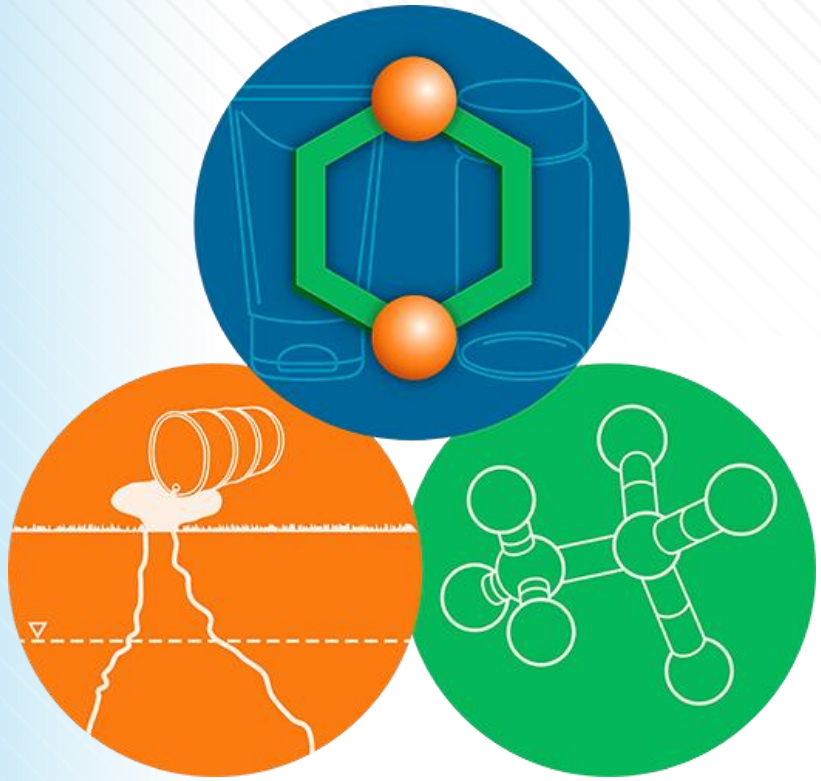
The Persistent Issues with 1,4-Dioxane

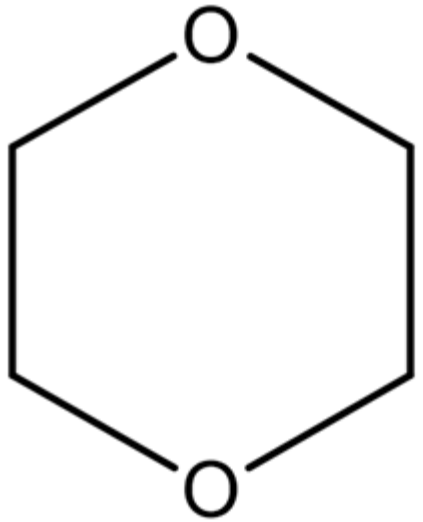


October 26, 2020

BURNS McDONNELL

Overview

- What is 1,4-dioxane?
- Why do we care about 1,4-dioxane?
  - Regulatory concerns
  - Fate and transport characteristics
  - Toxicological uncertainties
- Use 1,4-dioxane information and science to apply best practices at your sites



1,4-Dioxane

ITRC Disclaimer

This material was prepared as an account of work sponsored by an agency of the United States Government. Neither the United States Government nor any agency thereof, nor any of their employees, makes any warranty, express or implied, or assumes any legal liability or responsibility for the accuracy, completeness, or usefulness of any information, apparatus, product, or process disclosed, or represents that its use would not infringe privately owned rights. Reference herein to any specific commercial product, process, or service by trade name, trademark, manufacturer, or otherwise does not necessarily constitute or imply its endorsement, recommendation, or favoring by the United States Government or any agency thereof. The views and opinions of authors expressed herein do not necessarily state or reflect those of the United States Government or any agency thereof and no official endorsement should be inferred.

