

1. Introduction

1.1 Purpose

This Highlights document presents an overview of the information provided in the U.S. Environmental Protection Agency's (U.S. EPA) *Exposure Factors Handbook: 2011 Edition* (U.S. EPA, 2011). Excerpts of each chapter of the Handbook and summaries of key recommendations for each of the exposure factors are provided.

1.2 About the Handbook

The *Exposure Factors Handbook: 2011 Edition*, hereafter referred to as the *Exposure Factors Handbook* or Handbook, is the update of an earlier version prepared in 1997 (U.S. EPA, 1997). Its purpose is to (1) summarize data on human behaviors and characteristics that affect exposure to environmental contaminants, and (2) recommend values to use for these factors. These recommendations are not legally binding on any U.S. EPA program and should be interpreted as suggestions that program offices or individual exposure assessors can consider and modify as needed. Many of these factors are best quantified on a site- or situation-specific basis. The decision as to whether to use site-specific or national values for an assessment may depend on the quality of the competing data sets as well as on the purpose of the specific assessment. The Handbook includes full discussions of the issues that assessors should consider in deciding how to use these data and recommendations.

The Handbook reviews and summarizes data on the various factors used in the exposure assessment. It contains 19 chapters: an introduction (Chapter 1), a discussion about the variability and uncertainty in assessing exposure factors (Chapter 2), and non-chemical specific data on exposure factors in the following areas:

- ingestion of water and other select liquids (Chapter 3);
- non-dietary ingestion factors (Chapter 4);
- ingestion of soil and dust (Chapter 5);
- inhalation rates (Chapter 6);
- dermal exposure factors (Chapter 7);
- body weight (Chapter 8);

- intake of fruits and vegetables (Chapter 9);
- intake of fish and shellfish (Chapter 10);
- intake of meats, dairy products, and fats (Chapter 11);
- intake of grain products (Chapter 12);
- intake of home-produced foods (Chapter 13);
- total food intake (Chapter 14);
- human milk intake (Chapter 15);
- activity factors (Chapter 16);
- consumer products (Chapter 17);
- lifetime (Chapter 18); and
- building characteristics (Chapter 19).

1.3 Intended Audience

The *Exposure Factors Handbook* is intended for use by exposure assessors and risk assessors, both within and outside the U.S. EPA, as a reference tool and primary source of exposure factor information. It may be used by scientists, economists, and other interested parties as a source of data and/or U.S. EPA recommendations on numeric estimates for behavioral and physiological characteristics needed to estimate exposure to environmental agents.

1.4 Selection of Studies for the Handbook

Information in the *Exposure Factors Handbook* and in this Highlights document has been summarized from studies documented in the scientific literature and other publicly available sources. Studies were chosen that were seen as useful and appropriate for estimating exposure factors for both adults and children. The Handbook contains summaries of selected studies published through July 2011. Certain studies described in the Handbook are designated as “key,” that is, the most up-to-date and scientifically sound for deriving recommendations for exposure factors. The recommended values for most exposure factors are based on the results of the key studies (see Section 1.5 in the *Exposure Factors Handbook*). Other studies designated as “relevant,” meaning applicable or pertinent, but not necessarily the most important, are also summarized in the Handbook.

1.5 Approach Used to Develop Recommendations for Exposure Factors

U.S. EPA's procedure for developing recommendations included study review and evaluations, considering single versus multiple key studies, evaluating the variability of a factor across the population, and identifying uncertainties in the data. Based on these evaluations, U.S. EPA assigned a confidence rating to each factor. This qualitative rating is not intended to represent an uncertainty analysis; rather,

it represents U.S. EPA's judgment on the quality of the underlying data used to derive the recommendation. Table 1-1 summarizes the factors used in selecting studies for consideration in the Handbook and in evaluating data limitations. It should be noted that while U.S. EPA has developed recommendations for each exposure factor, different values may be appropriate in consideration of policy, precedent, strategy, or other factors such as site-specific information.

