Polychlorinated Biphenyls (PCBs) Total Maximum Daily Load for Cedar Creek & Milwaukee River (Thiensville Segment) Ozaukee County, WI

Columbia Pond, Ozaukee County, WI

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Introduction

Section 303(d) of the Clean Water Act (CWA) and the United States Environmental Protection Agency (U.S. EPA) require states to develop Total Maximum Daily Loads (TMDLs) for waterbodies that are not meeting water quality standards (WQS). The purpose of this TMDL is to identify the appropriate load of polychlorinated biphenyls (PCBs) from Cedar Creek that will result in reducing fish tissue concentrations in PCBs and meeting WQS in receiving waters that include Cedar Creek and the Milwaukee River.

Problem Statement

Background information

Cedar Creek is a 28-mile, warm water stream that runs through Washington and Ozaukee Counties of Southeastern Wisconsin and flows into the Milwaukee River at river mile 28. The land use in the Cedar Creek Watershed is primarily rural including agriculture (49%), wetlands (16%), grasslands and forest (26%), while urban areas cover about 3.5% of the watershed (WNDR 2001). The Wisconsin Department of Natural Resources (WDNR) placed the first 5 miles of Cedar Creek upstream of the confluence with the Milwaukee River on Wisconsin's 303(d) Impaired Waters List for Fish Consumption Advisories (FCAs)[1] due to PCBs in contaminated sediments (Figure 1 and Table 1).

Similarly, the Milwaukee River is a 48-mile long, warm water stream that runs through Fond du Lac, Washington, Ozaukee and Milwaukee Counties and discharges to Lake Michigan by way of the Milwaukee River Estuary in the City of Milwaukee, Milwaukee County. The Milwaukee River South Watershed land cover is a mix of urban use (33%) and rural use that include agriculture (25%), grasslands (21%), forests (12%) and wetlands (6%) (WDNR 2001).

The WDNR placed the first 30-miles of the Milwaukee River extending from Lake Michigan at river mile 0 to the Lime Kiln Dam (Village of Grafton, Ozaukee County) at river mile 30 on Wisconsin's 303(d) Impaired Waters List for Fish Consumption Advisories (FCAs) due to PCBs in contaminated sediment (Figure 1 and Table 1). Within the 30-mile long 303(d) listed reach of

[1] WDNR provides *statewide consumption advice* that applies to most of Wisconsin's inland waters, in addition to *special advice* for individual waterbodies; fish consumption advisories for specific waterbodies are issued when fish are found to contain contaminants at levels that may pose health risks to people who eat fish.

the Milwaukee River, two river segments contain significant concentrations and mass of PCBs in sediment that contribute to the river's fish consumption advisory.

The Milwaukee River Segment 1 extends from the river's confluence with Lake Michigan at river mile 0 to the Thiensville Dam at river mile 20. The Estabrook Impoundment is located in River Segment 1 in Milwaukee County and is a 103-acre and 0.9-mile long pool formed by the Estabrook Park Dam at river mile 7. The Estabrook Impoundment contains over 100,000 cubic yards of sediment contaminated with an estimated 5,200 Kg of PCBs. Previous work on the Milwaukee River system shows that remediation of the Estabrook Impoundment sediment deposit would result in a long-term reduction in PCB mass transport of up to 70% for the Milwaukee River (Baird & Associates 1997, Steuer *et al*. 1999).

The Milwaukee River Segment 2 extends from the Thiensville Dam at river mile 20 to the Lime Kiln Dam at river mile 30 in the Village of Grafton. River Segment 2 includes the Thiensville Impoundment, a 700-acre and 5-miles of free-flowing river. Median surficial PCB sediment concentrations are approximately 0.2 mg/kg and 1 mg/kg at intermediate sediment depths. While Thiensville Impoundment sediments contribute to PCB contamination in Milwaukee River fish and wildlife, the greatest benefit toward reducing PCBs in Milwaukee River fish and wildlife populations would result following an expedited remediation of PCB contaminated sediment in Cedar Creek (Baird & Associates, 1997).

Unlike the Milwaukee River Segment 1, River Segment 2 is directly and uniquely impacted by PCBs discharged from Cedar Creek. Furthermore, River Segment 2 resident fish and wildlife populations are generally confined between the Thiensville Dam and the Lime Kiln Dam. For these reasons**, this TMDL includes the first 5 miles of Cedar Creek upstream of the confluence with the Milwaukee River, and the entire 10 miles of the Milwaukee River's River Segment 2 that extends from the Thiensville Dam to the Lime Kiln Dam in the Village of Grafton (Figure 1).**

The priority of these waterbodies was updated to 'high' on the 2006 303(d) list.

Table 1. Excerpt from the 303(d) Impaired Waters List for Cedar Creek and the Milwaukee River, River Segment 2.

303(d) Impaired Waters Listed Segment	County	Stream Miles	Existing Use	Pollutants	Impairments	Source: Contaminated sediment
Cedar Creek (WBIC 21300)	Ozaukee	0-5	WWSF	PCBs	FCA	Yes
Milwaukee River Segment 2 (WIBC 15000)	Ozaukee	20-30	WWSF	PCBs	FCA	Yes

PCBs from two local companies located in the City of Cedarburg —now-closed Mercury Marine and Amcast Industrial—contaminated Cedar Creek and the Milwaukee River watersheds. The Mercury Marine Plant 2 and the Amcast facilities are responsible for contaminating Cedar Creek, the Milwaukee River and nearby surrounding areas that include the Quarry pond (Zeunert pond), some residential yards, the Wilshire stormwater retention basin and storm sewers. Consequently, Cedar Creek contributes to an annual average PCB mass of approximately 5 kg to the Milwaukee River (BBL, 2005).-Unfortunately PCB contamination caused by releases decades before is still present today because of the persistent nature of these chemicals.

The impaired segment of Cedar Creek flows through the Town of Cedarburg before reaching the Milwaukee River, and includes open stretches of stream as well as areas known as Ruck Pond, Columbia Pond, Wire and Nail Pond, and the former Hamilton Pond; the dam of the latter failed in 1996 and was permanently abandoned shortly thereafter. These portions of Cedar Creek and of the impaired Milwaukee River Segment 2 are classified as a Warm Water Sport Fish community, and supports a diverse fish community including: Bluegill, Black Crappie, Common Carp, Horneyhead Chub, Creek Chub, Common Shiner, Fathead Minnow, Bass, Northern Pike, Rock Bass, Largemouth and Smallmouth Bass, Walleye, Yellow Perch, Common White Sucker and four species of Redhorse (Greater, Silver, Shorthead and Golden).

Spring and fall migrations of Rainbow Trout (Steelhead) and fall migrations of Chinook and Coho Salmon from Lake Michigan occur along these reaches under appropriate river flow conditions that allow fish passage at the Thiensville Dam (BBL 2005, WDNR 2008). Similarly, native game and non-game fishes from Lake Michigan, the Milwaukee River Estuary and lower Milwaukee River are also able to move past the Thiensville Dam especially during their higher spring flow spawning runs when the dam's spillway is submerged (WDNR, 2008). Once these fishes are able to pass above the dam they may move up to the Milwaukee River's Lime Kiln Dam in Grafton and Cedar Creek's Wire and Nail Dam in Cedarburg.

All totaled, 42 species of fish have been identified from these Ozaukee County stream segments since 1970 including a number of sensitive State listed fish and other aquatic life include the Stripped Shiner (Endangered), Greater Redhorse (Threatened), Longear Sunfish (Threatened), Redfin Shiner (Special Concern) and Lake Sturgeon (Special Concern).

The Milwaukee Remedial Action Plan (RAP) Technical and Citizen's Advisory Committees recognized contaminated sediment as the major contributor to use impairments within the area of concern (AOC). The contaminated sediment management strategy of the RAP (WDNR 1995) identified remediation of upstream sources of contaminated sediments as a top priority.

In order to address the risk to human health and to the aquatic biota associated with the PCB contamination, and as a response to one of the identified Potential Reasonable Parties (Mercury Marine Corporation), the US EPA designated Cedar Creek as a Superfund Alternative Site for Wisconsin (EPA ID# WID988590261)[2]. The entire site consists of Mercury Marine's Plant 2, the former Amcast facility, associated migration pathways of PCBs to Cedar Creek (affected surrounding properties, the Wilshire stormwater basin, Zeunert Pond and storm sewers), and the segment of Cedar Creek from below the Ruck Pond dam to the point where it meets the Milwaukee River. This segment includes open stretches of creek as well as areas known as Columbia Pond, Wire and Nail Pond, and the former Hamilton Pond for a total of 5.1 creek

[2] For more information, see http://www.epa.gov/region5superfund/npl/sas_sites/WID988590261.htm

miles. The Superfund project boundary does not formally include the Milwaukee River. However, this does not limit the current boundary from being expanded to include the Milwaukee River.

One provision of the CERCLA[3], the Superfund Law, is a requirement for Natural Resource Trustees to evaluate the injuries that are caused by the presence of contaminants released or discharged to the site and when appropriate, claim damages for the compensation and restoration of the injuries for the period of time that the resource has been injured. The Natural Resource Trustees are currently evaluating initiation of the Natural Resources Damage Assessment (NRDA) process for this site. If it is determined that there is a reasonable chance to establish the claim, the amount of damages that will be sought will be at least partially based on the extent of the remediation and the speed with which water quality criteria are projected to be attained and fish consumption advisories removed. The current boundary of the Superfund Alternative Site does not preclude the natural Resource Trustees from evaluating and initiating a NRDA for other resources (e.g., Milwaukee River) impacted by contaminants released at the site.

Polychlorinated biphenyls (PCBs)

The manufacturing of PCBs was banned in the United States in 1977. Due to past discharge and dumping of wastes from businesses and industrial facilities in the past, PCBs were introduced into the environment and are detected in air, soil, surface water, sediment, plants and animals. Decades later, PCBs still remain in stream and river sediments because they are highly persistent and also tend to bind to the sediment particles. They are highly lipophilic and, therefore, more readily bind to sediments or accumulate in tissues rather than remain in the water column (Eisler and Belisle 1996, EPA 1999).

In areas of PCB contaminated sediment and water, like Cedar Creek, PCBs affect fish, wildlife and people as it is bioaccumulated through the food chain. Aquatic organisms get contaminated by PCBs mainly through exposure to or ingestion of sediments, by consumption of contaminated prey, and to a lesser extent by contact with surface water, as via exchange across the gill membrane. Aquatic organisms such as invertebrates and fish that are exposed to PCBs accumulate these substances in their bodies. The aquatic species at the top of the aquatic food chain, such as fish, generally have the highest PCBs concentrations. Fish ingestion is the primary exposure route for Cedar Creek and the Milwaukee River. Humans (anglers and their families), fish-eating fish, and fish-eating birds and mammals are at risk by consuming fish contaminated with PCBs.

Human exposure to PCBs is predominantly through the diet, and especially from fish and seafood products (EPA 1999). Despite a downward trend of PCB fish tissue concentrations reported by the National Contaminant Biomonitoring Program (EPA 1999), PCB contaminated fish remains a threat for human health. Various health effects in humans may result from exposure to PCBs such as: acne and rashes, neurological disorders and immunological changes in children (ATSDR, 2001). PCBs are very likely to be carcinogenic to humans according to the

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[3] Comprehensive Environmental Response, Compensation, and Liability Act (http://www.epa.gov/superfund/policy/cercla.htm)

EPA, the International Agency for Research on Cancer and the Department of Health and Human Services (DHHS). Animals that are exposed to PCBs may experience health effects such as anemia, liver damage, acne-like skin conditions, stomach and thyroid gland injuries, changes in the immune and reproductive systems, and behavioral alterations. In some cases, when animals are exposed to large amounts of PCBs, results include liver cancer and death (ATSDR, 2001).

Water Quality Standards

The goal of a TMDL is to restore the integrity of the waterbody in order to meet the water quality standards (WQS). Because of the current fish consumption advisory in effect for Cedar Creek, the following narrative WQS are not being met (NR 102.04 (1)(a) and (d), NR 102.01 (2))[4]:

"*(a) Substances that will cause objectionable deposits on the shore or in the bed of a body of water, shall not be present in such amounts as to interfere with public rights in waters of the state*";

"*(d) Substances in concentrations or combinations which are toxic or harmful to humans shall not be present in amounts found to be of public health significance, nor shall substances be present in amounts which are acutely harmful to animal, plant or aquatic life*";

Where the "*public rights*" refer to "*the protection of public health and welfare and the present and prospective uses of all waters of the state for public and private water supplies, propagation of fish and other aquatic life and wild and domestic animals, domestic and recreational purposes and agricultural, commercial, industrial, and other legitimate uses.*"

Target Identification

A numeric target can be used in a TMDL report to demonstrate the attainment of water quality standards. The target value for this TMDL is a fish tissue PCB concentration of **0.21 mg/kg**. Cedar Creek and the Milwaukee River were placed on the 303(d) Impaired Waters List because the fish tissue concentrations exceeded 0.21 mg/kg (Table 2). This value corresponds to the fish tissue concentration associated with "1 meal per month" fish consumption advice for PCBs according to the "Protocol for a Uniform Great Lakes Sport Fish Consumption Advisory" (Anderson *et al*. 1993) used by Wisconsin to issue specific fish consumption advisories (FCA).

The Great Lakes fish consumption advisory (Anderson *et al*. 1993) was developed based on a review of the existing advisory protocol and the risk of adverse health effects from consumption of PCB contaminated sport fish. While the review and discussion has been comprehensive, priority was placed upon understanding reproductive, developmental effects and cancer risks. The advisory utilizes a weight-of-evidence derived individual health protection value (HPV) of 0.05 μg/kg/day for PCBs residue ingested from fish tissue. The HPV is intended to encompass

[4] Based on public comments received and to add more clarification, the Department has modified the original report to reference the applicable paragraph of section NR 102.04 (1).

acceptable cancer, reproductive and developmental risks. The goal of the advisory is to keep the sport fish associated dietary PCB ingestion below 3.5 μg PCB per day, assuming a representative target consumer of 70 kg adult (154 lbs); ((0.05 μg/kg/day X 70 kg body weight = 3.5 μg PCB/day). A risk analysis shows that this protection value is reasonable and within the margins of exposure for no observed adverse effect levels (NOAEL) for both laboratory animal and human effects (Anderson *et al*. 1993). Careful consideration has been given to the uncertainties in cancer risk estimates for PCBs in fish tissue and to the assumptions used in their derivation. Reference is made to the conventional range of acceptable cancer risk utilized for USEPA regulatory programs. Details regarding the development of the Great Lake fish consumption advisory are provided in Anderson *et al*. (1993) (see Appendix A).

Currently, the special FCA applying to Cedar Creek downstream of Bridge Road (upper limit of the impaired segment) and to Zeunert Pond is "do not eat" any species of fish. The special FCA applying to the Milwaukee River Segment 2 varies according to the fish species and sizes (see details in Appendix B). The skin-on fillet PCB concentrations of fish collected from Cedar Creek (1977-2002) downstream of Bridge Road ranged from 0 to 160 ppm (n=171 with 47% of the samples exceeding 1.9 ppm, 38% ranging 0.21 to 1.9 ppm, and 15% less than 0.21 ppm total PCBs)[5]. For the Milwaukee River, the skin-on fillet PCB concentrations of fish collected between Grafton and Thiensville Dam (1984-2002) ranged from 0.055 to 17 ppm (n=108 with 27% of the samples exceeding 1.9 ppm, 54% ranging 0.21 to 1.9 ppm, and 19% less than 0.21 ppm total PCBs)[6]. The Appendix C provides a summary of selected skin-on fillet total PCB records.

Table 2. Criteria (shaded boxes) used from fish consumption advisories to add a waterbody on the 303(d) Impaired Waters List.

Total PCB concentration in fish (ppm or mg/kg)					
Consumption advice	Unlimited	1 meal/ week	1 meal/ month	1 meal/ 2months	Do not eat
Range	< 0.05	0.06 – 0.2	0.21 – 1.0	1.1 – 1.9	> 2

When gamefish species contain less than 0.21 ppm total PCBs or when panfish species contain less than 0.06 ppm total PCBs, these species will fall under Wisconsin's general advice and special PCB advice will not be necessary. While general consumption advice would continue to be necessary, Cedar Creek and the Milwaukee River could be removed from the 303(d) list.

Reaching the target value of 0.21 mg/kg of PCBs in fish tissue will allow the removal of the special FCA for Cedar Creek and the Milwaukee River and eventually leading to the protection of human health and of the aquatic biota.

Source Assessment

[5] Skin-on fillet samples collected upstream of Bridge Road (1977-2002) ranged from 0 to 82 ppm (n=30 with 7% of the samples exceeding 1.9 ppm, 7% ranging 0.21 to 1.9 ppm, and 87% less than 0.21 ppm total PCBs).

[6] Skin-on fillet samples collected upstream of Grafton to Newton (1993-2002) ranged from 0 to 0.3 ppm (n=45 with no sample exceeding 1.9 ppm, 2% ranging 0.21 to 1.9 ppm, and 98% less than 0.21 ppm total PCBs).

Cedar Creek joins the Milwaukee River near the Town of Cedarburg about 26 miles upstream of Milwaukee Harbor. The impaired five-mile stretch of Cedar Creek that runs through the Town of Cedarburg contains three dams that slow flow of the stream, causing contaminated sediment to settle out within the impoundments (Figure 1). Similarly, the Thiensville Dam impounds 5-miles of the Milwaukee River. Since the 1970's WDNR has known about PCB contamination in Cedar Creek through wastewater, sediment and fish samples containing traces of PCBs (Wawrzyn and Wakeman 1986). Four of five impoundments in Cedar Creek were identified as containing high levels of PCBs in sediments: Ruck Pond[7], Columbia Pond, Wire and Nail Pond, and Hamilton Pond. The main sources of PCBs are historical industrial PCB discharges from two companies (now-closed), Mercury Marine and Amcast Industrial.

Extensive studies on PCBs in sediment, suspended sediment, water and fish samples from Cedar Creek and the Milwaukee River were completed through the last 20 years by USGS, WDNR and Baird and Associates (see References below for a comprehensive list of reports). A mass balance study was completed by WDNR in 1993 (Westenbroek 1993). This mass balance study demonstrated the transport and fate of PCBs in Cedar Creek Project and included: PCB partitioning between particulate and dissolved phase, volatilization, settling, resuspension, and advection, as well as sediment bed diffusion and longitudinal dispersion as transport mechanisms. The mass balance study completed in 1997 and 1999 for the Milwaukee system (Baird and Associates 1997, Steuer *et al*. 1999) updated the study from Westenbroek (1993) by including the results of the remediation of Ruck Pond. Based on the mass balance study for the Milwaukee system (Baird and Associates 1997) and results from the most recent sediment sampling performed in 2003 (BBL 2005), the accumulated PCB mass from bottom-sediment surveys estimated for Cedar Creek and PCB sediment concentrations are presented below in Table 3.

[7] Ruck Pond was remediated in 1994.

Table 3. PCB mass and sediment concentrations in the impaired segment of Cedar Creek and the Milwaukee River Segment 2.

Location		Accumulated PCB Mass (kg) [2]	PCB Sediment Concentrations (mg/kg) [3]		
			Range	Mean	Number of samples
Cedar Creek	Ruck Pond [1]	12.6	6.6 to 73	7.11	24
	Columbia Pond	566	nd to 63	5.57	11
	Wire & Nail Pond	70	nd to 30	6.64	9
	Former Hamilton Pond	n/a	nd to 0.29	0.072	5
	Between Hamilton Pond and the mouth	n/a	0.17 to 1.9	0.765	4
Milwaukee River Segment 2	Thiensville Impoundment	265	0.08 to 0.35	0.2	13

(1) Post-remediation, the remediation results in a 99% PCB mass reduction; (2) Baird and Associates 1997; (3) Sediment sampling performed in Oct. and Nov. 2003 for Cedar Creek (BBL 2005) and in 1993 for the Milwaukee River Segment 2 (Baird and Associates 1997); nd: non-detected; n/a: not available

Overall, the sediment concentrations of PCBs measured in 2003 in the impaired segment of Cedar Creek ranged from non-detected to 73 mg/kg (BBL 2005). Prior to and immediately following remediation in 1994, no surficial sediment samples were below 8 mg/kg in Ruck Pond. In 2000, 75% of sediment samples collected in Ruck Pond where below 2 mg/kg (WDNR 2002). Even though the Ruck pond remediation was successful (99% reduction of the maximum PCB sediment concentration, Baird & Associates 1997 and WDNR 2002), mean PCB concentration levels in sediment (7.11 mg/kg) were high (median concentration of 1.15 mg/kg). This may be explained by a small area (10 m^2) and thin layer (few centimeters thick) of contaminated sediment remaining in Ruck Pond after remediation (WDNR 2002).

The Hamilton Dam on Cedar Creek failed in 1996; hence, the Hamilton Pond no longer exists. This dam failure caused flooding of streambanks and deposition of contaminated sediments onto the floodplains. While streambanks and newly formed floodplain soil were partially remediated, the contaminated sediments remaining in the stream were not remediated. In addition, PCB concentrations of floodplain soil samples exceeded 8 mg/kg. However, the PCB sediment concentrations measured in 2003 are all lower than 0.3 mg/kg.

A substantial amount of PCB contaminated sediment is present in the other two ponds: Columbia Pond (566 kg) and Wire and Nail Pond (70 kg) and the mean sediment concentrations are still high: respectively, 5.6 and 6.6 mg/kg (Table 3). All these PCB contaminated sediments can be resuspended and transported downstream to the Milwaukee River. WDNR predicted that approximately 32 kg of PCBs could export from Cedar Creek to the Milwaukee River between January 2000 through December 2006 based on a model simulation conducted in 2001 (WDNR 2002).

The PCB sediment concentrations measured in the Thiensville impoundment (Milwaukee River Segment 2) ranged from 0.08 to 0.35 mg/kg (top 10 cm) in 1993 (BBL 2005, Table 3). No PCB sediment concentration data are available following the Ruck Pond remediation and failure of the Hamilton Dam.

Other sources of PCBs may include the Quarry pond, Wilshire stormwater basin, storm sewers, and contaminated sites (Mercury Marine Plant 2 and Amcast properties and some residential yards). As mentioned above, Cedar Creek is a Superfund Alternative Site and the potential responsible parties for the PCB contamination in Cedar Creek include the Amcast Industrial and Mercury Marine Corporation. In 1994, Mercury Marine capped a stormwater discharge pipe from their facility and removed 7,500 cubic yards of sediment from Ruck Pond which was the impoundment with the highest concentration of PCBs in sediment and potential to be transported downstream. Although Amcast is bankrupt now, the site abandoned and the flow drains were capped, the stormwater runoff from this site reaches the Quarry pond and then eventually Wilshire stormwater basin, which drains into Cedar Creek[8]. In short, Wilshire pond collects the overflows from the Quarry pond and stormwater runoff from the contaminated sites (the two industrial proprieties and some residential yards) and drains into Cedar Creek. As a result, the PCB sediment concentration measured in Wilshire pond ranged from 1.3 to 52 mg/kg with a corresponding median of 6.7 mg/kg (nine samples collected on 4/27/2005 by ENSR). In March 2008, the total PCB concentrations measured in the water discharged from Wilshire pond were of 229.1 and 235.6 ng/L (mean: 232.4 ng/L). The current PCB load from Wilshire pond was estimated using the mean total PCB concentration in the outfall of 232.4 ng/L and the annual average flow of 127.1 mega liters per year. Hence, the current PCB load from Wilshire pond is equal to 29.5 g/year or 0.08 g/day as show here:

$$127.1 \text{ mega liters per year} \div 365 \text{ days} = 348{,}336 \text{ liters/day}$$

$$348{,}336 \text{ liters/day} \times 232.4 \text{ ng/L} = 0.08 \times 10^9 \text{ ng/day or } 0.08 \text{ g/day}$$

The Cedarburg Wastewater Treatment Facility (WPDES permit # 0020222) is the only point source located within the impaired section of Cedar Creek, but does not currently discharge PCBs into the stream[9]. Two other point sources are located upstream of the Cedar Creek impaired segment: the Village of Jackson Wastewater Treatment Facility (WPDES permit # WI-0021806) and on the North Branch of Cedar Creek is Schreiber Foods Inc. (WPDES # WI-0026751). However, no PCBs were detected in the biosolids of the Jackson facility; and Schreiber Foods is not expected to generate PCB given the nature of their activities as a dairy processor. Thus, these two upstream point sources do not contribute to the impairment for this TMDL.

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[8] The overflows from the Quarry pond are directed to the city storm sewer and then reach Wilshire pond.

[9] Cedarburg Wastewater Treatment Facility does not discharge detectable limits of PCBs in their effluent, therefore are in compliance and do not have PCBs limits in their permit. The same applies to their next permit issuance as PCBs were not detected in their most recent effluent samples collected in Dec. 2007.

The Milwaukee River Segment 2 receives discharges from multiple stormwater outfalls[10], but none of them contribute to the PCB impairment of the Milwaukee River Segment 2 since there are no known sources of PCBs in this area. Also, no industrial or municipal point sources exist within the impaired Segment 2. The Grafton Village Water and Wastewater Utility (WPDES permit WI- 0020184) located just upstream of Segment 2 is not known to generate PCBs since no PCBs were detected in the biosolids. The other point sources located upstream of Segment 2 are not sources of PCBs. Hence, the only source of PCBs for the Milwaukee River Segment 2 is uniquely the PCBs discharged from Cedar Creek.

Atmospheric PCB deposition is assumed to be a negligible input to Cedar Creek in comparison to the internal PCB sediment load. Moreover, PCB deposition (if any) is likely to be counterbalanced by volatilization of PCBs from the water column to the atmosphere (the maximum loss of PCBs by volatilization is about 1 g/day, Westenbroek 1993).

Overall, scouring, resuspension and continued transport of PCB contaminated stream bottom sediment constitute the main PCB load for Cedar Creek and the Milwaukee River Segment 2 (Thiensville to Grafton); and to a lesser extent, the discharge from Wilshire pond which receives stormwater runoff from the 2 industrial sites (Mercury Marine Plant 2 and Amcast), some residential yards, and the Quarry pond.

Linkage Analysis

The linkage analysis can be defined as the cause and effect relationship between the target value set and the sources of pollutant. For this TMDL, the linkage consists of a 2 step-process involving 1) the linkage of the fish tissue target to an appropriate PCB sediment concentration or Sediment Concentration Threshold (SCT) and; 2) the linkage of the PCB SCT to the PCB load.

Step 1: Linkage between the PCB fish tissue target and the PCB SCT

The linkage between the PCB fish tissue target of 0.21 mg/kg and the PCB sediment concentration in Cedar Creek is the basis of development for this TMDL. We assume that a reduction of PCB content in Cedar Creek's bottom sediments to a given threshold value (Sediment Concentration Threshold, SCT) will result in a reduction in the fish tissue PCB levels.

Fish are exposed to PCBs principally from direct (ingestion, contact) or indirect contact (eating contaminated aquatic organisms) with contaminated sediment. As mentioned previously, PCBs are almost non-soluble in water and bind to sediment particles. The PCB contained in sediment will continue to contaminate the fish unless the sediments are managed or remediated in some manner. Therefore, a decrease of PCB concentrations in stream bottom sediment of Cedar Creek will result in a reduction in the fish tissue PCB concentrations in Cedar Creek and the Milwaukee River.

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[10] Village of Grafton (WPDES permit WI-S050148-1), Town of Grafton ((WPDES permit WI-S050156-1), City of Mequon (WPDES permit WI-S050091-1), Village of Thiensville (WPDES permit WI-S050156-1), Ozaukee County (WPDES permit WI-S050075-1).

Food-web bioaccumulation models can be used to estimate the PCB SCT corresponding to a fish tissue target concentration. In this TMDL, to translate the fish tissue target to a corresponding sediment concentration, we used the results obtained from the Lower Fox Bioaccumulation Model (FRFood Model)[11] as part as the Risk Assessment Study (RETEC 2002). In this study, they obtained a PCB SCT of 0.11 mg/kg for a PCB goal in fish tissue of 0.14 mg/kg in carp [12].

The fish goal of 0.14 mg/kg corresponds to a risk-based PCB fish concentration (reasonable maximum exposure) for high-intake fish consumer of carp and a cancer risk of 10^{-4} (RETEC 2002, see table on p. 5-131, section 5.9.9). This fish value was chosen to derive the SCT in this TMDL because it: 1) is associated to the same cancer risk (10^{-4}) as the 0.21 ppm fish target value in this TMDL, and 2) allows for the protection of the majority of the population (including subsistence and recreational anglers[13]) since this value of 0.14 mg/kg aims to protect high-intake fish consumers. The fish tissue goal of 0.14 mg/kg is more protective than the fish tissue target of 0.21 mg/kg set for this TMDL which is part of the margin of safety for this TMDL (see below section *Margin of Safety*). Therefore, it is reasonable to use **0.11 mg/kg as the PCB SCT** for Cedar Creek that will lead to a PCB fish tissue reduction to the target of 0.21 mg/kg. This value of 0.11 mg/kg is slightly higher than the PCBs Sediment Quality Guideline for Wisconsin of 0.06 mg/kg but this guideline is based on data related only to benthic organisms and not fish.

Is it important to emphasize that the 0.11 mg/kg PCB SCT used here is not meant to be a clean-up criterion, but rather a long-term goal of sediment PCB concentration. This goal could be attained following the reduction of the PCB internal load by combination of sediment remediation and to a lesser extent natural attenuation (volatilization, microbial degradation, and dilution by clean sediment). The final selection of the remedial action levels is a policy decision left to the US EPA in consultations with the WDNR, as part of the feasibility study and Superfund Record of Decision.

Step 2. Linkage between PCB SCT and PCB load

The second step of the linkage analysis establishes the relationship between the PCB SCT of 0.11 mg/kg and the PCB load in Cedar Creek.

The movement of PCB in Cedar Creek and the Milwaukee River is highly dynamic and results from the scouring, resuspension, and deposition of contaminated sediments. During normal flow, scouring and resuspension is observed in the intermediate reaches between the impoundments, while deposition occurs mainly in the impoundments. Some deposition also takes place in the

[11] The FRFood Model is a series of mathematical equations that describe a food web and the transfer of bioaccumulating contaminants within that food web. The model includes uptake routes from sediment and water to benthic infauna and ultimately fish, and was constructed so that it could be used to either predict fish tissue concentrations from a given sediment concentration, or to predict sediment concentrations from a given fish tissue concentration. When the predicted concentrations were compared to the actual measured concentrations of total PCBs in fish collected in the Lower Fox River and Green Bay, the results were highly comparable (Retec 2002).

[12] The derivation of the SCT of 0.11 mg/kg is discussed in section 7.4.2 of the Risk Assessment Study (RETEC 2002) and also provided in table 7-9 of the same study (see STC-RME for high-intake of carp). Note that the SCTs are given for a 10^{-5} cancer risk and are an order of magnitude higher for a 10^{-4} cancer risk which is the corresponding cancer risk for the fish tissue goal in this TMDL.

[13] Fishing for subsistence has been shown to be highly probable in the Milwaukee River area (Pajak 1991).

lower stretch, between the former Hamilton pond and the mouth (Steuer *et al*. 1999). During high flow events however, it is expected that resuspension also occurs in the impoundments and the suspended solids transport downstream.

This resulting load of suspended solids in Cedar Creek can be used along with the PCB SCT to estimate the corresponding PCB load in the stream. The TSS load of 630 tons/year obtained just downstream of Colombia pond[14] for 1994-1995 was used here as the current TSS load for Cedar Creek (Steuer *et al*. 1999). Thus, using a current TSS load of 630 tons/year and a PCB SCT of 0.11 mg/kg, the estimated PCB load in Cedar Creek from the sediment would be 62.9 g/year or 0.17 g/day. The following equations describe the calculation:

$$630 \text{ tons/year} = 571{,}526 \text{ kg/year}$$

$$571{,}526 \text{ kg/year} \times 0.11 \text{ mg/kg} = 62{,}864 \text{ mg/year}$$

$$= 62.9 \text{ g/year}$$

$$= 0.17 \text{ g/day}$$

TMDL Development

The total loading capacity for PCBs in this TMDL is the sum of the wasteload allocation, the load allocation and the margin of safety, as generally expressed in the following equation:

TMDL = WLA + LA + MOS

TMDL = Total Maximum Daily Load
WLA = Wasteload Allocation
LA = Load Allocation
MOS = Margin of Safety

Wasteload Allocation (WLA)

Wilshire pond is the only point source that contributes to the impairment for this TMDL (see section *Source Assessment*). The **WLA for PCBs is 0 g/day** where the PCB concentration of the city of Cedarburg WWTP and Wilshire Pond effluents must be below the limit of detection (LOD) of the recommended analytical method for effluent monitoring (Table 4).

The load allocation for the city of Cedarburg **WWTP** is 0 g/day where the PCB concentration of the effluent must be below the LOD of the recommended analytical method in effect for effluent monitoring. This facility is not allowed to increase its discharge above the limit of detection

[14] Sampling site located 50 ft downstream of Colombia pond at Highland Rd.

since it does not currently discharge PCBs (concentrations below the limit of detection) into Cedar Creek[15].

The WLA for **Wilshire stormwater retention basin** is set to 0 g/day where the concentration at the outfall must be below the LOD of the analytical method in effect for effluent monitoring. The load allocation for Wilshire Pond would be of 0.000001 g/day using the human cancer criterion of 0.003 ng/L as the limit at the outfall[16]. However, this value of 0.003 ng/L is lower than the LOD of the analytical method currently applicable for effluent monitoring (method SW-846 8082).

Table 4. Point sources located within the impaired section of Cedar Creek

Point source	WPDES Permit number	WLA (g/day)
Wilshire retention pond	WI-S049972-2	0*
WWTP – city of Cedarburg	WI-0020222-07-0	0*

** Concentration at the outfall must be below the limit of detection (LOD) using the most recent recommended analytical method for effluent monitoring.*

Load Allocation (LA)

The loading of PCBs to Cedar Creek is due largely to nonpoint sources and to a lesser extent to point sources. Possible nonpoint sources of pollution include *internal load* from bed scour and resuspension of contaminated bottom sediments, and *external load* including run-off from contaminated sites in the watershed and atmospheric deposition. Since runoff waters are directed to the Wilshire pond by the storm sewer system (Wilshire pond is addressed as a point source, see above); PCB is not occurring naturally, and atmospheric deposition is likely to be counterbalanced by the PCB loss from volatilization, the external load allocation is set to zero. Hence, the entire load allocation for Cedar Creek is attributed to **the internal load from contaminated bottom sediments and is 0.17 g/day**.

Margin of Safety (MOS)

The MOS in a TMDL is used to account for variability of source inputs to the system and is either implicit or explicit. Making and documenting conservative assumptions in the TMDL analysis results in an implicit MOS. The MOS for the Cedar Creek PCB TMDL is implicit because the fish tissue target concentrations represent an integration of cycling of PCBs over all critical conditions and uses the edible portion of the fish as the endpoint for this TMDL. WDNR will propose to monitor PCB concentration in fish tissue and total PCB sediment concentrations over time. The special Fish Consumption Advisory for Cedar Creek will remain in effect until

[15] According to NR 106.06(2), the effluent limitation for new or additional discharge of PCBs may not exceed the most stringent water quality criterion. Here, the effluent limit would be set to 0.003 ng/l (human cancer criterion), which is below the limit of detection of the current recommended analytical method for effluent monitoring (WDNR 2007).