The information provided in documents, training curricula, and other print or electronic materials created by the Interstate Technology and Regulatory Council ("ITRC" and such materials are referred to as "ITRC Materials") is intended as a general reference to help regulators and others develop a consistent approach to their evaluation, regulatory approval, and deployment of environmental technologies. The information in ITRC Materials was formulated to be reliable and accurate. However, the information is provided "as is" and use of this information is at the users' own risk.

ITRC Materials do not necessarily address all applicable health and safety risks and precautions with respect to particular materials, conditions, or procedures in specific applications of any technology. Consequently, ITRC recommends consulting applicable standards, laws, regulations, suppliers of materials, and material safety data sheets for information concerning safety and health risks and precautions and compliance with then-applicable laws and regulations. ITRC, ERIS and ECOS shall not be liable in the event of any conflict between information in ITRC Materials and such laws, regulations, and/or other ordinances. The content in ITRC Materials may be revised or withdrawn at any time without prior notice.

ITRC, ERIS, and ECOS make no representations or warranties, express or implied, with respect to information in ITRC Materials and specifically disclaim all warranties to the fullest extent permitted by law (including, but not limited to, merchantability or fitness for a particular purpose). ITRC, ERIS, and ECOS will not accept liability for damages of any kind that result from acting upon or using this information.

ITRC, ERIS, and ECOS do not endorse or recommend the use of specific technology or technology provider through ITRC Materials. Reference to technologies, products, or services offered by other parties does not constitute a guarantee by ITRC, ERIS, and ECOS of the quality or value of those technologies, products, or services. Information in ITRC Materials is for general reference only; it should not be construed as definitive guidance for any specific site and is not a substitute for consultation with qualified professional advisors.

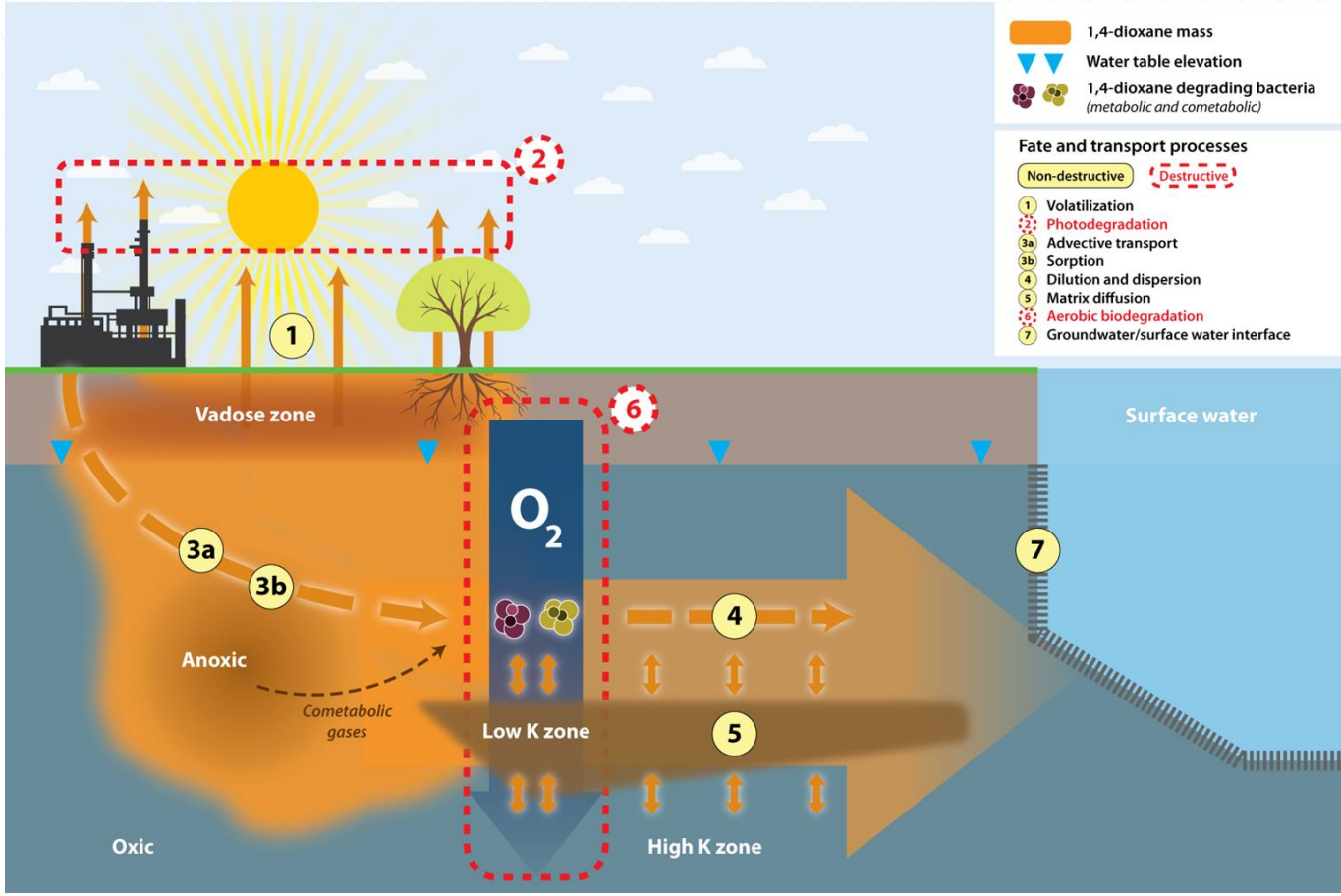
https://tphrisk-1.itrcweb.org/about-itrc/#disclaimer

