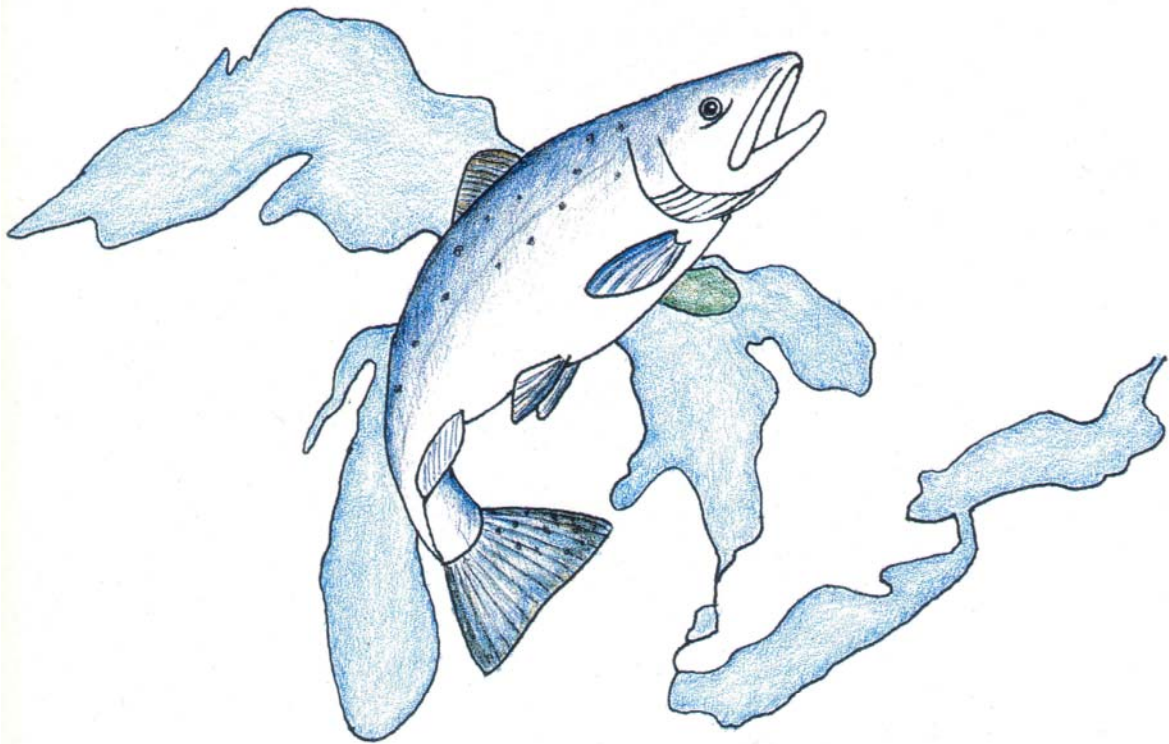


A Protocol for Mercury-based Fish Consumption Advice



An addendum to the 1993
“Protocol for a Uniform
Great Lakes Sport Fish Consumption Advisory”

May 2007

This “Protocol for Mercury-based Fish Consumption Advice: An addendum to the 1993 Protocol for a Uniform Great Lakes Sport Fish Consumption Advisory” is a product of the Great Lakes Consortium and only represents a consensus of the individual workgroup participants based on group discussions and review. Participants did not participate as official policy representatives of their state agencies but as knowledgeable and experienced individuals. Tribal and federal government representatives participated as observers. This document has not been officially reviewed or adopted by any participant’s State Health or Environmental Agency. An individual workgroup member’s agreement with the Final Draft does not represent a commitment by the state to adopt the protocol.

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Great Lakes Fish Advisory Workgroup Members

Co-Chairs:

Henry Anderson	Wisconsin Division of Public Health
Pat McCann	Minnesota Department of Health

Participants:

Jim Stahl	Indiana Department of Environmental Management
LaNetta Alexander	Indiana State Department of Health
Tom Hornshaw	Illinois Environmental Protection Agency
Robert Day	Michigan Department of Environmental Quality
Joe Bohr	Michigan Department of Environmental Quality
Kory Groetsch	Michigan Department of Community Health
Tony Forti	New York State Department of Health
Mylynda Shaskus	Ohio Environmental Protection Agency
Robert Frey	Pennsylvania Department of Environmental Resources
Thomas Barron	Pennsylvania Department of Environmental Protection
Candy Schrank	Wisconsin Department of Natural Resources
Dyan Steenport	Wisconsin Division of Public Health

I. Introduction

The Council of Great Lakes Governors' Toxics Agreement of 1986 established the goal of common fish consumption advisories on the Great Lakes. The Council's Fish Consumption Advisory Task Force, with representation from each of the eight Great Lakes States, was assigned the task of developing a single method for assessing risks and issuing fish consumption advisories. The Task Force developed the "Protocol for a Uniform Great Lakes Sport Fish Consumption Advisory" (hereafter referred to as the Protocol) for preparing polychlorinated biphenyl (PCB)-based fish advisories for the Great Lakes. In September 1993 the Protocol was submitted to the Council of Great Lakes Governors (Anderson, 1993). This document is an addendum to the Protocol and covers the addition of mercury to the Protocol and focuses on mercury-based advice for the sensitive population.

The Protocol was developed to promote consistency in the methods used by the Great Lakes States in issuing fish consumption advice. Consistency promotes public comprehension, acceptance and adherence to fish consumption advice. Due to the prevalence of fish consumption advice for PCBs in the Great Lakes, the Great Lakes States chose PCBs as the first group of chemicals for which they would develop a consistent method for issuing consumption advice with primary focus on the shared Great Lakes. Whereas the goal of the Protocol was focused on developing the same PCB-based advice for each Great Lake to be issued by each adjoining state, a uniform protocol for mercury would address inland waters and would not result in the same advice for inland waters. While a protocol can provide consistent methods for advisory determination, differences in actual advice may exist due to differences in species occurrence, contaminant concentrations, and other factors including implementation issues and differences in risk evaluations.

The Protocol has been instrumental in providing a common fish advisory methodology and communication structure for Great Lakes States. The states periodically coordinate communication strategies, joint outreach campaigns and advisory awareness evaluation projects. These efforts have only addressed PCB and other halogenated organic fish contaminants. There has been no mechanism to advance a coordinated mercury communication strategy in the Great Lakes States. Through a grant from U.S. EPA, Wisconsin organized a meeting in the fall of 2004 in Madison and follow-up conference calls to facilitate the development of the Protocol's mercury addendum. A survey to determine the current mercury advisory methods used by states was completed prior to the meeting in Madison.

