

Adm. ZUMMISCT

**Summary of Dioxin Peer Review Workshop On Chapter 7:
Epidemiology/Human Data - September 7-8, 1993**

**Tania Simoncelli
Environmental Defense Fund
September 9, 1993**

Summary of Dioxin Peer Review Workshop Chapter 7: Epidemiology/Human Data - September 7-8, 1993

The workshop opened with a review of the components and status of EPA's reassessment of dioxin, presented by Farland. In his brief review of the evidence arising from the state of science chapters, Farland stressed that it is becoming increasingly clear that 1) Effects from exposure to dioxin are Ah-receptor mediated 2) People are sensitive and 3) All related congeners should be considered.

Next, Linda Birnbaum gave an excellent presentation on dioxin toxicology. She emphasized repeatedly that what is most important is to think of dioxin as an environmental hormone that is able to modulate many factors. On the question of the possible relationship between receptor-mediated action and a threshold, she stressed that there is no evidence for nonlinearity at the biomolecular level. She cautioned against statements that certain animals are more or less sensitive to TCDD. For instance, we used to think of guinea pigs as especially sensitive and hamsters not sensitive. But in fact, the same biomolecular changes occur in both guinea pigs and hamsters upon exposure to TCDD. Hamsters are only less sensitive to dying. Since there is no threshold for binding to the receptor, we cannot assume that there is a threshold for effects. Birnbaum's discussion was crucial in placing the epidemiology chapter in its appropriate context.

David Bayliss gave a presentation summarizing the cancer section of chapter 7, followed by individual presentations by the panel. Commenters included Checkoway, Enterline, Ott, Smith, and Webb. Checkoway felt that the studies, as a whole, demonstrated a consistent relationship between STS (but not other cancers) and TCDD levels of exposure. He recommended continued follow-up on the most helpful cohorts, particularly Seveso. Enterline criticized an unevenness in evaluation of the studies for bias and confounding factors, and felt that the case control studies did not supply enough detail to warrant sufficient confidence. He felt that the Fingerhut study was clearly the best study, but that the specific plants had to be evaluated more closely for confounding factors, i.e. the presence of other chemicals. Ott was especially supportive of the NIOSH and Ranch Hand studies and warned that attention to increases in overall cancer risks should not be overshadowed by a focus on STS. Smith critiqued the style of writing as too interpretive, and said that the data should speak for itself. He questioned a relationship between dioxin and STS. Webb stated that more evidence needs to be placed on statistical significance and felt that the authors had clearly overinterpreted the significance of their data. She concluded that the results of the major cohort studies were not consistent and that there was no increased risk of cancer seen in low exposure groups. Her conclusion was greatly weakened when Farland asked how she found the data inconsistent when exposures were at a level where we would not expect to see effects in a such a small sample. Webb did not appear to understand his point and continued to

insist that since we could not see an increase in cancer in low exposure groups that TCDD is clearly not a carcinogen in humans.

The American Forest and Paper Association appointed their own epidemiology 'expert' panel, consisting of 7 witnesses who testified for the remainder of the afternoon. It was clear that the panel as a whole attempted to undermine the validity of the studies in the chapter by insisting that they did not demonstrate a causal relationship between TCDD and cancer and that they were tainted by confounding factors. They attempted to raise the standard of acceptance of the studies to one of proof of causation, rather than the appropriate one of association. A debate erupted over the panel's criticism of the lack of control for smoking in the Fingerhut study. Farland questioned whether or not they were implying that these workers actually smoked more than the population at large. Fingerhut patiently commented that it is wrong to assume that in the absence of smoking data there was an increase in lung cancer due to smoking. By the end of the 7-member panel, there was a sense that the focus of the meeting had shifted over the course of the day from one of attempting to determine how epidemiology studies might weigh in to a risk characterization of dioxin within a broad context to one of whether or not epidemiology studies prove that dioxin is a matter of concern. However, Farland reminded everyone that it is not causation that we are looking for in these studies; it is association. In addition, the Forest and Paper Association's insistence on bringing in their own panel seemed rather tactless and insulting to both the EPA and the official panel. Furthermore, their incessant and oftentimes unfounded criticisms of the studies only lessened the weight of their influence.

