Fact Sheet Date: March 12, 1998

NEW YORK STATE
- HUMAN HEALTH FACT SHEET -

Ambient Water Quality Value for Protection of Sources of Potable Water

SUBSTANCE: Polychlorinated biphenyls (PCBs)

CAS REGISTRY NUMBER: 1336-36-3

AMBIENT WATER QUALITY VALUE: 0.09 ug/L

BASIS: Oncogenic

I INTRODUCTION

The ambient water quality value applies to the water column and is designed to protect humans from the effects of contaminants in sources of drinking water; it is referred to as a Health (Water Source) or H(WS) value.

Regulations (6 NYCRR 702.2) require that the water quality value be based on the procedures in sections 702.3 through 702.7. Potential water quality values are derived below, and the value of 0.09 ug/L is selected for polychlorinated biphenyls (PCBs) as described under "Selection of Value."

II PRINCIPAL ORGANIC CONTAMINANT CLASSES AND SPECIFIC MCL (702.3)

A. Discussion

PCBs have a Specific MCL of 0.5 ug/L as defined in 700.1. This is a maximum contaminant level for drinking water established by the New York State Department of Health under the State Sanitary Code (10 NYCRR Part 5, Public Water Supplies).

The U.S. Environmental Protection Agency has established a maximum contaminant level goal (MCLG) of zero ug/L and a MCL of 0.5 ug/L for drinking water for PCBs.

B. Derivation of Water Quality Value

Regulations require that the water quality value for PCBs not exceed the Specific MCL of 0.5 ug/L.

III ONCOGENIC EFFECTS (702.4)

U.S. EPA (1995) conducted a comprehensive evaluation of the oncogenic effects of PCBs as part of its criteria development for the Great Lakes Water Quality Initiative (GLI). The GLI was a joint undertaking by U.S. EPA and the Great Lakes States and included representatives of interest groups. Its final regulations and the criteria document for this substance received extensive public review in a formal rule making process.

Subsequent to the publication of the GLI criteria, however, U.S. EPA (1996) completed a major re-evaluation of the oncogenicity of PCBs; this represents the Agency's current assessment and is attached as Exhibit I. The Department has reviewed this assessment and concludes both that PCBs are oncogens under New York's definition (6 NYCRR 700.1) and that U.S. EPA's 1996 assessment is appropriate for the derivation of a statewide value.

As shown in Exhibit I, U.S. EPA (1996) determined the cancer potency of PCB mixtures using a tiered approach. For exposure via ingestion of surface water, the Department believes the middle tier, upper bound potency (slope) of 0.4 $[mg/(kg \cdot day)]^{-1}$, for "low risk and persistence" to be the appropriate basis for a value to protect sources of drinking water. Use of the highest tier slope was rejected because the higher-chlorinated PCB congeners are less soluble in water; the lowest tier slope was rejected because the Department's experience indicates that more than 0.5% of PCB congeners in surface waters contain 4 or more chlorine atoms. Few data are available for groundwater; by analogy to surface water, the Department selected the slope of 0.4 $[mg/(kg \cdot day)]^{-1}$ for groundwater.

The slope factor is converted to a human dose, at a lifetime risk level of one-in-one million as shown below.

$$\text{Human dose} = \frac{\text{risk}}{\text{slope}} = \frac{10^{-6}}{0.4\ [mg/(kg \cdot day)]^{-1}}$$

$$= 2.5 \times 10^{-6}\ mg/(kg \cdot day) \equiv 2.5 \times 10^{-3}\ ug/(kg \cdot day)$$

The human dose above is converted to a potential water quality value based on a 70 kg adult consuming 2 liters of water per day as follows:

$$\text{Water Quality Value} = \frac{[2.5 \times 10^{-3} \text{ ug/(kg} \cdot \text{day)}]\ [70 \text{ kg}]}{[2 \text{ L/day}]}$$

$$= 0.0875 \text{ ug/L, rounded to } 0.09 \text{ ug/L}$$

IV NON-ONCOGENIC EFFECTS (702.5)

U.S. EPA (1995) also conducted a comprehensive review of toxicological data on non-oncogenic effects for PCBs as part of its criteria development under GLI and judged the database insufficient for Tier I Non-Human Cancer Criterion development. The Department made no further pursuit of a non-oncogenic value as it is not likely to be more stringent than the oncogenic value for PCBs.

