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Using 21st Century Science to Improve Risk-Related Evaluations

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Board on Environmental Studies and Toxicology

Presented at the Joint International Symposium: Global Past, Present and Future Challenges in Risk Assessment — Strengthening Consumer Health Protection
December 1, 2017

National Academy of Sciences

"…The Academy shall, whenever called upon by any department of the Government, investigate, examine, experiment, and report upon any subject of science…"

1863 Charter of the National Academy of Sciences

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The National Academies of Sciences, Engineering, and Medicine Today

3 Honorary Societies

National Academy of Sciences

National Academy of Engineering

National Academy of Medicine

And an Operating Arm

6 Divisions

60 Boards

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National Academies

75+ Consensus Reports in 2016

- Developed by committees of pro bono experts
- Peer-reviewed
- Identify future directions or priorities
- Resolve science controversies
- Provide “state of the science”
- Available to the public at http://nap.edu

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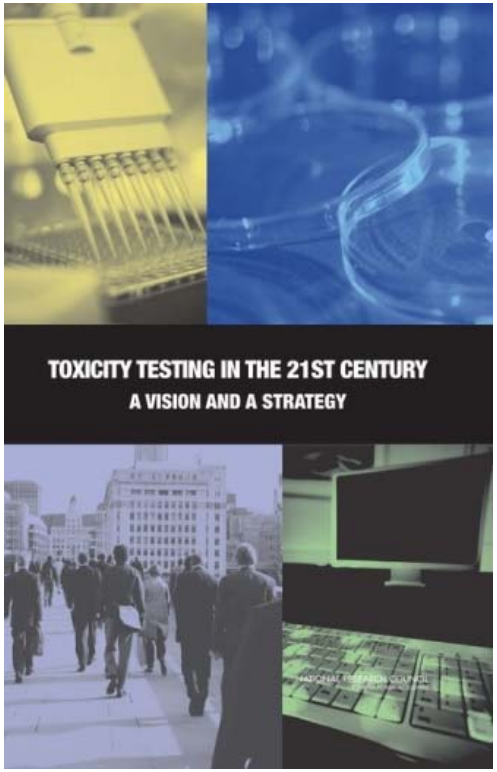
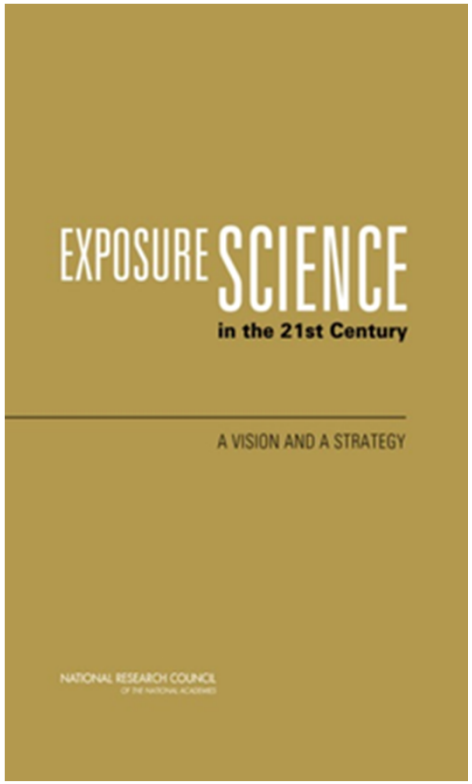
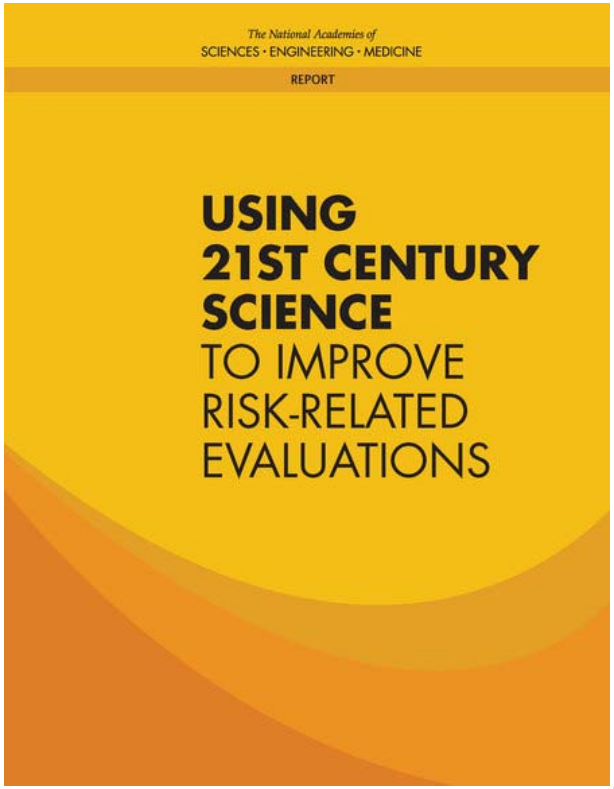
The Reports – Envisioning the Future







