

Contaminants Emerging from a New Look at Old Chemicals: Effects of TSCA Reform

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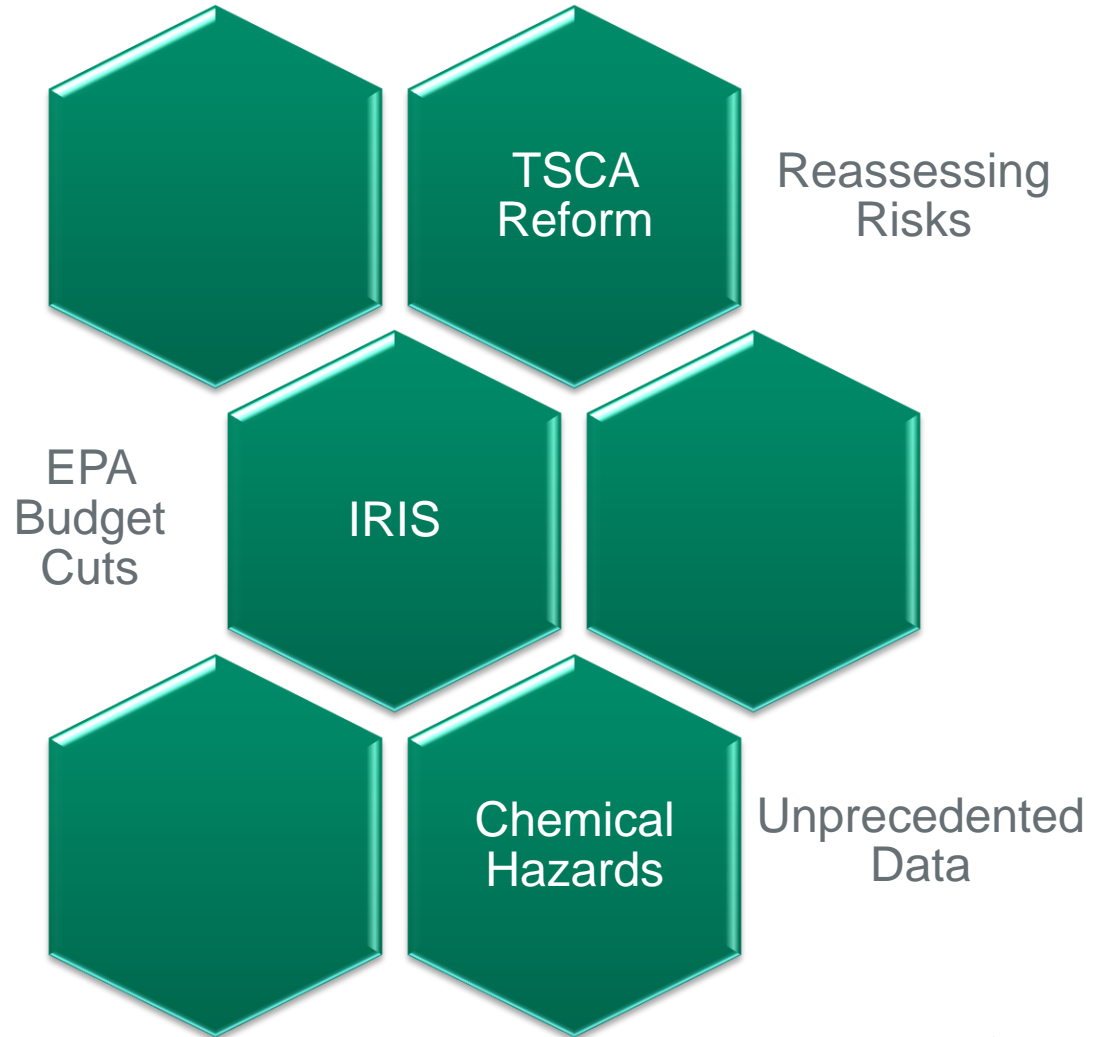
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The business of sustainability



Agenda

- Introduction to Toxic Substances Control Act (TSCA) and Chemical Safety Act (CSA)
- Characterizing Risk
- Implications for Site Remediation



Origins of TSCA

President's Council on Environmental Quality, April 1971:

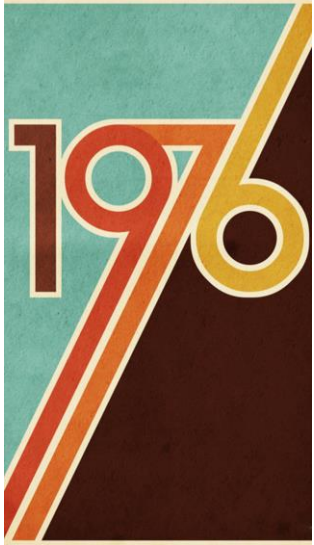
"Toxic substances are entering the environment"

