

**Basis and Background Document**

**Revised Human Health Water Quality  
Criteria for Total PCBs  
for the Protection of Human Health  
from Carcinogenic Effects**



**Delaware River Basin Commission  
West Trenton, New Jersey**

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## **Acknowledgments**

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Significant technical contributions were also made members of the Toxics Criteria Subcommittee of the Commission's Toxics Advisory Committee. Members of the subcommittee included the authors; Dr. Ronald MacGillivray of the Modeling, Monitoring and Assessment Branch; J. Bart Ruiter, DuPont Engineering Research and Technology; Dr. Steven Washburn, Environ Corp.; Lawrence Sandeen, Rohm & Haas Company; Steven Lubow, New Jersey Department of Environmental Protection; Denise Hakowski, U.S. EPA Region III; Wayne Jackson, U.S. EPA Region II; Dr. Roland Hemmett, U.S. EPA Region II; Timothy Kubiak, U.S. Fish and Wildlife Service; Bonita Moore, Pennsylvania Department of Environmental Protection; Carol Young, Pennsylvania Department of Environmental Protection; Dr. Steven Brown, Rohm & Haas Company; and Dr. Robert A. Hoke, Dupont Company.

The Toxics Advisory Committee made the final recommendations to the Commission regarding this water quality criterion. The current membership of the Committee can be found at [http://www.state.nj.us/drbc/toxics\\_list.htm](http://www.state.nj.us/drbc/toxics_list.htm).

## EXECUTIVE SUMMARY

Identification of the governing water quality criteria is an essential step in the TMDL process. For the Delaware Estuary, available water quality criteria for PCBs include human health criteria for carcinogenic and systemic effects, and both freshwater and marine acute and chronic aquatic life criteria. The current DRBC water quality criteria for PCBs in the Delaware Estuary were established in 1996. They pre-date the collection of site-specific bioaccumulation data for the Delaware Estuary and Bay and site-specific fish-consumption data for Zones 2 through 4 that are relevant to the development of human health water quality criteria. They are also inconsistent with current U.S. Environmental Protection Agency (EPA) guidance for the development of such criteria, and they vary by water quality zone. One consequence is that in order to ensure that the water quality criterion of 7.9 picograms per liter in the downstream portion of Zone 5 can be achieved, the allowable PCB loading to Zones 2 and 3, where the current criterion is 44.4 picograms per liter, must be even lower than would be required if the proposed uniform criterion were in place.

Several factors are causing regulatory agencies to update their current human health water quality criteria for PCBs. These factors include: 1) the change in the cancer potency factor for total PCBs reported in EPA's Integrated Risk Information System (IRIS), and 2) the issuance of a revised methodology for deriving ambient water quality criteria for the protection of human health (EPA-822-B-00-004) in the fall of 2000. The latter methodology also includes several new recommendations on the fish consumption rate to be used in criteria development, and the use of a bioaccumulation factor (BAF) rather than a bioconcentration factor (BCF).

A subcommittee of the Delaware River Basin Commission's Toxic Advisory Committee was tasked with developing revised human health criteria for five zones of the Delaware Estuary. Existing criteria for the estuary are 44.4 pg/l for Zones 2 and 3, 44.8 pg/l for Zones 4 and the upper portion of Zone 5, and 7.9 pg/l for the lower portion of Zone 5. The higher criteria in Zones 2, 3, 4 and the upper portion of Zone 5 are due to both a drinking water and fish consumption exposure in Zones 2 and 3, and a fish consumption only exposure in Zone 4 and Zone 5. The lower criterion in Zone 5 is due to a higher fish consumption rate being used.

Values for five factors were needed to develop the revised criteria. Three of the factors used EPA-recommended default values. These three factors were 1) risk-specific dose (2.0 mg/kg-day at a risk level of  $10^{-6}$ ), 2) body weight (70 KG), and 3) drinking water intake (2 liters/day). Site-specific data were needed to develop appropriate values for the other two factors: fish consumption at each trophic level, and BAF at each trophic level. Site-specific data for fish consumption in Zone 5 and Delaware Bay indicated an average consumption rate for all species of 17.46 grams per day. This value is remarkably close to the national default value of 17.5 grams per day. A second study by Faulds et al, 2004 examined catch and consumption patterns in Zones 2, 3 and 4 of the tidal Delaware River by intercepting and interviewing shore anglers at six sites in urban areas in and around the City of Philadelphia. Consumption data from this study were converted to grams per day, the unit used in the criteria equation, and resulted in consumption rates of 17.9 grams per day for channel catfish and 21.7 grams per day for white perch assuming a meal size of 8 ounces. The consumption rate selected for use in the criteria equation was 17.5 grams per day. This value is

consistent with the national default value and the site-specific data for Zones 2 through 6.

Field studies were conducted to provide PCB congener data on fish tissue concentrations of PCBs in species representative of two trophic levels, channel catfish and white perch. Ambient water concentrations of PCB congeners and organic carbon were also determined using low level sampling and analytical techniques for use in calculating the BAF in the new methodology. Data on the percent lipid of consumed fish were also determined from routine monitoring conducted by state agencies and the Commission since 1990. Data on the proportion of each trophic level consumed was assumed to be 50% based upon data from all zones that indicated roughly equal proportions for the two trophic levels.

