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ENVIRONMENTAL PROTECTION AGENCY

[FRL-8744-2; Docket ID No. EPA-HQ-ORD-2008-0789]

Literature Search for 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD)
Dose-Response Studies for Use in an Upcoming Expert Panel Workshop

AGENCY: Environmental Protection Agency.

ACTION: Notice; availability of a literature search, public review period, and request for information.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is announcing a 45-day public review and request for additional information on available peer-reviewed literature for 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) dose-response for use in human health risk assessment. An initial literature search was conducted by EPA through an Interagency Agreement with the Department of Energy's Argonne National Laboratory. Results of this preliminary search are available via the dioxin Web site <http://www.epa.gov/ncea/dioxin>. The public is invited to review the preliminary literature search results and submit any additional information, specifically peer-reviewed TCDD dose-response studies, to EPA that are not already identified in the literature search. Please submit any information in accordance with the instructions provided below. It is requested that the full publication be provided to EPA if possible. Results of this literature search will be used by scientists from EPA and other scientists from outside of EPA in the conduct of a scientific expert workshop, open to the public, to be held in Cincinnati, Ohio, on February 18-20, 2009. This workshop will be announced in a future Federal Register notice.

This notice provides: (1) A link to the electronic list of recent literature search results for TCDD dose-response; and (2) instructions to the public for submitting additional scientific information pertinent to TCDD dose-response assessment to EPA that is not already identified in the literature search.

DATES: The 45-day public comment period begins November 24, 2008, and ends January 8, 2009.

ADDRESSES: Please submit relevant scientific information, identified by docket ID number EPA-HQ-ORD-2008-0789, online at <http://www.regulations.gov> (EPA's preferred method); by e-mail to ord.docket@epa.gov; by mail to the Office of Environmental Information (OEI) Docket (Mail Code: 2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001 or by hand delivery or courier to the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC, between 8:30 a.m. and 4:30 p.m. Monday through Friday, excluding legal holidays. Please see SUPPLEMENTARY INFORMATION below for detailed instructions.

FOR FURTHER INFORMATION CONTACT: For information and help on submitting scientific information, please contact the OEI Docket by e-mail (ord.docket@epa.gov), by phone (202-566-1752), or by fax (202-566-1753). For information and help on accessing the Literature Search for TCDD Dose-Response and for technical information, please contact Glenn E. Rice, National Center for Environmental Assessment (Mail Code: MSA-110), Office of Research and Development, U.S. Environmental Protection Agency, Cincinnati, Ohio 45268; telephone: 513-569-7813; facsimile: 513-487-2539; or e-mail: rice.glenn@epa.gov.

SUPPLEMENTARY INFORMATION:

Background

In 1991, EPA announced that it would conduct a scientific reassessment of the potential health risks of exposure to dioxin and related compounds. EPA's Science Advisory Board (SAB) first reviewed the draft dioxin reassessment in 1995, and the document was revised to address SAB comments. In 2000, the SAB reviewed the integrated summary, risk characterization, and other information on toxic equivalency of dioxin-like compounds. Reports of the findings and recommendations of these SAB reviews are available on the SAB Web site at <http://www.epa.gov/sab> (see reports EPA-SAB-EC-95-021 and EPA-SAB-EC-01-006).

In 2003, EPA produced an external review draft of the multi-year comprehensive reassessment of dioxin exposure and human health effects (<http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=87843>). This draft dioxin reassessment document, titled Exposure and Human Health Reassessment of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds, consisted of three parts: (1) A scientific review of information relating to sources and exposures to TCDD and other dioxins in the environment; (2) detailed reviews of scientific information on the health effects of TCDD, other dioxins, and dioxin-like compounds; and (3) an integrated summary and risk

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characterization for TCDD and related compounds.

