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Beneficial Use Compendium:

A Collection of Resources and Tools to Support Beneficial Use Evaluations

Office of Resource Conservation and Recovery
Office of Land and Emergency Management
Washington, DC 20460

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List of Abbreviations

AASHTO	American Association of State Highway and Transportation Officials
AERMOD	American Meteorological Society/EPA Regulatory Model
AERSCREEN	American Meteorological Society/EPA Regulatory Screening Model
AMS	American Meteorological Society
ASTM	American Society for Testing and Materials
ASTSWMO	Association of State and Territorial Solid Waste Management Officials
ATSDR	Agency for Toxic Substances and Disease Registry
AWQC	ambient water quality criteria
BSAF	biota-sediment accumulation factor
CalEPA	California Environmental Protection Agency
CalTOX	California Total Exposure Model
C&D	construction and demolition
CDD/F	chlorinated dibenzo-p-dioxins and chlorodibenzofuran
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CFR	Code of Federal Regulations
CPSC	Consumer Product Safety Commission
CPV	cancer potency value
CSF	cancer slope factor
DAF	dilution and attenuation factor
DOT	Department of Transportation
DQA	data quality assessment
Eco-SSL	ecological soil screening level
EPA	Environmental Protection Agency
EPACMTP	EPA Composite Model for Leachate Migration with Transformation Products
EPI	Estimation Program Interface
FHWA	Federal Highway Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
HEAST	Health Effects Assessment Summary Tables
HEI	highly exposed individual
IEUBK	Integrated Exposure Uptake Biokinetic Model
IRC	Industrial Resource Council
IRIS	Integrated Risk Information System

IWAIR	Industrial Waste Air Model
IWEM	Industrial Waste Management Evaluation Model
L/S	liquid-to-solid
LANL	Los Alamos National Laboratory
MCLG	maximum contaminant level goal
MCL	maximum contaminant level
MINTEQA2	Metal Speciation Equilibrium for Surface and Ground Water Model
MRL	minimum risk level
MT3DMS	Modular Three-Dimensional Transport Multi-Species Model
NAAQS	National Ambient Air Quality Standards
NAPL	non-aqueous phase liquid
NAS	The National Academy Of Sciences
NEWMOA	Northeast Waste Management Officials' Association
NJDEP	New Jersey Department of Environmental Protection
NOAA	National Ocean And Atmospheric Administration
NOAEL	no observed adverse effect level
NPDWR	National Primary Drinking Water Regulation
NRWQC	National Recommended Water Quality Criteria
OEHHA	Office of Environmental Health and Hazard Assessment
ORD	Office of Research and Development
OLEM	Office of Land and Emergency Response
ORNL	Oak Ridge National Laboratory
OSWER	Office of Solid Waste and Emergency Response
PCB	polychlorinated biphenyl
PCDD/F	Polychlorinated Dibenzo-P-Dioxin And Chlorodibenzofurans
PM	particulate matter
PPRTV	provisional peer-reviewed toxicity value
PRG	preliminary remediation goal
QA	quality assurance
QC	quality control
RAGS	Risk Assessment Guidance for Superfund
RCRA	Resource Conservation and Recovery Act
REL	reference exposure level
RfC	reference concentration
RfD	reference dose

RMRC	Recycled Materials Resource Center
RSL	regional screening level
SMCL	secondary maximum contaminant level
SQuiRT	screening quick reference table
SSL	soil screening level
SVOC	semi-volatile organic compound
TEF	toxicity equivalency factor
TRIM	Total Risk Integrated Methodology Model
TSCA	Toxic Substances Control Act
U.S.	United States
URF	unit risk factor
USDA	U.S. Department of Agriculture
VISL	vapor intrusion screening level
VOC	Volatile Organic Compound

Section 1. Introduction

Industrial non-hazardous secondary materials ("secondary materials") are any materials that are not the primary product of manufacturing and other industrial sectors. Examples can include scrap and residuals from production processes and products recovered at the end of their useful life. Virtually all industrial sectors generate some form of secondary material during the course of normal operations. Some of these secondary materials can be generated in large quantities. In the United States alone, several billion tons of secondary materials are generated each year (U.S. EPA, 1987). Some examples include:

What Does "Non-Hazardous" Mean?

"Non-hazardous" is a legal definition and is not equivalent to "harmless" or "benign." Under federal law, non-hazardous wastes are those that are not either explicitly listed as hazardous under 40 CFR 261, Subpart D, and are not classified as ignitable, corrosive, reactive or toxic under 40 CFR 261, Subpart C, or are specifically excluded from regulation as hazardous waste.

- Steam electric utilities generated nearly 130 million tons of coal combustion residuals during the 2014 calendar year (ACAA, 2014).
- The metal casting sector generates approximately 9.4 million tons of spent foundry sands each year (AFS, 2007).
- The construction and demolition sector generated approximately 530 million tons of building-related construction and demolition materials in 2013 (U.S. EPA, 2015).

Once generated, secondary materials are often sent directly for disposal, but some have the potential to be used beneficially instead. Beneficial use involves the substitution of these secondary materials, either as generated or following additional processing, for some or all of the virgin, raw materials in a natural or commercial product (an "analogous product") in a way that provides a functional benefit, meets product specifications, and does not pose concerns to human health or the environment.

Many opportunities exist to beneficially use these secondary materials (e.g., coal fly ash as a replacement for cement in concrete, spent foundry sands as road subbase). Some of the potential benefits associated with the use of secondary materials include preservation of natural virgin resources, reduced air and water pollution from extraction activities, reduced greenhouse gas emissions, reduced production costs, and avoided use of landfill space. Because of the potential for numerous environmental, economic and performance benefits, the appropriate beneficial use of secondary materials can advance the goals of EPA's Sustainable Materials Management program, which emphasizes a materials management approach that aims to reduce impacts to human health and the environment associated with materials over their entire life cycle (e.g., extraction, manufacture, distribution, use, disposal).

1.1. Purpose and Scope

State, tribal and territorial regulatory bodies make the determinations whether to allow a given beneficial use under a wide variety of programs, some that are dedicated specifically to beneficial use and some that are handled under the purview of broader waste regulatory programs. A survey of these beneficial use programs conducted by the Association of State and Territorial Solid Waste Management Officials in 2006 found that, although the number of requests for determinations is increasing, "insufficient information to determine human or ecological impacts of use rather than disposal" has been a major barrier for states when reviewing proposed beneficial uses (ASTSWMO, 2007). The United States Environmental Protection Agency ("EPA" or "the Agency") Office of Land and Emergency Management developed this document ("the beneficial use compendium" or "the compendium") to help address this barrier.

EPA developed the *Methodology for Evaluating the Beneficial Use of Industrial Non-Hazardous Secondary Materials* (U.S. EPA, 2016) to help determine whether the potential for adverse impacts to human health and the environment from a proposed beneficial use is comparable to or lower than from an analogous product, or at or below relevant health-based and regulatory benchmarks. The methodology is intentionally broad in order to present a balanced discussion of the different aspects of the methodology. The beneficial use compendium is intended to provide a more detailed discussion of some specific considerations that may arise in particular evaluations, as well as a list of existing resources and tools that can assist with these evaluations.

The recommendations in the compendium are intended to be broad and flexible to allow integration within any existing evaluation programs; however, those that use the compendium are free to consider and incorporate other technically sound approaches. Use of both the methodology and the compendium is voluntary and does not change or substitute for existing laws, regulations, or any beneficial use determinations that govern the management of individual wastes on either a federal or state level. EPA encourages those individuals or entities who use both the methodology and the compendium to consult with relevant regulatory bodies to ensure that the application of both these documents are scientifically sound and accounts for any additional considerations required by these regulatory bodies. While protection of human health and the environment is a critical component of beneficial use determinations, EPA recognizes that additional considerations (e.g., existing state and federal requirements, public opinion, the existence of a market) may also factor into the final determination for a particular use.

1.2. Beneficial Use Compendium Organization

The compendium is divided into separate sections that mirror the phases and steps of the beneficial use methodology. Each beneficial use evaluation conducted with this methodology will progress through these three phases, but there is flexibility in which analytical steps are

used and the specific methods used to implement a particular step. The compendium is organized into multiple sections, each of which is intended to address one of these overarching phases or analytical steps. A summary flowchart that maps each phase and step to the corresponding section of the text where discussion can be found is presented in **Figure 1**.

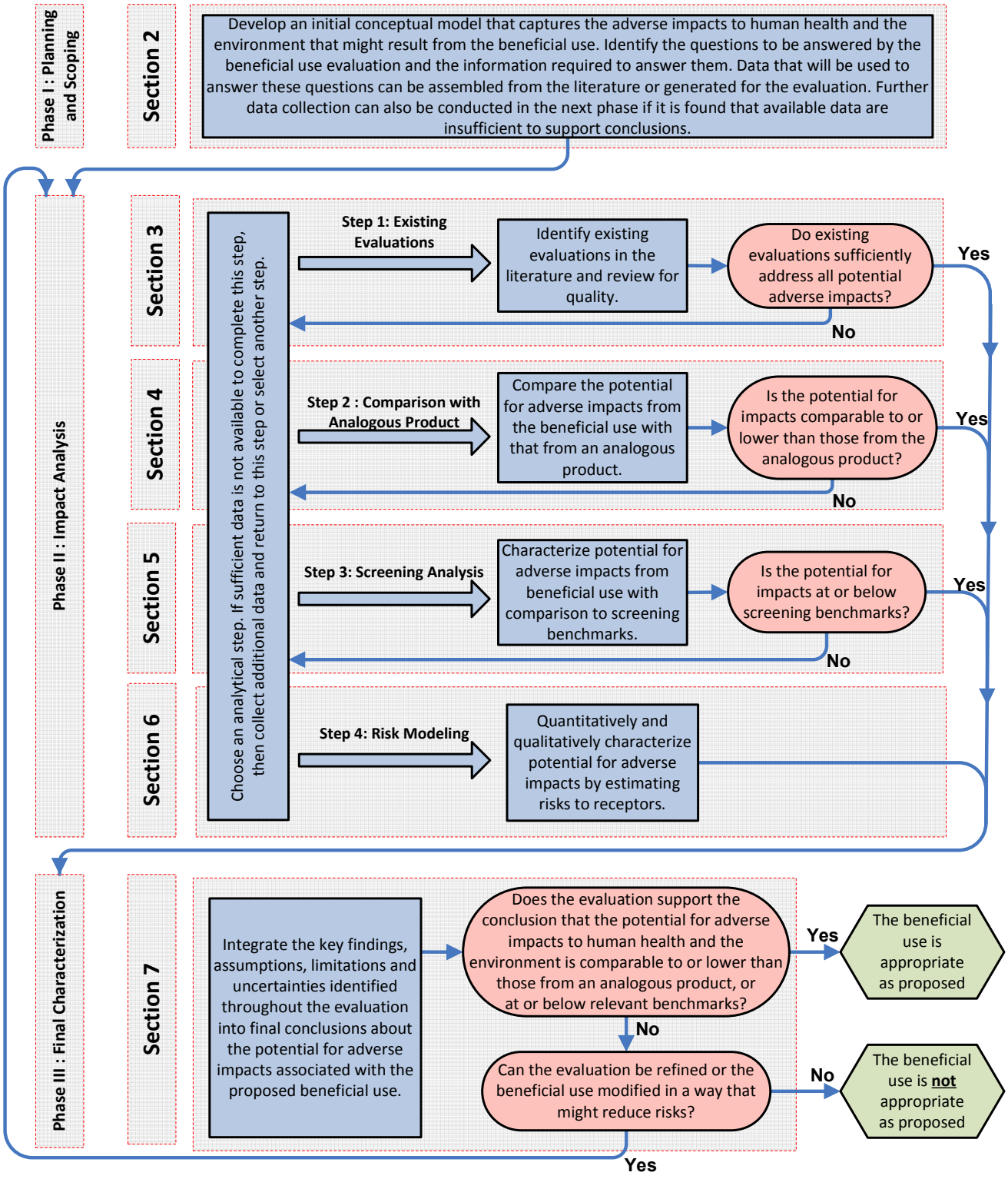

Figure 1. Summary flowchart for the organization of the beneficial use compendium.

For additional reference, a glossary and references are provided at the end of the compendium. The glossary presents a list of common terms that may be encountered when conducting or reviewing a beneficial use evaluation. The definitions presented may not be the only possible definitions and some terms may have different meanings in other contexts. The references provide a listing of all the references cited within the main text of the beneficial use compendium. Further information about these and additional resources can be found in the Appendix.

The appendix to the Beneficial Use Compendium is a library of additional resources that supplement and expand on the discussion in the main text of the beneficial use compendium. These resources provide information and tools that may aid in the development and execution of beneficial use evaluations. The resources provided in this appendix are from publicly available guidance documents, data sources, software programs and related informational materials.

Phase I:

Planning and Scoping

Section 2. Planning and Scoping

Planning and scoping is the first step of any beneficial use evaluation conducted with this methodology. During planning and scoping, the purpose, level of detail, and initial analysis plan for the beneficial use evaluation are established. Careful planning will ensure that the objectives of the evaluation are well-defined, are realistic and form a sound basis for a beneficial use determination. In addition, this preliminary work can help to determine future resource needs, scheduling requirements, and any outside parties that may be useful to consult during the evaluation process. This section builds on previous discussions in *Risk Characterization Handbook* (U.S. EPA, 2000b), *Framework for Human Health Risk Assessment to Inform Decision Making* (U.S. EPA, 2014), *Science and Decisions: Advancing Risk Assessment* (NRC, 2009) and other documents presented in **Sections 1**, **2**, **3** and **4** of the **Appendix** to demonstrate specific considerations relevant to the evaluation of beneficial uses.

2.1. Evaluation Scope

The first part of planning and scoping is to identify the questions to be answered by the evaluation. The following text explores several key questions pertinent to all beneficial use evaluations. While this discussion can help establish a strong foundation for an evaluation, it is not intended to provide an exhaustive list of the potential questions or considerations that may arise.

Key Questions to Ask

- What are the relevant stages of the lifecycle?
- What is the chemical and physical composition of the secondary material and beneficial use?
- What might be released to the environment?
- What happens to releases in the environment?
- What exposures may result from releases?
- What adverse impacts may result from exposures?
- What are the applicable risk management criteria?

The type and amount of information required to answer each question posed during planning and scoping will vary depending on the beneficial use and the methods that will be relied upon to carry out the evaluation. It is unlikely that all of the information needed to completely answer these questions will be available at the start of this stage. However, establishing a list of questions upfront can help identify areas where additional information is needed as the evaluation progresses. Additional resources that may be useful during planning and scoping are presented in **Section 1** of the **Appendix.**

2.1.1. What Are the Relevant Stages of the Lifecycle?

There are often multiple stages in the lifecycle of a beneficially used secondary material. Some common stages include generation, transport, storage, use and/or end of life management. However, not all materials will have the same lifecycle stages. For example, a secondary material that does not require additional processing after generation to be beneficially used may not have a distinct processing stage (e.g., fly ash used as a replacement for cement in concrete). Similarly, a beneficial use that is left in place at the end of its useful life will not

have a distinct disposal stage (e.g., spent foundry sand used as soil amendment). Environmental releases may be possible at any stage of the lifecycle, based on how the material is handled and the degree of contact with environmental media. The type and magnitude of releases can vary among the stages as the composition of the material and the environmental setting change. Therefore, it is important to define which stages of the lifecycle may result in environmental releases that warrant consideration in the beneficial use evaluation. **Figure 1** depicts examples of common lifecycle stages.

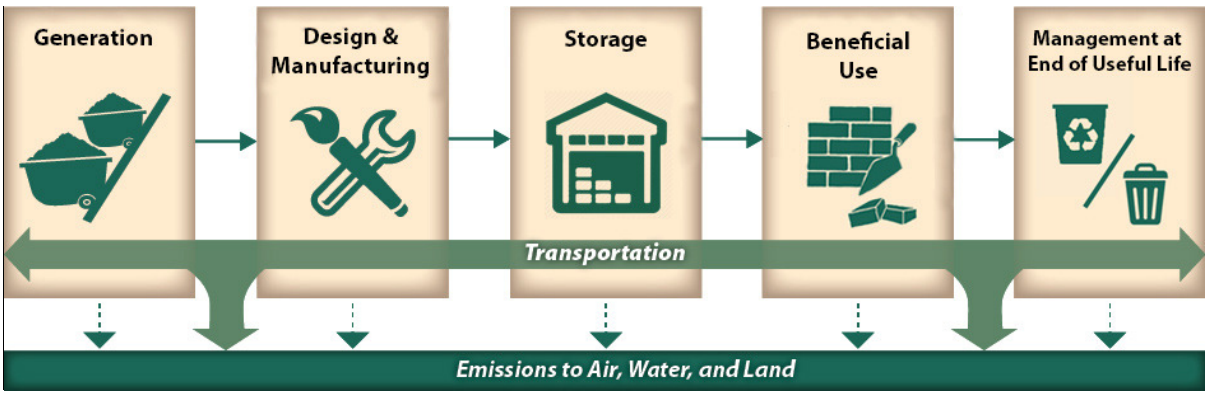

Figure 2. Common lifecycle stages for a secondary material.

2.1.2. What Is the Chemical and Physical Composition of the Secondary Material and Beneficial Use?

The chemical and physical composition of both the generated secondary material and the final beneficial use provide information on how these materials may interact with the environment during the different stages of the lifecycle. It is important to be aware that the composition of the beneficial use may not be exactly the same as that of the secondary material. While some secondary materials can be beneficially used as generated, others require additional processing prior to use. This processing can alter the chemical and physical composition of the materials.

The chemical composition of a beneficial use is all the different chemical constituents present in that material, regardless of source. Some may be introduced by the secondary material or by other raw materials. Some may be generated during the manufacturing process. Others may arise after the beneficial use is put in place, through processes such as chemical degradation. Although the secondary material may not be the source of every constituent, it may still interact with the other raw materials, resulting in higher constituent releases than would otherwise be expected. For example, the substitution of a virgin material with a secondary material may alter the pH or the reduction-oxidation (redox) potential in the resulting beneficial use, which might cause certain constituents to become more mobile. Therefore, it is important to understand both the identity and amounts of each chemical constituent associated with the beneficial use.

Consideration: Chemical Composition

- What are the raw materials used in the manufacturing process (e.g., ores, metals, acids, solvents)?
  - Any chemicals present in the raw materials may be incorporated into the beneficial use.
  - If raw materials are extracted directly from the ground, then any chemical constituents that occur naturally in the environment may be present.
- How are the raw materials handled before incorporation into the beneficial use?
  - Some processes, such as combustion, refinement or distillation, may act to reduce or concentrate the chemical constituents present in the raw materials.
- What chemical reactions take place during the manufacturing process?
  - Incomplete reactions or reactions with impurities may result in unplanned contaminants.
- Are high temperatures present at any point during the manufacturing process?
  - High-temperature processes, such as combustion, may create new chemical constituents (e.g., polycyclic aromatic hydrocarbons, dioxins/furans)

The physical composition of a beneficial use includes both its macroscopic and microscopic structure. This structure influences the amount of contact between the external and internal surface area of the beneficial use and the surrounding environmental media. On a macroscopic scale, a beneficial use will typically be either a liquid or solid. If it is a solid, it may also be monolithic or granular. On a microscopic scale, a monolithic solid may have internal pore spaces of varying size and interconnectivity, while a granular solid may be composed of a range of different particle sizes. However, this physical structure can change over time. A liquid may evaporate, leaving behind previously dissolved solids. A monolithic solid may be worn away into smaller pieces from chemical and/or physical erosion. Conversely, a monolithic solid may increase in density over time, reducing the internal porosity. Failure to account for these and other changes to the beneficial use may result in a mischaracterization of potential impacts to human health and the environment.

2.1.3. What Might Be Released into the Environment?

A stressor is any agent that can result in abnormal, harmful or undesirable impacts to human health or the environment. Stressors associated with the beneficial use of secondary materials are typically chemical (e.g., arsenic, lead) or physical (e.g., particulate matter) in nature. When environmental media come in contact with the beneficial use, stressors can be released. Water-soluble stressors can leach into storm/ground/surface water that passes over the beneficial use, while stressors with a sufficiently high vapor pressure can volatilize into the surrounding air. Even when the beneficial use is a monolithic solid, water and air can pass through interstitial pores or cracks and transport stressors into the surrounding environment. In some instances, the beneficial use itself may be transported through the environment. For example, one that is liquid can infiltrate into the ground or flow overland. One that is a granular solid, or one that can erode into a granular solid, may be blown by the wind or washed away overland by runoff.

Environmental media can play an active role in the release of stressors. These media can contain a variable mixture of organic and inorganic compounds, as well as an array of microbial life, which can interact with the beneficial use and accelerate releases by eroding the physical matrix of the beneficial use or altering the mobility of stressors (e.g., through prevailing redox conditions). Environmental media can also alter releases through changes in concentration, temperature, pressure, and other gradients. In extreme cases, the medium itself may physically erode the beneficial use through abrasion. Thus, it is important to understand not only which stressors are available to be released into surrounding environmental media, but also how the surrounding media may influence the release of these stressors.

Example: Effect of Sulfate Attack on Releases from Concrete

Sulfates [SO_4^{-2}] are ubiquitous in the environment and can come in contact with concrete through several routes that include contact with salt water, acid rain, bacterial reduction of hydrogen sulfide gas, and the raw materials incorporated into the concrete. Sulfates chemically react with the cement matrix of the concrete, altering and weakening its physical structure. Sulfates inside the concrete may also crystalize, placing additional internal stress on the concrete matrix. The net result is a loss of strength that can cause cracks in the concrete (TxDOT, 2011). These cracks allow greater contact with environmental media and may result in the increased releases of industrial materials incorporated in the concrete into the surrounding environment.

The timeframe over which releases occur will depend on the amount of a beneficial use that is applied in a given area, as well as how long the beneficial use remains at that location. Releases may continue until the total available mass of stressors is depleted or the beneficial use is removed. But, if the beneficial use is later replaced or reapplied, then releases may continue beyond that point. The total mass of stressors present can be estimated from the chemical composition and amount of a beneficial use applied in a location. However, it is important to be aware that the presence of a stressor in the beneficial use does not mean that it is available to be released into surrounding media (e.g., soluble). In some instances, some or all of a stressor may be bound within the physical matrix of the beneficial use to such a degree that no appreciable quantities can escape under standard environmental conditions. The extent to which stressors are present and available to be released from a beneficial use can vary as a result of heterogeneity of the raw materials and differences in design specifications. In the absence of detailed information on the availability of a stressor, the assumption that the total mass is available provides a protective, upper-bound on potential releases.

2.1.4. What Happens to Stressors Released into the Environment?

Once released into the environment, stressors may be transported between different media and across great distances. During transport, the stressor levels in the environment will not remain constant. Stressor levels may be diluted as the release mixes with surrounding environmental media. Stressors may also become bound to media and unavailable for further transport or effectively eliminated through chemical or biological degradation. The rates at

which these and other fate and transport processes occur are governed by the properties of the stressor, as well as the physical, chemical and biological characteristics of each medium.

Consideration: Transport Between Media

Stressors can partition between two environmental media that come into contact. It is possible that a single stressor will pass through multiple media before reaching a downgradient receptor.

For example, a stressor released to ground water may flow downgradient and discharge to surface water, where it accumulates in the tissue of a fish before that fish is caught and eaten by a fisher and their family.

While stressor properties (e.g., degradation rate) can often be approximated as constant during transport, the properties of a media (e.g., hydraulic conductivity) that stressors migrate through can change markedly, both spatially and temporally. Knowledge of the different locations a beneficial use might be applied will help to define the variability of these properties for each medium. If the beneficial use will be located within a limited geographic area, then collection of site-specific environmental data may be feasible. However, if the beneficial use will be located across a wide geographic area, then collection of site-specific data will quickly increase in difficulty. Instead, the evaluation may rely on existing regional or national data sources to help define media characteristics.

2.1.5. What Exposures May Result from Releases?

Exposures occur when a receptor comes in contact with a stressor. The various ways in which a receptor can come in contact with a stressor are called exposure routes. The most common exposure routes are ingestion, dermal contact and inhalation. A single receptor may be exposed through one or more routes simultaneously or at different times. The magnitude, frequency and duration of these exposures is influenced by the different physiological and behavioral characteristics of individual receptors. These characteristics can vary widely among the entire exposed population. Therefore, it is important to carefully identify the relevant types of receptors.

Consideration: Types of Exposure

Some relevant exposure routes may not be immediately obvious. While many exposures result from direct intake of environmental media, such as inhalation of ambient air, others may result from indirect intake, such as ingestion of trace amounts of soil that have adhered to skin or produce. Even though the rate of these incidental exposures may be small, they can still account for a non-negligible fraction of overall exposures.

Receptors are typically divided into two broad groups: human and ecological. Human receptors can be further subdivided based on the location of exposure (e.g., office, residence) and the age of the receptor (e.g., adult, child). Ecological receptors can be further subdivided based on taxonomic grouping (e.g., mammal, fish, plant), its position in the food chain (e.g., primary or secondary tropic level) and habitat (e.g., aquatic, terrestrial). These divisions can be used to identify any sensitive subpopulations and/or life stages in order to define the relevant range of receptor characteristics. The relevant receptors are not limited to those present on-site at the time the beneficial use is first applied. Exposures may occur at some point in the future, after a release

from the beneficial use has migrated some distance through the environment or after the local land use has changed.

2.1.6. What Adverse Impacts May Result from Exposures?

Adverse impact is a broad term for any abnormal, harmful or undesirable change that results from exposure to a stressor. The level of a stressor required to cause such a change and the severity of that change are dependent on the stressor properties, the route and magnitude of exposure, and the receptor characteristics. Because of the variable rates at which receptors are exposed and react to stressors, it is rarely possible to predict the exact extent to which adverse impacts will occur. Even when a receptor is exposed to high stressor levels, some adverse impacts may not occur or become apparent until years after the initial exposure. As a result, these adverse impacts are typically discussed based on the potential for occurrence. This potential might be estimated indirectly (e.g., through comparison with screening benchmarks) or directly (e.g., through the calculation of risks).

Adverse biological impacts to human health and ecological communities are typically divided into two main categories: carcinogenic and noncarcinogenic effects. Carcinogenic effects are those that result in the development of cancer. Noncarcinogenic effects are those that result in outcomes other than cancer. Some stressors are known to cause both carcinogenic and noncarcinogenic effects, depending on the route through which the receptor is exposed and the magnitude of the exposure. However, not all adverse impacts result in direct harm to the health of a living organism. Instead, an adverse impact may be an undesired change to the environment, such as the discoloration of a water body, the presence of an unpleasant odor, or the proliferation of a nuisance species. While these impacts may not result in direct harm, they may lead to public complaints and economic damages.

2.1.7. What Are the Applicable Risk Management Criteria?

Risk management criteria are used to define a point below which a proposed beneficial use can be concluded to not pose concerns to human health or the environment. These criteria may incorporate a range of pertinent risk-based, political, social, economic, legal and technological considerations. Some examples might be a risk level that result from exposures, a stressor level in media to which receptors could be exposed, or a stressor level associated with a natural or commercial product that would have otherwise been used. The absence of concentrations or exposures above these criteria is not always the same as the total absence of risk. Thus, before selecting criteria for use in a beneficial use evaluation, it is important to understand the considerations that are built into each. Some address specific, sensitive segments of the population that may or may not be relevant to the proposed beneficial use. Some are recommendations developed by various organizations, while others represent legally enforceable standards. However, all risk management criteria will be based on a level of acceptable risk, which is a fundamental policy decision. Individuals or entities that conduct beneficial use evaluations should engage with relevant regulatory organizations to ensure that the criteria selected are consistent with relevant state beneficial use requirements.

2.2. Conceptual Model

Preparation of the initial conceptual model is another aspect of planning and scoping. A conceptual model incorporates all the data gathered in response to the questions posed during planning and scoping into a graphical representation of the complete exposure pathways that will be evaluated for the beneficial use. These pathways consist of the source of stressors (i.e., the beneficial use), the routes through which released stressors can migrate through the environment, and the receptors that can be exposed. Conceptual models are useful tools to organize, visualize and communicate the scope of the evaluation. There is no standardized format for conceptual models; they can vary widely in terms of both layout and level of detail. A conceptual model provides general information on the major categories of stressors and receptors. Depicting every single stressor and receptor combination would quickly become unwieldly. **Figure 3** shows some of the different approaches that can be used to communicate the same information.

