

Weekly receipt of Environmental Impact Statements

Filed 09/22/2014 Through 09/26/2014  
Pursuant to 40 CFR 1506.9

#### Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: <http://www.epa.gov/compliance/nepa/eisdata.html>.

*EIS No. 20140282, Final EIS, NPS, TX, Big Thicket National Preserve Final General Management Plan, Review Period Ends: 11/03/2014, Contact: Doug Neighbor 409-951-6801.*

*EIS No. 20140283, Final EIS, NPS, TX, Lake Meredith National Recreation Area and Alibates Flint Quarries National Monument General Management Plan, Review Period Ends: 11/03/2014, Contact: Arlene Wimer 806-857-0309.*

*EIS No. 20140284, Draft Supplement, FHWA, VA, U.S. Route 460 Corridor, Comment Period Ends: 11/17/2014, Contact: Edward S. Sundra, 804-775-3357. The U.S. Department of Transportation's Federal Highway Administration, the U.S. Army Corps of Engineers, and the Virginia Department of Transportation are joint lead agencies for the above project.*

*EIS No. 20140285, Final EIS, USFS, CA, California Pacific Electricity Company 625 and 650 Electrical Line Upgrade Project, Review Period Ends: 11/03/2014, Contact: Robert Rodman 530-543-2613.*

*EIS No. 20140286, Draft EIS, USFS, CA, Jess Project, Klamath National Forest, Comment Period Ends: 11/17/2014, Contact: Angie Bell 530-842-6131.*

*EIS No. 20140287, Draft EIS, USFS, WA, Mt. Baker-Snoqualmie Invasive Plant Management, Comment Period Ends: 11/17/2014, Contact: Phyllis Reed 360-436-2332.*

*EIS No. 20140288, Draft EIS, BPA, OR, WA, Walla Walla Basin Spring Chinook Hatchery Program, Comment Period Ends: 11/24/2014, Contact: Donald L. Rose 503-230-3796.*

#### Amended Notices

*EIS No. 20140198, Draft EIS, NMFS, WA, Two Joint State and Tribal Resource Management Plans for Puget Sound Salmon and Steelhead Hatchery Programs, Comment Period Ends: 11/24/2014, Contact: Steve Leider 360-753-4650. Revision to the FR Notice Published 07/25/2014; Extending the Comment Period from 10/23/2014 to 11/24/2014.*

*EIS No. 20140236, Final EIS, USACE, WA, Lower Snake River Programmatic Sediment Management Plan, Review Period Ends: 09/22/2014, Contact: Sandra Shelin 509-527-7265. Revision to FR Notice Published 09/26/2014; Correction to the Review Period, which ended on 09/22/2014 and not 09/29/2014.*

Dated: September 30, 2014.

**Cliff Rader,**

*Director, NEPA Compliance Division, Office of Federal Activities.*

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### ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-ORD-2014; FRL-9917-45-ORD]

#### Notice of Availability of Guidance for Applying Quantitative Data To Develop Data-Derived Extrapolation Factors for Interspecies and Intraspecies Extrapolation

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of availability.

**SUMMARY:** This notice announces the availability of *Guidance for Applying Quantitative Data to Develop Data-Derived Extrapolation Factors for Interspecies and Intraspecies Extrapolation* (DDEF Guidance). This document lays out methods for calculation of factors compensating for the application of animal toxicity data to humans (interspecies) and for compensating for sensitive populations (intraspecies). The use of data to conduct these extrapolations rather than rely on default values advances EPA's policy of considering relevant data first when conducting its chemical assessments.

**DATES:** The document will be available October 3, 2014.

**ADDRESSES:** The *Guidance for Applying Quantitative Data to Develop Data-Derived Extrapolation Factors for Interspecies and Intraspecies Extrapolation* is available at the EPA Web site <http://www.epa.gov/raf/DDEF/index.htm>.

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

**SUPPLEMENTARY INFORMATION:** Historically, EPA has employed default

uncertainty factors in its computation of toxicity values (e.g., reference concentrations [RfC] and reference doses [RfD]) to compensate for an absence of data. Default uncertainty factors have historically been based on policy or regulatory positions rather than on empirical data applicable to the chemical of interest. Among the uncertainty factors used in EPA assessments are those compensating for a lack of information on how well animal models used in toxicity studies mimic humans (interspecies) and differences in response between the majority of the population (central tendency) compared with the sensitive individual (intraspecies). With the publication of *An Examination of EPA Risk Assessment Principles and Practices* "Staff Paper" published in 2004, and EPA's *Guidelines for Carcinogen Risk Assessment*, published in 2005, the Agency announced its policy of considering all relevant data before applying default values.

In 2011 EPA published *Recommended Use of Body Weight<sup>3/4</sup> as the Default Method in Derivation of the Oral Reference Dose*. In that guidance EPA listed the optimal approach as using a physiologically-based pharmacokinetic or other biologically-based model with the default approach using the ratio of body weights raised to the <sup>3/4</sup> power.

The DDEF Guidance lays out a computational process for using chemical-specific data on toxicokinetics (adsorption, metabolism, distribution and excretion) and toxicodynamics (response of the tissue to the active form of the agent).

It should be noted that the DDEF Guidance is the first EPA product to provide a method both for quantitative determination of relative sensitivity of the pharmacodynamic response in an assessment and for empirical determination of intraspecies sensitivity. As such, this method provides a valuable tool for identifying and quantifying sensitive populations and lifestages.

Dated: August 21, 2014.

**Robert Kavlock,**

*Interim EPA Science Advisor.*

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