7. REGULATIONS AND ADVISORIES

The international, national, and state regulations and guidelines pertaining to endosulfan and its metabolites in air, water, and other media are summarized in Table 7-1.

ATSDR has derived an intermediate-duration oral MRL of 0.005 mg/kg/day for endosulfan based on a NOAEL for immunological effects in rats (Banerjee and Hussain 1986).

ATSDR has derived a chronic-duration oral MRL of 0.002 mg/kg/day for endosulfan based on a NOAEL for hepatic effects in dogs (Hoechst 1989c).

EPA's Integrated Risk Information System (IRIS) lists an oral reference dose (RfD) of 0.006 mg/kg/day for endosulfan (IRIS 2000). No reference concentration (RfC) for chronic inhalation exposures to endosulfan was reported.

The U.S. EPA and the International Agency for Research on Cancer (IARC) have not classified endosulfan as to its carcinogenicity (IARC 1987, 1998). Studies conducted by the National Toxicology Program (NTP) using rats and mice indicated inadequate and negative evidence, respectively, for carcinogenic effect from endosulfan (NTP 1991). No data were available for studies conducted for the metabolites of endosulfan.

Endosulfan, α-endosulfan, and β-endosulfan have been designated as a hazardous substances pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980 (EPA 1995a, 1996b). The statutory source for this designation for the alpha- and beta- compounds is Section 307 of the Clean Water Act (CWA). In addition to Section 307 of the CWA, the designation for endosulfan is based on section 311(b)(4) of the CWA, and section 3001 of the Resource Conservation and Recovery Act (RCRA) (EPA 1995a). The owner and operator of any facility that produces, uses, or stores a CERCLA hazardous substance in an amount exceeding the "threshold planning quantity" are required to immediately report any release to any environmental media, if the amount released is equal to or exceeds the specified "reportable quantity" assigned to the substance. As a hazardous substance that is formulated as a solid, endosulfan is subject to either of two threshold planning quantities (EPA 1996b). If a solid hazardous substance exits in powdered form and has a particle size less than 100 microns, then it is subject to the lower number. If the solid does not meet this criteria, then it is subject to the higher number. The threshold reporting quantities for endosulfan are 10 and 10,000 pounds (4.54 and 4,540 kg)

Table 7-1. Regulations and Guidelines Applicable to Endosulfan

Agency	Description	Information	References
INTERNATIONAL Guidelines:			
IARC	Cancer Classification	None	IARC 1987
WHO	Drinking-water guideline values for health-related organics	None	WHO 1984
NATIONAL Regulations and Guidelines:			
a. Air:			
ACGIH	TLV-TWA (skin)	0.1 mg/m^3	ACGIH 1999
NIOSH	REL TWA (skin)	0.1 mg/m^3	NIOSH 1999
OSHA	PEL 8-hr TWA		
	Current	None	OSHA 1989a
	Vacated[a]	0.1 mg/m^3	OSHA 1993
	OSHA Standards for Shipyard Employment–endosulfan	0.1 mg/m^3	29 CFR 1915.1000, OSHA 1999a
	TLV for Construction Workers–endosulfan	0.1 mg/m^3	29 CFR 1926.55, OSHA 1999b
b. Water			
EPA	Ambient water quality criteria for protection of human health for alpha-, beta-endosulfan and endosulfan sulfate[b]:		EPA 1999c
	water and organisms	110 µg/L	
	organisms only	240 µg/L	
	Ambient water quality criteria for protection of aquatic life for alpha-, beta-endosulfan and endosulfan sulfate[b]:		EPA 1999c
	Freshwater	0.22 µg/L	
	Saltwater	0.034 µg/L	
	Universal treatment standards	Waste water	40 CFR 268.48, EPA 1999b
	alpha-endosulfan	0.023 mg/L	
	beta-endosulfan	0.029 mg/L	
	endosulfan sulfate	0.029 mg/L	
		Non-waste water	
	alpha-endosulfan	0.066 mg/L	
	beta-endosulfan	0.13 mg/L	
	endosulfan sulfate	0.13 mg/L	