In 2004, EPA asked the National Research Council of the National Academy of Sciences (NAS) to review the 2003 dioxin reassessment document. The NAS was charged with reviewing "EPA's modeling assumptions (including those associated with dose-response curve and points-of-departure dose ranges and associated likelihood estimates identified for human health outcomes); EPA's quantitative uncertainty analysis; and EPA's selection of studies as a basis for its assessments and gaps in scientific knowledge." The NAS was also charged with addressing two points of controversy: (1) The scientific evidence for classifying dioxin as a human carcinogen; and (2) the validity of the nonthreshold, low-dose, linear dose-response model and the cancer slope factor calculated through the use of this model. In addition, EPA asked the NAS to comment on the usefulness of toxic equivalency factors (TEFs) and uncertainties associated with their use in risk assessment, as well as the uncertainty associated with EPA's approach to analysis of food sampling and human dietary intake data, taking into consideration the Institute of Medicine's report, Dioxin and Dioxin-like Compounds in the Food Supply: Strategies to Decrease Exposure. In 2006, the NAS published its review titled, Health Risks from Dioxin and Related Compounds: Evaluation of the EPA Reassessment. The NAS identified three areas that required substantial improvement to support a scientifically robust risk characterization. These three areas were: (1) Justification of approaches to dose-response modeling for cancer and non-cancer endpoints; (2) transparency and clarity in selection of key data sets for analysis; and (3) transparency, thoroughness, and clarity in quantitative uncertainty analysis. The NAS provided EPA with recommendations to address their key concerns. The full NAS report, including recommendations, is available at http://books.nap.edu/catalog.php?record_id=11688.

EPA is now beginning to prepare a response to the NAS review of the 2003 draft dioxin reassessment, and the development of this preliminary Literature Search for TCDD Dose-Response is one of the first steps in this process. EPA's response to the NAS review of the 2003 draft dioxin reassessment will focus on understanding human dose-response for TCDD, addressing both cancer and non-cancer endpoints. EPA's objective is to address the key findings of the NAS review regarding health effects associated with dioxin exposure, while maintaining transparency and openness throughout the process and providing opportunity for public participation and comment.

To fully address the key concerns of the NAS, EPA will host a scientific expert panel workshop that will include scientists and experts from inside and outside of EPA. These experts will consider the literature on TCDD dose-response and discuss key scientific issues related to this subject area. The literature search results will be used by these expert panelists to provide EPA with a list of the key studies it should consider in its response to the NAS comments. This workshop will be announced in the Federal Register the near future.

The quantitative assessment of dioxin health effects is important to EPA and other organizations with a high level of interest in the health risks associated with dioxin exposures. EPA plans to conduct its dioxin work in a transparent manner, with the active and open involvement of both stakeholders and the public. EPA is initiating the process by identifying and engaging with various groups with interest and expertise in dioxin health effects assessment. To provide for expert peer involvement and review, the SAB Staff Office has solicited nominations of nationally recognized scientists for consideration of membership on an SAB Panel to provide advice on EPA's reassessment of the health risks from dioxin and related compounds (73 FR 61114).

The broad scope of dioxin science will likely require various workshops, consultations, and other discussions of the state of the science. EPA may solicit input and seek technical advice at various steps during its response to the NAS report. EPA commits to a general principle of keeping such discussions open and public, including the use of Federal Register notices in advance of conducting workshops and releasing interim drafts for review. EPA also has an internet site for posting progress reports and news, and for soliciting and sharing information on the latest developments in dioxin science (<http://www.epa.gov/ncea/dioxin>).

How To Submit Technical Input to the Docket (including via www.regulations.gov)

Submit your input, identified by Docket ID No. EPA-HQ-ORD 2008-0789, by one of the following methods:

On-line: www.regulations.gov. Follow the on-line instructions for submitting input.

E-mail: ORD.Docket@epa.gov.

Fax: 202-566-1753.

Mail: Office of Environmental Information (OEI) Docket (Mail Code: 2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. The phone number is 202-566-1752.

Hand Delivery: The OEI Docket is located in the EPA Headquarters Docket Center, Room 3334 EPA West Building, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center 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. Such deliveries are only accepted during the docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information. If you provide information by mail or hand delivery, please submit three copies.

Instructions: Direct your input to Docket ID No. EPA-HQ-ORD-2008-0789. Please ensure that your information is submitted within the specified open period. Information 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 information it receives in the public docket without change and to make this information available online at www.regulations.gov, including any personal information provided, unless the submission 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 through www.regulations.gov or e-mail. The www.regulations.gov Web site 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 information. If you send an e-mail directly to EPA without going through www.regulations.gov, your e-mail address will be automatically captured and included as part of the input that is placed in the public docket and made available on the Internet.

Dated: November 11, 2008.

Peter W. Preuss,
Director, National Center for Environmental Assessment.
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