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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-ORD-2020-0181; FRL-10011-36-ORD]

Notice of Public Comment Period on Technical Documents for External Peer Review and the Pool of Candidate Peer Reviewers for a Report on Physiologically Based Pharmacokinetic (PBPK) Modeling for Chloroprene and a Supplemental Analysis of Metabolite Clearance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public comment period and external peer review.

SUMMARY: The Environmental Protection Agency (EPA) is announcing a 30-day public comment period on documents associated with a Report on Physiologically Based Pharmacokinetic (PBPK) Modeling for Chloroprene and a Supplemental Analysis of Metabolite Clearance. These documents will undergo independent external scientific peer review managed by Versar (https://www.versar.com/), an EPA contractor. Public comments on the documents associated with the PBPK modeling will be provided to the external peer reviewers. Versar will convene a virtual meeting of the peer reviewers, which will be open to the public and include an opportunity to provide oral comments. In preparation for the external peer review, EPA is also announcing a 30-day public comment period on the pool of candidates to conduct the external peer review of the documents identified above. Versar will consider public comments on these candidates and evaluate any conflicts of interest and/or appearance of lack of impartiality, and

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will then select nine independent experts from the pool of 19 candidates. Information on the external peer review process, including details on how to provide comments on the proposed pool of candidates, is further described in this notice. Once complete, the final peer review report will be used to inform EPA's Reconsideration of a 2017 Request for Correction related to the Integrated Risk Information System (IRIS) assessment of chloroprene.

DATES: The 30-day public comment period on the technical documents and the list of proposed peer review candidates begins [**INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER**] and ends [**INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**]. Comments must be received on or before [**INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**].

ADDRESSES: Submit written comments to Docket ID No. EPA-HQ-ORD-2020-0181 no later than [**INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**]. Documents associated with this peer review will be available within the docket.

Submit comments on the pool of candidate peer reviewers to Versar no later than [**INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**] by one of the following methods: chloroprenePBPK@versar.com (Subject line: Chloroprene PBPK Peer Review); or by phone (301) 304-3121 (ask for Tracey Cowen). Please be advised that public comments are subject to release under the Freedom of Information Act.

FOR FURTHER INFORMATION CONTACT: *For information on how to submit comments on the technical documents contact:* the EPA Headquarters Docket Center; telephone: 202-566-

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1752; facsimile: 202-566-9744; or e-mail: Docket_ORD@epa.gov.

For general information contact: Dahnish Shams, CPHEA; telephone: 202-564-2758; or e-mail: shams.dahnish@epa.gov.

For information regarding the peer review contact: Versar at chloroprenePBPK@versar.com (Subject line: Chloroprene PBPK Peer Review); or by phone (301) 304-3121 (ask for Tracey Cowen).

SUPPLEMENTARY INFORMATION:

I. Background

On June 26, 2017, the U.S. EPA received a Request for Correction (RFC) provided on behalf of Denka Performance Elastomer LLC (DPE). In the RFC letter, DPE claimed that the *Toxicological Review of Chloroprene (CAS NO. 126-99-8) in Support of Summary Information on the Integrated Risk Information System (IRIS)*, disseminated by EPA's Office of Research and Development (ORD) in 2010, did not reflect the "best available science" or "sound and objective scientific practices" and requested correction. On January 25, 2018, EPA concluded in response that the underlying information and conclusions presented in the IRIS chloroprene assessment are consistent with the EPA's Information Quality Guidelines and that no evidence published since the 2010 IRIS Assessment would change its conclusions. On July 23, 2018, DPE submitted a Request for Reconsideration of Denial of Request for Correction (RFR) with regard to EPA's decision, and entered into discussions with EPA to address the uncertainties identified by EPA as documented in the RFC response. Additional information regarding the chloroprene RFC/RFR can be found at: https://www.epa.gov/quality/epa-information-quality-guidelines-

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requests-correction-and-requests-reconsideration#17002. Discussions with Denka LLC (DPE) and its contractor, Ramboll, are summarized on the IRIS website (https://cfpub.epa.gov/ncea/iris2/events.cfm#stakeholderMeetings).

An updated PBPK model is now available in a report: "Physiologically Based Pharmacokinetic (PBPK) Modeling for Chloroprene (Ramboll, 2020)". This report, and a Supplemental Analysis of Metabolite Clearance (U.S. EPA, 2020), will undergo external peer review to help to inform future decisions regarding the RFR.

