

Model uncertainty is associated with all models used in all phases of a risk assessment, because models and their mathematical expressions are simplifications of reality that are used to approximate real-world conditions and processes, and their relationships. Models do not include all parameters or equations necessary to express reality because of the inherent complexity of the natural environment and the lack of sufficient data to describe it. Even though the models used in the risk analyses are used widely and have been accepted for numerous applications, they each retain significant sources of uncertainty.

For example, in modeling the fate and transport of chemicals in groundwater, we did not assess complex hydrogeology such as karst or highly fractured aquifers. In general, fractured flow in groundwater can channel the contaminant plume, thus allowing it to move faster and more concentrated than in nonfractured flow environments. As a result, our modeling may underestimate the concentrations in the groundwater.

Also, there is considerable uncertainty in predicting the movement of contaminants over long periods of time. We assess the risk to receptors for the groundwater pathway over a time period of 10,000 years. There are likely to be significant changes in environmental conditions over time, yet the modeling methodology maintains constant assumptions over this 10,000 year period.

Parameter uncertainty occurs when (1) there is a lack of data about the parameters used in the equations, (2) the data that are available are not representative of the particular instance being modeled, or (3) parameter values cannot be measured precisely and/or accurately because of limitations in measurement technology.

The age of several of the databases used in this analysis to characterize the waste management units or the location of the receptors leads to uncertainty in the analysis. These databases contain information collected by the EPA in several surveys during the mid-to late 1980's. While these databases represent the best available information the Agency has, there may have been significant changes in waste management units or residential locations over the last 15–20 years. The uncertainty associated with these data may lead to an over or under estimate of risk.

For organic chemicals, single values for parameters such as partitioning coefficients and biodegradation rates were obtained from public literature

sources, yet there is general agreement that these types of values may be highly variable under different environmental conditions. We recognize that biodegradation rates are dependent on a variety of environmental conditions, thus where more than one rate was found, we chose the lowest one. We selected anaerobic degradation rates reported as the most appropriate for constituents within landfills. Depending on the site specific conditions, the degradation rates may underestimate or overestimate the amount of degradation that would occur in a landfill. Note that we did not, however, attempt to account for biodegradation in the subsurface, because we believe this degradation is more variable and difficult to predict. For metals, EPA used the MINTEQA model to estimate the variation in partitioning of metals as a function of subsurface chemistry. However, this model is still undergoing review, which indicates an additional source of uncertainty.

Limited data were available on the physical and chemical characteristics of dyes and/or pigments production waste. To address this, assumptions on the waste characteristics are based on general knowledge of dyes and pigments and other similar industrial wastes. In this analysis, EPA assumes that the dyes and/or pigments production wastes have the same general characteristics (e.g., fraction of organic carbon, pH, particle size) as other wastes.

We typically use regional databases to obtain the parameter values necessary to model contaminant fate and transport. Because the data that we used are not specific to the facilities at which the actual wastes are managed, the data represent our estimates of the generic site conditions. For an analysis where waste management locations are so variable, we believe this type of approach is reasonable and is the best method to address the fate and transport of constituents. Nevertheless, the use of these databases in lieu of site-specific data may result in either overestimates or underestimates of risk.

Sources of uncertainty in toxicological benchmarks include one or more of the following: extrapolation from laboratory animal data to humans, variability of response within the human population, extrapolation of responses at high experimental doses under controlled conditions to low doses under highly variable environmental conditions, and adequacy of the database (number of studies available, toxic endpoints evaluated, exposure routes evaluated, sample sizes, length of study, etc.). Toxicological benchmarks are designed

to be conservative (that potentially overestimates risk) because of the uncertainties and challenges associated with condensing toxicity data into a single quantitative expression. Uncertainty factors are applied to address limitations of the available toxicological data and are necessary to ensure that the RfD or RfC is protective of individuals in the general population. The use of uncertainty factors is based on long-standing scientific practice. Uncertainty factors, when combined, commonly range from 10 to 1000 depending on the nature and quality of the underlying data. The RfD/RfC methodology is expected to have an uncertainty spanning perhaps an order of magnitude.

Toxicological effects in children are also an area of uncertainty. Cancer slope factors and reference doses for children are based on comparing childhood exposure, for which we have age-specific data, with adult toxicity measures, where adequate age-specific dose-response data is lacking. This mismatch results in a large amount of uncertainty in the estimation of hazard quotients for children and the concern that we may be underestimating the potential impacts on children.

5. How Did EPA Use Damage Case Information?

We considered whether any damage cases exist that indicate impacts on human health or the environment from improper management of the wastes of concern, as required under the listing regulations (§ 261.11(a)(3)(ix)). Damage incidents might also provide some information on the potential of the waste constituents to migrate, persist, or degrade in the environment. We compiled damage incidents involving dyes and/or pigments production wastes for a previous proposal,³⁹ and we updated this report for today's proposal.⁴⁰ We found and reported eleven incidents in the August 1994 damage case report that appeared to involve some kind of contamination from the mismanagement of dye and/or pigment production wastes. Our updated analysis did not produce any other cases with useful information.

The available information on potential problems related to apparent mismanagement of dye and/or pigment wastes at manufacturing sites. The

³⁹ See the report prepared for the 1994 proposed rule, "Resource Damage Incidents for Dye and Pigment Industry," August 1994, in the docket for today's rule.

⁴⁰ See the updated report, "Damage Incident Analysis for the Identification and Listing of Wastes from the Production of Organic Dyes and Pigments," July 2003, in the docket for today's rule.