Foundation for Chemistry
RESEARCH & INITIATIVES

WORKSHOP 2: OPTIMIZING USES OF IH EXPOSURE DATA FOR OCCUPATIONAL RISK ASSESSMENT

April 20, 2023
11:00 am-1:00 pm EDT

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Disclaimer

- We are conducting this meeting under the Chatham House Rule. We understand that there might be members of the press in the audience. Audience members are free to use the information received during the workshop, but we ask that neither the identity nor the affiliation of any speaker be attributed to specific information.

- Speakers and panel members are sharing their individual expertise and not representing their employer or other organizations with which they are affiliated.

Workshop Logistics

- Everyone is on mute except for speakers and discussants.
- The chat is disabled.
- Please use the Q&A function to submit any questions or comments during the workshop for follow up by the moderator.
- There will be poll questions later in the program that will appear as a pop-up box. Please participate!
- An evaluation will be available when the workshop ends.
- If you experience technical difficulties, please email Schubert_Fabros@americanchemistry.com

AIHA Opening Remarks

Lawrence Sloan, MBA, FASAE, CAE
CEO

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FCRI Opening Remarks

Foundation for Chemistry
RESEARCH & INITIATIVES

Rob Simon

Executive Director of FCRI

Moderator Introduction

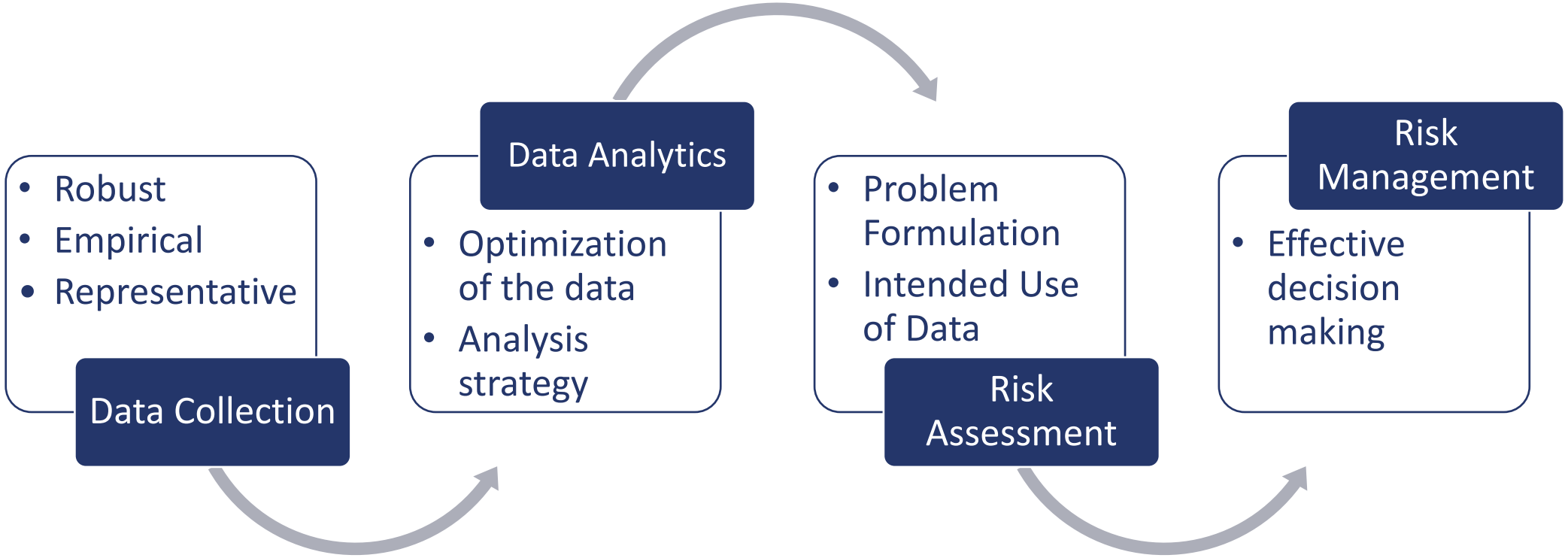
- Andrew Maier, MS, PhD, CIH, DABT, Fellow AIHA
  - Director of the OARS WEEL Committee
  - Principal Health Scientist at Stantec ChemRisk
  - Former IH in petrochemical industry, associate professor at University of Cincinnati
  - NIOSH Toxicology Fellow

Workshop Agenda

Time	Topic	Presenters
11:00 am - 11:05 am	Opening remarks	Larry Sloan, Rob Simon, Andy Maier
11:05 am - 11:25 am	Speaker presentation	Silvia Maberti
11:25 am - 11:40 am	Speaker presentation	Majd El-Zoobi
11:40 am - 11:55 am	Discussion and Audience polls	Facilitated Discussion
11:55 am - 12:00 pm	Break	
12:00 pm - 12:45 pm	Discussion and Audience polls	Facilitated Discussion
12:45 pm - 12:55 pm	Q&A	Speakers & Discussants
12:55 pm - 1:00 pm	Next Steps	Andy Maier

Opportunity and Challenge Statement

Systematic approaches are needed to optimize industrial hygiene data strategies.



Workshop Topics

Speakers and Discussants

Speakers

- Silvia Maberti, PhD
- Majd El-Zoobi, PE

Discussants

- Joe Damiano, MS, CIH, CSP, FAIHA*
- Louan Fisher, RQAP-GLP
- Heather Lynch, MPH, DABT
- Mwangi Ndonga, MS, CIH, CSP
- Ben Roberts, PhD, CIH
- Taylor Shockey, PhD, MPH
- Brian Van Deusen

*Joe Damiano was unable to participate in today's workshop as a panelist; however, Joe contributed discussion points and resources to the presentation.

Meet the speaker

Silvia Maberti, PhD
Senior Exposure Scientist
ExxonMobil Biomedical Sciences, Inc.

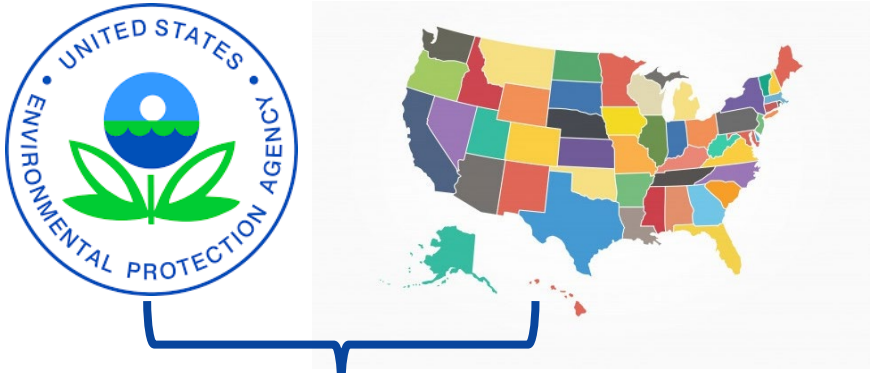
- 20 years of experience in occupational and community exposure assessment.
- Currently supporting exposure sciences needs for regulatory compliance; collaborating with multi-stakeholder organizations to improve chemical risk evaluations.
- As a consultant, derived risk-based corrective action values; developed occupational exposure assessment strategies, and vapor intrusion investigation methodologies.
- Expertise in qualitative and quantitative exposure assessment and modelling.

Optimizing Uses of IH Exposure Data for Occupational Risk Assessment

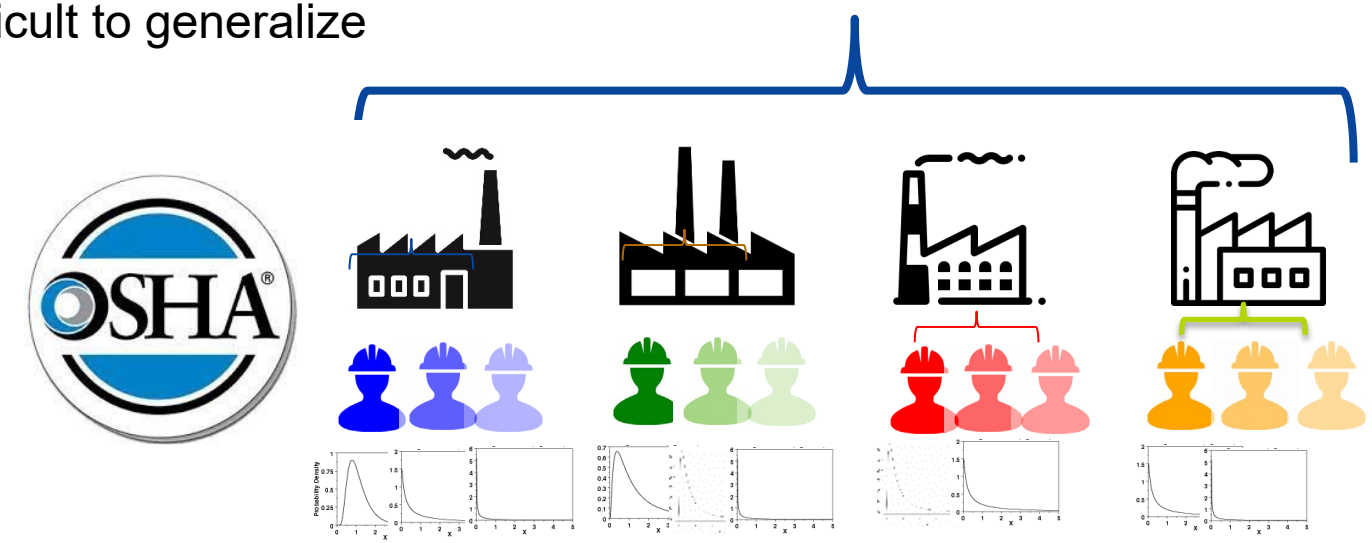
Silvia I Maberti, PhD

Risk Evaluation objectives differ

EPA: Must be broadly applicable



IH: Site specific, difficult to generalize



Contrasting Frameworks

Occupational Risk Assessment	TSCA Risk Evaluation
Problem formulation – Intended use of data	
Assess exposure potential for compliance and/or risk management	Characterize human health risk
Approach to data collection and analysis	
Tiered assessment based on exposure potential (targeted sampling). Similar Exposure Groups	Data aggregation to characterize exposure profile (random sampling, including ONUs). CoU or OES
Analytical tools / Data interpretation	
Metrics depend on type of data (full shift/ short term), type of hazard (chronic /acute), and decision (compliance, control, etc.).	Average and high-end percentile of distribution Metric based on the nature of the toxicity
Alternatives to quantitative assessments	
Tiered approach including models and some data.	CoU / OES

Problem Formulation - Intended use of data

Fit-for-purpose characterization

Why was that measurement made?

