

1,4-Dioxane: Overview & NJDEP Ground Water Quality Criterion

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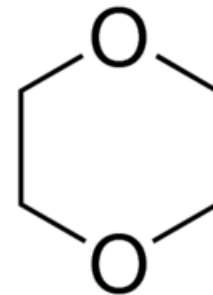
USGS Water Science Center

Lawrenceville, NJ

Information to be Presented:

- Properties and uses.
- Public water system occurrence data from USEPA Unregulated Contaminant Monitoring Rule (UCMR3) - New Jersey versus national.
- Basis of NJDEP Ground Water Quality Standard (adopted January 2018):
 - Human Health Ground Water Quality Criterion
 - Practical Quantitation Level – analytical basis (next talk - Dr. Lee Lippincott)

1,4-Dioxane Background Information



- Synthetic organic chemical.
- Miscible with water.
- Occurs in both surface water and ground water.
 - Associated with chlorinated solvents, particularly 1,1,1-trichloroethane – used as stabilizer.
 - Migrates rapidly through soil to ground water.
 - Does not readily biodegrade.
- Uses:
 - Solvent – in products such as adhesives, resins, oils, and waxes.
 - Used in manufacture of pharmaceuticals, certain plastics, and other products.
 - Impurity in antifreeze and cosmetics/personal care products.

New Jersey vs. National Public Water System (PWS) 1,4-Dioxane Detections in UCMR3 (2013-2015)

	<i>New Jersey PWS</i>		<i>National PWS (other than NJ)</i>	
	<i># Detects</i>	<i>% Detects</i>	<i># Detects</i>	<i>% Detects</i>
<i>≥ 0.07 µg/L (Reporting Level)</i>	<i>80/174</i>	<i>45.9%</i>	<i>997/4741</i>	<i>21.0%</i>
<i>> 0.35 µg/L (Health Reference Concentration)*</i>	<i>30/174</i>	<i>17.2%</i>	<i>311/4741</i>	<i>6.6%</i>

**Based on USEPA IRIS cancer slope factor and one-in-one million (1×10^{-6}) lifetime cancer risk.*

- Data for finished water at all large PWS (>10,000 customers) and a small subset of smaller PWS.
- Detected above *Reporting Level* and *Health Reference Concentration* more than twice as frequently in NJ than nationally.

1,4-Dioxane Reported in NJ

UCMR3

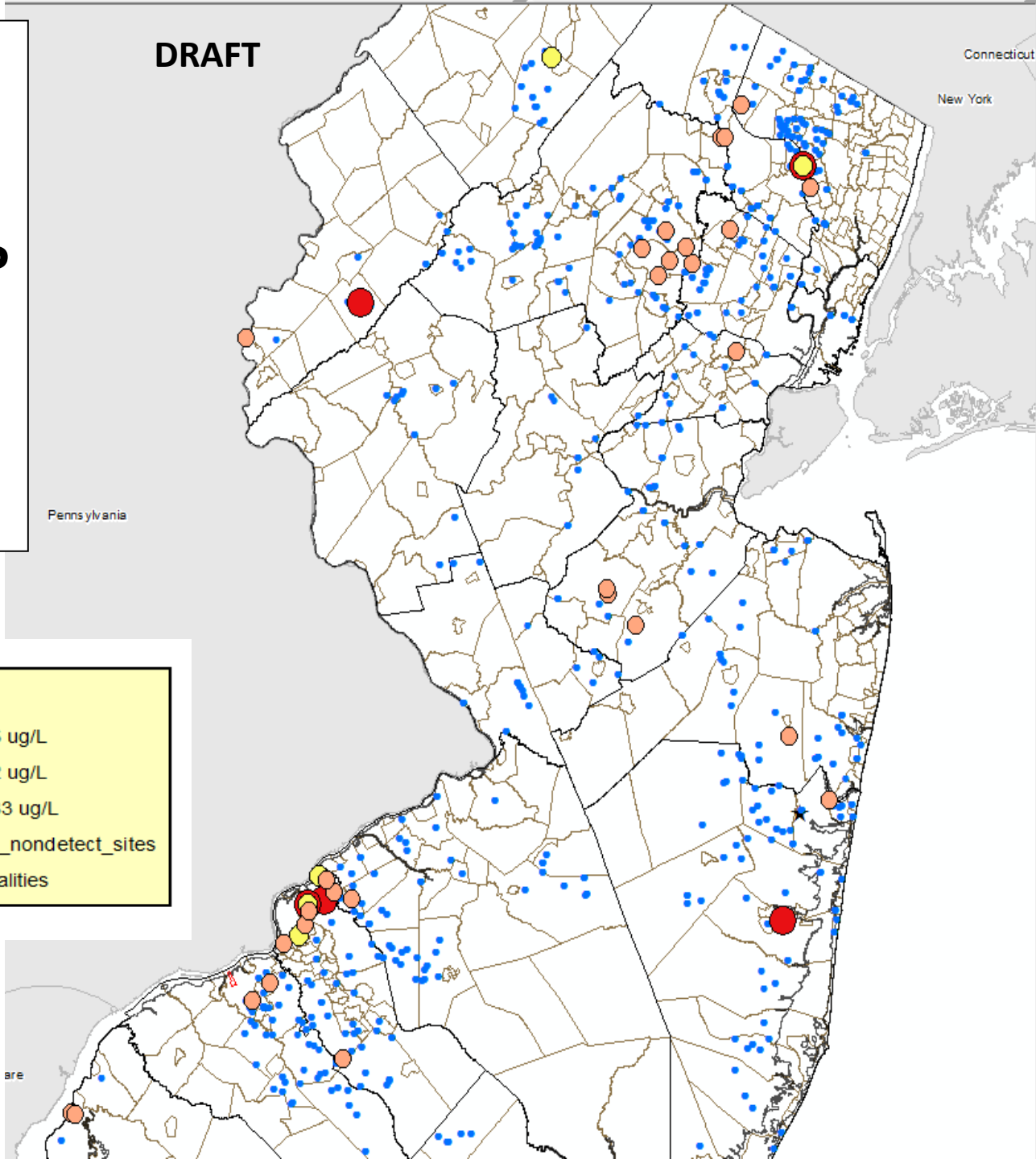
Results above NJDEP Ground Water Quality Standard (0.4 $\mu\text{g/L}$)

