CHAPTER 1

INTRODUCTION AND FLOWCHART

1.1 INTRODUCTION

This guidance is the fifth part (Part E) in the series *Risk Assessment Guidance for Superfund: Volume I - Human Health Evaluation Manual* (RAGS/HHEM) (U.S. EPA, 1989). Part A of this guidance describes how to conduct a site-specific baseline risk assessment. Part B provides guidance for calculating risk-based concentrations that may be used, along with applicable or relevant and appropriate requirements (ARARs) and other information, to develop preliminary remediation goals (PRGs) during project scoping. PRGs and final remediation levels can be used throughout the analyses in Part C to assist in evaluating the human health risks of remedial alternatives. Part D complements the guidance provided in Parts A, B and C and presents approaches to standardizing risk assessment planning, reporting and review. Part E is intended to provide a consistent methodology for assessing the dermal pathway for Superfund human health risk assessments. Part E incorporates and updates principles of the EPA interim report, *Dermal Exposure Assessment: Principles and Applications* (DEA) (U.S. EPA, 1992a). The DEA is considered guidance for all EPA environmental programs. Exhibit 1-1 illustrates the correspondence of RAGS/HHEM activities with the steps in the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) remedial process.

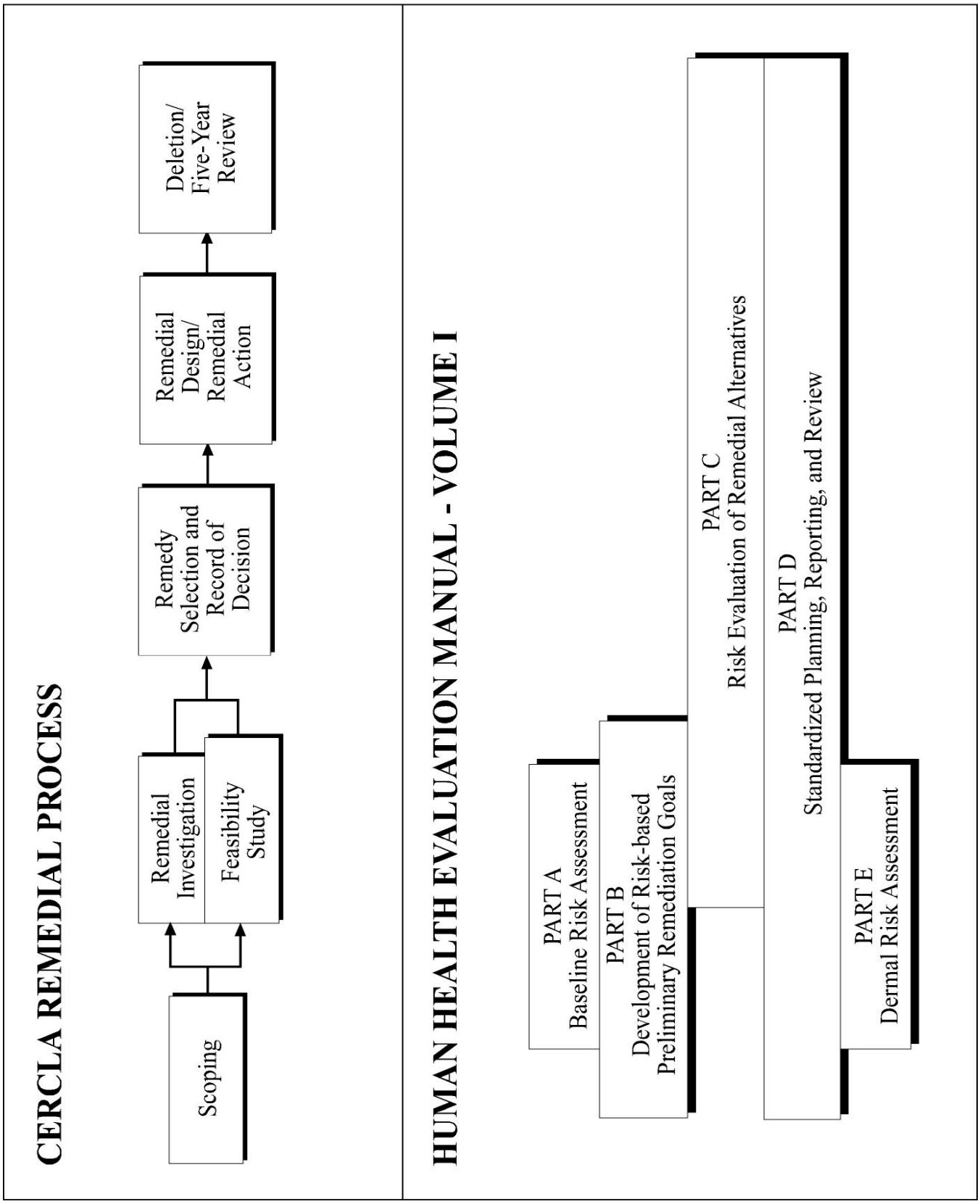
In January 1992, the Office of Health and Environmental Assessment (OHEA), in the Office of Research and Development (ORD) of the U.S. Environmental Protection Agency (EPA) issued an interim report, *Dermal Exposure Assessment: Principles and Applications* (U.S. EPA, 1992a). The 1992 ORD document, from now on referred to as DEA, provided guidance for conducting dermal exposure assessments. The conclusions of the DEA were summarized at the National Superfund Risk Assessors Conference in January 1992 when regional risk assessors requested that a workgroup be formed to prepare an interim dermal risk assessment guidance for the Superfund program based on the DEA. The Part E guidance serves to promote consistency in procedures used by the Regions to assess dermal exposure pathways at Superfund sites. In August 1992, a draft Superfund Interim Dermal Risk Assessment Guidance document was circulated for comment but was never issued as an Office of Solid Waste and Emergency Response (OSWER) Directive. This current guidance supersedes the 1992 Superfund document.