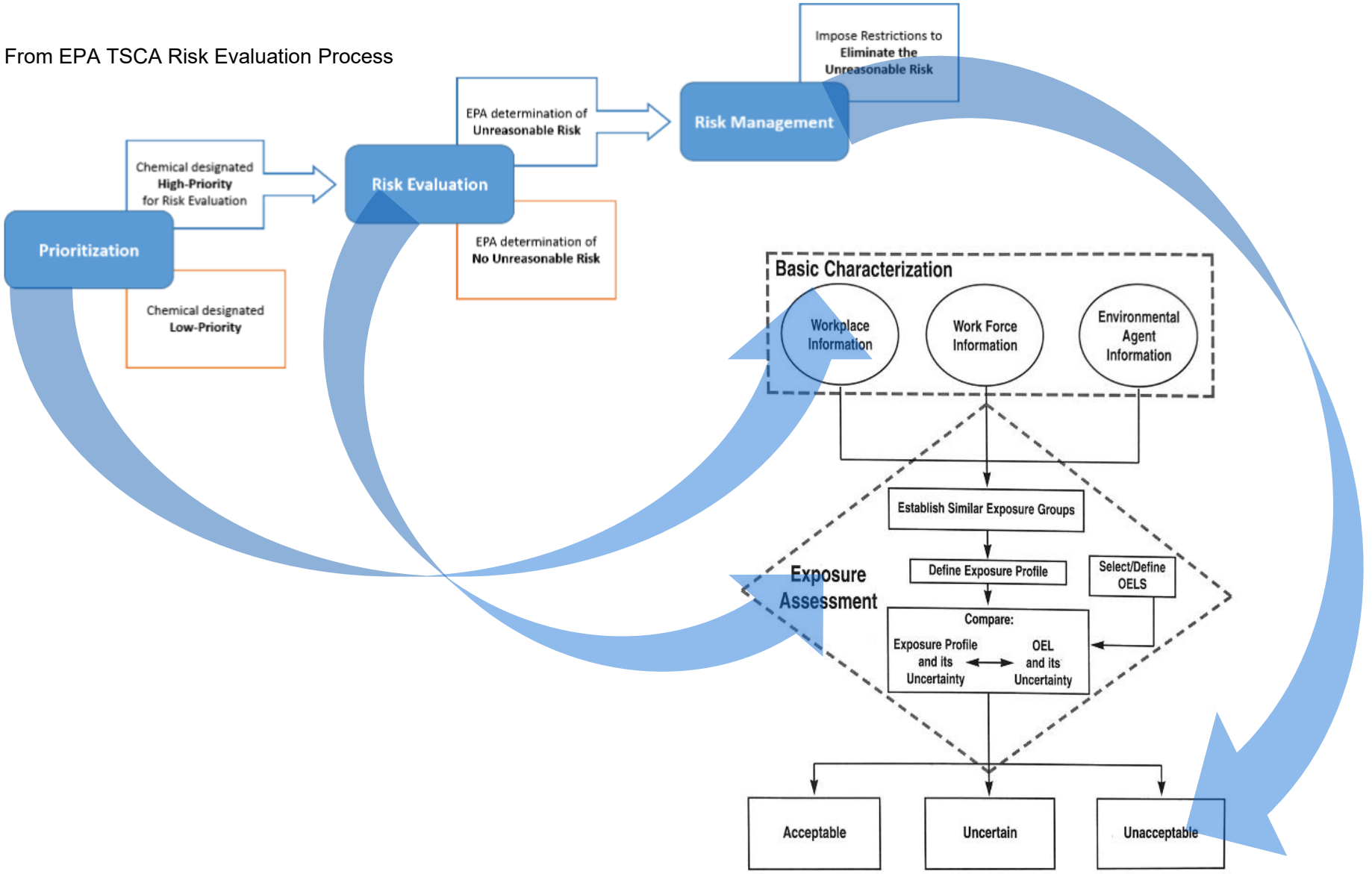
- Characterization of the activity / worker exposure
  - Site-based decisions vs sector-based registration decisions
  - Define exposure profile for epidemiological studies
- Assess compliance with a regulation (typically high-risk group)
- Control evaluation (focused on task/activity)
- Source characterization (right at emission point)

What is the underlying objective and methodology

- Full-shift samples to represent average chronic exposures
- Task samples
  - Duration of task and duration of exposure might be different and drive exposure profile

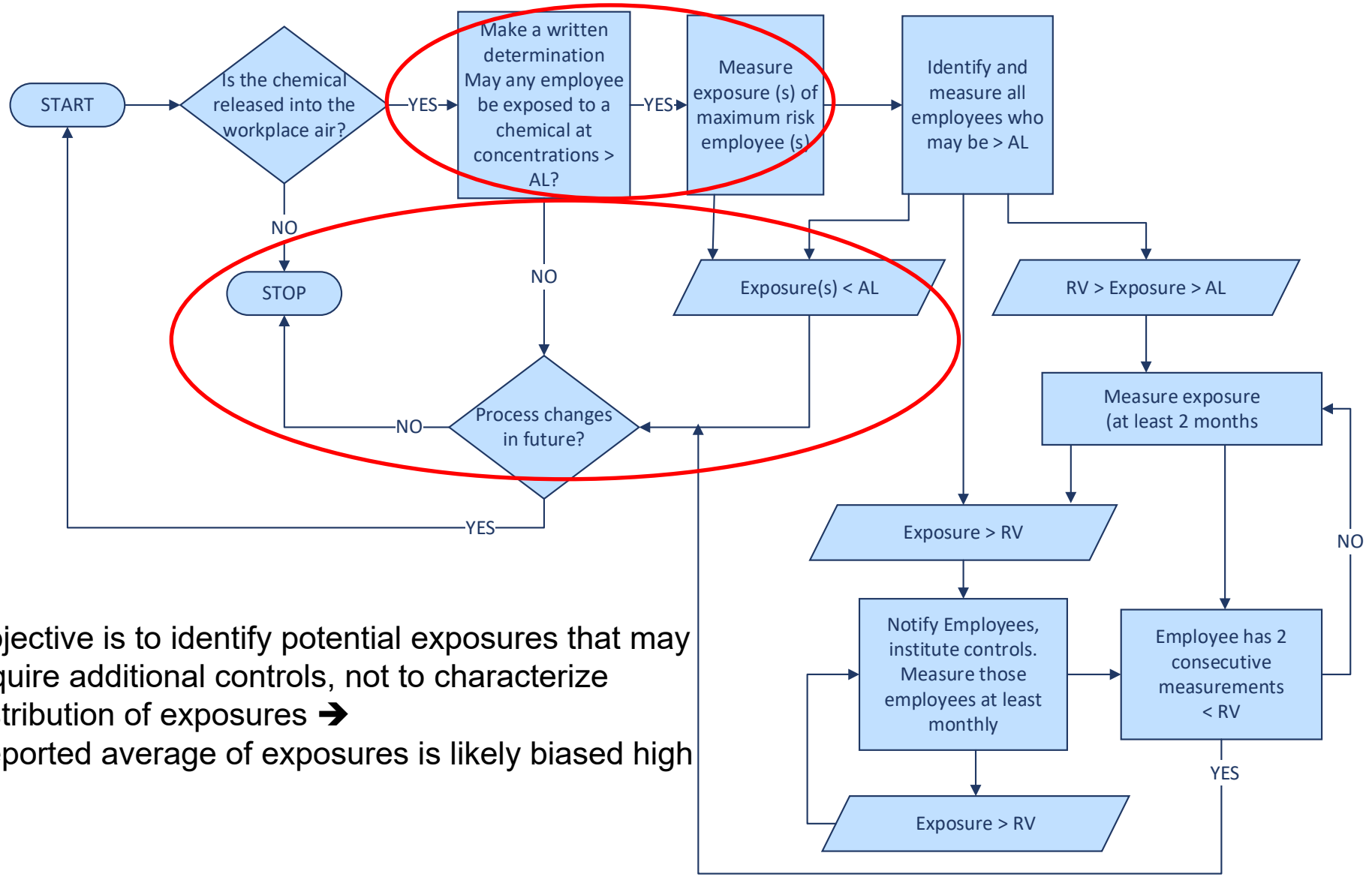
Tiered assessment concept applied in all stages

From EPA TSCA Risk Evaluation Process



Adapted from "A Strategy for Assessing and Managing Occupational Exposure" 4th Edition. S. D. Jahn, W. H. Bullock, J. S. Ignacio, AIHA Press 2015

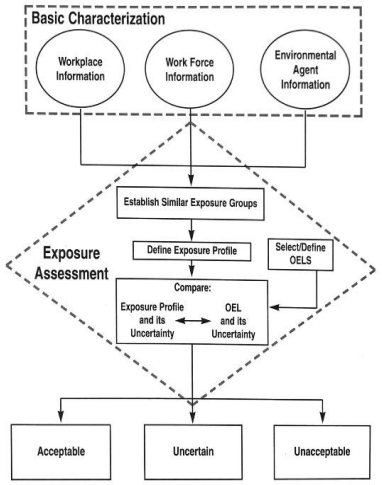
Tiered assessment concept applied in all stages



Objective is to identify potential exposures that may require additional controls, not to characterize distribution of exposures ➔
Reported average of exposures is likely biased high

Image adapted from NIOSH Occupational Exposure Sampling Manual (NIOSH (1977): Recommended exposure determination and measurement strategy.
AL = Action level (typically 0.5RV) RV = Reference value (PEL, TLV, other reference)

How does decision impact outcome?



