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# Evidence Integration of Exposure Data under TSCA

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## Systematic Review

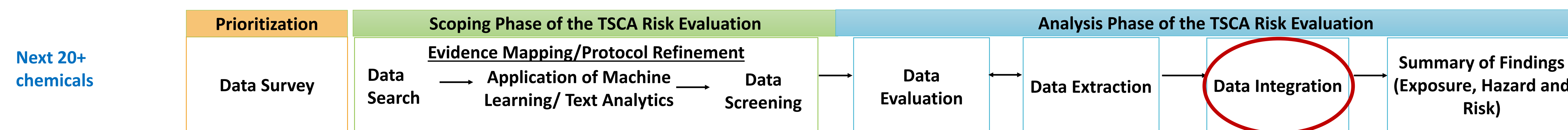
**Systematic Review is a comprehensive, unbiased, transparent and reproducible way to identify relevant literature on a topic.**

On June 22, 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act was signed into law amending the Toxic Substance Control Act (TSCA), the Nation's primary chemicals management law. The U.S. EPA's Office of Pollution Prevention and Toxics (EPA/OPPT) intends to apply systematic review in developing risk evaluations under TSCA.

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 process for integrating multiple data types supporting the exposure assessment.

## Data Integration Process within Systematic Review

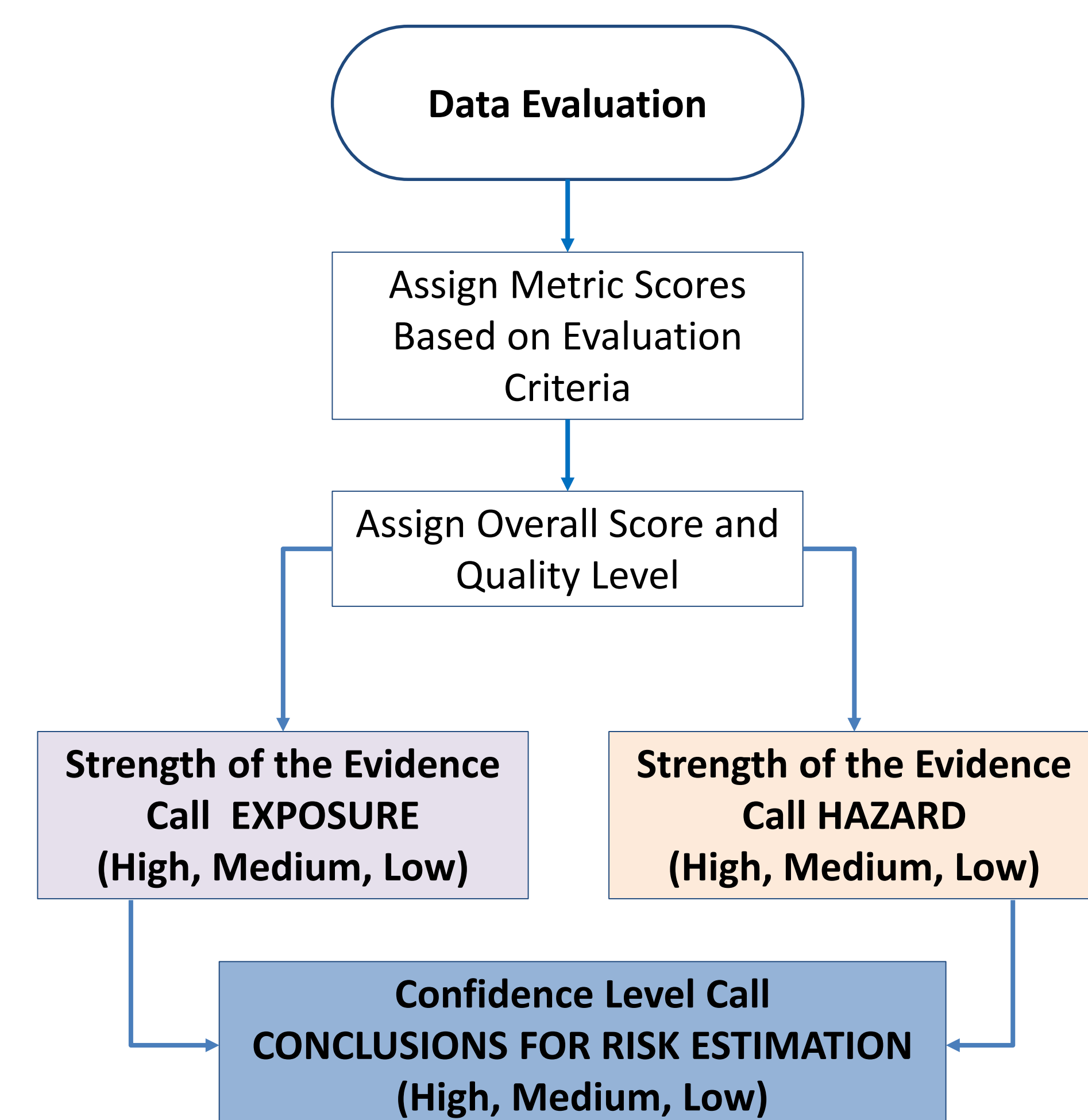
### Key Stages of the Systematic Review Process in TSCA Risk Evaluations



