1.0 Introduction

1.1 Background

The U.S. Environmental Protection Agency (EPA) Office of Solid Waste (OSW) is responsible for managing solid and hazardous waste as specified by the Resource Conservation and Recovery Act (RCRA) of 1976 and subsequent legislation, such as the Hazardous and Solid Waste Act (HSWA) of 1984. These acts and the programs developed to implement them were designed to protect human health and the environment. Thus, many of the regulatory decisions within the RCRA programs are based, at least in part, on the human health risk and environmental impacts of the regulatory options under consideration.

In recent years, as the RCRA program has evolved, and as new risk assessment methods have been developed, EPA's need for improved risk assessment models has greatly increased. The RCRA programs initially addressed only releases to ground water from land disposal operations and releases to air from waste incinerators and other types of boilers and industrial furnaces. However, the RCRA programs have expanded in scope over the years to encompass hundreds of constituents, thousands of waste streams, and many types of waste management practices, ranging from recycling and reuse to disposal and destruction techniques. Thus, new risk assessment models were needed to assess the types and magnitude of risks that fall under the broad purview of the RCRA programs.

In addition, in the mid-1990s, several groups within and outside of EPA came forward with recommendations or guidance for improving risk assessment methods. In 1996, EPA issued new guidelines for conducting exposure assessments and risk assessments (U.S. EPA, 1996f,g). These guidelines focused on improving the science underpinning the risk or exposure assessments that were being conducted, as well as improving the methods for characterizing the uncertainty in the risk estimates that are generated. In 1997, the Presidential/Congressional Commission on Risk Assessment and Risk Management (CRARM, 1997) issued a report on improving risk assessment methods used by the federal government. Also, EPA's Science Advisory Board (SAB) reviewed and commented on a number of EPA risk assessments and models, including the dioxin and mercury risk assessments (U.S. EPA, 1996e, 2000).

One of the assessments that the SAB reviewed was a national-level risk assessment effort conducted by OSW to support the proposed exit levels in the 1995 Hazardous Waste Identification Rule (HWIR). The proposed HWIR (60 FR 66344, December 21, 1995) was, in part, designed to establish contaminant-specific exit levels for low-risk solid wastes. Under this proposal, generators of listed hazardous wastes that could meet the new concentration-based criteria defined by the HWIR methodology would no longer be subject to the hazardous waste management system specified under Subtitle C of RCRA. This established a risk-based "floor" for low-risk hazardous wastes that would encourage pollution prevention, waste minimization, and the development of innovative waste treatment technologies. The rule also sought to reduce possible overregulation arising from the “mixture” and “derived-from” rules promulgated earlier.

The SAB concluded that the methodology proposed for the HWIR assessment “lacks the scientific defensibility for its intended regulatory use,” and the subcommittee made the following recommendations for establishing a scientifically defensible risk-based methodology applicable at the national level for the waste program (U.S. EPA, 1996a):

- Develop a true multipathway risk assessment in which a receptor receives a contaminant from a source via all pathways concurrently, a receptor is exposed to the contaminant via different routes, and the dose corresponding to each route is accounted for in an integrated way;

- Use a methodology that maintains mass balance;

- Before implementing the model, focus a validation effort on a few key exposure pathways of concern and those parameters that have a major impact on risks to human health and the environment;

- Examine model parameters systematically to ensure a consistent and uniform application of the proposed approach, and further, to ensure that the full suite of uncertainties is addressed in the final methodology;

- Discard the proposed screening procedure for selecting the initial subset of contaminants for ecological analysis and instead require that a minimum data set be satisfied before ecologically based exit criteria are calculated;

- Seek substantive participation, input, and peer review by EPA scientists and outside peer-review groups as necessary to evaluate the individual components of the methodology in much greater detail; and

- Reorganize and rewrite the documentation for both clarity and ease of use.

The SAB review findings led to a joint decision between OSW and EPA’s Office of Research and Development (ORD) to develop an integrated and improved source, fate and transport, exposure, and risk modeling tool that could be used to support national assessments and regulatory actions. In 1997, OSW and ORD began working together on the development of such a tool: the Multimedia, Multipathway, and Multireceptor Risk Assessment (3MRA) modeling system. The design of the 3MRA modeling system

- Follows the risk paradigm and recent EPA guidance and scientific recommendations;

- Addresses major review comments of the HWIR analysis in 1995, specifically those concerning the need for a true multipathway risk assessment methodology, the conservation of mass, the validation of the methodology and its components, and the substantive participation of EPA scientists and outside peer-reviewer groups in evaluating the methodology and its components;

- Is based on current science and a state-of-the-art modeling framework that facilitates consistent use of sound science models, controls model sequencing, facilitates data exchange, and provides data analysis and a results visualization tool;

- Has multimedia and multipathway exposure and risk assessment capabilities;

- Has human health and ecological exposure and risk characterization capabilities;

- Is based on a mass balance approach within the waste management units (WMUs);

- Represents variability in environmental fate and transport, exposure, and risk;

- Can quantitatively define the degree of protectiveness for a specific risk value (e.g., protective of 95 percent of the exposed population at a risk level of 10^{-6});

- Uses site-based data (i.e., actual geographic locations and associated environmental and population characteristics) to the extent available;

- Is applicable to multiple scales of analysis, including regional and national;

- Is capable of assimilating new science and component modules in the software system;

- Reflects quality assurance and control protocols and is reproducible; and

- Has a verified approach and components that have been compared with other analytical solutions, numerical models, and/or field data.

In addition to the above discussion on the background of the 3MRA modeling system, this section is intended to provide the necessary context to review the science modules (Sections 2 through 16 of this Volume), the databases developed to support the modeling system (Volume II), the quality assurance approach for the technology, science modules, and data (Volume III), and the sensitivity and uncertainty analyses conducted to date (Volume IV). The 3MRA technology is discussed in detail in Volume V of this report, *Technology Design and User's Guide*. The remainder of Section 1 provides an overview of the overall design goals, system technology and architecture of the science modules, and output generated by the modeling system to support national-scale, risk-based decision making. In keeping with EPA's goals for easy accessibility and clear and transparent documentation, EPA has released Version 1 of the 3MRA modeling system available on CD ROM from OSW, and on ORD's Center for Exposure Assessment Modeling (CEAM) Web site (http://www.epa.gov/ceampubl/mmedia/index.htm), along with all technical documentation and data files (http://www.epa.gov/epaoswer/hazwaste/id/hwirwste/risk.htm).

1.2 Overall Design Goals of the 3MRA Modeling System

The overall design goals for the 3MRA modeling system reflect one of the most important regulatory goals for OSW: determining when the chemical constituent concentrations in a waste stream, as managed, may pose unacceptable risks to human health and the environment. For example, certain generic waste streams are currently being managed as hazardous waste because of the way they were captured by the hazardous waste regulations (under Subtitle C of RCRA). However, some subset of these waste streams may not pose significant health or ecological risks if they are disposed of as non-hazardous industrial wastes (under with Subtitle D regulations). To quantify specific concentration-based criteria for determining which waste streams may "safely" exit the hazardous waste "cradle-to-grave" program, EPA could assess the potential health and ecological risks related to the management in Industrial Subtitle D units of certain wastes with low concentrations of hazardous contaminants. Waste streams containing concentrations below EPA-specified thresholds could exit the hazardous waste system; those containing concentrations above the thresholds would remain in the hazardous waste program.

