United States
Environmental
Protection Agency

Science Advisory
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EPA

AN SAB REPORT: REVIEW OF DRAFT FINAL EXPOSURE ASSESSMENT GUIDELINES

REVIEW OF THE OFFICE OF HEALTH AND ENVIRONMENTAL ASSESSMENT AND THE RISK ASSESSMENT FORUM'S DRAFT FINAL GUIDELINES FOR EXPOSURE ASSESSMENT (DATED MAY 8, 1991) BY THE INDOOR AIR QUALITY AND TOTAL HUMAN EXPOSURE COMMITTEE

NOTICE

This report has been written as a part of the activities of the Science Advisory Board, a public advisory group providing extramural scientific information and advice to the Administrator and other officials of the Environmental Protection Agency. The Board is structured to provide balanced, expert assessment of scientific matters related to problems facing the Agency. This report has not been reviewed for approval by the Agency and, hence, the contents of this report do not necessarily represent the views and policies of the Environmental Protection Agency, nor of other agencies in the Executive Branch of the Federal government, nor does mention of trade names or commercial products constitute a recommendation for use.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

January 13, 1992

OFFICE OF
THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

EPA-SAB-IAQC-92-015

Honorable William K. Reilly
Administrator
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Subject: Science Advisory Board's review of the Draft Final Exposure Assessment Guidelines (SAB Final Review Draft dated August 8, 1991).

Dear Mr. Reilly:

On September 12-13, 1991, the Indoor Air Quality and Total Human Exposure Committee of EPA's Science Advisory Board (SAB) reviewed the Agency's Draft Final Exposure Assessment Guidelines. This is the latest revision of the Agency's exposure guidelines, the SAB having reviewed and provided advice on earlier versions in 1986 and 1988. The Committee was asked by EPA's Risk Assessment Forum to provide advice on the following issues: a) Is the document scientifically sound and does it represent current thinking in exposure assessment? b) Are the concepts of exposure and dose presented in Chapter 2 consistent and well characterized? c) What are the Committee's views on the concepts and terms used in describing "high end exposure"? d) Is the presentation in Chapter 6 concerning the role of uncertainty analysis in exposure assessment, the sources of uncertainty, and approaches to characterizing uncertainty correct and scientifically adequate? e) Are the approaches described in Chapter 7 relating to communicating the results of exposure assessment well characterized and is the level of guidance presented sufficient?

The Committee found the draft document to be very well crafted and complete. It is scientifically sound, and a major improvement over previous efforts. We were pleased to observe that the current draft document includes new developments in the exposure assessment field since 1988, as well as providing satisfactory resolution of most of the general and specific SAB concerns contained in our previous reviews. We were also pleased to note the consistency of the approach and definitions with those in the 1991 National Academy of Sciences exposure assessment report. We believe that the draft document is

successful in setting out a broad theoretical framework for considering exposure assessment. We found the presentation of uncertainty analysis to be comprehensive, scientifically correct, and that it appropriately highlights the importance of uncertainty assessment in exposure assessment.

While the document is a vast improvement over earlier drafts, it can be further improved, especially with respect to the discussion of (high-end) exposures. Thus, we offer a number of suggestions for improving the draft document. For example, the discussion of exposure and dose that is presented in the draft requires clarification and should be more consistent.

We suggest a specific alternative framework for characterizing the (high-end) exposure. We believe that this will provide a firmer scientific basis for the expression of the exposure estimators that result from the application of the exposure assessment guidelines. The original figure (Figure 5.1) in the draft document provides points of discussion consistent with current risk descriptors. Our suggested alternative (Figure 1 in our attached report) provides a more logical basis for reporting the results of an exposure assessment to risk assessors, risk managers and the scientific community. Its features are described in the attached report.

The Science Advisory Board is pleased to have had the opportunity to review this draft final document and to offer our advice. We would appreciate your response to the advice we have provided in the attached report.

