



A **BlueRidge** Life Sciences Company

# Development of an Integrated Human and Environmental Health Safety Assessment Framework

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1) ToxStrategies

2) Beiersdorf AG

3) International Collaboration on Cosmetics Safety (ICCS)

# *Human health and environmental risk assessment have traditionally been siloed*

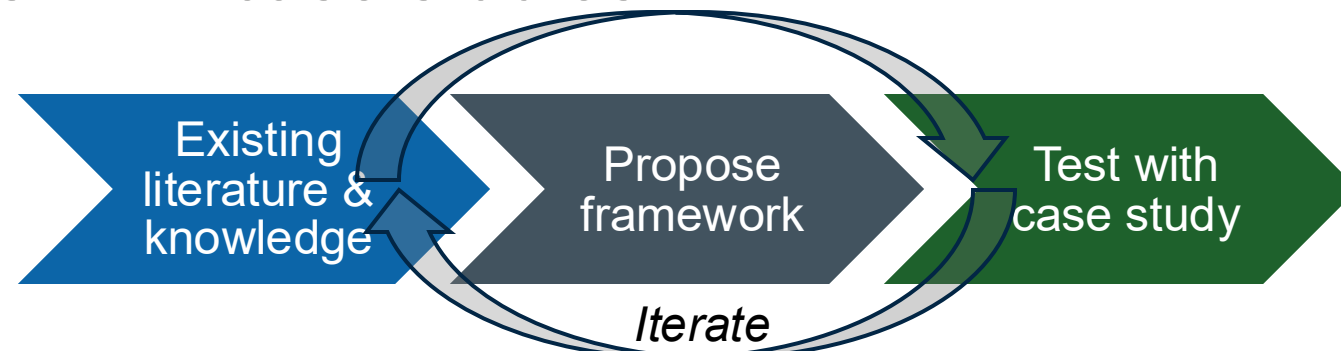
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- Human health and the health of the environment are intrinsically connected.
- With advances in non-animal, mechanistically based methods, opportunities are available to consider more overlap between approaches.
- Pressure to take a more holistic view of chemical impacts (e.g., one substance, one assessment; safe and sustainable by design) is pushing ecological and human health toxicologists to consider integration

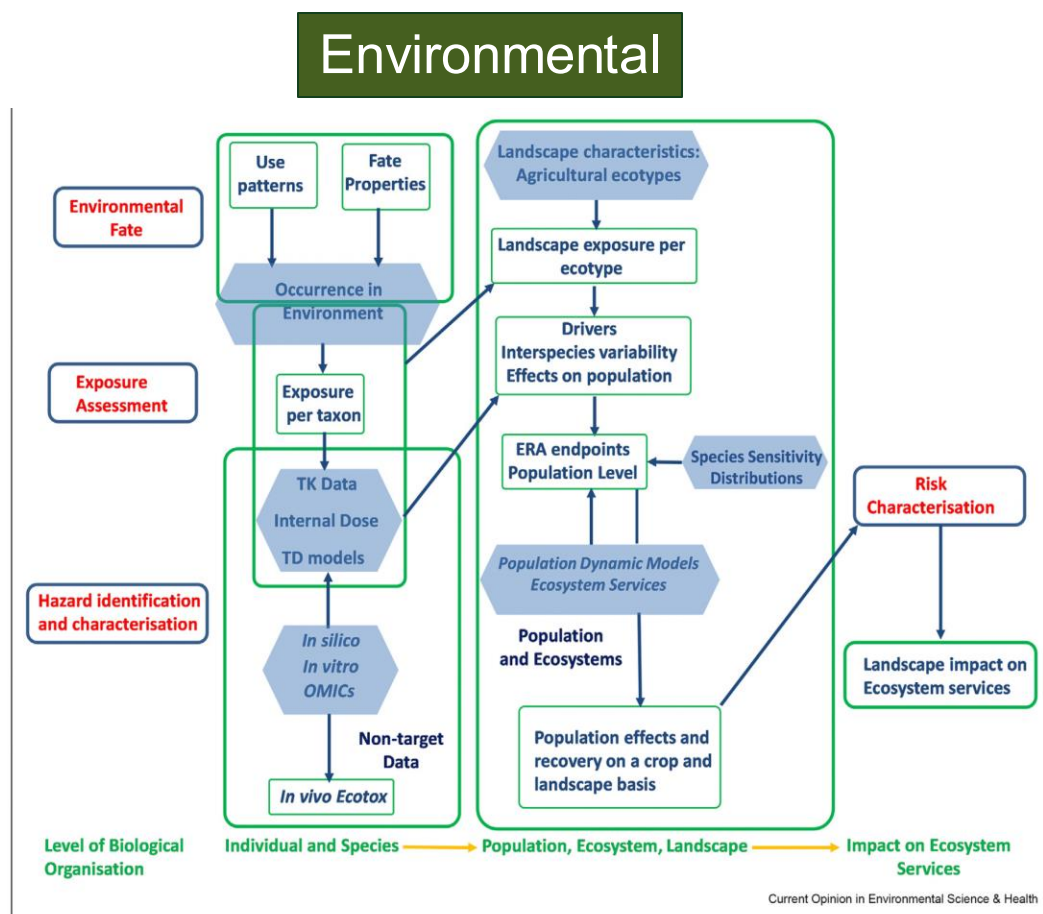
Objective: Develop an integrated human and environmental safety assessment framework and demonstrate framework performance with case studies using cosmetic ingredients

