

8. REGULATIONS AND ADVISORIES

International guidelines for ammonia were not located. National and state regulations and guidelines pertinent to human exposure to ammonia are summarized in Table 8-1.

Ammonium ion is regulated by the Clean Water Effluent Guidelines for the following industrial point sources: ferroalloy manufacturing; fertilizer manufacturing; glass manufacturing; inorganic chemicals; iron and steelmaking; landfills; nonferrous metals manufacturing; nonferrous metals forming and metal powder; paper and paperboard; petroleum refining; pharmaceutical manufacturing; pulp, meat products; and transportation equipment cleaning (EPA 2002j).

The FDA (1973) determined that concentrations of ammonia and ammonium compounds normally present in food do not suggest a health risk; ammonia and ammonium ions are recognized to be integral components of normal metabolic processes. However, some restrictions have been placed on levels of ammonium salts allowable in processed foods. Maximum allowable levels in processed foods are as follows: 0.04–3.2% ammonium bicarbonate in baked goods, grain, snack, foods and reconstituted vegetables; 2.0% ammonium carbonate in baked goods, gelatins and puddings; 0.001% ammonium chloride in baked goods and 0.8% in condiments and relishes; 0.6–0.8% ammonium hydroxide in baked goods, cheeses, gelatins and puddings; 0.01% monobasic ammonium phosphate in baked goods; and 1.1% dibasic ammonium phosphate in baked goods, 0.003% in nonalcoholic beverages, and 0.012% for condiments and relishes.

In addition to these values, ATSDR and EPA have established additional guidelines to protect people from the adverse health effects from inhaling ammonia or ingesting ammonium compounds. An acute inhalation MRL of 1.7 ppm has been derived based on the LOAEL of 50 ppm for mild irritation to the eyes, nose, and throat in humans exposed to ammonia vapors for 2 hours (Verberk et al. 1977). A chronic inhalation MRL of 0.3 ppm has been derived based on the NOAEL of 12.5 ppm for sense of smell, prevalence of respiratory symptoms (cough, bronchitis, wheeze, dyspnea, and others), eye and throat irritation, and pulmonary function parameters (FVC, FEV₁, FEV₁/FVC, FEF₅₀, and FEF₇₅) in humans exposed for an average of 15 years in a soda ash plant (Holness et al. 1989). An intermediate oral MRL of 0.3 mg NH₄/kg/day has been derived based on the NOAEL of 39.5 mg/kg/day for weight loss in rats exposed to ammonium sulfamate in drinking water 6 days/week for 90 days (Gupta et al. 1979). A chronic inhalation reference concentration (RfC) of 0.1 mg/m³ was derived (in 1991) by EPA based on

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the NOAEL for lack of evidence of decreased pulmonary function or changes in subjective symptomatology (Holness et al. 1989; IRIS 2002).

Ammonia has not undergone a complete evaluation under EPA's IRIS program for evidence of human carcinogenic potential.

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Table 8-1. Regulations and Guidelines Applicable to Ammonia

Agency	Description	Information	References
<u>INTERNATIONAL</u> Guidelines:			
IARC	Carcinogenicity classification	No data	
WHO	Drinking water quality guideline Ammonia		WHO 2002
	Threshold odor concentration	1.5 mg/L	
	Threshold taste concentration	35 mg/L	
	Health-based guideline	None proposed	
<u>NATIONAL</u> Regulations and Guidelines:			
a. Air			
ACGIH	TLV (8-hour TWA) Ammonia Ammonium chloride fume	25 ppm 10 mg/m ³	ACGIH 2001
	STEL (15-minute TWA) Ammonia Ammonia chloride fume	35 ppm 20 mg/m ³	ACGIH 2001
EPA	Accidental release prevention; toxic endpoint Ammonia (anhydrous) Ammonia (>20% concentration)	0.14 mg/L 0.14 mg/L	EPA 2002b 40CFR68, Appendix A
	Regulated toxic substance for accidental release prevention under Section 112(r) of the Clean Air Act; threshold quantity Ammonia (anhydrous) Ammonia (>20% concentration)	10,000 pounds 20,000 pounds	EPA 2002a 40CFR68.130, Table 1
NIOSH	REL (10-hour TWA) Ammonia Ammonium chloride fume	25 ppm 10 mg/m ³	NIOSH 2002b
	STEL (15-minute TWA) Ammonia Ammonium chloride fume	35 ppm 20 mg/m ³	NIOSH 2002b
	IDLH Ammonia Ammonium chloride fume	300 ppm No data	NIOSH 2002b
OSHA	PEL (8-hour TWA) for general industry Ammonia	50 ppm	OSHA 2002d 29CFR1910.1000, Table Z-1

