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2. ANALYSIS OF UNCERTAINTY

The chapters that follow will discuss exposure factors and algorithms for estimating exposure. Exposure factor values can be used to obtain a range of exposure estimates such as average, high-end and bounding estimates. It is instructive here to return to the general equation for potential Average Daily Dose (ADD_{pot}) that was introduced in the opening chapter of this handbook:

$$ADDpot = \frac{\text{Contaminant Concentration x Intake Rate x Exposure Durat}}{\text{Body Weight x Averaging Time}} \quad \text{(Eqn. 2-1)}$$

With the exception of the contaminant concentration, all parameters in the above equation are considered exposure factors and, thus, are treated in fair detail in other chapters of this handbook. Each of the exposure factors involves humans, either in terms of their characteristics (e.g., body weight) or behaviors (e.g., amount of time spent in a specific location, which affects exposure duration). While the topic of uncertainty applies equally to contaminant concentrations and exposure factors, the focus of this chapter is on uncertainty as it relates to exposure factors. Consequently, examples provided in this chapter relate primarily to exposure factors, although contaminant concentrations may be used when they better illustrate the point under discussion.

This chapter also is intended to acquaint the exposure assessor with some of the fundamental concepts and precepts related to uncertainty, together with methods and considerations for evaluating and presenting the uncertainty associated with exposure estimates. Subsequent sections in this chapter are devoted to the following topics:

- Reasons for concern about uncertainty
- Distinction between uncertainty and variability
- Types and sources of uncertainty
- Types and sources of variability
- Methods of analyzing uncertainty and variability
- Presenting results of uncertainty analysis.

Fairly extensive treatises on the topic of uncertainty have been provided, for example, by Morgan and Henrion (1990), the National Research Council (NRC, 1994) and, to a lesser extent, the U.S. EPA (1992, 1995). The topic commonly has been treated as it relates to the overall process of conducting risk assessments; because exposure assessment is a component of risk-assessment process, the general concepts apply equally to the exposure-assessment component.

2.1. CONCERN ABOUT UNCERTAINTY

Why should the exposure assessor be concerned with uncertainty? As noted by the U.S. EPA (1992), exposure assessment utilizes a broad array of information sources and analysis techniques. Even in situations where actual exposure-related measurements exist, assumptions or inferences will still be required because data are not likely to be available for all aspects of the exposure assessment. Moreover, the data that are available may be of questionable or unknown quality. Thus, exposure assessors have a responsibility to present not just numbers, but also a clear and explicit explanation of the implications and limitations of their analyses.

Morgan and Henrion (1990) provide an argument by analogy. When scientists report quantities that they have measured, they are expected to routinely report an estimate of the probable error associated with such measurements. Because uncertainties inherent in policy analysis (of which exposure assessment is a part) tend to be even greater than those in the natural sciences, exposure assessors also should be expected to report or comment on the uncertainties associated with their estimates.

Additional reasons for addressing uncertainty in exposure or risk assessments (U.S. EPA, 1992, Morgan and Henrion, 1990) include the following:

- Uncertain information from different sources of different quality often must be combined for the assessment
- Decisions need to be made about whether or how to expend resources to acquire additional information
- Biases may result in so-called "best estimates" that in actuality are not very accurate
- Important factors and potential sources of disagreement in a problem can be identified.

Addressing uncertainty will increase the likelihood that results of an assessment or analysis will be used in an appropriate manner. Problems rarely are solved to everyone's satisfaction, and decisions rarely are reached on the basis of a single piece of evidence. Results of prior analyses can shed light on current assessments, particularly if they are couched in the context of prevailing uncertainty at the time of analysis. Exposure assessment tends to be an iterative process, beginning with a screening-level

assessment that may identify the need for more in-depth assessment. One of the primary goals of the more detailed assessment is to reduce uncertainty in estimated exposures. This objective can be achieved more efficiently if guided by presentation and discussion of factors thought to be primarily responsible for uncertainty in prior estimates.

