# *EVALUATION OF MICHIGAN'S PROPOSED 1998 FISH ADVISORY PROGRAM*

***(A Science Report to Governor John Engler)***

***Prepared by***
***Michigan Environmental Science Board***
***Fish Consumption Advisory Panel***

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**JANUARY 1998**

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***(A Science Report to Governor John Engler)***

***Prepared by***
***Michigan Environmental Science Board***
***Fish Consumption Advisory Panel***

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**JANUARY 1998**

**(FIRST PRINTING)**


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***1st Printing January 1998: 500 Copies $1,000.00 (Cost per Copy: $2.00)***

***Printed by Authority of Executive Orders 1992-19 and 1997-3***

**Correct Report Citation:**

Fischer, L.J., P.M. Bolger, J.L. Jacobson, B.J. Premo, E.O. van Ravenswaay and K.G. Harrison. 1998. ***Evaluation of Michigan's Proposed 1998 Fish Advisory Program***, January 1998. Michigan Environmental Science Board, Lansing. vi + 67p.

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**Michigan Environmental Science Board**

**The Michigan Environmental Science Board (MESB) was created by Governor John Engler by Executive Order 1992-19 on August 6, 1992. The MESB is charged with advising the Governor, the Natural Resources Commission, the Michigan Department of Natural Resources and other state agencies, as directed by the Governor, on matters affecting the protection and management of Michigan's environment and natural resources. The MESB consists of nine members and an executive director, appointed by the Governor, who have expertise in one or more of the following areas: engineering, ecological sciences, economics, chemistry, physics, biological sciences, human medicine, statistics, risk assessment, geology and other disciplines as necessary. Upon the request of the Governor to review a particular issue, a panel, consisting of MESB members with relevant expertise, is convened to evaluate and provide recommendations on the issue.**

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***EVALUATION OF MICHIGAN'S***

***PROPOSED 1998 FISH ADVISORY PROGRAM***

***(A Science Report to Governor John Engler)***

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## *Evaluation of Michigan's Proposed 1998 Fish Advisory Program*

### The Problem

The discharge of chemicals into the environment that are potentially harmful to ecological and public health is decreasing due to increased regulation and enforcement of federal and state statutes. Unfortunately, past practices have allowed contaminant chemicals to enter the aquatic system and the persistent nature of some of these chemicals has led to their accumulation in fish. Of particular concern in this regard are PCBs, mercury, chlordane and other persistent pesticides. The harmful effect of these chemicals has been demonstrated in laboratory animals or humans (mercury) and advice, in the form of annual fish consumption advisories, that restricts consumption of more highly contaminated fish is a positive public health initiative. However, because of the beneficial nature of recreational activities surrounding angling and the health benefits of fish consumption as an alternative to less healthy dietary choices, consumption of sport-caught fish should not be unnecessarily restricted.

Michigan and its neighboring Great Lakes states all issue annual fish advisories but over the years these documents have lacked uniformity and consistency, which has eroded the credibility of the information provided by each state. An attempt has been made to develop a protocol to serve as the basis of a uniform sport-caught fish advisory for the Great Lakes (GLSFATF, 1993) but a Michigan Environmental Science Board (MESB) review of that procedure pointed out serious flaws in its conception (Fischer *et al*., 1995). At the present time, certain of the states have utilized the protocol in the construction of its advisory, others have modified it and others, including Michigan, have maintained the advisory process used in prior years. The U.S. Environmental Protection Agency (USEPA) has publicly disapproved of Michigan's reluctance to accept the proposed uniform advisory protocol for the Great Lakes and continues to urge that the state adopt it for the 1998 fishing season.

### The Charge

On September 5, 1997, Governor John Engler (Engler, 1997) requested that the MESB provide a scientific review of Michigan's proposed fish advisory process for the 1998 fishing season (Appendix 1). The letter states that the Michigan Department of Community Health (MDCH) proposes to use a modified procedure compared to that used for 1997. The changes proposed for 1998 would provide advice that represents increased restrictions on sport-caught fish consumption for the more vulnerable portion of the population, women of childbearing age and children. The uniform fish consumption advisory protocol proposed by the Council of Great Lakes Governors' Great Lakes Sports Fish Advisory Task Force (GLSFATF, 1993) would be used in the proposed 1998 advisory to provide added protection for women of childbearing age and children. The protocol was developed assuming PCBs represented the major contaminant of concern in fish. A Health Protection Value (HPV) of 0.05 micrograms per kilogram per day (µg/kg/day) of PCBs via fish consumption was selected and

utilized to develop restricted fish consumption categories. In its 1995 report, the MESB agreed that this HPV would be protective for pregnant women and children (Fischer *et al*., 1995).

MDCH also proposes that the advice provided in 1998 for the less vulnerable portion of the population, adult males and females beyond the childbearing years, would be less restrictive than for women of childbearing age and children and identical to the procedures used in 1997 for PCBs in fish. In addition, restrictive consumption advice based on mercury in fish would be identical to that used in 1997. This was more stringent for women of childbearing age and children and less restrictive for the rest of the population. This report addresses the scientific soundness of this proposed plan to provide sport fish consumption advice in 1998.

**MESB Response**

A Panel of scientists and consultants was formed by the MESB to address the Governor's letter and to review information relevant to Great Lakes fish advisories. Dr. Lawrence J. Fischer (toxicology, Michigan State University), chaired the Panel consisting of Dr. P. Michael Bolger (toxicology and food safety, U.S. Food and Drug Administration), Dr. Joseph L. Jacobson (epidemiology and psychology, Wayne State University), Dr. Bette J. Premo (environmental science and limnology, White Water Associates), Dr. Eileen O. Van Ravenswaay (agricultural economics, Michigan State University), and Mr. Keith G. Harrison (ecology, Michigan Environmental Science Board).

The Panel was provided and reviewed information collected by the MESB (Appendix 2). Special attention was given to more recently published information concerning contaminants in fish, particularly that appearing after the 1995 MESB report that reviewed the 1993 proposed uniform fish advisory protocol for the Great Lakes (Fischer *et al*., 1995). Drs. Fischer, Bolger and Jacobson and Mr. Harrison were on the 1995 MESB Panel and provided continuity for the present Panel. No meetings of the Panel occurred and communications were carried out largely by telephone, facsimile, and mail.

Two consultants with needed expertise were employed by the MESB to prepare reports that were used by the Panel to help formulate conclusions regarding the Michigan advisory for 1998. Mr. John L. Hesse (formerly of the MDCH) has been responsible for preparation of the annual fish advisory by the department in previous years. He was asked to prepare a report describing details of assignment of fish to the restricted consumption categories (Appendix 3). Dr. Michael A. Kamrin (Institute for Environmental Toxicology, Michigan State University) was asked to prepare a report on the risk assessment of PCBs and its use in fish advisories prepared in other Great Lakes States (Appendix 4). Panel members were requested to review the various materials and to provide their comments regarding the merit of the MDCH 1998 Michigan fish advisory proposal. Concurrence with the final report as it appears here was obtained from each member.

## Development of a Fish Advisory

The general procedure used by Michigan and other Great Lakes States for constructing a fish advisory is to first obtain an estimate of an acceptable (i.e., "safe") daily intake (ADI) value or reference dose (RfD) for each of the contaminants of concern; for example, PCBs, mercury and certain persistent, chlorinated pesticides. These values are obtained by a variety of methods including use of published regulatory values developed by federal agencies or ADI calculations made by state regulatory personnel. In addition to ADI values, yearly updated information on the concentrations of these chemicals in edible portions of fish is obtained from fish monitoring activities in selected Michigan lakes. These values, the ADI and the contaminant concentrations in fish are used to estimate how much fish can be consumed without exceeding the ADI and thereby encountering an unacceptable risk.

Consumption advice for fish, when deemed necessary, is usually presented in tables or charts indicating the name of the body of water, the species of fish under consideration, and the size of the fish. Fish size (i.e., length) is considered because, for most fish species, older and larger fish contain higher concentrations of contaminants. Because fish contaminant concentrations are not known for every body of water in the state, general advice regarding restricted consumption is given if the contaminant of concern is known to have a wide geographical distribution.

## Toxicity of PCBs

The current concentrations of PCBs in certain fish species, when evaluated in relation to the known toxicity of PCBs, usually provide the highest risk to public health compared to other contaminants in sport caught fish. There are large amounts of data from laboratory animal studies documenting the toxicity of PCBs and indicating their potential to produce harmful effects when exposure reaches sufficiently high levels. Much of this research is directed toward understanding the biochemical basis for the effects caused by these chemicals so that the risk to humans may be estimated with adequate knowledge of possible differences between animals and humans in response to PCB exposure. However, current information does not permit adequate certainty whether information obtained from animal or cellular studies can be used without modification to derive risk estimates for environmental exposures in humans. This uncertainty is the reason that a large amount of conservatism is applied to toxicological data from animal studies utilized in risk calculations. This conservatism is reflected in the application of safety/uncertainty factors in the calculation of ADI values and the use of the default approach recommended by the USEPA for cancer risk assessment.

Current fish advisories in many states are generally based on the reproductive/developmental effects of PCBs demonstrated in laboratory animal studies and suggested by data obtained in humans. The Great Lakes Fish Advisory Task Force considered these effects along with other effects of PCBs in developing the HPV of 0.05 µg/kg (GLSFATF, 1993). A review of these toxicological considerations is

provided in that document and the MESB fish advisory report (Fischer *et al*., 1995). Recent data obtained in humans lend additional support for the 0.05 µg/kg HPV (Jacobson and Jacobson, 1996). More recent laboratory animal studies also have confirmed that PCBs exhibit effects on reproductive capacity in laboratory animals (Foster, 1995; Brouwer *et al*., 1995; Sager and Girard, 1994; Kholkute, Rodriquez and Dukelow, 1994).

The human cancer risk from consumption of PCB-contaminated fish is uncertain because there is very little evidence indicating increased cancer risk due to human exposure to these chemicals, which are known to produce tumors in laboratory rodents. A statistical correlation between fish consumption and/or PCB levels in blood or other tissues with increased cancer risk in adult humans has been observed occasionally but the studies lack an acceptable level of scientific rigor and have not produced reproducible results. For example, earlier reports of an association between exposure to organochlorines (including PCBs) and breast cancer in women (Falck *et al*., 1992) have not been found in more current, larger studies. Hunter *et al*. (1997) were not able to observe a link between PCB exposure and breast cancer and concluded their report with the statement, "*There are good ecologic reasons to avoid the release of DDT and PCBs into our environment, but on the basis of our results the use of these compounds does not explain the high and increasing incidence of breast cancer.*"

Another study (Rothman *et al*., 1997) recently reported a statistical link between high levels of PCBs and non-Hodgkin lymphoma. Several previous studies have not found an association between PCBs and this blood-borne cancer and because of the preliminary nature of the present report the authors state, "*Before causal inferences can be made about PCB exposure and increased risk of non-Hodgkin lymphoma, these results require replication and potential confounding by risk factors not ascertained here should be examined. Moreover the inconsistency between our findings and those from studies of PCB-exposed occupational cohorts needs to be explained and the biological plausibility of this association requires further investigation*." It appears that recent reports of studies examining the link between PCBs and cancer are not producing results that indicate a greater risk than has been estimated in the past. Given this information, and the fact that occupational exposures to PCBs have not indicated a significant cancer risk, it would appear that Michigan's fish advisory for adult males and women beyond childbearing age does not need to be modified based on cancer risk estimates.

Use of animal data for estimation of human risk provides even more problems (Fischer *et al*., 1995). The highest estimated human risks using data from laboratory animals is associated with studies of the potential for these compounds to produce cancer. However, use of cancer risk assessment from results obtained in studies of tumors produced by high doses of commercial mixtures of PCBs produces highly uncertain risk estimates. Cane (1996) estimated that the risk from reasonable maximal consumption of Saginaw Bay walleye (skin-on fillet), an area of special concern in Michigan, was two additional cancer cases in 10,000 exposed individuals. This magnitude of risk has been judged acceptable by the USEPA, presumably because of the uncertainty

involved and because of the conservative nature of the cancer risk assessment process.

