EPA
United States
Environmental Protection
Agency

Program Office Collaboration: Biosolids Evaluation

Caroline L. Ring (EPA-ORD-CCTE); David Tobias (EPA-OW)

Chemicals Selected for OW Biosolids Proof-of-Concept

- The Clean Water Act requires OW to evaluate chemicals and microbes that occur in biosolids for harm to human health and the environment
- OW's sewage sludge surveys and literature surveys have found over 500 chemicals that have been detected in biosolids
- OW has developed a screening tool and probabilistic framework to evaluate risk for these chemicals
- OW needed a prioritization process to help determine which chemicals should be evaluated for first
- ORD applied the PICS process that was developed for TSCA to prioritize the biosolids chemicals for assessment

Future work for biosolids

- The PICS process could be updated to based the exposure values on the output of the biosolids tool as opposed to the exposure pathways from TSCA
- Finding future chemicals of concern in biosolids
  - SEEM could be updated to predict biosolids concentrations for chemicals outside of the chemicals currently detected in biosolids
  - These predicted biosolids concentrations would then be run through an updated PICS process to determine what chemicals outside of those currently found in biosolids may be of concern
  - OW would then consider those potential chemicals of concern for risk assessment or a future sewage sludge survey

United States Environmental Protection Agency

Overview

- What are biosolids?
- How EPA evaluates biosolids contaminants under the Clean Water Act
- Risk screening & assessment for biosolids contaminants has been slowed by lack of available data regarding hazard & exposure
- EPA Office of Water proposes a new process to increase efficiency
- EPA Office of Research & Development (ORD) Center for Computational Toxicology & Exposure (CCTE) researchers are working closely with OW to develop and adapt data & tools to support OW's decision-making process
  - CCTE collaboration: Curation of list of chemicals found in biosolids
  - CCTE collaboration: Chemical prioritization workflow
  - CCTE collaboration: High-throughput model of biosolids chemical occurrence

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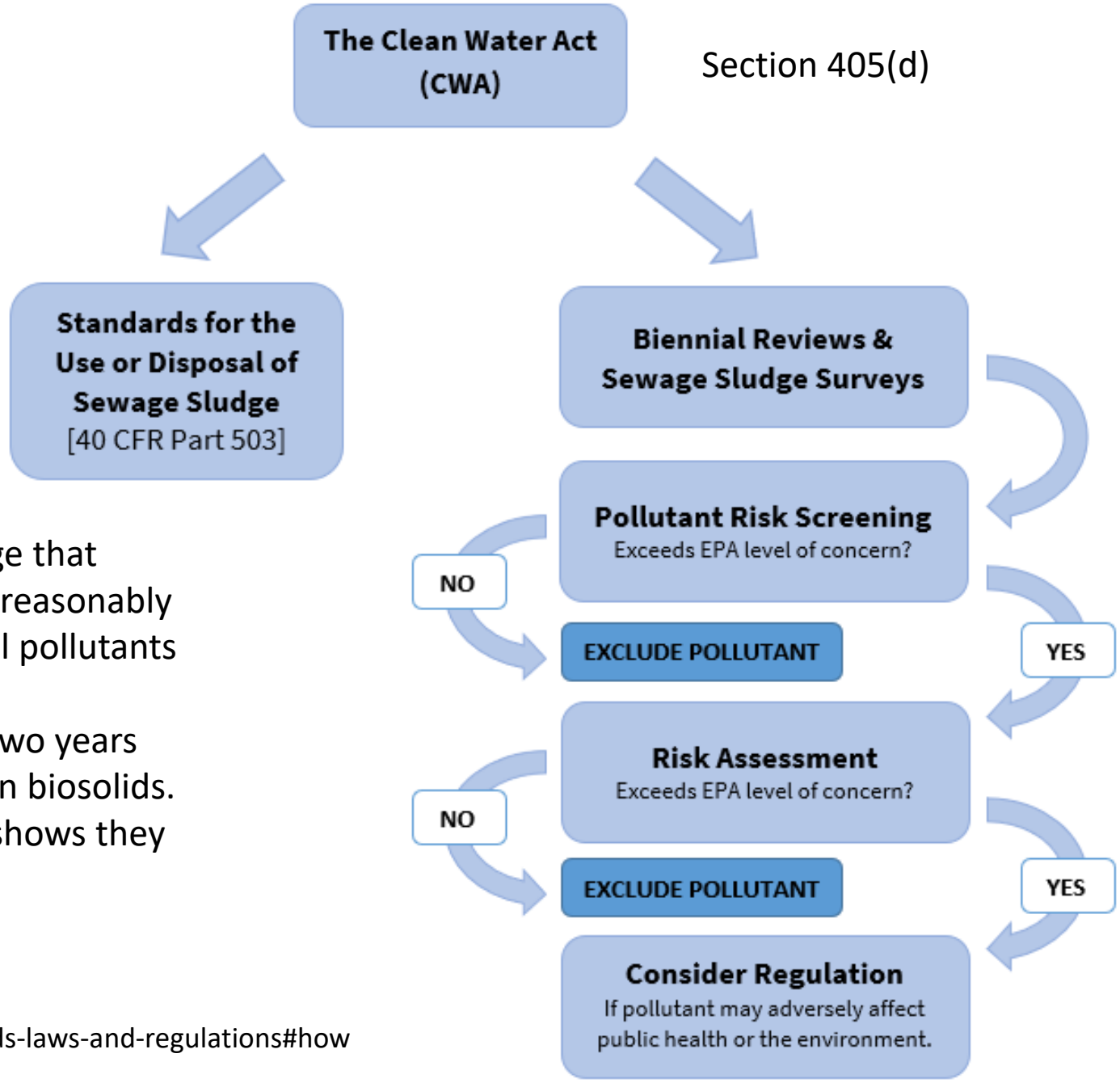
What are biosolids?

- Biosolids are treated sewage sludge.
- After wastewater treatment process, solid material is left over (material that was filtered out, settled out, etc.): these are *biosolids*
- Biosolids are further treated to remove disease-causing pathogens, reduce odor, etc.
- Then, biosolids are disposed of in one of several ways:
  - Land application: Biosolids may be used as fertilizer on agricultural land, soil amendment on non-agricultural land, etc
  - Landfill
  - Incineration
  - Other

EPA and biosolids under the Clean Water Act



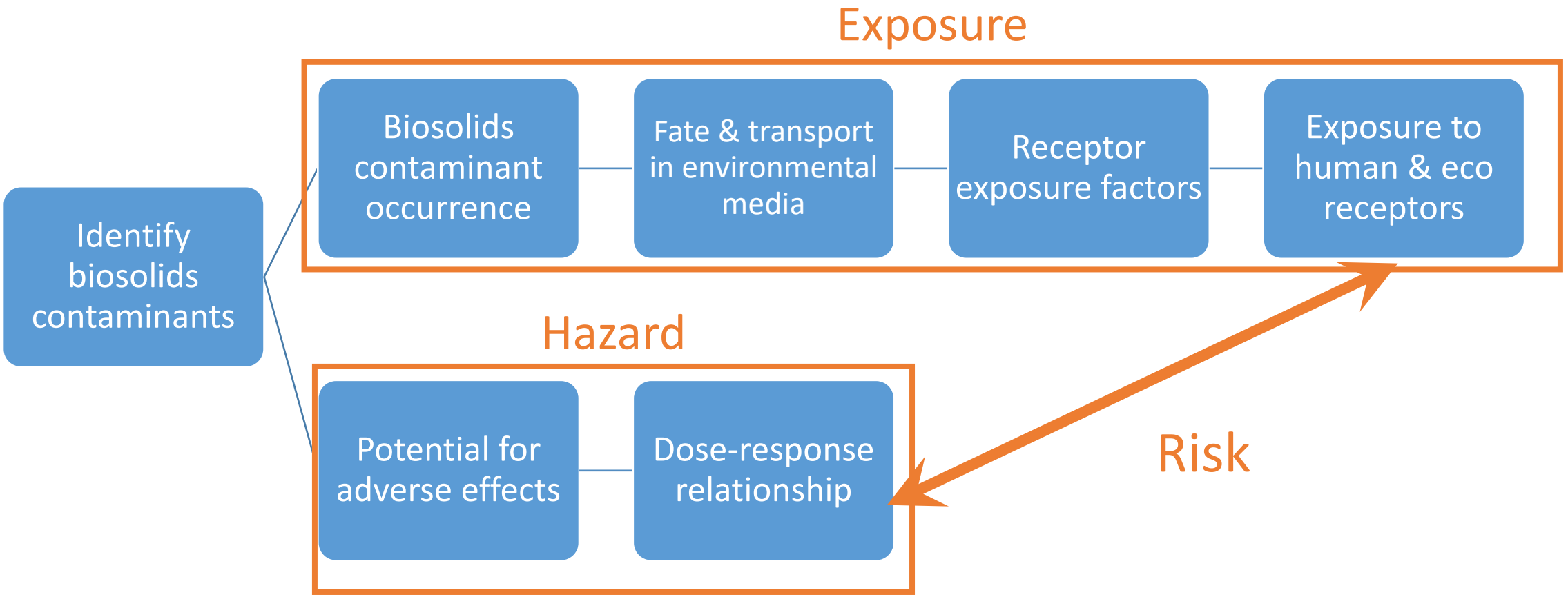
Section 405(d) of the CWA requires EPA to:

- Set standards for the use or disposal of sewage sludge that protect public health and the environment from the reasonably anticipated adverse effects of chemical and microbial pollutants (40 CFR Part 503)
- Review sewage sludge (biosolids) regulations every two years to identify any additional pollutants that may occur in biosolids.
  - Evaluate whether sufficient scientific evidence shows they may harm human health or the environment.
  - If so, then set regulations for those pollutants.

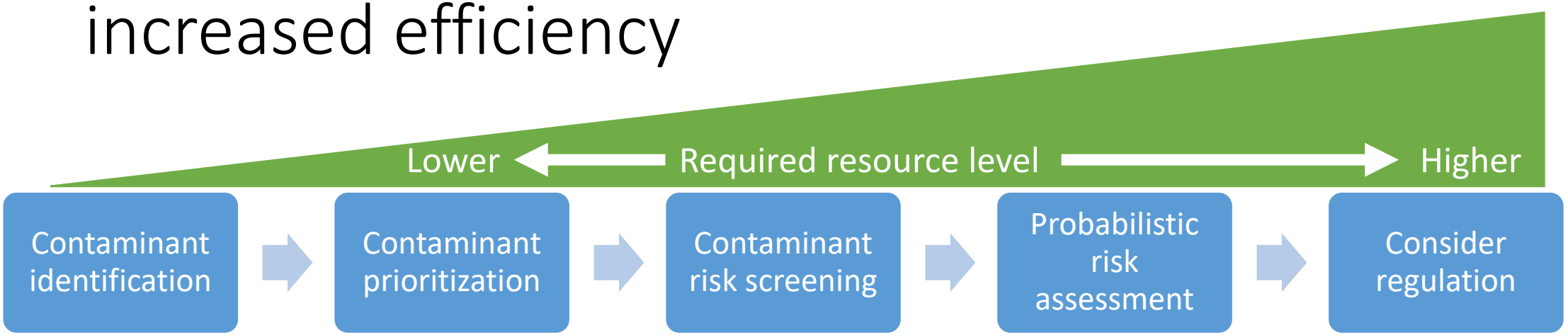
Source: https://www.epa.gov/biosolids/biosolids-laws-and-regulations#how

Data gaps in both exposure and hazard have slowed the evaluation process for biosolids contaminants.

[NRC 2002; USEPA 2018]



EPA's Office of Water proposes a new approach for increased efficiency



Based on data from biennial reviews and from national sewage sludge surveys, identify contaminants that occur in biosolids

Based on available information, determine which contaminants appear to have highest human & eco risk potential; prioritize these for risk screening.

For prioritized contaminants: Apply screening-level human & eco risk model. Predict exposures from biosolids; compare to toxicity thresholds to predict risk. If low, stop; if high, proceed to next step.

For contaminants where risk screening predicted high potential, perform a detailed probabilistic risk assessment. If risk is low, stop; if risk is high, proceed to next step.

If sufficient evidence shows that contaminant may harm human health or environment, set appropriate regulations

ORD-CCTE researchers are working with OW to develop data and tools to support this process (current focus on *chemical* contaminants)

Contaminant identification	Contaminant prioritization	Contaminant risk screening	Probabilistic risk assessment	Consider regulation
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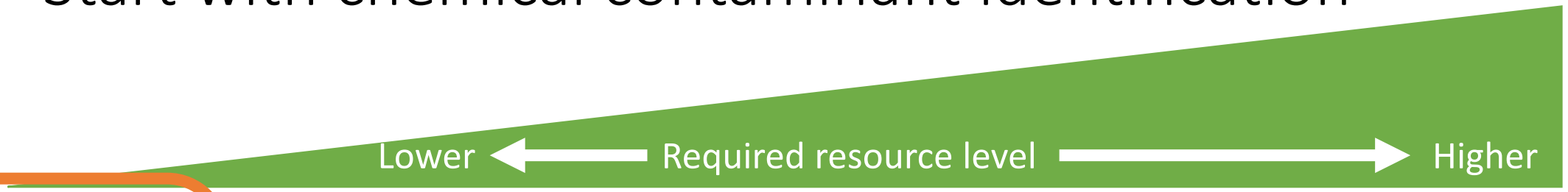
Start with chemical contaminant identification



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ORD-CCTE & OW collaborated to curate a list of chemical substances found in biosolids [Richman & Williams, in prep]

Chemicals found in biosolids were reported in:

- National Sewage Sludge Surveys (1988, 2001, 2009)
  - nationwide monitoring surveys of biosolids from wastewater treatment facilities
- Biennial Reports (2004-2019)
  - new monitoring data found in reviews of the published literature

Problem:

- Each of these reports was a totally separate effort
- Data formats and reporting standards changed between reports
- Chemical identifiers (names, CASRNs) were not standardized among reports