The workshop opened on Wednesday with comments from Peter deFur, who first delivered comments submitted by Dick Clapp. Clapp pointed out that the studies were not up to date, and gave as an example a 1993 editorial which points out the limitations of the Collins study. He also pointed out the importance of the recent IOM review and specifically, its conclusions that one Ranch Hand veteran died of STS and that a positive correlation exists between herbicide exposure and PCT in genetically susceptible individuals. Another comment was that the two parts of the document need to be better integrated. He also expressed dissatisfaction with the immunologic effects section. DeFur's points relative to chapter 7 were that the report needed a summary of epidemiology appropriate for non-epidemiologists, connections to other reassessment chapters, and a careful consideration of the language used to present the takehome message that dioxin increases the risk of cancer in humans. He also pointed out that the Bertazzi, NAS, and Hardell studies should also be included. His next set of points concerned the role of epidemiological analysis. He reminded the EPA and the panel that these studies have to be seen as only part, and probably not the most important part, of 'the big picture' of the health risks to humans from exposure to dioxin and related chemicals. In addition, epidemiology can not directly address the issue of causality, which is left appropriately to toxicologists and experimental

biologists. Peter concluded his comments by urging EPA to hasten the overall risk assessment process.

Marie Sweeney presented a summary of the noncancer section. Panelists who gave presentations for this section were Buck, Sweeney (Anne), Andrews, and Webb. Buck was disappointed by the lack of human reproductive studies and stressed that we cannot rely on statistical significance with so few studies. She pointed out that most reproductive endpoints have not been and could be studied, including female fecundity, conception, early pregnancy loss, ectopic pregnancy, induced abortion, and more developmental and functional childhood effects. Sweeney pointed out the importance of the Australian study, the Yu-Cheng and Yusho studies, and Vietnam studies. She was concerned about relying on self-reporting and also claimed that 'weak associations' should perhaps not be separated from 'future research needs'. Andrews pointed out that populations, such as Seveso, have to be studied now because concentrations of TCDD are decreasing as time continues.

Ellen Silbergeld's comments cautioned against the typical call for more research that was emphasized by so many people in all of the discussions. She pointed out that what we have learned over the past five years has not really added to our qualitative understanding of dioxin and dioxin-like compounds. We still know what we have known since 1985; namely, that TCDD and related compounds are highly toxic to humans and other species, they are persistent, and they are especially detrimental to developing organisms. In recognizing that current exposures are in many cases within the dose range associated with toxicity, it is crucial that we take steps now to identify and reduce all exposures to and inputs of dioxins, instead of allowing claims of scientific uncertainty to delay action. Many of Silbergeld's specific comments on chapter 7 were based on her overall criticism of the lack of a clear conclusion of the chapter and the lack of an integrated presentation of the data, especially in terms of how various effects might be related to one another. For the cancer section, she recommended that an indication be made that the limitations of the TCDD studies are common to all epidemiological research and not just to the TCDD studies, and that undue emphasis has been placed on publication bias, problems with latency, and cigarette smoking as a confounder. She also stated that figures 1 and 2 were not helpful and that she was not convinced by backward extrapolations from body burden points. In the noncancer effects section, she urged the inclusion of the Yusho and Yu-Cheng studies and rejected the US chemical workers studies as the 'principal studies' for this section. She expressed her disappointment with the immunotoxicity section and pointed out limitations to the neurotoxicity and reproductive effects sections, the latter especially because of the lack of data on women. She also stressed that if more research is to be done, it should not necessarily be in Seveso, where levels of contamination have been decreasing, but should be in a new cohort that is experiencing current exposure.