Sincerely,

Raymond C. Loehr

Dr. Raymond Loehr, Chair
Executive Committee
Science Advisory Board

Morton Lippmann

Dr. Morton Lippmann, Chair
Indoor Air Quality and Total Human
Exposure Committee

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ABSTRACT

On September 12-13, 1991, the Indoor Air Quality and Total Human Exposure Committee of EPA's Science Advisory Board (SAB) reviewed the Agency's Draft Final Exposure Assessment Guidelines. This is the latest revision of the Agency's exposure guidelines, the SAB having reviewed and provided advice on earlier versions in 1986 and 1988. The Committee was asked by the Risk Assessment Forum to provide advice on the following issues: a) Is the document scientifically sound and does it represent current thinking in exposure assessment? b) Are the concepts of exposure and dose presented in Chapter 2 consistent and well characterized? c) What are the Committee's views on the concepts and terms used in describing "high end exposure"? d) Is the presentation in Chapter 6 concerning the role of uncertainty analysis in exposure assessment, the sources of uncertainty, and approaches to characterizing uncertainty correct and scientifically adequate? e) Are the approaches described in Chapter 7 relating to communicating the results of exposure assessment well characterized and is the level of guidance presented sufficient?

The Committee found the draft document to be well crafted and complete, scientifically sound, and a major improvement over previous efforts. In addition, the Committee noted that the draft document is consistent in approach and definitions with the 1991 National Academy of Sciences exposure assessment report. The Committee was pleased that the current draft document included new developments in the exposure assessment field that have taken place since 1988. The Committee was also pleased to observe that it provided resolution of most of the general and specific SAB comments provided during its previous reviews. The description and discussion of (high-end) exposure was awkward and not as well done as the rest of the document, as noted previously by the Risk Assessment Forum. In this report, the Science Advisory Board offers an alternate framework for considering (high-end) exposures, that the Committee believes is sounder conceptually and analytically. The Committee also offers specific suggestions to improve the clarity and usefulness of the guidelines.

KEY WORDS: Exposure; dose; high end exposure; exposure assessment; exposure assessment guidelines.

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Ms. Carolyn Osborne, Program Assistant, Science Advisory Board, U.S. EPA, Washington, DC

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1. EXECUTIVE SUMMARY

On September 12-13, 1991, the Indoor Air Quality and Total Human Exposure Committee of EPA's Science Advisory Board (SAB) reviewed the Agency's Draft Final Exposure Assessment Guidelines. This is the latest revision of the Agency's exposure guidelines, the SAB having reviewed and provided advice on earlier versions in 1986 and 1988. The Committee was asked by the Risk Assessment Forum to provide advice on the following issues:

a) Is the document scientifically sound and does it represent current thinking in exposure assessment?

b) Are the concepts of exposure and dose presented in Chapter 2 consistent and well characterized?

c) What are the Committee's views on the concepts and terms used in describing "high end exposure"?

d) Is the presentation in Chapter 6 concerning the role of uncertainty analysis in exposure assessment, the sources of uncertainty, and approaches to characterizing uncertainty correct and scientifically adequate?

e) Are the approaches described in Chapter 7 relating to communicating the results of exposure assessment well characterized and is the level of guidance presented sufficient?

The Committee found the draft document to be very well crafted and complete, representing a scientifically sound and a major improvement over previous efforts. Not only does the current draft document include new developments in the exposure assessment field since 1988, the Committee was pleased to observe that it also provides resolution of most of the general and specific SAB comments provided during its previous reviews.

The Committee provided a number of suggestions for improving the draft. The discussion of exposure and dose that is presented in the draft requires clarification and should be more consistent. The draft document emphasizes the need to derive dose from exposure for the purpose of risk assessment. We believe that this argument is too exclusive; most epidemiological studies provide information on exposure-response relation and not dose-response relation. Using risk coefficients derived from epidemiological data, risk characterization is possible without the intermediate step of estimating dose. Therefore, we

suggest some modification of the general concepts of exposure and dose as presented in the draft document.

We also offered an alternative framework for characterizing the (high-end) exposures. The Committee felt that its version will provide a firmer scientific basis for the expression of the exposure estimators that result from the application of the exposure assessment guidelines. The original figure (Figure 5.1) in the draft document provides points of discussion consistent with current risk descriptors. The Committee's revised figure (Figure 1 in this report) provides a more logical basis for reporting the results of an exposure assessment to risk assessors, risk managers and the scientific community. Its features are described in the attached report. And finally, the Committee found the presentation of uncertainty analysis to be comprehensive and scientifically correct. The draft document presents a strong statement of the importance of uncertainty assessment in exposure assessment.