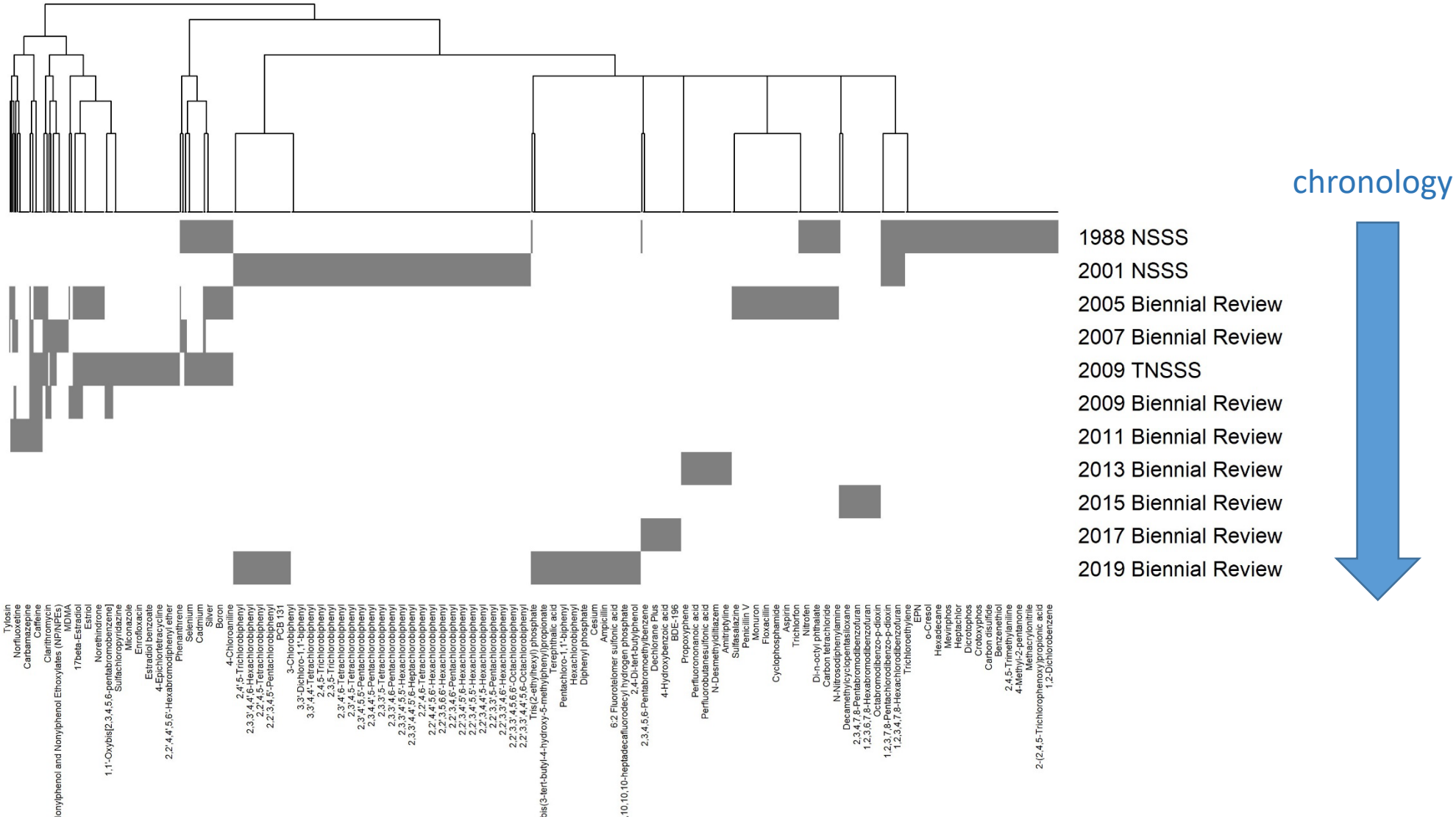
Difficult to combine data from different reports, let alone connect to other chemical data necessary for risk screening and assessment

ORD-CCTE & OW collaborated to curate a list of chemical substances found in biosolids [Richman & Williams, in prep]

Solution: Data curation

- Extract data from reports & harmonize formatting
- Standardize chemical names
  - Fix misspellings & typos
  - Identify synonyms
  - Identify neutral forms of salts & charged anionic perfluorinated compounds
- Identify individual components of chemical combinations
  - e.g. chemicals that can't be separated by standard analytical chemistry methods, such as co-eluting PCBs
- Identify correct CASRNs
- Map to DSSTox Substance IDs [Grulke et al. 2019]

Chemical identification result: Curated list of chemicals found in biosolids in each Biennial Review and National Sewage Sludge Survey [Richman & Williams, in prep]

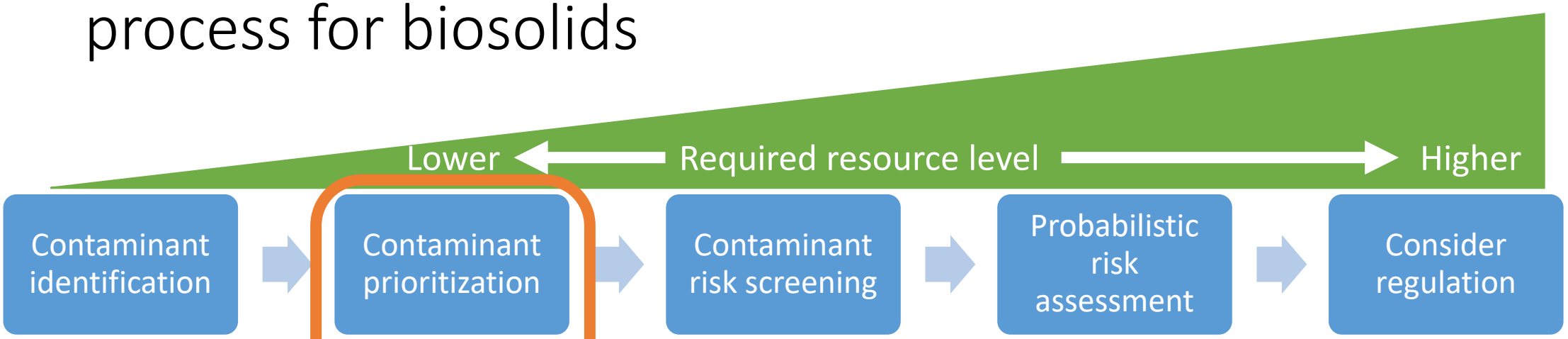


Chemical curation allows OW and ORD researchers to…

[Richman & Williams, in prep]

- Correctly determine when each chemical was identified
  - For example, the 2018-2019 Biennial Report reported 116 “newly identified” chemical pollutants in biosolids.
  - After curation, it turns out 41 of 116 had actually been identified previously!
- Query hazard-, exposure-, and risk-relevant data sources for biosolids chemicals, e.g. data available through the CompTox Dashboard [Williams et al. 2017]
  - Structure
  - Physical-chemical properties
  - Chemical categories
  - Chemical functional use
  - High-throughput exposure predictions
  - ToxCast/Tox21 high-throughput *in vitro* screening data
  - Existing *in vivo* toxicology data
- Enable application of a chemical prioritization workflow that pulls together structure, phys-chem, hazard and exposure data from multiple databases

This brings us to the need for a chemical prioritization process for biosolids



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For contaminants where risk was predicted to be high, determine appropriate threshold levels of contaminant in biosolids, to be enforced as regulations

Solution: adapt workflow originally developed in context of TSCA prioritization: PICS (Public Information Curation and Synthesis)

[previously presented to CSS BOSC by Dr. Richard Judson in February 2021]

PICS integrates publicly available information from multiple domains for chemical substances:

- hazard
- exposure
- persistence
- bioaccumulation

PICS synthesizes information from traditional methods and New Approach Methodologies

PICS was designed to:

- understand the overall **degree of potential concern** related to human health and the environment, based on available information
- understand the **relative coverage of potentially relevant information** about human health and ecological toxicity and exposure
- inform **level of effort and resources** that may be needed to evaluate a specific substance
- be **readily adaptable to address prioritization needs** under other mandates (not just TSCA!)