Using the 3MRA modeling system, constituent-specific distributions could be generated of cancer risks or hazards to humans and hazards to ecological receptors living in the vicinity of Industrial D waste sites that might manage exempted wastes. The 3MRA modeling system can produce national-level statistics that characterize risks and provide exit-level waste concentrations for a contaminant that meet specific criteria of policy makers. These policy criteria might include the following:

- The level of acceptable risk (e.g., 1 in 1 million),
- The probability of protection (e.g., 95 percent of the exposed population at a site),
- The probability that a particular site is protective at the risk level and population protection level specified,
- The risk to the exposed population at various distances from the site (e.g., 1,000 m),
- The risk to various receptor types (e.g., children, farmers, rare and endangered species), and
- The risk to each receptor type by each exposure pathway (e.g., inhalation of ambient air, ingestion of ground water used as drinking water).

To ensure that the modeling system could provide this type of information, OSW and ORD engaged in a series of discussions to identify the key functional requirements for the model, as well as the requirements for scientific defensibility that would shape the 3MRA modeling framework. The requirements are summarized below represent the core design decisions for the 3MRA modeling system.

1.2.1 Key Functional Requirements

The 3MRA modeling system is intended to be one of EPA's next generation of multimedia exposure and risk models to support regulatory decisions. EPA designed the modeling system specifically to meet the needs of OSW programs, but the model has the flexibility to be used for many EPA applications. In particular, it was designed to provide risk managers with information, at a national level, on exposure and risk to human and ecological receptors from the release of hazardous contaminants from the management of industrial wastes. Specific functional requirements for the design of the 3MRA modeling system include the following:

- ***Multiple Contaminants***. Many different constituents may be present in wastes regulated under RCRA. Therefore, the 3MRA modeling system was designed to use current science to model more than 400 constituents with very diverse physical-chemical properties and effects on humans and the environment. The science on which the fate and transport of contaminants in the environment is based differs for various types of constituents. In addition, the nature of national assessment methodologies requires the ability to adjust some physical-chemical properties that are dependent on environmental variables such as temperature. Within specified constraints, constituents were grouped in the following five categories: metals, organic chemicals, dioxin-like chemicals, mercury, and other special case chemicals, such as those that are miscible in water or are metabolized quickly. Even within these categories, distinctions must be made regarding bioaccumulation, metabolism, and transformation for organics and regarding congener-specific properties for dioxin-like chemicals.

- ***Multimedia.*** Traditionally, land disposal (i.e., landfilling) and destruction by combustion sources have been the predominant waste management scenarios used in the RCRA program. Release of a constituent to ground water is typically the primary pathway modeled for landfilling, and releases to air are the primary pathway modeled for combustion sources. However, a large quantity of hazardous and industrial wastes are managed as wastewaters in surface impoundments and tanks. Releases to air can be significant for some constituents managed in these types of WMUs. Similarly, the ash from combustion and the sludge from tanks and impoundments are sometimes applied to land, as are some organic wastes. For the 3MRA modeling system, new source models for surface impoundments, tanks, landfills, land application units (LAUs), and waste piles were developed to provide the ability to model releases to all environmental media (air, soil, and ground water).

- ***Multipathway.*** Once a contaminant is released to the environment, it is important to follow the transport and fate of the contaminant through all environmental media in order to capture all relevant pathways of exposure. In a national application of such a model, what may be a driving pathway in one type of environmental setting may be a small contributor to exposure in another. Also, given the broad range of chemical properties being considered, the ground water ingestion pathway may be important for one contaminant, the inhalation of ambient air for another contaminant, the ingestion of contaminated food crops or prey for another, and the ingestion of fish from contaminated streams for another. Therefore, the modeling system needed to include as many pathways as was feasible and scientifically defensible.

- ***Multireceptor***. The 3MRA modeling system was designed specifically to quantify the risk to ecological and human receptors. The 3MRA modeling system uses a site-based approach, in which various types of human and ecological receptors are spatially delineated around a WMU. This spatial component of the 3MRA modeling system is critical in analyzing the differential effects on human and ecological receptors in all media across the study area.

- ***Variability and Uncertainty***. Quantifying variability and uncertainty in exposure and risk estimates is an important capability of any modeling system. The 3MRA modeling system was designed with a two-stage Monte Carlo analysis capability, which enables users to distinguish between variability and uncertainty in input variables. In addition, EPA has conducted extensive sensitivity analyses and benchmarking against other similar models or model in order to understand the limitations and uncertainty of this modeling system.

- ***Programmatic Needs***. The 3MRA modeling system was designed with several specific science and technology requirements agreed upon by OSW and ORD. Key requirements included scientific defensibility (see Section 1.2.2) and a technology design that was adaptable to a wide range of future applications and the capability to incorporate into the system legacy codes that have been extensively peer reviewed and used in support of regulatory activities at EPA (see Volume V of this report). The following regulatory models or components of regulatory models have been incorporated into Version 1 of the 3MRA modeling system: Industrial Source Complex Short-Term Model, Version 3 (ISCST3) (U.S. EPA, 1995) for air dispersion and deposition; EPA's Composite Model for Leachate Migration with Transformation Products (EPACMTP) (U.S. EPA, 1996b,c,d, 1997) for subsurface transport; and EPA's Exposure Analysis Modeling System II (EXAMS II) (Burns et al., 1982; Burns, 1997) for surface water transport.

1.2.2 Scientific Defensibility Requirements

To address scientific defensibility, EPA implemented a systematic quality assurance program throughout the conceptual design, development, and application of the 3MRA modeling system. The program was designed to build confidence in the underlying science and technology, ensure that the system could produce reliable risk results, and to characterize the uncertainty and variability inherent in multimedia modeling. The major components of that program are described briefly below.

- ***Technical Review.*** The development of the 3MRA modeling system evolved from the ORD/OSW Integrated Research and Development Plan for the Hazardous Waste Identification Rule (U.S. EPA, 1998). This report represented the collaboration between ORD and OSW to define (1) the assessment strategy for national-scale risk analyses and (2) the design specifications of the 3MRA modeling framework. A critical component of this blueprint for the 3MRA modeling system was the technical review cycles required for the databases, science modules, and system technology. This iterative process ensured that the conceptual approach and implementation of the 3MRA modeling system was consistent and defensible across all data sources and science modules, as well as the software technology.

- ***Peer Review.*** The overall technical approach and each science-based module included in the 3MRA modeling system were peer reviewed. Teams of peer reviewers (at least three per module) provided critical feedback about the science-based modules. More than 45 independent experts reviewed the science modules to ensure that the theoretical concepts describing the processes within the release, fate, transport, uptake, exposure, and risk components were adequate representations of the processes to be evaluated. The peer review cycle has been an ongoing process since 1999, and is described in Volume III of this report. The process has recently included the acceptance of *The 3MRA Risk Assessment Framework - A Flexible Approach for Performing Multimedia, Multipathway, and Multireceptor Risk Assessments Under Uncertainty* (in press) by the International Journal of Human and Ecological Risk Assessment (Marin, et al., n.d.).

- ***Verification.*** All software components and databases underwent a series of tests to verify that the software and data were performing properly. At the heart of this protocol was the requirement that each component of the modeling system include a designed and peer-reviewed test plan that was executed by both the module developer and a completely independent modeler (i.e., someone who did not participate in the original module development). Prior to testing, each of the test plans was reviewed and revised, as appropriate, to ensure that the tests were comprehensive and addressed all of the major functions of the software and supporting databases. These procedures, test plans, test packages, and test results are fully documented and available to the public. Verification efforts for the 3MRA modeling system are described in Volume III of this report.

- ***Validation.*** True validation of the 3MRA modeling system for a national application would require validation over the full range of environmental settings that are relevant to the application. However, determining whether the modeling system is valid for the full range of settings was not possible because EPA was unable to find such a data set. Instead, individual modules and data sets were validated when appropriate data could be identified. A number of science modules were based on existing models/methods that had already been validated using field data and, therefore, prior validation studies and data were evaluated to determine their relevance to the 3MRA application. The use of legacy models developed by EPA was considered to be an important aspect of the overall validation efforts. A description of the validation efforts of the 3MRA modeling system, including the system, science modules, and supporting data, is documented in Volume III of this report.

