

Data annotation issues - Optimizing Uses of IH Exposure Data for TSCA Occupational Risk Evaluation (RE)

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Supporting EPA's forward path:

From EPA presentation at GlobalChem 2024:

- EPA wants to **use available data** in developing occupational exposure assessments
- EPA wants **data to be submitted early in the process** to inform development of draft scoping document
- EPA will use data to:
 - Develop more refined descriptions of OES to be assessed
 - Develop a more specific plan for analysis of occupational exposure
- These can lead to **reduced time for EPA** to produce draft risk evaluation

Bridging the gap between TSCA RE and IH assessments – Supporting EPA's path forward

- In general, want to repurpose data where possible but avoid over-extending it
 - Need to understand what is the goal of the assessment?
 - Existing (past) IH data collected for a different purpose with methodologies appropriate for that objective
- Need for efficient use of resources
 - It is not feasible to measure everything, everywhere, all the time
 - It is not feasible to assess every scenario in great detail with quantitative estimates depending on how granular a scenario is defined
 - We can assess every scenario using representative assessments
- Need for a systematic assessment approach that is:
 - Transparent and predictable
 - Strategic and efficient

The goal of this presentation is to provide suggestions to help EPA reduce time in producing the RE

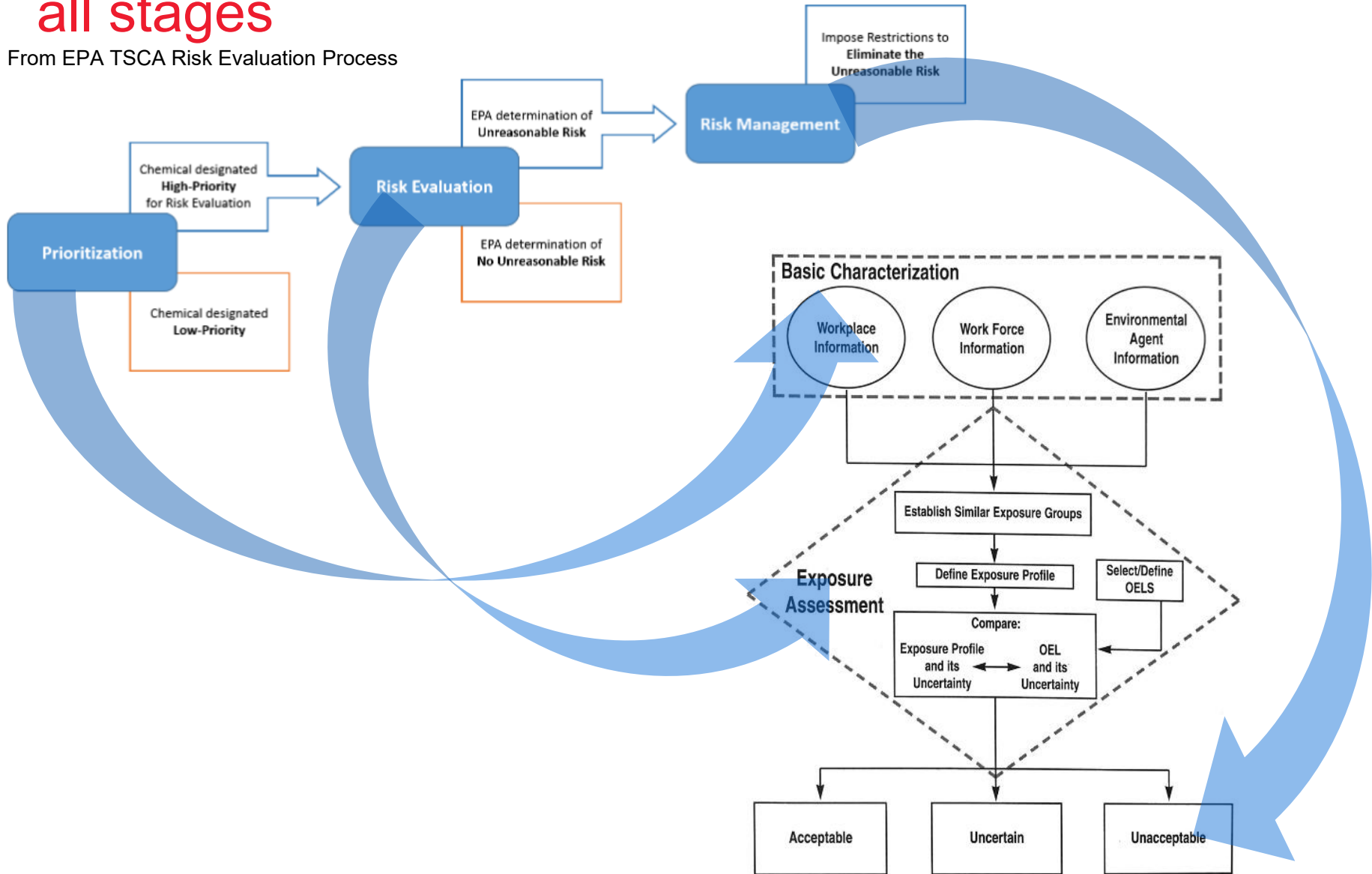
Bridging the gap between TSCA RE and IH assessments – Supporting EPA's path forward