PICS workflow: chemical scores for two metrics

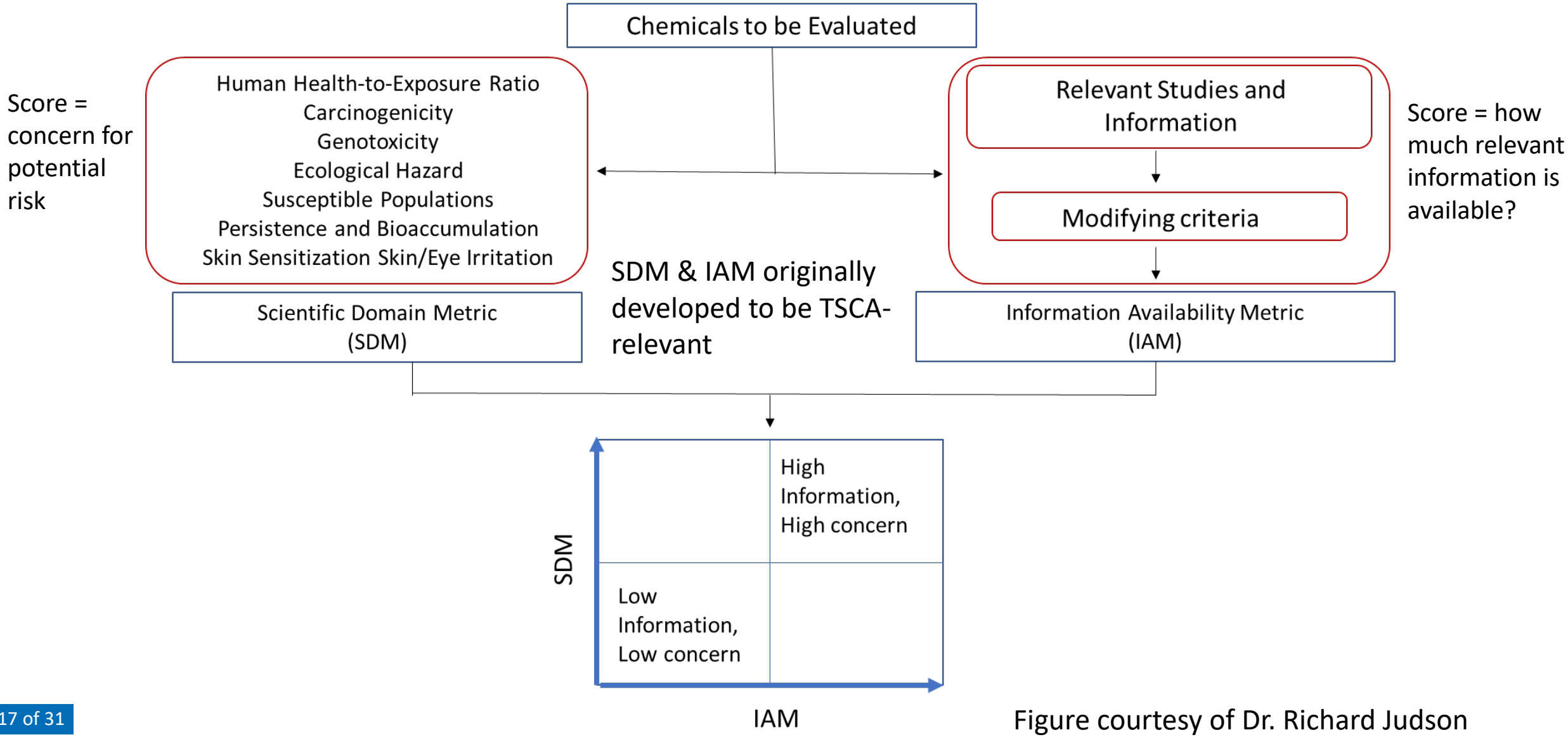
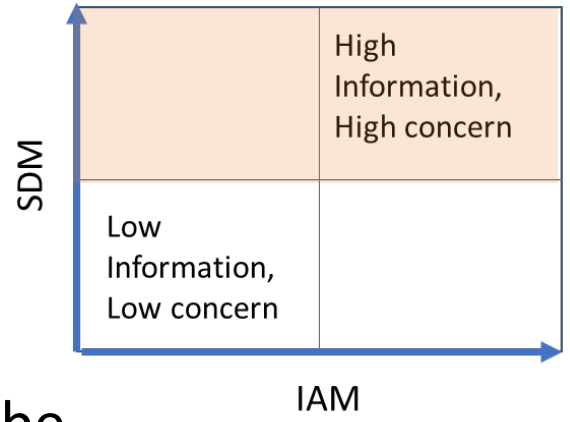


Figure courtesy of Dr. Richard Judson

PICS was adapted from TSCA prioritization to biosolids prioritization

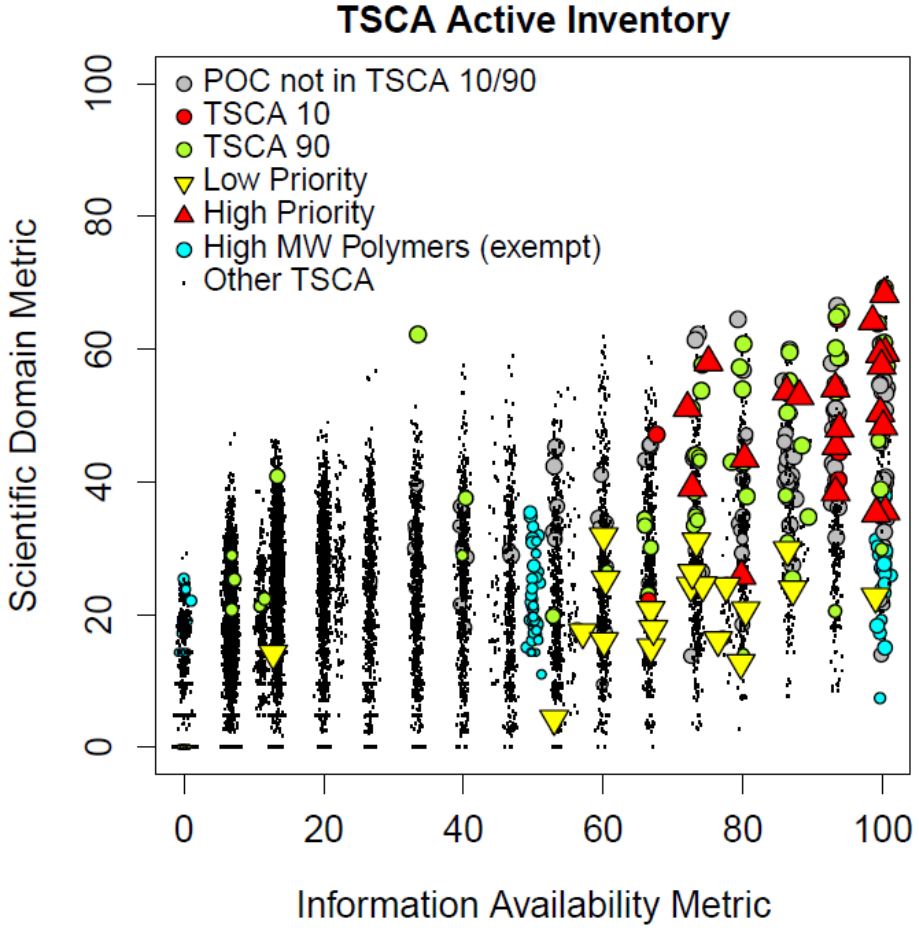
- Preliminary work: run PICS "as-is" for curated list of chemicals found in biosolids
  - Scientific domains as originally identified for TSCA
  - Information availability scoring & modification as originally identified for TSCA

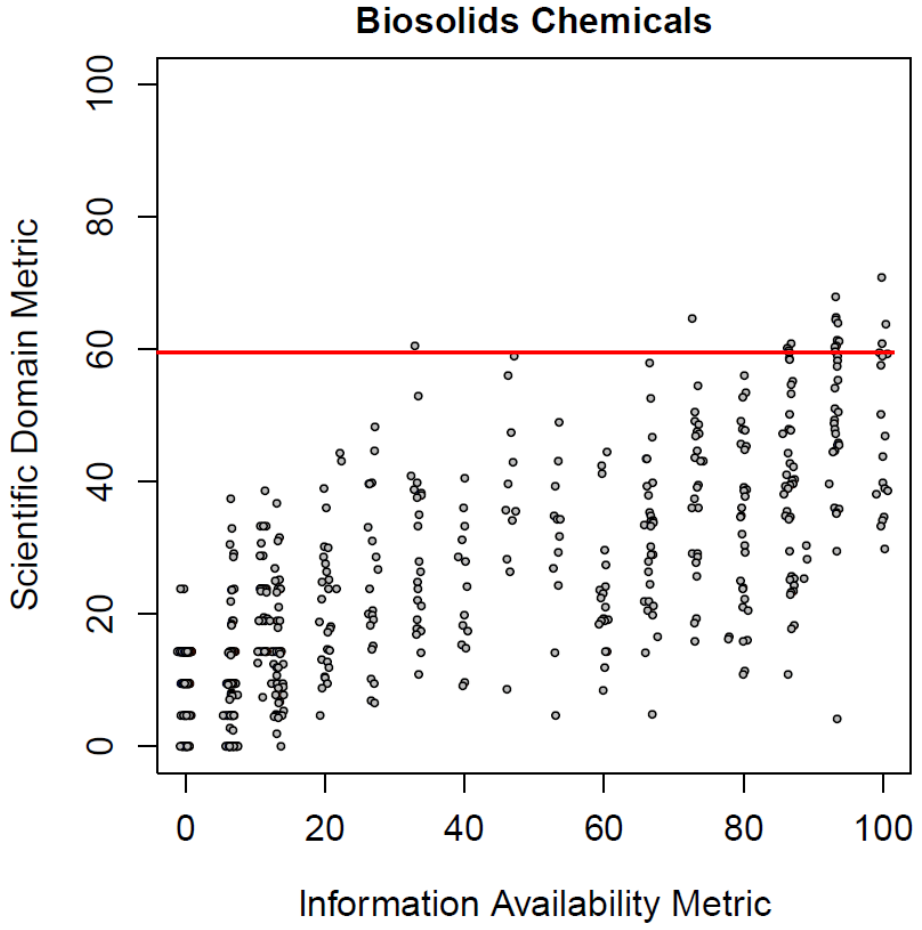
- Prioritization for biosolids based mainly on Scientific Domain Metric
  - "Low information, high concern" chemicals (if any) would not be excluded from priority list
  - Information Availability Metric helps with identifying data gaps that might be important in risk screening/assessment phases