Use of these data with the new EPA methodology results in a single criterion value of 15.9 pg/L. A probabilistic approach was also used to assess the impact of the uncertainty of the values used in the methodology. This analysis indicated that the median criterion value was close to that obtained using the deterministic approach, and that the interquartile range (25<sup>th</sup> percentile to the 75<sup>th</sup> percentile) fell between 6.2 pg/L to 49.7 pg/L.

In July 2005, the Commission's Toxics Advisory Committee (TAC) that had guided the development of a new human health water quality criterion for PCBs for the Delaware Estuary and Bay voted to recommend that the Commission adopt a revised criterion of 16 picograms per liter for Zones 2 through 6. This revised criterion will provide a uniform TMDL target throughout the estuary and eliminate the current sharp transition in criteria within the estuary.

## INTRODUCTION

Identification of the governing water quality criteria is an essential step in the TMDL process. For hydrophobic contaminants like polychlorinated biphenyls or PCBs, the ambient water quality criteria for the protection of human health is on the order of nanograms per liter to picograms per liter due to the high bioaccumulation of these compounds in fish tissue. As a consequence many water bodies are listed as impaired for PCBs including the Delaware River Estuary, resulting in the requirement to develop TMDLs for the water bodies.

As a consequence of the requirement of the 1986 amendments to the Clean Water Act many states were required to adopt water quality criteria for toxic pollutants including PCBs. Water quality criteria developed by EPA in the early 1980s were typically used to establish the states' water quality standards. These criteria were established using a methodology that addressed impacts to aquatic life, and both the carcinogenic and systemic effects of a chemical or, in the case of PCBs, a class of chemical compounds on human health by exposure through ingestion of water and fish (U.S. EPA, 1980b). This methodology included the consideration of six parameters: risk level, cancer potency factor, body weight, drinking water consumption, fish consumption, and the bioconcentration (BCF) of the chemical from water to fish tissue. The risk level is essentially a policy decision of the governmental agency adopting the criteria under their water quality standards regulations. Values for each of the remaining parameters were issued by the U.S. EPA for a group of chemicals referred to as the priority pollutants. While values for the cancer potency factor and BCF were chemical-specific, specified values for body weight, drinking water intake, and fish consumption were used in the methodology for all chemicals. The specified values for these parameters were 70 kilograms, 2 liters per day, and 6.5 grams per day, respectively.

The human health criteria for protection from carcinogenic effects initially recommended by EPA was 79 picograms per liter. This value was derived using a cancer potency factor of 4.3396 (mg/KG)/day (U.S. EPA, 1980b). This factor was subsequently revised in January 1990 to 7.7 (mg/KG)/day. This revision resulted in a recommended criterion value of 44.4 picograms per liter. By the mid-1990's, human health criteria had been adopted for the Delaware River Estuary by Delaware, Pennsylvania, the Delaware River Basin Commission (DRBC) and the U.S. EPA. Criteria established by the DRBC varied between areas of the estuary due to changes in the designated use and the use of a different value for fish consumption in the lower portion of the estuary (DRBC, 1996). The criteria for the estuary are 44.4 pg/l for Zones 2 and 3, 44.8 pg/l for Zones 4 and the upper portion of Zone 5, and 7.9 pg/l for the lower portion of Zone 5. The lower criterion in Zone 5 is due to a higher fish consumption rate being used while only Zones 2 and 3 are designated as a drinking water source.

Several actions require the criteria originally adopted by the DRBC and most states to be revised. The first is the revision of the cancer slope factor from 7.7 (mg/KG)/day to a range of factors based upon the persistence of the chemical in the environment and the bioaccumulation potential (U.S. EPA, 1999). For hydrophobic chemicals with high bioaccumulation potential like PCBs, the upper bound of the slope factor was recommended by the U.S. EPA. For total PCBs, this slope factor was 2.0 (mg/KG)/day. In 2000, the U.S. Environmental Protection Agency issued revised guidance on

developing human health criteria (U.S. EPA, 2000). Two significant changes recommended in this guidance were the recommendations to use site-specific values for fish consumption for the water body covered by the criteria, and to use a bioaccumulation factor or BAF rather than a BCF. In lieu of site-specific values on the consumption of fish by recreational fisherman, the guidance also recommended a default value of 17.5 grams per day. In February 2001, the Delaware River Basin Commission's Toxic Advisory Committee charged a subcommittee to develop revised criteria for the protection of human health from carcinogenic effects of total PCBs for use in the TMDLs being developed by the Commission for the Delaware River Estuary.

## METHODOLOGY

The subcommittee recommended that the revised criteria be developed using the October 2000 guidance issued by the U.S. EPA. The equation recommended in the guidance is:

$$AWQC = RSD \left[ \frac{BW}{DI + \sum_{i=2}^4 (FI_i \bullet BAF_i)} \right]$$

where:

AWQC =	Ambient Water Quality Criterion (mg/l)
RSD =	Risk-specific dose for carcinogens based on a linear low-dose extrapolation (mg/KG-day) such as $10^{-6}$ . Can also be expressed as Risk Level/Cancer Potency Factor.
BW =	Body weight (KG)
DI =	Drinking water intake per day (default = 2 Liters)
FI <sub>i</sub> =	Fish intake at trophic level i (where i = 1, 2, 3, 4)
BAF <sub>i</sub> =	Bioaccumulation Factor at trophic level i