A representative from Vietnam Veterans made a brief presentation expressing the organization's concern over the delays in the process, and

particularly, the lack of attention and action in New Jersey. His comments on dealing with people on a daily basis who have been exposed to dioxin and dioxin-like chemicals reminded everyone of the 'bottom line'; people are suffering from exposure to dioxin and dioxin-like chemicals. He also mentioned his disappointment that it seemed that 4 members of the panel had ties to the chemical industry.

In conclusion, Farland posed a general question to the panel as to how the human data might weigh in with the other state of science data for final risk characterization. He stressed that he was not asking whether or not the data proves that TCDD causes cancer or other effects in humans, but rather, was it consistent with the experimental and toxicological data. When many of the panelists (especially Enterline, Checkoway and Smith) stressed that the jury was still out and that they had to see more data, Silbergeld asked the panel to ask themselves what data would have to be produced to negate what we already know about TCDD. In their final statements, two members of the panel said that they felt that TCDD was a carcinogen in humans (Andrews and Buck). Two said that the data was not incompatible with animal data (Ott and Sweeney). Webb stated that, at most, dioxin is a weak carcinogen and the human data is important as a reassurance to populations experiencing low levels of exposure, and that the data does not even warrant the current action level standard. On noncancer effects, 3 panelists felt the data was inadequate at this point to make a statement (Andrews, Buck, Enterline). Smith and Sweeney felt that the data, particularly on reproductive effects, were consistent with what was expected from animal data. Ott stressed that the types of effects expected are extremely complex and that because of this, animal experiments must be relied on as a guide. Webb cautioned against using 'health effect' when effects were possibly laboratory anomalies, and stressed that final judgment should be withheld, especially "since humans do not behave the same as animals."



Dioxin Peer Review Workshop

Chapter 7. Epidemiology/Human Data

The Ritz-Carlton, Pentagon City
Arlington, VA
September 7-8, 1993

Agenda

TUESDAY SEPTEMBER 7

- 8:00AM Registration
- 9:00AM Welcome..... Gary Foley
Acting Assistant Administrator
Office of Research and Development (ORD)
U.S. Environmental Protection Agency (U.S. EPA)
- 9:15AM Introductions, Conflict Statements..... Panel
- 10:00AM Dioxin Reassessment..... William Farland
ORD, U.S. EPA
- Components
 - Status
 - Next Steps
- 10:30AM Break
- 10:50AM Dioxin Toxicology..... Linda Birnbaum
ORD, U.S. EPA
- 11:30AM Introduction to Cancer Section: Question & Answer..... David Bayliss
ORD, U.S. EPA
- 12:00NOON Individual Panelist Presentations (Cancer Section)
- 12:30PM Lunch
- 1:30PM Individual Panelist Presentations (continued)
- 2:30PM Public Comments
- 3:30PM Break
- 3:50PM Public Comments (continued)
- 4:45PM Wrap-Up..... William Farland

WEDNESDAY SEPTEMBER 8

- 9:00AM **Introduction to Non-Cancer Section:
Question & Answer** *Marie Haring Sweeney
National Institute for
Occupational Safety and Health*
- 9:30AM **Individual Panelist Presentations (Non-Cancer Section)**
- 10:30AM **Break**
- 10:50AM **Public Comments**
- 12:30PM **Lunch**
- 1:30PM **General Discussion:**
 • Emerging Studies
 • Research Needs
 • Other Topics
- 3:10PM **Break**
- 3:30PM **General Discussion (continued)**
- 4:45PM **Wrap-Up** *William Farland*

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SCHEDULED PUBLIC COMMENTS

Tuesday, September 7, 1993

- 1) **Dioxin Epidemiology Expert Panel**
Sponsored by the American Forest and Paper Association