[16] The effluent limitation shall be equal to the lowest water quality criterion when the background concentration is higher than the water quality criterion (ref. NR106.06(6)). The PCB concentrations measured in the water at Hamilton Pond are of 16, 27 and 15 ng/l (BBL 2005).

samples taken from fish from Cedar Creek have met the target value of 0.21 mg/kg of PCB. Also, we adopted a conservative approach by selecting a PCB SCT from the Lower Fox Study calculated for a fish tissue goal (0.14 mg/kg of PCB) slightly lower than the PCB fish tissue target of 0.21 mg/kg set for this TMDL.

Total Maximum Daily Load (TMDL)

The PCBs Total Maximum Daily Load for Cedar Creek is 62.9 g/year or **0.17 g/day**. To meet the TMDL of 0.17 g/day, a 98% reduction in PCB loading is needed (Table 4), assuming a total existing PCB load of 10.27 g/day.

Table 4. Wasteload and load allocations of PCBs for Cedar Creek.

	Existing load	Load allocation	Load Reduction	
	g/day	g/day	g/day	%
WLA				
WWTP of Cedarburg	0 (<LOD) *	0 *	0	0
Wilshire Pond	0.081	0 *	0.081	100
LA				
In-stream sediment	10.14	0.17	9.96	98
Total	10.27	**0.17**	10.10	98

** : The concentration at the outfall must be below the limit of detection (LOD) using the most recent recommended analytical method for effluent monitoring..*

A total maximum daily load of 0.17 g/day of PCBs will result in achieving DNR's goals of reducing fish tissue levels of PCBs in Cedar Creek to the target value of 0.21 mg/kg. This will allow for the removal of the special fish consumption advisory for Cedar Creek and will meet narrative water quality standards that aim to protect the public health and recreational activities. A PCB load reduction will also help to protect the aquatic biota living and wildlife in Cedar Creek and decrease the downstream PCB transport to the Milwaukee River.

Critical Condition

The environmental conditions, or critical conditions, that are used to calculate allowable loads must be defined in a TMDL. Selection of the critical condition involved assessment of potential source contributions under a variety of flow regimes (high, mean, and low). Episodic increases of particle-associated PCBs associated with resuspension of bed sediments may occur during storms (Steuer *et al*. 1999). However, the resulting effect on fish would not be instantaneous but be rather observed on a medium-term basis (weeks or months) because of the PCB transfer within the aquatic food chain. For this reason, there are no specific critical conditions used in the calculation of the Cedar Creek TMDL.

Seasonality

Seasonal variation needs to be addressed when developing a TMDL. The particle-associated PCBs in the water column vary with the seasons mainly as a result of flow. Based on monitoring data, more PCBs are likely to be transported downstream to the Milwaukee River during high flow events (Steuer *et al*. 1999). Considering fish tissue concentrations, seasonal trends in fish tissue concentrations correlate with summer conditions. Elevated summertime suspended solids and PCB levels can be linked to the growth and decay of algae in the water column. Particle-associated PCBs tend to increase in spring and summer associated with algal growth (Steuer *et al*. 1999). In addition, low flow conditions in the summer may also contribute to an augmentation of particle-associated PCBs in the water column due to an increase in biological benthic activity such as bottom-dwelling fish stirring up sediments and causing re-suspension of particle-associated PCBs into the water column. This TMDL will account for the seasonal trend by applying the fish tissue target to fish collected in the summer. By taking this into account, attainment of removing the fish consumption advisory in the summer, when fish are most impacted, and in turn, will be protective all other times of the year.

Monitoring

The WDNR intends to monitor the PCB fish tissue and sediment concentrations until it is deemed that the fish tissue target is being met or until funding for monitoring is discontinued. The fish tissue and sediment monitoring will be conducted at five sampling sites located 1) upstream of the impaired segment of Cedar Creek (reference site), 2) in the Ruck Pond, 3) in the Colombia Pond, 4) between Wire & Nail Pond and the mouth, and 4) in the Thiensville impoundment of the Milwaukee River. Other information will be also available from the 5-year monitoring for waters for which special fish consumption advisories are in effect.

Reasonable Assurance

Some initial actions have been implemented that will reduce PCBs availability to the Cedar Creek. PCBs became a ‘restricted chemical’ as a result of the federal Toxic Substance Control Act of 1976, thereby restricting its use and discharge. More specifically to Cedar Creek, the sediment remediation of Ruck Pond completed in 1994 (see above *Source Assessment* section) was successful with: 1) a 99% PCB mass reduction; 2) a reduction of 40% of median PCB concentration in water and; 3) a long-term PCB mass transport reduction of 95% based on modeling (WDNR 2002). Most importantly, the PCB levels in fish have shown a strong downward trend 6 years after the remediation was completed in 1994. A comparison of the pre-remediation to the post-remediation revealed that the PCB levels in carp dropped from 33.8 mg/kg to 2.75 mg/kg in at least 75% of the samples, while the median sediment concentration decreased from 1875 mg/kg to 1.15 mg/kg (WDNR, 2002). This strongly reinforced the hypothesis that the fish level target of 0.21 mg/kg could be eventually attained by reaching a SCT of 0.11 mg/kg.

Moving forward, the Cleanup Plan as part as the Superfund process includes not only the remediation of Cedar Creek itself, but also the following contaminated sites: Mercury Marine

Plant 2, Amcast property and Quarry pond (EPA 2007). A proposed cleanup plan for Cedar Creek providing the cleanup options should be completed by the end of 2008.

Numerous approaches and engineered controls can be taken to manage PCB contaminated sediment and the risk associated with PCBs: removal and disposal of the contaminated sediment, capping of contaminated sediments, and institutional controls such as advisories to the public, access restrictions, and prohibited activities. Any combination of these approaches should be used to manage the risk of PCBs in Cedar Creek and downstream to the Milwaukee River and Lake Michigan.

Overall, WDNR anticipates the total maximum daily load of 0.17 g/day established here could be attainable on a long-term basis, after remediation of the contaminated in-stream sediments, and the clean up of other areas of the site, along with natural attenuation including volatilization, microbial degradation, and dilution by clean sediment.

Implementation

Cedar Creek is part of the Great Lakes Basin, and ultimately the fate and transport of PCBs to the Milwaukee River and the Milwaukee River Area of Concern should be considered when exploring implementation actions for this TMDL. Despite the remediation efforts of Ruck Pond, human and ecological risks remain in effect downstream of the Ruck Dam in Cedar Creek to the Milwaukee River. Additional remediation is necessary in the Cedar Creek system to see a continual decline in sediment concentrations of PCBs, level of PCBs in fish tissue, and also exports of PCBs to the Milwaukee River[17].

Since Cedar Creek is a Superfund Alternative site, WDNR, EPA and the potential responsible parties are working together on a Remedial Investigation and Feasibility Study Reports (RI/FS). However, the comments from EPA, in consultation with WDNR, should be adequately addressed in the RI/FS conducted by ARCADIS BB&L for the Mercury Marine Corporation. It is important that the RI/FS proceed to completion and in a timely manner.

Model projections indicate system recovery is enhanced by removing contaminants from certain impoundments (Figure 2). In addition, after the Cedar Creek remedy is implemented, significant benefits could be expected including local and watershed-wide fish and wildlife bioaccumulation rate reductions, reduced human health risks associated with fish and wildlife consumption advisories, reduced ecological risk for fish eater animals, and elimination of the potential impacts associated with significant or catastrophic loading events (e.g. high flows or possible dam failure as experience in Hamilton Pond). For example, if the Wire and Nail dam would fail, approximately 70 kg of PCB stored could be released which is greater than the PCB transport estimated from Cedar Creek in the next 25 years (Baird and Associates 1997).

[17] In a similar situation downstream, concept-level remediation costs for the Estabrook Impoundment (Milwaukee River-downstream from Cedar Creek) could be in the range of $18 million to $36 million depending on the quantity of contamination addressed and the management strategy selected (WDNR 2005).

Even though Wilshire Pond currently contributes only a small fraction of the total PCB loads to Cedar Creek, implementation actions must be pursued at this site, along with the other contributing sources of PCBs to Wilshire Pond, including the Amcast property and the Quarry Pond.

Remedial actions completed at Cedar Creek will result in the removal of the fish consumption advisory for Cedar Creek at some time in the future.

Public Participation

A news release was sent to local newspapers and interest groups and individuals on May 21, 2008. The news release indicated the public comment period and how to obtain copies of the public notice and the draft TMDL. The news release, public notice, and draft TMDL was also placed on the DNR's website. This TMDL was subject for public review from June 5 through July 7. In addition, a public meeting was held at the Cedarburg Police Department (Cedarburg, WI) on June 5. During this 30-day comment, comments were received from US EPA, the Village of Thiensville, the Friends of the Milwaukee River, and Mercury Marine. A responsiveness summary to the public comments is provided in Appendix C.

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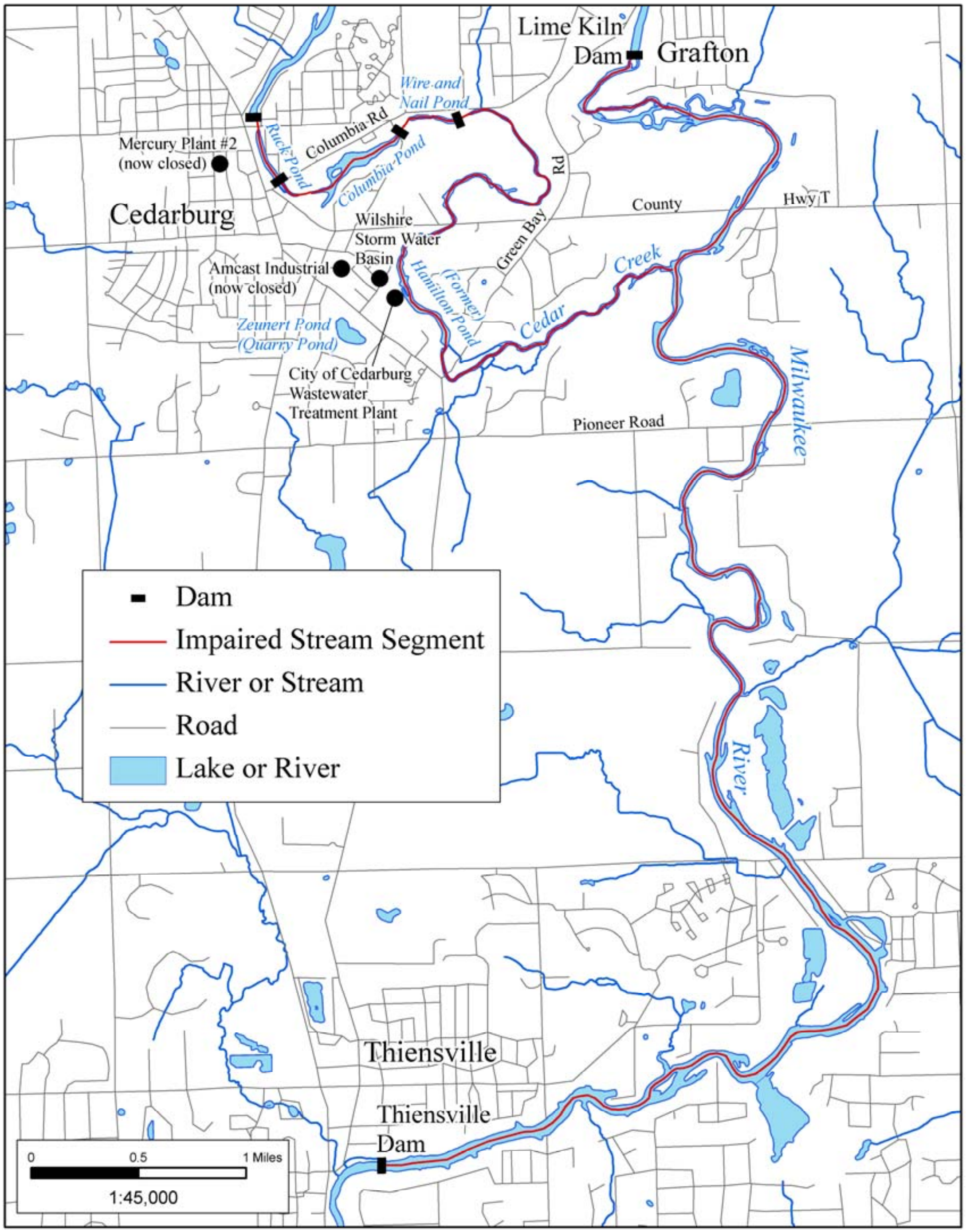

Figure 1. Impaired segments of Cedar Creek and of the Milwaukee River Segment 2 (Thiensville to Grafton) located in Ozaukee County, Wisconsin.

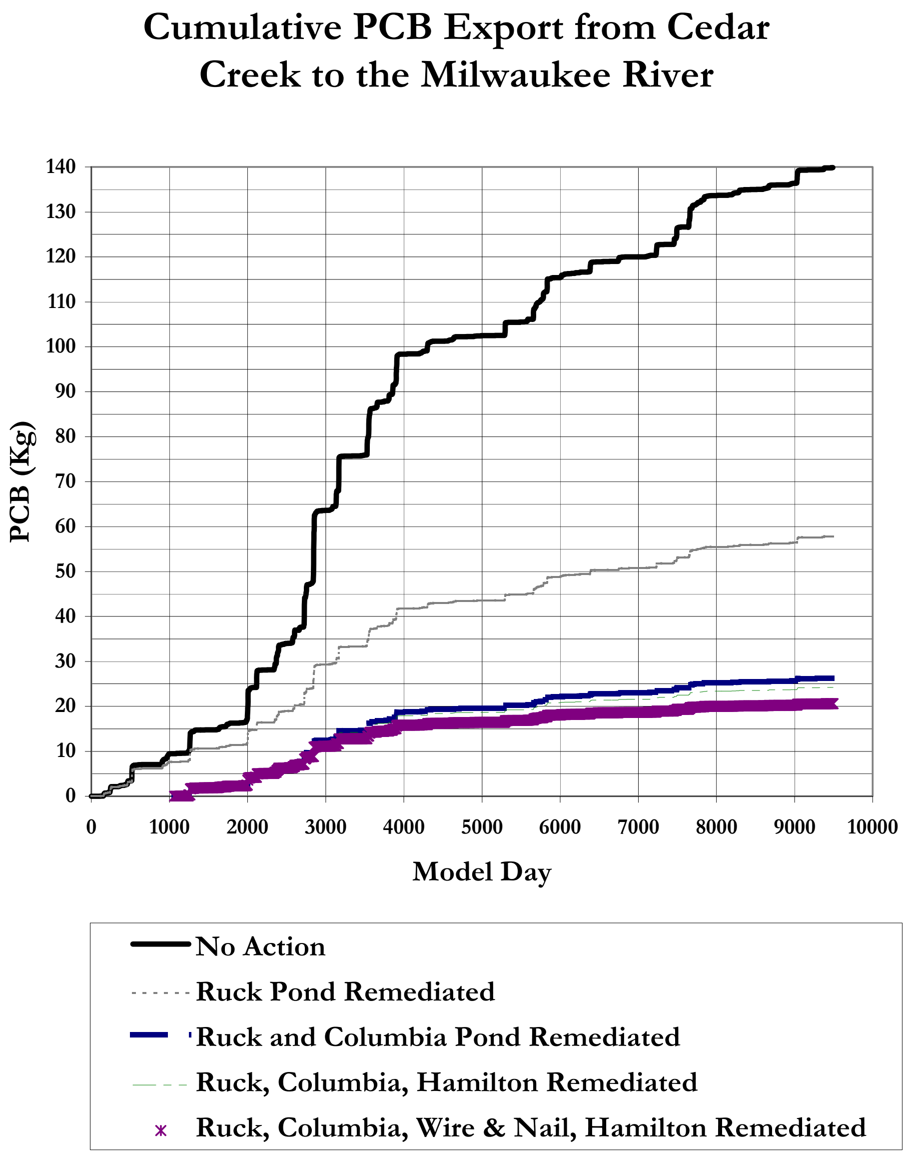

Figure 2. Model projections for different scenarios of mass removal of PCB in the impoundments on the Cedar Creek (Baird & Associates 1997).

Appendix A.
Special Fish Consumption Advice for PCBs and other chemicals for the Milwaukee system

Appendix A. Special Fish Consumption Advice for PCBs and other chemicals for the Milwaukee system

Waterbody/ Species	Unlimited	Eat no more than 1 meal a week or 52 meals/year	Eat no more than 1 meal/month or 12 meals/year	Eat no more that 1 meal every 2 months or 6 meals/year	Do Not Eat
Cedar Creek from Bridge Rd in the Village of Cedarburg including Zeunert Pond, downstream to the Milwaukee River					
All species					All sizes
Milwaukee River from the City of Grafton downstream to Estabrook Falls *					
Black Crappie			All sizes		
Carp					All sizes
Largemouth Bass			All sizes		
Northern Pike				All sizes	
Redhorse			All sizes		
Rock Bass			All sizes		
Smallmouth Bass			All sizes		
Trout and Salmon	*Follow the Lake Michigan PCB advisory below*				
Lake Michigan and the Milwaukee River up to the first dam					
Brown Trout			Less than 25"	Larger than 25"	
Chinook Salmon			Less than 36"	Larger than 36"	
Chubs			All sizes		
Coho Salmon			All sizes		
Lake Trout			Less than 23"	23-27"	Larger than 27"
Rainbow Trout		Less than 22"	Larger than 22"		
Smelt		All sizes			
Yellow Perch		All sizes			
Whitefish			All sizes		

***Note:** *Includes the Milwaukee River's River Segment 2 that extends from the Thiensville Dam to the Lime Kiln Dam in the Village of Grafton.*

Appendix B.

Summary of Wisconsin DNR total PCB concentrations in skin-on fillet fish samples from Cedar Creek and the Milwaukee River (1977-2004).

(LOD=limit of detection; LOD = 0.2 ppm prior to mid-1990s and = 0.05 ppm post mid-1990s)

Appendix B. Summary of Wisconsin DNR total PCB concentrations in skin-on fillet fish samples from Cedar Creek and the Milwaukee River (1977-2004). (LOD=limit of detection; LOD = 0.2 ppm prior to mid-1990s and = 0.05 ppm post mid-1990s)

Advisory Segment	Fish species	Data	time period 1977-1989	1990-1999	2000-2004	Grand Total
Cedar Creek - Bridge Road to Milwaukee River, Zeunert Pond	BLACK BULLHEAD	Number of samples		1	1	2
		min. Length (inches)		6.6	8.34	6.6
		max. Length (inches)		6.6	8.34	8.34
		Average Fat (%)		0.8	1.3	1.1
		Average PCBs (ug/g)		1.000	0.510	0.755
		min. PCBs (ug/g)		1.000	0.510	0.510
		max. PCBs (ug/g)		1.000	0.510	1.000
	BLACK CRAPPIE	Number of samples		10	4	14
		min. Length (inches)		8	7.4	7.4
		max. Length (inches)		12.75	11.3	12.75
		Average Fat (%)		0.5	0.5	0.5
		Average PCBs (ug/g)		3.630	0.518	2.741
		min. PCBs (ug/g)		0.200	0.110	0.110
		max. PCBs (ug/g)		11.000	0.710	11.000
	BLUEGILL	Number of samples		2	1	3
		min. Length (inches)		5.6	6.3	5.6
		max. Length (inches)		6.6	6.3	6.6
		Average Fat (%)		1.1	0.5	0.9
		Average PCBs (ug/g)		1.400	<LOD	0.933
		min. PCBs (ug/g)		1.100	<LOD	<LOD
		max. PCBs (ug/g)		1.700	<LOD	1.700
	CARP	Number of samples	15	25	21	61
		min. Length (inches)	14	19	15.4	14
		max. Length (inches)	26.8	30	27.9	30
		Average Fat (%)	4.2	2.2	1.2	2.4
		Average PCBs (ug/g)	35.882	11.204	2.655	12.817
		min. PCBs (ug/g)	0.200	0.170	0.076	0.076
		max. PCBs (ug/g)	160.000	58.000	11.000	160.000
	LARGEMOUTH BASS	Number of samples		6	6	12
		min. Length (inches)		10.7	7.7	7.7
		max. Length (inches)		15.75	15.1	15.75
		Average Fat (%)		0.8	0.5	0.7
		Average PCBs (ug/g)		2.093	0.698	1.396
		min. PCBs (ug/g)		0.860	0	0
		max. PCBs (ug/g)		3.000	1.500	3.000
	NORTHERN PIKE	Number of samples	13	12	7	32
		min. Length (inches)	9.8	14.1	15.9	9.8
		max. Length (inches)	22.6	28.25	23.2	28.25
		Average Fat (%)	0.6	0.4	0.6	0.5
		Average PCBs (ug/g)	12.738	2.616	0.538	6.273
		min. PCBs (ug/g)	0.790	0.110	0.066	0.066
		max. PCBs (ug/g)	27.000	6.200	1.300	27.000

Advisory Segment	Fish species	Data	time period 1977-1989	1990-1999	2000-2004	Grand Total
Cedar Creek - Bridge Road to Milwaukee River, Zeunert Pond (cont')	PUMPKINSEED	Number of samples		1		1
		min. Length (inches)		5.9		5.9
		max. Length (inches)		5.9		5.9
		Average Fat (%)		0.7		0.7
		Average PCBs (ug/g)		0.970		0.970
		min. PCBs (ug/g)		0.970		0.970
		max. PCBs (ug/g)		0.970		0.970
	RAINBOW TROUT	Number of samples		6		6
		min. Length (inches)		8.4		8.4
		max. Length (inches)		11.1		11.1
		Average Fat (%)		2.1		2.1
		Average PCBs (ug/g)		0.227		0.227
		min. PCBs (ug/g)		0.200		0.200
		max. PCBs (ug/g)		0.290		0.290
	ROCK BASS	Number of samples	14	8	3	25
		min. Length (inches)	5.66	6	8.37	5.66
		max. Length (inches)	10.7	9.25	9.45	10.7
		Average Fat (%)	0.5	0.6	0.4	0.5
		Average PCBs (ug/g)	2.903	1.273	0.710	2.050
		min. PCBs (ug/g)	0.580	0.100	0.130	0.100
		max. PCBs (ug/g)	7.700	2.700	1.100	7.700
	SMALLMOUTH BASS	Number of samples		1		1
		min. Length (inches)		14.8		14.8
		max. Length (inches)		14.8		14.8
		Average Fat (%)		1.8		1.8
		Average PCBs (ug/g)		7.700		7.700
		min. PCBs (ug/g)		7.700		7.700
		max. PCBs (ug/g)		7.700		7.700
	WALLEYE	Number of samples		1		1
		min. Length (inches)		16.7		16.7
		max. Length (inches)		16.7		16.7
		Average Fat (%)		1.4		1.4
		Average PCBs (ug/g)		1.200		1.200
		min. PCBs (ug/g)		1.200		1.200
		max. PCBs (ug/g)		1.200		1.200
	WHITE SUCKER	Number of samples	2	21	12	35
		min. Length (inches)	15.6	12.25	13.3	12.25
		max. Length (inches)	16.4	17.8	16.7	17.8
		Average Fat (%)	0.8	0.7	1.2	0.9
		Average PCBs (ug/g)	3.550	2.651	0.634	2.011
		min. PCBs (ug/g)	1.800	0.058	0.077	0.058
		max. PCBs (ug/g)	5.300	8.600	1.900	8.600
	YELLOW PERCH	Number of samples		1		1
		min. Length (inches)		6.7		6.7
		max. Length (inches)		6.7		6.7
		Average Fat (%)		0.8		0.8
		Average PCBs (ug/g)		2.0		2.0
		min. PCBs (ug/g)		2.0		2.0
		max. PCBs (ug/g)		2.0		2.0

Advisory Segment	Fish species	Data	time period 1977-1989	1990-1999	2000-2004	Grand Total
Cedar Creek - upstream of Cedarburg	BLACK CRAPPIE	Number of samples		2	3	5
		min. Length (inches)		7	10.2	7
		max. Length (inches)		7.9	13.5	13.5
		Average Fat		0.5	0.7	0.6
		Average PCBs (ug/g)		<LOD	0.017	0.010
		min. PCBs (ug/g)		<LOD	<LOD	<LOD
		max. PCBs (ug/g)		<LOD	0.052	0.052
	BLUEGILL	Number of samples		2		2
		min. Length (inches)		4.3		4.3
		max. Length (inches)		5.3		5.3
		Average Fat (%)		0.6		0.6
		Average PCBs (ug/g)		<LOD		<LOD
		min. PCBs (ug/g)		<LOD		<LOD
		max. PCBs (ug/g)		<LOD		<LOD
	CARP	Number of samples	4	5		9
		min. Length (inches)	19.5	22.2		19.5
		max. Length (inches)	29	23.3		29
		Average Fat (%)	4.9	4.1		4.4
		Average PCBs (ug/g)	30.350	0.051		13.517
		min. PCBs (ug/g)	0.200	<LOD		<LOD
		max. PCBs (ug/g)	82.000	0.078		82.000
	NORTHERN PIKE	Number of samples	1		2	3
		min. Length (inches)	15.8		16.4	15.8
		max. Length (inches)	15.8		20.75	20.75
		Average Fat (%)	0.2		0.6	0.4
		Average PCBs (ug/g)	1.400		<LOD	0.467
		min. PCBs (ug/g)	1.400		<LOD	<LOD
		max. PCBs (ug/g)	1.400		<LOD	1.400
	ROCK BASS	Number of samples	3		3	6
		min. Length (inches)	8		8.6	8
		max. Length (inches)	9.2		10	10
		Average Fat (%)	0.3		0.4	0.3
		Average PCBs (ug/g)	0.767		<LOD	0.383
		min. PCBs (ug/g)	0.200		<LOD	<LOD
		max. PCBs (ug/g)	1.900		<LOD	1.900
	WHITE SUCKER	Number of samples		2	3	5
		min. Length (inches)		15	14.5	14.5
		max. Length (inches)		17.5	17.15	17.5
		Average Fat (%)		1.0	1.2	1.1
		Average PCBs (ug/g)		<LOD	<LOD	<LOD
		min. PCBs (ug/g)		<LOD	<LOD	<LOD
		max. PCBs (ug/g)		<LOD	<LOD	<LOD

Advisory Segment	Fish species	Data	time period 1977-1989	1990-1999	2000-2004	Grand Total
Milwaukee River - Grafton to Thiensville Dam	BLACK CRAPPIE	Number of samples		1	4	5
		min. Length (inches)		11.5	9.6	9.6
		max. Length (inches)		11.5	10.5	11.5
		Average Fat (%)		1	0	1
		Average PCBs (ug/g)		0.440	0.097	0.165
		min. PCBs (ug/g)		0.440	0.055	0.055
		max. PCBs (ug/g)		0.440	0.140	0.440
	CARP	Number of samples	22	10	2	34
		min. Length (inches)	15.0	17.5	19.4	15.0
		max. Length (inches)	27.3	22.2	19.6	27.3
		Average Fat (%)	4	2	4	3
		Average PCBs (ug/g)	4.866	2.233	3.650	4.020
		min. PCBs (ug/g)	0.200	0.130	1.600	0.130
		max. PCBs (ug/g)	10.000	11.000	5.700	11.000
	LARGEMOUTH BASS	Number of samples	6	5	2	13
		min. Length (inches)	10.2	14.6	14.7	10.2
		max. Length (inches)	16.9	17.5	16.2	17.5
		Average Fat (%)	1	1	1	1
		Average PCBs (ug/g)	1.088	0.298	0.110	0.634
		min. PCBs (ug/g)	0.450	0.140	0.110	0.110
		max. PCBs (ug/g)	2.500	0.530	0.110	2.500
	NORTHERN PIKE	Number of samples	11	6	2	19
		min. Length (inches)	14.2	16.2	13.3	13.3
		max. Length (inches)	29.8	26.0	15.0	29.8
		Average Fat (%)	1	0	1	1
		Average PCBs (ug/g)	2.872	3.445	0.665	2.821
		min. PCBs (ug/g)	0.200	0.430	0.230	0.200
		max. PCBs (ug/g)	17.000	17.000	1.100	17.000
	REDHORSE	Number of samples	3	10	3	16
		min. Length (inches)	14.1	16.5	16.2	14.1
		max. Length (inches)	17.0	19.7	17.2	19.7
		Average Fat (%)	1	1	1	1
		Average PCBs (ug/g)	1.207	0.619	0.307	0.671
		min. PCBs (ug/g)	0.340	0.200	0.130	0.130
		max. PCBs (ug/g)	2.300	1.100	0.460	2.300
	REDHORSE, GREATER	Number of samples	1			1
		min. Length (inches)	17.3			17.3
		max. Length (inches)	17.3			17.3
		Average Fat (%)	2			2
		Average PCBs (ug/g)	3.100			3.100
		min. PCBs (ug/g)	3.100			3.100
		max. PCBs (ug/g)	3.100			3.100
	ROCK BASS	Number of samples	4	5	2	11
		min. Length (inches)	8.0	7.4	7.3	7.3
		max. Length (inches)	8.7	9.4	7.9	9.4
		Average Fat (%)	0	1	0	0
		Average PCBs (ug/g)	0.428	0.209	0.115	0.272
		min. PCBs (ug/g)	0.230	0.087	0.100	0.087
		max. PCBs (ug/g)	0.820	0.310	0.130	0.820

Advisory Segment	Fish species	Data	time period 1977-1989	1990-1999	2000-2004	Grand Total
Milwaukee River - Grafton to Thiensville Dam (cont')	SMALLMOUTH BASS	Number of samples	2		3	5
		min. Length (inches)	8.15		12.6	8.15
		max. Length (inches)	11.7		17.0	17.0
		Average Fat (%)	5		0	2
		Average PCBs (ug/g)	0.275		0.183	0.220
		min. PCBs (ug/g)	0.200		0.110	0.110
		max. PCBs (ug/g)	0.350		0.230	0.350
	WALLEYE	Number of samples	1	1		2
		min. Length (inches)	21.3	27.5		21.3
		max. Length (inches)	21.3	27.5		27.5
		Average Fat (%)	1	1		1
		Average PCBs (ug/g)	0.810	1.400		1.105
		min. PCBs (ug/g)	0.810	1.400		0.810
		max. PCBs (ug/g)	0.810	1.400		1.400
Milwaukee River - Newberg to Grafton	BLACK CRAPPIE	Number of samples			2	2
		min. Length (inches)			11.5	11.5
		max. Length (inches)			12.3	12.3
		Average Fat (%)			0.6	0.6
		Average PCBs (ug/g)			<LOD	<LOD
		min. PCBs (ug/g)			<LOD	<LOD
		max. PCBs (ug/g)			<LOD	<LOD
	CARP	Number of samples		10	3	13
		min. Length (inches)		17.9	18.6	17.9
		max. Length (inches)		22.5	22	22.5
		Average Fat (%)		2.9	4.2	3.2
		Average PCBs (ug/g)		0.130	0.092	0.121
		min. PCBs (ug/g)		0.000	0.073	<LOD
		max. PCBs (ug/g)		0.300	0.130	0.300
	NORTHERN PIKE	Number of samples		1		1
		min. Length (inches)		22.5		22.5
		max. Length (inches)		22.5		22.5
		Average Fat (%)		0.5		0.5
		Average PCBs (ug/g)		<LOD		<LOD
		min. PCBs (ug/g)		<LOD		<LOD
		max. PCBs (ug/g)		<LOD		<LOD
	REDHORSE	Number of samples		10	3	13
		min. Length (inches)		14.8	17.47	14.8
		max. Length (inches)		21	21	21
		Average Fat (%)		1.6	1.7	1.6
		Average PCBs (ug/g)		0.047	0.029	0.042
		min. PCBs (ug/g)		<LOD	<LOD	<LOD
		max. PCBs (ug/g)		0.081	0.045	0.081
	ROCK BASS	Number of samples		5	2	7
		min. Length (inches)		5.75	6.8	5.75
		max. Length (inches)		7.25	7.1	7.25
		Average Fat (%)		0.4	0.4	0.4
		Average PCBs (ug/g)		<LOD	<LOD	<LOD
		min. PCBs (ug/g)		<LOD	<LOD	<LOD
		max. PCBs (ug/g)		<LOD	<LOD	<LOD

Advisory Segment	Fish species	Data	time period 1977-1989	1990-1999	2000-2004	Grand Total
Milwaukee River - Newberg to Grafton (cont')	SMALLMOUTH BASS	Number of samples		9		9
		min. Length (inches)		11.5		11.5
		max. Length (inches)		17.2		17.2
		Average Fat (%)		0.7		0.7
		Average PCBs (ug/g)		0.020		0.020
		min. PCBs (ug/g)		<LOD		<LOD
		max. PCBs (ug/g)		0.082		0.082
Milwaukee River - upstream Newberg Dam	BLACK BULLHEAD	Number of samples	8			8
		min. Length (inches)	6.25			6.25
		max. Length (inches)	9.5			9.5
		Average Fat (%)	1.4			1.4
		Average PCBs (ug/g)	0.201			0.201
		min. PCBs (ug/g)	0.200			0.200
		max. PCBs (ug/g)	0.210			0.210
	CARP	Number of samples	2	5		7
		min. Length (inches)	18	16.2		16.2
		max. Length (inches)	26.5	18		26.5
		Average Fat (%)	1.4	3.4		2.8
		Average PCBs (ug/g)	0.255	0.132		0.167
		min. PCBs (ug/g)	0.240	<LOD		<LOD
		max. PCBs (ug/g)	0.270	0.240		0.270
	LARGEMOUTH BASS	Number of samples		1		1
		min. Length (inches)		13.9		13.9
		max. Length (inches)		13.9		13.9
		Average Fat (%)		1.1		1.1
		Average PCBs (ug/g)		<LOD		<LOD
		min. PCBs (ug/g)		<LOD		<LOD
		max. PCBs (ug/g)		<LOD		<LOD
	NORTHERN PIKE	Number of samples	1	1		2
		min. Length (inches)	14.5	17.8		14.5
		max. Length (inches)	14.5	17.8		17.8
		Average Fat (%)	0.2	0.3		0.3
		Average PCBs (ug/g)	0.2	<LOD		0.1
		min. PCBs (ug/g)	0.2	<LOD		<LOD
		max. PCBs (ug/g)	0.2	<LOD		0.2
	ROCK BASS	Number of samples	1	8		9
		min. Length (inches)	8	5.3		5.3
		max. Length (inches)	8	7.6		8
		Average Fat (%)	0.4	0.9		0.8
		Average PCBs (ug/g)	0.2	<LOD		<LOD
		min. PCBs (ug/g)	0.2	<LOD		<LOD
		max. PCBs (ug/g)	0.2	<LOD		0.2
	SMALLMOUTH BASS	Number of samples	3			3
		min. Length (inches)	5.6			5.6
		max. Length (inches)	15.3			15.3
		Average Fat (%)	0.5			0.5
		Average PCBs (ug/g)	0.2			0.2
		min. PCBs (ug/g)	0.2			0.2
		max. PCBs (ug/g)	0.2			0.2

Advisory Segment	Fish species	Data	time period 1977-1989	1990-1999	2000-2004	Grand Total
Milwaukee River - upstream Newberg Dam (cont')	WHITE SUCKER	Number of samples		5		5
		min. Length (inches)		9.3		9.3
		max. Length (inches)		12.5		12.5
		Average Fat (%)		1.0		1.0
		Average PCBs (ug/g)		<LOD		<LOD
		min. PCBs (ug/g)		<LOD		<LOD
		max. PCBs (ug/g)		<LOD		<LOD

Note: Additional data not shown are available for some time periods and locations (including Zeunert Pond) for black bullhead, bluegill, carp, clams, crappie, pumpkinseed, rainbow trout, redhorse, smallmouth bass, snapping turtle, walleye, and yellow perch. PCB concentrations vary between locations, species, and the size and lipid content of individual

Appendix C.
Protocol for a Uniform Great Lakes Sport Fish Consumption Advisory

Protocol
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Great Lakes Fish Advisory Task Force
Protocol Drafting Committee

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Executive Summary

The Great Lakes Sport Fish Consumption Advisory Task Force

The Great Lakes Sport Fish Consumption Advisory Task Force (Task Force) was created on an ad hoc basis in the early 1980's. The informal meetings attempted to share monitoring data and coordinate Lake Michigan consumption advisories on a lake-wide basis. The Task Force was formally established on a basin-wide basis by the Great Lakes Governors' Toxics Agreement in 1986. Task Force membership includes one representative from each Public Health and Environmental or Natural Resources Agency in the eight states bordering the Great Lakes (New York, Pennsylvania, Ohio, Michigan, Indiana, Illinois, Wisconsin, and Minnesota). Additional participants have included the Canadian Province of Ontario, the USEPA and Native American organizations. The Task Force is charged with developing a uniform sport fish consumption advisory protocol applicable to all the Great Lakes. Since its inception, the Task Force has met once or twice each year to share environmental sampling results, coordinate future sampling protocols and review the appropriateness of the placement of fish in each Lake's advisory.

