

8. REGULATIONS AND ADVISORIES

Table 8-1 summarizes international, national, and state regulations and guidelines on human exposure to PCBs.

ATSDR has derived an MRL of 0.03 $\mu\text{g}/\text{kg}/\text{day}$ for intermediate-duration oral exposure to PCBs. The intermediate oral MRL is based on a LOAEL of 0.0075 $\text{mg}/\text{kg}/\text{day}$ for neurobehavioral effects in infant monkeys that were exposed to a PCB congener mixture representing 80% of the congeners typically found in human breast milk from birth to 20 weeks of age (Rice 1997, 1998, 1999b; Rice and Hayward 1997, 1999a). An uncertainty factor of 300 was applied (10 for extrapolating from a LOAEL to a NOAEL, 3 for extrapolating from monkeys to humans, and 10 for human variability).

ATSDR has derived an MRL of 0.02 $\mu\text{g}/\text{kg}/\text{day}$ for chronic-duration oral exposure to PCBs. The chronic oral MRL is based on a LOAEL of 0.005 $\text{mg}/\text{kg}/\text{day}$ for immunological effects in adult monkeys that were evaluated after 23 and 55 months of exposure to Aroclor 1254 (Tryphonas et al. 1989, 1991a). An uncertainty factor of 300 was applied (10 for extrapolating from a LOAEL to a NOAEL, 3 for extrapolating from monkeys to humans, and 10 for human variability).

EPA has verified an oral reference dose (RfD) of 0.02 $\mu\text{g}/\text{kg}/\text{day}$ for Aroclor 1254 (IRIS 2000) based on dermal/ocular and immunological effects in monkeys, and an oral RfD of 0.07 $\mu\text{g}/\text{kg}/\text{day}$ for Aroclor 1016 based on reduced birth weight in monkeys (IRIS 2000).

The EPA has determined that PCBs are probable human carcinogens and assigns them the cancer weight-of-evidence classification B2 (IRIS 2000). The EPA has developed an approach for assessing cancer risk from environmental PCBs by considering both toxicity and environmental processes (Cogliano 1998; EPA 1996c; IRIS 2000). This approach uses animal studies of commercial PCB mixtures to develop a range of human cancer potency estimates and then considers the effect of environmental processes to determine appropriate values for representative classes of environmental mixtures. Additional discussion on EPA's cancer risk assessment, including the cancer slope factors and their corresponding exposure pathways, is provided in Chapter 3 (Section 3.2.8.3.2). IARC has determined that PCBs are probably carcinogenic to humans (Group 2A) (IARC 1987). The Department of Health and Human Services (DHHS) concluded that PCBs are reasonably anticipated to be carcinogenic in humans based on sufficient evidence of carcinogenicity in animals (NTP 2000).

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OSHA requires employers of workers who are occupationally exposed to PCBs to institute engineering controls and work practices to reduce and maintain employee exposure at or below permissible exposure limits (PELs). The employer must use engineering and work practice controls, if feasible, to reduce exposure to or below an 8-hour time-weighted average (TWA) of 1 mg/m³ for chlorodiphenyl (54% chlorine). Respirators must be provided and used during the time period necessary to install or implement feasible engineering and work practice controls (OSHA 1998a).

The Food and Drug Administration (FDA) sets tolerance limits for PCBs as “unavoidable poisonous or deleterious substances” in both animal and human food, and food-packaging materials (FDA 1998c).

PCBs have been designated as a hazardous substance pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980 (EPA 1998i) and as a toxic chemical under Section 313 of Title III of the Superfund Amendments and Reauthorization Act (SARA) of 1986 (EPA 1998i). Title III of SARA is also known as "The Emergency Planning and Community Right-to-Know Act (EPCRA) of 1986." As a chemical subject to the emergency planning and release reporting requirements of EPCRA, owners and operators of certain facilities that have PCBs on their sites in amounts exceeding a specified reporting threshold are required to report annually releases of PCBs to any environmental medium (EPA 1998d). The owners and operators of these facilities are also required to immediately report releases of PCBs to any environmental media if the amount released exceeds the “reportable quantity” of 1 pound (0.454 kg) (EPA 1998h). The statutory sources for designating PCBs as CERCLA hazardous substance are sections 311(b)(4) and 307(a) of the Clean Water Act (CWA), and section 112 of the Clean Air Act (CAA). The statutory reportable quantity for PCBs established by Section 102 of CERCLA is 10 pounds (4.54 kg) (EPA 1998h).