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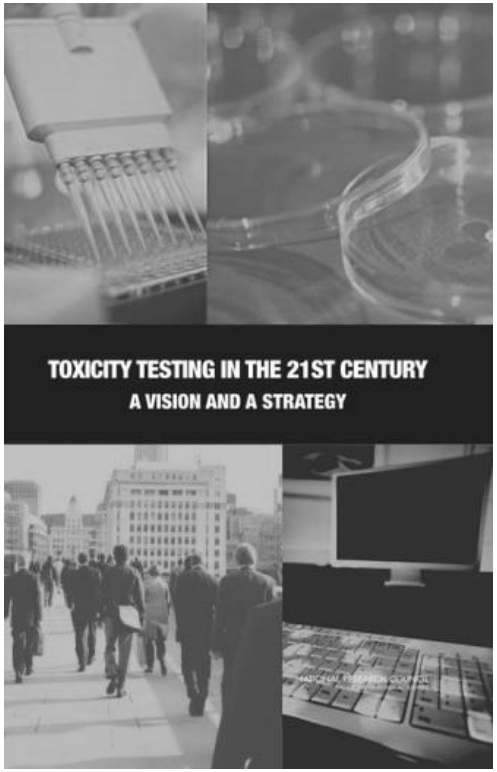
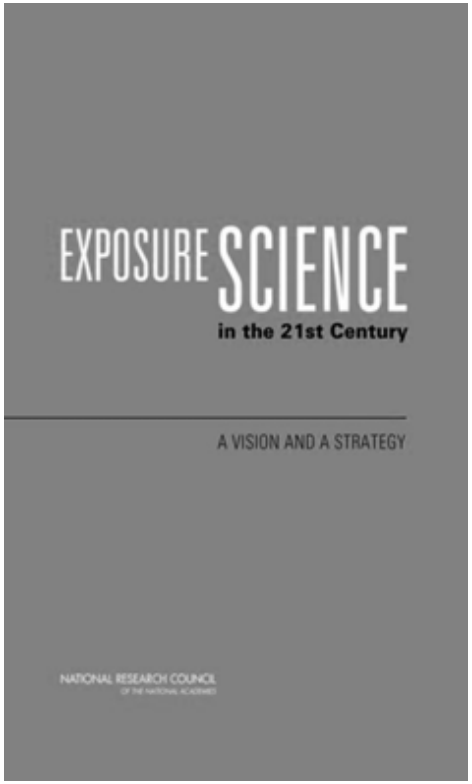
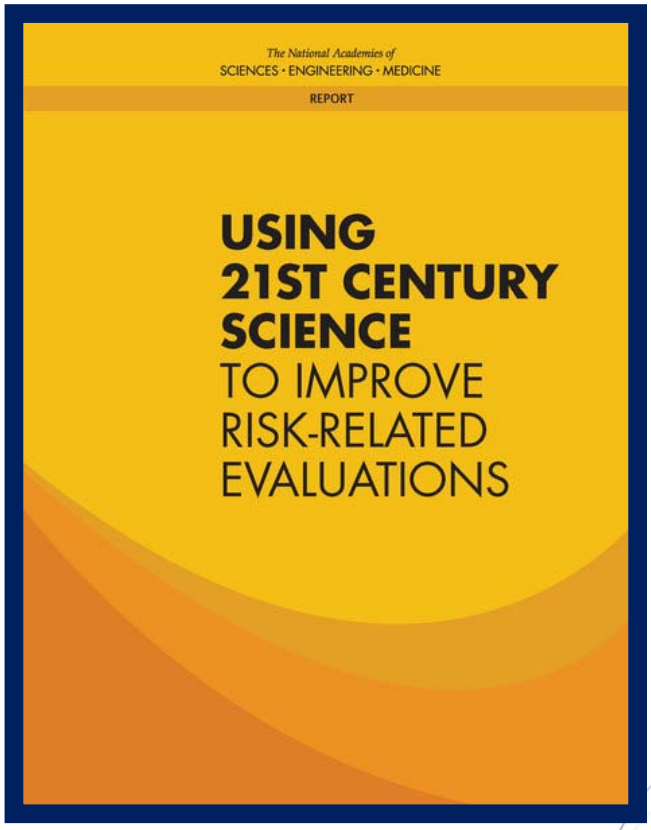
The Reports – Envisioning the Future







