# 2. Regulatory Framework

This section of the guidance document presents the information about the regulatory framework of 1,4-dioxane. Several federal government agencies have identified or regulated 1,4-dioxane as a hazardous substance since the early 1980s. However, 1,4-dioxane received increased scrutiny in the early 2000s after USEPA initiated a reassessment of the toxicity of 1,4-dioxane and began developing cleanup guidelines for various environmental media. In 2008, USEPA included 1,4-dioxane in the Safe Drinking Water Act Candidate Contaminant List (CCL) [(USEPA 2008a), (USEPA 2010), (USEPA 2017a)]. At the same time (early 2000s), analytical methods with lower detection and reporting limits (Cordone et al.) for soil and water samples became more readily available at commercial laboratories. Subsequently, investigators have detected 1,4-dioxane as a worldwide contaminant in various environmental media (such as air, soil, and water) and consumer products. In response to USEPA's classification of 1,4-dioxane as likely to be carcinogenic to humans (USEPA 2013b), numerous federal and state governments have developed laws and regulations to address potential exposure to 1,4-dioxane. This section of the guidance document discusses current 1,4-dioxane federal regulations, state regulations, and international standards. This material will provide users with background information that can be used in decision-making.

## 2.1 Federal Regulation of 1,4-Dioxane

There are currently at least 17 regulations from USEPA, the Food and Drug Administration (FDA), the Occupational Safety and Health Administration (OSHA), and the U.S. Department of Transportation (DOT) that impose various requirements for 1,4-dioxane. These regulations range from general surveillance and screening to formal risk management.

### 2.1.1 USEPA

USEPA addresses 1,4-dioxane in its various offices and programs. A summary of actions taken by USEPA on 1,4-dioxane are summarized below. The information is arranged by USEPA Office and by Program within each USEPA Office.

#### 2.1.1.1 Office of Water

##### 2.1.1.1.1 Health Advisories

Health advisories issued by USEPA provide information on drinking water contaminants that can cause human health effects that are known or anticipated to occur. USEPA issues health advisories for some contaminants when it does not establish enforceable drinking water standards. USEPA programs cite health advisories as a partial basis to require potentially responsible parties to implement response actions when drinking water sources are being threatened or contaminated (see Section 2.1.1.1.3).

In 1987, USEPA established a nonenforceable and nonregulatory health advisory for 1,4-dioxane of 4,120 µg/L for 1 day and 412 µg/L for 10 days of exposure to 1,4-dioxane in drinking water. In 2018, USEPA revised the health advisory established in 1987 for a 1-day and 10-day exposure, lowering the advisory levels to 4,000 µg/L and 400 µg/L, respectively.

Based on the data available in 1987, USEPA indicated that a concentration of 7–700 µg/L corresponded to a 1 in 1,000,000 and 1 in 10,000 cancer risk, respectively (USEPA 1987). In its *2012 Edition of the Drinking Water Standards and Health Advisories*, USEPA listed a health advisory of 35 µg/L for 1,4-dioxane based on a 1 in 10,000 lifetime cancer risk (USEPA 2012a). USEPA uses reference levels of 0.35–35 µg/L, which corresponds to 1:1,000,000 and 1:10,000 cancer risk, respectively, when communicating exposure risks associated with 1,4-dioxane in drinking water.

##### 2.1.1.1.2 Clean Water Act

USEPA has not published recommended surface water quality criteria for 1,4-dioxane under Section 304(a) of the Clean Water Act that are protective of aquatic life or human health. However, USEPA's Enforcement and Compliance History Online Database (Smith and Wojciechowski 1937) lists numerous NPDES permits with monitoring requirements for 1,4-dioxane and a limited number of permits containing effluent limits for the 2018 reporting period (USEPA 2019i). USEPA may also include effluent limitations in NPDES general permits. One example of this is in the NPDES General Permit for Remediation Activity Discharges for the Commonwealth of Massachusetts and the State of New Hampshire issued in 2017. This general permit includes a water quality and technology-based effluent limitation of 200 µg/L (USEPA 2017b).