The advisory goals are to: 1) maintain the health benefit of fish consumption, 2) minimize the potential for angler toxic chemical exposure, 3) use credible and understandable science and, 4) present the information in a manner conducive to maximal voluntary compliance.

Many of the sport caught species in the Great Lakes are also available in commercial fish markets (lake trout, walleye, catfish, smelt, perch, buffalo, carp). Experience has shown that maximum voluntary compliance is achieved when advisories provide a reference to publicly accepted regulatory standards. Thus, when initiated in the 1970s, sport fish consumption advisories provided anglers with a qualitative comparison of their catch to the FDA tolerances for marketplace fish. However, now there is general agreement that the current FDA tolerances for market fish are not adequately protective of public health, particularly those who consume sport fish.

Recent angler surveys have found that the frequency of fish consumption among anglers far exceeds the frequencies assumed by the FDA when they established the tolerances.[44,53,64] Such consumers are not adequately protected by the FDA tolerances.[18] In addition, anglers tend to concentrate their fishing in specific geographical locations which eliminates the nationwide contaminant dilution factor assumed in FDA tolerance setting. Angler sport fish consumers deserve advice that provides adequate protection and can accommodate their desire to selectively eat sport fish as often as they wish.

In 1989, the Task Force began an in-depth review of the existing advisory protocol to assure that it met the Task Force charge and goals and utilized the most effective risk reduction communication methods available to maximize voluntary compliance. In this protocol, the Task Force places more explicit emphasis upon quantitative methods of assessment of human health risks.

The Task Force has spent considerable time reviewing and discussing the risk of adverse health effects from consumption of contaminated sport fish. While the review and discussion has been comprehensive, priority was placed upon understanding reproductive, developmental effects and cancer risk. The Task force chose to focus the advisory protocol on PCBs, the chemical contaminant most frequently encountered in Great Lakes fish which necessitates guidance.

The advisory utilizes a weight-of-evidence derived individual health protection value (HPV) of 0.05 ug/kg/day for PCBs residue ingested from fish tissue. The HPV is intended to encompass acceptable cancer and reproductive/developmental risk. To assist in the process, the Task Force sent the final draft protocol out for peer review. The reviewers were a spectrum of scientists who had no association with the development of the HPV or protocol. The reviewer comments were helpful to the Task Force.

A risk analysis shows that this protection value is reasonable and within the margins of exposure for no observed adverse effect levels (NOAEL) for both laboratory animal and human effects (Table 2 & 3). Careful consideration has been given to the uncertainties in cancer risk estimates for PCBs in fish tissue and to the assumptions used in their derivation. Reference is made to the conventional range of acceptable cancer risk utilized for USEPA regulatory programs.

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Overview

Polychlorinated Biphenyls (PCBs) are a family of 209 individual compounds each referred to as a congener. Commercially, PCBs were sold as mixtures. In the United States the most widely used mixtures frequently contained 50 or more congeners and were marketed under the trade name Aroclor.[5] The laboratory animal toxicity testing upon which current regulations are based was done using these commercial mixtures.[28] The pattern of PCB congeners in environmental media, biota and in human tissues differ from the commercial product mixtures.[88] This is explained by differing individual congener environmental persistence and, once absorbed from the environment, differing organism efficiency in metabolizing and/or excreting the different congeners.[21] Current toxicological evaluation efforts are directed toward assessing the toxicity of individual congeners to better understand the risks posed by the mixtures found in the environment and human tissues.[29,127]

All the commercial PCBs mixtures tested have been found to cause reproductive and developmental effects in laboratory animals.[5] Ingestion no observable adverse effect levels (NOAEL), lowest observable adverse effect levels (LOAEL) and reference doses (RfD) can be calculated from these studies. Studies of wild mammals and birds have correlated the observation of adverse effects to the presence of PCBs and pesticide related residues in tissues.[105,114,115] Human investigations have confirmed that PCBs present in maternal blood cross the placenta and enter the fetal circulation.[42] PCBs are effectively excreted via lactation. Human epidemiologic studies have correlated maternal and fetal cord blood PCBs and Lake Michigan sport fish consumption with reproductive effects and infant developmental delays.[11,51,67,69] These human data have been used to estimate LOAEL and NOAEL and human RfDs.[95]

Laboratory animal studies have demonstrated that Aroclor 1260 and Aroclor 1254 cause benign and malignant liver nodules to occur.[28,125,126] However, review of these studies to re-characterize the tumors using current pathologic criteria have resulted in statistically significant excesses of tumors being described only in the studies with PCBs having 60% or greater chlorination.[119]

Assessment of human cancer risk experience has been limited to occupational exposure studies.[19,71] The results are considered equivocal for demonstrating a human cancer risk. The USEPA has categorized the whole family of PCBs on the basis of the Aroclor 1260 studies.[28] PCBs have been given a carcinogen category of B-2 by the USEPA, probable human carcinogen, sufficient evidence for animal carcinogenicity, insufficient evidence for human carcinogenicity.[28]

This report is organized to first discuss the sport fish consumption advisory protocol elements and then, using the proposed advisory protocol, present model advisories for each of the Great Lakes.
Please note that the model tables and specific advice for each of the Great Lakes are preliminary in nature and will be revised and updated to reflect the most current data prior to final advisory issuance.

Protocol Structure Components

The Task Force spent considerable time debating the components that would make up a uniform advisory protocol and would address the risk assessment and risk management issues. First and foremost was the selection of a health protection value on which to base the advisory. An appropriate value is needed to ensure a consistent and scientifically defensible human health endpoint for the protection of public health.

Each state can tailor the advisory language to fit their needs. Consistency in the overall messages that are sent to the fish consuming public is important. The Introductory Advisory Components selected by the Task Force present general information that the public needs in order to make an informed choice about fish consumption. Because the advisory is based on a weight-of-evidence human health protection value that considers all adverse health risks, including the possible link of contaminants to reproductive and cancer risk, the Task Force identified the need for a consistent statement regarding cancer risk.

A Cornell University study[46] identified specific advisory communication techniques that help effectively disseminate advisory information. The study recommendations included the preferred reading level as well as presentation style (cajoling vs. commanding language) and the use of diagrams. These suggestions have been incorporated into the advisory.

The method and statistics involved in the placement of fish into advisory categories is an integral part of an advisory. A consistent protocol is needed in order to ensure that all states use the same methods and so that there are not major fluctuations in advice from year to year.

Because a consistent advisory protocol requires a uniform sampling program, the Task Force felt it important to outline the basic components such as sample preparation and analysis.

The major advisory components which the Task Force identified and which are incorporated into the proposed protocol procedure are as follows.

Advisory Introduction Components

1. A general statement about contaminants, benefits and hazards.
2. A statement on cancer risk.
3. A statement on benefits of fish consumption.
4. Preparation and cooking advice.

Consumption Advice Components

5. Determine whether a meal unit dose reduction is appropriate to convert the raw fish residue data to a delivered dose.
6. Utilize a uniform meal size.
7. Utilize easily understood meal frequencies as Advisory Groups.

Hazard Identification Components

8. Select a fish flesh sample collection protocol for laboratory residue analysis.
9. Select uniform limits of detection for residues in tissues.
10. Establish whole fish size and species contaminant residue concentrations for use in placing fish into consumption categories.

Risk Assessment Components

11. Select a risk assessment procedure for assigning fish to consumption frequency groups.
12. Address issue of multiple contaminants.

Prospective Advisory Items

13. Develop a uniform method for deciding when to shift a size/species class into a higher or lower advisory category.
14. Coordinate the release of each state/province's annual advisory update.

The Task Force reached agreement on the specific components and the discussions on each item are summarized in the following sections. More detailed discussions of some of the issues can be found in the **Appendices I-V**.

1 A general statement about contaminants, benefits and hazards

Summary

The Task Force agreed on the use of a general hazard statement. This component is intended to provide a general overview of contaminants in fish, to give reasons as to why the public should be aware of the risks, and to serve as an introduction to the advisory. The Task Force agreed to the use of the following statement:

"Fish are good for you and good to eat. But some fish may take in contaminants from the water they live in and the food they eat. Some of these contaminants build up in the fish - and you - over time. These contaminants could harm the people who eat them, so it is important to keep your exposure to these contaminants as low as possible. This advisory helps you plan what fish to keep as well as how often and how much sport fish to eat. This advisory is not intended to discourage you from eating fish, but should be used as a guide to eating fish low in contaminants."

2 Statement includes cancer risk

Summary

While this advisory protocol is based on a weight-of-evidence health protection value, the Task Force acknowledges the studies linking cancer and exposure to certain contaminants and also the use of cancer risk assessment as the benchmark for regulatory programs. **Appendix I** contains a discussion of the potential cancer risks. The Task Force agreed to the use of the following cancer risk statement:

"Although this advisory is primarily based on effects other than cancer, some contaminants cause cancer in animals. Your risk of cancer from eating contaminated fish cannot be predicted with certainty. Cancer currently affects about one in every four people by the age of 70; primarily due to smoking, diet and hereditary risk factors. Exposure to contaminants in the fish you eat may not increase your cancer risk at all. If you follow this advisory over your lifetime, you will minimize your exposure and reduce whatever cancer risk is associated with those contaminants. At worst, using Environmental Protection Agency (EPA) methods, it is estimated that approximately one additional cancer case may develop in 10,000 people eating contaminated fish over their lifetime."

3 Statement includes benefits of fish consumption

Summary

In order for consumers to make an informed choice about fish consumption, the Task Force agreed that a statement regarding the health benefits from eating fish should be included. Based upon a review of the literature,[72,74,76,77,96] the Task Force agreed to the use of the following statement:

"When properly prepared, fish provide a diet high in protein and low in saturated fats. Many doctors suggest that eating a half-pound of fish each week is helpful in preventing heart disease. Almost any kind of fish may have real health benefits when it replaces a high-fat source of protein in the diet. You can get the health benefits of fish and reduce unwanted contaminants by following this advisory."

4 Provide preparation and cooking advice

Summary

The Task Force recognizes that skinning and trimming the fish and cooking it in the proper fashion can remove much of the fat from fish and therefore significantly reduce the levels of organic contaminants. Many anglers already skin and trim their fish. **Appendix II** includes a review of the literature on the impact of cleaning and cooking on the residue of contaminants in fish. The Task Force agreed to the use of the following statement in the advisory:

"Many contaminants are found at higher levels in the fat of fish. You can reduce the amount of these contaminants in a fish meal by properly trimming, skinning, and cooking your catch. Remove the skin and trim all the fat from the areas shown on the diagram below: the belly flap, the line along the sides of the fish, fat along the back, and under the skin.

Cooking does not destroy contaminants in fish, but heat from cooking melts some of the fat in fish and allows some of the contaminated fat to drip away. Broil, grill, or bake the trimmed, skinned fish on a rack so the fat drips away. Do not use the drippings to prepare sauces or gravies.

These precautions will not reduce the amount of mercury or other metals in a meal. Mercury is distributed throughout a fish's muscle tissue (the part you eat) rather than in the fat and skin. Therefore, the only way to reduce mercury intake is to reduce the amount of contaminated fish you eat.

IMPORTANT: Follow these cleaning and cooking directions. The meal advice that follows is for eating trimmed and skinned fish."

5 Determine whether a meal unit dose reduction is appropriate to convert the raw fish residue data to a delivered dose

Summary

The states agreed to the use of a 50% reduction factor for most species. The Task Force reviewed a number of documents related to contaminant reduction through various preparation methods (See **Appendix II**) The Task Force realizes that there may be inter-species variances in contaminant reduction by following the suggested guidelines, but feel the 50% reduction factor provides adequate representation of the various species encountered by consumers of sport fish. The standing committee will review this factor annually as more species specific reduction factors for cooking and cleaning methods become known.

NOTE: A 30% (0.3) reduction factor[157] will apply to species that are analyzed as skin-off fillets or skin-off steak (See **Appendix III**).

6 Utilize a uniform meal size

Summary

The Task Force agreed to the use of a 1/2 pound of raw fish per 70 kg body weight as the uniform meal size. It will be assumed that the meal size will change proportionally with body weight.

Most dietitians consider the best predictor of meal size to be the body mass of the individual. The meal size ratio for fish is commonly given as 227 gm/70 kg body weight. Smaller people generally eat smaller meal sizes. The 227 gm (1/2 pound) meal appears to be the most widely used for exposure assessment, often with the caveat that any overestimate provides an additional "margin of safety."

7 Use easily understood meal frequencies as advisory groups

Summary

The Task Force agreed to the use of the following five advisory categories which are used and commonly understood by anglers:

Unrestricted Consumption

One Meal a Week (52 meals/year)

One Meal a Month (12 meals/year)

One Meal every 2 Months (6 meals/year)

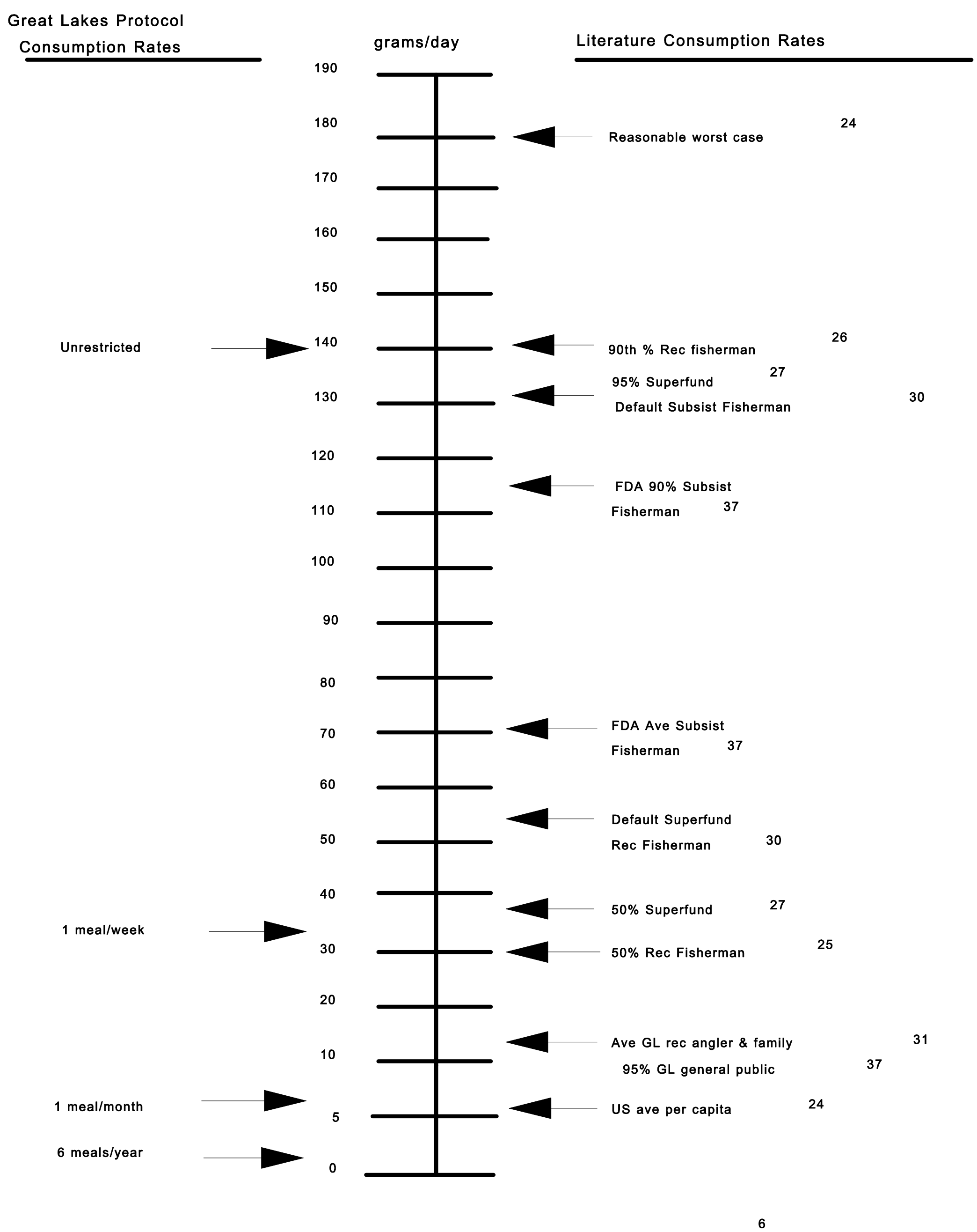
No Consumption (Do Not Eat)

A further discussion of the various ingestion rates found in the literature is provided in **Appendix IV**. **Figure 1** shows the relationship between these ingestion rate assumptions and the Task Force categories.

4 Figure 1

Comparison of Assumed Fish Consumption Rates

(Typical meal size assumed to be 0.5 pounds)



Adapted from Cox JP. TVA/WR-92/27, 1992

8 Select a fish flesh sample collection protocol for laboratory residue analysis

Summary

A raw, skin-on, fillet will be the primary sample to be analyzed for contaminants. The fish should be scaled, then filleted so as to include all flesh from the back of the head to the tail and from the top of the back down to **and including** the belly flap area of the fish. Remove all fins, the tail, head, viscera, and major bones (backbone and ribs).

The only exceptions to this sample type would be as follows: the skin will be removed from black bullhead, brown bullhead, yellow bullhead, channel catfish, flathead catfish and burbot, but fillets would still remain untrimmed. Sturgeon would be analyzed as a skin-off cross section (steak). Smelt should be gutted and the head removed. See **Appendix III** for a listing of species and associated analysis portion.

While some states use whole fish samples for trend monitoring, **whole fish samples will not be used for the purpose of issuing consumption advisories.**

9 Select uniform limits of detection for residues in tissues

Summary

The Task Force realizes that there are certain problems with current laboratory inconsistencies in detection limits. However, the group does not feel this should alter the advisory process, but rather, the advisory process should be used to foster the development of lower detection limits, method sharing, and greater consistency among laboratories.

Therefore, an interim approach for dealing with values below current detection limits is described in **Appendix V**. However, laboratories participating in the state monitoring programs should be encouraged to achieve a PCB detection limit of at least 0.05 ppm within the next 2 years.

10 Establish whole fish size and species contaminant residue concentrations for use in placing fish into consumption categories

Summary

Regression analysis will be the primary method used to determine placement of fish sizes into advisory groups. See **Appendix V** for a discussion of listing criteria, establishment of size ranges, compositing samples and shifting size ranges between consumption categories.

The standing committee members representing each state will meet annually to discuss new data, listing of new species/sites, and shifting of fish and/or size ranges to different consumption advice categories.

Data from so called "hot-spots" would be excluded from consideration for a lakewide advisory if it is determined, by weight of evidence and as judged by the standing committee, that the "hot-spot" data shows significant difference from overall lakewide data.

11 Select a risk assessment procedure for assigning fish to consumption frequency groups

Summary

The Task Force spent considerable time reviewing and discussing the selection of an appropriate adverse health endpoint(s) to use as a reference for the advisory. Instead of the usual single effect reference endpoint, a "weight-of-evidence" approach was chosen which would represent a composite of possible endpoints. However, adverse reproductive and neuro-development studies were given the most weight and included both human experience and controlled laboratory animal studies. After much discussion, a health protection value of 0.05 ug/kg/day PCB residue in sport fish was selected. The technical discussion document "Selection of a Health Protection Value for Regular Consumption of Great Lakes Sport Fish" is attached to this protocol as **Appendix I**. This document describes and summarizes the process used to select the health protection value.

A summary of the resulting risk calculations, and subsequent advisory groupings is discussed below.

Calculations for Protocol Groupings

Assumptions:

1. Health Protection Value = 0.05 ug PCB/kg/day
2. Average meal = 227 g (1/2 lb) uncooked fish
3. Representative target consumer is a 70 kg adult
4. Five advisory groups - meal rates = unrestricted (225/yr); 1/wk; 1/mo; 6/yr; none)
5. Assume skinning/trimming/cooking reduces residues 50% from raw, skin-on filet used to assess PCB residue level.

Calculation of Maximum Daily PCB Ingestion When Following Advisory

0.05 ug/kg/day X 70 kg body weight = 3.5 ug PCB/day. The goal of the advisory is to keep the sport fish associated dietary PCB ingestion below 3.5 ug PCB per day.

Advisory Calculations

Group 1

For unrestricted consumption or up to 225 meals/year (140 g sport fish/day)
3.5 ug/day PCB / 140 g/day fish / .5 (cleaning reduction)

0.05 ppm PCB in raw fish filet

Group 2

For consumption up to one meal a week (32 g sport fish/day)
3.5 ug/day PCB / 32 g/day fish / .5 (cleaning reduction)

0.22 ppm PCB in raw fish filet

Group 3

For consumption up to 1 meal per month (7.4 g sport fish/day)
3.5 ug/day PCB / 7.4 g/day fish / .5 (cleaning reduction)

0.95 ppm PCB in raw fish filet

Group 4

For vacationer consumption up to 6 meals/yr (3.7 g sport fish/day)
3.5 ug/day PCB / 3.7 g/day fish / .5 (cleaning reduction)

1.89 ppm PCB in raw fish filet

Group 5

Do not eat

Greater than 1.89 ppm PCB in raw fish filet

Model Advisory Groupings

Placement of fish species/size classes into consumption advice groups based upon fish tissue concentration of PCB.

Group 1
(Unrestricted Consumption)
raw fish filet with

0 - 0.05 ppm PCB

Group 2
(1 meal/week - 52 meals/year)
raw fish filet with

0.06 - 0.2 ppm PCB

Group 3
(1 meal/month- 12 meals/year)
raw fish filet with

0.21 - 1.0 ppm PCB

Group 4
(6 meals/year)
raw fish filet with

1.1 - 1.9 ppm PCB

Group 5
(No consumption)
raw fish filet with
> 1.9 ppm PCB

12. Address the issue of multiple contaminants

Summary

The Task Force agreed that the health protection value developed for the PCBs would in most instances account for the majority of the potential health risk from the mixture of chemicals present in the fish. For areas where other contaminants are present but not predominant, the health protection value for PCBs would be protective even considering possible additive effects. In areas where other compounds are predominant (i.e., mirex, chlordane, mercury) the most stringent health advice for a given compound would be calculated using new health protection values and advisories based on that compound.

The Task Force plans to develop new health protection values for other chemicals as needed. To establish priorities for developing new health protection values in addition to PCB, the Task Force will compare the existing fish monitoring results with the RfDs developed by USEPA (IRIS). The currently available IRIS RfDs are: Aldrin (3×10^{-5} mg/kg/day), Chlordane (6×10^{-5} mg/kg/day), DDT (5×10^{-4} mg/kg/day), Dieldrin (5×10^{-5} mg/kg/day) and Mirex (2×10^{-6} mg/kg/day). Chemicals responsible for the advisory in specific species/waterbodies will be listed in the advisory next to the subject species.

The Task Force will consider whether the next protocol revision should explicitly include a procedure to devise an health protection value index that will include the risks from all chemicals present in each species and lake monitored.

13. Develop a uniform method for deciding when to shift a size/species class into a higher or lower advisory category

Summary

The Task Force agreed there should be a documented method for shifting species and/or size classes of fish as the monitoring data warrants. **Appendix V** provides the detailed description of the method proposed.

14. Coordinate the release of each state/province's annual advisory update

The Task Force recognizes that coordination of advisory releases may not be entirely feasible since the states differ on the methods of distribution and mode of communication. Advisories that are printed in fishing regulation pamphlets would be dependent upon each individual state's fishing season. However, the standing committee for the Fish Advisory Task Force will meet annually in October to discuss new data, possible changes in advisory categories, and to coordinate advisories for the following year.

Model Advisory

A Guide to Your Health

Fish are nutritious and good to eat. But some fish may take in contaminants from the water they live in and the food they eat. Some of these contaminants build up in the fish - and you - over time. These contaminants could harm the people who eat them, so it is important to keep your exposure to these contaminants as low as possible. This advisory helps you plan what fish to keep as well as how often and how much sport fish to eat. This advisory is not intended to discourage you from eating fish, but should be used as a guide to eating fish low in contaminants.

Health Benefits

When properly prepared, fish provide a diet high in protein and low in saturated fats. Many doctors suggest that eating a half-pound of fish each week is helpful in preventing heart disease. Almost any kind of fish may have real health benefits when it replaces a high-fat source of protein in the diet. You can get the health benefits of fish and reduce unwanted contaminants by following this advisory.

Contaminants in Fish

Long lasting contaminants such as PCBs, DDT, and mercury build up in your body over time. It may take months or years of regularly eating contaminated fish to build up amounts which are a health concern. Health problems which may result from the contaminants found in fish range from small changes in health that are hard to detect to birth defects and cancer. Mothers who eat highly contaminated fish for many years before becoming pregnant may have children who are slower to develop and learn. The meal advice in this advisory is intended to protect children from these potential developmental problems. Adults are less likely to have health problems at the low levels that affect children.

Although this advisory is primarily based on effects other than cancer, some contaminants cause cancer in animals. Your risk of cancer from eating contaminated fish cannot be predicted with certainty. Cancer currently affects about one in every four people by the age of 70; primarily due to smoking, diet and hereditary risk factors. Exposure to contaminants in the fish you eat may not increase your cancer risk at all. If you follow this advisory over your lifetime, you will minimize your exposure and reduce whatever cancer risk is associated with those contaminants. At worst, using Environmental Protection Agency (EPA) methods, it is estimated that approximately one additional cancer case may develop in 10,000 people eating contaminated fish over their lifetime.

How to Use This Advisory

Measure your fish from the tip of the nose to the end of the tail. Find the location, species and size of fish you've caught in the tables that follow. The tables show each kind of fish which has been tested for contaminants. If a species is not listed, it has not been tested.

At the top of the tables, find the meal advice for the size fish you've caught. "No Restrictions" means you can eat as many meals as you like. "Do Not Eat" means no one should eat those fish because of very high contamination. The other three groups ("One Meal a Week", "One Meal a Month", "One Meal Every Two Months") are advice for how often to eat a fish meal. The amount of contaminants in a fish listed in the "One Meal a Month" group is four times higher than the amount of contaminants in a fish listed in the "One Meal a Week" group.

People who regularly eat sport fish, women of childbearing age, and children, are particularly susceptible to contaminants that build up over time. If you fall into one of these categories, you should be especially careful to space fish meals out according to the advisory table that follows. Your body can get rid of some contaminants, such as mercury, over time. Spacing the meals out helps prevent the contaminants from building up to harmful levels in the body. For example, if the fish you eat is in the "One Meal a Month Group", wait a month before eating another meal of fish from **any** restricted category.

Women beyond their childbearing years and men face fewer health risks from contaminants such as mercury. However, if you are in this group you should also follow the advisory to reduce your total exposure to contaminants. For these groups, it is the **total** number of meals that you eat during the year that becomes important and many of those meals can be eaten during a few months of the year. If most of the fish you eat are from the "One Meal a Week" category, you should not exceed 52 meals per year, likewise, if most of the fish you eat are in the "One Meal a Month" category, you should not exceed 12 meals per year. Remember, eating one meal of fish from the "One Meal a Month" group is comparable to eating four fish meals from the "One Meal a Week Group".

One meal is assumed to be one-half pound of fish (weight before cooking) for a 150 pound person. This meal advice is equally protective for larger people who eat larger meals, and smaller people who eat smaller meals.

Cleaning and Cooking Your Fish

Many contaminants are found at higher levels in the fat of fish. You can reduce the amount of these contaminants in a fish meal by properly trimming, skinning, and cooking your catch. Remove the skin and trim all the fat from the areas shown on the diagram below: the belly flap, the line along the sides of the fish, fat along the back, and under the skin.

Cooking does not destroy contaminants in fish, but heat from cooking melts some of the fat in fish and allows some of the contaminated fat to drip away. Broil, grill, or bake the trimmed, skinned fish on a rack so the fat drips away. Do not use the drippings to prepare sauces or gravies.

These precautions will not reduce the amount of mercury or other metals. Mercury is distributed throughout a fish's muscle tissue (the part you eat) rather than in the fat and skin. Therefore, the only way to reduce mercury intake is to reduce the amount of contaminated fish you eat.

IMPORTANT: You must follow these cleaning and cooking directions. The meal advice that follows is for eating trimmed and skinned fish.

Model Advisory Tables for Each Great Lake

Task Force Proposed

Meal Advice for Eating Sport Fish from **Lake Michigan**

DRAFT DRAFT DRAFT DRAFT DRAFT DRAFT DRAFT

Fish	No Restriction	One Meal a Week (52 meals/year)	One Meal a Month (12 meals/year)	One Meal every 2 Months (6 meals/year)	Do NOT Eat
Carp					All Sizes
Catfish					All Sizes
Chinook Salmon			< 26"	> 26"	
Coho Salmon		< 17"	17-28"	>28"	
Brown Trout			< 18"	18-27"	> 27"
Lake Trout			< 21"	21-26"	> 26"
Walleye		< 17"	17 - 26"	> 26"	
Whitefish			< 23"	> 23"	
Yellow Perch	< 9"	> 9"			
Brook Trout			All Sizes		
Pink Salmon			All Sizes		
Rainbow Trout			< 22"	> 22"	
Smelt	All Sizes				

NOTE: This is a DRAFT advisory table proposed by the Task Force. Categories for specific fish are subject to change as new data becomes available.

Task Force Proposed

Meal Advice for Eating Sport Fish from **Lake Superior**

DRAFT DRAFT DRAFT DRAFT DRAFT DRAFT DRAFT

Fish	No Restriction	One Meal a Week (52 meals/year)	One Meal a Month (12 meals/year)	One Meal every 2 Months (6 meals/year)	Do NOT Eat
Lake Trout (Leans)		< 20"	20 - 27"	> 27"	
Siscowet (Fats)				< 20"	> 20"
Chinook Salmon			All Sizes		
Coho Salmon		All Sizes			
Whitefish		All Sizes			
Rainbow Trout		All Sizes			
Brown Trout			All Sizes		
Smelt	All Sizes				

NOTE: This is a DRAFT advisory table proposed by the Task Force. Categories for specific fish are subject to change as new data becomes available.

Task Force Proposed

Meal Advice for Eating Sport Fish from **Lake Erie**

DRAFT DRAFT DRAFT DRAFT DRAFT DRAFT DRAFT

Fish	No Restrictions	One Meal a Week (52 meals/year)	One Meal a Month (12 meals/year)	One Meal every 2 Months (6 meals/year)	Do NOT Eat
Carp			< 20"	> 20"	
Channel Catfish				All Sizes	
Coho			All Sizes		
Lake Trout				All Sizes	
Rainbow Trout (Steelhead)			All Sizes		
Walleye*		< 24"	>24"		
Yellow Perch	All Sizes				
Chinook		< 19"	> 19"		
Smallmouth Bass			All Sizes		
White Bass			All Sizes		
Freshwater Drum		All Sizes			
White Perch			All Sizes		
Maumee Bay (also follow Lake Erie advisories for species not listed below)					
Carp				All Sizes	
Channel Catfish					All Sizes

* <u>All sizes</u> of **walleye** caught in the **Michigan waters of Lake Erie** should be consumed no more than once a month and not to exceed 12 meals/year

NOTE: This is a DRAFT advisory table proposed by the Task Force. Categories for specific fish are subject to change as new data becomes available.

Task Force Proposed

Meal Advice for Eating Sport Fish from **Lake Huron**

DRAFT DRAFT DRAFT DRAFT DRAFT DRAFT DRAFT

Fish	No Restrictions	One Meal a Week (52 meals/year)	One Meal a Month (12 meals/year)	One Meal every 2 Months (6 meals/year)	Do NOT Eat
Chinook Salmon			< 32"	> 32"	
Coho Salmon			All Sizes		
Brown Trout			< 22"	> 22"	
Lake Trout			< 25"	> 25"	
Rainbow Trout			All Sizes		
Burbot		< 20"	> 20"		
Walleye		<21"	> 21"		
Saginaw Bay (also follow Lake Huron advisories for species not listed below)					
Carp				< 23"	> 23"
Catfish			< 15"	15 - 21"	> 21"
Walleye		< 16"	> 16"		
Yellow Perch	< 8"	> 8"			
White Sucker		< 15"	> 15"		
Thunder Bay (also follow Lake Huron advisories for species not listed below)					
Carp					All Sizes

NOTE: This is a DRAFT advisory table proposed by the Task Force. Categories for specific fish are subject to change as new data becomes available.

Task Force Proposed

Meal Advice for Eating Sport Fish from **Lake Ontario**

DRAFT DRAFT DRAFT DRAFT DRAFT DRAFT DRAFT

Fish	No Restrictions	One Meal a Week (52 meals/year)	One Meal a Month (12 meals/year)	One Meal every 2 Months (6 meals/year)	Do NOT Eat
Chinook Salmon			< 15"	15-38"	> 38"
Coho Salmon				All Sizes	
Lake Trout		< 14"	14-17"	17-22"	> 22"
Rainbow Trout		< 16"	16-21"	21-27"	> 27"
Brown Trout		< 14"	14-18"	18-24"	> 24"
Smallmouth Bass			All Sizes		

NOTE: This is a DRAFT advisory table proposed by the Task Force. Categories for specific fish are subject to change as new data becomes available.

APPENDIX I

Selection of a Health Protection Value for Regular Consumption of Great Lakes Sport Fish

Selection of a Health Protection Value for Regular Consumption of Great Lakes Sport Fish

Background

In 1987 and 1989 the Task Force systematically surveyed methodologies used by each of the nine Great Lakes jurisdictions for issuing fish consumption advisories. The goal was to identify common advisory criteria as well as any inconsistencies. At the May 1990 Task Force meeting the survey results were presented.[61] The results highlighted improvement in coordination, but that the goal of a truly uniform protocol had not been achieved. A strategy to achieve such a common protocol was proposed.[34] Since that time, procedures to advance toward that goal and a plan for implementation have been developed.