2. INTRODUCTION

2.1 Background

In 1983, the National Academy of Sciences recommended that Federal regulatory agencies establish guidelines which would promote consistency and technical quality in risk assessment, and which would maintain the separation between risk assessment and risk management. As a result of this recommendation, the U.S. EPA began work in 1984 on risk assessment guidelines for carcinogenicity, mutagenicity, suspect developmental toxicants, chemical mixtures, and exposure assessment. These guidelines were subjected to Science Advisory Board (SAB) review prior to their September 1986 public release. The SAB concluded "...that the 1986 Guidelines for Estimating Exposures provide the framework for exposure assessment in a useful, diagrammatic way that aids overall understanding."[1] It also concluded that the guidelines were too limited in scope, and advised EPA to prepare additional guidelines on the measurements of exposure.

In December 1988 the Agency issued its Proposed Guidelines for Exposure Related Measurements[2]. This document was reviewed by the Science Advisory Board's Environmental Effects, Transport and Fate Committee (EETFC) December 1-2, 1988 in Washington, DC. The Committee concluded that:

> *...the draft guidelines for exposure-related measurements provide a useful introduction to the concepts that form the basis for techniques designed to measure and estimate human exposure. The guidelines represent a logical complement to the Guidelines for Estimating Exposures that were published and reviewed by the Board in 1986. It is recommended that these guidelines be integrated into a single guideline document. The integration will require careful attention to the linkages between measurements and modeling*[3].

In 1991, the Agency completed its revised Guidelines for Exposure Assessment[4]. This document combines, reformats and substantially updates the two earlier guideline

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[1] Evaluation of the Proposed Guidelines for Exposure-Related Measurements. Report of the Environmental Effects, Transport and Fate Committee. US EPA Science Advisory Board. EPA-SAB-EETFC-89-020, May 1989, Section 3.1 - reference to earlier SAB review.

[2] Federal Register 53(232):48830-48853.

[3] Evaluation of the Proposed Guidelines for Exposure-Related Measurements. Report of the Environmental Effects, Transport and Fate Committee. US EPA Science Advisory Board. EPA-SAB-EETFC-89-020, May 1989.

[4] Science Advisory Board Review Draft, August 8, 1991. The Guidelines were prepared as part of an interoffice guideline development program under the auspices of EPA's Risk Assessment Forum (RAF).

documents. The 1991 document includes new developments in the exposure assessment field since 1988, and offers resolution of general and specific SAB comments provided during its previous review. The 1991 guidelines, which are consistent with the latest thinking in exposure assessment (e.g., the recent National Academy of Sciences Report), were developed by the Agency's Risk Assessment Forum (RAF) and the Office of Health and Environmental Assessment (OHEA).

On September 12-13, 1991, the Indoor Air Quality and Total Human Exposure Committee (IAQTHEC) of the SAB met to review the 1991 Draft-Final Guidelines for Exposure Assessment. The meeting was held in Arlington, Virginia. This report was reviewed by and received the final approval of the SAB's Executive Committee at its October 29-30, 1991 meeting held in Washington, DC. At that meeting, the Executive Committee assigned the task of reviewing final edits and granting of final approval to two of its members who served on behalf of the entire Executive Committee. Their final approval was granted in early January 1992.

2.2 Charge to the Committee

Based upon a request from the Agency's Risk Assessment Forum, the Science Advisory Board has been asked to review the Draft Final Exposure Assessment Guidelines (SAB Review Draft dated August 8, 1991). The Committee has been asked to provide advice on the following issues:

a. Is the draft document scientifically sound and does it represent current thinking in exposure assessment?

b. Are the concepts of exposure and dose presented in Chapter 2 of the draft consistent and well characterized?

c. What are the Committee's views on the concepts and terms used in describing "high end exposure" (see Chapter 5 of the draft document)?

    1) Does the Committee agree with the use and definitions of the terms "reasonable worst case", "worst case" and "maximum exposure"?

    2) Does the subdivision of the "high end" range in the circumstances described in this section make sense? Will the subdivision of this range, based on a target percentile, imply that the Agency has more

faith in the detail it can provide than is warranted? Do the terms "reasonable worst case" and "maximum exposure" represent good choices to describe this subdivision? Should new terms be created?