Adapted from "A Strategy for Assessing and Managing Occupational Exposure" 4th Edition. S. D. Jahn, W. H. Bullock, J. S. Ignacio, AIHA Press 2015

OH exposure data can biased high within a specific location

Tiered approach to characterize exposures of concern **=** quantitative data for a smaller group of workers and substances

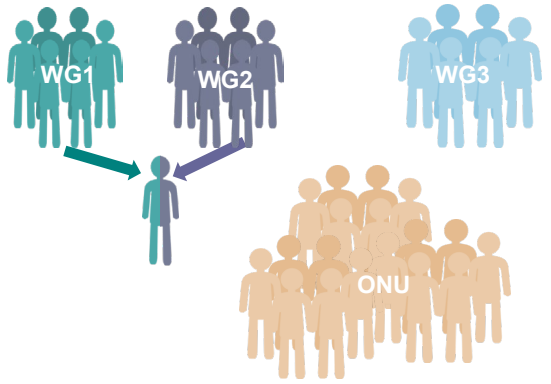
No quantitative assessment ≠ No assessment

➔ Quantitative assessment alone unlikely to be representative of all workers, only that SEG

SEG exposure ≠ Individual's exposure:

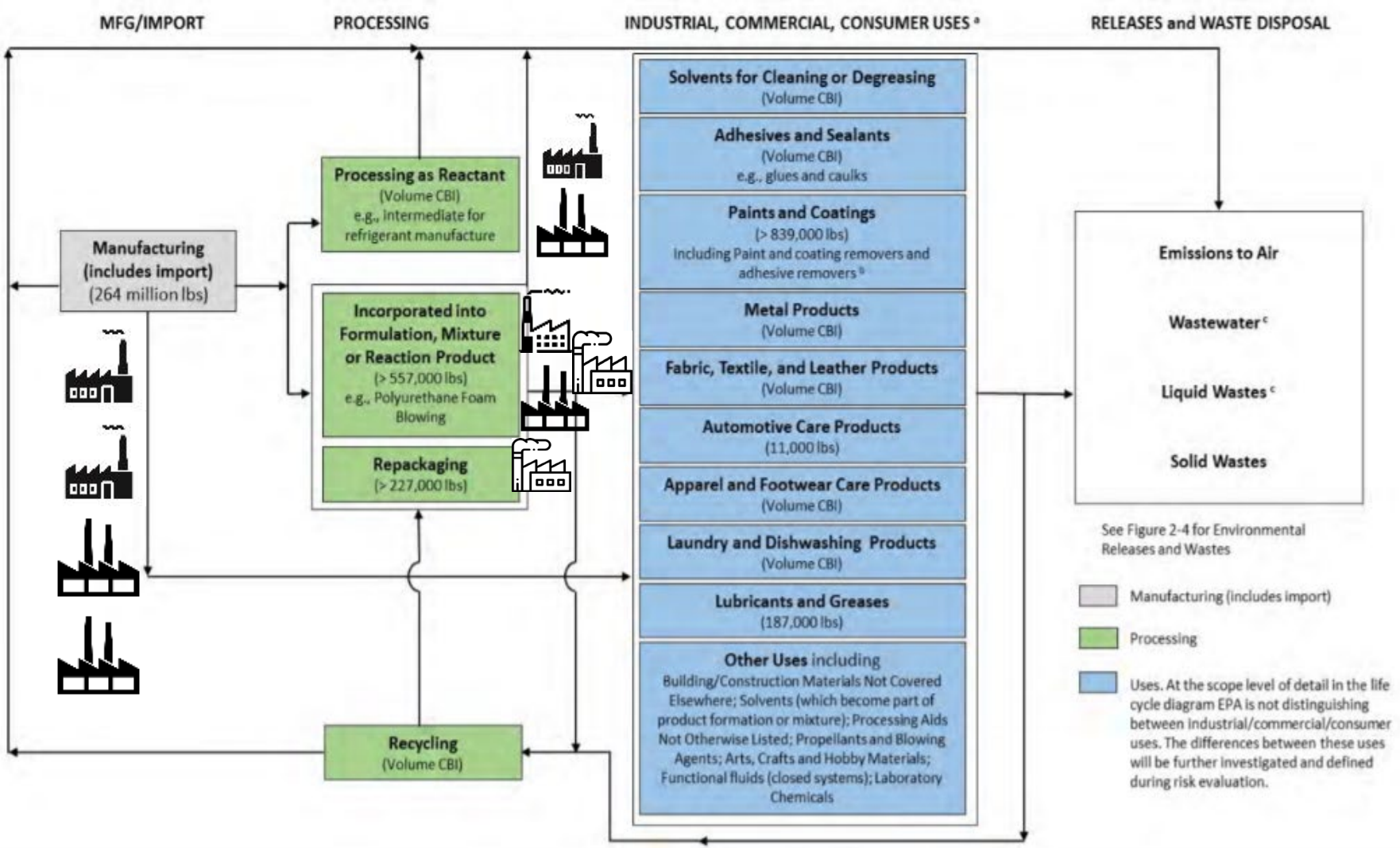
- Not all workers are exposed to the same concentrations
- Exposure patterns can differ by job description, task, or shift
- One worker can belong to different SEG

➔ Using only empirical measurements of exposure might not provide full distribution of exposures



Optimization of data collection & analysis

Conditions of Use vs Occupational Health Programs

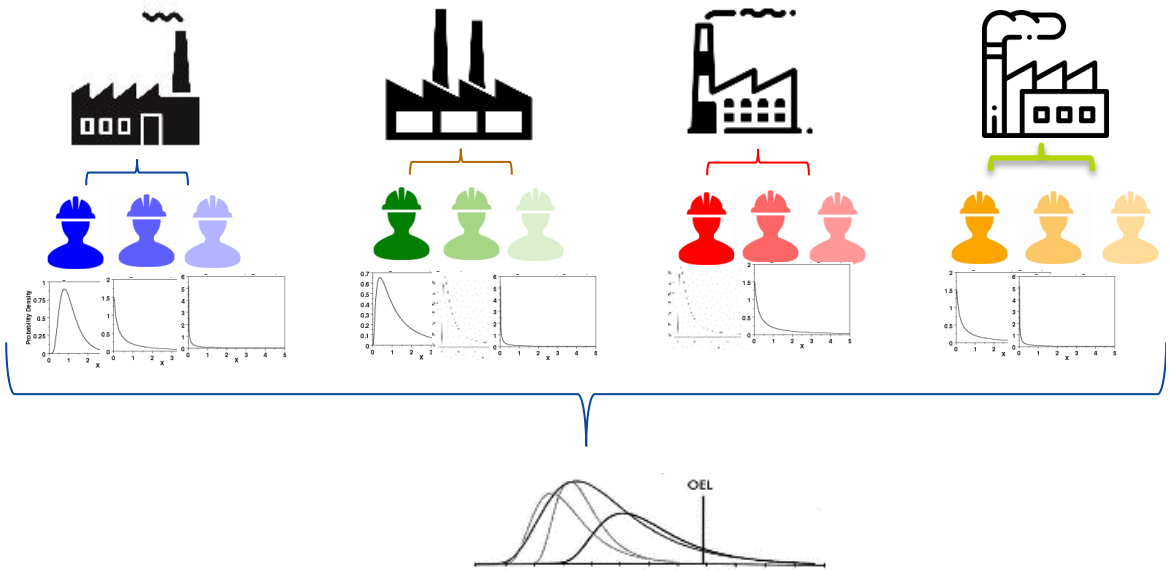


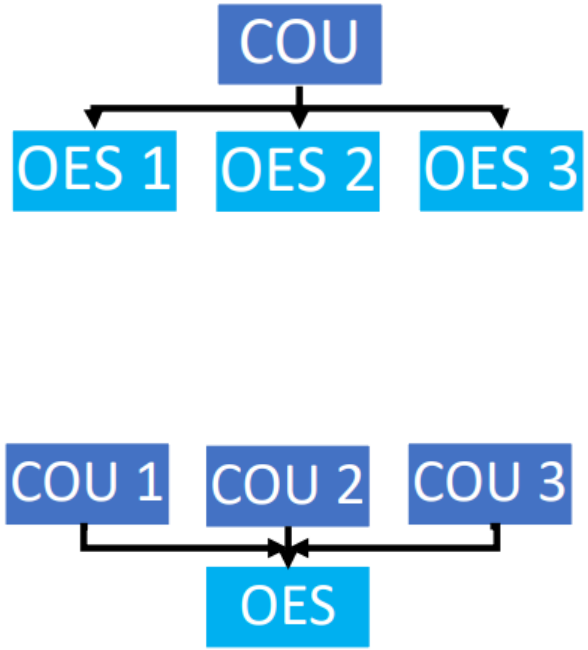
From EPA "Risk Evaluation for Carbon Tetrachloride" (2020) https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/final-risk-evaluation-carbon-tetrachloride#documents

How to generalize from site-specific information?