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The Task, The Sponsors, and The Report

Overall, the committee was asked to provide recommendations on integrating new scientific approaches into risk-based evaluations.

Sponsors: US Environmental Protection Agency; US Food and Drug Administration; National Institute of Environmental Health Sciences; National Center for Advancing Translational Sciences

- Advances in Exposure Science
- Advances in Toxicology
- Advances in Epidemiology
- A New Direction for Risk Assessment and Applications of 21st Century Science
- Model and Assay Validation and Acceptance
- Interpretation and Integration of Data and Evidence for Risk-Based Decision-Making

https://www.nap.edu/catalog/24635/using-21st-century-science-to-improve-risk-related-evaluations

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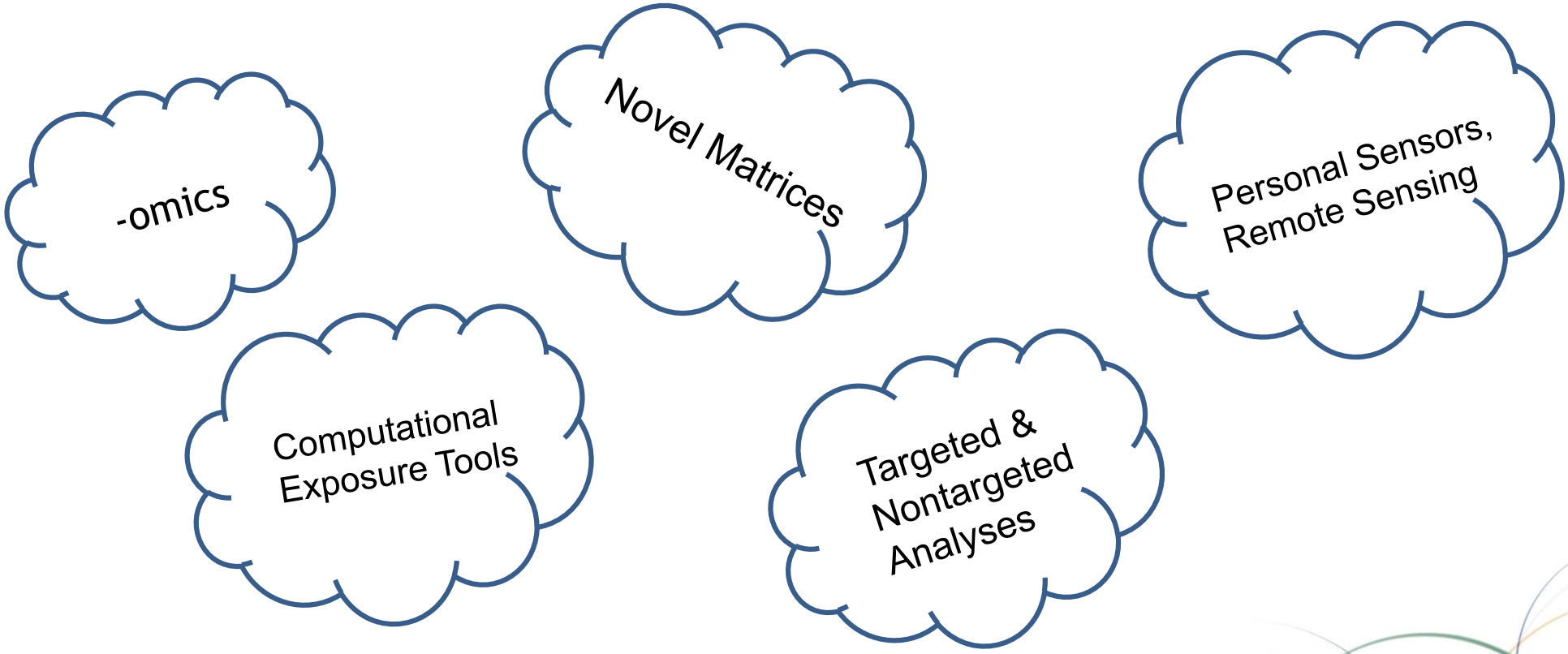
Exposure Science Advances

