

US EPA ARCHIVE DOCUMENT

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-ORD-2009-0694]

Notice of Availability of the External Review Draft of the Application of Quantitative Data to Develop Data-Derived Extrapolation Factors for Interspecies and Intraspecies Extrapolation.

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Document Availability for Public Comment.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is announcing a 60 day public comment period for the External Review Draft of “Application of Quantitative Data to Develop Data-Derived Extrapolation Factors for Interspecies and Intraspecies Extrapolation.” EPA is releasing this draft document solely for the purpose of seeking public comment prior to external peer review. The document will undergo independent peer review during an expert peer review meeting, which will be convened, organized, and conducted by an EPA contractor in the late fall 2009/early winter 2010 timeframe. The date of the external peer review meeting will be announced in a subsequent Federal Register notice. All comments received by the docket closing date (*60-days from the FR notice issuance*) will be shared with the external peer review panel for their consideration. Comments received after the close of the comment period may be considered by EPA when it finalizes the document. This document has not been formally disseminated by EPA. This draft interim guidance does not represent and should not be construed to represent any EPA policy, viewpoint, or determination. Members of the public may obtain the draft interim guidance from www.regulations.gov; or

www.epa.gov/raf/DDEF/index.htm or from Dr. Michael Broder via the contact information below.

This draft Interim Guidance for Data Derived Extrapolation Factors outlines approaches for developing factors for inter- and intra-species extrapolation based on data describing toxicokinetic and/or toxicodynamic properties of (a) particular agent (s). The draft document was developed to provide information to the regulated community and other interested parties about deriving and implementing extrapolation factors derived from data instead of defaults and to provide guidance for EPA staff in evaluating such data and/or information.

DATES: All comments received by the docket closing date (*60-days from the FR notice issuance*) will be shared with the external peer review panel for their consideration. Comments received beyond that time may be considered by EPA when it finalizes the document.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-ORD-2009-0694, by one of the following methods:

- **www.regulations.gov:** Follow the on-line instructions for submitting comments.
- **Email:** ORD.Docket@epa.gov
- **Mail:** ORD Docket, Environmental Protection Agency, Mailcode: 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460
- **Hand Delivery:** EPA Docket Center (EPA/DC), Room 3334, EPA West Building, 1301 Constitution Avenue, N.W., Washington, D.C. 20460, Attention Docket ID No EPA-HQ-ORD-2009-0694 Deliveries are only accepted from 8:30

a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. Special arrangements should be made for deliveries of boxed information.

INSTRUCTIONS: Direct your comments to Docket ID No. EPA-HQ-ORD-2009-0694. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected by statute through www.regulations.gov or e-mail. The www.regulations.gov website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA, without going through www.regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

DOCKET: All documents in the docket are listed in the www.regulations.gov index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material,

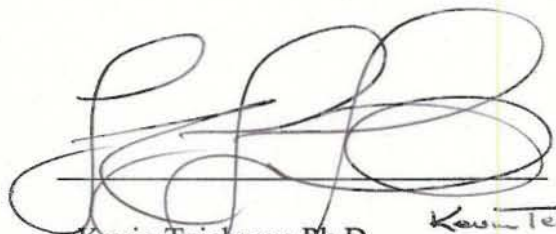
will be publicly available only in hard copy. Publicly available docket materials are available either electronically in www.regulations.gov or in hard copy at the ORD Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the ORD Docket is (202) 566-1752.

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

SUPPLEMENTARY INFORMATION: Key goals for the U.S. EPA include improving the transparency, objectivity, and scientific basis for health risk assessment. In 2005, a WHO-sponsored effort produced guidance on the development of Chemical-Specific Adjustment Factors (CSAFs). CSAFs are intended to replace default uncertainty factor values for inter- and intraspecies extrapolation in health risk assessment. The U.S. EPA recognizes several key differences between the WHO guidance and typical Agency risk assessment practices, policies and guidance developed. As such, in 2005, EPA's Risk Assessment Forum convened a technical panel that initiated work on developing draft guidance for use in replacing default values for inter- and intraspecies extrapolation/uncertainty factors. The draft document has been reviewed by the Risk Assessment Forum and the U.S. EPA's Science Policy Council's Steering Committee. The draft document is now available for public comment.

The draft document has been structured and developed in accord with existing Agency policies on health risk assessment. The draft document provides guidance for the evaluation of data describing interspecies differences in chemical disposition (toxicokinetics), interspecies differences in toxicant-induced response (toxicodynamics), intraspecies differences in chemical disposition (toxicokinetics), interspecies differences in toxicant-induced response (toxicodynamics). The document maintains the subdivision of the interspecies and intraspecies uncertainty factors into toxicokinetic and toxicodynamic components specified in the U.S. EPA Inhalation Reference Concentration methodology (U.S. EPA, 1994). EPA will consider all peer review and public comments in finalizing Application of Quantitative Data to Develop Data-Derived Extrapolation Factors for Interspecies and Intraspecies Extrapolation.

Dated: _____



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Billing Code: 6560-50P