"These substances can have severe effects"

"Existing legal authorities are inadequate"

"We should no longer be limited to repairing damage after it has been done; nor should we continue to allow the entire population or the entire environment to be used as a laboratory"

TSCA: not just for PCBs



Law allowed EPA to:

- Evaluate the risk from exposure to new chemicals and regulate if necessary to limit risk
- Require manufacturers to test chemicals for toxicity in some cases
- Regulate the use of existing chemicals

EPA could not require testing unless substance presents an unreasonable risk:

- ~62,000 chemicals grandfathered
- Approximately 10% of the chemicals brought to market since 1976 regulated





Frank R. Lautenberg Chemical Safety for 21st Century Act

(aka TSCA reform)



Signed into law June 2016

Mandatory requirement for EPA to evaluate existing chemicals with clear and enforceable deadlines

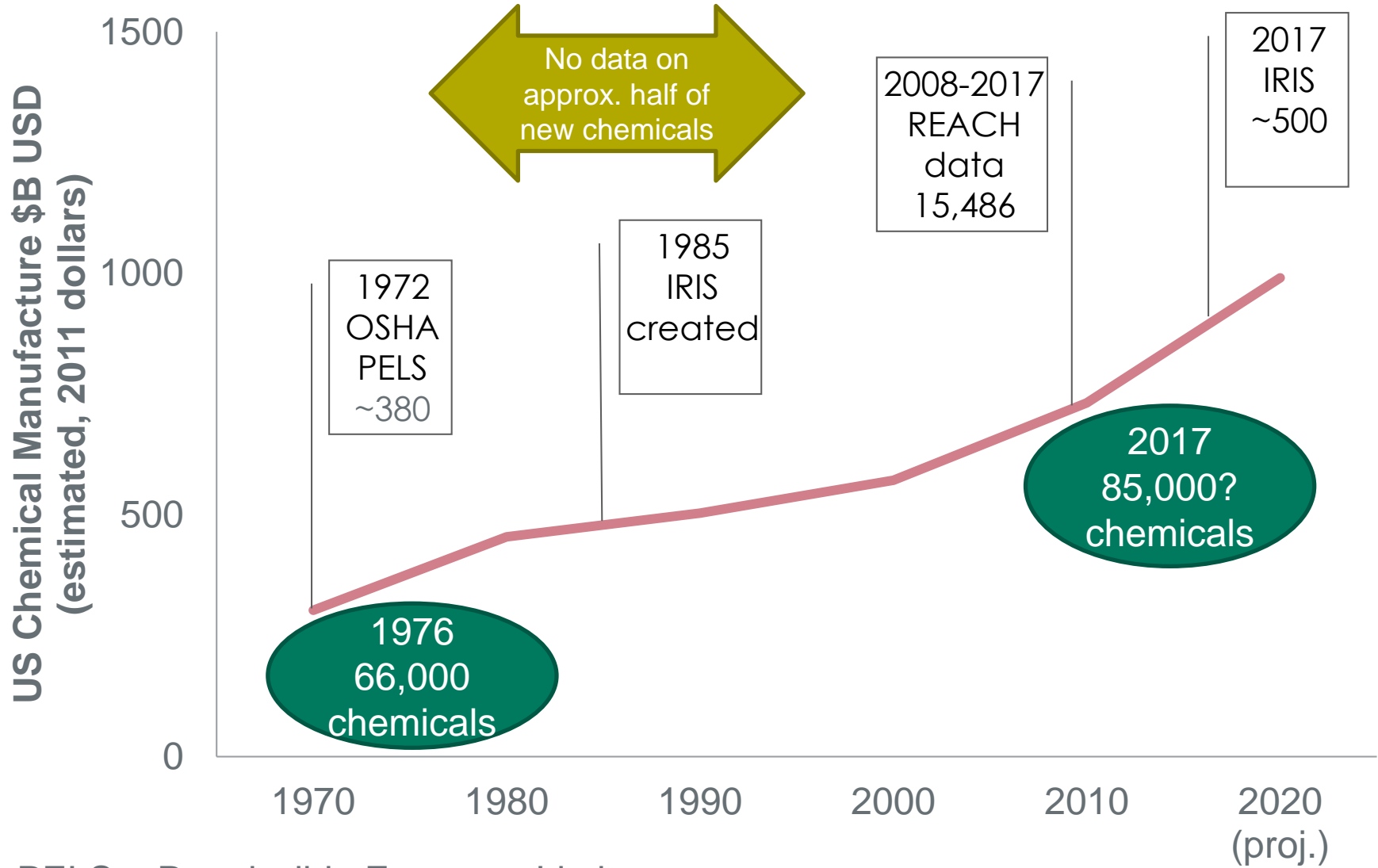


Requires risk assessment of prioritized existing chemicals



Is supposed to provide a consistent source of funding for EPA to carry out responsibilities