**The Health Protection Value (HPV) Approach**

The HPV for PCBs recommended by the Great Lakes Fish Advisory Task Force (GLSFATF, 1993) of 0.05 µg/kg/day will generally result in more restrictive fish consumption advice for women of childbearing age and children, than previously used in Michigan. This may be justified because reproductive and developmental changes can occur in laboratory animals after moderate to low doses of PCBs (Brouwer *et al*., 1995). The sensitivity difference between humans and laboratory animals exposed to PCBs is unknown because there are inadequate data in humans regarding exposure-toxicity relationships to compare with data from laboratory experiments. The application of reasonable safety/uncertainty factors (100 to 1000) to doses that do not produce harmful effects in animals yields ADI values consistent with use of the 0.05 value to protect human reproductive health. This is confirmed in the sensitivity analysis portion of the proposed Uniform Great Lakes Sport Fish Consumption protocol. Because of the conservative (i.e., low) HPV of 0.05 µg/kg/day used in the assignment of fish to the restricted consumption list, this Panel believes adequate protection is afforded for women of childbearing age and children. It has met general acceptance from the regulatory community and it is believed to be protective of public health.

**The Michigan Approach**

Initial fish advisories in Michigan in the 1970's were among the first to warn anglers of the dangers of PCBs in fish. At that time, the basis for the advisories was the U.S. Food and Drug Administration (USFDA) tolerance level for PCBs of five parts per million (ppm). An USFDA tolerance level represents a concentration in food that does not provide an unacceptable health risk to persons consuming fish with above average frequency. Thus, fish containing concentrations higher than the tolerance level are placed in a restricted consumption category. Dr. Michael Bolger (USFDA) points out that comparisons of the USEPA RfD and tolerance levels are difficult but the tolerance level is established in part on the basis of a health risk analysis as part of its development (Appendix 4). Michigan lowered the tolerance level to two ppm in 1981 in response to the USFDA's proposal at that time to adopt this level for fish sold commercially. No consumption was advised if the *average* concentration in monitored fish exceeded that trigger level. Then, emerging evidence on the toxicity of PCBs prompted Michigan in 1987 to adjust its advisory approach making it more restrictive. The revised procedure used the USFDA tolerance value of two ppm but a different method was adopted to assign fish to restricted consumption categories. When fish monitoring data indicated more than 50 percent of the fish of a given species in a particular lake were over the USFDA value, no consumption was advised. If between 10 percent and 49 percent exceeded the value, non-sensitive populations were advised to eat no more than one meal per week and when 10 percent or less exceeded the USFDA trigger, there were no restrictions on consumption. Based on experience with this system, Mr. John Hesse reports that the 11 percent exceedence corresponds to a

fish PCB contaminant level of about one ppm (Appendix 3). Thus, the consumption advisory was made approximately twice as restrictive within the contamination range in which PCB levels slightly exceed the trigger level in a small percentage of monitored fish.

The advice procedure described above was developed to protect the less sensitive portion of the population, adult men and women beyond the childbearing age. More restrictive advice for children and women of childbearing age has been the norm in Michigan and many other states for many years. In 1985, as a result of the report by Jacobson *et al.* (1985) regarding possible behavioral changes in children born to mothers who had higher PCBs levels and fish consumption, Michigan, Indiana, Illinois and Wisconsin adopted a more restrictive approach for the more sensitive portion of the population. When greater than 10 percent of the monitored fish exceeded the two ppm trigger level, no consumption was recommended for women of childbearing age and young children as described by Mr. Hesse (Appendix 3). As previously mentioned, this change essentially makes the trigger level one ppm instead of the USFDA value of two ppm.

Michigan now proposes to provide restrictive advice for women of childbearing age and children based on the HPV proposed by the Great Lakes Fish Advisory Task Force. Restrictive consumption will occur when average fish concentrations in a monitored species is greater than 0.05 ppm. This protective posture is taken on the general assumption that the unborn child and young children are particularly sensitive to chemical insult. This is a scientifically defensible position because the protective mechanisms normally present in the adult are underdeveloped in the fetal and young animal. In addition, there is specific evidence supporting an increased vulnerability to PCB toxicity in the fetus of both humans and laboratory animals (Jacobson and Jacobson, 1996; Gladen *et al*., 1988; Lilienthal and Winneke, 1991). Also, given the more current evidence of reproductive and developmental changes when laboratory animals are exposed to TCDD-like chemicals, including certain PCB congeners, it is prudent to strengthen the restricted consumption advice to the potentially more sensitive portion of the population.

**Conclusion**

In September 1995 the MESB concluded that the HPV of 0.05 µg/kg/day proposed in the 1993 draft Protocol for a Uniform Great Lakes Sport Fish Advisory (GLSFATF, 1993) was sufficiently protective of the most susceptible portion of the population (Fischer *et al*., 1995). Michigan's proposal to adopt that advisory approach for 1998 for women of childbearing age and children represents a cautious approach and has the support of the present MESB Panel. The 1995 MESB report also indicated that the same HPV appeared overly protective for the less sensitive portion of the population and that less restrictive advice could be applied in recognition of the benefits derived from consumption of fish in moderate quantities. The view of the current Panel is that there are no new data that require an alteration of this conclusion and there is merit in continuing to give less restrictive advice to consumers of sport-caught fish in the less

vulnerable portion of the population. This is consistent with the pattern of advice given in Michigan for over a decade. The Panel concludes that the 1998 MDCH proposal to serve the needs of both segments of the population with different fish consumption advice has a sound basis in the available scientific literature and makes good public health sense.

**Mercury**

Another fish contaminant of concern is mercury and its presence in fish primarily from inland lakes accounts for about 30 percent of the species-specific advisories for listed bodies of water in the 1997 Michigan Fishing Guide. Methylmercury, the major form of mercury in fish, is known to interrupt neurodevelopment in the fetus. Levels of total mercury greater than 0.5 ppm in monitored species results in restricted consumption advice and no consumption is recommended if values in fish exceed 1.5 ppm. For women of childbearing age and children, no consumption is advised if fish contain greater than 0.5 ppm of total mercury. In addition, general advice to restrict consumption of fish from unmonitored lakes in Michigan is provided in the Michigan Fishing Guide.

As pointed out by Mr. John Hesse (Appendix 3), Michigan's consumption advisory for mercury contaminated fish has been reviewed on a regular basis, the last occurring in 1994. Based on current knowledge regarding the threshold for producing toxicity in the human fetus, the advice that Michigan has provided in the past is adequate for protecting the public from the potential effects of methylmercury exposure via fish consumption. The recent lowering of the RfD for mercury by the USEPA from 0.3 µg/kg/day to 0.1 µg/kg/day was taken into consideration by the MDCH in developing the restricted consumption advice for mercury in fish. The results from two large epidemiology studies in fish-eating populations now taking place in the Seychelles Islands and in the Faroe Islands have not been satisfactorily evaluated at this time and this precludes their use for modification of the acceptable daily intake for mercury. The lack of any evidence that mercury exposure via consumption of fish containing levels of total mercury below 0.5 ppm is harmful to the developing fetus is consistent with the decision continue to utilize current consumption advisories for fish from Michigan's waters. Levels of maternal exposure to methylmercury in which effects in the human fetus have been observed are from accidental poisonings in Japan and Iraq where exposures were greater than 100-fold larger than those that can be obtained from regular consumption of Michigan's fish at current mercury levels. Thus an adequate margin of safety is provided by the Michigan advisory.

**Risk Communication**

Suggestions for improving the communication aspect of the Michigan Fishing Guide have been provided by Dr. Bette Premo and Dr. Eileen van Ravenswaay (Appendices 7 and 8, respectively). The Panel recommends attention be given to these suggestions, which should help to clarify and simplify risk communication with the public. In addition, the messages should be tailored as much as possible to the recipient audiences.

Targeted recipients of the message to reduce exposure to fish contaminants are those who are at higher risk because of high fish consumption or because of the potential of greater sensitivity to the toxic effects of fish contaminants. Thus subsistence anglers, including some Native American and Asian subpopulations, and women of childbearing age should receive tailored messages via effective routes of communication. The use of focus groups to evaluate the effectiveness of the communication should be considered. These suggestions are consistent with those previously provided by the MESB (Fischer *et al*., 1995).

Finally, it is important to note that effective risk communication requires simplicity and consistency in the message. Because Michigan and most other Great Lakes states have provided more restrictive fish consumption advice for women of childbearing age and children in the past compared to the advice given to adult males and women beyond childbearing age, it is reasonable (and scientifically justifiable) that this continue. Confusion and lack of trust within the public will be lessened with this approach. To advise all anglers that consumption should be restricted to protect the more vulnerable portion of the population and at the same time admitting that less vulnerable groups may be overprotected, as stated in the advisory from a neighboring state, does not represent a simple and clear message. The Panel believes that the plan for Michigan's 1998 advisory will avoid this type of communication problem.

**Uniformity of Current Advisories from Great Lakes States**

Dr. Michael Kamrin, under contract with the MESB, has prepared a report that compares the Michigan Advisory proposed for 1998 with the advisories used by other Great Lake States and Ontario in 1997 (Appendix 4). This comparison dispels the belief held by the USEPA and others that a uniform fish advisory has been adopted by all of the Great Lake States except Michigan. In fact, among the states and provinces comprising the Great Lakes basin, the advisories are quite variable in fundamental aspects such as the assumptions used, the number of fish consumption categories employed, the recommended consumption for fish caught in the same body of water, and the general consumption advice given for fish taken from waters that have not been involved in monitoring fish for contaminants. The method of presentation of the advisory, the degree of detail in the explanation for the advisory and other aspects of the risk communication procedure used exhibit even greater differences among the states. Dr. Kamrin points out that the variability in consumption advice among states cannot necessarily be attributed to the selection of the USFDA-based tolerance value as the basis for the advisory instead of the Great Lakes Task Force developed HPV. Rather, it seems apparent that different risk management judgments are being applied to the advisory process used in each state or province. Considering current scientific knowledge, it is not possible to state that the advisory used in one state is more grounded in scientific fact than that used by another state. Further, given the variable nature of the construction of each state's advisory and the uncertainties involved in the process used to calculate ADIs for contaminants in fish, it is neither reasonable nor scientifically justifiable to single out one or more states as shirking its responsibility for

protecting public health by providing inadequate advice concerning consumption of sport-caught fish.

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## Appendix 1

## September 5, 1997 Correspondence to the Michigan Environmental Science Board from Governor John Engler

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September 5, 1997

Dr. Lawrence Fischer, Chair
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Lansing, Michigan 48933

Dear Dr. Fischer:

I am committed to providing Michigan's citizens with accurate and understandable information regarding the consumption of sport fish. To address the concerns of our citizens, I am requesting the assistance of the Michigan Environmental Science Board in reviewing Michigan's policy that underlies providing advice about sport fish consumption. This is an area in which the Board can provide an important service to our State by providing valuable, nonbiased counsel. Relative risks must be weighed and meaningfully explained, and publicly distributed fish consumption advisories must be based on sound scientific principles. I request the Board's advice on the scientific principles that will form the basis of clear policy and an expanded document communicating advice about fish consumption for Michigan's anglers.

The Michigan Department of Community Health (DCH) has summarized the analysis of the 1995 Report of the Special Fish Advisory Science Panel as follows:

*For women of child bearing age and children less than 15 years of age, the use of a 0.05 micrograms of PCB per kilogram of body weight per day health protection value (0.05 Health Protective* Value or *HPV) is reasonable.*

*For adult males* and women *beyond child bearing years, the 0.05 HPV is too restrictive.*

With this understanding of the 1995 report, DCH is seeking to provide parallel advisories for these two population categories for the 1998-1999 fishing season. They are proposing to provide two sets of tables--one set of tables for women of child bearing age and children, and the other for adult males and women beyond child bearing age. These tables would be developed for each body of water and would contain consumption advice by fish species and size.