Mercury is a ubiquitous contaminant in fish. All the Great Lake States issue fish consumption advice based on mercury levels in fish. Therefore a consistent approach for issuing these advisories will be helpful in providing advice to the public. Development of a uniform Great Lakes protocol for mercury-based fish advisories also advances the objectives and supports the goals of many Great Lakes programs and initiatives for shared resources including: the U.S. Policy Committee's Great Lakes Strategy, State of Lakes

Ecosystem Conference (SOLEC) indicators, International Joint Commission (IJC) recommendations and the Great Lakes Regional Collaboration.

Fish consumption advisory program staff from state agencies in the Great Lakes basin developed this addendum. Prior to beginning development it was important to systematically characterize current advisory practices. The eight states adjoining the Great Lakes were surveyed to determine differences in current protocols to develop advice as of September 2004. Each of the eight Great Lakes States currently provides both site-specific and statewide consumption advice based on fish mercury content. Statewide advice in some states is based on other chemicals as well. Most of the Great Lakes states provide separate advice for the general and sensitive populations. Other protocol components vary between states such as meal advice categories used, significant figures, listing of site-specific versus statewide advice, and how fish tissue concentration data are analyzed. While differences in protocols to develop advice exist, differences in species occurrence and mercury accumulation, and fishing habits and regulations may be valid reasons for fish consumption advice to vary between states. Results from the survey are reported in Appendix B.

Like the PCB Protocol, this addendum recommends a Health Protection Value (HPV) and provides guidelines for deriving consumption advice for mercury-based advisories. The current U.S. EPA reference dose (RfD) is the proposed Great Lakes HPV for mercury for the sensitive population. Given current levels of mercury in fish, use of this RfD to determine fish consumption advice results in advice to limit the frequency of consumption of most predator fish. Future addenda will address mercury advice for the general population.

Not all elements of the Protocol are included in this addendum. Many elements of the Protocol address advisory structure and apply to any chemical (body size, meal size, meal frequencies). Some of these elements may need to be reexamined occasionally if additional information is available. Other elements may need to be modified specifically for the chemical (e.g. reduction of contamination levels in fish via trimming and cooking). The addition of mercury to the Protocol requires review of specific elements of the risk assessment component of the Protocol and necessitates addressing issues related to general, statewide or regional advisories and advice for purchased fish.

The states agreed to update the statement on benefits and data analysis components of the Protocol in this addendum. The updated benefits statement emphasizes the current American Heart Association (AHA) recommendation of two or more meals of fish per week and provides specific reasons for people (particularly pregnant women) to continue to eat fish.

Meal frequency advice categories were also evaluated to address the meal categories of FDA/U.S. EPA's national advice for purchased fish and to address consistency between the PCB protocol (site-specific), general mercury, and site-specific mercury advice.

In addition, consumption advice for purchased fish is also addressed in this addendum. Since mercury is present in all fish, merging of advice for purchased fish with the advice for locally caught fish provided on a state or local scale is an issue for mercury-based advisories. PCB-based advice ranges widely from site to site depending on past contamination issues and is not an issue for all fish.

II. Background on Mercury

Mercury is an element in the earth's crust. Mercury is released into the atmosphere during natural processes such as forest fires and volcanic eruptions. Some of the mercury in fish is from these natural sources. Mercury is also released during human activities such as when fossil fuels are burned to create electricity, during taconite processing and when products containing mercury are burned.

Mercury released into the atmosphere is mainly in elemental or inorganic forms. Mercury in the atmosphere can travel long distances. When mercury is deposited to an aquatic environment bacteria can convert it to an organic form, methylmercury. Methylmercury can accumulate in fish via bioaccumulation. Fish that are long-lived and higher on the food chain contain the highest levels of methylmercury. Consumption of fish is the major source of human exposure to methylmercury. Mercury in fish is primarily the methylmercury form. Total mercury is typically quantified and used as the endpoint to evaluate methylmercury ingestion from fish.

Human poisonings in Japan from eating contaminated fish in the 1950's and in Iraq from eating bread made from mercury contaminated seed grain in the 1970's brought world attention to the bioavailability, bioaccumulation and the toxicity of methylmercury. The neurotoxicity of methylmercury is well established through studies of these populations and animal studies. It is generally accepted that neurodevelopmental effects represent the most sensitive toxicological end-points from exposure to methylmercury. Large-scale epidemiological studies have been undertaken and are continuing to ascertain long-term low dose effects and a no-effect level for methylmercury. These and potentially other studies may continue to refine this information.

III. Original Great Lakes Protocol Components

The following is a list of the components included in the Protocol. Bolded components are updated in this addendum for mercury.

Advisory Introduction Components

- 1) General statement about contaminants, benefits, and hazards
- 2) Statement on cancer risk
- 3) **Statement on benefits of fish consumption**
- 4) Preparation and cooking advice

Consumption Advice Components

- 5) Meal unit dose reduction
- 6) Uniform meal size
- 7) **Easily understood meal frequency advisory groups**

Hazard Identification Components

- 8) Fish flesh sample collection protocol for residue analysis
- 9) Uniform limits of detection
- 10) **Fish size and contaminant concentration based consumption categories**
(Methods to examine data and determine appropriate advice.)

Risk Assessment Components

- 11) **Risk assessment for assigning fish to consumption frequency groups** (The health protection value and associated tissue residue concentrations)
- 12) Multiple contaminants

Prospective Advisory Items

- 13) Uniform method for deciding when to shift size/species class into another advisory category
- 14) Coordinate release of annual advisory

IV. Statement on benefits of fish consumption

There are eight points that should be included in a benefit statement for fish consumption. These points are:

- 1) Fish are a good source of protein (Gebhardt, 2002).
- 2) Fish are typically low in saturated fat (Gebhardt, 2002).
- 3) Fish are the main dietary source of long-chain omega-3 fatty acids (Kris-Etherton, 2002).
- 4) Fish are a good source of many vitamins and minerals (Gebhardt, 2002).
- 5) Nutrients from fish are believed to help prevent cardiovascular disease (Kris-Etherton, 2002).
- 6) Nutrients from fish are important for healthy fetuses (Holman, 1991).
- 7) The majority of benefits is achieved with modest fish consumption (one or two 4-6 oz servings per week) and may outweigh the risks to adults especially when high contaminant fish are avoided (Mozaffarian, 2006).
- 8) American Heart Association recommends at least two fish meals per week (AHA, 2005).

Example Benefits Statement:

Fish can be part of a healthy, balanced diet. Fish are generally low in saturated fat and high in protein. Fish contain a number of vitamins and minerals, and are the primary food source for omega-3 fatty acids. Studies suggest that omega-3 fatty acids may be beneficial

during fetal brain and eye development, and modest consumption of fish containing omega-3s may lower the risk of heart disease in adults. Health experts recommend that regular consumption of fish be included as part of a healthy diet.