Chemical Characterization: 1976 TSCA - 2016 CSA



PELS = Permissible Exposure Limits

IRIS = EPA's Integrated Risk Information System

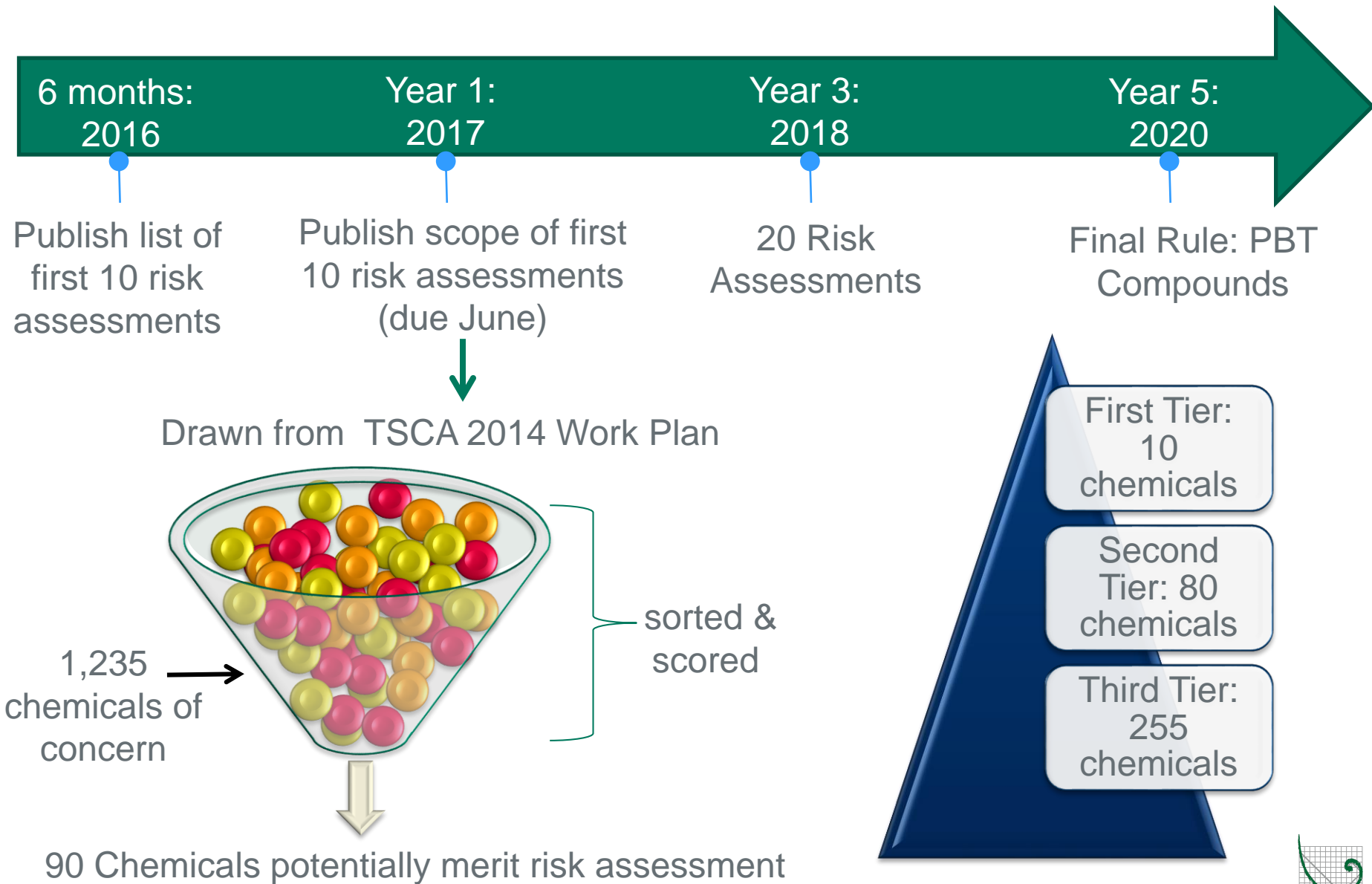
CSA Changes Risk Assessment Paradigm

EPA's New Look at Old Chemicals under the CSA: the Work Plan Process