PCBs are regulated by the Clean Water Effluent Guidelines as stated in Title 40. Sections 400–475, of the Code of Federal Regulations (CFR). For each point source category, PCBs may be regulated as a group of chemicals controlled as Total Toxic Organics or may have a specific Regulatory Limitation. The point source categories for which PCBs are controlled as a Total Toxic Organic include electroplating (EPA 1981) and metal finishing (EPA 1983a). The point source category for which PCBs has a specific regulatory limitation is steam electric power generating (EPA 1982b).

If waters and their sediments become contaminated from sources such as atmospheric deposition and discharges from industrial, municipal, or agricultural operations, toxic substances could concentrate in the tissue of fish and wildlife. Currently, 679 advisories restricting the consumption of PCB-contaminated

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fish, shellfish, and wildlife have been issued in 37 states and in one U.S. Territory (American Samoa) (EPA 2000b).

The Toxic Substances Control Act (TSCA) bans manufacturing, processing, and distributing PCBs in commerce. It also bans the use of PCBs outside of totally enclosed systems (EPA 1998a). In addition to authorizing the EPA to regulate PCBs, TSCA also provides the EPA with the authority to modify these bans if it is shown that such modifications would not present unreasonable risks to human health and the environment. On June 29, 1998, the EPA published amendments in the Federal Register to the regulatory requirements for the manufacture, processing, distribution in commerce, use, cleanup, storage, and disposal of PCBs (EPA 1998a). These amendments add regulatory provisions authorizing certain uses of PCBs; authorizing the manufacture, processing, and distribution in commerce of PCBs for use in research and development activities; specifying additional alternatives for the cleanup and disposal of PCBs; and clarifying the processing for disposal exemption. These amendments also add sections establishing standards and procedures for disposing of PCB remediation waste and certain products manufactured with PCBs; establishing procedures for determining PCB concentration; establishing standards and procedures for decontamination; establishing controls over the storage of PCBs for reuse; and establishing a mechanism for coordinating TSCA disposal approvals for the management of PCB wastes among various Federal programs. They also update several marking, recordkeeping, and reporting requirements.

The amendments contained in the final rule will be codified in the CFR at 40 CFR 750 and 40 CFR 761. The final rule authorizes certain uses of PCBs and materials contaminated with PCBs to continue if exposures can be controlled, and if removal and disposal of the material would be costly or impractical. More flexibility in selecting disposal technologies for PCBs is also allowed, and the list of available decontamination procedures has been expanded. The final rule allows disposal of PCBs from decontamination activities, but does not require previously needed disposal approval (EPA 1998a). The amendments add provisions for disposing of PCB remediation waste and certain products containing PCBs. TSCA does not allow state disposal rules for PCBs to be preempted, particularly if the method of disposal is described.

Some of the substances regulated by the requirements in 40 CFR 761 are dielectric fluids, solvents, oil, waste oils, heat transfer fluids, hydraulic fluids, paints or coatings, sludges, slurries, sediments, dredge spoils, soils, and materials containing PCBs as a result of spills. The regulatory applicability for these substances depends in part on the concentration of PCBs present (EPA 1998a). Numerical standards are usually expressed as the weight of PCBs per weight of liquid (e.g., milligrams per liter) or non-liquid

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matrix (e.g., milligrams per kilogram). The final rule provides two options for determining what regulatory requirements apply to materials PCB-containing materials. The first option requires that the PCB concentration be determined (weight-to-weight or weight-to-volume) and then the regulatory requirements for the found concentration and the type of material are applied. Unless it is otherwise noted in the regulation, the weight or volume is determined using the total weight of the material and not the calculated weight or volume of PCBs within the substance. For non-liquid PCBs, the concentration must be determined on a dry weight basis. The concentration of PCBs in liquids and multi-phasic materials must be determined on a wet weight basis and an analysis of each phase, respectively. The second option allows an assumption to be made that the PCB concentration is 500 ppm. When the second option is chosen, it would not be necessary to determine the PCB concentration; however, the most restrictive regulatory requirements will need to be met.

Although there are exceptions, such as waste oils used for energy recovery, PCB wastes are generally regulated for disposal under TSCA at concentrations of 50 ppm. The requirements for the disposal of PCB liquids and PCB items will be codified at 40 CFR 761.60. Disposal requirements for PCB remediation waste or PCB bulk product waste will be codified in 40 CFR 761.61 and 761.62, respectively. When the components of a waste are PCBs and non-PCB contaminants, and the PCB component is approved for disposal, the non-PCB component must meet the requirements of all other applicable statutes or regulatory authorities prior to disposal (EPA 1998a).