Work together to clarify the goal and approach for the assessment

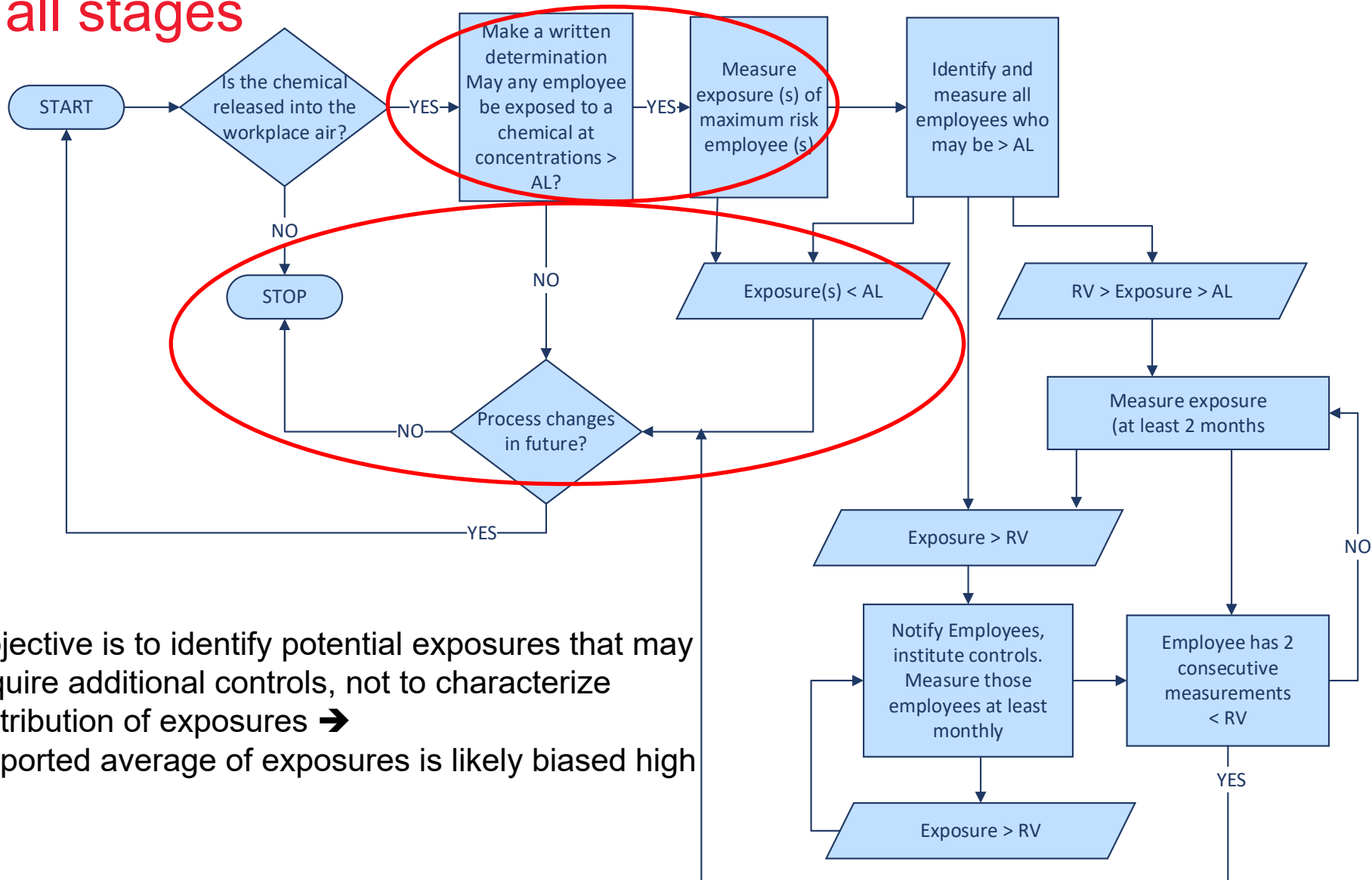
- Use of data for Risk Evaluation
- Use the information for risk management
- *"A characterization of the distribution of exposures for a given COU/OES combination that represents the reasonable central tendency and upper end of exposure inclusive of workplaces in the U.S. for routine or normal operating conditions".*
 - Do we mean the distribution of the subcomponent of all exposures such that we are characterizing the central tendency of only reasonable worst-case exposures or ALL exposures?
 - Do we intend to include or exclude non-routine exposures (e.g. spills special procedures that have separate control plans) - and how to define "routine vs non-routine"
 - Are there other requirements in terms of "representative" that define data inclusion/exclusion?