## Approach to develop an integrated framework

- Global collaboration by cosmetic safety assessors (human and ecological health experts) facilitated by the International Collaboration on Cosmetic Safety (ICCS).
  - Focus on non-animal methods
- Evaluate the current state of the science
  - *Are integrated frameworks available?*
  - *Where is the overlap or differences between human and environmental next generation risk assessment?*
- Build off existing literature and knowledge, propose framework, iterate and test with case studies.



# Frameworks available across disciplines



Systems-based approach for Environmental Risk Assessment highlighting the steps and role of NAM-based data and at different levels of biological organisation (modified from Astuto et al., 2022). Legend: TK: Toxicokinetics, TD: Toxicodynamics, -Standard Methods, -NAM-based methods.

Source: Di Nicola et al (2023). <https://doi.org/10.1016/j.coesh.2022.100416>

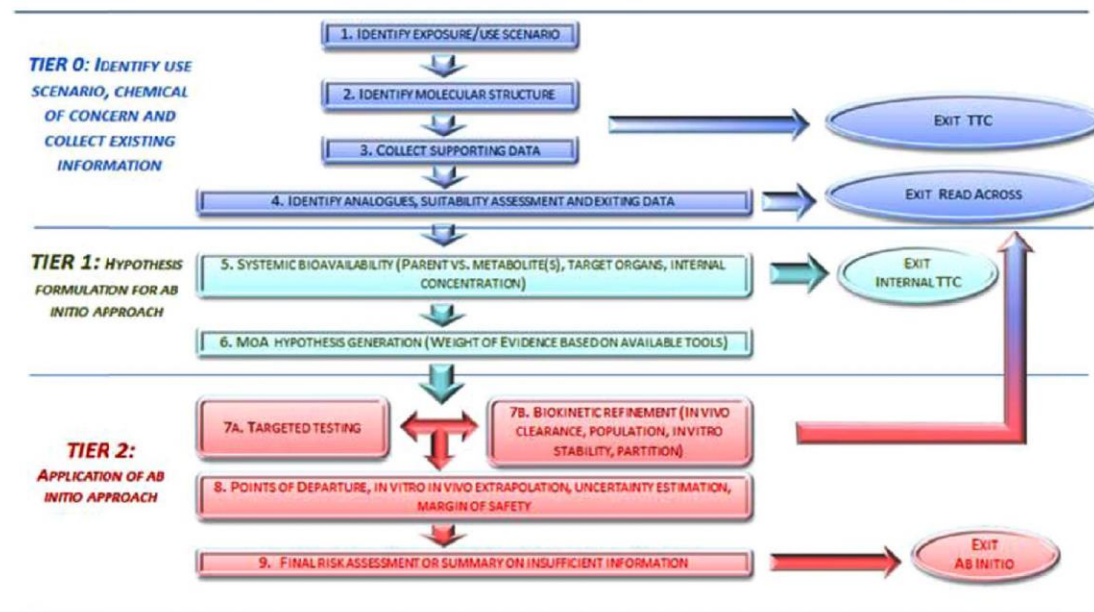


Fig. 1. Workflow for the safety assessment of chemicals without animal testing.