Develop a framework to map COUs & OES

- Stakeholder dialog
- Contextual information



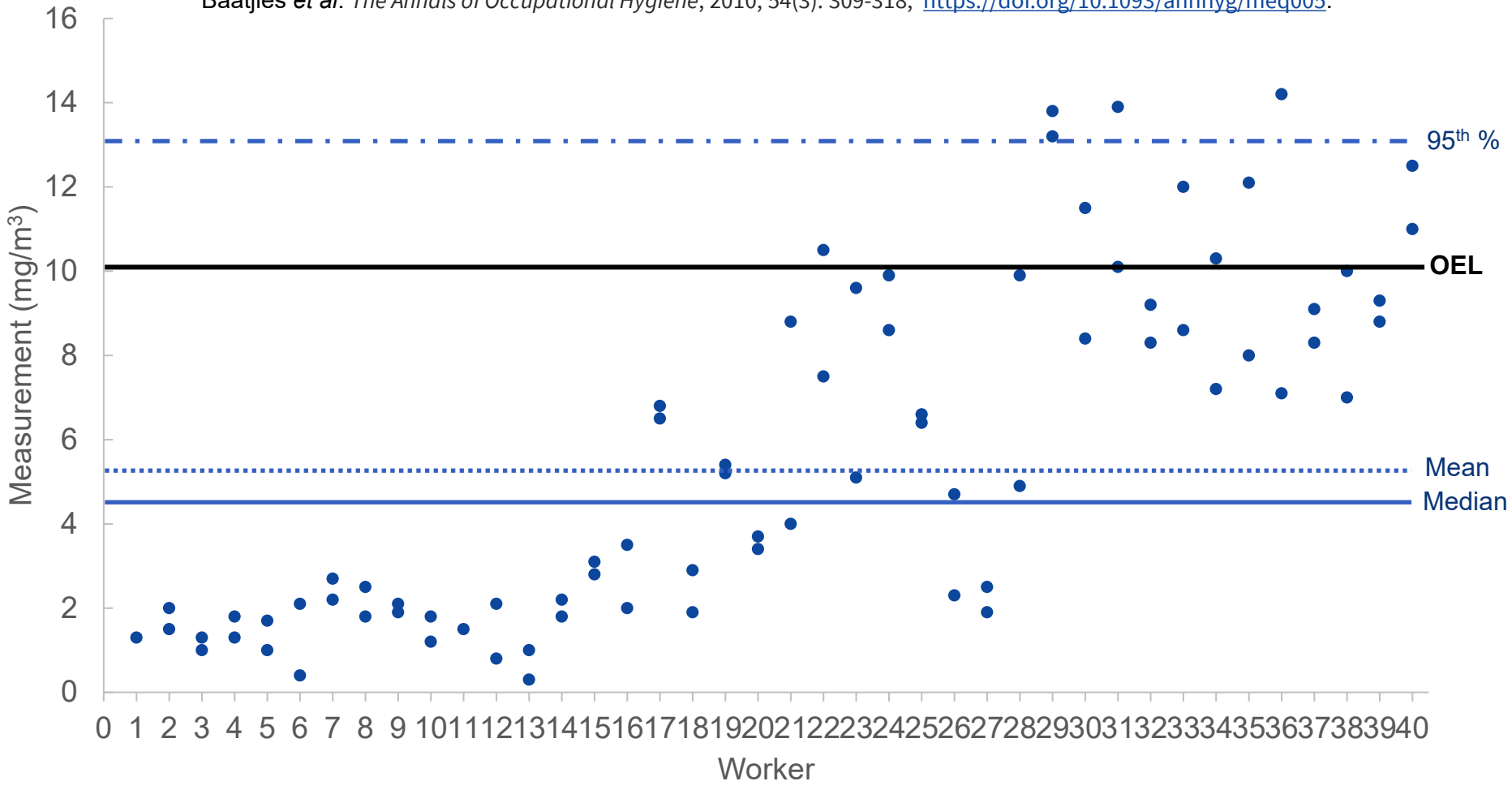


From EPA SOT presentation, 2021

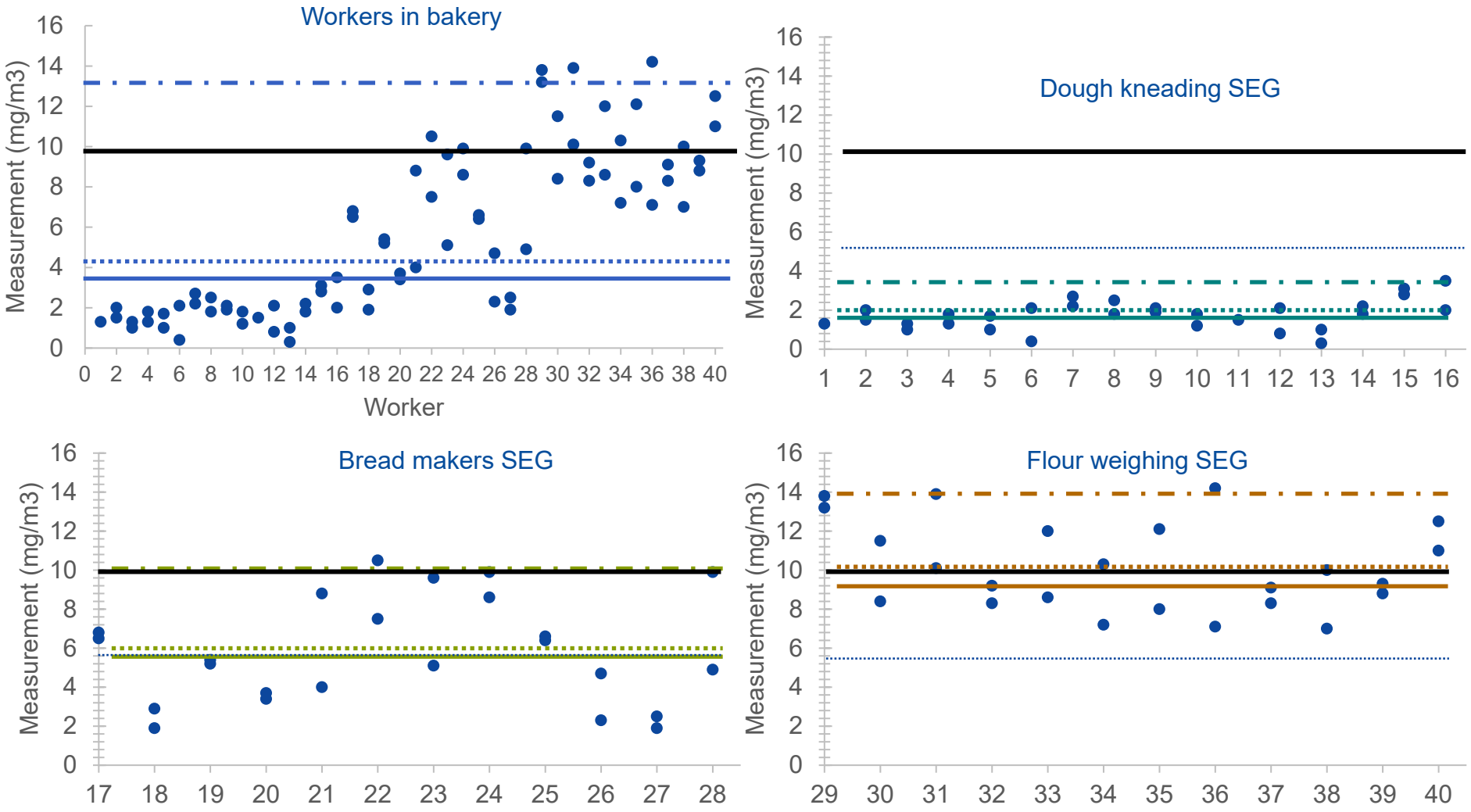
COU = Condition of Use
OES = Occupational Exposure Scenario

