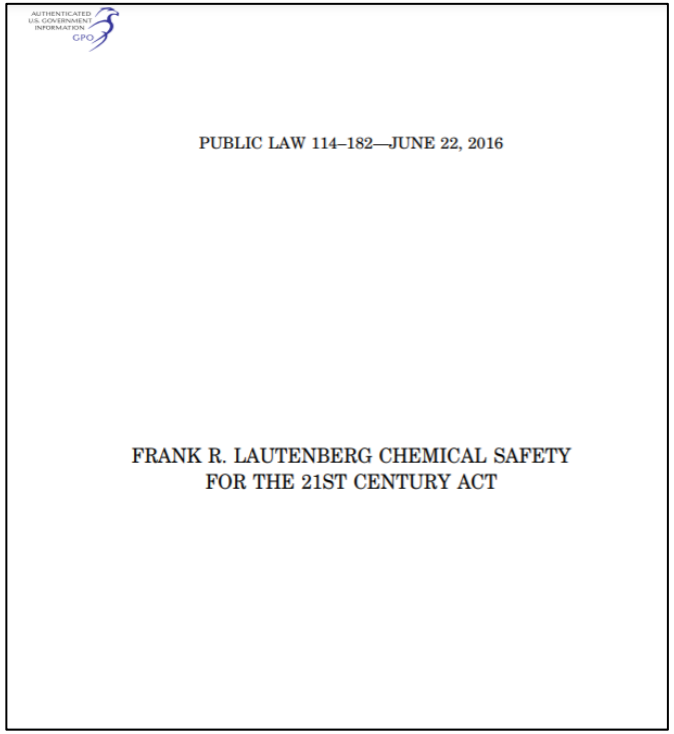
Biosolids Pollutant Prioritization

Richard Judson, PhD
US Environmental Protection Agency
National Biosolids Meeting
November 2-5, 2021

The views presented are those of the author and do not necessarily represent the views of the US EPA.

Origin of Prioritization Approach: TSCA

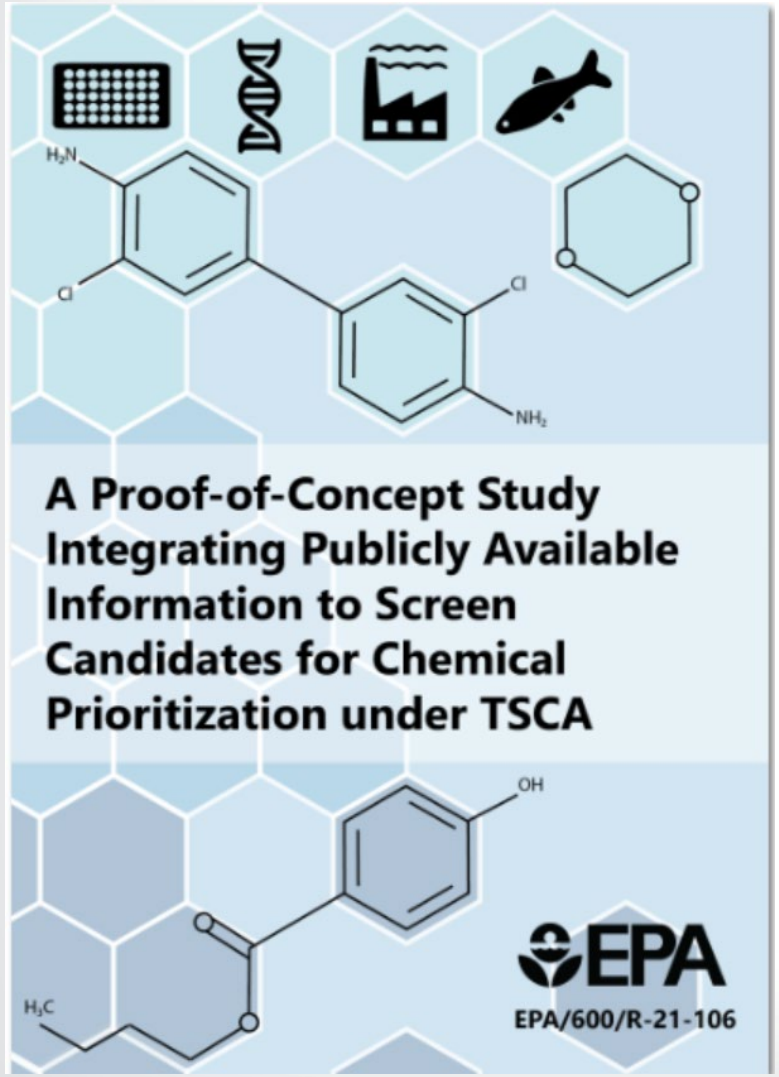
- The Toxic Substances Control Act (TSCA) regulates the introduction of new and existing chemicals.
- TSCA was amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (June 22, 2016)
- EPA required to make determination if chemical substance presents an unreasonable risk of injury to human health or the environment. Determinations are risk-based.
- Periodically, sets of substances must be designated as high or low priority for risk assessments


PUBLIC LAW 114–182—JUNE 22, 2016

FRANK R. LAUTENBERG CHEMICAL SAFETY FOR THE 21ST CENTURY ACT

https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act

Defining Intended Application of PICS Approach (Public Information Curation and Synthesis)