Tiered and targeted assessment concept applied in all stages

From EPA TSCA Risk Evaluation Process



Tiered and targeted 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

Fit-for-purpose characterization and Representativeness

Measurement objective

- Characterization of the activity / worker exposure (site vs sector)
- Assess compliance with a regulation (typically high-risk group)
- Control evaluation (focused on task/activity)
- Source characterization (at emission point, not bz)

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
- Generally following AIHA / NIOSH / OSHA exposure assessment strategy

Fit-for-purpose characterization and Representativeness

Exposure data may be most useful when collected and used for a specific purpose

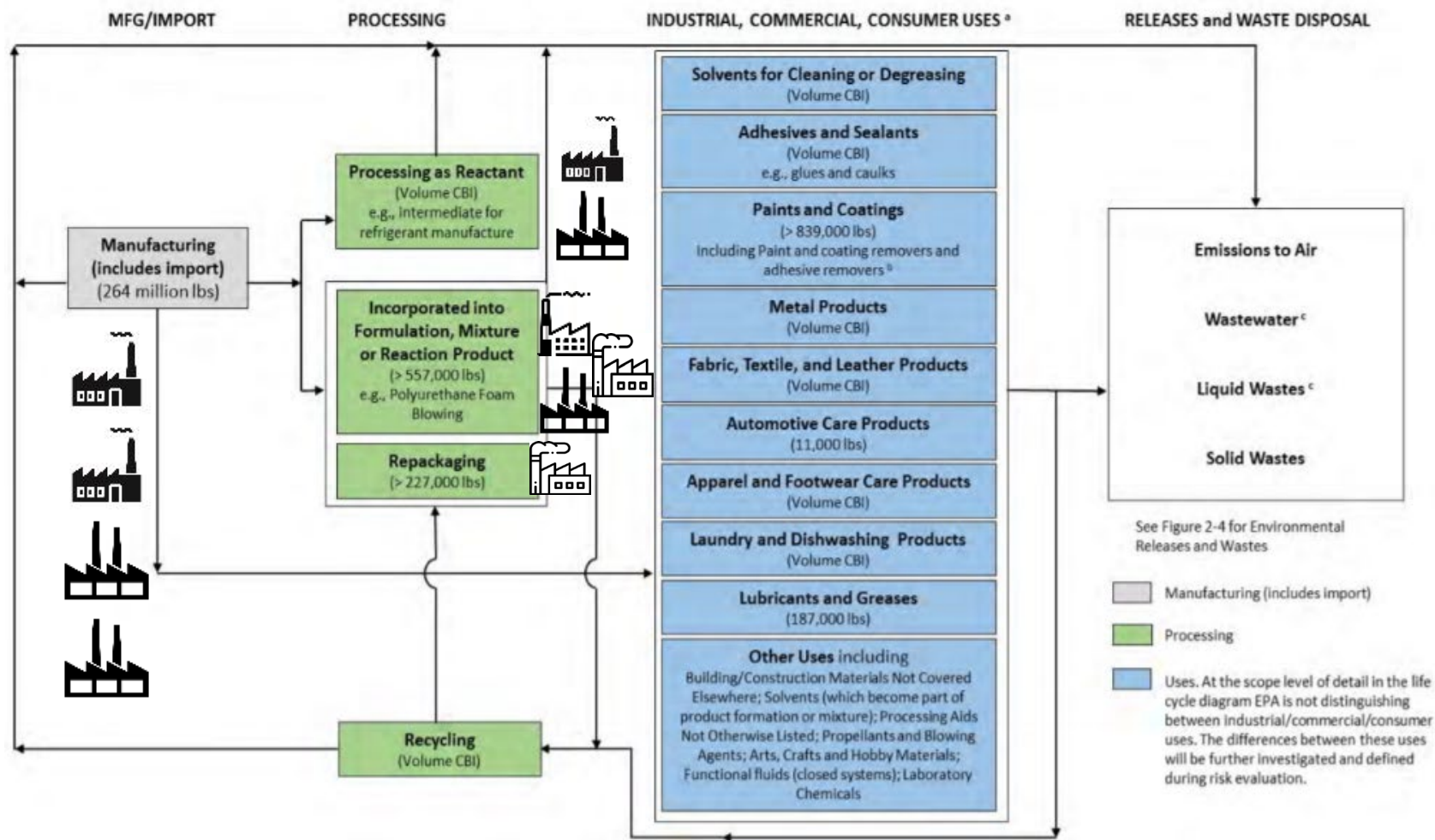
- Data can be “repurposed,” but we must do so with caution
- If the stated goal is to characterize full range of exposure experienced by workers (in the site, company, or industry), then IH monitoring data may not be adequate