The decision to renew efforts to resolve jurisdictional differences of policy and scientific opinion was facilitated by the publication of the USEPA ambient water quality criteria under Section 304(a) of Clean Water Act[23], the USEPA Guidance Manual for Assessing Human Health Risks from Chemically Contaminated Fish and Shellfish[25], the availability of the ATSDR Toxicological Profiles[1,2,3,4,5], the publication of the Technical Support Document from the National Wildlife Federation Lake Michigan Sport Fish Consumption Advisory Project[18], and the commitment of the Great Lakes Protection Fund to support research to fill data gaps.[90] A similar toxicologic review and research process was occurring concurrently in Canada.[16] These Great Lakes Basin related activities provide an excellent opportunity to achieve international and State jurisdictional agreement on a Great Lakes sport fish consumption advisory protocol.

Central to action to resolve the jurisdictional policy and procedural differences was the recognition that the existing Great Lakes fish consumption advisory protocols, which used the FDA "tolerances" and "action levels"[8] for commercial fish as a guide for advising sport angler's on fish consumption, were no longer appropriate.[18,48,54]

Some were cautious about abandoning the proven advisories. While the existing advisory protocol process was no longer considered "state-of-the-art" risk assessment as employed by the USEPA, the existing advisories were well recognized and accepted by anglers.[44,45,46,53] Documented voluntary compliance was reducing angler exposures and being reflected in reduced body burdens of contaminants in at least one state[47]. At issue was whether a significant public health risk remained for those carefully following these advisories and whether that residual risk was sufficient to warrant more restrictive advice.[18,48,54] Many states expressed concern that any change in their advisory needed to result in a significant public health gain to offset any possible increase in risk due to a decrease in compliance with a new and unfamiliar advisory. On the other hand, other states expressed optimism that compliance would increase with a new advisory that the public understood, was consistently applied across the Great Lakes. Despite these concerns about compliance, a Task Force consensus was reached that a more refined, clearly enunciated, science-based protocol was needed. However, a significant public health gain would likely occur because adoption by all Great Lakes jurisdictions would assure public confidence in the validity of the revised advice. An international agreement with Canada would complete unification and thus, resolve existing public confusion.

Introduction

From 1990 through 1992, The Task Force toxicology working sub-group, with the assistance of each jurisdictions scientific staff, systematically reviewed and discussed the risk of adverse human health effects from ingestion of the chemical contaminants present in Great Lakes sport fish. To facilitate the most efficient use of available time and resources, the toxicology group decided to focus in a stepwise fashion on different contaminants, beginning with an evaluation of PCBs.

PCBs were chosen first because: 1) they are the principal contaminant responsible for placement of fish on the current Great Lakes advisories; 2) they are the most ubiquitous contaminant and are monitored in all jurisdictions; 3) they have the largest multi-lake fish tissue data base; 4) they have been studied extensively in laboratory animals and wildlife and; 5) human exposure and health outcome data are available.

Having made the decision to no longer use the FDA tolerances as the comparison value for sport fish consumption guidance, the Task Force needed to develop an appropriate replacement. The Task Force decided to designate the new comparison an individual health protection value (HPV).

The Task Force considered utilizing alternative existing values developed by the USEPA to replace the FDA tolerance. These included the Human Cancer Potency Factor for PCBs ($q1^*$) with a selected risk level determination, and the non-cancer oral risk reference dose (RfD) approach. However, it was felt that conflict with regulatory programs would complicate adoption should the Task Force select one of these values as the HPV. For instance, a 10^{-5} risk level would be more restrictive for sport fish consumption than the 10^{-4} risk level used in the public drinking water program PCB MCL. Alternatively, a 10^{-4} choice as acceptable individual lifetime cancer risk could be interpreted to undermine a jurisdiction's Clean Water Act Section 304(a) enforcement program that utilized a more restrictive 10^{-5} or 10^{-6} criterion target for fish. Some states have a very structured process to adopt RfDs and thus could not support use of a PCB RfD that did not conform to their own methodology or already adopted values.

The complexities of the existing inter-jurisdictional regulatory differences and policies regarding cancer risk methodologies, acceptable risk levels, and RfD development could easily intrude upon the advisory process, unacceptably delaying implementation of the advisory until all the ramifications were considered and resolved.

Health Protection Value Derivation

The Task Force decided to use a weight-of-evidence approach which would consider all the existing toxicologic values and studies to develop an individual health protection value (HPV) that would be uniquely derived for the Great Lakes Sport Fish Advisory Process.

It was intended that by considering all the available information and distilling it into a single HPV the most robust and stable HPV possible would emerge. While new toxicologic information is being published regularly and the cancer risk assessment process and RfD development remain fluid, a composite HPV would be provide greater stability and be less likely to need to change precipitously should federal science policy or individual cancer potency factors be revised, or new RfDs adopted by USEPA.

The Task Force did not develop and utilize a quantitative method to assign "weights" to specific studies which could then be combined to derive the HPV. The Task Force process represented an expert committee approach. The Task force did not make judgements or weight decisions on individual studies. Thus, as one of the Peer Reviewers pointed out, it is difficult for non-task force members to fully understand how each study affected the final HPV.

A quantitative weight-of-evidence method is being developed for the Task Force by Sielken, Inc. under a Great Lakes Protection Fund grant. This project's deliverables will provide the means to explicitly assign weights to issues and studies. The set of computer programs will address carcinogenicity separately from non-cancer endpoints. This approach will allow the user to evaluate the impact of specific weighting decisions.

The Task Force had several broad parameters which guided the HPV development. The first was that the HPV should fall within the one in 10^4 - 10^6 life-time cancer risk range. The second was that toxicologic and epidemiologic studies of adverse reproductive and neuro-developmental end-points were given greater evaluation time and therefore consideration in the HPV selected than other toxicologic endpoints.

After completing the review process and discussing the strengths and weaknesses of the toxicologic data, the Task Force adopted a weight-of-evidence derived health protection value (HPV) of 0.05 ug/kg/day total PCBs residue from fish, as the basis for advice to anglers on consumption of their Great Lakes sport fish. While individually nearly all of the studies considered and referenced in this discussion had identified weaknesses and flaws, taken collectively the Task Force felt the data supported the selected HPV.

While a small residual exposure above background remains (less than an order of magnitude), the Task Force believes this HPV provides reasonable protection from adverse health effects from PCBs ingested as a consequence of consuming Great Lakes sport fish and that the HPV is soundly supported by the scientific evidence reviewed.

NOTE:

Some may view, and wish to use this HPV as an RfD. Those choosing to do so must keep in mind that, unlike the traditional RfD process which usually selects a single critical study to derive the RfD, this HPV uniquely represents a consensus of Task Force expert professional judgement on the adverse effect weight-of-evidence and is intended only for deriving the fish consumption advisory. The HPV is not intended as an acceptable "total dietary" PCB exposure as it only addresses that part of the total exposure that comes from sport fish. The HPV is not dependent upon an individual animal or human study, or a single adverse outcome endpoint.

The Task Force recognizes that State and USEPA derived RfDs and Cancer Potency Factors are valuable in risk assessment and risk management and do not advocate that our HPV supplant their validity and continued use.

Adverse Health Effects

The Task force believes that whenever possible it is preferable to base risk assessments on human epidemiologic data. Because of the inherent exposure assessment weaknesses and potential for confounding, such human data has seldom been used as the principle support for quantitative risk assessment. With these caveats in mind, the Task Force placed emphasis upon review of the human epidemiologic studies and specifically those most relevant to ingestion of sport fish, but not to the exclusion of traditional toxicologic evidence from animal studies. There have been many reviews of the published literature on the observed adverse effects of PCB ingestion by laboratory animals and humans.

The published literature contains hundreds of articles detailing the toxicology of PCBs as well as pesticide residues commonly identified in Great Lakes fish species.[5,11,18,21,25,71,95,118,127] The Task Force was not charged with the task of providing a comprehensive written review of this literature. Many excellent reviews are available and, for those wishing more detailed information, the Task Force has provided selected summary references **(references 1 -31)**, key individual human epidemiologic studies specifically reviewed by the Task Force **(references 32 - 99)**, and laboratory animal toxicologic studies **(references 100 - 138)**, and studies related to toxicant reduction from trimming, other preparation and cooking techniques **(references 139 - 157)** in **Appendix VI**.

The following sections are intended to outline the scientific conceptual framework for the Task Force derived health protection value (HPV).

Cancer Risk

Quantitative carcinogen risk assessment has become the standard methodology utilized in the United States to model potential human cancer risk from specific exposure circumstances.[22] The regulation of most carcinogens is based upon the results of such assessments coupled with the selection of an acceptable lifetime cancer risk, usually between 1×10^{-7} and 1×10^{-4}. While conceptually simple, the multiplicity of animal to man extrapolation models, default assumptions, and toxicologic uncertainties in the predictive value of the results have led to risk estimates, based upon the same animal study, which differ by several orders of magnitude.[75] For this methodology to meet the regulatory programmatic needs of the USEPA, that agency developed a policy statement which provided a uniform approach to consistent, comparable risk estimates.[22] Scientific advances, especially in toxicology and laboratory science since the policy was implemented, have led to careful scrutiny and re-evaluation of the current carcinogen risk assessment practices.

Unfortunately, the two federal agencies with programs related to fish residues (FDA[8] and USEPA[22]), historically and currently, continue to utilize different cancer risk estimate methodologies. For instance, to extrapolate the small laboratory animal dose to a human dose the USEPA uses a surface area scaling factor (body weight to the 2/3 power) and the FDA utilizes a body weight scaling factor. This single difference, one of several, produces risk estimates nearly an order of magnitude different when applied to data generated from the Norback et al. rat bioassay.[126] Differences such as this cause public confusion. When these and other agency policy differences are carried through to final regulatory standards, the differences between agencies become even greater. The current draft of the USEPA document "Fish Sampling and Analysis: A Guidance Document for Issuing Fish Advisories"[31] recommends a fish tissue screening value of 0.01 ppm PCBs. The FDA PCBs tolerance for commercial fish is 2.0 ppm. The

Task Force has repeatedly encouraged the agencies to resolve their differences and adopt a single methodology.

In response to the state's priority for a uniform scaling factor, the USEPA, FDA and Consumer Products Safety Commission published a compromise consensus method for cross-species scaling on the basis of body weight raised to the 3/4's power.[116] Application of this technical adjustment would reduce the current EPA Human Cancer Potency Factor ($q1^*$) from 7.7 $(mg/kg/day)^{-1}$ to 4.95 $(mg/kg/day)^{-1}$.

Laboratory Animal Toxicology

Despite the 1992 interagency agreement to use the new scaling factor, the USEPA Human Cancer Potency Factor ($q1^*$) as listed in the USEPA Integrated Risk Information System (IRIS)[28] remains 7.7 $(mg/kg/day)^{-1}$ and the FDA has not begun to re-evaluate their PCB tolerance for commercial fish. The IRIS value is derived from the 1985 study by Norback and Weltman[126] which reported an excess of both benign and malignant liver tumors among female Sprague-Dawley rats chronically fed Aroclor 1260.

In 1991 a review of four of the 2-year oral exposure rat bioassay studies was completed.[119] The criteria for classifying hepatic proliferative lesions in the rat had been revised by the National Toxicology Program[123] since the four bioassay results had been published. The review confirmed the carcinogenicity of Aroclor 1260 (no changes in classification of lesions in the Norback and Weltman study) and in the other two 60% chlorination of PCBs studies.[120,128] Reclassification of some lesions seen in the Aroclor 1254 bioassay[125] resulted in the loss of statistical significance for either increased benign or malignant tumors.

The IEHR[119] report proposed a new methodology for calculating a Human Cancer Potency Factor for PCBs with 60% chlorination. They recommended using the geometric mean of the cancer potency factors derived using the results from the new pathology review classification of the four study groups. This methodology would yield a Human Cancer Potency Factor of 1.9 $(mg/kg/day)^{-1}$.[119]

Human Epidemiological Studies

All the human cohort mortality studies of exposure to PCBs involve occupational settings.[19,36,39,40,59,71,86] In an industrial setting, the route of exposure is predominantly via inhalation and/or skin absorption rather than ingestion. The human cancer experience data is inconsistent and as a whole inconclusive as to cancer risks identified.[5] These and other studies have not been used to quantitatively develop human cancer unit risk estimates. The Task Force agrees with the USEPA conclusion that the existing human occupational mortality data, while supportive of the animal studies, does not lend itself to cancer risk extrapolations.[28]

Because PCBs and some chlorinated pesticides such as DDT/DDE have been shown to have cancer promotor and estrogen-like activity, associations with other cancers have also been investigated.[12] A recent study suggested PCBs may play a role in the development of breast cancer.[50] Another, larger case-control study able to control for more confounding risk factors found a statistically increasing risk of breast cancer for women as their serum DDT/DDE residues increased. PCBs, while showing an upward risk trend, did not reach statistical significance.[99]

Conclusion

PCBs have been given a carcinogen category of B-2 by the USEPA, probable human carcinogen, sufficient evidence for animal carcinogenicity, insufficient evidence for human carcinogenicity.[28] Considerable uncertainties in estimating human cancer risk from prolonged consumption of sport fish contaminants exist. The observation that PCBs in fish and human tissues do not have the same congener pattern as the commercial grade 60% chlorinated PCB found to be carcinogenic in small laboratory animals, adds further uncertainty to using human cancer risk estimation as the sole basis for a sport fish consumption advisory. These issues led to the Task Force decision to not base the advisory HPV solely upon a Human Cancer Potency Factor ($q1^*$) but rather utilize a weight-of-evidence derived value and discuss the range of possible life-time cancer risks for that value.

Non-cancer Risk

To predict human health effects from laboratory animal exposure to non-carcinogenic chemicals, toxicologists rely upon the concept that a threshold dose exists below which no effects are observed and that predictably humans respond to chemicals in a similar fashion to laboratory animals. Animal bioassays with multiple exposure levels are specifically designed to determine the dose of a chemical at which no observable adverse effects occur. This dose is known as the NOAEL. If a NOAEL can not be identified from the study (all exposures cause an adverse effect) then the lowest dose causing an adverse effect is called the lowest observable adverse effect level (LOAEL). While laboratory animal bioassays are most commonly utilized to establish LOAEL and NOAELs, human epidemiological studies can sometimes be utilized.

A Reference Dose (RfD)[49] can be determined from the NOAEL or LOAEL by dividing by uncertainty factors. Uncertainty factors to account for differences between species, differing sensitivity within a species, experiment duration or using a LOAEL instead of a NOAEL.[28] When uncertainty factors (up to 10X each) are combined, typical total adjustments for uncertainty ranges from 100X to 1000X. The RfD is thus based on the assumption that thresholds exist for certain toxic effects. In general, the RfD 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 effects during a lifetime.[28]

Table 2 and Table 3 summarize some of the NOAELs and LOAELs derived from published studies and RfDs which others have developed and used. These are offered for comparative purposes.

Laboratory Animal Toxicology

The USEPA is currently reviewing all available animal bioassay data with the goal of establishing RfDs for as many individual Aroclor mixtures as possible. To date they have proposed one RfD for Aroclor 1016.[28]

In the past they have used the NOAEL for Rhesus monkey (Aroclor 1248 exposure) postnatal decreased body weight (14 ug/kg/day) and an uncertainty factor of 100 to generate an oral Rfd of 0.1 ug/kg/day. This RfD was used in the development of a PCBs drinking water advisory level of 3.5 ug/L for adults.[15,24,109]

Preliminary USEPA reviews suggest an oral RfD for Aroclor 1254 in the range of 0.05 ug/kg/day based on the Rhesus monkey studies showing immunological and menstrual/endocrine abnormalities and applying an uncertainty factor of 100. These effects occurred at a LOAEL of 5 ug/kg/day.[134]

The USEPA also intends to derive an RfD for PCB congener mixtures most commonly found in the environment. Such an RfD is likely to be a composite of multiple non-cancer bioassays.

IRIS Summary Aroclor 1016 RfD

The IRIS Aroclor 1016 RfD has been controversial and is the subject of a pending lawsuit. Many of the studies reviewed by USEPA during the development of the RfD were considered by the Task Force.

Because the IRIS review is concise the Task Force felt it was appropriate to present it. The review is presented for its study summaries not for its conclusions.

Since 1/1/93 the USEPA has listed on IRIS a reference dose (RfD) for Aroclor 1016. The USEPA review for Aroclor 1016 used a monkey reproductive bioassay to derive a reduced birth weights LOAEL of 28 ug/kg/day and a NOAEL 7 ug/kg/day.[107,121,130,131] An uncertainty factor of 100 was used to derive an Aroclor 1016 oral RfD of 0.07 ug/kg/day.

RfD Summary Table From IRIS

IRIS

Topic: AROCLOR 1016

Critical Effect	Experimental Doses*	UF	MF	RfD
Reduced birth weights	NOAEL: 0.25 ppm in feed (0.007 mg/kg-day)	100	1	7E-5 mg/kg-day
Monkey Reproductive Bioassay	LOAEL: 1 ppm in feed (0.028 mg/kg-day)			
Barsotti and van Miller, 1984[107]; Levin et al., 1988[121]; Schantz et al., 1989, 1991[130,131]				

*Conversion Factors: Dams received a total average intake of 4.52 mg/kg (0.25 ppm) or 18.41 mg/kg (1 ppm) throughout the 21.8-month (654 days) dosing period. These doses are equivalent to 0.007 mg/kg-day and 0.028 mg/kg-day for the identified NOAEL and LOAEL respectively.

Toxicology Summary from IRIS[28]

These are a series of reports that evaluated perinatal toxicity and longterm neurobehavioral effects of Aroclor 1016 in the same groups of infant monkeys.[107,121,130,131] Aroclor 1016 is a commercial mixture of polychlorinated biphenyls (PCBs) devoid of chlorinated dibenzofurans.[107] Analysis of the commercial feed used for this study revealed contamination with congeners specific for Aroclor 1248, present in the parts per billion range. These congeners were present in the control as well as test diets.

Aroclor 1016 was administered to groups of 8 adult female rhesus monkeys via diet in concentrations of 0, 0.25 or 1.0 ppm for approximately 22 months. Based on a reported total Aroclor intake of 4.52 and 18.41 mg/kg over the 22 month exposure period,[130,131] the low- and high-doses are estimated to be 0.007 and 0.028 mg/kg-day, respectively. Exposure began 7 months prior to breeding and continued until offspring were weaned at age 4 months. No exposure-related effects on maternal food intake, general appearance, hematology, serum chemistry (SGPT, lipid, and cholesterol analyses) or number of breedings were observed.[107]

All monkeys had uncomplicated pregnancies, carried their infants to term and delivered viable offspring. Teratologic examinations were not performed. Mean birth weights of the infants in the control, 0.007 and 0.028 mg/kg-day dose groups were 521 g, 491 g and 442 g, respectively.[107] The decrease in birth weight in the high-dose group was significantly ($p < 0.01$) lower than in controls. Further statistical analysis of the infant birth weight data by the Agency indicated that gestation length did not significantly affect birth weight and the distribution of male and female infants in the various dose groups could not

account for the difference in birth weights among the dose groups. Agency reanalysis of the data confirmed the significant decrease in body weight for the high-dose infants, although slightly different average values were obtained.
Males that had sired some infants were exposed to Aroclor 1248, so the birth weight data were also analyzed excluding these infants. The results for this adjusted data indicated that control infants weighed 528 g, low-dose infants weighed 486 g, and high-dose infants weighed 421 g. Even with this adjustment there was still a significant difference ($p < 0.01$) in birth weight for the high-dose group when compared with controls.

No significant differences between treatment and control groups were detected in neonatal head circumference or crown-to-rump measurements. Both exposure groups showed consistent weight gains, but infant weights in the high-dose group were still lower (864 g) at weaning, although not significantly different from the controls (896g).

Hyperpigmentation was present at birth in the low- and high-dose infants but did not persist once dosing was stopped. This clinical change was determined not to be a critical adverse effect. The concentration of Aroclor 1016 in breast milk was higher than the maternal dose. No exposure-related hematologic effects were observed in the infants during the nursing period.[107] One of the offspring in the high-dose group went into shock and died on the day following weaning for unknown reasons.[130,131]

Behavioral testing of the infant monkeys was first performed at age 14 months and no overt signs of PCB toxicity were observed.[130,131] Two-choice discrimination-reversal learning was assessed using simple left-right spatial position, color and shape discrimination problems, with and without irrelevant color and shape cues. One of the offspring in the low-dose group stopped responding early in testing for an unknown reason and could not be induced to resume; therefore, test results were obtained using 6, 7 and 6 infants in the control, low- and high-dose groups, respectively. The offspring in the high-dose (0.028 mg/kg-day) group were significantly ($p < 0.05$) impaired in their ability to learn the spatial position discrimination problem (i.e., achieved 9 correct choices in 10 trials), requiring more than 2.5 times as many trials as their age-matched controls. There were no significant learning differences between these groups on this problem during overtraining (ability to achieve greater than or equal to 90% correct choices in two consecutive daily sessions) or position reversals.

The only other exposure related effect was significantly facilitated learning ability ($p < 0.05$) on the shape discrimination problem at 0.028 mg/kg-day. Performance on delayed spatial alternation (a spatial learning and memory task) was assessed in the offspring monkeys at age 4-6 years.[121,131] The two Aroclor-exposed groups were not significantly different from controls ($p < 0.05$) in test performance. However, the exposed groups did significantly ($p < 0.05$) differ from each other. The difference between the two exposed groups was due to a combination of facilitated performance at the low-dose (0.007 mg/kg-day) and impaired performance at the high-dose (0.028 mg/kg-day). Although these data are insufficient for establishing an exposure-effect relation due to the lack of difference between exposed and control groups, the investigators suggested that the performance deficit at 0.028 mg/kg-day may have been exposure related.

The investigators noticed that a paradoxical biphasic effect occurred on the same test when comparing low-dose and high-dose infants. This same effect has been observed for lead-exposed monkeys. To summarize the above, adult monkeys that ingested 0.007 or 0.028 mg/kg/day doses of Aroclor 1016 for approximately 22 months showed no evidence of overt toxicity. Effects occurring in the offspring of these monkeys consisted of hairline hyperpigmentation at greater than or equal to 0.007 mg/kg-day, and decreased birth weight and possible neurologic impairment at 0.028 mg/kg-day. Based on the reduced birth weights of prenatally-exposed monkeys, the 0.007 mg/kg-day dose is the NOAEL and the 0.028 mg/kg-day dose is a LOAEL in monkeys.

The results of the neurobehavioral tests in the monkey offspring at 14 months and 4-6 years of age indicate adverse learning deficits at the 0.028 mg/kg-day maternal dose. Evaluation of these data is complicated by possible inconsistencies in the outcome of both the discrimination-reversal learning tests (learning was impaired and facilitated on different problems) and the delayed spatial alternation test (performance significantly differed between the two exposed groups, but not between either test group and the control). However, there is evidence suggesting that deficits in discrimination-reversal learning and delayed spatial alternation are related to decreased brain dopamine,[131] which has been observed in monkeys orally exposed to Aroclor 1016.[132,133]

Behavioral dysfunctions, including deficits in visual recognition and short-term memory, also have been observed in infants of human mothers who consumed fish contaminated with PCB mixtures of unknown composition.[51,52,56,67,70]

Uncertainty Factor Discussion from IRIS[28]

A 3-fold factor is applied to account for sensitive individuals. The results of these studies, as well as data for human exposure to PCBs, indicate that infants exposed transplacentally represent a sensitive subpopulation.

A factor of 3 is applied for extrapolation from rhesus monkeys to human. A full 10-fold factor for interspecies extrapolation is not considered necessary because of similarities in toxic responses and metabolism of PCBs between monkeys and humans and the general physiologic similarity between these species. In addition, the rhesus monkey data are predictive of other changes noted in human studies such as chloracne, hepatic changes, and effects on reproductive function.

A factor of 3 is applied because of limitations in the data base. Despite the extensive amount of animal laboratory data and human epidemiologic information regarding PCBs, the issue of male reproductive effects is not directly addressed and two-generation reproductive studies are not available. As the study duration was considered as somewhat greater than subchronic, but less than chronic, a partial factor of 3 is used to account for extrapolation from a subchronic exposure to a chronic RfD.

Other Federal Agency RfD or Equivalent Values

Table 1 summarizes RfDs adopted or recommended by various groups. The **Agency for Toxic Substances and Disease Registry** (ATSDR) in their Toxicological Profile for Selected PCBs[5] summarized the NOAEL, LOAEL results from 118 studies in Table 2-2 of that document. They organized the adverse effects into six outcome groups; death, systemic effects, immunological, developmental, reproductive and cancer.

Although similar to an RfD, the ATSDR derives a value they refer to as the Minimal Risk Level (MRL). The MRL for PCBs is 0.005 ug/kg/day. ATSDR concluded immunological effects appear to be the most sensitive health endpoint and chose the Tryphonas et al.[135], 27 month, 7 days per week Aroclor 1254 gavage of monkeys study as the basis for deriving their MRL. In that study decreased IgG and IgM response to sheep red blood cells was seen at the lowest exposure dose of 0.005 mg/kg/day. This LOAEL was divided by an uncertainty factor of 1000 to derive the MRL.

The **Tennessee Valley Authority** (TVA) in their evaluation of their fish tissue contaminant data[6] developed and utilized a RfD for PCBs of 0.05 ug/kg/day.

The Biological Water Quality Subcommittee of the **Ohio River Valley Sanitation Commission** (ORSANCO) in their 1989 draft proposed an RfD of 0.1 ug/kg/day for low chlorinated PCBs such as Aroclor 1016 and 1242[20] based upon the same monkey study[107] used by the USEPA in 1988 to derive the RfD used in the water quality criteria document. The adverse heath endpoint was low infant birth weight with a NOAEL of 0.01 mg/kg/day and an uncertainty factor of 100.

They proposed a separate RfD for the higher chlorinated PCBs such as Aroclor 1254 and Aroclor 1260. The reference dose was an order of magnitude lower at 0.01 ug/kg/day.

The **Joint FAO/WHO Expert Committee on Food Additives** evaluated PCBs in 1990. They concluded that they could not establish a precise numerical value for tolerable intake in humans. They identified the monkey bioassay as the most appropriate animal model for estimating human risks from PCBs. From the monkey studies they considered, they concluded that 0.04 mg/kg/day was the no effect level.[7]

After completing their 1989 review of the PCB literature, the **National Wildlife Federation** utilized three oral RfDs of 0.05 ug/kg/day (thyroid/endocrine dysfunction in rats), 0.2 ug/kg/day (liver function abnormality) and 0.01 ug/kg/day (behavior/neuro-development delay) when calculating their hazard index.[18]

For the thyroid/endocrine RfD the NWF relied upon two studies. The first[112] exposed groups of 10 female Sprague-Dawley rats to Aroclor 1254 for five months and observed a significant depression in serum T_4 levels at the lowest dose (0.05 mg/kg/day). This dose did not result in significant liver toxicity. The second study[113] exposed groups of 10 Sprague-Dawley rats to Aroclor 1254, 1242 and 1016 for five months and observed decreased adrenal weight and decreased serum adrenal hormone levels at the lowest dose (0.05 mg/kg/day). The NWF applied an uncertainty factor of 1000 to the LOAEL derived from these studies (0.05 mg/kg/day) to derive this RfD.

The NWF selected the study by Bruckner et al.[111] as the basis for their liver toxicity based RfD. This study fed groups of six Sprague-Dawley rats Aroclor 1242 containing diets for up to six months. At the lowest dose (0.2 mg/kg/day) liver lipid levels were elevated and urinary coproporphyrin excretion significantly increased. Mixed function oxidase activity was induced in a dose dependant fashion with induction occurring at the lowest administered dose. A LOAEL of 0.2 mg/kg/day) was identified. An uncertainty factor of 1000 was applied with the result of an oral RfD of 0.2 ug/kg/day.

The Allen et al[101] study of Rhesus monkeys fed Aroclor 1248 containing diets three times a week for 18 months formed the basis for the NWF RfD for developmental/behavior abnormality. Abnormal behavior patterns were seen at the lowest dose (0.01 mg/kg/day). This LOAEL of 0.01 mg/kg/day was divided by an uncertainty factor of 1000 to derive the RfD of 0.01 ug/kg/day.

Table 1

Organization
Reference Doses (RfD)

ATSDR (MRL)
0.005 ug/kg-day (neuro)

NWF
0.01 ug/kg-day (neuro)
0.05 ug/kg-day (liver)
0.2 ug/kg-day (endocrine)

ORSANCO
0.01 ug/kg-day (1254/60)
0.1 ug/kg-day (1016/1242)

TVA
0.05 ug/kg-day

IRIS (Aroclor 1016)
0.07 ug/kg-day

FAO\WHO Estimate
0.04 - 0.4 ug/kg-day

Table 2

Human and Monkey Bioassay Derived NOAELs and LOAELs for PCBs

HUMAN DATA

			Margins of Exposure over 0.05 ug/kg/day*
NOAEL[95] (Visual recognition memory)	=	0.027 ug/kg/day	0.5
NOAEL[95] (Brazelton/Bayley motor function)	=	0.093 ug/kg/day	2.
NOAEL[85] Reproductive/behavior	=	0.05 ug/kg/day	1.
NOAEL[a] (Visual recognition memory)	=	0.048 ug/kg/day	1.
NOAEL[a] (Brazelton/Bayley motor function)	=	0.16 ug/kg/day	3.
NOAEL[b] (Visual recognition memory)	=	0.095 ug/kg/day	2.
NOAEL[b] (Brazelton/Bayley motor function)	=	0.32 ug/kg/day	6.
NOAEL[c] (Visual recognition memory)	=	0.16 ug/kg/day	3.
NOAEL[c] (Brazelton/Bayley motor function)	=	0.54 ug/kg/day	11.
NOAEL[d] (Visual recognition memory)	=	0.47 ug/kg/day	9.
NOAEL[d] (Brazelton/Bayley motor function)	=	1.61 ug/kg/day	32.

ANIMAL DATA

NOAEL[109] (Monkey - Aroclor 1248 fetal body weight)	=	14. ug/kg/day	280.
LOAEL[109] (Monkey - 1248 learning/memory)	=	1.4 ug/kg/day	28.
LOAEL[134] (Monkey - 1254 reprod/immune)	=	5.0 ug/kg/day	100.
LOAEL[107] (Monkey - 1016 learning defects)	=	28.0 ug/kg/day	560.
NOAEL[28] (Monkey 1016 body weight	=	7.0 ug/kg/day)	140.

a = PCBs half-life assumed to be 10 yrs
b = PCBs half-life assumed to be 5 yrs
c = PCBs half-life assumed to be 3 yrs
d = PCBs half-life assumed to be 1 yr

* Task Force exposure level chosen for evaluating sport fish consumption 0.05 ug/kg/day

Table 3

Human and Laboratory Bioassay Derived RfDs for PCBs

HUMAN DATA

Source	NOAEL/LOAEL	Uncertainty Factor	RfD
Tilson[95] (Visual recognition memory)	0.027 ug/kg/day	10	0.0027 ug/kg/day
Tilson[95] (Brazelton/Bayley motor function)	0.093 ug/kg/day	10	0.0093 ug/kg/day
Minnesota[85] Reproductive/behavior	0.5 ug/kg/day (LOAEL)	10	0.05 ug/kg/day

ANIMAL DATA

Source	NOAEL/LOAEL	Uncertainty Factor	RfD
USEPA[28] Monkey 1016 body weight	7.0 ug/kg/day)	100	0.07 ug/kg/day
Monkey - Aroclor 1248 body weight[109]	14. ug/kg/day	100	0.14 ug/kg/day
Monkey - 1248 learning/memory[109]	1.4 ug/kg/day (LOAEL)	100	0.01 ug/kg/day
Monkey - 1254 reprod/immune[134]	5.0 ug/kg/day (LOAEL)	100	0.05 ug/kg/day
Monkey - 1016 learning defects[107]	28.0 ug/kg/day (LOAEL)	1000	0.028 ug/kg/day
NWF[18] - rat thyroid	50. ug/kg/day (LOAEL)	1000	0.05 ug/kg/day
NWF[18] - rat liver	200. ug/kg/day (LOAEL)	1000	0.2 ug/kg/day
NWF[18] - monkey behavior	10. ug/kg/day	1000	0.01 ug/kg/day

Human Epidemiological Studies

Intuitively, the most appropriate data for assessing the non-cancer human health risks should come from human epidemiologic study. However, the strengths and advantages to the use of human data are often outweighed by inherent study design weaknesses, difficulty in determining actual exposure doses and in establishing reliable and reproducible dose-response relationships. When more than one study is available, the results are often inconsistent. Thus, animal data is often judged most appropriate for primary support of RfD development and epidemiologic data in a secondary support role.

The human health consequences of chronic, low level ingestion exposure to PCBs are not well understood. Because adverse reproductive effects are among the most sensitive effects in animal bioassays, researchers have focused investigation of possible human health effects upon adverse reproductive effects and infant and child developmental delays. Two acute PCBs poisoning episodes, one in Japan[60] and one in Taiwan[83] have been studied carefully over several decades.[73] In these instances prenatal exposure to complex mixtures of degraded PCBs produced infant developmental delay as measured by motor and mental function tests. These abnormalities persisted into the early school ages (last time examined). All the mothers had been clinically ill and many of the children also had signs and symptoms of illness. A major confounder to the study observation was the presence of heat degradation products of PCBs including highly toxic polychlorinated dibenzofurans.[73]

An occupationally PCB exposed group of female capacitor workers was studied by Taylor et al.[93] After controlling for some possible confounding factors such as twinning, sex, maternal genetic factors and illness during pregnancy, they found a statistically significant decrease in mean birth weight and gestational age. However, other confounding factors such as cigarette smoking and alcohol consumption were not assessed and the mean decrease in birth weight was small (-30 grams) and the clinical significance of the decrease questionable.

A prospective study of 856 breast fed infants in North Carolina were identified at birth and followed periodically for up to 60 months has been reported in a series of publications.[56,57,81,82] Higher in utero PCB exposure, assessed as maternal breast milk fat PCBs concentration, was associated with hypotonicity and hyporeflexia on the Brazelton Neonatal Behavioral Assessment Scales[38]. No association was seen with birth weight, head circumference or gestational age. Maternal serum, maternal breast milk, placenta and cord serum were tested. Most of the PCB levels in cord serum were below the laboratory limit of detection.