2.2. UNCERTAINTY VERSUS VARIABILITY

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

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

- That the measurements were faulty, thereby ascribing to uncertainty what was actually caused by variability
- That the moon's orbit was random, thereby not allowing uncertainty to shed light on seemingly unexplainable differences that are in fact variable and predictable.

A more fundamental error in the above situation would be to incorrectly estimate the true distance, by assuming that a few observations were sufficient. This latter pitfall -- treating a highly variable quantity as if it were invariant or only uncertain -- is probably the most relevant to the exposure or risk assessor.

Now consider a situation that relates to exposure, such as estimating the average daily dose by one exposure route -- ingestion of contaminated drinking water. Suppose that it is possible to measure an individual's daily water consumption (and concentration of the contaminant) exactly, thereby eliminating uncertainty in the measured daily dose. The daily dose still has an inherent day-to-day variability, however, due to changes in the individual's daily water intake.

It is impractical to measure the individual's dose every day. For this reason, the exposure assessor may estimate the average daily dose (ADD) based on a finite number of measurements, in an attempt to "average out" the day-to-day variability. The individual has a true (but unknown) ADD, which has now been estimated based on a sample of measurements. Because the individual's true average is unknown, it is uncertain how close the estimate is to the true value. Thus, the variability across daily doses has been translated into uncertainty in the ADD. Although the individual's true ADD has no variability, the estimate of the ADD has some uncertainty.

The above discussion pertains to the ADD for one person. Now consider a distribution of ADDs across individuals in a defined population (e.g., the general U.S. population). In this case, variability refers to the range and distribution of ADDs across individuals in the population. By comparison, uncertainty refers to the exposure assessor's state of knowledge about that distribution, or about parameters describing the distribution (e.g., mean, standard deviation, general shape, various percentiles).

As noted by the National Research Council, the realms of uncertainty and variability have fundamentally different ramifications for science and judgment. For example, uncertainty may force decision-makers to judge how probable it is that exposures have been overestimated or underestimated for every member of the exposed population, whereas variability forces them to cope with the certainty that different individuals are subject to exposures both above and below any of the exposure levels chosen as a reference point.

2.3. TYPES OF UNCERTAINTY

The problem of uncertainty in exposure or risk assessment is relatively large, and can quickly become too complex for facile treatment unless it is divided into smaller and more manageable topics. One method of division (Bogen, 1990) involves classifying sources of uncertainty according to the step in the risk assessment process (hazard identification, dose-response assessment, exposure assessment or risk characterization) at which they can occur. A more abstract and generalized approach preferred by some scientists is to partition all uncertainties among the

three categories of bias, randomness and true variability. These ideas are discussed later in some examples.

The U.S. EPA (1992) has classified uncertainty in exposure assessment into three broad categories:

1. Uncertainty regarding missing or incomplete information needed to fully define exposure and dose (Scenario Uncertainty).

2. Uncertainty regarding some parameter (Parameter Uncertainty).

3. Uncertainty regarding gaps in scientific theory required to make predictions on the basis of causal inferences (Model Uncertainty).

Identification of the sources of uncertainty in an exposure assessment is the first step in determining how to reduce that uncertainty. The types of uncertainty listed above can be further defined by examining their principal causes. Sources and examples for each type of uncertainty are summarized in Table 2-1 and discussed in further detail below.

The sources of **scenario uncertainty** include descriptive errors, aggregation errors, errors in professional judgment, and incomplete analysis. Descriptive errors include information errors such as the current producers of the chemical and its industrial, commercial, and consumer uses. Information of this type is the foundation for fate-and-transport analysis and the eventual development of exposure pathways, scenarios, exposed populations, and exposure estimates.

Aggregation errors arise as a result of lumping approximations. Included among these are assumptions of homogeneous populations, temporal approximations such as assuming steady-state conditions for a dynamic process, and spatial approximations such as using a 2-dimensional mathematical model to represent a 3-dimensional aquifer.

Errors in professional judgment can come into play in virtually every aspect of the exposure assessment process, including defining appropriate exposure scenarios, selecting environmental fate models, determining representative environmental conditions, etc. Judgment errors can be the result of limited experience, or can arise when the assessor has difficulty separating opinion from fact.