### Key Terms in Data Integration

|                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|--------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Data Quality Score</b>                                    | Quantitative score calculated following evaluation of discipline-specific and data type-specific data evaluation domains and metrics according to predefined scoring criteria and accounting for metric weighting factors.                                                                                                                                                                                                                                                                 |
| <b>Weight of the Scientific Evidence</b>                     | <i>Weight of scientific evidence</i> means a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a preestablished 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. (40 CFR Part 702) |
| <b>Strength of the Evidence Score for Hazard or Exposure</b> | Qualitative judgment (high, medium, low) describing the strengths, limitations, and relevance of the body of information related to hazard or exposure.                                                                                                                                                                                                                                                                                                                                    |
| <b>Confidence Level for Risk Estimation</b>                  | Qualitative judgment (high, medium, low) describing the certainty of the risk estimate considering the strength the evidence scores for hazard and exposure and the limitations, and relevance.                                                                                                                                                                                                                                                                                            |

## Evidence Integration Workflow



## Considerations for Exposure Assessment

### Physical and Chemical Properties & Environmental Fate and Transport

- Measured data from (guideline) studies
- Robust estimation methodologies with appropriate domain of applicability
- Measurements or estimates in environmental media that reflect what is known about the properties of the chemical
- Partitioning (e.g., air, water, soil)

### Environmental Releases

- Emission scenarios that correspond to activities related to the conditions of use (manufacture, import, processing, disposal or use) of the chemical
- Incorporation of knowledge of industrial practices, equipment, throughput and efficiencies related to the COUs
- Regulated limits for emissions, releases or environmental concentrations
- Industry or facility specific emissions

### Human and Environmental Exposure

- Scenario specific exposure factors and use patterns
- Habits and practices aligned with conditions of use
- Incorporation of variability, uncertainty and sensitivity
- Measured concentrations with robust sampling methodologies and relevant sample size
- Modeling algorithms or constructs that reflect specific exposure scenarios and account for chemical specific inputs and parameterization
- Temporal and spatial relevance

## Data Integration for Exposure Assessment

**Selection of Data:** EPA selects data for use from data extraction/evaluation phase of systematic review. EPA will only use data/information rated as High, Medium, or Low. Any data rated as unacceptable will not be used.

**Assessment of Data and Results:** EPA typically provides data and results representative of *central tendency* conditions and *high-end* conditions.

**Integration of Data Sets:** EPA may integrate data sets to develop a distribution of environmental releases or exposures representative of the condition of use.

**Integration of Data for Modeling and Calculations:** EPA may use measured or estimated data to calculate exposure/release metrics required for risk characterization. These calculations require additional parameter inputs (e.g., exposure duration and frequency, lifetime years, release frequency).