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Table 8-1. Regulations and Guidelines Applicable to PCBs

Agency	Description	Information	References
<u>INTERNATIONAL</u>			
Guidelines:			
IARC	Carcinogenic classification	Group 2A ^a	IARC 1987
<u>NATIONAL</u>			
Regulations and Guidelines:			
a. Air			
ACGIH	TLV for occupational exposure (8-hour TWA)		ACGIH 1998
	Aroclor 1242 - (53469-21-9)	1 mg/m ³	
	Aroclor 1254 - (11097-69-1)	0.5 mg/m ³	
NIOSH	REL (10-hour TWA)		NIOSH 2000
	Chlorodiphenyl (42% chlorine) - (53469-21-9)	0.001 mg/m ³	
	Chlorodiphenyl (54% chlorine) - (11097-69-1)	0.001 mg/m ³	
OSHA	PEL (8-hour TWA)		OSHA 1998a
	Aroclor 1242 (53469-21-9)	1 mg/m ³	29 CFR
	Aroclor 1254 (11097-69-1)	0.5 mg/m ³	1910.1000 ³
	PEL (TWA) for shipyards		OSHA 1998b
	Aroclor 1242 (53469-21-9)	1 mg/m ³	29 CFR
	Aroclor 1254 (11097-69-1)	0.5 mg/m ³	1915.1000
	PEL (TWA) for construction		OSHA 1998c
	Aroclor 1242 (53469-21-9)	1 mg/m ³	29 CFR
	Aroclor 1254 (11097-69-1)	0.5 mg/m ³	1926.55
b. Water			
EPA	Drinking water standard for PCBs	5x10 ⁻⁴ ppm	EPA 1999e 40 CFR 141.32
	MCL for community water systems and non-transient, non-community water systems for PCBs	5x10 ⁻⁴ mg/L	EPA 1999g 40 CFR 141.61
	MCLG for PCBs	0 mg/L	EPA 1999f 40 CFR 141.50
	MCL	5x10 ⁻⁴ mg/L	EPA 1996d
	Concentration at cancer risk of 10 ⁻⁴	5x10 ⁻⁴ mg/L	
	Cancer classification	B2 ^b	

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Table 8-1. Regulations and Guidelines Applicable to PCBs (continued)

Agency	Description	Information	References
<u>NATIONAL</u> (cont'd)			
	Human health consumption of: water and organism ^c organism only ^c	1.7x10 ⁻⁴ µg/L 1.7x10 ⁻⁴ µg/L	EPA 1999a
	Groundwater PQL ^d	50 µg/L	EPA 1999c 40 CFR 264 App. IX
	Universal Treatment Standards waste water standard ^e non-waste water standard ^e	0.10 mg/L ² 10 mg/kg ³	EPA 1998e 40 CFR 268.48
FDA	Bottled water PCBs (1336-36-3)	0.0005 mg/L	FDA 1999a 21 CFR 165.110
c. Food FDA	Tolerances for PCB residues		FDA 1996c
	Infant and junior foods	0.2 ppm	
	eggs	0.3 ppm	
	milk (fat basis)	1.5 ppm	
	manufactured dairy products (fat basis)	1.5 ppm	
	fish and shell fish (edible portion; excludes head, scales, viscera, and inedible bones)	2 ppm	
	poultry (fat basis)	3 ppm	
	Action level for PCB residues in red meat on a fat basis	3 ppm	FDA 1996b
	Use of PCBs in the production, handling, and storage of animal feeds which then transfer to human food produced by animals	Yes	FDA 1998a 21 CFR 500.45
	Indirect food additives, manufacturing of food- packaging material	Yes	FDA 1998b 21 CFR 509.15
	Temporary tolerances for residues of PCBs as unavoidable environmental or industrial contaminants		FDA 1998c 21 CFR 509.30
	Finished animal feed for food- producing animals (except feed concentrates, feed supplements, and feed premixes)	0.2 ppm	

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Table 8-1. Regulations and Guidelines Applicable to PCBs (continued)

