



Information Sheet 3

Dioxin Reassessment Process: What is the Status of the Reassessment and How Was the Reassessment Developed?

The U.S. Environmental Protection Agency's (EPA or Agency) is continuing to work towards completion of its reassessment of dioxin exposure and human health effects entitled, *Exposure and Human Health Reassessment of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds* - - the dioxin reassessment. The purpose of this *information sheet* is to describe the process that EPA has used in developing the reassessment and to inform the public about the remaining steps needed to bring this complex scientific activity to a close.

STATUS: On October 15th, 2004, the EPA transmitted to the National Academy of Sciences (NAS) the NAS Review Draft of EPA's *Exposure and Human Health Reassessment of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds*, in preparation for the first meeting of the NAS panel scheduled for November 22 and 23, 2004, in Washington, DC. For detailed information on the NAS's dioxin review activity, titled "[Review of EPA's Assessment of the Health Implications of Exposure to Dioxins](http://www.nas.edu)," please visit the NAS website at www.nas.edu. This will bring you to a description of the project, a list of the provisional panel, and information about the upcoming meeting.

BACKGROUND: In April 1991, EPA announced that it would conduct a scientific reassessment of the health risks of exposure to dioxin and dioxin-like compounds. EPA began this task in light of significant advances in our scientific understanding of mechanisms of dioxin toxicity, significant new studies of dioxin's carcinogenic potential in humans and increased evidence of other adverse health effects. EPA has worked to make each phase of the dioxin reassessment an open and participatory process. These efforts have included the involvement of outside scientists as principal authors of several chapters, frequent public meetings to report progress and take public comment, and publication of early drafts for public comment and peer review. Early in the reassessment process, EPA held public meetings (1991 and 1992) to inform the public of the Agency's plans and activities for the reassessment, to hear and receive public comments and reviews of the proposed plans, and to receive any current, scientifically relevant information. In 1992 and 1993, the Agency convened three peer-review workshops to review early drafts of the reassessment chapters. The Agency remains committed to an open and participatory process as it approaches the final reassessment.

STRUCTURE OF FINAL REASSESSMENT DOCUMENT: The final dioxin reassessment will consist of three parts. *Part I. Estimating Exposure to Dioxin-Like Compounds* will include three volumes that focus on sources, levels of dioxin-like compounds in environmental media, and human exposures. *Part II. Health Assessment for 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds* will consist of two volumes that include information on critical human health end points, mode of action, pharmacokinetics, dose-response, and TEFs. Part II will have nine chapters. *Part III. Integrated Summary and Risk Characterization for 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds* will be a stand alone document. In this part, key findings pertinent to understanding the potential hazards and risks of dioxins are described and integrated, including a discussion of all important assumptions and uncertainties.

1994 PUBLIC REVIEW DRAFT AND 1995 SCIENCE ADVISORY BOARD REVIEW: In September 1994, EPA released the external review drafts of the health effects and exposure documents.

EPA took public comment on the drafts, followed by Science Advisory Board (SAB) review of the draft dioxin re assessment in May 1995. The SAB's report was received in Fall of that year. In its report to the Agency, the SAB responded favorably to most of the reassessment, but recommended revision of two key sections. The SAB recommended that Chapter 8: Dose-Response Modeling for TCDD and the Risk Characterization document, be revised. Further, it recommended development of an additional document that would focus on the toxic equivalency factors (TEFs) for dioxin and dioxin-like compounds. In addition to these substantive recommendations, the SAB suggested that the redrafting process include broader participation of outside scientists from both public and private sectors. They also requested that the two redrafted chapters and the new TEF chapter be submitted to independent external peer review, before being returned to the SAB for re-review. With respect to Chapters 1-7 of the health document and the full exposure reassessment document, the SAB accepted these sections. It suggested that they be updated to address public and SAB comments and to incorporate new scientific data, but stated that no further review of these sections by the SAB was needed.

POST-SAB REVISION PROCESS: After receipt of the SAB's 1995 report, the Agency worked with over 40 stakeholders from the private and public sectors, representing environmental, industry, academic, state, and other public interest and public health communities, on next steps and to gather input on possible approaches for conducting the revision process. The Agency has tried to keep these individuals apprised of reassessment activities at critical points in the revision process. These stakeholder groups have been important avenues of public input as the revised dioxin reassessment sections have been made available for public comment. The three draft sections recommended for revision and subsequent review by the SAB were:

Part II. Chapter 8: Dose-Response Modeling → This chapter was revised using a writing team process. The writing team was composed of a dozen leading scientific experts in fields related to dioxin health effects and quantitative risk assessment. These experts came from a wide range of public and private organizations, as well as academia. The draft Chapter 8 underwent public comment and external peer review in March 1997. The writing team developed the draft final chapter based on the peer review and public comments and any relevant new scientific data, in January 2000.