- PICS scientific domains & information availability can be modified for biosolids based on feedback from stakeholders

PICS TSCA case study results vs. Biosolids preliminary results





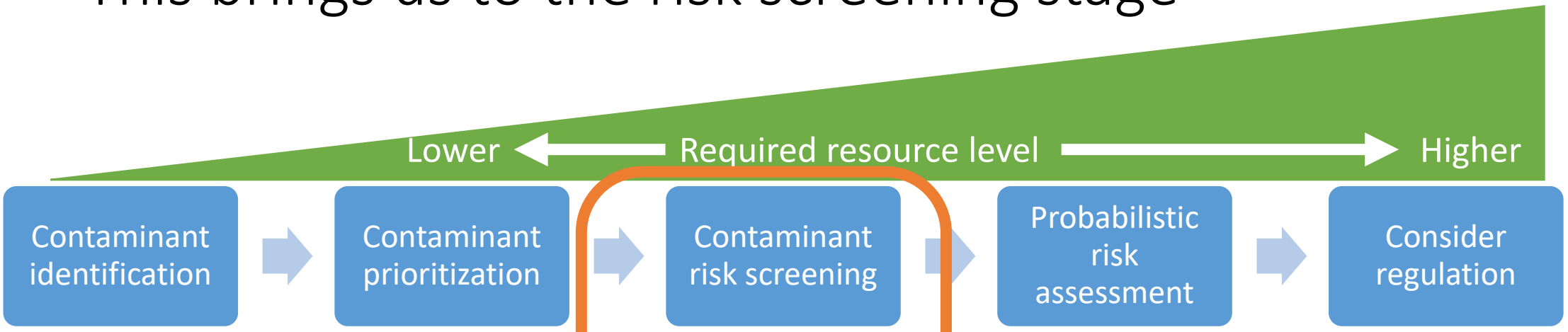
Distribution of SDM/IAM is similar in biosolids chemicals and in TSCA Active Inventory

Scientific Domain Metric criteria (red line) can be used to prioritize chemicals for risk screening

[POC = TSCA Proof of Concept chemical subset]

slide adapted from Dr. Richard Judson

This brings us to the risk screening stage



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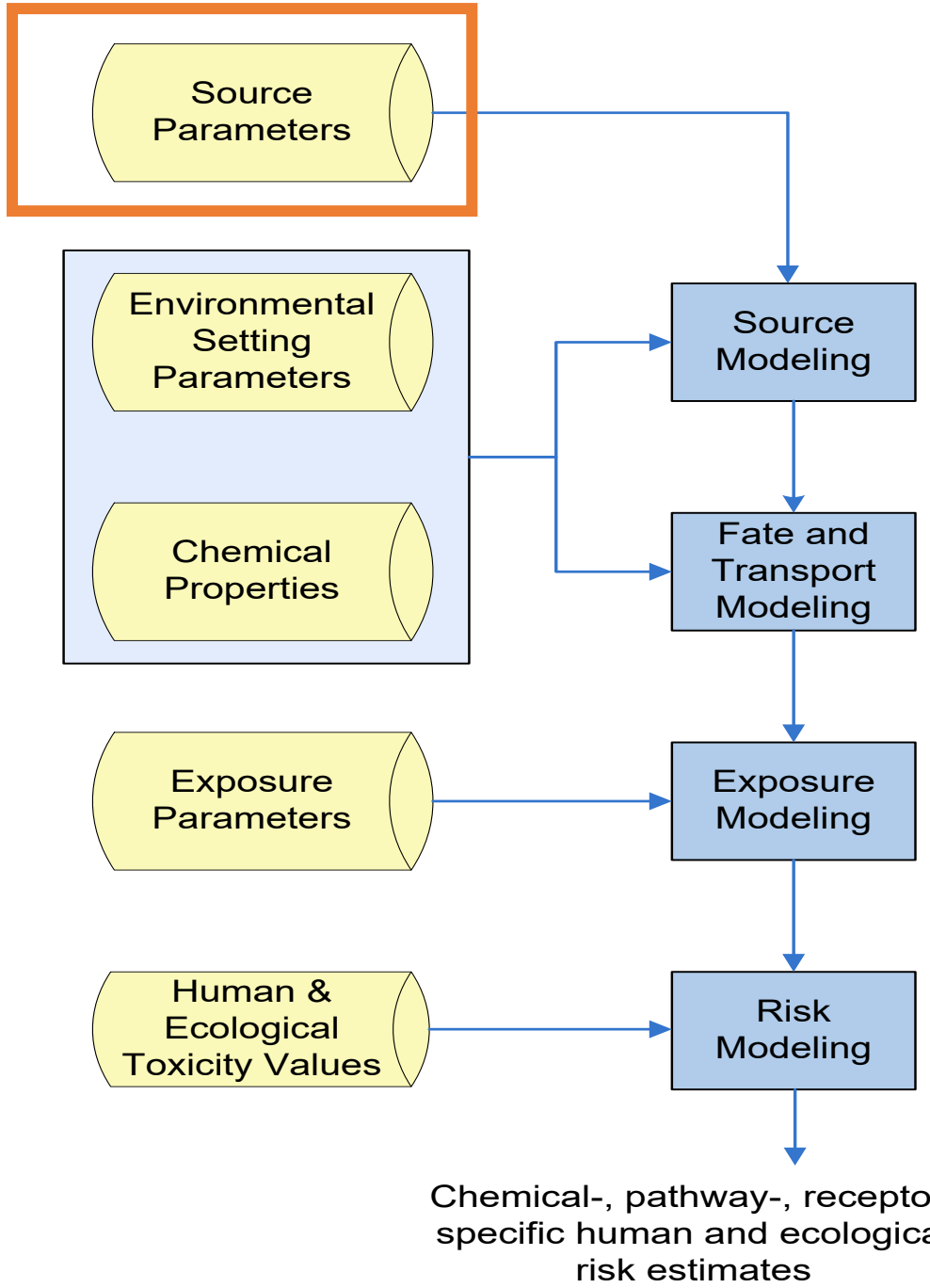
For risk screening, OW has developed Biosolids Screening Tool (BST) — but BST requires biosolids concentrations as input!

Measured biosolids concentrations are only available for about half of chemicals on the curated biosolids list.