PBT = Persistent, Bioaccumulative, Toxic

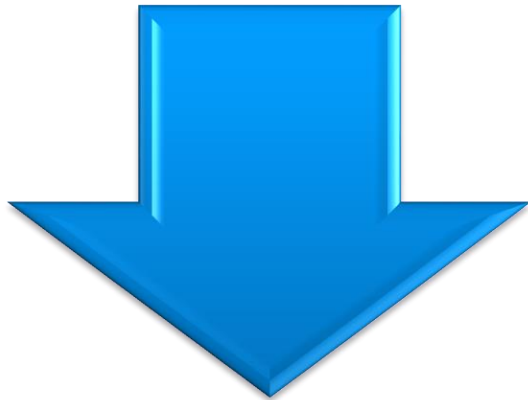
Timeline for CSA EPA Risk Assessments



Implications for Site Cleanup

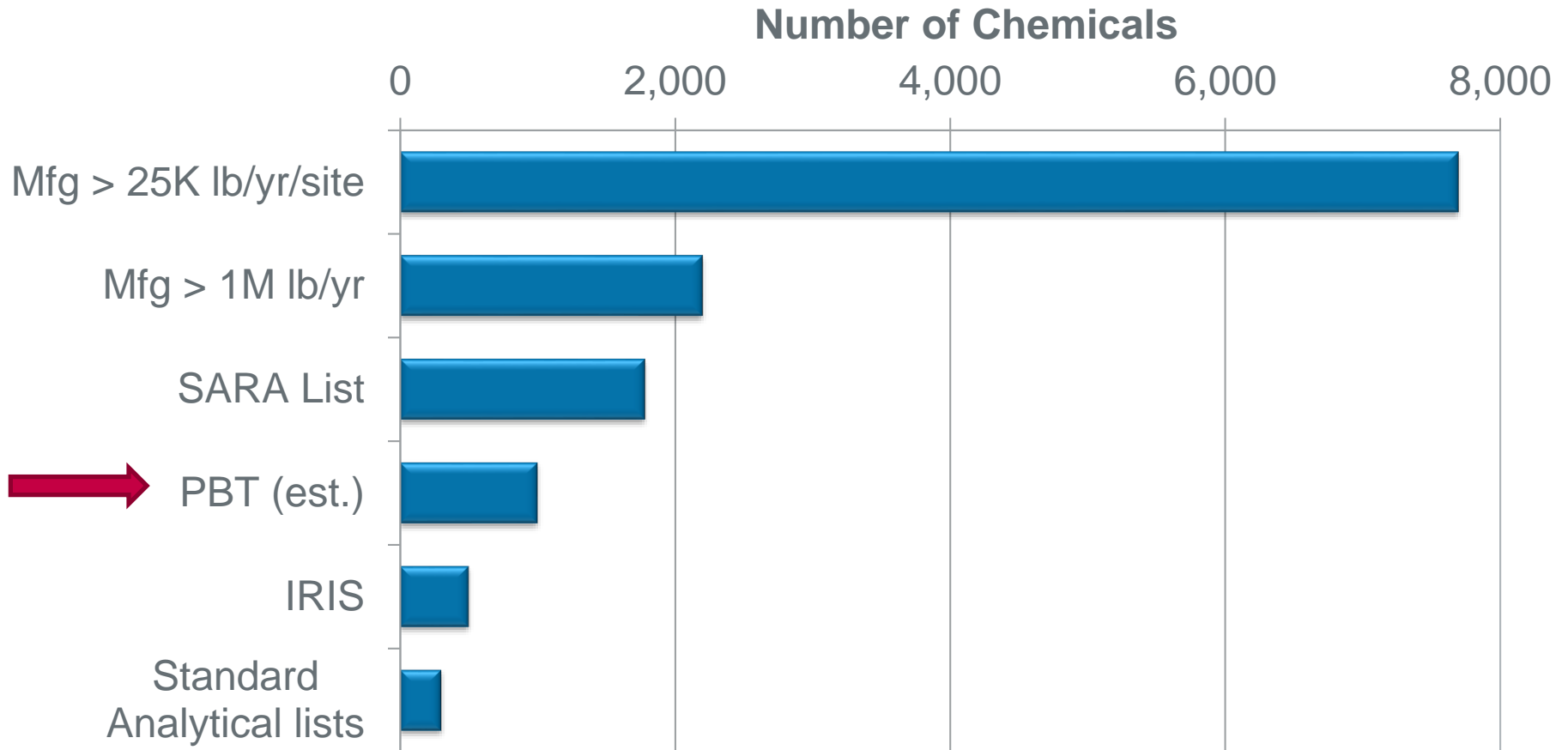


New
contaminants of
concern?