Suresh H. Moolgavkar, The Fred Hutchinson Cancer Research Center
Raymond S. Greenberg, Emory University
Jack Mandel, University of Minnesota
Roy Shore, New York University Medical Center
Allan Okey, University of Toronto
Joseph Rodricks, ENVIRON Corporation
Thomas Starr, ENVIRON Corporation

- 2) **Peter deFur, Environmental Defense Fund**

Wednesday, September 8, 1993

- 1) **Jim Tozzi, Multinational Business Services**
- 2) **Peter deFur, Environmental Defense Fund**
- 3) **Donald Mattison, University of Pittsburgh**
- 4) **Peter Montague, Environmental Research Foundation**



United States
Environmental Protection Agency
Office of Research and Development

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2 Adm 3

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October 20, 1993

BY FAX 703 528-5795

Admiral E.R. Zumwalt, Jr., USN (Ret.)
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Dear Admiral Zumwalt,

It was my feeling that there could be conflicts of interest by members of EPA's Peer Review Panel. During introductions and "Conflict Statements" the following statements were made by the peer reviewers themselves:

- M. Gerald Ott - "Previously worked for Dow Chemical". Dr. Ott is now employed by BASF.
- Philip Checkoway - "Reviewed a paper for Dr. Ott"
- Philip Enterline - "Previously worked for Monsanto"
- Karen Webb - "Resident doctors rotate through Monsanto. Also did consulting for companies related to Dioxin studies."

Allan Smith, it was told to me at a later date, does "expert witness" testimony during worker's compensation cases on behalf of the chemical companies.

Admiral Zumwalt, during the proceedings at the Workshop it seemed as through the EPA scientists were fighting the Peer Reviewers as well as the Pulp and Paper Industry panel of scientists. I realize that I do not have hard facts about conflicts of interest, but the feeling persists.

Sincerely yours,



Michael Eckstein
 Chairman

Agent Orange/Dioxin Committee

P.S. Please note new State Council address and phone/fax.

A NOT-FOR-PROFIT NATIONAL VETERANS SERVICE ORGANIZATION



E. R. ZUMWALT, JR.
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October 19, 1993

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Dear Michael:

I'd appreciate it if you could give me what information you have concerning the potential conflicts of the following members of the EPA's Peer Review Panel: Harvey Checkoway, Philip Enterline, M. Gerald Ott, Allan Smith and Karen Webb.

Sincerely,

Admiral E.R. Zumwalt, Jr., USN (Ret.)

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Sined

10/19

5.00



Dioxin Peer Review Workshop

Chapter 7. Epidemiology/Human Data

The Ritz-Carlton, Pentagon City
Arlington, VA
September 7-8, 1993

Peer Review Panel

used to work for EPA
→ Dioxin Peer Review Panel?

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reviewed Ott's paper

would be work for Dioxin
human data not supports actual data
SES data indicates union (cont. long) may relate

human data not strong enough to keep current action level.

her residents (dr's) rotat thru Monsanto

does expert witness testimony for chem. co's in worker's comp cases

ECKSTEIN TOLD THIS BY EPA'S, BAYLISS

***MICHAEL ECKSTEIN OF NSWA REPORTED THAT THE * INDIVIDUALS REPORTED THEIR OWN INFORMATION ~~WAS ASKED~~ DURING THEIR OPENING REMARKS WHEN ASKED ABOUT A CONFLICT OF INTEREST**

Enterways

CRITICISM:

not universal criteria for studies
case control studies not described in enough detail to
feel comfortable w/ concl.
— not shown sig. exposure

~~Probs w/ conclusions~~

~~Fig 2 doesn't understand~~

MATTSON

Reprod. / Diabetes

Reprod. toxicity + Develop. toxicity.
animals: only w/ systemic toxicity
humans: inadequate evidence

Diabetes - v. weak assoc.

NIOSH report: NIOSH + RH studies used epid. ~~definition~~ definition
(which is dif from clinical definition)

Eckstein:

4 of ~~the~~ panelists had past ^{or current} association w/ chemical co's.