Occupational Exposure Assessment for New Chemicals:

Inhalation Exposure to Dust / Particulate

TSCA Exposure Workshop May 2024

Ariel Hou
U.S. Environmental Protection Agency
Office of Chemical Safety and Pollution Prevention

Overview

- Background
  - Information required to be submitted by a manufacturer
  - Risk assessment paradigm
- New chemicals workflow
- Occupational exposure assessment
- Solid/Particulate issues
  - Case study
  - Data / Modeling needs

Background

- Mandated by section 5 of the Toxic Substances Control Act (TSCA), EPA's New Chemicals program reviews and manages the potential risk to human health and the environment from chemicals new to the marketplace prior to manufacture
- EPA must review a chemical under the “conditions of use,” defined as the circumstances under which the chemical is intended, known or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of

Information Required by Regulation

- Chemical Identity
- By-products and impurities
- Estimated production/import volume
- Manufacturing process
- Proposed uses and amounts for each use
- Human exposure information
- Disposal methods and estimates of releases to the environment
- Existing test data in notifier's possession or control concerning human and environmental effects

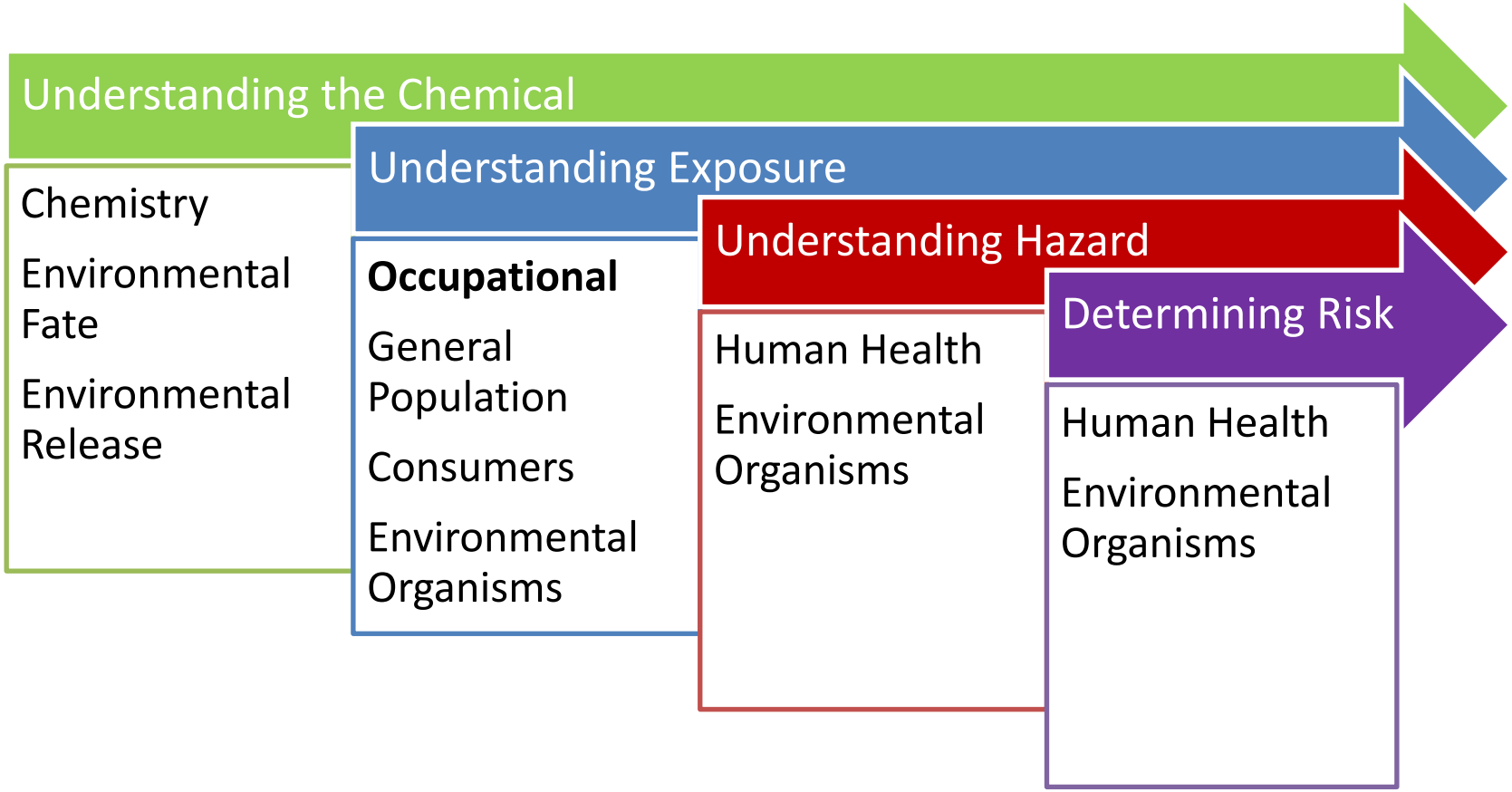
Risk Assessment Paradigm for New Chemicals

