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United States Environmental Protection Agency

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Dioxin

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EPA's Science Plan for Activities Related to Dioxins in the Environment

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UPDATE

EPA announced the release of the final *Reanalysis of Key Issues Related to Dioxin Toxicity and Response to NAS Comments, Volume 1*, in a February 17, 2012, Press Release. This document provides hazard identification and dose-response information on 2,3,7,8- tetrachlorodibenzo-p-dioxin (TCDD) and the most up-to-date analysis of non-cancer health effects from TCDD exposure. The report also include a reference dose (RfD) and a detailed and transparent description of the underlying data and analyses. EPA will complete Reanalysis, Volume 2, containing the full dioxin cancer assessment, as expeditiously as possible. In Volume 2, EPA will complete the evaluation of the available cancer mode-of-action data, and will augment the cancer dose-

response modeling, including justification of the approaches used for dose response modeling of the cancer endpoints, and an associated quantitative uncertainty analysis.

DISCLAIMERS:

- **Volume 1 (noncancer) of the Reanalysis contains some descriptive cancer information. The cancer information in Volume 1 should not be used for regulatory or risk management decision-making.**
- **Volumes 1 and 2 of the Reanalysis will supersede the 2003 draft dioxin Reassessment.**
- **The 2003 draft dioxin Reassessment includes a disclaimer that the document should not be cited or quoted. As such, information in this draft document should not be used for regulatory or risk management decision-making.**

Abstract

The U.S. Environmental Protection Agency is currently addressing several issues related to dioxins and dioxin-like chemicals in the environment. These include the comprehensive human health and exposure assessment for dioxin, commonly called the *dioxin reassessment* and a review of dioxin soil clean-up levels currently in use across the United States. To move forward with both of these efforts, as well as other dioxin related activities, a plan with interim milestones has been developed and it is outlined below.

EPA's Exposure and Human Health Reassessment of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds; Response to NAS and Completion of Dioxin Reassessment

1. EPA will release a draft report that responds to the recommendations and comments included in the National Academy of Sciences' (NAS) 2006 review of EPA's 2003 draft dioxin reassessment.

UPDATED May 21, 2010: The draft response to comments report titled *EPA's Reanalysis of Key Issues Related to Dioxin Toxicity and Response to NAS Comments (External Review Draft)* ("Draft Dioxin Reanalysis") was completed and released for public review and comment on May 21, 2010.

- EPA's National Center for Environment Assessment (NCEA) in the Office of Research and Development, will prepare a limited response to key comments and recommendations in the NAS report (draft response to comments report).
- The draft response will focus on dose-response issues raised by the NAS and will include an analysis of relevant new key studies.

- The draft response will be provided for public review and comment and independent external peer review.
- The draft response will also include an evaluation of some of the significant recommendations that are difficult for the Agency to address given the current state of science, and a detailed rationale for these conclusions.
- The peer review will be conducted by the EPA Science Advisory Board, an independent review body chartered under the Federal Advisory Committee Act.
- The draft response to comments report will be completed and released for public and peer review by December 31, 2009.

2. EPA will provide the draft response to comments report for internal and external review.

UPDATED May 21, 2010 and June 23, 2010: EPA released a Draft Dioxin Reanalysis report for a 120-day public review and comment period as stated in the Dioxin Science Plan and announced in a May 21, 2010 Federal Register (FR) Notice, with the extension in a June 23, 2010 FR Notice.

- The draft response to comments report will also undergo both internal EPA review and interagency review.
- The availability of the draft report for public review and the start of the comment period will be announced in the *Federal Register*.
- The draft report will be publicly available on EPA's Web site (www.epa.gov/dioxin).

3. The SAB will review the science content of the response to comments report.

UPDATED August 26, 2011: The SAB released their final report reviewing EPA's Reanalysis of Key Issues Related to Dioxin Toxicity and Response to NAS Comments.

- The SAB's review will focus on the analyses of the new dose-response studies, and the rationale for the recommendations that EPA could not implement.
- EPA will work with the SAB to ensure that the SAB's report is completed in a timely manner.