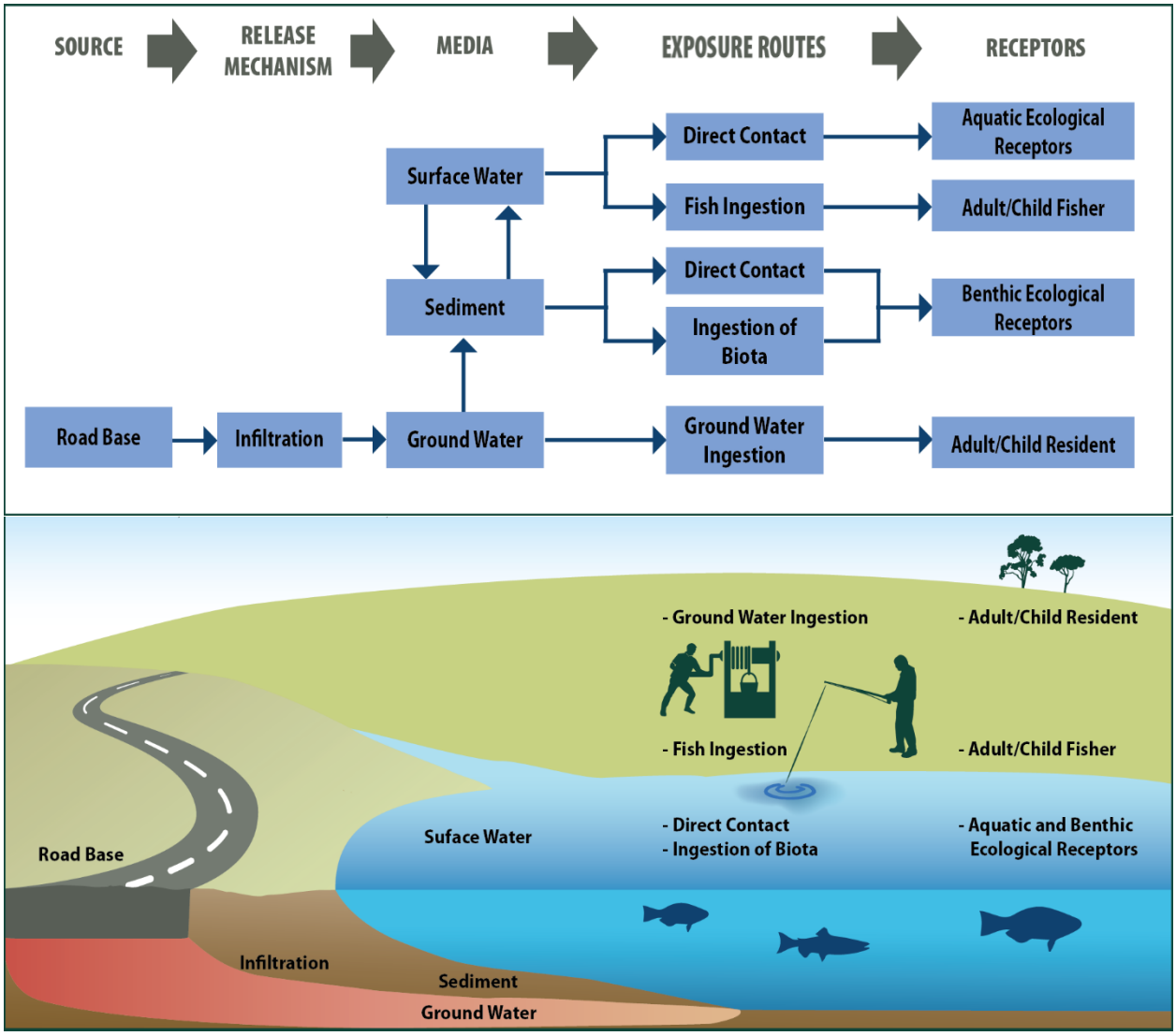

Figure 3. Two different approaches to depicting the same conceptual model.

2.3. Analysis Plan

Development of an analysis plan is another important aspect of planning and scoping. This plan identifies the general analytical steps that will be used to characterize the potential for adverse impacts from the proposed beneficial use and the specific approaches that will be used to implement these steps. For any given step, there may be multiple approaches available. The primary aim of drafting an analysis plan at this phase of the evaluation is to identify the steps and approaches that make the best use of available resources, to minimize the potential for unforeseen setbacks, and to foster agreement when multiple parties are involved in scoping the evaluation. Additional resources that may be useful during development of the analysis plan are presented in **Sections 2**, **3** and **4** of the **Appendix**.

2.3.1. Analytical Steps and Approaches

If all of the data that will be relied upon in the beneficial use evaluation are available during this phase, then careful review can reveal which analytical steps and approaches the data can support. However, if no data collection has yet taken place, or if additional rounds of data collection are anticipated, it can be more difficult to identify the most suitable methods. When additional data are needed, a decision can be made to either review the literature for existing data or to generate the necessary data. The benefit of generating new data is that it allows the quality and quantity of data to be tailored to the specific needs of the evaluation. Yet the planning, sampling and analysis necessary to generate new data can be resource intensive. Therefore, this option can also be reserved until a later stage of the evaluation, if it is found that data drawn from the literature are insufficient to reach well-substantiated conclusions. The analysis plan is not static and may change as new information becomes available.

Because of the substantial variability in the types of secondary materials generated, the potential beneficial uses for each material, and the amount and quality of data available to characterize each, there is no single analysis plan structure best suited for every evaluation. Therefore, the next phase of this document highlights several broad steps built around similar analytical methods, as well as the considerations and potential pitfalls associated with each. The methods discussed are broad so as to remain applicable to any beneficial use evaluation. There are no limitations on which or how many different methods can be used within an evaluation, so long as the application of each is rooted in sound science. The benefit of multiple methods is the ability to systematically eliminate individual stressors or entire exposure pathways that can be shown to pose no concern before investing in increasingly complex and resource-intensive methods. However, there is the potential for these simpler methods to be too general or too likely to overestimate the potential for adverse impacts to effectively streamline an evaluation. It can be helpful to seek input from experts in the field of risk assessment to identify which specific steps and approaches make the best use of available data.

2.3.2. Accounting for Uncertainty

Uncertainties are gaps in the understanding of a system and will exist to some degree in any beneficial use evaluation. Uncertainty can bias results and lead to incorrect conclusions if it is

not considered and accounted for during the evaluation. Therefore, it is important to identify and, to the extent possible, mitigate the potential sources of uncertainty as the evaluation progresses. The National Research Council has identified three main categories of uncertainty (NRC, 2013):

- Variability and heterogeneity introduce uncertainty when the available data are not sufficient to characterize the relevant properties of stressors, media, receptors and other components of the conceptual model. Variability and heterogeneity are natural parts of environmental systems and cannot be eliminated through further study. However, the associated uncertainties can be minimized through collection of additional data to better define the range and distribution of key variables.
- Models introduce uncertainty through the simplifying assumptions used to approximate real-world conditions, processes and relationships. These assumptions are necessary to allow solutions to mathematical equations and fill gaps in available knowledge. However, the simplification of complex systems may misrepresent real-world conditions to an unknown degree. The associated uncertainty can be minimized by identifying the most suitable model and, where possible, replacing default assumptions with data that are more representative of the proposed beneficial use.
- Limitations of the current scientific knowledge may introduce uncertainty through a lack of consensus about, or a fundamental ignorance of, particular aspects of the system under evaluation. This can be the most difficult type of uncertainty to identify and address. Neither the collection nor the analysis of additional data is likely to reduce this type of uncertainty before a decision must be made.

Both the direction and magnitude of the uncertainties are important. The direction of an uncertainty is the tendency for that uncertainty to push a predicted value higher or lower than the true value. The magnitude of an uncertainty is the extent to which that uncertainty may cause the predicted value to deviate from the true value. It is often impossible to quantify both the direction and magnitude of an uncertainty due to the very data limitations that cause the uncertainty. Still, identifying potential sources of uncertainty upfront can inform the selection of analytical steps and approaches that make the best use of available data. In addition, knowledge of the different sources of uncertainty can focus any further data collection efforts on areas that will provide the greatest returns.

2.4. Summary

Planning and scoping is the initial step of any beneficial use evaluation, conducted before the start of any analysis. This step helps to avoid unforeseen setbacks and to build early consensus when multiple parties are involved in the evaluation. Documentation of any conceptual models or decision trees that are developed is encouraged to increase the clarity and transparency of the evaluation. The subsequent sections of this document highlight individual steps that can be used to characterize the potential for adverse impacts to human health and

the environment, as well as the considerations and potential pitfalls associated with each. Those individuals or entities who use the beneficial methodology are encouraged to become familiar with all of the phases and analytical steps, as well as the specific considerations associated with each, before deciding which to incorporate into a beneficial use evaluation.

Phase II:

Impact Analysis

Section 3. Existing Evaluations

Existing evaluations consist of the identification, review and application of the findings made in the available literature that are relevant to the beneficial use. This step can be separated into three sequential stages. In the first stage, all potentially relevant evaluations of the specific beneficial use are identified from the existing literature. In the second stage, the quality of the data and analyses contained in these evaluations is reviewed to determine whether the findings are of sufficient quality to draw conclusions about the beneficial use. In the third and final stage, the findings determined to be of adequate quality are applied to the ongoing beneficial use evaluation and used to determine which of the potential exposures warrant further consideration through other analytical steps. This section builds on documents and tools presented in **Section 3** of the **Appendix.**

3.1. Identification Stage

Existing evaluations are those that present findings germane to the proposed beneficial use. These existing evaluations may include previous beneficial use evaluations, peer-reviewed studies or technical reports published by government agencies, academic institutions, trade associations and other sources. The identification and systematic review of these existing evaluations is the same as for any other type of literature search and can easily be conducted in parallel with other data collection efforts.

There are many potential sources of existing evaluations and it is important not to prematurely exclude any data source from consideration. Published journals and monographs can be accessed through public libraries and online literature databases. Carefully selected search terms can help to maximize search results. Other potential sources are technical reports authored by public authorities, academic institutions, and non-governmental organizations, such as trade associations and public interest groups. These technical reports may exist as grey literature that are not publicly catalogued and may require contacting the authors to obtain a copy. Literature reviews are a useful place to begin, as they can provide an overview of the findings from multiple evaluations, identify trends and relationships among different evaluations, or highlight sources of uncertainty or disagreement in the current science. At a minimum, these literature reviews can provide a list of additional references that will facilitate further data collection efforts.

A major hurdle to the identification of applicable existing evaluations is access. Even when an evaluation has been located, it may not be available for free. Costs may range from relatively small amounts for a single journal article to large sums for a single technical report. Even when the cost of each individual evaluation is small, the cumulative costs of a literature search can compound quickly. Unnecessary expenditure of funds can be minimized through a review of publicly available abstracts. It is often possible to glean enough information from these abstracts to determine whether an existing evaluation is germane to the proposed beneficial

use. Yet, while it is possible to gauge the relevance of an evaluation based on abstracts alone, it can be much more difficult to determine whether the quality of the data and analyses contained in the existing evaluation are sufficient without reviewing the full documentation.

3.2. Review Stage

As each existing evaluation is identified, it is important to review the underlying data and analyses to determine whether the reported findings are of adequate quality to form the basis for conclusions about the beneficial use. The goal of this review is to ensure that the uncertainties introduced through the use of these existing evaluations are not too great. Each beneficial use evaluation will be able to tolerate different types and amounts of uncertainty and still reach well-substantiated conclusions. For example, an evaluation that finds all estimated exposures to be far below relevant benchmarks will be able to tolerate a greater magnitude of uncertainty about the range of possible releases and exposures than an evaluation with estimated exposures near benchmarks. One example might be the ability of an evaluation to tolerate non-detects with high detection limits in the dataset. As a result, what constitutes adequate data quality can vary and will require professional judgment. The following text details the five data quality assessment factors that EPA considers when reviewing external data sources (U.S. EPA, 2003a). Additional resources that may be helpful when considering data quality are presented in **Section 4** of the **Appendix**.

3.2.1. Applicability and Utility

Applicability and utility is the extent to which the findings of an existing evaluation are relevant for the intended use. This means that the data, analyses and findings presented in the existing evaluation support a similar set of conclusions when applied to the conceptual model for the proposed beneficial use. **Table 1** presents example questions that may be helpful to consider when reviewing the applicability and utility of an existing evaluation.

Table 1. Considerations for Applicability and Utility

▪ Does the existing evaluation capture the current properties of the beneficial use?	It is important to ensure that the existing evaluation reflects the current secondary material and proposed beneficial use. The properties of both may change over time from unintended changes during use (e.g., erosion) or intended changes to the processes by which the secondary material or beneficial use are generated (e.g., updated pollution control technologies). In addition, the beneficial use may be exposed to environmental conditions different from those considered in the existing evaluation (e.g., annual rainfall) or may be used differently (e.g., greater mass applied, greater percentage of virgin materials replaced).
▪ Are the findings applicable to the beneficial use?	An existing evaluation may not have the same scope as the beneficial use evaluation and certain aspects, such as the simplifying assumptions, may not be the same between the two evaluations. If the beneficial use is shown to pose no concern under a more stringent existing evaluation, then the findings may still be applicable to the ongoing beneficial use evaluation. However, if the existing evaluation is less stringent than agreed upon for the beneficial use evaluation, then further analysis may be warranted.

3.2.2. Clarity and Completeness

Clarity and completeness are the degree to which an existing evaluation transparently documents its assumptions, analytical methods, quality assurance protocols and other key information. An evaluation that is both clear and complete provides enough detail that an outside party with access to the proper tools can replicate the analyses. **Table 2** presents example questions that may be helpful to consider when reviewing the clarity and completeness of an existing evaluation.

Table 2. Considerations for Clarity and Completeness

▪ Are all of the raw data available for review?	Authors may choose to present only summary statistics in the publicly available documents for any number of reasons, such as space limitations in some scientific journals. However, it may still be possible to obtain the underlying raw data by contacting the authors.
▪ Are all key assumptions and methods discussed in the text?	Assumptions made in an existing evaluation may be valid in the context of that evaluation, but may not hold true for the ongoing beneficial use evaluation. Therefore, it is important to understand the analytical methods and key assumptions that underpin the findings. A critical review of the documentation for the existing evaluation is important because authors may not recognize or explicitly discuss some assumptions implicit in the analyses conducted. In addition, authors may rely on citations to other literature sources to detail more common methods and assumptions.

3.2.3. Soundness

Soundness is the extent to which the methods employed by an existing evaluation are reasonable and consistent with the intended application. This means that any methods used to collect and measure data have demonstrated the technical ability to reliably and repeatedly achieve desired levels of accuracy and precision, and that any methods used to analyze and interpret data; such as equations, models and simplifying assumptions; are adequately justified and based on accepted scientific principles. **Table 3** presents example questions that may be helpful to consider when reviewing the soundness of an existing evaluation.

Table 3. Considerations for Soundness

▪ What quality assurance and quality control (QA/QC) has been conducted?	QA/QC is undertaken to demonstrate both the accuracy and the precision of reported data. Proper QA/QC procedures provide confidence that reported values are not the result of contamination or other artifacts introduced during sample collection, preparation or analysis.
▪ Are the detection limits used sufficiently low?	Non-detect data do not necessarily indicate the absence of a stressor, only that the levels fall somewhere between the specified detection limit and zero. This information may still be useful. However, if there is the potential for adverse impacts at levels below the detection limit, then reliance on these non-detects may introduce an unacceptably large amount of uncertainty into the ongoing beneficial use evaluation.

3.2.4. Variability and Uncertainty

Variability and uncertainty is the extent to which the existing evaluations effectively characterize how the data and assumptions relied upon, the laboratory methods used, and the interpretation of results affect the evaluation. Effective characterization of the major sources of variability and uncertainty provides greater confidence that there are no unaddressed data gaps and that the basis for the reported findings is sound. **Table 4** presents some questions that may be helpful to consider when reviewing the variability and uncertainty of an existing evaluation.

Table 4. Considerations for Variability and Uncertainty

▪ Do the data capture the environmental conditions that could be present at each relevant stage of the lifecycle?	An existing evaluation may consider environmental conditions (e.g., extreme pH) that cannot or will not exist outside a laboratory setting. These extreme conditions may bound the range of theoretically possible releases. However, the highest releases for every stressor do not always occur at one extreme (e.g., acidic). Instead, higher releases may occur under more typical conditions (e.g., neutral) or closer to the other extreme (e.g., basic). It is important to be aware of how the different environmental conditions affect releases and whether the conditions considered in the existing evaluation reflect the range relevant to the proposed beneficial use.

3.2.5. Evaluation and Review

Evaluation and review is the extent to which an existing evaluation underwent independent verification, validation and peer review. An independent review is one conducted by objective (i.e., free of any real or perceived conflicts of interest) technical experts who were not associated with the generation of the work under review, either directly or indirectly, through substantial contribution or consultation during its development, and who do not stand to benefit from the review. Independent reviews are intended to identify any errors or bias present in how data are collected, handled or interpreted and to ensure that the findings are accurate, reliable and unbiased. **Table 5** presents example questions that may be helpful to consider when reviewing the level of review that an existing evaluation has undergone.

Table 5. Considerations for Evaluation and Review

▪ Have the models used undergone independent validation/verification?	Models and the underlying mathematical expressions are simplifications of reality that are used to approximate real-world conditions, processes and relationships. Model validation and verification determine whether the model executes as intended and whether the model accurately represents the environmental system. These reviews provide confidence that the model used in the existing evaluation operates as intended.
▪ Where did the funding for this study originate? ▪ Are reviewers free from conflicts of interest?	In some cases, a generator, beneficial user or other party with a financial stake may perform or commission an evaluation of beneficial uses. These evaluations can be good sources of information, but there is the potential for either a real or perceived conflict of interest. However, an independent external peer review of these evaluations can help to alleviate some of these concerns.

3.3. Application Stage

Once the existing evaluations have been identified and determined to be of adequate quality, the findings can form the basis for conclusions about the proposed beneficial use. The findings might support the conclusion that some or all of the potential exposures do not pose concern and do not warrant further evaluation. Conversely, the findings might support the conclusion that some or all of the potential exposures warrant further evaluation or are so great that there is adequate confidence the beneficial use is inappropriate as proposed.

The aim of this step is to avoid additional, substantial analyses beyond those presented in the existing evaluations. The use of data to conduct further analyses is addressed through other steps discussed in this document. However, there are some instances where it may be possible to discuss the findings of an existing evaluation in the context of some additional, supporting information to allow conclusions about the beneficial use as a whole. Supporting information is also drawn from the existing literature, and is used to reinforce the existing evaluation by providing greater certainty that the findings are applicable to the full range of relevant environmental conditions, exposure scenarios, or other sources of variability. If the findings of an existing evaluation, together with any supporting information, are adequate to demonstrate that the potential for adverse impacts is comparable to or lower than from an analogous product, or at or below relevant regulatory and health-based benchmarks, then no further evaluation would be necessary.

Example: Supporting Information

A hypothetical historical evaluation analyzed the potential release and migration of an organic chemical from a secondary material placed outdoors on the ground surface. This evaluation found that leaching from the secondary material results in exposures below levels of concern, based on relevant risk management criteria. These findings alone would not be applicable to a beneficial use of the secondary material that mixes it with other raw materials because the properties of the beneficial use may result in higher releases than the secondary material alone.

A separate supporting study is identified that analyzed the leaching from the actual beneficial use. It is determined that this study did not sufficiently capture the variability of the beneficial use enough to stand as the sole basis for conclusions. However, the study found that leaching from the beneficial use is consistently lower than from the secondary material by itself. When considered in the context of the supporting study, the findings of the historical evaluation may be sufficient to eliminate leaching of this chemical from further consideration, assuming that there are no confounding factors that warrant further consideration, such as the potential for releases from the beneficial use to increase over time as it ages.

3.4. Potential Sources of Uncertainty

Because this step relies on findings drawn from existing evaluations, it also introduces all of the sources of uncertainty associated with those findings into the beneficial use evaluation. While supporting information can help to minimize these uncertainties, they may also contain and contribute additional sources of uncertainty. Documentation of the magnitude and

direction of the major sources of uncertainty in the existing evaluations can help demonstrate that reliance on these findings does not introduce an unacceptable amount of uncertainty into the beneficial use evaluation.

3.5. Summary

The benefit of reviewing existing evaluations is the potential to save resources by preventing a duplication of effort. This step can be especially useful when a literature search has already been planned as part of data collection efforts. If existing evaluations are identified that are of adequate quality and demonstrate that the potential for adverse impacts from the proposed beneficial use is below levels of concern, based on the selected risk management criteria, then no further evaluation is warranted for that those specific releases or exposures. However, if after review and application of all identified existing evaluations, there remain exposures that require further consideration, then the data from these existing evaluations can be assembled with those from other literature sources for use in subsequent analytical steps.

Section 4. Comparison with Analogous Product

This step is a comparison of the beneficial use to a product already available on the market that the beneficial use replaces (an "analogous product"). The secondary material substitutes for some or all of the virgin materials found in the analogous products to create the beneficial use. A single beneficial use may be able to substitute for more than one analogous product. The purpose of this comparison is to determine whether the potential for adverse impacts to human health and the environment from the beneficial use is comparable to or lower than from an analogous product. This section discusses some of the considerations involved in the design and implementation of these comparisons. This section builds on documents and tools presented in **Section 5** of the **Appendix.**

4.1. Considerations when Planning the Comparison

The industrial processes that generate secondary materials can introduce chemical constituents and other stressors that are not found in any of the analogous products. As a result, there is the potential that stressors in a beneficial use are wholly absent from all analogous products. When the secondary material introduces stressors into the beneficial use that are not found in any analogous product, this would be sufficient information to demonstrate that the beneficial use is not comparable and that further evaluation for these stressors is warranted. Conversely, if there are stressors associated with the analogous product that are wholly absent from the beneficial use, then this is sufficient information to demonstrate that exposures to these stressors would be lower with the beneficial use and do not warrant further comparison.

This comparison assumes the same receptors will be present, regardless of whether a beneficial use or an analogous product is selected, and that the characteristics, behavior, and sensitivity of these receptors are unchanged. Thus, any differences in exposures and subsequent adverse impacts are driven only by changes in the stressor levels present in the environmental media. A direct comparison of stressor levels at the point of exposure may involve some amount of fate and transport modeling if field measurements are not available, which can greatly increase the complexity of this step. However, it is often possible to use a surrogate in place of measured stressor levels to reduce the computational burden. For the purposes of this step, a surrogate is data on one variable (e.g., constituent release rate) that can be used to reliably approximate the magnitude of another (e.g., stressor levels at point of exposure) and, as a result, can substitute for the other in the comparison. It is important that a clear and consistent proportional relationship can be demonstrated between these two variables. The stronger the relationship, the greater confidence that comparison results are accurate.

One potential surrogate is the rate at which stressors are released into environmental media. Because many stressors are released in trace concentrations, it can often be assumed that surrounding environmental conditions will dictate the fate and transport of these constituents, regardless of the source. The same constituent released at the same rate would be anticipated to result in the same stressor levels in downgradient environmental media. However, this

assumption may not be valid when a beneficial use markedly changes the ambient pH, ionic strength, or other environmental conditions that could affect fate and transport. Such a scenario is most likely to occur when a fine, granular beneficial use is applied in large quantities relative to the surrounding environmental media.

Another possible surrogate is the bulk concentration of stressors, if it can be shown that both releases and resulting stressor levels at the point of exposure are directly and consistently proportional to these concentrations. This is easiest to demonstrate when receptors are exposed directly to the beneficial use. However, this assumption may not be valid when there are multiple factors that control the release rate. For example, changes to the level of organic carbon, soluble salts, and other chemical components (some of which may not be identified as potential stressors) may inhibit or facilitate the release of stressors in ways that cannot be predicted based solely on bulk concentration. Changes to the physical composition can also affect releases by altering the size and connectivity of internal pore spaces that allow stressors to escape into surrounding media. These changes can result in different release rates, even when bulk concentrations are identical.

Example: Surrogates

A hypothetical secondary material is proposed for use as generated. The secondary material is a fine powder that can be beneficially used by mixing small amounts with soils to improve structure and promote drainage. The analogous product it replaces is a virgin material of similar composition that must be transported from a mine located a considerable distance away. There are multiple inorganic chemical constituents that are known to be present in both the beneficial use and the analogous product.

For exposures through direct ingestion of the beneficial use or analogous product that are mixed with the soil, the bulk concentration of chemical constituents might be used as a surrogate. Because the stressors are directly ingested, the concentration at the point of exposure is directly proportional to the bulk concentration in the beneficial use and analogous product. However, such a comparison presumes that the bioavailability of stressors within the beneficial use is comparable to those in the analogous product.

For exposures through ingestion of impacted groundwater, bulk concentration is often a poor indicator of actual release rates and, thus, a poor surrogate for stressor levels at the point of exposure (U.S. EPA, 2009). However, it may be possible to use measured release rates instead. Because both the beneficial use and analogous product are used in small amounts relative to the surrounding soil, and because all of the constituents are released in trace levels, it can often be assumed that the chemical constituents released behave similarly once mixed with environmental media where ambient conditions dictate fate and transport.

The secondary material may be only one of several raw materials used in the manufacture of a beneficial use. The mixing of these raw materials can cause changes to the physical or chemical composition of the materials and result in substantially different releases and resulting stressor levels in downgradient environmental media than would be predicted based on knowledge of the individual raw materials. If it can be shown that neither the secondary

material nor the replaced virgin material interact with the other raw materials in a way that would change either the physical or chemical composition of these or other raw materials, it may be possible to directly compare these two raw materials. Otherwise, it is better to compare the final beneficial use and analogous product, rather than any individual raw material. However, in such a comparison, it is important to account for the natural variability of each raw material to ensure that the effects of substituting the secondary material are not obscured by the variability of other raw materials.

Example: Cement vs Aggregate in Concrete

The portland cement used in standard concrete mixes undergoes extremely complex chemical reactions when mixed with water, transforming it from a granular powder into a monolithic solid with a complex matrix of internal pores. The size and interconnectivity of these pores influences the rate that stressors can be released from inside the concrete. Substituting a secondary material for some or all of the cement can alter the density of the concrete by changing the size and connectivity of the pores. Because of the changes to the chemical and physical composition of the raw cementitious materials, it is unlikely that a direct comparison of the raw materials will provide an accurate estimate of the comparability of the beneficial use and analogous product.

The large stone aggregate used in standard concrete mixes is effectively inert and does not react with the cementitious matrix that surrounds it. If the secondary material that replaces this aggregate is also inert and does not result in changes to the physical composition, such as the size of internal pores, then it may be reasonable to compare the secondary material directly to the aggregate it replaces under the environmental conditions relevant to the concrete matrix. Releases from the two materials into the internal pores would be subjected to the same conditions before escaping into surrounding environmental media.

4.2. Considerations when Conducting the Comparison

Once the exposure pathways and any relevant surrogates that will be compared have been identified, a review of the available data will help determine the comparison approaches that are best suited for the beneficial use evaluation. During this review, it is important to identify the different sources of variability within the available dataset to ensure that these sources do not obscure actual differences or, conversely, cause the appearance of differences that do not exist. There may be several sources of variability beyond the natural heterogeneity of individual raw materials incorporated into the beneficial use and analogous product. Two common examples are differences in the design of the beneficial use and analogous product and differences in sample measurement:

- Variability in design arises when the beneficial use and analogous product do not have a fixed design specifications. In these cases, varying amounts of each raw material are used to meet the specific needs of a project. Altering the ratio of raw materials directly affects both the chemical and physical composition of the beneficial use and analogous product,

which, in turn, can alter the magnitude of releases and the resulting stressor levels in downgradient environmental media.

- Variability in sample measurement arises when there are differences in how samples are collected and analyzed. One common example is differences in the laboratory conditions under which samples are analyzed. These conditions may be specified by the test methods (e.g., pH) to mimic environmental conditions that may be present in the field or may simply reflect the ambient laboratory conditions at the time the tests are performed (e.g., temperature).

When data are compiled from the literature, there is a greater chance for these types of variability to be present and go unrecognized in the resulting dataset. If a particular source of variability is not the focus of a study, it may not be controlled for in the experimental design or even discussed in the text. This information can sometimes be reliably inferred from information reported or obtained by contacting the authors. But, if key information is unknown, the data may introduce an unacceptable amount of uncertainty into the beneficial use evaluation. Some ways that these sources of variability might be controlled for is ensuring the full range of variability is equally well represented or by subdividing the samples into related categories for separate comparisons.

Example: Variability in Leachate Data as a Function of pH

Multiple leaching tests have been developed by EPA and other organizations to address different environmental conditions (more detail provided in **Section 3** of **Appendix A**). If the comparison relies on data drawn from the existing literature, it is likely that the available dataset will contain samples collected with more than one of these leaching tests. Some of these tests specify the initial pH of the sample, while others specify the final equilibrium pH. This can result in an uneven distribution of data over the entire pH scale, only a portion of which may be relevant to the beneficial use evaluation. Data within the relevant pH range may be clustered around a single pH value, resulting in disproportionate representation of this pH in a comparison of the full dataset. If there is not even representation over the relevant pH range, it may still be possible to group data into smaller pH brackets and compare these brackets. However, if data are too sparse to conduct a comparison over part of the relevant pH range, it may not be appropriate to draw final conclusions because the leaching behavior of different materials can differ markedly with changes in pH.

Whether comparing stressor levels at the point of exposure or some surrogate, it is critical that comparisons consider the entire distribution of potential values, rather than individual data points. This ensures that both the magnitude and frequency of possible values are reflected in the comparison. While an analogous dataset may contain one or a few data points that are higher than any in the beneficial use dataset, such a limited comparison would not provide enough context for these data points. These high values may be valid measurements, but may also be statistical outliers within the larger dataset. And while this may indicate that higher

exposures could result from the analogous product, the beneficial use will not always substitute for this relatively small subset of the analogous product. Thus, there remains the possibility that the beneficial use will result in higher exposures in a majority of cases. A comparison of full distributions, including any extreme values that are valid data, provides a greater confidence in the final conclusion whether the proposed beneficial use and analogous product are comparable or not.

The most suitable methods for comparing data will depend in part on the magnitude of any differences that exist between the distributions for the beneficial use and analogous product. When differences are so great that there is little or no overlap between distributions, then a simple graphical or tabular presentation of the distributions or relevant summary statistics may suffice to demonstrate that differences exist. But, as the extent of overlap increases, more sophisticated methods may be necessary to demonstrate whether apparent differences in the available data reflect two separate distributions. Statistical tests are one of the most common and powerful methods available to compare distributions. A great deal has previously been written about the use of statistical tests to compare constituent concentrations in environmental media (U.S. EPA 1974; 2013). Additional resources that may aid in the selection and application of statistical tests and other methods are presented in **Section 5** of the **Appendix**.