Table 1 1. Considerations Used to Rate Confidence in Recommended Values

General Assessment Factors	Increasing Confidence	Decreasing Confidence
Soundness		
<i>Adequacy of Approach</i>	The studies used the best available methodology and capture the measurement of interest.	There are serious limitations with the approach used; the study design does not accurately capture the measurement of interest.
	As the sample size relative to that of the target population increases, there is greater assurance that the results are reflective of the target population.	The sample size is too small to represent the population of interest.
	The response rate is greater than 80 percent for in-person interviews and telephone surveys, or greater than 70 percent for mail surveys.	The response rate is less than 40 percent.
	The studies analyzed primary data.	The studies are based on secondary sources.
<i>Minimal (or defined) Bias</i>	The study design minimizes measurement errors.	Uncertainties with the data exist due to measurement error.
Applicability and Utility		
<i>Exposure Factor of Interest</i>	The studies focused on the exposure factor of interest.	The purpose of the studies was to characterize a related factor.
<i>Representativeness</i>	The studies focused on the U.S. population.	Studies are not representative of the U.S. population.
<i>Currency</i>	The studies represent current exposure conditions.	Studies may not be representative of current exposure conditions.
<i>Data Collection Period</i>	The data collection period is sufficient to estimate long-term behaviors.	Shorter data collection periods may not represent long-term exposures.
Clarity and Completeness		
<i>Accessibility</i>	The study data could be accessed.	Access to the primary data set was limited.
<i>Reproducibility</i>	The results can be reproduced or the methodology can be followed and evaluated.	The results cannot be reproduced, the methodology is hard to follow, and the author(s) cannot be located.
<i>Quality Assurance</i>	The studies applied and documented quality assurance/quality control measures.	Information on quality assurance/quality control was limited or absent.
Variability and Uncertainty		
<i>Variability in Population</i>	The studies characterize variability in the population studied.	The characterization of variability is limited.
<i>Uncertainty</i>	The uncertainties are minimal and can be identified. Potential biases in the studies are stated or can be determined from the study design.	Estimates are highly uncertain and cannot be characterized. The study design introduces biases in the results.

Table 1 1. Considerations Used to Rate Confidence in Recommended Values (continued)

Evaluation and Review		
General Assessment Factors	Increasing Confidence	Decreasing Confidence
<i>Peer Review</i>	The studies received high level of peer review (e.g., they are published in peer reviewed journals).	The studies received limited peer review.
<i>Number and Agreement of Studies</i>	The number of studies is greater than 3. The results of studies from different researchers are in agreement.	The number of studies is 1. The results of studies from different researchers are in disagreement.

1.6 The Use of Age Groups When Assessing Exposure

When the *Exposure Factors Handbook* was published in 1997, no specific guidance existed with regard to which age groupings should be used when assessing children’s exposure. More recently, U.S. EPA established a consistent set of age groupings and published guidance on this topic (U.S. EPA, 2005). The 2011 edition of the Handbook attempts to present data in a manner consistent with the U.S. EPA’s recommended set of age groupings for children. To this date, no specific guidance is available with regard to age groupings for presenting adult data. Therefore, adult data (i.e., >21 years of age) are presented using the age groups defined by the authors of the individual studies. No attempt was made to re-analyze the data using a consistent set of age groups for adults. In cases where data were analyzed by U.S. EPA, age categories were defined as finely as possible based on adequacy of sample size.

The selection of rates (e.g., inhalation, ingestion, dermal) to be used for exposure assessments depends on the life stage of the exposed population and the specific activity levels of this population during various exposure scenarios. The recommended values for adults and children (including infants) for use in various exposure scenarios are presented in each chapter.

1.7 Considering Life Stage When Calculating Exposure and Risk

In recent years, there has been an increased concern regarding the potential impact of environmental exposures among children and other susceptible populations such as older adults and pregnant/lactating women. As a result, U.S. EPA and others have developed policy and guidance, and undertaken research to better incorporate life-stage data into human health risk assessment (Brown et al., 2008). A framework for considering life stages in human health risk assessments was developed by U.S. EPA in the report entitled, *A Framework for Assessing Health Risks of Environmental Exposures to Children* (U.S. EPA, 2006). Although the framework discusses the importance of incorporating life stages in the evaluation of risks to children, the approach can also be applied to other life stages that may have their own unique susceptibilities, such as older individuals.