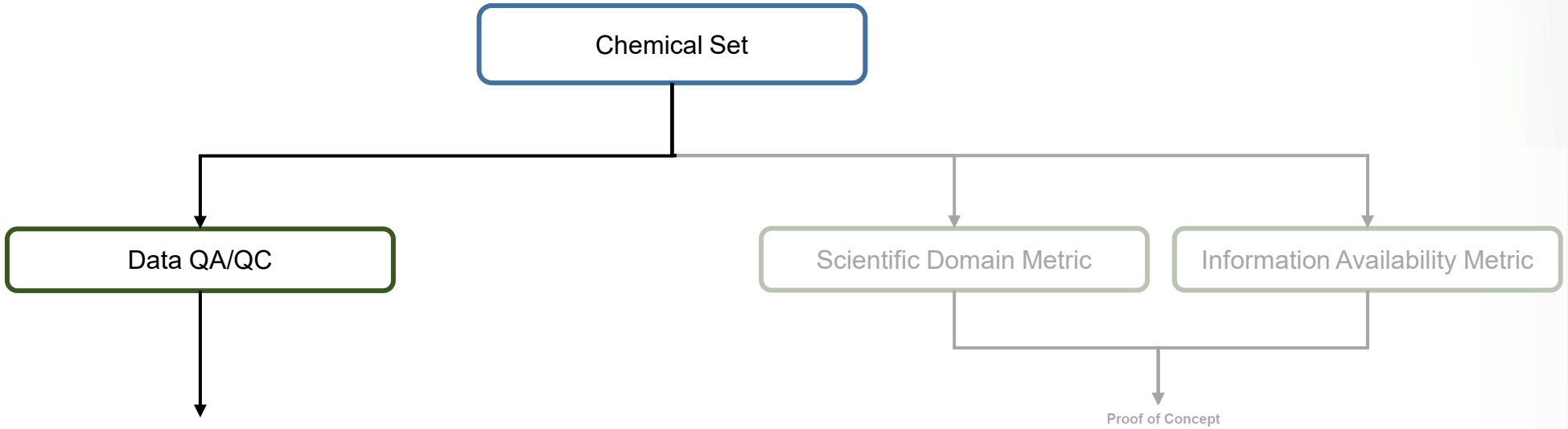
- **The PICS approach was intended to:**
  - Understand the landscape of publicly-available information on large inventories of chemicals
  - Provide a transparent and reproducible process for integrating available information and identifying potential information gaps
  - Increase efficiency and manage workload by focusing expert review on substances that may have a greater potential for selection as high- or low-priority candidates
  - Create a flexible and sustainable process that can adapt to scientific advances and continual generation of new safety-related information
  - Organize the process into modular workflows that can be readily updated or adapted to address scientific advances and prioritization needs under other mandates
- **The PICS approach was <u>not</u> intended to:**
  - Create a ranked list of substances
  - Signal that the EPA has concerns with particular substances or categories of substances
  - Supplant expert judgment and review
  - Utilize confidential business information
  - Incorporate systematic review of information to address study and data quality

https://www.epa.gov/chemical-research/translation-and-knowledge-delivery

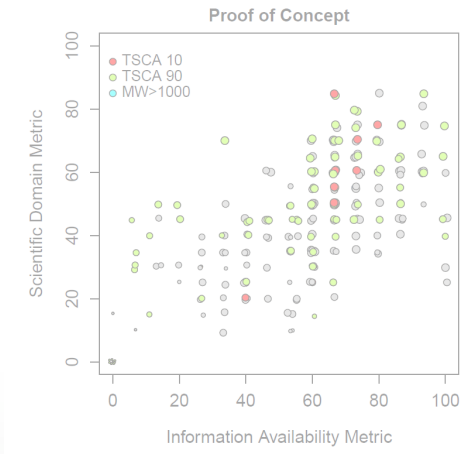
Chemicals Selected for OW Biosolids Proof-of-Concept

- 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

Overall Workflow: QA/QC First



- Specific data domain and data source error rates
- Data QA plan for TSCA active inventory
- Resource estimates for data QC
- QC Tool (beta)

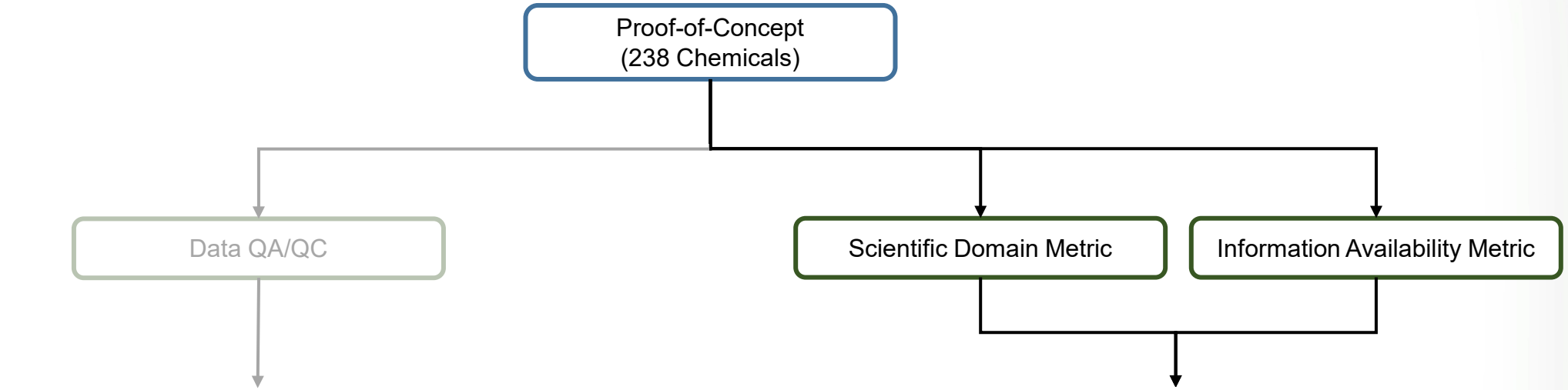


Data Extraction and Quality Control

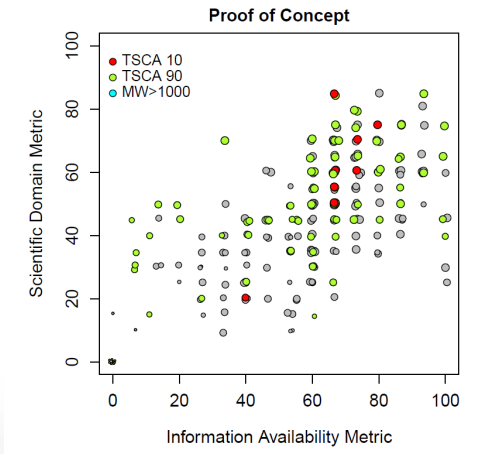
- **Data extracted from "Type 1" data sources**
  - Type 1 data sources are publicly available and readily searchable, enabling data extraction in structured form
  - Consistent with approach outlined in the Near-term Strategy