At six and 12 month followup examination, Bayleys Scales of Infant Development were used and the psychomotor index showed a downward trend with increasing transplacental exposure to PCBs.[56] Mental index scores were not associated with PCBs exposure. DDE was included in the laboratory analyses performed on breast milk fat but was not related to psychomotor scores. At subsequent examination the observed behavioral effects were not seen.[57]

A prospective study of 1112 women in Green Bay, Wisconsin who were seen at the time of a positive pregnancy test evaluated potential associations between adverse reproductive outcomes and historic Lake Michigan sport fish consumption habits.[47] The typical effects of known confounders were seen; negative associations between birth size measures and cigarette smoking, consumption of alcohol and caffeine, and positive associations with gestational age, birth order, weight gain during pregnancy, male babies, and rural residence. Contrary to expectations, PCB exposure (sport fish consumption) was positively associated with birth weight for most women (the exception being those women who gained more than 34 lb during pregnancy). Serum PCBs concentrations were performed on 106 women and correlated positively with local sport fish consumption (Pearson correlation of 0.666). The PCBs concentration was based upon the sum of 13 individual PCB congeners. Serum PCBs sums were low (only 23% had PCBs above the detection limit of 0.6 ng/ml for each congener). The highest congener sum was 5.0 ng/ml. Consumption of highly contaminated sport fish was quite low in this population. This study suggests that if adverse reproductive effects occur due to sport fish consumption, there is likely a threshold for such effects.

A series of papers have reported prospective observation of Michigan children born to women who consumed contaminated fish from Lake Michigan.[51,52,66,67,68,69,70,84] Reduced birth weight, head circumference, gestational age and developmental behavioral changes were noted in the exposed children when compared to a group of children born to non-sport fish consuming women. The children were assessed at birth, 7 months of age and at 4 years. These studies attempted to correlate maternal sport fish consumption, serum PCBs, breast milk PCBs and cord serum PCBs with reproductive and developmental outcome observations and assess dose-response relationships. The women had consumed Lake Michigan fish for an average of 16 years, averaging 6.7 kg of fish per year, the median being two 1/2 lb meals per month. The contamination levels in the different fish species were estimated based upon research monitoring performed at the Large Lakes Research Station (USEPA) at Grosse Ile, Michigan. Actual species specific meals consumed were standardized to the equivalent contaminant level in Lake Trout. Maternal serum PCBs concentration (as Aroclor 1260) for all women averaged 5.5 ng/ml (ppb). The exposed group averaged 6.1 ng/ml and the unexposed group 4.1 ng/ml.

Dose-response analyses[52] indicated that the greatest decrease in birth weight and head circumference were seen in infants of mothers who consumed 6.6 - 41.7 kg/year. Effects were observed at consumption rates as low as 2-3.4 kg/yr. The mean birth weight was 190 grams less in the exposed group compared to the unexposed.

At seven months of age some of the children were re-evaluated and found to have decreased scores on a visual recognition memory test.[67] The decreased performance was associated with increasing cord serum PCBs concentrations but not maternal fish consumption. Maternal fish consumption was not correlated with cord serum PCBs concentration. At four years of age, cord serum PCBs levels greater than 1.5 ng/ml were associated with lowered scores on another short-term memory test (McCarthy Scale)[69], but not on the long-term memory component of the test battery. This group of children continues to be followed.

As with many human epidemiologic studies, results are difficult to evaluate. While statistically significant differences between study groups were seen, the clinical significance of the differences is difficult to assess. The actual Lake Michigan fish related PCB exposure of the women was only indirectly assessed. Despite the reports of high fish consumption, maternal serum PCBs concentrations were not markedly elevated when compared to the controls (6.1 ng/ml vs 4.1 ng/ml) far from the median 50 ng/ml serum levels seen in the frequent fish consuming anglers studied by Humphrey.[63] The dose-response relationships are not established or consistent between exposure measures. While the studies focused upon PCBs, the fish consumed were likely to contain a mix of other toxic chlorinated chemicals such as DDE, Aldrin and Dieldrin and perhaps metals such as mercury and lead. While the PCBs concentration is likely to be a good indicator for all the chemicals present, how much of the risk described is due solely to the PCBs is unknown. While attempts were made to statistically control for other maternal risk factors known to affect the outcomes measured, not all potential confounding issues could be considered (alcohol, caffeine, maternal weight and drug usage).

Utilization of Epidemiologic Data to Estimate RfDs

Central to the ability to utilize epidemiologic health outcome data to estimate RfDs is the accuracy of the chemical dose estimation. Two options exist to estimate human NOAEL and LOAEL PCBs values from the Michigan and North Carolina cohort studies. The first is to use the available biomarker data (serum PCBs or adipose/fat PCBs concentration) and pharmacokinetics data to estimate the past exposures necessary to achieve the observed body burdens. The second method utilizes sport fish monitoring information and dietary recall of sport fish consumption to estimate the delivered dose of chemical. Both of these methods have been used to estimate RfDs.

RfD Based Upon Dose Estimation From Body Burden Residues

Human NOAELs were developed by Tilson et al. in 1990.[95] They used decreased infant motor development and infant visual recognition memory thresholds identified in a combined array of the Michigan and North Carolina reproductive study data.

For the percent abnormal on the Brazelton[38] (mean score on Bayleys) test results (primarily motor function), visual inspection of the test score data points arrayed by breast milk PCBs residue was used to identify the threshold where the effects seemed to begin. This occurred at a maternal breast milk fat PCBs residue level of 3.4 ppm (95% percentile level in the North Carolina general population data[82]). For abnormal visual recognition memory, studied only in the Michigan infants[67], a PCBs residue level of 1.0 ppm in breast milk was identified as the threshold (mean breast milk of the subset of women tested in the Michigan group was 0.8 ppm).

It was necessary to convert these breast milk PCBs threshold concentration into a mg/kg/day NOAEL before use as an RfD. Tilson did this by applying the following assumptions.

<u>Assumptions</u>

1. Average women is age 25.
2. Body weight 60 kg.
3. Average 60 kg women has 25% body fat.
4. Threshold for decreased infant motor function seen at 3.4 ppm PCBs in maternal breast milk fat of primiparous, 25 year old women; or at 1.0 ppm PCBs for decreased infant visual recognition memory score.
5. PCBs are equally distributed in all adipose tissue.
6. Breast milk fat PCBs concentration = body adipose tissue PCBs.
7. Once ingested, PCBs remain in the adipose tissue, ie no appreciable metabolism or excretion occurs - except via breast feeding.

Formula

$$\text{PCBs NOAEL in mg/kg body weight/day} = \frac{\text{(\% body fat) X (Threshold PCBs level in mg/kg breast milk fat)}}{\text{(Maternal age in days)}}$$

NOAELs and resulting RfDs Proposed by Tilson

Infant Motor Function

NOAEL = 0.093 ug/kg/day
RfD = NOAEL / uncertainty factor 10X for intra-species = 0.0093 ug/kg/day

Infant Visual Recognition Memory

NOAEL = (0.027 ug/kg/day)
RfD = NOAEL / uncertainty factor 10X for intra-species = 0.0027 ug/kg/day

Impact on RfD of PCB Excretion/metabolism Pharmacokinetics

The Tilson approach, assuming no PCBs excretion/metabolism converts the breast milk fat NOAEL body burden to the lowest possible NOAEL expressed as a daily dose for a women of a given age. The Task Force felt modifying the Tilson model to include a PCBs mixture half-life would better fit the available pharmacokinetics information. Estimates of the kinetics of PCBs elimination from humans have been made and range from 3 months for some of the lower chlorination to 9 years for higher chlorinated congeners.

The study by Buhler et al.[41], using a single bolus oral dose of ^{13}C labeled PCBs (329 ug/kg bw) given orally to a single, 50 year old male volunteer, followed isomer specific elimination for 260 days. This study used only a single subject. Buhler found that congener 153 and 138 had half-lives of slightly less than a year (321 and 338 days) and congener 180 a shorter 124 days. Elimination of congeners followed first order kinetics.

The USEPA (Milt Clark personal communication) has concluded that this study should not be used as a basis for pharmacokinetic determinations. Their comments can be summarized as follows. The single bolus dose is quite different from the chronic low dose dietary exposures which should lead to a near equilibrium state. There are other potential confounders in this study which may have biased the results toward shortening the estimated half-lives. Little is known about the health status of the subject (ie AHH induction status). During the observation period, food was not restricted or analyzed for PCB content. The data was analyzed as the ratio of $^{13}C/^{12}C$. Other uncontrolled dietary sources of ^{12}C PCB would affect the ratio to make it appear that the rate of elimination was greater and thus shorten the half-life estimation by an unknown period. No internal laboratory standard was used to correct for extraction efficiency.

Chen attempted to estimate congener specific elimination rates of PCBs by studying the group acutely poisoned in Taiwan.[42] They reported that serum concentrations of congener #153 decreased less than 10% over 300-500 days. This data suggests a half-life of 5.4 - 9.9 years.

Congeners 153 and 138 are the two most prevalent isomers found in the Lake Michigan anglers and isomer 180 is the third most prevalent.[88]

The other studies assessing metabolism/excretion have been based upon occupational cohort studies and provide estimates specific to the Aroclor types. Phillips et al.[80] described a median half-live for Aroclor 1242 of 2.6 yrs and median of 4.8 years for Aroclor 1254.

Steele[89], and Taylor[94] calculated a mean half-life of 1.8 years for Aroclor 1242, 3.3 years for Aroclor 1254 and 4.1 years for Aroclor 1260.

Based upon these studies, it is apparent that Tilson's assumption of no metabolism or excretion was overly conservative. The impact of first order kinetic half-lives of one, three, five and 10 years upon the conversion of the PCBs breast milk fat concentration to NOAEL daily doses was considered by the Task Force.

The following summarizes the analyses performed by the Task Force.

<u>Assumptions from Tilson et al.</u>

1. Average 60 kg women has 25% body fat
2. Decreased infant motor function threshold of 3.4 ppm PCBs in maternal breast milk fat; or at 1.0 ppm PCBs for decreased infant visual recognition memory score.
3. PCBs are equally distributed in all adipose tissue
4. Breast milk fat PCBs concentration = body adipose tissue PCBs concentration

<u>Additional Assumptions</u>

1. Theoretical mother PCBs body burden has reached a steady state equilibrium
2. Metabolism/excretion of PCBs mixture half-life = 1 yr (365 days), 3 yrs (1095 days), 5 yrs (1825 days), or 10 years (3650 days)

Adding a half-life assumption to the Tilson model and assuming near steady state equilibrium, maternal age at time of infant birth drops out of the formula. The model estimates the annual daily dose needed to maintain the target breast milk fat PCBs body burden.

<u>Modified Formula for Estimating NOAELs from PCBs in Breast Milk Fat</u>

PCBs NOAEL in mg/kg body weight/day =

$$\frac{(\%\ \text{body fat}) \times (\text{PCBs in mg/kg breast fat}) \times .693\ (\text{1st order kinetics})}{(1/2\ \text{life in days})}$$

<u>Assumption of 1/2 life = one year (365 days)</u>

Infant Motor Function NOAEL = 1.61 ug/kg/day
Visual Recognition Memory NOAEL = 0.475 ug/kg/day

Assumption of 1/2 life = three years (1095 days)

Infant Motor Function NOAEL = 0.54 ug/kg/day
Visual Recognition Memory NOAEL = 0.16 ug/kg/day

Assumption of 1/2 life = five years (1825 days)

Infant Motor Function NOAEL = 0.32 ug/kg/day
Visual Recognition Memory NOAEL = 0.095 ug/kg/day

Assumption of 1/2 life = ten years (3650 days)

Infant Motor Function NOAEL = 0.16 ug/kg/day
Visual Recognition Memory NOAEL = 0.048 ug/kg/day

Comparing the NOAELs proposed by Tilson with those derived using the half-life estimate method suggests that Tilson may have underestimated the NOAELs based on a 25 year old female by a factor of 2 - 6 fold depending on the elimination kinetic assumed.

RfD Based Upon Dose Estimation From Diet

In 1990 the Minnesota Department of Health[85] completed an analysis of the non-cancer human epidemiologic data and derived an human RfD using a methodology which estimated a PCBs Lowest Observed Adverse Effect Level (LOAEL) from the dietary sport fish consumption history information in the study of Michigan sport fish consumers.[51,65,67,68,69]

Assumptions Utilized in Minnesota Model Development

1. Reproductive/developmental effects were seen in the lowest exposure group
2. 7.4 g/day = fish consumption mid-point of lowest exposure group
3. 4.12 ug/g = average fish tissue PCBs residue (year of study)
4. 62 kg = average pre-pregnancy weight of study women

Calculation of LOAEL

1. 7.4 g/day X 4.12 ug/g = 30.5 ug/day PCBs
2. 30.5 ug/day / 62 kg = 0.5 ug/kg/day (LOAEL)

Calculation of RfD

A human RfD for the reproductive/ developmental effects seen in the Michigan study was derived by Minnesota by applying an uncertainty factor of 10 (conversion of LOAEL to NOAEL).

Minnesota RfD = 0.05 ug/kg/day

Conclusion

The RfDs developed by other expert groups (Table 1) ranged from 0.005 ug/kg/day to 0.4 ug/kg/day (FAO/WHO applying an uncertainty factor of 100 instead of 1000 from their NOEL of 40 ug/kg/day).

The animal bioassay derived RfDs summarized in Table 3 range over more than an order of magnitude from a low of 0.01 ug/kg/day to 0.2 ug/kg/day. The uncertainty factors used to derive the RfDs were either 100 or 1000. The RfDs clustered near the high end of the range.

NOAEL estimates from the human data range from 0.027 ug/kg/day to 1.61 ug/kg/day. RfD estimates based upon the human epidemiologic data ranged from 0.0027 ug/kg/day to 0.05 ug/kg/day. An uncertainty factor of 10 was used to derive each RfD.

The Task Force concluded that no single NOAEL or RfD was most appropriate for advisory use. A weight-of-evidence derived value that integrated all the reviewed data was the conclusion. Even though the health protection value (HPV) chosen (0.05 ug/kg/day) is the same value as some of the NOAELs and RfDs summarized, these values and the studies they were derived from should not be given or assumed to have more weight than any of the other reports reviewed.

Sensitivity Analysis

A major Task Force consideration in the decision to develop a new protocol was whether a significant public health risk remained for those carefully following the existing advisories and whether that residual risk was sufficient to warrant more restrictive advice. Any change in the advisories needed to result in a significant public health gain.

To assess the public health gain from following the new protocol, it is possible to compare the expected annual dose of PCBs anglers would accrue under the existing advisories to the target under the new protocol. The new protocol is specifically designed to limit the dose of PCBs from sport fish to less than 0.05 ug/kg/day. For a 70 kg person this would allow 3.5 ug PCBs per day or 1.3 mg PCBs per year. The current advisory does not set a target dose. However such a dose can be estimated by considering the PCBs concentration in existing sport fish and assuming consumption rates.

As an example, the most recent Wisconsin and Michigan monitoring results for coho salmon from Lake Michigan indicate the average PCBs contamination is about 0.8 mg/kg (ppm). None of the recently sampled fish exceeded 2.0 mg/kg and over the past 5 years less than 10% exceeded 2.0 mg/kg. Thus these fish fit into the "lowest" category of all current fish advisories (except Minnesota). Anglers are advised only to trim and cook fish before eating them and would allow consumption up to once a week or more.

Angler surveys indicate average consumption is about one meal per week (about 30 g/day). A 70 kg angler consuming 52 meals (1/2 lb per meal, 227 g/meal, 32 g/day) of trimmed, cooked fish would consume about 4.7 mg of PCBs per year, or roughly 4 times the target of the current advisory. However, a recreational angler consuming at the 90th percentile[26] (140 g /day) but following advisory warnings to trim and cook fish to reduce PCBs would receive about 20,000 ug PCBs over a years time, or 16 times the new protocol's target. Therefore, depending on the advice a state gives and angler consumption patterns, anglers may be exceeding the HPV by 4 (for average angler or 50% consumption rate) to 20 times (top 10% of anglers). This exceedence could be even greater, up to 32-fold higher than the HPV, if anglers do not trim and cook the fish to minimize PCBs. For all states other than Minnesota, the new protocol does provide significant public health exposure reduction over the current advisories.

A state, such as Minnesota, that now gives maximal advice to reduce consumption could also make potential exposure reductions from the new protocol by way of increased compliance. The Minnesota advisory lists Lake Superior fish with 0.8 mg/kg PCBs in the 5 meal per year category, and assumes fish are not trimmed and cooked to maximize contaminant loss. Anglers following the current Minnesota advisory would receive 0.9 mg PCBs per year or roughly 0.75 of the target dose. This example shows that a state which already gives maximal current advice to reduce consumption will, under the new protocol continue to maintain approximately the same level of exposure. The potential public health benefit for such a state to adopt the uniform advisory is not in reducing an individual's PCB exposure but in having greater angler compliance because the uniform advisory has greater credibility.

Residual Risk

Even closely following the Task Force protocol, PCBs from sport fish will be the predominant dietary source of PCBs for anglers. The most recent 1982-1984[58,78] estimates of average PCBs dietary intake in the United States from the USFDA are 0.042 ug/day or 15.33 ug per year (1% of protocol target). This is down from the 1980-1982[55] estimate of 0.19 ug/day or 69.35 ug/year (5% of protocol target).

Estimate of Serum PCB Levels Associated With Protocol

Anglers who have had their serum PCBs level determined want to have the results interpreted. While the Task Force can not attribute an individual level of risk to such numbers or predict the likelihood of an adverse health event occurring, it is possible to estimate the contribution to serum PCBs levels under the various sport fish consumption examples discussed. The formula developed by the Task Force to evaluate the epidemiology based RfDs can be used to estimate steady-state serum PCBs.

$$\text{PCBs NOAEL in mg/kg body weight/day} = \frac{\text{(\% body fat) X (mg/kg PCBs breast milk fat) X .693 (1st order kinetics)}}{\text{(1/2 life in days)}}$$

Solving the formula for PCBs in mg/kg breast milk fat results in the following formula which can be used to estimate the PCBs equilibrium body burden contribution under the consumption and individual parameters chosen.

$$\text{PCBs mg/kg fat} = \frac{\text{(PCBs exposure in mg/kg/day) X (1/2 life in days)}}{\text{(\% body fat) X .693 (1st order kinetics)}}$$

Additional Assumption

1. Breast milk fat PCB residue = body adipose tissue PCB.
2. Serum = .5% lipid/fat ie PCB serum = PCB adipose/200

3. 1/2 life = 10 years (3650 days)
4. body fat = 25% of body mass

Applying these assumptions and assuming a steady-state, long-term consumption of 3.5 ug PCBs per day, the estimate of the contribution of sport fish consumption to serum PCBs concentration is 0.36 ng/ml (ppb).

Using the 90th percentile recreational consumption rate of sport fish averaging 0.8 mg/kg (112 ug PCBs per day) the resulting contribution to serum PCBs estimate is 11.8 ng/ml.

An angler who consumes one meal a week of the 0.8 mg/kg PCBs contaminated sport fish (25.9 ug PCBs per day) would have such a diet contribute 2.7 ng/ml PCBs.

The most recent followup of the long-term fish-eaters study in Michigan found the anglers averaged 38 sport fish meals per year and their serum PCBs averaged 19.0 ng/ml. The control population who ate very little sport fish averaged 6.8 ng/ml PCBs.[62]

A recently completed survey of 108 charterboat captains in Wisconsin found average consumption of 33 sport fish meals per year. The mean serum PCBs was 9.67 ng/ml (M. O'Brien personal communication).

It must be kept in mind that the above estimates of dietary contribution to PCBs body burdens do not account for higher exposure to PCBs in the past and the slow excretion of PCBs accumulated under exposure circumstances that may have been more than an order of magnitude higher (fish contaminant levels have declined nearly 80% over the past decade). It may be a decade or more before the measured body burdens approximate the estimates.

Risk Analysis of Task Force Health Protection Value (HPV)

One method to assess the appropriateness of the health protection value is to consider the margins of exposure (MOE) around the value. Typically the MOE is the ratio of a NOAEL to the value in question. The resulting number can be compared to the uncertainty factors applied to a NOAEL to derive an RfD.

Cancer Risk

Cancer risk estimates for PCBs at the Task Force proposed HPV of 0.05 ug/kg/day using the USEPA $q1^*$ of $(7.7 \text{ mg/kg/day})^{-1}$ (95% upper bound confidence level estimate) and $(5.5 \text{ mg/kg/day})^{-1}$ (most likely estimate) are 3.8×10^{-4} and 2.7×10^{-4} respectively. These estimated cancer risks may overestimate risk by an order of magnitude given that scaling factors have changed and reanalysis of the data used to calculate the current $q1^*$ may occur. These estimates may over- or under- estimate risks given that not all PCBs mixtures have caused cancer in animals and PCBs mixture in fish do not generally match Aroclor 1260.

Although these estimated cancer risks are slightly above the 1×10^{-4} cancer risk, the upper end of the normally acceptable range for regulatory programs, the uncertainties in these cancer risk estimates specific for fish residues were recognized in the Task Force evaluation and in the selection of the HPV.

Non-cancer Risk

Table 2 includes the Margins-of-Exposure (MOE) over the NOAEL values reviewed by the Task Force proposed sport fish tissue PCBs residue dose of 0.05 ug/kg/day. For the human calculations these range from 0.5 to 32 for the NOAELs and 10 for the LOAEL. The margins of exposure over the PCBs reproductive / developmental health endpoints from the animal data ranged from 28 to 600. The margins of exposure for reproductive/developmental effects, reviewed in conjunction with the specific health endpoints and studies, are within the range normally considered acceptable by regulatory agencies and scientific advisory groups.

Peer Review of HPV

The Task Force sent the Protocol to a spectrum of scientists not associated with the development of HPV for comment specifically on the process and "weight-of-evidence" approach used by the Task Force. Five reviews were received and carefully considered by the Task Force. The reviewers provided comprehensive comments. The Task Force is grateful and appreciative that the reviewers were willing to donate their time and expertise to assist. The reviewers reaffirmed the Task Force conclusion that many of the studies considered had shortcomings. Nearly all of the reviewer comments detailed issues of which the Task Force were aware and which the Task Force had discussed at length.

This document remains a "working paper" and may well undergo further refinement. However, the Task Force felt the HPV and advisory protocol which is based upon the HPV was sufficiently complete to forward to the Council of Great Lakes Governors for further consideration.

APPENDIX II

Reduction in Lipophilic Chemicals as a Consequence of Sport Fish Preparation and Cooking Advice

Reduction in Lipophilic Chemicals due to Sport Fish Preparation and Cooking Advice

The proposed Great Lakes States' sport fish advisory calls for a standard raw, skin-on fillet to be used as the analytical sample. Exceptions to this include catfish, bullheads, burbot, and sturgeon for which the skin is removed. The concentration of contaminants found in the standard sample (expressed as mg/kg tissue wet weight) is utilized to place fish into the sport fish consumption advisory matrix.

To estimate the risk from consuming a standard sample of fish, it is necessary to estimate the delivered dose of chemical (usually expressed as mg/kg body weight/day.) Typically the dose is converted into units of exposure, which for sport fish consumption, is a "standard" meal. A "standard" meal is usually considered to be 1/2 lb (227 gm) of raw "standard fish fillet." Thus, a meal of 1 mg PCB/kg standard fish fillet could maximally deliver 0.227 mg PCB.

The Great Lakes Fish Advisory Task Force has decided to make quantitative risk assessment a more prominent component in the development of its sport fish consumption advisory. Each component of the risk assessment methodology is being reviewed.

In recognition that contaminants can be reduced from those found in the standard fillet, all advisories routinely highlight exposure reduction actions. These include instructions on how to trim away fatty tissue and skin and recommendations on cooking methods. The appropriateness of the risk assessment default assumption that 100% of the contaminants in the raw, skin-on fillet are ingested is being reviewed. The published literature references on the reduction of contaminants as a result of trimming of the raw fillet and/or during cooking was reviewed.

Effects of Trimming

Lipophilic chemicals preferentially concentrate in the fat of fish. In general, fish which contain high concentrations of lipid are likely to have higher concentrations of lipophilic chemicals. Lipid content of fish tissues vary with higher concentrations in skin, dorsal fat, lateral line fat and dark muscle, belly area and viscera.[149] Whole fish analyses for lipid content invariably exceed the lipid content of edible fillet portions. Trimmed edible fillets (skin, belly fat, lateral and dorsal fat and dark muscle removed) contain less lipid than the untrimmed fillet.[140,145,148,149,153] As the lipid content of the edible portion rises, there is a disproportionate rise in the total fish lipid content indicating increased lipid deposition in belly, viscera and skin. Thus it has been reported in a "fatty" fish such as lake trout the ratio of lipid content in edible portion (7.2% lipid) to whole fish (17.1% lipid) was .42 compared to a "lean" fish such as cod where the same ratio was .93 (.65% lipid vs .70% lipid).[147] This suggests that selective removal of high lipid tissues from the edible portion of a fish fillet (trimming) will be most effective at reducing lipid content (and lipophilic contaminants) the higher the lipid content in the fish.

Lipid and contaminant reduction from trimming fat and removing skin has been investigated for species relevant to the Great Lakes (lake trout,[145,146,147,149,154,155] brown trout,[143,144,148,149,153] rainbow trout,[144,147] coho salmon,[144,146,149,154] chinook salmon,[149,150] smallmouth bass,[148,149] carp,[142,151,156] perch[146]). Saltwater species (bluefish,[140,152] striped bass,[139,149] white croaker[145]) have also been tested. Representative results are summarized in **Table 1**.

Table 1

Summary of Contaminant Reductions Reported due to Trimming

Species	Activity	Contaminant	Reduction	Reference
lake trout	trimming	DDT	54%	# 146
	dressing	DDT	0%	# 146
coho	trimming	DDT	62%	# 146
	dressing	DDT	0%	# 146
brown trout	trimming	PCB,mirex	46,44%	# 153
	trimming	PCB,mirex,DDE	43,45,52%	# 148
smallmouth bass	trimming	PCB,mirex,DDE	64,64,54%	# 148
perch	dressing	DDT	90%	# 146
bluefish	trimming	PCB	59%	# 140

Effects of Cooking

Cooked-weight fish is always less than the uncooked-weight. On average, a 1/2 lb raw weight sample reduces to 1/3 lb cooked weight. During cooking weight is reduced due to loss of water, liquefying of fats and volatilization.[148,149,152,155] Different cooking methods result in different weight losses.[149,152,155] Loss of fat is usually proportional to water loss. In the studies reviewed, weight loss ranged from 15-50% depending on the cooking method. Microwave cooking resulted in the least weight loss and broiling/baking the highest.[155]

In most studies the contaminant concentration (on a mg/kg basis) after cooking was most often the same as before cooking. There was considerable variation with some tests actually resulting in higher levels in cooked than raw samples (most often broiled samples).

When weight loss and oil loss is factored in, total delivered contaminant dose per meal was consistently, significantly reduced. **Table 2** summarizes the reduction in total delivered contaminants reported due to cooking.

Table 2

Summary of Contaminant Reductions Reported due to Cooking

Species	Activity	Contaminant	Reduction	Reference
lake trout	broiling	DDT	64 - 72%	# 146
	frying	DDT	64 - 72%	# 146
	broiling	PCB,dieldrin,DDT	53,48,39%	# 156
	Roasted	PCB,dieldrin,DDT	34,25,30%	# 156
	Microwave	PCB,dieldrin,DDT	26,47,54%	# 156
	baking	PCB	10 - 17%	# 157
	charbroiling	PCB	12 - 59%	# 157
	salt boiling	PCB	10%	# 157
brown trout	smoking	PCB,mirex,DDE	27,39,27%	# 148
	broiling	PCB,mirex,DDE	0,26,20%	# 148
smallmouth bass	baking	PCB,mirex,DDE	16,21,16%	# 148
	frying	PCB,mirex,DDE	74,75,75%	# 148
bluefish	baking	PCB	8%	# 140
	broiling	PCB	8%	# 140
	frying	PCB	8%	# 140
	poaching	PCB	8%	# 140
	baking	PCB	27%	# 152
carp	deep fat frying	PCB	32 - 42%	# 157
	pan frying	PCB	18 - 32%	# 157
chinook	baking	PCB	32 - 43%	# 157
	charbroiling	PCB	33 - 56%	# 157
	charbroiling/ scoring	PCB	42 - 51%	# 157
	canning	PCB	33 - 39%	# 157
siscowet	baking	PCB	19%	# 157
	charbroiling	PCB	30%	# 157
	salt boiling	PCB	19%	# 157

Several studies reported the combined effects of careful trimming and cooking. These are summarized in **Table 3**.

Table 3

Summary of Contaminant Reductions Reported due to Combining Trimming and Cooking

Species	Activity	Contaminant	Reduction	Reference
brown trout	trim,cook	PCB,mirex	78,74%	# 148
smallmouth bass	trim,cook	PCB,mirex	80%	# 148
bluefish	trim,cook	PCB	67%	# 140

Discussion

Taken as a whole, the literature indicates a contaminant reduction factor of 50% due to trimming and cooking is a realistic expectation for all the lipophilic contaminants of concern in the Great Lakes. From the literature it is clear that a reduction in delivered dose of contaminant is greatest when careful trimming includes skin and fat removal. This appears to apply to the full gamut of lipophilic chemicals commonly identified in Great Lakes sport fish. While skin removal prior to cooking appears preferable, simply discarding the skin after cooking also increases the reduction from the standard fillet. While the most data exists for brown trout and lake trout, other freshwater species such as smallmouth bass and salt water species such as bluefish also exhibit similar body lipid distributions and contaminants can be reduced via trimming procedures. Carp has been less well studied and trimming/cooking reductions may be less, although study methodology may have accounted for the lower reductions reported.[156]

All manner of cooking reduces the delivered contaminant dose. Cooking alone has a greater range of reductions reported. The variation is somewhat dependent on the type of raw sample. On average, cooking offers nearly the same reduction factor as trimming when the beginning raw sample is the untrimmed fillet. Zabik, et al.[157] showed an average loss of 30% PCBs in five Great Lakes fish species prepared with five cooking methods starting with skin off, trimmed fillets. An average loss of 33% occurred regardless of cooking method.

When the starting sample is a skinned and trimmed fillet, the reduction due to cooking is less. This reduction occurs less from a selective loss of contaminants than loss of contaminated fat during the cooking process. On a mg/kg basis, little change in tissue contaminant concentration occurs because water loss is proportional to fat loss. Since the cooked sample weight is significantly lower than the uncooked weight, when the tissue contaminant concentration remains the same, the total contaminants in the consumed meal portion is less. Not all the losses can be accounted for via water and fat loss. Some authors indicate that the heat of cooking volatilizes contaminants and may account for up to 10% of the reduction in contaminants. Deep frying fish appears to further reduce contaminants via transfer from fish fat to cooking oil.

The combination of trimming and cooking offers the greatest reductions, reported to be at 60-80%.

Recommendation

Most, but not all anglers report routinely trimming their catch. Separately accounting for trimming reduction would under-estimate the risk for those not routinely trimming their catch of the most highly contaminated species. Virtually all Great Lakes sport fish caught is consumed after cooking. While different cooking methods result in a range of reductions, cooking of untrimmed fillets resulted in the greatest cooking reduction which was only sightly less on average than that from trimming alone.

It is recommended that a single contaminant reduction factor of 50% be utilized in converting the dose present in a 1/2 lb raw standard, skin-on fillet meal to the dose remaining after the meal is cooked. This factor is most appropriate for the salmonid species and other species evaluated as skin-on fillets. For other species commonly analyzed with the skin-off, a reduction factor of 30% should be used in order to take into account for the loss of contaminants due only to cooking.[157] For other species, particularly those consumed whole, these reduction factors should be evaluated.

APPENDIX III

Species Associated Analysis Portion and Compositing of Samples

Species Associated Analysis Portion and Compositing of Samples

Uniform Tissue Sample

A raw, skin-on, fillet will be the primary sample to be analyzed for contaminants. The fish should be scaled, then filleted so as to include all flesh from the back of the head to the tail and from the top of the back down to **and including** the belly flap area of the fish. Remove all fins, the tail, head, viscera, and major bones (backbone and ribs).

The only exceptions to this sample type would be as follows: the skin will be removed from black bullhead, brown bullhead, yellow bullhead, channel catfish, flathead catfish and burbot, but still remain untrimmed. Sturgeon would be analyzed as a skin-off cross section (steak). Smelt should be gutted and the head removed.

Whole fish samples should never be used for the purpose of issuing consumption advisories.

Sample Type

Individual samples are **preferred**. However, if composites are used, the length of the smallest fish should be within 90% of the largest fish. In conducting the regression analysis, each fish in the composite would be described by individual data points representing the individual lengths of fish within the composite and the projected corresponding contaminant concentration as determined by the contaminant concentration of the composite and the slope of the regression line at that point. <u>Therefore it is very important that the length of each fish in the composite sample be recorded</u>.

If the smallest fish is not within 90% of the largest fish, the composite will be represented by a single data point using the average length and average contaminant concentration for the composite.

Under **no** circumstances should a composite be made up of fish with a size difference (largest to smallest) greater than 75%.

Standard Portions for Analysis for Consumption Advisories

Standard Sample	Common Name	Scientific Name
Skin - on Fillet	Yellow Perch	*Perca flavescens*
	Walleye	*Stizostedion vitreum*
	Sauger	*Stizostedion canadense*
	Largemouth Bass	*Micropterus salmonides*
	Smallmouth Bass	*Micropterus dolomieui*
	Bluegill	*Lepomis macrochirus*
	Pumpkinseed	*Lepomis gibbosus*
	Rock Bass	*Ambloplites rupestris*
	White Bass	*Morone chrysops*
	Black Crappie	*Pomoxis nigromaculatus*
	White Crappie	*Pomoxis annularis*
	Green Sunfish	*Lepomis cyanellus*
	Longear Sunfish	*Lepomis megalotis*
	Warmouth	*Lepomis gulosus*
	Muskellunge	*Esox masquinongy*
	Northern Pike	*Esox lucius*
	Sucker Family	*Catastomidae*
	Carp	*Cyprinus carpio*
	Freshwater Drum (Sheepshead)	*Aplodinotus grunniens*
	Bigmouth Buffalo	*Ictiobus cyprinellus*
	Smallmouth Buffalo	*Ictiobus bubalus*
	Redhorse family	*Moxostoma* spp.
	Lake Whitefish	*Coregonus clupeaformis*
	Round Whitefish	*Prosopium cylindraceum*
	Lake Herring	*Coregonus artedii*
	Bloater Chub	*Coregonus hoyi*
	Lake Trout (lean and (Siscowett)	*Salvelinus namaycush*
	Rainbow Trout (Steelhead)	*Oncorhynchus mykiss*
	Brown Trout	*Salmo trutta*
	Brook Trout	*Salvelinus fontinalis*
	Splake	*S. fontinalis* X *S.namaykush*
	Atlantic salmon	*Salmo salar*
	Chinook salmon	*Oncorhynchus tschawytscha*
	Coho Salmon	*Oncorhynchus kisutch*
	Pink Salmon	*Oncorhynchus gorbuscha*
	Striped Bass	*Morone saxatilis*
Skin - off Fillet	Black Bullhead	*Ictalurus melas*
	Brown Bullhead	*Ictalurus nebulosus*
	Yellow Bullhead	*Ictalurus natalis*
	Channel Catfish	*Ictalurus punctatus*
	Flathead Catfish	*Pylodictis olivaris*
	Burbot	*Lota lota*
Skin - off Steak	Lake Sturgeon	*Acipenser fulvescens*
	Shovelnose Sturgeon	*Scaphirynchus platorynchus*
Headless, gutted	Rainbow Smelt	*Osmerus mordax*

APPENDIX IV

Fish Consumption Rate Estimates

The following is a summary of the consumption data put together by the Tennessee Valley Authority (TVA)[6];

> A National Ocean Pollution Program Office report estimated that average annual fish consumption increased fifty percent between 1980 and 1988 from 10 pounds to 15 pounds per person.[17]
>
> Some studies averaged the intakes of "fish eaters" with "non fish eaters" to get a per capita average that is misleading for both categories of consumers.
>
> Fish consumption varies with demographic variables such as age, sex, ethnic group and region of the country. The most commonly cited studies of recreational anglers were done on the west coast.