Overview of Biosolids Screening Tool modeling framework

Simulates multiple exposure pathways relevant to land application, incineration, and surface disposal

Figure from OW

How CCTE can help: Develop a model to rapidly *predict* biosolids concentrations for data-poor chemicals

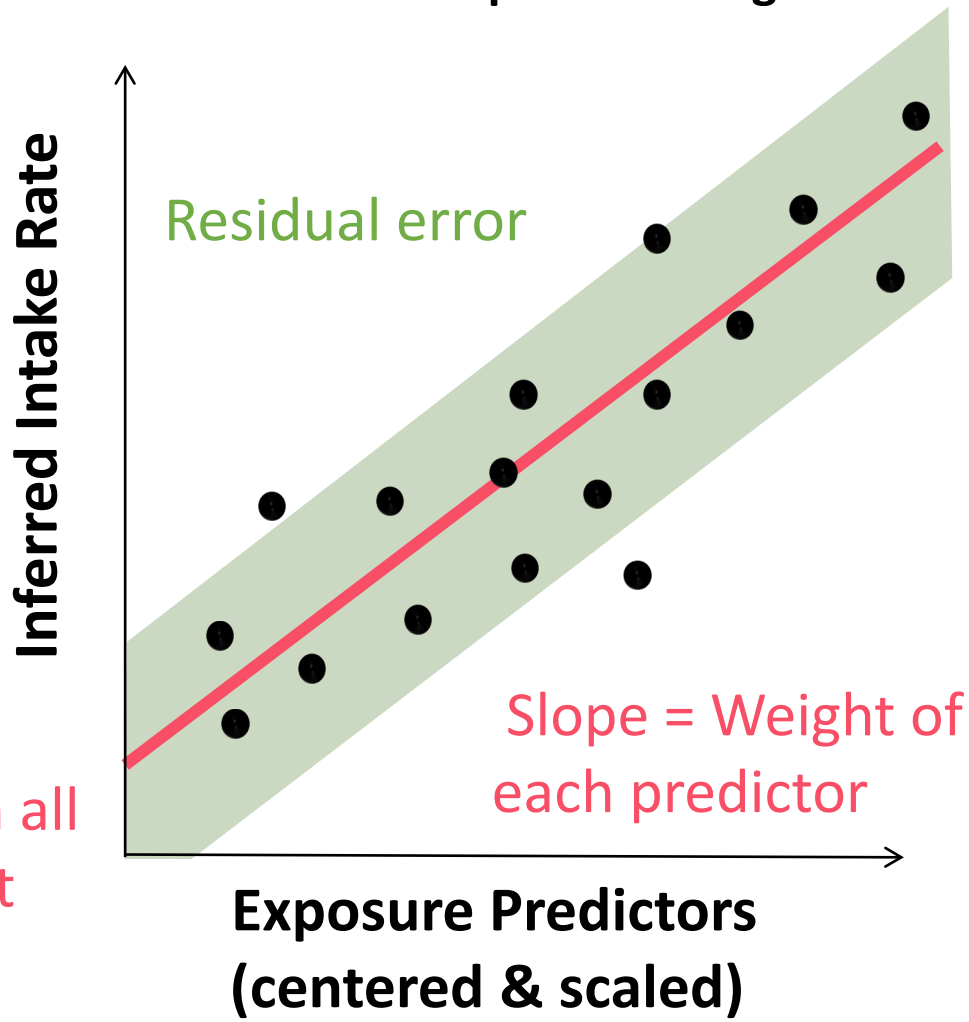
- Require minimal chemical-specific data
  - e.g. little data available for liquid:solid partitioning in sludge; biodegradation in sludge
- Require minimal fate & transport-related data
  - e.g. little data available for wastewater treatment plant (WWTP) operating parameters
- But make use of any relevant data that *is* available
- Not computationally intensive – can rapidly make predictions for hundreds or thousands of chemicals (even if predictions are uncertain)
  - detailed WWTP models infeasible
- Characterize *variability* in predicted biosolids concentrations
  - Be able to predict upper percentiles
- Characterize *uncertainty* in predicted biosolids concentrations

Relevant previous work: SEEM3, a consensus model for human aggregate daily intake rate (mg/kg/day)

SEEM3 = Systematic Empirical Evaluation of Models, version 3

Ring et al. (2019)

SEEM3 is a multiple linear regression!



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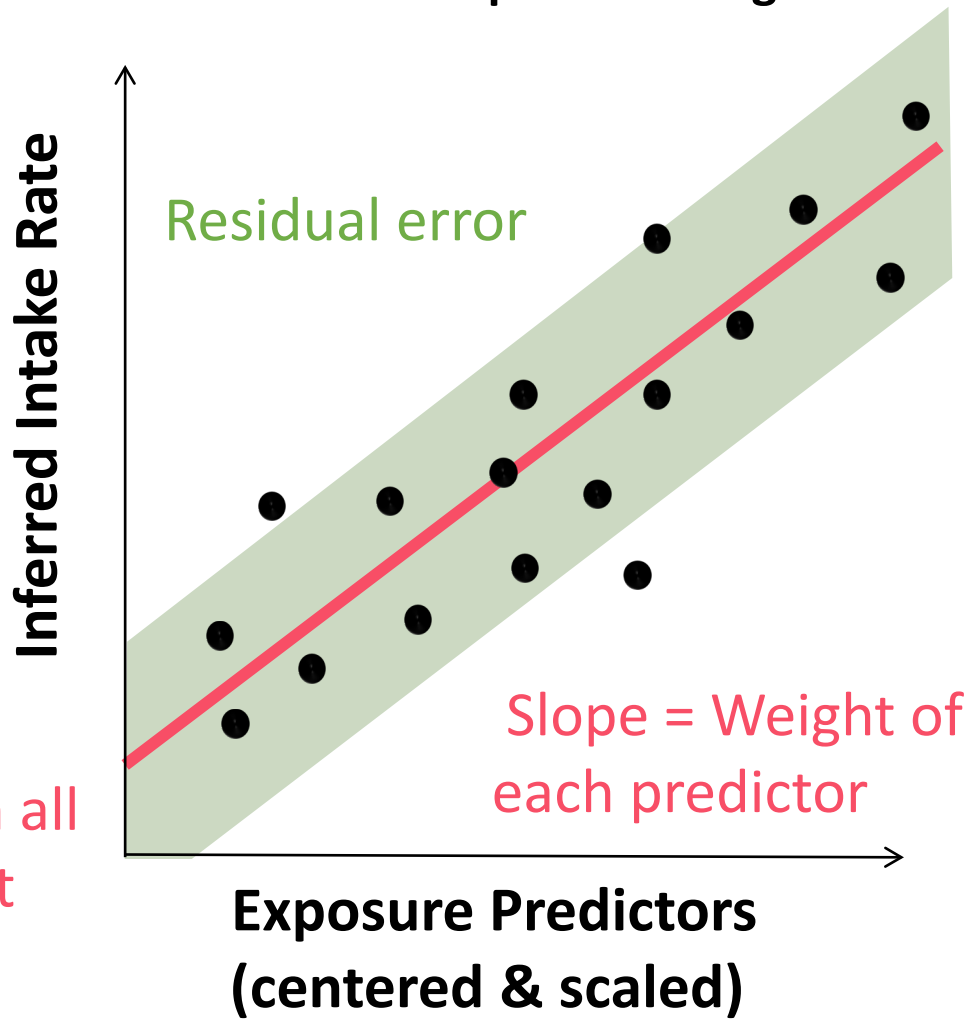
Train model on median intake rates inferred from CDC NHANES biomonitoring data