3) Does the Committee concur with the discussion of the difficulties associated with characterizing the highest actual or potentially exposed individual?

d. Is the presentation in Chapter 6 of the draft document concerning the role of uncertainty analysis in exposure assessment, the sources of uncertainty, and approaches to characterizing uncertainty correct and scientifically adequate?

e. Are the approaches described in Chapter 7 of the draft document relating to communicating the results of exposure assessment well characterized and is the level of guidance presented sufficient?

3. SPECIFIC FINDINGS

3.1 Concepts of Exposure and Dose

EPA Question: Are the concepts of exposure and dose that are presented in Chapter 2 of the draft document consistent and well characterized?

The Committee considers the proposed guidelines for exposure assessment to be an important advance over the previous versions, and an excellent documentation of progress since the drafting of the previous guidelines. One significant improvement is the development of definitions and concepts that are mutually consistent. This alone will bring about a considerable simplification and sharpening of exposure assessments as well as the communication of these exposure assessments to all clients, and especially to the risk assessors.

There is still some confusion between concepts of dose and dose rate as well as that of delivered dose and dose rate. These terms are being used in the document in a somewhat interchangeable and not mutually exclusive way. The Committee feels that it may be unnecessary and possibly counter-productive to try and account for all the terms that have ever been used in different settings that may have overlapping definitions in different disciplines. The "absorbed dose" has somewhat different meanings in dermatology, radiation biology, and toxicology/pharmacology. The "delivered dose" is a concept that clearly overlaps. It might be wiser to use one kind of terminology per concept and to add the various dose alternatives to a glossary.

The draft document emphasizes the need to derive dose from exposure for the purpose of risk assessment. We believe that this argument is too exclusive; most epidemiological studies provide information on exposure-response relation and not dose-response relation. Using risk coefficients derived from epidemiological data, risk characterization is possible without the intermediate step of estimating dose. For example, the risk assessment for ETS that was conducted by EPA used an empirically derived exposure-response relation. Radon risks are also estimated without calculating dose. The exposure-response relation observed in studies of underground miners is extrapolated to the indoor environment. Dose characterizations have been carried out, but primarily for the purpose of addressing uncertainties in this extrapolation. Therefore, we suggest some modification of the general concepts of exposure and dose, as they are laid out in the draft document. In a number of locations the document indicates that it is limited to consideration of the exposure of humans to chemical agents, and that some of the considerations and treatment may be of use in the assessment of exposures to microbiological agents, and to exposures of non-human species.

The Agency Staff may wish to consider giving the Guidelines a more appropriate title such as "Guidelines for the Assessment of Human Exposures to Chemicals"?

There were a number of instances throughout the draft document where at the ends of sections and chapters the Agency provided advice and cautions. We believe these should have been placed in more prominent positions in the beginning of the section or chapter. Some of these comments were cautions about the process that the exposure assessor should observe, and about limitations to the power and applicability of assessment procedures. Others dealt with the insights and training to develop judgments which often need to be made before the design of the assessment process is accepted. For example, this could be expressed in Figure 2-1 of the draft document where to the right of the "organ" symbol one should see an arrow designating "elimination".

The Committee was advised at its meeting that these guidelines are aimed at exposure assessors and the people requesting such assessments, those who will be using these exposure assessments in carrying out risk assessments, and finally to those who will be making risk management decisions. In general, many of these individuals will have different disciplinary backgrounds. We were pleased at the recognition of this diversity in the draft document, and in general urge that as much as possible be done to establish effective linkages between exposure assessors and their clients before a protocol for an exposure assessment is committed to or approved. The exposure assessor should be familiar with the ways an exposure assessment is used later, and expend a serious effort in anticipating this use. Careful design, which takes into account what is already known about the fate of the agent, and the biological action of the agent in the human body will allow a much more useful exposure assessment. As an example, the averaging time in an exposure assessment is very likely to be affected by events inside the body. Similarly, peak exposure conditions are of great importance in some risk assessments and immaterial in others. Our understanding of the processes within the body are progressing rapidly and the exposure assessment guidelines should anticipate that more such developments will occur.

The Agency noted in the draft document that there is a need to integrate the exposure assessment with the other elements of the risk assessment and the risk management process. In Chapter 5 of the draft there is considerable discussion of the connections between exposure assessment and risk assessment. The Committee feels that the focus of Chapter 5 wavered between exposure assessment and risk assessment. Too much of the discussion and the presentation is concerned with risk assessment, and therefore diverts from exposure assessment.