- ***Model Comparison.*** The 3MRA modeling system is undergoing a comparative analysis with EPA's Total Risk Integrated Methodology (TRIM) (U.S. EPA, 2002), which is currently under development. The objective of the model comparison effort is to increase confidence that the 3MRA modeling system produces estimates consistent with other multimedia models. A description of the model comparison efforts is documented in Volume III of this report.

- ***Environmental Data Comparison.*** Modeled results from the 3MRA modeling system are being compared with a multimedia data set for an actual industrial site for which media monitoring data and field data (e.g., fish concentrations) were available for mercury. These data represent a snapshot of mercury in the surrounding environment rather than a continuous measure of its presence during the operation of an industrial facility. Although the data set does not vary as a function of time or include estimates of exposure and risk, the comparison will yield important insights into the performance of multimedia models. A description of this comparison effort is documented in Volume III of this report.

- ***Representative National Data Set.*** A comprehensive data collection approach was developed to parameterize the modeling system for 201 sites in accordance with the site-based approach described in this document. The site-based data are intended to provide a representative data set for a national-level assessment and, to a large degree, serve as the test data set for the 3MRA modeling system. This data collection plan described the general collection methodology for the major types of data (for example, facility location, land use, soil characteristics, and receptor locations), including quality assurance and quality control procedures and references for data sources. The data collection effort for the representative national data set is documented in Volume II of this report.

- ***Sensitivity and Uncertainty Analyses.*** As the level of assessment complexity grows, it becomes both more difficult and more important to establish comprehensive and quantitative expressions of uncertainty. Uncertainty analysis can be a difficult task, especially for complex, integrated, multimedia models such as the 3MRA modeling system. Thus, a formal program focusing on sensitivity and uncertainty analysis for complex modeling systems was initiated at ORD. The early focus of this program is the investigation of parameter sensitivities and system uncertainties within the 3MRA modeling system. To facilitate this evaluation, ORD has recently developed a Windows-based parallel computer cluster. This supercomputer for Modeling Uncertainty and Sensitivity Evaluation (SuperMUSE), comprising 176 client PCs and supporting software infrastructure that allows exhaustive experimentation of the 3MRA modeling system. A complete description of the computational and software framework for conducting evaluation strategies for the 3MRA modeling system, the SuperMUSE system, and initial results of the evaluation efforts are presented in Volume IV of this report.

1.3 Overview of the 3MRA Modeling System Technology

The 3MRA modeling system was developed as a predictive tool to provide risk assessment support for the types of risk management decisions that are made within OSW. OSW applies risk assessment modeling tools in a variety of situations; one application is the conduct of site-based national-level risk assessments to support rulemaking for the identification of hazardous waste. Consequently, the 3MRA modeling system needed to be able to model waste management environmental settings that are representative of the range of environmental settings found in the United States, and within this broad range of settings, to simulate the release, fate, and transport of many contaminants in waste undergoing a range of physical and biochemical processes. More than 400 constituents are regulated under the RCRA programs. EPA needs to consider the impacts of these released contaminants on humans and the environment within the broad range of environmental settings. This requires a modeling tool that encompasses releases to all media, transport within those media, uptake in terrestrial and aquatic food webs, and exposure of specific receptors to contaminated media and food items.

The 3MRA modeling system predicts human and ecological risks at a statistically selected number of waste management sites across the United States, and accumulates statistics on the estimated risks at each of these sites in order to generate national distributions of risks. This site-based modeling is applied for each combination of site, WMU, chemical, and concentration level in a given waste stream. The assessment methodology is national in scale and site-based; that is, risks are assessed at individual sites across the United States and rolled up to represent a national distribution of risks. The resulting national distribution of risks forms the basis for determining waste stream constituent concentrations that satisfy criteria reflecting the percentage of nationwide receptors and sites that are "protective." When a simulation is complete, the risk estimates are organized into expressions of the probability of protection for different constituent concentration levels in waste streams. These risk outputs can be expressed as a function of several dimensions, for example, waste unit type, human receptor type, or the distance from the WMU. This ability to express risks and hazard as a function of different attributes provides the decision makers significant flexibility to ask "what if" questions leading up to final decisions. The primary technology requirements related to the application of the 3MRA modeling system to national level human and ecological risk assessments are as follows:

- Facilitate "plug and play" functionality throughout the modeling system to allow new science, modules, and data to be integrated into the system as the state of multimedia modeling science and software development continues to evolve;

- Conduct simulations using the 3MRA modeling system science modules and databases; each simulation representing a combination of site, chemical, WMU, and waste constituent concentration;

- Generate and store risk matrices, i.e., risk estimates as a function of site, exposure area, exposure pathway, exposure route, contact medium, receptor, receptor type, and Monte Carlo realization; and

- Provide a flexible framework that can accommodate alternate policy formulations including different measures of protection, and both waste and leachate concentration regulatory limits.

Figure 1-1 provides an overview of the 3MRA modeling system design. As suggested in this figure, the system is constructed of components that manage the processing, flow, and storage of information through the system, including input/output files and a variety of supporting databases. At the top of Figure 1-1, the looping structure used to conduct national-scale analyses is summarized, including the site location loop, the WMU loop, the number of iterations, and the number of chemicals (which are simulated individually). The function of each component that serves to manage, process, and store information is summarized below. For additional information and details on the 3MRA technology, see Volume V of this report, *Technology Design and User's Guide*.

- **System User Interface (SUI).** This processor represents the user access point to the technology. Via the SUI, the user selects which combinations of sites, WMUs, constituents, and constituent concentrations in waste streams to be simulated, and the number of Monte Carlo simulations to be executed per site. The SUI also provides the user with the ability to configure the computer directory structure where individual components of the system are stored. Finally, the SUI manages the overall execution of the user-defined national assessment.

- **Site Definition Processor (SDP).** This processor performs all data retrieval from the site, regional, national, and chemical databases and organizes the data into a series of "site simulation files" that contain the input data for each of the seventeen science models. The site definition in the figure includes both the selection of site characteristics from data sources at multiple spatial scales (i.e., local, regional, and national), as well as the estimation and selection of chemical properties.

- **Multimedia Simulation Processor (MMSP).** This processor manages the invocation, execution, and error handling associated with the seventeen individual science models that simulate source release, multimedia fate and transport, food web dynamics, and human/ecological exposure and risk. The multimedia, multipathway simulation includes all of the science modules linked together to predict behavior of constituents from source release through exposure and risk.

- **Chemical Properties Processor (CPP).** This processor accesses the chemical properties database and either transfers or calculates all requested data. The CPP provides a single location within the modeling system where chemical data is available.

- **Exit Level Processor I (ELP I).** This processor assimilates the individual site risk results and builds a risk summary database containing data used to assess national protection criteria.

