

be satisfied before ecologically based exit criteria are calculated;

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

(g) Reorganize and rewrite the documentation for both clarity and ease of use.

As a result of the methodology reviews, the Office of Solid Waste (OSW) collaborated with the Office of Research and Development (ORD) to develop and document a sound science foundation, supporting data for an assessment, and related software technology for an integrated, multimedia modeling system (entitled 3MRA) following the recommendations of the SAB and other reviewers. This effort was initiated with the peer review of an integrated research and development plan (ORD/OSW Integrated Research and Development Plan for the Hazardous Waste Identification Rule (HWIR), 1998 available at: <http://www.epa.gov/epaoswer/hazwaste/id/hwirwste/risk.htm>), that describes the assessment methodology, the technical bases for the integrated multimedia modeling system, and quality controls to be followed during the developmental process. The Multimedia, Multipathway, and Multireceptor Risk Assessment (3MRA) modeling system represents a collection of science-based models and databases that have been integrated into a software infrastructure that is based on the FRAMES (Framework for Risk Analysis in Multimedia Environmental Systems) concept, which provides a computer-based environment for linking environmental models and databases and managing the large amounts of information within the system, including the visualization of outputs. This integrated multimedia modeling system provides national-level estimates of human and ecological risks resulting from long-term (chronic) chemical release from land-based waste management units. Over 45 experts participated in the peer review process of the underlying science within the 3MRA modeling system.

The EPA plans to use the modeling system to help inform managers on a variety of decisions in the waste program, such as setting concentration-based exit criteria for wastes in the hazardous waste management regulations, or deciding whether technology-based standards are protective of human health and the environment.

3. Proposed Charge to the Panel: The EPA is asking the SAB to focus its review in the following four areas: assessment methodology, 3MRA modeling system, modeling system evaluation, and modeling system documentation. Charge questions related to those areas are identified in the relevant section below.

Assessment Methodology

The 3MRA assessment methodology presents a strategy for estimating national distributions of human and ecological risks resulting from long-term (chronic) chemical release from land-based waste management units. The national distribution is constructed by performing "site-based" assessments at a statistically significant number of randomly sampled hazardous waste site locations across the U.S. In the assessment methodology, a pollutant is released from a waste management unit to the various media (air, water, soil) according to its chemical properties and characteristics of the unit. The pollutant is transported through the media and exchanged between media via system linkages. Receptors are exposed concurrently to the pollutant via multiple pathways/routes resulting in an integrated dose.

The methodology describes a tiered approach for populating data files for each site evaluation. The approach is referred to as "site-based" because the assignment of data values for the site being simulated occurs according to a tiered protocol. Data values are filled first with data at a site level; when site data are not available, a statistically sampled value from a geographically relevant regional distribution of values are used; and lacking a representative regional distribution for the variable, a value from a national distribution is assigned.

The 3MRA methodology was designed specifically to include Monte Carlo simulation methods to address both uncertainty and variability in the risk outputs. Statistical distributions for many modeling parameters were developed and upon implementation provide a statistical measure of variability and uncertainty, *i.e.*, the range and distribution of potential exposures and risks occurring at a site. When applied to the sites in a national assessment, the result is a statistical measure of variability and uncertainty, and national distributions of risks. The sites currently in the database are randomly selected from sites across the United States to represent the national variability in waste management scenarios and locations. The methodology for selecting the sites

allows for measures of protection to be calculated at the site level and aggregated over all the sites to develop the national distribution of risks.

Charge Question 1: While the EPA had the assessment methodology peer reviewed prior to the development of the 3MRA modeling system, does the SAB have any additional comments about the methodology as implemented?

3MRA Modeling System

To implement the 3MRA methodology, the EPA chose to develop a comprehensive software-based modeling system, which facilitates the consistent use of sound-science models through a framework that controls model sequencing, facilitates data exchange, and provides data analysis and results visualization tools. Following modern Object Oriented software design and development principles and honoring the use of legacy models (*i.e.*, fate and transport models that have a long history of use at the EPA), the EPA has constructed a modern modeling system that facilitates the consistent and reproducible application of the 3MRA modules and databases to problems requiring a national-scale assessment of site-based risks. The 3MRA modeling system is underpinned by a software infrastructure named FRAMES. FRAMES provides a computer-based environment for linking and applying environmental models and managing the large amounts of information within the system.

The 3MRA modeling system consists of: (a) 17 science-based modules that estimate chemical fate, transport, exposure, and risk; (b) 7 system processors that select data for model execution; manage information transfer within the system; "roll-up" site-based results into distributions of risk at the national level; and provide a visualization of the system outputs; and (c) multiple databases that (currently) contain the data for waste managements sites across the country as well as regional and national distributions of data values, (d) a software infrastructure (framework) based on FRAMES.

The 3MRA system was designed to provide flexibility in producing distributions of hazards or risks at sites that may manage exempted waste because the final regulatory decision framework for defining chemical-specific exit levels has not been formulated. The system is designed to allow the evaluation of human health impacts to the general population or selected subpopulations and the impact of varying the measures of protection at different probability levels. The system