Federal Agencies have made various recommendations for default assumptions:

(1) Exposure Factors Handbook[26] recommends use of the following values for fish consumption rates among recreational anglers:

> 50th percentile - 30 g/day
> 90th percentile - 140 g/day

(2) Risk Assessment Guidance for Superfund[27] recommends use of the following values for fish consumption rates in evaluating residential exposure:

> 50th percentile - 38 g/day
> 95th percentile - 132 g/day

(3) Risk Assessment Guidance Document for Superfund: Supplemental Guidance "Standard Default Exposure Factors"[30] requires the following assumptions about fish consumption rates:

> subsistence fishers - 132 g/day
> recreational anglers - 54 g/day

(4) Guidance Manual for Assessing Human Health Risks from Chemically Contaminated Fish and Shellfish[25] makes no general recommendations, but discusses values from 6.5 g/day (U.S. per capita average) to 180 g/day (reasonable worst case).

(5) The FDA Center for Food Safety and Applied Nutrition has evaluated the potential intake of subsistence fishers by assuming that fish is substituted for red meat and poultry in a normal diet. Using information from the Market Research Corporation of America Menu Census VI (1977-78), FDA derived the following assumptions[37]:

> mean for subsistence fishers - 69 g/day
> 90th percentile for subsistence fishers - 116 g/day

(6) Bolger et al. (1990) cite a U.S. Department of the Interior survey of fishing in 1985 which assumed that one fishing trip lead to consumption of 8 ounces of fish. Their estimate of fish consumption rates of recreational fishers - based on the number of recreational fishing trips they make were:

average 13.1 g/day

90th percentile estimated at 26 to 40 g/day

(7) U.S. EPA "Proposed Water Quality Guidance for the Great Lakes System" cites 15 g/day as the average consumption rate of regionally caught fish by sport anglers and their families. This same consumption rate of 15g/day approximates at least the 90% consumption level of regionally caught fish for the regional population as a whole, i.e., anglers as well as non-anglers.[31]

The Task Force agreed to the use of the following five advisory categories which are used and commonly understood by anglers:

Unrestricted Consumption

One Meal a Week (52 meals/year)

One Meal a Month (12 meals/year)

One Meal every 2 Months (6 meals/year)

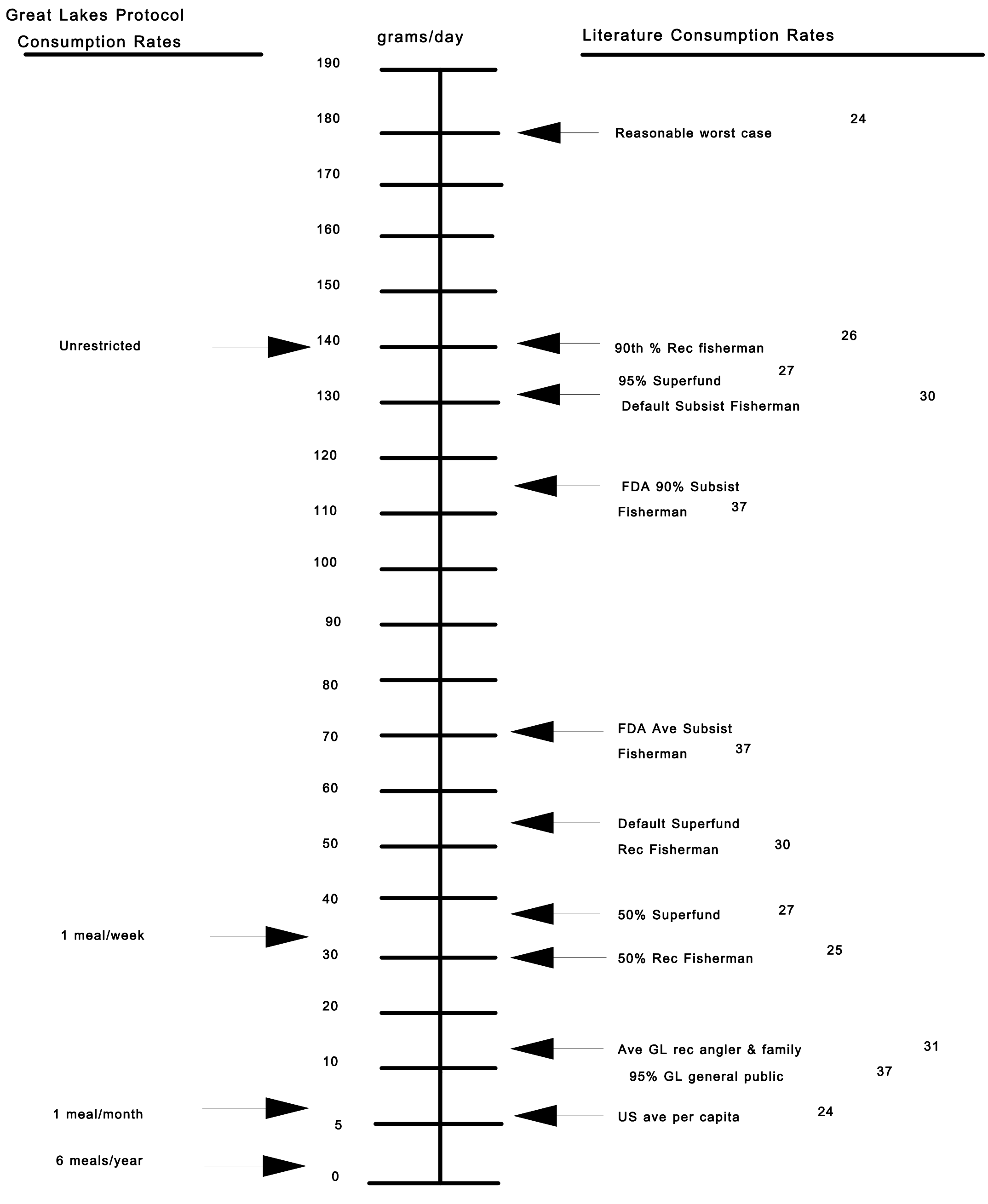
No Consumption (Do Not Eat)

Figure 1 shows the relationship between these ingestion rate assumptions and the Task Force categories.

Figure 1

Comparison of Assumed Fish Consumption Rates

(Typical meal size assumed to be 0.5 pounds)



Adapted from Cox JP. TVA/WR-92/27, 1992 6

APPENDIX V

Listing and Delisting Criteria and Establishment of Size Ranges

Method for Listing Sites or Shifting Size Ranges into Different Consumption Categories

The standing committee members representing each state will meet annually to discuss new data, listing of new species/sites, and shifting of size ranges to different consumption advice categories.

Listing Criteria

In the interest of protecting public health, a minimum of one year of data would be needed to place a site and/or species on an advisory. The annual meeting of the standing committee would be used as the forum for the proposed change. The strength of the data and confidence in the data will be considered.

However, if an emergency arises where it is felt there is an imminent impact to human health, an advisory can be initiated by any state as long as each jurisdiction is contacted by the state issuing the advisory to ensure a consistent public communication effort.

Establishment of Fish Size Ranges for Placement in Consumption Groups

Regression models will be used to examine the relationship between fish length and PCB concentrations. Fish will be placed in consumption categories by using a best fit regression based on the r^2 value. In addition, the biological plausibility and weight of evidence will be considered by the standing committee, given the understanding that a regression approach must remain consistent for a specific species from a given waterbody in order to have continuity from year-to-year for determining changes in the advisory.

Linear

P
C
B

Length

Curvilinear

P
C
B

Length

The relationship between fish length and PCB concentration will be analyzed using a regression analysis to determine the equation which best describes this relationship. The equation with the highest r^2, with a minimum of 0.6, will be used taking into consideration the statistical significance of the regression equations examined.

If the data set contains concentration values which are reported as less than the level of detection, the preferred approach will be to use a regression method which deals with censored observations. However, the appropriate regression methods are not well known or available. There are statistical methods for treatment of less than detectable concentrations, but these methods are primarily for determining the mean of a set of data and not for determining the best fit equation. These methods include assigning all than detected values equal to 1/2 of the LOD or assigning values based on an assumed or extrapolated distribution.

Until a method of conducting a regression analysis which automatically deals with censored data in an appropriate manner can be incorporated, the following procedures will be used for determining a regression equation to describe the relationship between length and PCB concentration:

a. If an initial regression analysis indicates that the relationship between PCB concentration and length is a linear relationship, a regression analysis will be conducted using the data reported at greater than the LOD. If this procedure derives an equation with an r^2 of 0.6 or greater and the level of significance is acceptable, this equation will be used to describe the relationship between fish length and PCB concentration. The appropriate consumption category will be determined by extrapolating the equation to size ranges corresponding to concentrations less than detection limits. Although extrapolation beyond the data set is not technically recommended, it is one way of estimating the values of the censored data.

b. In some cases the initial regression analysis will indicate that the relationship between PCB concentration and length is more appropriately described with a nonlinear equation. In these cases, a nonlinear regression analysis using only the data which is reported at greater than the level of detection will be used to determine the best fit equation. The size ranges corresponding to concentrations less than detection limits will be extrapolated from this equation. It may be necessary to examine the lower part of the curve separately and determine two regression equations to describe the relationship between PCB concentration and fish length.

In some cases, available data will not be sufficient to enable an equation to be generated with an r^2 of greater than 0.6. Also, in some cases the ability of laboratories to detect low concentrations of PCBs (the level of detection) will not allow determination of which category the fish should be placed. For those cases with below level of detection values, the following procedures will be used depending on the amount of data above the level of detection:

a. 100% of the data for a species from a given waterbody is below the level of detection. Fish will be placed in the category corresponding to a value of 1/2 of the LOD. For example, if all fish are below the detection limit of 0.1 ppm, they will be assigned the value of 0.05 ppm and therefore fall into Category 1 of the advisory.

b. Larger fish in the species have concentrations greater than the LOD: this provides evidence that contaminant levels are approaching the LOD and therefore a more conservative approach is warranted. Fish of the larger size will be placed in the category corresponding to the mean value of the detectable concentrations. Smaller fish (with undetectable concentrations) will be placed in the consumption category that is one group less restrictive than the category defined by the detectable values.

c. The concentration data is scattered both above and below the LOD: calculate the mean concentration of all fish, giving undetectable data a value of 1/2 the LOD and calculating a mean using all data. All fish, regardless of size, would then be placed in that advisory category. The same method would be used if all data is above the detection limit, but no correlation is evident, the mean value of the data will be taken and fish placed into that advisory category.

a.

P
C
B

Length

b.

P
C
B

Length

c.

P
C
B

Length

Shifting Size Ranges between Consumption Categories

A weight of evidence approach will be used to determine whether or not to shift sizes in consumption categories for a given species. To be considered, a jurisdiction wishing to change a lakewide advisory would be required to submit to the standing committee, a minimum of two separate years of data (three separate years of data is preferred) taken over a maximum of (the last) 5 years. The committee will then decide whether the change is warranted based on the weight of evidence such as the data presented, trends in that species as well as other species (i.e. the forage base), biological considerations and other environmental factors such as water/sediment data.

The Task Force can be utilized as a peer review body should states seek advice on hotspots or intrastate waterbodies.

"Hot Spots"

Data from so called "hot-spots" would be excluded from consideration for a lakewide advisory if it is determined, by weight of evidence and as judged by the standing committee, that the "hot-spot" data shows significant difference from overall lakewide data.

APPENDIX VI

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Appendix D.
Responsiveness Summary to Public Comments

APPENDIX D. RESPONSIVENESS SUMMARY TO PUBLIC COMMENTS

Cedar Creek & Milwaukee PCB TMDL
Public Comment Period June 5-July 7, 2008

A total of four different entities submitted comments on the Cedar Creek & Milwaukee River PCB TMDL. The following section presents their comments and the respective responses prepared by the Department. The comment letters received are provided following the comments-responses section.

	Comments submitted on:
• Village of Thiensville	07-03-2008
• US EPA	07-07-2008
• Mercury Marine	07-07-2008
• Friends of the Milwaukee's Rivers	07-07-2008

Village of Thiensville's Comments

Submitted by Karl V. Hetz, President and Dianne S. Robertson, Administrator (07-03-08)

1. "…The Village of Thiensville strongly requests that the Thiensville Impoundment be included when Superfund Project Funds are requested. At a future date it would be unconscionable to suggest that citizens of Thiensville and Mequon, who own the dam, should be responsible for cleanup when they were not the ones who contaminated…"
Response: This comment is beyond the scope of this TMDL and was redirected to Scott Hansen of the Superfund Program (US EPA) since the cleanup process will be addressed by this program.

US EPA's Comments
Submitted by Dave Werbach (Watersheds and Wetlands Program) and the Superfund Program (07-07-08)

Water Program, US EPA

1. Page 3, middle paragraph: It would be very helpful to add the names of the dams discussed in this and other sections onto Figure 1 (or another figure).
Response: The names of the Thiensville and Lime Kiln dams were added on Figure 1 to add clarification. Since the names of the impoundments on Cedar Creek are specified on Figure 1, the Department did not add the names of the dams, since the ponds and dams carry the same name.

2. Page 3, last paragraph: Suggest changing last sentence to "…confluence with the Milwaukee River and the entire 10 miles…" The current language could imply that there is more of Segment 2 that is not addressed by the TMDL.
Response: The change was made into the TMDL report.

3. Page 9, bottom: The TMDL discusses point sources on Cedar Creek. Are there any point sources on the Milwaukee River Segment 2? Are there any other permitted storm water discharges other than Wilshire Pond, on either segment? Additional discussion on the Milwaukee River is needed.

Response: More specifications regarding point sources on the Milwaukee River Segment 2 were added in the "*Source Assessment*" section of the TMDL report.

4. Where is the information used to set the 0.21 target? Given the large amount of data and material on the Lower Fox, I have been unable to find the discussion. I suggest the Chapter (?) be pulled out and attached, as a clear reference. I think I found the determination of the 0.11 sediment level, but that chapter should be attached as well, or very specifically referenced.
Response: The fish target of 0.21 ppm was not taken from the Lower Fox studies as suggested in the comment. As mentioned in the TMDL, the 0.21 ppm fish tissue target "*…corresponds to the fish tissue concentration associated with "1 meal per month" fish consumption advice for PCBs according to the "Protocol for a Uniform Great Lakes Sport Fish Consumption Advisory (Anderson et al. 1993)*." The protocol was added as an Appendix to the report as reference for the reader (please see also below the response to comment 6 from the Superfund Program).
Additional specific references to sections and tables of the RETEC report (2002) related to the determination of the 0.11 ppm sediment concentration threshold were added to the *Linkage Analysis* section of the TMDL report.

Superfund Program, US EPA

1. "Page 5 - the document talks about the current boundary of the Superfund site... It should state Superfund Alternative site or just site. It happens twice on that page."
Response: The change was made to the TMDL report.

2. "Page 15, Reasonable Assurance section - The second paragraph states, "Moving forward, the Cleanup plan as part as the Superfund includes not only..." I think the sentence should state, "Moving forward, the Cleanup plan as part of the Superfund process, includes not only...""
Response: The change was made to the TMDL report.

3. "Page 15, Reasonable Assurance section - The last sentence on this page should state, "A proposed cleanup plan for Cedar Creek providing the cleanup options should be completed by the end of 2008."
Response: The change was made to the TMDL report.

4. (The US EPA suggested miscellaneous changes to paragraphs on Pages 16 and 17 of the draft report.)
Response: The department integrated the suggestions into the TMDL report.

5. "The description of the coverage of the TMDL listed on page two indicates that the TMDL deals with Cedar Creek and a 10 mile segment of the Milwaukee River (Segment 2). There is little discussion of the Milwaukee River sediments and their PCB concentrations included in the rest of the text. The TMDL should either be revised to reflect that this is a TMDL for Cedar Creek or the State should include data and discussion for Segment 2 of the Milwaukee River."
Response: The discussion in the TMDL primarily focused on the sediment concentrations in the impaired segment of Cedar Creek since the contaminated sediments in this reach are the major source of PCB for this segment of the Milwaukee River. Nevertheless, the available sediment concentration data for the Milwaukee River Segment 2 were added to the TMDL as suggested in the comment. Discussions on the potential point sources for Segment 2 of the

Milwaukee River were also added in the *Source Assessment* section of the TMDL to complete the information already provided on Segment 2 in the *Problem Statement* section.

6. "On page 7, a target of 0.21 mg/kg is set out without any background information or justification. There needs to be some narrative text and supporting background reports to substantiate the 0.21 mg/kg target level. If this number is just taken from State fish advisories, then the background studies that developed those fish advisory numbers need to be summarized and presented. Without further information, it is impossible to tell what risk level the 0.21 mg/kg target is designed to address. As part of this report and for the supporting record, all the underlying reports on how the 0.21 mg/kg number was set and chosen should be included in an appendix."
Response: The TMDL specified clearly that the target of 0.21 mg/kg corresponds to the fish consumption advice (1 meal/month) developed by the Protocol for a Uniform Great Lakes Sport Fish Consumption Advisory (Anderson *et al*. 1993). To address the comment, a more detailed explanation on the basis used to develop the fish concentration advisory was added in the *Target Identification* section of the TMDL report. The Protocol was also attached as an Appendix to the report as reference.

Mercury Marine's Comments
Submitted by Tom Baumgartner, Director Environmental Compliance (07-07-08)

General Comment (1): "Based on our experience and our review of the TMDL approach, our "bottom-line" conclusion is that the proposed TMDL is not the proper mechanism for addressing the PCB issues associated with the Creek. The TMDL process is ill-suited to Cedar Creek, as it was never intended to be used to address contaminated sediment issues. As demonstrated at the June 5, 2008 public meeting, moving forward with a TMDL at the same time as a Superfund cleanup process is underway only creates unnecessary confusion with the public. Consistent with DNR policy as set forth in Department publications and practice – see Fox River TMDL – the PCB sediment issues should be addressed through the on-going EPA Superfund process and not through a TMDL. Thus, the proposed TMDL is unnecessary and should be withdrawn."
Response: This general comment is addressed in the responses to comments # 1.1 and 1.2 below.

General Comment (2): "…the proposed TMDL is legally deficient, does not satisfy the administrative procedure requirements of Chapter 227, Wis. Admin. Code, and is inconsistent with the stated policy of the Department."
Response: This general comment is addressed in the responses to comment # 1.1 and 1.2 below.

General Comment (3): "Further, as discussed below in more detail, the technical approach is deficient as it relies on generic information and unfounded assumptions as opposed to the wealth of site-specific data collected on Cedar Creek in accordance with the strict EPA data-quality requirements. Why the Department would elect to ignore the site-specific Cedar Creek data is nowhere explained in the proposed TMDL and is a major technical deficiency."
Response: This general comment is addressed in the responses to technical comments # 4 to 6 below.

1. (Comment 1 from the comment letter is broke down here in three comments,1.1 to 1.3)
1.1 "…addressing contaminated PCB sediment through a TMDL is contrary to the Department's policy position and contrary to the manner in which TMDLs are applied in other settings, such as the Fox River. As stated on the Department's own website: *Waters*

impaired by contaminated sediment and atmospheric deposition of mercury do not fit EPA's general description of TMDLs. This type of impaired water will be managed by EPA's Superfund program or through the Department's Watershed Management program or Remediation and Redevelopment program. The contaminated sediments in Cedar Creek are being addressed under the U.S. EPA Superfund program."
Response: TMDLs have been completed and approved by US EPA across the nation (including Region 5) that address impairments by contaminated sediment and atmospheric deposition of mercury. The citation on the WDNR website is not a "policy", but rather an outdated general statement regarding a previous EPA position that is no longer applicable. In order to eliminate confusion in the future, the language has been removed from the Impaired Waters website.

1.2 "The Department's policy is also incorporated into the TMDL being developed for the Fox River. TMDL Fact Sheet – Fox River, August 16, 2007 ("Fox River Fact Sheet"). In the Fox River TMDL, the Department specifically defers the PCB sediment issues to the U.S. EPA Superfund process by stating the TMDL only addresses "excess phosphates and sediment loading from landscape. . . ." See Fox River Fact Sheet, page 2. In terms of applying Department policy, there is no factual distinction between Cedar Creek and the Fox River – both have impairments due to PCB contaminated sediments and both are being addressed through the U.S. EPA Superfund process. Yet, the Fox River TMDL process follows the Department's stated policy while Cedar Creek does not. No reason exists for treating Cedar Creek in an inconsistent manner and no rationale is provided for deviating from Department policy as is required by Chapter 227, Wis. Stats."
Response: As stated in the response above to comment 1.1, it is incorrect to identify or characterize the general descriptive language previously posted on the WDNR website as "Department policy".
Regarding the portion of the comment which compares this TMDL with actions on the Lower Fox River, the Lower Fox River differs from the Cedar Creek & Milwaukee River TMDL since the record of decision for the Lower Fox River is signed and implementation started and is on schedule. The TMDL for the Lower Fox River is going to be developed this next year for the pollutants of total suspended solids (TSS) and phosphorus (P). Cedar Creek currently has no other pollutants listed or they would have also been addressed in this TMDL. In the case of Cedar Creek, the Remedial Investigation and Feasibility Study as part of the Alternative Superfund Project has not been completed yet and no clean up plan is scheduled. Hence, the Department prepared the TMDL to identify the appropriate maximum load that will lead to a reduction in the fish tissue PCB level in order to raise the Fish Consumption Advisory, and then meet water quality standards in the impaired segments of Cedar Creek and the Milwaukee River.

1.3 "In addition, a review of U.S. EPA Region 5 approved TMDLs reveals no precedent supporting the Cedar Creek approach. TMDLs are to be prepared to address point source discharges and non-point runoff. TMDLs are not to be used to address legacy issues such as contaminated sediment. Moreover, in this instance, developing a TMDL serves no practical value. The industrial use of PCBs is banned, and its use ceased decades ago. As stated in the proposed TMDL, all significant point source inputs to Cedar Creek were identified and controlled (e.g. elimination of discharges from industrial facilities). As such, no significant external PCB loadings to Cedar Creek are currently occurring, and thus, there is no need to specify an additional "load" (i.e. TMDL) that may be allowed to enter the system. Rather, and as stated in the TMDL, the primary "source" of PCBs in the system is sediment-associated PCBs that are already in the system. Both the external

(former industrial facilities) and internal (sediments) PCB sources are being addressed under the U.S. EPA Superfund program."
Response: It is incorrect to state that TMDLs are not to be used to address legacy issues. A similar approach, i.e. to define a sediment concentration target and to use a site-specific PCB transport and fate model to determine the maximum load, was used in many other TMDLs, such as for Newport Bay (USEPA 2002), San Francisco Bay (CRWQCB 2007), and Potomac River (ICPBR 2007). Moreover, the approach used in the TMDL is recommended by the US EPA when addressing PCB issue (US EPA 2008).

There are over 260 TMDLs approved in the United States for PCBs, and many specifically address PCBs causing fish consumption advisories. Historical sediment contamination by PCBs is addressed in numerous approved TMDLs around the Nation including region 5. Here are a few examples: Calleguas Creek, CA (CCWMP 2005), Kawkawlin River, MI (MDEQ 2002), Mississippi River, MO (MDNR 2006), Newport Bay, CA (USEPA 2002), Potomac River, MD (ICPBR 2007), Rock Creek, DC (USEPA 2003a), San Francisco Bay, CA (CRWQCB 2007) (to be approved this year), Schuylkill River, PA (USEPA 2007a) and Shenandoah River, VA (VDEQ 2001).

The Department is required to produce TMDLs for waters listed on the 303(d) list and the EPA does not make any distinction in the source of the contaminant to be address in a TMDL, whether it is an external source (e.g. runoff waters) or an internal source (e.g. contaminated stream bottom sediment). The TMDL Regulations (40CFR Part 130.7 (c)(1)(ii)) state that "TMDLs shall be established for all pollutants preventing or expected to prevent attainment of water quality standards…" A goal of a TMDL is to result in the achievement of the appropriate water quality standard (WQS). The WQS in NR 102.04 (1) is not being met in Cedar Creek and the Milwaukee River because of the current fish consumption advisory in effect as the result of PCB contaminated sediment. A TMDL must "be established at a level necessary to implement the applicable water quality standards" (Section 303(d)(1)(C) of the Clean Water Act). The EPA has determined that PCBs are a "core indicator" in the assessment determinations regarding fish consumption and there is no distinction made regarding the source of the water quality impairment (USEPA 2005). Even if PCBs are banned, the contaminated sites in the Cedar Creek watershed, including industrial sites and impacted-receiving sites, are still today a source of PCBs as pointed out in the TMDL draft report. Even if "…*PCB sources are being addressed under the U.S. EPA Superfund program*" as stated in the comment, there are no prohibitions in EPA guidance about developing a TMDL on a Superfund site (pers. comm., D. Werbach, US EPA). Examples of approved PCB TMDLs involving Superfund sites come to support this, like the Delaware River TMDL (USEPA 2003b) and the Red Clay River TMDL (USEPA 2007b).

For all these reasons, it is not only appropriate but mandatory to prepare a TMDL addressing both internal sources (contaminated sediment) and external sources (contaminated sites) in order to achieve the fish tissue goal and reaching the promulgated water quality standards.

2. "The TMDL, if finalized, constitutes a decision under Chapter 227, Wis. Stats., subject to the appeal rights afforded aggrieved parties. No mention is made in the TMDL of the appeal rights. These appeal rights should be included so that all parties understand the process to be used to challenge the final TMDL."
Response: The EPA does not currently require states to mention the appeal rights in TMDL reports. At this time, however, the Department is currently developing guidance regarding

appeal rights as supported by Wisconsin Statutes that will be posted on the Department's public website upon completion. For information purposes, a TMDL is not final until after the EPA review and decision process has been completed. Regardless of state law, U.S. EPA has informed the Department that TMDL reports may be contested in federal court upon completion and approval by U.S. EPA.

3. "(…) the TMDL has no bearing on the U.S. EPA cleanup process. (…)legally the TMDL is not an applicable, relevant or appropriate requirement ("ARAR") under federal law, since it has not gone through the required Chapter 227, Wis. Stats., rulemaking process, and [because] the TMDL policy most certainly is not applied in a consistent manner. (…) the proposed TMDL is not (…) a substitute for such [sediment cleanup] rules (…) (emphasis added)."
Response: The Department has promulgated water quality standards in state administrative rules and TMDLs are established to achieve these promulgated standards. It is the Department's position that the state water quality standards (WQS) used as the basis of the TMDL will be an ARAR. However, EPA has the authority to make the final decision on what is considered an ARAR at the site. The WQS used to develop the TMDL were promulgated in the Wisconsin Administrative Code under s. NR 102.04 (1). Moreover, the preparation of a TMDL for impaired waters is required under ss 303(d) of the Clean Water Act. It is the Department's position that the state WQS and the enforceable requirements of the CWA are one of the many ARARS which impact the selection of remedial action under CERCLA.

In a document titled "*Integrating Water and Waste Programs to Restore Watersheds, A Guide for Federal and State Project Managers*" (USEPA 2007c), the EPA Offices of Water and Solid Waste and Emergency Response have provided guidance to the EPA Project Managers on how Water Quality Standards and TMDLs may relate to establishing ARARs as well as how the RI/FS process may provide information relating to the development of a TMDL. The following is an excerpt from that document which helps inform the response to this comment:

> "TMDLs established by states, territories or authorized Indian tribes, may or may not be promulgated as rules. EPA-established TMDLs are not promulgated as rules, are not enforceable and, therefore, are not ARARs. TMDLs established by states, territories or authorized tribes should be evaluated on a regulation-specific and site-specific basis. Even if a TMDL is not an ARAR, it may aid in setting protective cleanup levels and may be appropriately a to-be-considered (TBC) guidance. Project managers should work closely with regional EPA Water Program and state personnel to coordinate matters relating to TMDLs. The project manager should remember that even when a TMDL or WLA is not enforceable, the WQS on which they are based may be ARARs. TMDLs can also be useful in helping project managers evaluate the impacts of continuing sources, contaminant transport and fate and effects. Similarly, Superfund's RI/FS may provide useful information and analysis to the federal and state water programs charged with developing TMDLs. For more information, see EPA Contaminated Sediment Remediation Guidance for Hazardous Waste, OSER 9355.0-85, December 2005, page 3-8, www.epa.gov/superfund/health/conmedia/sediment/guidance.htm."

The Department has not proposed a sediment clean up process or standard in the draft Cedar Creek and Milwaukee River TMDL. Rather, the TMDL provides a long term goal for sediment PCB concentrations to reach in order to reduce the PCB concentration in fish tissue to a level which will lead to the removal of the Fish Consumption Advisory. This goal will be achieved following the clean up of the contaminated sediment and to some extent as a result of natural attenuation including volatilization, microbial decomposition, and dilution by clean sediment.

4. (Comment 4 from the letter is broken down here in two comments, 4.1 and 4.2)

4.1 "The proposed TMDL does not account for the movement of fish and wildlife populations in the area and assumes that these populations stay in Cedar Creek and accumulate their PCB body burden from exclusively within this area. This assumption is flawed, as the fish and wildlife populations (e.g. waterfowl, other birds, mammals) of this area can and do move between the Cedar Creek and other areas where they may be exposed to other PCB sources."

Response: The Department believes the assumptions used to develop the TMDL accurately represent the general movement of the resident fish populations. In the PCB impacted Cedar Creek reach, the dams associated with Ruck Pond, Columbia Pond and the Wire & Nail Pond are barriers to fish movement from the Milwaukee River and Lake Michigan. Similarly, in the PCB impacted reach of the Milwaukee River, the Department believes it is accurate to assume that resident fish populations are confined between the Thiensville-Mequon Dam at river mile 20 to the Grafton Lime Kiln Dam at river mile 30; and the reach of Cedar Creek between its confluence with the Milwaukee River at river mile 0 to the Wire & Nail Dam at river mile 3.6. Prior to the abandonment of the Hamilton Dam, Cedar Creek fish were confined to river mile 1.4 and the Milwaukee River.

Fish from the upstream reaches of Cedar Creek <u>unimpacted</u> by PCB-contaminated sediment can move downstream to these ponds. Fish tissue samples from the unimpacted reach (STH 60) do not exceed the concentrations requiring a waterbody specific consumption advisory. Similarly, fish from the unimpacted PCB reach of the Milwaukee River can move downstream of the Village of Grafton Bridge St. (STH 60) dam and become exposed to contaminated sediments in the Milwaukee River as well as Cedar Creek. There is no evidence that significant PCB contamination exists in the Milwaukee River upstream from it's confluence with Cedar Creek. Fish from the unimpacted PCB reach of the Milwaukee River do not exceed the concentrations requiring a waterbody-specific consumption advisory. Migratory salmonids have been observed in this system from Lake Michigan to the area immediately above the Thiensville Dam but only under ideal flow conditions. Migratory salmonids collected directly from Lake Michigan and the lower reaches of the Milwaukee River and Estuary were not used in the decision to list the affected reaches of this TMDL. The FCA applying to salmonids that might be present in Milwaukee River is the Lake Michigan PCB advisory.

4.2 "With specific regard to the migratory fish species such as rainbow trout, Chinook salmon and Coho salmon cited in the proposed TMDL as occurring in this segment of the river system, data from DNR studies (Eggold *et al*., 1996) at other PCB sites demonstrate that such species accumulate the vast majority of their adult PCB body burden during their residence time in Lake Michigan and that "the river accumulation of PCBs contributes minimally to the overall PCB body burden present in adult fish. The proposed TMDL fails to account for the Department's own scientific conclusions and fails to acknowledge that the proposed TMDL will have no significant effect on PCB levels in these fish."

Response: The primary goal of the study cited (Eggold *et al*. 1996) was to determine if salmonid stocking could resume on the Sheboygan River. Nevertheless, the study showed that coho salmon smolts and rainbow trout smolts do accumulate PCB from the river

PCB-contaminated sediments which contribute to the overall PCB accumulated in their tissue during their life (Eggold *et al*. 1996).

As mentioned in the TMDL, the migration of fish from Lake Michigan is seasonal and limited by appropriate river flow conditions that allow fish passage at the Thiensville Dam. The vast majority of fish present in Cedar Creek and the Milwaukee River are resident fish and the observation of salmonid species is seldom and anecdotal. Eggold *et al*. (1996) showed that smallmouth bass transplanted into a PCB sediment contaminated reach of the Sheboygan River accumulated rapidly high level of PCBs (within one or two months). This reinforces the fact that fish can accumulate PCBs from a PCB sediment contaminated area within a short period of time, whether they are resident fish or migratory fish.

Contrary to the statement that the TMDL *"…fails to acknowledge that the proposed TMDL will have no significant effect on PCB levels in these fish* [migratory fish species] (emphasis added).", the reduction in the PCB load through the attainment of the PCB sediment target will have a positive effect on all –resident or non-resident– fish present in Cedar Creek and the Milwaukee River since these fish are exposed to the PCBs in the contaminated reaches. Moreover, any fish species, including salmonids, present in the impaired segments of Cedar Creek and the Milwaukee River will be monitored as part of the post-implementation evaluation to determine if body burdens change.

The TMDL was prepared to address non-attainment of the water quality standards due to high PCB levels in fish tissue. The impact of PCBs on wildlife is beyond the scope of this study. Nevertheless, the implementation of this TMDL should reduce fish tissue concentrations of PCB which will have a positive impact on wildlife species with a high content fish diet, including those species known to feed upon from the impacted reaches (e.g., mink, blue heron, osprey and eagle) or suspected of eating fish from the impacted reaches (e.g., river otter).

5. "The linkage analysis, which is essential to development of a TMDL, is flawed and technically unsupported:"

Response: See responses to the sub-comments 5.1 to 5.7 (bullet points in the comment letter).

5.1 "The linkage analysis is defined as the cause and effect relationship between the target value and the pollutant sources (Proposed TMDL, at 10). For this proposed TMDL, the critical linkage analysis is based on the following: "[w]e assume that a reduction of PCB content in Cedar Creek's bottom sediments to a given threshold value (…) will result in a reduction in the fish tissue PCB levels" (emphasis added). This assumption is the primary technical justification for the proposed TMDL and cites no supporting technical information or site-specific data when, in fact, substantial available data exists that shows this assumption to be incorrect. Specifically, the draft Remedial Investigation Report (BBL 2005) cited in the proposed TMDL contains data showing that PCB levels in certain creek fish species are not closely related to sediment PCB levels."

Response: The fish-sediment linkage approach is used in many approved TMDLs (e.g. CRWQCB 2007, and see list of other approved PCB TMDLs provided in response to comment 1.3) and is recommended by the US EPA (2008). A commonly accepted method for relating tissue and sediment concentrations and used by many federal agencies (e.g. US EPA, NOAA) is by calculating a biota-sediment accumulation factor (BSAF) along with models (USEPA 2000, NOAA 2000). This BSAF method is based on the relationship between toxic compounds found in sediment and the accumulation in biota (see also comment 6.1). Note that the result from the Food web Model was used in this TMDL since this approach considers mechanistic aspects of bioaccumulation and the chemical reactions and physicochemical processes taking place, while the BSAF is based only on a one to one relationship between sediment and fish tissue PCBs concentrations.