4.3. Potential Sources of Uncertainties

Some uncertainty may be introduced into the evaluation because the comparison provides an indirect estimate of the potential for adverse impacts from the beneficial use, and only demonstrates whether this potential is comparable to or lower than that from the analogous product. The analogous product selected for comparison acts as the risk management criteria in this step. It is intended to represent an alternative scenario that is not anticipated to pose concerns to human health or the environment. This presumption can often made because analogous products are composed of virgin materials, have broad public acceptance, and already have limitations placed on appropriate use as a result of years on the market. Yet, the analogous product is later found to be inappropriate for a particular use, this may warrant a reevaluation of any stressors eliminated through the comparison to determine whether the beneficial use poses similar concerns.

Comparisons can be complicated by the fact that a beneficial use is not always applied in the same way as the analogous product it replaces. For example, the advantage of a beneficial use may be cost savings from smaller or less frequent applications than the analogous product. In this example, the beneficial use might result in reduced releases to the soil, even when the bulk stressor concentrations in the beneficial use are somewhat higher. It can be difficult to integrate this additional source of variability into the comparison because, among other things, it requires information on the range of application rates for both the beneficial use and the analogous product. Actual use rates can be influenced by economic considerations, public perception, and other factors that make precise estimates difficult and add further uncertainty

into the comparison. In this specific example, where the analogous product is used at a higher quantity or frequency, it may still be possible to compare it with the beneficial use under the assumption that both are used in the same way. Because this assumption overestimates the mass loading from the beneficial use, there will be greater confidence that these results are protective if the comparison finds a lower potential for adverse impacts from the beneficial use.

Regardless of the level of sophistication, quantitative comparisons will only be as reliable as the available data allow. The presence of natural heterogeneity among and within samples, matrix interference, high detection limits, and other sources of uncertainty can obscure the true distributions and result in erroneous conclusions when the magnitude of uncertainties are greater than the actual differences. Some sources of uncertainty, such as natural heterogeneity, might be reduced through the collection of additional data. Yet others, such as the sensitivity of available laboratory equipment, are unlikely to be resolved in a timeframe relevant to the beneficial use evaluation. One way to mitigate these remaining uncertainties is to provide supplementary information to corroborate the results of the initial comparison. Some examples might include quantitative comparison of additional surrogates or qualitative discussion drawn from the literature about stressor behavior under similar environmental conditions. Although there are likely to be uncertainties associated with the supplementary sources of information, the more evidence that can be provided to support the initial comparison, the more confidence there will be in the results.

4.4. Summary

The purpose of this step is to determine whether the potential for adverse impacts to human health and the environment from the proposed beneficial use is comparable to or lower than from an analogous product. The substitution of a secondary material for a virgin material can change the chemical and physical composition of the original analogous product in a number of ways that can affect releases and subsequent exposures. It is critical that these and other differences are identified and accounted for to ensure that the comparisons are valid for the range of relevant circumstances. If the potential for exposures from the beneficial use that are higher than from the analogous product, or unique to the beneficial use, then these additional exposures warrant further evaluation in another analytical step.

Section 5. Screening Analysis

Screening analysis is a streamlined step that minimizes the amount of data and computation required to reach well-substantiated conclusions. A screening can be conducted in several ways, but the type and amount of available data will often dictate which approaches are most suitable. Many of these screening methods aim to reduce the complexity of the modeled system by using a combination of high-end data and simplifying assumptions, which result in exposure estimates that are anywhere from a reasonable upper bound to unrealistically extreme. If an exposure is found to be below levels of concern based on these methods, it can be eliminated from further consideration with a high degree of confidence. This section discusses the selection of screening benchmarks and some methods available to conduct a screening. This section builds on documents and tools presented in **Sections 6**, **7** and **8** of the **Appendix.**

5.1. Selection of Screening Benchmarks

A screening benchmark is a discrete value, typically a concentration in environmental media (e.g., soil, ground water), set at a level below which exposures are not anticipated to pose concern. These benchmarks are compared with high-end stressor levels that may occur in environmental media to identify individual stressors or entire exposure pathways that do not warrant further evaluation. However, given that the exposures estimated in the screening are biased high, an exceedance of screening benchmarks at this step does not necessarily mean that the beneficial use poses concern, only that further evaluation may be warranted.

The specific screening benchmarks relevant to a particular beneficial use evaluation will be determined by the relevant stressors, exposure pathways and receptors. Relevant screening benchmarks may have already been developed by federal, state and non-governmental organizations. If an evaluation relies on these existing benchmarks, it is important to consider how well each aligns with the conceptual model. Existing screening benchmarks may also consider technological, economic and other factors (e.g., background concentrations) that are not relevant to the ongoing beneficial use evaluation. Even if a benchmark does not perfectly align with the conceptual model, it may still be useful. A screening benchmark that differs from the conceptual model (e.g., based on sensitive receptors that are not present) might still be useful if it can be used to demonstrate that an exposure does not pose concern for the receptors that are present.

Alternatively, evaluation-specific benchmarks can be derived. This allows the benchmarks to incorporate a set of risk management criteria or to capture considerations specific to that evaluation. The development of benchmarks requires integration of information on the stressors released, the environmental media impacted, the receptors exposed and the risk management criteria selected. **Table 6** presents a discussion of some potentially relevant

considerations. More information on how to calculate screening benchmarks, as well as links to some existing benchmarks, is presented in **Section 6** of the **Appendix**.

Table 6. Considerations for Screening Benchmarks

Dose-Response Relationship	These relationships describe the likelihood and severity of health effects that may result from exposure to a stressor ("the response") as a function of the magnitude and route of exposure ("the dose"), and are developed through the analysis of data from the scientific literature. The shape of these relationships (e.g., linear) depends on the properties of the stressor, the type of response that may occur (e.g., tumor, incidence of disease), and the susceptibility of the exposed receptor (U.S. EPA, 1989). Screening benchmarks rely on a point estimate of these relationships, expressed as a single toxicity value, to capture the potential for health effects. Further information can be found in **Section 7** of the **Appendix.**
Exposure Factors	Exposure factors are the physiological, behavioral and sociological attributes of a receptor that determine the magnitude of potential exposures. Relevant examples might include age, body weight, ingestion rate of water or produce, and life expectancy. For each factor, there can be a great deal of variability among the individuals in a population (U.S. EPA, 2011). Screening benchmarks rely on a point estimate of these factors, often specific to a sensitive subpopulation (e.g., children), to capture the magnitude of potential exposures. Further information can be found in **Section 8** of the **Appendix.**
Exposure Duration	Exposure duration is the amount of time that a receptor is exposed to a stressor. Acute values are developed for exposures that occur over a short period of time. Chronic values are developed for prolonged or repeated exposures, which can last for many years (U.S. EPA, 2011). Other values may be developed for intermediate (i.e., subchronic) lengths of time. Screening benchmarks generally focus on chronic exposures because associated health effects often occur at lower exposure levels. However, it is important to be aware that some acute health effects, such as developmental toxicity, can occur at even lower levels. Further information can be found in **Section 8** of the **Appendix.**
Risk Management Criteria	Screening benchmarks typically represent high-end (e.g., reasonable maximum) or bounding (e.g., worst-case) exposures, which are higher than those expected to occur for the majority of the population. The decision of how extreme to make these values represents a risk management decision. The use of stressor levels and screening benchmarks in this step that approach a worst-case scenario or even more extreme values may provide greater confidence in the decision to remove stressors from further evaluation, but it can also negate the usefulness of the screening by causing the appearance that all stressors pose concern.

There are instances where a single benchmark has been developed for a group of structurally similar stressors (e.g., PCB toxicity equivalence factors) or for cumulative exposures across multiple media (e.g., blood lead levels), but these are uncommon. As a result, a beneficial use evaluation is likely to need multiple screening benchmarks to address the different stressors and exposure routes contained in the conceptual model. It is generally not necessary to identify screening benchmarks for every single receptor that may be exposed, as benchmarks developed for the highly exposed individuals (HEIs) within a population will also be protective of other

individuals with lower exposures. Yet it is important to be aware that the HEI may not be the same for all exposure pathways.

For some stressors, there may be no screening benchmarks available and insufficient data to allow the calculation of values. This is often due to insufficient data on the dose-response relationship for a stressor, as other data gaps are easier to fill with generic, protective assumptions. The absence of this type of data does not necessarily mean that there is no potential for adverse impacts. In the absence of quantitative benchmarks for comparison, a qualitative discussion of these stressors can still be provided. Information such as the tendency of a chemical stressor to bioaccumulate, the stressor fate and transport, or the behavior and toxicity of similar stressors might be drawn upon to better characterize the potential for adverse impacts. However, even when a suitable surrogate is available, there will be some uncertainty associated with physical and chemical data that cannot be quantified.

5.2. Comparison at Point of Release

A comparison of stressor concentrations at the point of release to screening benchmarks assumes negligible dilution or attenuation occurs after release into the environment in order to capture the highest theoretically possible exposures. For some exposure pathways, such as ingestion of ground water, this assumption may greatly overestimate potential exposures. For other exposure pathways, such a direct hand-to-mouth ingestion of the beneficial use, this assumption may be more realistic. If exposures at the point of release are found to be below all levels of concern as defined by the selected screening benchmarks, then no further evaluation is warranted for that particular exposure route. However, when employing these methods, it is important to be aware that some stressors may not be present at the point of release. Some may be formed as the result of complexation, transformation or degradation processes and occur at higher levels downgradient from the beneficial use (e.g., transformation of elemental mercury into methyl-mercury; U.S. EPA, 1997b). Therefore, consideration of exposures beyond the point of release may still be warranted.

The available data on releases may be reported as a rate, rather than a concentration. In these cases, some additional calculation and potentially some additional data will be needed to convert these rates into concentrations in environmental media before a comparison to screening benchmarks is possible. For releases that can be approximated as constant over time, assumption of steady state conditions may allow a relatively straightforward calculation. Steady state is the point at which stressor levels released from the beneficial use equilibrate with a defined volume of media in contact with the beneficial use, and the stressor levels within that volume are effectively constant. When there are appreciable losses of the stressor from the media, whether through stressor degradation, transport of impacted media away from the beneficial use, or other processes that affect equilibrium, steady state can be calculated through a mass balance of the stressor levels released into and lost from the media. When losses from the media are minimal compared to releases, steady state can be defined by gradients

present between the beneficial use and the media (e.g., concentration, pressure). The calculated steady state levels represent the highest sustained concentrations a receptor could be exposed to and provide an upper bound on potential chronic exposures.

Example: Steady State

A hypothetical beneficial use is proposed as a building material, but it has the potential to emit volatile chemicals into the air at low rates. Habitable structures are generally required to maintain a certain air exchange rate with the outdoors, resulting in non-negligible losses from the transport of air between the building interior and the outdoors. Thus, at a minimum, calculation of a steady state concentration will require a balance between the emission of volatiles into the building and the loss of volatiles along with air to the outdoors. Losses to the outdoors will not be constant, as the air exchange rate will fluctuate based on temperature, barometric pressure, the presence of open doors/windows, and other factors. But a single low-end value can be selected under the assumption that environmental conditions present will minimize air exchange and that all doors/windows remain closed. In addition to air exchange, other considerations may be important on a case-by-case basis, including chemical degradation and adsorption/desorption from household surfaces (e.g., carpet, furniture). An example of a mass balance for stressors in indoor air is shown in **Figure 5**.

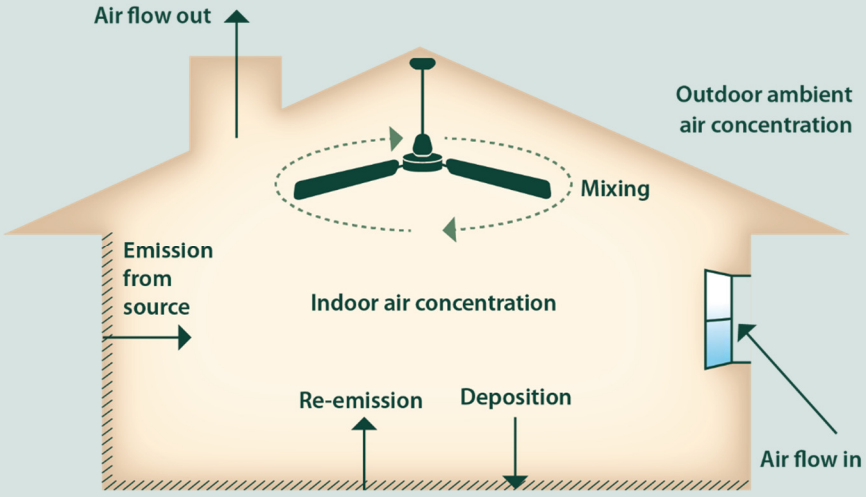

Figure 4. Mass balance of stressors in a home

5.3. Comparison at Point of Exposure

Often, stressors will migrate some distance through the environment before reaching a receptor. During transport, stressor levels can be diminished through dilution, dispersion, degradation, precipitation and other processes. They may also be increased through the complexation, transformation or degradation of other stressors. Comparisons at the point of exposure account for the change in stressor concentrations that result from these processes before estimation of exposure levels. These approaches are more realistic than a comparison at the point of release, but are still intended to remain protective through the use of data and assumptions that bias the calculated exposures higher than are likely to occur during use.

The potential magnitude of reduction in stressor levels can be quickly estimated by applying previously developed dilution and attenuation factors (DAFs), which are ratios of initial stressor levels at the point of release and final stressor levels at the point of exposure. The development of these ratios can require a great deal of complex modeling. Therefore, at this stage of the evaluation, the aim is to identify existing DAFs that provide an effective bound on the environmental conditions relevant to the beneficial use. Because DAFs are dependent on the properties of the stressor and a given medium, rather than the stressor source, these ratios may still be applicable to a beneficial use evaluation even when the source of the stressors is different. However, stressors can interact with media in ways that are non-linear with respect to concentration, temperature and other factors. In addition, interactions between different stressors have the potential to affect fate and transport. As a result, it is important to understand and discuss the basis for a DAF to demonstrate that the magnitude of reduction identified is applicable to the beneficial use evaluation.

Example: Ground Water Dilution-Attenuation Factors from New Jersey

In 2012, the New Jersey Department of Environmental Protection (NJDEP) established a committee to review and update guidance for developing site-specific soil remediation standards based on potential impacts to ground water. Drawing from previous EPA guidance (U.S. EPA, 1996), the NJDEP identified a single, default DAF for all stressors and discusses how to modify this default to account for site-specific considerations. Although this guidance was originally developed for cleanups, the DAFs may also be relevant to beneficial uses mixed with soil or otherwise applied to the land. Further information on this DAF can be found in *Development of a Dilution-Attenuation Factor for the Impact to Ground Water Pathway* (NJDEP, 2013).

Dilution and attenuation can also be estimated through fate and transport models, which combine mathematical equations and user-provided data to estimate the difference in stressor levels present at the point of release and point of exposure. These models vary widely in complexity, but some have been developed specifically for screening-level evaluations. These screening models deliberately reduce the complexity of the modeled system with simplifying assumptions in order to provide a protective estimate of exposures. Consequently, screening models typically require fewer user-defined inputs than other models. The inputs required by specific screening models will vary, but are typically point estimates of stressor concentrations at the point of release and some of the more-sensitive environmental variables. As a result, screening models require a risk management decision on how to calculate these point values. In some instances, models may provide default inputs for some variables that a beneficial use evaluation may choose to rely on, provided these defaults can be shown to provide an upper bound for the scenario under evaluation. Additional resources that may be helpful during selection of screening and other models are presented in **Section 8** of the **Appendix**.

5.4. Potential Sources of Uncertainty

The screening analysis can be relatively quick to carry out because it replaces variability with point estimates and fills data gaps with simplifying assumptions. As a result, quantitative estimates of exposure levels and the screening benchmarks used for comparison will contain high levels of uncertainty. The magnitude of these uncertainties may not be quantifiable, but the direction should, on the whole, be toward an overestimation of potential exposures. This results in an analysis that is biased toward the retention of some stressors that do not actually pose concern. Yet this approach also affords a high degree of confidence in the decision to screen out stressors found to be below screening benchmarks.

Each different screening approach provides a single, quantitative estimate of potential stressor levels in a medium that is then compared to individual screening benchmarks. This comparison requires collapsing the variability associated with stressor release rates, fate and transport mechanics, and receptor characteristics down to point values. This is not the same as eliminating or completely ignoring variability, because variability is an inherent part of natural systems that can never be eliminated. The selection of point values requires an understanding of variability to determine what constitutes a high-end value. To ensure that a screening remains protective of sensitive receptors within the population, enough variables are set to a high-end value to ensure that the screening does not underestimate the potential for adverse impacts. A beneficial use evaluation may set every last variable to a high-end value; however, this may reduce the efficacy of the screening analysis and retain more stressors for further evaluation than is necessary. Reducing the selected value for some variables does not necessarily make a screening less protective, as the calculated exposures might still reflect or exceed the upper bound of realistic exposures. Yet, without incorporation of variability into the evaluation, it is not possible to know where the calculated exposures fall relative to the true distribution of possible exposures.

Consideration: Selecting High-End Values

In instances where both the range and distribution of a variable are well known, either a maximum or an upper percentile value might be used, based on the needs of the particular evaluation. Where the distribution is poorly characterized, a maximum value may still be useful. However, as the amount of data decreases there will be greater uncertainty that the maximum reported value falls near the true maximum, or is even representative of the high-end for that variable. Depending on the amount of available data, it may still be possible to use statistical analysis to calculate an upper confidence limit for data (U.S. EPA, 2002). Even in the worst-case scenario where there is great uncertainty surrounding both the range and distribution of data, it may still be possible to use a bounding estimate that is known to fall outside the true range, so long as justification is provided for the selected value. There is no “bright line” available to determine which approach for deriving a point value is best suited for a given evaluation. Therefore, professional judgment is critical.

5.5. Summary

A number of approaches are available to implement a screening analysis. Depending on the needs of an evaluation, the use of more than one step may be helpful. These screening methods typically incorporate uncertainty into the evaluation in a precautionary manner, and are neither designed nor intended to provide a precise quantification of exposures or the potential for adverse impacts. The benefit of this step is the reduced need for more resource-intensive analytical methods. While this step may provide sufficient information to prioritize resources and rule out exposures for further evaluation, the calculated exposure levels may not be meaningful beyond the limited context of the screening. Therefore, any exposures found to be above screening levels should be retained for further evaluation. However, if more refined analyses cannot be performed and other sources of information are not available, this may indicate that uncertainties are too great to demonstrate whether the beneficial use is appropriate as proposed.

Section 6. Risk Modeling

Risk modeling consists of a refined, quantitative and qualitative characterization of the potential for adverse impacts from the proposed beneficial use. This is accomplished with more realistic data and models that are used to calculate risks. These calculated risks represent quantitative estimates of the probability that adverse impacts will occur. The objective of this step is to reduce the source of uncertainty remaining in the evaluation enough to allow conclusions about potential risks associated with the proposed beneficial use. Simply calculating risks for the exposures estimated from screening-level analyses will not provide much additional information for decision-makers. Because of the more rigorous data requirements, risk modeling is the most complex analytical step discussed in this document. As a result, it may be worthwhile to first review the results obtained from previous steps to determine whether they can be further refined. The remainder of this section details some considerations involved in identifying the most suitable model or models. This section builds on documents and tools presented in **Sections 9** and **10** of the **Appendix.**

6.1. Model Selection

There are numerous models available to address different components of an exposure pathway. Individual models may quantify stressor releases ("source term models"), transport of stressors in environmental media ("fate and transport models"), receptor uptake ("exposure models"), likelihood and severity of health effects ("dose-response models"), or a combination thereof. The following text focuses on the selection of fate and transport models because these are the type most likely to be encountered as part of beneficial use evaluations.

All models have strengths and limitations, so it is important to weigh the pros and cons of each carefully. The most complex models will not always be those best suited for an evaluation. Complex models require increasingly precise datasets, which may not be feasible to collect as the geographic scale of the evaluation increases. And running models with insufficient data can actually result in greater uncertainty associated with model results. Even when enough data are available, the added specificity in these models may not add value to the evaluation when less complex models are sufficient to reach a definitive conclusion. Conversely, use of less complex models will involve greater reliance on simplifying assumptions and high-end estimates to ensure that the evaluation remains protective. Some evaluations may not be able to tolerate this additional level of uncertainty and still be able to reach final conclusions. Given these complexities, it may be useful to consult experts knowledgeable in the fields of risk assessment and environmental fate and transport modeling during the selection process. Further discussion of some considerations involved in model selection can be found in *Risk-Based Corrective Action Fate and Transport Models: Compendium and Selection Guidance* (ASTM, 1998); specific state agencies may have more tailored guidance available. Examples of other readily available fate and transport models are presented in **Section 9** of the **Appendix**.

6.1.1. Model Assumptions

As a result of the extremely complex nature of environmental systems, the mathematical equations needed to account for all the chemical or physical processes that might affect stressor fate and transport may not be known, may not have known solutions, or may require a prohibitive amount of time and resources to solve. To address this issue, models often rely on simplifying assumptions to reduce the number and/or complexity of the equations that must be solved. Other models avoid solving these equations altogether by developing empirical relationships identified through field or laboratory experiments. Both means of addressing environmental complexity can place limitations on the types of stressors, environmental conditions, or chemical and physical processes a given model can consider. While the model may still run and return results outside of these limits, the results may not be meaningful. Therefore, it is important to read the supporting documentation for each model to understand the major assumptions and to ensure that the models are valid for the proposed beneficial use.

6.1.2. Deterministic and Probabilistic Models

Inputs are the data that the user provides the model in order for it to run. These inputs are generally data on the characteristics of stressors (e.g., concentration), environmental media (e.g., hydraulic conductivity), or potential receptors (e.g., distance from the source). Fate and transport models can be divided into two broad categories based on the amount of data required for each model input. Deterministic models treat each input as a constant that can be characterized by a single value. The inputs provided by the user are used to conduct one model run (or "iteration"), which in turn generates a single output representative of that unique combination of inputs. Probabilistic models treat inputs as variables that require a distribution of possible values. The inputs provided are used to conduct multiple model iterations, each with a varied combination of inputs. All of the individual outputs from each model run are compiled to generate a distribution of outputs based on probability of occurrence. The relationship between probabilistic and deterministic inputs and outputs is shown in **Figure 6**.

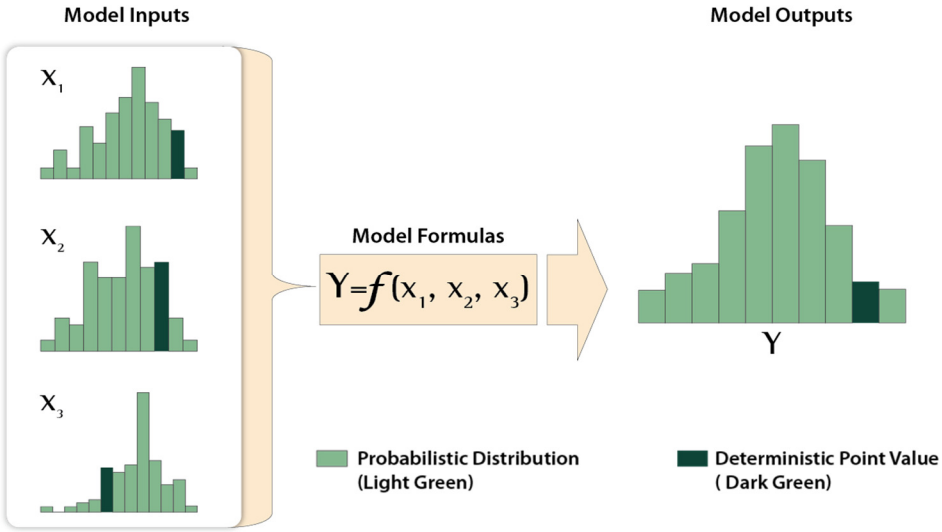

Figure 5. Relationship between probabilistic/deterministic inputs and outputs.

Because the primary difference between deterministic and probabilistic models is the amount of data required, some probabilistic models can be made deterministic by assigning only a single value to each input and some deterministic models can be made probabilistic by running varied inputs and aggregating the results. Yet, the use of a model counter to its intended application is unlikely to be the most effective use of resources when other, more suitable models are available. Furthermore, models are not required to be entirely deterministic or probabilistic. Some may be designed to accept a combination of single values and distributions as inputs, while others may have default values or distributions built into the model framework. These hybridized models are an attempt to minimize computational intensity, while maximizing the precision of the model by focusing heightened data requirements on the most sensitive variables.

Consideration: The Monte Carlo Simulation

A Monte Carlo simulation is a specific type of probabilistic analysis characterized by random sampling of probability distributions provided by the user for each input variable. In a Monte Carlo simulation, the selected model is run deterministically many times, with a different set of values selected each time. Repeating this process enough times produces a distribution of outputs. The greater number of model runs, the more stable and well-defined the resulting distribution will be. Yet, due to the large number of model runs required, a Monte Carlo simulation may take considerable time to complete for more complex models.

Monte Carlo simulations are useful because they reduce the potential for human error and bias when accounting for numerous variables. In addition, the extensive number of simulations provides a great deal of data that can be used to identify correlations between variables and the sensitivity of a model to changes in the different variables. However, the results of a Monte Carlo simulation will only be as accurate as the model and data provided allow. Additional discussion about Monte Carlo simulations can be found in *Guiding Principles for Monte Carlo Analysis* (U.S. EPA, 1997a).

The benefit of more deterministic modeling is the comparatively small amount of data required. When deterministic modeling is sufficient to support final conclusions about a given beneficial use, there may not be the need for more complex modeling. However, when there is potential for risks above the selected risk management criteria it can be difficult to draw conclusions because deterministic models do not provide information on the likelihood that the combination of inputs modeled will actually occur. In this scenario, it may be more practical to use a probabilistic model. The benefit of more probabilistic modeling is increased precision from accounting for the variability of inputs and the ability to tie individual outputs to a probability of occurrence. This provides greater context for model outputs. However, even with large datasets, there will likely be some uncertainty that results from natural variability. Additional discussion of the advantages and disadvantages of probabilistic analysis is provided in *Risk Assessment Guidance for Superfund: Volume III—Part A* (U.S. EPA, 2001), as well as in other references presented in **Section 10** of the **Appendix.**

6.1.3. Lumped- and Distributed-Parameter Models

Environmental media can be highly variable, both spatially and temporally. Some examples of variability that may be pertinent to an evaluation are changes in the depth to water table, soil composition and wind speed. Fate and transport models can be divided into two broad categories based on how each accounts for these variations. Lumped-parameter models treat environmental media as homogenous within the region of interest. Each medium is characterized by a single set of input parameters (either individual values or distributions). Distributed-parameter models divide the region of interest into a grid. Each cell in this grid is assigned a separate set of input parameters. **Figure 7** shows the different handling of a variable (soil hydraulic conductivity) within a defined watershed for lumped and distributed models.

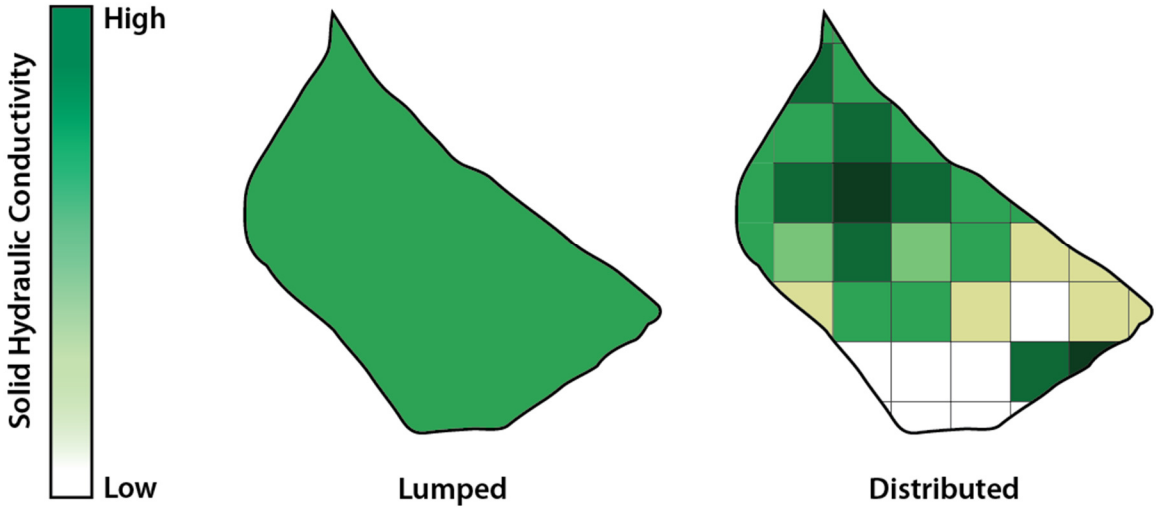

Figure 6. Example of deterministic lumped and distributed inputs for a watershed.

The benefit of lumped-parameter modeling is the comparatively small amount of data required. This type of model is most suitable for scenarios where variations in environmental media can be ignored with respect to distance, time or both without introducing unacceptable amounts of uncertainty into the evaluation. However, when the potential for unacceptable risks is identified and there is the potential for significant variations in the media that could impact fate and transport, it may be difficult to draw final conclusions. In this case, it may be worthwhile to consider distributed-parameter modeling. The benefit of distributed-parameter models is the greater precision provided. However, because of the amount of information required, this type of model is better suited for site-specific or small-scale evaluations for which well-characterized environmental data are obtainable.

6.2. Calculation of Risk

Calculated risks are quantitative estimates of the probability that adverse impacts will occur. Fate and transport models typically output stressor levels in environmental media as a function of time, distance from the point of release, or both. Additional steps are necessary to combine these stressor levels with data on receptor characteristics and stressor toxicity to calculate risks.