Source: Berggren et al (2017). <https://doi.org/10.1016/j.comtox.2017.10.001>

**Human Health**

# Early efforts to integrate human & ecological risk assessments - framework identified from 2003 publication

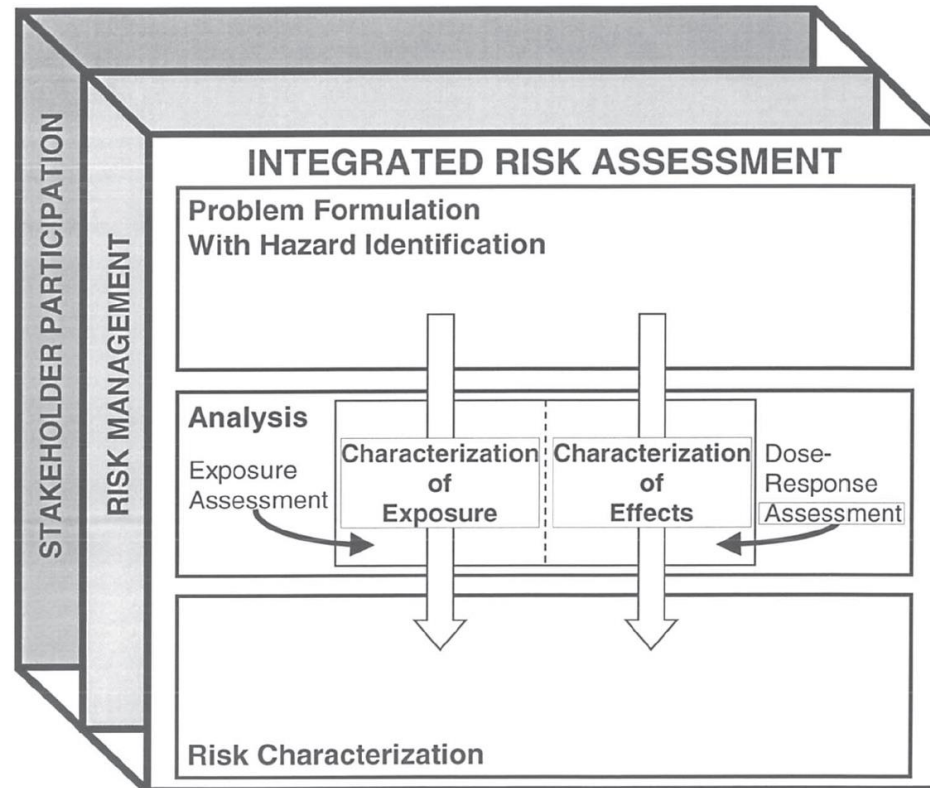


Figure 1. A framework for integrated human health and ecological risk assessment (modified from USEPA 1998). Risk assessors, risk managers, and stakeholders perform parallel activities that may interact at various stages.

