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A Framework to Evaluate Environmental Impact of Engineered Nanomaterials

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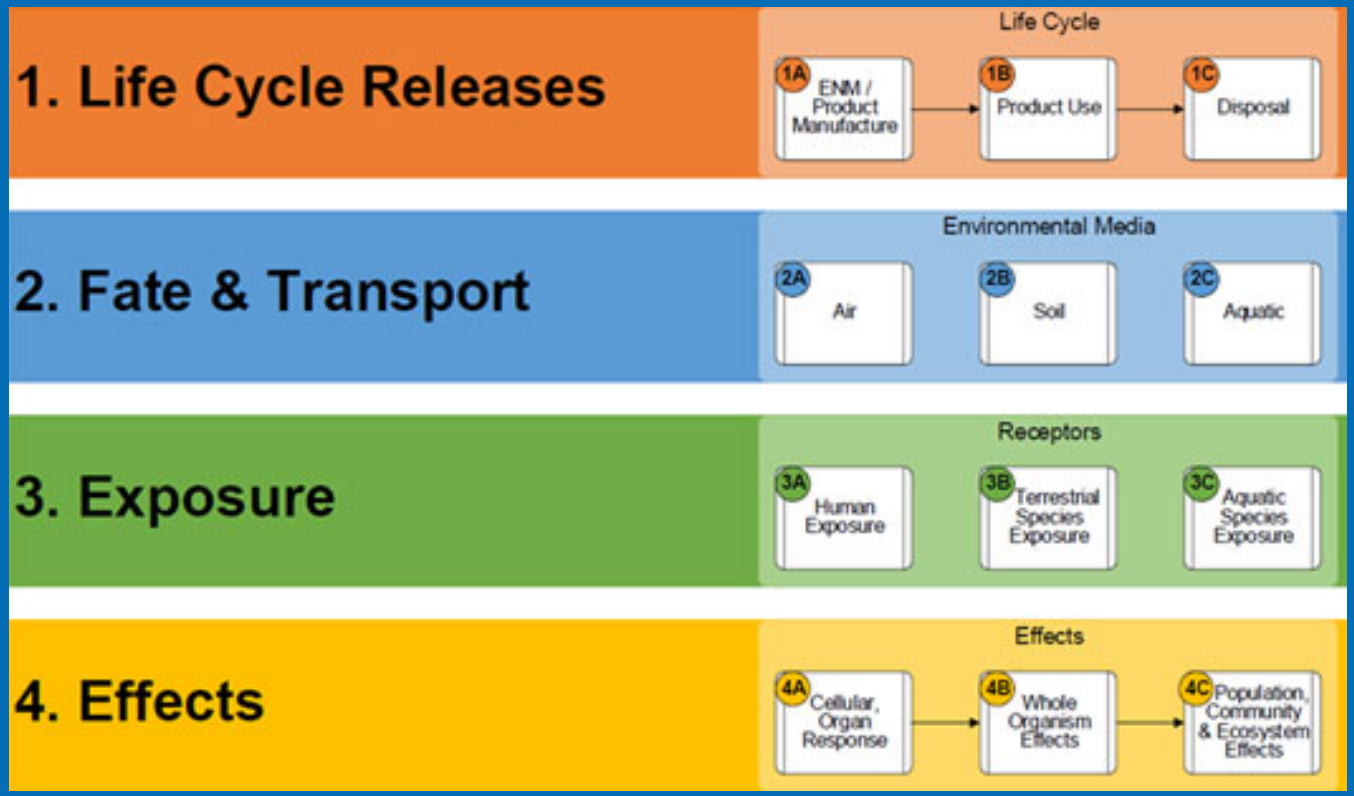

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What decisions do we need to make?