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Table 2-1. Three Types of Uncertainty and Associated Sources and Examples

Type of Uncertainty	Sources	Examples
Scenario Uncertainty	Descriptive errors	Incorrect or insufficient information
	Aggregation errors	Spatial or temporal approximations
	Judgment errors	Selection of an incorrect model
	Incomplete analysis	Overlooking an important pathway
Parameter Uncertainty	Measurement errors	Imprecise or biased measurements
	Sampling errors	Small or unrepresentative samples
	Variability	In time, space or activities
	Surrogate data	Structurally-related chemicals
Model Uncertainty	Relationship errors	Incorrect inference on the basis for correlations
	Modeling errors	Excluding relevant variables

A potentially serious source of uncertainty in exposure assessments arises from incomplete analysis. For example, the exposure assessor may overlook an important exposure pathway due to lack of information regarding the use of a chemical in a consumer product, or may fail to include an important population subgroup that has increased susceptibility to adverse health effects of exposure.

Sources of **parameter uncertainty** include measurement errors, sampling errors, variability, and use of generic or surrogate data. Measurement errors may be random or systematic. Random errors result from imprecise measurements. For example, two observers who time an individual's activity may record different durations. Similarly, the second analysis of a split sample will not necessarily yield the same result as the first analysis. Systematic errors reflect a bias or tendency to measure something other than what was intended, as could occur if an ambient monitoring design inadvertently over-represented heavily industrialized areas. Similarly, body weight would be systematically overestimated if all measurements were made using fully clothed individuals.

Sampling errors tend to reduce sample representativeness. The general purpose of sampling is to collect information on some fraction of a population in order to make an inference about the entire group. If the sample size for a given data collection effort is relatively small, then the random sampling error associated with that effort will tend to be correspondingly large. If the exposure assessment uses data that were generated for another purpose, then uncertainty will arise if the data do not represent the exposure scenario being analyzed. For example, use of product sales information to infer residential usage patterns may be misleading if residential and commercial sales cannot be reliably distinguished.

The inherent variability in environmental and exposure-related parameters is a major source of uncertainty. For example, meteorological and hydrological conditions change seasonally at a given location, soil characteristics exhibit large spatial variability, and human activity patterns depend on the age, sex, and geographic location of specific individuals in the population. Although uncertainty and variability are treated in this chapter as different entities, it is noteworthy that variation in one quantity can contribute to uncertainty in another (NRC, 1994). The most relevant example involves the influence of the variability in a quantity on the uncertainty of its mean -- when the quantity varies by orders of magnitude, even relatively large data sets may be insufficient to pin down the mean with the desired degree of precision.

Generic data are commonly used when site-specific data are not available. Examples include standard emission factors for industrial processes and generalized descriptions of environmental settings. Surrogate data are commonly used when chemical-specific data are not available. One example is the use of structurally-related chemicals as surrogates for the chemical of interest. An example of surrogate data not pertaining to chemicals is the use of an individual's heart rate to infer his/her breathing rate. Since surrogate data introduce additional uncertainty, they should be avoided if actual data can be obtained.

Relationship and modeling errors are the primary sources of **model uncertainty**. Relationship errors include flaws in environmental fate models and poor correlations between chemical properties or between structure and reactivity. Modeling errors arise because models tend to be simplified representations of physical and chemical processes. Even after the exposure assessor has selected the most appropriate model, he or she still faces the question of how well the model represents actual conditions. This question is compounded by the overlap between modeling uncertainties and other uncertainties (e.g., natural variability in environmental inputs, model representativeness, aggregation errors). The dilemma facing exposure assessors is that many existing models (particularly the very complex ones) and the hypotheses contained within them cannot be fully tested (Beck, 1987), although certain components of the model may be testable. Even if a model has been validated under a particular set of conditions, its application in cases beyond the test conditions will introduce uncertainty.

Because uncertainty in exposure assessments is fundamentally tied to a lack of knowledge concerning important exposure factors, strategies for reducing uncertainty necessarily involve reduction or elimination of knowledge gaps. Example strategies to reduce uncertainty include (1) collection of new data using a larger sample size, an unbiased sample design, a more direct measurement method or a more appropriate target population, and (2) use of more sophisticated modeling and analysis tools.