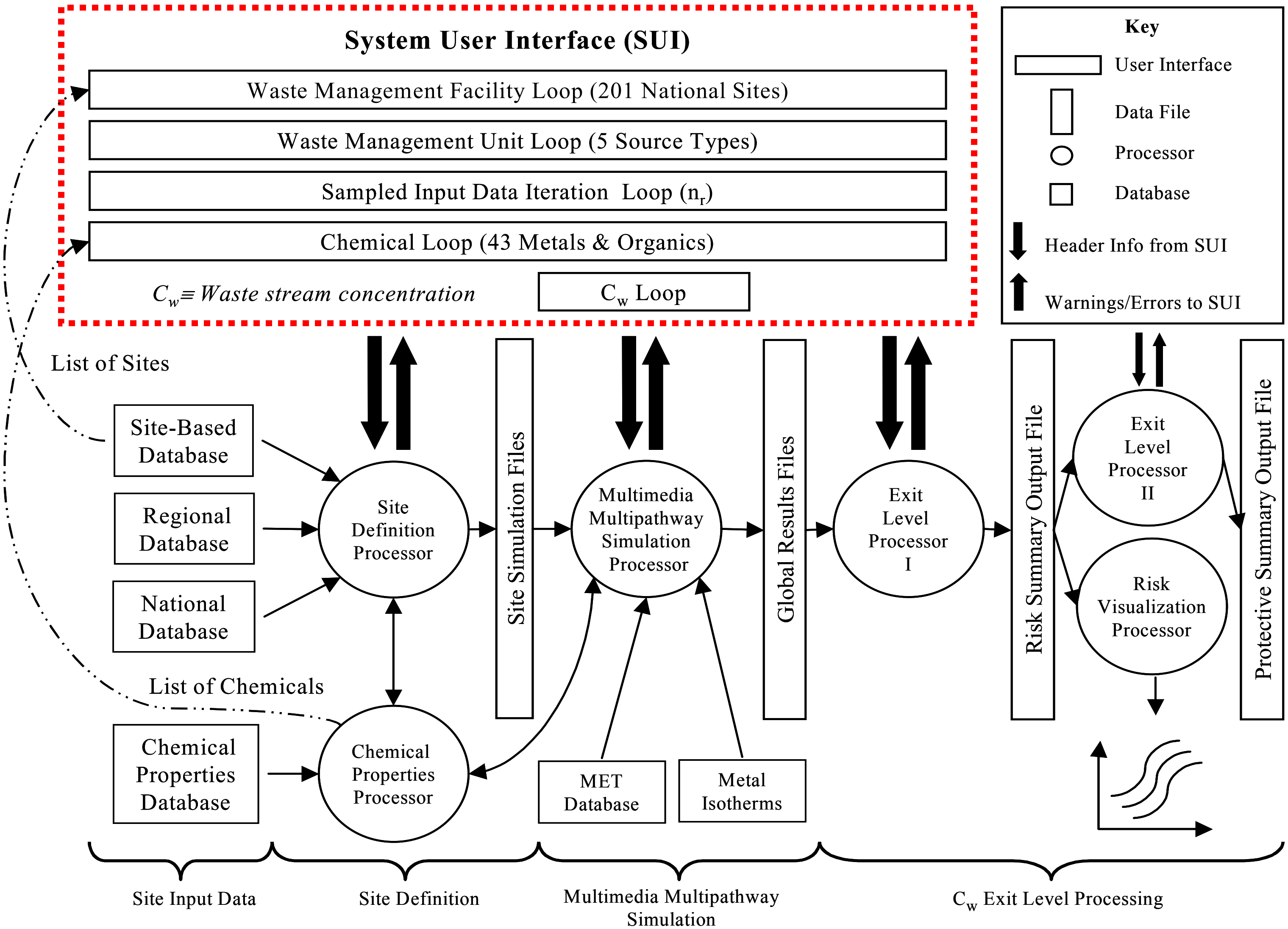


Figure 1-1. 3MRA modeling system design.

- **Exit Level Processor II (ELP II).** This processor reads the risk summary database created by the ELP I and generates, based on regulatory criteria, specific national exemption levels.

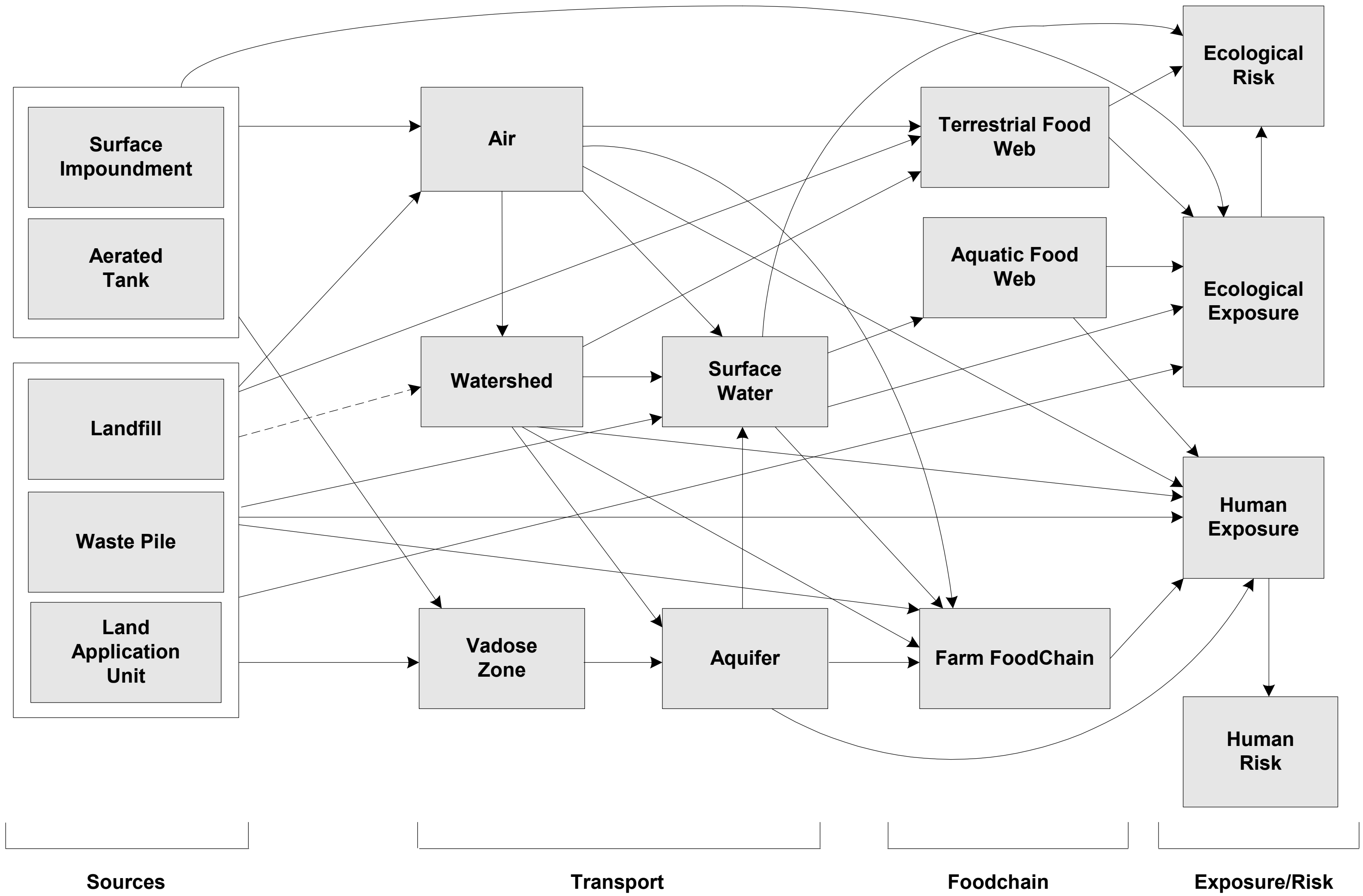
- **Risk Visualization Processor (RVP).** This processor is identical to the ELP II except that it presents results in graphical form.

