RISK: Health, Safety & Environment (1990-2002)

Volume 7 | Number 1 Article 4

January 1996

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Dioxin: Reassessing the Risk*

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Summary

For over 25 years, scientists have studied dioxin, a potent animal carcinogen. Yet opinions remain divided with regard to its human health risk. Based on new data, the Environmental Protection Agency (EPA) has been updating its assessment of dioxin risk since 1991. In December 1994, EPA submitted for review a final draft report to its Science Advisory Board (SAB), a group of independent experts. Several months later, the news media reported highly critical comments by some SAB members, raising concerns among those who want to ensure that EPA's decisions are based on sound science.

The SAB completed its review last September and approved most of the report.[1] However, it withheld approval of two chapters pending extensive revisions.

The House Committee on Science held a hearing on the dioxin reassessment December 13, 1995, and the House and Senate Committees on Appropriations have directed the agency to incorporate SAB recommendations into its report.

This paper briefly describes the state of scientific knowledge about dioxin, the reassessment project, the SAB review, scientific issues that remain unresolved, EPA dioxin regulations under development and recommendations of the Committees on Appropriations.

Background

Dioxin (2,3,7,8–tetrachlorodibenzodioxin or TCDD) is produced in very small quantities as a by-product of combustion, some chemical

* Views expressed here are the author's and do not necessarily represent those of the Congressional Resarch Service (CRS).

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1 Environmental Protection Agency, Science Advisory Board (SAB), **An SAB Report: A Second Look at Dioxin** (1995).

manufacture, chlorine bleaching of pulp and paper, and other industrial processes. In the U.S., municipal and medical waste incineration are dominant known sources. Low levels have been found in many parts of the world. Because of dioxin's physical and chemical properties, it is found primarily in soil, sediments and biota (that is, living things).

Dioxin was identified in the 1970's as the most potent animal carcinogen ever tested. Although further research has confirmed its cancer-causing potential for all types of animals tested, some animals are found less susceptible to dioxin's effects than others; for example, males and females develop tumors at different sites and rates.

Studies of the number of people likely to get cancer from being exposed to dioxin are inconclusive, in part because scientists could not be certain how much dioxin they were exposed to. Also, they probably were also exposed to diverse mixtures of chemicals. Further, in most cases, the numbers of people exposed were too small to allow accurate measurements of changes in cancer rates, those exposed were mostly healthy adult males (who may be less sensitive), or not enough time had passed for most cancers to develop.[2] Although scientists have interpreted the significance of these studies in various ways, they generally agree that human data are "limited," and dioxin is a "probable" human carcinogen under some conditions of exposure.[3]

Research also has shown that dioxin elicits many toxic responses besides cancer; e.g., it is known to cause chloracne in highly exposed people. Also, although further research is needed, evidence suggests that it may affect levels of human male reproductive hormones. In various test animals, dioxin and related compounds impair reproduction, interfere with vitamin A storage, and adversely affect the immune system and embryo development, among other things.

Without at least potential exposure, there is no risk. Yet, dioxin has been found in tissue samples taken from people living in the U.S. — probably originating mainly from foods, especially meat and fish. Whether exposure from such sources is high enough to harm health is unknown, but currently EPA is gathering more data to integrate into its final dioxin risk reassessment report.

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2 Most cancers develop 15 to 30 years after exposure. *See e.g.,* Judith S. Mausner & Shira Kramer, Epidemiology: An Introductory Text 320 (2d Ed. 1985).

3 SAB, *supra* note 2, at 4.

Notwithstanding scientific uncertainties, EPA has regulated dioxin emissions to protect public health and the environment. Some EPA critics charge that existing and proposed regulations are too stringent given the available scientific evidence, but others argue for additional limits and have called for phasing out all production and use of chlorinated organic compounds that do not readily degrade to harmless substances.

EPA's Reassessment Project

EPA completed two risk assessments for dioxin in 1985 and 1988. Stakeholders have carefully observed and often participated. The 1985 assessment led EPA to classify dioxin as a probable human carcinogen based on adequate animal data. After reviewing the 1988 risk assessment, the SAB concluded that EPA should "follow up on this excellent start" by developing new methods for estimating human exposure to dioxin and relating exposure levels to health risks.[4] Current dioxin reassessment responds to that request.

General scientific interest in the project was spurred by evidence published during the early 1990's that fueled long-standing controversies. Several published scientific studies of people exposed to dioxin failed clearly to document large increases in cancer rates. This convinced some scientists that people might be less sensitive to dioxin than some test animals. Others argued that new human data were consistent with animal data, given exposure levels. The former group of scientists also interpreted new knowledge about how dioxin affects cells to mean that very low levels of exposure to dioxin might be harmless or even beneficial; they wanted this reflected in EPA cancer risk assessment models. Again, other scientists disagreed.