Each of the parameters used in the revised criteria methodology was evaluated by a subcommittee of the Delaware River Basin Commission's Toxic Advisory Committee. The evaluation approach involved the review of the rationale provided in the EPA guidance document for establishing national values for each of the parameters, and the evaluation of site-specific data for each of the parameters. The site-specific data available for evaluation included data on the consumption of fish by recreational fishermen in the lower estuary, Zones 5 and 6 (DNREC, 1994), and in the more urban portions of the estuary, Zones 2 through 4 (Faulds et al, 2004). DRBC also funded two studies to provide data for use in establishing bioaccumulation factors for PCBs. The first study involved measuring the concentration of PCBs in sediments and various trophic levels of the food chain of selected sport species in the Delaware River Estuary (Ashely et al, 2004). This study examined PCB

concentrations in invertebrates, small prey fish, channel catfish and white perch in the fall of 2001 and the spring of 2002 in four zones of the estuary (Zones 2 - 5) that were the focus of TMDL development. The second study involved the measurement of 124 PCB congeners in water samples collected at 15 locations in Zones 2 through 5 (DRBC, 2003). Data from fish tissue surveys conducted in the estuary were also examined to determine the percent lipid of the consumed portion of channel catfish and white perch caught in the estuary (Greene, 2002).

In order to assess the uncertainty in the parameters that are used in the criteria equation, a probabilistic analysis was conducted using @Risk software (Palisade Corporation, 2004). This analysis involves assigning distributions to selected equation parameters and some of their components. Table 1 indicates which of the parameters and their components were assigned a distribution or a fixed value. The distributions used for each parameter and component were determined from the source of the data or from statistical analysis of the data.

Table 1: Summary of Parameters and Data Used in Calculating Human Health Criteria for Carcinogens

Parameter	Policy	Fixed Value	Distribution Used
Risk Level of $10^{-6}$	X		
Body weight - 70 kilograms		X	
Drinking water intake per day - 2 liters per day		X	
Cancer potency factor			Uniform
Fish intake at each trophic level			
Total consumption rate			Triangular
Proportion of each trophic level species		X	
Bioaccumulation factor at each trophic level ( $BAF_i$ )			
Octanol-water partition coefficient ( $K_{ow}$ )			Discrete
Particulate organic carbon (POC)			Lognormal
Dissolved organic carbon (DOC)			Lognormal
% lipid of consumed portion			Lognormal
<b>Intermediate Parameters</b>			
Fraction of PCB freely-dissolved in water			Calculated
Baseline BAF for channel catfish			Gumbel
Baseline BAF for white perch			Gumbel

<b>Parameter</b>	<b>Policy</b>	<b>Fixed Value</b>	<b>Distribution Used</b>
Trophic level BAF for channel catfish			Calculated
Trophic level BAF for white perch			Calculated

The distributions were then sampled 10,000 times using the Latin Hypercube procedure and summarized in frequency distributions.

## **RESULTS**

The value(s) selected for each parameter in the revised criteria equation are discussed below:

### **Cancer potency factor**

The value selected for use is the upper bound factor for total PCBs published in the U.S. EPA's Integrated Risk Information System (U.S. EPA, 2004). This factor was first published in 1997 along with central estimate and upper bound factors for high risk and persistence, low risk and persistence, and lowest risk and persistence as a result of a reevaluation of the data on the carcinogenicity of PCB Aroclors. The upper bound slope factor is recommended for use where there is exposure through the food chain; dioxin-like, tumor-promoting, or persistent congeners are present; or early life exposure is expected. The subcommittee recommended the use of the upper bound estimate of 2.0 (mg/KG)/day.

### **Body weight**

The value selected for use is the average weight of male and female adults of 70 kilograms. This value is recommended by the U.S. EPA for establishing ambient water quality criteria (U.S. EPA, 2000). Although it is slightly lower than that reported in the latest National Health and Nutrition Examination Survey (NHANES III). The mean body weight of men and women ages 18 to 74 years observed in this survey was 75.6 kilograms. U.S. EPA recommends continued use of 70 kilograms for consistency since this value is used in the Integrated Risk Information System for deriving cancer slope factors and unit risks for drinking water.

### **Risk level**

The risk level used in establishing ambient water quality criteria is a risk management policy decision. It is defined as the number of cases of disease such as cancer in a population exposed to a chemical or chemicals. While the U.S. EPA believes that a risk level of either  $10^{-5}$  or  $10^{-6}$  may be acceptable as a *de minimus* risk for the general population, it uses a level of  $10^{-6}$  for criteria actions under Sections 304(a) and 303(c) of the Clean Water Act. The agency believes that this risk level reflects an appropriate risk for the general population, and is consistent with the policies and regulations of the agency as a whole (U.S. EPA, 2000). The recommendation of a range of risk



levels does provide flexibility to government entities in establishing water quality standards.

A risk level of 1 additional cancer case in 1 million exposed individuals or  $10^{-6}$  was selected for use in the equation. This risk level is used by the Commission, the states of Delaware and New Jersey, and the Commonwealth of Pennsylvania in establishing their water quality standards. In March 2003, the Commission adopted Resolution 2003-11 following discussion of the recommendations of the Commission's Toxics Advisory Committee on revised human health criteria and wildlife criteria for total PCBs. This resolution directed the Commission staff to solicit comment on the revised human health criteria for PCBs including the appropriate cancer risk level.