Why Do We Care About 1,4-Dioxane?

- Hazardous Substance under CERCLA/RCRA

- CERCLA
  - screening levels* used for screening and informing cleanup goals
  - **RSL**** **= 0.46 µg/L groundwater**
    = 5.3 mg/kg soil
    = 0.56 µg/m³ (0.16 ppm) air

*screening levels – not cleanup standards
** Regional Screening Levels (RSL) shown at 10^{-6} cancer risk level for residential exposure



See Figure 3-3 in ITRC Guidance Document for complete figure with additional details

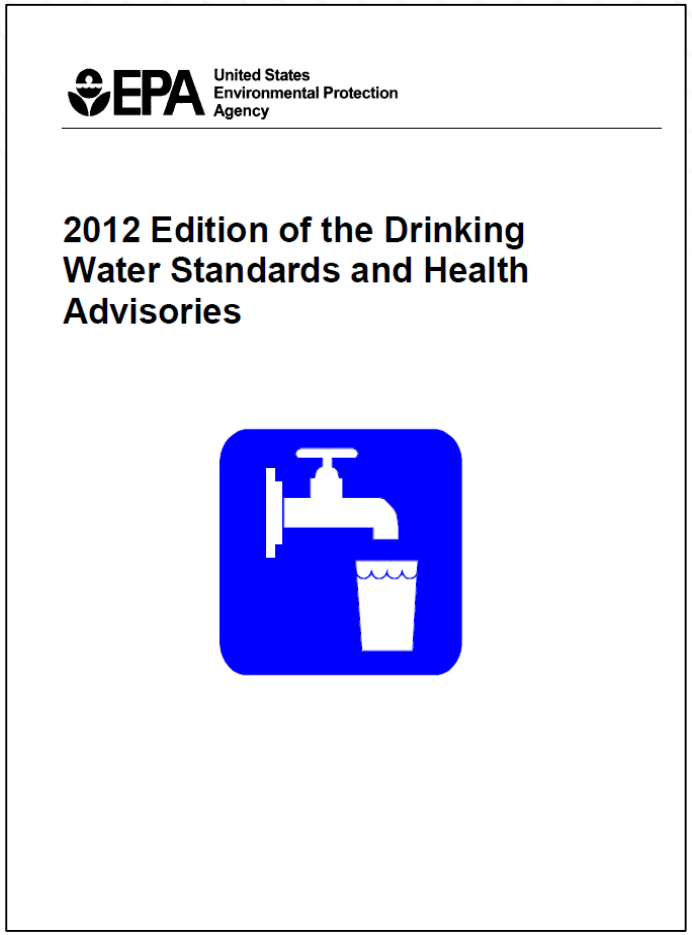
***DISCLAIMER**: CSM is an example and may not be applicable to all release types or settings*