##### 2.1.1.1.3 Safe Drinking Water Act—Drinking Water

The Safe Drinking Water Act (SDWA) establishes the requirements that USEPA must follow in adopting standards for drinking water quality and monitoring requirements for public water systems. Although USEPA has not adopted an MCL for 1,4-

dioxane, under the SDWA Third (2009) and Fourth (2016) CCL, USEPA has identified 1,4-dioxane as a chemical known to occur in public drinking water systems that may require regulation [(USEPA 2009); (USEPA 2017e)]. In USEPA's fourth preliminary regulatory determination, published in the Federal Register on March 10, 2020, USEPA did not make a preliminary determination to regulate 1,4-dioxane because the it had not determined whether there is meaningful opportunity for public health risk reduction (USEPA 2020a). USEPA noted that ongoing work developing a newer USEPA oral slope factor or a forthcoming 1,4-dioxane public consultation from Health Canada may inform a regulatory determination in the future. The comment period for the fourth regulatory determinations was open until June 10, 2020, and the determination has not been finalized at this time (December 2020).

USEPA required all drinking water systems serving more than 10,000 people to sample for 1,4-dioxane from 2013–2015 as part of the UCMR3 (USEPA 2012). UCMR3 also included a representative number of public water systems serving less than 10,000 people. UCMR3 included reference concentrations for 1,4-dioxane, corresponding to a 1:1,000,000 and 1:10,000 cancer risk (0.35–35 µg/L) to allow interpretation of sampling results when detections are above the minimum RLs. Sampling under this program identified that 22% of the public water systems tested had detectable levels of 1,4-dioxane above the RL of 0.07 µg/L, and 7% had 1,4-dioxane levels above the lower end of USEPA's Reference Concentration range of 0.35–35 µg/L (USEPA 2012b). None of the public water systems tested had 1,4-dioxane in their drinking water above 35 µg/L (USEPA 2017a). Currently, there are no federal requirements for public water systems to continue monitoring, and there are no water quality standards under the SDWA.

USEPA has used its authority under Section 1431 of the SDWA to direct responsible parties to implement response actions to abate 1,4-dioxane contamination at sites in Arizona and Florida ((USEPA 2007) and (USEPA 2003a)). USEPA's most recent guidance for using its emergency authority under Section 1431 of the SDWA references exceedances of health advisories under certain conditions as a basis for issuing enforcement orders to responsible parties (USEPA 2018b).

#### 2.1.1.1.4 SDWA—Underground Injection Control

USEPA regulates the construction, operation, permitting, and closure of injection wells used to place fluids underground for storage or disposal. According to data from USEPA's 2016 TRI data, 13,000 pounds of 1,4-dioxane was disposed to Class I underground injection control (UIC) wells that year (USEPA 2019b). Class I wells are used to inject hazardous and nonhazardous wastes into deep, confined rock formations. Class I wells are typically drilled thousands of feet below the lowermost underground source of drinking water. Approximately 800 operational Class I wells exist in the United States. The geologies of the Gulf Coast and the Great Lakes areas are suited for these types of wells. The TRI data does not include any data associated with the release of 1,4-dioxane to Class II-VI UIC wells. Although not reported to the TRI, 1,4-dioxane is listed as a chemical that has been injected into over 3,204 oil and gas wells based on data obtained from FracFocus, a national nongovernment hydraulic fracturing registry (GWPC 2020). Wells that are used to inject fluids associated with oil and natural gas production are considered Class II UIC wells. USEPA identified 1,4-dioxane in water produced from Class II UIC wells in Barnett, Texas, at concentrations ranging from 3.1–12 µg/L (USEPA 2016a). The presence of organic contaminants such as 1,4-dioxane in wastewater derived from hydraulic fracturing (which the oil and gas industry calls "produced water") creates challenges for reusing or disposing of large volumes of water produced from Class II wells.

Class V wells include storm water drainage wells, septic system leach fields, and agricultural drainage wells. Aquifer recharge wells and aquifer storage and recovery wells are also regulated as Class V injection wells (USEPA 2019d). USEPA has stated that treated wastewater discharged in Class V UIC wells may be contaminated with 1,4-dioxane. Although USEPA has not established regulations for 1,4-dioxane in Class V wells, states can use their authority under the SDWA to address contamination issues associated with wastewater discharges or reuse. For wastewater, USEPA provides specific recommendations for treating wastewater containing 1,4-dioxane prior to reuse (USEPA 2019d). USEPA has identified reverse osmosis and advanced oxidation processes (AOPs) as options for removing 1,4-dioxane from wastewater. See Section 6.2 for information on 1,4-dioxane in wastewater treatment.

### 2.1.1.2 Office of Chemical Safety and Pollution Prevention (OCSPP)

#### 2.1.1.2.1 Toxic Substances Control Act

The Toxic Substances Control Act (TSCA), as amended in 2016 by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA), requires mandatory evaluation of existing chemicals, risk-based assessments, and increased public transparency. 1,4-Dioxane is one of the first 10 chemicals undergoing chemical risk evaluation, a TSCA Section 6(b) requirement (USEPA 2018b). 1,4-Dioxane was selected for evaluation based on hazard information identified by USEPA and recommendations from stakeholders.