Under TSCA, OPPT evaluates and regulates, as appropriate, the full life cycle of a chemical, i.e., manufacture (including import), processing, distribution in commerce, use and disposal

- Risk assessments for a wide variety of industrial chemicals
- Data availability/quality varies, but generally limited/incomplete

New Chemicals Workflow

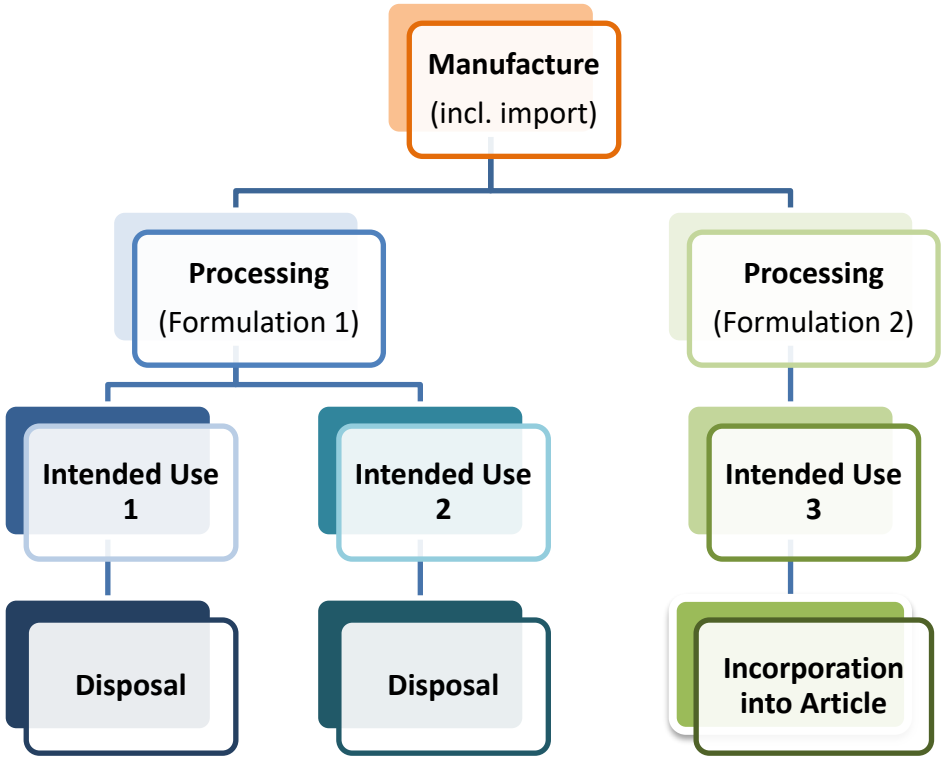
New Chemicals Workflow



New Chemicals Workflow (continued)

Occupational Exposure Assessment

Process Roadmap



1. **Identify "Conditions of Use"**
   a. Review the new chemical submission to understand the lifecycle of the new chemical substance (manufacture/import, processing, use and disposal)
   b. Review the intended uses that will occur in the U.S.