Aggregating all data together might not clearly communicate the actual risk

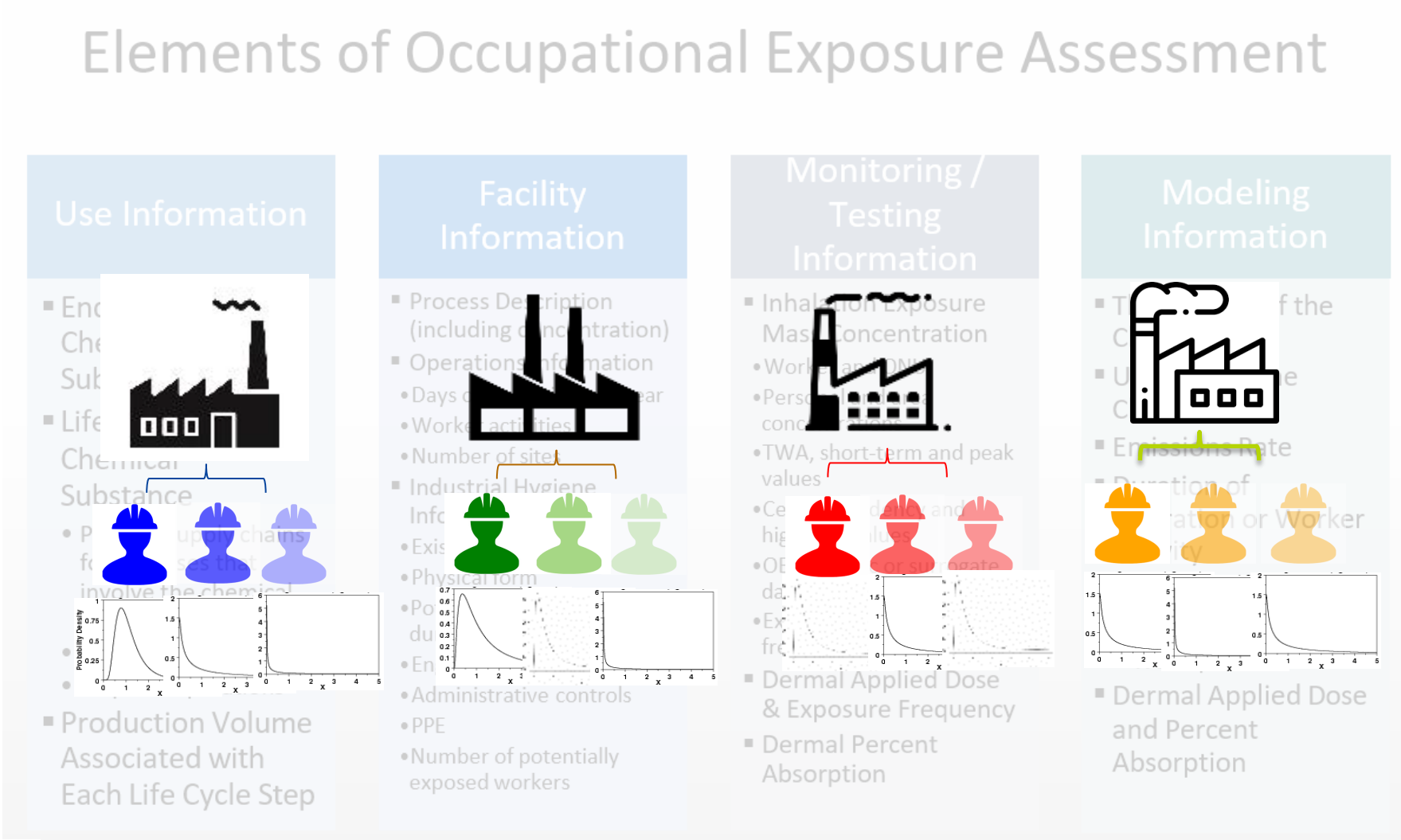
Hypothetical example of inhalable dust in bakeries adapted from
Burdof, *Occup Environ Med* 2005;62:344–350. doi: 10.1136/oem.2004.015198
Baatjies *et al*. *The Annals of Occupational Hygiene*, 2010; 54(3): 309-318, https://doi.org/10.1093/annhyg/meq005.



Validate data aggregation to avoid misassignment of controls & risk miscommunication



Amount of information requested per unit per site could be overwhelming depending on objective

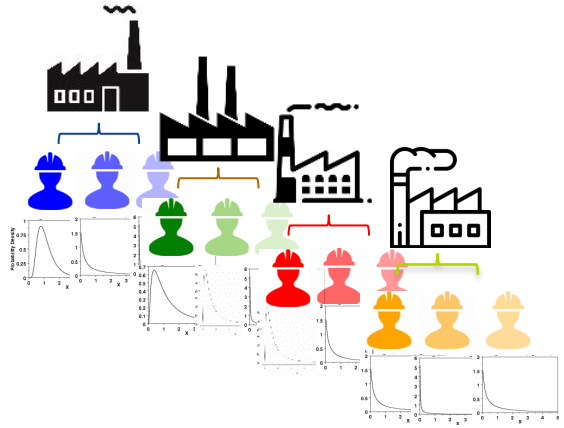


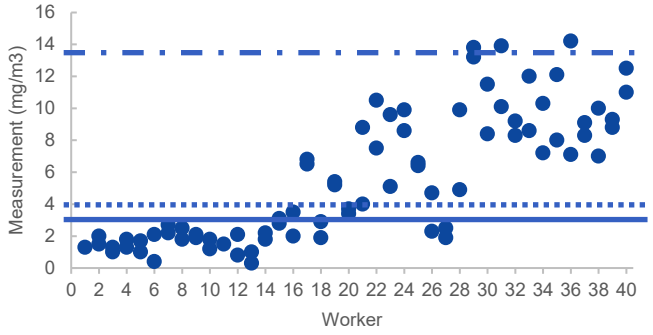
How does decision impact outcome?

Sampling strategy and data aggregation depends on problem formulation

- Identifying what controls are needed
- Characterize exposures associated with a health outcome

➔Contextual information, statistics, and professional judgment needed to validate SEGs and data representativeness





Must validate SEG composition and exposure profile.

- Over-estimation of exposures (and over-protection) for a group
- Under-estimation of exposures (and under-protection) for others

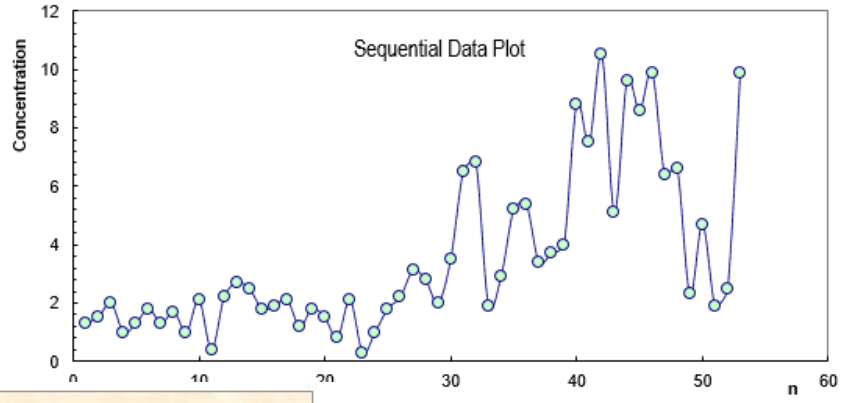
➔ Aggregation across industries and/or dis-similar groups may lead to misassignment of controls and miscommunication of risk

Analytical tools / Data interpretation

Data quality and data analytics

AIHA
Protecting Worker Health

Multilingual IHSTAT+



Descriptive statistics

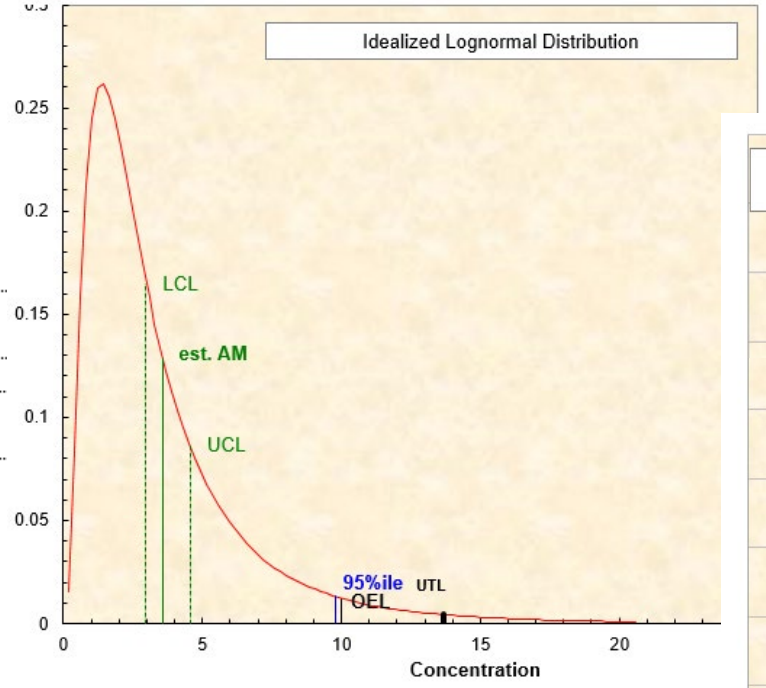
Number of samples (n)	53
Maximum (max)	10.5
Minimum (min)	0.3
Range	10.2
Mean	3.52
Median	2.2
Standard deviation (s)	2.78
Geometric mean	2.62
Geometric standard deviation	2.23
Percent above OEL	1.9%

