



## Project Summary

# Recommendations for and Documentation of Biological Values for Use in Risk Assessment

**This document was prepared by the Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office, Cincinnati, OH, for the Office of Solid Waste and Emergency Response. This document consists of an extensive compilation of values gleaned from published literature sources for lifespan, body weight, food consumption, water consumption and inhalation volumes for a wide range of predominately mammalian species. Synthesis of this information to provide recommendations concerning parameters for conversion of exposure data (drinking water, food and air concentration) from mammalian toxicological studies to dose estimates in units of milligrams/kilogram body weight/day is provided.**

***This Project Summary was developed by EPA's Environmental Criteria and Assessment Office, Cincinnati, OH, to announce key findings of a research project which is fully documented in a separate report (see Project Report ordering information at back).***

### Introduction

Reference values for parameters such as food consumption, fluid consumption and ventilatory volume have been widely utilized across the Agency to estimate mg/kg/day doses from experimental exposure concentrations expressed as ppm in air, water or food. While it is preferable to utilize measured parameters specific to the particular study, frequently these data are not reported. Estimation of a mg/kg/day dose was historically an integral component of Acceptable Daily Intake (ADI) devel-

opment and currently is required for Reference Dose (RfD) and Reportable Quantity (RQ) calculations. Reference values for body weights, while important for the above uses, are also required (in the absence of experimental values) for surface area estimates, which are utilized in both the RQ and cancer methodologies. The only Published Agency guidance concerning which values to utilize in risk assessment are allometric equations for food consumption and ventilatory volume for rats and mice. These equations were given in the Methodology for the Ambient Water Quality Criteria Documents and were based upon an extremely limited data set.

In the absence of formal guidance, ad hoc positions have been developed, which differ across the different Agency offices. These differences frequently result because each office has utilized a different, small subset of the available data as a basis for their reference values.

While the variability introduced by these differing values is generally quite small in a quantitative sense, qualitatively this variability has profound effects in terms of apparent consistency of risk assessment numbers across offices. In addition, achieving agreement concerning these numbers within the framework of a particular risk assessment where several offices are involved frequently requires utilization of time and resources, which could be better applied to the resolution of other issues.

This document provides the first extensive compilation of experimental data for these parameters for all of the commonly used laboratory species including values for food and water consumption, inhalation volume, body weight and lifespan. This database is

synthesized to provide recommendations concerning parameters for conversion of exposure data (food, water or air concentration) into dose estimates in units of mg/kg body weight/day. It is anticipated that these recommendations will be of utility for risk assessment in terms of estimating doses from mammalian toxicology studies when the studies fail to report intake values for the

experimental animal relevant to the medium in which the toxicant is administered.

### Results and Conclusions

Data are presented in two forms, estimates of each parameter for animal of unknown body weight, as well as allometric equations for parameter estimation for animals of known body

weight. Data were adequate to provide estimates of inhalation volume, body weight, food and water consumption for twelve mammalian species. Parameters were estimated separately for individual sexes and strains wherever data allowed. This document is currently undergoing evaluation as a potential framework to achieve a consensus agreement concerning default physiological parameters.

**Karen Blackburn** is the EPA Project Officer (see below).

The complete report, entitled "Recommendations for and Documentation of Biological Values for Use in Risk Assessment," (Order No. PB 88-179 874/AS; Cost: \$32.95, subject to change) will be available only from:

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Springfield, VA 22161  
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