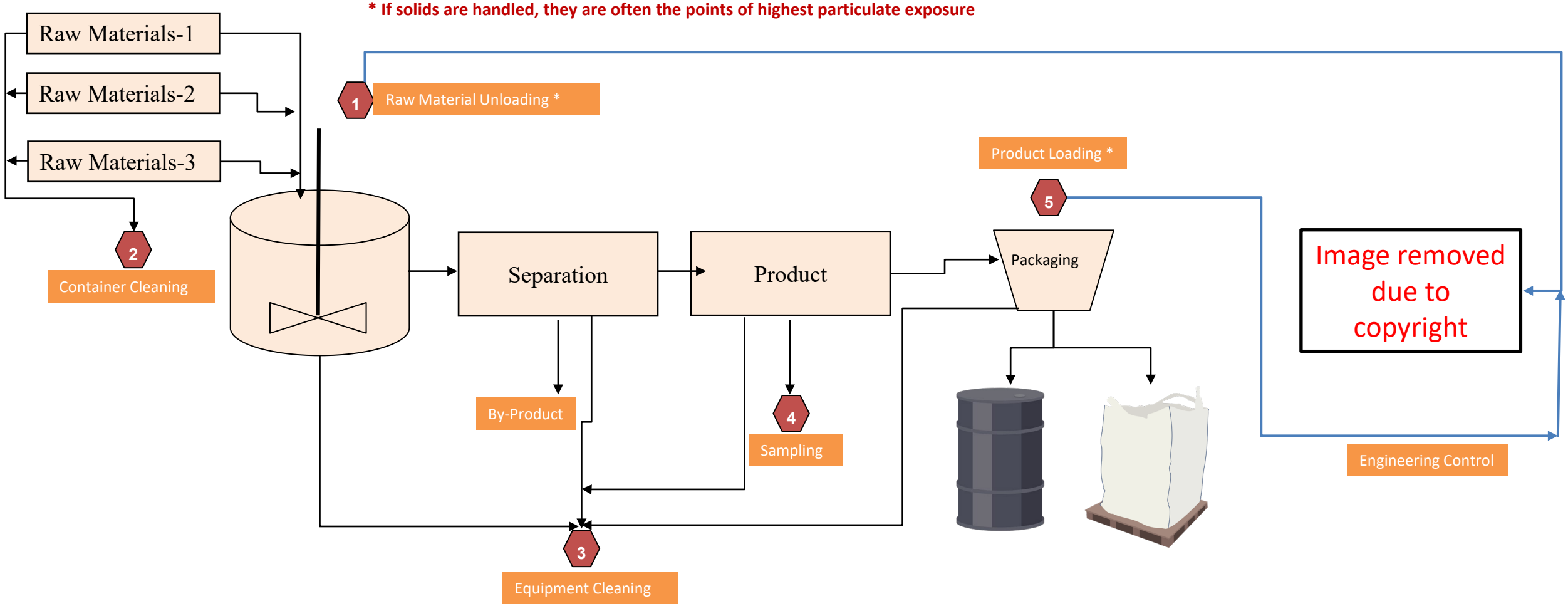
2. **Construct "Exposure Scenarios"**
   a. Consider physical form of NCS at each lifecycle stage and p-chem properties of NCS
   b. Review the process description and relevant Generic Scenario (GS) /Emission Scenario Document (ESD) to understand potential release and exposure points
   c. Identify exposure routes and pathways