1.4 Overview of the 3MRA Science Module Architecture

The MMSP can be viewed as an integration of science-based modules within an assessment strategy, i.e., procedures by which the modules are combined and applied to perform the risk assessment. The 3MRA modeling system simulates contaminant releases from a WMU to the various media (air, water, soil) based on the physical-chemical properties of the constituent, the characteristics of the modeled WMU, and the environmental setting (e.g., meteorological region) in which the facility is located. Once released from the WMU, the constituent is transported through environmental media and into biological compartments such as produce, beef, and fish. Human and ecological receptors included in the simulation may be exposed concurrently to contaminated media and food through multiple pathways and routes of exposure. For each receptor that is included in the simulation, the 3MRA modeling system performs risk/hazard calculations based on aggregate exposures modeled through space and time. The linkages among the science modules are depicted in Figure 1-2.

Figure 1-3 illustrates the conceptual layout of a typical 3MRA modeling system site. As suggested by this figure, the 3MRA site model represents a comprehensive multimedia approach to assessing the potential impacts of chemical releases from land-based WMUs. Shown in Figure 1-3 are the primary site layout features including the WMU at the center of the Area of Interest (AOI), which extends 2 kilometers from the unit boundary by default. The concentric distance "rings" are used to characterize risk as a function of distance. Other physical features of the site layout include watersheds, surface water networks, aquifers, ecological habitats, home ranges of resident ecological species, and human population distributions. These features are explicitly delineated and the relative connectivity determined for each site included in the assessment.

To the extent possible, the site layout data are based on site-specific information. However, site data were not available for all sites, and resource limitations associated with collecting the data are prohibitive. Consequently, the supporting data for the representative national data set are based on a tiered approach to data collection that includes site-specific-, regional-, and national-level data. During any execution of the modeling system, the most preferred data source is site-specific followed by regional. Finally, lacking either a site-specific or regional source of data, a national-scale statistical distribution of the variable is sampled and assigned to the site. Each of these databases is available to the system and, as new data become available, the system automatically acts on this hierarchy. In all, several hundred variables are required to model any given site.



The dashed line indicates that soil concentrations for the local (land-based source) and regional watersheds may be added together to estimate total soil concentrations for areas (e.g., habitats) that include both regional and local watershed components.

Figure 1-2. Linkages among the source, fate, transport, exposure, and risk modules fo the 3MRA modeling system.

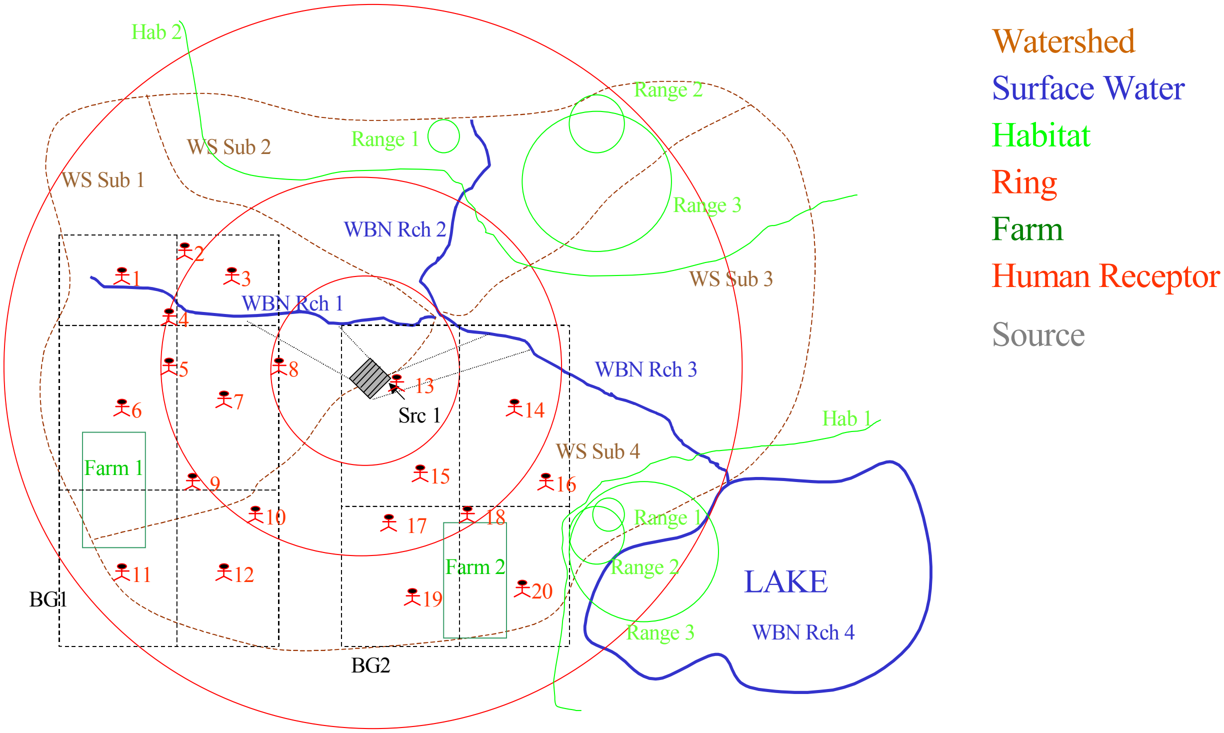


Figure 1-3. Conceptual layout of typical 3MRA modeling system site.

The loading of chemical constituents into the WMU, and the release of these constituents is simulated given the specific environmental characteristics delineated for site layout. The general steps in the site-based modeling are as follows:

- Simulate the loading of waste streams to land-based WMUs (including surface impoundments, landfills, land application units, waste piles, and aerated tanks) over the lifetime of the WMU;
- Simulate the release of constituents from the WMU to air (volatilization, particle re-entrainment), vadose zone (leaching), and watersheds and surface waters (overland runoff/erosion);
- Simulate the fate and transport of contaminants in and between major environmental media (air, watershed soils, vadose zone, ground water, surface water, and sediments);
- Simulate movement of contaminants through the farm food chain and aquatic and terrestrial food webs;
- Simulate human and ecological exposure via selected pathways (for human receptors, the pathways include air inhalation, shower air inhalation, ground water ingestion, soil ingestion, produce ingestion, beef ingestion, milk ingestion, fish ingestion, and breast milk ingestion for infants);

- Estimate human and ecological risk per receptor per pathway, and aggregate pathways and receptors as appropriate; and
- Repeat this sequence for each of a series of waste concentrations (C_w) to establish a quantitative relationship between C_w and risk or hazard.

1.5 Overview of Results Generated by the 3MRA Modeling System

The 3MRA modeling system produces two measures of protection that can be used in regulatory decision making. The first measure of protection is the nationwide distribution of risks for receptors of concern. Specifically, a concentration limit can be defined by the percent of nationwide receptors of concern that exceed a given risk level falling below a specific percent (e.g., 95 percent of all receptors across all sites, all pathways, and all WMU types within 2 km of the WMU incur a risk of 10^{-6} or less). Because the risk/HQ data at the site level is stored by indices including receptor type, exposure pathway, exposure ring distance, and WMU, it is possible to construct "views" of the national-scale protectiveness that reflect varying combinations of the indices. For example, protection measures can be applied to individual receptor types, combinations of receptor types, individual WMUs, etc. The second measure of protection is the nationwide distribution of sites that are protected. The limit can be defined under this protection measure by the percentage of protected sites nationwide that is greater than a given target level. A site is protective if the percentage of site-based receptors incur a risk/HQ less than a specified target value.