Drinking Water - Safe Drinking Water Act (SDWA)

U.S. EPA Office of Water – Safe Drinking Water Act:

- Standards for drinking water quality and monitoring requirements for public water systems
  - No maximum contaminant level (MCL)
- Identified as a chemical known to occur in public drinking water systems and may require regulation
  - Candidate Contaminant List (CCL) since 2008
- January 2021, EPA “has not determined whether there is a meaningful opportunity for public health risk reduction”
  - Continuing to evaluate for MCL

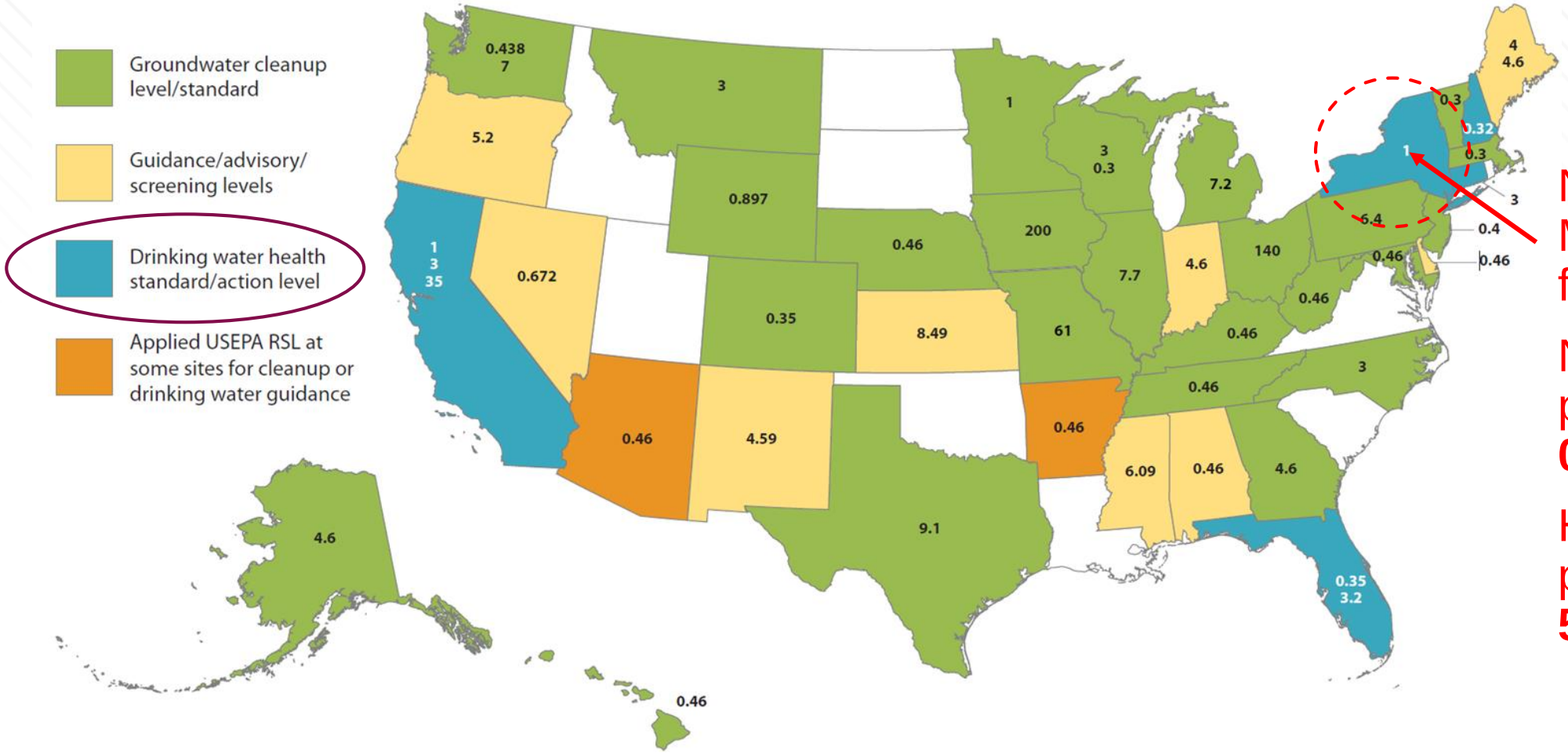
Drinking Water - Health Advisory - Guidance