- **Narrow Sense**: EPA Registration of Nanomaterials
  - TSCA – Toxics Substances Control Act
    - Chemicals are considered as “new” or “existing” based on molecular identity – not particle size
    - Reauthorized in 2016 as Frank R. Lautenberg Chemical Safety for the 21st Century
      - Expanded testing authority and promoted alternative testing approaches
      - Did not change consideration of nanomaterials
  - FIFRA – Federal Insecticide Fungicide and Rodenticide Act
    - Chemicals are registered based on intended function as a biocide
    - Has greater authority than TSCA to require product testing for registration
- **Broad Sense:** Become predictive of environmental behavior of nanomaterials

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Transformative Science

- Toxicity Testing in the 21st Century: A Vision and a Strategy (NRC, 2007)
- Exposure Science in the 21st Century: A Vision and a Strategy (NRC, 2012)
- Growing number of ENM; can't afford to test one-by-one
- Need to become predictive:
  - Behavior of ENM depends complex interactions between chemical and physical properties and environmental and biological factors
  - Our approach:
    - Build a framework to help organize relevant information and identify key determining factors
    - Identify key factors and functional assays that will simplify assessments

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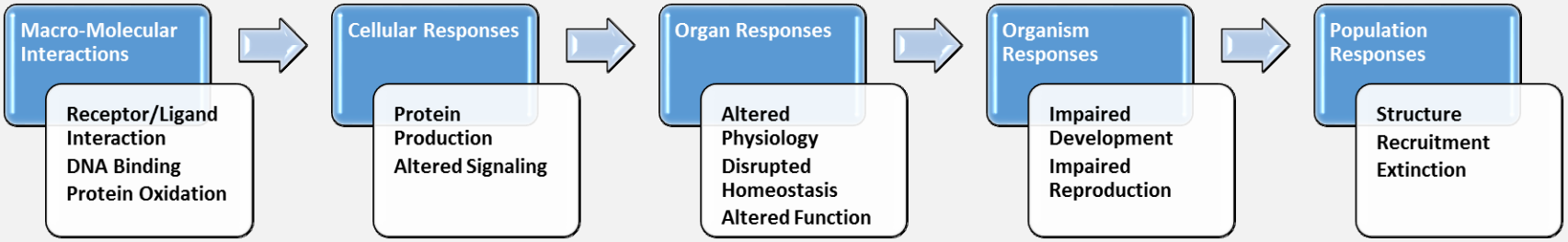
Aggregate Exposure Pathway (AEP)

Teeguarden, et al. (2016), Environ Sci Technol; doi:10.1021/acs.est.5b05311

Adverse Outcome Pathway (AOP)