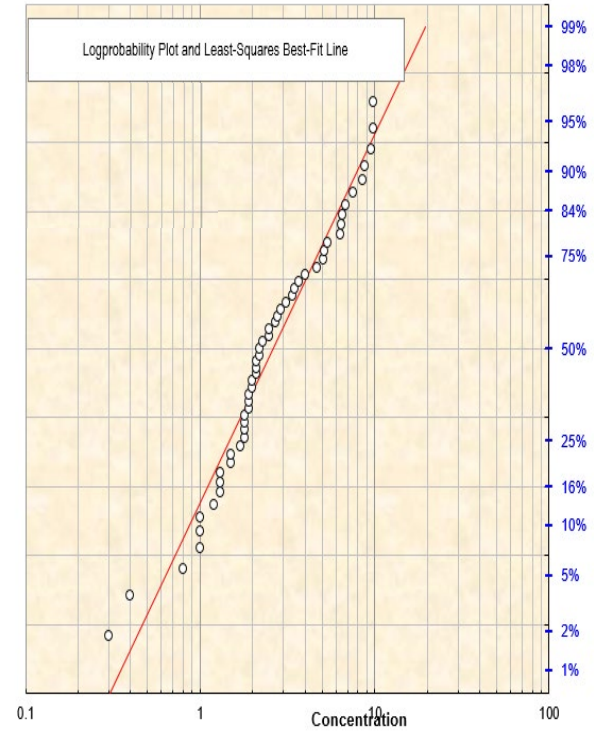
Test for distribution fit

W-test of log-transformed data	0.955
Lognormal (α = 0.05) ?	**Yes**
W-test of data	0.824
Normal (α = 0.05) ?	**No**

Lognormal parametric statistics

Estimated Arithmetic Mean - AM est.	3.580
LCL1,95% - Land's "Exact"	2.980
UCL1,95% - Land's "Exact"	4.560
95th Percentile	9.787
UTL 95% 95%	13.7
Percent above OEL	4.7%
LCL1,95% %>OEL	2.18
UCL1,95% %>OEL	9.43





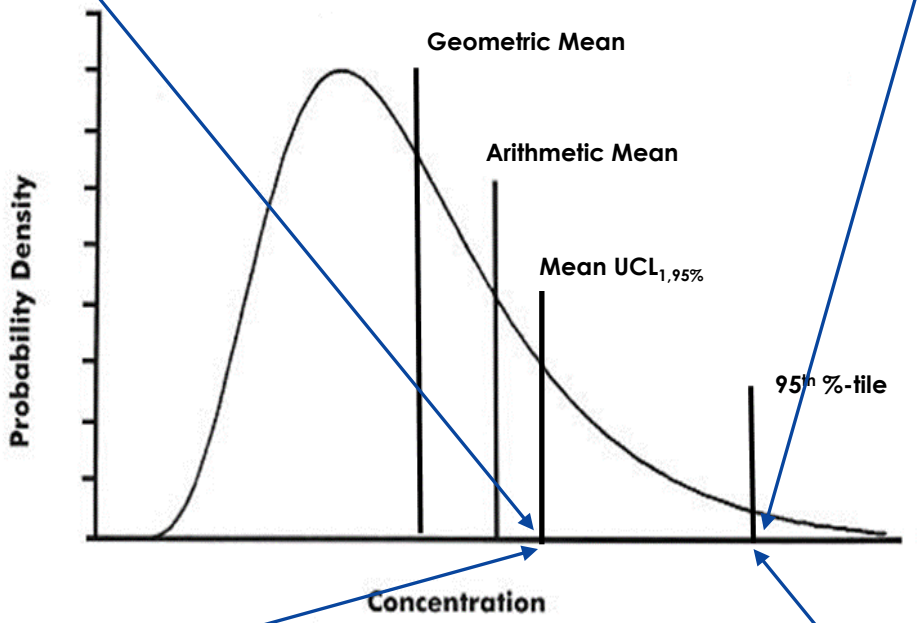
Exposure metrics depend on objective & toxicity

Chronic-acting hazards

- Long Time Average

Acute hazards

- Irritants / Asphyxiants
- Immediate response



Chronic Exposures

- Average over the day
- Representative of long-term average

Acute Exposures

- Short duration
- Frequent or not

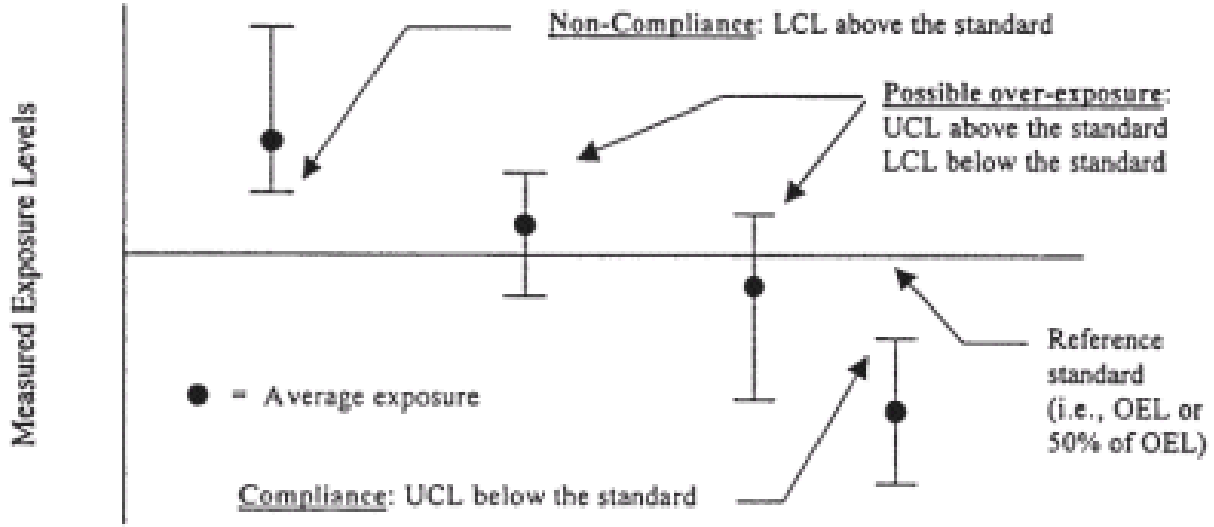
It is critical to align exposure metric to dose metric

Limit of Detection

A concentration below LOD does not imply measured concentrations at that level and will bias high the estimates of exposure.

Samples below method detection limit are accepted as representing exposures below the Occupational Exposure Limit (as long as LOD < OEL)

OELs used until now are greater than proposed ECELs



Determining Compliance with Occupational Exposure Limits (OELs)

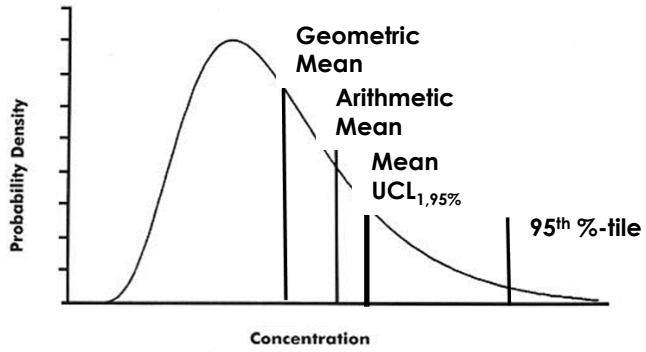
Image adapted from NIOSH Occupational Exposure Sampling Manual (NIOSH (1977): Determining compliance with occupational exposure limits

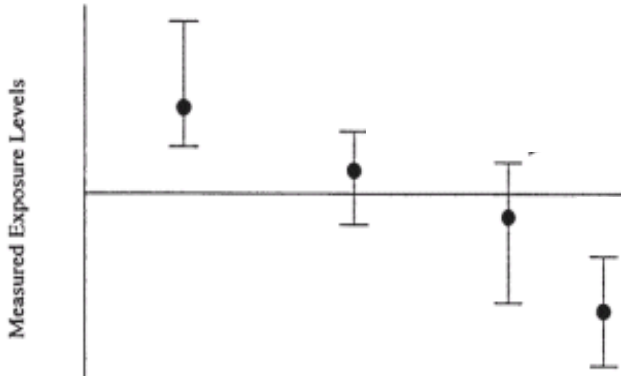
How does decision impact outcome?

Data analytics to help decision-making

- Measures of central tendency defined by objective
- Level of detailed analysis depends on problem formulation

➔ Disregarding the context in which the sample was taken will hinder the ability to determine if the data is representative or not for the objective.





Measurements below limit of detection do not imply over-exposure

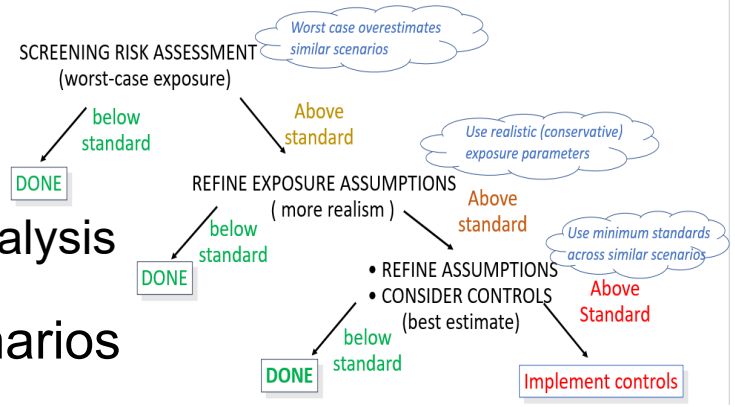
- Data aggregation requires imputation of censored data
- Approaches to compensate for evolving methods in historical data

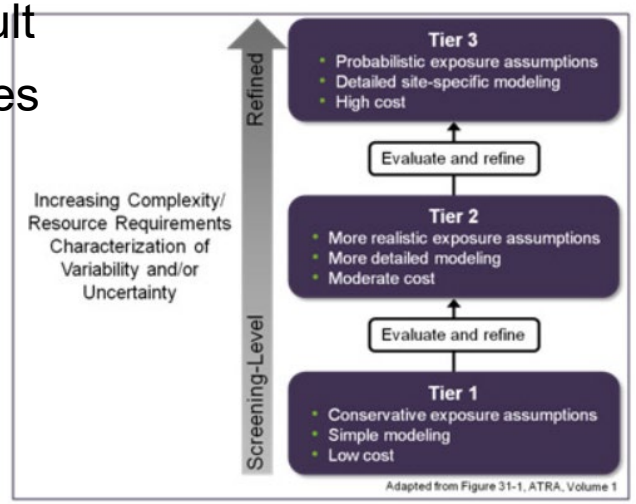
➔ Important to understand the limits for reliable quantification and decision-making

Potential path

Streamline assessments: Screen out the easy ones, focus on the not-so-easy!