Agency	Description	Information	References
<u>NATIONAL</u> (cont'd)			
c. Food			
	Animal feed components of animal origin, including fishmeal and other by-products of marine origin and in finished animal feed concentrates, supplements, and premixes intended for food-producing animals	2 ppm	
	Paper food-packaging material intended for or used with finished animal feed and any components intended for animal feeds	10 ppm	
d. Other			
ACGIH	Aroclor 1242 (53469-21-9) Biological Exposure Index Carcinogenic classification	No data No data	ACGIH 1998
	Aroclor 1254 (11097-69-1) Biological Exposure Index Carcinogenic classification	No data A3 ^f	
EPA	Aroclor 1254 (11097-69-1) Carcinogenic classification	Evaluation incomplete	IRIS 2000
	Oral slope factor	See PCBs	
	RfD (oral)	2x10 ⁻⁵ mg/kg-day	
	Aroclor 1248 (12672-29-6) Carcinogenic classification	Evaluation incomplete	IRIS 2000
	Oral slope factor	See PCBs	
	RfD (oral)	Not verified	
	Aroclor 1016 (12674-11-2) Carcinogenic classification	Evaluation incomplete	IRIS 2000
	Oral slope factor	See PCBs	
	RfD (oral)	7x10 ⁻⁵ mg/kg-day	

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Table 8-1. Regulations and Guidelines Applicable to PCBs (continued)

Agency	Description	Information	References
<u>NATIONAL</u> (cont'd)			
d. Other (cont'd)			
EPA	Polychlorinated biphenyls (PCBs) (1336-36-3)		IRIS 2000
	Carcinogenic classification	B2 ^g	
	Oral slope factor		
	Environmental exposure routes:		
	High risk and persistence	2.0 per (mg/kg)/day	
	Low risk and persistence	0.4 per (mg/kg)day	
	Lowest risk and persistence	0.07 per (mg/kg)/day	
	RfD (oral)	See Aroclor 1016, 1248, and 1254	
	Reportable quantity pursuant to Section 311 of the Clean Water Act	1 pound	EPA 1999h 40 CFR 117.3
	Toxic Pollutant Effluent Standards and Prohibitions	Yes	EPA 1998a 40 CFR 129.4
	Toxics Chemical Release effective date under section 372.30	1/1/87	EPA 1999d 40 CFR 372.65
	PCB waste regulated under Toxic Substance Control Act	Yes	EPA 1998b 40 CFR 261.8
	Toxic pollutant designated pursuant to section 307(a)(1) of the Act	Yes	EPA 1999j 40 CFR 401.15
	Hazardous substance in accordance with section 311(b)(2)(A) of the Act	Yes	EPA 1999i 40 CFR 116.4
	Hazardous constituent	Yes	EPA 1998r 40 CFR 261, app. viii
	Application to land used for the production of food chain crops and animal feed	Yes	EPA 1998q 40 CFR 257.3-5
USC	List of hazardous air pollutants	Yes	USC 1999 42 USC 7412
	Manufacture of PCB	Banned 2 years after 1/1/77	USC 1998 15 USC 2605
	Process or distribution in commerce	Banned 2.5 years after 1/1/77	

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Table 8-1. Regulations and Guidelines Applicable to PCBs (continued)

Agency	Description	Information	References
<u>STATE</u>			
Regulations and Guidelines:			
a. Air:			
HI	List of hazardous air pollutants	Yes	UATW 1999d
AL	Human health consumption of: water and organism ^h organism only ⁱ for Aroclor 1016 (12674-11-2) Aroclor 1221 (11104-28-2) Aroclor 1232 (11141-16-5) Aroclor 1242 (53469-21-9) Aroclor 1248 (12672-29-6) Aroclor 1254 (11097-69-1) Aroclor 1260 (11096-82-5)	9.7x10 ⁻⁸ mg/L 9.7x10 ⁻⁸ mg/L	UATW 1999a
AZ	PCBs (1336-36-3) Oral HBGL MCL Aroclor (12674-11-2) Oral HBGL	0.005 µg/L 0.5 µg/L 0.49 µg/L	FSTRAC 1999
CO	Groundwater for PCBs (1336-36-3) Human health consumption of PCBs (1336-36-3): water and organism water only	0.005 µg/L 4.4x10 ⁻⁵ µg/L 0.005 µg/L	CDC 1999c CDC 1999d
HI	MCL for community and non-transient, and non-community water systems PCBs (1336-36-3) Freshwater Acute Chronic Saltwater Acute Chronic	5x10 ⁻⁴ mg/L 2.0 µg/L 0.014 µg/L 10 µg/L 0.03 µg/L	UATW 1999b UATW 1999c
ID	Fish consumption Primary water standard	7.9x10 ⁻⁵ µg/L 5x10 ⁻⁴ mg/L	UATW 1999e

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Table 8-1. Regulations and Guidelines Applicable to PCBs (continued)

