

STATE OF MICHIGAN



JOHN ENGLER, Governor

MICHIGAN ENVIRONMENTAL SCIENCE BOARD

P.O. BOX 30026, LANSING, MICHIGAN 48909

Internet: <http://www.great-lakes.net/partners/mesb/mesb.html>

E-mail: mesb@state.mi.us

January 21, 1997

The Honorable John Engler, Governor
State of Michigan
Executive Office
P.O. Box 30013
Lansing, Michigan 48909

Dear Governor Engler:

On November 20, 1996, you requested the Michigan Environmental Science Board (MESB) to review additional information provided to you by the Agency for Toxic Substances and Disease Registry (ATSDR) and U.S. Environmental Protection Agency (USEPA) regarding the impact of exposure to polychlorinated biphenyls (PCBs) and to determine if this material alters any of the findings and recommendations which the MESB - Council of Great Lakes Governors (CGLG) Special Fish Advisory Panel presented to the CGLG in September 1995. A Panel, composed of two MESB and six guest scientist members, was assigned to the task (see Attachment 1). All members of the MESB Panel had served previously on the MESB - CGLG Special Fish Advisory Panel.

Each Panel member was requested to review the PCB data provided by the ATSDR and USEPA and any other pertinent peer-reviewed and nonpeer-reviewed information and to respond back to the Panel Chair. Copies of the guest Panel members' responses are attached (Attachment 2).

For reference, the principal findings of the MESB - CGLG Special Fish Advisory Panel in its review of the (September 1993) draft document entitled, *Protocol for a Uniform Great Lakes Sports Fish Consumption Advisory* (Protocol) included:

- (a) the selected Health Protection Value (HPV) that drives the fish consumption advisory would be protective for women of childbearing age and young children as it recognizes the relatively high sensitivity of the fetus to the toxic effects of the major contaminants in fish (PCBs and mercury),
- (b) the less sensitive portion of the population (e.g., males and older women) could receive less restrictive fish consumption advice. The draft Protocol does not provide for this.
- (c) adequate scientific information to support the calculation of the HPV was not provided in the draft Protocol. This deficiency would make it difficult to change the HPV in a consistent manner if new scientific information were to become available that required a change to be made, and
- (d) the lack of any data and, therefore, any recognition in the draft Protocol of the known beneficial aspects of consuming fish. To adopt a fish advisory developed from the draft Protocol would unnecessarily suggest to the less susceptible portion of the population that they should consume less fish, thereby effectively reducing the beneficial health effects that they otherwise would receive from fish consumption.

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Based on the results of its review of the available information, the MESB Panel concludes that the data presented by the ATSDR and USEPA do not alter the original findings or conclusions presented in September 1995 by the MESB - CGLG Special Fish Advisory Panel. In particular, the recently published Jacobson and Jacobson (1996) data, which indicates that the fetus is more susceptible than adults to potential harm from fish consumption, were made known to the MESB - CGLG Special Fish Advisory Panel during its deliberations by Dr. Joseph Jacobson and were fully evaluated at that time. The Lonky et al. (1996) paper appears to be supportive of the conclusions reached by Jacobson and Jacobson (1996). The data recently compiled by the USEPA on PCB risk assessment for cancer (EPA/600/P-96/001F) also were known to the MESB - CGLG Special Fish Advisory Panel through presentations and data provided by the USEPA at that time. The ATSDR and USEPA December 1996 summary of public health implications of PCB exposure presents much of what was previously reviewed by the MESB - CGLG Special Fish Advisory Panel and this Panel. Its suggested extensions of the effects of PCB exposure through the use of preliminary data and unsupported conclusions are of concern. Finally, none of the new data provided to the Panel take into account or address the reduction of health benefits which could be realized by providing advice to a large segment of society to unnecessarily restrict fish consumption.

In summary, it is the consensus of the MESB Panel that the new information provided by the ATSDR and USEPA are not sufficient to alter any of the conclusions regarding the draft Protocol or the applicability of its derived HPV which were reached by the MESB - CGLG Special Fish Advisory Panel in its 1995 report to the Council of Great Lakes Governors.

The MESB appreciates the opportunity to revisit the issue of the scientific basis for fish advisories and is willing to continue this assistance as needed.