- Tiered approach to screen out scenarios
  - Exceedance does not imply risk, just further analysis
- Generic Exposure Scenarios / Sentinel Scenarios
  - Framework to map COUs and OES
  - Representative of industries with similar activities
  - Based on assumptions and modelled data
  - Yield a “worse-case” (not necessarily realistic) result
  - Can be used to assess Risk Management Measures
- Rely on industry knowledge of processes to identify applicable scenarios and RMM
- Use to identify data gaps for higher-tier.





Example Application of Tiered Approach to Exposure Assessment (U.S. EPA, 2004)

Meet the speaker

Majd El-Zoobi, PE
Chemical Engineer, U.S. EPA OCSPP, Existing Chemicals Risk Assessment Division

- 18 years at EPA as a Chemical Engineer in the Office of Chemical Safety and Pollution Prevention (OCSPP)
- Prior to joining EPA, he worked as a project, process design, and production engineer in the chemical industry
- Expertise in exposure assessment

Occupational Exposure Assessments in TSCA Risk Evaluations

Majd El-Zoobi, M.S., P.E.

Many Paths, One Goal – Protecting Worker Health: An AIHA Workshop Series on Occupational Risk Assessment

April 2023 Workshop: Optimizing Uses of IH Exposure Data for Occupational Risk Assessment

April 20, 2023

Disclaimer: The views expressed in this presentation are solely those of the author(s) and do not represent the policies of EPA. Mention of trade names or commercial products should not be interpreted as an endorsement by EPA.

Outline


EPA’s TSCA occupational exposure assessment objectives
EPA’s data needs for occupational exposure assessment
EPA’s data collection, evaluation, and integration
Assessment of inhalation exposure & monitoring data

Introduction to TSCA Existing Chemicals Risk Evaluations

Purpose:

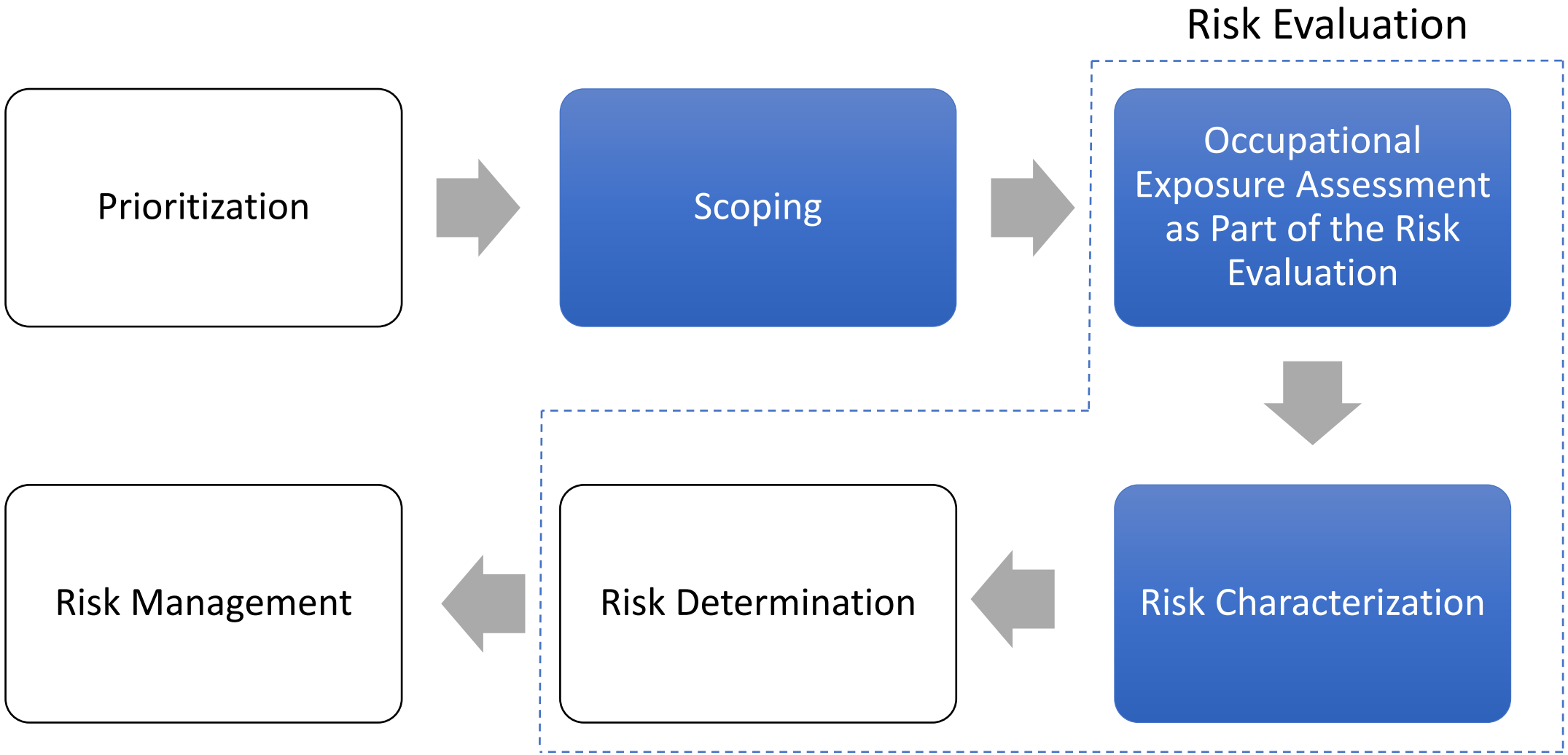
To determine whether chemicals present unreasonable risks to human health or the environment under the conditions of use

Scope:

- Out-of-Scope Chemicals (e.g., pesticides regulated under FIFRA, foods/drugs/cosmetics regulated under FFDCA)

- TSCA Inventory: ~ 87,000 chemical substances
  - ~ 42,000 chemical substances potentially active in commerce

Occupational Exposure Assessment as Part of the Overall Process



TSCA Occupational Exposure Assessment Objectives: Conditions of Use (COUs)

COU Definition:

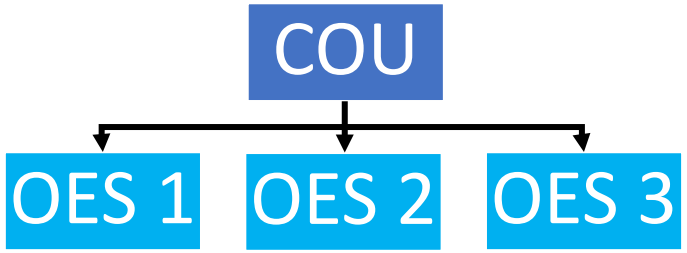
Life-Cycle Stage	Category	Subcategory
Manufacturing / Import	…	…
Processing	…	…
Distribution in commerce	…	…
Industrial use	…	…
Commercial use	…	…
Disposal / Recycling	…	…

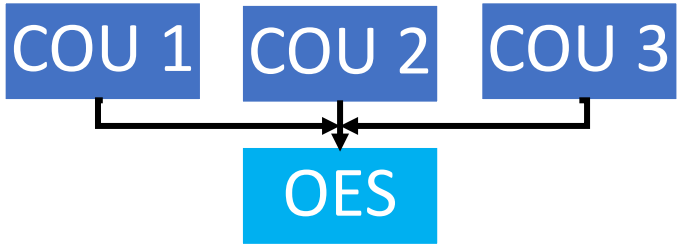
COU Example:

Risk Evaluation	Life Cycle	Category	Subcategory
1-BP	Industrial/ Commercial Use	Solvent (for Cleaning or Degreasing)	Batch Vapor Degreaser (e.g., Open-Top, Closed-Loop)

TSCA Occupational Exposure Assessment Objectives: Occupational Exposure Scenarios (OES)

A COU may be associated with one or more OES or multiple COUs may be associated with a single OES





The following is assessed for each OES:

- All relevant routes of exposure
- Central tendency and high-end worker and ONU exposures
- Depending on the available human health hazard data, each of the assessed exposures may include acute, subchronic, and chronic (cancer and non-cancer) exposures

EPA's Data Needs: Elements of Occupational Exposure Assessment

Use Information

- ❑End-Uses of Chemical Substance
- ❑Life Cycle of Chemical Substance
  - Industries involving the chemical substance that are parts of the supply chains for the end-uses
  - Recycling operations
  - Disposal operations
- ❑Production Volume Associated with Each Life Cycle Step

Facility Information

- ❑Process Description (including concentration)
- ❑Operations Information
  - Days of operation per year
  - Worker activities
  - Number of sites
- ❑Industrial Hygiene Information
  - Existing OELs
  - Physical form
  - Potential exposure routes, durations and frequencies
  - Engineering controls
  - Administrative controls
  - PPE
  - Number of potentially exposed workers

