List of Candidates for the External Peer Review of a Report on Physiologically Based Pharmacokinetic (PBPK) Modeling for Chloroprene and a Supplemental Analysis of Metabolite Clearance
July 2020

The U.S. Environmental Protection Agency's (EPA) Center for Public Health and Environmental Assessment (CPHEA) announced in a recent *Federal Register* Notice that it is initiating a peer review of a report titled "Incorporation of in vitro metabolism data in a physiologically based pharmacokinetic (PBPK) model for chloroprene" developed by Ramboll, a contractor to Denka Performance Elastomer, LLC (DPE), and an "Uncertainty analysis of in vitro metabolic parameters and of in vitro to in vivo extrapolation used in a PBPK model for chloroprene" developed by EPA. These documents will undergo external scientific peer review managed by Versar, an EPA contractor. Versar has identified nationally and internationally recognized experts with experience and expertise in one or more of the following areas: physiologically based pharmacokinetic (PBPK) modeling, statistics, mass transport fluid dynamics and molecular diffusion, and metabolic rates *in vitro*.

Attached is a List of Candidates with affiliation and expertise. In total, Versar has identified candidates based on their relevant expertise and willingness to serve. From this pool, the Versar will identify 9 experts to serve as peer reviewers: three (3) PBPK modelers, three (3) statisticians, two (2) metabolic rate in-vitro experts, and one (1) a mass transport/fluid dynamics person.

Versar will make the final decision about who will serve on the external review panel based on all relevant information. This will include a conflict of interest (COI) screening of the candidates to ensure that the experts have no COI. The screening will be conducted in accordance with Section 4.6 of EPA's *Peer Review Handbook* (4th Edition, EPA/100/B-15/001, 2015). Criteria used in evaluating a candidate includes: a) scientific and/or technical expertise, knowledge, and experience; b) availability and willingness to serve; c) absence of financial conflicts of interest; d) skills working in advisory committees and panels; and e) for the panel as a whole, diversity of scientific expertise and viewpoints. A balanced panel is characterized by inclusion of candidates who possess the necessary domains of knowledge, the relevant scientific perspectives (which, among other factors, can be influenced by work history and affiliation), and the collective breadth of experience to adequately address the general charge.

Questions or comments about the peer review process, including the information on the candidates, should be submitted to Versar, Inc. by email: chloroprenePBPK@versar.com (Subject line: Chloroprene PBPK Peer Review); or by phone (301) 304-3121 (ask for Tracey Cowen). Comments on the candidate peer reviewers are due on August 24, 2020.

Attachment 1. List of Candidates

Guohua An, M.D., Ph.D.
University of Iowa
Expertise: PBPK modeling

Leslie Z. Benet, Ph.D.
University of California San Francisco
Expertise: Metabolic rates *in vitro*

James V. Bruckner, Ph.D.
University of Georgia
Expertise: PBPK modeling; Metabolic rates *in vitro*

Michael J. Daniels, Ph.D.
University of Florida
Expertise: Statistics

Stephen S. Ferguson, Ph.D.
National Toxicology Program Division (DNTP) at the National Institute of Environmental
Health Sciences (NIEHS)
Expertise: Metabolic rates *in vitro*

Bernard T. Golding, Ph.D.
Newcastle University, UK
Expertise: Metabolic rates *in vitro*

Jeffrey Heys, Ph.D., P.E.
Montana State University
Expertise: Mass transport fluid dynamics and molecular diffusion

Nan-Hung Hsieh, Ph.D.
Texas A&M University
Expertise: PBPK modeling; Statistics

Zhoumeng Lin, BMed, Ph.D., D.A.B.T.
Kansas State University
Expertise: PBPK modeling; Statistics

Jochem Louisse, Ph.D.
Wageningen Food Safety Research (WFSR),
part of Wageningen University and Research, the Netherlands
Expertise: PBPK modeling; Metabolic rates *in vitro*

Annie Lumen, Ph.D.
FDA NCTR
Expertise: PBPK modeling

Kenneth M. Portier, Ph.D.
Independent Consultant
Expertise: Statistics; PBPK modeling

Dhaval K. Shah, Ph.D.
University of Buffalo
Expertise: PBPK modeling, Statistics; Metabolic rates *in vitro*; Mass transport fluid dynamics and molecular diffusion

Kan Shao, Ph.D.
Indiana University
Expertise: Statistics

Jordan Ned Smith, Ph.D.
Pacific Northwest National Laboratory (PNNL)
Expertise: PBPK modeling; Metabolic rates *in vitro*

Gong Tang, Ph.D.
University of Pittsburgh, Graduate School of Public Health
Expertise: Statistics

Raymond S. H. Yang, Ph.D.
Colorado State University
Expertise: PBPK modeling; Statistics; Metabolic rates *in vitro*; Mass transport fluid dynamics and molecular diffusion

Qiang Zhang, Ph.D.
Emory University
Expertise: PBPK modeling

Yiliang Zhu, Ph.D.
University of New Mexico School of Medicine
Expertise: Statistics