A standard way of calculating risk is with equations similar to those used to calculate screening levels. However, instead of solving for a stressor level that corresponds to a specified risk level, the equations are rearranged to solve for a risk level that corresponds to the modeled exposure level. These calculations can be accomplished either manually or with the aid of a model. Regardless of the approach used, it is important to understand the assumptions that underlie these calculations.

Consideration: Discussion of Risk

The risk of adverse impacts to human health and ecological communities can be expressed in different ways (U.S. EPA, 1989):

Carcinogenic effects are typically discussed only for human receptors because of limited available data for ecological receptors. Risks are often expressed as an increase in probability of occurrence that results from an increase in exposure. A 1×10^{-6} risk is equivalent to one additional incidence of cancer for every 1,000,000 individuals exposed.

Noncarcinogenic effects are typically discussed for both human and ecological receptors. Risks are expressed as a ratio (or "hazard quotient") of the stressor level present and the level below which no effects are known or anticipated to occur. Ratios greater than one indicate an effect may occur, with a higher ratio indicating greater potential for occurrence. However, this ratio does not directly correspond to a probability of occurrence.

Similar to stressor levels in environmental media, risks can be calculated deterministically or probabilistically. Deterministic risks are calculated using a single stressor level together with point estimates for exposure factors and stressor toxicity. The selected stressor level may represent the single output from a deterministic model or a single percentile from the distribution output by a probabilistic model. Deterministic risk calculations generally aim to combine high-end (e.g., ingestion rate) and mid-range (e.g., body weight) exposure factors to estimate risks for highly-exposed individuals that are both protective and reasonable, rather than worst-case scenarios. Additional estimates for more moderately exposed individuals are also helpful to place the overall risks in better context (U.S. EPA, 1992). In cases where a beneficial use is placed in a single location with minimal heterogeneity, this type of model might generate a reasonable approximation of real-world conditions. However, when a secondary material is planned for wide-scale beneficial use, deterministic models are best used like screening models to evaluate a high-end exposure scenario.[1]

Alternatively, probabilistic risks may be calculated to capture variability. Probabilistic risks incorporate the range of potential stressor levels generated by probabilistic models, as well as the range of possible exposure factors to generate a more complete distribution of potential

1) Screening models like those discussed in **Section 5** are often deterministic. However, these screening models frequently contain simplifying assumptions that may result in uncertainties that are too great to permit final conclusions about risks.

risks. However, toxicity values are typically left as point estimates. Yet, while probabilistic risks incorporate the variability of exposure factors, it is important to note that certain exposure factors have been studied and characterized for the United States population more extensively than others. Even with the best available data, some level of uncertainty will likely be introduced through the risk calculations.

There may be additional factors beyond total stressor levels present, receptor characteristics and stressor-specific toxicity that impact actual risks. Failure to consider these additional factors may result in an over- or underestimation of potential risks. The relative importance of these factors will differ on a case-by-case basis as a result of different receptors, stressors and environmental media involved in a given evaluation. The information necessary to conduct a quantitative evaluation of these factors may not be available or feasible to collect. Instead, it may only be possible to discuss these factors qualitatively and to indicate the potential to change the calculated risks. **Table 7** briefly discusses some of these considerations. Additional resources that may be helpful during risk calculation, including those listed below, are presented in **Section 10** of the **Appendix**.

Table 7. Examples of Additional Factors Relevant to Risk Calculations

Bioavailability	Bioavailability is the fraction of a stressor present in an environmental medium that will be available for distribution to and interaction with tissues and organs. The actual extent of bioavailability is determined by a host of different environmental factors (e.g., particle size, moisture, redox potential) and receptor characteristics (e.g., age, sex, nutritional state). Further discussion about bioavailability can be found online in the *Bioavailability of Contaminants in Soils and Sediments: Processes, Tools, and Applications* (NRC, 2003) and *Incorporating Bioavailability Considerations into the Evaluation of Contaminated Sediment Sites* (ITRC, 2011).
Aggregate Exposure	Aggregate exposure is the combined exposure to a single stressor through multiple exposure pathways (e.g., oral, inhalation) that share a potential health effect. These aggregate exposures may be simultaneous or sequential, but all occur within the critical window for the health effect. Further discussion about aggregate exposures can be found in *The Framework for Cumulative Risk Assessment* (U.S. EPA, 2003b).
Cumulative Exposure	Cumulative exposure is the combined exposure to multiple stressors that produce the same health effect. These different stressors may interact with one another in antagonistic or synergistic ways that serve to mitigate or exacerbate potential health effects. The extent of these interactions may change based on the level of the stressors present and the order of exposure. Further discussion about the concept of cumulative exposure can be found in *The Framework for Cumulative Risk Assessment* (U.S. EPA, 2003b).

6.3. Potential Sources of Uncertainty

A main focus of risk modeling is reducing uncertainty to the point where well-substantiated conclusions can be made about the potential for adverse impacts to human health and the

environment from the proposed beneficial use. This is typically accomplished by replacing the assumptions and point estimates from the screening analysis with more realistic data. Such assumptions can be retained where desired as a factor of safety, so long as it does not interfere with the ability to draw conclusions from the model results. The following text discusses some common sources of uncertainty associated with risk modeling. These sources may not be unique to risk modeling, but are often more pronounced in this method.

6.3.1. Data Uncertainty

As empirical data replace the point estimates and simplifying assumptions from the screening analysis, the magnitude and direction of uncertainties in the evaluation will shift. The extent of this shift is determined by how well the available data capture the full variability of each input variable. Because even large datasets are unlikely to perfectly capture the full extent of real-world variability, some amount of uncertainty will be introduced through the data used. Careful management of the available data can minimize the impact of this uncertainty on the evaluation.

The most conspicuous source of uncertainty is the amount of data available to define each variable. The less data available for a given variable, the less confidence that the distribution for that variable is well-defined. Yet, while collection of more data will result in some increase in overall confidence, the resulting reduction in uncertainty will not be the same for each variable. This is because each variable has a different amount of natural variability and models may have different sensitivities to incremental changes in a variable based on the underlying equations. As a result, collecting greater amounts of data on variables that are known to be highly variable or that have a greater impact on model results will do more to reduce uncertainty. Some models already identify and address these influential variables through heightened input requirements or through discussion in the associated documentation. When it is unknown which variables exert the greatest influence on model outputs, sensitivity analyses can be conducted.

Consideration: Sensitivity Analyses

Sensitivity analysis is a broad set of tools that can provide insights about the relative importance of different model inputs. There are many possible methods for these analyses. Some involve something as simple as varying one or a few model inputs, usually from "low" to "high" values, while holding other variables constant and observing the changes in model outputs. Others require more complex correlation and regression analyses. This information can inform whether to conduct additional analyses or prioritize resource allocations for additional data collection efforts. However, sensitivity analyses offer no additional insight about the likelihood of a certain combination of inputs occurring. Further discussion of this topic can be found in Appendix A of the *Risk Assessment Guidance for Superfund: Volume III—Part A* (U.S. EPA, 2001).

Another major source of uncertainty is any data processing that is conducted to aggregate and prepare the collected data for use in the selected model. Uncertainty can be introduced in this process when additional calculations are used to transform data into a form that differs from what was explicitly measured, such as the conversion of measured precipitation rates into infiltration rates or the conversion of measured non-detect data to approximated concentrations. These uncertainties can be compounded when the data are drawn from multiple sources. Discrepancies in how the data are collected between sources can contribute different types and magnitudes of uncertainty to the larger dataset. As a result, the data from each source may need to be handled differently to properly account for these discrepancies. Even when the data have been successfully aggregated, the sum of all these individual data points is unlikely to provide a complete, continuous distribution for any given variable. This can result in further uncertainty about how well the data points capture the full distribution. Additional steps can be taken to approximate a more complete distribution from the available data. This can be an effective way to ensure that the extreme tails of a distribution are captured, but not over-represented.

Considerations: Developing Probability Distributions

The most straightforward approach to developing a data distribution is to use the measured data as an empirical distribution, where the probability of occurrence is tied only to the frequency at which a value appears in the dataset. However, this approach can introduce a great deal of uncertainty when the available data are not well characterized or are heavily censored (i.e., when there is a large percentage of non-detects). It may be possible to better characterize the distribution by fitting available data to a known parametric distribution (e.g., lognormal, gamma, Weibul). But some datasets will not fit well into a known distribution, making it difficult to consider the potential for values more extreme than those present in the dataset. When too few data are available to support fitting the data to a distribution, it may still be feasible to use available summary statistics (e.g., minimum, maximum, median) as constraints to generate a distribution that minimizes the assumptions built into the distribution (sometimes referred to as a maximum entropy distribution). However, there is often no "bright line" available to determine which of these or other methods is best suited for a given evaluation. Therefore, some amount of professional judgment will be necessary. Some additional discussion about these concepts can be found in *Options for Development of Parametric Probability Distributions for Exposure Factors* (U.S. EPA, 2000a).

When preparing probability distributions, it is important to be aware that the different variables do not exist in a vacuum. There can be strong correlation between certain variables, such as pH and leachate concentration or age cohorts and body weight. Treating every variable as independent has the potential to skew modeled risks through the use of input combinations that rarely occur in the real world. A careful review of the literature can help identify the various correlations that exist within natural systems, to the extent that these correlations have been previously characterized. Where data are sufficient, these correlations can be captured quantitatively in the beneficial use evaluation by linking variables together. This may involve the development of multiple, separate distributions for certain variables that capture trends in

one variable as a function of changes in another. Where correlations are known or suspected, but sufficient data are not available to link the variables, this source of uncertainty can still be explored qualitatively as discussed in **Section 7 (Final Characterization)**.

6.3.2. Model Uncertainty

Models and the underlying mathematical expressions are inevitably a simplification of real-world conditions, processes and relationships. Model uncertainty results from the inability to exactly replicate all of the individual minutiae involved in environmental fate and transport. However, careful review of the available models can minimize the uncertainty by ensuring that the selected model captures major environmental processes relevant to the beneficial use evaluation.

Review of the available verification and validation that has been conducted for the model is one way to determine the accuracy of model results for the environmental conditions relevant to the proposed beneficial use. Model verification helps determine whether the model code executes as intended. During this process, the model is reviewed to identify and fix any errors that could cause it to crash or improperly implement the computer code. This is accomplished through a combination of peer review and beta testing. Independent peer review identifies any errors in the conceptual framework and mathematical expressions relied on in the model, while beta testing involves running the model under a range of conditions to identify errors that may occur. When a model has undergone this level of review, there is greater confidence that both model code and the underlying mathematical formulas are sound.

Even if the mathematical formulations are theoretically sound, the necessary simplifications can ignore real-world heterogeneity (e.g., aquifer discontinuity) or neglect environmental processes (e.g., colloidal transport) that can impact fate and transport. Model validation helps to determine whether a model accurately represents the environmental system in question. Validation studies evaluate the accuracy and precision of a given model by comparing stressor levels predicted by the model to actual levels measured in either the field or laboratory. If a model is shown to perform well for the environmental conditions relevant to the beneficial use evaluation, then there is much greater confidence that the simplifying assumptions included in the model do not add appreciable uncertainty to the evaluation.

6.4. Summary

Risk modeling is the most complex of the analytical methods discussed in this document. It relies on more realistic data and models that refine the estimates of release, fate, transport and exposure that are used to provide a more realistic estimate the actual risks to receptors than a screening analysis. The primary goal of this step is to minimize the uncertainty present in the evaluation to the extent necessary to reach final conclusions that can support a beneficial use determination. However, it is important to emphasize that attempts to make the evaluation more realistic will not necessarily result in a reduction in the overall amount of uncertainty.

This is because empirical data can introduce additional types of uncertainty that arise from imperfect knowledge about the system under evaluation. The direction and magnitude of these new uncertainties may not be as obvious as those associated with high-end or worst-case assumptions. However, such assumptions can be retained where desired as a factor of safety, so long as they do not interfere with the ability to draw conclusions from model results. Regardless, it is important to ensure that any data used are of adequate quantity, quality and specificity for the model selected. Even the most accurate model will not generate meaningful results if the underlying data are of poor quality.

Phase III:

Final Characterization

Section 7. Final Characterization

Final characterization is the third and final phase of a beneficial use evaluation. The goal is to integrate the key findings, assumptions, limitations and uncertainties identified throughout the evaluation into a final conclusion about the potential for adverse impacts to human health and the environment from the proposed beneficial use. While this may involve some further quantitative and qualitative analysis of the data, the emphasis is on providing context for the results of the beneficial use evaluation in as transparent, clear, consistent and reasonable a manner as possible to inform decision-makers and the general public. This section builds on previous discussions in *Risk Characterization Handbook* (U.S. EPA, 2000b), *Framework for Human Health Risk Assessment to Inform Decision Making* (U.S. EPA, 2014), *Science and Decisions: Advancing Risk Assessment* (NRC, 2009) and other documents presented in **Section 11** of the **Appendix.**

7.1. Summary of Analytical Results

It is useful to provide a concise summary of the analyses conducted and the results obtained. While it is important to have this information documented in greater detail elsewhere to foster transparency and reproducibility, some readers may not have the technical background to parse this more comprehensive discussion. A concise summary that is free of excessive technical jargon helps a wider audience follow the progression of logic through the evaluation and understand how the individual analyses helped answer the questions posed in planning and scoping. This streamlined summary becomes increasingly important as the evaluation grows in complexity because the greater variety and quantity of model inputs and outputs can obscure the variables that exert the greatest influence on calculated risks. The summary can be used to highlight key variables and assumptions that drive these risks. For example:

- Summary of stressors found to pose concern for receptors, including:
  - Sensitive subpopulations that may be more susceptible to adverse impacts than the general population.
  - Environmental conditions that result in higher potential for adverse impacts.
- Description of major decisions that form the basis for the evaluation:
  - Basis for excluding any stressors, exposure pathways or receptors from analysis.
  - Rationale for selection of analytical methods and any alternatives considered.
  - Key assumptions, policy decisions and risk management considerations that factored into decisions.
  - Use of extrapolation or other handling of raw data.
- Known strengths and weaknesses of the assessment:
  - Existence of any major data gaps.
  - Known limitations of any models used.
  - Potential for calculated risks to change over time.

7.2. Characterization of Uncertainties

As stated in the discussion of planning and scoping in **Section 2**, the presence of uncertainty can bias analytical results and lead to incorrect conclusions if it is not accounted for during the evaluation. During planning and scoping, there is an opportunity to manage uncertainty through the selection of methods that either minimize it or deliberately bias it in a known, protective direction. Yet some sources of uncertainty will inevitably remain in the evaluation. The aim in this phase of the evaluation is to document the remaining sources and, to the extent practicable, discuss the potential for evaluation results to change if these uncertainties could be fully addressed. There is currently no single recognized guidance on how to characterize uncertainties (U.S. EPA, 2000b). Thus, professional judgment will be required to determine how to characterize the various uncertainties and how to present this information.

Quantitative characterization can be the most informative way to discuss uncertainty. The aim is to use available data to provide numerical estimates of the extent that uncertainties may alter reported results. This typically involves varying the models, inputs and assumptions used in previous analyses and detailing how the resulting results differ from previous best estimates. The quantification of uncertainties can only be conducted where data is available, and will still be subject to any uncertainties associated with the data and models used. As a result, this type of characterization can give the misleading appearance of greater certainty than actually exists. This problem can be minimized with an accompanying discussion that acknowledges the limitations of quantitative characterization and places the calculations in proper context.

When data are insufficient to express uncertainties numerically, qualitative characterization can provide additional useful information. The aim is to review available lines of evidence and to summarize the potential for uncertainties to alter results through narrative descriptors, such as “low” or “high.” This qualitative interpretation of evidence is subjective and may suffer from ambiguity due to a lack of standardized criteria to define the descriptors used. Therefore, it is essential that a clear and transparent rationale is provided for any conclusions that result from this type of characterization.

There may be many sources of uncertainty within a single evaluation. While it is critical to acknowledge each of these sources, it can be counterproductive to devote extensive discussion to those unlikely to alter evaluation results. For example, discussion focused on uncertainties surrounding stressors that screened out based on a worst-case scenario is unlikely to raise any doubts about the conclusion that these stressors will not pose concern. Sensitivity analyses can help identify the individual variables that exert the greatest influence on the evaluation results and help to focus the discussion of uncertainties. It is common to discuss each uncertainty separately, but it is important to keep in mind that these different sources can compound and exert a greater influence on analytical results together than separately. Unfortunately, information on the relationship between different uncertainties can be sparse, so this type of discussion is often qualitative by necessity.

7.3. Characterization of Potential for Adverse Impacts

The final part of a beneficial use evaluation is consideration of analytical results, together with information on uncertainties, to draw conclusions about the potential for adverse impacts from the proposed beneficial use. These conclusions are intended to communicate a clear picture of potential for adverse impacts, as well as the overall confidence in these conclusions. Decision-makers will use the conclusions presented along with other pertinent considerations (e.g., existing state and federal requirements, public opinion, the existence of a market) to determine whether to allow a use, either as proposed or with some additional conditions. Therefore, it is critical to emphasize any considerations that may influence this determination. **Table 8** presents questions that may be helpful to consider when developing these conclusions.

Table 8. Considerations for Discussing Conclusions

▪ What is the overall picture based on analytical results?	It is important to provide sufficient context for the any numerical results presented in the conclusion. This often means breaking out results in multiple ways to capture variations both between and within different receptor cohorts. Different subpopulations (e.g., children, asthmatics) can vary considerably from the general population. Even within a given exposure cohort, the potential for adverse impacts are not constant because of differences in the behavior, physiology and sensitivity between individual receptors. Presenting a range of possible results can capture the extent to which results may change between highly exposed individuals and more typical members of the population.
▪ Can the potential for adverse impacts be reduced through management?	Sensitivity analyses may reveal that any concerns identified are driven by a specific subset of possible uses. Identifying these subsets can help decision-makers define limits on the beneficial use. For example, a proposed beneficial use may still be appropriate so long as additional conditions are met, such as: ▪ The secondary material substitutes for less than a certain percentage of the virgin materials. ▪ The concentrations of a constituent in the secondary material used are below specified levels. ▪ The use is not exposed to extreme conditions (e.g., flooding, high temperatures). ▪ The use is restricted based on certain features (e.g., greater than a certain distance from water bodies). It may be possible to incorporate variability and uncertainty into these conclusions to delineate between the subsets of possible uses where there is: 1) high confidence that a beneficial use is appropriate, 2) enough uncertainty that additional consideration is warranted on a case-specific basis, or 3) high confidence that a beneficial use is not appropriate.
▪ Do uncertainties place limitations on the conclusions?	Data may not be available to characterize the behavior of a beneficial use for all possible variations in beneficial use design or environmental conditions to which the use may be exposed. Such data gaps can make it difficult to draw unqualified conclusions about the beneficial use, but it may still be possible to draw conclusions about the aspects for which data are available. It is important to highlight the distinction between major sources of uncertainty that may be reduced through additional data collection (e.g., variability) and those that are unlikely to be resolved in the immediate future (e.g., limitations of available models). This can help decision-makers weigh the potential benefits of further data collection and analysis prior to a beneficial use determination.

Glossary

This glossary lists common terms that may be encountered in a beneficial use evaluation and may contain terms beyond those introduced in this document. The definitions presented may not be the only possible definitions and some terms may have different meanings in other contexts. These definitions do not constitute the Agency's official use of terms and phrases for regulatory purposes, and should not be used to alter or supplant those found in any other federal document. Official terminology can be found in the laws and related regulations as published in such sources as the *Congressional Record* and *Federal Register.*

A

Abiotic – Neither alive nor derived from living organisms.

Absorption – The process by which a liquid or gas is drawn into and fills the empty voids of a porous material.

Accuracy – The degree to which a measurement reflects the true quantitative value of a variable.

Acidic – An aqueous solution with a pH below 7.

Acute Health Effect – A health effect in which symptoms develop rapidly. These symptoms may subside after the exposure stops.

Acute Exposure – Occurring over a short timeframe, typically under 24 hours in duration.

Adsorption – The physical adherence or bonding of ions and molecules onto the surface of another molecule.

Advection – Transport driven by the bulk flow of a liquid or gas.

Adverse Impact – Any abnormal, harmful or undesirable change that results from being exposed to stressors in the environment.

Aerobic – Occurring in the presence of oxygen (e.g., O_2).

Aerosol – A suspension of fine liquid and/or solid particles in air.

Agent – See: **Stressor**.

Aggregate – Material formed from the loosely compacted mass of granular material.

Aggregate Exposure – The combined exposure to a single stressor through multiple exposure pathways (e.g., oral, inhalation) that share a potential health effect.

Air – The mixture of gases present at the earth surface; typically composed of 79.0% N_2, 20.9% O_2, and less than 0.1% a mixture of CO_2, Ar, He, and hundreds of other gases originating from both natural and artificial sources.

Air Exchange Rate – The rate at which outside air replaces indoor air in a space. Expressed in one of two ways: 1) the number of changes of outside air per unit of time (e.g., air changes

per hour; ACH) and 2) the rate at which a volume of outside air enters per unit of time (e.g., cubic feet per minute; cfm).

Albedo - The proportion of the incident light or radiation that is reflected by a surface.

Alkalinity - A measure of the capacity of water to neutralize acid without significant pH change. It is often associated with the presence of hydroxyl (OH^-), carbonate (CO_3^{-2}), and/or bicarbonate (HCO_3^-) radicals in the water.

Anaerobic - Occurring in the absence of both free oxygen (e.g., O_2) and bound oxygen (e.g., NO_2) in a given medium.

Analogous Product - A natural or commercial product available on the market that is replaced by a beneficial use.

Anion - An ion with a negative charge.

Anisotropic - Having properties that change as a function of direction.

Anoxic - Occurring in the absence of free oxygen (e.g., O_2). Bound oxygen (e.g., NO_2) may still be present.

Antagonistic Effect - A biologic response to exposure to multiple substances that is less than would be expected if the known effects of the individual substances were summed together.

Anthropogenic - Of human origin.

Aquiclude - A saturated geological formation with insufficient porosity to support any significant water removal or to contribute to the overall ground water regime.

Aquifer - An underground geological formation, or group of formations, that is saturated and sufficiently permeable to yield economically significant quantities of water to wells or springs.

Aquitard - A saturated geologic formation that is permeable enough to contribute to regional ground water flow, but not permeable enough to supply water for economic use.

Attenuation - The process in which contaminant concentrations diminish in a medium due to filtration, biodegradation, dilution, sorption, volatilization and other processes.

B

Background - The concentration of a chemical substance in the environment not due to the site or activity under consideration. Background levels may be naturally occurring (i.e., ambient concentrations of substances present in the environment without human influence) or anthropogenic (i.e., concentrations of substances present in the environment due to human-made, but non-site, sources).

Base Flow - The part of the stream flow that is not attributable to direct runoff from precipitation or snowmelt, usually sustained by ground water upwelling.

Basic - An aqueous solution with a pH above 7.

Bedrock - A layer of solid rock that underlies the soil; can be permeable or non-permeable.

Benthic - Pertaining to the bottom zones of water bodies, where oxygen levels are typically low.

Bias - A systematic error, or deviation from the truth, in results or inferences. Bias can exist between test results and the true value (absolute bias, or lack of accuracy) or between results from different sources (relative bias). If different laboratories analyze a sample for which the true value is known, the absolute bias from the true value would be the difference between that value and the value measured by a laboratory. If different laboratories analyze the same sample, the relative biases among the laboratories would be the differences among the results from the different laboratories.

Bioaccumulation - A general term for the net accumulation of substances in the tissue of an organism at levels higher than those that occur in the surrounding environment.

Bioassay - A standardized procedure for determining the effects of an environmental variable or a substance on a living organism.

Bioavailable - A measure of the fraction of a substance present in a medium that is available to interact with and affect an exposed receptor.

Bioconcentration - The net accumulation of a chemical directly from an environmental medium into an organism.

Bioconcentration Factor (BCF) - The ratio of a contaminant concentration in biota to its concentration in the surrounding medium.

Biodegradation - The decomposition of a chemical that is mediated by a biotic organism, such as bacteria or fungi.

Biodiversity - A measure of the numbers of different species of plants and animals found in a natural environment. Used as an indicator of the overall health of an ecosystem.

Biomagnification - The cumulative increase in the concentration of a substance in successively higher levels of the food chain due to predation.

Biota - All species of animal, plant and other life forms.

Biotic - Relating to, or resulting from, living things.

Biotransformation - The conversion of one substance into another within the body.

Biotransformation Factor (BTF) - An empirical ratio relating the chemical concentration in biota; such as produce, livestock or animal products (such as eggs); to the amount of chemical to which the plant or animal is exposed in soil, feed or other media.

Bounding Estimate - A point value estimate for a distribution that is above the highest (upper bound) or below the lowest values (lower bound) that may realistically occur.

Buffer (Chemical) - A material in a solution that adds resistance to changes in pH when the solution is diluted or mixed with acids or bases.

C

Cancer - A disease of heritable, somatic mutations affecting cell growth and differentiation, characterized by an abnormal, uncontrolled growth of cells.

Cancer Slope Factor - An upper bound, approximating a 95% confidence limit, on the increased cancer risk from a lifetime exposure to a stressor.

Carcinogen - An agent that can cause or contribute to cancer.

Cation - An ion with a positive charge.

Chemical - Any organic or inorganic substance with a defined molecular structure.

Chemical Abstract Service (CAS) Number - A number assigned by the CAS to identify a chemical based on the molecular structure. Individual chemicals can have many multiple common names, but each chemical is assigned a single CAS number.

Chemical Mixture - Any combination of two or more chemicals that retain distinct identities when placed together.

Chronic Health Effect - A health effect that occurs as a result of repeated or long-term exposures.

Chronic Exposure - Occurring constantly or intermittently over a long duration, ranging from several weeks to a lifetime.

Cohort - A group of people within a population who are assumed to have similar characteristics (e.g., age, location, occupation, exposure) during a specified period.

Colloid - A fine particle ranging in size from 1 to 500 nanometers in diameter. Due to the small size, these particles tend to remain suspended in water and can be a major source of turbidity.

Concentration - The total mass of a substance present in a defined volume of a media.

Confined Aquifer - An aquifer bounded above and below by impermeable beds (e.g., bedrock) or by beds of distinctly lower permeability than that of the aquifer itself (e.g., clay).

Consolidation - The densification of soil or other granular material by gravity or mechanical force, which may result in the expulsion of excess water from pore spaces.

Contaminant - Any physical or chemical stressor present in a given medium with the potential to pose a threat to human health or the environment. See also: **Pollutant.**

Control - In an experiment, a control is the baseline group that receives no treatment or a neutral treatment. This group is used to assess the effects of a treatment by comparing the treatment group to the control group.

Correlation - An estimate of the degree to which two sets of variables vary together, with no distinction between dependent and independent variables.

Corrosive - Liquid or aqueous substances that will destroy and damage other materials with which it comes into contact. EPA regulates corrosive wastes with a pH less than or equal to 2.0 or greater or equal to 12.5, as well as those that corrode steel at rates of 6.35 mm or more per year (determined by the National Association of Corrosion Engineers), as characteristic hazardous wastes. These and other hazardous wastes fall outside the scope of this document.

Cumulative Distribution Function (CDF) - An equation that defines the likelihood (or probability) that a variable will be less than or equal to a specified value.

Cumulative Exposure - The combined exposure to multiple stressors that produce the same adverse effect.

D

Data Quality - All features and characteristics of data that bear on its ability to meet the stated or implied needs and expectations of the user.

Data Quality Objective (DQO) - Qualitative and quantitative statements of the overall level of uncertainty that a decision-maker is willing to accept in results or decisions derived from environmental data. DQOs provide the statistical framework for planning and managing environmental data operations consistent with the data user's needs.

Degradation - The process of breaking down a chemical through natural or anthropogenic processes.

Deposition - The settling out of sediment, dust, gas, aerosols or other materials that have been entrained by wind or water.

Desorption - The removal of a chemical from a solid to which it is attached or a liquid in which it is dissolved.

Detection Limit - The lowest concentration of a chemical that can be distinguished reliably from zero by a given analytical method.

Diffusion - Transport driven by the presence of a concentration gradient.

Dilute - To make less concentrated by mixing with additional materials.

Dispersion - Mixing that occurs during advective transport caused by variations in velocity on a microscopic level.

Disposal - The final placement or destruction of wastes.

Distribution Coefficient (K_d) - The ratio of the concentrations between two compartments in a system at equilibrium. For example, between the solid (i.e., adsorbed) phase and the liquid (i.e., dissolved) phase in environmental media.

Downgradient - The direction in which stressor transport will occur as a result of gradients within environmental media.

Duplicate - Two measurements made concurrently and in the same location, or side-by-side. Used to evaluate the precision of the measurement method.

E

Ecological - Pertaining to the interactions among living organisms and their physical surroundings.

Element - A pure substance that cannot be further decomposed by chemical means.

Eluate - The leachate produced from exposing a material to eluent.

Eluent - A solvent intended to test the extent of leaching from a solid material.

Endangered Species - A species in danger of extinction throughout all or a significant portion of its range/habitat.

Endpoint (Health Effect) - An observable or measurable biological change or chemical concentration (e.g., metabolite concentration in a target tissue) that is used as an indicator of a health effect.

Ephemeral Stream - A stream that goes dry during long periods without rain.

Equilibrium - Stable conditions in which relevant properties remain more or less constant over a period and there is little or no inherent tendency for change.

Eutrophication - The enrichment of water bodies by nutrients (e.g., phosphorus, nitrogen). Elevated nutrient levels can cause unwanted growth of algae, which in turn can result in depleted oxygen levels in the water when the algae die and decay.

Evapotranspiration - The combined loss of water from a given area by evaporation from the land and transpiration from plants.

Exposure - Contact between a receptor and a stressor.