These measures of protection are combined in the 3MRA modeling system to allow a user to specify both the percentage of receptors nationwide as well as the percentage of sites that are to be protected (e.g., 95 percent of the sites are protective of 99 percent of the site-based receptors). To transform the site-based risk/HQ data into these national measures of protectiveness requires that the population counts be converted to population percentages and accumulated across all sites. With the risk/HQ indices preserved from the site results (i.e., receptor, pathway, ring distance, WMU, etc.), one can query the database containing results and generate the desired estimates of national protectiveness. Figure 1-4 presents an example corresponding to a query for a target risk level of 10^{-6} from the iterations corresponding to a waste concentration of 10^{-3} mg/kg. The figure indicates that there is a 5 percent chance that the level of protection (percent of receptors that would be protected at the target risk level for the given waste concentration) would be less than or equal to 85 percent. Similarly, there is a 25 percent chance that less than or equal to 93 percent of the receptors would be protected at the target risk level for the given waste concentration. Querying the output data base for different waste concentrations can produce the set of graphs such as those shown in Figures 1-5(a), (b), and (c). The figures show how the percent protection varies as a function of the target risk, the waste concentration, and the confidence limit, and can be used to select the waste concentration that meets a specified protection measure. These types of figures could also be produced for subsets of receptors to investigate the effects of selecting a waste concentration on secondary protection measures.

These risk results are produced by three processors (ELP I, ELP II, and RVP) that collectively accumulate, transform, and present information generated by the individual site-based risk assessments in the form of measures of site and population protectiveness at the national level. The ELP I reads individual site-based human-health risk and hazard and

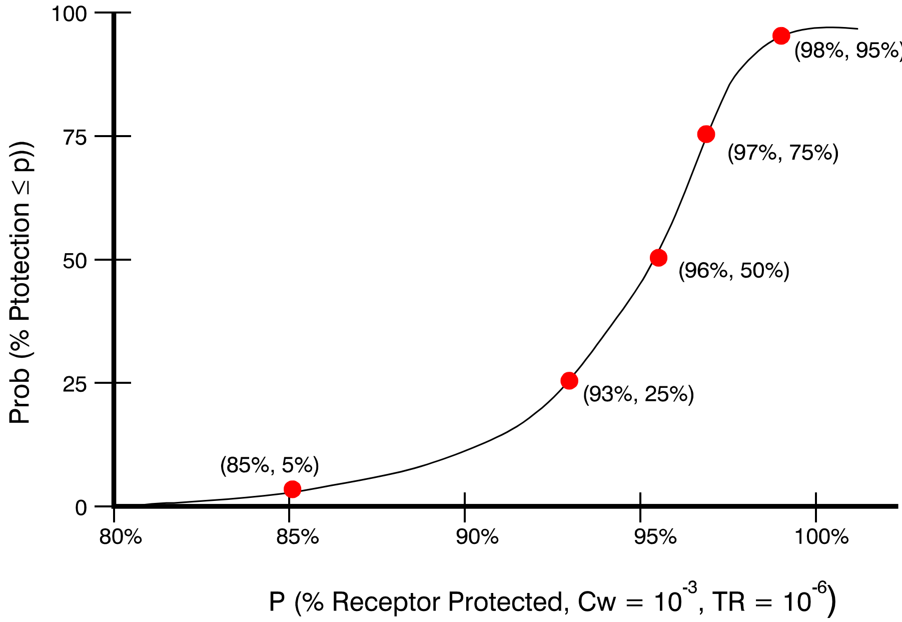


Figure 1-4. Probability that percent protection is less than P for a given waste concentration and target risk level.

ecological hazard results from the Human and Ecological Risk Modules, transforms the population counts into percentages of receptor populations protected, and stores the resulting risk and hazard information in a series of national Risk Summary Output Files (RSOFs). The RVP and ELP II processors query the RSOF in response to specific criteria for protective measures and produce graphical and tabular views of the trade off between levels of constituent concentration in waste streams and levels of protectiveness. With the combination of the RSOF database and the RVP/ELP II, the following type of question can be asked: "What is the maximum allowable constituent concentration for waste streams entering landfills such that at least 90 percent of all receptors at 95 percent of the sites nationwide incur a risk less than 10^{-6}?" In addition, the RVP allows the user to query and summarize the information stored in the RSOFs and graphically view the results of such queries. The user is prompted for a set of scenario attributes (that is, WMU type, constituent, distance, receptor type, cohort, etc.) and a level of protection (for example, risk of 1.0×10^{-6} or HQ of 1.0, etc.). The RVP uses this information to construct plots showing the probability of protecting human or ecological receptors (in the group of receptors defined by the scenario attributes) as a function of C_w. Using information obtained from the RSOFs, the probability of protecting a given receptor is determined by taking the group of receptors defined by the scenario attributes across all sites and plotting the percentage of those receptors that are protected (that is, have a risk or hazard value equal to or below the level of protection). Because each site is simulated with multiple realizations, several probability curves are plotted, each corresponding to the chosen confidence levels (for example, 5 percent, 50 percent, 95 percent). These plots are called Protective Summary Output curves. The RVP creates a Protective Summary Output curve for human risk, human hazard quotient (HQ), and ecological HQ, depending on the appropriateness and existence of the data for the constituent chosen. Figures 1-6 and 1-7 illustrate the human risk protective summary and ecological hazard protective summary plots produced by the RVP, respectively.