Given the fact that the relationship between PCBs in fish tissue and in sediment is well established, a reduction in the PCB level in sediment will (indeed) result in a reduction in the fish tissue PCB levels.

Regarding the statement that "…*PCB levels in certain creek fish species are not closely related to sediment PCB levels*", it should be clarified that BBL (2005) did not observed a similar trend between PCB level in fish tissue and in sediment for PCB levels in game fish and caged fish, but did observed similar changes in fish concurrently with the on-site PCB sediment concentrations for forage fish from Cedar Creek.

1) Game fish: While forage fish are benthic-feeders (such as sucker and carp) and hence, are often in contact with sediment, "*the primary route of PCB uptake* [for game fish] *is likely to be dietary (food chain) exposure* [through consumption of contaminated prey (e.g. forage fish)] *rather than direct uptake from the sediments , and, given the mobility of game fish, their PCB residue is not closely related to sediment PCB levels in their immediate vicinity* (emphasis added)" (excerpt from BBL 2005). So, the PCB accumulated by game fish is ultimately from contaminated sediment, whether is from indirect (contaminated prey) or direct (e.g. contact with sediment). Even if it is not in their "immediate vicinity," game fish are likely to be in contact with contaminated sediment in Cedar Creek.

2) Caged fish: In this case, the BBL report (2005) stated that "*the water column is the primary source of PCBs in the caged fish*." The PCB present in the water column (either in dissolved form or attached to sediment particles) comes from the sediment through PCB transfer to the water (diffusion, burial, resuspension, bioturbation, bio-uptake by algae, etc).

Overall, the relationship between fish and sediment can be direct (e.g. for benthic feeding fish, contact with sediment) or indirect through the transfer of PCB from sediment to the water or from feeding on contaminated fish (e.g. game fish feeding on forage fish). This supports that there is a relationship between PCB level in fish and PCB laden sediments and that a reduction in the sediment PCB levels will lead in a decrease in the fish tissue PCB concentration.

5.2 "The proposed TMDL (pages 6-7) states that 0.21 mg/kg PCB in fish tissue is the basis for the TMDL. Then, on page 11 this value is simply discarded in favor of 0.14 mg/kg. No site-specific technical justification is provided. Without site-specific information, the Department could arbitrarily select any number less than 0.21 mg/kg on the basis that it "is more protective." A critical TMDL endpoint such as this should not be based on mere assumption but must be supported by site-specific technical data."

Response: The fish concentration of 0.14 ppm was chosen because this value: 1) is associated to the same cancer risk (10^{-4}) as for the 0.21 ppm fish target value in the TMDL[18], and 2) allows the protection of the majority of the population (including subsistence and recreational anglers) since this value of 0.14 ppm aims to protect high-intake fish consumers. The fish tissue level of 0.21 ppm falls between the risk-based fish concentrations[19] of 0.14 ppm for high-intake fish consumer, and 0.24 ppm for recreational angler (RETEC 2002, section 5.9.9). Then, to select the corresponding sediment concentration threshold from the Lower

[18] The fish tissue target of 0.21 ppm in the TMDL corresponds to the fish tissue concentration associated with "1 meal per month" fish consumption advice for PCBs used by Wisconsin to issue fish consumption advisories (FCA) and is associated with a risk cancer of 10^{-4} (Anderson et al. 1993, WDNR 2008).
[19] Risk-based fish concentration for RME (reasonable maximum exposure) and a cancer risk of 10^{-4}.

Fox study, we opted for the more protective value of fish concentration of 0.14 ppm, set for high-intake fish consumer, to allow for the protection of all level of fish consumption that result from the different fishing habits, recreational and subsistence anglers. Fishing for subsistence has been shown to be highly probable in the Milwaukee River area (Pajak 1991).

Also, the use of a lower limit for the fish tissue concentration (0.14 ppm) than the target of 0.21 ppm accounts for the uncertainty of using modeling and is part of the margin of safety (MOS) in the TMDL. A MOS is required in the development of a TMDL and may be an explicit value or a set of conservative assumptions built into the analysis. The MOS is intended to account for uncertainty in water quality modeling and an uncertainty inherent to natural systems.

The TMDL report was modified to include additional specifications and information about the selection of the 0.14 ppm value.

5.3 "The proposed fish tissue PCB goal of 0.14 mg/kg was developed for the Fox River using chemical, ecological, and exposure information specific to the Fox River. No similar site-specific effort was made for Cedar Creek. (…) As described in the Fox River risk assessment (RETEC, 2002) and cited in the proposed TMDL, 0.14 mg/kg was the lowest value of many calculated in the Fox River Risk Assessment and was based on a "high-intake fish consumer eating carp." The exposure assumptions used to develop the 0.14 mg/kg value for the Fox River are based on survey data for three highly-exposed subpopulations (low income minority, Native American and Hmong) that are specific to the Fox River and not present at Cedar Creek. As stated in the Cedar Creek Remedial Investigation Report, carp are not targeted by anglers in Cedar Creek, and there is no documentation of high-intake (subsistence) fishers on Cedar Creek. To date, no data or studies exist in the record supporting the proposed TMDL showing that the Department conducted any studies of fishing habits by subpopulations along Cedar Creek. Without such data, it is arbitrary and capricious to simply import a site-specific value from the Fox River based on site-specific Fox River survey data to Cedar Creek and merely "assume" the value to be scientifically correct."

Response: The fish tissue concentration of 0.14 ppm developed for the Lower Fox River study was used to derive the sediment concentration threshold (SCT) for the TMDL since Cedar Creek and the Fox River share many similarities: the fishery is diverse, includes the full range of feeding types (omnivores, insectivores, generalists and carnivores), and has similar lipid content and longevity. As such, the mechanisms operating the food chain, PCB uptake and accumulation rates are similar. Likewise, organic content of sediment, particle size and PCB content are similar.

Moreover, the fish concentration of 0.14 ppm corresponds to the same cancer- risk level (10^{-4}) for the fish tissue target of 0.21 ppm in the TMDL (See response to 5.2 above). Contrary to statement in the comment, this value of 0.14 ppm is not "*the lowest value of many calculated in the Fox River Risk Assessment*": the lowest risk-based fish concentration is two orders of magnitude lower 0.0014 ppm for high-intake of carp corresponding to a cancer risk of 10^{-6}.

The carp was used as the fish species indicator in deriving the sediment concentration threshold (SCT) because carp is a resident species and is directly exposed to the PCBs from the contaminated Cedar Creek and Milwaukee River reaches. Carp are also among the most susceptible fish species to contain high level of PCB because of its high fat content and benthic feeding habits (WDNR 2008).

While carp may not be a primary target species for many anglers, they are routinely consumed by anglers throughout the state. A study conducted in the Milwaukee River area found that carp are one of the most "fished for" species and that people harvest carp in the Thiensville impoundment (see p.16 and table 4 in Pajak 1991). For this reason, carp are included in the development of fish consumption advisories (FCAs) because they could be consumed. In fact, this species is included in the FCA for Cedar Creek. Furthermore, the sediment concentration threshold (SCT) of 0.11 ppm used in the TMDL is stringent enough to allow for the protection of high-intake consumer of walleye, which is one of the preferred targets of anglers (the SCT corresponding to high-intake consumer of walleye is of 0.14 ppm).

While no site-specific studies have been conducted regarding fishing habits for Cedar Creek, the Department has consistently recognized the possibility that all waterbodies in Wisconsin may be used by people fishing for subsistence. In fact, fishing for subsistence has been shown to be highly probable in the Milwaukee River area (Pajak 1991). A case in point is the means by which human health criteria are established in Chapter NR 105 of the Wisconsin Administrative Code. In that rule, the assumption is that the general Wisconsin citizen consumes 20 grams of fish per day. This contrasts with an assumption of 15 grams per day used to develop the federal Great Lakes Water Quality Initiative. This philosophy supports the use of carp as a species that should be considered in the development of the TMDL and its associated water quality goals.

In summary, opting for a conservative approach by using a fish concentration developed for high-intake of carp allows for the protection of a majority of the population, including both recreational and subsistence anglers regardless of whether they target and/or consume carp. This approach therefore is neither “arbitrary” nor “capricious”.

5.4 “The model relating the target fish PCB concentration to a target sediment PCB concentration (“the Fox River bioaccumulation model”) was developed for a completely different site and assuming it applies to Cedar Creek without any studies or verification is scientifically unsound. As stated in the Fox River model documentation (ThermoRetec, 2001), the Fox River model was specifically designed to “accurately depict food web dynamics in the Lower Fox River and Green Bay.” The documentation adds that the modeling work involved “a comprehensive review of the Lower Fox River and Green Bay food webs: prey species, percent composition of diets of various predator species, and lipid contents and weights of the prey and predators of the system.” Such key model information is obviously highly site-specific and unique to the Fox River, and has no bearing or applicability to Cedar Creek. Furthermore, the Fox River model states that “calibration of the FRFood Model was conducted using site-specific [i.e. Fox River] total PCB data for sediment and water as well as site-specific dietary relationships and lipids.” (ThermoRetec, 2001). Nothing exists in the record for this proposed Cedar Creek TMDL to show that (i) DNR developed an independent site-specific model for Cedar Creek or (ii) the site-specific complex model developed for the Fox River (which uses key information that only applies to the Fox River) automatically can be applied to Cedar Creek. The only basis cited by DNR for importing site-specific Fox River modeling into the proposed Cedar Creek TMDL was an assumption that it could be used because both sites involved PCBs.”

Response: The sediment concentration thresholds (SCTs) obtained for the Lower Fox River Foodweb modeling were used in the development of the TMDL because the numerous similarities between Cedar Creek and the Lower Fox River regarding the fishery (species, feeding types, lipid content and longevity) and the sediment characteristics (organic content, particle size and PCB content) (see response to comment 5.3). Based on these similarities and knowing that these parameters (fishery and sediment characteristics) were key factors in the development of the Lower Fox Foodweb Model, the SCT derived from the model is used with confidence for the calculation of a maximum PCB load.

5.5 "Using a target sediment PCB concentration as the "endpoint" or target for the TMDL process is inappropriate. Calculation of a target sediment concentration is highly site-specific and subject to considerable uncertainty. As noted above, the relationship between sediment and fish tissue PCB concentrations depends on many site-specific factors, including physical and chemical properties of the PCB mixture and the receiving water body, partitioning between various compartments of the ecosystem (i.e. sediments, water, biota), food web structure and rates/amounts of PCB transfer between various components of the food web. None of these components were addressed in the proposed TMDL, and no quantitative food-web modeling effort was performed for Cedar Creek."

Response: In development of the TMDL, the Department utilized a *sediment concentration threshold* (SCT) to calculate the total maximum daily load of PCB that would allow fish to be consumed safely. When existing special fish consumption advisories are removed, the affected segments of Cedar Creek and the Milwaukee River will be considered to be meeting water quality standards. Using this approach, the fish tissue target is the "end point" of this TMDL, not the sediment concentration threshold. The sediment concentration threshold serves as the mechanism to achieve the endpoint which is eliminating the need for a specific fish consumption advisory. This is specified in the TMDL report: "*The purpose of this TMDL is to identify the appropriate load of polychlorinated biphenyls (PCBs) from Cedar Creek that will result in reducing fish tissue concentrations in PCBs and meeting WQS [water quality standard] in receiving waters that include Cedar Creek and the Milwaukee River* (emphasis added)."

5.6 "The Fox River fish and sediment target values were developed using data for a PCB mixture that significantly differs in terms of its physical, chemical, and toxicological properties from the PCB mixture present at Cedar Creek. This difference in PCB type directly affects the fish uptake and linkage analysis. The two industrial facilities along Cedar Creek used PCBs specifically designed to satisfy fire safety standards for hydraulic fluids used at die cast plants. The PCBs in the Fox River were from the manufacturing and recycling of carbonless copy paper (RETEC, 2002). This difference in PCB type is a key factual distinction ignored in the proposed TMDL."

Response: The PCB mixtures used originally in the Fox River basin and the ones found in the Cedar Creek present some similarities even if the use for industrial purpose differs. The PCB mixture originally used in the Fox River basin was Aroclor 1242 (RETEC 2002), which is also found in the Cedar Creek system along with Aroclor 1260 (the predominant mixture), 1248 and 1254, either in soil, sediment, water or fish (BBL 2005). More specifically, Aroclor 1242 was detected in high concentrations in sediments collected from Columbia pond and Hamilton pond (BBL 2005), and in the groundwater beneath the Plant 2 Site and in floor samples of that site (BBL 2007).

Aroclor 1242 is composed of lower chlorinated congeners (predominantly di- to tetrachlorinated congeners) than 1248, 1254 and 1260, the latter being the most predominant Aroclor present in Cedar Creek. It is known that PCB uptake by aquatic organisms through bioconcentration (uptake from water) and bioaccumulation (combined uptake via food, sediment, and water) increase with higher chlorination of the PCB congeners (ATSDR 2000). Because the contamination of the Fox River was caused by lower chlorinated mixtures of PCB congeners (Aroclor 1242), the model may (at worse) slightly underestimate the bioaccumulation of PCBs by organisms in the Cedar Creek system where the predominant Aroclor 1260 is made of higher chlorinated congeners.

Even if the PCB mixtures may differ between the Fox River and Cedar Creek, the SCT derived from the Fox River study can be used in the TMDL since total PCB data were used in the Fox River Study. The sediment concentration threshold values calculated in the Fox River study were derived using: 1) total PCB data for sediment and water as input in the Fox River Foodweb Model and, 2) the risk-based fish tissue concentrations which were calculated using total PCB fish concentrations (RETEC 2002, section 7 and 5, respectively).

5.7 "Assuming a TMDL is legal and/or technically supportable for the Cedar Creek situation (which it currently is not), the appropriate target endpoint is fish tissue concentration based on human exposure and risk, not an "assumed" back-calculated sediment concentration. A fish tissue target is closely associated with the Clean Water Act ("CWA") goal of protecting public health as it directly addresses the primary route of human exposure to PCBs, i.e. fish consumption. A fish tissue target for the proposed TMDL is also consistent with the manner in which fish advisories are issued. Finally, the fish tissue target matches recent USEPA approaches for developing water quality criteria for bioaccumulative substances under the CWA (e.g. U.S. EPA, 2001). Using this approach, the ultimate goal of the TMDL (assuming it even applies to contaminated sediments) would be to reduce fish PCB levels to a target level that would reflect an acceptable risk to fish consumers and would allow a reduction of the current fish consumption advisory."
Response: We agree that the endpoint of the TMDL is indeed the fish tissue target concentration of 0.21 ppm and the ultimate elimination of the special fish consumption advisory (see response to comment 5.5).

6.1 "The proposed TMDL fails to acknowledge that the sediment PCB target level of 0.11 mg/kg is technically infeasible and cannot be achieved even under optimal conditions. More specifically, Ruck Pond is cited as an example of a cleanup that was according to the Department an "unqualified success." (WDNR, 2001). However, the very expensive remediation of Ruck Pond only was able to achieve an overall post-remediation sediment value of 7.11 mg/kg. The fact that the concentration proposed by DNR as the SCT (0.11 mg/kg) could not be met under optimal conditions on a project that DNR touts as an unqualified success raises serious questions regarding the validity of the target value. The proposed TMDL fails to account for the Ruck Pond experience even though DNR has this Cedar Creek site-specific data readily available to it."

Response

The Department assumes that the sediment concentration threshold (SCT) of 0.11 ppm in the TMDL is feasible considering the success of the Ruck Pond remediation. The post-remediation study of Ruck Pond (WDNR 2002) showed that the minimum PCB sediment concentrations was of 0.07 ppm just a few months after the remediation, which is even lower than the target of 0.11 ppm. This fact stresses the feasibility of the SCT of the TMDL. The value of 7.11 ppm reported in the comment constitutes the mean PCB concentration in sediment (7.11 mg/kg) and was high because of a small area (10 m^2) and thin layer (few centimeters thick) of contaminated sediment remaining in Ruck Pond after remediation (WDNR 2002). However, even if the achievement of the SCT is feasible based on the Ruck Pond remediation results, the SCT value "*…is not meant to be a clean-up criterion, but rather a long-term goal of PCBs concentration in sediment*." (Excerpt from the TMDL report).

Secondly, the Department assumed that the SCT (0.11 ppm) to be reasonable given the fact that this value falls within the range of sediment quality guidelines developed by the state of Wisconsin, other states, federal agencies and Canada (see Table 1 below).

Table 1. Comparison of Sediment Quality Guidelines developed by states, Federal Agencies and Canada.

Other States or Entities	Threshold Effect Level, Effect Range-Low (ppm)	Probable Effect Level, Effect Range-Median* (ppm)
Wisconsin [(1)]	0.060	0.676
Florida [(2)]	0.060	0.680
Minnesota [(3)]	0.060	0.680
NOAA - Sediment PCB Guideline [(4)]	0.0227	0.180
USGS - Freshwater Consensus-based Criteria [(5)]	0.0598	0.676
Canada - Sediment Quality Guideline for the Protection of Aquatic Life [(6)]	0.0341	0.277

NOTES
** Value above which adverse effects frequently occurs. [(1)] WDNR 2003, [(2)] FDEP 2003, [(3)] MPCA 2007, [(4)] NOAA 1999 [(5)], Ingersoll et al. 2000 & MacDonald et al. 2000, [(6)] CCME 2001*

6.2 "The proposed TMDL should highlight the successes already achieved at the Cedar Creek site. Information presented in the TMDL document (Appendix B) shows marked decreases in Cedar Creek fish PCB levels over time for all species for which sufficient data are available to support a comparison. For example, PCB levels in largemouth bass decreased from 2.093 mg/kg (1990-1999) to 0.698 mg/kg (2000-2004); PCB levels in northern pike decreased from 12.783 mg/kg (1977-1989) to 2.616 mg/kg (1990-1999) to 0.538 mg/kg (2000-2004), and PCB levels in rock bass decreased from 2.903 mg/kg (1977-1989) to 1.273 mg/kg (1990-1999) to 0.710 mg/kg (2000-2004)."

Response: The Department has attempted to underline the success of the Ruck Pond Remediation in the TMDL report (see *Source Assessment* and *Reasonable Assurance* in the TMDL report). In fact, the reductions in fish tissue concentrations following that effort support the aim of the TMDL to set the appropriate load leading to the removal of the special fish consumption advisory, with the ultimate goal of meeting the narrative water quality standards. Updating the Ruck Pond Remediation Assessment Study to include data collected since the results presented in Appendix A is outside the scope of the TMDL.

6.3 "The proposed TMDL improperly proposes remedial action which is outside the scope of the TMDL. Rather, remedial decisions are made by U.S. EPA in the Superfund process. More specifically, the statement that "if Columbia Pond and Wire and Nail Pond are remediated [as opposed to just Columbia Pond], significant benefits could be expected" (page 16) is conjecture and not supported by any data or other technical information."

Response: Changes were made in the TMDL report.

Friends of the Milwaukee's Rivers' Comments
Submitted by Cheryl Nenn, Milwaukee Riverkeeper (07-07-08)

1. "The proposed Sediment Concentration Threshold for PCBs is not protective enough of Cedar Creek and the Thiensville-Grafton segment of the Milwaukee River. [1.1]….we have been contacted in the past from out of state fishermen and downstream fishermen that were not aware of this advisory ["do not eat fish at any time"], and have eaten fish likely contaminated with PCBs from Cedar Creek and the downstream portion of the Milwaukee River…. we feel that the proposed level of PCBs in Cedar Creek fish of 0.21

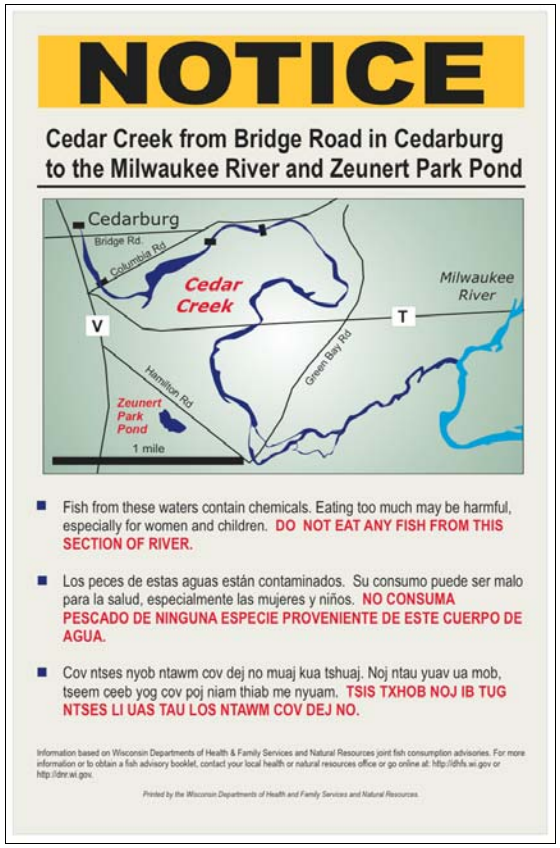
mg/kg (that the SCT was based on), is likewise too high and not protective enough of fish or human populations.

[2.1] Ideally, the proposed Sediment Concentration Threshold for PCBs in Cedar Creek should be 0 mg/kg. While we understand that reaching a zero discharge level *may* not be possible for large areas of contamination such as the Fox River, we feel that a 0 mg/kg limit is an achievable target on Cedar Creek. Although, that said, our research has shown that other areas of the country have much lower SCTs…" (emphasis added)

Response: The first issue raised in comment 1.1 is a concern for the Department. In this regard, there is a clear need for a better education of the anglers using Cedar Creek and the Milwaukee River. We will share your comment with our Fish Consumption Advisory Program as the Department posts signs on waterbodies when all fish are contaminated to the status of "Do Not Eat Any Meals". Below is a picture of what our fish contamination advisory signs. In the stormwater ponds, Quarry Pond (of Cedar Creek) etc., and if only some fish exceed criteria for FCAs, posting signs related to water quality and human health issues is a responsibility of the county.

The fish tissue goal of 0.21 mg/kg (which correspond to the limit to eat safely 1 meal/week) was developed using sound scientific basis by the Protocol for a Uniform Great Lakes Sport Fish Consumption Advisory (Anderson *et al*. 1993). Reaching this fish goal will lead to the removal of the special fish consumption advisory for the impaired segment of Cedar Creek and Segment 2 of the Milwaukee River and the removal of these waterbodies from the impaired water list. The Department believes that this will be beneficial for the population since this will lead to the protection of the human health.

Regarding comment 2.1, the Department is confident that reaching a sediment concentration threshold of 0.11 mg/kg will result in a decrease of the PCB levels in fish to the goal of 0.21 mg/kg. Also, the Department assumes that the sediment goal of 0.11 mg/kg is realistic and achievable given the post-remediation results from the Ruck pond (see above the response to comment 6.1 from Mercury Marine). The sediment goal is also reasonable allowing the fact that the SCT falls within the range of sediment quality guidelines established by other US agencies and also Canada (see above the response to comment 6.1 from Mercury Marine).



Fish consumption advisory sign posted on Cedar Creek.

2. "The proposed Fish Tissue Targets for PCBs for Cedar Creek and the Thiensville-Grafton segment of the Milwaukee River are not protective enough. Better Assumptions are needed for establishing fish tissue targets for PCBs for the proposed TMDL. It is also much higher than the standard used in other areas of North America… …[we] are confused that the DNR would use the proposed Fox River SCT and not their proposed fish tissue target. Why can Cedar Creek fish be more contaminated with PCBs than Fox River fish? …We understand that the 0.21 mg/kg standard was based on as estimated "1 meal per month" fish consumption advice for PCBs that has been used by Wisconsin to issue fish consumption advisories in the past according to the "Protocol for a Uniform Great Lakes Sport Fish Consumption Advisory" (Anderson et al. 1993); however, we feel that this standard is out of date and should be readdressed. FMR strongly encourages DNR to ensure that the assumptions used in the fish tissue target for Cedar Creek are based on current science and factor in actual fish consumption values for our area if possible and levels of risk…. The proposed fish tissue targets seem vastly higher than those being used in other areas of the country, do not seem based on current scientific literature (other than a 1993 protocol), and should likewise be reduced significantly."

Responses: The fish tissue target of 0.21 mg/kg was the criterion used to add the two waterbodies (first 5 miles of Cedar Creek and the Milwaukee River Segment 2) on the 303(d) Impaired Water List. In order to remove any waterbodies placed on the 303(d) list, the Department is required by the US EPA to use the same listing criteria for the delisting. However, the Department understands and agrees that, in order for this goal to be fully protective, better education should be implemented to make sure that the population is aware of the fish consumption advisory currently in place.

The fish consumption advisories (FCAs) for the State of Wisconsin are established using the Protocol for a Uniform Great Lakes Sport Fish Consumption Advisory (Anderson *et al*. 1993), and a revaluation of the FCA limits set in the Protocol is beyond the scope of this TMDL (see also above responses to comment 1 from Friends of Milwaukee River and to comment 4 from US EPA, Water Program.)

3. "FMR is concerned about extrapolating Fox River PCB data and models for Cedar Creek and the Grafton-Thiensville portion of the Milwaukee River. The 0.11 mg/kg SCT was based on the work that has been done determining the Fox River threshold and the Fox SCT was designed to meet a fish tissue target of 0.14 mg/kg, which is more protective than the proposed Cedar Creek fish target. Thus, we understand that the WDNR feels that due to a certain margin of safety allowed under the TMDL process that using the Fox River model data is justified, and will meet the proposed fish tissue target of 0.21 mg/kg, which is significantly higher (as mentioned above) than the fish tissue standard for the Fox River. We can not think of any other justification for this decrease in the fish tissue target for PCB removal other than an economic one? We are still unclear how the 0.21 target was chosen, instead of the more protective 0.14 from the Fox River (which many scientists think is also not protective enough of human health). Given that Cedar Creek is a vastly smaller watershed than the Fox River, we don't feel that using the Fox River model to estimate risk in this system is even appropriate. The cost requirements of removing PCBs in the Fox River system as opposed to the Cedar Creek system are vastly increased—as the area affected is much larger and PCBs more dilute. We acknowledge that Mercury Marine has already spent over $8 Million dollars cleaning up the Ruck Pond, and that they are largely bearing the cost of the clean-up at this point, since Amcast Industrial has declared bankruptcy. However, since a TMDL is supposed to be driven by science and not economics, we don't feel that the economic argument should be weighed in here, if that indeed is coloring this analysis. Furthermore, 90% of the contaminated sediments are presently upstream of the Amcast discharge point—most being contained in the Columbia and Wire& Nail Ponds. We do acknowledge that cost is a factor and understand that cost will be considered as part of the Superfund remedial investigation and feasibility process. However, we would encourage WDNR to enact a stricter SCT and fish tissue target for this proposed TMDL, and to develop a model specific for Cedar Creek if there is enough data to do so. This is not recommended in an effort to delay this TMDL process, but to ensure that the eventual clean-up targets are adequate to protect water quality, wildlife, and human populations.
Responses: The Department assumed that the use of the Fox River Model was justified and valuable to determine the PCB sediment goal in this TMDL considering the similarities within the Fox River and the Cedar Creek systems (see above responses to comment 5.3 and 5.4 from Mercury Marine). The fish tissue goal in this TMDL of 0.21 mg/kg was selected only because it was the criterion used to place the Cedar Creek and Milwaukee River Segment 2 on the 303(d) Impaired List (see response to comment 2 above), and no economical reasons interfered in this selection. The economical factors will be rather taken into account in the Cleanup Plan decision as part of the Superfund Project. Contrary to the statement in the comment, the goals set in this TMDL are long term goal and not "clean-up targets" as clearly specified in the TMDL report.

4. "The proposed TMDL document does not adequately address potential PCB sources from Publicly Owned Treatment Works (POTWs). …we would recommend that (if not already doing so) POTWs use Method 1668A to measure PCB concentrations in their effluent. Although this test is expensive, it can achieve a pg/L detection limit as opposed to a 0.5 ug/L detection limit, and thus further verify that these plants are not a definitive source of PCBs. There is a clear relationship between treatment and PCBs concentrations, and these POTWs could still be a significant source of loading based on the industrial history of the area. … Likewise, we'd encourage that similar monitoring of other potential sources such as the Quarry pond, Wilshire stormwater basin, and nearby storm sewers be analyzed using the same test to ensure that they are not actively contributing PCBs to the rivers during dry or wet weather. It is unclear whether or not this analysis has been done."

Responses: The Department agrees that the use of the analytical Method 1668A for effluent monitoring would ensure that the Cedarburg Wastewater Treatment Plant (WWTP) and the Wilshire Pond do not discharge significant PCB loads to Cedar Creek. However, the Cedarburg WWTP and Wilshire Pond are required to use the analytical methods specified in NR 219, which is currently Method 8082. The rule NR 219 is currently under revision and the Method 1668A should be included in the list of analytical methods for effluent monitoring in NR 219 as recommended by the Department in spring 2008.

For informational purposes, the Wilshire Pond's effluent was tested in spring 2008 using Method 1668A as mentioned in the TMDL since no PCB data at the effluent was available (Wilshire pond receives overflow waters from the Quarry pond and stormwater from the surrounding area, including the contaminated sites of Mercury Marine Plant 2 and Amcast).

5. "WDNR should provide more meaningful opportunities fore public comment on proposed TMDLs. It is our understanding that a large part of any TMDL process is eliciting public opinion on proposed clean-up standards and getting community support behind a plan for cleaning up our waterways. FMR was very disappointed by the lack of meaningful public participation in the proposed Cedar Creek TMDL.

While FMR has been largely keeping updated of the process, it is clear that most of the attendees at the public hearing on June 5, 2008 at the Cedarburg Police Department have not been. FMR knew very little about this TMDL process until we were invited to the public meeting. We were also very heartened and affected by public comments from adjacent residents that have been largely unable to conduct erosion control efforts, streambank stabilization, to plant gardens, or even conduct routine maintenance on parts of their riparian properties due to the current PCB contamination in the creek and adjacent floodplains. While we understand that the DNR is not in charge of the Superfund efforts, DNR does have significant oversight and is leading the process to get this Creek clean. We feel, in retrospect, that there should have been much more than a single public hearing to elicit feedback from these owners as well as other stakeholders in this TMDL process. It is clear that many attendees were very frustrated. The information is so technical, that it took most of the meeting for participants to try to understand the process let alone provide meaningful comment. It is also our understanding from conversing with colleagues throughout the country that most TMDL efforts involve creation of technical advisory committees and much more collaboration with the local communities and stakeholders. Furthermore, there was a noticeable absence of residents from the Grafton and Thiensville areas, which are downstream of Cedar Creek and also affected by this TMDL. We likewise encourage DNR and EPA to look at innovative ways of cleaning up this PCB problem and implementing this TMDL (and subsequent Superfund efforts) so that residents don't have to wait several more decades before they can safely and fully use their properties."

Response: At the public meeting (held on June 5, 2008) the Department acknowledged the confusion manifested by the public concerning the TMDL and the Superfund Cleanup processes, and provided clarifications in the differences in the two processes. The US EPA was informed of the concerns regarding the clean-up process expressed from the citizens during the meeting since the clean-up process is part of the Superfund Program and the US EPA is the leader of the effort. Yet, this TMDL is <u>not</u> a clean-up plan or part of the clean up process. Also, contrary to the statement in the comment that "*…any TMDL process is eliciting public opinion on proposed clean-up standards…*", the goal of a TMDL is to determine the maximum load allocation of a given pollutant, and not to developed "*clean-up standards*". This is clearly specified in the TMDL (see Linkage Analysis section): "*Is it important to emphasize that the PCB SCT used here is not meant to be a clean-up criterion, but rather a long-term goal of PCBs concentration in sediment.*"

In regards to the remainder of your comment, we understand the importance of stakeholder involvement in improving water quality in Wisconsin. The Department's Impaired Waters Program is currently working on a communication and outreach strategy to allow for more input in the development and implementation of TMDLs in the future. In addition, EPA only requires the states to have some sort of public meeting or comment period during the development of TMDLs (i.e. in some cases a 30-day comment period only and no public meeting required). Under ideal circumstances, we would have had more public input opportunities for the Cedar Creek and Milwaukee River Segment 2 TMDL. Due to limited staff, resources and time constraints, the Department was limited to the public meeting held for this TMDL and the public comment period that followed.

6. "FMR requests that the proposed TMDL consider recreational exposure to PCBs and risk to human health and safety posed by proposed PCB levels."

Response: The first 5 miles of Cedar Creek and the Milwaukee River Segment 2 were added to the 303(d) Impaired Water List for Fish Consumption Advisories (FCAs) due to PCBs in contaminated sediments, and this was the basis and justification for the development of this TMDL. As mentioned in the comment (see letter attached), water quality standards for recreational uses exist only for bacteria, and not for PCBs. Also, since this is a human health issue, Ozaukee County Public Health and the Department of Health and Family Services should be notified of this concern.

In conclusion, the Department believes that the implementation of this TMDL will also lead to a decrease in the PCB level in the water column which would have beneficial effects on the other recreational water uses along with fisheries.

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VILLAGE OF THIENSVILLE

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July 3, 2008

RECEIVED

JUL - 7 2008

BUREAU OF WATERSHED MGNT

Ms. Valerie Villeneuve
Wisconsin DNR WT/2
P.O. Box 7921
Madison, WI 53707

RE: Total Maximum Daily Load Report
Public Comment

Dear Ms. Villeneuve:

Please consider this letter from the Village of Thiensville as public comment on the Draft Total Maximum Daily Load Report.

It is quite concerning that PCBs from two "local" companies located in the City of Cedarburg – now-closed Mercury Marine and Amcast Industrial – contaminated Cedar Creek and the Milwaukee River and ultimately are responsible for the PCB contamination in the sediments of the Thiensville Impoundment.

Currently fish are able to move up and past the Thiensville Dam during higher spring flow as fish are spawning. The City of Mequon and the Village of Thiensville are considering converting the Thiensville Dam to a fish ladder to make the Milwaukee River more fish friendly. We now question whether that is the proper thing to do, do we really want to send fish up the Milwaukee River from the Thiensville Impoundment to Cedarburg Cedar Creek only to be subject to more contamination?

In addition the Village of Thiensville is undergoing the Pigeon Creek Flood Mitigation Project, which will also provide pools for fish and remove impediments upstream for fish passage.

The Village of Thiensville strongly requests that the Thiensville Impoundment be included when Superfund Project Funds are requested. At a future date it would be unconscionable to suggest that citizens of Thiensville and Mequon, who own the dam, should be responsible for cleanup when they were not the ones who contaminated. To wait to see if the PCBs are covered by waiting 30+ years is unacceptable to not only the fish but to the citizens of the Village of Thiensville and citizens of the State of Wisconsin who actively use the Milwaukee River for fishing, boating and swimming.

Sincerely,

Karl V. Hertz, President

Dianne S. Robertson, Administrator

Comments received from the US EPA (Watershed and Wetland Program, and Superfund Program) on July 7, 2008.