II. Information About this Peer Review

Versar is considering a list of candidates from which to select the independent, external, peer review panel. The List of Candidates (LoC) document has been posted to the docket at https://www.regulations.gov (Docket ID No. EPA–HQ–ORD–2020-0181) and is included below. After review and consideration of public comments, Versar will select from this pool the final list of nine (9) peer reviewers in a manner consistent with EPA's Peer Review Handbook 4th Edition, 2015 (EPA/100/B-15/001). Versar will independently conduct a conflict of interest (COI) screening of candidates to ensure that the selected experts have no COI. EPA will announce the peer review panel meeting date, location, and registration details, along with the final list of peer reviewers selected by Versar, at least 30 days prior to the peer review meeting, on the EPA IRIS website (https://www.epa.gov/iris). Teleconference and webinar information regarding this public meeting will be provided through the IRIS website (https://www.epa.gov/iris) and via EPA's IRIS listserv. To register for the IRIS listserv, visit IRIS website at https://www.epa.gov/iris/forms/staying-connected-integrated-risk-information-

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system#connect. Specific questions or comments on the peer review process should be directed to Versar by e-mail: chloroprenePBPK@versar.com (Subject line: Chloroprene PBPK Peer Review); or by phone (301) 304-3121 (ask for Tracey Cowen). Comments or questions regarding the peer review candidates must be provided to Versar by [**INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**].

1. Guohua An, M.D., Ph.D., Iowa State University
2. Leslie Z. Benet, Ph.D., University of California San Francisco
3. James V. Bruckner, Ph.D., University of Georgia
4. Michael J. Daniels, Ph.D., University of Florida
5. Stephen S. Ferguson, Ph.D., National Institute of Environmental Health Sciences (NIEHS), National Toxicology Program Division (DNTP)
6. Bernard T. Golding, Ph.D., Newcastle University, UK
7. Jeffrey Heys, Ph.D., P.E., Montana State University
8. Nan-Hung Hsieh, Ph.D., Texas A&M University
9. Zhoumeng Lin, BMed, Ph.D., D.A.B.T., Kansas State University
10. Jochem Louisse, Ph.D., Wageningen Food Safety Research (WFSR), part of Wageningen University and Research, the Netherlands
11. Annie Lumen, Ph.D., Food and Drug Administration (FDA), National Center for Toxicological Research (NCTR)
12. Kenneth M. Portier, Ph.D., Independent Consultant
13. Dhaval K. Shah, Ph.D., University of Buffalo

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14. Kan Shao, Ph.D., Indiana University

15. Jordan Ned Smith, Ph.D., Pacific Northwest National Laboratory (PNNL)

16. Gong Tang, Ph.D., University of Pittsburgh, Graduate School of Public Health

17. Raymond S. H. Yang, Ph.D., Colorado State University

18. Qiang Zhang, Ph.D., Emory University

19. Yiliang Zhu, Ph.D., University of New Mexico School of Medicine

III. How to Submit Technical Comments to the Docket

Please note that questions or comments regarding the peer review process, including comments on the candidate pool of peer reviewers, should be directed to chloroprenePBPK@versar.com (Subject line: Chloroprene PBPK Peer Review); or by phone (301) 304-3121 (ask for Tracey Cowen). Comments on the technical documents related to the PBPK modeling should be submitted to Docket ID No. EPA-HQ-ORD-2020-0181, by one of the following methods:

- Online: https://www.regulations.gov. Follow the online instructions for submitting comments.
- E-mail: Docket_ORD@epa.gov.
- Fax: 202-566-9744. Due to COVID-19, there may be a delay in processing comments submitted by fax.
- Mail: U.S. Environmental Protection Agency, EPA Docket Center (ORD Docket), Mail Code: 28221T, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. The phone number is 202-566-1752. Due to COVID-19, there may be a

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delay in processing comments submitted by mail.

Note: The EPA Docket Center and Reading Room is currently closed to public visitors to reduce the risk of transmitting COVID-19. Docket Center staff will continue to provide remote customer service via e-mail, phone, and webform. The public can submit comments via www.Regulations.gov or e-mail. No hand deliveries are currently being accepted.

Instructions: Direct your comments to Docket ID No. EPA-HQ-ORD-2020-0181. Please ensure that your comments are submitted within the specified comment period. Comments received after the closing date will be marked "late," and may only be considered if time permits. It is EPA's policy to include all comments it receives in the public docket without change and to make the comments available online at www.regulations.gov, including any personal information provided, unless a comment includes information claimed to be Confidential Business Information (CBI) or other information for which disclosure is restricted by statute. Do not submit information through www.regulations.gov or e-mail that you consider to be CBI or otherwise protected. 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

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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. For additional information about EPA's public docket visit the EPA Docket Center homepage at www.epa.gov/epahome/dockets.htm.

Docket: 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 materials, such as copyrighted material, are 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 in the EPA Headquarters Docket Center.

Dated:

Wayne E. Cascio,

Director, Center for Public Health & Environmental Assessment.

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