- Provide information for drinking water contaminants that can / are known to / anticipated to cause human health effects
- Issued when an enforceable drinking water standard has not been established
- Lifetime cancer risk level of 35 µg/L (10-4 cancer risk)

See Section 5 ITRC Guidance Document for more detailed information

Drinking Water - State Regulation



New York 2020 MCL of **1 µg/L** is first in the US

New Jersey proposed MCL of **0.33 µg/L**

Health Canada proposed MAC of **50 µg/L**

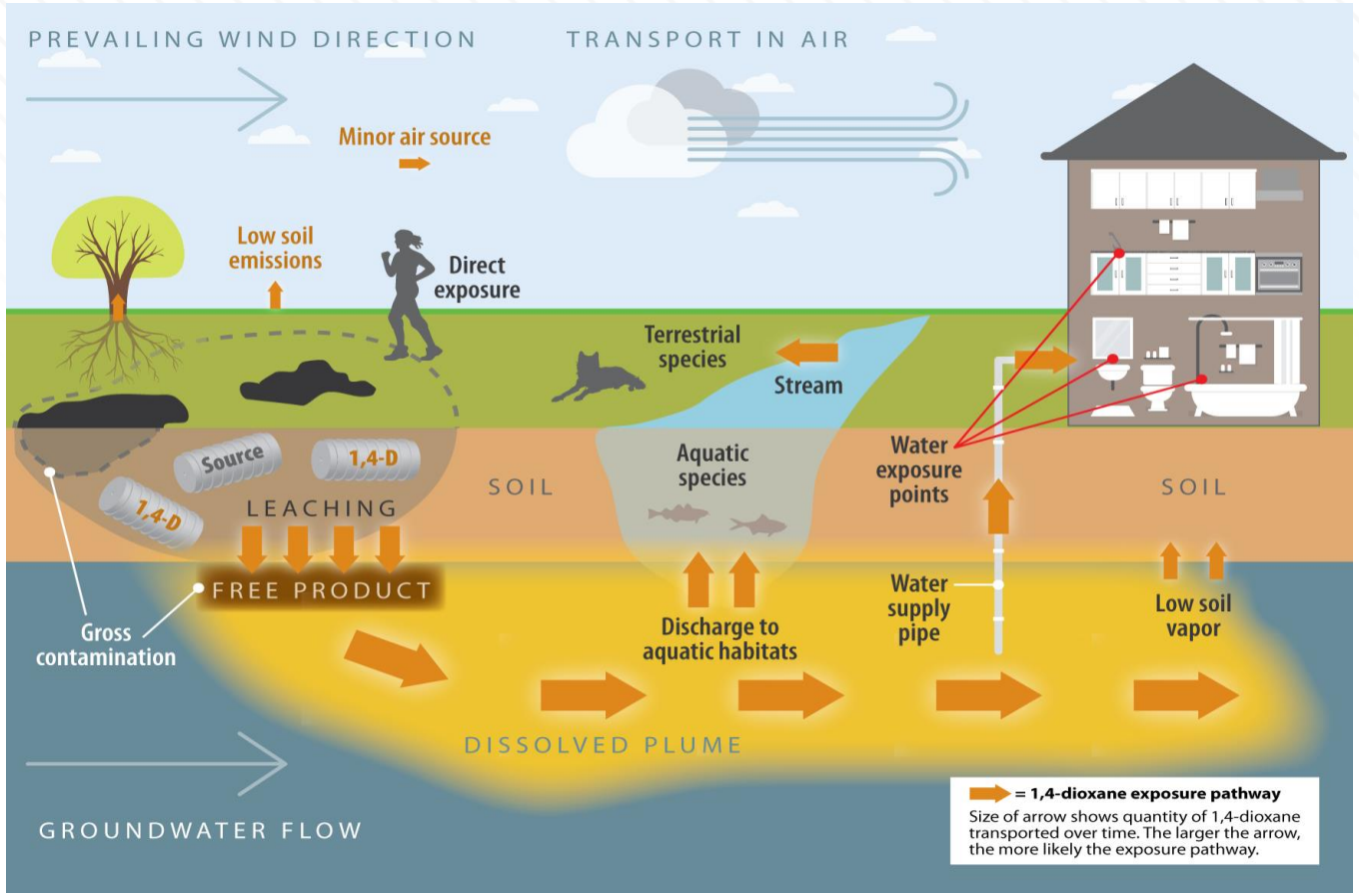
See Appendix A and Figure 2-1 ITRC Guidance Document for more detailed information