V CHEMICAL CORRELATION (702.7)

A value based on chemical correlation for oncogenic or non-oncogenic effects is not derived. Data are sufficient to derive an oncogenic value and a non-oncogenic-based value is not likely to be more stringent.

VI SELECTION OF VALUE

The H(WS) value is designed to protect humans from oncogenic and non-oncogenic effects from contaminants in sources of drinking water. To protect for these effects, regulations (6 NYCRR 702.2(b)) require that the value be the most stringent of the values derived using the procedures found in sections 702.3 through 702.7. The oncogenic value of 0.09 ug/L (6 NYCRR 702.4) is the most stringent value derived by these procedures and is the ambient water quality value for PCBs.

VII REFERENCES

6 NYCRR (New York State Codes, Rules and Regulations). Water Quality Regulations, Surface Water and Groundwater Classifications and Standards: Title 6 NYCRR, Chapter X, Parts 700-705. Albany, NY: New York State Department of Environmental Conservation.

10 NYCRR (New York State Codes, Rules and Regulations). Public Water Systems: Title 10 NYCRR, Chapter 1, State Sanitary Code, Subpart 5-1. Albany, NY: New York State Department of Health, Bureau of Public Water Supply Protection.

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New York State Department of Environmental Conservation
Division of Water
SJS
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EXHIBIT I

ORAL CARCINOGENICITY ASSESSMENT FOR PCBs

[From U.S. EPA, 1996 (printed March, 1997)]

1 - IRIS
NAME - Polychlorinated biphenyls (PCBs)
RN - 1336-36-3
CARO -

o CLASSIFICATION:	B2; probable human carcinogen.
o BASIS FOR CLASSIFICATION:	A 1996 study found liver tumors in female rats exposed to Aroclors 1260, 1254, 1242, and 1016, and in male rats exposed to 1260. These mixtures contain overlapping groups of congeners that, together, span the range of congeners most often found in environmental mixtures. Earlier studies found high, statistically significant incidences of liver tumors in rats ingesting Aroclor 1260 or Clophen A 60 (Kimbrough et al., 1975; Norback and Weltman, 1985; Schaeffer et al., 1984). Mechanistic studies are beginning to identify several congeners that have dioxin-like activity and may promote tumors by different modes of action. PCBs are absorbed through ingestion, inhalation, and dermal exposure, after which they are transported similarly through the circulation. This provides a reasonable basis for expecting similar internal effects from different routes of environmental exposure. Information on relative absorption rates suggests that differences in toxicity across exposure routes are small. The human studies are being updated; currently available evidence is inadequate, but suggestive.
o ORAL SLOPE FACTOR:	See txt
o DRINKING WATER UNIT RISK:	See txt
o DOSE EXTRAPOLATION METHOD:	Linear extrapolation below LED10s (U.S. EPA, 1996b)

o RISK/WATER CONCENTRATIONS:

Drinking Water Concentrations at Specified Risk Levels:

Risk Level	Concentration
E-4 (1 in 10,000)	See txt
E-5 (1 in 100,000)	See txt
E-6 (1 in 1,000,000)	See txt

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o ORAL DOSE-RESPONSE DATA:

Tumor Type -- Liver hepatocellular adenomas, carcinomas, cholangiomas, or cholangiocarcinomas
Test Animals -- Female Sprague-Dawley rats
Route -- Diet
Reference -- Brunner et al., 1996; Norback and Weltman, 1985

	Administered Dose (ppm)	Human Equivalent Dose (mg/kg)/day	Tumor Incidence
Aroclor 1260			
	0	0	1/85
	25	0.35	10/49
	50	0.72	11/45
	100	1.52	24/50
Aroclor 1254			
	0	0	1/85
	25	0.36	19/45
	50	0.76	28/49
	100	1.59	28/49
Aroclor 1242			
	0	0	1/85
	50	0.75	11/49
	100	1.53	15/45
Aroclor 1016			
	0	0	1/85
	50	0.72	1/48
	100	1.43	7/45
	200	2.99	6/50
Aroclor 1260 (Norback and Weltman, 1985)			
	0	0.75	1/45
	100/50/0	1.3	41/46

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o ADDITIONAL COMMENTS:

The cancer potency of PCB mixtures is determined using a tiered approach that depends on the information available. The following tier descriptions discuss all environmental exposure routes:

TIERS OF HUMAN SLOPE FACTORS FOR ENVIRONMENTAL PCBs

HIGH RISK AND PERSISTENCE

Upper-bound slope factor: 2.0 per (mg/kg)/day
Central-estimate slope factor: 1.0 per (mg/kg)/day

Criteria for use:
- Food chain exposure
- Sediment or soil ingestion
- Dust or aerosol inhalation
- Dermal exposure, if an absorption factor has been applied
- Presence of dioxin-like, tumor-promoting, or persistent congeners
- Early-life exposure (all pathways and mixtures)

LOW RISK AND PERSISTENCE

Upper-bound slope factor: 0.4 per (mg/kg)/day
Central-estimate slope factor: 0.3 per (mg/kg)/day

Criteria for use:
- Ingestion of water-soluble congeners
- Inhalation of evaporated congeners
- Dermal exposure, if no absorption factor has been applied

LOWEST RISK AND PERSISTENCE

Upper-bound slope factor: 0.07 per (mg/kg)/day
Central-estimate slope factor: 0.04 per (mg/kg)/day

Criteria for use: Congener or isomer analyses verify that congeners with
more than 4 chlorines comprise less than 1/2% of total PCBs.

Slope factors are multiplied by lifetime average daily doses to estimate the cancer risk. SAMPLE CALCULATIONS ARE GIVEN IN U.S. EPA (1996a). Although PCB exposures are often characterized in terms of Aroclors, this can be both imprecise and inappropriate. Total PCBs or congener or isomer analyses are recommended.

When congener concentrations are available, the slope-factor approach can be supplemented by analysis of dioxin TEQs to evaluate dioxin-like toxicity. Risks from dioxin-like congeners (evaluated using dioxin TEQs) would be added to risks from the rest of the mixture (evaluated using slope factors applied to total PCBs reduced by the amount of dioxin-like congeners). SAMPLE CALCULATIONS ARE GIVEN IN U.S. EPA (1996a).

Depending on the specific application, either central estimates or upper bounds can be appropriate. Central estimates describe a typical individual's risk, while upper bounds provide assurance that this risk is not likely to be underestimated if the underlying model is correct. The upper bounds calculated in this assessment reflect study design and provide no information about sensitive individuals or groups. Central estimates are useful for estimating aggregate risk across a population. Central estimates are used for comparing or ranking environmental hazards, while upper bounds provide information about the precision of the comparison or ranking.

Some PCBs persist in the body and retain biological activity after exposure stops (Anderson et al., 1991a). Compared with the current default practice of assuming that less-than-lifetime effects are proportional to exposure duration, rats exposed to a persistent mixture (Aroclor 1260) had more tumors, while rats exposed to a less persistent mixture (Aroclor 1016) had fewer tumors (Brunner et al., 1996). Thus there may be greater-than-proportional effects from less-than-lifetime exposure, especially for persistent mixtures and for early-life exposures.

Highly exposed populations include some nursing infants and consumers of game fish, game animals, or products of animals contaminated through the food chain. Highly sensitive populations include people with decreased liver function and infants (Calabrese and Sorenson, 1977).

Because of the potential magnitude of early-life exposures (ATSDR, 1993; Dewailly et al., 1991, 1994), the possibility of greater perinatal sensitivity (Calabrese and Sorenson, 1977; Rao and Banerji, 1988), and the likelihood of interactions among thyroid and hormonal development, it is reasonable to conclude that early-life exposures may be associated with increased risks. Due to this potential for higher sensitivity early in life, the "high risk" tier is used for all early-life exposure.

It is crucial to recognize that commercial PCBs tested ie estimates, administered doses were expressed as a lifetime daily average calculated from weekly body weight measurements and food consumption estimates (Keenan and Stickney, 1996). Doses were scaled from rats to humans using a factor based on the 3/4 power of relative body weight.

UNIT RISK ESTIMATE AND DRINKING WATER CONCENTRATIONS

For ingestion of water-soluble congeners, the middle-tier slope factor can be converted to a unit risk estimate and drinking water concentrations associated with specified risk levels.

