Considerations for Aerosol Risk Assessment

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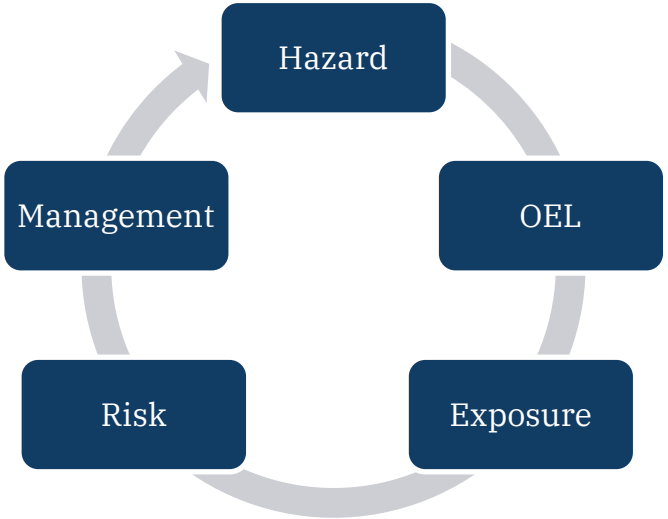
Objective

- Work together on a list of key considerations for addressing aerosols in the risk evaluations

- Work toward a methods guide to ensure consistency in addressing considerations across chemicals using the best available science

Aerosol Characteristics Impact all Aspects of RA/RM

- Mode of action and nature of effects
- Determination of the point of departure and health benchmarks
- Sampling approach and generalizability of data
- Interpretation of the risk characterization (e.g., MOE)
- Assessment of exposure controls



Aerosol Characteristics and Why They Matter

- **Particle Chemistry**
  - Molecular composition – analytical method determination, biological mode of action
  - Reactivity – potential for direct respiratory effects and tissue interactions
  - Solubility – respiratory tract clearance and potential for systemic effects
- **Particle Form (shape and physical state)**
  - Potential for enhanced surface reactivity – surface area
  - Aerodynamic characteristics – fiber vs spherical particle
  - Phase changes with duration – evaporation of liquid aerosols
- **Particle Size Distribution**
  - MMAD and GSD – impact on near-field exposure and respiratory deposition modeling
  - Considerations for nanoscale particles – extrapolating effect data

Some Considerations from Recent Risk Evaluations

- Analytical detection of specific fibers at needed LOD in mixed fiber matrix
  - Required LOQ might not be achievable
- Sampling for a very low ECEL in a high-dust work environment
  - Potential for collection filter particle overload
- In most cases sampling method (total aerosol)
  - May not align with inhalable fraction, requiring conversion
  - Many chemicals also have a separate benchmark for respirable fraction

Some Considerations from Recent Risk Evaluations

- Emission sources and control assumptions
  - Empirical data often high variability
  - Performance based on design characteristics and use – achieve adequate capture velocity?
- Sampling for phase changes
  - Semi-volatiles may need additional method development
- Modeling can be done but added complexity
  - MMAD changes with time – particle condensation, agglomeration, evaporation
  - Settling characteristics affected by microenvironment
  - No optimum off-the-shelf model – benefit from additional research!

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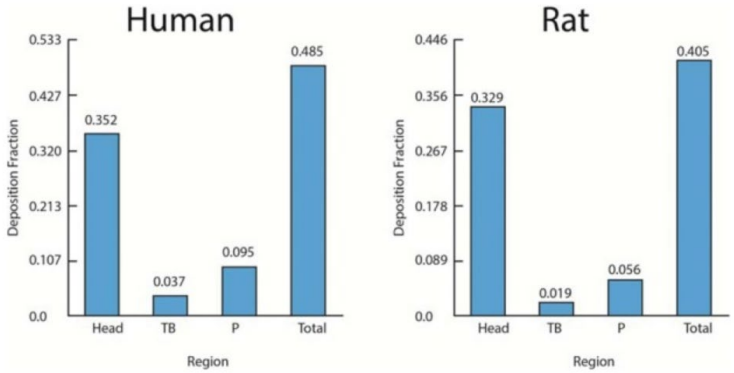
Some Considerations from Recent Risk Evaluations

- Assessing the basis and consideration of particle overload in the lungs
  - Determines need for both inhalable and respirable sampling
- Uncertainties in identifying appropriate read across compound for data poor particulates
  - Impacts selected ECEL (or POD)
- Dose response for semi-volatiles
  - What is the most appropriate dose metric?
  - Translating toxicology from one form to another form
    - Impact of local dose density vs total mass

Particle Lung Dosimetry Modeling

- Standardized application of inhalation dosimetry for estimating human equivalent POD
  - Modeling approach and inputs
  - EPA Multi-path Particle Dosimetry (MPPD) Model?
  - Use of workplace exertion and particle characteristics in MPPD?



Kuempel, E. D., Sweeney, L. M., Morris, J. B., & Jarabek, A. M. (2015). Advances in Inhalation Dosimetry Models and Methods for Occupational Risk Assessment and Exposure Limit Derivation. Journal of Occupational and Environmental Hygiene, 12(sup1), S18–S40. https://doi.org/10.1080/15459624.2015.1060328

› Thank You and Please Share Ideas or Thoughts

- Other key issues you have identified
- Key guidance's or resources to harmonize methods