Example New Chemical Lifecycle

Lifecycle Stage	Assessed Operation	Applicable GS or ESD
Manufacture of pigment	Manufacture of new chemical substance (pigment)	N/A
Processing: Production of Pigment and Ink Formulation	Formulation of coating	N/A
Use 1: Application of Printing Inks	Use of formulated pigment product in commercial printing (e.g., newspaper)	2001 Printing Inks GS
Use 2: Use of Pigment in Extruded Plastic	Use of formulated pigment in plastic production	2004 Plastic Processing GS

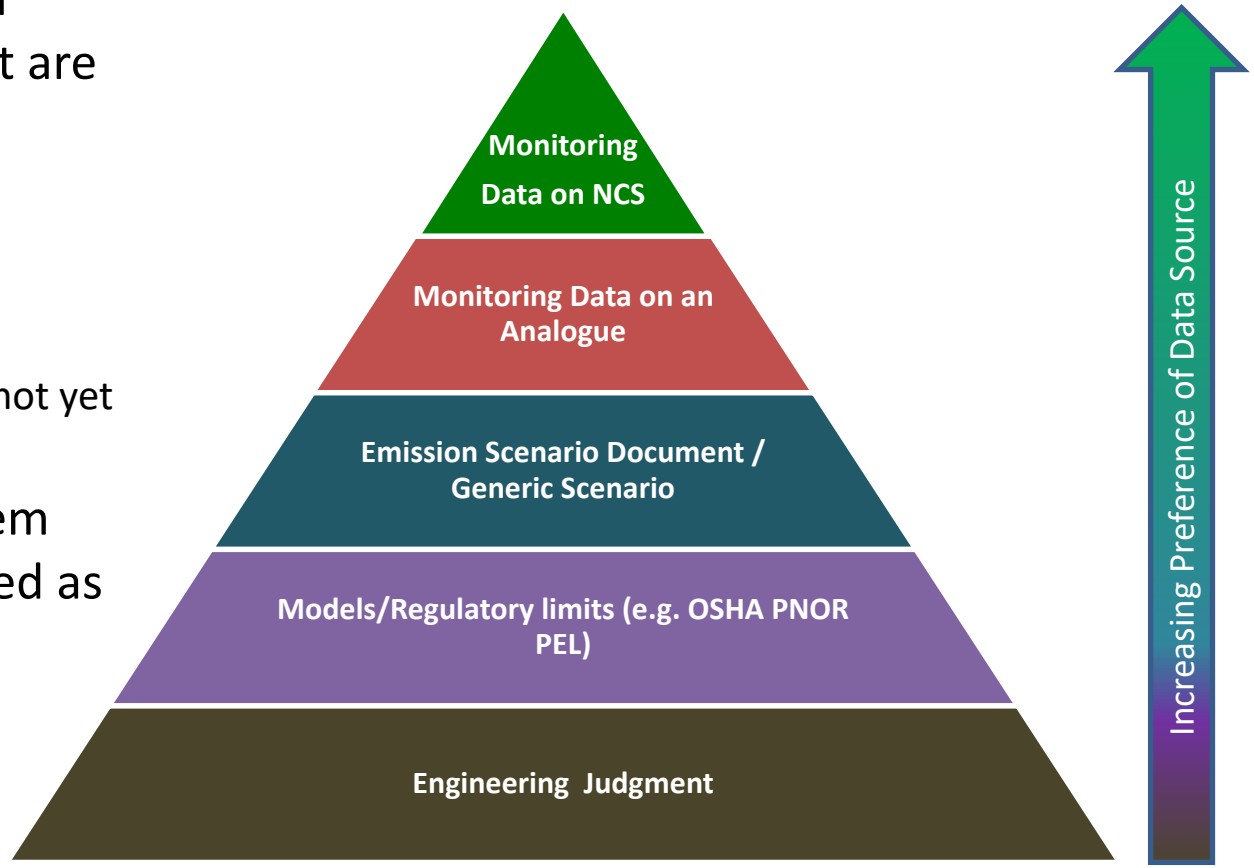
Occupational Exposure Assessment

*** If solids are handled, they are often the points of highest particulate exposure**

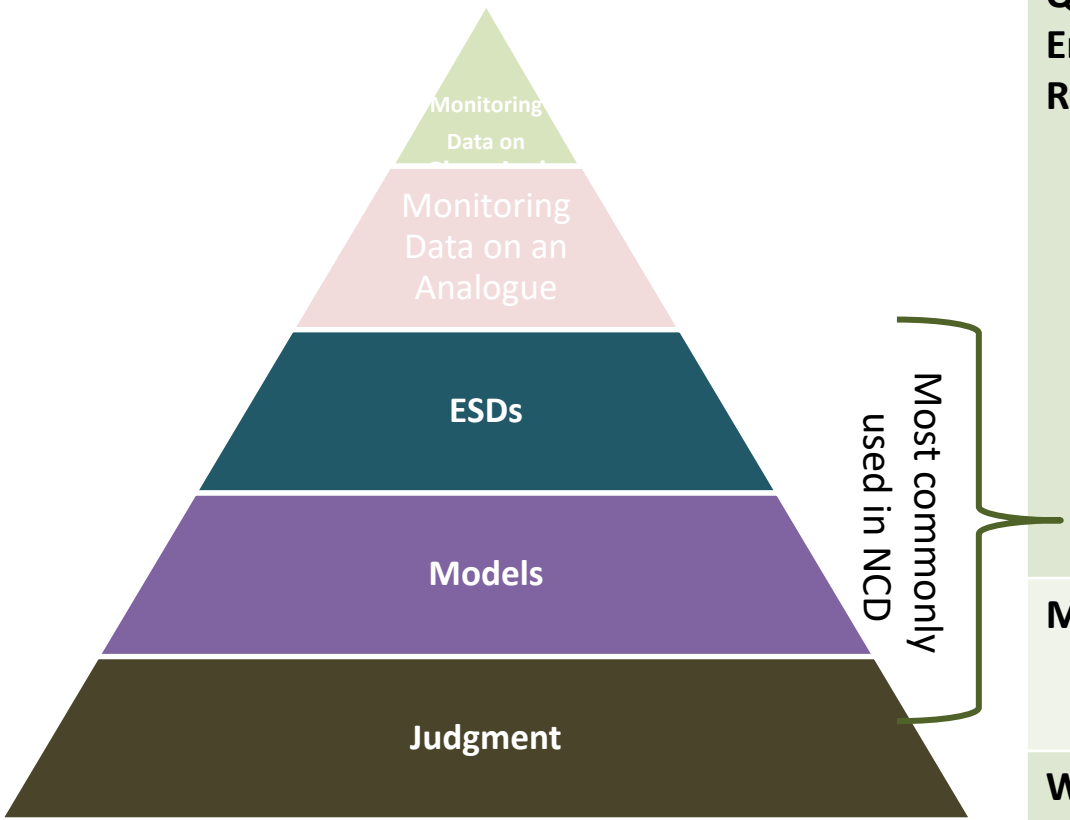


Occupational Exposure Assessment

- **Data Hierarchy:**
  - Highest tiered data is measured data (i.e., personal breathing zone monitoring) specific to the NCS that are collected in a way that would be *representative* of actual, high-end worker exposure
  - This is often not achievable for new chemicals
    - Not yet manufactured in the U.S.
    - Facility to manufacture, process, or use the chemical may not yet exist
  - Monitoring data for an analogue with similar p-chem properties and exposure characteristics may be used as surrogate



Critical Data, Defaults and Assumptions



	Critical Information & Data	Defaults and Assumptions
Quantity of Environmental Release	**Tier 1:** Measured or estimated release quantity with basis **Tier 2:** 1. Production volume 2. Physical form and concentration 3. Batch size or throughput 4. Operation days/yr 5. Process description 6. Number of site(s) 7. Identity of the site with details of process and waste handling practices	Parameters are set to be protective for environment and human health
Media of Release	Specific media of release	All potential media unless a GS/ESD/model is available for the scenario
Worker Exposure	Concentration of NCS exposed per activity Duration of exposure Engineering control	Highest concentration of the process ≤ 8 hr/day (typically) No engineering control