- **Quality control (QC) was performed on the data for the proof-of-concept chemicals in order to:**
  - Estimate the accuracy of the data used in this case study
  - Inform the development of formal quality assurance (QA) plan
  - Obtain information on the scope and resources needed to perform QC for larger sets of chemicals

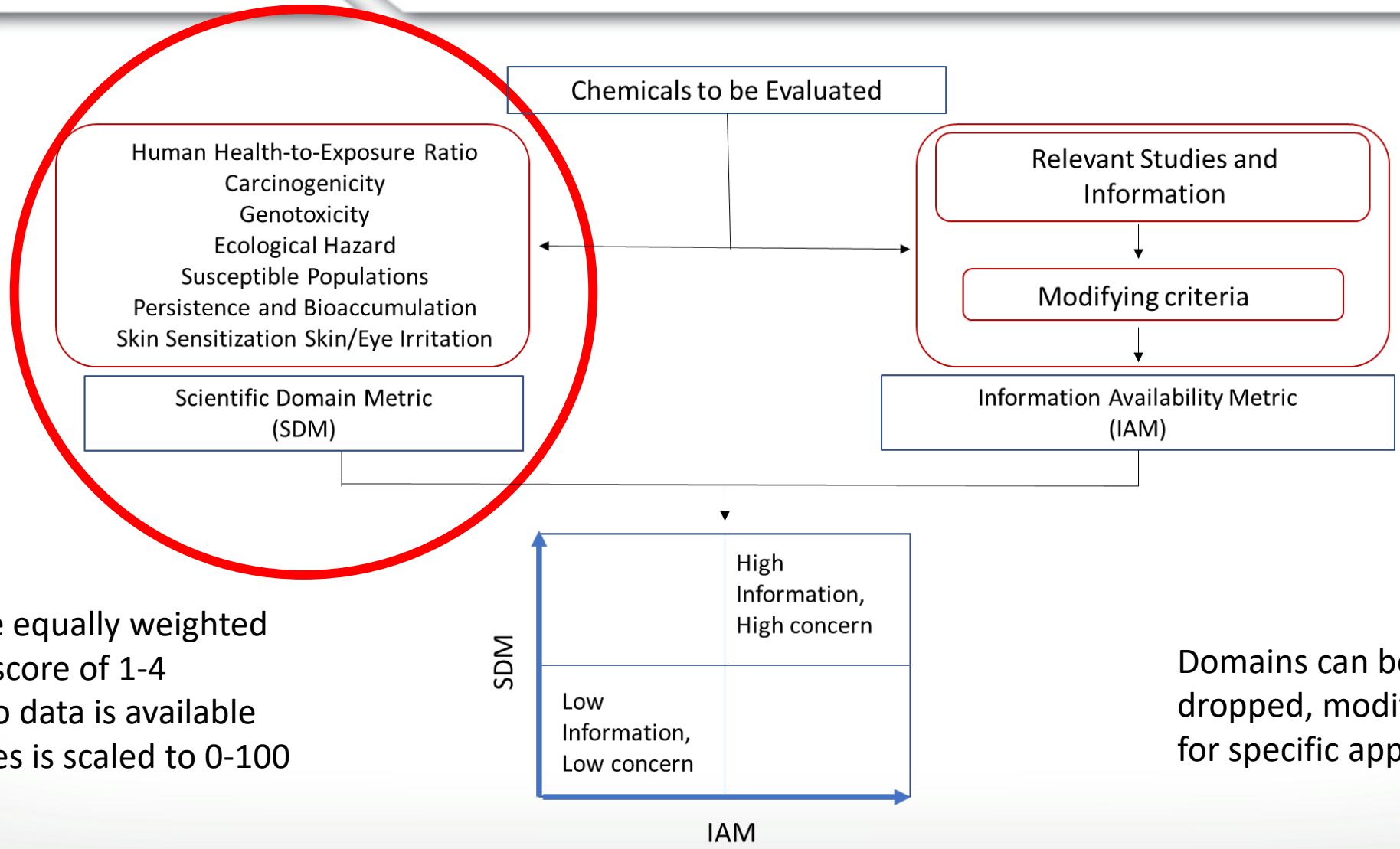
Proof-of-Concept



- Specific data domain and data source error rates
- Data QA plan for TSCA active inventory
- FTE estimates for data QC
- QC Tool (beta)



Public Information Curation and Synthesis (PICS) Approach



Domains are equally weighted
Each gets a score of 1-4
Score=0 if no data is available
Sum of scores is scaled to 0-100

