

Update to 2006 Children's Health Risk Assessment Framework

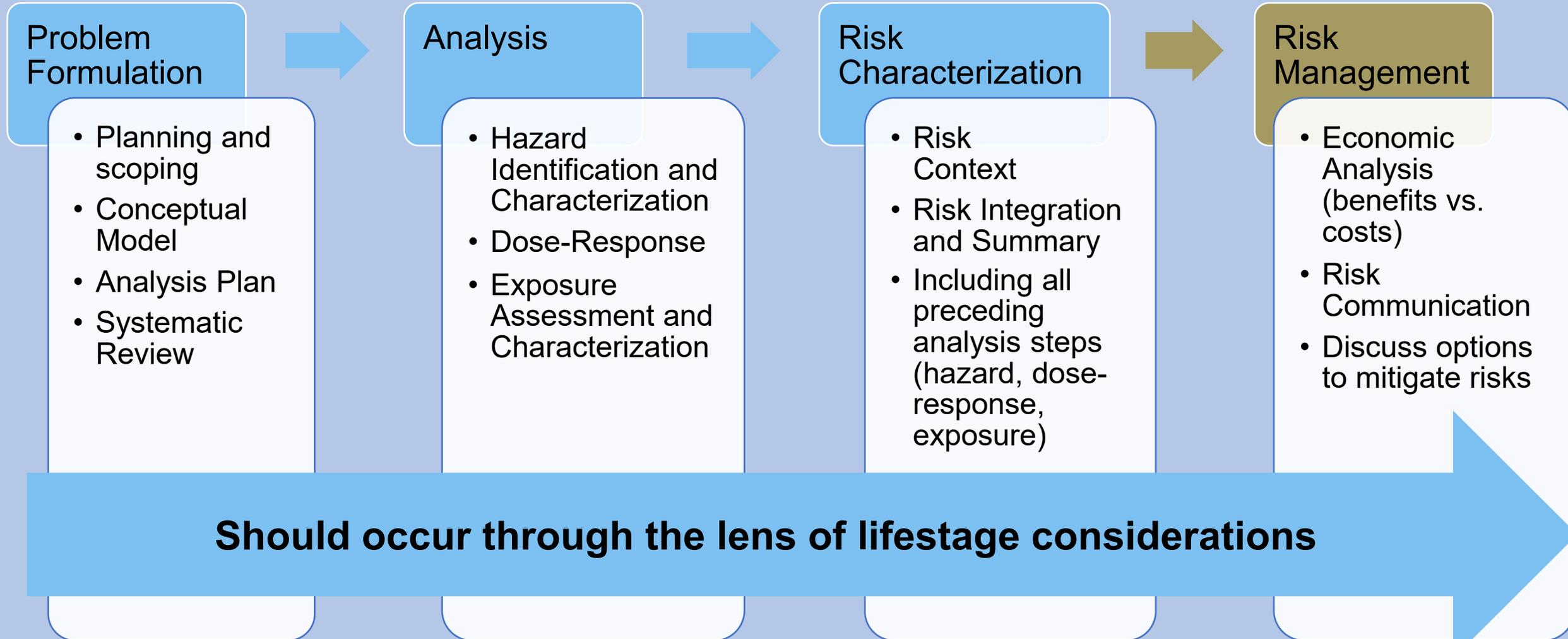
Greg Miller

Senior Science Policy Advisor, OCHP

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Risk Assessment Process Overview



What is a Lifestage?

- EPA defines lifestage as a distinguishable time frame in an individual's life characterized by unique and relatively stable physiology and behaviors*
- Lifestages are distinct from subpopulations
 - Lifestages: All humans pass through “lifestages” such as infant, toddler, child, and adolescent.
 - Subpopulation: refers to a relatively fixed portion of the population, such as groups based on ethnicity or genetic polymorphism.

What is a Lifestage Approach to Risk Assessment?