### **Drinking water intake rate**

A value of 2.0 liters/day was selected for this parameter. This value was used in the development of the 1980 national water quality criteria, and continues to be recommended by the U.S. EPA in the 2000 guidance (U.S. EPA, 2000). This recommendation was based upon a more recent survey of food intake by individuals conducted by the U.S. Department of Agriculture entitled "1994-96 Continuing Survey of Food Intake by Individuals" (U.S.D.A., 1998). This survey reported a mean and 90<sup>th</sup> percentile drinking water consumption for adults 20 years of age and older of 1.1 and 2.2 liters/day, respectively. The U.S. EPA believes that new studies continue to support the use of 2.0 liters/day as a reasonable and protective consumption rate for the general population (U.S. EPA, 2000).

### **Fish consumption rate**

In the 2000 guidance, the U.S. EPA recommends that a hierarchy of preference be used in the selection of a fish consumption rate for use in the criteria equation (U.S. EPA, 2000). This hierarchy is: 1) the use of local data on fish consumption patterns, 2) use of data reflecting similar geography or population groups for the water body of concern, 3) use of data from national surveys, and 4) use of the U.S. EPA default consumption rates. The default rate recommended by the U.S. EPA for both recreational fisherman and the general population is 17.5 grams per day. This rate is based upon the 1994-96 Continuing Survey of Food Intake by Individuals (U.S.D.A., 1998)

Two sources of data were available on the fish consumption patterns of recreational fisherman in the Delaware River Estuary. A study commissioned by the State of Delaware examined catch and consumption patterns in Zones 5 and 6, the lower portion of the tidal Delaware River and Delaware Bay (KCA, 1994). The study involved dockside intercepts and follow-up phone interviews of over 800 participants. The northern part of Zone 5 adjoins the urban area of Wilmington, and the surrounding suburban area of New Castle County in Delaware. The second study by Faulds et al, 2004 examined catch and consumption patterns in Zones 2, 3 and 4 of the tidal Delaware River by intercepting and interviewing shore anglers at six sites in Pennsylvania. These zones include the urban areas in and around the City of Philadelphia.

The average consumption of all species in Zones 5 and 6 was 17.46 grams per day, and the maximum fish consumption by any particular demographic group was 53.9 grams per day (KCA,

1994). Channel catfish and white perch were consumed at approximately equal rates. Faulds et al (2004) reported that channel catfish, striped bass and white perch were the most frequently consumed species in Zones 2 through 4. Ethnic groups reporting the highest consumption were Cambodian, Vietnamese and Afro-American. Faulds et al (2004) reported the number of meals of the species consumed by shore anglers. This data was converted to grams per day, the unit used in the criteria equation, and resulted in consumption rates of 17.9 grams per day for channel catfish and 21.7 grams per day for white perch assuming a meal size of 8 ounces.

The consumption rate selected for use in the criteria equation was 17.5 grams per day. This value is consistent with the national default value and the site-specific data for Zones 2 through 6. The consumption data reported by Faulds et al (2004) on urban fisherman in Zones 2 - 4 was not substantially higher than the rate observed in the lower estuary, and did not support the use of a different consumption rate for zones in the Philadelphia area, especially in light of the management benefits associated with a consistent, estuary-wide criterion.

### **Bioaccumulation factor**

Bioconcentration factors, or BCFs, represent the accumulation of chemical in an aquatic species due to uptake from the water only. In contrast, bioaccumulation factors, or BAFs, represent the accumulation due to all routes of exposure, including exposure through the water and through the consumption of contaminated prey and sediment. Use of a bioaccumulation factor rather than a bioconcentration factor was endorsed by the Commission's Toxics Advisory Committee at their meeting in February 2001 and directed by the Commission in Resolution 2000-13 in March 2003. The 2000 guidance calls for the use of a separate factor for each of the trophic levels represented in the species consumed in the water body for which the criteria will apply. In the case of the Delaware Estuary, two trophic levels were used. Trophic level 3 represents species whose diet consists of consumers of primary producers and detritus, principally invertebrates such as amphipods of the genus *Gammarus*. The species selected to represent this trophic level was the channel catfish. Trophic level 4 represents species whose diet includes more fish. The species selected to represent this trophic level was the white perch. The use of a single value for the BAF for these two trophic levels was unanimously endorsed by the Commission's Toxics Advisory Committee in February 2003.

The 2000 guidance recommends two possible procedures for deriving BAFs for nonionic organic chemicals (U.S. EPA, 2000). Procedure #1 is recommended for nonionic organic chemicals with  $\log K_{ow}$  values equal to or greater than 4.0 where metabolism is expected to be sufficiently low. PCB homologs have  $\log K_{ow}$  values that range from 4.69 for monochlorobiphenyls to 8.18 for decachlorobiphenyls. The guidance specifically mentions PCBs as a group of chemicals for which Procedure #1 is deemed appropriate. Procedure #1 contains four methods for calculating the BAFs. The first method uses field measurements to derive the BAFs. The 2000 guidance recommends this method over the other three methods which utilize predictive approaches for establishing BAFs (U.S. EPA, 2000).