Villeneuve, et al. Tox Sci., 2014, 142:312-320

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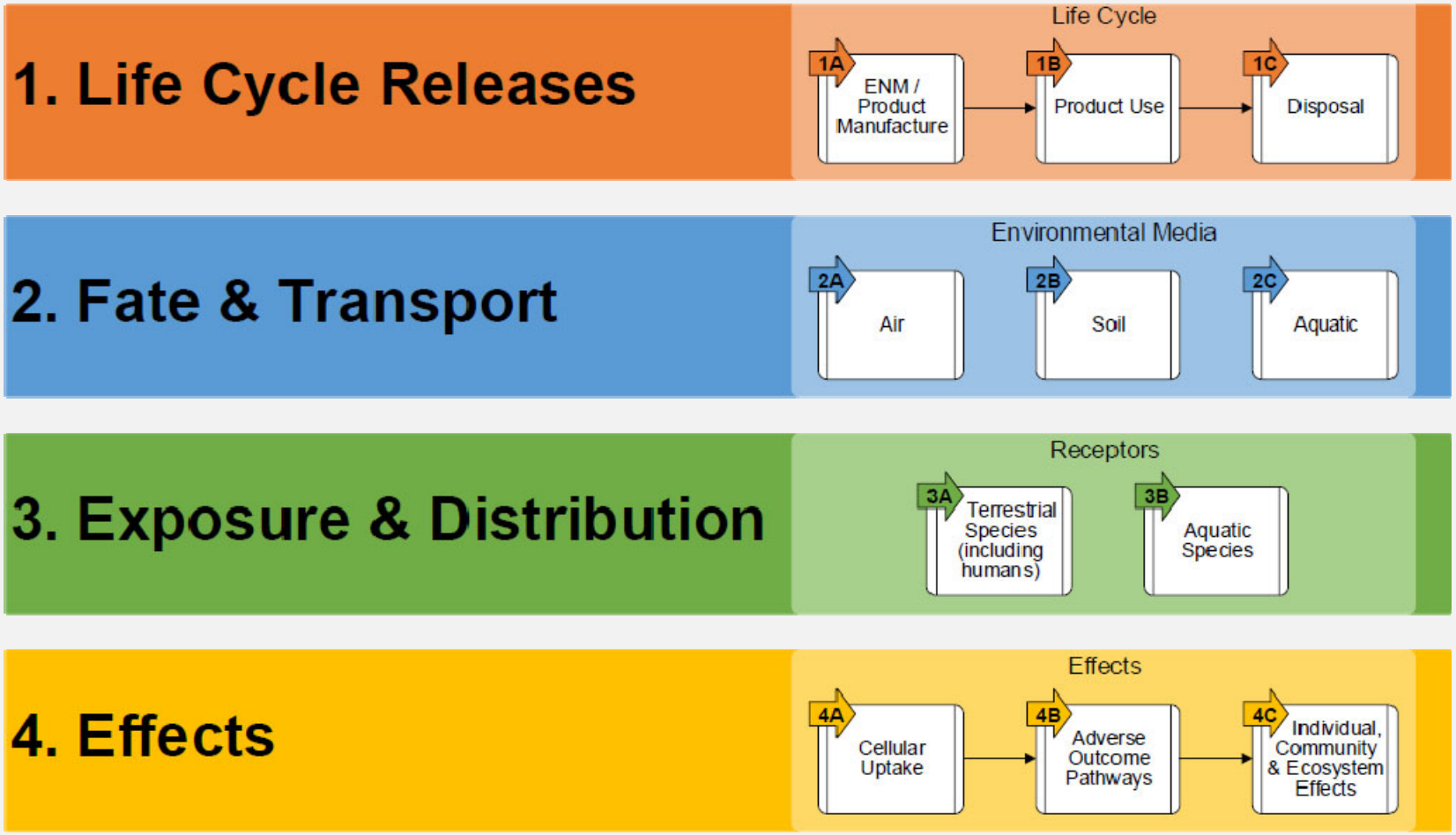
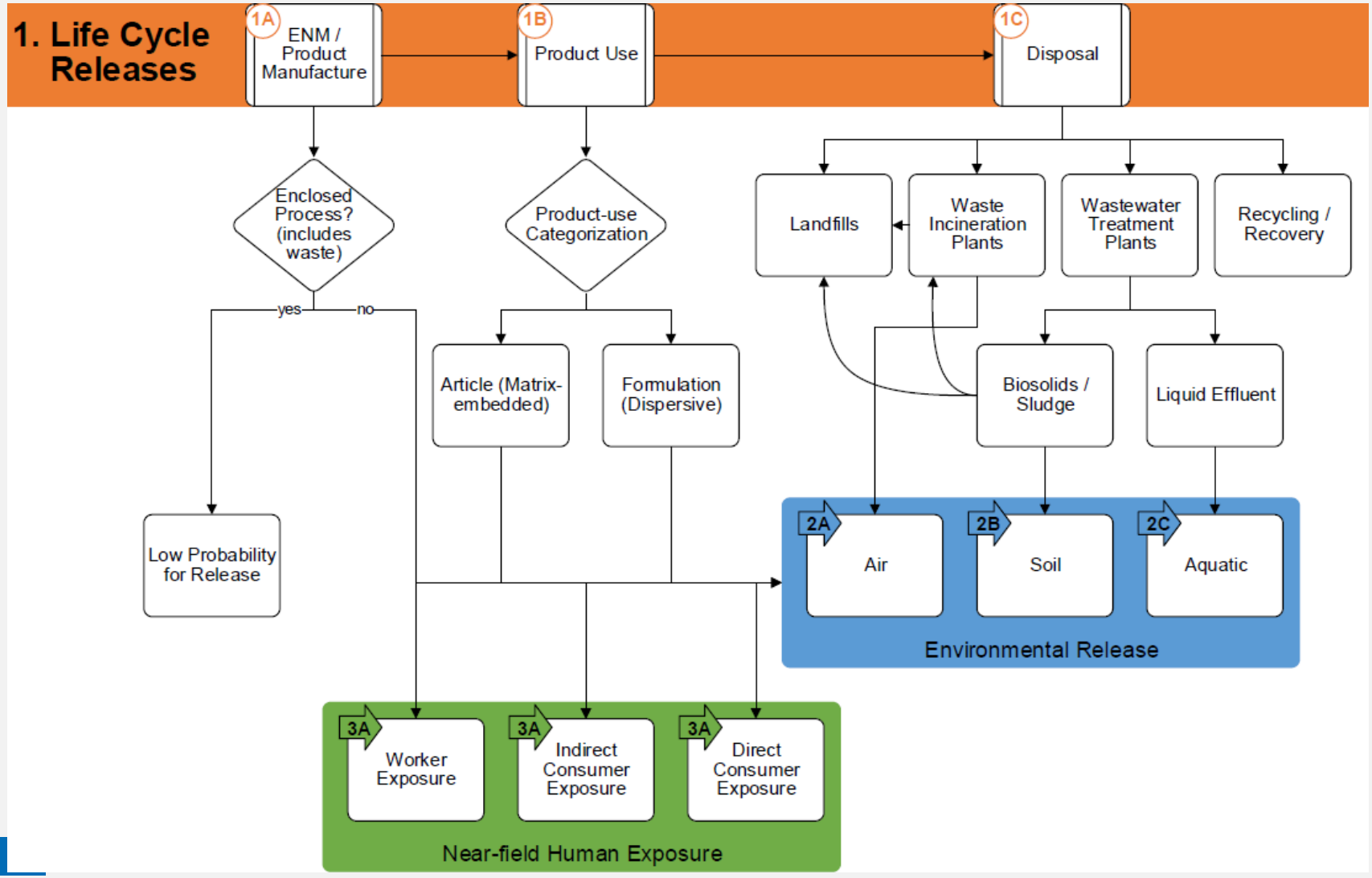
Comprehensive Framework