Solid / Dust Issues

General Context

- Limited OPPT models available to assess worker inhalation exposure to airborne dusts:
  - EPA/OPPT Small Volume Solids Handling Inhalation Model
  - OSHA Total Particulates Not Otherwise Regulated (PNOR) Permissible Exposure Limit (PEL)-Limiting Model
  - OSHA Respirable PNOR PEL-Limiting Models
  - OSHA PEL-Limiting Model for Substance-Specific Particulates

Existing Inhalation Exposure Models

- EPA/OPPT Small Volume Solids Handling Inhalation Model
  - Applicable for handling 'small volume' (<54 kg/worker-shift) of solid/powdered material (see basis in ChemSTEER User Guide)
  - Scooping, weighing, and pouring activities
  - Typical and worst-case exposure value derived from a dye weighing study

Existing Models (Continued)

- OSHA Total and Respirable PNOR PEL-Limiting Model(s)
  - Exposure concentration based on OSHA PEL for Particulate, Not Otherwise Regulated (PNOR)
    - 15 mg/m^3 as 8-hour time weighted average (TWA) for total particulates
    - 5 mg/m^3 as 8-hour TWA for respirable particulates
  - Adjusted for weight fraction of NCS in particulate
  - Assumption that industries are required to comply with OSHA permissible exposure limits
- Other exposure models based on OSHA PEL for specific substances (e.g., metals)

Challenges

- Existing models and approaches are very conservative and not scenario- or industry-specific
- Limited ways to account for exposure reduction resulting from engineering control (EC) without measured data on EC effectiveness
- Lack of method to correlate air release (release quantity in kg/day) with worker exposure concentration (mg/m3)
- PNOR PELs are intended for nuisance / inert dust (mineral, inorganic, or organic)