## Modeling Approaches – Deterministic and Probabilistic

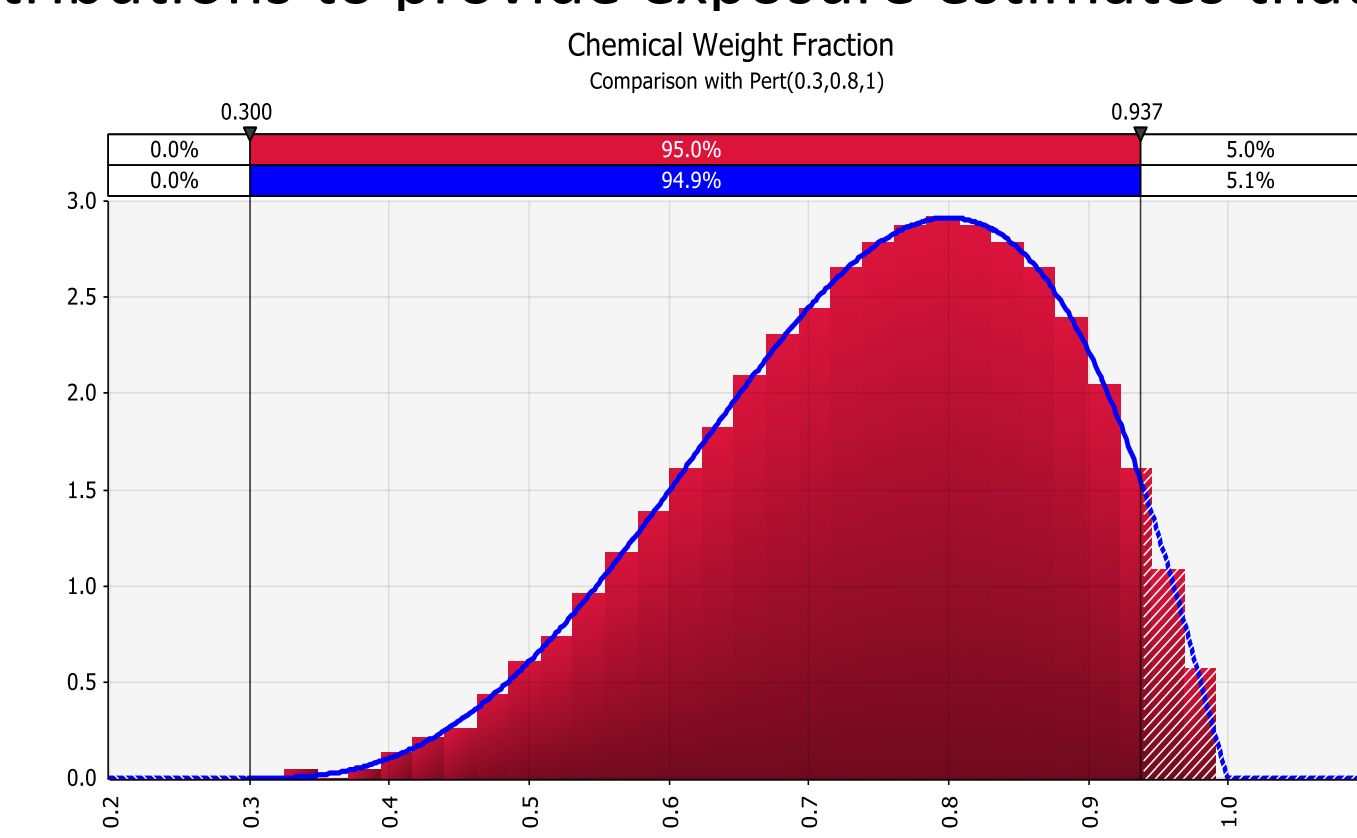
EPA may use modeling approaches to estimate environmental releases, and environmental, occupational, consumer and general population exposures. EPA/OPPT has an existing suite of peer-reviewed models that can be used for exposure and environmental release estimation. Alternately, EPA may develop new approaches or models. Exposure estimations may be deterministic, probabilistic, or a combination thereof.

**Deterministic Calculations:** EPA may use combinations of point estimates of each parameter to estimate a central tendency and high-end exposure or release value. Examples include:

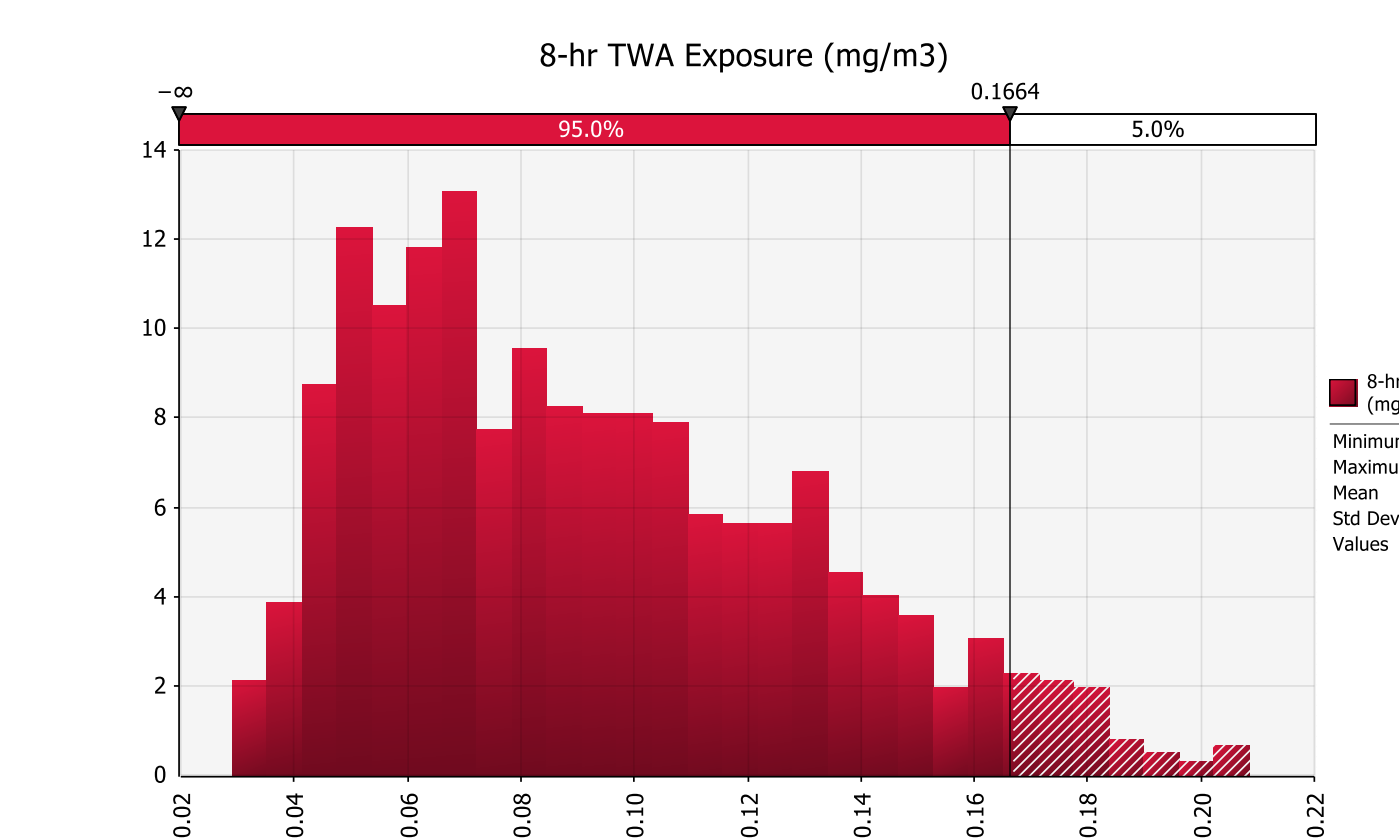
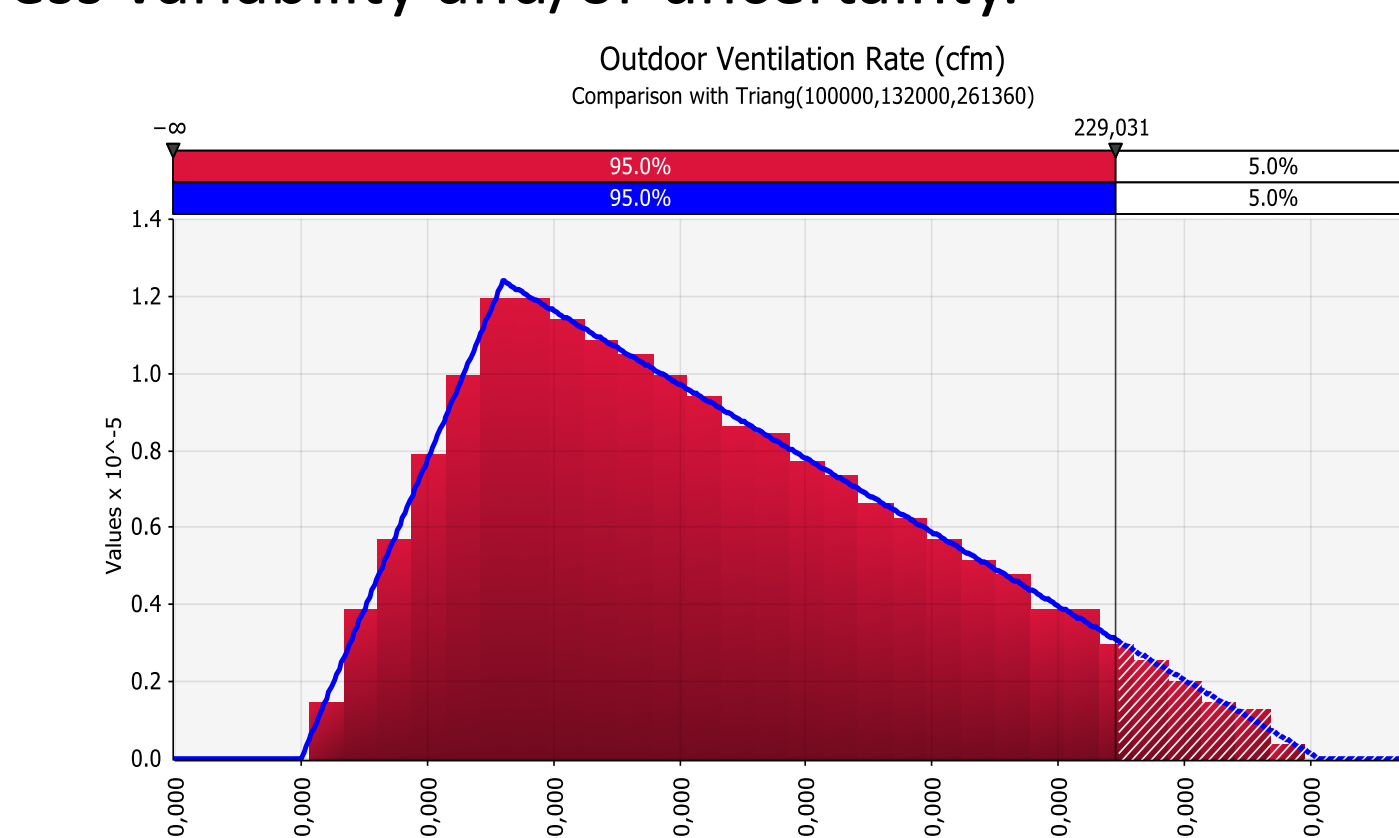
- Applying process-specific loss fractions to production volume to calculate daily or annual release to each environmental medium (e.g., kg/site-day, kg/site-yr)
- Use of engineering release values with receiving water stream flows to estimate environmental concentrations (e.g., µg/l)
- Use of estimated environmental concentrations and human exposure factors (e.g., intake rates) to estimate human dose (e.g. mg/kg bw/day)