- Considers the relevant periods of exposure in developmental lifestages and subsequent outcomes that may not be expressed until later lifestages (i.e., latency)
- Explicitly considers existing data -- as well as data gaps -- for both exposure and health outcomes at various lifestages

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A Framework for Assessing Health Risk of Environmental Exposures to Children



A Framework for Assessing Health Risk of Environmental Exposures to Children



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CH 2006 Framework Authors

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- ❖ Carole Kimmel, ORD*
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- ❖ Hisham El-Masri, ORD
- ❖ Jacqueline Moya, ORD*
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* retired

Objectives of 2006 Children's Health Risk Framework

- To provide an overarching framework* for a more complete assessment of health risks to children
 - consistent with EPA's then-current risk assessment approaches
- To provide a single resource for information on children's health risk assessment
- To bring a focus to lifestage-specific issues in every risk assessment

*The Framework is not a guidance/guideline document but rather serves as an informational reference for EPA risk assessors

Children's Health Risk Framework Update

OBJECTIVE:

- To update the 2006 Children's Health Risk Framework to incorporate new science and approaches in risk assessment.

WHY:

- Reflect EPA Children's Health Policy (2021)
 - Addition of reproductive and developmental effects
 - Definition of "children" as up to 21 years of age
 - Additional focus on latent effects throughout the lifespan and future generations from early life exposure
 - Explanation of expectation of inclusion into EPA risk assessments, provided relevant data are available
- Need to incorporate new science and risk assessment approaches published since 2006 (see slide 9)

Children's Health Risk Framework Update

APPROACH:

- Framework will be updated incrementally on a chapter-by-chapter basis.
 - First phase of review will cover the 2006 Introduction and Lifestage Specific Problem Formulation.
 - Future rounds of review will cover the remainder of the document.
- Seeking reviewers with expertise in risk assessment methodology.
 - Familiarity with existing EPA guidance documents is a plus.
- Primary intention is to seek CHPAC input on figure development to highlight children's health risks at various stages of the risk assessment development process.
- Potential need to also seek CHPAC input on targeted Framework issues.

Risk Assessment Guidance since 2006

- *Recommended Use of Body Weight 3/4 as the Default Method in Derivation of the Oral Reference Dose.* Risk Assessment Forum, U.S. Environmental Protection Agency, 2006.
- *Guidance for Applying Quantitative Data to Develop Data-Derived Extrapolation Factors for Interspecies and Intraspecies Extrapolation.* U.S. Environmental Protection Agency, 2011.
- Child-Specific Exposure Scenarios Examples. U.S. Environmental Protection Agency, 2014.
- *Exposure Factors Handbook.* U.S. Environmental Agency. 2011. (with ongoing updates)
- *Advances In Inhalation Gas Dosimetry For Derivation of A Reference Concentration (RfC) and Use In Risk Assessment.* U.S. Environmental Protection Agency, 2012.
- *Benchmark Dose Technical Guidance.* Risk Assessment Forum, U.S. Environmental Protection Agency, 2012.
- *Framework for Human Health Risk Assessment to Inform Decision Making.* Risk Assessment Forum, U.S. Environmental Protection Agency, 2014
- *ORD Staff Handbook for Developing IRIS Assessments.* Center for Public Health and Environmental Assessment, U.S. Environmental Protection Agency, 2022.
- U.S. EPA. Policy on Children's Health. October 2021.

Outputs of a Lifestage-Specific Approach

- Explicit statement of where extrapolations are made across lifestages (e.g., adult to child).
- Explicit statement of what we *do* know about susceptibility (e.g., certainty).
- Explicit statement of what we *do not* know about susceptibility (e.g., data gaps and uncertainty).

Benefits of Using the Lifestage Approach

- More complete evaluation of the potential for vulnerability at different life stages
- Encourages evaluation of potential for toxicity at all developmental life stages – including evaluation of data gaps
- Addresses integration of toxicity and exposure information across life stages
- Focuses on understanding underlying biological events and critical developmental periods (MOA)
- Disclaimers:
 - Lack of data for different life stages is not meant to imply an obligatory use of uncertainty factors
 - Does not explicitly consider cumulative risk although covers relevant concepts
 - The Children's Health Risk Framework is not a guidance/guideline document but rather serves as an informational reference for EPA risk assessors.

Topics for CHPAC Discussion

- How many CHPAC members are familiar with the 2006 Children's Health Risk Framework?
 - Have you used it in your work?
 - Have you encountered any limitations of the document?
- We are looking for ways to better adapt the document for use in an online environment. Do you have any ideas that would make this document more accessible to users?
 - Note, we intend to change the layout of the report.
- Do you have thoughts on whether this Framework is useful to the public? How might we make it more useful?
- Are you aware of any graphical images or figures that you think would be useful in conveying aspects of the lifestage approach to the risk assessment process?

Thank you!

For more information, please contact:
EPA Office of Children's Health Protection
[epa.gov/children](https://www.epa.gov/children)