Monitoring / Testing Information

- ❑Inhalation Exposure Mass Concentration
  - Worker and ONU
  - Personal and area concentrations
  - TWA, short-term and peak values
  - Central tendency and high-end values
  - OES-specific or surrogate data
  - Exposure duration & frequency
- ❑Dermal Applied Dose & Exposure Frequency
- ❑Dermal Percent Absorption

Modeling Information

- ❑Throughput of the Chemical
- ❑Use Rate of the Chemical
- ❑Emissions Rate
- ❑Duration of Operation or Worker Activity
- ❑Ventilation Rate
  - Exchange rate
  - Workspace volume
- ❑Dermal Applied Dose and Percent Absorption

EPA Data Needs: Hierarchy of Information Used for Occupational Exposure Assessment

Monitoring Data

- Personal monitoring and directly applicable
- Area monitoring and directly applicable
- Personal monitoring and potentially applicable
- Area monitoring and potentially applicable

Modeling Approaches

- Surrogate monitoring data
- Fundamental modeling approaches
- Statistical regression modeling approaches

Occupational Exposure Limits

- Company-specific OELs (for site-specific exposure assessments)
- OSHA Permissible Exposure Limits (PELs)
- Voluntary limits: ACGIH TLV, NIOSH REL, Occupational Alliance for Risk Science (OARS), Workplace Environmental Exposure Level (WEEL) [formerly by AIHA]

EPA's Data Search, Evaluation & Integration

Data Sources:

- Peer-Reviewed and Gray Literature
- TSCA Submissions (e.g., 8(a), 8(d) and 8(e))
- Information from Data Gathering Options
- Models
- Public Comments

EPA's Data Quality Evaluation: Metrics for Monitoring Data & Data Other than Monitoring or Release Data

Data Type	Metric Name
Monitoring Data	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
Data Other than Monitoring or Release Data	Methodology; Geographic Scope; Applicability; Temporal Representativeness; Sample Size; Metadata Completeness Informing the Accessibility and Clarity Domain; Metadata Completeness Informing the Variability and Uncertainty Domain

Assessment of Worker Inhalation Exposure Based on Monitoring Data: An Example

n-Methylpyrrolidone (NMP) Risk Evaluation:

- 37 COUs and 17 OESs

- Assessment Approaches:
  - monitoring data: 8 OESs
  - monitoring data & math modeling: 5 OESs
  - math modeling: 4 OESs

- Sources of Monitoring Data: Peer Reviewed Literature, NIOSH Health Hazard Evaluations, OSHA's Chemical Exposure Health Data, Industry Submissions

Assessment of Worker Inhalation Exposure Based on Monitoring Data: A Case with Relatively More Data

Risk Evaluation	Life Cycle	Category	Subcategory	Occupational Exposure Scenario
NMP	Industrial/ Commercial Use	Solvents (for Cleaning or Degreasing)	Use in Electrical Equipment, Appliance and Component Manufacturing for Use in Semiconductor Manufacturing	Semiconductor Manufacturing

- Personal breathing zone worker monitoring data submitted by the Semiconductor Industry Association
- 118 samples from 14 sites
- EPA assessed worker exposure in the case of 6 worker tasks or job functions separately

Assessment of Worker Inhalation Exposure Based on Existing Monitoring Data: Challenges

Examples of Challenges:

Challenge	OES	Resolution
Small data set	1-BP – Processing / Formulation	Exposure assessed based on a single data point
Data are summary statistics of various data sets	HBCD – Recycling of E-Waste	Central tendency and high-end exposures assessed based on median and maximum values, respectively
Incomplete meta data	HBCD – Processing of HBCD to Produce XPS Foam Using XPS Masterbatch	Exposure assessed based on this data due to lack of any other suitable data

THANK YOU

Workshop Discussants

- Joe Damiano, MS, CIH, CSP, FAIHA*
- Louan Fisher, RQAP-GLP
- Heather Lynch, MPH, DABT
- Mwangi Ndonga, MS, CIH, CSP
- Ben Roberts, PhD, CIH
- Taylor Shockey, PhD, MPH
- Brian Van Deusen

*Joe Damiano was unable to participate in today's workshop as a panelist; however, Joe contributed discussion points and resources to the presentation.

Discussion Questions

1. Given that there are different uses of IH data (i.e. applications and objectives) - how do data collection strategies differ across intended uses?

2. What methods can be used to ensure that data are representative of the worker population of interest – what are the challenges in implementing data grouping strategies?

3. What approaches and systems are in place to increase confidence in and generalizability of IH data – how can they be enhanced?

4. What techniques and tools for IH data analytics are available for risk decision making - what are some emerging optimization approaches?

Poll Question #1

What is the most frequent reason you collect worker exposure data?

A. To evaluate compliance with a regulatory occupational exposure limit (OEL).

B. To evaluate effectiveness of existing controls (engineering, administrative, PPE).

C. To evaluate adverse health effects among workers for use in an epidemiology study or medical surveillance program.

D. To support risk assessments for regulatory purposes.

Discussion Question #1

Given that there are different uses of IH data (i.e. applications and objectives) - how do data collection strategies differ across intended uses?

BREAK

11:55am – 12:00pm

Poll Question #2

How often do you apply the concept of Similar Exposure Groups (SEGs) when planning to collect worker exposure data?

A. Always

B. Frequently

C. Infrequently

D. Rarely

Discussion Question #2

What methods can be used to ensure that data are representative of the worker population of interest - what are the challenges in implementing data grouping strategies?

Poll Question #3

Select which of these data quality concepts you *formally* apply most often when evaluating exposure data:

A. Systematic Review

B. Good Laboratory Practice (GLP)

C. Standardized Data Annotations

D. None of these

Discussion Question #3

What approaches and systems are in place to increase confidence in and generalizability of IH data - how can they be enhanced?

Poll Question #4

What tool or technique do you most often use to characterize worker exposure data?

A. Calculate the descriptive statistics manually.

B. Use an AIHA tool (IHDA-AIHA, IHSTAT, etc.).

C. Use another statistical program or tool.

D. My datasets do not usually require statistical analyses.

Discussion Question #4

What techniques and tools for IH data analytics are available for risk decision making - what are some emerging optimization approaches?

Questions?

Next steps

- The slides will be available to download following the workshop.
  - Please take advantage of the additional resources provided at the end of the presentation slide deck.
- Please complete your evaluation, available immediately following the end of this webinar and by email. Thank you!
- Look for an article in The Synergist covering today's webinar.
- Consider joining us for another workshop in the series:
  - **June 29, 2023**: Exposure Modeling
  - **September 21, 2023**: Dermal Risk Assessment
  - **November 9, 2023**: Risk Characterization and Risk Management

Thank You

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Resources

- **Discussion Questions #1 and #2 –**
  - NIOSH Occupational Exposure Sampling Manual (1977)
  - ECETOC. Targeted Risk Assessment (TRA)
  - EPA Guidelines for statistical analysis of occupational exposure data (1994)
  - EPA ExpoBox Tools
  - NIOSH Practices in Occupational Risk Assessment (2020). https://www.cdc.gov/niosh/docs/2020-106/pdfs/2020-106revised032020.pdf
  - A Strategy for Assessing and Managing Occupational Exposures, 4th Edition. S.D. Jahn, W.H. Bullock and J.S. Ignacio. AIHA Press 2015.
  - Pesticide Cumulative Risk Assessment: Framework for Screening Analysis. https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/pesticide-cumulative-risk-assessment-framework
  - EPA Risk Assessment Overview. https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/overview-risk-assessment-pesticide-program

Resources

- **Discussion Question #3 –**
  - EPA Draft Protocol for Systematic Review in TSCA Risk Evaluations. https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/draft-protocol-systematic-review-tsca-risk-evaluations
  - AIHA Technical Framework: Big Data. https://www.aiha.org/education/frameworks/technical-framework-big-data
  - Synergist Article: Industrial Hygiene Data Standardization
  - EPA TSCA Gool Laboratory Practice Standards. 40 CFR Part 792. https://www.ecfr.gov/current/title-40/chapter-I/subchapter-R/part-792
  - EPA Good Laboratory Practices Standards Compliance Monitoring Program. https://www.epa.gov/compliance/good-laboratory-practices-standards-compliance-monitoring-program
  - Society of Quality Assurance. https://www.sqa.org/
  - Occupational Pesticide Handler Exposure Data | US EPA
  - Worker Exposure Assessment Methods – FIFRA Scientific Advisory Panel. https://www.regulations.gov/docket/EPA-HQ-OPP-2006-0856
  - Joint ACGIH-AIHA Task Group on Occupational Exposure Databases. Data Elements for Occupational Exposure Databases: Guidelines and Recommendations for Airborne Hazards and Noise. Appl. Occup. Envir. Hyg. 11:1294-1311, 1996.

AIHA Risk Assessment Tool Kit

- **Discussion Question #4 -**
  - Data Collection tools:
    - IH/OEHS Exposure Scenario Tool (IHEST)
  - Basic Characterization tools:
    - Basic Exposure Assessment and Sampling Spreadsheet
  - Preliminary/ Initial Exposure Assessment (Tier 1) tools:
    - SDM 2.0
  - Refined Assessment (Tier 2) tools:
    - IHMOD
    - IH SkinPerm
    - ODHMOD
    - Dermal Risk Assessment Model (DRAM)
    - FR Assessment Tool
  - Refining/ Validation the Exposure Assessment tools:
    - IHDA-AIHA
    - ExpoStats
    - IHSTAT
    - IHSTAT Bayes

https://www.aiha.org/public-resources/consumer-resources/apps-and-tools-resource-center/aiha-risk-assessment-tools