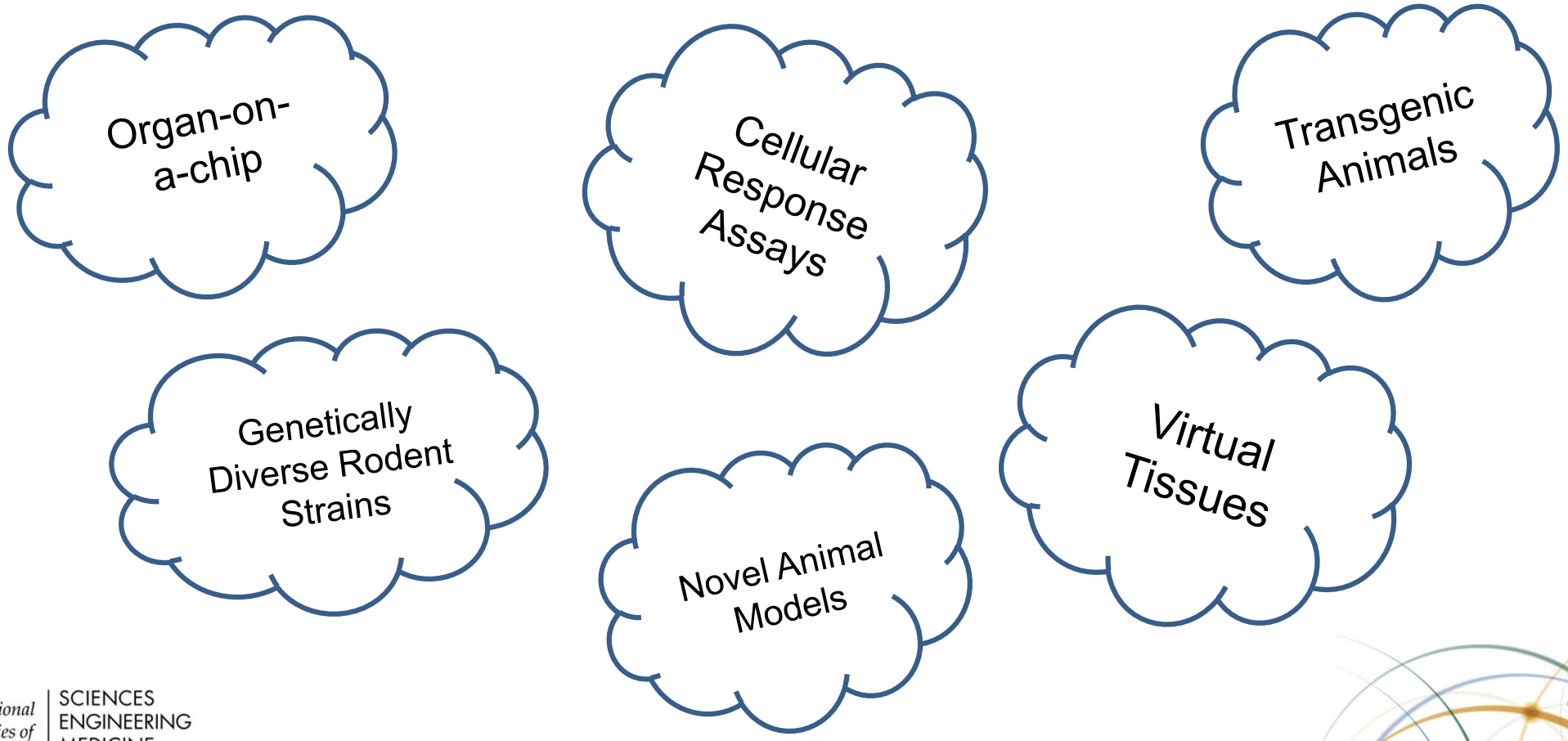


Challenges to Advancing Exposure Science

- Expanding and coordinating exposure-science infrastructure.
- Aligning environmental and test-system exposures.
- Integrating exposure information.

Integrating "measured and modeled data is a key step in