This 2002 Superfund RAGS Part E, Interim Supplemental Guidance for Dermal Risk Assessment (from now on referred to as RAGS Part E) is the result of Superfund Dermal Workgroup meetings from FY 95 through FY 00 on issues associated with the characterization of risk resulting from the dermal exposure pathway. RAGS Part E updates the recommendations presented in the DEA, the updated *Exposure Factors Handbook* (U.S. EPA, 1997a), and additional information from literature as cited. Users of this guidance are strongly encouraged to review and understand the material presented in the DEA. This guidance is considered interim, pending release of any update to the DEA from ORD. As more data become available, RAGS Part E may be updated.

It should be noted that this document limits its guidance on dermal exposure assessment to the discussion of systemic chronic health effects resulting from low-dose, long-term exposure. However, acute chemical injury to the skin should also be examined to present an accurate and comprehensive assessment of toxicity through the dermal route. The potential for direct dermal contact resulting in dermal effects such as allergic contact responses, urticarial reactions, hyperpigmentation, and skin cancer should be discussed qualitatively in the exposure section of the risk assessment.

This document does not provide guidance on quantifying dermal absorption of chemicals resulting from exposure to vapors. The Superfund Dermal Workgroup agreed with the finding in the DEA report that many chemicals, with low vapor pressure and low environmental concentrations, cannot achieve adequate vapor concentration to pose a dermal exposure hazard.

EXHIBIT 1-1
RELATIONSHIP OF THE HUMAN HEALTH EVALUATION TO THE CERCLA PROCESS



For chemicals with the potential to achieve adequate vapor concentrations, this guidance assumes that they are primarily absorbed through the respiratory tract. Additional information on dermal absorption of chemical vapors can be found in the DEA, Chapter 7.

1.2 ORGANIZATION OF DOCUMENT

This guidance is structured to be consistent with the four steps of the Superfund risk assessment process: hazard identification, exposure assessment, toxicity assessment, and risk characterization. Chapters 2.0 - 5.0 of RAGS Part E follow these steps:

Chapter 2: Hazard Identification– identifies those chemicals that make a significant contribution to exposure and risk at a Superfund site.

Chapter 3: Exposure Assessment– evaluates the pathways by which individuals could be exposed to chemicals present at a Superfund site.

Chapter 4: Toxicity Assessment– identifies the potential adverse health effects associated with the contaminants of concern identified at the site.

Chapter 5: Risk Characterization– incorporates information from the three previous chapters to evaluate the potential risk to exposed individuals at the site. This chapter also contains a discussion of the uncertainties associated with estimating risk for the dermal pathway.

Chapter 6: Summary and Recommendations– provides a summary of the main points for each step in the dermal risk assessment process and recommendations for future data needs to improve the evaluation of dermal exposures.

1.3 FLOWCHARTS

The following flowcharts (Exhibit 1-2 and Exhibit 1-3) facilitate the process of performing a dermal risk assessment, by identifying the key steps and the locations of specific information. Separate flowcharts are provided for the water and the soil pathways. Descriptions of the processes illustrated in both flowcharts follow.