New cleanup
goals?

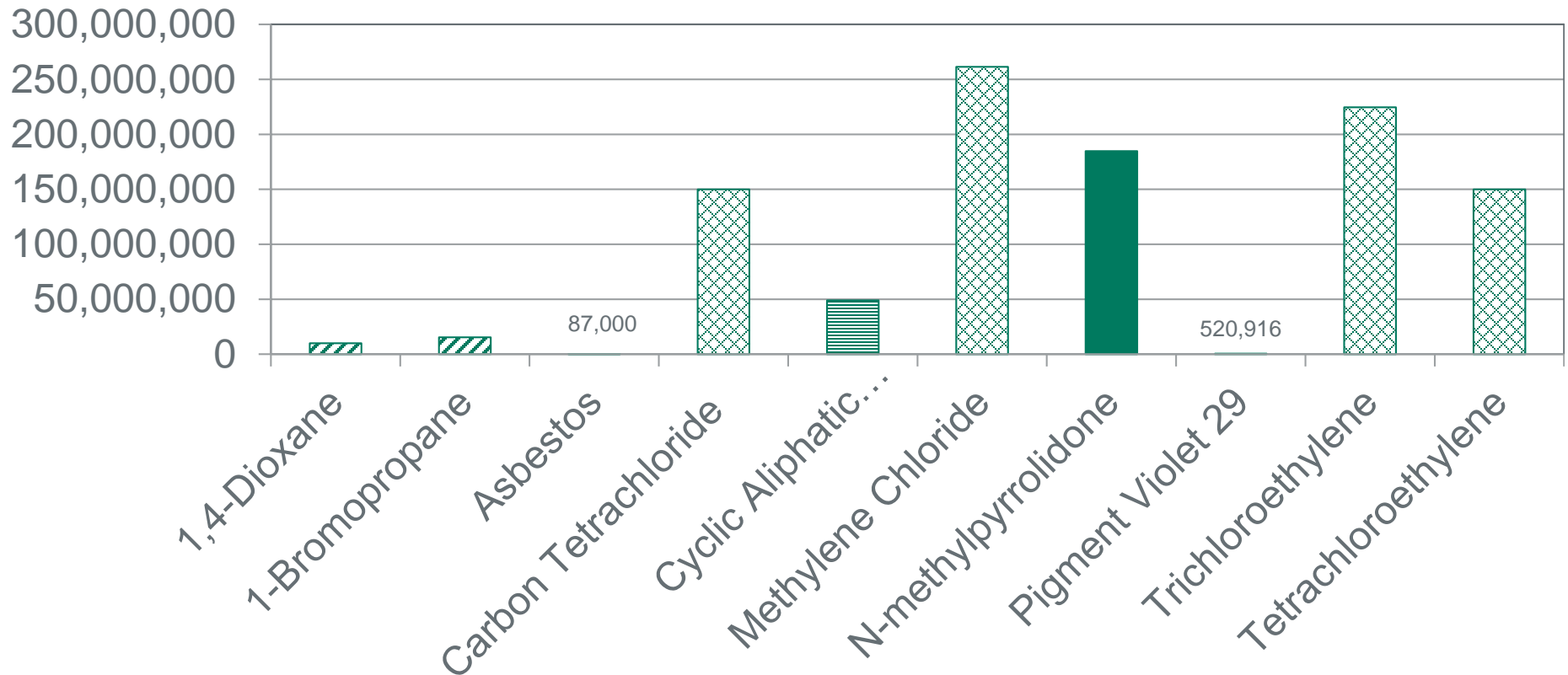
Implications for Site Investigation and Cleanup



- We find what we look for
- Under 1976 TSCA, little to no data on fate and transport, toxicity or ecotoxicity of most chemicals

Top Ten TSCA Work Plan Chemicals

Est. Annual US Production (lb/yr)