In June 2017, USEPA released a 1,4-dioxane risk evaluation scoping document for conditions of use, which was further modified in June 2018 with the release of the problem formulation (USEPA 2017c). These documents clarified that USEPA

would be evaluating the risk of 1,4-dioxane exposure to workers and occupational nonusers (workers who do not directly handle the chemical but who perform work in an area where the chemical is present) "during industrial and commercial conditions of use such as manufacturing, processing, distribution, use, and disposal." This risk evaluation explicitly excludes the unintentional occurrence of 1,4-dioxane in consumer products as a result of contamination of ethoxylated ingredients. Under the amended TSCA, states are preempted from pursuing regulatory action on chemicals for uses that USEPA evaluates in the risk evaluation. By excluding this use, states are not preempted from taking action on the presence of 1,4-dioxane in consumer products from contamination of ethoxylated ingredients.

In June 2019, USEPA released the Draft Risk Evaluation for public comment in docket EPA-HQ-OPPT-2019-0238 through August 30, 2019. The evaluation looked at 14 uses associated with the manufacturing (including import), processing, distribution, use, and disposal of 1,4-dioxane.

USEPA made the following initial determinations in the draft risk evaluation of 1,4-dioxane:

- No unreasonable risks to occupational nonusers. USEPA found no unreasonable risks to workers in the general area of 1,4-dioxane use but not directly in contact with the chemical.
- Unreasonable risks to workers in certain circumstances.
- No unreasonable risk to the environment for all the conditions of use included in the draft risk evaluation.
- Concerns of consumer exposure or exposure of the general public through ambient water or air were deferred because "other environmental statutes administered by EPA such as the Clean Air Act, the SDWA, the CWA, and RCRA, adequately assess and effectively manage these exposures."

The circumstances and conditions involved in an unreasonable risks to workers include manufacturing (domestic), processing, industrial use (intermediates, processing aids, laboratory chemicals, adhesives and sealants, professional film cement, and printing and printing compositions), and disposal.

USEPA received public comment and peer review by the TSCA Science Committee on Chemicals on the draft risk evaluation. The TSCA Science Committee on Chemicals did not accept the draft's conclusion that "other environmental statutes administered by EPA adequately assess and effectively manage these exposures"—that is, exposure of consumers and the general public. They noted that it was not clear that other statutes are being used to evaluate the risks of 1,4-dioxane exposure in the general public. As part of the process, USEPA will consider those comments in finalizing the risk evaluation and, if it finds unreasonable risks, "will propose actions to address those risks" (USEPA 2019e).

TSCA Section 8(e) requires manufacturers (including importers), processors, and distributors to immediately notify USEPA if they obtain information that supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment. USEPA's Chemview Databases contain 12 Substantial Risk Reports from manufacturers for 1,4-dioxane from 1989 through 1995.

#### 2.1.1.2.2 Emergency Planning and Community Right-to-Know Act

The storage, use, and release of 1,4-dioxane is also subject to the reporting requirements of the TRI under the Emergency Planning and Community Right-to-Know Act (USEPA 2015). According to the most recent data submitted to USEPA under the TRI, 50 facilities released a total of 614,514 pounds of 1,4-dioxane in 2017, down from a total of over 1.7 million pounds in 2014 [(USEPA 2019b); (USEPA 2015b)]. Of the 2017 total, about 58,000 pounds (9%) were released to water.

### 2.1.1.3 Office of Land and Emergency Management

#### 2.1.1.3.1 Comprehensive Environmental Response, Compensation, and Liability Act

1,4-Dioxane is considered a hazardous substance under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) [(USEPA 2019f); (USEPA 2004a)]. USEPA has established screening levels using risk assessment guidance from the USEPA Superfund program that are used for site screening and as initial cleanup goals (USEPA 2020a). Screening levels are not de facto cleanup standards but rather levels that, when exceeded, warrant further action or study. (Note: further actions or study may be warranted even if these screening levels are not exceeded.) USEPA has established oral and inhalation health-based regional screening levels (RSLs) for 1,4-dioxane for tap water and soil exposures, respectively. USEPA has also developed an RSL for soil for the protection of groundwater. These values are based on cancer effect and target risk of 1 in 1 million (1:1,000,000) (USEPA 2018f). See Section 5 for information on toxicity and risk.