2.4. TYPES OF VARIABILITY

Variability in exposure is related to an individual's location, activity, and behavior or preferences at a particular point in time, as well as pollutant emission rates and physical/chemical processes that affect concentrations in various media (e.g., air, soil, food and water). The

variations in pollutant-specific emissions or processes, and in individual locations, activities or behaviors, are not necessarily independent of one another. For example, both personal activities and pollutant concentrations at a specific location might vary in response to weather conditions, or between weekdays and weekends.

At a more fundamental level, three types of variability can be distinguished:

- Variability across locations (Spatial Variability)
- Variability over time (Temporal Variability)
- Variability among individuals (Inter-individual Variability).

Spatial variability can occur both at regional (macroscale) and local (microscale) levels. For example, fish intake rates can vary depending on the region of the country. Higher consumption may occur among populations located near large bodies of water such as the Great Lakes or coastal areas. As another example, outdoor pollutant levels can be affected at the regional level by industrial activities and at the local level by activities of individuals. In general, higher exposures tend to be associated with closer proximity to the pollutant source, whether it be an industrial plant or related to a personal activity such as showering or gardening. In the context of exposure to airborne pollutants, the concept of a "microenvironment" has been introduced (Duan 1982) to denote a specific locality (e.g., a residential lot or a room in a specific building) where the airborne concentration can be treated as homogeneous (i.e., invariant) at a particular point in time.

Temporal variability refers to variations over time, whether long- or short-term. Seasonal fluctuations in weather, pesticide applications, use of woodburning appliances and fraction of time spent outdoors are examples of longer-term variability. Examples of shorter-term variability are differences in industrial or personal activities on weekdays versus weekends or at different times of the day.

Inter-individual variability can be either of two types: (1) human characteristics such as age or body weight, and (2) human behaviors such as location and activity patterns. Each of these variabilities, in turn, may be related to several underlying phenomena that vary. For example, the natural variability in human weight is due to a combination of genetic, nutritional, and other lifestyle or environmental factors. According to the central limit theorem, variability arising from independent factors that combine multiplicatively generally will lead to an approximately lognormal distribution across the population, or across spatial/temporal dimensions.

According to the National Research Council (NRC 1994), variability can be confronted in four basic ways when dealing with science-policy questions surrounding issues such as exposure or risk assessment. The first is to ignore the variability and hope for the best. This strategy tends to work best when the variability is relatively small. For example, the assumption that all adults weigh 70 kg is likely to be correct within ±25% for most adults.

The second strategy involves disaggregating the variability in some explicit way, in order to better understand it or reduce it. Mathematical models are appropriate in some cases, as in fitting a sine wave to the annual outdoor concentration cycle for a particular pollutant and location. In other cases, particularly those involving human characteristics or behaviors, it is easier to disaggregate the data by considering all the relevant subgroups or subpopulations. For example, distributions of body weight could be developed separately for adults, adolescents and children, and even for males and females within each of these subgroups. Temporal and spatial analogies for this concept involve measurements on appropriate time scales and choosing appropriate subregions or microenvironments.

The third strategy is to use the average value of a quantity that varies. Although this strategy might appear as tantamount to ignoring variability, it needs to be based on a decision that the average value can be estimated reliably in light of the variability (e.g., when the variability is known to be relatively small, as in the case of adult body weight).

The fourth strategy involves using the maximum or minimum value for an exposure factor. This is perhaps the most common method of dealing with variability in exposure or risk assessment -- to focus on one time period (e.g., the period of peak exposure), one spatial region (e.g., in close proximity to the pollutant source of concern), or one subpopulation (e.g., exercising asthmatics).

2.5. METHODS OF ANALYZING UNCERTAINTY AND VARIABILITY

Exposure assessments often are developed in a phased approach. The initial phase usually screens out the scenarios that are not expected to pose much risk, to eliminate them from more detailed, resource-intensive review. Screening-level assessments typically examine exposures that would fall on or beyond the high end of the expected exposure distribution. Because screening-level

analyses are usually included in the final exposure assessment, the final document may contain scenarios that differ quite markedly in sophistication, data quality, and amenability to quantitative expressions of uncertainty.