However, when scientists representing a full range of opinions met in 1990 at the Banbury Center of Cold Spring Harbor Laboratory, they agreed that evidence now supports the following conclusions:[5]

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4 SAB, Resolution on the Use of Mathematical Models by EPA for Regulatory Assessment and Decision-Making (1989).

5 *See* Biological Basis for Risk Assessment of Dioxins and Related Compounds, Banbury Report No. 35, (Michael A. Gallo, Robert J. Scheuplein & Kees A. van der Heijden eds. 1991).

- people and animals respond to dioxin in similar ways;
- other similar chemicals were likely to behave like dioxin; and
- a new risk assessment model should be developed based on cell biology.

EPA began in 1991 to reassess the risks of dioxin. The current risk assessment differs from previous dioxin assessments in several ways. It:

- is a very public process, inviting observation and comment from interest groups as well as scientists;
- addresses risks to the environment as well as to human health;
- assesses risks from health effects other than cancer; and
- assesses risks of "related chemicals" as well as dioxin per se.

"Related chemicals" are other compounds containing chlorine or bromine whose molecules are shaped like TCDD and produce similar toxic effects, including some other dioxin compounds, some furan compounds, some polychlorinated biphenyls (PCBs), and some polybrominated biphenyls (PBBs).

More than 100 outside scientists have participated over four years in the EPA project, attending workshops and public meetings, drafting and reviewing portions of the EPA report and performing laboratory research. EPA's draft report on the ecological risks of TCDD and related chemicals is expected to be completed next year. A draft final report on human health risks was released for public review and comment September 13, 1994[6] and was submitted to the SAB for review in December.[7]

SAB Review

The SAB appointed 39 scientists to a committee which met in May 1995 to review the draft dioxin assessment. Many news reports of this meeting emphasized critical comments and challenged the science employed by the EPA draft; at least one Op Ed piece concluded that EPA's research was policy or politically driven.[8] This alarmed many who are concerned about whether EPA's decisions are based on sound

6 59 Fed. Reg. 46980.

7 The draft is not a statement of EPA findings or policy because it is not complete; it was released to elicit public comment and has not been approved by EPA officials.

8 Kathryn E. Kelly, *Cleaning up EPA's Dioxin Mess,* Wall Street Journal, June 29, 1995, at 16.

science. SAB Chair, Morton Lippmann, responded to this charge by calling it "misguided and misleading,"[9] while the EPA Assistant Administrator for Research and Development argued that:[10]

> the dioxin assessment has been exemplary of an open and participatory scientific process, involving hundreds of scientists from outside of the agency.

The SAB Executive Committee did not complete its review until September.[11] The final SAB report approved EPA's exposure assessment chapters and the first seven chapters of the health assessment with relatively minor changes. The Committee withheld endorsement of Chapter 8 pending revisions. Specifically, the SAB criticized EPA's reliance on a single dose-response model for estimating cancer risk and advised discussing reasonable alternative models that posit little increase in risk at very low levels of dioxin exposure. The SAB also advised EPA to note that TCDD is not a complete carcinogen — that is, its effects depend on other factors. However, almost all SAB members agree that TCDD is likely to increase cancer incidence under some exposure conditions.[12] Chapter 9 of the health assessment summarizes the previous chapters and characterizes the risk. The SAB also withheld endorsement of this chapter, although it noted three strengths:

- evaluating a group of compound classes, rather than a single compound;
- focusing attention on various non-cancer effects; and
- providing a useful comparative perspective by highlighting the fact that the margin of safety (between background exposures and levels of exposure where effects have been observed in test animals) for dioxin-like compounds is smaller than that EPA usually accepts for many other compounds.

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9 Letter submitted to Editor, Wall Street Journal, printed in the SAB newsletter, Happenings, July 1995, at 4.

10 Robert J. Huggett, Letter to the Editor, Wall Street Journal, July 19, 1995, at A-13.

11 SAB, *supra* note 1.

12 The SAB, *supra* note 1, reports, at 4:

> One Member contends that no epidemiological study has produced evidence that is widely accepted by the scientific community, including the International Agency for Research on Cancer, as being convincing for the human carcinogenicity of dioxin.

However, the SAB urged additional external peer review of the chapter and identified three key weaknesses:[13]

- not describing non-cancer risks in a way that can facilitate meaningful analysis of the incremental benefits of management options;
- not fully identifying and analyzing important uncertainties; and
- tending to overstate the possibility for danger.

EPA will revise its report in response to the SAB comments. The agency expects the revision to take at least a year.