Under CERCLA, 1,4-dioxane is a "hazardous substance" with a reportable quantity (RQ) of 100 pounds. Any release of 1,4-dioxane in a quantity equal to or greater than this RQ from a vessel, offshore facility, or onshore facility must be immediately reported to the National Response Center (NRC).

#### 2.1.1.3.2 Resource Conservation and Recovery Act

1,4-Dioxane is a "U listed" hazardous waste under 40 CFR 261.24 of the Resource Conservation and Recovery Act (RCRA) if it is a "discarded commercial product" (for example, a bottle of technical grade 1,4-dioxane that has reached its expiration date). Based on its flash point, 1,4-dioxane could be classified as a D001 characteristic flammable waste if present in an aqueous solution with as little as 3%–4% by weight [(Astbury 2004); (USEPA 1980)]. 1,4-Dioxane is listed in Appendix IX—Groundwater Monitoring List of RCRA, 40 CFR 264—Standards for Owners and Operators of Hazardous Waste Treatment, Storage and Disposal Facilities. The Appendix IX Groundwater Monitoring List is the detection-monitoring constituent list for facilities that are permitted under RCRA 40 CFR 264.

### 2.1.1.4 Office of Air and Radiation (OAR)

#### 2.1.1.4.1 Clean Air Act

1,4-Dioxane is a Hazardous Air Pollutant (HAP) under Section 112 (42 U.S.C. § 7412) of the Clean Air Act. Section 112(d) states that USEPA must establish National Emission Standards for Hazardous Air Pollutants (NESHAPs) for each category or subcategory of major sources and area sources of HAPs [listed pursuant to Section 112(c)]. The standards must require the maximum degree of emission reduction that USEPA determines to be achievable by each particular source category. Several source-specific NESHAPs are applicable to 1,4-dioxane, including the following:

- Organic HAPs from the Synthetic Organic Chemical Manufacturing Industry (40 CFR Part 63, Subpart F)
- Organic HAPs from the Synthetic Organic Chemical Manufacturing Industry for Process Vents, Storage Vessels, Transfer Operations, and Wastewater (40 CFR Part 63, Subpart G)
- Off-Site Waste and Recovery Operations (40 CFR Part 63, Subpart DD)
- Wood Furniture Manufacturing Operations (40 CFR Part 63, Subpart JJ)
- Pharmaceuticals Production (40 CFR Part 63, Subpart GGG)
- Group IV Polymers and Resins (thermoplastic product manufacturing) (40 CFR Part 63, Subpart JJJ)

1,4-Dioxane is subject to the New Source Performance Standards for equipment leaks of volatile organic compounds (VOCs) in the synthetic organic chemicals manufacturing industry for which construction, reconstruction, or modification began after January 5, 1981, and on or before November 7, 2006 (40 CFR Part 60, Subpart VV).

### 2.1.1.5 Office of the Administrator—Office of Children's Health Protection

When selecting compounds for the pilot of the Voluntary Children's Chemical Exposure Program (VCCEP), USEPA elected to focus on compounds that had been detected in various biological monitoring programs. 1,4-Dioxane was added to the VCCEP as the result of its being detected in the breath of individuals monitored during the Total Exposure Assessment Methodology (TEAM) studies of the mid-1980s (USEPA 2011). The source of this 1,4-dioxane was never determined, although low levels of the compound were detected in both ambient and indoor air in the same locale during the same period. In 2007, Ferro Corporation, the only company in the United States that was still manufacturing 1,4-dioxane at that time, volunteered at USEPA's request to complete an assessment of 1,4-dioxane for its Zachary, Louisiana, manufacturing facility. A 2007 study by the Sapphire Group for the Ferro Corporation found "1,4-dioxane does not pose an unacceptable non-cancer or cancer risk to children" (Sapphire 2007). This study used different cancer potency factors than did USEPA and California. In a report titled *EPA's Voluntary Chemical Evaluation Program Did Not Achieve Children's Health Protection Goals—Report No. 11-P-0379*, USEPA's Office of Inspector General found that Ferro Corporation never received a data needs decision from USEPA regarding the report (USEPA 2011). Under TSCA, USEPA can compel data collection from its industry partners, but it neither used this authority nor made a finding that the available data submitted by Ferro Corporation was adequate.