The first step in using measured data to derive the BAFs is to calculate Baseline BAFs. Baseline

BAFs are defined as a BAF in units of Liters/kilogram-lipid that is based upon the concentration of freely dissolved chemical in the ambient water and the lipid-normalized concentration in the fish tissue (U.S. EPA, 2000). Baseline BAFs are calculated using the formula:

$$\text{Baseline } BAF_i^{fd} = \left[ \frac{\text{Measured } BAF_T^t}{f_{fd}} - 1 \right] \left[ \frac{1}{f_l} \right]$$

where:

- Baseline  $BAF_i^{fd}$  = BAF based upon the total concentration of the chemical in tissue and ambient water  
 Measured  $BAF_T^t$  = BAF based upon the total concentration of the chemical in tissue and ambient water  
 $f_l$  = The fraction of tissue that is lipid  
 $f_{fd}$  = The fraction of the total chemical that is freely-dissolved in water

Zone-specific data on PCB concentrations in fish tissue and ambient water were obtained from two studies: a bioaccumulation study conducted by the University of Maryland and the Academy of Natural Sciences in the fall of 2001 and spring of 2002 (Ashley et al, 2004), and ambient water measurements of PCBs conducted by the Delaware River Basin Commission in late 2001 and early 2002 (DRBC, 2003). Each of these studies measured a common set of 124 congeners which were summed to derive total PCB concentrations. The fraction of the total chemical that is freely-dissolved in water is determined using the octanol water partition coefficient, and the concentration of particulate organic carbon and dissolved organic carbon in the ambient waters determined in surveys conducted by DRBC in the fall 2001 and spring 2002. The formula is:

$$f_{fd} = \frac{1}{\left[ 1 + (POC \cdot K_{ow}) + (DOC \cdot 0.08 \cdot K_{ow}) \right]}$$

where:

- POC = Particulate organic carbon concentration in ambient water in Kilograms/liter  
 $K_{ow}$  = octanol water partition coefficient for the chemical  
 DOC = Dissolved organic carbon concentration in ambient water in Kilograms/liter  
 $f_{fd}$  = The fraction of the total chemical that is freely-dissolved in water

Table 2 contains the ambient water, tissue concentration, organic carbon concentrations and fraction lipid that were used in the derivation of the Baseline BAFs.

Table 2: Data used in the derivation of the Baseline BAFs.

Study Period	Tissue Concentration (ng/g)	Ambient Water Concentration (pg/L)	POC (mg/L)	DOC (mg/L)	fraction lipid
Fall 2001		3194.4	1.51	6.44	
Channel catfish	1230.4				0.0892
White perch	1013.4				0.0734
Spring 2002		4691.8	1.84	10.74	
Channel catfish	1621				0.0817
White perch	1127.6				0.0684

Baseline BAFs are then converted to trophic level BAFs using the following formula:

$$BAF_{(TLn)} = \left[ \text{Baseline } BAF_l^{fd} \cdot (f_l)_{TLn} + 1 \right] \cdot (f_{fd})$$

where

- $BAF_{(TLn)}$  = Final trophic level baseline BAF expressed on a freely-dissolved and lipid-normalized basis for trophic level n  
 $\text{Baseline } BAF_l^{fd}$  = BAF based upon the total concentration of the chemical in tissue and ambient water  
 $f_l$  = The fraction of tissue that is lipid for trophic level n  
 $f_{fd}$  = The fraction of the total chemical that is freely-dissolved in water

Table 3 lists the Baseline BAFs, fraction lipid of consumed tissue, fraction of chemical freely-dissolved and the final trophic level BAFs.

Prior to calculating the water quality criterion, the proportion of fish intake from each trophic level must be determined. Faulds et al, 2004 reported that 42.6% of the fish consumed by shore anglers in Zones 2 through 4 were channel catfish while 42% of the fish consumed were white perch. Since these data indicated similar proportions for both trophic levels 3 and 4, equal proportions of each trophic level were assumed in calculating the revised ambient water quality criteria.

Table 3: Values used in the calculation of final trophic level baseline BAFs.

<b>Trophic Level</b>	<b>Baseline BAF (L/KG-lipid)</b>	<b>fraction lipid of consumed tissue</b>	<b>fraction freely-dissolved</b>	<b>Trophic Level BAF (L/KG-lipid)</b>
Level 3 - Channel catfish				
Fall 2001	35,288,611	0.0387	0.122	167,200
Spring 2002	44,088,605	0.0387	0.095	162,465
Level 4 - White perch				
Fall 2001	22,458,380	0.0248	0.122	68,190
Spring 2002	35,267,280	0.0248	0.095	83,281

### Criterion calculation

Values for each of the parameters in the criteria equation presented in the 2000 guidance and the resulting ambient water quality criterion for the protection of human health from the carcinogenic effects of PCBs for Zones 2 through 5 is presented in Table 4.

Table 4: Parameter values used in the equation for calculating the human health criterion for the protection from carcinogenic effects for PCBs.

<b>Parameter</b>	<b>Value</b>
Risk Level	$1 \times 10^{-6}$
Cancer potency factor	2.0 (mg/KG)/day
Risk Specific Dose	$5.0 \times 10^{-7}$
Body Weight	70 KG
Drinking Water Intake	2.0 liters/day
Fish Intake	17.5 grams per day
Proportion of fish intake at each trophic level	Trophic level 3 - 0.5 Trophic level 4 - 0.5
BAF at each trophic level	Trophic level 3 - 164,832 Trophic level 4 - 75,736
<b>Ambient Water Quality Criterion</b>	<b>15.9 picograms/liter</b>

This ambient water quality criterion applies where exposure is from drinking water and fish consumption or only from fish consumption.