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

Agency	Description	Information	References
<u>NATIONAL</u> (cont.)			
OSHA	PEL (8-hour TWA) for construction industry Ammonia	50 ppm	OSHA 2002c 29CFR1926.55, Appendix A
	PEL (8-hour TWA) for shipyard industry Ammonia	50 ppm	OSHA 2002a 29CFR1915.1000
	Highly hazardous chemical, toxic, and reactive for general industry; threshold quantity ^a Ammonia Ammonia solutions (>44% of ammonia by weight)	10,000 pounds 15,000 pounds	OSHA 2002e 29CFR1910.119, Appendix A
	Highly hazardous chemical, toxic, and reactive for construction industry; threshold quantity ^a Ammonia Ammonia solutions (>44% of ammonia by weight)	10,000 pounds 15,000 pounds	OSHA 2002f 29CFR1926.64, Appendix A
	Occupational safety and health standards; storage and handling of anhydrous ammonia		OSHA 2002g 29CFR1910.111
	Occupations involved in agriculture that are particularly hazardous for the employment of children below the age of 16	Transporting, transferring, or applying anhydrous ammonia	OSHA 1998 29CFR570.71 (a)(11)
	Safety and health regulations for construction; blasting and use of explosives; common blasting agent is a mixture of ammonium nitrate and carbonaceous combustibles		OSHA 2002b 29CFR1926.914(e)
b. Water			
EPA	Hazardous substance designated pursuant to Section 311(b)(2)(A) of the Clean Water Act Ammonia Ammonium chloride Ammonium fluoride Ammonium hydroxide		EPA 2002h 40CFR116.4, Table A

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

Agency	Description	Information	References
<u>NATIONAL</u> (cont.)			
EPA	Reportable quantity of hazardous substances designated pursuant to Section 311 of the Clean Water Act		EPA 2002i 40CFR117.3
	Ammonia	100 pounds	
	Ammonium chloride	5,000 pounds	
	Ammonium fluoride	100 pounds	
	Ammonium hydroxide	1,000 pounds	
USC	Assurances of availability of adequate supplies of chemicals necessary for treatment of water	Ammonia	USC 2002a 42USC300j
c. Food			
EPA	Residues from ammonium chloride, ammonium hydroxide, and ammonium sulfate are exempted from the requirement of a tolerance when used in accordance with good agricultural practice as inert (or occasionally inactive) ingredients in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest		EPA 2002e 40CFR180.1001(c)
	Ammonium nitrate is exempt from the requirement of a tolerance when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to growing crops only		EPA 2002e 40CFR180.1001(d)
	The fungicide ammonia is exempted from the requirement of a tolerance when used after harvest on the raw agricultural commodities grapefruit, lemons, oranges, and corn grain for feed use only		EPA 2002f 40CFR180.1003
FDA	Direct food substances affirmed as generally recognized as safe	Ammonium chloride	FDA 2001a 21CFR184.1138
	Direct food substances affirmed as generally recognized as safe	Ammonium hydroxide	FDA 2001b 21CFR184.1139