Domains can be added, dropped, modified as need for specific applications

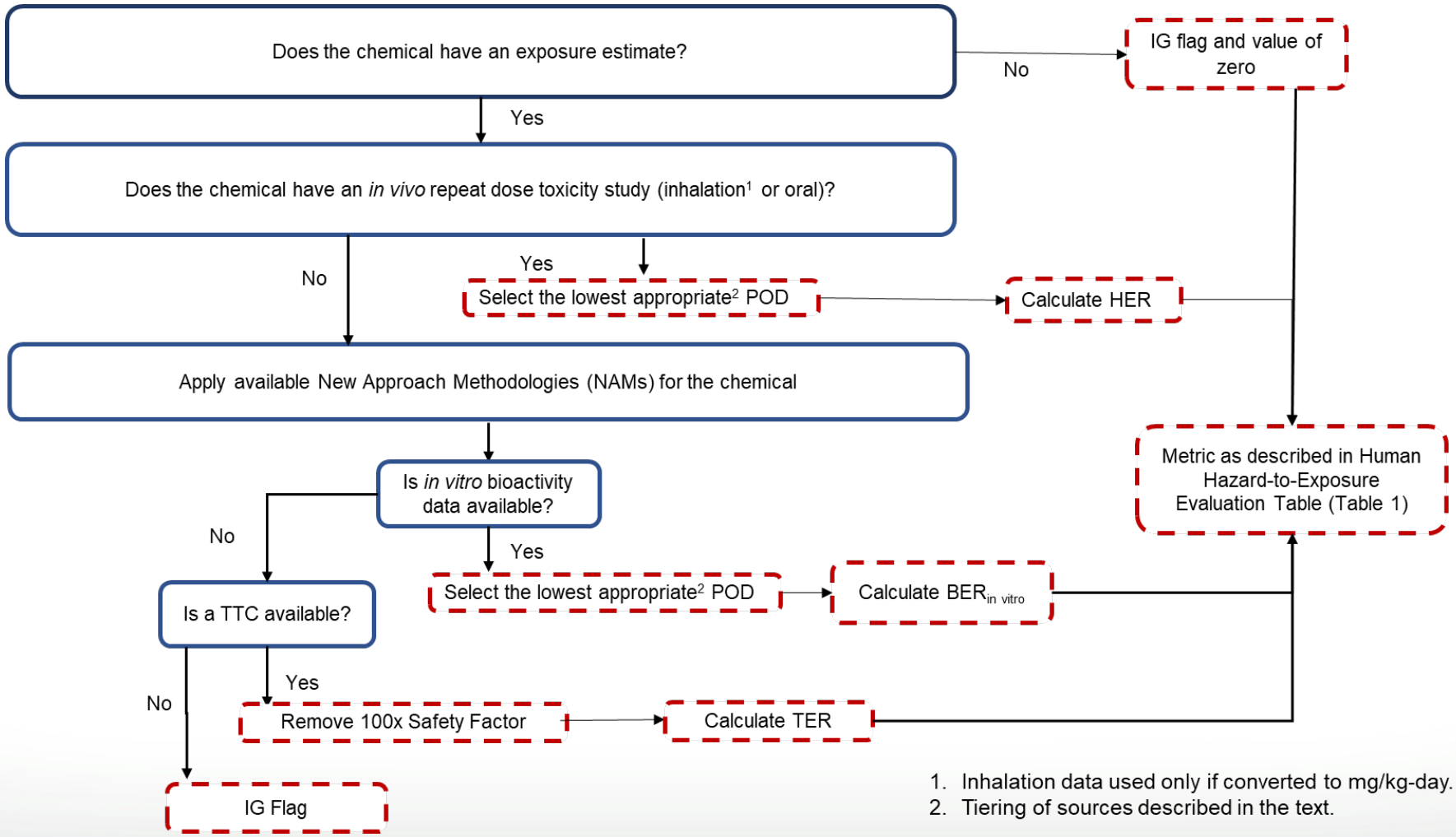
Scientific Domain Metric

- Seven scientific domains were selected based on:
  - Previous use in TSCA prioritization activities (i.e., TSCA workplan)
  - Statutory language in the amended TSCA
  - Consultation with OCSPP management and staff
- Tiered workflows for each scientific domain designed based on the current state of the science
- The overall scientific domain metric is determined by summing the results from the individual scientific domain workflows

Notes on Scientific Domains

- Human Hazard-to-Exposure Ratio
  - Oral POD / general model of exposure (SEEM3)
  - PODs from in vivo studies, in vitro to in vivo extrapolation and TTC
  - Need to replace exposure model with one that is biosolids-specific
- Carcinogenicity
- Genotoxicity
- Ecological Hazard
  - POD for vertebrates, invertebrates, plants; short and long term
  - Use in vivo studies and QSAR models
  - Potentially incorporate ecological exposure
- Susceptible Populations
  - For case study, only childrens' exposure was considered
- Persistence and Bioaccumulation
- Skin Sensitization and Skin/Eye Irritation