developing coherent exposure narratives, in evaluating data concordance, and ultimately in determining confidence in an exposure assessment."

Toxicology Advances



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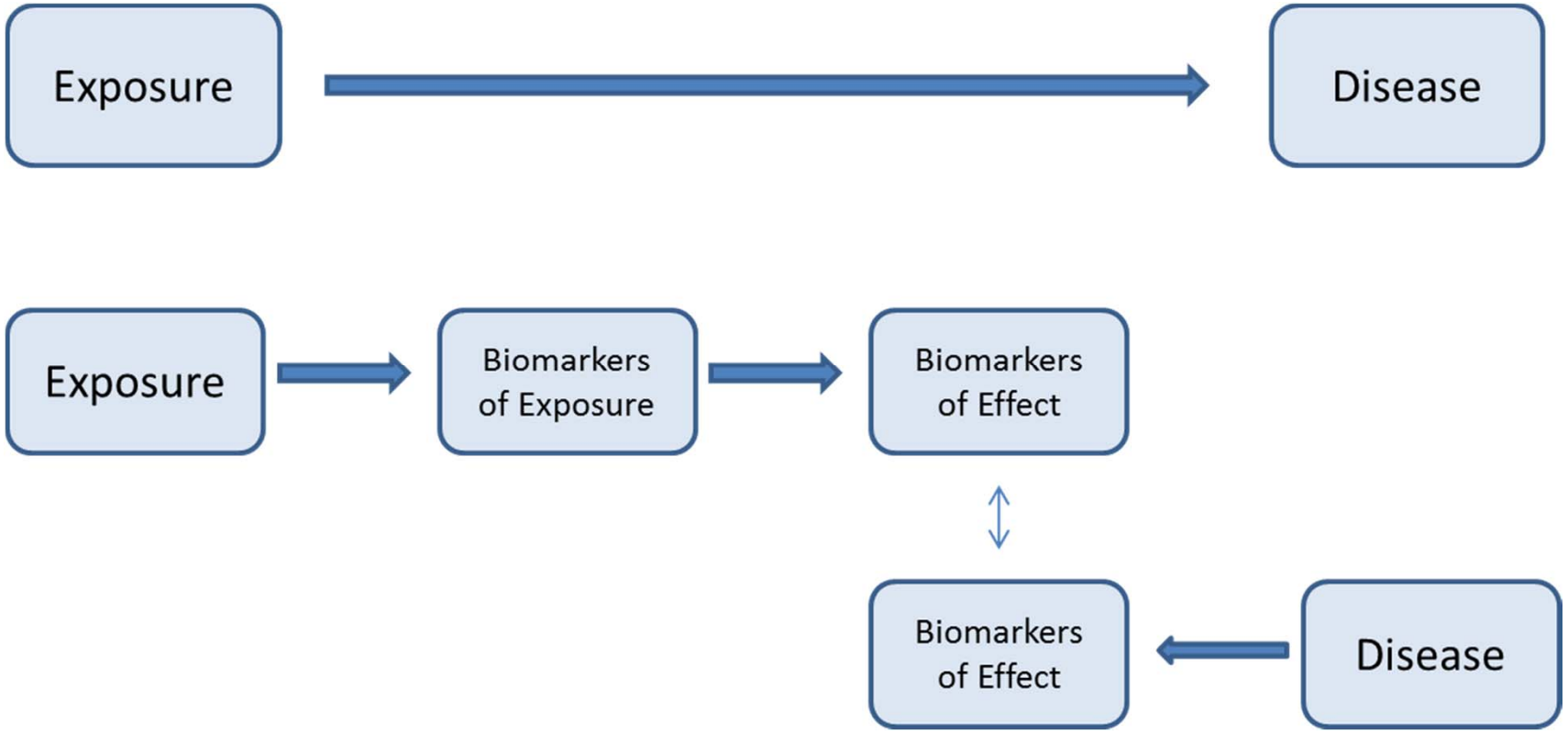
Challenges to Advancing Toxicology

