Data Evaluation Criteria for Exposure and Engineering Studies

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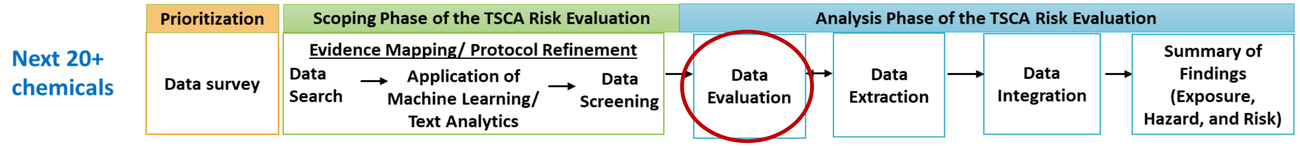
Systematic Review Process

Systematic Review is a comprehensive, unbiased, transparent and reproducible way to identify relevant literature on a topic.

For the purpose of the RE rule the definition EPA is adopting states: "Weight of scientific evidence means a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance."

This involves implementing a structured process to identify, evaluate, and integrate evidence for the hazard and exposure assessments developed for risk evaluation. This poster describes the Data Evaluation process assessing the quality of multiple data types supporting the exposure assessment.

Data Evaluation Process within Systematic Review under TSCA



Key Terms in Data Evaluation

Domain Data evaluation is intended to assess the following four main study attributes or domains for Reliability, Representativeness, Accessibility/Clarity, and Variability/Uncertainty

Metric Domains are assessed by evaluating sub-categories of study

Criteria Specific criteria are developed for each metric, which express conditions of the confidence level assigned to the metric (high, medium, low, or unacceptable)

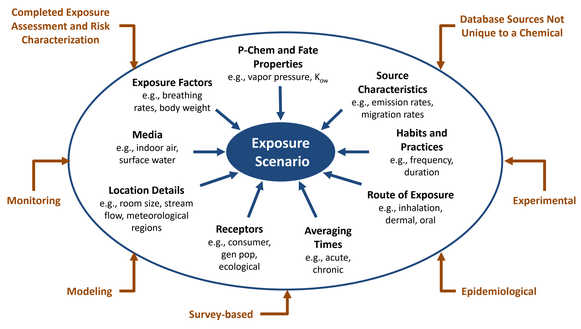
Data Types for Data Evaluation

For Exposure Studies:

1. Monitoring Data
2. Modeling Data
3. Survey-based Data
4. Epidemiological Data
5. Experimental Data
6. Database Sources Not Unique to a Chemical
7. Completed Exposure Assessments and Risk Characterization

For Engineering Studies:

1. Monitoring Data
2. Environmental Release Data
3. Published Models for Exposures or Releases
4. Completed Exposure or Risk Assessments
5. Reports for Data or Information Other than Exposure or Release Data