3.2 Discussion of "High End" Exposure

EPA Question: What are the Committee's views on the concepts and terms used in describing "high end exposure" (see Chapter 5 of the Draft document)?

We are concerned about a definition of "high end exposure" as simply being above about the 90th percentile, as well as the extension of this boundary to describe risk. When applied to risk, this terminology has the potential to make it seem that all risks in the high end are comparable, regardless of the nature and severity of the health effect. We do not recommend replacing the existing terminology with potentially ambiguous terminology.

3.2.1 Definitions

EPA Question: Does the Committee agree with the use and definitions of the terms "reasonable worst case", "worst case" and "maximum exposure"?

We recognize the historical significance of the terms "reasonable worst case", "worse case", "maximum exposure"; and "maximally exposed individual (MEI)". We reviewed these terms in the context of the Draft Final Exposure Assessment Guidelines, and found them incongruent with the quantitative approach recommended in the text. We feel that these terms have only qualitative value.

3.2.2 High End Range

EPA Question: Does the subdivision of the "high end" range in the circumstances described in this section make sense? Will the subdivision of this range, based on a target percentile, imply that the Agency has more faith in the detail it can provide than is warranted? Do the terms "reasonable worst case" and "maximum exposure" represent good choices to describe this subdivision? Should new terms be created?

The subdivision "high end" (>90th percentile) is consistent with the risk descriptor "high risk". In fact, it places similar weights and probably similar "uncertainties" on the analysis and evaluation of population exposure. Other exposure estimators which parallel specific risk descriptors are: a) the mean or median exposures; b) the definition or estimation of an actual distribution of population exposures; c) a default exposure distribution option; and d) a bounding estimate of exposure.

The targeted "high end" percentile is sufficiently broad to minimize over-reliance on a single number. The confidence in any value or group of values will be achieved by acquiring more data on background exposures, analogous exposures, and/or high exposure

sub-groups that are not participating in highly unusual personal behavior (e.g. sniffing glue, cleansing hands in gasoline). No new terms should be developed for estimators of exposure. An exposure assessment should present the statistical features of a distribution with interpretation, and any bounding estimates, and their inherent assumptions, to the risk assessor.

The extent of protection in any given case should explicitly be stated in terms of the percentile of the population considered at risk, i.e., if the intent is to protect 95 or 99% of the population, the risk estimates or guidelines should be stated in those terms.

3.2.3 Highest Exposed Individual

EPA Question: **Does the Committee concur with the discussion of the difficulties associated with characterizing the highest actual or potentially exposed individual?**

The Committee concurs with the discussion on the difficulties with characterization of the highest actual or potentially exposed individuals.