-through Jan 2016-

DRAFT

Legend

- ◊ 0.41-1.6 ug/L
- ◊ 1.61-3.2 ug/L
- 3.21-5.83 ug/L
- UCMR3_nondetect_sites
- Municipalities



10/19/2016

Considerations in Development of New Jersey Ground Water Quality Standards (GWQS) & MCLs

Standard	Health-based MCL/Ground Water Quality Criterion*	Analytical PQL	Treatment Removal
GWQS	X	X	Not considered
Drinking Water MCL	X	X	X

**Human health risk assessment approaches and assumptions are the same for GWQS and MCLs.*

1,4-Dioxane GWQS – 0.4 ug/L (adopted January 2018)

- Human Health Criterion – 0.4 µg/L
- PQL – 0.1 µg/L

NJDEP Human Health Ground Water Quality Criterion for 1,4-Dioxane

Based on USEPA (2013) Integrated Risk Information System (IRIS) assessment.

- IRIS is one of the default sources of toxicity factors (cancer slope factors and Reference Doses) for NJ Ground Water Quality Criteria.
 - As specified in the New Jersey Ground Water Quality Standards (GWQS) regulations (N.J.A.C. 7:9C).
- Alternative value can be used if relevant scientific information indicates that alternative value is more appropriate than default value.
- NJDEP review concluded that USEPA IRIS assessment for 1,4-dioxane is a scientifically valid and appropriate basis for the Ground Water Quality Criterion.

USEPA IRIS Assessment of 1,4-Dioxane

- Classified as “**likely to be carcinogenic to humans.**”
- ***Oral Cancer Slope Factor – 0.1 (mg/kg/day)⁻¹***
 - Based on liver tumors in female mice in 2 year drinking water study (Kano et al., 2009)
 - Also caused liver tumors in male mice, male and female rats, and male guinea pigs.
 - Caused nasal, mammary gland, and peritoneal tumors in rats.
- ***Oral Reference Dose – 0.03 mg/kg/day.***
 - Based on liver and kidney degeneration and necrosis in male rats (Kociba et al., 1974).
- NJ Ground Water Quality Criterion based on **carcinogenicity** – more sensitive than non-cancer effects.
- IRIS assessment also includes *Inhalation Unit Risk* factor for carcinogenic risk and non-cancer *Inhalation Reference Concentration*.

1,4-Dioxane Ground Water Quality Criterion

Based on one-in-one million (1×10^{-6}) cancer risk from lifetime drinking water exposure, as specified in NJ Ground Water Quality Standards regulations:

$$\text{Criterion} = \frac{10^{-6} \times 70 \text{ kg}}{(0.1 \text{ mg/kg/day})^{-1} \times 2 \text{ L/day}} = 0.00035 \text{ mg/L} = 0.35 \text{ }\mu\text{g/L}$$

Where:

- 10^{-6} = lifetime cancer risk
- $0.1 \text{ (mg/kg/day)}^{-1}$ = cancer slope factor
- 70 kg = average adult weight
- 2 L/day = assumed daily drinking water consumption

Criterion of **$0.35 \text{ }\mu\text{g/L}$** is identical to UCMR3 Health Reference Concentration. Criterion rounded to one significant figure (specified in NJ GWQS) is **$0.4 \text{ }\mu\text{g/L}$** .

Public Comments and NJDEP Responses on 1,4-Dioxane Ground Water Quality Criterion

- USEPA cancer risk assessment guidelines specify **non-threshold approach (i.e. cancer slope factor) as default** unless a threshold mode of action is established.
- For 1,4-dioxane, cancer slope factor is used because **mode of action for carcinogenicity has not been established**.
- Commenters submitted two papers (Dourson et al., 2014; Dourson et al., 2017) concluding that:
 - 1,4-Dioxane causes liver tumors through a threshold mode of action involving cell toxicity followed by regenerative growth.
 - Risk assessment for 1,4-dioxane should be based on the threshold (i.e. Reference Dose) for these non-cancer effects.
- Detailed NJDEP reviews concluded that Dourson et al. (2014; 2017) **do not establish a mode of action** for 1,4-dioxane carcinogenicity and **do not demonstrate that a threshold (Reference Dose) approach is appropriate**.
 - These NJDEP reviews are posted online at <https://www.state.nj.us/dep/dsr/supportdocs/11-chemicals-response.pdf> and https://www.nj.gov/dep/rules/adoptions/adopt_20180116c.pdf
- Furthermore, the modes of action for other types of tumors (nasal, mammary gland, peritoneal) caused by 1,4-dioxane are unknown.

Future Development of Health-based MCL for 1,4-Dioxane

- Health Effects Subcommittee will review basis of NJDEP Ground Water Quality Criterion.
- Health Effects Subcommittee will also evaluate additional information:
 - More recent studies identified in literature search.
 - Studies submitted in response to DWQI call for information.

Thank you!