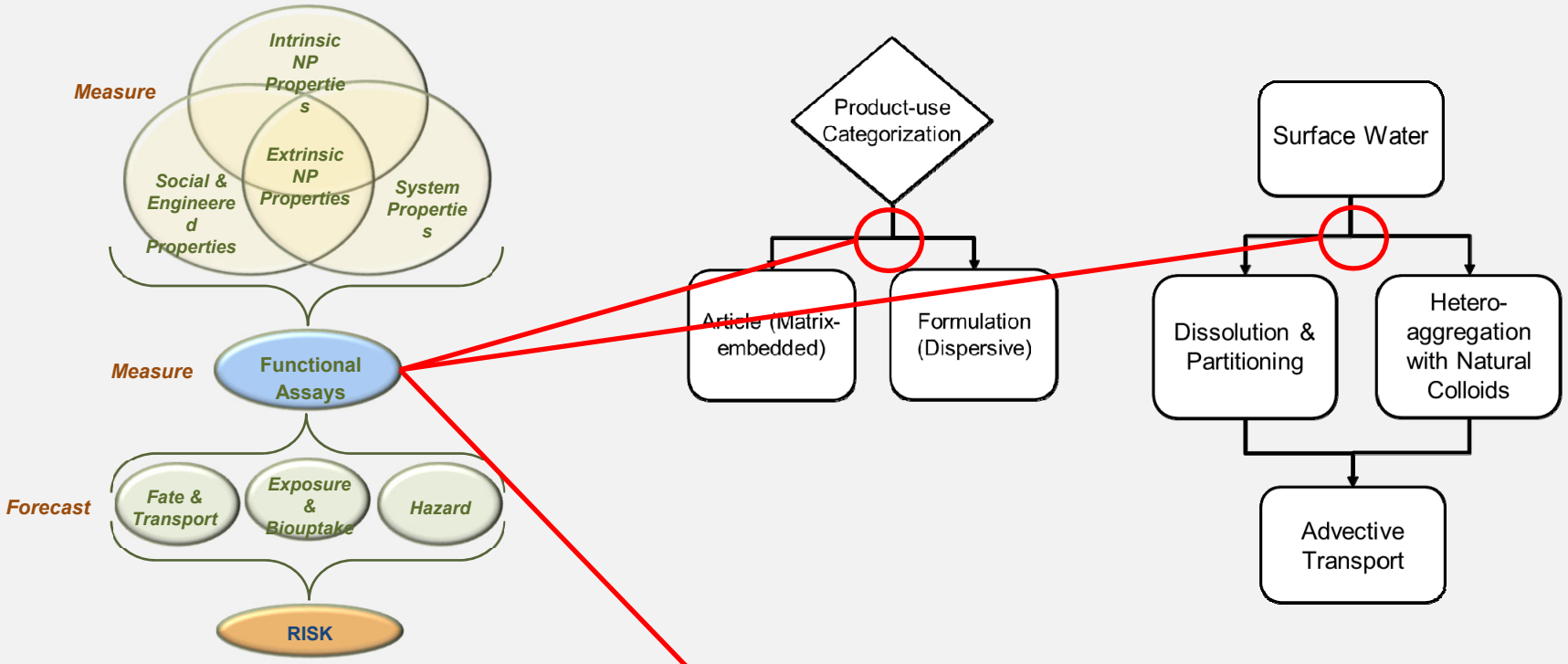


Boyes et al., CRITICAL REVIEWS IN TOXICOLOGY, 2017

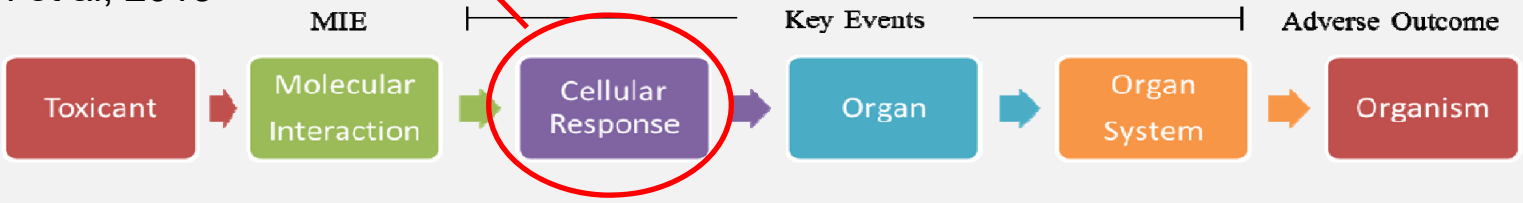
Release Across Product Life Cycle



Functional Assays Along Framework



Hendren et al, 2015



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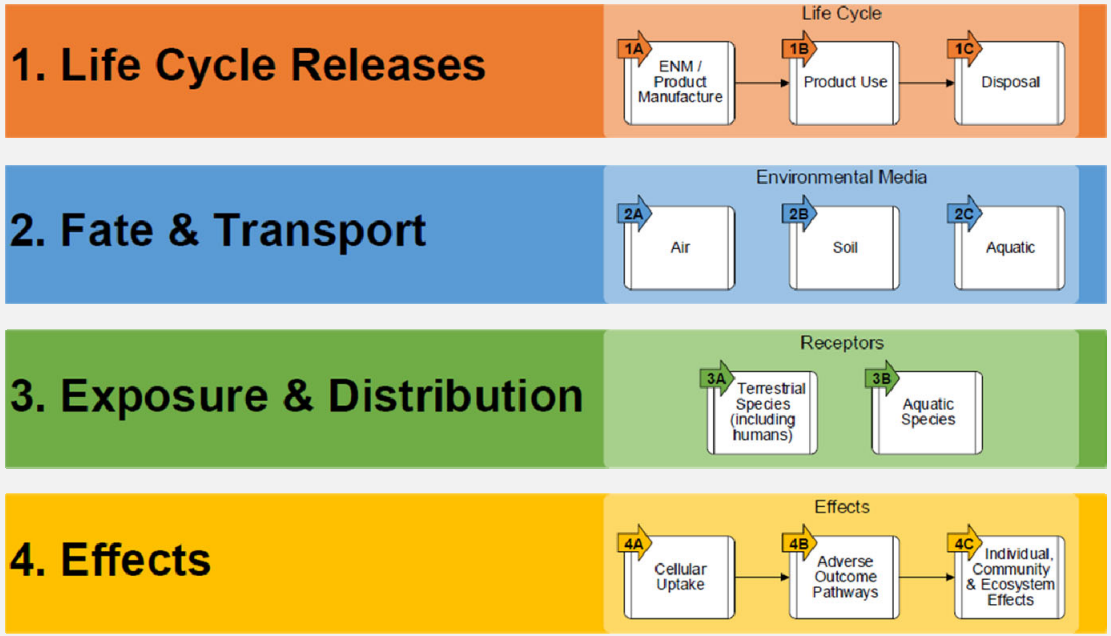
Conclusions

- AOP/AEP approach to evaluate nanomaterial risks
- A four-component framework with key decision points
- Targeted functional assays for the decision points



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Thank you!