NMP: Approved as a substitution for methylene chloride in the 1990's



Possible human carcinogen



Probable human carcinogen

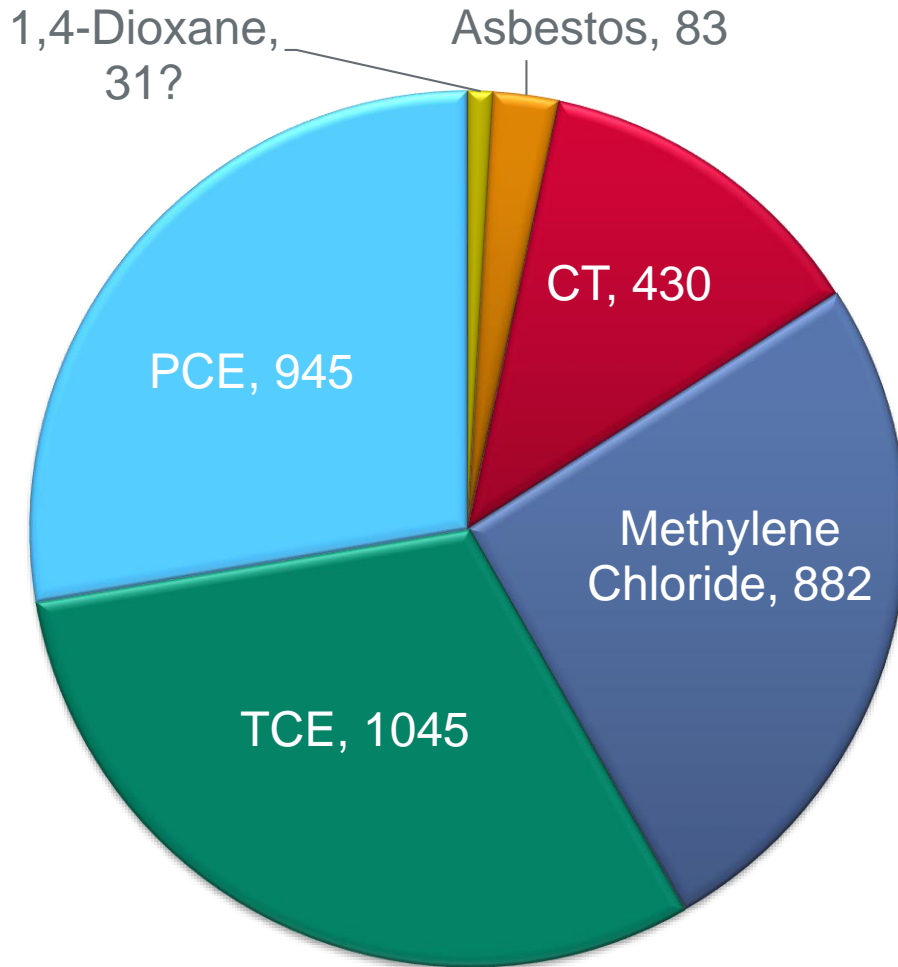


Aquatic toxicity



Reproductive toxicity, non-cancer

Number of Superfund Sites Affected?



No published records, or not analyzed:

- Bromopropane
- Cyclic Aliphatic Bromide Cluster
- N-methylpyrrolidone
- Pigment Violet 29

What about the next 80?