In creating these new tables, DCH would propose to use the 0.05 HPV as part of the standard in the tables for women of child bearing age and children, if appropriate. DCH would continue to augment this standard for particular bodies of water and species of fish where application of the currently used trigger levels for other contaminants would create more restrictive consumption advice. For example, walleye greater than 22 inches long in Lake Michigan, using the 0.05 HPV for PCBS, would dictate no consumption restrictions. DCH proposes to continue to apply FDA standards for mercury in the same manner that has been used for more than a decade, recommending in that case that the consumption of these large walleyes from Lake Michigan by women of child bearing age and children be no more than one meal a month. DCH proposes to use the FDA standards and fish consumption assignment procedures that it is presently using in all the tables for adult men and women beyond child bearing age.

I hereby request that the Michigan Environmental Science Board carefully review this proposed approach to fish consumption advisories, and provide to me and DCH your response and recommendations on using this methodology. Should the Board determine that an alternative approach would be more factually informative and helpful to anglers, please share this as well. Any recommendation you may advance could help lay the foundation for future policy determination on this matter of significant public importance.

Please forward to me and DCH your recommendations by October 17, or as soon thereafter as feasible. Thank you for your assistance in this very important public service.

Sincerely,

John Engler
Governor

cc: Mr. Keith G. Harrison, Executive Director, MESB
Mr. James K. Haveman, Jr., Director, DCH
Mr. Russell J. Harding, Director, DEQ

## Appendix 2

## Review Material Sent to the Michigan Environmental Science Board Fish Consumption Advisory Panel

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## Appendix 3

## Criteria used by the Michigan Department of Community Health for Sportfish Consumption Advisories

**Report Prepared for the**
**Michigan Environmental Science Board by Mr. John L. Hesse**

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**CRITERIA USED BY THE**
**MICHIGAN DEPARTMENT OF COMMUNITY HEALTH[1]**
**FOR SPORTFISH CONSUMPTION ADVISORIES**

**SUMMARY PREPARED BY**
**JOHN L. HESSE, CONSULTANT TO THE**
**MICHIGAN ENVIRONMENTAL SCIENCE BOARD**

In a letter dated September 5, 1997, Governor John Engler asked the Michigan Environmental Science Board (MESB) to evaluate the Michigan Department of Community Health's (MDCH) policies and criteria for providing advice to anglers about consumption of sport-caught fish.

The summary that follows describes the basis for MDCH fish consumption advisories in the recent past and discusses proposed modifications to the approach for the 1998 advisory. For additional background, the Science Board is also being provided copies of a draft book chapter titled "Case Study: Sport Fish Consumption Advisories in the Great Lakes Region" soon to be published by John Wiley and Sons in the book, *Environmental Risk Harmonization*, Dr. Michael Kamrin, Editor (1).

A 1986 draft procedures document titled*, State of Michigan Sport Caught Fish Consumption Advisories: Philosophy, Procedures, and Process* (2) has already been provided to the MESB Members to give an historical perspective and greater detail. It can serve as a resource to MESB Members who have questions about areas of the fish contaminant program not covered in this summary. Reviewers of the 1986 draft procedures document, however, must be aware that procedures described in Section H (Application of Trigger Levels) were not implemented as proposed and should be disregarded. Some of the other details in that document may also be out-of-date. MESB members who have detailed questions about current fish contaminant monitoring procedures should contact the Michigan Department of Environmental Quality for the most up-to-date information on that program.[2]

## MICHIGAN TRIGGER LEVELS

Michigan has historically based its trigger levels for fish consumption advisories (Table 1) on the U.S. Food and Drug Administration (FDA) guidelines used to regulate fish sold in the marketplace. However, for two contaminants (dioxin and mercury), Michigan's trigger levels are lower that those set by FDA. It is also important to note here that there are significant differences in how the Michigan trigger levels are applied as compared to FDA regulation of fish in the market. These differences will be described in a later section.

Although Michigan has advisories in place due to eight different contaminants, excess levels of mercury, PCBs, chlordane and dioxins account for the vast majority of Michigan's current advisories. At various times, the Michigan Department of Public Health (MDPH) has independently reviewed the toxicological basis for each of these advisory trigger levels to determine if revisions were needed for protection of sport fish consumers. The historical basis for Michigan's trigger levels for mercury, PCBs, chlordane and dioxins is briefly discussed below. The other four contaminants include DDT, PBB, PAHs, and Toxaphene.

**Mercury** – In 1970, Michigan became the first state in the nation to issue fish consumption advisories. These resulted from the discovery of elevated mercury levels in fish from Lake St. Clair and Lake Erie downstream from two chlor-alkali facilities using the mercury-cell process. After conferring with FDA and Canadian officials, Michigan decided to utilize the existing 0.5 parts per million (ppm) FDA action

[1] On April 1, 1996, the Michigan Department of Public Health was absorbed into the newly formed Department of Community Health. This document uses the departmental identifiers in effect at the time of the event.
[2] The person currently in charge of the Fish Contaminant Monitoring Program is Mr. Bob Day, telephone: (517) 335-3314.

level as the basis for advice to anglers. The Canada Directorate of Health and Welfare was also using this standard for regulation of commercial fish. This standard was adopted into the Michigan Public Health Code (PA 368, as amended) requiring fish consumption advisories to be issued when 0.5 ppm is exceeded.

In 1979, the FDA action level was raised to 1.0 ppm due to a combination of factors, including evaluation of new data from mercury exposed populations in Japan and Sweden that suggested the dose-response observed in those poisonings was not applicable to other populations. According to FDA, the earlier 0.5 ppm action level proved to be overly conservative and unrealistic (3). The federal government in Canada maintained 0.5 ppm as their action level.

Following the FDA action in 1979, MDPH again reviewed the basis for the 0.5 ppm trigger level. The World Health Organization (WHO) had recommended a daily maximum intake of 35 micrograms (Tg) total mercury (or 30 Tg of methylmercury). This corresponded to an average consumption of approximately one pound of fish per week contaminated at 0.5 ppm or ½ pound per week at 1.0 ppm. Based on this, Michigan decided to advise the general public (excluding women of childbearing are and children) to eat no more than one meal per week of fish with mercury concentrations ranging from 0.5 to 1.5 ppm and to eat none at concentrations over 1.5 ppm. Because the fetus and young children were assumed to be more sensitive to mercury, women of childbearing age and children age 15 or under were advised not to eat any fish containing more than 0.5 ppm.

In the early 1980s, MDPH/Michigan Department of Natural Resources (MDNR) officials discovered widespread occurrence of mercury in inland lakes throughout the state. Approximately 70 percent of lakes tested had some fish samples exceeding 0.5 ppm, and 30 percent showed at least one fish species tested with average concentrations over 0.5 ppm. Due to budgetary limitations, only about 15 - 20 lakes each year can be tested out of more than 11,000 inland lakes in the state. It would take hundreds of years to test all lakes. After compiling and analyzing data from approximately 100 lakes, MDPH saw a rather consistent pattern and made a policy decision in 1988 to issue a generic advisory that would apply to all inland lakes statewide. This was to provide precautionary advice to people even for lakes that had not yet been tested.

When considering the generic advisory, Michigan took a new look at the basis for the WHO recommended maximum daily intake for mercury. In the Japanese/Minamata Bay case study, the lowest observed adverse effect level (LOAEL) in adults was estimated to occur at a blood concentration of 200 micrograms per liter (Tg/l or parts per billion, ppb). Using estimated rates of mercury uptake and a half-life of about 70 days, the LOAEL was equivalent to an intake rate of about 300 Tg Hg/day for a 70 kg person (approximately equal to 4.0 Tg/kg body weight). Using a safety factor of 1/10 to estimate a No Observed Adverse Effect Level (NOAEL) in adults from the LOAEL yields a blood level of 20 Tg/l and an intake level of 30 Tg/day of methyl mercury (0.4 Tg/kg body weight). These calculations supported Michigan's advice to the general adult population to eat no more than one meal per week of fish contaminated at 0.5 - 1.5 ppm Hg and none above 1.5 ppm.

Michigan's re-evaluation of literature resulting from the mercury poisoning epidemics in Japan and Iraq found that the fetus might be about 4 times more sensitive to mercury toxicity than adults. Considering this, Michigan revised its earlier "no consumption" advice for women and kids to now allow up to one meal per month of fish containing mercury levels ranging from 0.5 to 1.5 ppm. This was 1/4 of the frequency recommended for the general population.

For purposes of the generic advisory, data from all lakes were pooled for each species tested and analyzed to determine the average sizes at which the mercury concentration would be expected to exceed the 0.5 ppm trigger level. The generic advisory reads as follows:

> *"No one should eat more than one meal a week of fish of the following kinds and sizes from any of Michigan's inland lakes: rock bass, perch, or crappie over 9 inches in length; or any size largemouth bass, smallmouth bass, walleye, northern pike, or muskie. Nursing mothers, pregnant*

*women, women who intend to have children, and children under age 15 should not eat more than one meal per month of these fish."*

The few lakes for which one or more species had mercury concentrations exceeding 1.5 ppm have been listed specifically in the advisory tables. Because streams are not covered by the generic advisory, individual streams with fish exceeding even 0.5 ppm are listed, as are a few fish from the Great Lakes.

In April 1993, the MESB completed a review of mercury in Michigan's environment (4). One of the MESB recommendations was that MDPH periodically re-evaluate the basis for its mercury-based fish consumption advisories as new information about mercury effects becomes available.

Another re-evaluation by MDPH was triggered in 1994 when the U.S. Environmental Protection Agency (EPA) announced a proposal to lower their Reference Dose (RfD) for mercury from 0.3 Tg/kg/day to 0.1 Tg/kg/day (later adopted, May 1995). The revised RfD was based largely upon re-analysis of data from the historical human poisoning incident in Iraq. The new RfD has been somewhat controversial, even with disagreement within EPA. Promulgation of a new RfD came at a time when two major studies of human populations exposed to mercury through fish consumption were well underway in the Farowe and Seychelle Islands. Preliminary analysis of the Seychelle data was not suggesting the need for more restrictive advisory criteria but had not yet been adequately peer reviewed.

MDPH participated in a joint review of the situation at the June 1994 meeting of Michigan's interagency Fish and Wildlife Contaminant Advisory Committee (FAWCAC). If EPA's new RfD were applied to Michigan's fish consumption advisories, it would result in only slightly more restrictive advice. Michigan officials decided to not modify its mercury criteria until the new human studies have been adequately peer-reviewed and published.

**Polychlorinated Biphenyls (PCBs)**

As with mercury, Michigan was involved in the discovery of PCB contamination in fish and in 1971, was one of the first states to issue advice to anglers regarding this contaminant. Initial advisories were based upon the FDA tolerance level of 5.0 ppm in place at that time.

Michigan was aggressive at identifying sources of PCB contamination and was the first state to ban the use of PCBs through legislation passed in 1975. The EPA banned PCBs nationally four years later pursuant to the Toxic Substances Control Act. By 1979, levels of PCBs in Great Lakes fish had already dropped significantly.

In 1979, FDA announced a proposal to lower the PCB tolerance level in fish from 5.0 ppm to 2.0 ppm. Michigan independently reviewed the proposal and adopted the 2.0 ppm level in 1981 (5), two years prior to FDA's decision to do the same. Michigan and FDA evaluations were based primarily upon the carcinogenicity of PCBs as estimated by cancer risk models in use at that time. At 2.0 ppm, the estimated excess risk of cancer was approximately one in 100,000 ($10^{-5}$). In rules promulgated under the Water Resources Commission Act (PA 245, Rule 57), Michigan had adopted a policy establishing a risk level of $10^{-5}$ to serve as the basis for regulating contaminant discharges to surface waters. The establishment of the 2.0 ppm trigger level for PCBs was consistent with that policy.