V. Risk Assessment

Much of the information in this risk assessment section has been taken from the U.S. EPA Water Quality Criterion for the Protection of Human Health: Methylmercury (U.S. EPA, 2001). Information in the Water Quality Criterion was mainly taken from the Mercury Study Report to Congress (MSRC) (U.S. EPA, 1997b-h) and the National Academy of Sciences National Research Council report, Toxicological Effects of Methylmercury (NRC, 2000).

The primary source of human exposure to methylmercury is through consumption of fish (U.S. EPA, 1997c). This reflects the tendency of aquatic organisms to bioaccumulate methylmercury. Fetuses may be exposed transplacentally and infants may be exposed to methylmercury through ingestion of breast milk (ATSDR, 1999).

Methylmercury is efficiently absorbed from the gastrointestinal tract and is readily absorbed into the blood and distributes to all tissues. Approximately 90% of the absorbed dose of methylmercury is excreted in the feces (U.S. EPA, 1997e). Urinary excretion is minor. The estimated whole body half-life of methylmercury in humans reported by U.S. EPA is between 70 and 80 days (U.S. EPA, 2001).

Mercury is incorporated into the hair of exposed humans and animals. Hair analysis is a tool for monitoring exposure to methylmercury. Information from physiologically-based pharmacokinetic (PBPK) modeling is utilized to estimate the relationship between the measure of exposure used in epidemiological studies (mercury in hair and blood) and the daily ingested dose (U.S. EPA, 2001).

Methylmercury is toxic at elevated doses to humans and animals and causes a variety of adverse effects. There are no data to indicate that methylmercury is carcinogenic in humans. It induces tumors in animals only at high doses. According to the Guidelines for Cancer Risk Assessment methylmercury would be classified as not likely to be carcinogenic for humans under conditions of exposure typical in the environment (U.S. EPA, 2001).

U.S. EPA has developed a reference dose (RfD) for methylmercury. This is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious health effects during a lifetime. U.S. EPA has published three separate RfDs for methylmercury since 1985 (U.S. EPA, 2001). All were based on human studies.

The critical end-points from the original RfD of 0.3 µg/kg/day, published in 1985, were central nervous system (CNS) effects, including ataxia and paresthesia in Iraqi adults exposed to methylmercury through consumption of bread made from contaminated seed grain (summarized by Clarkson et al., 1976; Nordberg and Strangert, 1976; and WHO, 1976). The RfD for methylmercury was determined based on a Lowest-Observed-Adverse-Effect-Level (LOAEL) of 0.003 mg/kg-day (corresponding to 200 µg/L blood concentration) and an uncertainty factor (UF) of 10 to adjust the LOAEL to a No-Observed-Adverse-Effect-Level (NOAEL). An additional UF of 10 for sensitive individuals for chronic exposure was not thought to be necessary, as the adverse effects were seen in what was thought to be the most sensitive group.

In 1995 U.S. EPA established an RfD of 0.1 µg/kg/day to be protective of infants born to mothers exposed to methylmercury during pregnancy. The analysis for the RfD used the combined incidence of all neurological effects in children exposed in utero in IRAQ. Data by Marsh et al. (1987) summarize clinical neurologic signs of 81 mother-and-child pairs. Maternal hair mercury concentration was used as the exposure metric. Using several default assumptions, a benchmark dose (BMD) of 11 ppm maternal hair mercury was converted to a maternal exposure level of 44 µg mercury/L blood using a 250:1 ratio (U.S. EPA, 1997e). A composite UF of 10 was used. This UF was applied to account for variability in the human population, in particular the wide variation in biological half-life of methylmercury and the variation that occurs in the hair-to-blood ratio for mercury. In addition, the UF takes into account lack of a two-generation reproductive study and lack of data for possible long-term sequelae.

At the time the 1995 RfD was published data from new large scale epidemiological studies of seafood-consuming populations in the Seychelles and Faroe Islands had either not been published in the peer-reviewed press or not been subjected to rigorous scientific review.

In 2001 U.S. EPA re-evaluated the methylmercury RfD. This revision was in response to a congressionally mandated evaluation of an appropriate RfD for methylmercury by the National Research Council (NRC). The NRC report made several recommendations on the appropriate basis for a revised RfD (NRC, 2000). The Committee reviewed three epidemiological longitudinal developmental studies: the Seychelles Islands, the Faroe Islands, and the New Zealand Study which had recently been peer reviewed and intensively analyzed. All three studies are well designed and carried out. However, some results from these studies are in conflict. None of the factors that have been suggested to account for the finding of adverse outcomes associated with in utero mercury exposure in the Faroes and New Zealand studies, and the lack of this association in the Seychelles Islands study, adequately explains the differences in the study outcomes.

The NRC recommended use of data from the Faroe Islands study for derivation of the RfD (NRC, 2000). The NRC also recommended BMD analysis as the most appropriate method of quantifying the dose-response relationship and recommended use of the Boston Naming Test (BNT) as the critical endpoint. The lower bound on the 5% response rate (BMDL) for the BNT from the Faroe Islands study is 58 ppb mercury in cord blood. NRC recommended that an UF of at least 10 be used. A factor of 2 to 3 was recommended for

biological variability in dose estimation. They also recommended an additional factor to account for data gaps relating to possible long-term neurological effects not evident in childhood, as well as possible effects on the immune and cardiovascular systems (NRC, 2000).

U.S. EPA used a composite UF of 10 for its RfD. A factor of 3 was applied for pharmacokinetic variability and uncertainty in estimating an ingested mercury dose from cord blood. Additional areas of concern including possible long-term sequelae, lack of a two-generation reproductive study, and selection of critical effect (concern that there may be observable cardiovascular or immunological effects at exposures below the BMDL), support the use of an overall UF of 10.

For the most part U.S. EPA incorporated the recommendations of the NRC and a peer-review panel in the development of the 2001 RfD. The NRC committee reached consensus that the value of U.S. EPA's current 1995 RfD for methylmercury, 0.1 µg/kg/day, was a scientifically justifiable level for the protection of public health. However, the committee recommended that the Iraqi study no longer be used as the critical study for developing the RfD (NRC, 2000). U.S. EPA and NRC both agreed that a positive study, one that shows statistically significant associations between prenatal mercury exposure and adverse outcomes, is the strongest public health basis for an RfD. The critical endpoint for the U.S. EPA 2001 methylmercury RfD is developmental neurotoxicity in 7-year-old children in the Faroe Island Study. The U.S. EPA RfD of 0.1 µg/kg bw/day reflects the range of neuropsychological test results in the Faroese children exposed in-utero. These neuropsychological tests are indicators of the ability of a child to learn and process information.