Persistent &
Bioaccumulative

Cumulative
Score

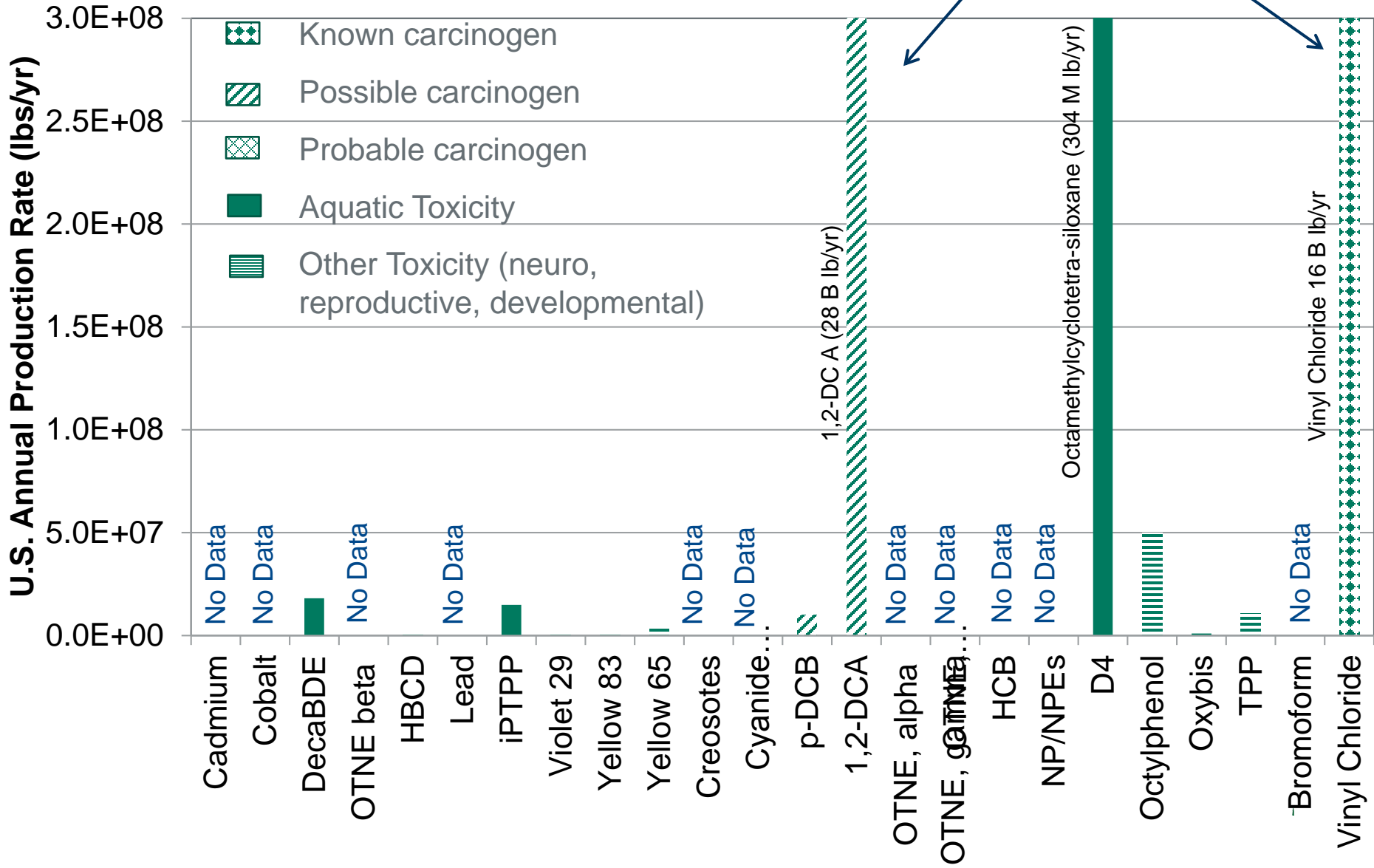
Toxicity

Exposure
Potential

Chemical Triage:

- Ranked 1 – 3 in each category
- 24 score a 8 or 9

What about those 24?



New Cleanup Goals?

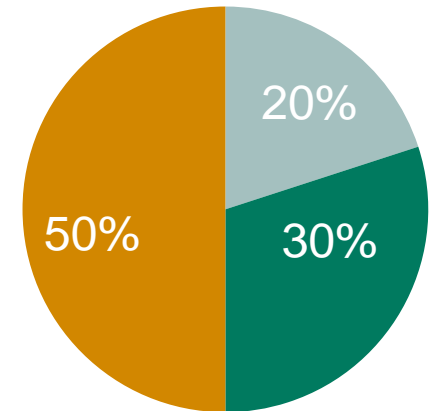
Under the CSA, EPA

- Emphasizes certain endpoints: PBT, reproductive/developmental toxicity, neurotoxicity, respiratory sensitization
- Considers new sources of data, (i.e. European Union regulation REACH)

New focus and data sources could mean changes in dose response considerations that affect clean-up levels.

