples ranging from quite simple exposure assessments and their related uncertainties to more complex systems. Throughout the discussion, analogy should be made to each of the paradigms discussed- uncertainty in scenarios, parameters, and models- to tie in with the preliminary discussion. These examples should be well-chosen in that they will be used as guidelines by users of this Handbook. If this is not done, I suggest shortening the chapter and prompting the reader to assess the literature independently by providing a more complete bibliography.

Specific Comments

The definitions of uncertainty characterization and uncertainty assessment are, I believe, not at variance with commonly accepted nomenclature, but are not in agreement with it either. These are new terms.

At the top of page 8-3, there is a discussion of "incomplete analysis" with an example given focusing on overlooking an important pathway in an exposure. Why isn't this model misspecification?

Parameter uncertainty is most easily understood by Monte Carlo simulation, especially for random errors and sampling errors. Systematic errors are harder to model if they are unknown. Such procedures as bounding estimates, expert judgement, and the like come with essentially unknown (and unknowable) errors. This is not discussed clearly in the section.

Sensitivity analyses are useful but repeated simulation followed by analysis of variance also supplies a useful, and often powerful, technique in lieu of simple "high-low" simulation. The hierarchy of sensitivity analysis, analytical uncertainty propagation, Probabilistic uncertainty analysis, and classical statistical methods is not a lock-step with regard to complexity and data needs, especially in a simulation model. Data needs are minimal as more simulations can be run to generate more data and, thereby establish the importance of parameters.

At the bottom of page 8-5, a suggestion is made that is "average" values are needed, they can be computed accurately by using average values for each parameters. What type of average are we looking for here? Suppose distributions are highly skewed (as is likely in exposure assessment)? Suppose parameters are correlated? Further possibilities exist which can make this assumption total invalid. This deterministic approach to analysis is poor. Further, given the availability of commercial software, the statements regarding the difficulty of repeating the simulations is not warranted. Also, the last two sentences stating ".. Monte Carlo analysis assumes that the distributions of each variable are independent." is just wrong. There is nothing in Monte Carl analysis that makes this assumptions. Most new software is quite capable of including either Pearson or Spearman correlation among distributions using either standard techniques for linear algebra on normal distributions or the techniques of Iman and Conover on other distributions.

The discussion of skewness and data sparseness at the end of section 8.1.2 is incomplete. There needs to be an assessment of the effect of < LOD values on the distributions estimated as well as effects on other parts of the distribution if stratification is effected to increase the "tail" proportion of samples. You can't get something for nothing.

The discussion of Model Uncertainty (Section 8.1.3) borders on philosophical. It discusses the way things should be done without a lot of practicality. All of these things are desirable, but how does one approach a real problem?

Section 8.2 on the Presentation of Uncertainty Analysis Results is the first Presentation of this type of material I have seen. It is a good idea but needs expansion.

In summary, Chapter 8 is an embryonic development of methods of uncertainty analysis. I believe it to be an essential component of the Exposure Factors Handbook but one that needs extensive expansion and thought.

Andrew Persily

Table 7-3

These four houses have certainly been the subject of much interesting analysis, but there are others out there was well. They are not necessarily representative of anything, and I wonder about the implication that they are "the ones" to use. Why include these four houses and no others? At least include some references to other house layouts. I wouldn't be surprised if the National Association of Home Buildings (NAHB) could help you on this?

Table 7-4

Similar to comment on Table 7-3, I am concerned about the presentation of this information as uniquely representative of what's out there in the residential sector.

Top of page 7-1

My concerns regarding the measurement uncertainty associated with the interzone flows determined with the PFT technique are at least an order of magnitude greater than the single zone air change rates. The PFT interzone data is rarely presented with any uncertainty estimates, and non-physical results (negative airflow rates) are common. The so-called "heuristic relationship" developed by Koontz and Rector may be a very good analysis of a questionable dataset, but its presentation does not reflect any questioning of its appropriateness or reliability. It is not a generality accepted approach.

1st paragraph of section 7.3.2

I am not comfortable with the reference to outdoor contaminant concentrations being zero. This is a very inappropriate assumption in many situations. Outdoor concentrations are in fact higher than indoors quite often.

Section 7.3.4

While mixing within spaces and the variation in contaminant concentrations are clearly critical to exposure, I am not sure I see how the two studies cited here will help the user. They are both interesting, quality work, but what does one do with them? How does the analysis account for imperfect mixing? I am not advocating the use of mixing factors; in fact, it might be worth including a discussion of mixing factors since the reader is probably familiar with them and would benefit from a discussion of the fundamental problems with the concept. So what constructive information can you provide on imperfect mixing? Not much. You can tell them about computational fluid dynamics, but I'm not sure what else will help.