Table 7-1. Regulations and Guidelines Applicable to Endosulfan *(continued)*

Agency	Description	Information	References
NATIONAL (contd)			
	Water Quality Guidance for the Great Lakes System—Pollutants that are bioaccumulative	Yes	40 CFR 132, EPA 1995d
c. Food:			
	Pesticide Classification for endosulfan and endosulfan sulfate	Chlorinated organic pesticide	40 CFR 180.3 EPA 1998g
	Tolerances for endosulfan and endosulfan sulfate residues in or on raw agricultural commodities	0.1–2.0 ppm range for 79 commodities	40 CFR 180.182, EPA 1998h
	Pesticide Tolerances in Food–endouslfan and endosulfan sulfate residue in or on dried tea	24 ppm	40 CFR 185.2600 EPA 1998k
d. Other:			
ACGIH	Cancer Classification	A4[c]	ACGIH 1999
ATSDR	Minimal Risk Level		
	intermediate-duration oral	0.005 mg/kg/day	Banerjee and Hussain 1986
	chronic-duration oral	0.002 mg/kg/day	Hoechst 1989c
EPA	RfD (Oral) Carcinogenic classification Oral slope factor	$6x10^{-3}$ mg/kg/day No data No data	IRIS 1999
	Reportable quantities of hazardous substances		40 CFR 302.4, EPA 1999d
	Endosulfan - designated CERCLA hazardous substance under sections 311(b)(4), and 307(a), of the Clean Water Act and RCRA section 3001	1 pound (0.454 kg)	
	Alpha-endosulfan - designated CERCLA hazardous under section 307(a) of the Clean Water Act	1 pound (0.454 kg)	
	Beta-endosulfan - designated CERCLA hazardous under section 307(a) of the Clean Water Act	1 pound (0.454 kg)	

Table 7-1. Regulations and Guidelines Applicable to Endosulfan *(continued)*

Agency	Description	Information	References
NATIONAL (contd)			
	Endosulfan sulfate - designated CERCLA hazardous under section 307(a) of the Clean Water Act	1 pound (0.454 kg)	
	Statutory source for designation as a CERCLA Hazardous Substance	Yes	Clean Water Act, U.S. Congress 1977
	Designated hazardous substance in accordance with section 311(b)(2)(a) of the Act	Yes	40 CFR 116.4 EPA 1998l
	Toxic chemical release reporting; community right-to-know list	Not included	40 CFR 372.65, EPA 1998j
	Included in the list of organic pesticide active ingredients	Yes	40 CFR 455.67, EPA 1998e
	Identification and Listing of endosulfan as a Hazardous Waste	Yes	40 CFR 261.33, EPA 1999a
	Designated toxic pollutant under Section 307(a)(1) of the Act– endosulfan and its metabolites	Yes	40 CFR 401.15 EPA 1998m
STATE Regulations and Guidelines:			
a. Air:			
Arizona	Average acceptable ambient air concentrations[d] (1 hour) (24 hours)	 2.4 µg/m^3 0.8 µg/m^3	NATICH 1992
Connecticut	Average acceptable ambient air concentrations[d]— (8 hours)	2 µg/m^3	
Florida (Pinella)	Average acceptable ambient air concentrations[d] (8 hours) (24 hours) (1 year)	 1 µg/m^3 0.24 µg/m^3 0.05 µg/m^3	
Idaho	Acceptable concentration Occupational exposure level	0.005 mg/m^3 0.1 mg/m^3	Idaho Department of Health and Welfare 1999
Kansas	Average acceptable ambient air concentrations[d]— (1 year)	0.238 µg/m^3	NATICH 1992
Nevada	Average acceptable ambient air concentrations[d]— (8 hours)	0.002 µg/m^3	
North Dakota	Average acceptable ambient air concentrations[d]— (8 hours)	1x10^{-3} µg/m^3	
Oklahoma	Average acceptable ambient air concentrations[d]— (24 hours)	1.0 µg/m^3	