- Accounting for metabolic capacity in assays.
- Understanding and addressing other limitations of cell systems.
- Addressing biological coverage.

Advances in Epidemiology



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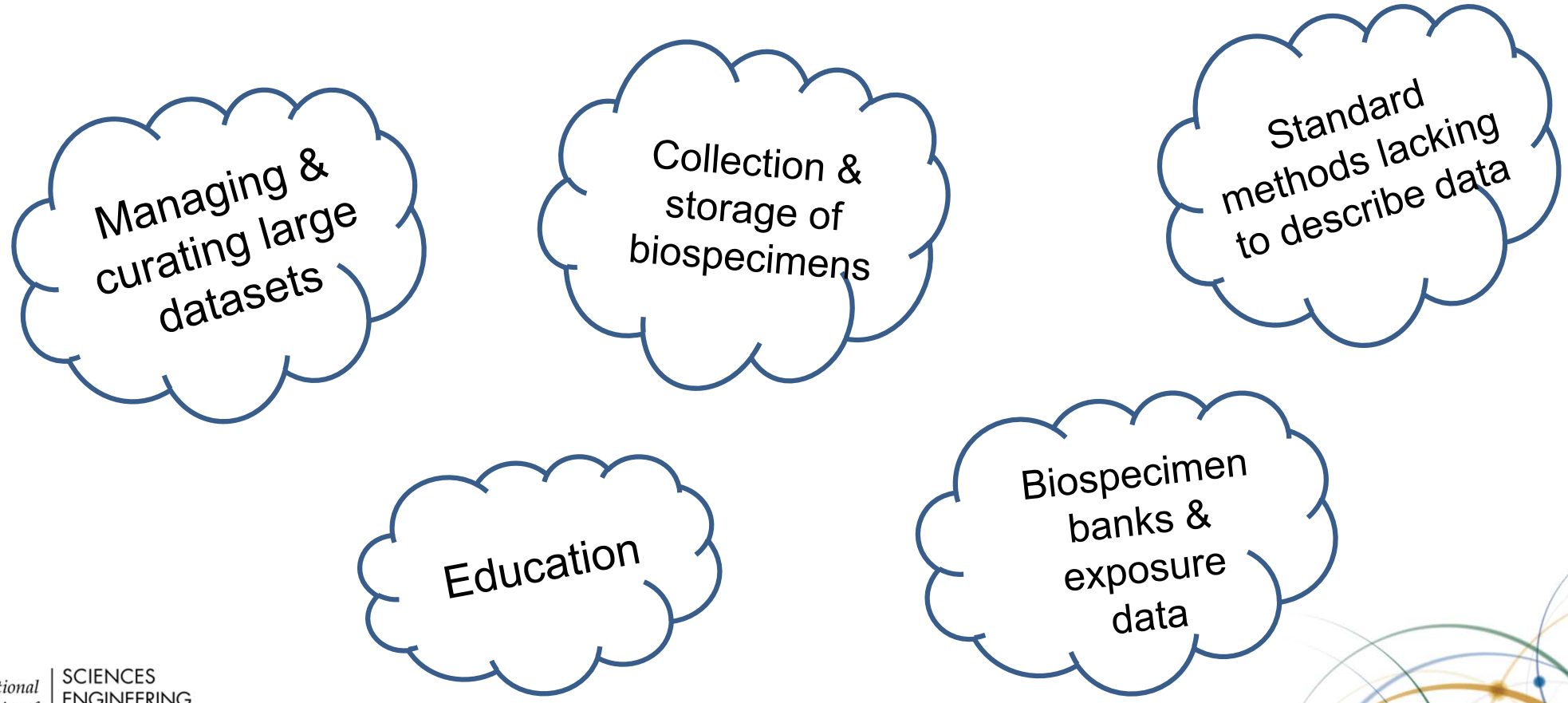
Challenges to Advancing Epidemiology



