CHAPTER 7. REGULATIONS AND GUIDELINES

Pertinent international and national regulations, advisories, and guidelines regarding NDMA 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 NDMA.

Table 7-1. Regulations and Guidelines Applicable to N-Nitrosodimethylamine (NDMA)

Agency	Description	Information	Reference
	Air		
EPA	RfC	Not evaluated	IRIS 1987
WHO	Air quality guidelines	No data	WHO 2010
	Water & Food		
EPA	Drinking water standards and health advisories		EPA 2018a
	1-Day health advisory (10-kg child)	No data	
	10-Day health advisory (10-kg child)	No data	
	DWEL	No data	
	Lifetime health advisory	No data	
	10^{-4} Cancer risk	0.00007 mg/L	
	National primary drinking water regulations	Not listed	EPA 2009
	RfD	Not evaluated	IRIS 1987
	Provisional peer-reviewed toxicity values		EPA 2007
	Provisional RfD, subchronic and chronic	$8x10^{-6}$ mg/kg/day	
WHO	Drinking water quality guidelines		WHO 2022
	Guideline value	0.0001 mg/L	
FDA	Substances Added to Food[a]	Not listed	FDA 2020b
	Action level for malt beverages	5 ppb (0.005 mg/L)	FDA 2005a
	Action level for rubber baby bottle nipples	10 ppb (µg/kg)	FDA 2005b
	Acceptable intake limit in drug products	96 ng/day[b]	FDA 2021
	Cancer		
HHS	Carcinogenicity classification	Reasonably anticipated to be a human carcinogen	NTP 2021

Table 7-1. Regulations and Guidelines Applicable to N-Nitrosodimethylamine (NDMA)

Agency	Description	Information	Reference
EPA	Carcinogenicity classification	B2[c]	IRIS 1987
	Inhalation unit risk	1.4×10^{-2} per µg/m^3	
	Cancer slope factor	51 per mg/kg/day	
	Cancer slope factor	21 per mg/kg/day	EPA 2016
IARC	Carcinogenicity classification	Group 2A[d]	IARC 1987
	Occupational		
OSHA	PEL (8-hour TWA) for general industry, shipyards and construction	No data	OSHA 2021a, 2021b, 2021c
	Worker exposure to be controlled through the required use of engineering controls, work practices, and personal protective equipment, including respirators		OSHA 2021d
NIOSH	REL (up to 10-hour TWA)	No data[e]	NIOSH 2019
	Emergency Criteria		
EPA	AEGLs-air	No data	EPA 2018b
DOE	PACs-air		DOE 2018a
	PAC-1[f]	0.082 mg/m^3	
	PAC-2[f]	0.9 mg/m^3	
	PAC-3[f]	10 mg/m^3	

[a]The 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."
[b]Limit if NDMA is the only nitrosamine. If the total quantity of nitrosamine impurities exceeds 26.5 ng/day, the manufacturer should contact the FDA for evaluation.
[c]B2: probable human carcinogen.
[d]Group 2A: probably carcinogenic to humans.
[e]Potential occupational carcinogen.
[f]Definitions of PAC terminology are available from DOE (2018b).

AEGL = acute exposure guideline levels; 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; TWA = time-weighted average; WHO = World Health Organization