VI. Meal Frequency Advisory Groups

Many states separate advice for eating mercury-contaminated fish into two tiers, one for the sensitive population and one for the general population. The sensitive population is generally defined by states as women of childbearing age and children. The age of children included in the sensitive population is not consistent. For states that use this tiered approach, the 1985 U.S. EPA RfD is generally used to derive advice for the general population and advice for the sensitive population is developed using the current 2001 U.S. EPA RfD. This tiered approach is used by states in an effort to not restrict women beyond childbearing age and men to the levels of consumption recommended to women of childbearing age and children, because there are many reported benefits to fish consumption and data may not support the more restrictive advice for men. Future assessments of adverse effects in adults, cardiovascular effects in particular, may result in changes to this approach. However, to date an adequate dose-response evaluation for cardiovascular effects has not yet been conducted.

The survey of the Great Lakes States in August of 2004, Appendix B, showed that six of eight states used a two-tier approach to provide mercury-based fish consumption advice. Three of these six used the 1985 and 2001 RfDs as described above [Minnesota,

Wisconsin, Illinois]. Indiana uses a slightly different HPV that was developed by the Minnesota Department of Health for the sensitive population prior to the 1995 U.S. EPA RfD revision. Michigan uses a modified FDA action level approach. New York State considers several factors when deriving fish advisories, including sample and analytical data characteristics, health risk assessment, U.S. FDA marketplace standards, etc. (For more details, see Supplemental Information on New York State Advisories at the end of Appendix B). Pennsylvania's and Ohio's consumption advice is constructed based upon safe limits for the sensitive population using the 2001 U.S. EPA RfD, and is uniformly applied to the general population.

As a starting point, the Great Lakes States agreed to work towards developing a uniform protocol for mercury-based fish advisories for the sensitive population. This addendum focuses on mercury-based advice for the sensitive population. The current U.S. EPA RfD of 0.1 µg Hg/kg/day is the proposed Great Lakes HPV for mercury for this population. The sensitive population is defined as women of childbearing age and children under age 15. Future addenda will address mercury advice for the general population.

A. Assumptions

The following assumptions are used in calculating mercury concentrations corresponding to meal frequency groups.

- 1) Health Protection Value = 0.1 µg Hg/kg/day
- 2) Assume a constant ratio between body weight and meal size. A consumer who is 70 kg is assumed to eat a meal = 227 g (1/2 lb) uncooked fish. This ratio is assumed to stay constant i.e. if a person weighs more they would eat proportionately more and one who weighs less would eat proportionately less.
- 3) Five advisory groups (meal frequencies) available to choose from = unrestricted (225/yr); 2/wk; 1/wk; 1/mo; none.
- 4) Assume skinning/trimming/cooking does not reduce residues. Mercury accumulates in muscle tissue, not fat. Mercury concentrations in the fillet are not expected to be reduced by cooking or cleaning (Morgan et al, 1994).
- 5) Methylmercury concentration is equal to total mercury measured in fish tissue.

B. Calculation of Maximum Daily Hg Ingestion When Following Advisory

The goal of the advisory is to keep dietary Hg ingestion on average below 0.1 µg Hg per kg body weight per day. For a 70 kg person this equals 7 µg Hg/day.

$$0.1 \mu\text{g Hg/kg/day} \times 70 \text{ kg body weight} = 7 \mu\text{g Hg/day}$$

Advisory Calculations

(Using the body weight to meal size ratio assumption from Section VI.A.)

- Unrestricted Consumption (\Rightarrow 225 meals/yr = 18.75/mo = 140 g fish/day)
Keep intake $< 7 \mu\text{g Hg per day} / 140 \text{ g fish/day}$
 $< 0.05 \text{ ppm Hg in raw fish filet}$
- Two meals/week (104 meals/year = 64 g fish/day)
Keep intake $< 7 \mu\text{g Hg per day} / 64 \text{ g fish/day}$
 $\leq 0.11 \text{ ppm Hg in raw fish filet}$
- One meal/week (52 meals/year = 32 g fish/day)
Keep intake $< 7 \mu\text{g Hg per day} / 32 \text{ g fish/day}$
 $\leq 0.22 \text{ ppm Hg in raw fish filet}$
- One meal/month (12 meals/year = 7.4 g fish/day)
Keep intake $< 7 \mu\text{g Hg per day} / 7.4 \text{ g fish/day}$
 $\leq 0.95 \text{ ppm Hg in raw fish filet}$
- No Consumption
 $> 0.95 \text{ ppm Hg in raw fish filet}$

VII. Contaminant Concentration Based on Meal Frequency Categories

Proposed meal frequency categories presented in the Protocol for a Great Lakes Fish Consumption Advisory (for PCBs) and in this addendum are options for consideration by the Great Lakes States. Some states may not adopt some of the categories because of conflicts this would present with other (e.g., general) advisories. Other issues may also be involved.

Mercury-based advice may be developed for a specific site or for a species, region, or state (general advice). The original Protocol for PCBs was developed for the Great Lakes and therefore was site-specific in nature. Site-specific advice is developed with contaminant data for fish from a specific waterbody. General advice should be easy to remember and may apply to waters for which no specific information is available. This is an example of one rationale for having different meal categories for site-specific and general type advisories.

A general advisory is any type of advice that provides consumption information for an entire species or group of species or sizes of a species and applies to a group or type of water. So, general advice is applied to a species or type of fish and a type/location of waterbody. Examples of general advice would be: walleye $> 18''$ from the inland lakes - 1 meal per month; panfish from all inland waters - 1 meal per week; or, carp from major rivers - 1 meal/month. The term statewide is a modifier of a general advisory. A general advisory could be applied statewide, to certain types of waterbodies, or a group of

waterbodies. As a result, statewide would not be used to describe the type of advice but rather to general advice that applies statewide. Regional advisories are another type of general advisory. For example, in New York women of childbearing age and children under the age of 15 are advised to avoid eating certain fish species from Adirondack and Catskill regions. This regional advice was issued because certain fish species from these regions have higher mercury levels than other fish species and the same fish species from other regions of the state.

A site-specific advisory is a set of advice that applies to one or more species for a particular named waterbody and is based on site-specific data for that location.

The Protocol for PCB-based advice provides guidelines for 5 meal frequencies: unlimited, 1 meal per week, 1 meal per month, 6 meals per year, and do not eat. The meal frequencies were what the original Council’s Fish Consumption Advisory Task Force thought the public could more easily remember (1 meal per week, 1 meal per month); would inform the public where to fish and what to eat and which species/locations to avoid (do not eat). In addition, the task force wanted to provide information to occasional fish eaters.

The mercury-based general and site-specific advisories primarily followed the same format. However, the six meals per year advice is not included as an option and a two meals per week option was added. Providing advice that addresses benefits as well as risk warrants adding the two meals per week meal frequency category. Indiana, Minnesota and Wisconsin currently provide two meals per week advice for purchased fish. In addition recent federal commercial fish consumption advice has a meal frequency category of two meals per week for several commercial species. Eliminating the six meals per year advice for mercury makes the “do not eat” cut-off equal to the FDA action level and addresses the issue of bolus doses.