Fate and Transport of 1,4-Dioxane – Critical Characteristics

Property	Units	1,4-D	Benzene	TCE	1,1,1-TCA	1,1-DCA	1,1-DCE
Water solubility	g/L	1000	1.8	1.1	0.91	5.04	5.06
Vapor pressure	mm Hg (at 25˚C)	23.8	95.2	72.6	124	227	234
Henry's Law constant	atm-m3/mol (at 25˚C)	4.8×10^{-6}	5.48×10^{-3}	9.1×10^{-3}	1.6×10^{-2}	5.62×10^{-3}	5.8×10^{-3}
Log K_{oc}	Dimension-less	0.54	1.92	1.81	2.18	1.55	1.48
Boiling point	˚C	101	80	87	74	57.4	32

See Table 3.1 in ITRC Guidance Document for complete table with additional parameters

Exposures of Highest Concern: Drinking Water, Groundwater, Surface Water



ITRC Guidance Document Figure 5.1

- Drinking water ingestion primary concern
- Not likely to remain in surface soil
- Low dermal absorption
- Unlikely to volatilize out of water
- **Ecological Receptors:** Most likely through aquatic routes

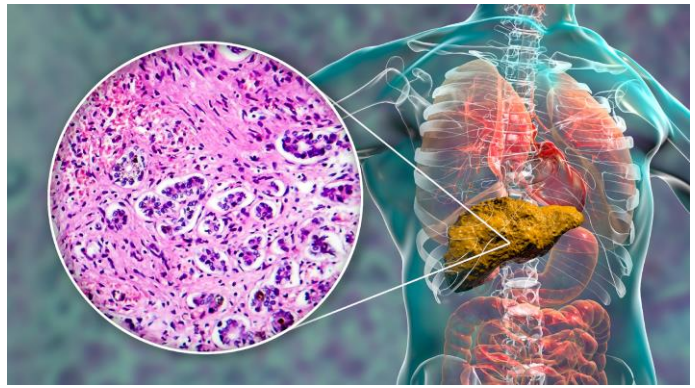
Human Health – Hazard Identification

- Non cancer effects
  - Oral: Liver and kidney
  - Inhalation: Eye and respiratory

- Cancer
  - “possibly carcinogenic” (IARC)
  - “likely to be carcinogenic” (EPA)
  - Rodent tumors
    - Liver, kidney, nasal, peritoneum, mammary gland
  - HOWEVER, experts have different interpretations on cancer risk
    - Cancer Mode of Action (MOA)
      - USEPA
      - Health Canada (and others)

What are the potential health effects?