Publication of research by the Jacobsons and their colleagues (6) in 1984 on a cohort of Lake Michigan fisheaters brought increased concerns about the extra sensitivity of the human fetus to possible neurobehavioral effects from PCB exposures. Taking these findings into consideration, Michigan and the other Lake Michigan states (Indiana, Illinois and Wisconsin) jointly decided in 1985 to modify how the 2.0 ppm PCB trigger level was being applied. The Lake Michigan Fish Advisory Task Force agreed that when 11 percent or more of samples for a particular fish species exceeded 2.0 ppm, women of childbearing age and young children would be advised not to eat that species. It chose to use a percentage of the FDA action level rather than application of a totally risk-based number in order to maintain some linkage with how fish were being regulated in the market. This modified procedure will be described in more detail later in this report.

In 1986, a new task force of representatives from all the Great Lakes jurisdictions began working toward development of a risk-based standard and protocol for issuing advisories. A draft approach, which focused primarily on protection against neurobehavioral risks to the fetus and young children, was first presented for discussion purposes at an annual meeting of the American Fisheries Society in 1989. Two years later, Minnesota chose to implement a version of the protocol that had been under development by the Great Lakes Task Force. In September 1993, the Task Force submitted the draft to the Council of Great Lakes Governors (7) for consideration to be implemented throughout the Great Lakes basin. Ohio, Pennsylvania, Indiana, Wisconsin, and Illinois have since implemented the draft protocol in various forms.

The PCB advisory level in the draft protocol, which has been implemented by most of the Great Lakes states, is based upon a "Health Protection Value (HPV)" of 0.05 Tg PCB/kg/day. A Special Fish Advisory Science Panel established by the MESB reviewed the draft protocol and issued its report in September 1995 (8). The Panel supported the use of the HPV for women of childbearing age but judged that it was overly protective for other segments of the population.

**Chlordane**

The 0.3 ppm FDA tolerance level for chlordane has always served as the trigger level for fish advisories in Michigan. Michigan bases its decisions on total chlordane as calculated from the sum of 5 major isomers consistent with guidelines of the FDA. Some jurisdictions calculate total chlordane based upon as few as 2 isomers. In 1983, Michigan initiated several actions regarding chlordane, including: (A) a carcinogenic risk analysis and review of the fish consumption advisory trigger level, (B) classification of chlordane in Michigan as a restricted-use pesticide and (C) submittal of environmental monitoring data to the EPA in support of cancellation proceedings for its only remaining registrations (as a termiticide). Chlordane was classified as a suspect human carcinogen, having been shown to cause liver cancer in animals. Using accepted cancer models in place at that time, the estimated cancer risk at 0.3 ppm for chlordane was very close to the target of $1 \times 10^{-5}$ excess cancer rate established a few years earlier pursuant to surface water quality standards. No change in the trigger level was considered necessary.

Subsequently, in 1984, the EPA canceled registrations for chlordane use to control termites associated with structures. This completed a national phase out of all chlordane uses initiated by the EPA in 1978. Michigan currently has several advisories involving chlordane as the primary contaminant.

**Dioxins**

At the request of the MDNR in the mid-1970s, Dow Chemical Company at Midland, Michigan tested for dioxins in resident fish populations upstream and downstream from their facility's discharge into the Tittabawassee River. In 1978, Dow issued a report of their findings to state officials showing dioxin contamination [including the more toxic forms such as 2,3,7,8-tetrachlorodibenzodioxin (TCDD)] in numerous fish species downstream from Midland. They had also conducted uptake studies with caged fish held in their outfalls and at various points in the river. The results confirmed Dow as a source of dioxin contamination, probably related to past production of pentachlorophenol and herbicides such as 2,4,5-T formulated from 2,4,5-trichlorophenol. Pentachlorophenol production was believed to be associated only with contamination by the higher chlorinated, less toxic forms of dioxin. Concentrations of TCDD were as high as 695 parts per trillion (ppt) found in carp.

Although MDPH had no trigger level for dioxins, an advisory against eating any fish from the Tittabawassee River was issued almost immediately upon receipt of the Dow report as a precautionary action because of the extreme toxicity of this group of chemicals.

MDPH solicited advice from the FDA relative to a level of concern for dioxin in fish tissue consumed by humans. FDA had not established an official action or tolerance level for dioxins. In 1979 and 1980, the FDA transmitted letters to Michigan providing general advice suggesting that people should limit their consumption of fish containing more than 25 ppt of TCDD to two to four meals per month and should not eat any fish with 50 ppt or more.

In the meantime, the Michigan findings soon triggered national attention to dioxins. During the early to mid-1980s, various states and Canadian government developed trigger levels for fish advisories. The EPA initiated a national fish contaminant survey that included analysis for dioxins and a special dioxin sampling project conducted nationally as well. Michigan contributed samples to both of these studies and continued to expand its own fish analysis for dioxins as well. In February 1986, the MDPH submitted a report (9) to the Michigan Environmental Review Board documenting the basis for a Michigan trigger level of 10 parts per trillion TCDD. The criterion was based upon a cancer risk analysis using a multi-stage model, a cancer slope factor of $3.57 \times 10^{4}$ (mg/kg/day) $^{-1}$, a dose per unit body weight species conversion factor, and evaluation of two consumption rates [Note: Michigan has adopted the toxic equivalency factor approach used by EPA that incorporates less toxic congeners of dioxin in samples into a single concentration equated to the toxicity of 2,3,7,8-TCDD]. The states of New York and Wisconsin also had selected 10 ppt for advisory purposes. The Canadian criterion was set at 20 ppt. Minnesota and the EPA were proposing use of 0.7 ppt. By 1986 contaminant levels in Tittabawassee game fish species had declined to levels below 10 ppt and MDPH proposed relaxation of the advisory relating to game fish. Average TCDD concentrations in game fish were at approximately 7 ppt. The EPA objected to this partial relaxation of advisories. Based upon EPA objections, Michigan modified their decision in 1986 to remove game fish from the advisory completely. Instead a general statement was issued that read:

> *"Some fish, especially carp and catfish, from the Tittabawassee and Saginaw Rivers have been found to contain PCBs and dioxins. We strongly advise that no one eat any carp or catfish from the Saginaw River or the Tittabawassee River downstream from Midland. We suggest that no one eat large quantities of other species from these waters. Women who intend to have children should eat no more than one meal per month of these fish."*

In addition to dioxins in the Tittabawassee and Saginaw rivers, Michigan issued advisories in 1988 for sections of two rivers downstream from paper mills with Kraft bleaching operations. Dioxin minimization programs by the two companies have resulted in dramatically lower dioxin levels in resident fish. The advisory on the Escanaba River below the Mead Paper Mill was lifted in 1993 when levels ranged from less than 1 - 3 ppt in contaminated species for two years in a row. The advisory on large carp in the Menominee River downstream from the Champion Paper Company remains in effect but levels have declined similarly. Under current MDPH policies, two years of data showing fish below the trigger level are needed before an advisory can be lifted.

Lake trout in Lake Huron are currently under advisories due to elevated dioxins (> 10 ppt) from unknown sources.

## MODIFICATION OF TRIGGER LEVEL APPROACH TO PROVIDE EXTRA PROTECTION

By 1985, the FDA guidelines were criticized by some people and organizations as being inappropriate for use in issuing fish consumption advisories to sport anglers. Reasons include, (A) that fish purchased in the market are assumed to come from a variety of sources and fish consumed by anglers often originate from the same body of water. If that body of water is contaminated, this leads to a continual exposure to contaminants., (B) the FDA by law has to consider economic impacts. Therefore, the regulatory levels may not be entirely health-based and (C) the FDA levels are designed to protect the average fish eater nationally and do not take into consideration fish eating habits of local populations that may differ significantly from the national average. For example, some fish consumption surveys suggest that anglers tend to eat about two to three times more fish than the general population eating only fish purchased from restaurants and the markets.

The Lake Michigan Task Force considered switching in 1985 to risk-based criteria rather than continuing use of FDA guidelines. However, this was rejected because of the 'orders of magnitude' uncertainty associated with new, more conservative, cancer risk projections at that time, and the likelihood that anglers would not accept advisories that were greatly different from criteria upon which fish were being regulated in the market. It was feared that compliance with advisories may greatly decrease, resulting in even more exposure to contaminants for some people.

Beginning with the 1987 advisory, the Lake Michigan states decided to provide extra protection to anglers and sensitive populations by simply reducing the required number of samples exceeding the trigger level to 11 percent rather than requiring that the mean concentration exceed the trigger level as in the past. This system was applied to all organic contaminants individually as follows:

- When 10 percent or less of the samples of a species and size range exceed a trigger level, there are no restrictions on consumption for any population.

- When 11 - 49 percent of the samples of a species and size range exceed a trigger level, women of childbearing age and children under 15 are advised not to eat any. The remainder of the population should restrict consumption to no more than one meal per week.

- When more than 50 percent of the samples exceed a trigger level, no one should eat these fish. At this point FDA would remove fish from the market.

Based upon experience with this system, MDPH has noted that when 11 percent of the samples exceed a trigger level, the mean concentration is generally about ½ of the trigger level. Using PCBs with a trigger level of 2.0 ppm, for example, this would occur at a mean concentration of approximately 1.0 ppm.

A plot of 1995 and 1996 chinook salmon data for Lake Michigan as shown in Figure 1 serves as a good example of how the modified application of a FDA action level (PCBs at 2.0 ppm in this case) was used by the Lake Michigan jurisdictions beginning in 1987. Based upon this set of data, no restrictions were placed on consumption of chinook salmon less than 21 inches in length. For sizes 21 - 32 inches, women of childbearing age and children were advised not to eat any, while the remainder of the population could eat up to one meal per week. At 32 inches and above, everyone was advised to eat none.

For comparison purposes, consider this same set of samples in Figure 1 as being in a commercial fisherman's daily catch from Lake Michigan and that a FDA inspector selected a sample to be analyzed for comparison to the 2.0 ppm action level for PCBs. In this case, however, 10 fish representative of all sizes in the catch would be composited into a single sample for laboratory analysis. It is very easy to conceive that the PCB concentration might very likely be less than 2.0 ppm. The result is that all sizes would be considered acceptable for purchase and consumption by the general public, including women of childbearing age or children. The purchaser would not think once about whether to eat these fish since there would be no advisory posted in the marketplace.

Health agencies in each of the Great Lakes states advise anglers to skin fish and trim away fatty areas prior to cooking. Several studies have shown that such trimming, in combination with cooking in ways that remove oils, results in a 50 percent or greater reduction of fat-soluble organic contaminants. This reduction is not taken into consideration in most risk assessments but would result in significantly less exposure than assumed in risk assessments generated from raw fish data.

The procedure for issuing advice based upon mercury differs from the approach described above for the fat-soluble organic contaminants. Instead of using percent exceedances to establish the level of advice, MDPH plots a length/concentration regression based upon all fish in the sample for a particular species and body of water. Length-specific advice is then determined by where the regression line crosses the 0.5 ppm trigger level for the "restrict consumption" category and where it crosses the 1.5 ppm concentration line. If the regression line does not cross the 1.5 ppm boundary within the size range of fish in the sample or within the normal maximum size for that species, no specific advisory is issued for that body of water if it is adequately covered by the generic statewide advisory. If any species exceeds 1.5 ppm of mercury, the fish species and the body of water are then specifically listed in the advisory tables indicating what sizes should not be eaten. Educational materials always try to make it clear that skinning and trimming of fat does not reduce mercury levels in fish tissue.

**PROPOSED MODIFICATION IN MICHIGAN'S APPROACH FOR 1998**

As mentioned above in the discussion of PCBs as a Great Lakes contaminant, the draft uniform protocol submitted to the Council of Great Lakes Governors in September 1993 was reviewed by the MESB Special Fish Advisory Science Panel composed of scientists from each of the Great Lakes states. The Panel issued its report in September 1995. The Panel supported the use of the HPV for women of childbearing age but judged that it was overly protective for other segments of the population. The Panel did not propose an alternative HPV, nor has the Task Force that developed the draft protocol initiated any effort to fill this need. For the 1998 Michigan fish consumption advisory, the MDCH is proposing use of the HPV for evaluating PCB levels in fish relative to consumption advice for women of childbearing age and children. For this sensitive population, fish would be placed into one of five advisory categories in a format consistent with those described in the draft protocol (Figure 2). The modified method of applying the FDA guidelines as described above would be used for the remainder of the population.