Dermal Risk Assessment Process for Water Pathway – The screening process illustrated in Exhibit 1-2 identifies those chemicals that should be evaluated for the dermal pathway. The process identifies those chemicals where the dermal pathway has been estimated to contribute more than 10% of the oral pathway, using conservative residential exposure criteria. Screening tables in Appendix B (Exhibit B-3 for organics and Exhibit B-4 for inorganics) help provide a recommendation as to whether the dermal pathway should be evaluated for a given chemical. If so, the next step is to determine the rate of migration of the chemical through the skin, using the dermal permeability coefficient (K_p), derived from either experimentally measured or predicted values. If default residential exposure assumptions are appropriate for the risk assessment, then the absorbed dose, DA_{event} term, can be extracted from either Exhibit B-3 or B-4, and used with the chemical concentration to calculate the dermally absorbed dose (DAD) term. If default residential exposure assumptions are not appropriate, references to the specific equations and information sources are provided in the Exhibit 1-2 flowchart. Finally, the procedures for the toxicity assessment and risk characterization steps are also outlined.

Dermal Risk Assessment Process for Soil Pathway – There is no screening process for eliminating chemicals in a soil matrix from a dermal risk assessment, as there is for the water pathway. The first step in the hazard identification process illustrated in Exhibit 1-3 is to determine if quantitative dermal absorption from soil (ABS) values are available for the chemical to be evaluated. If not, the decision whether or not to use default values as surrogates for those chemicals without specific recommended values must be made. If data are available, a site-specific ABS value could be used. Section 3.0, Exposure Assessment, summarizes exposure parameter values for a reasonable maximum exposure (RME) exposure scenario as well as activity-specific values. The steps in the toxicity assessment and risk characterization are the same for both the soil and water pathways.