According to the U.S. EPA (1992), uncertainty characterization and uncertainty assessment are two ways of describing uncertainty at different degrees of sophistication. Uncertainty characterization usually involves a qualitative discussion of the thought processes used to select or reject specific data, estimates, scenarios, etc. Uncertainty assessment is a more quantitative process that may range from simpler measures (e.g., ranges) and simpler analytical techniques (e.g., sensitivity analysis) to more complex measures and techniques. Its goal is to provide decision makers with information concerning the quality of an assessment, including the potential variability in the estimated exposures, major data gaps, and the effect that these data gaps have on the exposure estimates developed.

A distinction between uncertainty and variability was made in Section 2.2. Although the qualitative approach mentioned above applies more directly to uncertainty and the quantitative process more so to variability, there is some degree of overlap. In general, either method provides the assessor or decision-maker with insights to better evaluate the assessment in the context of available data and assumptions. The following paragraphs briefly describe some of the more common procedures for analyzing uncertainty and variability in exposure assessments. Principles that pertain to presenting the results of uncertainty analysis are discussed in the next section.

Several approaches can be used to characterize uncertainty in parameter values. When uncertainty is high, the assessor may use order-of-magnitude bounding estimates of parameter ranges (e.g., from 0.1 to 10 liters for daily water intake). Another method describes the range for each parameter including the lower and upper bounds as well as a "best estimate" (e.g., 1.4 liters per day) determined by available data or professional judgement. When sensitivity analysis (discussed below) indicates that a parameter profoundly influences exposure estimates, the assessor should develop a probabilistic description of its range. If there are enough data to support their use, standard statistical methods are preferred. If the data are inadequate, expert judgment can be used to generate a subjective probabilistic representation. Such judgments should be developed in a consistent, well-documented manner. Morgan and Henrion (1990) and Rish (1988) describe techniques to solicit expert judgment.

Most approaches to quantitative analysis examine how uncertainties in values of specific parameters translate into the overall uncertainty of the assessment. Details may be found in reviews such as Cox and Baybutt (1981), Whitmore (1985), Inman and Helton (1988), Seller (1987), and Rish and Marnicio (1988). These approaches can generally be described (in order of increasing complexity and data needs) as: (1) sensitivity analysis; (2) analytical uncertainty propagation; (3) probabilistic uncertainty analysis; or (4) classical statistical methods (U.S. EPA 1992). The four approaches are summarized in Table 2-2 and described in greater detail below.

Table 2-2. Approaches to Quantitative Analysis of Uncertainty

Approach	Description	Example
Sensitivity Analysis	Changing one input variable at a time while leaving others constant, to examine effect on output	Fix each input at lower (then upper) bound while holding others at nominal values (e.g., medians)
Analytical Uncertainty Propagation	Examining how uncertainty in individual parameters affects the overall uncertainty of the exposure assessment	Analytically or numerically obtain a partial derivative of the exposure equation with respect to each input parameter
Probabilistic Uncertainty Analysis	Varying each of the input variables over various values of their respective probability distributions	Assign probability density function to each parameter; randomly sample values from each distribution and insert them in the exposure equation (Monte Carlo)
Classical Statistical Methods	Estimating the population exposure distribution directly, based on measured values from a representative sample	Compute confidence interval estimates for various percentiles of the exposure distribution

Sensitivity analysis is the process of changing one variable while leaving the others constant to determine its effect on the output. This procedure fixes each uncertain quantity at its credible lower and upper bounds (holding all others at their nominal values, such as medians) and computes the results of each combination of values. The results help to identify the variables that have the greatest effect on exposure estimates and help focus further information-gathering efforts. However, the results themselves can be sensitive to the choices of nominal values and lower/upper bounds, and do not indicate the probability of a variable being at any point within its range; therefore, this approach is most useful at the screening level, to determine the need for and direction of further analyses.