Upper-bound slope factor:	0.4 per (mg/kg)/day
Upper-bound unit risk:	1 x 10-5 per ug/L

Drinking water concentration associated with a risk of:

1 in 10,000	10 ug/L
1 in 100,000	1 ug/L
1 in 1,000,000	0.1 ug/L

These estimates should not be used if drinking water concentrations exceed 1000 ug/L, since above this concentration the dose-response curve in the experimental range may provide better estimates.

For food chain exposure or ingestion that includes contaminated sediment or soil, the slope factor for "high risk and persistence" should be used instead.

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o DISCUSSION OF CONFIDENCE:

Joint consideration of cancer studies and environmental processes leads to a conclusion that environmental PCB mixtures are highly likely to pose a risk of cancer to humans. Although environmental mixtures have not been tested in cancer assays, this conclusion is supported by several complementary sources of information. Statistically significant, dose-related, increased incidences of liver tumors were induced in female rats by Aroclors 1260, 1254, 1242, and 1016 (Brunner et al., 1996). These mixtures contain overlapping groups of congeners that, together, span the range of congeners most frequently found in environmental mixtures. Several congeners have dioxin-like activity (Safe, 1994) and may promote tumors by different modes of action (Silberhorn et al., 1990); these congeners are found in environmental samples and in a variety of organisms, including humans (McFarland and Clarke, 1989).

The range of potency observed for commercial mixtures is used to represent the potency of environmental mixtures. The range reflects experimental uncertainty and variability of commercial mixtures, but not human heterogeneity or differences between commercial and environmental mixtures. Environmental processes alter mixtures through partitioning, transformation, and bioaccumulation, thereby decreasing or increasing toxicity. The overall effect can be considerable, and the range observed for commercial mixtures may underestimate the true

range for environmental mixtures (Hutzinger et al., 1974; Callahan et al., 1979). Limiting the potencyextensively studied (Hutzinger et al., 1974; Callahan et al., 1979) and can be associated with exposure pathway, thus the use of exposure pathway to represent environmental processes increases confidence in the risks inferred for environmental mixtures. For example, evaporated or dissolved congeners tend to be lower in chlorine content than the original mixture; they tend also to be more inclined to metabolism and elimination and lower in persistence and toxicity. On the other hand, congeners adsorbed to sediment or soil tend to be higher in chlorine content and persistence, and bioaccumulated congeners ingested through the food chain tend to be highest of all. Rates of these processes vary over several orders of magnitude (Hutzinger et al., 1974; Callahan et al., 1979). When available, congener information is an important tool for refining a potency estimate that was based on exposure pathway.

Extrapolation to environmental levels is based on models that are linear at low doses. Low-dose-linear models are appropriate when a carcinogen acts in concert with other exposures and processes that cause a background incidence of cancer (Crump et al, 1976; Lutz, 1990). Even when the mode of action indicates a nonlinear dose-response curve in homogeneous animal populations, the presence of genetic and lifestyle factors in a heterogeneous human population tends to make the dose-response curve more linear (Lutz, 1990). This is because genetic and lifestyle factors contribute to a wider spread of human sensitivity, which extends and straightens the dose-response curve over a wider range.

Uncertainty around these estimates extends in both directions. The slope factor ranges primarily reflect mixture variability, and so are not necessarily appropriate for probabilistic analyses that attempt to describe model uncertainty and parameter uncertainty. Estimates based on animal studies benefit from controlled exposures and absence of confounding factors; however, there is uncertainty in extrapolating dose and response rates across species. Information is lacking to evaluate high-to-low-dose differences. PCBs are absorbed through ingestion, inhalation, and dermal exposure, after which they are transported similarly through the circulation (ATSDR, 1993). This provides a reasonable basis for expecting similar internal effects from different routes of environmental exposure. Information on relative absorption rates suggests that differences in toxicity across exposure routes are small. The principal uncertainty, though, is using commercial mixtures to make inferences about environmental mixtures.

When exposure involves the food chain, uncertainty extends principally in one direction: through the food chain, living organisms selectively bioaccumulate persistent congeners, buioxin-like nature of some PCBs raises a concern for cumulative exposure, as dioxin-like

congeners add to background exposure of other dioxin- like compounds and augment processes associated with dioxin toxicity. This weighs against considering PCB exposure in isolation or as an increment to a background exposure of zero. Confidence in this assessment's use of low-dose- linear models is enhanced when there is additivity to background exposures and processes (Crump et al, 1976; Lutz, 1990).

REFERENCES

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RN - 1336-36-3

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