Example Scientific Domain Workflow: Human Hazard-to-Exposure Evaluation

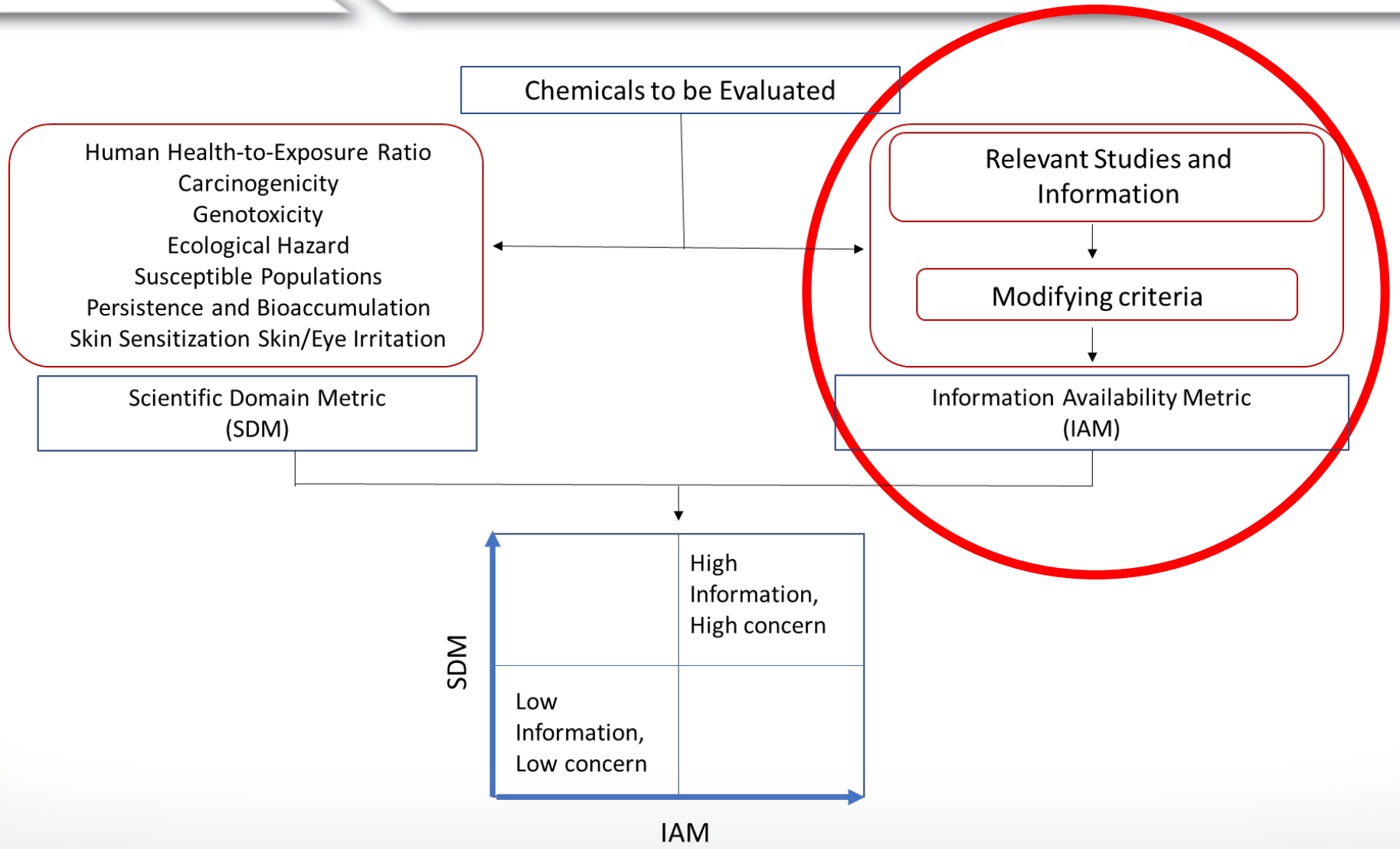


1. Inhalation data used only if converted to mg/kg-day.
2. Tiering of sources described in the text.

Example Scientific Domain Workflow: Human Hazard-to-Exposure Evaluation

Table 1. Criteria used to calculate the human hazard to exposure ratio domain metric	
Metric	HER, BER, or TER value[1]
0	No available data (hazard or exposure)
1	The lower the Hazard-to-Exposure Ratio, the higher the metric value Use the lowest of HER, BER, TER Mapping from HER/BER/TER to Metric uses bins / cutoffs
2	
3	
4	
Information Gathering (IG) Flags: Note concerning key study types with no in vivo data (repeat dose, reproductive, developmental); secondary source data; predicted data; lack of exposure data	
[1] HER, hazard-to-exposure ratio calculated based on in vivo repeat dose toxicity studies divided by the median ExpoCast exposure estimate; BER, bioactivity-to-exposure ratio calculated based on IVIVE bioactivity estimates divided by the median ExpoCast exposure estimate; TER, TTC-to-exposure ratio calculated based on the TTC divided by the median ExpoCast exposure estimate.	

Public Information Curation and Synthesis (PICS) Approach



Information Availability Metric

- Included in PICS approach to evaluate the amount of information available for use in any future chemical substance risk evaluation
- Ideally, a chemical going into risk assessment will have existing data in many domains
- Based on the potentially relevant information for exposure, human health and ecological hazard
- Modifying criteria (based on OPPT new chemicals program and consultation with OPPT technical staff) applied to make the metric context-specific
- Incorporates information gathering (IG) flags to highlight data gaps

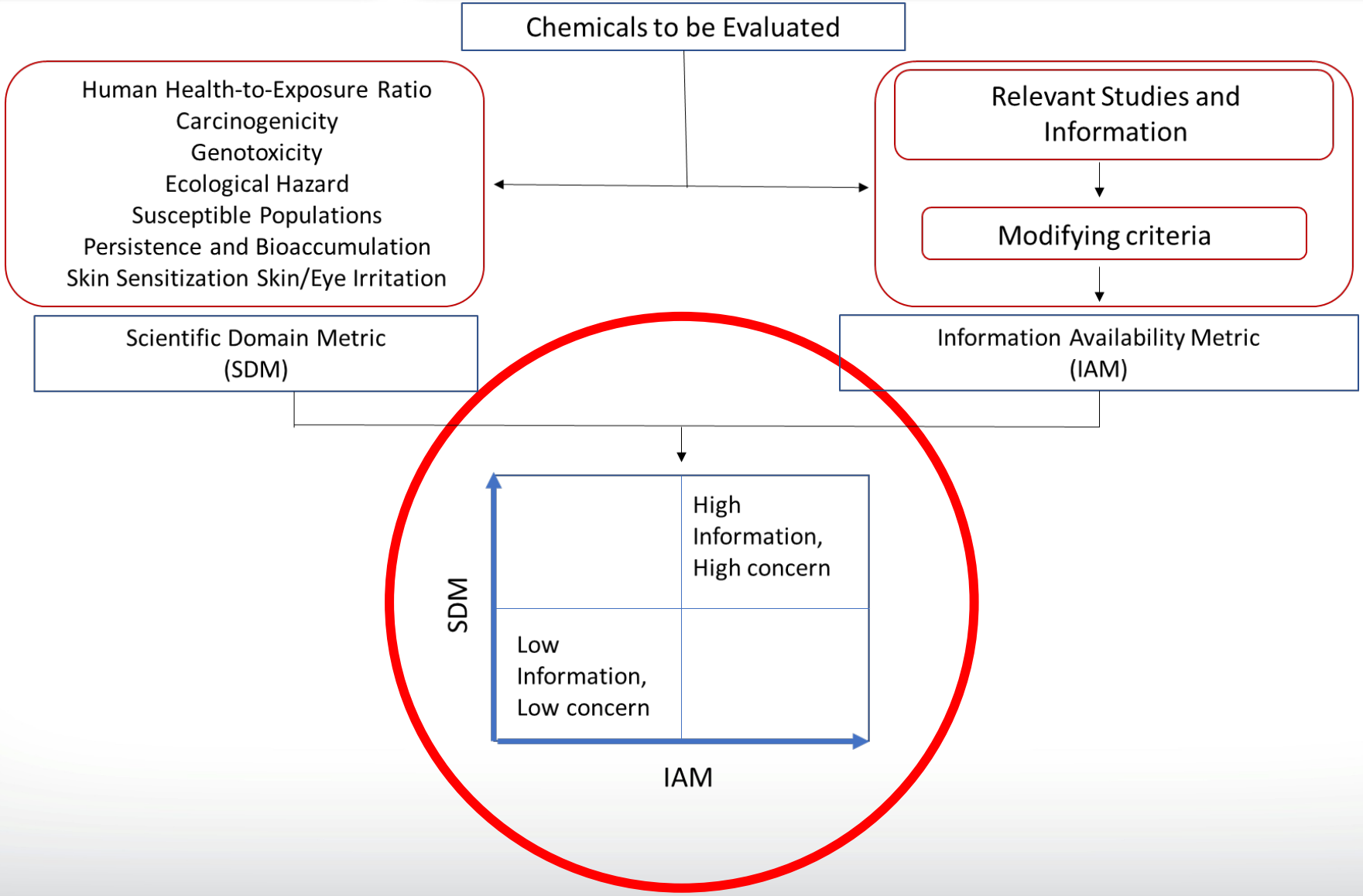
Information Availability Metric Calculation