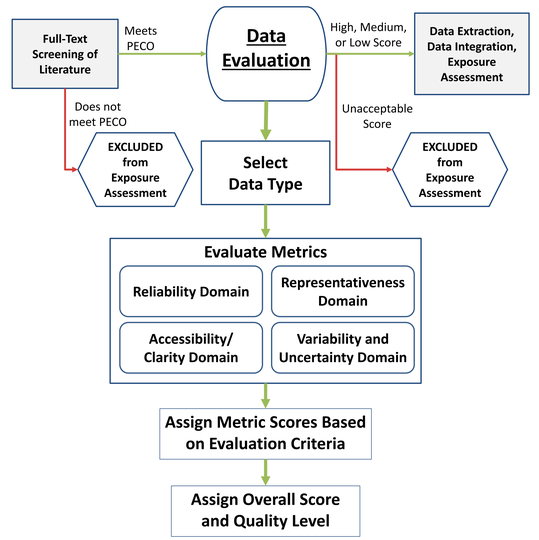


Evaluation Metrics by Data Type Across All Domains

Exposure
Monitoring Data: 10 metrics
Sampling Methodology; Analytical Methodology; Selection of Biomarker of Exposure; Geographic Area; Temporality; Spatial and Temporal Variability; Exposure Scenario; Reporting of Results; Quality Assurance; Variability and Uncertainty
Modeling Data: 6 metrics
Mathematical Equations; Model Evaluation; Exposure Scenario; Model and Model Documentation Availability; Model Inputs and Defaults; Variability and Uncertainty
Survey-based Data: 8 metrics
Data Collection Methodology; Data Analysis Methodology, Geographic Area; Sampling/Sampling Size; Response Rate; Reporting of Results; Quality Assurance; Variability and Uncertainty
Epidemiological Data: 18 metrics
Measurement or Exposure Characterization; Reporting Bias; Exposure Variability and Misclassification; Sample Contamination; Method Requirements; Matrix Adjustment; Method Sensitivity; Stability; Use of Biomarker of Exposure; Relevance; Population; Participant Selection; Comparison Group; Attrition; Documentation; QA/QC; Variability; Uncertainties
Experimental Data: 9 metrics
Sampling Methodology and Conditions; Analytical Methodology; Selection of Biomarker of Exposure; Testing Scenario, Sample Size and Variability; Temporality; Reporting of Results; Quality Assurance; Variability and Uncertainty
Completed Exposure Assessments and Characterizations: 4 metrics
Methodology; Exposure Scenario; Documentation of References; Variability and Uncertainty
Database Sources Not Unique to a Chemical: 8 metrics
Sampling Methodology; Analytical Methodology; Geographic Area; Temporal; Exposure Scenario; Availability of Database and Supporting Documents; Reporting of Results; Variability and Uncertainty

Engineering
Monitoring Data: 7 metrics
Sampling and analytical methodology; Geographic Scope; Applicability; Temporal representativeness; Sample size; Metadata completeness informing the Accessibility and Clarity domain; Metadata completeness informing the Variability and Uncertainty domain
Environmental Release Data: 7 metrics
Methodology; Geographic Scope; Applicability; Temporal representativeness; Sample size; Metadata completeness informing the Accessibility and Clarity domain; Metadata completeness informing the Variability and Uncertainty domain
Published Models for Exposures or Releases: Up to 6 metrics
Methodology; Geographic Scope; Applicability; Temporal representativeness; Metadata completeness informing the Accessibility and Clarity domain; Metadata completeness informing the Variability and Uncertainty domain
Completed Exposure or Risk Assessments: Up to 7 metrics
Methodology; Geographic Scope; Applicability; Temporal representativeness; Sample Size; Metadata completeness informing the Accessibility and Clarity domain; Metadata completeness informing the Variability and Uncertainty domain
Reports for Data or Information Other than Exposure or Release Data: Up to 7 metrics
Methodology; Geographic Scope; Applicability; Temporal representativeness; Sample size; Metadata completeness informing the Accessibility and Clarity domain; Metadata completeness informing the Variability and Uncertainty domain

Data Evaluation Workflow



Weighted Scoring System by Metrics

Overall Score=

$$\sum(\text{Metric Score} \times \text{Weighting Factor}) \div \sum(\text{Metric Weighting Factors})$$

High	Medium	Low	Range of Overall Score:
≥1 and < 1.7	≥1.7 and <2.3	≥2.3 and ≤3	**1 to 3**

Scoring System: Metrics for Study Quality

High	No notable deficiencies or concerns are identified in the domain metric that are likely to influence results [score of 1]
Medium	Minor uncertainties or limitations are noted in the domain metric that are unlikely to have a substantial impact on results [score of 2]
Low	Deficiencies or concerns are noted in the domain metric that are likely to have a substantial impact on results [score of 3]
Unacceptable	Serious flaws are noted in the domain metric that consequently make the data/ information source unusable [score of 4]
Not rated/ applicable	Rating of this metric is not applicable to the data/information source being evaluated [no score] Not rated/applicable will also be used in cases in which studies cite a literature source for their test methodology instead of providing detailed descriptions. In these circumstances, EPA will score the metric as Not rated/Applicable and capture it in the reviewer's notes. If the data/information source is not classified as "unacceptable" in the initial review, the cited literature source will be reviewed during a subsequent evaluation step and the metric will be rated at that time.

Scoring System: Overall Data Quality Levels/Scores

A numerical scoring method is used to convert the confidence level for each metric into the overall quality level for the data/information source (illustrated in the box to the right under "Demonstration of Data Evaluation Workflow"). A study is disqualified from further consideration if the confidence level of one or more metrics is rated as Unacceptable [score of 4].

Planning, Execution, and QA/QC Considerations

- Develop a PECO statement to identify studies that should be evaluated. A PECO statement defines the Population, Exposure, Comparator and Outcome
- Select data evaluation tool and tracking system (i.e., DistillerSR)
- Develop guidance document with detailed instructions, media specific considerations, and examples
- Implement procedures for monitoring progress and tracking results
- Train reviewers to promote data evaluation in a consistent manner across reviewers
- Incorporate quality control measures involving two reviewers and conflict arbitration

Acknowledgement
Hassan Husain, Versar, Inc., Springfield, VA

Reference
U.S. EPA. 2018. Application of Systematic Review in TSCA Evaluations. EPA Document# 740-P1-8001

U.S. Environmental Protection Agency

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NASEM Review of the Environmental Protection Agency's Toxic Substance Control Act Systematic Review Guidance Document