Exposure Factor - Data on human behavior and physiological characteristics that can be used to estimate the magnitude of potential exposures to stressors present in environmental media.

Exposure Pathway - The physical course that a chemical or pollutant takes from the source to the exposed receptor.

Exposure Route - The way that a stressor passes into an organism after contact (e.g., ingestion, inhalation, dermal absorption).

Extrapolation - The estimation of new data points outside the bounds of a discrete set of known data points.

F

Fate - The final disposition of a particular stressor in the environment as a result of adsorption, degradation or transformation.

Floodplain - A relatively flat expanse of land bordering a river that experiences flooding during periods of high discharge; often defined based on the frequency with which the flooding occurs (e.g., 100-year floodplain).

Flux - The rate of mass transfer through or between environmental media.

Friable - Easily broken apart with the force exerted by an unassisted human hand.

G

Geological - Referring to the history and structure of the solid portion of the earth (e.g., rocks, soils, minerals).

Gradient - Variations in a property (e.g., concentration) over a specified distance.

Granular - Consisting of small grains or particles.

Greenhouse Gas - Any gas that affects the overall heat-retaining properties of the Earth's atmosphere (e.g., methane, nitrous oxide, ammonia, sulfur dioxide, carbon dioxide and certain chlorinated hydrocarbons).

Grey Literature - Literature produced by government, academics, business and industry in print and electronic formats outside of the traditional commercial or academic publishing and distribution channels

Ground Water - Any water present underground between the porous spaces of soil and rock.

H

Half-Life - The time required for half of the mass of a substance to be degraded, transformed or destroyed within a given medium.

Hazard - The potential for danger, harm or irreversible adverse health effects to occur.

Hazard Identification - The process of determining whether a stressor has the potential to cause an increase in the incidence or severity of a particular adverse health effect.

Hazard Index (HI) - The sum of more than one hazard quotient for multiple substances and/or multiple exposure pathways to estimate aggregate risk.

Hazard Quotient (HQ) - A ratio of the estimated exposure level to a substance and a toxicity value at which no adverse health effects are known or anticipated to occur.

Heavy Metals - A group of metals with high molecular weights (e.g., arsenic, chromium, copper, lead, mercury, silver, zinc).

Heterogeneous - Having properties that differ across the region of interest.

High-End Estimate - A point value estimate for a distribution that is typically at or above the 90th percentile, but not higher than the highest value that may realistically occur.

Homogeneous - Material properties are identical across the area of interest.

Hydraulic Conductivity - The rate at which water can move through an aquifer or other permeable medium.

Hydraulic Head - The force exerted by a column of liquid expressed by the height of the liquid above the reference point at which the pressure is measured (e.g., sea level).

Hydrocarbon - An organic compound containing only hydrogen and carbon atoms.

Hydrolysis - A degradation process in which a chemical is broken into smaller parts through reaction with water molecules.

Hydrophilic - The property of attracting and mixing well with water molecules; characteristic of polar or charged molecules.

Hydrophobic - The property of dissolving readily in organic solvents, but not in water; resisting wetting; and not containing polar groups or sub-groups.

I

Ignitable - Liable to undergo strongly exothermic decomposition due to high heat or readily combustible materials that can cause fire through friction. EPA regulates substances classified as ignitable as characteristic hazardous wastes. These and other hazardous wastes fall outside the scope of this document.

Impervious - Having such low permeability as to effectively prevent any fluids or gases from infiltrating into or passing through the material.

Indirect Impact - An impact where a stressor acts on supporting components of the ecosystem (such as food availability), which in turn has an adverse impact on ecological receptors.

Industrial Non-hazardous Secondary Material - Any materials that are not the primary products from industrial, manufacturing and commercial sectors. Examples can include scrap and residuals from production processes and products that have been salvaged at the end of their useful life.

Initial Abstraction - The amount of water from a precipitation event that is sequestered by vegetation, evaporation and infiltration before overland runoff begins.

Infiltration - The downward entry of water into a soil or rock surface.

Inert - Stable and unreactive under the specified set of environmental conditions.

In Situ - Refers to testing or action conducted in the field or under natural conditions, rather than replicated in a laboratory setting (literally, “in place”).

Interface - The contact zone between two materials of different chemical or physical composition.

In Vitro - Refers to testing or action conducted outside a living organism (e.g., inside a test tube or culture dish; literally, "in glass").

In Vivo - Refers to testing or action conducted inside a living organism (literally, "in life").

Instrument Detection Limit (IDL) - A quantitative limit on the detection capabilities of a given piece of analytical equipment, set at a concentration equal to three times the standard deviation (3σ) of a series of 10 replicate measurements.

Interception - The process by which precipitation is captured on the surfaces of vegetation and other impervious surfaces and evaporates before it reaches the land surface.

Interpolation - The estimation of new data points within the bounds of a discrete set of known data points.

Ion - An atom that has lost or gained one or more electrons, becoming an electrically charged particle.

Isotherm (Adsorption) - A mathematical relationship that describes, for a constant temperature, the equilibrium of the adsorption of a material at a surface as a function of concentration.

Isotope - Atoms of the same atomic number but having different atomic weight due to a variation in the number of neutrons.

Isotropic - Uniform in all directions.

L

Latency Period - The time between the first exposure to a stressor and the manifestation or detection of an adverse impact.

Leachate - Any liquid, together with any substances dissolved or suspended in the liquid, that has percolated through or drained from a solid material.

Leaching - The process by which chemicals or contaminants are dissolved into and transported away by a liquid.

Lifecycle - All the different stages a material may undergo, including material acquisition, manufacture, use/reuse/maintenance, and ultimate disposition.

Lifestage - A distinguishable time frame in a person's life characterized by unique and relatively stable behavioral and/or physiological characteristics that are associated with development and growth. EPA guidance recommends consideration of the following childhood age groups.

- Age groups less than 12 months old: birth to <1 month, 1 to <3 months, 3 to <6 months, and 6 to <12 months.

- Age groups greater than 12 months old: 1 to <2 years, 2 to <3 years, 3 to <6 years, 6 to <11 years, 11 to <16 years, and 16 to <21 years.

Some other lifestages that may be important to consider when assessing human exposure are pregnancy, nursing and old age.

Littoral - Dealing with the shallow area of a water body where sunlight penetrates easily and oxygen levels are typically high.

Lowest Observed Adverse Effect Level (LOAEL) - The lowest dose or exposure level at which there is a statistically or biologically significant increase in the frequency or severity of an adverse health effect in the exposed population as compared with an appropriate, unexposed control group.

Lysimeter - A device for measuring percolation and leaching losses from a column of soil under controlled conditions.

M

Matrix (Environmental) - The solid framework of a porous environmental medium.

Media (Environmental) - Specific environmental compartments with distinct properties, such as air, water and soil.

Metabolite - Any substance produced by metabolism or a metabolic process.

Method Detection Limit (MDL) - A quantitative limit on the detection capabilities of a given analytical method performed by a given laboratory, set at the minimum concentration of a substance that can be reliably determined to be greater than zero with at least 99% confidence.

Migration - The transport of a stressor through environmental media.

Mobility - The ability of a chemical, element or pollutant to move into and through the environment.

Model - A mathematical representation of a natural system that is intended to mimic the behavior of the real system, allowing description of empirical data and predictions about untested states of the system. Use of models is usually facilitated by computer programming of the mathematics and construction of a convenient input and output format.

Monolithic - Having a large, cohesive structure that cannot be broken apart without considerable effort.

Monte Carlo - A method of probabilistic analysis that uses repeated random sampling from the distribution of values for each of the variables in a calculation (e.g., lifetime average daily exposure) to derive a distribution of estimates (of exposures) in the population.

Municipal Waste - Waste generated within homes, offices, and commercial or institutional establishments (such as stores and hospitals). Industrial office and lunchroom waste is also classified as municipal waste.

Mutagenicity - The potential for a chemical to increase the frequency of mutations by directly or indirectly modifying the structure of DNA or its expression.

N

Natural Resource - Land, fish, wildlife, biota, air, soil, water, ground water, and other materials or energy supplied by nature and its processes independent of anthropogenic refinement.

Non-aqueous Phase Liquid (NAPL) - A liquid which may be either denser (DNAPL) or lighter (LNAPL) than water and that does not easily mix or dissolve in water, remaining as a separate phase.

Nonpoint Source - Pollution sources that are diffuse, without a single identifiable point of origin.

No Observed Adverse Effect Level (NOAEL) - An exposure level at which there are no statistically or biologically significant increases in the frequency or severity of adverse effects between the exposed population and its appropriate control; some effects may be produced at this level, but they are not considered to be adverse or precursors to adverse effects.

No Observed Effect Level (NOEL) - An exposure level at which there are no statistically or biologically significant increases in the frequency or severity of any effects between the exposed population and its appropriate control.

O

Order of Magnitude - A difference in values by a factor of ten.

Organic - Relating to, or derived from living matter.

Organic Soil - Soil composed of predominantly organic material rather than mineral material.

Overland Flow - Water from precipitation, irrigation or other sources that flows over the ground surface, rather than soaking into it, and eventually enters into a body of surface water.

Oxidation - The loss of electrons in a chemical reaction.

P

Parameters - An input in a mathematical equation or model.

Partial Pressure - The portion of total vapor pressure in a system due to one or more constituents in the vapor mixture.

Partition Coefficient (K_d) - See **Distribution Coefficient.**

Percolation - The slow movement of water through the pores in soil or permeable rock.

Permeability - The relative ease with which rock, soil or sediment will transmit a liquid or gas.

Persistent - Describes chemicals that do not break down, or that degrade very slowly, and remain in the environment for an extended period of time.

pH - A measure of how acidic or basic an aqueous solution is. Defined as the negative logarithm of the hydrogen ion concentration.

Photolysis - A degradation process in which a chemical is broken into smaller parts by ultraviolet light.

Piezometer - A non-pumping well, generally of small diameter, that is used to measure to elevation of the water table or potentiometric surface.

Point Estimate - A single value used to define an input variable (e.g., concentration). Typically a mean, median or upper percentile based on the full range of observed values.

Point Source - Pollution sources that are discharges from a single, identifiable point of origin (e.g., pipe, smokestack).

Point Value - A single, constant value used to characterize a variable.

Pollutant - Any agent that can render water, soil, air or another natural resource unfit for a given use.

Pore Space - The empty, interstitial spaces within a soil, sediment or other solid material.

Pore Water - Water occupying space between sediment or soil particles.

Potable - Suitable for human consumption.

Practical Quantitation Limit (PQL) - The lowest concentration that can be reliably measured under routine operating conditions in a given laboratory based on the specified limits of precision and accuracy.

Precipitation (Chemistry) - The formation of a solid phase substance within a liquid mixture through chemical reactions, adsorption or other means that can be physically separated from the liquid.

Precipitation (Meteorology) - Water that falls to the ground as rain, snow, sleet or hail.

Precision - A measure of the closeness, or agreement, among individual measurements.

Probability Density Function (PDF) - An equation that defines the likelihood (probability) that a variable will be a specified value.

Q

Quality Assurance (QA) - A system of management activities intended to ensure that a product will be of the type and quality needed by the user. QA deals with setting policy and implementing an administrative system of management controls that cover planning, implementation and review of data collection activities.

Quality Control (QC) - Scientific precautions, such as calibrations and duplications, that are necessary to identify any defects in the actual products produced.

R

Radical - An atom, molecule or ion with unpaired valence electrons, causing it to be highly reactive.

Reactive - Refers to materials with the capability to explode or undergo violent chemical change when exposed to certain conditions, such as mixture with water, exposure to pressure or heat, or exposure to acidic conditions. EPA regulates substances classified as reactive as characteristic hazardous wastes. These and other hazardous wastes are outside the scope of this document.

Reasonable Maximum Exposure (RME) - The highest exposure that is reasonably likely to occur, often defined somewhere within the range of the 90th and 99.9th percentiles of all possible exposures.

Recalcitrant - Resistant to degradation in the environment through natural processes.

Receptor - A living entity exposed to a stressor.

Recharge - The process of adding uncontaminated water to the saturated zone through the infiltration of precipitation.

Reduction - The loss of oxygen or the gain of electrons in a chemical reaction.

Reference Concentration (RfC) - An estimate of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious noncancer effects during a lifetime.

Reference Dose (RfD) - An estimate of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious noncancer effects during a lifetime.

Refractory - Resistant to biological degradation.

Release - Any spilling, leaking, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, dumping or otherwise disposing of potential stressors into the environment.

Replicate - Duplicate analysis of an individual sample. Used for quality control to evaluate the precision of the measurement method.

Representativeness - The degree to which a sample is characteristic of the whole medium, exposure or dose for which the samples are being used to make inferences.

Risk - The expected frequency or probability of adverse impacts resulting from exposure to stressors.

Risk Assessment - Qualitative or quantitative evaluation of the risks posed to human health and/or the environment by the actual or potential presence or release of hazardous substances, pollutants or contaminants.

Risk Management - The process of evaluating and selecting between alternative responses to risk, which may also include consideration of political, legal, economic and behavioral factors.

Runoff - See **Overland Flow.**

S

Sample - A fragment of some larger material (e.g., soil) that is collected to be tested or analyzed.

Saturation - The state in which no more of a fluid can be absorbed by a porous material.

Sediment - Soil and other small, granular material settled at the bottom of, or entrained in the flow of, a water body.

Seep - A place where water flows or ponds due to the intersection of an aquifer with the Earth surface.

Sensitivity (Model) - The variation in output of a model with respect to changes in the values of the model's input(s).

Sensitivity (Receptor) - Differences in response to a stressor that can arise due to numerous biological factors such as lifestage (windows of enhanced sensitivity), genetic polymorphisms, gender, disease status, nutritional status, etc.

Soil - Unconsolidated materials that compose the superficial geologic strata (material overlying bedrock) consisting of some combination of clay, silt, sand or gravel-sized particles, as classified by the U.S. Natural Resources Conservation Service.

Solubility - The ability or tendency of one substance to dissolve into another at a specified temperature and pressure; generally expressed in terms of the amount of solute that will dissolve in a given amount of solvent to produce a saturated solution.

Solute - A substance dissolved in a solution.

Solvent - A substance in which a solute is dissolved to form a mixture.

Sorption - A generic term that refers to both the processes of absorption and adsorption.

Source - An entity or action that releases stressors to the environment.

Species (Chemical) - A specific form of an element that is defined by the isotopic composition, electronic or oxidation state, and complex or molecular structure. Changes in this form may alter mobility in the environment and toxicity to receptors.

Species (Receptors) - A group of organisms that actually or potentially interbreed and are reproductively isolated from all other such groups; a taxonomic grouping of morphologically similar individuals.

Spring - See **Seep.**

Steady State - The state in which fluxes of a substance between environmental media has reached a balance and the concentrations within each are effectively constant.

Stressor - Any biological, chemical or physical entity that can cause or induce an adverse response in receptors.

Subpopulation - Some subset of the full, exposed population.

Surface Water - Water that is naturally open to the atmosphere, such as rivers, lakes, reservoirs, streams and seas.

Surficial Aquifer - The geologic formation nearest the natural ground surface that is an aquifer, as well as lower aquifers that are hydraulically interconnected with this aquifer.

Surrogate Data - Substitute data or measurements on one substance used to estimate analogous or corresponding values of another substance.

Susceptibility - Differences in potential risks resulting from variation in both toxicity response (sensitivity) and exposure rate (as a result of gender, life stage, and behavior).

Synergistic Effect - A biologic response to exposure to multiple substances that is greater than would be expected if the known effects of the individual substances were summed together.

T

Target Organ - The biological organ(s) affected by a stressor.

Teratogen - A substance that may cause birth defects.

Threatened Species - A vulnerable species that is likely to become endangered in the near future.

Threshold - A dose or exposure below which a specified, measureable effect is not observed.

Topography - The changes in surface elevation associated with geographic features, such as hills, valleys and plains, that shape the surface of the Earth.

Total Dissolved Solids (TDS) - The total mass of dissolved constituent particles that will pass through a filter with pores around 2 microns (0.002 centimeters) in size.

Total Suspended Solids (TSS) - The total mass of constituent particles that will be filtered out with pores around 2 microns (0.002 centimeters) in size.

Toxic - A generic term for substances that are harmful or fatal when ingested or absorbed. EPA regulates certain toxic substances that may be released above specified levels, as defined

by the Toxicity Characteristic Leaching Procedure (TCLP), as characteristic hazardous wastes. These and other hazardous wastes are outside the scope of this document.

Toxicity - Deleterious or adverse biological effects elicited by a chemical, physical or biological agent.

Toxicity Value - A numerical estimate of the dose-response curve for a stressor that is used to quantify the probability of adverse impacts.

Transformation - A change in a chemical or physical state of a stressor.

Transmissivity - The rate at which a liquid moves through an aquifer. This is a function of the liquid, the aquifer media, and the thickness of the aquifer.

Transpiration - The process by which water vapor escapes from living plants, generally through the leaves, and enters the atmosphere.

Transport - The conveyance of a substance within an environmental medium or between media.

Trophic Level - A feeding relationship within an ecosystem (e.g., predation) that determines the route of energy flow and the pattern of chemical cycling.

Turbidity - Cloudiness in water caused by suspended materials.

U

Uncertainty - Imperfect knowledge concerning the present or future state of a system under evaluation.

Uncertainty Factor (UF) - One of several, generally 10-fold, default factors used in deriving toxicity values from experimental data. The factors are intended to account for 1) variation in susceptibility among the members of the human population, 2) uncertainty in extrapolating animal data to humans (i.e., interspecies uncertainty), 3) uncertainty in extrapolating from data obtained in a study with less-than-lifetime exposure (i.e., extrapolating from subchronic to chronic exposure), 4) uncertainty in extrapolating from a LOAEL rather than from a NOAEL, and 5) uncertainty associated with extrapolation when the database is incomplete.

Unconfined Aquifer - An aquifer that has a free water table.

Unit Risk - The upper-bound excess lifetime cancer risk estimated to result from continuous exposure to an agent at a concentration of 1 microgram per liter (µg/L) in water, or 1 microgram per cubic meter ($\mu g/m^3$) in air.

Upgradient - The direction away from which stressor transport will occur as a result of gradients within environmental media. Environmental media upgradient from a source are typically assumed to be free of contamination.

Uptake - The processes by which stressors are transferred from environmental media and into a receptor.

Upwelling - The flow or ponding of water due to the intersection of an aquifer with the Earth surface.

Useful Life - The period over which a product or beneficial use is used for the purpose it was acquired. This may or may not be the same as the physical life or economic life.

V

Vadose Zone - The subsurface soils and partially saturated pore spaces above the water table.

Vapor - The gaseous phase of any substance that is liquid or solid at atmospheric temperatures and pressures.

Vapor Pressure - A measure of a substance's volatility, or its propensity to partition to the vapor (gaseous) phase from its condensed phase (solid or liquid).

Variability - A quantitative description of the range or spread of possible values for a variable.

Variable - Elements in an equation or model that may change in value.

Void - See **Pore Space.**

Volatile - The property of having a high vapor pressure, readily converting from a liquid or solid state into a gaseous vapor under atmospheric temperatures and pressures.

W

Waste Water - Used water from an individual home, a community, a farm or an industry that contains dissolved or suspended matter.

Watershed - An area of land where all of the water that flows through or over it or drains off to the same stream, river, lake or other water body.

Water Table - The upper surface of the zone of saturation, defined as the point where the water pressure is equal to the atmospheric pressure.

Well - Any shaft or pit that is dug or bored into the earth, generally cylindrical in form and often walled with bricks or tubing to prevent the earth from caving in around it.

Worst-Case Exposure - The maximum possible exposure that can conceivably occur, regardless of whether this exposure actually occurs within the exposed population.

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Appendix

Disclaimer

This document ("the beneficial use compendium" or "the compendium") was prepared by the United States Environmental Protection Agency ("EPA" or "the Agency") Office of Land and Emergency Management. The beneficial use compendium and the methodology it references are intended to be useful to those who conduct or review beneficial use evaluations, as well as other interested stakeholders, including states, local governments, tribal authorities, regulated communities, and the general public. The information contained in the compendium is based on the Agency's current understanding of the range of issues and circumstances involved with the beneficial use of industrial non-hazardous secondary materials ("secondary materials"). It is not intended to address the combustion of non-hazardous secondary materials for energy, the use/reuse of municipal solid waste, or the regulation of hazardous waste. Use of the beneficial use compendium is voluntary and does not change or substitute for any federal or state statutory or regulatory provisions or requirements. The compendium does not preclude the use of any other available approaches. Nothing in the compendium is intended to establish binding requirements on EPA or any other entity. Accordingly, EPA may revise or depart from the approach outlined in the beneficial use compendium and the methodology it references at any time, without prior notice. Any reference to specific commercial products, process or service by trade name, trademark, manufacturer or otherwise does not constitute or imply its endorsement, recommendation or favoring by the United States government. Such references are provided for informational purposes only.

Table of Contents

Introduction

This appendix is intended to be a library of resources that can aid in the development and review of beneficial use evaluations. These resources represent publicly available guidance documents, data sources, software programs and other materials compiled from EPA, federal and state agencies, academic institutions and private organizations. The primary aim of this appendix is to make these disparate resources more accessible by assembling them all in one location. All of the citations and external weblinks presented in this appendix are current as of the publication of this document.

The resources presented in this appendix were selected for their general applicability. EPA recognizes that many of these resources were originally developed specifically to address Superfund and other contaminated waste sites; however, many aspects of these resources are also germane to the evaluation of environmental impacts that may result from the beneficial use of secondary materials. More tailored resources may be available from specific regions or states.

To help place these resources into context, this appendix is structured to loosely parallel the discussion in the main document. Each section addresses a single, general topic and provides some available resources relevant to that topic. EPA has made no attempt to rank the different resources based on potential relevance, as the scope of different beneficial use evaluations can vary considerably. Instead, to aid in navigation, each resource has been categorized as either general or specific:

- General resources provide a broad discussion or guidance for a given topic. These resources are typically finalized documents that will not be subject to change. Therefore, they are organized by the date of publication. Where older documents have been updated, each of the editions are provided for historical context.
- Specific resources are existing tools that can be used directly in a beneficial use evaluation with little or no modification. These resources are more likely to be updated periodically. Therefore, these resources are organized alphabetically.

A given section may present one or both type of resource, based on what was available at the time this appendix was compiled. These resources are provided for informational purposes only. Inclusion in this appendix does not impose an obligation to consider or rely upon any of the resources listed here, nor does it indicate that any of these materials are the most appropriate or most applicable for any given evaluation. Professional judgment should be used when reviewing and incorporating the information in these resources, as some of their conclusions may be based on subjective interpretation of available data. Different conclusions may be appropriate for a given beneficial use evaluation based on policy, precedent, evaluation-specific considerations or other pertinent factors.

A.1 Planning and Scoping

The following compilation of resources supplements the discussion of planning and scoping provided in **Section 2** of this document. The resources contain recommendations on how to define the scope and analytical framework for a risk assessment. These principles can also be applied to beneficial use evaluations to define the conceptual model, potential data needs, a realistic schedule for completion, and outside parties that may be able to provide assistance.

A.1.1 General Resources

Date: September 1986
Title: Standard Scenarios for Estimating Exposure to Chemical Substances During Use of Consumer Products
Author: U.S. EPA/Office of Toxic Substances
Details: This document provides standard scenarios that can be used to derive exposure estimates for chemical substances in consumer products. It presents values for some parameters required to estimate exposure drawn from available, published sources of information.

Date: May 1998
Title: Guidelines for Ecological Risk Assessment, Chapter 2: Planning the Risk Assessment and Chapter 3: Problem Formulation Phase
Author: U.S. EPA/Office of the Science Advisor
Details: These chapters describe the basic structure and starting principles for evaluating scientific information on the adverse effects of stressors on the environment to improve the quality and consistency of ecological risk assessments.

Date: December 2001
Title: Risk Assessment Guidance for Superfund (RAGS) Volume I—Part D, Chapter 3: Risk Assessment Data Needs and Tasks During the Remedial Investigation
Author: U.S. EPA/Office of Solid Waste and Emergency Response (OSWER)
Details: This chapter describes EPA guidance on the data requirements for conducting human health risk assessments at Superfund sites. It discusses the different planning tables that have been developed to encourage clear and consistent documentation of important data, calculations and conclusions during planning and scoping.

Date: December 2000
Title: Risk Characterization Handbook, Chapter 2: Preparing for a Risk Assessment and its Risk Characterization—Planning and Scoping
Author: U.S. EPA/Science Policy Council
Details: This chapter explains the goals and principles of risk characterization, the importance of planning and scoping for a risk assessment, the essential elements to address in a risk characterization, the factors that risk managers consider in decision-making, and the forms the risk characterization takes for different audiences.

Date: January 2002

Title: Lessons Learned on Planning and Scoping for Environmental Risk Assessments

Author: U.S. EPA/Science Policy Council

Details: Intended to encourage formal planning and scoping practices to improve environmental risk assessments, this document provides lessons learned from case studies following the release of the 1997 document *Guidance on Cumulative Risk Assessment—Part 1: Planning and Scoping*.

Date: September 2006

Title: A Framework for Assessing Health Risk of Environmental Exposures to Children, Chapter 3: Lifestage-Specific Problem Formulation

Author: U.S. EPA/Office of Research and Development (ORD)

Details: This document provides an overarching framework for a more complete assessment of children's exposure to environmental agents and the resulting potential health risks within the EPA risk assessment paradigm. This chapter includes information on planning and scoping to help characterize exposures and outcomes during all developmental life stages, creating a conceptual model, and preparing an analysis plan.

Date: 2009

Title: Science and Decisions: Advancing Risk Assessment, Chapter 3: The Design of Risk Assessments

Author: National Research Council

Details: This chapter discusses planning, scoping and problem formulation. Elements of scope to consider during planning and scoping, methodology considerations in problem formulation, and major elements of an analysis plan are presented in this chapter.

Date: April 2014

Title: Framework for Human Health Risk Assessment to Inform Decision Making, Chapter 2: Initiation of the Risk Assessment Process and Chapter 3: Public, Stakeholder and Community Involvement.

Author: U.S. EPA / Risk Assessment Forum

Details: This document is intended to provide information on the overarching process for conducting human health risk assessments. These chapters includes information on how to conduct planning and scoping, problem formulation and stakeholder engagement.

A.1.2 Specific Points of Contact

These tables list some federal, state and nongovernmental organizations that have experience with the beneficial use of secondary materials. It may be useful to seek input from these or other parties during planning and scoping. These organizations may be able to share data or other pertinent information on a proposed beneficial use, similar beneficial uses, or the secondary materials incorporated into these uses.

American Association of State Highway and Transportation Officials (AASHTO)

Overview:	AASHTO is a nonprofit, nonpartisan association representing highway and transportation departments in the 50 states, the District of Columbia and Puerto Rico. It represents all five transportation modes: air, highways, public transportation, rail and water. Its primary goal is to foster the development, operation and maintenance of an integrated national transportation system. The AASHTO Center for Environmental Excellence offers products and programs for technical assistance, training, information exchange, partnership-building opportunities and quick access to environmental tools.
Website:	environment.transportation.org/environmental_issues/waste_manage_recyc/

Association of State and Territorial Solid Waste Management Officials (ASTSWMO)

Overview:	The ASTSWMO Solid Waste Subcommittee established a Beneficial Use Task Force to study how different states manage requests to allow the beneficial use of non-hazardous, secondary materials. The task force's primary goal is to collect and share information that will assist U.S. states and territories in developing or improving programs and processes to handle these requests.
Website:	www.astswmo.org/main/mmp_pubs.html

Industrial Resource Council (IRC)

Overview:	The IRC is a collaboration of nonprofit industry associations working together to promote the appropriate use of materials generated by key national manufacturing sectors. The IRC partners with the U.S. EPA, the Federal Highway Administration, AASHTO and the Recycled Materials Resource Center in supporting the appropriate use of secondary materials in transportation, construction and other applications. These efforts include the development of codes, standards and regulatory guidance, the documentation of field projects involving secondary materials.
Website:	www.industrialresourcescouncil.org/

Interstate Technology and Regulatory Council (ITRC)

Overview:	The ITRC is a public-private coalition working to reduce barriers to the use of innovative environmental technologies that reduce compliance costs and maximize cleanup efficacy. ITRC produces documents and training intended to broaden and deepen technical knowledge and expedite quality regulatory decision making while protecting human health and the environment.
Website:	www.itrcweb.org

National Center for Manufacturing Sciences (NCMS)

Overview:	NCMS is a nonprofit, membership-based consortium. Membership is limited to organizations which have a substantial manufacturing presence in North America. The organization developed and maintains a site that identifies state regulations and programs related to the beneficial use of secondary materials. Searches can be done by either state or secondary material. In addition, provides links to potential points of contact in each state, and in other organizations.
Website:	www.beneficialuseportal.org

Northeast Waste Management Officials' Association (NEWMOA)

Overview:	NEWMOA is an inter-state association consisting of Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island and Vermont. The organization was established to coordinate the inter-state handling of hazardous and solid waste, pollution prevention, and waste site cleanup activities. Part of the organization's stated mission is to implement environmentally sound solutions for proper reuse and recycling discarded materials that have value.
Website:	www.newmoa.org

Recycled Materials Resource Center (RMRC)

Overview:	The mission of the RMRC is to test, evaluate and develop guidelines for recycled materials and to provide outreach to reduce barriers to the use of recycled materials in highways. The advisory board includes representatives from United States Department of Transportation (DOT) Federal Highway Administration (FHWA), U.S. EPA, New Hampshire DOT, AASHTO, ASTSWMO, industry, and highway trade associations.
Website:	rmrc.wisc.edu

U.S. Army Corp of Engineers

Overview:	The Army Corps of Engineers works to develop and maintain the navigable waters of the Unites States. The agency has experience with the beneficial use of dredged sediment and secondary materials in infrastructure and habitat restoration projects.
Website:	www.usace.army.mil

U.S. Department of Agriculture (USDA)

Overview:	The USDA Cooperative State Research, Education, and Extension Service maintains offices that may be able to provide useful information on the beneficial use of secondary materials in agriculture. These offices are located in a network of local or regional offices, as well as in the land-grant universities of each state and territory.
Website:	www.csrees.usda.gov/Extension

U.S. Department of Transportation (U.S. DOT)

Overview:	The Federal Highway Administration (FHWA) is an agency within the U.S. DOT that supports state and local governments in the design, construction, and maintenance of the Nation's highway system (Federal Aid Highway Program) and various federally and tribal owned lands (Federal Lands Highway Program). The FHWA has established policy for the recycling of aggregates and other highway construction materials in roadway construction.
Website:	www.fhwa.dot.gov/pavement/recycling/index.cfm

U.S. Environmental Protection Agency (U.S. EPA)

Overview:	The U.S. EPA Sustainable Materials Management (SMM) Program was established to support the productive and sustainable use/reuse of resources throughout all stages of their life cycles, from resource acquisition through disposal. The SMM Program seeks to avoid or minimize impacts to the environment while also accounting for economic efficiency and social considerations.
Website:	www.epa.gov/smm/sustainable-management-industrial-byproducts

A.2 Stressor Characterization

The following compilation of resources supplements the discussion of stressor characterization provided in **Section 2**. These resources describe the sources, the physical and chemical properties, and the environmental behavior of various stressors. This information can be used during planning and scoping to help identify the types of stressors associated with an secondary material or beneficial use and the routes through which these stressors may be released into the surrounding environment.