Andrew Persily
July 7, 1995

2nd paragraph on page 7-12

In addition to the caveats on the PFT data based on its representativeness, there are also important questions regarding measurement bias with this technique. See the article by Max Sherman in Building Environment (Vol. 21, 135-144, 1986) in which is discusses the negative bias in using this technique to conduct long-term measurements.

UNITED STATES DEPARTMENT OF COMMERCE
National Institute of Standards and Technology
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Building 226, Room A 313

20 July 1995

Helen Murray
Eastern Research Group, Inc.
110 Hartwell Avenue
Lexington, MA 02173-3198

Dear Ms. Murray,

After a little more thought, I have two additional comments on the Exposure Factors Handbook. They are as follows:

Section 7.3
Why not discuss the use of models to predict whole building air change rates and interzone airflow rates? A widely-accepted single-zone model to predict whole building rates (sometimes referred to as the LBL model) is presented in the ASHRAE Fundamentals Handbook. Several multi-zone mass balance models also exist, which can be used to predict airflow rates in multi-zone building airflow systems. Examples of such models include CONTAM, BREEZE and COMIS.

Section 7.3.2
There are more recent surveys of the airtightness of U.S. homes. See for example the paper by Sherman and Dickeroff in the 1994 proceedings of the 15th conference of the Air Infiltration and Ventilation Centre (AIVC), or contact Max Sherman (through Joan Daisey) directly for even more recent information than in that paper.

If you have any questions, please contact me at (301) 975-6418 or at apersily@nist.gov.

Sincerely,

Andrew Persily
Group Leader, Indoor Air Quality and Ventilation
Building Environment Division
Building and Fire Research Laboratory

NIST

Thomas Phillips

July 14, 1995

Helen Murray
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Lexington, MA 02173-3198

Dear Ms. Murray:

Subject: COMMENTS ON EXPOSURE FACTORS HANDBOOK, JUNE 1995 EXTERNAL REVIEW DRAFT

Brief comments from my initial review of the Handbook are summarized below. The focus is on issues listed and the comments are on the Reference Residence as well as other subject areas, as requested by Dr. Wood in his June 29 letter to reviewers.

1. USEFUL PRESENTATION OF DATA

1a. In general, this draft has improved the usefulness of data by presenting more frequency distributions. However, some of the sections do not take full advantage of such data. For example, the distributions for housing volume (Ch. 7.2), air exchange rate (Ch. 7.3), and time spent in locations (Ch. 5.3) are not presented. Is it presumed that exposure assessors will obtain the original data sets and reports and be able to analyze them in a short amount of time? Or are these distributions presented in another EPA report?

<u>It would seem most useful and convenient to have the distributions all in one package, at least for the critical parameters where extensive data are available, as in the examples given above.</u> It would also seem consistent with EPA's effort to promote consistency in calculating exposure and dose because it minimizes major sources of inconsistency such as the use of different percentiles or the incorrect analyses of data.

1b. For AER data (Ch. 7.3), it would be useful to emphasize data from population-based samples and from studies with QA/QC programs in place. The amalgamation of all samples in the U.S. treats all data as equal in quality, which is really not the case. The panel in the previous review round agreed on this concept, as I recall.

1c. For house volume data (Ch. 7.2), it would be useful to include data for slab-on-grade homes. This type of home is the predominant type in California and some neighboring states.

1d. As a general concept for indoor pollution, it would be worth mentioning and adding to Figure 7-1 that 1) pollutants from groundwater and soil gas can enter the home though the slab or crawlspace foundation, especially if there is building depressurization, and 2) chemical reactions can not only remove indoor pollutants but they may add or create pollutants that could be equally or more harmful than the original pollutants emitted. See the work by Weschler and others for examples of carpet pollutants changing over time.

1e. If building materials data are presented, include examples to show how they would be used. The data from Tucker (Table 7-9) show what materials might be of interest, but it is not clear how the data would be used, especially if each building is a very specific case. In addition, the example for gypsum board seems to be low by a factor of 2-3 for typical new construction in California. What is the source of these data?

1f. Include estimates of the effect of different mechanical ventilation systems on AERs in homes (Ch. 7.3). Breakdowns of this type would be useful is narrowing the data distribution somewhat and deciding which way to lean in estimating AER. For example, homes with forced air systems generally have tighter shells (no ductwork and wall penetrations to leak), homes with whole house or exhaust ventilation, or heat-recovery ventilation will tend to have higher AER's when the system operates, and forced air systems or large exhaust systems can increase pollutant transport via building depressurization.