Table 7-1. Regulations and Guidelines Applicable to Endosulfan *(continued)*

Agency	Description	Information	References
STATE (contd)			
Pennsylvania	Average acceptable ambient air concentrations[d]— (1 year)	2.4 µg/m^3	
Texas	Average acceptable ambient air concentrations[d]		
	(30 minutes)	1 µg/m^3	
	(1 year)	0.1 µg/m^3	
Virginia	Average acceptable ambient air concentrations[d]— (24 hours)	1.7 µg/m^3	
Washington	Average acceptable ambient air concentrations[d]— (24 hours)	0.3 µg/m^3	
Wisconsin	Acceptable emission levels		Wisconsin Department Natural Resources 1997
	<25 feet	$8.4x10^{-3}$ lbs/hr	
	25 feet	$3.4x10^{-2}$ lbs/hr	
b. Water:			
Alabama	Aquatic life:	acute (µg/L) / chronic (µg/L)	BNA 1998
	Freshwater–alpha-endosulfan and beta-endosulfan	0.22 / 0.56	
	Marine alpha-endosulfan and beta-endosulfan	acute (µg/L) / chronic (µg/L)	
		0.34 / $8.7x10^{-3}$	
	Aquatic Life Criteria for alpha-, and beta-endosulfan:		Alabama Department of Environmental Management 1998
	Freshwater acute	0.22 µg/L	
	Freshwater chronic	$5.6x10^{-2}$ µg/L	
	Marine acute	$3.4x10^{-2}$ µg/L	
	Marine chronic	$8.7x10^{-3}$ µg/L	
	Human health criteria for alpha- and beta-endosulfan and endosulfan sulfate[e]:		
	water and fish	$3.5X10^{-4}$ mg/L	
	water only	$4.3X10^{-4}$ mg/L	
Arizona	Drinking water quality guidelines for Endosulfan	74 µg/L	FSTRAC 1995
	Human health based guidance levels (HBGLS)for ingestion of contaminents in drinking water		Arizona Department of Health Services 1999
	Oral HBGL	42 ug/L	
Colorado	Aquatic life based criteria for surface waters— endosulfan		Colorado Department of Public Health and Environment 1999
	Acute	0.11 µg/L	
	Chronic	0.056 µg/L	
	Human health based for surface water— endosulfan sulfate		
	water and organism	110 µg/L	
	water only	Not given	

Table 7-1. Regulations and Guidelines Applicable to Endosulfan *(continued)*

Agency	Description	Information	References
STATE (contd)			
Hawaii	Health guidelines applicable to all water:		Hawaii Department of Health 1999
	Freshwater		
	acute	0.22 µg/L	
	chronic	0.056 µg/L	
	Saltwater		
	acute	0.034 µg/L	
	chronic	0.0087 µg/L	
	Fish consumption	52 µg/L	
Kansas	Surface water quality standards for aquatic life for endosulfan, and alpha- and beta-endosulfan		Kansas State Health and Environment 1998
	acute	0.22 mg/L	
	chronic	0.056 mg/L	
New Jersey	Ground water quality for endosulfan, alpha- and beta-endosulfan, and endosulfan sulfate	0.4 µg/L	New Jersey Dept of Environmental Protection 1993

[a]Since June 27, 1974, OSHA had promulgated permissible exposure limits (PELs) for approximately 264 toxic substances. On January 18, 1989, OSHA promulgated more protective PELs for approximately 376 toxic substances. In July 1992, the 11th Circuit Court Appeals rescinded the 1989 promulgation. On March 23, 1993, OSHA resumed enforcing the air contaminant exposure limits that were in effect prior to the issuance of the new limits in 1989 (i.e., OSHA 1974 PELs). Prior to the 1989 promulgation, OSHA had not established a PEL for endosulfan. On June 30, 1993, OSHA published in the Federal Register a final rule announcing the revocation of the 1989 exposure limits.

[b]This criterion is based on 304(a) aquatic life criterion issued in 1980 and was also issued in EPA 440/5-80-046, EPA 1980a. The values are different as they are derived differently.