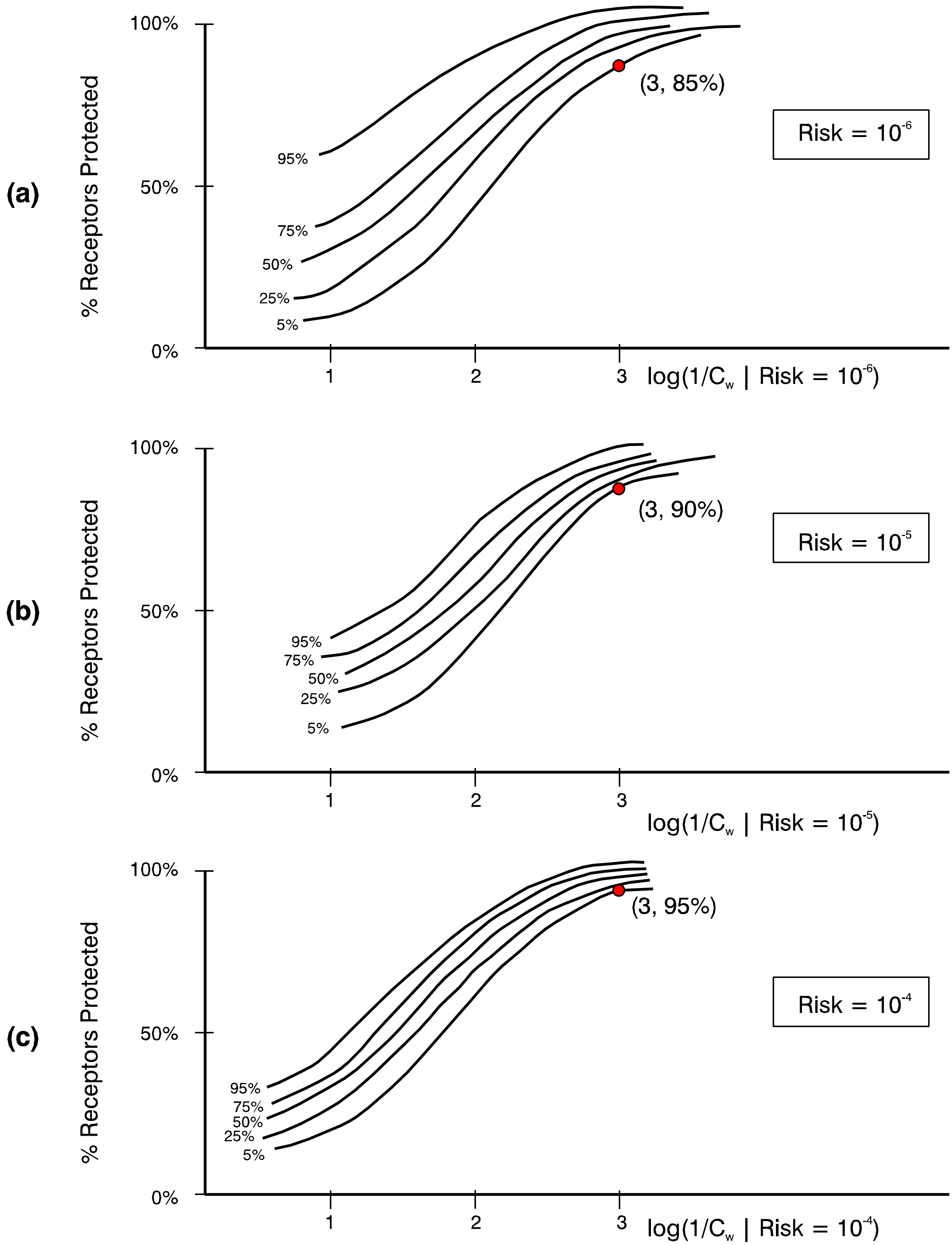


Figure 1-5. Percent of receptors protected for different waste concentrations and risk levels.

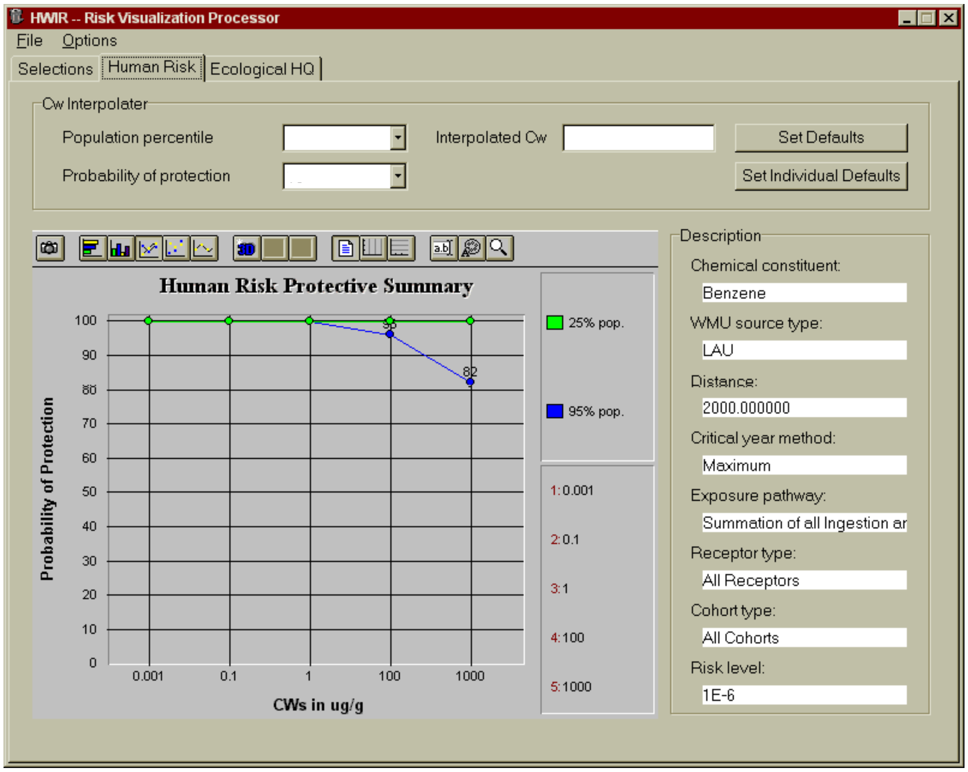


Figure 1-6. Protective Summary Output figure for human risk.

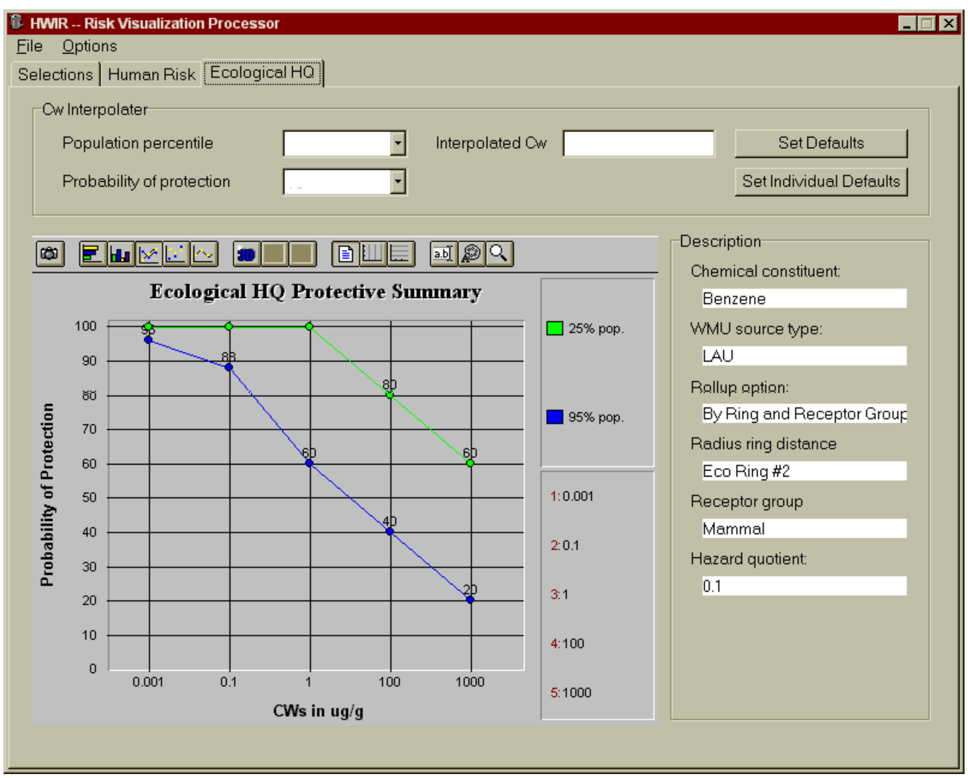


Figure 1-7. Protective Summary Output figure for ecological HQ.

1.6 Organization of This Document

The first three sections of this document (including this introduction) discuss the modeling system as a whole. Section 2 presents an overview of the modeling approach from a conceptual viewpoint and describes the assessment strategy and the general approach for its implementation. Section 3 provides a discussion of the development and use of spatial data in this model, which are fundamental to developing variability in exposure and risk estimates across a site.

The remaining sections describe the WMU source, fate and transport, exposure, and risk modules. Figure 1-8 shows which section describes each module. The five source modules are covered in two sections, one for land-based sources (LAUs, landfills, and waste piles) and one for wastewater systems (surface impoundments and tanks).