## 2.1.2 Food and Drug Administration

FDA is the federal agency responsible for protecting public health through ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, and the nation's food supply, cosmetics, and radiation-emitting products. Since the 1980s, FDA has recommended that manufacturers remove 1,4-dioxane from its products. FDA has not established a limit for 1,4-dioxane in cosmetic products but does provide information on its website about independent studies by other entities that recommend that the concentration of 1,4-dioxane in cosmetics be limited to no more than 10 ppm (FDA 2019). The agency also periodically monitors the presence of 1,4-dioxane in cosmetics.

FDA also has issued nonbinding recommendations for 1,4-dioxane as a Class 2 solvent in pharmaceutical products. The nonbinding recommendation is that a patient's daily exposure to 1,4-dioxane should not exceed 3.8 mg/day. The National Academy of Sciences (NAS) established a maximum specification of 10 ppm for 1,4-dioxane in the ingredient polysorbate, a

food additive (NAS 2003). FDA also lists it as an indirect food additive [21 CFR 175.105] (FDA 2003). In addition, FDA set a limit on 1,4-dioxane at 10 ppm in approving glycerides and polyglycerides for use as excipients in products such as dietary supplements (21 CFR 172.736). FDA considered the same level, 10 ppm, to be an acceptable limit for 1,4-dioxane during its consideration of a spermicide, N-9, in a contraceptive sponge product (prior to at least 1997) (ATSDR 2012).

### 2.1.3 Occupational Safety and Health Administration

In June 1993, OSHA established a permissible exposure limit (PEL) in air for 1,4-dioxane of 100 ppm or 360 mg/m$^3$ as an 8-hour time-weighted average (TWA) (OSHA 2017). While OSHA has established a PEL for 1,4-dioxane, it has recognized that many of its PELs are outdated and inadequate for ensuring the protection of worker health. OSHA recommends that employers follow one of the following:

- The California OSHA limit of 0.28 ppm (1 mg/m$^3$)
- The National Institute for Occupational Safety and Health (NIOSH) recommended exposure limit of 1 ppm (3.6 mg/m$^3$) as a 30-minute ceiling
- The American Conference of Governmental Industrial Hygienists (ACGIH) threshold limit value (TLV) of 20 ppm (USEPA 2017c)

### 2.1.4 Department of Energy

The Department of Energy adopted an exposure threshold in 10 CFR 851.23—Worker Safety and Health Program, requiring the use of the 2005 ACGIH TLV of 20 ppm for 1,4-dioxane in air, which is more protective than the OSHA PEL.

### 2.1.5 Department of Transportation (USDOT)

In accordance with the Federal Materials Transportation Act, the USDOT has adopted regulations 49 CFR Part 171, 40 CFR 173.202, and 40 CFR 173.242. Under these rules, 1,4-dioxane is considered a hazardous material, and special requirements have been set for marking, labeling, and transporting this material. 1,4-Dioxane has a United Nations identification number of 1165 for transport. It is listed as a Class 3 material because it has a flash point equal to or below 60 degrees Celsius (°C) (140 degrees Fahrenheit [°F]). In accordance with 49 CFR172, only 5 liters of 1,4-dioxane may be transported on a passenger plane, and only up to 60 liters may be shipped on a commercial aircraft.

### 2.1.6 U.S. Coast Guard, Department of Homeland Security

Minimum requirements have been established for safe transport of 1,4-dioxane on ships and barges. In accordance with 49 CFR 172.519(f), the U.S. incorporated by reference the International Maritime Dangerous Goods Codes: Incorporating Amendment 33-06. Additionally, the U.S. Coast Guard has established regulations pursuant to 46 CFR 151.12 relative to the shipping of 1,4-dioxane on marine vessels.

## 2.2 State Regulation of 1,4-Dioxane

Several states have developed standards and guidance values for 1,4-dioxane in water, soil, and air across multiple regulatory programs, and these standards and guidance values vary broadly among the state programs. **Figure 2-1** provides a summary of current regulatory and guidance concentrations established by some states for drinking water and groundwater. Details on how each state regulates 1,4-dioxane are included in Appendix A, which contains a narrative summary of state-specific regulations and hyperlinks to additional information. **Figure 2-1** shows 1,4-dioxane state regulatory values for drinking water and groundwater, separated by general category (groundwater cleanup level and standard; guidance, advisory, and screening levels; drinking water health standard and action level; and applied USEPA RSL at some sites for cleanup or drinking water guidance). Appendix A has more detailed information about the categories and values. Note that **Figure 2-1** is meant to be a quick guide to state websites where information is available on regulatory standards and guidance. Please refer to Appendix A for additional information and to the state websites for the most current information.