If a contaminant, other than PCBs, is detected at a level that would result in a more restrictive advisory using the current MDCH approach than that generated by the HPV for PCBs in the same samples, the more restrictive advice would apply for women of childbearing age and children. Each contaminant that exceeds a trigger level will be listed with the advisory, even though the advisory is based upon the contaminant that is most restrictive.

## RISK COMMUNICATION

Figure 3 represents a mock-up provided by MDCH of a proposed format for advisories to be issued in 1989. Note that it provides separate advice for the sensitive population and for the general population. It must be noted that the most recent contaminant data have not been incorporated into the mock-up. It is for illustration purposes only.

New language will be developed to incorporate appropriate recommendations from the MESB Special Fish Advisory Science Panel relative to improved risk communication, as well as using language and formats that other states have found to be effective as they have implemented the draft protocol. Special emphasis will be given to provide a better balance between health benefits from eating fish versus the risks.

The goal of MDCH is to not get people to eat less fish but to make informed decisions about the safest fish to eat and how to prepare them to minimize any potential risks.

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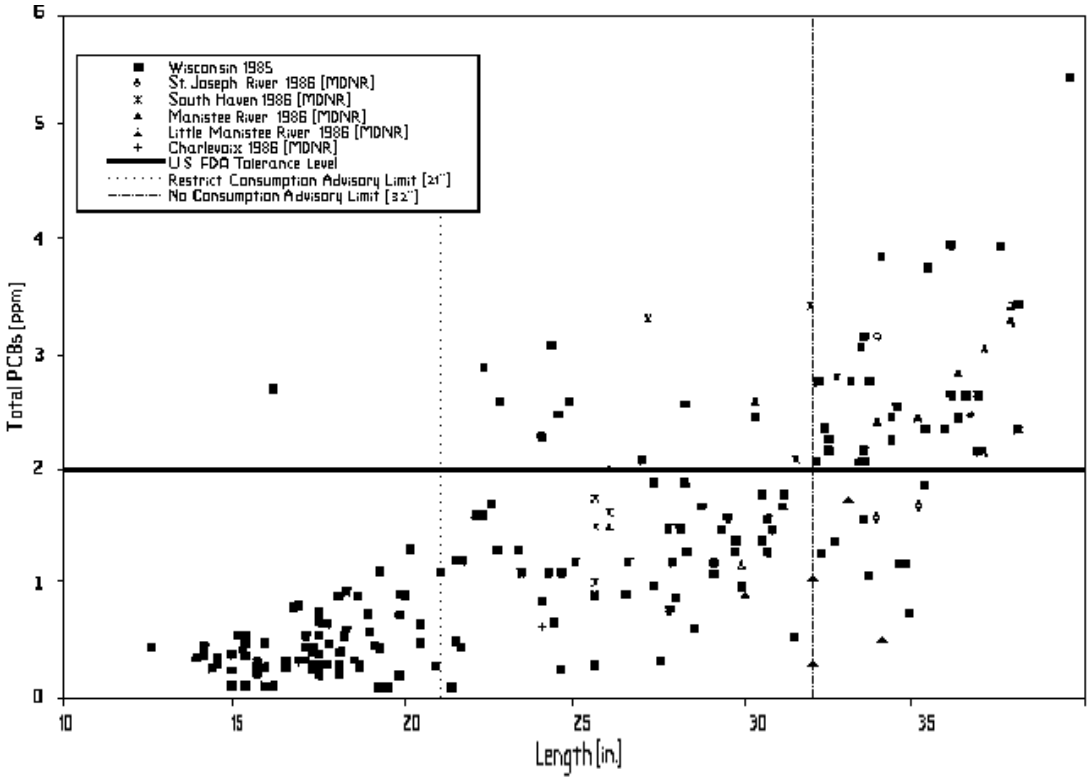
Table 1. List of contaminants and trigger levels currently used by MDCH in establishment of fish consumption advisories.

| Chemical | MDCH Advisory Trigger | |
|---|---|---|
| Chlordane | 0.3 | ppm[a] |
| DDT | 5.0 | ppm[b] |
| Dieldrin | 0.3 | ppm |
| Dioxin | 10.0 | ppt[c] |
| Endrin | 0.3 | ppm |
| Heptachlor | 0.3 | ppm |
| Mercury | 0.5 | ppm |
| Mirex | 0.1 | ppm |
| PCB | 2.0 | ppm[d] |
| Toxaphene | 5.0 | ppm |

a. Total chlordane isomers and related compounds.
b. Total DDT and metabolites (DDE and DDD).
c. Total chlorinated dioxins and furans as toxic equivalents of 2,3,7,8-tetrachlorodibenzodioxin (2,3,7,8-TCDD).
d. Total PCBs.

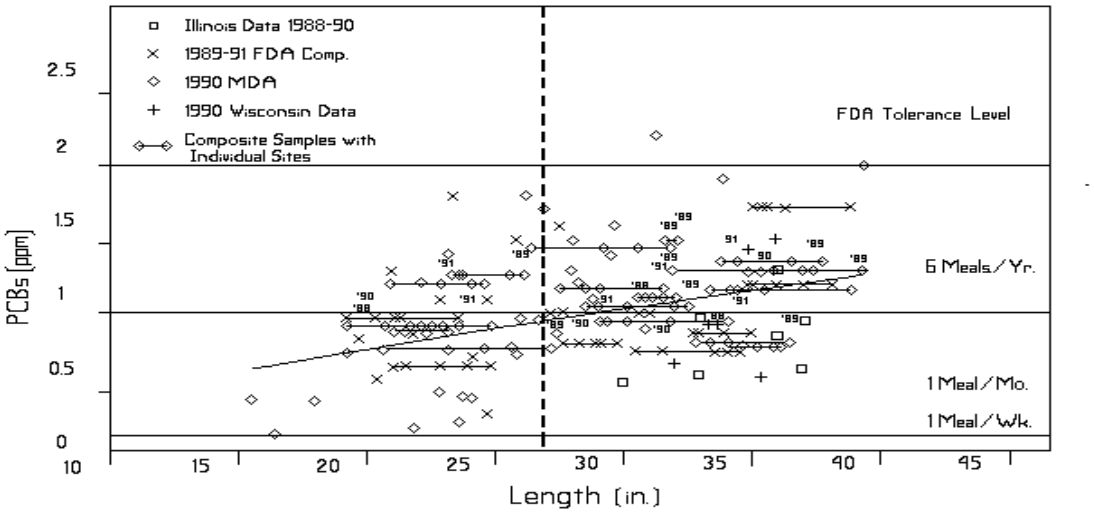
ppm = parts per million
ppb = parts per billion
ppt = parts per trillion

Figure 1. PCB concentrations vs. fish length in chinook salmon from Michigan and Wisconsin waters of Lake Michigan, 1985-1986.



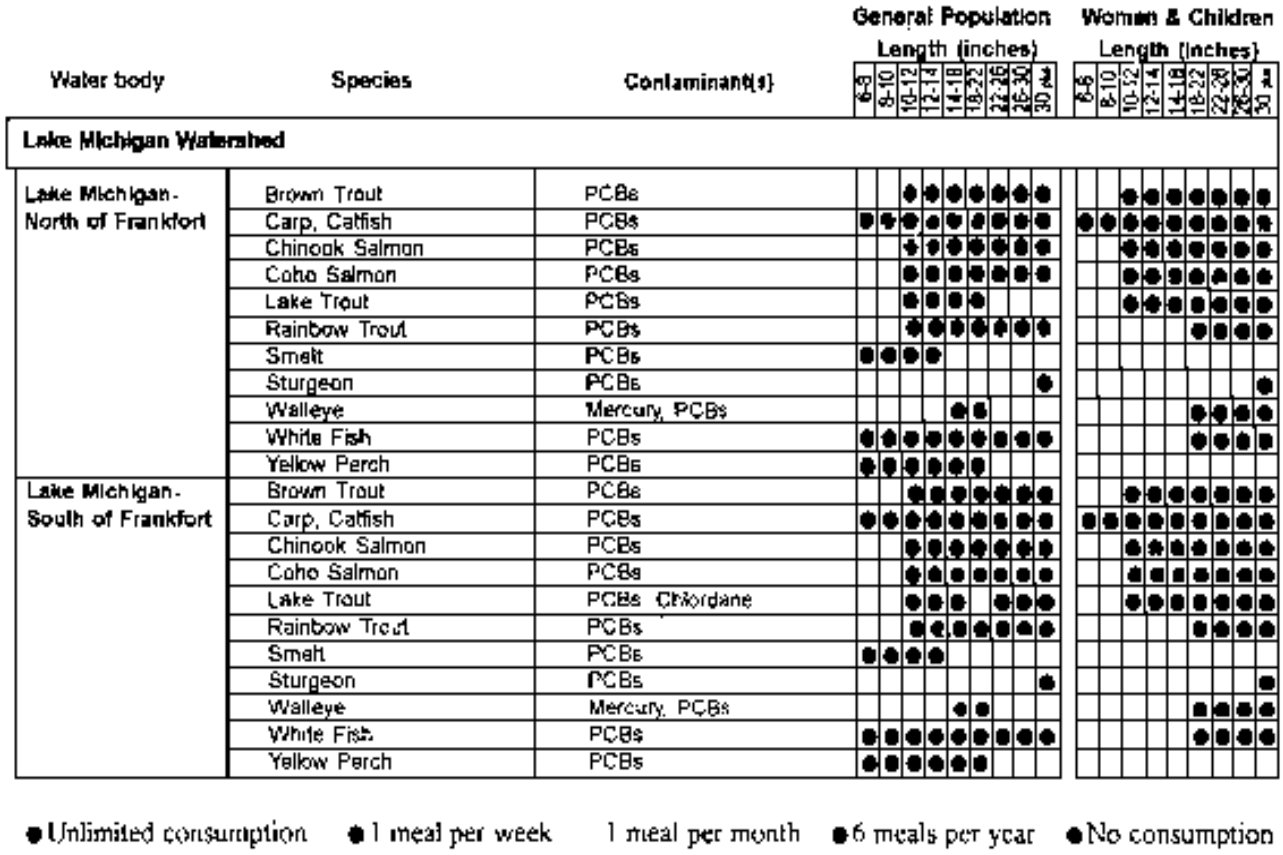

Note: The vertical dotted line represents the division between fish in the unrestricted consumption (less than 21 inches) and the restricted consumption categories (between 21 and 32 inches). The vertical dashed line represents the division between the restricted consumption (between 21 and 32 inches) and no consumption categories (32 inches or longer).

Figure 2. PCB concentrations vs. fish length in chinook salmon from Michigan, Illinois, and Wisconsin waters of Lake Michigan, 1988-1991, and tentative advisory categories using the Task Force proposed protocol.




Note: Fish to the left of the vertical dashed line (less than 27 inches) would be placed in the one meal per month category. Those to the right of the dashed line (27 inches or longer) would be placed in the six meals per year category.

Figure 3. Mockup of a proposed format for advisories to be issued in 1998.



## Appendix 4

## Risks to Less-Sensitive Populations from Consumption of Sport Fish Containing PCBs,

**Report prepared for the Michigan Environmental Science Board by Michael A. Kamrin, Ph.D., Institute for Environmental Toxicology, Michigan State University.**

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**RISKS TO LESS-SENSITIVE POPULATIONS FROM CONSUMPTION OF SPORT FISH CONTAINING PCBS**

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There are a wide variety of approaches that might be taken to developing a sport fish consumption advisory for less-sensitive populations. To provide an appreciation of the spectrum of possibilities, it is helpful to examine the approaches that are currently in effect or proposed in the Great Lakes states. Following a summary of these approaches will be a discussion of how the two components of the risk assessment process; toxicity assessment and exposure assessment, were applied in each approach. This comparison will illuminate the strengths and weaknesses of each advisory and provide guidance in arriving at a consumption advisory most appropriate for less-sensitive populations.