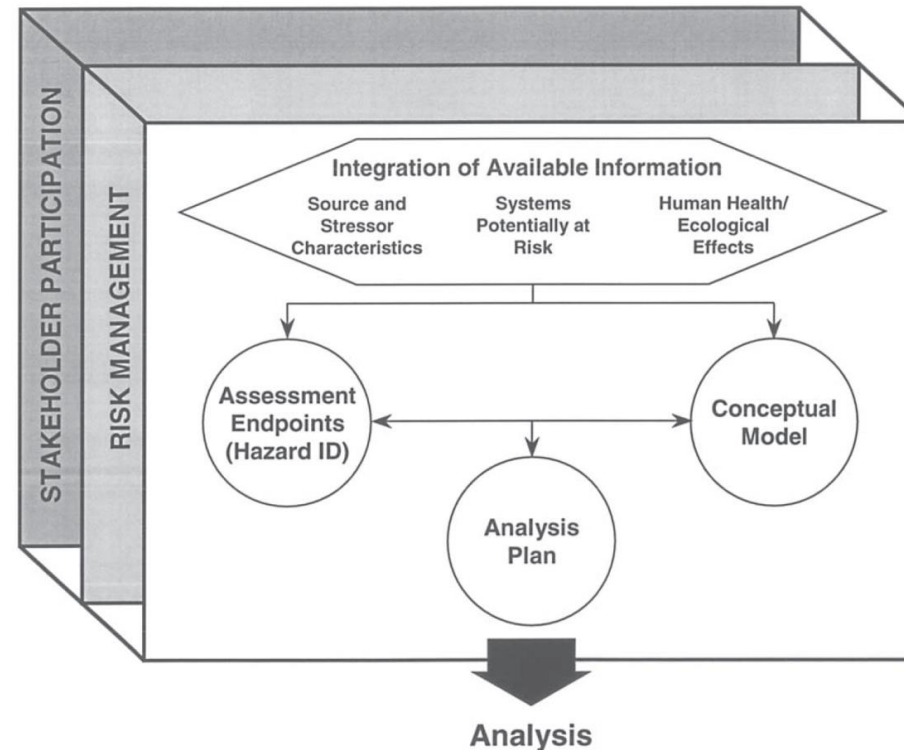


Figure 2. The problem formulation stage of an integrated risk assessment. Risk management and stakeholder activities are parallel and may interact with the problem formulation process to a greater or lesser extent depending on circumstances (modified from USEPA 1998).

Suter et al (2003). Framework for the Integration of Health and Ecological Risk Assessment. Human and Ecological Risk Assessment: An International Journal, 9(1), 281-301. <https://doi.org/10.1080/713609865>

## *The risk assessment paradigm is built for flexibility*

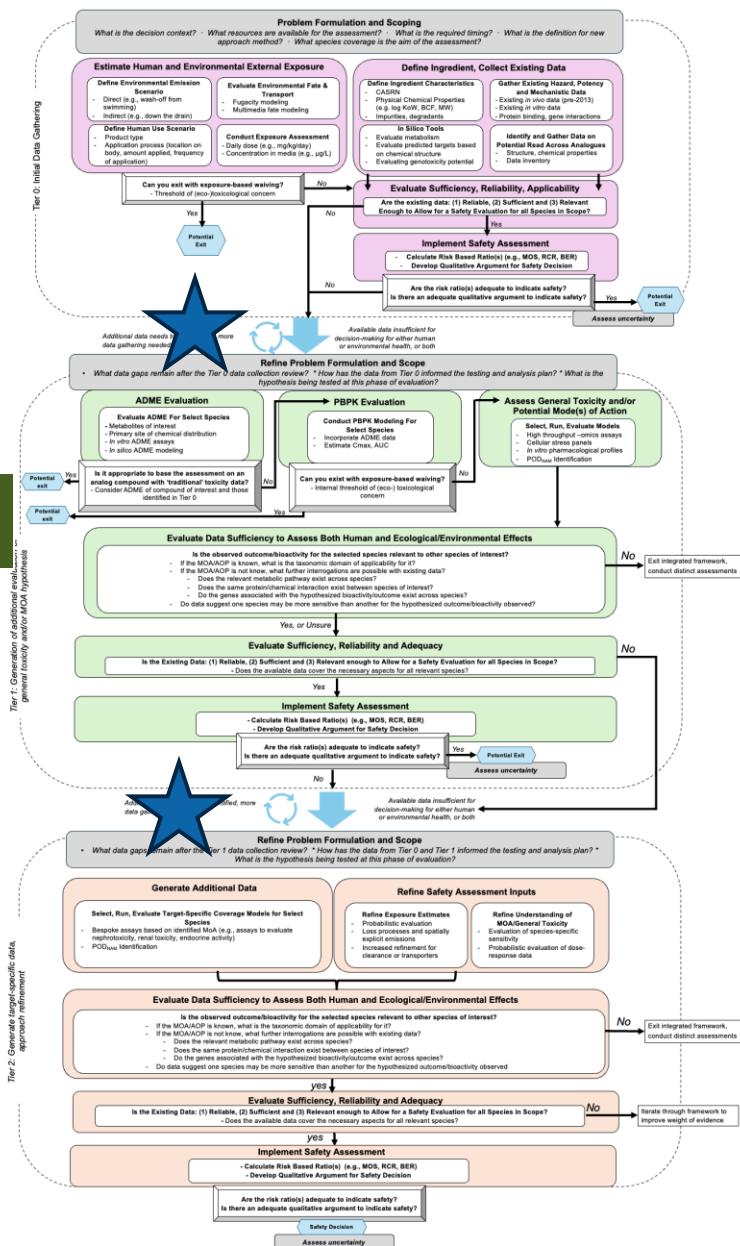
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- Processes are similar regardless of protection goal (human, environment, both)
- The backbone of an integrated framework is a well-developed problem formulation with an understanding of biological mechanisms