Available data categories	Modifying Criteria				
1.Mammalian Acute 2.One of (mammalian subchronic, mammalian repeat dose, mammalian chronic) 3.Mammalian reproductive 4.Mammalian developmental 5.Mammalian neurotoxicity 6.Mammalian cancer 7.Mammalian genotoxicity 8.Skin Sensitization or eye corrosivity 9.Exposure 10.Eco aquatic plant acute 11.Eco aquatic invertebrate acute 12.Eco aquatic vertebrate acute 13.Eco aquatic plant repeat dose 14.Eco aquatic invertebrate repeat dose 15.Eco aquatic vertebrate repeat dose	None	Is there a high-quality public risk assessment (cancer or non-cancer)?	Is this a chemical intermediate AND a short environmental half-life (hours)?	Is this a chemical with low water solubility (< 0.1 mg/L)*?	Is this a chemical with MW > 1000 OR an exempt polymer?
	Add 1 for categories 1-15 with available data	Add 8 for the assumption that all mammalian data is available (1-8 on list of data categories) plus 1 for categories 9-15 with available data	Add 1 for categories 1-9 with available data	Add 1 for categories 1-8 with available data	Add 1 for categories 8 and 9 with available data
	Divide by the denominator (15)	Divide by the denominator (15)	Divide by the denominator (9)	Divide by the denominator (8)	Divide by the denominator (2)
	Scale to percent.				
	IAM				

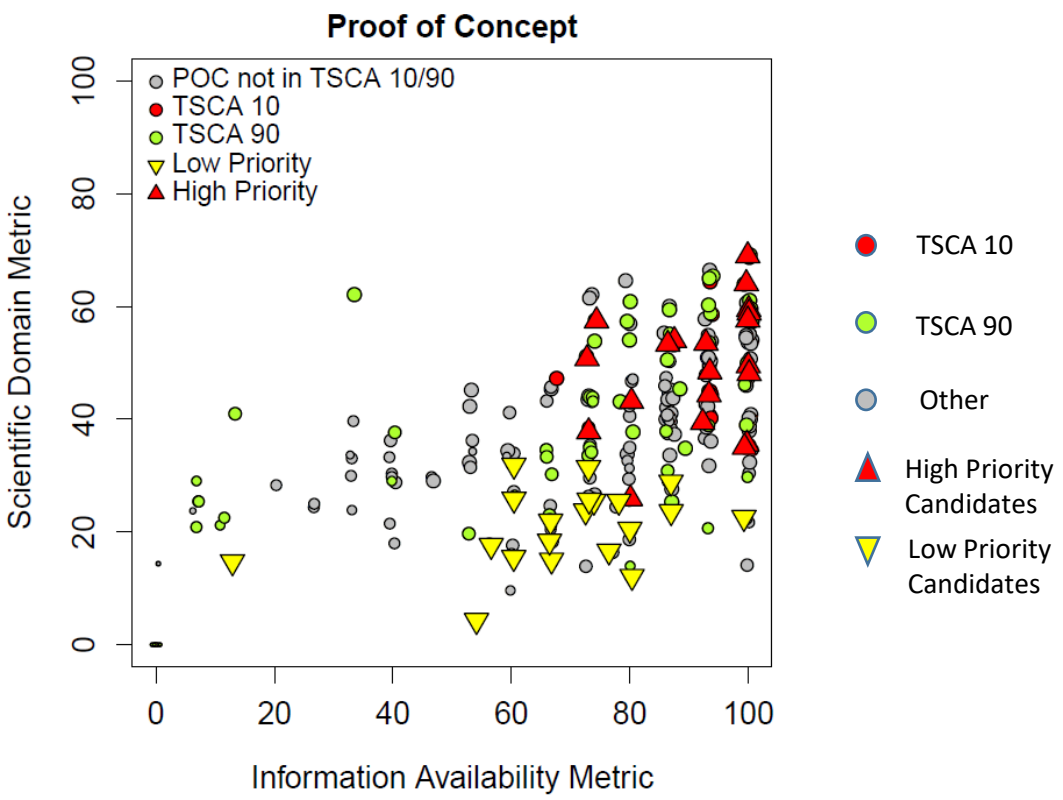
Basis: Chemicals with certain physico-chemical properties are unlikely to pose a risk to certain species classes or through certain exposure routes.

Therefore, data on those species or exposure routes is not relevant to risk assessment

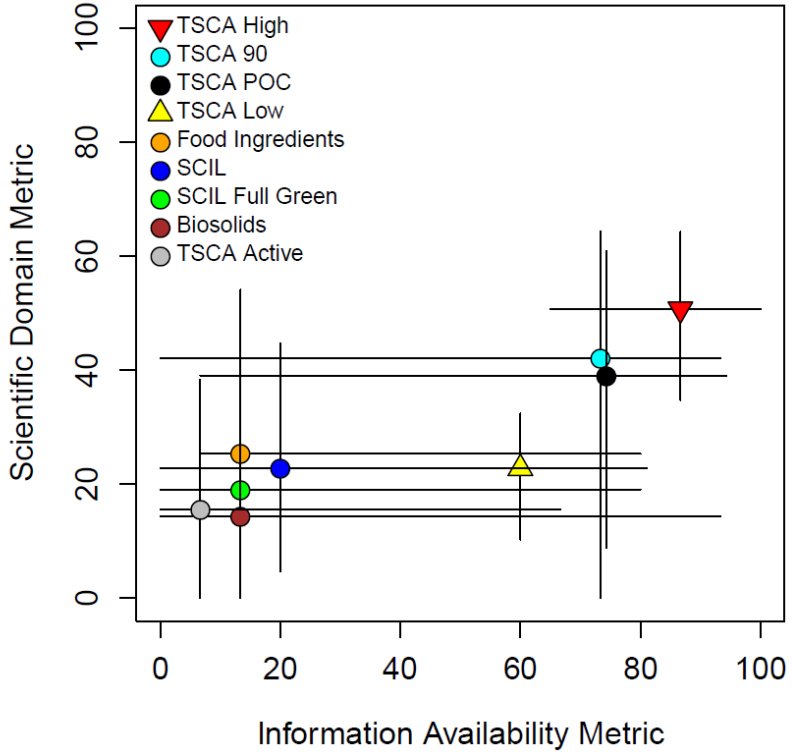
Public Information Curation and Synthesis (PICS) Approach