Analytical uncertainty propagation examines how uncertainty in individual parameters affects the overall uncertainty of the exposure assessment. The uncertainties associated with various parameters may propagate through a model very differently, even if they have approximately the same uncertainty. Since uncertainty propagation is a function of both the data and the model structure, this procedure evaluates both input variances and model sensitivity. Application of this approach to exposure assessment requires explicit mathematical expressions of exposure, estimates of variance for each variable of interest, and the ability to obtain a mathematical (analytical or numerical) derivative of the exposure equation.

Although uncertainty propagation is a powerful tool, it should be applied with caution: It is difficult to generate and solve the equations for the sensitivity coefficients. The technique is most accurate for linear equations, so any departure from linearity must be carefully evaluated. In addition, assumptions such as variable independence and error normality must be verified. Finally, the information to support required parameter variance estimates may not be readily available. In some cases, analytical uncertainty propagation may be more difficult than probabilistic uncertainty analyses, discussed below.

The most common example of **probabilistic uncertainty analysis** is the Monte Carlo method. This simulation technique assigns a probability density function to each input parameter, then randomly selects values from each of the distributions and inserts them into the exposure equation. Repeated calculations produce a distribution of predicted values, reflecting the combined impact of variability in each input to the calculation.

The principal advantage of Monte Carlo simulation is its very general applicability. There is no restriction on the form of the input distributions or the relationship between input and output. Correlations among input parameters can be expressed and taken into account, and computations are straightforward. However, Monte Carlo analysis does have its disadvantages -- the exposure assessor should only consider using it when there are credible distribution data (or ranges) for most key variables. Even if these distributions are known, it may not be necessary to apply this technique. For example, one could use central-tendency values (e.g., means, medians) for each input parameter to develop a preliminary estimate of "typical exposure," recognizing that this combination of parameters will not necessarily yield the average obtained through Monte Carlo simulation. In addition, it is not necessary to use this technique if a bounding exposure estimate indicates that the particular pathway or chemical being assessed does not present a significant risk.

As noted by Morgan and Henrion (1990), analysis of Monte Carlo inputs and outputs also can shed light on the attribution of uncertainty to specific input parameters. For example, the correlation between any input and the output provides an indication of the linear contribution of each input to output uncertainty, and is therefore a global measure of uncertainty importance. In a similar vein, multiple regression analysis indicates the relative linear contribution of each input to output uncertainty, after statistically removing the effects attributable to other inputs, provided that standardized regression coefficients are examined. Rank-order correlations and scatterplots of each input against the output offer the means to investigate nonlinear relationships that may be important.

Classical statistical methods can be used to analyze variability and uncertainty in measured exposures. Given a data set of measured exposure values for a series of individuals, the population distribution may be estimated directly, provided that the sample design captures a representative sample. Measured exposure values can also be used to directly compute confidence intervals for percentiles of the exposure distribution (ACS, 1989). When the exposure distribution is estimated from measured exposures for a probability sample of population members, confidence interval estimates for percentiles of the exposure distribution are the primary uncertainty characterization. Data collection, survey design, and the accuracy and precision of measurement techniques should also be discussed.

Often the observed exposure distribution is skewed because many points within the sample distribution fall at or below the detection limit, in the case of concentrations, or because few points fall at the upper end of the

distribution. Fitting the data to a distribution type can be problematic in these situations because (1) there is no way to determine the distribution of values below the detection limit and (2) data are usually scant in low-probability areas (such as upper-end tails) where numerical values may vary widely. Thus, for many data sets, means and standard deviations may be good approximations, but the tails of the distribution will be much less well-characterized. For data sets where sampling is still practical, the sample may be stratified in order to over sample the tail, thereby increasing the precision with which that portion of the distribution can be estimated.

A variety of approaches can be used to quantitatively characterize the uncertainty associated with model constructs. One approach uses different modeling formulations (including the preferred and plausible alternatives) and assumes that the range of outputs represents the range of uncertainty. This strategy is most useful when available data do not support any "best" approach, or when a model must be used to extrapolate beyond the conditions for which it was designed.