A.2.1 General Resources

Date: February 2009

Title: Biota-Sediment Accumulation Factor (BSAF) Dataset

Author: U.S. EPA/ORD

Details: This dataset includes approximately 20,000 BSAFs for non-ionic, organic chemicals (e.g., polyaromatic hydrocarbons) collected from 20 different locations. Data are available for species such as lobster, crayfish and benthic invertebrates in freshwater, tidal and marine ecosystems. The purpose of the dataset is to provide tools to: 1) evaluate the reasonableness of BSAFs measured from other locations; 2) build a BSAF dataset for other locations; 3) conduct a bounding assessment of risks for locations where limited or no bioaccumulation data are available; 4) identify underlying relationships and dependences of BSAFs on ecosystem conditions and parameters; and 5) compare polychlorinated biphenyl, polychlorinated dibenzo-p-dioxin and polychlorinated dibenzofuran residues to residue-effects data.

Date: November 2012 (Version 4.11)

Title: Estimation Program Interface (EPI) Suite Software

Author: U.S. EPA/Office of Pollution Prevention and Toxics and Syracuse Research Corp.

Details: This software provides users with screening-level estimates of the physical, chemical and environmental fate properties of over 40,000 chemicals. The suite is composed of 17 individual models that provide information on specific chemical properties. The only input required to run each model is the chemical structure of the stressor. This chemical structure can be identified through a Chemical Abstract Service number or using the name lookup function.

A.2.2 Specific Stressor Categories

The following tables briefly describe some general categories of stressors that are most likely to be associated with secondary materials. This list is provided as a reference and is not intended to be comprehensive. There may be many individual stressors grouped under each category, based on similar chemical structures or other commonalities. However, the mobility and toxicity of the different stressors within a category can vary greatly. Thus, while an understanding of the general categories of stressors that may be present can provide valuable information during planning and scoping, it is important to also identify and characterize each of the specific stressors.

Asbestos

Overview:	Asbestos is the name given to a group of naturally occurring silicate minerals that are resistant to heat and corrosion. Asbestos has historically been used in a number of products, such as insulation for pipes (e.g., steam lines), floor tiles and other building materials. As a result, asbestos is most likely to be associated with construction and demolition debris. The asbestos contained in these materials is referred to as friable if it can be crumbled, pulverized or reduced to a powder by the pressure of an ordinary human hand. The most likely exposure route for asbestos is the inhalation of airborne particulates.
Further Information:	cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1026tr.pdf www.atsdr.cdc.gov/asbestos/

Chlorinated Dibenzo-p-Dioxins and Chlorodibenzofurans (CDD/Fs)

Overview:	CDD/Fs are a family of chlorinated organic compounds that have either a dioxin or furan as the central ring, and are sometimes referred to simply as "dioxins" and "furans." The largest source of CDD/Fs in the environment is as an unintentional byproduct from industrial processes. Some examples of the processes that may produce these compounds are the manufacture of certain pesticides, preservatives, disinfectants and paper products, as well as the low-temperature combustion of chemical products, plastic, paper and wood. The most likely exposure routes for CDD/Fs are through the ingestion of contaminated water, food and dust/soil, although exposures through inhalation of particulate matter and dermal contact may also occur.
Further Information:	www.epa.gov/expobox/exposure-assessment-tools-chemical-classes-other-organics www.atsdr.cdc.gov/substances/toxchemicallisting.asp?sysid=29

Metals

Overview:	Metals are a broad category of naturally occurring, inorganic elements that are found throughout the environment. Specific examples include arsenic, lead, mercury and selenium. Metals cannot be created or destroyed through biological or chemical processes. However, these processes can alter the speciation of the metal and complex it into different inorganic or organic compounds. These changes have the potential to affect both mobility in the environment and toxicity to receptors. Although metals are often discussed as isolated elements, few metals are found alone in the environment. Common sources of elevated metal levels are combustion, refinement, distillation or other procedures that concentrate metals naturally present in the raw materials (e.g., rocks, ore). The most frequent exposure routes for metals are through the ingestion of contaminated water, food and dust/soil; the inhalation of vapor (e.g., elemental mercury) or particulate matter; and dermal contact.
Further Information:	www.epa.gov/expobox/exposure-assessment-tools-chemical-classes-inorganics-and-fibers www.atsdr.cdc.gov/substances/toxchemicallisting.asp?sysid=37

Particulate Matter

Overview:	Particulate matter is a complex mixture of extremely small solid particles and/or liquid droplets. These particles may be composed of a number of different substances, such as acids (e.g., nitrates and sulfates), organic chemicals, metals and/or soil particles. Particulate matter may be associated with any granular solid or liquid that can become suspended in the air. Of particular concern is the size of the particulate matter, specifically the amount of the material less than 10 micrometers ("inhalable coarse particulates" or "PM_{10}") and 2.5 micrometers ("fine particulates" or "$PM_{2.5}$") in diameter. These are the particulates that can pass through the throat and nose and enter into the lungs. The most likely exposure route for PM_{10} and $PM_{2.5}$ is the inhalation of airborne particulates.
Further Information:	www.epa.gov/pm/

Pesticides

Overview:	A pesticide is any substance used to kill, repel or control certain forms of plant or animal life that are considered to be pests. They often have a complex chemical structure and may be either organic or inorganic in nature. Pesticides used for their intended purpose are often applied to building materials. As a result, pesticide residues may be associated with construction and demolition debris. The most frequent exposure routes for pesticides are through the ingestion of contaminated water, food and dust/soil, the inhalation of particulate matter, and exposure through dermal contact.
Further Information:	www.epa.gov/expobox/exposure-assessment-tools-chemical-classes-pesticides www.atsdr.cdc.gov/substances/toxchemicallisting.asp?sysid=31

Radionuclides

Overview:	Radionuclides are a specific subset of metals that have unstable atomic nuclei. All radionuclides eventually undergo a process called radioactive decay, wherein the atomic structure of the element changes, often accompanied by the release of ionizing radiation (e.g., alpha particles, gamma rays). Like other inorganics, most radionuclides in the environment are found complexed with inorganic or organic compounds. However, this complexation does not affect the rate or risk of radioactive decay for an atom. Common sources of elevated radionuclide levels are combustion, refinement, distillation or other procedures that concentrate metals naturally present in the raw materials (e.g., rocks, ore). The most frequent exposure routes for radionuclides are through the ingestion of contaminated water, food and dust/soil, the inhalation of gas (e.g., radon) or particulate matter, exposure through dermal contact, and direct exposure to external radiation.
Further Information:	www.epa.gov/radiation www.atsdr.cdc.gov/substances/toxchemicallisting.asp?sysid=27

Semi-Volatile Organic Compounds (SVOCs)

Overview:	SVOCs are any organic compounds that have boiling points in the vicinity of 240 to 400°C. Examples of some broad classes of SVOCs include polyaromatic hydrocarbons (PAHs), phenols and phthalates. Some examples of the processes that can produce these compounds are primary aluminum and coke production, products containing plasticizers, petrochemical refinement, rubber tire and cement manufacturing, bitumen and asphalt industries, wood preservation, and the low-temperature combustion of chemical products, plastic, paper and wood. The most frequent exposure routes for SVOCs are through the ingestion of contaminated water, food and dust/soil, the inhalation of particulate matter, and exposure through dermal contact.
Further Information:	www.epa.gov/expobox/exposure-assessment-tools-chemical-classes-other-organics PAHs: www.atsdr.cdc.gov/substances/toxsubstance.asp?toxid=25 Phthalates: www.atsdr.cdc.gov/substances/toxchemicallisting.asp?sysid=41

Volatile Organic Compounds (VOCs)

Overview:	VOCs are organic compounds that will readily evaporate around normal indoor atmospheric conditions. Examples of common VOCs include benzene, trichloroethane, trichloroethylene and xylene. Some examples of the processes that produce these compounds are the production and use of adhesives, solvents, paints, resins, varnish, lithography and printing, vinyl coating and asphalt. The most frequent exposure routes for VOCs are through the ingestion of contaminated water, food and dust/soil, the inhalation of vapor or particulate matter, and exposure through dermal contact.
Further Information:	www.epa.gov/expobox/exposure-assessment-tools-chemical-classes-other-organics www.atsdr.cdc.gov/substances/toxchemicallisting.asp?sysid=7

A.3 Environmental Releases

The following compilation of resources supplements the discussion of stressor identification and characterization in **Section 2**. These resources detail methods that can be used to estimate the stressor levels present in an secondary material or beneficial use and the rate at which these stressors may be released into surrounding media based on the prevailing environmental conditions. These references can be used to help determine which methods will generate data best suited for a particular evaluation or, when an evaluation relies solely on published data, an understanding of the assumptions built into the procedures for these and similar methods can help determine whether the data generated are representative of the beneficial use under evaluation.

A.3.1 General Resources

Date: February 2014

Title: Methods for Evaluating Solid Waste, Physical/Chemical Methods (SW-846)

Author: U.S. EPA/OSWER

Details: This manual provides test procedures and guidance approved by EPA, which are recommended for use in conducting the evaluations and measurements needed to comply with the RCRA. This manual presents the state-of-the-art in routine analytical tests adapted for the RCRA program. Contains procedures for field and laboratory quality control, sampling, determining hazardous constituents in wastes, determining the hazardous characteristics of wastes, and for determining physical properties of wastes. It also contains guidance on how to select appropriate methods. The methods presented have been validated for the specific set of environmental media and constituents listed for each method. However, a given method may be relevant to additional media and constituents, provided the user can demonstrate the appropriateness of the intended application.

Date: December 2014

Title: LeachXS Lite (version 2.0.38)

Author: U.S. EPA/ORD

Details: LeachXS Lite™ is a data management and visualization tool and an essential part of the Leaching Environmental Assessment Framework (LEAF). The tool allows users to evaluate and characterize the release of material constituents based on comparisons derived from leaching test results for a wide range of materials and waste types (e.g., secondary or recycled materials, stabilized waste and construction materials). Users that want to work with leaching test results (e.g., EPA Methods 1313 through 1316) of their own can use Microsoft Excel® templates for uploading data into LeachXS database.

A.3.2 Specific Analytical Methods

The following tables detail several methods developed by EPA and other organizations that can simulate the release of stressors from secondary materials and beneficial uses. These tables provide a general description of each method and highlight the specifications for sample preparation and release simulation that determine how well these releases reflect the range of conditions a beneficial use may be exposed to in the real world.

ASTM Method D3987-06: Shake Extraction of Solid Waste with Water

Overview:	This method is a batch leaching test designed to estimate releases of inorganics and non-volatile organics from granular solid materials. Leachate is produced by mixing the solid sample with unbuffered water and agitating the mixture continuously for around 18 hours. The water is then filtered and analyzed for constituent concentrations. The method is intended to provide equilibrium liquid-solid partitioning at the natural pH of the material.					
Release Type:		Solid	✓	Liquid		Gas
Specifications:	▪ Assumes that there is enough contact time to achieve equilibrium between the liquid and solid phases. This may overestimate releases if liquid passes through or over the material quickly. ▪ The material is finely ground before sampling. May overestimate releases if the material is monolithic. ▪ The leachant is unbuffered, distilled water (pH ≈ 7.0). Sample will tend to reflect the natural pH conditions of the material in isolation. However, these conditions may overestimate or underestimate actual releases if the prevailing conditions driven by the surrounding media are different. ▪ The liquid to solid (L/S) ratio is 20:1. This is a point estimate of releases and does not provide information on how releases may change as the cumulative L/S ratio increases.					
Website:	www.astm.org/Standards/D3987.htm					

EPA Method 1311: Toxicity Characteristic Leaching Potential (TCLP)

Overview:	Method 1311 is a batch leaching test designed to estimate releases of inorganic and organic compounds from solids and liquids. Leachate is produced by mixing solid test samples with water buffered to a pH around 2.9 and agitating the mixture continuously for around 18 hours. This leachate or any liquid samples are then filtered and analyzed for constituent concentrations. The method is intended to provide equilibrium liquid-solid partitioning under typical conditions found in a municipal solid waste landfill.					
Release Type:		Solid	✓	Liquid		Gas
Considerations:	▪ Assumes that there is enough contact time to achieve equilibrium between the liquid and solid phases. May overestimate releases if liquid passes through or over the beneficial use quickly. ▪ The material is finely ground before sampling. May overestimate releases if the beneficial use is monolithic. ▪ Leachant pH is buffered to be acidic (pH ≈ 2.9). These conditions may overestimate or underestimate actual releases if the prevailing conditions driven by the surrounding environmental media are different. ▪ The L/S ratio is 20:1. This is a point estimate of releases and does not provide information on how releases change as the cumulative L/S ratio increases.					
Website:	www.epa.gov/hw-sw846/sw-846-test-method-1311-toxicity-characteristic-leaching-procedure					

EPA Method 1312: Synthetic Precipitation Leaching Procedure (SPLP)

Overview:	Method 1312 is a batch leaching test designed to estimate releases of inorganic and organic compounds from solids and liquids. Leachate is produced by mixing solid test samples with water buffered to a pH around 4.2 and agitating the mixture continuously for around 18 hours. This leachate or any liquid samples are then filtered and analyzed for constituent concentrations. The method is intended to provide equilibrium liquid-solid partitioning under the conditions that mimic acidic rain.					
Release Type:		Solid	✓	Liquid		Gas
Considerations:	▪ Assumes that there is enough contact time to achieve equilibrium between the liquid and solid phases. May overestimate releases if liquid passes through or over the beneficial use quickly. ▪ The material is finely ground before sampling. May overestimate releases if the beneficial use is monolithic. ▪ Leachant pH is buffered to be acidic (pH ≈ 4.2). These conditions may overestimate or underestimate actual releases if the prevailing conditions driven by the surrounding environmental media are different. ▪ The L/S ratio is 20:1. This is a point estimate of releases and does not provide information on how releases change as the cumulative L/S ratio increases.					
Website:	www.epa.gov/hw-sw846/sw-846-test-method-1312-synthetic-precipitation-leaching-procedure					

EPA Method 1313: Liquid-Solid Partitioning as a Function of Eluate pH for Constituents in Solid Materials Using a Parallel Batch Extraction Procedure

Overview:	Method 1313 is a batch leaching test designed to estimate releases of inorganics and non-volatile organics from granular solid materials. A total of nine leachate samples are produced by mixing solid test samples with water buffered to one of nine pH values between 2 and 13. The mixtures are then agitated continuously for between 24 and 74 hours, based on particle size. This leachate is then filtered and analyzed for constituent concentrations. The method is intended to provide equilibrium liquid-solid partitioning under the range of plausible field pH values.					
Release Type:		Solid	✓	Liquid		Gas
Considerations:	▪ Assumes that there is enough contact time to achieve equilibrium between the liquid and solid phases. May overestimate releases if liquid passes through or over the beneficial use quickly. ▪ Material is finely ground before sampling to facilitate equilibrium conditions. May overestimate releases if the beneficial use is monolithic. ▪ Leachant pH is buffered to nine different levels between 2 and 13 in different samples to capture the effect of pH on releases. ▪ The L/S ratio is 10:1. This is a point estimate of releases and does not provide information on how releases may change as the cumulative L/S ratio increases.					
Website:	www.epa.gov/hw-sw846/validated-test-method-1313-liquid-solid-partitioning-function-extract-ph-using-parallel					

EPA Method 1314: Liquid-Solid Partitioning as a Function of Liquid-to-Solid Ratio for Constituents in Solid Materials Using an Up-flow Percolation Column Procedure

Overview:	Method 1314 is an up-flow column leaching extraction procedure designed to estimate releases of inorganics and non-volatile organics from granular solid materials. Leachate samples are produced by pumping water at a low flow rate over the material. This resulting leachate is collected at specified cumulative L/S ratios, filtered and analyzed for constituent concentrations. The method is intended to provide leachate concentrations as a function of the cumulative L/S ratio, which can be related to a time scale when data on mean infiltration rate, density and column height are available. The data may also provide insight into the impact of organic carbon release and the influence of dissolved organic carbon on the partitioning of inorganic constituents.					
Release Type:		Solid	✓	Liquid		Gas
Considerations:	▪ Assumes that there is enough contact time to achieve equilibrium between the liquid and solid phases. May overestimate releases if liquid passes through or over the beneficial use quickly. ▪ Material is finely ground prior to sampling to facilitate equilibrium conditions. May overestimate releases if the beneficial use is monolithic. ▪ The leachant is unbuffered, distilled water (pH ≈ 7.0). Sample will reflect the natural pH conditions of the material in isolation. However, these conditions may overestimate or underestimate actual releases if the prevailing conditions driven by the surrounding environmental media are different. ▪ Samples are collected at specific cumulative L/S ratios between 0.2:1 and 10:1 to capture the effect of increasing cumulative L/S ratio on releases.					
Website:	www.epa.gov/hw-sw846/validated-test-method-1314-liquid-solid-partitioning-function-liquid-solid-ratio					

EPA Method 1315: Mass Transport Rates of Constituents in Monolithic or Compacted Granular Materials Using a Semi-dynamic Tank Leaching Procedure

Overview:	This method is a batch leaching test designed to measure releases of inorganics from monolithic or compacted granular materials. Leachate samples are produced by placing the test sample in a tank filled with unbuffered water for a specified time period, at which point the sample is moved to a new tank of water. This process is repeated nine times. The leachate from each tank is then filtered and analyzed for constituent concentrations. The method is intended to provide diffusion-controlled mass transfer rates (release rates). Diffusivity and tortuosity can be estimated through analysis of the resulting leaching data.					
Release Type:		Solid	✓	Liquid		Gas
Considerations:	▪ Assumes that there is enough contact time to achieve equilibrium between the liquid and solid phases. May overestimate releases if liquid passes through or over the beneficial use quickly. ▪ The material is either monolithic or compacted into a mold before sampling. May underestimate releases if the beneficial use is an uncompacted granular material. ▪ The leachant is unbuffered, distilled water (pH ≈ 7.0). Sample will reflect the natural pH conditions of the material in isolation. However, these conditions may overestimate or underestimate actual releases if the prevailing conditions driven by the surrounding environmental media are different. ▪ Samples are collected at five times at a liquid to surface area ratio of 10:1 to capture releases over time.					
Website:	www.epa.gov/hw-sw846/validated-test-method-1315-mass-transfer-rates-constituents-monolithic-or-compacted					

EPA Method 1316: Liquid-Solid Partitioning as a Function of Liquid-to-Solid Ratio for Constituents in Solid Materials Using a Parallel Batch Extraction Procedure

Overview:	This method is a parallel batch leaching test to estimate releases of inorganics and non-volatile organics from granular solid material. Leachate samples are produced by placing the test sample in five different tanks filled with unbuffered water and different L/S ratios, ranging between 0.5:1 and 10:1. The mixtures are then agitated continuously for between 24 and 74 hours, based on particle size. The resulting leachate is then filtered and analyzed for constituent concentrations. The method is intended to provide leachate concentrations as a function of the L/S ratio. The method also allows identification of the mode of leaching for constituents (washout or solubility-limited).					
Release Type:		Solid	✓	Liquid		Gas
Considerations:	▪ Assumes that there is sufficient contact time to achieve equilibrium between the liquid and solid phases. May overestimate releases if liquid passes through or over the beneficial use quickly. ▪ Material is finely ground prior to sampling to facilitate equilibrium conditions. May overestimate releases if the beneficial use is monolithic. ▪ The leachant is unbuffered, distilled water (pH ≈ 7.0). Sample will reflect the natural pH conditions of the material in isolation. However, these conditions may overestimate or underestimate actual releases if the prevailing conditions driven by the surrounding environmental media are different. ▪ Samples are collected at five cumulative L/S ratios between 0.5:1 and 10:1 to capture the effect of increasing cumulative L/S ratio on releases.					
Website:	www.epa.gov/hw-sw846/validated-test-method-1316-liquid-solid-partitioning-function-liquid-solid-ratio-solid					

A.4 Data Quality

The following compilation of resources supplements the discussion of data quality in **Section 3** of this document. These resources detail the various factors that can affect data quality, as well as the available quality assurance/quality control measures that increase confidence in collected data. This information can help to ensure that primary and secondary data are of sufficient quality to support defensible conclusions about a beneficial use.

A.4.1 General Resources

Date: December 1989

Title: RAGS Volume I—Part A, Chapter 5: Data Evaluation

Author: U.S. EPA/OSWER

Details: Describes the process of data evaluation in risk assessments. The outcome of this evaluation is the identification of a set of chemicals that are likely to be site-related and reported concentrations of acceptable quality for use in the risk assessment.

Date: May 1992

Title: Guidance for Data Usability in Risk Assessment: Parts A and B

Author: U.S. EPA/OSWER

Details: These documents are designed to provide a consistent basis for making decisions about the minimum quality and quantity of environmental analytical data sufficient to support decisions at Superfund sites. Addresses how to design sampling and analytical activities to meet data quantity and quality needs, procedures for assessing the quality of data, and options for combining data of varying quality from different sources.

Date: November 2002

Title: Guidance on Environmental Data Verification and Data Validation

Author: U.S. EPA/Office of Environmental Information

Details: This guidance explains how to implement data verification and data validation in the context of EPA's Quality System, and provides practical advice and references. This guidance describes an array of data verification and data validation practices to promote common understanding and effective communication among environmental laboratories, field samplers, data validators and data users. This guidance also describes the related subjects of data integrity (how to help detect possible falsification of data) and data suitability (how to anticipate and support decisions about the usability of the data).

Date: June 2003

Title: Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information

Author: U.S. EPA/Science Policy Council

Details: This document provides information on the considerations that EPA takes into account when evaluating the quality of scientific and technical information that is submitted to the Agency, or that is gathered or generated by EPA, for various

Date: February 2006

Title: Data Quality Assessment: A Reviewer's Guide

Author: U.S. EPA/Science Policy Council

Details: This guide provides general guidance to organizations on assessing data quality criteria and performance specifications for decision-making. EPA has developed a process for performing the data quality assessment (DQA) process for project managers and planners to determine whether data are of the type, quantity and quality needed to support Agency decisions.

Date: February 2006

Title: Data Quality Assessment: Statistical Methods for Practitioners

Author: U.S. EPA/Science Policy Council

Details: This document describes the different statistical methods that can be used in DQAs when evaluating environmental data sets. A DQA is the scientific and statistical evaluation of environmental data to determine if they meet the planning objectives of the project, and are of the right type, quality and quantity to support their intended use.

A.5 Statistical Methods

The following compilation of resources supplements the discussion of statistical methods provided in **Section 4** of this document. The resources contain recommendations on how to select and apply different statistical tests to the comparison of environmental media. These principles can also be applied to beneficial use evaluations to compare stressor levels present in or released from a beneficial use and analogous product.

A.5.1 General Resources

Date: May 1974

Title: Basic Environmental Statistics Notebook

Author: U.S. EPA/Water Program Operations

Details: This document introduces the a number of concepts and applications of statistics to environmentally-oriented studies. Emphasis is placed on parametric tests of significance and sampling from normally distributed data.

Date: September 2002

Title: Guidance for Comparing Background and Chemical Concentrations in Soil for CERCLA Sites

Author: U.S. EPA/OSWER

Details: This document is intended to assist with the evaluation of back-ground concentrations at CERCLA sites. This document recommends statistical methods for characterizing reliable representation of background concentrations of chemicals in soil.

Date: September 2002

Title: Statistical Methods in Water Resources

Author: U.S. Department of the Interior/U.S. Geological Survey

Details: This document presents statistical methods likely to be of greatest usefulness to water resources scientists. Yet all topics can be directly applied to many other types of environmental data. The document emphasizes topics not always found in introductory statistics textbooks, and often not adequately covered in statistical textbooks for scientists and engineers.

Date: March 2009

Title: Statistical Analysis of Ground Water Monitoring Data at RCRA Facilities: Unified Guidance

Author: U.S. EPA/ ORCR

Details: This documents provides a suggested framework and recommendations for the statistical analysis of groundwater monitoring data at RCRA facility units to determine whether ground water has been impacted by a hazardous constituent release. This document provides examples and background information that will aid in successfully conducting statistical analyses.

Date: September 2013

Title: ProUCL Version 5.0.00 User Guide: Statistical Software for Environmental Applications for Data Sets with and without Nondetect Observations

Author: U.S. EPA/ORD

Details: ProUCL is a tool that provides numerous and varied statistical methods and graphical tools to address many environmental sampling and statistical issues. It can be run on environmental data sets with and without nondetect data samples. Calculating upper statistical limits is a primary function of the software and the graphical analyses offered includes probability plots, histograms, box plots, and line/trend plots.

A.6 Screening Benchmarks

The following compilation of resources supplements the discussion of screening benchmarks provided in **Section 5** of this document. These resources address the development and application of benchmarks to identify the stressors that do not warrant further evaluation. The general resources listed below provide models and guidance that can be used to calculate benchmarks, while the specific resources provide some sources of pre-developed benchmarks. This information can be used to select appropriate, existing benchmarks or to calculate evaluation-specific benchmarks. However, the parties conducting the evaluation are encouraged to engage with the appropriate regulatory bodies during the planning and scoping process to identify any benchmarks required by state or federal law.

A.6.1 General Resources

Date: June 2009

Title: Integrated Exposure Uptake Biokinetic (IEUBK) Model Version 1.1

Authors: U.S. EPA/OSWER

Details: The IEUBK Model is used to predict the risk of elevated blood lead levels in children (under the age of seven) that are exposed to environmental lead from many sources. The model also predicts the risk that a typical child, exposed to specified media lead concentrations, will have a blood lead level greater or equal to the level associated with adverse health effects.

Link: www.epa.gov/superfund/lead-superfund-sites-frequent-questions-risk-assessors-integrated-exposure-uptake

Date: May 2014

Title: Vapor Intrusion Screening Level (VISL) Calculator

Authors: U.S. EPA/OSWER

Details: VISL is a spreadsheet calculator that lists chemicals considered to be volatile and toxic through the inhalation pathway and calculates human health screening levels for ground water, soil gas and indoor air.

Link: www.epa.gov/vaporintrusion

A.6.2 Specific Human Health Benchmarks

The following tables provide some specific screening benchmarks that have been developed by EPA and other organizations. These tables provide a summary of each set of values and highlight the relevant receptors, stressors and media to help determine how well each set of benchmarks reflects the exposure scenarios anticipated for a given beneficial use evaluation. The focus of these tables is on the information anticipated to be most pertinent to beneficial uses, but a given set of benchmarks may include additional media, exposure routes, or stressors.