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

☆ **Use a tiered approach to model exposures and inform targeted data needs:**

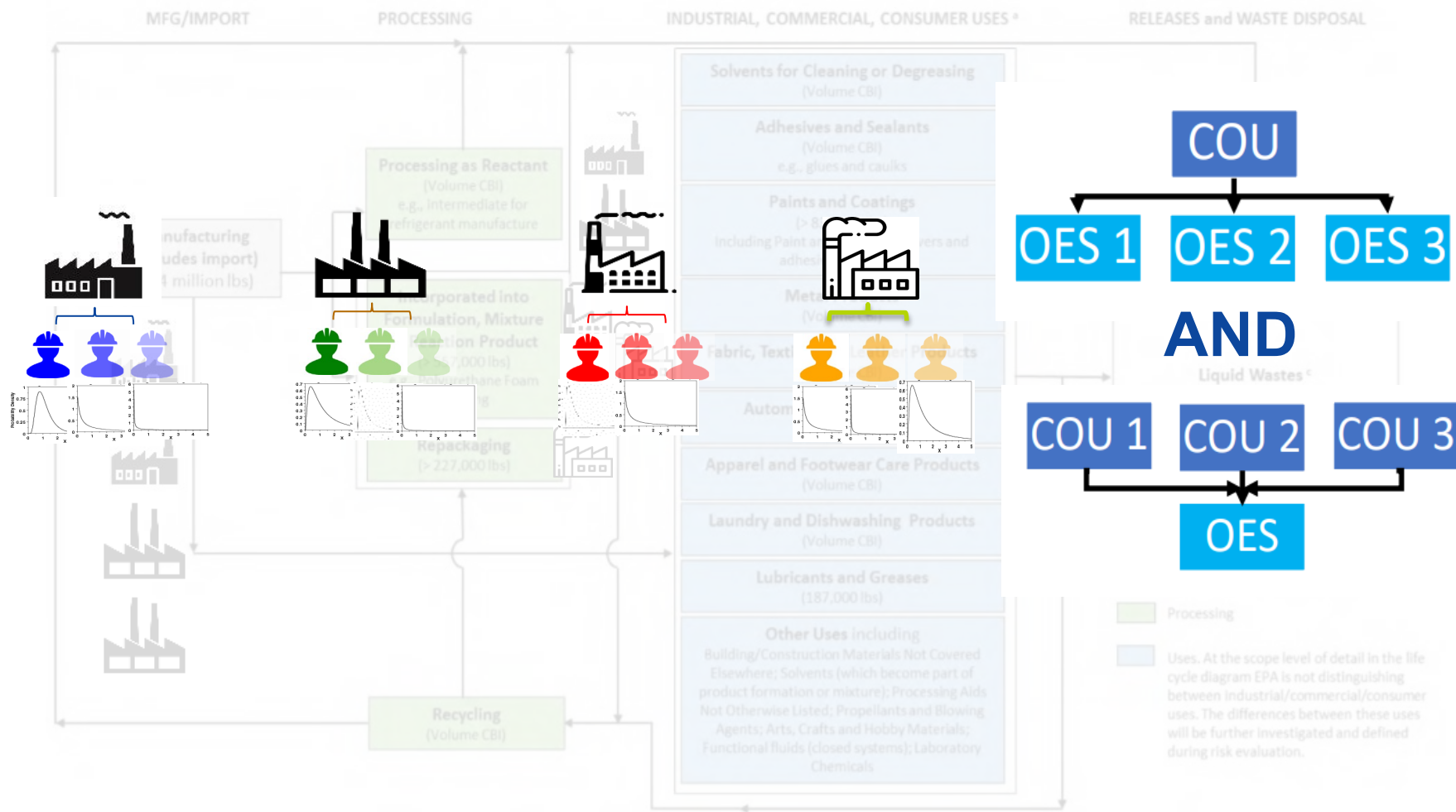
- ☑ Simple, conservative, minimal info to screen exposures of no concern
- ☑ Increase information / scenario refinement as needed
- ☑ Use measured data to validate models