Alternative approaches

The first approach is that proposed by the Great Lakes Sport Fish Advisory Task Force (Task Force); namely to use a single advisory for both sensitive and less-sensitive populations. This advisory proposed by the Task Force is based on studies of reproductive/developmental effects and suggests a Health Protective Value (HPV), a value similar to an Acceptable Daily Intake, of 0.05 Tg/kg/day. The Task Force recommends using five different consumption categories with a lowest frequency category of one meal every two months. The Task Force HPV corresponds to a recommendation that fish with PCB contaminant levels of above 1.0 ppm but below 2.0 ppm should be eaten no more than six times per year (GLSFATF, 1993).

The second approach for less sensitive populations is that currently in effect in Michigan and being suggested by the Michigan Department of Community Health for use in the advisory for the upcoming 1998 fishing season. This approach utilizes the Task Force analysis for sensitive populations and proposes the current advisory as the model for less-sensitive populations. The advisory for these populations is based on a modification of the U.S. Food and Drug Administration (FDA) PCB tolerance level of 2.0 ppm for fish sold in interstate commerce. Under this approach, when more than 50 percent of the fish of a certain species and size range exceed the trigger level, no consumption is advised; when 11 to 49 percent exceed the trigger, non-sensitive populations are advised to eat no more than one meal a week; and when 10 percent or less exceed the trigger, there are no restrictions on consumption. Based on experience with this system, the 11 percent exceedence corresponds to a fish PCB contaminant level of about 1.0 ppm (Hesse, 1997).

The third approach is that taken by the Province of Ontario. This is also based on studies of reproductive effects and an evaluation by Health Canada of these studies. Health Canada determined that the Tolerable Daily Intake (TDI), again similar to an Acceptable Daily Intake, of 1 Tg/kg/day (Grant, 1983). The Ontario advisory includes five different consumption categories with a least frequent consumption category of one meal per month. The recommendation pertaining to fish containing between 1.0 and 2.0 ppm PCB is to restrict consumption to no more than two meals a month. This advice is applicable to both sensitive and less sensitive populations. Only for fish with PCB contaminant levels above 2.0 ppm is the advice more stringent for sensitive populations.

A fourth approach is that adopted by the state of New York. This is based on the FDA tolerance level and includes three consumption categories for less sensitive populations. Unlimited consumption is recommended for fish containing less than 2.0 ppm; one meal a month for fish containing 2.0 to 6.0 ppm; and no consumption for fish with over 6.0 ppm PCBs. For sensitive populations, there are just two categories. The recommendation is no more than one meal/week for fish up to 2.0 ppm and no consumption for fish with over 2.0 ppm PCBs.

The approach taken by the state of Indiana is the fifth one to consider. Indiana bases its recommendations for less sensitive populations on the Task Force report but uses a more stringent approach for sensitive populations. There are three consumption categories for such populations; do not eat fish containing greater than 0.21 ppm; eat no more than one meal a month of fish containing 0.06 to 0.20 ppm; and unlimited consumption for fish with less than 0.05 ppm PCBs.

Illinois' approach represents a mixture of approaches previously described. The Task Force approach is applied only to fish advisories for Lake Michigan: the current Michigan approach is applied to fish advisories for inland waters. Thus advisories for less sensitive populations are different from those for sensitive populations with regards to fish from inland waters but not for fish from Lake Michigan.

Examining these approaches, it can be seen that, for less sensitive populations, the recommended consumption levels of fish containing somewhat more than 1.0 ppm PCBs ranges from four meals a month in Michigan to one meal every two months in states that have adopted the Task Force recommendations. (Table 1) The range of recommendations for sensitive populations is shown in Table 2. Examination of some of the assumptions behind these advisories (Table 3) shows that there is not unanimity among the states.

While Tables 1, 2 and 3 reveal differences in the bases for the advisories, a close examination of the fish consumption advisories of the various Great Lakes states reveals other inconsistencies: (1) there are a number of inconsistencies in advice provided for the same species and size in the open waters of the same Great Lake (Tables 4, 5 and 6); (2) there are also inconsistencies in advice for consumption of fish in bodies of water that are not explicitly addressed in the advisory (Table 7); and (3) no one state or group of states are consistently more or less restrictive than other states. The variations from state to state are usually within a factor of four although this factor may be larger (but hard to assign an exact number to) when advice changes from specific to general; e.g., one meal a month changing to unlimited. It should be noted that this kind of change is widespread in states; e.g., Pennsylvania, which does not provide any general advice for consumption of fish not explicitly mentioned in the advisory. Thus, it appears that variability from state to state is, in a number of cases, greater than occurs due to the selection of one or another approach to developing the advisory; e.g., FDA vs. the U.S. Environmental Protection Agency (EPA). Considering this state of affairs, it is impossible to say that one state is more or less protective than another. Instead, it is clear that many factors influence the final advisory and the use of FDA or EPA values is only one part of the decision-making process.

Toxicological considerations

In keeping with the recommendations and proposals made during the last few years by the EPA (EPA, 1996) as well as other national groups, such as the National Academy of Sciences (NRC, 1994) and the Commission on Risk Assessment and Risk Management (P/CCRARM, 1997), the toxicity assessment will be based on an examination of all of the evidence rather than any one study.

a. Non-cancer effects

As indicated above, the current fish consumption advisories are generally based on reproductive/developmental effects. For example, all the human data and almost all of the animal data cited in the Task Force report are from studies of reproductive/developmental effects. Thus, the advisories are designed to protect the most sensitive populations; particularly, the fetus. They do not specifically provide guidance for less sensitive members of the population; e.g., adult males and women who cannot bear children.

The one study of adult animals (Tryphonas *et al.,* 1989), which really is part of a series of studies, that is relied on by the EPA in its Reference Dose derivation and mentioned by the Task Force reports on immunological effects in monkeys after PCB exposure. However, as discussed in the Michigan Environmental Science Board (MESB) report (Fischer *et al*., 1995), the "*biological significance of these results should be interpreted with caution*." The report also notes that even after considering

epidemiological studies, "*no conclusive evidence exists that exposure to these compounds in fish induces significant immune dysfunction in humans*."

Further, the MESB notes that based on human studies "*the developing fetus was reported to be markedly more vulnerable to low level environmental PCB exposure than the newborn child or adult*." It adds that "*Results from studies in animal studies in laboratory animals support this view*." Because no neurobehavioral effects were observed when exposure occurred postnatally in either animals or humans, it is not possible to quantitate this difference in sensitivity.

As pointed out by the MESB, the discussion in the Task Force report focused on effects to the most sensitive life stage, the fetus, and thus does not apply to females who are not capable of bearing children and to adult males. The Task Force report does not explicitly address the scientific rationale behind the decision to recommend one advisory for all populations. There is, however, a recommendation that careful adherence to the recommended time between meals as well as total number of meals is important for sensitive populations but less so for less sensitive populations.

b. Cancer effects

As indicated in various documents, such as the Task Force report, uncertainties in extrapolating cancer data from high dose laboratory animal studies to human exposures at environmentally relevant doses and the differences between the commercial mixtures of PCBs tested in the laboratory and the mixtures found in fish led all of the risk managers to choose to base advisories on non-cancer effects. Indeed, a reflection of these uncertainties is that the EPA has lowered its estimate of the potency of PCBs in the two years since the MESB report (EPA, 1997).

In addition, the EPA has published a possible approach for dealing with the differences between test mixtures of PCBs and those found in fish (EPA, 1996). This approach is based on a combination of analytical data on PCB congener compositions in fish and the concept of Toxicity Equivalents. This concept posits that a number of the PCB congeners act by the same mechanism as dioxin and vary only in potency. Thus, an overall assessment of toxicity can be gained by multiplying the concentration of each congener by its potency and adding these products up to get an overall dose measure. Then, in the case of cancer, the overall dose can be multiplied by the dioxin potency factor to calculate the risk from these congeners. The EPA suggests that the non-dioxin like congeners also be thought of as carcinogenic and the potency factor calculated from the commercial mixtures be applied to them to calculate the risk. The total risk would then be calculated by adding the risk from the non-dioxin like congeners to that from the dioxin like ones.

There are a number of problems with this approach, however. One is that it is not at all clear that the commercial mixture potency factor is applicable to the non-dioxin like congeners since it is derived from a mixture of dioxin like and non-dioxin like congeners. Second, it appears that these two types of congeners act by different mechanisms so it is questionable whether or not it is appropriate to add the risks of each together. Third, since all of the dioxin like congeners compete for the same receptor with each other as well as dioxin and other dioxin like compounds in the environment, it is not clear that simple addition will accurately reflect the potency of mixtures of such congeners.

At least as important, there are wide disparities in the values for the carcinogenic potency of dioxin. For example, Canada and European nations have published potency values that are two to three orders of magnitude lower than that published by the EPA (EPA, 1988). Since these values are all based on the same experimental data, this indicates that there is significant controversy about the best way to interpret these data. Such large differences in potency dwarf the differences in recommended consumption of contaminated fish among the Task Force, Ontario and FDA.

<u>Exposure considerations</u>

To utilize the HPV or TDI to derive fish consumption recommendations, it is necessary to make a number of exposure assumptions. Since the recommendations are provided in terms of meals consumed, the

size of an average fish meal must be decided. All approaches utilize the same fish meal size; i.e., ½ pound or 227 grams. A second exposure issue is whether or not to take into account reductions in PCB concentrations as a result of preparation and cooking. The Task Force adopted the policy of reducing the measured concentration by 50 percent to account for these reductions. Neither the traditional Michigan advisory nor the Ontario advisory include any reduction in exposure based on preparation and/or cooking.

A third exposure issue is whether or not to assume that the PCBs in fish represent the only sources of PCBs in the diet. If so, then the full HPV or TDI would be available from fish. If not, then the HPV or TDI would have to be reduced to take into account the other sources of PCBs so that the total exposure would not exceed the acceptable daily intake. The Task Force and the traditional Michigan approach assume that no other PCB sources need to be considered. Ontario, however, assumes that PCBs from sport fish represent only 50 percent of the total PCBs exposure. Thus, only half of the TDI, or 0.5 Tg/kg/day, is the maximum acceptable daily intake from fish.

It is informative to look at the implications of these differences in exposure assumptions on the advisory recommendations. If, for example, Ontario adopted the assumption that the measured levels should be reduced by 50 percent to account for preparation and cooking, then the maximum number of meals in each category in Table 1 would be doubled. On the other hand, if the Task Force adopted the Ontario assumption that only 50 percent of the HPV should be allowed from fish, then the maximum number of meals in each category in Table 1 would be halved. Each of these changes would essentially lead to assigning fish with a given level of contamination to a different category; in the extreme case it could change a fish into or out of the no consumption category.

Conclusion

Currently available toxicological data do not provide a clear basis for calculating an acceptable daily intake value for PCBs in less sensitive populations, either on the basis of carcinogenic or non-carcinogenic effects. However, the evidence can provide some guidance. In particular, both human and laboratory animal data strongly suggest that the adult is less sensitive to the effects of PCBs than the fetus. Thus, the HPV of 0.05 Tg/kg/day appears to be overprotective of less sensitive populations.

Since studies indicated that the same dose produced significant effects on the fetus and no effects in the post-natal period (Fischer *et al.,* 1995), and a factor of ten is assumed to be the usual ratio among experimental doses, a factor of ten between the dose causing effects in sensitive and less sensitive populations is reasonable. Using the Ontario approach which in turn is based on survey data, eight meals a month is considered the practical upper limit of consumption; i.e., greater than eight meals a month is equivalent to unlimited consumption. Substituting this value for unlimited on Table 1, it can be seen that all three approaches fall within this factor of ten.