Proof-of-Concept Results

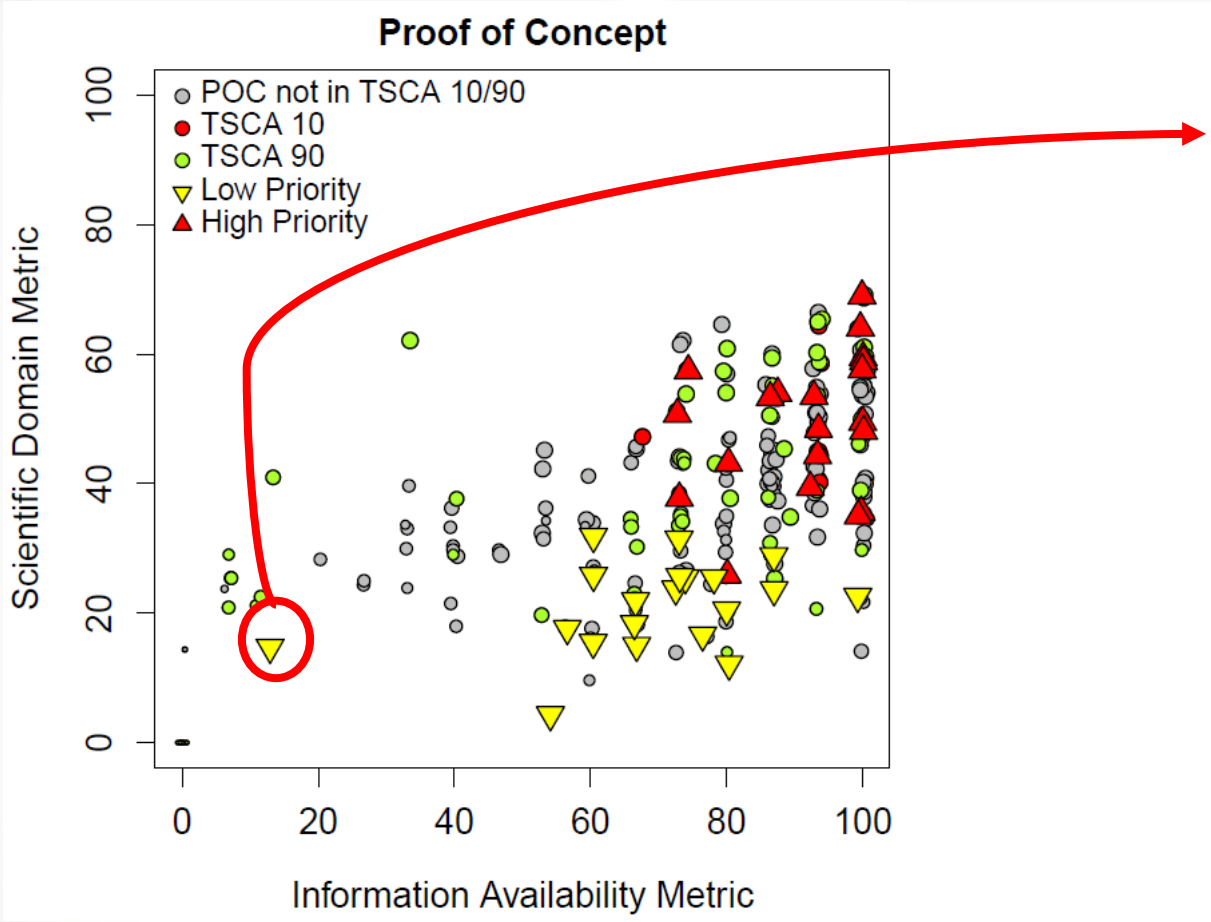


Plot of the information availability vs. scientific domain metrics for the POC238 set of chemical substances. Positions of points are staggered for ease of visualization.



Plot showing distributions of metric scores for selected chemical substance lists. For each list, the point shows the median scientific domain and information availability metrics. The whiskers span 90% of the distributions. Data here is taken from the lists across the TSCA Active Inventory.