Conditions of Use vs OES vs Task/Activity vs SEG



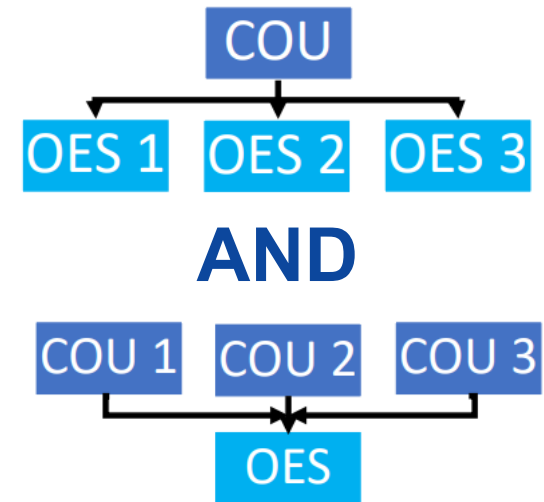
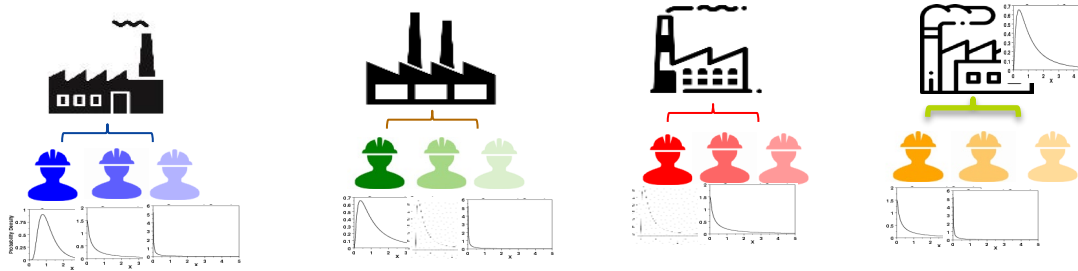
From EPA "Risk Evaluation for Carbon Tetrachloride" (2020) <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/final-risk-evaluation-carbon-tetrachloride#documents>