Following principles of NGRA, a tiered, iterative, exposure-led framework can be built that integrates human and environmental considerations



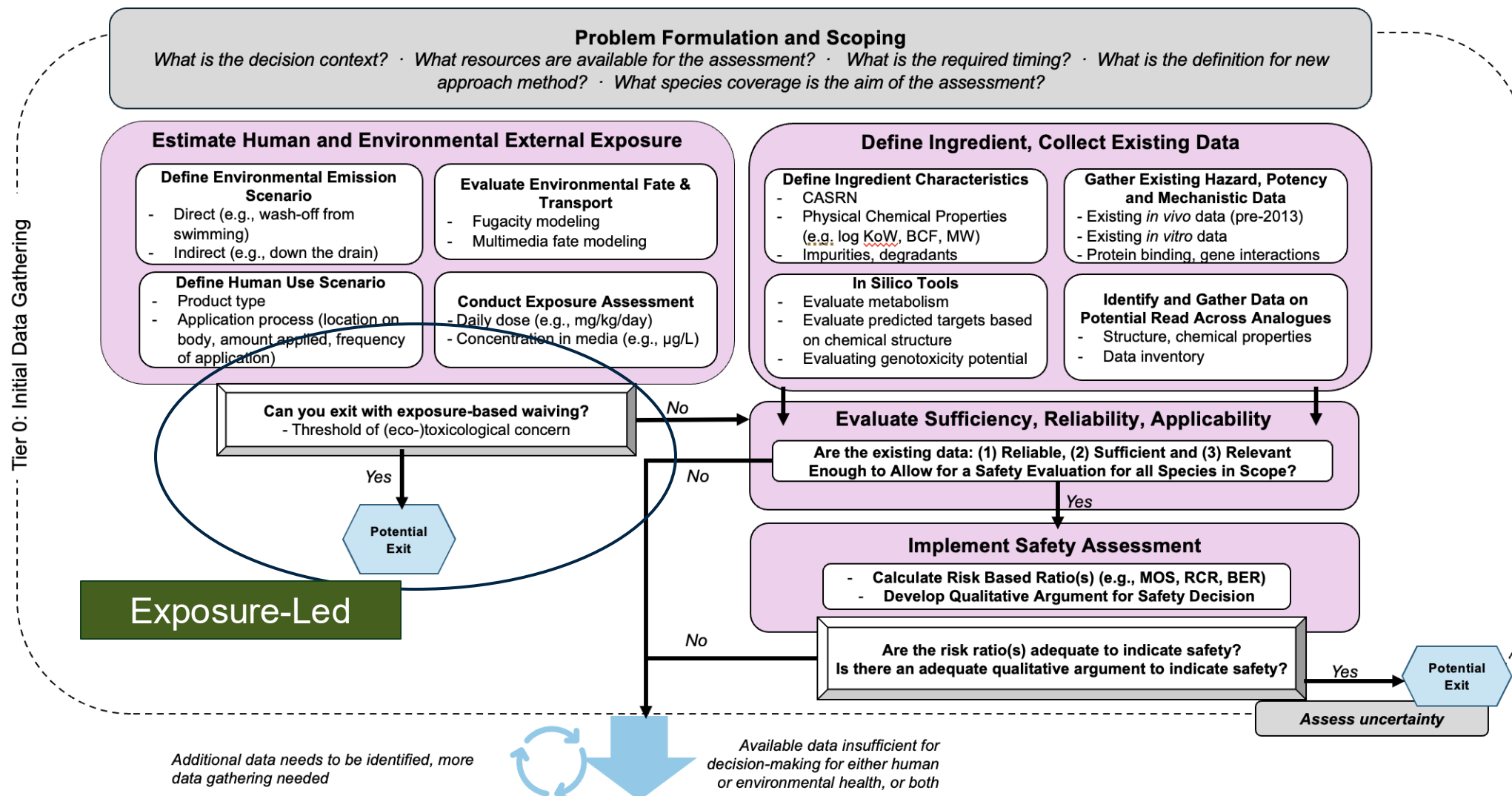
# Draft Detailed Integrated Framework Was Developed