Exhibit 1-2 WATER PATHWAY

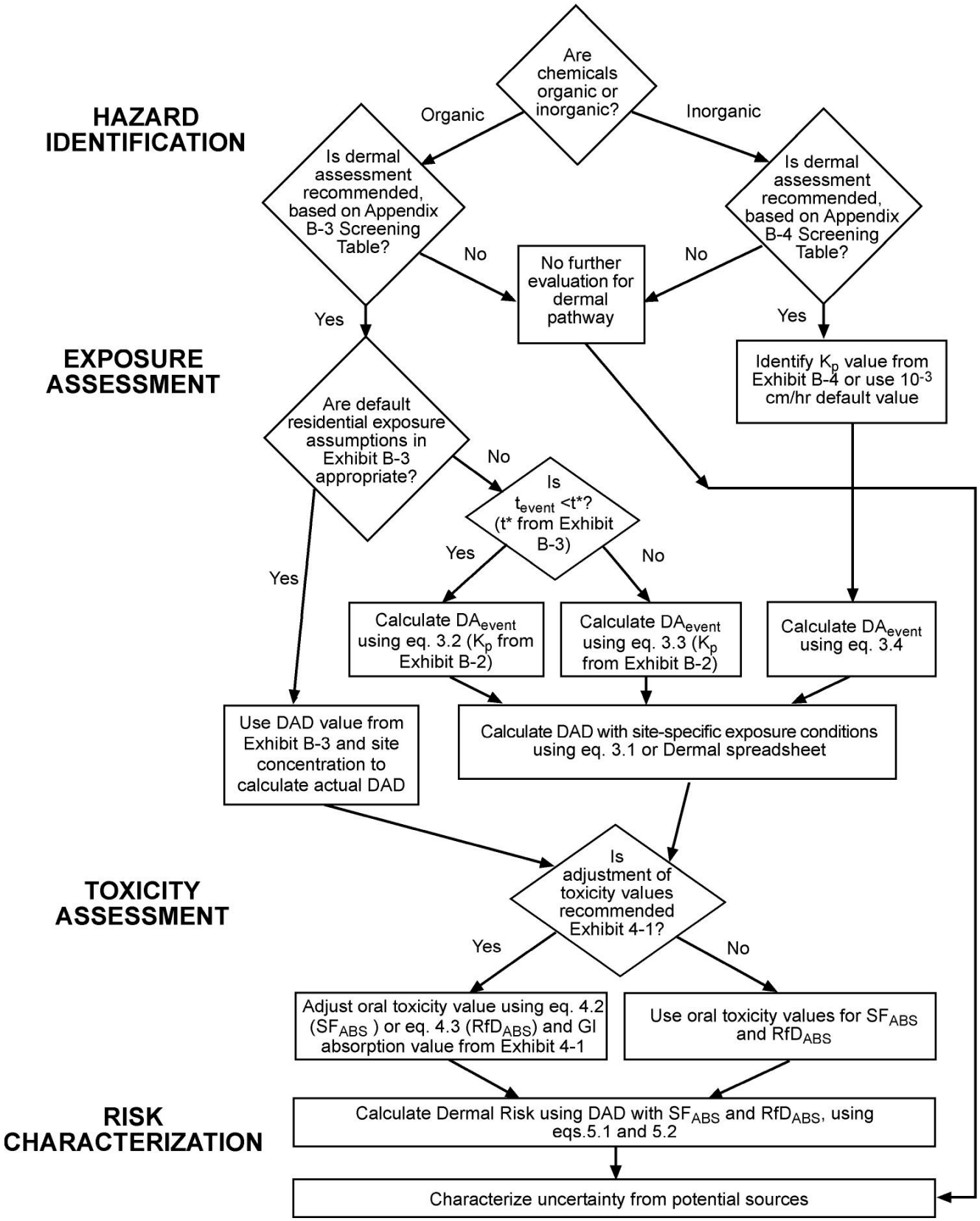
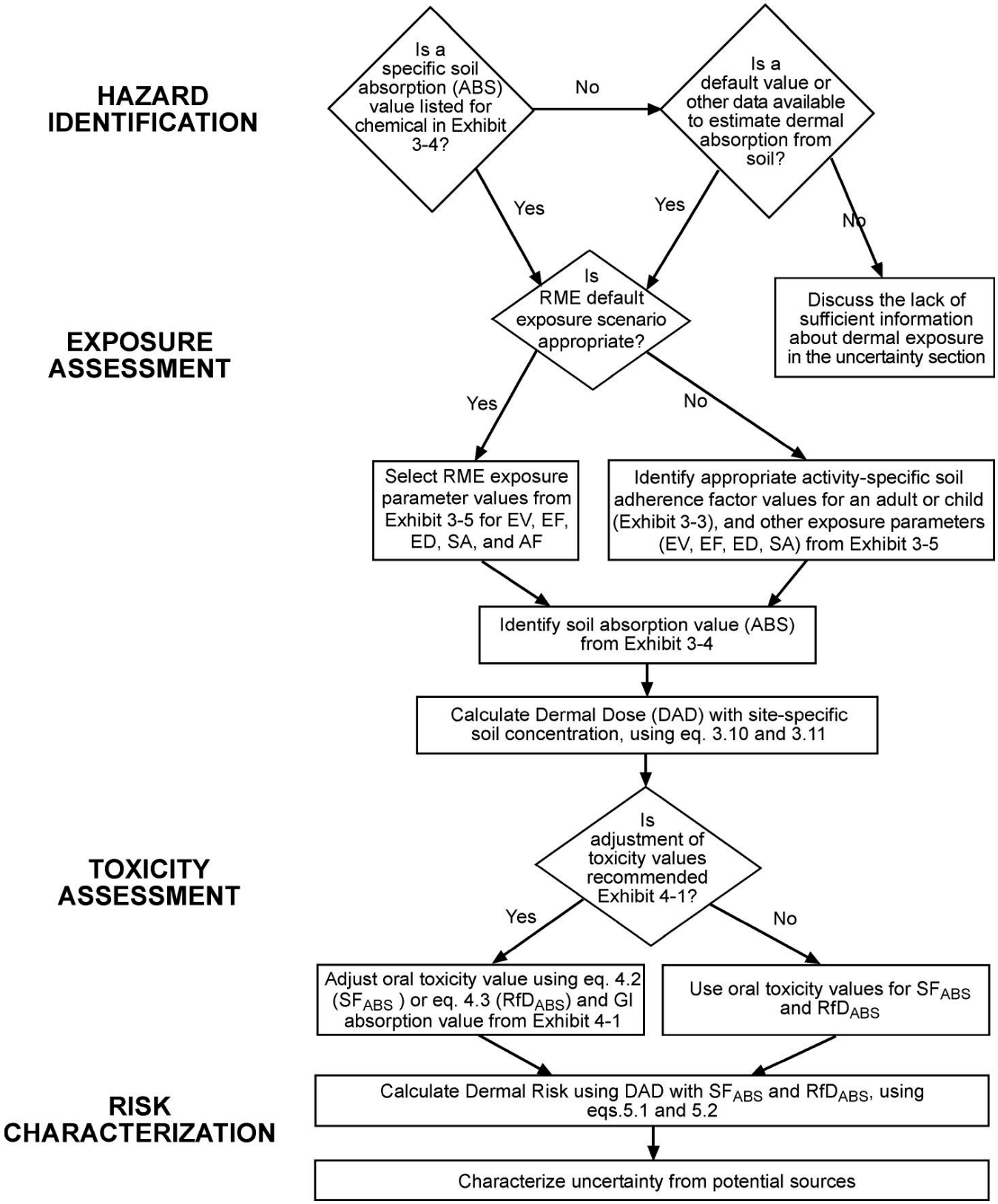



Exhibit 1-3 SOIL PATHWAY