Current Issues

When risk assessments evaluate the potential for harm of toxic substances, a purely scientific prediction is impossible, because there are too few data or theories are not well validated. To fill these gaps, scientists must use their own judgments which often are controversial because different scientists make different judgments leading to different risk estimates which may have strong implications for regulatory policies and impacts on various stakeholders. Such controversies are inherent in most risk assessments but have been especially vigorous in the dioxin reassessment project that is apparently particularly important to scientists and policy makers. In part the issue's importance and the vigor of the debate may be due to the groundbreaking nature of the project (i.e., EPA's attempt to assess risks for health effects other than cancer as well as risks of groups of related chemicals) or to the difficulty of analyzing health risks for a compound that affects poorly understood and complex biological processes including immune responses and reproduction. Moreover, the fundamental nature of the scientific questions involved in the dioxin risk assessment means that some scientists are heavily invested intellectually and professionally in their points of view. Timing of the reassessment also may affect its perceived importance: The EPA draft report was issued just as Congress began debating whether to endorse specified principles of risk assessment and risk characterization. For

13 The SAB, *supra* note 1, reports, at 5:

> several SAB Members do not agree with this statement and regard the EPA presentation as appropriately conservative within the context of public health protection.

EPA, the dioxin reassessment report is an opportunity to demonstrate its competence and the evolution of its risk assessment practices.

Thus, although scientists working on the project could agree on how to describe experimental evidence relevant to dioxin exposure and toxicity in the earlier chapters of the draft final report, they are still struggling to summarize and interpret the objective evidence to construct models and characterize risk. Similarly, although the SAB report attempted to present a single scientific viewpoint with regard to its assessment of dioxin risk and the EPA draft, occasional footnotes indicate intransigent areas of disagreement.[14]

Key unresolved scientific issues relevant to decisions of risk managers and policy makers include whether:

- there is a low level of exposure to dioxin that is harmless (that is, whether there is a threshold);
- current exposures to dioxin-like compounds in the U.S. are likely to be harmful to adults or children; and
- all the most important sources of dioxin emissions and human exposure are known.

None of these questions are expected to be answered definitively in the EPA final document.

In the face of such uncertainty, the agency must implement environmental statutes, and it is currently developing several regulations regarding technologies that are likely to further limit dioxin emissions. For example, the Clean Air Act, as amended, requires EPA to promulgate performance standards, including emission standards, for large municipal waste incinerators and medical waste incinerators by November 1991 and November 1992, respectively. When these deadlines were missed, EPA was sued by the Sierra Club and Natural Resources Defense Council. Under a consent decree, EPA is required to issue a final rule for municipal waste incinerators by October 31, 1995.[15] A final rule for medical waste incinerators is expected by April 1996. Both the Clean Air Act and the Solid Waste Disposal Act authorize EPA regulation of pollutant emissions from incinerators, kilns, other industrial furnaces and boilers that burn hazardous waste. A settlement agreement[16] requires EPA to propose combustion stan-

14 *See, e.g., supra* notes 12 & 13.

15 NRDC v. EPA, Nos. CV-92-2093 and CV-93-028 (E. D.N.Y 1994).

16 Horsehead Resource Development Co. Inc. v. EPA, No. 91-1221 (Oct. 22,

dards by September 20, 1995 and promulgate a rule by December 15, 1996. (An informal agreement has extended the 1995 deadline for two months.) Both the Clean Air Act and the Clean Water Act require regulation of pollutant releases from major industrial sources. EPA has designated the pulp and paper industry a "major source" of hazardous air pollutants, including dioxin. A combined air and water rule addressing pollutant releases was proposed December 17, 1993. EPA plans to issue the final rule no earlier than this winter.

House Appropriations Committee Recommendations

In House and Senate reports on the FY 1996 appropriations bill, H.R. 2099, the Appropriations Committees expressed concern that the EPA draft dioxin risk characterization document:[17]

> does not accurately reflect the science on exposures to dioxins and their potential health effects...[,] EPA selected and presented scientific data and interpretations... dependent upon assumptions and hypotheses that deserve careful scrutiny...[,] and inaccuracies and omissions... were the result of the Agency's failure to consult with and utilize the assistance of the outside scientific community....

Thus, the Committees propose directing EPA to respond to SAB concerns about its report and to consult with scientists in other agencies in rewriting chapters 8 and 9. The House Committee also directed EPA to report back on compliance within 90 days of enactment of H.R. 2099 [subsequently vetoed] and to report to Congress prior to spending any funds "on further advancing the reassessment of any rules using the reassessment as a basis." This restriction, if enacted, might prevent EPA from developing any new rules that raise or lower dioxin limits based on the risk reassessment. Yet, it apparently would have no affect on the development of such rules as long as they were not so based.

1993).

17 H. Rept. 104-201, at 53–4; Senate Rept. 104-40, at 89.