Meal Frequency Categories versus Mercury Concentration

Fish Meals	Fish Mercury Concentration (ppm)
Unrestricted	0 ≤ 0.05
2 meals/week	>0.05 ≤ 0.11
1 meal/week	>0.11 ≤ 0.22
1 meal/month	>0.22 ≤ 0.95
No Consumption	>0.95

VIII. Evaluation of Edible Portion Fish Contaminant Data for Determining Meal Frequency Consumption Advice

The development of site-specific sport fish consumption advisories and general advisories for a state or region can be accomplished using a variety of methods depending on the quantity and characteristics of the data and site specific or regional considerations. This section includes some methods that could be used to develop site specific or general mercury advisories. However, none of these suggestions are meant to be prescriptive. Lastly, the resulting advice would ideally be reviewed by local biologists who manage the waters and be examined in the context of applicable fishing regulations, catch rates, consumption information, and other factors.

A. Site-Specific Advisories

Different approaches to examine fish contaminant data may be appropriate when developing site- and species- specific consumption advisories. In many cases, the different approaches will result in the same determination of appropriate advice. Mercury concentrations in fish tend to be variable and dependent on the species and length (or age) of the fish as well as the waterbody. In addition, sample sizes and sampling protocol may vary between sites. For example, individual samples are collected at most sites but composite samples are collected in some instances. Wide distributions of lengths are targeted but not always available and sample sizes may vary depending on the availability of a particular species of interest. Also, the history of the site may dictate the sampling protocol and may influence final decisions regarding the development or modification of sport fish consumption advisories.

The following techniques could be considered and use of more than one approach may be advantageous in some cases:

Length Versus Concentration and Regression Models

Mercury concentrations often increase with the size of the fish and this relationship should be examined when developing species/site-specific advisories. Consumption advice could be determined using the regression equation that describes the relationship between size and mercury concentration to solve for the sizes of the species that falls under the meal frequency category. Mercury relationship with length may be more characteristic of long-lived piscivorous species like walleye, northern pike, trout, or some species of bass. Site-specific regression models can be used to quantify the relationship between mercury concentrations and fish size in cases where fish contaminant data conform to the underlying assumptions of this statistical method. For example, linear regression models require a linear relationship (or a relationship that can be made linear using data transformations) between fish size and mercury concentrations as well as homogenous concentration variance across the range of fish sizes. In addition, uncensored data, single samples (as opposed to composite samples), and relatively high coefficients of determination (r^2) are preferable. Length information for each sample is required. Also, regression equations should not be extrapolated beyond the fish lengths represented by the available data.

Mean or Median Concentrations

All data for a given species at a given site can be pooled to calculate species-specific mean or median concentrations in cases where no relationship with length exists or where data is insufficient to determine length-concentration relationship. The advice would be determined by the meal frequency category in which the mean or median concentration falls. Site-specific mean or median concentrations can be estimated for size categories (e.g. 5-10" or 18-21") in cases where mercury concentrations increase with fish size. However, a regression approach to develop advice would provide a more consistent consideration of concentration-size relationship. Median and mean concentrations do not require the same underlying assumptions necessary for the regression approach. Median concentrations are advantageous when site-specific data include censored data (data that is assigned a value because it is below the method detection limit) because unlike mean concentrations, median concentrations can be estimated without assigning a concentration to censored data. However, for mercury and fish of consumable sizes, censored results would not be a major concern. The disadvantage of considering only median or mean values for species-site advice is that the range or distribution of concentrations is not considered unless minimum and maximum concentrations are also examined.

Frequency Distribution Within Meal Categories

The frequencies of sample results within meal categories for a species at a site can also be used to evaluate appropriate advice. This approach would provide the percentage of mercury results for species and sites that fall into the different meal categories (e.g. 1% in "unlimited", 90% in "1 meal per week", 9% in "do not eat"). This approach may be advantageous for species-sites where data is limited or variable or where there is not a strong mercury-length relationship but where mercury concentrations range widely. This approach may supplement the use of the other approaches to improve confidence in advisory decisions.

B. General Advisories

Great Lakes basin jurisdictions have collected enough mercury data to predict many of the species and sizes of fish that tend to have elevated mercury concentrations as well as the waterbody types that tend to support fish with elevated levels of mercury. Agencies have used this information to develop general advisories covering certain species or sizes of fish from all waterbodies within a state or region or from certain types of waterbodies (e.g. inland lakes). Data coverage should be considered in determining extension of the general advisory statewide, regionwide or to waterbody types. These general advisories are typically supplemented by site -specific advisories that are either more or less restrictive than the general advisory.

The following techniques could be considered in determining general advice for a species that extends statewide, region-wide or to a type of waterbody:

Length Versus Concentration and Regression Models

Length versus concentration plots are often useful given the relatively strong relationship between fish length and mercury concentration in many species of fish. The relationship of mercury concentration with length or age of a species is known to vary widely between waterbodies. Therefore, the between site variability in the relationship between mercury and fish length (age) confounds analysts ability to use regression analyses on a geographical basis wider than site-specific to predict lengths at which mercury concentrations exceed trigger levels. However, regression analysis may be appropriate to develop general consumption advice if the mercury-length relationship is consistent between waterbody within a state, region, fish species or a type of waterbody. Consumption advice would be determined using the regression equation that describes the relationship between size and mercury concentration to solve for the sizes of the species that falls under the meal frequency category.

Mean or Median Concentrations

For general advice, the appropriate meal advice category can be based on species mean or median concentrations using all data for a species on a statewide, regional, or waterbody type basis. All statewide, region-wide, or waterbody type data for a given species can be pooled to calculate species specific mean or median concentrations. The general advisory approach assumes that people eat a variety of fish species and fish sizes from a variety of waters over a lifetime. Therefore the advice is appropriately based on mean or median concentrations. Also, additional site-specific advice can be provided for the sizes, sites, or exceptions that require more stringent consumption advice.

Frequency Distributions Within Meal Categories

The frequencies of sample results for a species within meal categories can also be used to evaluate appropriate advice on a statewide, regional, or hydrologic basis. Species specific regional or statewide mercury concentration frequency distributions can be used to identify the meal frequencies that include most of the samples for each given species. Frequency distributions can also be developed for certain waterbody types (e.g., inland lakes or reservoirs) or size ranges. This approach may be advantageous for species without a strong mercury-length relationship but where mercury concentrations range widely.