When differences in exposure assumptions are taken into account, it can be even more clearly seen that risk management considerations appear to have a very important role in the advisory process. Thus, simplified statements about one or another advisory not being protective of health appear to be expressions of value judgments rather than based on scientific data.

Indeed, this analysis suggests that within the bounds of current knowledge, all three approaches are protective of less sensitive groups. Thus, other factors need to be considered in making a decision. Perhaps the most important one is risk communication. One of the basic rules of risk communication is that simpler messages are easier to communicate and lead to greater response than more complex ones. On this basis the traditional Michigan approach would be favored. In addition, if the traditional Michigan approach is adopted, anglers could be told that the system they are familiar with provides adequate protection for less sensitive populations but accumulating data suggest that it is prudent that the most sensitive individuals follow the more stringent advice proposed by the Task Force. This strategy might also be beneficial in preventing citizens from gaining the incorrect impression that scientists now know that the previous advisories were not protective of the health of most anglers. Such an impression could easily undermine citizen confidence in the government officials responsible for consumption advice and thus undermine compliance with future advisories.

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TABLE 1

COMPARISON OF 1997/8 FISH ADVISORIES: ADVICE FOR LESS SENSITIVE POPULATIONS

| | Fish PCB concentrations | | | | |
|---|---|---|---|---|---|
| Advice | **Task Force** | **Michigan**[†] | **Ontario** | **New York** | **Indiana** |
| Do not eat | >1.9 ppm | >2.0 ppm | >4.0 ppm | >6.0 ppm | >1.9 ppm |
| 1 meal/2 month | 1.1-1.9 ppm | NA | NA | NA | 1.1-1.9 ppm |
| 1 meal/month | 0.21-1 ppm | NA | 2.0-4.0 ppm | 2.0-6.0 ppm | 0.21-1 ppm |
| 2 meal/month | NA | NA | 1.0-2.0 ppm | NA | NA |
| 1 meal/week | 0.06-0.2 ppm | 1-2 ppm | 0.5-1 ppm | <2.0 ppm | 0.06-0.2 ppm |
| unlimited* | <0.05 ppm | <1 ppm | <0.5 ppm | <0.05 ppm | NA |

*Ontario defines unlimited as up to 8 meals/month
[†]Proposed for 1998-99
NA = Not applicable

TABLE 2

COMPARISON OF 1997/8 FISH ADVISORIES: ADVICE FOR SENSITIVE POPULATIONS

Fish concentrations

| Advice | **Task Force** | **Michigan** | **Ontario** | **New York** | **Indiana** |
|---|---|---|---|---|---|
| Do not eat | >1.9 ppm | >1.9 ppm | >2.0 ppm | >2.0 ppm | >0.21 ppm |
| 1 meal/2 month | 1.1-1.9 ppm | 1.1-1.9 ppm | NA | NA | NA |
| 1 meal/month | 0.21-1 ppm | 0.21-1 ppm | NA | 0.06-0.20 ppm | NA |
| 2 meal/month | NA | NA | 1.0-2.0 ppm | NA | NA |
| 1 meal/week | 0.06-0.2 ppm | 0.06-0.2 ppm | 0.5-1 ppm | <2.0 ppm | NA |
| unlimited* | <0.05 ppm | <0.05 ppm | <0.5 ppm | <0.05 ppm | NA |

_____

*Ontario defines unlimited as up to 8 meals/month
NA = not applicable

TABLE 3

COMPARISON OF FISH ADVISORY ASSUMPTIONS FOR PCBS

| Assumption | Jurisdictions that utilize this assumption |
|---|---|
| Due to cooking, preparation, etc., measured concentration in fish should be reduced by 50% | Illinois (Lake Michigan only), Ohio, Pennsylvania, Minnesota, Wisconsin |
| 50% reduction in allowable intake to account for non-sport fish PCB exposure | Ontario |
| Allowable intake should be same for all populations | Illinois (Lake Michigan only), Ohio, Pennsylvania, Minnesota, Wisconsin |
| Allowable intake should be less for sensitive populations | New York, Indiana, Ontario, Michigan, Ohio<br>Illinois (inland lakes only) |
| Advisory for adults based on calculated acceptable daily intake | Illinois (Lake Michigan only), Ohio, Pennsylvania, Minnesota, Wisconsin, Indiana, Ontario |
| Advisory for adults based on FDA standards for commercial fish | Illinois (inland lakes only), New York, Michigan |

TABLE 4

COMPARISON OF LAKE ERIE ADVISORIES

| Fish | **Pennsylvania** | **Ohio** | **Michigan** |
|---|---|---|---|
| Yellow Perch | Unlimited | Unlimited | no advice |
| Walleye<23" | One meal/wk | One meal/wk | no advice |
| Walleye>23" | One meal/month | One meal/wk | no advice |
| Drum | One meal/wk | One meal/wk | no advice |
| Coho | One meal/month | One meal/month | no advice |
| Rainbow Trout | One meal/month | One meal/month | no advice |
| Smallmouth Bass | One meal/month | One meal/month | no advice |
| White perch | One meal/month | One meal/month | no advice |
| White Bass | One meal/month | One meal/month | no advice |
| Lake Whitefish | One meal/month | no advice | no advice |
| Carp <20" | One meal/month | One meal/month | do not eat |
| Carp>20" | One meal/2 months | One meal/2 months | do not eat |
| Lake Trout | One meal/2 months | One meal/2 months | no advice |
| Catfish | One meal/2 months | One meal/2 months | do not eat |
| Chinook <19" | no advice | One meal/wk | no advice |
| Chinook >19" | no advice | One meal/month | no advice |

TABLE 5

COMPARISON OF LAKE SUPERIOR ADVISORIES

| Fish | **Minnesota** | **Wisconsin** | **Michigan** |
|---|---|---|---|
| Lake Trout <18" | One meal/week | One meal/week | Unlimited |
| Lake Trout 18-30" | One meal/month | One meal/month | Sens. Do not eat |
| Lake Trout >30" | One meal/2 months | One meal/2 months | Do not eat |
| Ciscowet <18" | One meal/2 months | One meal/2 months | Unlimited |
| Ciscowet >18" | Do not eat | Do not eat | Do not eat |
| Chinook <22" | One meal/wk | One meal/wk | No advice |
| Chinook >22" | One meal/month | One meal/month | No advice |
| Coho | One meal/week | One meal/week | No advice |
| Rainbow trout | Unlimited | unlimited | No advice |
| Brown trout | One meal/month | One meal/month | No advice |
| Lake Whitefish | One meal/week | One meal/week | No advice |
| Lake Herring | One meal/week | One meal/week | No advice |
| Smelt | Unlimited | One meal/week | No advice |
| Walleye | No advice | Unlimited | No advice |

TABLE 6
COMPARISON OF MICHIGAN AND WISCONSIN GREEN BAY ADVISORIES

| Fish | Wisconsin | Michigan |
|---|---|---|
| Brook Trout | no advice | **<14" unlimited, >14" do not eat** |
| Brown Trout | <14" one meal/month, >14" one meal/2 month | **<18" sens. do not eat, >18" do not eat** |
| Carp | do not eat | do not eat |
| Catfish | 1 meal/2 months | d**o not eat** |
| Lake Trout | no advice | **<22" unlimited, >22" sen. do not eat** |
| Northern Pike | <22" one meal/wk, >22" one meal/month | <26" unlimited, **>26" do not eat** |
| Rainbow Trout | one meal/month | <22" unlimited, **>22" do not eat** |
| Splake | <16" one meal/month, 16-20" one meal/2 months | <18" sen. do not eat, **>18" do not eat** |
| Sturgeon | do not eat | do not eat |
| Walleye | <17" one meal/month, 17-26" one meal/2 months | <18" unlimited, **>18" do not eat** |
| White bass | do not eat | do not eat |
| Yellow perch | one meal/wk | no advice |
| Smallmouth bass | one meal/month | no advice |
| Sucker | one meal/month | no advice |
| Chinook | <29" one meal/wk, >29" one meal/month | no advice |
| Whitefish | one meal/2 month | no advice |

*__Bold__ indicates advice that is more stringent in Michigan than in Wisconsin based on current Michigan advisory.

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TABLE 7

GENERAL ADVICE FOR WATERS NOT LISTED IN ADVISORY

| State (No. of Water Bodies Listed) | |
|---|---|
| Indiana (52 rivers or streams; 38 lakes) | "If you don't know the safety of the fish in the lake or river you are fishing Read the Summary of this Advisory (benefits and risks). Assume the fish are in a Group 2 Advisory (1 meal/week for adults and 1 meal/month for sensitive groups). Follow the cooking instructions provided" |
| New York (32 rivers or creeks; 29 lakes/ponds) | "The general health advisory for sportfish is that you eat no more than one meal per week taken from the state's freshwaters" |
| Pennsylvania (18 rivers or creeks; 3 lakes) | No general advice |
| Wisconsin (23 rivers; 7 lakes)* | "The majority of waters tested in Wisconsin do not contain contaminated fish that pose a health a health hazard" |
| Ohio (27 rivers or streams: 3 lakes) | "Low background levels of mercury were found in nearly all samples tested from various Ohio bodies of water. This has prompted the health department to advise that women of childbearing age and young children (age 6 and under)- eat not more than one meal per week of fish (any species) from any Ohio body of water" No general advice for other groups. |
| Minnesota (about 50 rivers; and >700 lakes) | "If you can't find your fishing location or fish in the tables follow the Guidelines to Reduce Your Health Risk: Keep smaller fish for eating; Eat fish that are less contaminated; Eat smaller meals when you eat big fish and eat them less often; Clean and cook your fish properly" |
| Michigan (30 rivers; 20 lakes) | "If you fish in waters and for species not listed in the chart, keep in mind the following: Larger and older fish tend to collect more contaminants; Fish that eat other fish tend to collect contaminants such as mercury; Fatty fish tend to collect PCBs and similar chemicals; Trimming fat from your fish during preparation and cooking will reduce the amounts of chemicals such as PCBs...there are no known ways to remove mercury from fish. |

* for PCBs

## Appendix 5

## Correspondence from
## Dr. Michael Bolger, U.S. Food and Drug Administration

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
200 C Street SW HFS-308
Washington DC 20204

November 12, 1997

Dr. Lawrence J. Fischer
Chairperson MESB
Institute for Environmental Toxicology
Michigan State University
C-231 Holden Hall
East Lansing, MI 48824-4603

Dear Larry:

The following are a few thoughts I had regarding the proposed change in the PCB trigger levels that the State of Michigan will use in issuing fishing advisories for women of childbearing age and children. I found the summary provided by Mr. John Hesse to be most useful. Mr. Hesse points out that for mercury and PCBs the State used a lower trigger level than FDA's action level for methylmercury (MeHg) and tolerance for PCBs. While it is true that the trigger level for mercury is one-half of the action level of I ppm for MeHg, the level of 2 ppm for PCBs is not different. What is different is how the trigger level of 2 ppm is used in prompting advisories for certain segments of the population. When 11 percent or more of fish samples for a particular species exceed 2 ppm, women of child-bearing age and children will be advised not to consume that species. The level of 2 ppm is identical to the FDA tolerance of 2 ppm. The State's proposal to adopt the PCB-HPV for fish advisories for women of child-bearing age and children is a reasonable one. The justification for this change is that scientific evidence indicates these are the most sensitive segments of the population. The evidence does not indicate that the HPV is appropriate for the rest of the population and this position is consistent with the 1995 report of the Special Fish Advisory Science Panel. In addition, the proposal to continue using 2 ppm as the PCB trigger level for the rest of the population is also a reasonable one. It provides continuity with the existing advisory program for the rest of the population, particularly where there is a lack of evidence that they have the same level of sensitivity to the effects of PCBs as women of child-bearing age and children do. It also provides some level of consistency to the tolerance level that is used for commercial species. It must be pointed out that the average level of fish consumption was not the only level of PCB exposure considered in formulating the PCB tolerance. This is a misconception I have often seen and heard, and one repeated by Mr. Hesse in his narrative, but it is incorrect. The lifetime risk of cancer and reproductive hazards was also considered for upper percentile levels of exposure (Cordle et al., Environ. Health Perspec. 45:171-182, 1982 - see Table 4). The tolerance is a standard which included a quantitative consideration of risk at different levels of PCB exposure, including upper percentile levels. The consideration of risk is part of several methodologies, including the HPV, reference dose, minimal risk level, establishment of tolerances, and all are therefore risk-based. They are different methodologies that are difficult to compare, but it is incorrect to say that some are risk based while others are not. The consideration of risk, whether it is zero, negligible or $1 \times 10^{-6}$ is part of these methodologies.