Sincerely,

Lawrence J. Fischer, Ph.D., Chair
Michigan Environmental Science Board

Keith G. Harrison, M.A., R.S., Cert. Ecol.
Executive Director
Michigan Environmental Science Board

cc: MESB Members
MESB Fish Panel Members
Mr. James K. Haveman, Jr., Director, MDCH
Dr. Russell J. Harding, Director, MDEQ
Ms. Mary Sheehy, Executive Director, CGLG

Attachments (2)

Attachment 1. List of Panel Members

Lawrence J. Fischer, Ph.D.(Michigan State University)Chair
P. Michael Bolger, Ph.D.(U.S. Food and Drug Administration) . .Guest Panel Member
Gary P. Carlson, Ph.D. (Purdue University) Guest Panel Member
Joseph L. Jacobson, Ph.D.(Wayne State University).Guest Panel Member
Mark A. Roberts, M.D., Ph.D.(Medical College of Wisconsin) . . .Guest Panel Member
Peter T. Thomas, Ph.D.(Corning Hazleton) Guest Panel Member
Kendall B. Wallace, Ph.D.(University of Minnesota)Guest Panel Member
Keith G. Harrison, M.A., R.S., Cert. Ecol.(State of Michigan)Ex.Officio

Attachment 2. Fish Advisory Panel Guest Scientists' Responses

December 15, 1996

Dear Dr. Fischer:

At your request, I have reviewed the materials you sent me regarding recent findings relating to the effects of contemporary environmental exposure to PCBs. Nothing in these materials leads me to conclude that we should modify the recommendations in our previous report to the Great Lakes Governors.

Sincerely,

Joseph L. Jacobson, Ph.D., Professor
Department of Psychology
College of Science
Wayne State University
71 W. Warren Avenue
Detroit, MI 48202

December 16, 1996

Dear Dr. Fischer:

I have completed a review of the material which you recently sent regarding Governor Engler's letter and the information received from EPA on PCBs and any impact that this might have on the recommendations which our committee made in its report "Critical Review of the Proposed Uniform Great Lakes Fish Advisory Protocol". While this is new information, there is essentially no new insight into the problem of establishing a Health Protection Value (HPV).

The EPA document primarily discusses a new carcinogenicity study of PCBs in rats. The rat liver tumors which were observed are not unexpected. I don't feel that this was ever really the issue, i.e., this finding is not in itself questionable. What does change is the upper bound slope value(s) calculated by EPA.

The updated study by Jacobson reemphasizes the concern for the establishment of a HPV for women of child-bearing age. As noted in our report, the HPV of 0.05 mg/kg/day is probably protective of human health for this particular group. The additional information does not appear to change our recommendation that there should be a second value for the remaining, less susceptible portion of the population. As noted in our report, for various reasons using the data on rat liver tumors appears to produce a result that suggests an unreasonably high risk and thus other endpoints should be sought for establishing this additional HPV.

In conclusion, I am still in agreement with the original recommendations made in our report.

Sincerely,

Gary P. Carlson, Ph.D.
Professor of Toxicology
School of Health Sciences
Purdue University
1338 Civil Engineering Building
West Lafayette, IN 47907-1338

December 30, 1996

Dear Dr. Fischer,

It is my opinion that the information provided in the Jacobson and Jacobson (NEJM, 1996) and the Lonky et al. (JGLR, 1996) manuscripts along with the EPA document (EPA/600/P-96/001F) do not warrant substantive revision to the current Critical Review of a Proposed Uniform Great Lakes Fish Advisory Protocol.

The Jacobson paper presents an eloquent update of an ongoing monitoring program for families who reported to have consumed large amounts of Great Lakes sports fish in the early 1980's. In 1990, these same authors reported their data for offspring of these women at the age of 4 years. The 1996 publication revisits these same individuals who have since attained the age of 11 years. The 'new' findings support and extend the earlier evidence suggesting a potential risk for the in utero exposure to PCB's (via consumption by the pregnant woman of contaminated Great Lakes sport fish) on the neurological and intellectual performance of the offspring. Specifically, the recent paper alerts to the potential 'long-term' risks to the offspring of pregnant women who consume large amounts of highly contaminated Great Lakes sport fish.

These are important and scientifically sound observations that must be considered in contemplating the risks associated with consuming Great Lakes fish. However, they do not alter the position of the panel in reviewing the proposed protocol. In fact, these new observations reinforce the panel's recognition that unborn fetuses may be far more vulnerable than any other exposure group and that separate criteria should be established for pregnant women, distinct from that for non-pregnant women, children, and adult males.

The Lonky et al. paper provides important substantiating evidence for the conclusions initially reported by the Jacobsons. The fact that the exposure assessment is based purely on subjective interview and recall, with no quantitative measurements of serum or tissue PCB concentrations, is a serious distraction from the strength of this particular study. Accordingly, the paper leads no new insight into the appropriateness of the 0.05 mg/kg/day HPV and fails to warrant modification of the current critique.