Maximum Contaminant Levels (MCLs)

Overview:	MCLs are regulatory standards that represent the maximum permissible level of a contaminant in water delivered to any user of a public water system serving 25 people. They have been developed for approximately 90 constituents and environmental indicators under the National Primary Drinking Water Regulations ("NPDWRs" or "primary standards").					
Media:		Soil	✓	Ground Water		Air
		Sediment	✓	Surface Water		Fish Tissue
Exposures:	✓	Ingestion		Inhalation		Dermal
Stressors:	✓	Metals	✓	VOCs	✓	SVOCs
	✓	Other: Dioxins/Furans, Radionuclides				
Basis:	The development of maximum contaminant level goals (MCLGs) is the first step in establishing MCLs. For most constituents, MCLGs are set at a level below which there is no known or expected risk to human health and which allow an adequate margin of safety. For known or probable human carcinogens, MCLGs are set equal to zero. MCLs are set as close to MCLGs as practicable after consideration of the cost and feasibility of available sampling, measurement and removal technologies.					
Developer:	U.S. EPA/Office of Water					
Website:	www.epa.gov/ground-water-and-drinking-water/table-regulated-drinking-water-contaminants					

National Ambient Air Quality Standards (NAAQs)

Overview:	NAAQs are regulatory standards established by EPA for six pollutants in ambient air throughout the United States. Standards are set as a maximum allowable concentration averaged over a given timeframe.					
Media:		Soil		Ground Water	✓	Air
		Sediment		Surface Water		Fish Tissue
Exposures:		Ingestion	✓	Inhalation		Dermal
Stressors:	✓	Metals		VOCs		SVOCs
	✓	Other: Particulate Matter				
	Notes: Standards are available for carbon monoxide, lead, nitrogen dioxide, ozone, particulate matter and sulfur dioxide.					
Basis:	NAAQS are based on comprehensive studies of available ambient air monitoring data, health effects data, and material effects studies. ▪ Primary standards are designed to protect human health, with an adequate margin of safety, including sensitive populations such as children, the elderly and people suffering from respiratory diseases. ▪ Secondary standards are designed to protect public welfare from any known or anticipated adverse effects of a pollutant (e.g., unacceptable damage to crops and vegetation, buildings and property, and ecosystems).					
Developer:	U.S. EPA/Office of Air					
Website:	www.epa.gov/criteria-air-pollutants/naaqs-table					

National Recommended Water Quality Criteria (NRWQC)

Overview:	NRWQC, also known as ambient water quality criteria (AWQC), are values developed by EPA to protect human and ecological health from the harmful effects of pollutants in surface water.					
Media:		Soil		Ground Water		Air
		Sediment	✓	Surface Water	✓	Fish Tissue
Exposures:	✓	Ingestion	✓	Inhalation		Dermal
	Additional Notes: Ingestion benchmarks are developed for both for the consumption of water and aquatic organisms (e.g., fish) together and for consumption of organisms alone. Inhalation is considered together with ingestion in non-cancer screening benchmarks.					
Stressors:	✓	Metals	✓	VOCs	✓	SVOCs
	✓	Other: Dioxin/Furan, pH, Suspended Solids, Turbidity				
Basis:	▪ Human health benchmarks for carcinogens are based on a 1×10^{-6} excess lifetime cancer risk. ▪ Human health benchmarks for non-carcinogens are based on an HQ of 1, the threshold below which adverse effects are not known to occur.					
Developer:	U.S. EPA/Office of Water					
Website:	www.epa.gov/wqc/national-recommended-water-quality-criteria					

Preliminary Remediation Goals (PRGs) for Radionuclides

Overview:	PRGs are screening benchmarks for human health derived from equations combining exposure assumptions with chemical-specific toxicity values. Users may select from default screening benchmarks or may calculate their own using the PRG Calculator.					
Media:	✓	Soil	✓	Ground Water	✓	Air
	✓	Sediment	✓	Surface Water	✓	Fish Tissue
	✓	Other: Produce, Two-Dimensional Surfaces, Three-Dimensional Buildings				
Exposures:	✓	Ingestion	✓	Inhalation		Dermal
	✓	Other: External Exposure				
	Notes: Default screening benchmarks are developed both for each individual exposure route and for all exposure routes considered together.					
Stressors:		Metals		VOCs		SVOCs
	✓	Other: Radionuclides				
Basis:	▪ Default PRGs for carcinogens are based on a 1×10^{-6} cancer risk. ▪ User-defined PRGs are generated by the calculator based on a cancer risk selected by the user.					
Developer:	U.S. EPA/OSWER and Oak Ridge National Laboratory (ORNL)					
Website:	Soil/water/air PRGs: epa-prgs.ornl.gov/radionuclides/ Outdoors hard surface PRGs: epa-sprg.ornl.gov/ Indoor building PRGs: epa-bprg.ornl.gov/					

Regional Screening Levels (RSLs)

Overview:	RSLs are benchmarks derived for multiple media from equations combining exposure assumptions with chemical-specific toxicity values. Users may select from default screening benchmarks or may calculate their own using the calculator.					
Media:	✓	Soil	✓	Ground Water	✓	Air
	✓	Sediment	✓	Surface Water	✓	Fish Tissue
Exposures:	✓	Ingestion	✓	Inhalation	✓	Dermal
	Notes: Screening benchmarks are developed both for each individual exposure route and for all exposure routes considered together.					
Stressors:	✓	Metals	✓	VOCs	✓	SVOCs
	✓	Other: Dioxin/Furan				
Basis:	▪ Default values for carcinogens are based on a 1×10^{-6} cancer risk. ▪ Default values for non-carcinogens are based on a hazard quotients of 0.1 or 1. ▪ User-defined values are generated by the RSL calculator based on a cancer risk or hazard quotient selected by the user.					
Developer:	U.S. EPA/Regions 3, 6 and 9, and ORNL					
Website:	www.epa.gov/risk/regional-screening-levels-rsls					

Secondary Maximum Contaminant Levels (SMCLs)

Overview:	SMCLs, also called National Secondary Drinking Water Regulations (NSDWRs), set non-mandatory water quality standards. EPA does not enforce these secondary levels. They are established only as guidelines to assist public water systems in managing their drinking water for aesthetic considerations, such as taste, color and odor. These stressors are not considered to present a risk to human health at the SMCL. At present, SMCLs have been developed for 15 stressors.					
Media:		Soil	✓	Ground Water		Air
		Sediment	✓	Surface Water		Fish Tissue
Exposures:	✓	Ingestion		Inhalation		Dermal
Stressors:	✓	Metals		VOCs		SVOCs
	✓	Other: Color, Corrosivity, Odor, Foaming Agents, pH, Total Dissolved Solids				
Basis:	The lowest concentration at which these associated adverse effects are not known or anticipated to occur under typical conditions found in public water systems.					
Developer:	U.S. EPA/Office of Water					
Website:	www.epa.gov/dwstandardsregulations/secondary-drinking-water-standards-guidance-nuisance-chemicals					

A.6.3 Specific Ecological Benchmarks

The following tables provide some sources of ecological screening benchmarks that have been developed by EPA and other organizations. These tables provide a summary of each set of values and highlight the relevant receptors, stressors and media to help determine how well each set of benchmarks reflects the exposure scenarios anticipated for a given beneficial use evaluation. The focus of these tables is on the information anticipated to be most pertinent to beneficial uses; however, a given set of benchmarks may include additional media, exposure routes or stressors.

Ecological Soil Screening Levels (Eco-SSLs)

Overview:	Eco-SSLs are soil concentrations for approximately 20 chemicals developed to be protective of ecological receptors that commonly come into contact with soil or ingest biota that live in or on soil.					
Media:	✓	Soil		Ground Water		Air (Pore Gas)
		Sediment		Surface Water	✓	Biota
Exposure Route:	✓	Ingestion		Inhalation	✓	Direct Contact
	Notes: Ingestion of soil and biota considered for mammals, birds and invertebrates. Direct contact also considered for plants and invertebrates.					
Stressors:	✓	Metals	✓	VOCs	✓	SVOCs
	Notes: Benchmarks are available for 17 metals, pentachlorophenol, and total polyaromatic hydrocarbons.					
Basis:	Derived from a review of the literature on the lowest concentration at which no observed adverse effects levels (NOAELs) were observed for plants, invertebrates, birds and/or mammals. A					
Developer:	U.S. EPA/OSWER					
Website:	www.epa.gov/ecotox/ecossl					

ECORISK Database

Overview:	The ECORISK Database is a screening tool developed by the Los Alamos National Laboratory to evaluate impacts from chemicals and radionuclides in soil, water, sediment and air on the ecological receptors. Screening levels are calculated for receptors in various functional feeding guilds (e.g., carnivores, herbivores, insectivores) or drawn from the peer-reviewed literature.					
Media:	✓	Soil		Ground Water	✓	Air (Pore Gas)
	✓	Sediment	✓	Surface Water		Biota
Exposure Route:	✓	Ingestion	✓	Inhalation	✓	Direct Contact
Stressors:	✓	Metals	✓	VOCs	✓	SVOCs
	✓	Others: Dioxins/Furans, Pesticides, Radionuclides.				
Basis:	Dependent on individual benchmark source.					
Developer:	Los Alamos National Laboratory (LANL)					
Website:	www.lanl.gov/community-environment/environmental-stewardship/protection/eco-risk-assessment.php					

Great Lakes Initiative Clearinghouse

Overview:	The Clearinghouse is a central access point for available data from State and Tribal environmental agencies. It contains information on criteria, toxicity data, exposure parameters and other supporting documents used in developing water quality standards in the Great Lakes Watershed. It currently contains data provided by Indiana, Minnesota, New York, Ohio, and Wisconsin.					
Media:		Soil		Ground Water		Air (Pore Gas)
		Sediment	✓	Surface Water		Biota
Exposures:	✓	Ingestion		Inhalation	✓	Direct Contact
Stressors:	✓	Metals	✓	VOCs	✓	SVOCs
	✓	Others: Pesticides, Dioxins/Furans				
Basis:	Dependent on individual benchmark source.					
Developer:	State and Tribal environmental agencies					
Website:	www.epa.gov/gliclearinghouse/					

National Recommended Water Quality Criteria (NRWQC)

Overview:	NRWQC, also known as ambient water quality criteria (AWQC), are values developed by EPA to protect human and ecological health from the harmful effects of pollutants in surface water.					
Media:		Soil		Ground Water		Air (Pore Gas)
		Sediment	✓	Surface Water		Biota
Exposures:	✓	Ingestion		Inhalation	✓	Direct Contact
Stressors:	✓	Metals	✓	VOCs	✓	SVOCs
	✓	Other: Dioxin/Furan				
Basis:	Ecological benchmarks based on a review of all available toxicological literature for both acute and chronic effects. If warranted, criteria may also be a function of different water quality criteria (e.g., pH, temperature, hardness).					
Developer:	U.S. EPA/Office of Water					
Website:	www.epa.gov/wqc/national-recommended-water-quality-criteria					

Risk Assessment Information System Database

Overview:	Oak Ridge National Laboratory developed and compiled a searchable database of ecological screening benchmarks from a number of sources for a range of aquatic organisms, soil invertebrates, and terrestrial plants.					
Media:	✓	Soil		Ground Water		Air (Pore Gas)
	✓	Sediment	✓	Surface Water	✓	Biota
Exposures:	✓	Ingestion		Inhalation	✓	Direct Contact
Stressors:	✓	Metals	✓	VOCs	✓	SVOCs
	✓	Other: Pesticides				
Basis:	Dependent on individual benchmark source.					
Developer:	Oak Ridge National Laboratory (ORNL), University of Tennessee, and Bechtel Jacobs Corp.					
Website:	rais.ornl.gov/tools/eco_search.php					

Screening Quick Reference Tables (SQuiRTs)

Overview:	SQuiRTs is a compilation of ecological screening benchmarks developed by EPA, other U.S. agencies, Canada, the Netherlands and the United Nations. This reference tool was developed to help evaluate potential risks from inorganic and organic contaminants in water, sediment and soil.					
Media:	✓	Soil		Ground Water		Air (Pore Gas)
	✓	Sediment	✓	Surface Water		Biota
Exposures:	✓	Ingestion		Inhalation	✓	Direct Contact
Stressors:	✓	Metals	✓	VOCs	✓	SVOCs
	✓	Other: Radionuclides, Pesticides				
Basis:	Dependent on individual benchmark source.					
Developer:	National Ocean and Atmospheric Administration (NOAA)					
Website:	Benchmarks: response.restoration.noaa.gov/sites/default/files/SQuiRTs.pdf FAQs: response.restoration.noaa.gov/environmental-restoration/environmental-assessment-tools/squirt-cards-faq.html					

A.7 Toxicity Values

The following compilation of resources supplements the discussion of receptor exposure factors provided in **Section 5** and **Section 6** of this document. These resources identify different sources of toxicity values, detail how these values are derived, and provide recommendations on how to select the most appropriate values when more than one are available for a single exposure scenario. This information may be used in the beneficial use evaluation to calculate screening values or risks.

A.7.1 General Resources

Date: December 1989

Title: RAGS Volume I—Part A: Human Health Evaluation Manual
Chapter 7: Toxicity Assessment

Author: U.S. EPA/OSWER

Details: Provides step-by-step guidance for locating EPA toxicity assessments and accompanying values, and advises how to determine which values are most appropriate when multiple values exist. Prior to this procedural discussion, background information regarding EPA's methods for toxicity assessment is provided to help the risk assessor understand the basis of the toxicity values and the limitations of their use.

Date: December 2003

Title: Human Health Toxicity Values in Superfund Risk Assessments

Author: U.S. EPA/OSWER

Details: This document presents the OSWER technical and policy recommendations regarding the use of human health toxicity values in risk assessments. A tiered approach is provided to prioritize the selection of chemical toxicity data based on the quality of the underlying toxicity database and the extent of peer review.

Date: April 2007

Title: Identification and Selection of Toxicity Values/Criteria for CERCLA and Hazardous Waste Risk Assessments in the Absence of IRIS Values

Author: Environmental Council of the States (ECOS), Department of Defense

Details: This document provides recommendations from ECOS on identifying and selecting toxicity values for those chemicals for which an IRIS toxicity value is not available.

Date: December 2010

Title: Dioxin Toxicity Equivalency Factors (TEFs) for Human Health Risk Assessments of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin and Dioxin-Like Compounds

Author: U.S. EPA/Risk Assessment Forum

Details: This document describes the updated EPA approach for evaluating the human health risks from exposures to environmental media that contain dioxin-like compounds. EPA recommends that the toxicity equivalence factor (TEF) methodology, a component mixture method, be used to evaluate human health risks posed by these mixtures, using 2,3,7,8-tetrachlorodibenzo-p-dioxin as the index chemical.

Date: June 2012

Title: Ecological Structure Activity Relationships (ECOSAR)

Authors: U.S. EPA/Office of Pollution Prevention and Toxics

Details: ECOSAR is a computerized predictive system that estimates aquatic toxicity. The program estimates a chemical's acute (short-term) toxicity and chronic (long-term or delayed) toxicity to aquatic organisms such as fish, aquatic invertebrates, and aquatic plants by using computerized structure activity relationships.

Date: May 2013

Title: Tier III Toxicity Value White Paper

Author: U.S. EPA/Human Health Risk Assessment Forum

Details: This paper articulates issues pertaining to the selection of toxicity values when multiple Tier III values are available and provides recommendations on processes that will improve the transparency and consistency of evaluating, selecting and documenting these values.

Date: Constituent-Specific

Title: ATSDR Toxicological Profiles

Author: ATSDR/Division of Toxicology

Details: Provides toxicological profiles for stressors found at National Priorities List and other federal sites. Chemical names can be searched alphabetically. Each toxicological profile contains a review of key studies and other data characterizing the exposure-related health effects and pertinent characteristics and processes that affect human exposures. Sections include other relevant information on releases to the environment, environmental fate, levels monitored in the environment, potential exposures, and analytical methods. Numerical toxicity values for many of these chemicals are available through the ATSDR minimum risk levels (MRLs).

A.7.2 Specific Human Health Toxicity Values

The tables below provide specific examples of human health toxicity values for chemical stressors derived by EPA and other organizations. These tables contain a general description of each set of values; highlight the relevant receptors, exposure timeframe and exposure route that determine how well each set of values reflect the types of exposures anticipated for a given beneficial use; and provide links to where the values can be found. Values are developed for the specific timeframes and exposure routes listed in the tables only when sufficient data are available for a given chemical.

California Environmental Protection Agency (CalEPA)

Overview:	CalEPA has developed two sets of toxicity values, cancer potency values (CPVs) for carcinogens and reference exposure levels (RELs) for non-carcinogens, for 120 chemicals regulated under the California Hot Spots Air Toxics Program. These values have undergone internal peer review by various California agencies and have been the subject of public comment.					
Timeframe:	✓	Chronic		Sub-chronic		Acute
Route:	✓	Oral	✓	Inhalation		
Developer:	State of California/Office of Environmental Health and Hazard Assessment (OEHHA) and Air Resources Board					
Website:	www.arb.ca.gov/toxics/healthval/healthval.htm					

Health Effects Assessment Summary Tables (HEAST)

Overview:	HEAST is a listing of provisional human health toxicity values. EPA has developed four sets of toxicity values, cancer slope factor (CSF, ingestion) and unit risk factor (URF, inhalation) for carcinogens and reference dose (RfD, ingestion) and reference concentration (RfC, inhalation) for noncarcinogens. Although the toxicity values in HEAST have undergone review and have the concurrence of individual EPA program offices, they have not been reviewed as extensively as those in IRIS. The HEAST tables for chemical constituents are not periodically updated at this time.					
Timeframe:	✓	Chronic		Sub-chronic		Acute
Route:	✓	Oral	✓	Inhalation		
Developer:	U.S. EPA/OSWER					
Website:	Chemicals: cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=2877					

Integrated Risk Information System (IRIS)

Overview:	IRIS is the EPA human health assessment program that evaluates information on the health effects of more than 550 chemical stressors. EPA has developed four sets of toxicity values, CSF (ingestion) and URF (inhalation) for carcinogens and RfD (ingestion) and RfC (inhalation) for noncarcinogens. Each chemical has undergone multiple rounds of extensive internal and public review. The file for each stressor contains descriptive and quantitative information on the potential health effects.					
Timeframe:	✓	Chronic		Sub-chronic		Acute
Route:	✓	Oral	✓	Inhalation		
Developer:	U.S. EPA/ORD					
Website:	www.epa.gov/IRIS/					

Provisional Peer-Reviewed Toxicity Values (PPRTVs)

Overview:	PPRTVs provide information on the cancer and non-cancer effects of various chemical stressors. EPA has developed four sets of toxicity values, CSF (ingestion) and URF (inhalation) for carcinogens and RfD (ingestion) and RfC (inhalation) for noncarcinogens. PPRTVs are derived after a review of the relevant scientific literature using the methods, sources of data and guidance for value derivation used by the EPA IRIS Program. All PPRTVs receive internal review by EPA scientists and external peer review by independent scientific experts.					
Timeframe:	✓	Chronic	✓	Sub-chronic		Acute
Route:	✓	Oral	✓	Inhalation		
Developer:	U.S. EPA/OSWER and ORNL					
Website:	hhpprtv.ornl.gov					

Minimum Risk Levels (MRLs)

Overview:	MRLs are substance-specific health guidance levels developed by ATSDR for only the non-carcinogenic endpoints associated with each chemical. An MRL is an estimate of the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse health effects over a specified duration of exposure. MRLs are derived for acute, intermediate and chronic exposure durations for oral and inhalation routes of exposure.					
Timeframe:	✓	Chronic	✓	Sub-chronic	✓	Acute
Route:	✓	Oral	✓	Inhalation		
Developer:	ATSDR					
Website:	www.atsdr.cdc.gov/mrls/index.asp www.atsdr.cdc.gov/toxprofiles/index.asp					

A.7.3 Specific Ecological Toxicity Data

The tables below provide specific sources of toxicity data for chemical stressors derived by EPA and other organizations. These tables contain a general description of each data set and provide links to where the values can be found. Each database may contain diverse types of data on different chemicals, media, receptors, exposure durations and adverse effects that will require careful handling and interpretation before use.

Ecological Toxicology (ECOTOX) Database

Overview:	ECOTOX is a database that provides information on adverse effects of a range of single chemical stressors to ecologically relevant aquatic and terrestrial species. The primary source of data included in this database is peer-reviewed literature.
Developer:	EPA/ORD
Website:	cfpub.epa.gov/ecotox/

ECORISK Database

Overview:	The ECORISK Database is a screening tool developed by the Los Alamos National Laboratory to evaluate impacts from chemicals and radionuclides in soil, water, sediment and air on the ecological receptors. This database includes toxicity data for plants, worms, birds and mammals based on evaluation of peer-reviewed toxicity study literature. The other data available for terrestrial and aquatic receptors and for radionuclides come from the EPA, ORNL, the International Atomic Energy Agency for radionuclides, and other sources.
Developer:	EPA/ORD
Website:	www.lanl.gov/environment/protection/eco-risk-assessment.php

Great Lakes Initiative Clearinghouse

Overview:	The Clearinghouse is a central access point for available data from State and Tribal environmental agencies. It contains information on criteria, toxicity data, exposure parameters and other supporting documents used in developing water quality standards in the Great Lakes Watershed. It currently contains data provided by Indiana, Minnesota, New York, Ohio, and Wisconsin.
Developer:	State and Tribal environmental agencies
Website:	www.epa.gov/gliclearinghouse/

A.8 Exposure Factors

The following compilation of resources supplements the discussion of receptor exposure factors in **Section 5** and **Section 6** of this document. These resources identify and compile data on physiological, behavioral and cultural factors that can influence human and ecological exposures. This information can be used to characterize the magnitude, frequency and duration of potential exposures. Some of the listed resources represent different editions of the same document and are provided for the historical context and discussion contained therein.

A.8.1 General Resources for Human Exposure

Date: June 1991

Title: Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual, Supplemental Guidance: Standard Default Exposure Factors

Author: U.S. EPA/OSWER

Details: This guidance recommends exposure factors based on the data contained in the original 1989 *Exposure Factors Handbook*. The exposure factors discussed are defaults used in many historical OSWER risk assessments in the absence of site-specific data.

Date: August 1997

Title: Exposure Factors Handbook

Author: U.S. EPA/ORD

Details: This handbook summarizes data on human behaviors and characteristics that affect exposure to environmental contaminants and recommends values to characterize these factors. It includes discussions of the issues assessors should consider in deciding how to use these data and recommendations.

Date: September 2006

Title: Example Exposure Scenarios

Author: U.S. EPA/ORD

Details: Outlines scenarios for various exposure pathways and to demonstrate how data from the 1997 *Exposure Factors Handbook* may be applied for estimating exposures. It should be noted that the example scenarios presented here have been selected to best demonstrate the use of the various key data sets in the *Exposure Factors Handbook* and represent commonly encountered exposure pathways.

Date: September 2008 (Full Document)
October 2009 (Highlights)

Title: Child-Specific Exposure Factors Handbook

Author: U.S. EPA/ORD

Details: Focuses on various factors used in assessing exposure, specifically for children 0 to < 21 years old. This handbook provides nonchemical-specific data on exposure factors for the EPA-recommended set of childhood age groups.

Date: September 2011 (Full Document)
October 2011 (Highlights)

Title: Exposure Factors Handbook: 2011 Edition

Author: U.S. EPA/ORD

Details: This handbook summarizes data on human behavioral and physiological characteristics that affect exposure to environmental contaminants and provides exposure/risk assessors with recommended values for these factors that can be used to assess exposure among both adults and children. This handbook incorporates the changes in risk assessment practices based on the need to consider life stages rather than subpopulations.

Date: February 2014

Title: Human Health Evaluation Manual, Supplemental Guidance: Update of Standard Default Exposure Factors

Author: U.S. EPA/OSWER

Details: Based on the recommendations from *Exposure Factors Handbook: 2011 Edition*, several OSWER default exposure factors were identified that warranted updates. This guidance presents the updated recommended values. This guidance supplements the *Risk Assessment Guidance for Superfund: Human Health Evaluation Manual (RAGS), Part A through E*. Where numerical values differ from those presented in Part A or E, the factors presented in this guidance should be considered updates to the older values.

A.8.2 General Resources for Ecological Exposure

Date: December 1993

Title: Wildlife Exposure Factors Handbook

Author: U.S. EPA/ORD

Details: This handbook provides data, references and guidance for conducting a screening-level risk assessment of common wildlife species exposed to toxic chemicals in the environment.

Date: Species-Specific

Title: Mammalian Species Series

Author: American Society of Mammalogists

Details: The American Society of Mammalogists has published these documents since 1969, with 20 to 30 new accounts issued each year. Each account summarizes the current understanding of the biology of a single species, including systematics, distribution, fossil history, genetics, anatomy, physiology, behavior, ecology and conservation.

A.9 Fate and Transport Models

The following compilation of resources supplements the discussion of fate and transport models provided in **Section 5** and **Section 6** of this document. These resources detail some models that can be used to predict the extent to which dilution and attenuation occurs as stressors migrate through the environment. These models may be used to estimate stressor levels at the point of exposure as part of either a conservative screening assessment or a more realistic risk assessment. While the specific models discussed in some of the general resources may no longer be the most relevant or current for beneficial use evaluations, the discussion about fate and transport considerations and model selection may still be useful.

A.9.1 General Resources

Date: March 1994

Title: Evaluation of Unsaturated/Vadose Zone Models for Superfund Sites

Author: U.S. EPA/ORD

Details: This report summarizes research findings that address the sensitivity and uncertainty of model output due to uncertain input parameters. The objective of the research was to determine the sensitivity and uncertainty of travel time, concentration, mass loading and pulse width of contaminants at the water table due to uncertainty in soil, chemical, and site properties for four models: Regulatory and Investigative Treatment Zone (RITZ), Vadose Zone Interactive Processes (VIP), Chemical Movement in Layered Soils (CMLS) and HYDRUS.

Date: November 1998

Title: RBCA Fate and Transport Models: Compendium and Selection Guidance

Author: American Society of Testing and Materials (ASTM)

Details: This document catalogs and describes non-proprietary fate and transport models that are readily available for risk-based corrective action (RBCA) at the time of publication. It is meant to function as a compendium and resource guide, assisting the user in the model selection process. It is not intended to be a comprehensive review of every available fate and transport model or a comprehensive guidance on the use of any single model. The guidance does not endorse models listed or attempt to rank them or evaluate their performance or accuracy.

A.9.2 Specific Fate and Transport Models

These tables summarize several publicly available models that have been developed by EPA and other organizations to estimate the fate and transport of stressors through the environment. The models listed are publicly available and nonproprietary. These models vary widely in scope and complexity. Each table provides a general summary of a model; highlight the different data requirements, outputs and limitations of the model; and provide a link to where the model can be found.

American Meteorological Society/EPA Regulatory Model (AERMOD)

Overview:	AERMOD is a steady-state plume model that estimates the amount of atmospheric dispersion and deposition during windblown transport of stressors. The model has two pre-processors designed to handle transport over variable terrain and account for inhomogeneity within the air column. AERMOD may be appropriate to estimate exposures to particulate matter, gases and vapors released from beneficial uses exposed to outdoor air.