Conditions of Use vs OES vs Task/Activity vs SEG



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

Conditions of Use vs OES vs Task/Activity vs SEG

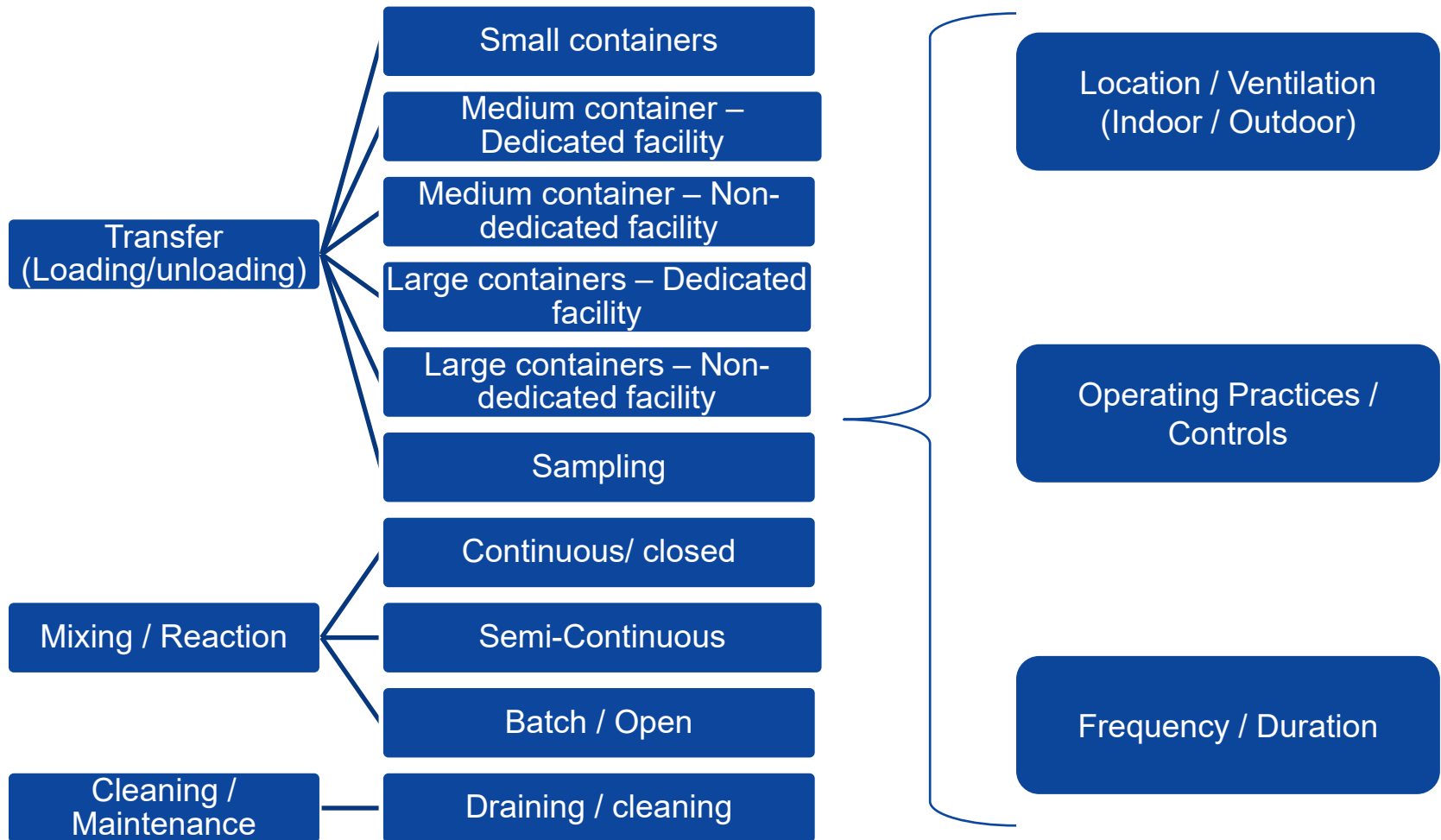


Traditional OH monitoring data might not align with COUs / category / subcategory as currently defined (potentially multiple COUs, Categories, SEGs, operating conditions, etc.)

☆ **Create an inventory of Sentinel OES and allow manufacturers and users to inform what is applicable to their sector**

- ☑ Identify common exposure determinants independent of COU but specific to user type / sector
- ☑ Systematic approach of mapping of data to relevant OES

Example of a Use map: OES at Manufacture / Formulation



How to combine/use disparate sources of information (format, data elements, owners)

Use Information

- End-Uses of Chemical Substance
- Life Cycle of Chemical Substance
 - Parts of supply chains for end-uses that involve the chemical substance
 - 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

Dissimilar collection of information (format, amount, data elements, owners, location)

Amount of information requested could be overwhelming

For owners:

- Data collected/used by different entities within organization
- Multiple formats and locations
- Not 1:1 relationship
- Without understanding of need, data integration might be inadequate

For Agency:

- Multiple formats
- Multiple SEGs per COU per category no easy mapping
- Contextual information might not be informative enough

☆ **A standard process informs data collection/sharing**