### Probabilistic analyses of parameters

POC, DOC, % lipid for channel catfish, and % lipid for white perch were each treated as lognormal distributions based upon the underlying data. The octanol water partition coefficient, which is used to calculate the fraction of freely dissolved chemical, was treated as a discrete distribution, with homolog-specific Kow values assigned to different frequencies based upon the possible number of PCB congeners at each homolog level. Fish consumption rate was considered as a triangular distribution with a minimum of zero, a most likely value of 17.46 grams per day, and a maximum value of 53.9 grams per day, based upon the KCA study (1994). The cancer potency slope was treated as a uniform distribution spanning a range from 1 to 2 (mg/KG-d)<sup>-1</sup>. Finally, baseline BAFs for channel catfish and white perch were specified as Gumbel distributions based upon best fits to the field data.

The distributions described above, in combination with the fixed values for risk level, body weight, and drinking water ingestion, were sampled 10,000 times using the Latin Hypercube procedure to produce a range of possible water quality criterion values for the protection of human health from carcinogenic effects, each with an associated frequency. The results of the probabilistic analysis from exposure through drinking water and fish consumption, and through fish consumption only are presented in Table 5 and Figure 1. The 50<sup>th</sup> percentile of the criterion was 16.4 pg/liter for both exposure scenarios.

Table 5: Results of probabilistic analysis using @Risk.

Percentile	Ambient Water Quality Criterion	
	Fish and Water Consumption	Fish Consumption Only
10%	3	3
25%	6.2	6.2
<b>50%</b>	<b>16.4</b>	<b>16.4</b>
75%	49.6	49.7
90%	144.5	145.4

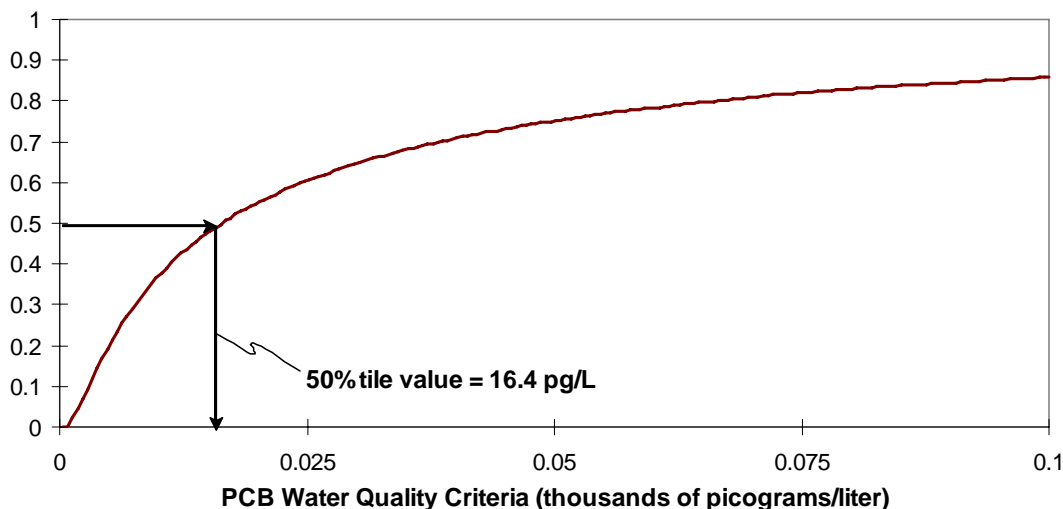


Figure 1: Distribution of ambient water quality criterion for PCBs

## DISCUSSION

The keystone of any TMDL is the water quality criterion upon which it is based. In developing TMDLs for PCBs for the Delaware Estuary, several factors influence the selection of the governing criterion. These factors include: 1) a change in the cancer potency factor for total PCBs reported in EPA's Integrated Risk Information System, 2) the possible future adoption of wildlife criteria for PCBs, and 3) the issuance of a revised methodology for deriving ambient water quality criteria for the protection of human health in the fall of 2000. The latter methodology also includes several new recommendations on the fish consumption rate to be used in criteria development, and the use of a bioaccumulation factor (BAF) rather than a bioconcentration factor (BCF).

Another confounding factor that influences the development of TMDLs for hydrophobic contaminants like PCBs in interstate waters is the existence of different human health criteria adopted by bordering states. Furthermore, the requirement under the Clean Water Act that states update their criteria every three years can result in changing criteria over time, thus making the basis of the TMDLs difficult to establish. An example of the impact of these factors is the human health criteria for Zones 2 through 5 of the Delaware Estuary. In 1996, the Delaware River Basin Commission, the states of Delaware and New Jersey, and the Commonwealth of Pennsylvania all had the same criteria for PCBs, 44.4 picograms/liter. With the issuance of a revised slope factor and revised methodology for deriving human health criteria by the U.S. EPA, the adoption of different criteria by each of the three states during their triennial review was possible depending on the extent to which the new data and methodology were implemented. In 2004, both Delaware and New Jersey proposed revised human health criteria for PCBs. Delaware developed its revised criterion using the new cancer slope factor and site-specific fish consumption data, and derived a value of 64 picograms per liter. New Jersey developed its revised criterion using only the new cancer slope factor, deriving a value of 170 picograms per liter. In September 2006, New Jersey adopted a criterion of 64 picograms per liter using both the new cancer slope factor and the national default

fish consumption value of 17.5 grams per day. The Commission still retains the criterion value of 44.4 picograms per liter adopted in 1996.