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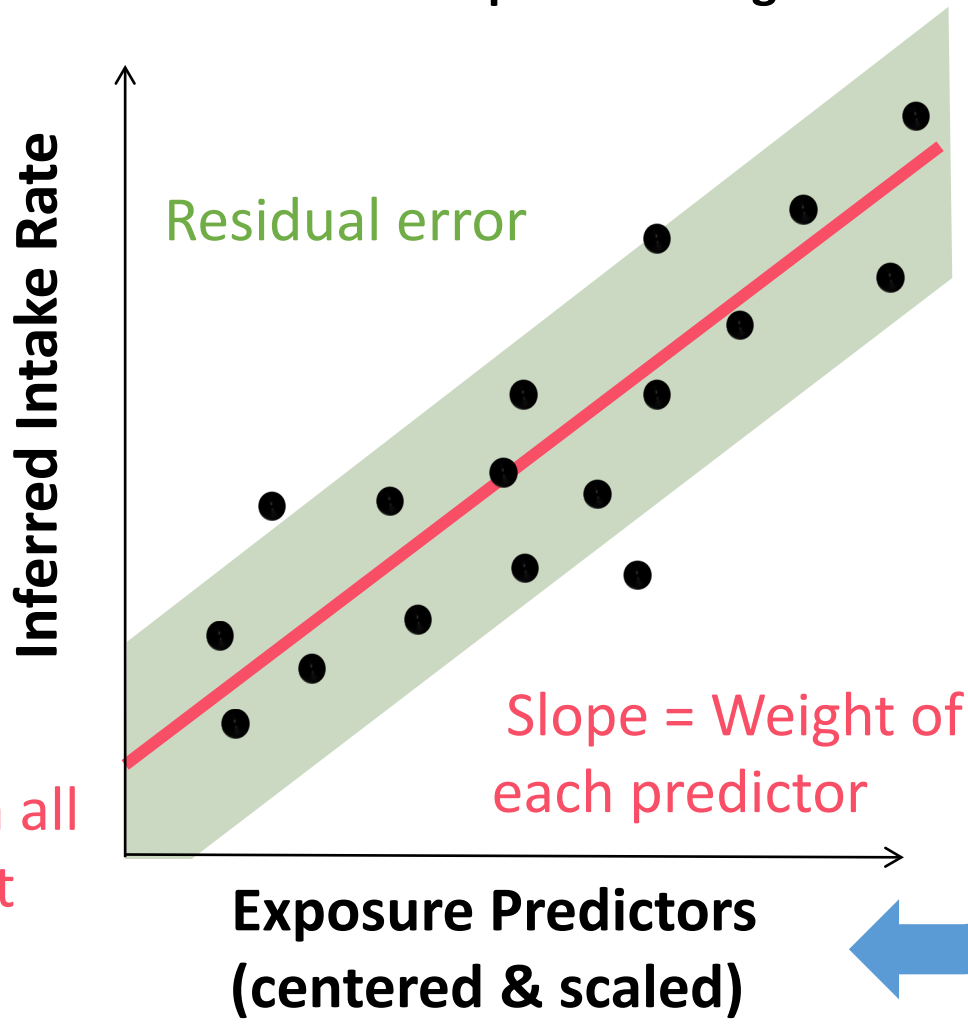

Exposure Predictors:

- Predictions of HT exposure models (USETox, RAIDAR, FINE, SHEDS-HT…)
- Chemical production volume (U.S.)
- Existing EPA pesticide exposure assessments
- Presence on Stockholm Convention list of banned persistent organic pollutants

Missing predictor data: Impute mean

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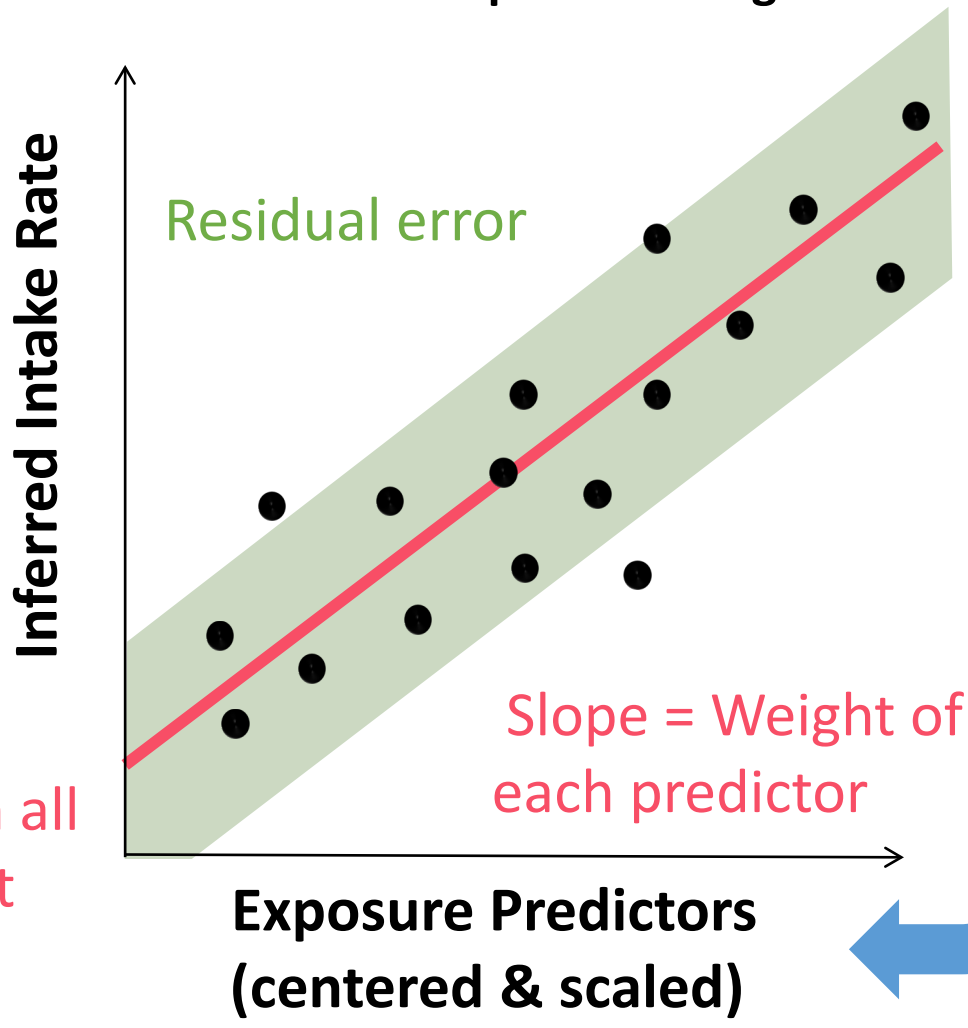
Bayesian inference = *Probabilistic* estimates of intercept, slopes, and residual error



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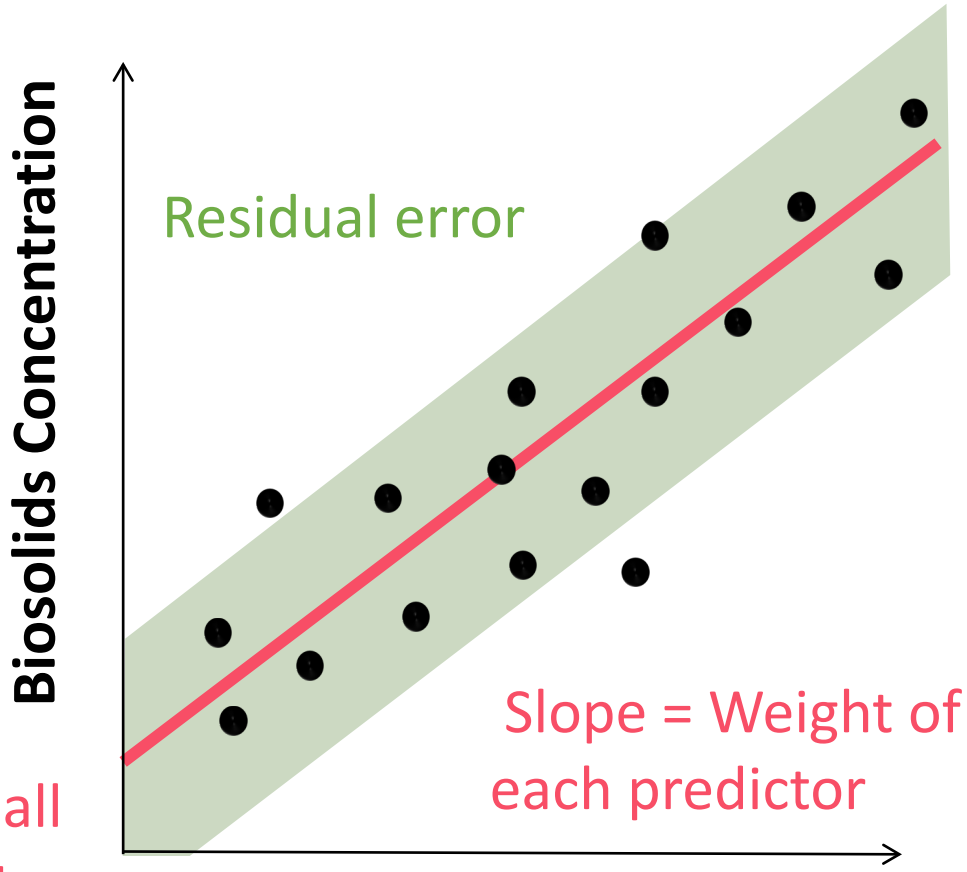
Work in Progress: Build a "Biosolids SEEM3" to predict biosolids concentrations

Train model on biosolids monitoring data from National Sewage Sludge Surveys

Bayesian inference = *Probabilistic* estimates of intercept, slopes, and residual error



Intercept = Conc. when all predictors at mean value

Exposure Predictors (potential):

- Predictions of down-the-drain models (SHEDS-HT)
- Predictions of industrial wastewater release models (ChemSTEER?)
- Toxics Release Inventory data on wastewater releases
- Chemical production volume (U.S.)
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Work in Progress: Build a "Biosolids SEEM3" to predict biosolids concentrations

Challenge: Predict upper-percentile concentrations, not just median
Solution: Bayesian quantile regression?