4. EPA will review impacts of the draft response to comments report on the Agency's 2003 draft dioxin reassessment.

UPDATED August 29, 2011: EPA announced a plan for moving forward to complete the dioxin Reanalysis. EPA will complete Volume 1 of the Reanalysis (noncancer) and post it to the IRIS database by the end of January 2012. EPA will then address the SAB comments related to the cancer portion of the Reanalysis and will post Volume 2 of the Reanalysis (cancer) to the IRIS database as expeditiously as possible.

- Throughout the development of the draft response to comments report, NCEA will determine whether any new analyses included in the draft response to comments report will require some, or extensive, revisions to EPA's 2003 draft dioxin reassessment.
- This process will continue during the SAB and public review period.

- NCEA will provide an estimated completion date for the 2003 draft dioxin reassessment
- NCEA will complete any changes expeditiously.

5. EPA will release the final response to comments report and focus on completion of the dioxin reassessment.

UPDATED February 17, 2012: EPA released the final Reanalysis of Key Issues Related to Dioxin Toxicity and Response to NAS Comments, Volume 1, and posted it to the IRIS database. This document provides hazard identification and dose-response information on 2,3,7,8- tetrachlorodibenzo-p-dioxin (TCDD) and includes a reference dose (RfD).

- By the end of 2010, EPA will release the final response to comments report.
- By the end of 2010, EPA expects to complete the final dioxin human health and exposure assessment and release it to the public, subject to further consideration of the science.
- The release date of the final dioxin human health and exposure assessment is dependent on the scope and complexity of the revisions that will need to be made to the 2003 draft assessment based on the contents of the final response to comments report.

Other Dioxin Related Activities

6. EPA will review currently available information from an exposure study by the University of Michigan.

UPDATED September 30, 2009: The EPA's Review of the University of Michigan Dioxin Exposure Study (September 2009) was posted to the EPA website on September 30, 2009.

- NCEA, working together with EPA's Region 5 and the Office of Solid Waste and Emergency Response (OSWER), will review currently available information from the University of Michigan study of dioxin exposures in the Midland, Michigan area
- EPA will determine the relationship of this work to addressing potential risks from dioxin exposure
- The review of the study will be completed by September 30, 2009.

7. EPA will evaluate information about the basis for dioxin soil clean-up levels.

UPDATED December 30, 2009: OSWER's Draft Recommended Interim Preliminary Remediation Goals for Dioxin in Soil at CERCLA and RCRA Sites (December 2009) (Draft Report) was announced on December 30, 2009.

UPDATED December 31, 2009: EPA's Review of State Soil Cleanup Levels for Dioxin (December 2009) (Final Report) was provided to OSWER and posted to the EPA website on December 31, 2009.

- NCEA will review information about the basis for state dioxin soil clean-up levels.
- NCEA will prepare a report for OSWER that includes a survey and evaluation of the clean-up levels in the states

- The report will characterize the science that these values are based on, as well as the degree of peer review, if any that was done.
- This report will be completed before December 31, 2009, and provided to OSWER.
- OSWER will announce an updated interim dioxin soil clean-up level to the public by December 31, 2009.

8. EPA will release final report on Dioxin Toxicity Equivalency Factors (TEF)

UPDATED December 2010: EPA's final report *Recommended Toxicity Equivalence Factors (TEFs) for Human Health Risk Assessments of 2,3,7,8-Tetrachlorodibenzo-p-dioxin and Dioxin-Like Compounds (December 2010)* has been posted to the EPA website.

- EPA will complete its report entitled, *Recommended Toxicity Equivalency Factors (TEFs) for Human Health Risk Assessments of Dioxin and Dioxin-Like Compounds*.
- This document will describe EPA's updated approach for evaluating the human health risks from exposures to environmental media containing dioxin-like compounds.
- The report is expected to recommend the use of consensus TEF values for 2,3,7,8-tetrachlorodibenzo-*p*-dioxin and dioxin-like compounds published in 2005 by the World Health Organization.
- This report will be completed and released to the public by December 31, 2009.

Federal Register Notices

- FR Notice: Jan 7, 2010
- Press Release: Sep 30, 2009
- Press Release: May 26, 2009

Contact

Louis J. D'Amico

phone: 703-347-0344

email: damico.louis@epa.gov

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