Adoption of the revised human health criteria for carcinogenic effects for PCBs presented in this paper by the Commission will result in a uniform standard that fully implements the October 2000 guidance issued by the U.S. EPA. Even if the three states bordering the estuary have different criteria for PCBs depending on the extent to which they have implemented the new guidance, provisions in the standards of New Jersey and Delaware deferring to standards adopted by the Commission will make the revised criteria the governing criteria. Pennsylvania water quality standards do not have language deferring to the Commission's standard, but do have regulations stating that the more stringent of state, interstate or international criteria will apply in interstate or international bodies of water.

Wildlife criteria could theoretically be more stringent than human health criterion for carcinogenic effects. Factors affecting the relative stringency of each criteria include the numerical values of both the wildlife and human health criteria, and the exposure duration used in applying the criteria. The exposure duration for human health criteria for protection from carcinogenic effects is 70 years. The exposure duration for wildlife criteria is 90 days. Figure 2 compares the assimilative capacity (a close analog of a TMDL) of Zones 2 - 5 of the Delaware Estuary based upon existing human health criteria, proposed wildlife criteria, and revised human health criteria implementing one or more recommendations of the October 2000 guidance. This graph indicates that existing criteria are not the most controlling, and that only by fully implementing the recommendations of the October 2000 guidance with respect to the cancer slope factor, fish consumption rates and the use of BAFs will the revised human health criteria be controlling.

## CONCLUSION

Revised human health criteria for the protection of human health from carcinogenic effects were developed using the updated cancer potency factor of 2.0 (mg/KG)/day and the October 2000 guidance issued by the U.S. EPA. Two significant changes recommended in this guidance were to use site-specific values for fish consumption for the water body covered by the criteria, and to use a bioaccumulation factor or BAF rather than a BCF. A value of 17.5 grams/day was selected for use in the criteria formula. This value is similar to site-specific values of 17.5 and 19.8 grams per day observed in two studies conducted in the Delaware Estuary, and is also the recommended national default value. Site-specific BAFs were developed for two trophic levels in the estuary using fish tissue data collected during the fall 2001 and spring 2002, and data on concentrations of PCB congeners in water samples collected during the same time period. Trophic level BAFs of 164,832 L/KG-lipid for trophic level 3 and 75,736 L/KG-lipid for trophic level 4 were determined using these data.



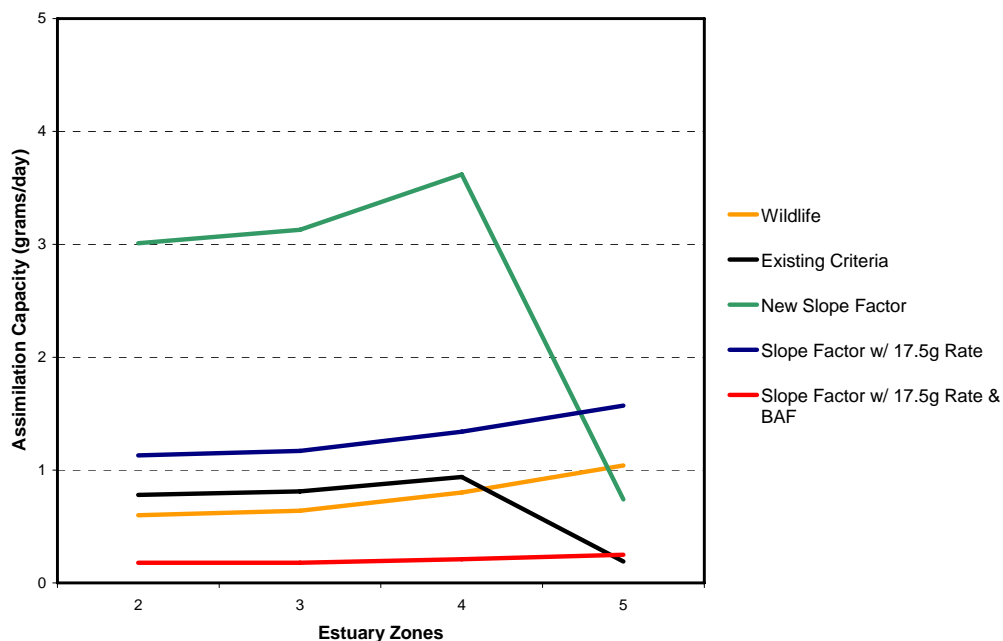


Figure 2: Comparison of assimilative capacity at different criteria values.

Values for other parameters in the criteria equation were a risk level of  $10^{-6}$ , body weight of 70 kilograms, drinking water intake of 2.0 liters/day. The revised ambient water quality criterion for the protection of human health from carcinogenic effects of exposure through drinking water and fish consumption using these parameter values is 15.9 picograms/L.