☆ **Build COU/ sentinel OES “use map” in collaboration with industry and value chain**

- ☑ Standardize data format and elements
- ☑ Rationalize information requested (and inform gaps for generation)
- ☑ Easily include new COU/categories if OESs are already represented
- ☑ Easily include risk management or common practices

Potential areas for collaboration

Multi-sector / stakeholder collaboration to develop a predictable approach that allows for:

- Collection of information from the whole value chain
- Easy screening of COUs/OES while conservative
- Inform risk management requirements

[European Experiences in the Development of Approaches for the Successful Control of Workplace Health Risks | Annals of Work Exposures and Health | Oxford Academic \(oup.com\)](#)

[The Use of Tiered and Targeted Approaches for Human Health E... : Epidemiology \(lww.com\)](#)

Potential areas for collaboration

Potential activities:

- Pre-defined generic/sentinel exposure scenarios that yield upper bound exposure estimates
 - Provide mutual understanding of minimal set of inputs needed and underlying assumptions
 - Define decision criteria including uncertainty / variability / representativeness
- Build an inventory of templates for value chain to help build COUs and identify common practices
 - Harmonize language throughout the value chain
 - Permit stakeholders to provide, generate data that is fit-for-purpose
 - Target data collection and gathering on elements needed
 - Informs type of risk management
 - Expedites integration of new COUs/Categories if sentinel scenarios are the same