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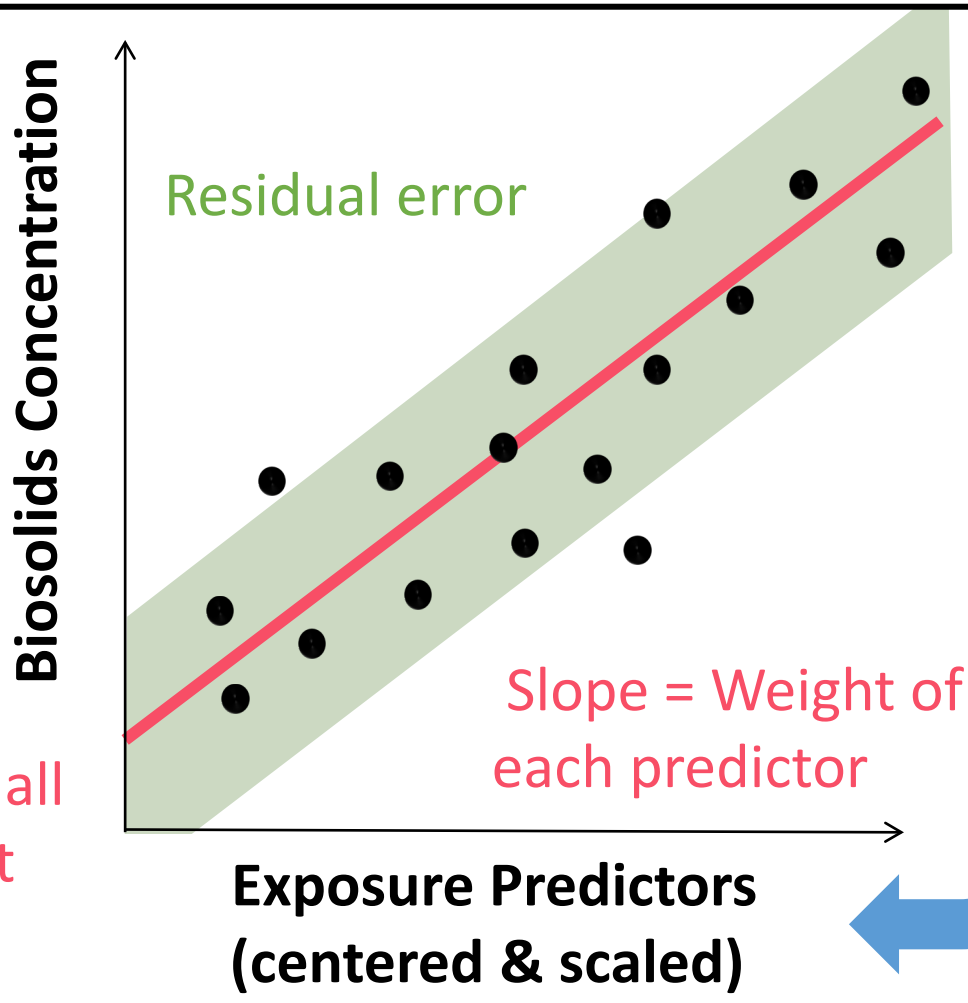

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Summary

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- OW has a need to fill data gaps to more efficiently evaluate biosolids contaminants
- CCTE researchers are working with OW Biosolids to provide data and tools to support biosolids chemical prioritization and screening
  - Curation of list of chemicals found in biosolids
  - PICS prioritization workflow
  - High-throughput model to predict biosolids chemical concentrations

Key People

- OW Biosolids
  - Liz Resek
  - David Tobias
  - Tess Richman (ORISE)
- ORD CCTE
  - Caroline Ring
  - Paul Kruse (ORISE)
  - Tony Williams
  - Richard Judson
  - PICS Proof of Concept Team (see next slide)
  - Marc Russell
  - Kristin Isaacs

PICS Proof of Concept Team

- Abhishek Komandur
- Allison Eames
- Amar Singh
- Andrew Greenhalgh
- Anita Pascocello
- Anita Simha
- Ashley Jackson
- Carlie LaLone
- Carolyn Gigot
- Catherine Gibbons
- Chris Grulke
- Chris Grulke
- Chris Lau
- Colleen Elonen
- Dale Hoff
- Dan Vallero
- Dan Villeneuve
- David DeMarini
- Doug Young
- Elaina Kenyon
- Eric Weber
- Grace Patlewicz
- Janet Burke
- Jason Lambert
- Jeff Dean
- Jeffry Dean
- Jeremy Dunne
- Johanna Congleton
- John Cowden
- John Nichols
- John Wambaugh
- Katherine Phillips
- Kathie Dionisio
- Katie Paul-Friedman
- Kelly Garcia
- Kent Thomas
- Kristin Isaacs
- Lauren Koval
- Lawrence Burkhard
- Leora Vegosen
- Leslie Hughes
- Mary Gilbert
- Maureen Gwinn
- Michael Gonzalez
- Nagu Keshava
- Richard Judson
- Sarah Warren
- Todd Martin
- Tony Williams
- Urmila Kodavanti
- Yu-Sheng Lin

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Thank you!

Questions?

References

Grulke, C. M., Williams, A. J., Thillanadarajah, I., & Richard, A. M. (2019). EPA's DSSTox database: History of development of a curated chemistry resource supporting computational toxicology research. *Comput Toxicol, 12*. doi:10.1016/j.comtox.2019.100096

NRC. (2002). *Biosolids Applied to Land: Advancing Standards and Practices* (978-0-309-08486-4). Retrieved from The National Academies Press: https://www.nap.edu/catalog/10426/biosolids-applied-to-land-advancing-standards-and-practices

Ring, C. L., Arnot, J. A., et al. (2019). Consensus Modeling of Median Chemical Intake for the US Population Based on Predictions of Exposure Pathways. *Environmental Science & Technology, 53*(2), 719-732. doi:10.1021/acs.est.8b04056

USEPA. (1995). *A Guide to the Biosolids Risk Assessments for the EPA Part 503 Rule*. (EPA-832-B-93-005). Washington, DC Retrieved from https://www.epa.gov/sites/production/files/2018-11/documents/guide-biosolids-risk-assessments-part503.pdf

USEPA. (2018). *EPA Unable to Assess the Impact of Hundreds of Unregulated Pollutants in Land-Applied Biosolids on Human Health and the Environment*. (Report No. 19-P-0002). Washington, DC Retrieved from https://www.epa.gov/biosolids/office-inspector-general-reports-biosolids-program

USEPA. (2021a). Biennial Reviews of Sewage Sludge Standards. Retrieved from https://www.epa.gov/biosolids/biennial-reviews-sewage-sludge-standards

USEPA (2021b). Sewage sludge surveys. Retrieved from https://www.epa.gov/biosolids/sewage-sludge-surveys

Williams, A. J., Grulke, C. M., et al. (2017). The CompTox Chemistry Dashboard: a community data resource for environmental chemistry. *J Cheminform, 9*(1), 61. doi:10.1186/s13321-017-0247-6