Part II. Chapter 9: TEFs for Dioxin and Related Compounds → This new document was developed as a result of a recommendation from the SAB to gather in one place the discussion and scientific information on the complex issue and use of TEFs for dioxin and dioxin-like compounds. The draft was developed by an internal writing team with assistance from international experts.

Part III. Integrated Summary and Risk Characterization → This section also followed the writing team process. A preliminary revised draft was developed by a writing group made up of scientists from a wide range of public and private organizations, as well as academia, and was reviewed by the stakeholders. This preliminary draft was used as the framework for an extensively revised document developed by a small internal EPA writing group.

OTHER MAJOR MILESTONES:

External Peer Review Meeting - On July 25 and 26, 2000, a two-day external peer review workshop was conducted in Washington, DC. This peer review meeting was for the purpose of reviewing the draft *TEF chapter* and draft *Part III. Integrated Summary and Risk Characterization*. The Agency used a private contractor to plan and conduct the meeting and to identify and secure the services of independent expert scientists as peer reviewers. The public was invited to attend the peer review meeting as observers and a limited amount of time was made available for comments by the observers. General view was that addition of the TEF chapter was beneficial and added to the strength of the reassessment and that the

characterization document was much improved over the previous draft. Major points of discussion were the following key dioxin science issues: the characterization of cancer risk, how to extrapolate between animals and humans, quantitative estimates of cancer risk, noncancer effects seen close to background exposures, and children's risk. The Agency used the peer review report, the public comments made at the meeting, and the public comments submitted as a result of the public comment period announced in the Federal Register on June 12, 2000, to revise the two documents in preparation for review by the SAB.

SAB Dioxin Reassessment Review Subcommittee Meeting - On November 1 and 2, 2000, the SAB's Dioxin Reassessment Review Subcommittee (DRRS) met to review the draft "*Exposure and Human Health Reassessment of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds.*" The focus of the review was on three draft documents: *Part II. Chapter 8: Dose-Response Modeling*; *Part II. Chapter 9: TEFs for Dioxin and Related Compounds*; and *Part III. Integrated Summary and Risk Characterization*. There was considerable discussion on several significant science issues related to dioxin and Subcommittee consensus was not reached on some of them. Nevertheless, at the conclusion of the meeting, the review panel stated that they were confident that the Agency could address their review comments and that they did not need to see the document again. The Subcommittee further encouraged the Agency to expeditiously complete the dioxin reassessment. The two day meeting included over 40 public comments. The draft DRRS review report was submitted to the SAB's Executive Committee for review and approval in Spring 2001.

SAB Executive Committee Review Meeting - After a public meeting on May 15, 2001, the SAB's Executive Committee endorsed a review report of the draft dioxin reassessment contingent upon changes to address some of the differing scientific opinions raised in the review report. On May 31, 2001, the SAB forwarded its final review report to the Administrator. Upon receipt of the DRRS report, the Agency, after careful review and analysis of the SAB comments, began revision of the draft reassessment to address both SAB and public comments. EPA completed revision of the draft reassessment in response to SAB and public comments.

Dioxin IWG Review Process - On January 17, 2003, the revised draft dioxin reassessment was transmitted by EPA to the Interagency Working Group on Dioxin (Dioxin IWG). The Dioxin IWG is made up of federal agencies that address health, food, and the environment. These agencies are working together to ensure a coordinated federal approach to dioxin related issues. These activities include research on dioxin exposure and effects, and coordinated efforts to measure dioxin levels in the environment and food and to reduce dioxin risks. The Dioxin IWG, under the auspices of the National Science and Technology Council, provides the overall mechanism for coordinating these activities.

Because EPA is committed to ensuring that the dioxin reassessment has a strong scientific foundation, the Agency requested input from the IWG regarding the need and benefit of further review of the draft reassessment. The IWG recommended that the draft reassessment should be reviewed by the NAS.

NAS Review - The NAS project titled "[Review of EPA's Assessment of the Health Implications of Exposure to Dioxins](#)," began in June 2004. Information on the NAS dioxin review can be found on the NAS website at www.nas.edu. On September 9, 2004, the NAS posted in *Current Projects*, their review of EPA's draft dioxin reassessment, including a description of the project scope. The draft assessment will be reviewed by an expert panel convened under the auspices of the NAS Board on Environmental Studies and Toxicology ([BEST](#)). On September 10, 2004, the NAS has made available the names of the Provisional Committee, and opened a 20-day comment period for input on the provisional panel members.

That comment period closed on September 30, 2004. The first meeting of the NAS dioxin review panel is scheduled for November 22 and 23, 2004, at the National Academy of Sciences Building, 2100 C St. NW, Washington, DC. The review by the NAS is expected to take approximately 18 months.

EPA CONTACT:

Linda C. Tuxen, NCEA, ORD (8601D), Washington, DC 20460

E-Mail: *tuxen.linda@epa.gov*

Tel: 202-564-3332; FAX: 202-565-0090