Hazard Identification



IARC = International Agency for Research on Cancer

Health Canada = MOA is Non-Genotoxic and Threshold

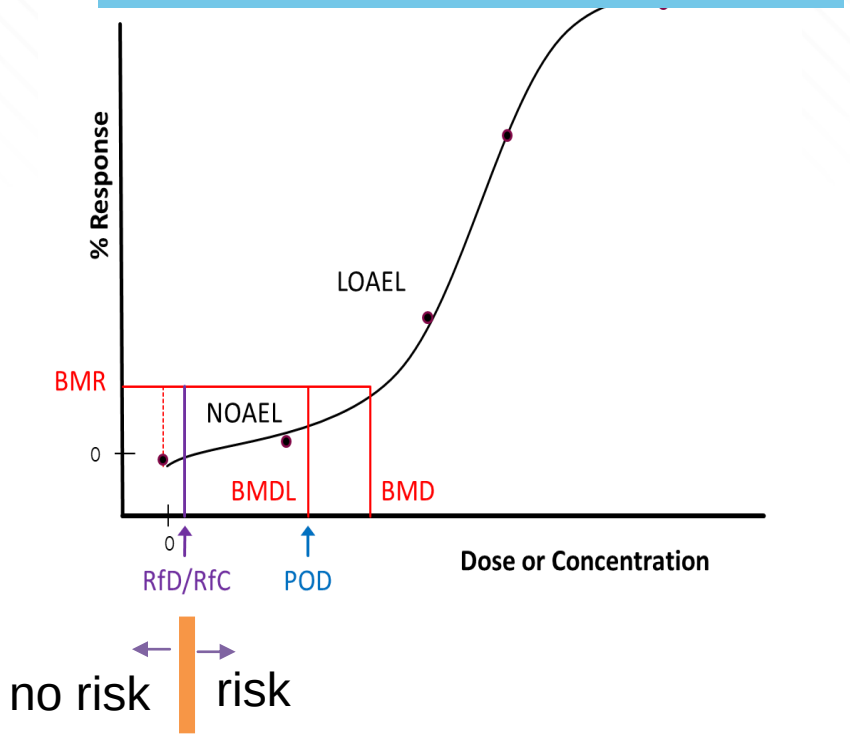
Health Canada 2018 Mode of Action conclusions

"Using a MOA analysis, the weight of evidence supports a non-genotoxic MOA, with 1,4-dioxane inducing liver tumours through a regenerative proliferation-induced MOA."

- and is reasonable for other human-relevant tumor types
- also adopted by WHO and other international agencies
- and supported by recent publications