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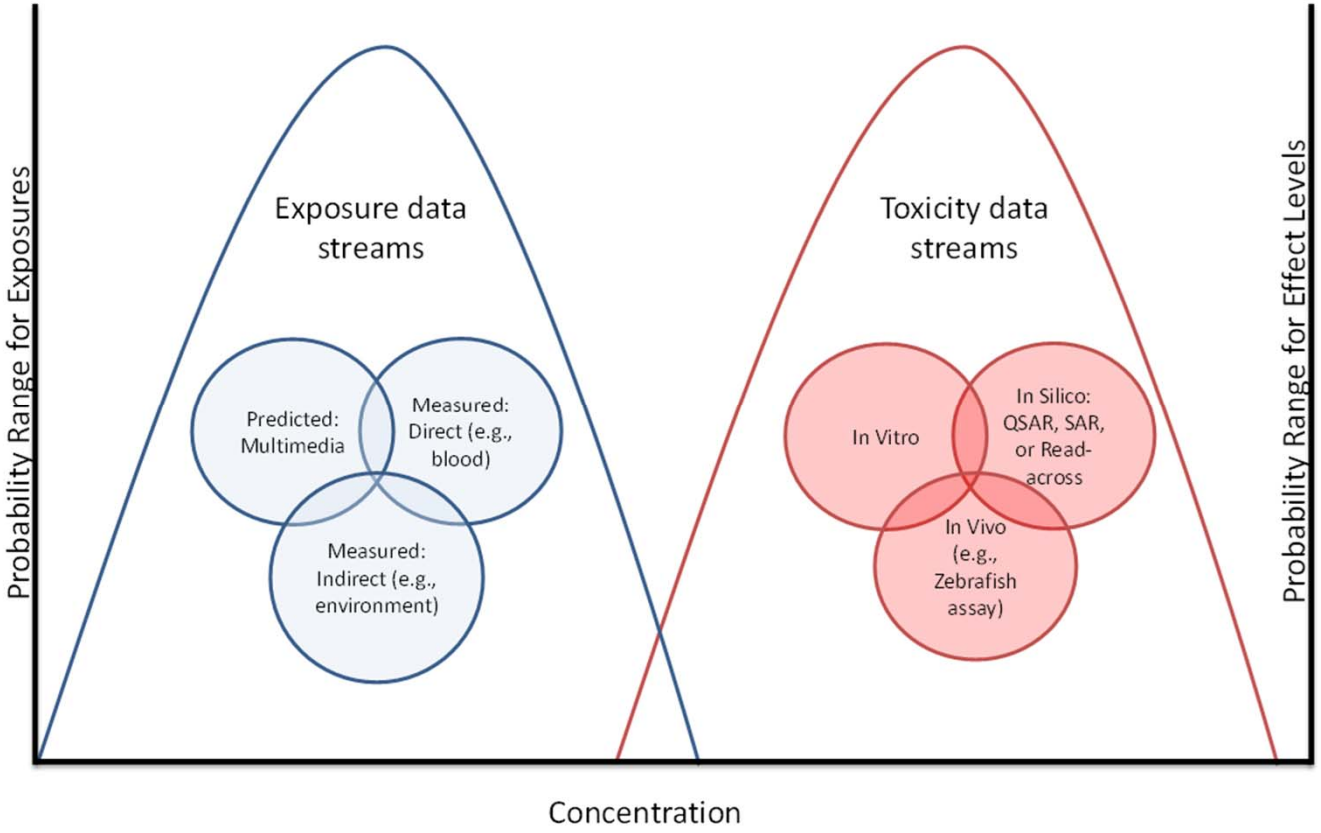
APPLICATIONS