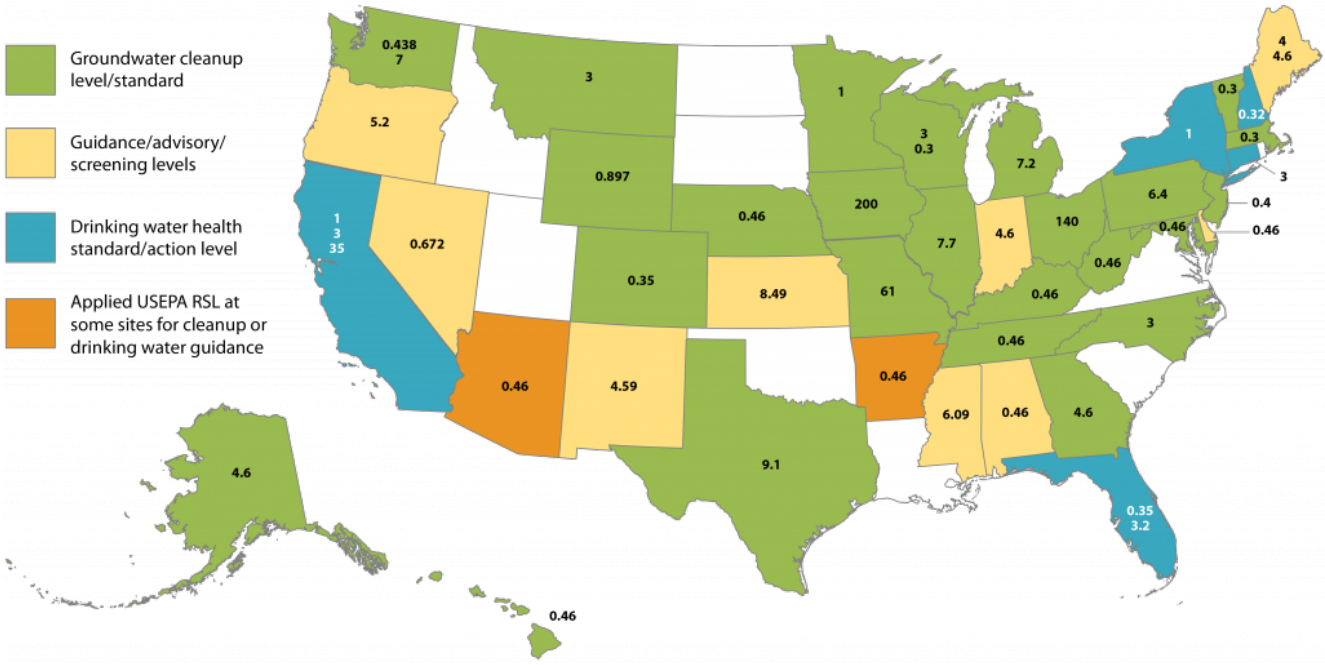



**Figure 2-1. 1,4-Dioxane State Regulatory Values for Drinking Water and Groundwater (µg/L).**
*Source: ITRC 1,4-Dioxane Team, 2020.*

In July 2019, ITRC conducted a state survey to gather information about how states regulate 1,4-dioxane and to identify states that had developed enforceable standards and guidance values for drinking water, groundwater, surface water, or soil. It also aimed to gather information on how states manage 1,4-dioxane during site investigation, remediation, and routine groundwater monitoring activities at regulates sites. The survey found that regulation and requirements vary from state to state. Among the states that responded to the ITRC survey, multiple states (AK, CA, CO, CT, FL, GA, IA, IN, KY, MA, MD, ME, MI, MN, NE, NM, RI, SC, TX, VA, VT, WA, WI, and WY) require site investigations to sometimes include the sampling and testing of soil or water (or both) for 1,4-dioxane. In general, these states require sampling for 1,4-dioxane if there is evidence that the compound may have been historically used or if the site exhibits chlorinated solvent contamination. In the ITRC survey, CO and MI indicated that they have adopted 1,4-dioxane surface water quality standards. Some states (NC, NH, and NY) have established requirements for sampling of 1,4-dioxane at most waste sites and landfills. Other states (ID, LA, ND, SC, UT, and VA) have no standards, policies, or guidance for addressing 1,4-dioxane contamination. A few states have product labeling and consumer products laws. Additional information on these is in Section 2.2.2.