The results of a probabilistic analysis of selected equation parameters and some of their components indicated a 50<sup>th</sup> percentile value of 16.4 picograms/L for the revised water quality criterion. This value is close to that obtained with the deterministic approach.

The values obtained using the revised criteria equation are approximately 2.5 more stringent than the criteria in Zones 2 - 4 and in the upper portion of Zone 5, and 2.2 times less stringent than the current criterion in the lower portion of Zone 5. Criteria of this magnitude would be more stringent than the wildlife criterion proposed for the State of New Jersey. Use of a revised water quality criterion for the development of TMDLs for PCBs in the Delaware Estuary will ensure consistency and stability in the value of the TMDLs.

In July 2005, the Commission's Toxics Advisory Committee (TAC) that had guided the development of a new human health water quality criterion for PCBs for the Delaware Estuary and Bay voted with no objections to recommend that the Commission adopt a revised criterion of 16 picograms per liter for Zones 2 through 6.

## REFERENCES

- Ashley, J.T.F., D.J. Velinsky, M Wilhelm, J.E. Baker, D. Secor, M. Toaspern. (2004) *Bioaccumulation of Polychlorinated Biphenyls in the Delaware River Estuary*. Academy of Natural Sciences, Philadelphia, PA. Report No. 03-03F submitted to the Delaware River Basin Commission. January 15, 2004.
- Delaware River Basin Commission. (1996) *Water Quality Regulations, Administrative Manual - Part III*. West Trenton, NJ. October 23, 1996.
- Delaware River Basin Commission. (2003). *Calibration of the PCB Water Quality Model for the Delaware Estuary for Penta-PCBs and Carbon*. West Trenton, NJ. September 2003.
- Faulds, A., N. Connelly, B. Knuth, J. Benowitz, J. Matassino, K.P. Norton. (2004) *Patterns of Sport-fish Consumption at Six Pennsylvania Sites Along the Tidal Portion of the Delaware River with Special Emphasis on Shore Anglers*. Report prepared for the Pennsylvania Coastal Zone Management Program. Project Number: CZ1:02PD.09. March 31, 2004.
- Greene, R.W. (2002) Chemical contaminant data for fish and shellfish from the Delaware Estuary. Data base prepared for the Delaware River Basin Commission, West Trenton, NJ. Available at <http://www.state.nj.us/drbc/fishtiss.htm>.
- Palisade Corporation, 2004. @RISK. Palisade Corp., Newfield, NY. Available at <http://www.palisade.com/html/risk.asp>.
- U.S. Department of Agriculture, 1998. *1994-1996 Continuing Survey of Food Intake by Individuals*. Agricultural Research Service. NTIS CD-ROM, accession number PB98-500457.
- U.S. Environmental Protection Agency. (1980a) *Guidelines and methodology used in the preparation of health effect assessment chapters of the consent decree water criteria documents*. Federal Register 49:46294.
- U.S. Environmental Protection Agency. (1980b) *Ambient Water Quality Criteria for Polychlorinated Biphenyls*. Office of Water, Criteria and Standards Division. EPA 440/5-80-068. October 1980.
- U.S. Environmental Protection Agency. (1999) Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants; States' Compliance - Revision of Polychlorinated Biphenyls (PCBs) Criteria. Federal Register **64** (216), 61182-61196.
- U.S. Environmental Protection Agency. (2000) *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000)*. Office of Water, Office of Science and Technology. EPA 822-B-00-004. October 2000.

U.S. Environmental Protection Agency. (2004) Polychlorinated Biphenyls (PCBs) (CASRN 1336-36-3). Integrated Risk Information System. U.S. EPA , Office of Science & Technology. Washington, D.C. Available at <http://www.epa.gov/iris/subst/0294.htm>.

## **Appendix A**

### **Comparison of Current and Revised Criteria for Total PCBs for the Protection of Human Health in Zones 2 through 6 of the Delaware River**

**Revised Water Quality Criteria for Total PCBs**  
Delaware River Basin Commission

Parameter	Cancer Potency Factor	BCF/BAF	% Lipid of Consumed Fish	Consumption Rate (Grams/day)	Basis for Consumption Rate	Freshwater Criteria (picograms/l)		Marine Criteria (picograms/l)
						Fish & Water Ingestion (Zones 2 & 3)	Fish Ingestion Only (Zones 4 & 5)	Fish Ingestion Only
Total PCBs	7.70e+00	31200 <sup>a</sup>	3.0	6.5	Old default value	44.4	44.8	-
Total PCBs	7.70e+00	31200 <sup>a</sup>	3.0	37.0	Current DRBC value	-	-	7.9
<b>Total PCBs</b>	2.00e+00	164,832 <sup>b</sup> 75,736 <sup>c</sup>	3.9 <sup>b</sup> 2.5 <sup>c</sup>	17.5 (50% - Level 3 and 4)	National default and Estuary-Specific Data	<b>16.0</b>	<b>16.0</b>	<b>16.0</b>

a - BCF from 1980 Ambient Water Quality Criteria document.

b - BAF for trophic level 3 (mean of Fall 2001 and Spring 2002).

c - BAF for trophic level 4 (mean of Fall 2001 and Spring 2002).

Notes: Values were developed using percent lipid values from estuary data base of fillet samples, and a consumption rate of 17.5 grams per day.