Iterative

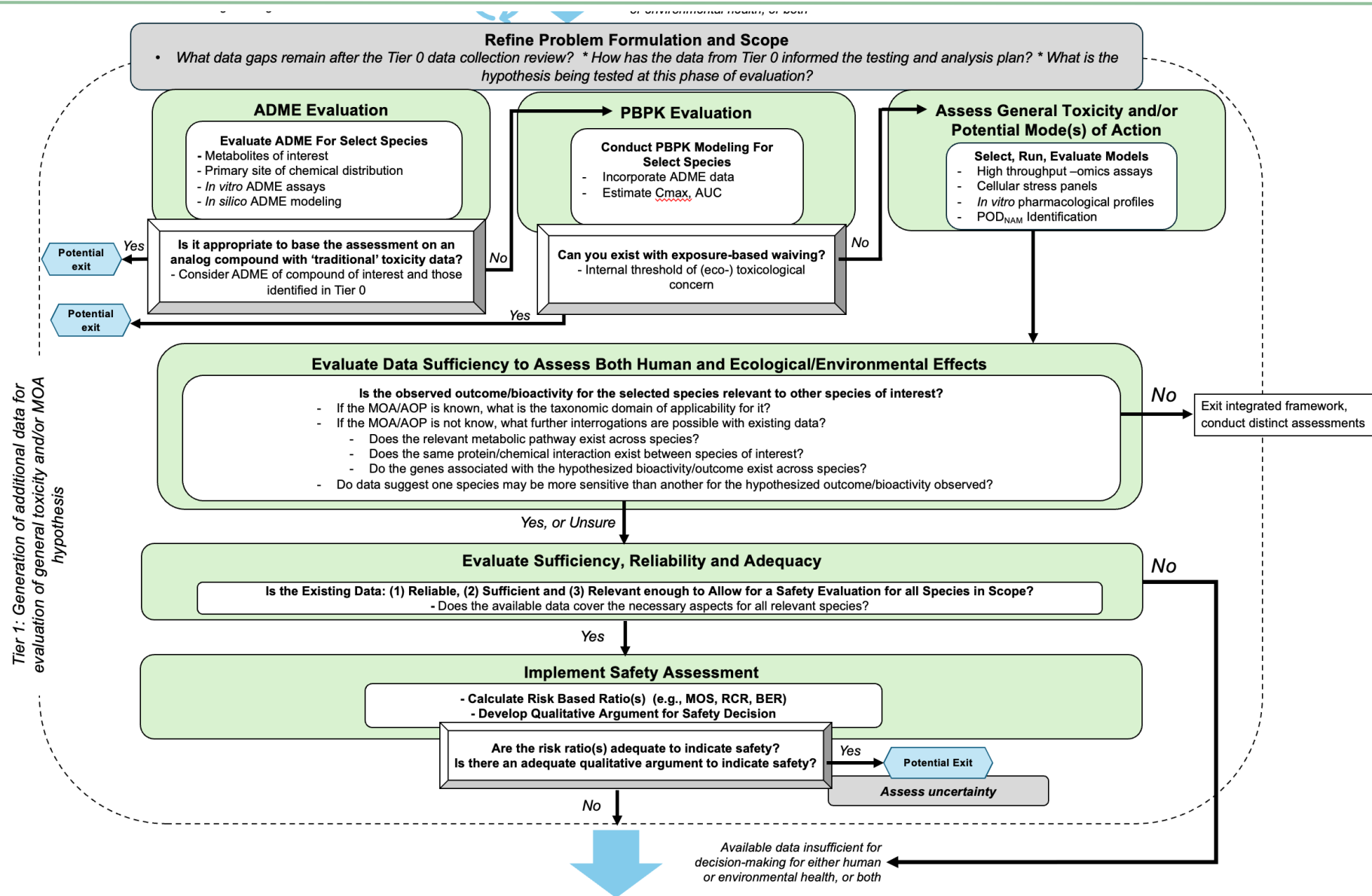
Tiered

# Tier 1: Problem Formulation, Exposure & Existing Data Assessment



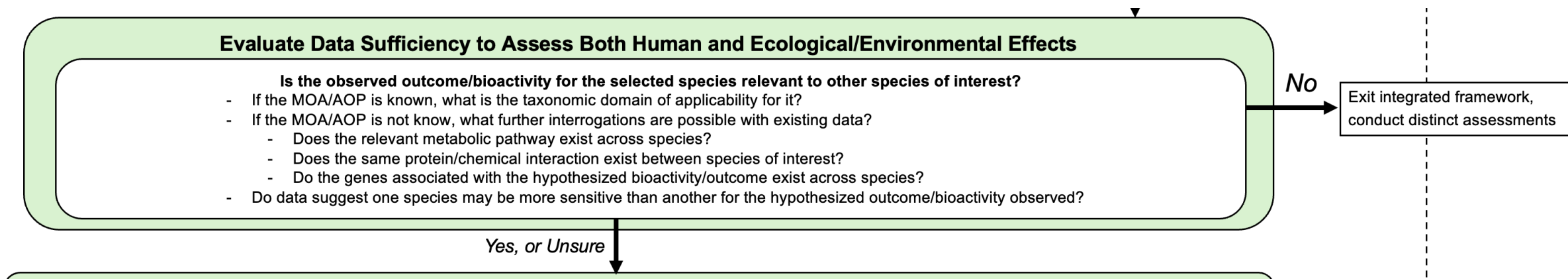


# Tier 2: Refine Problem Formulation, Refine Exposure, Develop Data. Assess Feasibility for Integration

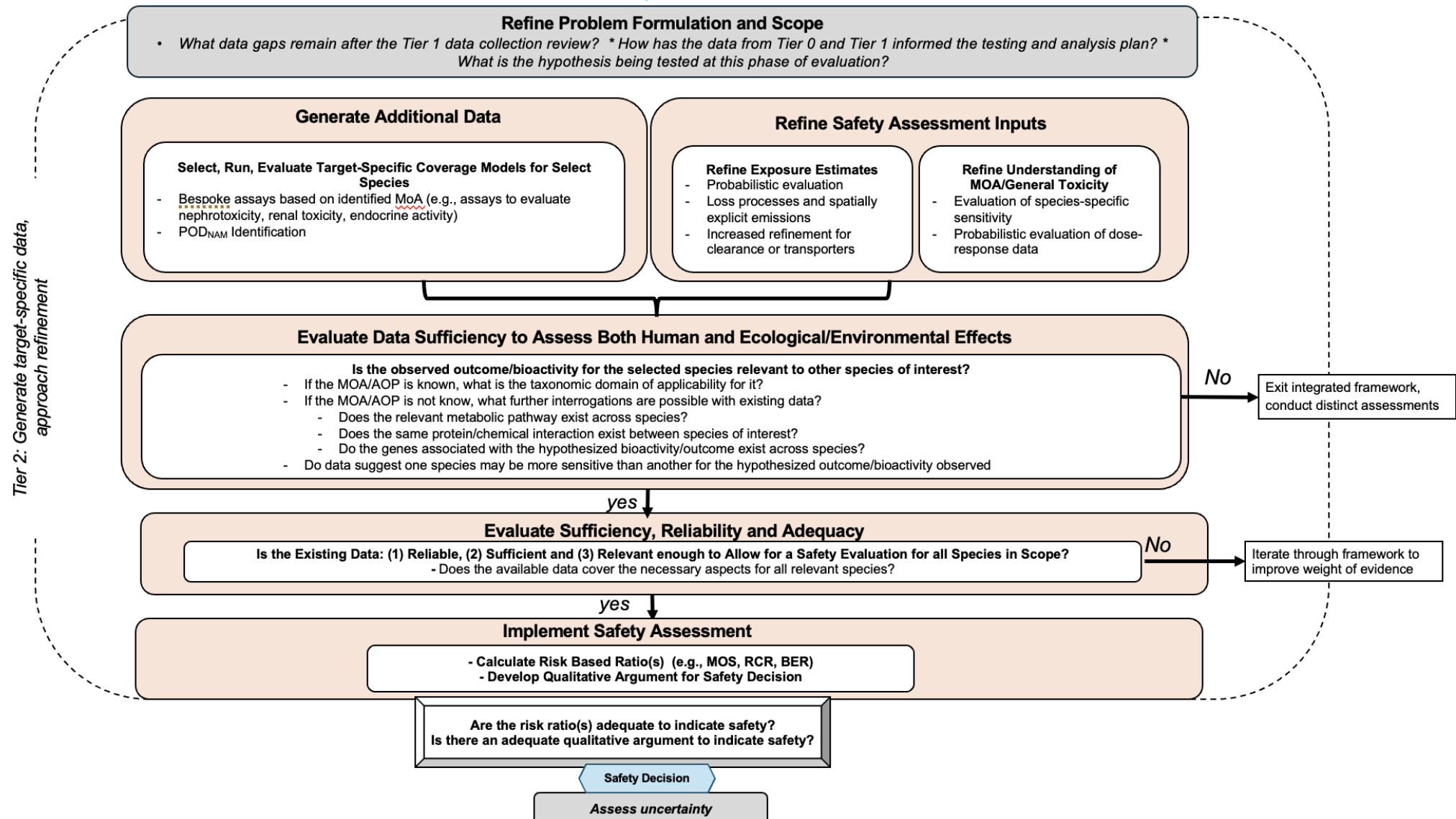


# Crux of the integrated framework is an understanding on MOA/AOP

Understanding MOA/AOP frameworks facilitates interoperability and integration of human and ecological effects data.



# Tier 3: Refine Problem Formulation, Generate Additional Data, Refine Exposure and Hazard, Assess Feasibility for Integration



## *A change in direction refocused framework specifically on next generation **environmental** risk assessment*

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- *Rationale:* Recognition that the environmental side of NGRA is less established and needs further development before full integration of disciplines.
- BUT! The integration remains.
- The previously shown framework will be simplified but still include the consideration of data traditionally used for human health risk assessment.
- Case study chemical selection is underway for subsequent demonstration of NGeRA framework process
- Data gathering for case study chemicals includes both environmental and human health evidence streams

## *Initial conclusions: Framework is flexible to accommodate any type of risk assessment and includes human and environmental evidence*

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- The project challenges the idea of continuing to work in silos between human health and environmental risk assessment
- Data and lessons learned can (and should!) be shared between disciplines for a more holistic consideration of chemical risk
- Results from the planned case studies forthcoming in the next year
- This will provide insights into more complete integration of disciplines
- Unilever case study (*next talk*) will demonstrate how they have begun the integration of the lines of evidence

# Questions?

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## Acknowledgements:

This project is being developed and steered by the  
**ICCS Next Generation Risk Assessment Case Study Workgroup**