C. Role of Site-Specific (versus General) Advisories

Site-specific advisories offer agencies the ability to provide consumption advice for waterbodies that may be atypical. Certain waterbodies may have fish with higher than usual mercury concentrations and these waterbodies should be covered by more stringent advisories. Likewise, waterbodies that are found to have fish with lower than usual concentrations could be exempted from general advisories. It is left up to each state to decide when to provide site-specific advice versus general advice or both i.e. when not to provide unrestricted site-specific advice which is less stringent than the mercury general advice and when to provide site-specific advice (more stringent than general or as duplicate to general).

IX. Purchased Fish Consumption Advice

To account for the total exposure of an individual to methylmercury, consumption of both purchased fish and locally caught fish need be taken into account when deciding how much and choosing which types of fish to eat. There is a Federal Advisory for women of childbearing age and children for consumption of purchased fish based on mercury levels in fish (FDA, 2004b). In addition, some of the Great Lakes States currently provide quantitative advice for purchased fish. At a minimum, reference to the Federal Advisory should be included with states' fish consumption advice.

If a state includes quantitative advice for purchased fish the methods described in this protocol should be used in conjunction with published data, such as the Food and Drug Administration data on mercury fish (FDA, 2004a), to determine meal advice.

X. Utilization of the Protocol

This "Protocol for Mercury-based Fish Consumption Advice; An addendum to the 1993 Protocol for a Uniform Great Lakes Sport Fish Consumption Advisory" is a product of the Workgroup and only represents agreement among the participants.

Each Workgroup member was asked to comment on whether they find the protocol useful, intend to utilize the protocol and if so, their "next steps" and implementation timeline. All states responded that the Protocol addendum is a useful document.

Many of the Great Lakes States (Ohio, Illinois, Indiana, Wisconsin and Minnesota) are already using methods that are fairly consistent with the methods outlined in the Protocol. These states are working towards implementing the Protocol for the 2007 or 2008 advisory season. Implementation may include briefing of administration, data analysis, public information, and generation of informational materials. Illinois, Indiana, Wisconsin, and Minnesota plan to maintain separate advice for the general population. Ohio plans to implement the Protocol for the general population and sensitive populations equally in 2007 but would consider a two-tiered system if other states agreed to implement a consistent approach.

Pennsylvania does not plan to implement the Protocol given that the advisory categories do not match their current categories. They plan to maintain statewide consistency with their established consumption advisory protocols, and not have a different regional protocol for the Great Lakes portion of Pennsylvania.

In Michigan the Protocol will be used to stimulate discussion on fish consumption advice that is developed using health-based mercury fish tissue concentrations. The Protocol will act as a starting point for trying to develop a process to update Michigan's Fish Consumption Advisory. The impediment is uncertainty regarding the implications of this change compared to the need for the change. The Department of Community Health

currently does not provide explicit funding for updating or maintaining the fish consumption advisory program.

New York will consider information in the Protocol as one of several tools when deriving advisories for both high risk groups and the general population, but is unlikely to use the Protocol's mercury guideline concentrations as "bright lines" to derive fish advisories for either high risk or general populations. New York State workgroup members thought that additional discussion needs to be added to the risk assessment and benefits sections. To the risk assessment portion, they would like addition of a discussion of new studies and analyses of some of the fish-consuming populations and a discussion of the derivation of criteria by other health organizations. They would also like a discussion of benefits in the context of risk management and believe the utility of the Protocol would be enhanced if it included at least a qualitative discussion of how the fish advisory process should consider both the risks of methylmercury and the benefits of fish consumption. Participation in a workgroup to review general population mercury advisories would depend on the structure, goals and objectives.

For informational purposes the protocol will be shared with organizations such as the Association of State and Territorial Health Officials (ASTHO) and the Environmental Council of the States (ECOS) for distribution to all states.

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Appendix A - Application/Implementation Issues

When both PCBs and mercury are detected in fish tissue, advice will be based on the contaminant that results in the most conservative advice for the sensitive population. If the advice for the sensitive population is the same for both mercury and PCBs then the default is PCB advice since that would result in the most conservative advice for the general population.

Examples (see also table below)

1. If both PCB and mercury concentrations equal 0.3 ppm then the overall advice would be one meal per month based on PCBs.
2. If mercury equaled 0.3 ppm and PCB equaled 0.1 then advice would be one meal per month based on mercury.

Meal Frequency Categories versus Mercury and PCB Concentrations

Fish Meals	Fish Mercury Concentration (ppm)	Fish PCB Concentration (ppm)
Unrestricted	0 – 0.05	0 – 0.05
2 meals/week	>0.05 – 0.11	—
1 meal/week	>0.11 – 0.22	>0.05 – 0.22
1 meal/month	>0.22 – 0.95	>0.22 – 0.95
6 meals/year	—	>0.95 – 1.89
No Consumption	>0.95	>1.89

Appendix B - Survey of Great Lakes States Mercury Fish Advisory Methods

September 16, 2005

Fish advisory program managers from the eight Great Lakes States were contacted by phone and surveyed about their state's current mercury-based fish advisory approach. The intent of the survey was to gather information on similarities and differences in current approaches to facilitate working towards consistency and investigate the potential to add mercury to the Protocol for a Uniform Great Lakes Sport Fish Consumption Advisory (the Protocol).

Adding mercury to the Protocol would include updating the risk assessment for assigning fish to the consumption frequency groups component, item number 11 of the Protocol. Two additional components may also need to be added to a mercury addendum to the Protocol. Because of the ubiquitous nature of mercury in fish many states issue advice for all waters of their state or some portion of waters. A procedure for these general advisories would therefore also need to be addressed in the Protocol if mercury were added. Consumption of fish is the major source of human exposure to methyl mercury. All sources of fish in the diet should be considered when making choices about eating fish. From a public health standpoint recommendations about consuming purchased fish should be included along with advice for eating locally caught fish.

The survey results reported here include the details of risk assessment for mercury, procedures used to derive and issue general mercury-based advisories if applicable, inclusion of advice for purchased fish and data analysis methods used. These survey results were presented at a meeting of the States and GLIFWC in September 2004 in Madison WI. Changes in advisory methods occurring after this meeting are not included in the results reported in this document.

Results

Each of the eight Great Lakes States currently provides both site-specific and statewide consumption advice based on fish mercury content. Statewide advice in some states is based on other chemicals as well. A variety of approaches are used to derive the mercury-based advice. The details of these approaches contribute to differences observed in fish consumption advice between states. Choice of meal advice categories used, significant figures, listing of site-specific versus statewide advice and data analysis techniques also influence consistency amongst states.

Sensitive Population (SP)

In Pennsylvania and Ohio no sub-population is defined as more sensitive to mercury exposure therefore the same advice for fish consumption based on mercury is given to everyone. The remaining Great Lakes states provide separate advice for the general and sensitive populations. Women-of childbearing-age and children less than fifteen years of

age are defined as the sensitive population. Advice for this sensitive population is more restrictive than that for the general population.