The EPA document summarizes recent data regarding the carcinogenicity of PCB's. However, for reasons documented in the critique, it was determined that non-cancer end-points are most appropriate for this particular assessment. I do not believe that the evidence reviewed in the EPA document is sufficiently compelling to warrant changing this decision.

Thank you for this opportunity to review the evidence concerning the proposed uniform fish consumption advisories. Please contact me should you desire further detail or clarification. Thank you for inviting me to participate and I welcome additional opportunities to contribute to this extremely important initiative.

Sincerely,

Kendall B. Wallace, Ph.D., D.A.B.T.
Associate Professor
Department of Biochemistry - Molecular Biology
University of Minnesota, Duluth Campus
10 University Drive
Duluth, Minnesota 55812-2487

January 3, 1997

Dear Dr. Fisher:

I have reviewed the information that you recently sent to me regarding Governor Engler's request to the Special Fish Advisory Panel. In our panel report we concluded that the Health Protection Value (HPV) of 0.05 mg/kg/day is probably protective for even the most sensitive human populations.

Recent studies by Jacobson and Jacobson (1996) and Lonky et al., (1996) concerning the behavioral changes in individuals from families consuming contaminated fish emphasize the sensitivity of perinatal exposure to these toxicants. The recently completed PCB risk assessment for cancer published by the EPA (EPA/600/P-96/001F) summarizes the major lifetime carcinogenicity studies including one recently completed in 1996. As expected, the most significant finding was an increased incidence of liver tumors in rats.

It is my opinion that this new information does not change the conclusions reached by the Special Fish Advisory Panel concerning the adequacy of the current HPV for even the most susceptible populations. This includes any potential effects on the immune system.

I once again appreciate the opportunity to participate in this review process. If I can be of further help or if you have questions, please do not hesitate to contact me.

Sincerely,

Peter T. Thomas, PhD
Director, Toxicology
Corning Hazleton Inc.
P.O. Box 7545
Madison, WI 53707-7545

January 10, 1997

Dear Mr. Harrison:

I have reviewed the material in the original package you sent me several weeks ago, as well as the EPA-ATSDR document that was recently sent. Almost all of the information provided in this material was available to the Fish Advisory Panel during its deliberations. In particular, the results of the recent study by Jacobson and Jacobson (1996) which is cited prominently in this material was already known by the Panel, since Dr. Jacobson was a member. The study by Lonky et al. (1996) is very difficult to evaluate, since no PCB measurements were provided and the surrogate of fish exposure is a rather uncertain biometric of PCB exposure. The allusions in the EPA-ATSDR document to non-peer-reviewed and preliminary data from the ATSDR studies cannot be evaluated. No data was provided and any conclusions based on such incomplete information would be entirely premature. The EPA's reexamination of the PCB cancer risk assessment was also known by the Panel, but the Panel and the task force which derived the PCB HPV concluded that adverse developmental end-points were more critical than cancer, particularly for exposures that were not chronic but varied in duration and frequency. In summary, I have concluded that none of the material provided would lead me to support a change in any of the recommendations made by the Panel in its report to the Great Lakes Governors.

I want to thank you for the opportunity to again be involved in this important public health issue, and if I can be of further assistance, please contact me at any time.

Sincerely,

Michael Bolger, Ph.D., D.A.B.T.
Contaminants Branch (HFS-308)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration, 200 C St. S.W.
Washington, D.C. 20204

January 13, 1997

Dear Dr. Fischer:

I have reviewed the information that you provided (articles by Jacobson, Lonky and EPA) with your letter of December 3, 1996 and compared this new information with the notes from our previous meeting and from the final report of the committee. I do not believe that this information is sufficient to alter or cause us to reconsider our September 1995 report. I do believe that it is important that we collectively and individually continue to be observant of published material that may have significant bearing on the Panel's recommendations. This goes for published data regarding contamination levels in fish as well. I feel it is important to address the problem from multiple levels in order to maximize our effectiveness in preventing future problems.

Thank you for the opportunity to continue to be a part of this review process. If I can be of further assistance please do not hesitate to contact me directly.

Sincerely,

Mark A. Roberts, M.D., Ph.D.
Associate Professor and Acting Chair
Department of Preventive Medicine
Medical College of Wisconsin
8701 Watertown Plank Road Milwaukee, WI 53226