**Probabilistic (Stochastic) Calculations:** Where data are available, EPA may pursue Monte Carlo simulations or other probabilistic approaches using the full distribution of each parameter to derive a distribution of the final exposure metric results and select the 50<sup>th</sup> and 90-95<sup>th</sup> percentiles of this resulting distribution as the central tendency and high-end result, respectively.

**Deterministic and Probabilistic Calculations:** EPA may use a combination of measured or deterministic values in combination with known or estimated distributions to provide exposure estimates that address variability and/or uncertainty.



**Figure 1.** Example Distributions of Model Input Parameters for an Exposure Model using a Probabilistic Approach



**Figure 2.** Example Probabilistic Modeling Results showing a Distribution of Exposure Outcomes

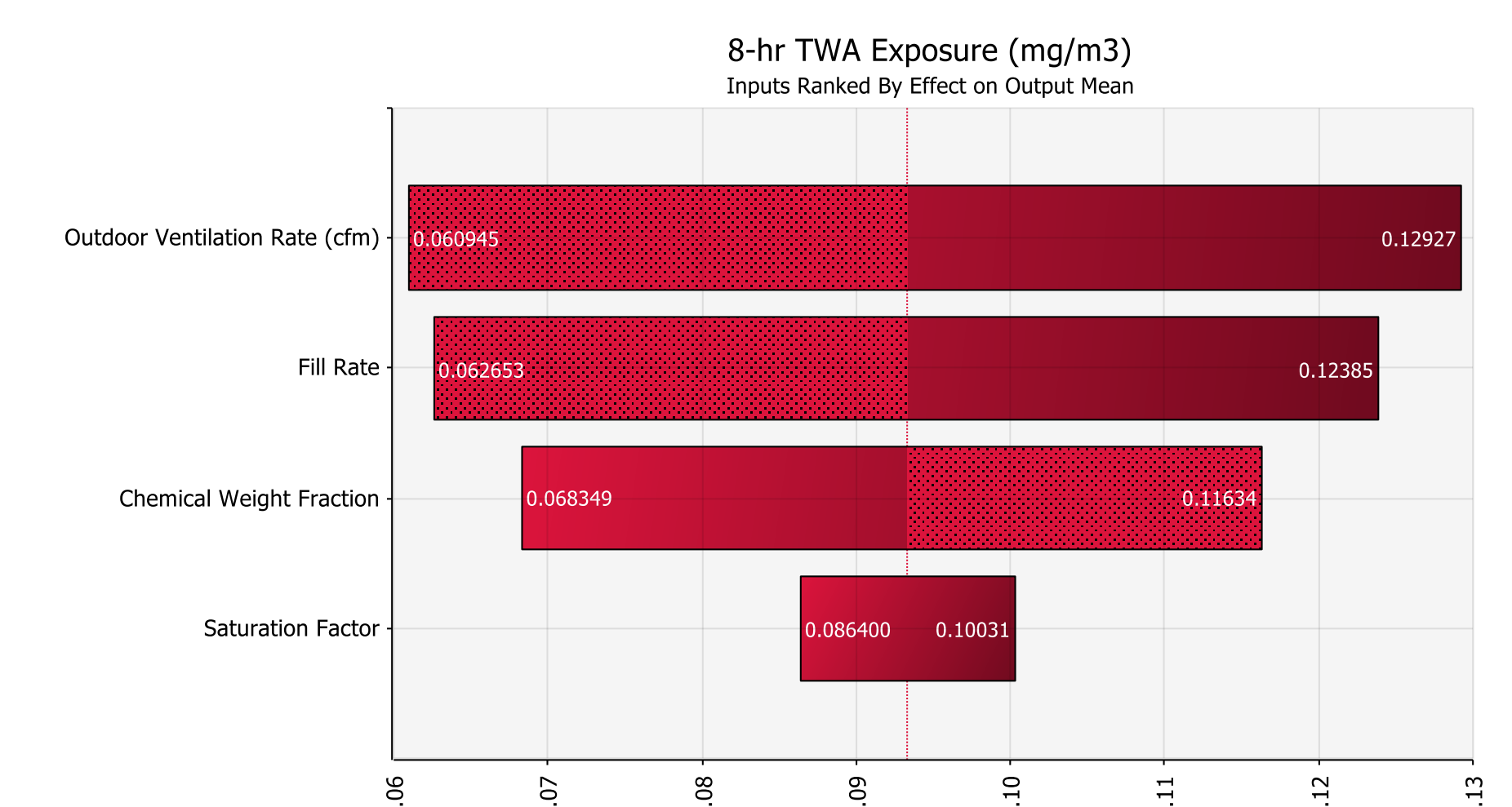
## EPA Exposure Tools and Models

EPA may use modeling approaches to estimate exposures, including fate and transport properties, engineering releases, and human and environmental exposures. Some of OPPT's models are listed here:

- Using Predictive Methods to Assess Exposure and Fate under TSCA: <https://www.epa.gov/tsc-screening-tools/using-predictive-methods-assess-exposure-and-fate-under-tsc#fate>
- Estimation Program Interface – Suite (EpiSuite™)
- Chemical Screening Tool for Exposures and Environmental Releases (ChemSTEER)
- Exposure and Fate Assessment Screening Tool (EFAST)
- Integrated Indoor-Outdoor Air Calculator (IIOAC)
- Consumer Exposure Model (CEM)
- Multi-chamber Concentration and Exposure Model (MCCEM)
- Indoor Environmental Concentrations in Buildings with Conditioned and Unconditioned Zones (IECCU)

## Sensitivity Analysis

**Sensitivity Analysis** is the study of the effects of inputs of a mathematical model on the model outputs. This type of analysis may be performed as part of the Monte Carlo simulation.



**Figure 3.** Example Sensitivity Analysis Showing Relative Impacts of Input Parameters on the Model Results