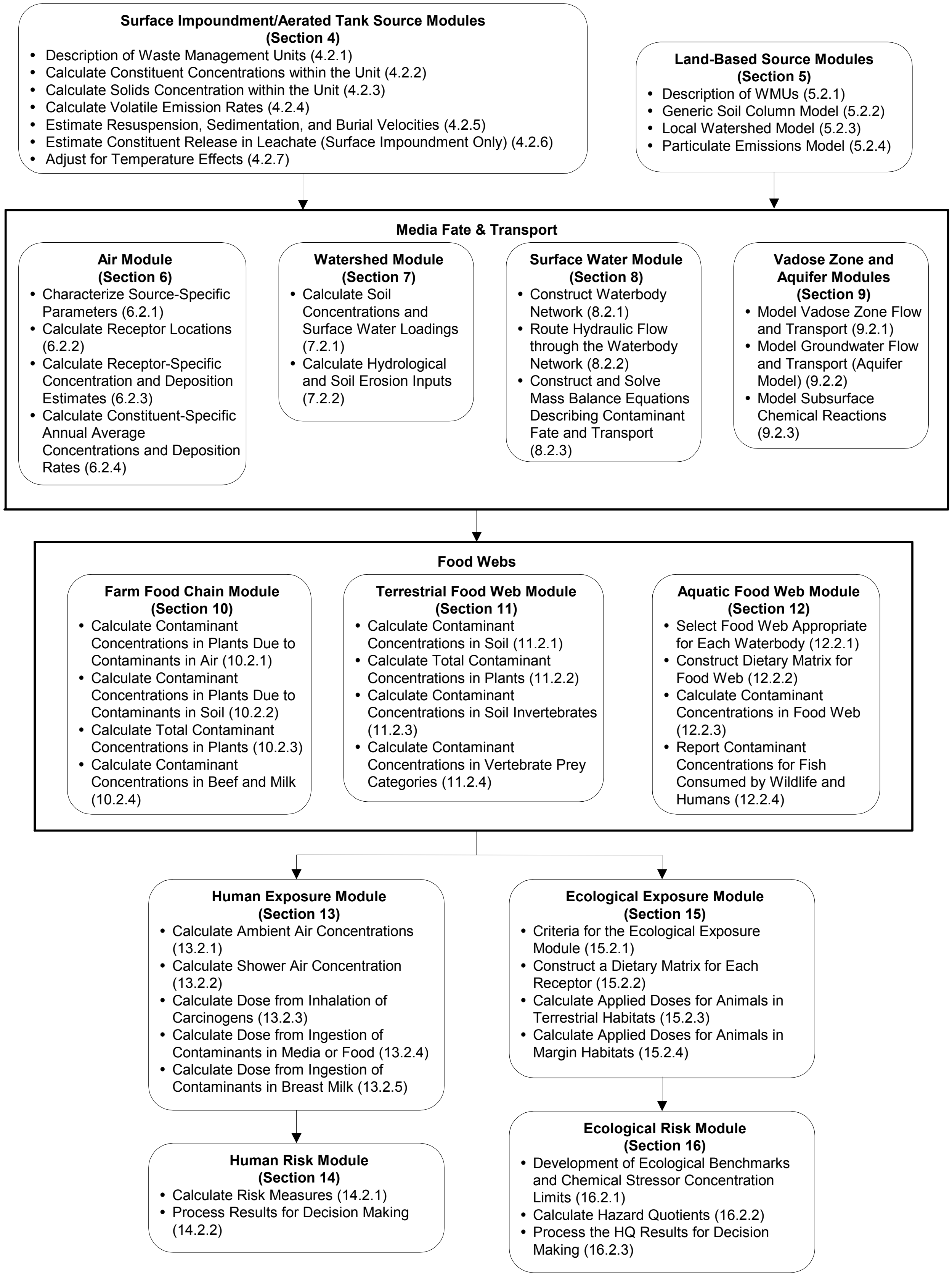


Figure 1-8. Document organization.

1.7 References

Burns, L.A. 1997. *Exposure Analysis Modeling System (EXAMS II): User's Guide for Version 2.97.5*. EPA-600/R-97/047. Athens, GA: U.S. Environmental Protection Agency.

Burns, L.A., D.M. Cline, and R.R. Lassiter. 1982. *Exposure Analysis Modeling System (EXAMS): User Manual and System Documentation*. EPA-600/3-83-023. Athens, GA: U.S. Environmental Protection Agency, Environmental Research Laboratory.

CRARM (Presidential/Congressional Commission on Risk Assessment and Risk Management). 1997. *Risk Assessment and Risk Management in Regulatory Decision Making*. Final Report, Volume 2. Washington, DC: Government Printing Office.

Hazardous Waste Identification Rule (HWIR). 1995. *Federal Register* 60:245. December 21, p. 66344.

Marin, C.M., V. Guvanasen, and Z.A Saleem. n.d. The 3MRA risk assessment framework - a flexible approach for performing multimedia, multipathway, and multireceptor risk assessments under uncertainty. *International Journal of Human and Ecological Risk Assessment* (in press; scheduled for publication December 2003).

Resource Conservation and Recovery Act. 1976. 42 U.S.C. s/s 6901 et seq. Available online: http://www4.law.cornell.edu/uscode/42/ch82.html.

U.S. EPA (Environmental Protection Agency). 1995. *User's Guide for the Industrial Source Complex (ISC3) Dispersion Models. Volume II: Description of Model Algorithms.* EPA-454/B-95-003b. U.S. Environmental Protection Agency, Emissions, Monitoring, and Analysis Division, Office of Air Quality Planning and Standards, Research Triangle Park, NC. September.

U.S. EPA (Environmental Protection Agency). 1996a. *An SAB Report: Review of a Methodology for Establishing Human Health and Ecologically Based Exit Criteria for the Hazardous Waste Identification Rule (HWIR).* EPA-SAB-EC-96-002. Washington, DC: Science Advisory Board. May.

U.S. EPA (Environmental Protection Agency). 1996b. *EPACMTP Sensitivity Analysis.* Washington, DC: Office of Solid Waste. March.

U.S. EPA (Environmental Protection Agency). 1996c. *EPA's Composite Model for Leachate Migration with Transformation Products (EPACMTP): Background Document*. Washington, DC: Office of Solid Waste. September.

U.S. EPA (Environmental Protection Agency). 1996d. *EPA's Composite Model for Leachate Migration with Transformation Products, EPACMPT.* Background Document for Finite Source Methodology for Chemicals with Transformation Products. R09-96-588. Washington, DC: Office of Solid Waste. October.

U.S. EPA (Environmental Protection Agency). 1996e. *Mercury Study Report to Congress, Volumes V, VI, VII, and Supplement. SAB Review Draft.* EPA-452/R-96-001a-h. Washington, DC: Office of Air Quality Planning and Standards and Office of Research and Development. June.

U.S. EPA (Environmental Protection Agency). 1996f. *Proposed Guidelines for Carcinogen Risk Assessment. Notice of Availability and Opportunity to Comment on Proposed Guidelines for Carcinogen Risk Assessment*. *Federal Register* 61 FR 17960-18011. April 23.

U.S. EPA (Environmental Protection Agency). 1996g. *Proposed Guidelines for Ecological Risk Assessment*. Risk Assessment Forum, Washington, DC. Web site at http://www.epa.gov/ORD/WebPubs/ecorisk.

U.S. EPA (Environmental Protection Agency). 1997. *EPA's Composite Model for Leachate Migration with Transformation Products (EPACMTP): User's Guide*. Office of Solid Waste. Washington, DC.

U.S. EPA (Environmental Protection Agency). 1998. *ORD/OSW Integrated Research and Development Plan for the Hazardous Waste Identification Rule (HWIR).* Washington, DC.

U.S. EPA (Environmental Protection Agency). 2000. *Exposure and Human Health Reassessment of 2,3,7,8-Tetrachlorobinzo-p-Dioxin (TCDD) and Related Compounds. Part III: Integrated Summary and Risk Characterization for 2,3,7,8-Tetrachorodibenzo-p-Dioxin (TCDD) and Related Compounds (SAB Review Draft).* EPA/600-P-00/00Bg. Washington, DC: National Center for Environmental Assessment, Office of Research and Development. September.

U.S. EPA (Environmental Protection Agency). 2002. *Total Risk Integrated Methodology: TRIM Fate Documents.* Available online: http://www.epa.gov/ttn/atw/urban/trim/trimpg.html.