## 2.2.1 Drinking Water Standards

The July 2019 ITRC state survey additionally indicated that at this time, no state has established a state MCL or drinking water standard for 1,4-dioxane. On July 14, 2019, the State of New York initiated rulemaking to adopt an MCL of 1 µg/L for 1,4-dioxane (NYSDOH 2019). When a state adopts an MCL for a contaminant, public water systems must routinely sample their sources of water for the contaminant. If the MCL is exceeded, the public must be notified, and actions must be taken to correct the violation. Despite the lack of state drinking water MCLs, most states have regulations, standards, and guidance for 1,4-dioxane sampling and analysis in groundwater and/or surface water. Information on this is available in Section 2.2 and in Appendix A.

### 2.2.2 Product Labeling and Consumer Products Laws

1,4-Dioxane is found in several consumer products as an unwanted by-product of various chemical reactions that occur during the manufacturing processes (CCE 2019). See Section 1 for more information. In recent years, regulatory action has been considered at both the federal (USEPA and FDA) and state levels to evaluate the intentional or unintentional use of 1,4-dioxane in products as a way to mitigate exposure to 1,4-dioxane through drinking water and product use. This form of source control may serve as a more cost-effective means to reduce 1,4-dioxane exposure when compared to the expensive treatment needed to remove 1,4-dioxane from the waste stream that can contaminate the environment and drinking water sources.

***California's Safer Consumer Products Program***

Launched in 2013, the California Department of Toxic Substances Control's (DTSC) Safer Consumer Products (SCP) regulations outline a framework for DTSC to regulate product-chemical combinations (Priority Products) that require manufacturers to evaluate alternatives. The SCP program selects Priority Products based on the potential for exposure to a chemical in the product to contribute to adverse impacts to human health or the environment. DTSC then requires manufacturers to consider the product's full life cycle when selecting alternatives to avoid substitutions with adverse impacts.

In the summer of 2019, DTSC announced that it has been researching the presence of 1,4-dioxane as a contaminant in personal care and cleaning products based on concerns for exposure to 1,4-dioxane through product use and drinking water. DTSC outlined these concerns in a background document. Additionally, DTSC provided a discussion draft of an Alternatives Analysis Threshold proposal, which included calculations of down-the-drain impacts of select personal care and cleaning products on the concentration of 1,4-dioxane in wastewater effluent (DTSC 2019).

DTSC solicited stakeholder feedback on several topics, including the potential for adverse impacts from 1,4-dioxane in consumer products, the presence of 1,4-dioxane in personal care and cleaning products, and the feasibility of removing it from these products. Public meetings were held in June and August 2019, with a public comment period across that same time frame. Inputs received from the stakeholder engagement process will inform DTSC's decisions on potentially proposing Priority Products containing 1,4-dioxane in the future.

***California Safe Drinking Water and Toxic Enforcement Act of 1986—Proposition 65***

1,4-Dioxane is listed as a chemical known to cause cancer under California's Safe Drinking Water and Toxic Enforcement Act of 1986 (commonly referred to as Prop 65). Prop 65 requires manufacturers, distributors, and retailers to provide warning labels on products containing 1,4-dioxane at concentrations expected to result in human exposures above the Safe Harbor Level of 30 µg/day (CAOEHHA 2013b). Prop 65 also prohibits companies from discharging 1,4-dioxane to sources of drinking water.

***California Cleaning Products Right to Know Act***

California's Cleaning Products Right to Know Act requires that manufacturers disclose all ingredients in cleaning products beginning in 2020 (online disclosure) and 2021 (on-label disclosure), including 1,4-dioxane if present in the final product at or above a concentration of 0.001% or 10,000 µg/L (California 2017a).

***NY Regulation of 1,4-Dioxane in Cleaning and Personal Care Products***

New York enacted a law that prohibits the sale of personal care and cleaning products with 1,4-dioxane concentrations above 2 ppm after December 31, 2022, and above 1 ppm after December 31, 2023. The law also prohibits the sale of cosmetics with concentrations above 10 ppm after December 31, 2022. Every 2 years, starting no later than 2025, the New York State Department of Environmental Conservation will evaluate if it should lower these thresholds (NYSDOH 2019).

