CHAPTER 7. REGULATIONS AND GUIDELINES

Pertinent international and national regulations, advisories, and guidelines regarding DEHP in air, water, and other media are summarized in Table 7-1. This table is not an exhaustive list, and current regulations should be verified by the appropriate regulatory agency.

ATSDR develops MRLs, which are substance-specific guidelines intended to serve as screening levels by ATSDR health assessors and other responders to identify contaminants and potential health effects that may be of concern at hazardous waste sites. See Section 1.3 and Appendix A for detailed information on the MRLs for DEHP.

Table 7-1. Regulations and Guidelines Applicable to DEHP					
Agency	Description	Information	Reference		
Air					
EPA	RfC	Not evaluated	IRIS 1988		
WHO	Air quality guidelines	Not listed	WHO 2010		
Water & Food					
EPA	Drinking water standards and health advisories		EPA 2018a		
	DWEL	0.7 mg/L			
	10 ⁻⁴ cancer risk	0.3 mg/L			
	National primary drinking water regulations	;	EPA 2009c		
	Maximum contaminant level	0.006 mg/L			
	Public health goal	0			
	RfD	2x10 ⁻² mg/kg/day	<u>IRIS 1988</u>		
WHO	Drinking water quality guidelines		WHO 2017		
	Guideline value	0.008 mg/L (8 µg/L)			
	Tolerable daily intake	25 μg/kg body weight			
FDA	Substances added to food ^a	Not listed	FDA 2020		
	Indirect additives used in food contact substances ^b	Allowed for some uses	FDA 2019a		
	Allowable level in bottled water	0.006 mg/L	FDA 2019b		
	Tolerable intake value (oral)	0.04 mg/kg/day	FDA 2001		
Cancer					
HHS	Carcinogenicity classification	Reasonably anticipated to be a human carcinogen	NTP 2016		
EPA	Carcinogenicity classification	Group B2 ^c	IRIS 1988		
IARC	Carcinogenicity classification	Group 2Bd	IARC 2013		

7. REGULATIONS AND GUIDELINES

Table 7-1. Regulations and Guidelines Applicable to DEHP					
Agency	Description	Information	Reference		
Occupational					
OSHA	PEL (8-hour TWA) for general industry, shipyards, and construction	5 mg/m ³	OSHA <u>2019a</u> , <u>2019b</u> , <u>2019c</u>		
NIOSH	REL (up to 10-hour TWA)	5 mg/m³ e	NIOSH 2019		
	STEL	10 mg/m ³			
Emergency Criteria					
EPA	AEGLs-air	Not listed	EPA 2018b		
DOE	PACs-air		DOE 2018a		
	PAC-1 ^f	10 mg/m³			
	PAC-2 ^f	1,000 mg/m ³			
	PAC-3 ^f	6,100 mg/m ³			

^aThe Substances Added to Food inventory replaces EAFUS and contains the following types of ingredients: food and color additives listed in FDA regulations, flavoring substances evaluated by FEMA or JECFA, GRAS substances listed in FDA regulations, substances approved for specific uses in food prior to September 6, 1958, substances that are listed in FDA regulations as prohibited in food, delisted color additives, and some substances "no longer FEMA GRAS."

AEGL = acute exposure guideline levels; CFR = Code of Federal Regulations; DEHP = di(2-ethylhexyl)phthalate; DOE = Department of Energy; DWEL = drinking water equivalent level; EAFUS = Everything Added to Food in the United States; EPA = Environmental Protection Agency; FDA = Food and Drug Administration; FEMA = Flavor and Extract Manufacturers Association of the United States; GRAS = generally recognized as safe; HHS = Department of Health and Human Services; IARC = International Agency for Research on Cancer; IRIS = Integrated Risk Information System; JECFA = Joint FAO/WHO Expert Committee on Food Additives; NIOSH = National Institute for Occupational Safety and Health; NTP = National Toxicology Program; OSHA = Occupational Safety and Health Administration; PAC = Protective Action Criteria; PEL = permissible exposure limit; REL = recommended exposure limit; RfC = inhalation reference concentration; RfD = oral reference dose; STEL = short-term exposure limit; TWA = time-weighted average; WHO = World Health Organization

^bThe Indirect Additives Used in Food Contact Substances list is a compilation of substances found in 21 CFR parts 175–178.

^cGroup B2: probable human carcinogen.

^dGroup 2B: possibly carcinogenic to humans.

ePotential occupational carcinogen.

^fDefinitions of PAC terminology are available from DOE (2018b).