Proof-of-Concept Results

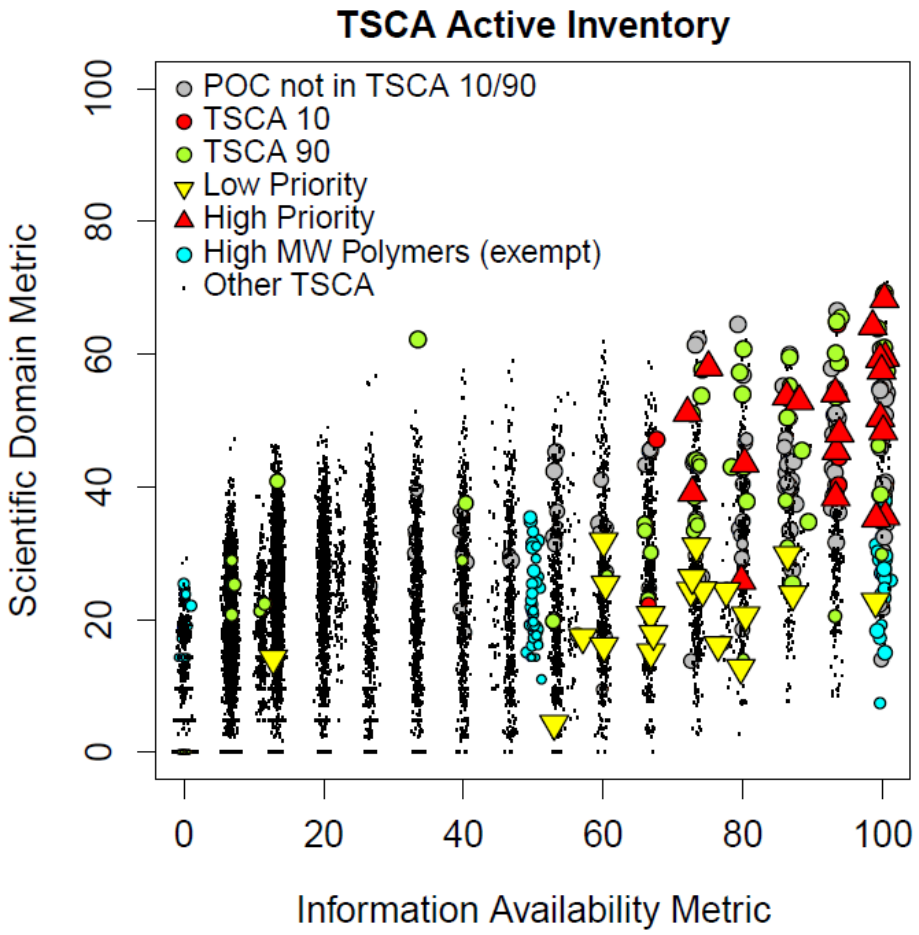


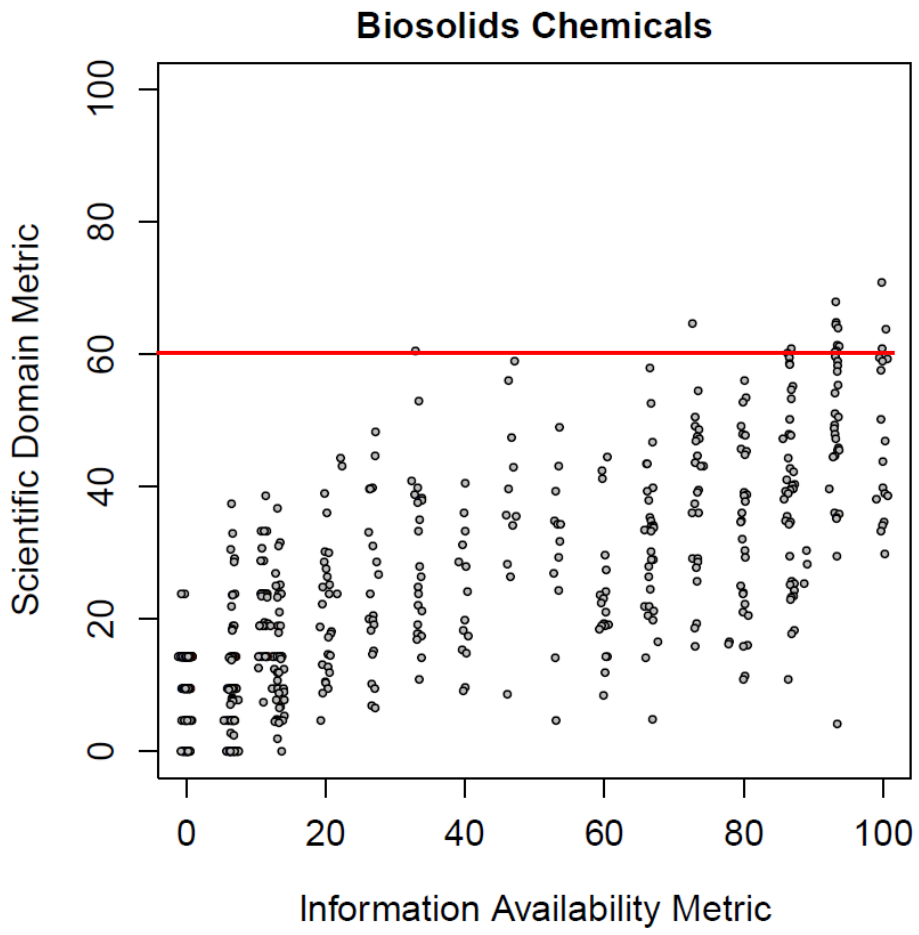
Plot of the information availability vs. scientific domain metrics for the POC238 set of chemical substances. Positions of points are staggered for ease of visualization.

Calcium D-Gluconate

- Scientific domain metric related to lack of human hazard assessment and ecological hazard data in the public domain.
- Similar to other chemicals on the low priority list.
- Read across may have been used for this determination.

Biosolids Results





Trends in biosolids chemicals closely track those for TSCA

Biosolids Details

Name	Public Hazard Assessments
Benzo(a)pyrene	noncancer / cancer
Benzene	noncancer
PFOA	noncancer
2,4-Dichlorophenoxyacetic acid (2,4-D)	noncancer
1,2-Dichloropropane	noncancer / cancer
Trichloroethylene	noncancer
1,1'-Oxybis[2,3,4,5,6-pentabromobenzene]	noncancer / cancer
p,p'-DDT	noncancer / cancer
2,4-Dichlorophenol	noncancer
4-Chloroaniline	noncancer / cancer
Bisphenol A	noncancer
Phenol	noncancer
Benzoic acid	noncancer
N-Nitrosopiperidine	
p-Cresol	
Naphthalene	noncancer / cancer

Chemicals with SDM>60%

Most chemicals with high hazard / risk values have existing public risk assessment

Key Takeaways

- The PICS approach:
  - Increases understanding of the landscape of publicly available information
  - Efficiently identifies high and low priority candidates among large chemical inventories for expert review
  - Provides a transparent and reproducible process for integrating available information and identifying potential information gaps
  - Incorporates results from domain-specific workflows that can be readily updated or adapted to address scientific advances and prioritization needs under other mandates

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