

US EPA ARCHIVE DOCUMENT

ENVIRONMENTAL PROTECTION AGENCY

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Notice of Availability of the Benchmark Dose Technical Guidance**AGENCY:** Environmental Protection Agency (EPA)**ACTION:** Notice of Availability

SUMMARY: The U.S. Environmental Protection Agency is announcing the availability of *Benchmark Dose Technical Guidance* (BMD). This document was developed as part of an agency-wide guidance development program by a technical panel of the EPA's Risk Assessment Forum. Drafts were peer reviewed internally by EPA scientists and externally by experts from academia, industry, and other federal and state government agencies. When appropriate, the EPA intends to use the guidance prospectively in conducting risk assessments.

ADDRESSES: The BMD document is available electronically through the EPA's Web site at <http://www.epa.gov/raf/publications/benchmarkdose.htm>.

FOR FURTHER INFORMATION CONTACT: Dr. Michael W. Broder, Risk Assessment Forum, Office of the Science Advisor (8105R), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; on telephone number (202) 564-3393; facsimile number (202) 564-2070; or email broder.michael@epa.gov.

SUPPLEMENTARY INFORMATION: In support of its mission to protect human health and the environment, the EPA routinely conducts risk assessments on chemical agents that may be toxic to humans. A key component of the risk assessment process involves evaluating the dose-response relationship between exposure to the agent and the observed effect. The dose-response assessment is a two-step process: (1) defining a point of departure (POD); and (2) extrapolating from the POD for relevance to environmental exposures. Traditionally, the no observed adverse effect level (NOAEL) or

lowest observed adverse effect level (LOAEL) methods were used for establishing the POD for noncancer endpoints. The BMD method gained favor within the risk assessment community over time because it incorporates and conveys more information than the NOAEL/LOAEL methods. The EPA conducted workshops and symposia about the application of BMD methodology and the development of relevant guidance.

The BMD document focuses on the use of the BMD methodology for human health risk assessments. The document discusses computation of BMD values and their confidence limits, data requirements, dose-response assessment, and reporting recommendations that are specific to BMD values. Although the EPA has generated its own BMD software (<http://www.epa.gov/ncea/BMDS/index.html>), this document supports the use of other relevant, well-documented software packages.

Date

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