3.2.4 Defining High End Exposure Graphically

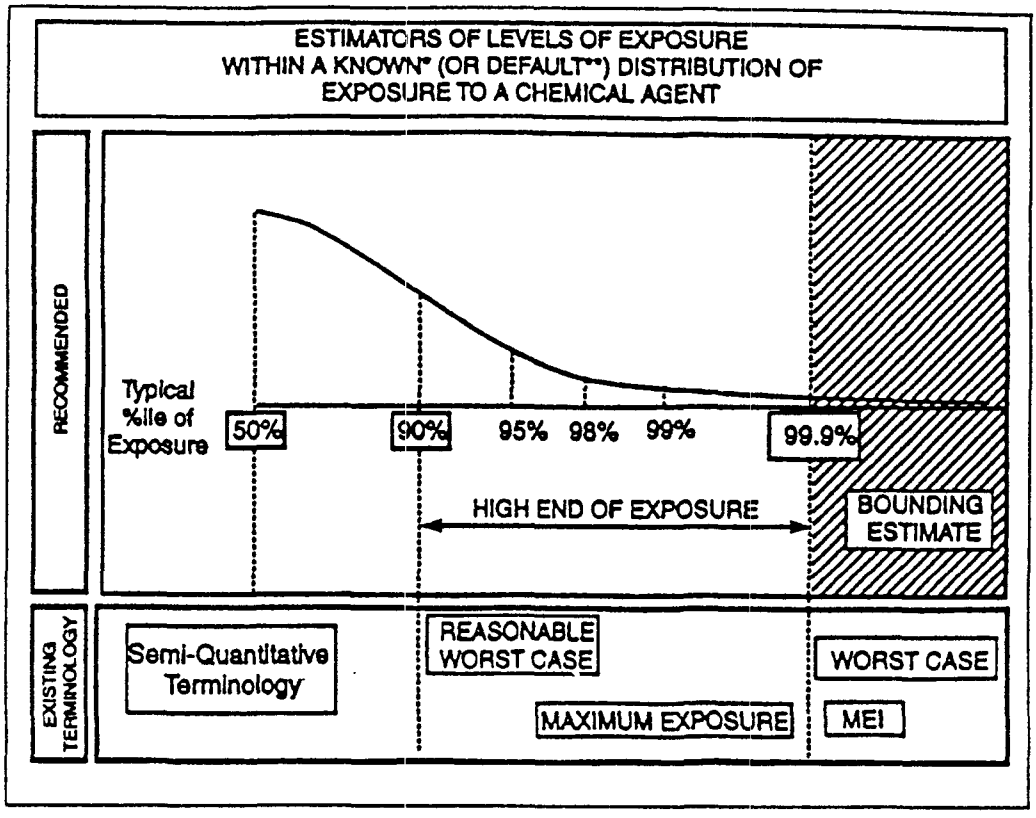
Taking into account the above answers, and the discussion with EPA Staff at the meeting, the Committee reached consensus on a recommended modification of Figure 5.1 (see page 76 of the draft document). The revised version provides a basis for the expression of the exposure estimators that result from the application of the exposure assessment guideline. Figure 5.1 provides points of discussion consistent with current risk descriptors. Our revision of that figure (see Figure 1, below) provides a more logical quantitative basis for reporting the results of an exposure assessment to risk assessors, risk managers and the scientific community. We believe that these revisions to Figure 5.1 are an amalgamation and simplification of the ideas expressed within Chapter 5.

3.3 Uncertainty Analysis

EPA Question: **Is the presentation in Chapter 6 concerning the role of uncertainty analysis in exposure assessment, the sources of uncertainty, and approaches to characterizing uncertainty correct and scientifically adequate?**

The Committee found the presentation of uncertainty analysis in Chapter 6 of the document to be comprehensive and scientifically correct. The Chapter presents a strong statement of the importance of uncertainty assessment in exposure assessment. The approach

Figure 1
Recommended Alternative to Figure 5.1 of the Draft EPA Document



Primary features of Figure 1 are the following:

a. Separation of the semi-quantitative measures of exposure from the quantitative estimators of exposures depicted in the figure.

b. Emphasis on determining or estimating a distribution of population exposure (not concentration) and selection of a default distribution when the actual distribution is not available or too little information can be obtained to estimate the distribution.

c. Identification of several statistical estimators of exposure: 1) 50th percentile; 2) 90th percentile, the "High End", 3) 95th percentile, 4) 98th percentile and a range for bounding estimates.

d. The Bounding Estimate is an estimate of individual exposure or dose where the estimate is intentionally constructed to be higher than the individual in the distribution having the 99.9th percentile exposure. A bounding estimate can be useful in constructing statements that the exposure is "not greater than .....".

* Measured Distribution of Exposure.

** The Default Distribution - in the absence of sufficient data to establish the form of the distribution of exposure (not concentrations) for the population of interest, a default distribution using a log-normal format should be employed. It should be defined on the basis of median and geometric standard deviation values established using the best information available on the concentrations and the human activity patterns that lead to exposure.

presented in Chapter 6 correctly recognizes that uncertainty analysis cannot be done by following a formula, that such a process can range from a very simple to a quite complex process, and that the process requires scientific judgment. Both qualitative (choice of model or measurement method, underlying assumptions, etc.) and quantitative aspects of uncertainty are recognized and clearly presented. The types of uncertainties that must be considered have been clearly identified and the various approaches which may be taken to evaluate and/or estimate uncertainty are scientifically correct and adequate.

3.4 Communicating Exposure Assessment

EPA Question: Are the approaches described in Chapter 7 of the draft document relating to communicating the results of exposure assessment well characterized and is the level of guidance presented sufficient?

The Committee found the approaches described to be clear and orderly. However, we believe that the chapter could use more emphasis on communicating and interpreting the results. We discussed the possibility of a more standardized exposure assessment format, but recognized that this might stifle creativity and result in formats that were "etched in stone". As a result, we do not recommend such a course.

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