[c]Not classifiable as a human carcinogen

[d]The values listed in NATICH 1992 as "acceptable ambient concentrations guidelines or standards" may not be referred to as such by certain States and localities. For example, the values listed for Connecticut are referred to as "hazard limiting values"

[e]The following equations were used to calculate the values as given in the Alabama State laws:
Consumption of water and fish: Concentration (mg/L) = (HBW X RfD) / [(FCR X BCF) + WCR]
Consumption of water only: Concentration (mg/L) = (HBW X RfD) / (FCR X BCF)
HBW = human body weight, set at 70 kg
RfD = reference dose, 0.00005 mg/(kg-day) for alpha-, beta-endosulfan, and endosulfan sulfate
FCR = fish consumption rate, set at 0.030 kg/day
BCF = bioconcentration factor, 270 L/kg for alpha-, beta-endosulfan, and endosulfan sulfate
WCR = water consumption rate, set at 2 L/day

ACGIH = American Conference of Governmental Industrial Hygienists; ATSDR = Agency for Toxic Substances and Disease Registry; CERCLA = Comprehensive Environmental Response, Compensation, and Liability Act; CFR = code of federal regulations; EPA = Environmental Protection Agency; FSTRAC = Federal State Toxicology and Regulatory Alliance committee; IARC = International Agency for Research on Cancer; IRIS = Integrated Risk Information System; NATICH = National Air Toxics Information Clearinghouse; NIOSH = National Institute of Occupational Safety and Health; OSHA = Occupational Safety and Health Administration; PEL = permissible exposure limit; PQL = practical quantitation limit; REL = recommended exposure limit; RfD = oral reference dose; TLV= threshold limit value; TWA = time-weighted average; WHO = World Health Organization

(EPA 1996b). The reportable quantity for endosulfan and its metabolites is 1 pound (0.454 kg) (EPA 1995a). Endosulfan and its metabolites do not appear on the list of toxic chemicals subject to Section 313 of the Emergency Planning and Community Right-to-Know-Act of 1986 (EPA 1995c).

Endosulfan and its metabolite, endosulfan sulfate, are classified as a chlorinated organic pesticides. The EPA regulates endosulfan and endosulfan sulfate as pesticide chemicals and has established tolerance limits for their residues in or on raw agricultural commodities. Tolerances for "total residue" for each of these insecticides ranging from 0.1 (negligible residue) ppm to 2 ppm have been established for approximately 79 commodities (EPA 1982a). Many pesticide chemicals within the chlorinated organic pesticide class have pharmacological effects related to other classes of pesticides. For example, pesticide chemicals in the chlorinated organics, arsenic-containing, metallic dithiocarbamates, and the cholinesterase-inhibiting classes have related pharmacological effects. When applied to agricultural commodities, and there is no contrary evidence, pesticide chemicals that cause related pharmacological effects are regarded as having an additive deleterious action (EPA 1993b). Tolerances established for such related pesticide chemicals may limit the amount of common component (e.g., As_2O_3) that may be present, the amount of biological activity (e.g., cholinesterase inhibition), or the total amount of related pesticide chemical that may be present (EPA 1993b). The EPA has established a tolerance limit of 24 ppm for endosulfan residues in or on dried tea. When endosulfan is applied to growing tea this limit reflects a residue level of 0.1 ppm in beverage tea (EPA 1988d).

Between June 27, 1974 and January 18, 1989, the Occupational Safety and Health Administration (OSHA) had promulgated protective, permissible exposure limits (PELs) for approximately 264 toxic substances (OSHA 1993). The OSHA PELs were established to protect workers against adverse health effects resulting from exposure to hazardous substances. The PELs determined for hazardous substances are enforceable, regulatory limits on allowable indoor air concentrations. OSHA requires employers of workers who are occupationally exposed to these hazardous air contaminants to institute engineering controls and work practices to reduce and maintain employee exposure at or below PELs. An employer must ensure that an employee's exposure in any 8-hour work shift of a 40-hour week does not exceed the 8-hour time-weighted average (TWA) established for the air contaminant (OSHA 1993). On January 18, 1989, OSHA promulgated more protective PELs for approximately 376 toxic substances. Endosulfan was included among 164 toxic substances not previously regulated (OSHA 1989b). The newly established PEL for endosulfan was set at 0.1 mg/m^3 (OSHA 1989a). OSHA also provided a "skin designation" for endosulfan. The skin designation would indicate a potential for dermal absorption and the need for employers to implement the use of good work practices including providing workers with