Health Protection Value (HPV)

In Illinois, Indiana, Minnesota and Wisconsin separate HPVs are used for fish consumption advice for the sensitive population and general population for mercury based advice. For the general population these four states use the 1985 EPA IRIS RfD of 0.3 µg/kg/day. This RfD was based on the dose response relationship of mercury exposure and paresthesia in adults from the Iraq poisoning. Illinois, Minnesota and Wisconsin use the current US EPA IRIS RfD of 0.1 µg/kg/day for the sensitive population. Pennsylvania and Ohio use this RfD for advice for all populations. This RfD is based on neuro-developmental effects reported in the Faroe Islands study.

Indiana uses 0.07 µg/kg/day as the HPV for the sensitive population, This HPV was derived and used by Minnesota prior to the development of the current EPA RfD. At the time the HPV of 0.07 µg/kg/day was developed the IRIS RfD was 0.3 µg/kg/day and as mentioned above was based on adult effects. WHO (reference) stated that the fetus was likely to be 4 to 5 times as sensitive as an adult nervous system to the effects of mercury. This HPV utilizes a factor of 4.3 to reduce the adult-based RfD to a developmental HPV of 0.07 µg/kg/day. Because this factor of 4.3 is equal to the ratio of days per month divided by days per week it provides a logistically pleasing relationship between advice for the SP and GP by allowing a shift of one advice category between populations i.e. one meal per week advice for the GP equals one meal per month advice for the SP.

Michigan currently does not use an HPV approach for mercury based consumption advice; Michigan uses a “modified” FDA action level approach. New York State considers several factors when deriving fish advisories, including sample and analytical data characteristics, health risk assessment, U.S. FDA marketplace standards, etc. (For more details, see Supplemental Information on New York State Advisories at the end of this Appendix).

Advisory Groupings

All states analyze total mercury in fish and assume that 100% of this mercury is methylmercury. The meal size used to calculate meal advice concentration ranges is 227 g (1/2 lb) uncooked fish. No loss factor is assumed for skinning/trimming/cooking. If a state includes unrestricted advice it is defined as 225 meals per year as in Great Lakes protocol.

Table 1. Meal Advice versus Mercury Concentration (ppm) in Fish - Sensitive Population (NY*, MI, IN, IL, WI, and MN) and All Populations (PA and OH)

	NY	PA	OH	MI	IN	IL	WI	MN
HPV (µg/kg/day)	na*	0.1	0.1	na	0.07	0.1	0.1	0.1
Fish Meals								
unrestricted		0-0.12				<= 0.06		<= 0.05
1 meal/week		0.13-0.25	0.05-0.219		<0.16	>0.06-0.23	0.05-0.22	> 0.05-0.2
2 meals/month		0.26-0.50						
1 meal/month		0.51-1.0	0.220-.999	> 0.5	0.16-0.65	>0.23-0.94	0.22-1	> 0.2-1.0
6 meals/year		1.1-1.90	1.0-1.99			>0.94-1.89		
no consumption	> = 1.0*	> 1.9	>2	> 1.5	> 0.65	> 1.89	> 1.0	> 1.0

* See Supplemental Information on New York State Advisories at the end of this Appendix.

Note the differences between PA, OH, IL, WI and MN. An HPV of 0.1 is used by all of these states. The differences in mercury concentrations corresponding to meal advice category are due to significant figures, choice of meal advice category included and default body weight (PA uses a body weight of 72 kg from the 1999 EPA Guidance, the other states use a body weight of 70 kg from the Great Lakes Protocol and current EPA guidance).

Table 2. Meal Advice vs Mercury Concentration in Fish - General Population

	NY*	MI	IN	IL	WI	MN
HPV (µg/kg/day)	na*	na	0.3	0.3	0.3	0.3
Fish Meals						
unrestricted			< 0.16	< 0.16	<0.16	<= 0.16
1 meal/week	*	> 0.5	0.16-0.65	0.16-0.65	0.16-0.65	>0.16-0.65
1 meal/month	1.0 – 1.9		0.66-2.8	0.66-2.8	>0.65	>0.65-2.8
6 meals/year			2.81-5.6	2.81-5.6		
no consumption	>= 2.0	> 1.5	> 5.6	> 5.6		> 2.8

* See Supplemental Information on New York State Advisories at end of this Appendix.

IN, IL, WI and MN all use an HPV of 0.3 for the general population. Because mercury levels in fish have not been measured at levels WI's method only includes mercury concentrations up to one meal per month. Minnesota does not include the six meals per year category. The approach Indiana uses has the advantage of one meal category difference between the SP and GP advice. When using 0.1 and 0.3 for SP and GP HPVs there is some overlap in advice for the two populations, i.e. for some fish concentrations both SP and GP could have advice of one meal per week.

Tables 3, 4 and 5 provide details on statewide advisories, site-specific advisories and purchased fish consumption advice by state. Waters included in statewide advice are not the same in all the Great Lakes states. The waters included range from only inland lakes to all waters including Great Lakes. Which waters have site-specific advice effects listings such as the 303d list and the EPA counts of number of advisories by state.

A final detail covered in the survey that can affect consistency between state’s advisories is the use of “and” versus “or” between meal advice categories. For example, some state’s advice says that in one month a person can eat four meals of once per week fish “and” one meal of once per month fish. While other state’s advice says that if a person consumes a once per month fish then do not eat any other meals of fish that month. Pennsylvania and Minnesota use “or”. Wisconsin uses “and”. New York, Ohio, Indiana and Illinois do not specify “and” or “or” in their published advice.

Table 3. Statewide Advice, Basis and Data Analysis

State	Sensitive Population Advice	General Population Advice	Waterbodies Included	Basis
New York	One meal/week all fish species and sizes	Same as SP	Fresh waters and some marine waters at mouth of Hudson	Some chemicals are commonly found in New York State fish (mercury and PCBs for example), fish from all waters have not been tested and fish may contain unidentified contaminants.
Pennsylvania	One meal/week all fish species and sizes	Same as SP	All waters including Great Lakes	Officially based on mercury but includes BJP for all contaminants
Ohio	One meal/week all fish species and sizes	Same as SP	All waters including Great Lakes	Based on Hg national guidance of 1 meal/ week and increasing number of site-specific 1 meal/wk Hg advisories (current means analysis supportive, 90% of samples since 1988 are > 0.05ppm)
Michigan	One meal/month for crappie, rock bass or perch over 9 inches in length and any size largemouth bass, smallmouth bass, walleye, northern pike, or muskie	One meal/week for crappie, rock bass or perch over 9 inches in length and any size largemouth bass, smallmouth bass, walleye, northern pike, or muskie	Inland lakes only	Established about 15 years ago based on Hg, regression analysis, about 2/3 of lakes had samples exceeding 0.5ppm Hg
Indiana	Limit to 1 meal per month: All black bass (smallmouth, largemouth, and spotted), channel catfish, flathead catfish shorter than 38 inches, walleye or sauger shorter than	Limit to 1 meal per week: All black bass (smallmouth, largemouth, and spotted), channel catfish, flathead catfish shorter than 38 inches, walleye or sauger shorter than	All waters including Great Lakes	Predominance of data for PCBs and Hg, BPJ (few samples of same species and size)

