

CHAPTER 7. REGULATIONS AND GUIDELINES

Pertinent international and national regulations, advisories, and guidelines regarding ethylene oxide 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 ethylene oxide.

Table 7-1. Regulations and Guidelines Applicable to Ethylene Oxide

Agency	Description	Information	Reference
Air			
EPA	RfC	Not assessed	EPA 2016 , IRIS 2021
OEHHA	RfC (chronic)	30 µg/m ³ (18 ppb)	OEHHA 2008
WHO	Air quality guidelines	No data	WHO 2010
Water & Food			
EPA	Drinking water standards and health advisories	Not listed	EPA 2018d
	National primary drinking water regulations	Not listed	EPA 2009
	RfD	Not assessed	EPA 2016 , IRIS 2021
WHO	Drinking water quality guidelines	No data	WHO 2017
FDA	Substances added to food	No longer FEMA GRAS ^a	FDA 2021
Cancer			
HHS	Carcinogenicity classification	Known to be a human carcinogen	NTP 2016
EPA	Carcinogenicity classification	Carcinogenic to humans	EPA 2016
	Inhalation unit risk (lifetime-based for lymphoid and female breast cancer combined)	5.0x10 ⁻³ per µg/m ³ (9.1x10 ⁻³ per ppb) for environmental ethylene oxide exposures up to about 40 µg/m ³ (20 ppb)	
	Inhalation unit risk (adult-based for lymphoid and female breast cancer combined)	3.0x10 ⁻³ per µg/m ³ (5.5x10 ⁻³ per ppb) for environmental ethylene oxide exposures up to about 40 µg/m ³ (20 ppb)	
IARC	Carcinogenicity classification	Group 1 ^b	IARC 2012 , IARC 2021

7. REGULATIONS AND GUIDELINES

Table 7-1. Regulations and Guidelines Applicable to Ethylene Oxide

Agency	Description	Information	Reference
Occupational			
OSHA	PEL (8-hour TWA) for general industry, shipyards, and construction	1 ppm (1.83 mg/m ³)	OSHA 2021a , 2021b , 2021c
	Excursion limit ^c (15-minute) for general industry, shipyards, and construction	5 ppm (9.15 mg/m ³)	
NIOSH	REL (up to 10-hour TWA)	<0.1 ppm ^d (<0.183 mg/m ³)	NIOSH 2019
	Ceiling REL (10-minute/day)	5 ppm (9.15 mg/m ³)	
	IDLH	800 ppm (1,464 mg/m ³)	NIOSH 1994
Emergency Criteria			
EPA	AEGLs-air ^e		EPA 2018e
	AEGL 2 ^f		
	10-minute	80 ppm (146.4 mg/m ³)	
	30-minute	80 ppm (146.4 mg/m ³)	
	60-minute	45 ppm (82.35 mg/m ³)	
	4-hour	14 ppm (25.62 mg/m ³)	
	8-hour	7.9 ppm (14.46 mg/m ³)	
	AEGL 3 ^f		
	10-minute	360 ppm (658.8 mg/m ³)	
	30-minute	360 ppm (658.8 mg/m ³)	
	60-minute	200 ppm (366 mg/m ³)	
	4-hour	63 ppm (115.29 mg/m ³)	
	8-hour	35 ppm (64.05 mg/m ³)	

7. REGULATIONS AND GUIDELINES

Table 7-1. Regulations and Guidelines Applicable to Ethylene Oxide

Agency	Description	Information	Reference
DOE	PACs-air		DOE 2018a
	PAC-1 ^g	5 ppm (9.15 mg/m ³)	
	PAC-2 ^g	45 ppm (82.35 mg/m ³)	
	PAC-3 ^g	200 ppm (366 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 from use in food, delisted color additives, and some substances "no longer FEMA GRAS."

^bGroup 1: carcinogenic to humans.

^cExposure not to exceed 5 ppm as averaged over a sampling period of 15 minutes.

^dPotential occupational carcinogen.

^eNo recommendations for AEGL 1 due to insufficient data.

^fDefinitions of AEGL terminology are available from U.S. Environmental Protection Agency (EPA 2018f).

^gDefinitions of PAC terminology are available from U.S. Department of Energy (DOE 2018b).

AEGL = acute exposure guideline level; DOE = Department of Energy; EAFUS = Everything Added to Food in the United States; EPA = Environmental Protection Agency; FAO = Food and Agricultural Organization of the United Nations; FDA = Food and Drug Administration; FEMA = Flavor and Extract Manufacturers Association; GRAS = generally recognized as safe; HHS = Department of Health and Human Services; IARC = International Agency for Research on Cancer; IDLH = immediately dangerous to life or health; 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; OEHHA = California's Office of Environmental Health Hazard Assessment; 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; TWA = time-weighted average; WHO = World Health Organization