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

Agency	Description	Information	References
<u>NATIONAL</u> (cont.)			
FDA	Direct food substances affirmed as generally recognized as safe	Ammonium sulfate	FDA 2001c 21CFR184.1143
	Drug products containing certain active ingredients offered over-the-counter		FDA 2001d 21CFR310.545(a)
	Expectorant drug product	Ammonium chloride	
	Fever blister and cold sore treatment drug product	Ammonia solution	
	Insect bite and sting drug products	Ammonia solution and Ammonium hydroxide	
	Food additives permitted in feed and drinking water of animals	Anhydrous ammonia	FDA 2001e 21CFR573.180
	Substance generally recognized as safe when used in accordance with good manufacturing or feeding practices	Ammonium hydroxide	FDA 2001f 21CFR582.1139
	Substance generally recognized as safe when used in accordance with good manufacturing or feeding practices	Ammonium sulfate	FDA 2001g 21CFR582.1143
d. Other			
CPSC	Federal Caustic Poison Act Ammonia water and any preparation containing free or chemically uncombined ammonia, including ammonium hydroxide and "hartshorn", in a concentration of 5% or more		CPSC 2001 16CFR1500.129(1)
EPA	Ammonia		IRIS 2002
	Carcinogenicity classification	No data	
	RfC	1×10^{-1} mg/m ³	
	RfD	No data	
	CERCLA hazardous substance designated pursuant to Section 311(b)(4) of the Clean Water Act		EPA 2002d 40CFR302.4(a)
	Reportable quantity		
	Ammonia	100 pounds	
	Ammonium chloride	5,000 pounds	
	Ammonium fluoride	100 pounds	
	Ammonium hydroxide	1,000 pounds	

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

Agency	Description	Information	References	
<u>NATIONAL</u> (cont.)				
EPA	Extremely hazardous substance Ammonia		EPA 2002c 40CFR355, Appendix A	
	Reportable quantity	100 pounds		
	Threshold planning quantity	500 pounds		
	Toxic chemical release reporting; Community right-to-know; effective date for reporting Ammonia ^b Ammonium nitrate (solution)	01/01/87 01/01/87 ^c	EPA 2002g 40CFR372.65(a)	
USC	Imposition of Superfund tax on any taxable chemical sold by the manufacturer, producer, or importer Ammonia	\$2.64 per ton	USC 2002d 26USC4661	
	Refund or credit of Superfund tax paid when ammonia is used as a fertilizer		USC 2002b 26USC4662	
	Superfund taxable substance	Ammonium nitrate	USC 2002c 26USC4672	
<u>STATE</u> Regulations and Guidelines:				
a. Air		No data		
b. Water		No data		
c. Food		No data		
d. Other		No data		
Florida	Toxic substance Ammonia Ammonium chloride Ammonium fluoride Ammonium nitrate Ammonium sulfate		BLR 2002	
	Massachusetts	Hazardous substance Ammonia Ammonium chloride Ammonium fluoride Ammonium hydroxide Ammonium nitrate Ammonium sulfate		BLR 2002

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

Agency	Description	Information	References
<u>STATE (cont.)</u>			
Minnesota	Hazardous substance Ammonia Ammonium chloride, fume		BLR 2002
New Jersey	Hazardous substance Ammonia		BLR 2002
New York	Hazardous substance Ammonia Ammonium chloride Ammonium fluoride Ammonium hydroxide		BLR 2002
Pennsylvania	Hazardous substance Ammonia Ammonium chloride Ammonium fluoride Ammonium hydroxide		BLR 2002

^aPotential for a catastrophic event at or above the threshold quantity.

^bAmmonia: includes anhydrous ammonia, aqueous ammonia from water, dissociable ammonium salts, and other sources; 10% of total aqueous ammonia is reportable under this listing.

^cAmmonium nitrate (solution) is removed from this listing; the removal is effective 07/02/95, for the 1995 reporting year.

ACGIH = American Conference of Governmental Industrial Hygienists; BLR = Business & Legal Reports, Inc. CERCLA = Comprehensive Environmental Response, Compensation, and Liability Act; CFR = Code of Federal Regulations; CPSC = Consumer Protection Safety Commission; EPA = Environmental Protection Agency; FDA = Food and Drug Administration; IARC = International Agency for Research on Cancer; IDLH = immediately dangerous to life and health; IRIS = Integrated Risk Information System; NIOSH = National Institute of Occupational Safety and Health; OSHA = Occupational Safety and Health Administration; PEL = permissible exposure limit; ppm = parts per million; REL = recommended exposure limit; RfC = inhalation reference concentration; RfD = oral reference dose; STEL = short-term exposure limit; TLV = threshold limit value; TWA = time-weighted average; USC = United States Code; WHO = World Health Organization