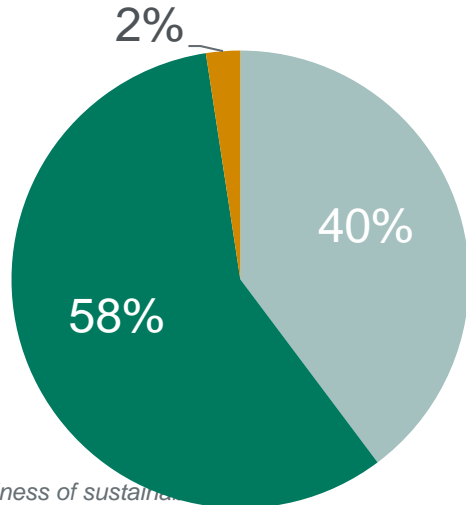
IRIS Status of First 10 Chemicals

- Not in IRIS
- IRIS entry > 10 yrs old
- IRIS entry < 10 yrs old



Next 80 Chemicals

- Not in IRIS
- > 10 years
- < 10 years

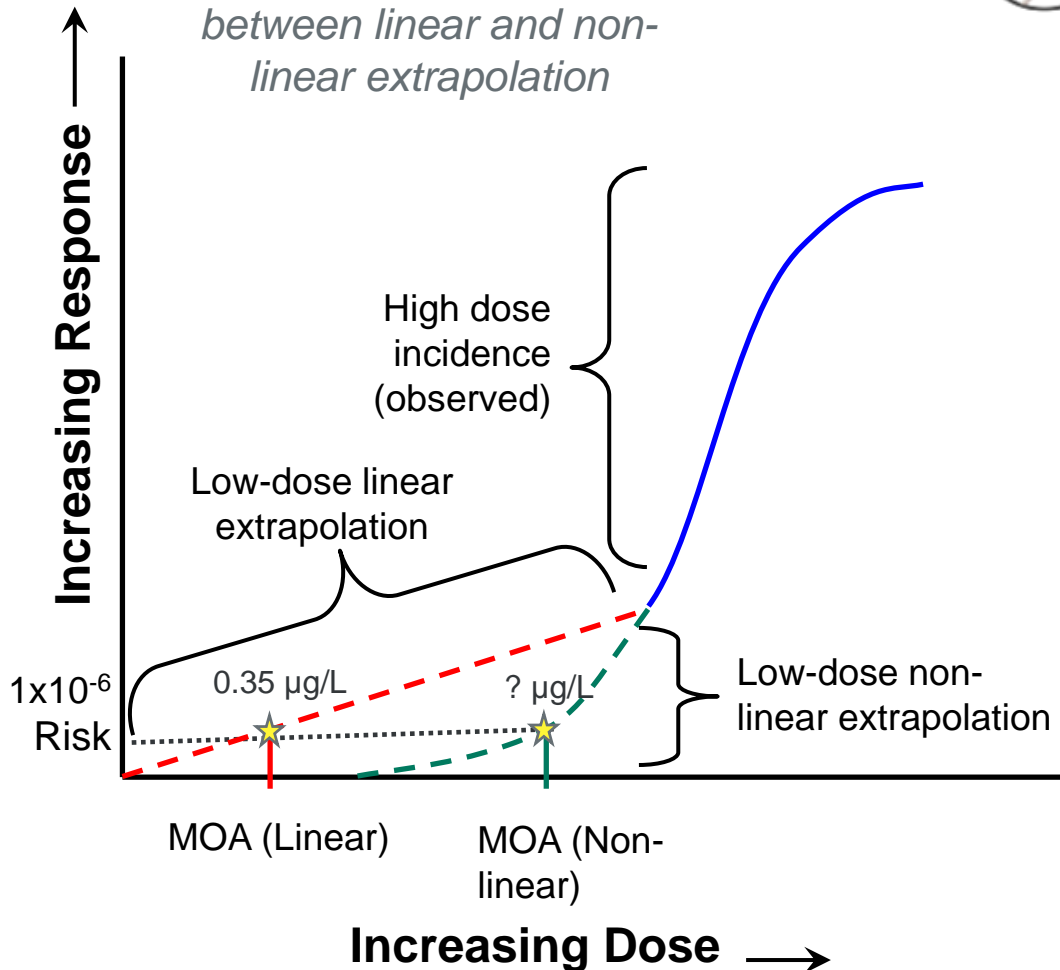


1,4-Dioxane Toxicity Evaluation



Alliance for Risk Assessment

Example difference between linear and non-linear extrapolation



Re-evaluated Mode of Action (MOA) for 1,4-dioxane :

- Obtained information on Japanese cancer bioassay (mouse liver histopathology)
- Concluded information supported a non-linear (threshold) MOA
- Risk-based groundwater standard $\sim 350 \mu\text{g/L}$
- TSCA must use best available science in risk assessment documents

Takeaways

Chemical Safety Act (CSA) may impact:

- New contaminants of concern
- New cleanup goals
- Potential lack of predictability about ARARs
- Impact at five-year review



Extent depends upon:

$=f(x)$

- Potential for release of target compounds into environment, past or future
- Potential for new or changed Agency assessment of hazard
 - Date of last IRIS update and potential for new data or endpoints

Wild cards:

- So far, CSA implementation untouched by Administration's regulatory roll-back and cost-cutting but stay tuned
- Potential for IRIS defunding



How do we manage this?

We have the tools to

- Anticipate potential outcomes
- Contribute to the scientific discussion
- Make informed technical and business decisions



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