Agency	Description	Information	References
<u>STATE</u> (cont'd)			
b. Water:			
KS	Acceptable water concentrations		
	Aquatic life		CDC 1999e
	Acute	2 mg/L	
	Chronic	0.014 mg/L	
	Public health		
NJ	Food procurement	7.9×10^{-6} mg/L	
	Domestic water supply	0.5 mg/L	
NJ	Groundwater quality criteria for PCBs (1336-36-3)	0.02 µg/L	CDC 1999a
c. Fish and Wildlife Advisory for PCB ¹ :			EPA 2000b
AL		Fish	
AR		Fish	
CT		Fish	
DE		Fish	
HI		Fish	
IA		Fish	
IN		Fish	
KY		Fish	
LA		Fish	
MA		Fish, turtles, and frogs	
ME		Fish	
MI		Fish	
MO		Fish	
MS		Fish	
NJ		Fish	
NY		Fish, and waterfowl	
OH		Fish	
PA		Fish	
RI		Fish	
SC		Fish	
TN		Fish	

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Table 8-1. Regulations and Guidelines Applicable to PCBs (continued)

Agency	Description	Information	References
<u>STATE</u> (cont'd)			
c. Fish and Wildlife Advisory for PCB ^j : (cont'd)			EPA 2000b
TX		Fish	
VA		Fish	
WI		Fish	

^aProbably carcinogenic to humans

^bSufficient evidence from animal studies to assume probable human carcinogen

^cThis criterion is based on carcinogenicity of 10⁻⁶ risk. Alternate risk levels may be obtained by moving the decimal point (e.g., for a risk level of 10⁻⁵, move the decimal point in the recommended criterion one place to the right.)

^dPQL: practical quantitation limit; this PQL is an average value for PCB congeners.

^eThe waste water and non-waste water standard applies to all PCB isomers.

^fConfirmed animal carcinogen with unknown relevance to humans

^gProbable human carcinogen

^hderived from equation 18 for consumption of water and fish which is as follows:

$$\text{Conc. (mg/L)} = (\text{HBW} \times \text{RL}) / (\text{CPF} \times [(\text{FCR} \times \text{BCF}) + \text{WCR}])$$

Where:

HBW = human body weight, set at 70 kg

RL = risk level, 1x10⁻⁵

CPF = cancer potency factor, 7.7 (kg-day)/mg

FCR = fish consumption rate, set at 0.030 kg/day

BCF = bioconcentration factor, given in appendix A, 31200 l/kg

WCR = water consumption rate, 2 l/kg

ⁱderived from equation 19 for consumption of fish only which is as follows:

$$\text{Conc. (mg/L)} = \{\text{HBW} \times \text{RL}\} / (\text{CPF} \times \text{FCR} \times \text{BCF})$$

Where:

HBW = human body weight, set at 70 kg

RL = risk level, 1x10⁻⁵

CPF = cancer potency factor, 7.7 (kg-day)/mg

FCR = fish consumption rate, set at 0.030 kg/day

BCF = bioconcentration factor, given in appendix A, 31200 l/kg

^jThis information, current as of 2000, is based on the EPA Fish and Wildlife Advisory Database searched 8/00 on the Internet at <http://www.epa.gov/OST/fishadvice/>. For more detailed information, consult your state public health or natural resources department. A fish or wildlife advisory will specify the bodies of water or hunting areas with restrictions. The advisory will indicate the species and size of fish or game of concern. The advisory may completely ban consumption or recommend limiting the number of servings of a certain fish or wildlife species to less than a particular frequency. The advisory may indicate that only certain parts of the fish or game should be consumed and recommend preparation methods to minimize exposure. The advisory may have stricter restrictions than for the general public to protect pregnant women, nursing mothers, and young children. Each state, Native American tribe, or U.S. territory chooses its own criteria for issuing fish and wildlife advisories.

CFR = Code of Federal Regulations; EPA = Environmental Protection Agency; FDA = Food and Drug Administration; HBGL = health based guidance levels for drinking water; IARC = International Agency for Research on Cancer; IRIS = Integrated Risk Information System; MCL = maximum contaminant limit; MCLG = maximum contaminant limit goal; NIOSH = National Institute of Occupational Safety and Health; OSHA = Occupational Safety and Health Administration; PEL = permissible exposure limit; PQL = practical quantitation limit; RfD = oral reference dose; REL = recommended exposure release; TLV = threshold limit value; TWA = time-weighted average; USC = United States Code