Model Type:	✓	Deterministic		Probabilistic		
Spatial Variability:	✓	Lumped		Distributed		
Media:		Soil		Ground Water	✓	Air
		Sediment		Surface Water		Food

Required Inputs:	▪ Source type (e.g., single point, capped stack, horizontal stack, rectangular area, circular area, flares, volume). ▪ Source characteristics (e.g., emission rate, release height, dimensions). ▪ Building characteristics (e.g., height, width, distance from source). ▪ Hourly meteorology (e.g., temperature, wind speed/direction, cloud cover). ▪ Terrain (e.g., albedo, bowen ratio, roughness length, elevation). ▪ Coordinate system (e.g., cartesian grid, polar grid, single discrete point). ▪ Receptor data (e.g., population size, distance from source, urban/rural).
Model Outputs:	▪ Time-averaged air concentration and land deposition rates as a function of location (x-, y-, z-axis) for specified averaging time (e.g., 1-hr, 3-hr, 24-hr). ▪ Occurrences (time and location) of a stressor concentration exceeding a user-specified threshold.
Major Assumptions:	▪ Constant, temporally averaged meteorological conditions are present during each modeled hour. ▪ Exposed receptors are less than 50 km away from the source. ▪ In the stable boundary layer of the atmosphere, stressor concentrations in both vertical and horizontal direction fit a normal distribution. ▪ Stressors are chemically inert.
Developer:	U.S. EPA/Office of Air and American Meteorological Society (AMS)
Website:	www3.epa.gov/scram001/dispersion_prefrec.htm

American Meteorological Society/EPA Regulatory Model Screen (AERSCREEN)

Overview:	AERSCREEN is the screening version of AERMOD. This model is designed to conservatively account for atmospheric dispersion during windblown transport of stressors. AERSCREEN may be appropriate to estimate exposures to particulate matter, gases and vapors released from beneficial uses exposed to outdoor air.					
Model Type:	✓	Deterministic		Probabilistic		
Spatial Variability:	✓	Lumped		Distributed		
Media:		Soil		Ground Water	✓	Air
		Sediment		Surface Water		Food
Required Inputs:	▪ Source type (e.g., single point, capped stack, horizontal stack, rectangular area, circular area, flares, volume). ▪ Source characteristics (e.g., emission rate, release height, dimensions). ▪ Building characteristics (e.g., height, width, distance from source). ▪ Hourly meteorology (e.g., temperature, wind speed/direction, cloud cover). ▪ Terrain (e.g., albedo, bowen ratio, roughness length, elevation). ▪ Receptor data (e.g., population size, distance from source, urban/rural).					
Model Outputs:	▪ Worst-case 1-hr time-averaged air concentration at a given elevation and distance. ▪ Worst-case 3-hr, 8-hr, 24-hr and annual time-averaged concentrations based on modeled 1-hr concentration.					
Major Assumptions:	▪ Constant, temporally averaged meteorological conditions are present during each modeled hour. ▪ Exposed receptors are less than 50 km away from the source. ▪ Receptors are located along the centerline of plume. ▪ Stressors are inert and recalcitrant. ▪ Deposition does not occur.					
Developer:	U.S. EPA/Office of Air and AMS					
Website:	www3.epa.gov/scram001/dispersion_screening.htm					

California Total Exposure (CalTOX) Model

Overview:	CalTOX is a spreadsheet-based model that simulates the fate and transport of stressors through different environmental media originating from releases to soil, air and/or water along with the magnitude of resulting exposures. CalTOX can conduct uncertainty and variability analyses through Monte Carlo simulations. This model may be applicable to outdoor beneficial uses that are exposed to precipitation and wind.
Model Type:	✓ Deterministic ✓ Probabilistic **Note:** The model can be run deterministically with single-value inputs, but all model inputs for transport, transformation and exposure assessment can be probabilistic.
Spatial Variability:	✓ Lumped Distributed **Note:** CalTOX is a compartmental model that does not account for the spatial variations of a stressor within each media.
Media:	✓ Soil ✓ Ground Water ✓ Air ✓ Sediment ✓ Surface Water ✓ Food **Note:** Food pathway includes produce, meat, dairy, eggs and fish.
Required Inputs:	▪ Stressor properties (e.g., partition coefficients, vapor pressure, degradation rates, toxicity values). ▪ Meteorology (e.g., wind speed, temperature, rainfall, deposition velocity). ▪ Hydrogeology (e.g., bulk density, erosion rates, infiltration rate, ground water recharge, root zone depth, porosity, runoff rate, surface water depth). ▪ Exposure factors (e.g., ingestion rate, body weight, exposure duration).
Model Outputs:	▪ Media-specific human health exposure concentrations. ▪ Probability or cumulative density function of environmental concentrations. ▪ Human health risks from exposure to different media.
Major Assumptions:	▪ Stressor concentrations are uniform within the media of interest. ▪ Mass transport across different environmental media is one-dimensional. ▪ Evaluation timescale is on the order of years. ▪ Stressor transport and transformations across/within media are first-order processes. ▪ Ratio of dry land to surface water is large (≥ 90% dry land). ▪ Stressor concentrations are treated either as constant with a continuous source or as time-varying based on the initial concentrations in each soil layer. ▪ Stressors are not mixed polarity dissociating organics (e.g., surfactants), volatile metals (e.g., mercury) or inorganic chemical with high vapor pressure.
Developer:	State of California/Department of Toxic Substances Control
Website:	www.dtsc.ca.gov/AssessingRisk/caltox.cfm

EPA Composite Model for Leachate Migration with Transformation Products (EPACMTP)

Overview:	EPACMTP simulates the fate and transport of leached stressors through the subsurface environment. The model combines two separate modules to account for advection, dispersion and diffusion through the unsaturated and saturated zones. The model is designed to run either deterministically or probabilistically. EPACMTP was originally designed to evaluate stressor releases from land disposal units (e.g., landfills); however, the current version can also be used to evaluate ground water impacts from the land application of secondary materials.					
Model Type:	✓	Deterministic	✓	Probabilistic		
Spatial Variability:	✓	Lumped		Distributed		
Media:		Soil	✓	Ground Water		Air
		Sediment		Surface Water		Food
Required Inputs:	▪ Source characteristics (e.g., geometry, depth below ground). ▪ Stressor properties (e.g., initial leachate concentration, MINTEQA2-derived sorption isotherms, degradation rate). ▪ Meteorology (e.g., precipitation rate). ▪ Hydrogeology (e.g., temperature, depth to aquifer, hydraulic conductivity, aquifer thickness). ▪ Receptor location (e.g., distance from source, depth of well, angle of well off away from the plume centerline).					
Model Outputs:	▪ Deterministic simulation outputs stressor concentrations at the top of the water table or at a downgradient receptor well. ▪ Probabilistic simulation outputs the distribution of either peak or time-averaged stressor concentrations at a downgradient receptor well as a function of both distance (x-, y-, and z-axis) and time.					
Major Assumptions:	▪ Soil and aquifer media properties are homogenous. ▪ The modeled source is the only contributor of stressors to the environment. ▪ Transformation (e.g., hydrolysis, oxidation, biodegradation) of stressors follow first-order kinetics. ▪ The surficial aquifer is unconfined and has a constant saturated thickness. ▪ Stressors are not non-aqueous phase liquids (NAPL) or volatiles. ▪ The stressor concentration entering the unsaturated soil is either constant or depletes at a first-order rate.					
Developer:	U.S. EPA/OSWER and HydroGeoLogic, Inc.					
Website:	www.epa.gov/smm/epas-composite-model-leachate-migration-transformation-products-epacmtp					

HYDRUS-1D

Overview:	The HYDRUS models simulate the fate and transport of heat and chemical solutes (as well as viruses, bacteria, colloids, and nanoparticles) through variably-saturated (i.e., unsaturated, partially or fully saturated) subsurface environments. This model accounts for advection, gaseous and liquid diffusion, dispersion, sorption, and chemical transformation of stressors within the variably saturated media. HYDRUS-1D is a one-dimensional version of the model available in the public domain. This model may be applicable to outdoor beneficial uses that are exposed to precipitation.							
Model Type:	✓	Deterministic		Probabilistic				
Spatial Variability:		Lumped	✓	Distributed				
Media:		Soil	✓	Ground Water		Air		
		Sediment		Surface Water		Food		
Required Inputs:	▪ Stressor properties (e.g., dispersivity, diffusion coefficients, adsorption isotherm coefficients, Henry's law constants, production and degradation rates, attachment/detachment rates). ▪ Hydrogeology (e.g., soil types and layers, depth of soil profile, hydraulic conductivity, retention properties, soil bulk density, porosity, initial water content, and initial pressure head). ▪ Meteorology (e.g., time-dependent precipitation, evaporation rate, transpiration rate, temperature, solar radiation).							
Model Outputs:	▪ Graphical representation of changes in stressor concentration, water content, pressure head, and temperature as a function of time at user-specified observational nodes within the soil profile. ▪ Graphical representation of profiles of stressor concentration, water content, pressure head, and temperature as a function of depth (z-axis) at user-specified times). ▪ Actual and cumulative water and solute fluxes, pressure head, and water content at flow boundaries (i.e., at the surface or bottom of the soil profile).							
Major Assumptions:	▪ Stressors are not NAPL. ▪ Stressor transport is limited to the vertical, horizontal or inclined direction. ▪ Transformation (e.g., degradation, volatilization, precipitation) follows zero- or first-order kinetics. ▪ Partitioning between liquid and gas phases are linear and in equilibrium (but solid-liquid phase partitioning processes can be nonlinear and non-equilibrium).							
Developers:	University of California Riverside and PC-Progress Incorporated							
Website:	http://www.pc-progress.com/en/Default.aspx?hydrus-1d							

Industrial Waste Air (IWAIR) Model

Overview:	IWAIR is composed of three modules that simulate the volatilization of stressors from solid and liquid materials into the surrounding air, the subsequent fate and transport downgradient, and the resulting risk to receptors. This model may be applicable to outdoor beneficial uses that passively emit gas or vapor.					
Model Type:	✓	Deterministic		Probabilistic		
Spatial Variability:	✓	Lumped		Distributed		
Media:		Soil		Ground Water	✓	Air
		Sediment		Surface Water		Food
Required Inputs:	▪ Source properties (e.g., area, depth, application rate, bulk density, porosity, total stressor mass). ▪ Stressor properties (e.g., vapor pressure, diffusivity in air and water, soil biodegradation rate, hydrolysis constant, henry's law constant). ▪ Dispersion modeling parameters (e.g., source type, height aboveground of a WMU, wind speed, wind direction, mixing height, air stability class, receptor type, distance to potential receptors). ▪ Exposure factors (e.g., inhalation rate, body weight, exposure duration).					
Model Outputs:	▪ Human health risks from inhalation of vapor-phase emission. ▪ Allowable stressor concentration at source pre-calculated from exposure level concentration without an appreciable adverse effect at the receptor point.					
Major Assumptions:	▪ No more than six stressors are present during a single model run. ▪ The source and surrounding environmental media are in equilibrium. ▪ Biodegradation, hydrolysis and adsorption processes are considered for an impoundment waste containing low concentrations of organics chemicals; however, these processes are not considered when the waste is over saturated with organic chemicals. ▪ Biodegradation is accounted for in emission modeling for landfills, waste piles and land application units, but hydrolysis is not considered. ▪ Volatilization is the primary route through which stressors are released; releases through sorption to windblown particulates is negligible. ▪ Any biodegradation or hydrolysis of stressors occurs through first-order kinetics. ▪ Both wet and dry depletion of vapors from the atmosphere is negligible. ▪ No emission control technologies are in place.					
Developer:	U.S. EPA/OSWER					
Website:	www.epa.gov/smm/industrial-waste-air-model-iwair					

Industrial Waste Management Evaluation Model (IWEM)

Overview:	IWEM is a screening-level model that conservatively implements EPACMTP to simulate the fate and transport of stressors leached into the subsurface environment. The model accounts for advection, dispersion, diffusion, and chemical transformation processes during transport through unsaturated and saturated subsurface media. The model uses predefined probability distributions for several input parameters to capture potential national variability. The remaining user-defined inputs are deterministic. The model also compares stressor levels at the point of exposure to user-specified screening levels. The current version is designed to consider releases from beneficial use in land application, road construction, embankments and structural fill that are exposed to precipitation.					
Type:	✓	Deterministic	✓	Probabilistic		
Spatial Variability:	✓	Lumped		Distributed		
Media:		Soil	✓	Ground Water		Air
		Sediment		Surface Water		Food
Inputs:	▪ Source characteristics (e.g., geometry, density, hydraulic conductivity, leachable mass of stressors). ▪ Stressor properties (e.g., initial leachate concentration, partitioning coefficient). ▪ Overland flow characteristics (e.g., runoff rate, manning's number). ▪ Soil data (e.g., soil type, infiltration rate into soil). ▪ Hydrogeology (e.g., ground water depth, hydraulic conductivity, aquifer thickness). ▪ Meteorology (e.g., annual rainfall, evaporation rate). ▪ Receptor location (e.g., distance from source, angle offset from plume centerline).					
Outputs:	▪ 90th percentile of maximum time-averaged stressor concentration at the receptor location as a function of location (x-, y-, and z-axis). ▪ Comparison of an exposure point stressor concentration with a pre-calculated health-based concentration.					
Major Assumptions:	▪ Source characteristics are constant. ▪ Releases only occur through the dissolution of stressors into water percolating through the source. ▪ The rate of infiltration through the source and unsaturated zone is constant on an annualized basis. ▪ Until all available mass is depleted, the stressor concentration in leachate from the source is either constant or decreasing over time through first-order kinetics. ▪ Stressor transport through the unsaturated soil is one-directional, entirely downward toward underlying ground water. ▪ The surficial aquifer is unconfined and has a constant saturated thickness. ▪ Both unsaturated and saturated soils are homogenous and isotropic. ▪ Geochemical interactions between stressors and environmental media are equilibrium sorption process. ▪ All biochemical transformation (e.g., hydrolysis, oxidation, biodegradation) follow first-order kinetics. ▪ Stressors are not NAPLs or volatiles.					
Developer:	U.S. EPA/OSWER					
Website:	www.epa.gov/smm/industrial-waste-management-evaluation-model-version-31					

Metal Speciation Equilibrium for Surface and Ground Water (MINTEQA2)

Overview:	MINTEQA2 is a geochemical speciation model that simulates equilibrium partitioning of total chemical mass among the dissolved species, adsorbed species, gas phase species, precipitates, and soluble complexes with organic and inorganic ligands under a variety of environmental conditions. The outputs from MINTEQA2 can help identify the likely speciation and partitioning coefficients of chemical stressors for use in other fate and transport models.					
Model Type:	✓	Deterministic		Probabilistic		
Spatial Variability:	✓	Lumped		Distributed		
Media:	✓	Soil	✓	Ground Water		Air
		Sediment	✓	Surface Water		Food
Inputs:	▪ System chemistry (e.g., ionic strength, alkalinity, pH, redox potential, temperature, initial concentration of major ions). ▪ Simulation design (e.g., adsorption model options, precipitation options, number of model iterations).					
Outputs:	▪ Equilibrium mass distribution of species in dissolved, precipitated, adsorbed, and volatilized states. ▪ Each time when solid precipitation occurs, the model outputs a pre-equilibrium, or provisional mass distribution, of species in the dissolved, precipitated, adsorbed and volatilized states. ▪ Ionic strength, pH, pE, electrostatic surface potential, and charge at both equilibrium and any provisional states. ▪ Saturation indices of all database solids.					
Major Assumptions:	▪ Temperature of the modeled system is below 100ºC. ▪ System is at chemical equilibrium, with no net flux of mass or energy. ▪ Water is in contact with geologic materials for a sufficient time to allow all chemical reactions to go to completion. ▪ Gases present have constant partial pressure.					
Developer:	U.S. EPA/ORD					
Website:	www.epa.gov/exposure-assessment-models/minteqa2					

Modular Three-Dimensional Transport Multi-Species (MT3DMS) Model

Overview:	MT3DMS is an extension of a USGS model (MODFLOW) that simulates the fate and transport of chemical constituents leached to ground water. Together, these models solve for three-dimensional transport in the saturated zone. This model may be applicable to outdoor beneficial uses exposed to precipitation, where transport through the unsaturated zone is already known or can be neglected.					
Model Type:	✓	Deterministic		Probabilistic		
Spatial Variability:		Lumped	✓	Distributed		
Media:		Soil	✓	Ground Water		Air
		Sediment	✓	Surface Water		Food
Inputs:	▪ Cell dimensions (e.g., number of columns, rows, and layers). ▪ Cell boundary conditions (e.g., impermeable boundaries, hydraulic head). ▪ Hydrogeology of each cell (e.g., hydraulic conductivity, recharge rate, porosity, dispersivity). ▪ Meteorology (e.g., precipitation rate). ▪ Stressor characteristics (e.g., initial concentration at water table, distribution coefficient).					
Outputs:	▪ Stressor concentration as a function of distance (x-, y- and z- axis) and time. ▪ Graphical presentation of stressor migration as a function of distance and time.					
Major Assumptions:	▪ Where ground water is intercepted by surface water, the stressor concentration in surface water is equal to the concentration in ground water. ▪ Non-equilibrium sorption and other biochemical reactions follow first-order kinetics and are reversible (equilibrium-controlled sorption may be linear or non-linear). ▪ Chemical and hydrogeological parameters are uniform throughout each cell.					
Developer:	U.S. Army Corps of Engineers					
Website:	hydro.geo.ua.edu/mt3d/					

Total Risk Integrated Methodology (TRIM); TRIM.FaTE Module

Overview:	TRIM.FaTE is a compartmental mass-balanced model that describes the movement and transformation of stressors over time through a user-defined, bounded, spatially explicit topography that includes both abiotic (e.g., air, soil, water) and biotic (aquatic food-web) compartments. It provides an inventory, over time, of a stressor throughout the entire modeled system and predicts stressor concentrations in multiple environmental media that can be used as inputs to estimate human and ecological exposure and risk. TRIM.FaTE may be applicable to outdoor beneficial uses affected by precipitation and wind.					
Model Type:	✓	Deterministic		Probabilistic		
Spatial Variability:	✓	Lumped		Distributed		
	Note: TRIM is a compartmental model that does not account for the spatial variations of a stressor within a given media.					
Media:	✓	Soil	✓	Ground Water	✓	Air
	✓	Sediment	✓	Surface Water	✓	Food
	Note: Food pathway includes fish.					
Required Inputs:	▪ Source properties (e.g., location, height, stressor-specific emission rate). ▪ Stressor properties (e.g., initial concentrations within each medium, stressor boundary concentrations, degradation rate, partitioning coefficients, stressor-specific physical properties). ▪ Meteorology (e.g., wind direction and speed, ambient air temperature, air mixing height, precipitation rate). ▪ Environmental media properties (e.g., soil bulk density, sediment porosity, lake residence time, fraction of precipitation that runs off).					
Model Outputs:	▪ Stressor concentration in each environmental medium as a function of time.					
Major Assumptions:	▪ Stressor concentrations are homogenous within a compartment of interest. ▪ The properties of each medium are homogenous and isotropic within a compartment. ▪ Advection, dispersion, diffusion, biochemical transformations and biotic uptake follow first-order kinetics. ▪ Chemical partitioning between phases assumes equilibrium. ▪ Stressors are either recalcitrant or decay according to first-order kinetics.					
Developer:	U.S. EPA/ORD and Office of Air and Radiation, Lawrence Berkeley National Laboratory, ORNL, University of Tennessee, ICF Consulting, MCNC-North Carolina Supercomputing					
Website:	www.epa.gov/fera					

WiscLeach

Overview:	WiscLeach is a Web-based model designed to simulate the fate and transport of stressors leached to ground water from secondary materials beneficially used in road stabilization and embankment/structural fill, and may also be applicable to other land applications. The model is based on three analytical solutions to the advection-dispersion-reaction equation that describe transport in the unsaturated and saturated zones and ground water. This model solves for one- and two-dimensional stressor transport in the unsaturated and saturated zones, respectively.					
Model Type:	✓	Deterministic		Probabilistic		
Spatial Variability:	✓	Lumped		Distributed		
Media:		Soil	✓	Ground Water		Air
		Sediment		Surface Water		Food
Required Inputs:	▪ Source characteristics (e.g., geometry, density, hydraulic conductivity, depth to road stabilization layer, porosity, slope of embankments). ▪ Stressor properties (e.g., leachate concentration, retardation factors in road stabilization layer and subgrade, molecular diffusion coefficient). ▪ Hydrogeological data (e.g., depth to ground water, aquifer porosity and hydraulic conductivity, regional hydraulic gradient). ▪ Meteorological data (e.g., annual precipitation rates). ▪ Receptor location (e.g., distance to receptor or other point of compliance, depth of well).					
Model Outputs:	▪ Stressor concentrations in unsaturated and saturated zones as function of location (x-, y- and z-axis) and time. ▪ Contour plots of the stressor plume within unsaturated and saturated zones.					
Major Assumptions:	▪ The characteristics of the stressor source and underlying environmental media are homogenous and isotropic. ▪ Mass loss through overland runoff and evapotranspiration are negligible. ▪ Transport through the source and unsaturated zone is constant and downward (but transport through dispersion is three-dimensional. ▪ Transport in ground water dominated by advection in the direction of the downgradient receptor (but stressor transport through dispersion is three-dimensional). ▪ Stressor adsorption to media follows zero-order kinetics and is reversible. ▪ Stressors are inert and recalcitrant. ▪ Stressors are neither volatile nor NAPL.					
Developer:	Recycled Materials Resource Center (RMRC) at the University of Wisconsin–Madison and Jackson State University,					
Website:	wiscleach.engr.wisc.edu/index.html					

A.10 Risk Calculation

The following compilation of resources supplements the discussion of risk calculation in **Section 6** of this document. These resources address approaches to estimate the magnitude of receptor exposures, as well as some of the factors that may act to mitigate or exacerbate the risk from these exposures. This information may help account for the variability in receptor exposure and response when conducting a probabilistic risk assessment. However, it is important to note that the relative importance of some of these topics will vary based on the different receptors, stressors and environmental media associated with a particular beneficial use. Some of the older listed resources have been further expanded upon in more recent documents also included the list. These older documents may still contain useful information and are provided for the historical context and discussion contained therein.

A.10.1 General Resources

Date: September 1986
Title: Guidelines for the Health Risk Assessment of Chemical Mixtures
Author: U.S. EPA/OSWER
Details: This guide provides a consistent approach for evaluating data on the chronic and subchronic effects of chemical mixtures. A procedural guide, it emphasizes broad underlying principles of various science disciplines (e.g., toxicology, pharmacology, statistics) necessary for assessing health risk from chemical mixture exposure. It also discusses approaches to analyze and evaluate the various data.

Date: December 1989
Title: Risk Assessment Guidance for Superfund Part A, Volume I: Human Health Evaluation Manual Chapter 6: Exposure Assessment
Author: U.S. EPA/OSWER
Details: Chapter 6 of this document describes procedures for conducting an exposure assessment as part of the baseline risk assessment process at Superfund sites. The objective of the exposure assessment is to estimate the type and magnitude of exposures to the chemicals of potential concern that are present at or migrating from a site. The results of the exposure assessment are combined with chemical-specific toxicity information to characterize potential risks.

Date: May 1992
Title: Supplemental Guidance to RAGS: Calculating the Concentration Term
Author: U.S. EPA/Risk Assessment Forum
Details: This bulletin explains the concentration term used in estimate exposures, discusses basic concepts about the concentration term, generally describes how to calculate the concentration term, presents examples to illustrate several important points, and identifies where additional help can be found.

Date: December 1992

Title: Guidelines for Exposure Assessment

Author: U.S. EPA/ORD

Details: This document addresses principles and procedures to guide risk assessments and to inform decision-makers and the public about these procedures. In particular, the guidelines standardize terminology used in exposure assessment and in many areas outline the limits of sound scientific practice. They discuss and reference a number of approaches and tools for exposure assessment, along with their appropriate use. These guidelines are intended to convey the general principles of exposure assessment, not to serve as a detailed instructional guide.

Date: March 1997

Title: Guiding Principles for Monte Carlo Analysis

Author: U.S. EPA/Risk Assessment Forum

Details: This document provides a general framework and broad set of principles important for ensuring good scientific practices in the use of Monte Carlo analysis. Many of the principles apply generally to the various techniques for conducting quantitative analyses of variability and uncertainty, though they focus on Monte Carlo analysis. These guiding principles are intended to serve as a minimum set of principles and are not intended to prevent the use of new or innovative improvements where scientifically defensible.

Date: August 2000

Title: Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures

Author: U.S. EPA/Office of the Science Advisor

Details: This document updates the risk assessment paradigm for mixtures from the 1986 *Guidelines for the Health Risk Assessment of Chemical Mixtures*. The document is organized according to the type of data available to the risk assessor, ranging from data-rich to data-poor situations. Procedures are described for assessment using data on the mixture of concern, data on a toxicologically similar mixture, and data on the mixture component chemicals. No single approach is recommended in this supplementary guidance. Instead, guidance is given for the use of several approaches depending on the nature and quality of the data.

Date: December 2001

Title: RAGS Volume III—Part A: Process for Conducting Probabilistic Risk Assessment

Author: U.S. EPA/OSWER

Details: This document provides policies and guiding principles on the application of probabilistic risk assessment (PRA) methods to human health and ecological risk assessments. It focuses on Monte Carlo analysis as a method of quantifying variability and uncertainty in risk. This document introduces a tiered approach to PRA, beginning with a point estimate analysis and progressing to increasing levels of complexity until the scope of the analysis satisfies decision-making needs.

Date: May 2003

Title: Framework for Cumulative Risk Assessment

Author: U.S. EPA/Office of the Science Advisor

Details: This document discusses chemical risks to human health in the context of the effects from a variety of stressors. The framework has two purposes, one immediate and one longer-term. It immediately offers a basic structure and provides starting principles for cumulative risk assessments. The process it describes provides wide latitude for planning and conducting cumulative risk assessments in many diverse situations, each based on common principles discussed in the report. The process also will help foster a consistent approach for conducting and evaluating cumulative risk assessments, for identifying key issues, and for providing operational definitions for terms used in cumulative risk assessments. In the longer term, the document offers the basic principles around which to organize a more definitive set of cumulative risk assessment guidance.

Date: July 2004

Title: RAGS Volume I—Part E: Supplemental Guidance for Dermal Risk Assessment

Author: U.S. EPA/OSWER

Details: This document is supplemental guidance to RAGS Volume I and contains methods for conducting dermal risk assessments. EPA has found these methods generally to be appropriate. However, for each dermal risk assessment, users must decide whether these methods, or others, are appropriate, depending on the facts.

Date: March 2007

Title: Framework for Metals Risk Assessment

Author: U.S. EPA/Office of the Science Advisor

Details: The document presents key guiding principles based on the unique attributes of metals (as differentiated from organic and organo-metallic compounds) and describes how these metals-specific attributes and principles may then be applied in the context of risk assessment guidance and practices. There are unique properties, issues and processes within these principles that risk assessors need to consider when evaluating metal compounds.

Date: May 2007

Title: Guidance for Evaluating the Oral Bioavailability of Metals in Soils for Use in Human Health Risk Assessment

Author: U.S. EPA/OSWER

Details: This document provides guidance on how to assess site-specific oral bioavailability of metals in soils for use in human health risk assessments. Specifically, it provides: 1) a recommended process for deciding when to collect site-specific information on the oral bioavailability of metals in soils; 2) a recommended process for documenting the data collection, analysis and implementation of a validated method that would support site-specific estimates of oral bioavailability; and 3) general criteria that EPA would normally use to evaluate whether a specific bioavailability method has been validated for regulatory risk assessment purposes. This guidance focuses on media-specific relative bioavailability and does not address adjustments to default absolute bioavailability values.

Date: February 2011

Title: Incorporating Bioavailability Considerations into the Evaluation of Contaminated Sediment Sites

Author: Interstate Technology and Regulatory Council

Details: This guidance is constructed to assist the user in identifying the most relevant places within an exposure assessment that bioavailability can be assessed and which tools and methods are most useful and appropriate. The document also provides case studies that highlight the application of bioavailability assessment tools and methodologies in contaminated sediment sites.

Date: December 2011

Title: RAGS Volume III—Part A: Process for Conducting Probabilistic Risk Assessment

Author: U.S. EPA/OSWER

Details: This document provides policies and guiding principles on the application of probabilistic risk assessment methods to human and ecological risk assessment. It focuses on Monte Carlo analysis as a method of quantifying variability and uncertainty in risk. This is intended to be most accessible to those readers who are familiar with risk assessment and basic statistical concepts. The guidance introduces a tiered approach to probabilistic risk assessment, beginning with a point estimate analysis and progressing to increasing levels of complexity until the scope of the analysis satisfies decision-making needs.

Date: July 2014

Title: Risk Assessment Forum White Paper: Probabilistic Risk Assessment Methods and Case Studies

Author: U.S. EPA/Office of the Science Advisor

Details: This document provides a general overview of the value of probabilistic analyses and similar or related methods, as well as examples of current applications across the Agency. The goal of this publication is not only to describe potential and actual uses of these tools, but also to encourage their further implementation in human, ecological and environmental risk analysis and related decision-making.

A.11 Final Characterization

The following compilation of resources supplements the discussion of final characterization provided in **Section 7** of this document. These resources address the considerations related to the evaluation of variability and uncertainty; the integration findings, assumptions, limitations and uncertainties into final conclusions; and the presentation of information. This information can be used to guide the documentation of information about the beneficial use evaluation to ensure that it is transparent, clear, consistent and informative for both decision-makers and other members of the audience. Some of the older listed resources have been further expanded upon in more recent documents also included the list. These older documents may still contain useful information and are provided for the historical context and discussion contained therein.

A.11.1 General Resources

Date: December 1989

Title: RAGS Volume I—Part A: Human Health Evaluation Manual, Chapter 8: Risk Characterization

Author: U.S. EPA/OSWER

Details: This document describes the process of risk characterization and provides some guidance on the interpretation, presentation and qualification of evaluation results. Exhibits illustrate several ways to present the discussion of uncertainty and variability.

Date: February 1992

Title: Guidance on Risk Characterization for Risk Managers and Risk Assessors

Author: U.S. EPA/Risk Assessment Council

Details: This guidance describes risk results in reports, presentations and decision packages. It addresses problems that may affect public perception regarding the reliability of scientific assessments and related regulatory decisions.

Date: 1994

Title: Science and Judgment in Risk Assessment

Author: National Academy of Sciences

Details: The first part of the report examines the background and current practices of risk assessment. It discusses the historical, social, and regulatory contexts of quantitative risk assessment, EPA's approach to applying risk assessment principles, and identifies ways in which the process might be improved.

Date: December 1994

Title: An Introductory Guide to Uncertainty Analysis in Environmental and Health Risk Assessment

Author: DOE and ORNL

Details: This document presents guidelines for evaluating uncertainty in mathematical equations and computer models applied to assess human health and environmental risk. Analytical and numerical methods for error propagation are presented, along with methods for identifying the most important contributors to uncertainty. The guide emphasizes the need for subjective judgment to quantify uncertainty when relevant data are absent or incomplete.

Date: February 1995

Title: Guidance for Risk Characterization

Author: U.S. EPA/Science Policy Council

Details: This guide is an update to the 1992 *Guidance on Risk Characterization for Risk Managers and Risk Assessors*, and describes principles for developing and describing EPA risk assessments, with a particular emphasis on risk characterization. This guidance does not substantially revise the 1992 document, but it includes some clarifications and changes to give more prominence to certain issues, such as the need to explain the use of default assumptions.

Date: October 1996

Title: Risk Characterization for Ecological Risk Assessment of Contaminated Sites

Author: DOE and ORNL

Details: This document describes the approach for estimating risks based on individual lines of evidence and then combining them through a process of weighing the evidence. The lines of evidence are integrated independently so that the implications of each are explicitly presented. This makes the logic of the assessment clear and allows independent weighing of the evidence by risk managers and stakeholders.

Date: December 2000

Title: Risk Characterization Handbook

Author: U.S. EPA/Science Policy Council

Details: This guide is based on the 1995 *Guidance for Risk Characterization*, and is designed to provide an understanding of the goals and principles of risk characterization, the importance of planning and scoping for a risk assessment, the essential elements to address in a risk characterization, the factors that are considered in decision-making by risk managers, and the forms the risk characterization takes for different audiences.

Date: 2003

Title: Bioavailability in Soils and Sediments: Processes, Tools, and Applications. National Academies

Author: National Research Council

Details: This report assesses the current understanding of processes that affect the degree to which chemical contaminants in soils and sediments are bioavailable to humans, animals, microorganisms and plants. It seeks to address the most pressing issues and to contribute toward developing common frameworks and language to build a mechanistic-based perspective of bioavailability processes.

Date: 2009

Title: Science and Decisions: Advancing Risk Assessment, Chapter 4: Uncertainty and Variability—The Recurring and Recalcitrant Elements of Risk Assessment

Author: National Research Council

Details: This chapter reviews approaches to address uncertainty and variability and comments on whether and how the approaches have been applied to EPA risk assessments. It also discusses how uncertainty and variability are applied to each of the stages of the risk assessment process and defines key terminology related to uncertainty and variability.

Date: 2013

Title: Environmental Decisions in the Face of Uncertainty

Author: National Research Council

Details: This document provides guidance on approaches to managing risk in different contexts when uncertainty is present. It also provides guidance on how information on uncertainty should be presented to help risk managers make sound decisions and to increase transparency in its communications with the public about those decisions.

Date: April 2014

Title: Framework for Human Health Risk Assessment to Inform Decision Making, Chapter 4: Risk Assessment

Author: U.S. EPA / Risk Assessment Forum

Details: This document is intended to provide information on the overarching process for conducting human health risk assessments. These chapters includes information on how to conduct risk characterization.

EPA530-R-16-009