***Reporting Laws for Chemicals of High Concern to Children Reporting Laws***

Several states have adopted reporting laws for chemicals in children's products. Requirements are triggered if 1,4-dioxane is present in a product at a concentration greater than 1 ppm. The following laws and regulations require manufacturers to report to the state when a product contains 1,4-dioxane in excess of this amount:

- Oregon Toxic-Free Kids Act—ORS 431A.258
- Vermont States' List of Chemicals of High Concern to Children (see Vermont Statute Title 18, Chapter 38A) and the Chemicals of High Concern in Children's Products Rule
- Washington State's Children's Safe Products Law (see Chapter 70.240 RCW) and the Children's Safe Products Reporting Rule, Chapter 173-334 WAC

***State Right-to-Know Acts***

1,4-Dioxane is regulated as a "hazardous substance" pursuant to New Jersey's Worker and Community Right to Know Act and implementing regulations (8:59 N.J. Admin. Code § 9.1). Under the act and its implementing regulations, employers are required to, among other things, complete surveys listing the names and quantities of hazardous substances stored at their facilities and label each container with the chemical name and CAS number of the container's ingredients. In addition, public sector employees are required to maintain at each facility a Right-to-Know (RTK) Central File that includes a copy of the facility's RTK Survey, Safety Data Sheets, N.J. DOT Hazardous Substance Fact Sheets, and a copy of the RTK Hazardous Substance List. Pennsylvania has similar requirements (34 Pa. Code § 307-323).

### 2.2.3 Wastewater Reuse

The California State Water Resources Control Board (Water Board) adopted a "Water Quality Control Policy for Recycled Water" on December 11, 2018. The policy includes sampling for 1,4-dioxane in treated wastewater that will be reused (i.e., effluent water reuse) and includes a monitoring trigger level (MTL) of 1 µg/L. An MTL is the concentration above which response actions may be required. The Water Board's Science Advisory Panel established MTLs for constituents of emerging concern in recycled water in its final report (California 2018). A recent permit issued by the Water Board required 0.5-log removal (68.4% reduction) of 1,4-dioxane in wastewater that is treated for reuse (California 2017b).

The New Hampshire Department of Environmental Services (NHDES) has adopted administrative rule Env-Wq 402—Groundwater Discharge Permits and Registrations. Entities discharging nondomestic wastewater to the groundwater or domestic wastewater in excess of 10,000 gallons per day must obtain a groundwater discharge permit from NHDES. This includes entities that are using treated wastewater to irrigate golf courses, to make snow, or to recharge aquifers. The permittee must demonstrate through routine monitoring that groundwater at the compliance monitoring locations that are downgradient of the designated discharge zone meets Ambient Groundwater Quality Standards (AGQS). Pursuant to Section 402-251 of the Groundwater Discharge Permits and Registrations rules, the level of 1,4-dioxane in treated wastewater to be discharged to groundwater can exceed the AGQS so long as the discharger complies with certain conditions. These conditions include, but are not limited to, expanding the testing of public and private drinking water wells beyond 1,000 feet if:

(a) testing shows the presence of 1,4-dioxane in a private or public drinking water supply well at a concentration that exceeds the applicable AGQS, and
(b) it is more likely than not that the permitted discharge is the source of the 1,4-dioxane.

### 2.2.4 Cannabis

The Oregon Health Authority has identified 1,4-dioxane as a solvent that may be used to extract or concentrate the active ingredients from cannabis. A 2015 document, *Technical Report: Oregon Health Authority's Process to Determine which Types of Contaminants to Test for in Cannabis Products and Levels for Action*, established an action level of 380 µg/g for 1,4-dioxane contamination in cannabis products (Oregon 2015). Additionally, the Association of Public Health Laboratories (APHL) published a guidance document for state medical cannabis testing programs in 2016 that established concentration limits for 1,4-dioxane in solvents used to extract cannabis (APHL 2016).

## 2.3. International Regulation

The World Health Organization (WHO) and several other countries have guidelines or standards for 1,4-dioxane in drinking water (WHO 2017). The ITRC 1,4-Dioxane Team conducted extensive research into international standards and guidelines, and **Table 2-1** summarizes the standards that are reported. Standards and guidelines established by different international bodies may be derived and applied using protocols and conditions that are unique to that entity. It is not necessarily appropriate to compare values from one international body against that of another.

**Table 2-1. Comparison of federal and international health values**

| Country/Organization | Concentration (µg/L) | Description of value referenced |
|---|---|---|
| USEPA | 35*/0.35†/0.46† | Health advisory level/reference value/RSL |
| WHO | 50 | Suggested drinking water threshold |
| Japan | 50 | Adopted WHO threshold |
| Canada | 50 | Proposed maximum acceptable concentration for drinking water |
| New Zealand | 50 | Drinking water standards for New Zealand |

*Corresponds to a 1:10,000 cancer risk. †Corresponds to a 1:1,000,000 cancer risk.