gloves, coveralls, goggles, and other appropriate equipment in order to prevent skin exposures (NIOSH 1997). Because the 1989 promulgation was rescinded by the 11th Circuit Court Appeals in July 1992, only those PELs in place prior to the 1989 rule are currently enforced by OSHA. On June 30, 1993, OSHA published in the Federal Register a final rule announcing the revocation of the 1989 exposure limits, including the newly established limits for endosulfan (OSHA 1993). Currently, there is no OSHA PEL for endosulfan. However, the National Institute for Occupational Safety and Health (NIOSH) and several states adopted the 0.1 mg/m^3 exposure limit for endosulfan that was initially promulgated by OSHA (NIOSH 1992, 1997). In the construction industry, exposure of employees to endosulfan through inhalation, ingestion, skin absorption, or contact should not exceed the "Threshold Limit Values(TLVs) of Airborne Contaminants for 1970" established by the American Conference of Governmental Industrial Hygienists (ACGIH) (OSHA 1997a). The ACGIH exposure limit for endosulfan is 0.1 mg/m^3 (ACGIH 1998a; OSHA 1997a, 1997b).

Endosulfan and its metabolites are included on the list of toxic pollutants regulated by the Effluent Guidelines and Standards provided in Subchapter N of Title 40 of the Code of Federal Regulations (40 CFR) (EPA 1992c). Pursuant to the Clean Water Act (CWA) these regulations prescribe effluent limitations guidelines for existing sources, standards of performance for new sources, and pretreatment standards for new and existing sources (EPA 1992c). The point source categories for which endosulfan sulfate is a regulated toxic pollutant are the electroplating (EPA 1986a), steam electric power generating (EPA 1992d), and metal finishing (EPA 1986b).

Endosulfan is regulated as a waste water pollutant in discharges from new and existing facilities that formulate, package, and repackage pesticide products. Facilities of this type make up two subcategories of the Pesticide Chemicals Point Source Category—Subcategory C: Pesticide Formulating, Packaging and Repackaging, which includes facilities that also manufacture pesticide active ingredients (PAIs), and Subcategory E: Repackaging of Agricultural Pesticides Performed at Refilling Establishments (EPA 1996a). As of January 6, 1997, the regulatory limit for Subcategory C facilities on the discharge of waste water pollutants into navigable waters and into publicly owned treatment works (POTWs) is a choice between zero discharge or compliance with the pollution prevention alternative provided in Table 8 of 40 CFR 455 (EPA 1996a). Subcategory E facilities are required to achieve the "zero" criterion for discharge of waste water pollutants (EPA 1996a). Some of the PAIs to which these effluent guidelines and standards do not apply are sanitizers, including pool chemicals; microorganisms, such as *Bacillus thuringiensis;* and certain liquid chemical sterilants that are used on critical or semi-critical medical devices (EPA 1996a). Complete listings of PAIs that are not required to meet the Subcategory C

and E guidelines and standards can be found in 40 CFR 455.40 and 40 CFR 455.60, respectively. Endosulfan sulfate is regulated and monitored along with other toxic organic compounds as total toxic organics (TTO) in the discharges from the aluminum forming point source category (EPA 1988b). The term total toxic organic means the sum of the masses or concentrations of all toxic organic compounds found in the discharge at a concentration greater than 0.010 mg/L (EPA 1988b).

In terms of toxicity, NIOSH recommends that endosulfan be recognized as a Group 1 Pesticide (NIOSH 1992). Pesticides in Group 1 pose a significant risk of adverse acute health effects at low concentrations or carcinogenic, teratogenic, neurotoxic, or reproductive effects (NIOSH 1992).