Case Study

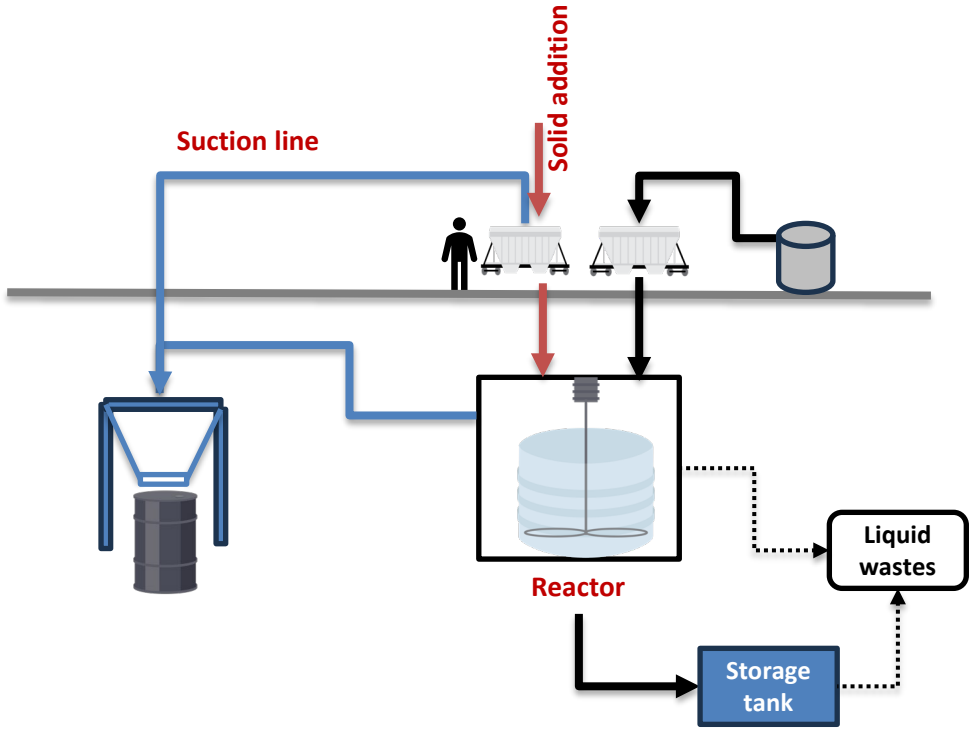
Image removed due to copyright

Where Engineering Controls *separates the worker from the chemical*, (*e.g.*, permanent enclosures, glove boxes, closed system transfer) EPA can determine that exposure is mitigated / negligible.

Case Study (continued)

EC can provide different degrees of effectiveness, depending on factors such as: EC position/design; degree of containment; air flow; work position; how the equipment is installed, operated, and maintained.

Case Study (continued)



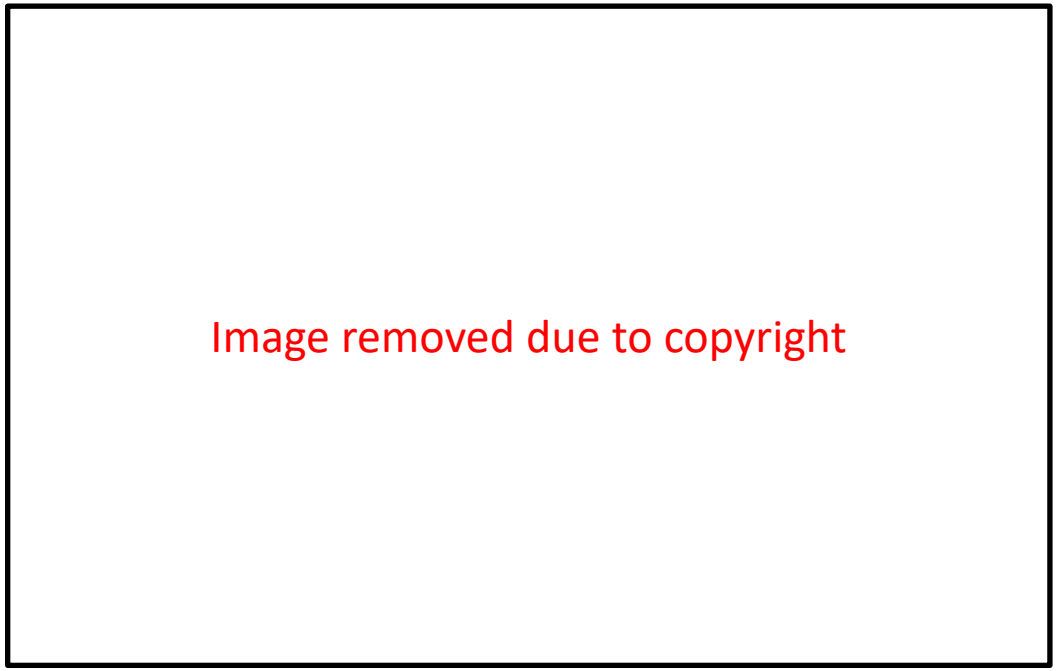
Detailed diagrams and pictures are often helpful for EPA to understand the specific condition of use, worker activity, and exposure scenario

Images removed due to copyright

Case Study (continued)

EPA does not have default values to determine the minimum efficiency for every type of control.

There are additional challenges in correlating effectiveness of EC with actual exposure reduction for workers.



Data and Modeling Needs

- Models that estimate inhalation exposure to solids/dusts under different scenarios/conditions of use
- Exposure data that can serve as surrogate for specific scenarios
- Effectiveness data for different type of engineering controls (measured)
- Studies that correlate EC effectiveness with reduction in exposure concentrations
- Methods to predict exposure concentration using p-chem properties of substance and ventilation parameters

Questions?