The issues of verifying computer code and verifying the model are not the same, and should be performed in separate steps. Often there may be simplifications in the programming that lead to errors, even though the model formulation is correct. Once the computer code is verified, the model output can be compared with real data to evaluate the model itself.

Where the data base is sufficient, the exposure assessor should characterize the uncertainty in the selected model by describing the validation and verification efforts. The validation process compares the performance of the model to actual observations under situations representative of those being assessed. Burns (1985) discusses approaches for model validation. The verification process confirms that the model computer code produces the correct numerical output. In most situations, only partial validation is possible due to data deficiencies or model complexity.

2.6. PRESENTING RESULTS OF UNCERTAINTY ANALYSIS

Comprehensive qualitative analysis and rigorous quantitative analysis are of little value for use in the decision-making process, if their results are not clearly presented. In this chapter, variability (the receipt of different levels of exposure by different individuals) has been distinguished from uncertainty (the lack of knowledge about the correct value for a specific exposure measure or estimate). Most of the data that are presented in this handbook deal with variability directly, through inclusion of statistics that pertain to the distributions for various exposure factors. The uncertainty surrounding data for the exposure factors has been discussed qualitatively, by describing the limitations and assumptions of each study or data set.

Any exposure estimate developed by an assessor will have associated assumptions about the setting, chemical, population characteristics, and how contact with the chemical occurs through various exposure routes and pathways. The exposure assessor will need to examine many sources of information that bear either directly or indirectly on these components of the exposure assessment. In addition, the assessor will be required to make many decisions regarding the use of existing information in constructing scenarios and setting up the exposure equations. In presenting the scenario results, the assessor should strive for a balanced and impartial treatment of the evidence bearing on the conclusions with the key assumptions highlighted. For these key assumptions, one should cite data sources and explain any adjustments of the data.

It is not sufficient to merely present the results of these many decisions using different exposure descriptors. A discussion also must be included that describes key assumptions and indicates the parameters that are believed to have the greatest impact on the exposure estimate(s). The exposure assessor should strive to address questions such as:

- What is the basis or rationale for selecting these assumptions/parameters, such as data, modeling, scientific judgment, Agency policy, "what if" considerations, etc.?

- What is the range or variability of the key parameters? How were the parameter values selected for use in the assessment? Were average, median, or upper-percentile values chosen? If other choices had been made, how would the results have differed?

- What is the assessor's confidence (including qualitative confidence aspects) in the key parameters and the overall assessment? What are the quality and the extent of the data base supporting the selection of the chosen values?

The exposure assessor also should qualitatively describe the rationale for selection of conceptual and mathematical models. This discussion should address their verification and validation status, how well they represent the situation being assessed (e.g., average or high-end estimates), and any plausible alternatives in terms of their acceptance by the scientific community.

Although incomplete analysis is essentially unquantifiable as a source of uncertainty, it should not be ignored. At a minimum, the assessor should describe the rationale for excluding particular exposure scenarios; characterize the uncertainty in these decisions as high, medium, or low; and state whether they were based on data, analogy, or professional judgment. Where uncertainty is high, a sensitivity analysis can be used to establish credible upper limits on exposure by way of a series of "what if" questions.

Although assessors have always used descriptors to communicate the kind of scenario being addressed, the 1992 Exposure Guidelines establish clear quantitative definitions for these risk descriptors. These definitions were established to ensure that consistent terminology is used throughout the Agency. The risk descriptors defined in the Guidelines include descriptors of individual risk and population risk. Individual risk descriptors are intended to address questions dealing with risks borne by individuals within a population, including not only measures of central tendency (e.g., average or median), but also those risks at the high end of the distribution. Population risk descriptors refer to an assessment of the extent of harm to the population being addressed. It can be either an estimate of the number of cases of a particular effect that might occur in a population (or population segment), or a description of what fraction of the population receives exposures, doses, or risks greater than a specified value. The data presented in the Exposure Factors Handbook is one of the tools available to exposure assessors to construct the various risk descriptors.

2.7. REFERENCES FOR CHAPTER 2

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