Threshold MOA = there is only risk above a certain threshold level of exposure

= DW threshold of <u>50 µg/L</u>
no concern if exposure is below threshold



See Section 5.2 ITRC Guidance Document for more detailed information

USEPA = MOA is Unknown

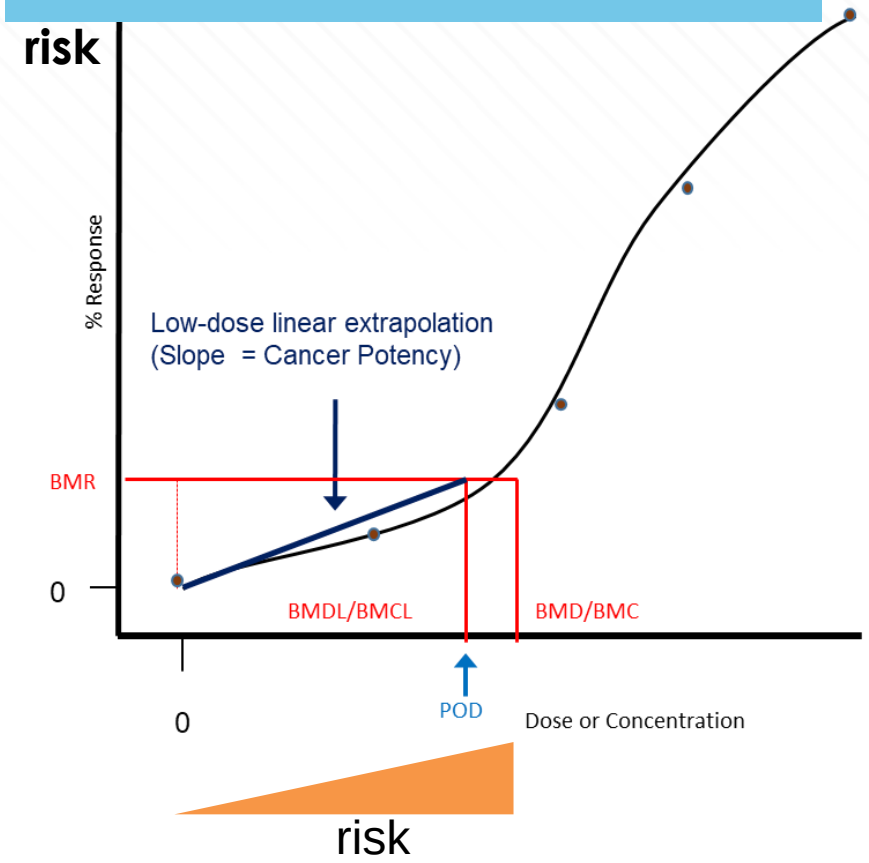
- 2 USEPA Assessments
  - 2013 Integrated Risk Information System (IRIS)
  - 2020 Toxic Substances Control Act (TSCA)
- Mode of Action conclusions

"The available evidence is **inadequate to establish a mode of action** (MOA) by which 1,4-dioxane induces liver tumors in rats and mice."

(USEPA 2013)

Default dose response model = any increase in exposure, increases risk

= DW threshold of 0.35 – 35 µg/L for 10^{-6} to 10^{-4} cancer



See Section 5.2 ITRC Guidance Document for more detailed information

Impact of MOA Decision on Drinking Water Threshold Values

- Unknown MOA =

DW value of

0.35 – 35 µg/L (HA)
or
0.46 – 46 µg/L (RSL)

for 10^{-6} to 10^{-4} cancer risk

- Threshold MOA involving cell proliferation =

DW value of

50 µg/L

Source of toxicity information can have significant impact on risk characterization

Hierarchy of Toxicity Values for Risk Assessment Best Professional Judgement Necessary

Tier 1

EPA Integrated Risk Information System (IRIS)

Tier 2

EPA Peer-Reviewed Provisional Toxicity Values (PPRTV)

Tier 3

- Agency for Toxic Substances and Disease Registry
- Other EPA offices (e.g., Office of Water)
- States, International Agencies, etc.

CONSIDERATIONS

- ☑ State-of-science methods, consistent with EPA
- ☑ Transparent
- ☑ **Best available research**
- ☑ Peer-reviewed

1,4-Dioxane - Toxicity and Risk Assessment

Conclusions

- Low screening levels driving cleanup concerns
- No federal MCL for drinking water: State and international DW values vary from 0.3 to 50 µg/L (part per billion)
- Fate and transport characteristics should dictate investigation planning
- Cancer risk is the primary concern for human health and long-term exposures
- Science is still evolving regarding how 1,4-dioxane causes cancer
- Selected toxicity value(s) for risk assessments should be consistent with established guidance and policies, well justified

MOA


BURNS McDONNELL®