Comments on the Cedar Creek, WI draft TMDL
Dave Werbach 6/10/08

1. Page 3, middle paragraph: It would be very helpful to add the names of the dams discussed in this and other sections onto Figure 1 (or another figure).
2. Page 3, last paragraph: Suggest changing last sentence to "…confluence with the Milwaukee River and <u>the entire</u> 10 miles…" The current language could imply that there is more of Segment 2 that is not addressed by the TMDL.
3. Page 9, bottom: The TMDL discusses point sources on Cedar Creek. Are there any point sources on the Milwaukee River Segment 2? Are there any other permitted storm water discharges other than Wilshire Pond, on either segment? Additional discussion on the Milwaukee River is needed.
4. Where is the information used to set the 0.21 target? Given the large amount of data and material on the Lower Fox, I have been unable to find the discussion. I suggest the Chapter (?) be pulled out and attached, as a clear reference. I think I found the determination of the 0.11 sediment level, but that chapter should be attached as well, or very specifically referenced .

<u>The comments below are from our Superfund program</u>.

1. Page 5 - the document talks about the current boundary of the Superfund site… It should state Superfund Alternative site or just site. It happens twice on that page.

2. Page 15, Reasonable Assurance section - The second paragraph states, "Moving forward, the Cleanup plan as part as the Superfund includes not only…" I think the sentence should state, "Moving forward, the Cleanup plan as part of the Superfund process, includes not only…"

3. Page 15, Reasonable Assurance section - The last sentence on this page should state, "A proposed cleanup plan for Cedar Creek providing the cleanup options should be completed by the end of 2008.

I am basically going to write the way I think the paragraphs should be on Pages 16 and 17. I will put my changes in bold.

Numerous approaches and engineered controls can be taken to manage PCB contaminated sediment and the risk associated with PCBs: removal and disposal of the contaminated sediment, **capping of sediments** , and institutional controls such as advisories to the public, assess restrictions, and prohibited activities. **Any combination of** these approaches should be used ~~in combination with remediation~~ to manage the risk of PCBs in Cedar Creek and downstream to the Milwaukee River and Lake Michigan.

Overall, WDNR anticipates the TMDL of 0.17 g/day established here could be attainable on a long-term basis, after remediation of the contaminated in-stream sediments, and the ~~contaminated sites under the Superfund~~ **cleanup of other areas of the site** , along with the natural attenuation including volatilization, microbial degradation, and dilution by clean sediment.

Comments received from the US EPA (Watershed and Wetland Program, and Superfund Program) on July 7, 2008.

Since Cedar Creek is a **Supefund Alternative** site, WDNR, EPA and the potentially responsible parties are working together on a RI/FS. However, the comments from **EPA, in consultation with WDNR**, should be adequately addressed in the RI/FS reports conducted by **ARCADIS** BBL for the Mercury Marine Corporation. It is important that the RI/FS proceed to completion ~~and~~ in a timely manner. ~~The approved schedule for the RI/FS report to be completed was April of 2005.~~

Model projections indicate system recovery is enhanced by removing contaminants from certain impoundments ~~(e.g. Columbia Pond on Cedar Creek)~~ (Figure 2). ~~Based on the high resident PCB mass in Colombia Pond, a mass removal of sediments could reduce the transport of PCB and will enhance the natural recovery of the Cedar Creek system (Baird & Associates, 1997).~~ In addition, ~~if Columbia Pond and Wire and Nail Pond are remediated,~~ **after the Cedar Creek remedy is implemented,** significant benefits could be expected including local and watershed-wide fish and wildlife bioaccumulation rate reductions, reduced human health risks associated with fish and wildlife consumption advisories, reduced ecological risk for fish eater animals, and elimination of the potential impacts associated with significant or catastrophic loading events (e.g. high flows or **possible** dam failure as experienced in Hamilton Pond). **For example**, if the Wire and Nail Pond dam would fail, approximately 70 kg of PCB stored could be released which is greater than the PCB transport estimated from Cedar Creek in the next 25 years (Baird & Associates 1997).

Even ~~if~~ **though** Wilshire Pond currently contributes only ~~to~~ a small fraction of the total PCB inputs to Cedar Creek, implementation actions must be pursued at this site, along ~~to~~ **with** the contributing sources of PCBs to Wilshire Pond including the Amcast property and the Quarry Pond.

~~Specific remdiation~~ **Remedial** actions **completed** at Cedar Creek, ~~the contaminated sites along the stream including Wilshire Pond reflecting the goal of this TMDL~~ will likely result in the removal of the fish consumption advisory for Cedar Creek **at some time in the future.**

<u>Additional Superfund comments:</u>

First, the description of the coverage of the TMDL listed on page two indicates that the TMDL deals with Cedar Creek and a 10 mile segment of the Milwaukee River (Segment 2). There is little discussion of the Milwaukee River sediments and their PCB concentrations included in the rest of the text. The TMDL should either be revised to reflect that this is a TMDL for Cedar Creek or the State should include data and discussion for Segment 2 of the Milwaukee River.

Second, on page 7, a target of 0.21 mg/kg is set out without any background information or justification. There needs to be some narrative text and supporting background reports to substantiate the 0.21 mg/kg target level. If this number is just taken from State fish advisories, then the background studies that developed those fish advisory numbers need to be summarized and presented. Without further information, it is impossible to tell what risk level the 0.21 mg/kg target is designed to address. As part of this report and for the supporting record, all the underlying reports on how the 0.21 mg/kg number was set and chosen should be included in an appendix..

MERCURY
Mercury Marine

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July 7, 2008

Ms. Valerie Villeneuve
Wisconsin Department of Natural Resources
Bureau of Watershed Management
101 South Webster Street (WT/2)
P.O. Box 7921
Madison, WI 53707-7921

Re: Comments on Proposed Total Daily Maximum Load Determination for Cedar Creek

Dear Ms. Villeneuve:

Mercury Marine is submitting these comments in response to the Wisconsin Department of Natural Resources ("DNR" or "Department") proposed "total maximum daily load" ("TMDL") determination for Cedar Creek. Mercury Marine understands the concerns of DNR when it comes to issues associated with PCB contamination. However, Mercury Marine, as the company currently moving forward with the investigation and cleanup of the Creek, also understands and directly deals with the complexity of addressing contaminated sediment. Based on our experience and our review of the TMDL approach, our "bottom-line" conclusion is that the proposed TMDL is not the proper mechanism for addressing the PCB issues associated with the Creek. The TMDL process is ill-suited to Cedar Creek, as it was never intended to be used to address contaminated sediment issues. As demonstrated at the June 5, 2008 public meeting, moving forward with a TMDL at the same time as a Superfund cleanup process is underway only creates unnecessary confusion with the public. Consistent with DNR policy as set forth in Department publications and practice – *see* Fox River TMDL – the PCB sediment issues should be addressed through the on-going EPA Superfund process and not through a TMDL. Thus, the proposed TMDL is unnecessary and should be withdrawn.

In addition to these important policy considerations, the proposed TMDL is legally deficient, does not satisfy the administrative procedure requirements of Chapter 227, Wis. Admin. Code, and is inconsistent with the stated policy of the Department. Further, as discussed below in more detail, the technical approach is deficient as it relies on generic information and unfounded assumptions as opposed to the wealth of site-specific data collected on Cedar Creek in accordance with the strict EPA data-quality requirements. Why the Department would elect to ignore the site-specific Cedar Creek data is nowhere explained in the proposed TMDL and is a major technical deficiency.

LEGAL/PROCEDURAL COMMENTS

1. With respect to the proposed TMDL, addressing contaminated PCB sediment through a TMDL is contrary to the Department's policy position and contrary to the manner in which TMDLs are applied in other settings, such as the Fox River. As stated on the Department's own website:

> Waters impaired by contaminated sediment and atmospheric deposition of mercury do not fit EPA's general description of TMDLs. This type of impaired water will be managed by EPA's Superfund program or through the Department's Watershed Management program or Remediation and Redevelopment program.

The contaminated sediments in Cedar Creek <u>are</u> being addressed under the U.S. EPA Superfund program. No reason or rationale is provided in the proposed TMDL or at the public meeting for deviating from the Department's stated policy.

The Department's policy is also incorporated into the TMDL being developed for the Fox River. TMDL Fact Sheet – Fox River, August 16, 2007 ("Fox River Fact Sheet"). In the Fox River TMDL, the Department specifically defers the PCB sediment issues to the U.S. EPA Superfund process by stating the TMDL only addresses "excess phosphates and sediment loading from landscape. . . ." *See* Fox River Fact Sheet, page 2. In terms of applying Department policy, there is no factual distinction between Cedar Creek and the Fox River – both have impairments due to PCB contaminated sediments and both are being addressed through the U.S. EPA Superfund process. Yet, the Fox River TMDL process follows the Department's stated policy while Cedar Creek does not. No reason exists for treating Cedar Creek in an inconsistent manner and no rationale is provided for deviating from Department policy as is required by Chapter 227, Wis. Stats.

In addition, a review of U.S. EPA Region 5 approved TMDLs reveals no precedent supporting the Cedar Creek approach. TMDLs are to be prepared to address point source discharges and non-point runoff. TMDLs are not to be used to address legacy issues such as contaminated sediment. Moreover, in this instance, developing a TMDL serves no practical value. The industrial use of PCBs is banned, and its use ceased decades ago. As stated in the proposed TMDL, all significant point source inputs to Cedar Creek were identified and controlled (*e.g.* elimination of discharges from industrial facilities). As such, no significant external PCB loadings to Cedar Creek are currently occurring, and thus, there is no need to specify an additional "load" (*i.e.* TMDL) that may be allowed to enter the system. Rather, and as stated in the TMDL, the primary "source" of PCBs in the system is sediment-associated PCBs that are already in the system. Both the external (former industrial facilities) and internal (sediments) PCB sources are being addressed under the U.S. EPA Superfund program.

2. The TMDL, if finalized, constitutes a decision under Chapter 227, Wis. Stats., subject to the appeal rights afforded aggrieved parties. No mention is made in the TMDL of the appeal rights. These appeal rights should be included so that all parties understand the process to be used to challenge the final TMDL.

3. If the Department proceeds with the proposed TMDL, we agree that the TMDL has no bearing on the U.S. EPA cleanup process. Moreover, legally the TMDL is not an applicable, relevant or appropriate requirement ("ARAR") under federal law, since it has not gone through the required Chapter 227, Wis. Stats., rulemaking process, and as demonstrated above, the TMDL policy most certainly is not applied in a consistent manner in the state (although it should be). Since the Department has no sediment cleanup rules, the proposed TMDL is not and cannot, without proper notice and rulemaking pursuant to Ch. 227, Wis. Stats., be a substitute for such rules especially given the Department's decision since 1992 (when the Natural Resources Board removed sediment from the scope of the NR 700 rules and directed independent rulemaking for sediments) to not develop and promulgate a sediment cleanup process and standard.

TECHNICAL COMMENTS

4. The proposed TMDL does not account for the movement of fish and wildlife populations in the area and assumes that these populations stay in Cedar Creek and accumulate their PCB body burden from exclusively within this area. This assumption is flawed, as the fish and wildlife populations (*e.g.* waterfowl, other birds, mammals) of this area can and do move between the Cedar Creek and other areas where they may be exposed to other PCB sources. With specific regard to the migratory fish species such as rainbow trout, Chinook salmon and Coho salmon cited in the proposed TMDL as occurring in this segment of the river system, data from DNR studies (Eggold et al., 1996) at other PCB sites demonstrate that such species accumulate the vast majority of their adult PCB body burden during their residence time in Lake Michigan and that "the river accumulation of PCBs contributes minimally to the overall PCB body burden present in adult fish." The proposed TMDL fails to account for the Department's own scientific conclusions and fails to acknowledge that the proposed TMDL will have no significant effect on PCB levels in these fish.

5. The linkage analysis, which is essential to development of a TMDL, is flawed and technically unsupported:

- The linkage analysis is defined as the cause and effect relationship between the target value and the pollutant sources (Proposed TMDL, at 10). For this proposed TMDL, the critical linkage analysis is based on the following: "[w]e assume that a reduction of PCB content in Cedar Creek's bottom sediments to a given threshold value . . . will result in a reduction in the fish tissue PCB levels" (emphasis added). This assumption is the primary technical justification for the proposed TMDL and cites no supporting technical information or site-specific data when, in fact, substantial available data exists that shows this assumption to be incorrect. Specifically, the draft Remedial Investigation Report (BBL 2005) cited in the proposed TMDL contains data showing that PCB levels in certain creek fish species are not closely related to sediment PCB levels. For whatever reason, the Department elected to disregard this critical site-specific information and instead sought to justify the proposed TMDL through an assumption.

- The proposed TMDL (pages 6-7) states that 0.21 mg/kg PCB in fish tissue is the basis for the TMDL. Then, on page 11 this value is simply discarded in favor of 0.14 mg/kg. No site-specific technical justification is provided. Without site-specific information, the Department could arbitrarily select any number less than 0.21 mg/kg on the basis that it "is more protective." A critical TMDL endpoint such as this should not be based on mere assumption but must be supported by site-specific technical data.

- The proposed fish tissue PCB goal of 0.14 mg/kg was developed for the Fox River using chemical, ecological, and exposure information specific to the Fox River. No similar site-specific effort was made for Cedar Creek. (If the Fox River is to be used to justify a TMDL value, then the Fox River TMDL precedent should be used and the Cedar Creek TMDL process should stop.) As described in the Fox River risk assessment (RETEC, 2002) and cited in the proposed TMDL, 0.14 mg/kg was the lowest value of many calculated in the Fox River Risk Assessment and was based on a "high-intake fish consumer eating carp." The exposure assumptions used to develop the 0.14 mg/kg value for the Fox River are based on survey data for three highly-exposed subpopulations (low-income minority, Native American and Hmong) that are specific to the Fox River and not present at Cedar Creek. As stated in the Cedar Creek Remedial Investigation Report, carp are not targeted by anglers in Cedar Creek, and there is no documentation of high-intake (subsistence) fishers on Cedar Creek. To date, no data or studies exist in the record supporting the proposed TMDL showing that the Department conducted any studies of fishing habits by subpopulations along Cedar Creek. Without such data, it is arbitrary and capricious to simply import a site-specific value from the Fox River based on site-specific Fox River survey data to Cedar Creek and merely "assume" the value to be scientifically correct.

- The model relating the target fish PCB concentration to a target sediment PCB concentration ("the Fox River bioaccumulation model") was developed for a completely different site and assuming it applies to Cedar Creek without any studies or verification is scientifically unsound. As stated in the Fox River model documentation (ThermoRetec, 2001), the Fox River model was specifically designed to "accurately depict food web dynamics in the Lower Fox River and Green Bay." The documentation adds that the modeling work involved "a comprehensive review of the

Lower Fox River and Green Bay food webs: prey species, percent composition of diets of various predator species, and lipid contents and weights of the prey and predators of the system." Such key model information is obviously highly site-specific and unique to the Fox River, and has no bearing or applicability to Cedar Creek. Furthermore, the Fox River model states that "calibration of the FRFood Model was conducted using site-specific [*i.e.* Fox River] total PCB data for sediment and water as well as site-specific dietary relationships and lipids." (ThermoRetec, 2001). Nothing exists in the record for this proposed Cedar Creek TMDL to show that (i) DNR developed an independent site-specific model for Cedar Creek or (ii) the site-specific complex model developed for the Fox River (which uses key information that only applies to the Fox River) automatically can be applied to Cedar Creek. The only basis cited by DNR for importing site-specific Fox River modeling into the proposed Cedar Creek TMDL was an assumption that it could be used because both sites involved PCBs. The derivation of a target sediment PCB concentration is the linchpin of the proposed Cedar Creek TMDL. That linchpin cannot be based only on an "assumption" that the Fox River information is applicable to Cedar Creek, without any site-specific model or factual data to support the conclusion. Relying on an assumption for such a key conclusion is arbitrary and capricious. As such, the proposed TMDL is legally deficient and should not proceed until all necessary work, such as technically valid modeling using Cedar Creek site-specific data, is performed, appropriately peer reviewed and tested.

- Using a target sediment PCB concentration as the "endpoint" or target for the TMDL process is inappropriate. Calculation of a target sediment concentration is highly site-specific and subject to considerable uncertainty. As noted above, the relationship between sediment and fish tissue PCB concentrations depends on many site-specific factors, including physical and chemical properties of the PCB mixture and the receiving water body, partitioning between various compartments of the ecosystem (*i.e.* sediments, water, biota), food web structure and rates/amounts of PCB transfer between various components of the food web. None of these components were addressed in the proposed TMDL, and no quantitative food-web modeling effort was performed for Cedar Creek.

- The Fox River fish and sediment target values were developed using data for a PCB mixture that significantly differs in terms of its physical, chemical, and toxicological properties from the PCB mixture present at Cedar Creek. This difference in PCB type directly affects the fish uptake and linkage analysis. The two industrial facilities along Cedar Creek used PCBs specifically designed to satisfy fire safety standards for hydraulic fluids used at die cast plants. The PCBs in the Fox River were from the manufacturing and recycling of carbonless copy paper (RETEC, 2002). This difference in PCB type is a key factual distinction ignored in the proposed TMDL. Again, merely assuming site-specific work done on the Fox River for one type of PCB can be imported wholesale into the Cedar Creek situation is technically unsound.

- Assuming a TMDL is legal and/or technically supportable for the Cedar Creek situation (which it currently is not), the appropriate target endpoint is fish tissue concentration based on human exposure and risk, not an "assumed" back-calculated sediment concentration. A fish tissue target is closely associated with the Clean Water Act ("CWA") goal of protecting public health as it directly addresses the primary route of human exposure to PCBs, *i.e.* fish consumption. A fish tissue target for the proposed TMDL is also consistent with the manner in which fish advisories are issued. Finally, the fish tissue target matches recent USEPA approaches for developing water quality criteria for bioaccumulative substances under the CWA (*e.*g. U.S. EPA, 2001). Using this approach, the ultimate goal of the TMDL (assuming it even applies to contaminated sediments) would be to reduce fish PCB levels to a target level that would reflect an acceptable risk to fish consumers and would allow a reduction of the current fish consumption advisory.

6. The proposed TMDL fails to acknowledge that the sediment PCB target level of 0.11 mg/kg is technically infeasible and cannot be achieved even under optimal conditions. More specifically, Ruck Pond is cited as an example of a cleanup that was according to the Department an "unqualified success." (WDNR, 2001). However, the very expensive remediation of Ruck Pond only was able to achieve an overall post-remediation sediment value of 7.11 mg/kg. The Creek was temporarily diverted around Ruck Pond to allow work to be performed "in the dry". All sediments were removed from the Pond, down to bedrock, to the extent practicable using conventional earth-moving equipment. Brushes, brooms, and squeegees were used to extensively clean the bedrock surface. Post-remediation sediment sampling in Ruck Pond (before the mat was placed (see below)) showed PCB concentrations ranged from 8.3 to 280 mg/kg (*i.e.*, all greater than the proposed Sediment Concentration Threshold [SCT] of 0.11 mg/kg) in the seven samples collected from the minimal amount of sediment that remained. In accordance with DNR's approval, earthen construction materials initially used as roadbed materials were spread in an approximate six-inch thick mat across the pond bottom in places where the highest post-remediation PCB concentrations were noted in order to cap the area. The fact that the concentration proposed by DNR as the SCT (0.11 mg/kg) could not be met under optimal conditions on a project that DNR touts as an unqualified success raises serious questions regarding the validity of the target value. The proposed TMDL fails to account for the Ruck Pond experience even though DNR has this Cedar Creek site-specific data readily available to it.

The proposed TMDL should highlight the successes already achieved at the Cedar Creek site. Information presented in the TMDL document (Appendix B) shows marked decreases in Cedar Creek fish PCB levels over time for all species for which sufficient data are available to support a comparison. For example, PCB levels in largemouth bass decreased from 2.093 mg/kg (1990-1999) to 0.698 mg/kg (2000-2004); PCB levels in northern pike decreased from 12.783 mg/kg (1977-1989) to 2.616 mg/kg (1990-1999) to 0.538 mg/kg (2000-2004), and

PCB levels in rock bass decreased from 2.903 mg/kg (1977-1989) to 1.273 mg/kg (1990-1999) to 0.710 mg/kg (2000-2004).

The proposed TMDL improperly proposes remedial action which is outside the scope of the TMDL. Rather, remedial decisions are made by U.S. EPA in the Superfund process. More specifically, the statement that "if Columbia Pond and Wire and Nail Pond are remediated [as opposed to just Columbia Pond], significant benefits could be expected" (page 16) is conjecture and not supported by any data or other technical information. In fact, information presented in the TMDL report (Figure 2) shows no significant differences in effect on PCB transport between remediating only Columbia Pond and remediating both Columbia and Wire and Nail Ponds.

TECHNICAL REFERENCES SUPPORTING TECHNICAL COMMENTS

Eggold, B.T., Amrhein, J.F. and M.A. Coshun (1996), *PCB Accumulation by Salmonine Smolts and Adults in Lake Michigan and its Tributaries and its Effect on Stocking Policies*, Journal of Great Lakes Research 22(2):403-413.

RETEC, *Final Baseline Human Health and Ecological Risk Assessment. Lower Fox River and Green Bay, Wisconsin*, December 2002.

ThermoRetec, *Fox River Food (FRFood) Model Documentation Memorandum. Lower Fox River and Green Bay Wisconsin. Remedial Investigation and Feasibility Study*, July 13, 2001.

U.S. Environmental Protection Agency, *Water Quality Criterion for the Protection of Human Health: Methylmercury. Office of Science and Technology*, Office of Water, U.S. EPA, Washington, DC, EPA-823-R-01-001, January 2001.

Wisconsin Department of Natural Resources, *The State of the Milwaukee River Basin*, PUBL WT 704, 2001.

CONCLUSION

We appreciate the opportunity to submit these comments. For legal, policy and technical reasons, the proposed TMDL should be withdrawn. Key pieces of the proposed TMDL lack site-specific factual underpinning and until such site-specific work is completed the TMDL is premature. The above conclusion is reinforced by the Department's policy of not developing TMDL for contaminated sediment issues. No reason is presented to justify deviating from Department policy. Consistent with that policy the proposed TMDL should be withdrawn.

Very truly yours,

Director, Environmental Compliance
Mercury Marine, Div. of Brunswick Corp.

Comments received from Friends of the Milwaukee's Rivers on July 7, 2008

July 7, 2008

Valerie Villeneuve
WDNR Water Resources Management Specialist
Wisconsin DNR WT/2
P.O. Box 7921
Madison, WI 53707

Re: FMR Comments on Cedar Creek and Milwaukee River (Grafton-Thiensville Segment) PCB TMDL

Dear Valerie,

On behalf of Friends of Milwaukee's Rivers (FMR), we are submitting the following comments on the proposed TMDL for Cedar Creek and the Milwaukee River (North of Thiensville to Grafton), which addresses PCB contamination largely from Mercury Marine and Amcast Industrial. It is our understanding that this TMDL addresses in-stream sediment PCB contamination, external sources of PCBs, and fish tissue PCB contamination. It identifies the maximum allowable load of PCBs that will result in reducing fish tissue concentrations of PCBs and is designed to clean-up the river to an extent that it meets water quality standards. The report also includes proposed actions for reaching the goals for removing PCBs and associated monitoring efforts. We also understand that this TMDL, if approved by EPA, has ramifications on target levels for contaminated sediment clean-up of the associated Cedar Creek Superfund site involving the same responsible parties, even though the TMDL and Superfund boundaries don't perfectly overlap. That said FMR is in support of extending the Superfund boundaries to reach down to the Thiensville impoundment of the Milwaukee River, and to overlap with this proposed TMDL.

Comment: The proposed Sediment Concentration Threshold for PCBs is not protective enough of Cedar Creek and the Thiensville-Grafton segment of the Milwaukee River.

Based on *preliminary* research that FMR has done of other PCB TMDLs throughout North America, we feel that the proposed Cedar Creek sediment concentration threshold (SCT) for PCBs of 0.11 mg/kg (or ppm) is too high--or in other words, not protective enough of Cedar Creek, the wildlife that inhabit it, and the human populations that live adjacent to the Creek or eat the fish from Cedar Creek. While we realize that Cedar Creek currently is 1 of 3 waterbodies in the State with a "do not eat fish at any time" advisory, we have been contacted in the past from out of state fishermen and downstream fishermen that were not aware of this advisory, and have eaten fish likely contaminated with PCBs from Cedar Creek and the downstream portion of the Milwaukee River. Regardless of the advisory, people are eating these fish, and we feel that the proposed level of PCBs in Cedar Creek fish of 0.21 mg/kg (that the SCT was based on), is likewise too high and not protective enough of fish or human populations.

Ideally, the proposed Sediment Concentration Threshold for PCBs in Cedar Creek should be 0 mg/kg, especially since this contamination has a known source and identified responsible parties. While we understand that reaching a zero discharge level *may* not be possible for large areas of contamination such as the Fox River, we feel that a 0 mg/kg limit is an achievable target on Cedar Creek. Although, that said, our research has shown that other areas of the country have much lower SCTs. The sediment objective for San Francisco Bay's PCB TMDL was 1 µg/kg or 0.001 mg/kg, which is several orders of magnitude below the proposed Cedar Creed SCT of 0.11 mg/kg. Likewise, in Ontario, SCT levels are established at 0.01 mg/kg for "no effect" on wildlife and 0.07 mg/kg or ppm for "low effect"—higher SCTs are considered to have higher impacts on water quality and wildlife (see http://www.ene.gov.on.ca/envision/gp/B1-3.pdf).

Comment: The proposed Fish Tissue Targets for PCBs for Cedar Creek and the Thiensville-Grafton segment of the Milwaukee River are not protective enough. Better Assumptions are needed for establishing fish tissue targets for PCBs for the proposed TMDL.

We feel that the proposed fish tissue target for PCBs in Cedar Creek fish of 0.21 mg/kg (that the SCT was based on), is likewise too high and not protective enough of fish or human populations. It is also much higher than the standard used in other areas of North America. The San Francisco Bay TMDL was backed out from a fish tissue target of 10 µg/kg wet weight for specific, regularly consumed fish (shiner surfperch and white croaker) or 0.01 mg/kg. This target is also vastly more protective than the proposed target for Cedar Creek of 0.21 mg/kg. The fish tissue target in San Francisco was based on increased cancer risk level of 1 in 100,000 assuming a mean body weight of 70 kg per person and a fish consumption rate of 0.032 kg/day (which was based on actual Bay fish consumption data). Likewise, Georgia has a fish tissue target for PCBs of 0 .1 mg/kg, which is about half of the proposed fish tissue target for Cedar Creek and closer to the Fox River fish tissue goal of 0.14 mg/kg. Furthermore, the PCB Sediment Quality Guideline for Wisconsin is 0.06 mg/kg (although this guideline addresses benthic organisms and not fish). Given this, we feel that the proposed fish tissue target for Cedar Creek should be much lower than that proposed, and are confused that the DNR would use the proposed Fox River SCT and not their proposed fish tissue target. Why can Cedar Creek fish be more contaminated with PCBs than Fox River fish?

Although, FMR realizes that there is probably little to no fish consumption data for Cedar Creek largely because the public has been discouraged from eating any fish at all due to the PCB contamination, we still feel that the approach for determining the target was very lax. We understand that the 0.21 mg/kg standard was based on as estimated "1 meal per month" fish consumption advice for PCBs that has been used by Wisconsin to issue fish consumption advisories in the past according to the "Protocol for a Uniform Great Lakes Sport Fish Consumption Advisory" (Anderson *et al.* 1993); however, we feel that this standard is out of date and should be readdressed. FMR strongly encourages DNR to ensure that the assumptions used in the fish tissue target for Cedar Creek are based on current science and factor in actual fish consumption values for our area if possible and levels of risk. This has been established in other parts of the country of ensuring an decreased risk of 1 in 100,000 or 1 in 1,000,000 for eating contaminated fish—or another standard that DNR can show protects the most vulnerable populations in our area that eat fish in Cedar Creek and the downstream Milwaukee River for subsistence (much more frequently than one meal per month). Cedar Creek and Milwaukee River fish from the Thiensville-Grafton area are travelling to downstream portions of our watershed, where people eat fish much more frequently than one meal per month in many cases. The proposed fish tissue targets seem vastly higher than those being used in other areas of the country, do not seem based on current scientific literature (other than a 1993 protocol), and should likewise be reduced significantly.

Comment: FMR is concerned about extrapolating Fox River PCB data and models for Cedar Creek and the Grafton-Thiensville portion of the Milwaukee River

We understand that the WDNR used the models developed for the Fox River clean-up area to estimate the risks posed by these TMDL targets for PCBs, and that the agency does not have funds to do a Cedar Creek specific model. The 0.11 mg/kg SCT was based on the work that has been done determining the Fox River threshold and the Fox SCT was designed to meet a fish tissue target of 0.14 mg/kg, which is more protective than the proposed Cedar Creek fish target. Thus, we understand that the WDNR feels that due to a certain margin of safety allowed under the TMDL process that using the Fox River model data is justified, and will meet the proposed fish tissue target of 0.21 mg/kg, which is significantly higher (as mentioned above) than the fish tissue standard for the Fox River.

We can not think of any other justification for this decrease in the fish tissue target for PCB removal other than an economic one? We are still unclear how the 0.21 target was chosen, instead of the more protective 0.14 from the Fox River (which many scientists think is also not protective enough of human health). Given that Cedar Creek is a vastly smaller watershed than the Fox River, we don't feel that using the Fox River model to estimate risk in this system is even appropriate. The cost requirements of removing PCBs in the Fox River system as opposed to the Cedar Creek system are vastly increased—as the area affected is much larger and PCBs more dilute. We acknowledge that Mercury Marine has already spent over $8 Million dollars cleaning up the Ruck Pond, and that they are largely bearing the cost of the clean-up at this point, since Amcast Industrial has declared bankruptcy. However, since a TMDL is supposed to be driven by science and not economics, we don't feel that the economic argument should be weighed in here, if that indeed is coloring this analysis. Furthermore, 90% of the contaminated sediments are presently upstream of the Amcast discharge point—most being contained in the Columbia and Wire& Nail Ponds. We do acknowledge that cost is a factor and understand that cost will be considered as part of the Superfund remedial investigation and feasibility process. However, we would encourage WDNR to enact a stricter SCT and fish tissue target for this proposed TMDL, and to develop a model specific for Cedar Creek if there is enough data to do so. This is not recommended in an effort to delay this TMDL process, but to ensure that the eventual clean-up targets are adequate to protect water quality, wildlife, and human populations.

Comment: The proposed TMDL document does not adequately address potential PCB sources from Publicly Owned Treatment Works (POTWs).

The TMDL document notes that the Cedarburg Wastewater Treatment Facility is the only point source located within the impaired section of Cedar Creek, and they don't currently discharge PCBs into the Creek. The footnote mentions that the POTW does not discharge "detectable" limits of PCBs in their effluent, and thus are in compliance and do not have PCBs. It also notes that PCBs were not detected in the most recent effluent samples in December 2007. Likewise, the report notes that the Village of Jackson POTW had no PCBs detected in the biosolids and thus is not expected to generate PCBs.

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Although POTWs are not original sources of PCBs, they do act as conduits for PCBs that have been inadvertently or deliberately introduced into sewer systems over the years. Not knowing what method is required for PCB testing at these plants, it is impossible for us to know whether or not past monitoring has been sufficient to adequately determine the sources of PCBs from these plants. Based on research in other areas of the country, it has been found that often POTWS are getting "non-detects" because they are only using a 0.5 ug/L detection limit, and thus there isn't enough data to accurately estimate loading.

Thus we would recommend that (if not already doing so) POTWs use Method 1668A to measure PCB concentrations in their effluent. Although this test is expensive, it can achieve a pg/L detection limit as opposed to a 0.5 ug/L detection limit, and thus further verify that these plants are not a definitive source of PCBs. There is a clear relationship between treatment and PCBs concentrations, and these POTWs could still be a significant source of loading based on the industrial history of the area. The Delaware River PCB loading study (Available at http://www.state.nj.us/drbc/regs/pcb-new.pdf.) has compelling information in it that demonstrates that fish contamination in their area is not only due to "historic" sediment contamination, but is actively entering the waterways from treatment plants on a fairly regular basis. Given the small number of facilities discharging to Cedar Creek (and the fact that there are separate sewers and not combined sewers) this would seem to be a worthwhile and not overly expensive precaution. Likewise, we'd encourage that similar monitoring of other potential sources such as the Quarry pond, Wilshire stormwater basin, and nearby storm sewers be analyzed using the same test to ensure that they are not actively contributing PCBs to the rivers during dry or wet weather. It is unclear whether or not this analysis has been done.

Comment: WDNR should provide more meaningful opportunities fore public comment on proposed TMDLs

It is our understanding that a large part of any TMDL process is eliciting public opinion on proposed clean-up standards and getting community support behind a plan for cleaning up our waterways. FMR was very disappointed by the lack of meaningful public participation in the proposed Cedar Creek TMDL.

While FMR has been largely keeping updated of the process, it is clear that most of the attendees at the public hearing on June 5, 2008 at the Cedarburg Police Department have not been. FMR knew very little about this TMDL process until we were invited to the public meeting. We were also very heartened and affected by public comments from adjacent residents that have been largely unable to conduct erosion control efforts, streambank stabilization, to plant gardens, or even conduct routine maintenance on parts of their riparian properties due to the current PCB contamination in the creek and adjacent floodplains. While we understand that the DNR is not in charge of the Superfund efforts, DNR does have significant oversight and is leading the process to get this Creek clean. We feel, in retrospect, that there should have been much more than a single public hearing to elicit feedback from these owners as well as other stakeholders in this TMDL process. It is clear that many attendees were very frustrated. The information is so technical, that it took most of the meeting for participants to try to understand the process let alone provide meaningful comment. It is also our understanding from conversing with colleagues throughout the country that most TMDL efforts involve creation of technical advisory committees and much more collaboration with the local communities and stakeholders.

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Furthermore, there was a noticeable absence of residents from the Grafton and Thiensville areas, which are downstream of Cedar Creek and also affected by this TMDL.

We likewise encourage DNR and EPA to look at innovative ways of cleaning up this PCB problem and implementing this TMDL (and subsequent Superfund efforts) so that residents don't have to wait several more decades before they can safely and fully use their properties.

Comment: FMR requests that the proposed TMDL consider recreational exposure to PCBs and risk to human health and safety posed by proposed PCB levels.

It was our understanding, as explained at the public meeting, that the WDNR did not consider recreational effects of the proposed TMDL because the State of Wisconsin doesn't currently have water quality standards for recreation (or at least for PCBs—there are standards for bacteria). This is of little consolation to the fishermen, paddlers, and residents that are using Cedar Creek and the downstream portion of the Milwaukee River for aquatic recreation. Indeed, the Thiensville Dam impoundment is often used for swimming, waterskiing, boating, and other recreational activities, as is the entire proposed Milwaukee River segment. I would argue that most people in the immediate areas of Cedarburg, Grafton, Thiensville, and Mequon have a much greater chance of coming into contact with PCBs through recreational exposure than from eating contaminated fish (downstream Milwaukee populations more likely affected by fish contamination). Thus, we would encourage DNR and EPA to consider recreational exposures in this TMDL analysis to ensure that proposed clean-up levels and loading levels are protective of human health and safety.

Thank you for consideration of these comments. Please feel free to call with any questions or comments at (414) 287-0207 ext. 29.

Sincerely,

Cheryl Nenn

Milwaukee Riverkeeper

CC: Lynn Broaddus, FMR
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