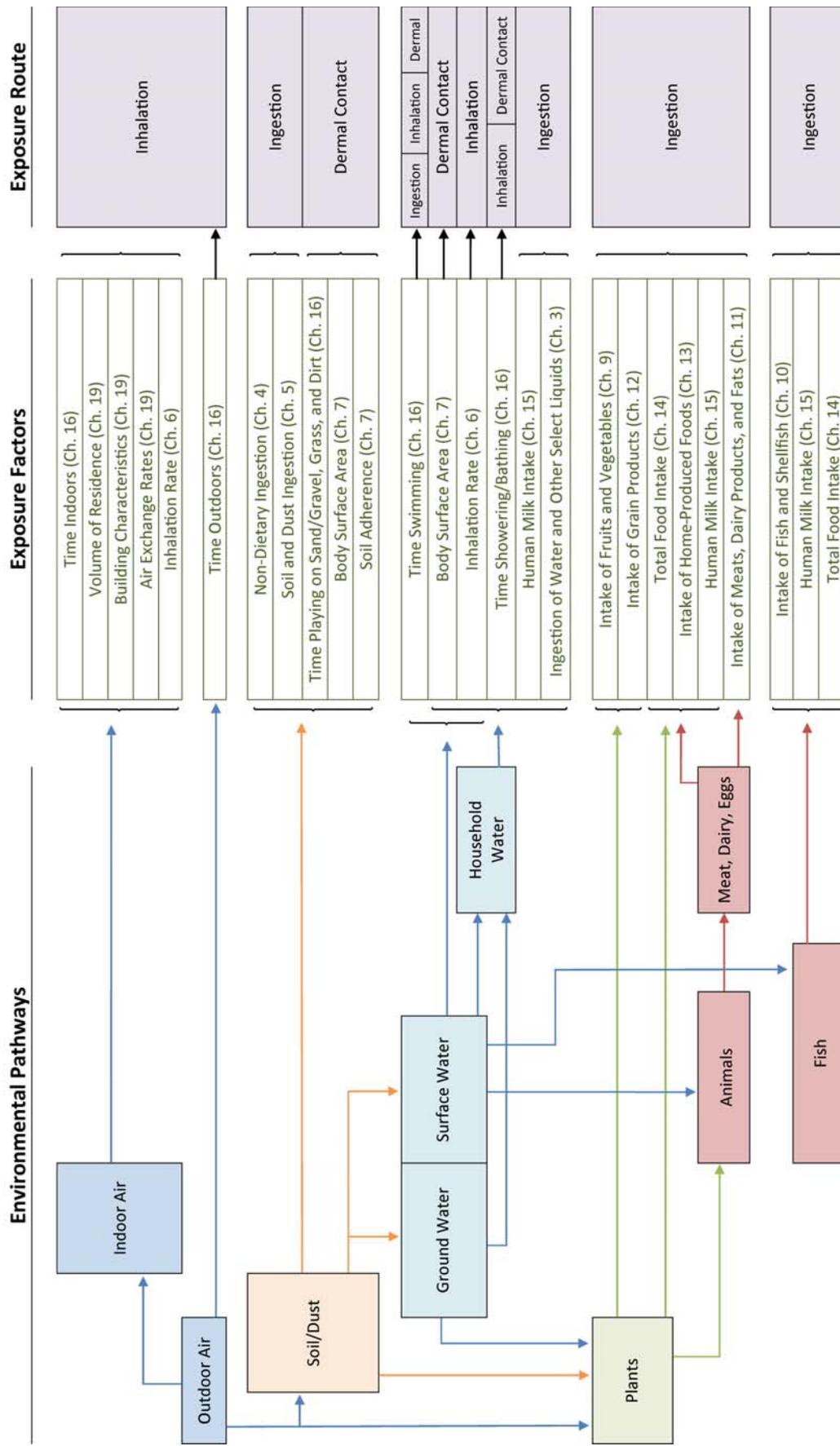
1.8 Fundamental Principles of Exposure Assessment

The definition of exposure as used by the International Programme on Chemical Safety (IPCS, 2001) is the “contact of an organism with a chemical or physical agent, quantified as the amount of chemical available at the exchange boundaries of the organism and available for absorption.” This means contact with the visible exterior of a person such as the skin, and openings such as the mouth, nostrils, and lesions. The individual’s activity patterns as well as the concentration of the chemical will determine the magnitude, frequency, and duration of the exposure.

The exposure becomes an absorbed dose when the chemical crosses an absorption barrier. When the chemical or its metabolites interact with a target tissue, it becomes a target tissue dose, which may lead to an adverse health outcome. This approach has been used historically in exposure assessments and exposure modeling. It is usually referred to as the source-to-dose approach. In recent years, person-oriented approaches and models have gained popularity. This approach is aimed at accounting for cumulative and aggregate exposures to individuals (Georgopoulos, 2008; Price et al., 2003). The person-oriented approach can also take advantage of information about the individual’s susceptibility to environmental factors (e.g., genetic differences) (Georgopoulos, 2008).

There are three approaches to calculate exposures: (1) the point-of-contact approach, (2) the scenario evaluation approach, and (3) the dose reconstruction approach (U.S. EPA, 1992). The data presented in the Handbook are generally useful for evaluating exposures using the scenario evaluation approach. See Section 1.10 in the *Exposure Factors Handbook* for more detailed information on exposure assessment, including dose equations and the use of exposure factors in probabilistic analyses. Figure 1-1 provides a schematic diagram that shows the linkages of a select number of exposure pathways with the exposure factors presented in the Handbook and the corresponding exposure routes.

Figure 1-1. Schematic Diagram of Exposure Pathways, Factors, and Routes



Notes:
 The pathways presented are selected pathways. This diagram is not meant to be comprehensive.
 Consumer Products (Ch. 17), such as perfume, are not shown on this diagram. Humans can be exposed to consumer products through all pathways and routes.
 Body Weight (Ch. 8) and Lifetime (Ch. 18) potentially modify all exposure pathways.