The continued use of a trigger level of 0.5 ppm for mercury appears to be a prudent public health position, particularly because of concerns regarding effects of MeHg on the developing fetus. At this point, there is no compelling reason to have a lower level. Evidence published from the on-going study in the Seychelles islands indicates the absence of MeHg-associated effects in this fish-eating population. The recent report from the study in the Faroe Islands probably has more to do with the effects of PCBs than it does with those of MeHg. All in all, the approach of using a trigger level of 0.5 ppm for mercury fish advisories can be supported by the available scientific evidence.

I hope you find these brief comments useful in your difficult task of providing guidance to your Governor's office on the proposed advisory procedure.

Sincerely yours,

Michael Bolger, Ph.D, D.A.B.T.
Chief, 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
(Tel.) 202-205-5234
(Fax) 202-260-0498
(email) mbolger@bangate.fda.gov

## Appendix 6

## Correspondence from
## Dr. Joseph L. Jacobson, Wayne State University

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Dr. Lawrence Fischer, Chair
Michigan Environmental Science Board
C-231 Holden Hall
East Lansing, Michigan 48824
Fax: 517-355-4603

October 28, 1997

Dear Dr. Fischer:

I am writing to reiterate my support for the use of the 0.05 HPV standard as a basis for advising women of child-bearing age, infants, and children regarding consumption of sport fish. That criterion is consistent with the data from our study indicating risk to fetal CNS development in the offspring of women with PCB body burdens of at least 1.0 μg/g (fat basis). Given that w have found virtually no adverse effect from exposure to much higher levels of PCBs transmitted via breast-feeding, there does not appear to be any need to use the stringent HPV standard for adult men and women beyond the child-bearing years. Continuing to adhere to the FDA 2.0 ppm tolerance level, therefore, seems appropriate for those groups.

Sincerely,

Joseph L. Jacobson, Ph.D.
Professor
Wayne State University
College of Science
Department of Psychology
71 W. Warren Avenue
Detroit, Michigan 48202
Tel. (313) 577-2800
Fax (313) 577-7636

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## Appendix 7

## Correspondence from
## Dr. Bette J. Premo, White Water Associates, Inc.

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WHITE WATER ASSOCIATES, INC.
Ecological Consulting and Environmental Laboratory Services
429 River Lane
P.O. Box 27
Amasa, Michigan 49903
Phone (906) 822-7889
Fax (906) 822-7977

October 23, 1997

Larry Fischer, Ph.D.
Institute for Environmental Toxicology
Michigan State University
C-231 Holden hall
East Lansing, Michigan 48824-1206

Dear Larry:

Thank you for the opportunity to provide comment on the Fish Consumption Advisory, I have reviewed Michigan's Advisory and those of other states, I also asked my 67 year old mother-in-law and my 12 year old son to read Michigan's advisory and give comment on their impressions. Both are fisherpersons and neither have read the advisories prior to this time. My comments and theirs are presented below.

The Michigan Department of Community Health Fish Consumption Advisory as presented in the 1997 Michigan Fishing Guide is a good start at presenting the needed information.

I appreciate the fact that this advisory is presented in the Fishing Guide because of its wide distribution to people who purchase a fishing license, however, the information is somewhat buried and by being placed in the back of the guide denotes not much importance. I also wonder how this information is transmitted to Native Americans who don't necessarily purchase licenses.

The chart of specific advisories is well presented and is easier to read and translate than those from any of the other states. There are also fewer sites listed than in the other states. I am left wondering whether the waters in our state are simply cleaner than the others or if we have not sampled as diligently.

In general, I enjoy the fewer number of pages in Michigan's advisory. It makes it much easier to wade through. However, perhaps a page more would cover the items listed below.

Other specific recommendations are given below:

**Diagram**

The diagram which describes that a fish has fat on its back, sides and belly is too small and confusing. According to that diagram there is no "safe" meat. It is difficult to see the dark areas that the arrows are pointing to.
(See Minnesota for better example)

**Soups**

Michigan's is the only advisory that states "Don't use fish to make soups". Is there any reason why fillet meat should not be used in soup.

**Define Meal**

In other advisories a fish "meal" is defined: “... one meal is assumed to be a half pound (8 ounces) of fish for a 150 pound person. Subtract or add 1 ounce of fish for every 20 pounds of body weight...”. Also the spacing of meals for women of childbearing age and children is specified in the US EPA 1997 Supplement. These items seem important to understand.

**How do contaminant's get into fish?**

The other advisories have at least a couple of sentences that describe how things like PCBs and mercury get Into a fish.

**What are health risks of eating contaminated fish?**

People can better evaluate their risk if they can be given information on what are the potential effects of these contaminants (see page 83 of Pennsylvania advisory). The childhood developmental problem potential may impact expectant mothers and other adults may be soothed to learn that in the case of cancer from PCBs that risk may only be 1/2,50-10,000 in eating a lifetime of fish.
Michigan's advisory does a good job of describing the health benefits of eating fish.

**Where does this information come from, why should I believe it?**

Just a few words that describe the current monitoring effort, EPA studies, etc. would help to frame the validity of the consumption advisories.

Thanks again for the opportunity to provide comment.

Sincerely,

Bette J. Premo, Ph.D,

## Appendix 8

## Correspondence from
## Dr. Eileen O. van Ravenswaay, Michigan State University

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**RECOMMENDATIONS FOR IMPROVING RISK COMMUNICATION**

**Prepared by Eileen van Ravenswaay, Michigan State University**

The Michigan Department of Community Health (MDCH) has made several major improvements to its fish advisory for 1997. The table format and color coding is much easier to read. However, a few more changes could significantly increase the effectiveness of the advisory in communicating risks. Recommended changes are itemized below.

1. The MDCH fish advisory isolates advice about avoiding mercury from the main table of advice about fish in specific water bodies. The text of the mercury warning is in a separate box which is not in color like the main table, and the font is identical to the rest of text in the pamphlet. This makes the mercury advice less prominent than the other advice. If it is meant to be equally prominent, it should be included in the table with the other advisories. For example, it could be incorporated as follows:

Water body - All Inland Lakes and Reservoirs not Listed in the Three Watersheds

| Species | Contaminant | Length (inches) | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | 6-8 | 8-10 | 10-12 | 12-14 | 14-18 | 18-22 | 26-30 | 30+ |
| Rock Bass | Mercury | | | | | | | | |
| Yellow Perch | Mercury | | | | | | | | |
| Crappie | Mercury | | | | | | | | |
| Bass | Mercury | | | | | | | | |
| Walleye | Mercury | | | | | | | | |
| Northern Pike | Mercury | | | | | | | | |
| Muskellunge | Mercury | | | | | | | | |
| Rock bass | Mercury | | | | | | | | |

2. The text about the chart of specific advisories explains that if a specific water body or kind of fish is not listed in the chart, anglers are to follow the general advice given on page one. However, in the symbol key for the colored dots, there is no explanation of what an empty box means. Individuals who do not read the text carefully may mistakenly conclude that empty boxes indicate no need for precaution. This possibility would be avoided if the restriction implied by the empty boxes were explained in the symbol key on the bottom of page two.

3. Since not all locations are tested, they are not included in the table. However, this could lead to confusion if anglers do not carefully read the text about what to do when a site is not listed. To avoid this confusion, include in each watershed section of the table a row for "all other locations" which directs the reader to look at the general instructions now listed in the four bullets of section 1 of the brochure or which is keyed to the empty box in the symbol key.

4. The diagram on how to prepare fish is very small and not in color. This suggests it is not very important. A separate insert that can be used during cooking would be useful.

5. The advisory is unclear about whether people are supposed to consider their consumption of commercial fish in counting the number of meals per time period. Whether intended or not, the advisory suggests that they should. For example, its title is "fish advisory" rather than "sport fish advisory." Similarly, the text repeatedly refers to the benefits and risks of "eating fish" or "eating Michigan fish" rather than "eating sport fish." This point needs to be clarified because research on anglers suggests that on average about two-thirds of their fish consumption is of commercial fish.

6. The second sentence of the fish advisory is misleading. There is no research showing that consumption of Michigan fish has beneficial health effects. Rather, research shows that fish consumption of all kinds is beneficial.

7. The purpose of the advisory is obscured by including statements about the benefits of fish consumption. It is not the purpose of the advisory to affect the **total amount** of fish people choose to consume. The purpose is to affect **which** fish people choose to consume **each time** they decide to eat fish. There are many choices people could make about where to fish, when to fish, what to fish for, or whether to buy fish rather than eat their catch. The purpose of the advisory is to help them make an informed choice each time they choose. This purpose needs to be clearly stated.

8. An informed choice would be aided by providing some relative risk information. For example, is eating one inland lake fish more risky for a fetus than having one alcoholic drink or four? Is eating one carp from Lake Erie more risky than smoking one cigarette or ten cigarettes?

9. The plan to have two versions of the fish advisory--one for women of child-bearing age and children and another for every one else--will reduce confusing abbreviations and clutter in the brochure and highlight the differences in risk associated with stage of life.

10. Since it is known that certain groups of individuals consume large amounts of sport fish, targeting geographic areas or media sources of those individuals may be warranted.

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## AVAILABLE REPORTS (1993 - 1998)

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Fischer, L.J., P.M. Bolger, J.L. Jacobson, B.J. Premo, E.O. van Ravenswaay and K.G. Harrison. 1998. ***Evaluation of Michigan's Proposed 1998 Fish Advisory Program,* January 1998**. Michigan Environmental Science Board, Lansing. vi + 67p.

Long, D.T., W.E. Cooper, W.B. Harrison III, R.H. Olsen, B.J. Premo and K.G. Harrison. 1997. ***Evaluation of Directional Drilling under the Great Lakes, October 1997***. Michigan Environmental Science Board, Lansing. 8p.

Fischer, L.J., R.Y. Demers, J. R. Harkema, R.H. Kummler, K.R. Rosenman, G.T. Wolff and K.G. Harrison. 1997. ***Evaluation of Air Quality and Human Health Issues involving Particulate Matter and Ozone, August 1997***. Michigan Environmental Science Board, Lansing. xii + 82p.

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Olsen, R.H., B.J. Premo and K.G. Harrison. 1994. ***(Report on Bacteriological and Macrophyte Contamination of Lake St. Clair), Correspondence to Governor John Engler, August 26, 1994***. Michigan Environmental Science Board, Lansing. 2p.

Fischer, L.J., R.J. Cook, R.Y. Demers, B.J. Premo, E.O. van Ravenswaay and K.G. Harrison. 1994. ***Impacts of Chlorine Use on Environmental and Public Health, June 1994***. Michigan Environmental Science Board, Lansing. xi + 67p.

Fischer, L.J., J.W. Bulkley, R.J. Cook, R.Y. Demers, D.T. Long, R.H. Olsen, B.J. Premo, E.O. van Ravenswaay, G.T. Wolff and K.G. Harrison. 1993. ***Mercury in Michigan's Environment: Environmental and Human Health Concerns, April 1993***. Michigan Environmental Science Board, Lansing. xiii + 144p.

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Copies of the above reports may be obtained free of charge by either writing to:

**Michigan Environmental Science Board**
**Knapps Centre, Suite 340, P.O. Box 30680**
**Lansing, Michigan 48909-8180**

or downloading from the MESB Internet Home Page at
**<http://www.great-lakes.net/partners/mesb/mesb.html>**