State	Sensitive Population Advice	General Population Advice	Waterbodies Included	Basis
	24 inches, northern pike, white bass, striped bass shorter than 28 inches, rock bass, other species. Do Not Eat Any Fish in this Group: Walleye and sauger longer than 24 inches, flathead catfish longer than 38 inches, and striped bass longer than 28 inches.	24 inches, northern pike, white bass, striped bass shorter than 28 inches, rock bass, other species. Limit to 1 meal per month: Walleye and sauger longer than 24 inches, flathead catfish longer than 38 inches, and striped bass longer than 28 inches.		
Illinois	One meal/wk for all predators	Unlimited for all species and sizes	All waterbodies except Great Lakes	Means analysis across years and sizes, limited data for regression analysis, distribution within meal advice category (2/3 to 3/4 of predator fish sampled required 1/wk advice for SP), BPJ
Wisconsin	1 meal/wk: panfish, bullhead, perch; 1 meal/mo: all other species; Do not eat: muskie	Unlimited: panfish, bullhead, perch; 1 meal/wk: all other species	All waterbodies except Great Lakes	Hg, means analysis, frequency distribution within meal category
Minnesota	1 meal/wk: panfish, bullhead, perch; 1 meal/mo: all other species, walleye < 20", northern < 30"; Do not eat: muskie and large northern and walleye	Unlimited: panfish, bullhead, perch; 1 meal/wk: all other species	All waters including Great Lakes	Hg and PCBs, means analysis, frequency distribution within meal category, length cut-offs considered regression analysis and harvest rates

Table 4. Site Specific Advice Listing Criteria and Data Analysis/Logic

State	Site-specific data analysis/logic
States that list site-specific advice if it is more restrictive than Statewide Advice	
New York	Regression analysis if supported by data, otherwise arithmetic mean. GP: listed if concentration warrants either 1/mo or eat none. SP: if advice for GP is more restrictive than Statewide advice for any species then SP = eat none for all species and sizes in that water*. 96 waters listed in 2004.
Pennsylvania	About 60 samples per year are analyzed, generally one composite sample per species maybe two sizes. Two years of data in same advice category are needed to list advice.
Ohio	Regression analysis if enough data, otherwise means analysis.
Illinois	Listed if mean of panfish > 0.06 ppm or predator > 0.23 ppm (need 2 yrs of data). Currently 10 waters are listed for Hg advice.
Wisconsin	Screen first to ID high fish mercury waters using 1 ppm for game fish and 0.5 ppm for panfish as screen. For high waters do regression for gamefish and frequency distribution within meal advice categories for panfish. BPJ. If panfish are listed at 1/mo for SP then they are also listed for GP at 1/wk. If any gamefish sample is >= 1 ppm then SP advice = DNE.
Michigan	Regression analysis if $r^2 > 0.6$ otherwise use median within size classes
States that list site-specific advice if different than Statewide Advice – list both less & more restrictive	
Indiana	Generally not enough data for statistical analysis. Predominance of data – BPJ. Use composite samples w/focus on variety of species, sizes and waterbodies. Will use one composite sample for advice.
Michigan	Use Regression analysis if enough data, otherwise, medians within a length group. If advisory is more or less stringent, list it in the book.
States that list site-specific advice for all tested waters	
Minnesota	Means analysis by species and size class and within five years of most recent sampling. Composites for bottom feeders and panfish. Individual fish samples for predator species.

* See Supplemental Information on New York State Advisories at the end of this Appendix.

Table 5. Purchased Fish Consumption Advice

<u>State</u>	Include Advice on Commercial Fish Consumption?	Provide Reference or Web Link to EPA/FDA	Use exact EPA/FDA text?	Provide Other Advice	Mercury Data Source for Other Advice
New York	yes	yes	shortened, reorganized language, no white tuna info	no	n/a
Pennsylvania	no	yes	no	no	n/a
Ohio	no	yes	no	no	n/a
Michigan	yes	no link	No -2003 MI FCA: DNE 4 species WOCBA and Kids <15, 2004 MI FCA: same as 2003 on-line, no booklet	no	n/a
Indiana	yes	no link	no	Used FDA Hg data to put popular species into meal advice categories	FDA web site
Illinois	no	link to FDA Food Safety on PH's Food, Drugs and Dairies web site	no	no	n/a
Wisconsin	yes	yes	no	Used FDA Hg data to put popular species into meal advice categories	FDA web site
Minnesota	yes	yes	no	Used FDA Hg data to put popular species into meal advice categories	FDA web site

*Supplemental Information on New York State Advisories.

New York State uses considerable judgement and weighs many factors when setting fish advisories. Advisories are established based on data from specific species of fish from a specific water body, based on recognizing general trends for a specific contaminant that may hold across a number of water bodies and species (even if data are not available from all of those water bodies), and based on environmental conditions in New York State. The balance between the benefits and risks of eating fish with methylmercury may be different for at risk populations (women of childbearing age, infants and young children) versus the general population. NYSDOH takes these differences into account during the fish advisory setting process.

The following are some important features of the NYSDOH advisories and advisory-setting process:

1. NYSDOH issues a general advisory to eat no more than one meal per week of fish from all New York State fresh waters because some chemicals are commonly found in New York State fish (e.g., mercury and PCBs), fish from all waters have not been tested, fish may contain unidentified contaminants (e.g., PBDEs).
2. When reviewing fish contaminant data to determine fish advisories for a specific water body or region, the New York State Department of Health considers the following:
 - fish contaminant levels, including fish sampling characteristics (e.g., number and type of samples, species, age, length, percent lipid, sample location, etc.) and patterns of contamination;
 - health risks;
 - populations at greater potential risk;
 - the FDA marketplace standard;
 - health benefits; and
 - risk communication issues.
3. NYSDOH recommends that infants, children under the age of 15 and women of childbearing age EAT NO fish at all from waters with specific advisories. Thus NYSDOH provides protective advice to a high-risk population where data suggest contamination without needing species-specific data.
4. DOH also issues regional advisories for two large areas in New York State (the Adirondack and Catskill Mountain regions) where women of childbearing age and children under 15 are advised to avoid eating specific fish species from these region's waterbodies that contain elevated mercury levels.
5. The New York State Department of Environmental Conservation (NYSDEC) samples and tests fish in New York State waters. The NYSDEC sampling is biased towards finding contamination problems because it focuses on fish species that are most likely to have high contaminant levels.