1g. Time spent in locations or microenvironments should be emphasized more, and the time spent in activities should be greatly de-emphasized. Numerous tables and extensive discussions are devoted to time spent in various activities (Ch. 5.3), but it is not clear how such sociological observations relate to exposure assesors' data needs. It is clear that time spent in various locations has direct input into exposure modeling, as discussed in NAS reports by Sexton and Ryan and by others.

2. GROUPING OF KEY VS. RELEVANT STUDIES

2a. It is not clear why a re-analyses of CARB's adult activity pattern study, but not the original study, is included. By the way, the original study includes a comparison to national data for time spent in locations.

3. INTERPRETATION AND UNCERTAINTY OF DATA

3a. It is not clear what criteria were used to estimate inhalation rates. I would recommend giving priority to direct measurements versus calculations based on heart rate (which has been shown in several studies to be a poor proxy). The consideration of lab vs. field data, and the effect of various stressors produced by the protocol itself, should be included.

4. DATA GAPS AND FUTURE RESEARCH NEEDS

4a. Obviousely we need better data on pollutant source strengths and AERs. I would add to that list the removal, transport, and transformation processes, especially for particles, metals, and semi-VOC which adhere to and build up in building surfaces such as carpets. Most importantly, I would add personal monitoring data and/or biological monitoring data as a means of setting realistic benchmarks for any exposure assessment or modeling.

Yours truly,

T. J. Phillips

Thomas J. Phillips

APPENDIX C

WORKSHOP AGENDA

EPA United States
Environmental Protection Agency

Peer Review Workshop on Revisions to the Exposure Factors Handbook

Doubletree Hotel Park Terrace
Washington, DC
July 25-26, 1995

Final Agenda

Workshop Chair: **P. Barry Ryan**
Rollins School of Public Health at Emory University
Atlanta, GA

TUESDAY, JULY 25, 1995

7:30AM Registration/Check-in

8:30AM Welcome
William Wood, Director, Risk Assessment Forum, U.S. Environmental Protection Agency (U.S. EPA)

8:45AM Plenary Session: EPA Charge to the Peer Reviewers
Michael Callahan, National Center for Environmental Assessment, U.S. EPA

9:15AM Summary of Premeeting Comments: Workshop Chair and Work Group Leaders

- Workshop Chair: P. Barry Ryan
- Work Group 1: Barbara Petersen
- Work Group 2: John Kissel
- Work Group 3: Steven Colome
- Work Group 4: Bert Hakkinen

10:30AM **BREAK**

11:00AM Observer Questions and Brief Comments

11:20AM Work Group Sessions

- Work Group 1: Food and beverage consumption
- Work Group 2: Nondietary and dermal exposure factors
- Work Group 3: Human activity patterns
- Work Group 4: Housing characteristics and indoor environments

12:00PM **LUNCH**

(over)

TUESDAY, JULY 25, 1995 (continued)

1:15PM	Work Group Sessions - continued
4:00PM	Plenary Session: Status Report by Work Group Leaders
5:00PM	ADJOURN

WEDNESDAY, JULY 26, 1995

8:30AM	Work Group Sessions - continued
12:00PM	LUNCH
1:15PM	Plenary Session: Summary and General Discussion
2:45PM	BREAK
3:00PM	Observer Comments
4:30PM	ADJOURN

APPENDIX D

WORK GROUP ASSIGNMENTS

EPA United States
Environmental Protection Agency

Peer Review Workshop on Revisions to the Exposure Factors Handbook

Doubletree Hotel Park Terrace
Washington, DC
July 25-26, 1995

Work Group Assignments

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1st Floor

Food and beverage consumption

Work Group Leader: Barbara Petersen
EPA Resource Person: Jackie Moya

J. Mark Fly
Patricia Guenther
Mary Hama
Paul Price
John Risher
Frances Vecchio

Work Group #2
CABINET ROOM
2nd Floor

Nondietary and dermal exposure factors

Work Group Leader: John Kissel
EPA Resource Person: John Schaum

Dennis Druck
Larry Gephart
Peter Robinson
Brad Shurdut

Work Group #3
CHAIRMAN'S SUITE
2nd Floor

Human activity patterns

Work Group Leader: Steven Colome
EPA Resource Person: Karen Hammerstrom

Edward Avol
Neil Klepeis
John Robinson

Work Group #4
DIRECTOR'S SUITE
2nd Floor

Housing characteristics and indoor environments

Work Group Leader: Bert Hakkinen
EPA Resource Person: Kevin Garrahan

James Axley
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APPENDIX E

FINAL OBSERVER LIST

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Environmental Protection Agency

Peer Review Workshop on Revisions to the Exposure Factors Handbook

Doubletree Hotel Park Terrace
Washington, DC
July 25-26, 1995

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