Priority-Setting



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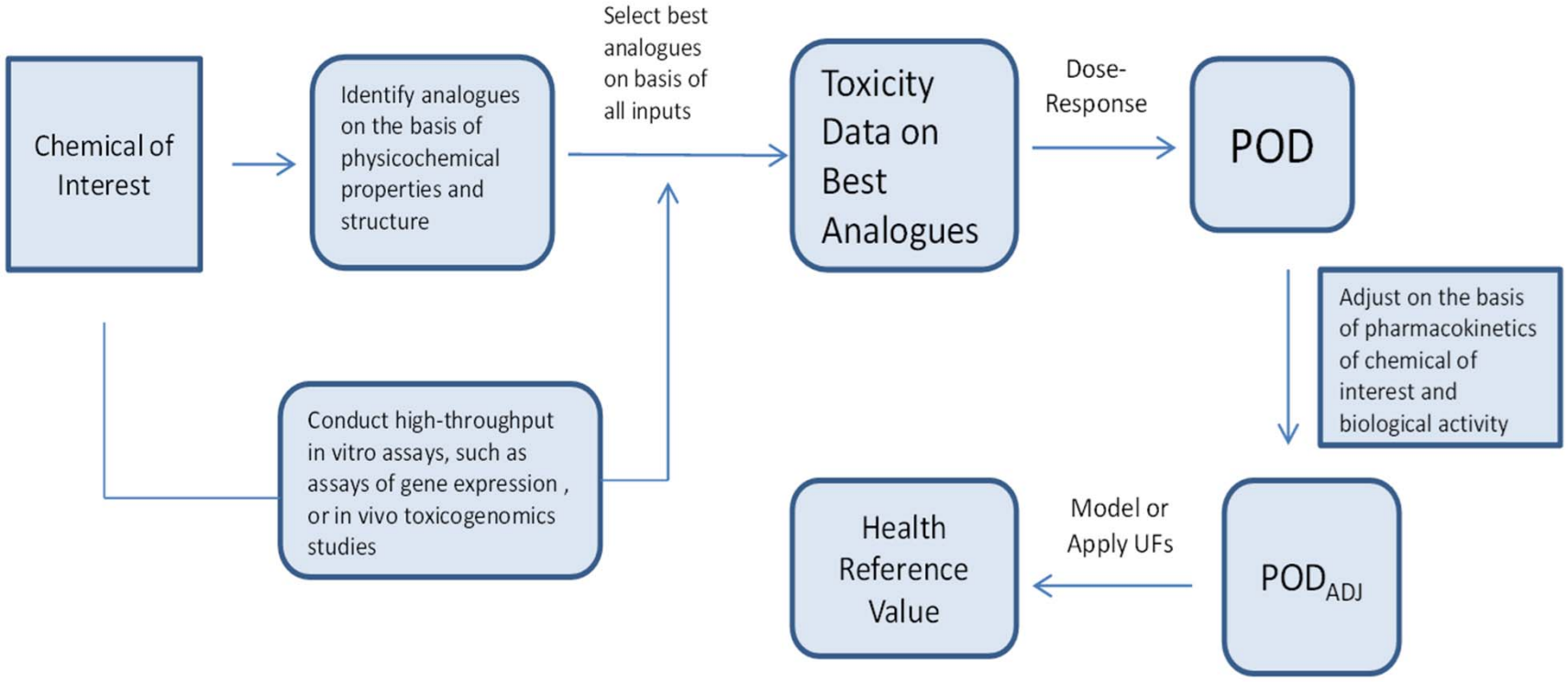
Chemical Assessment



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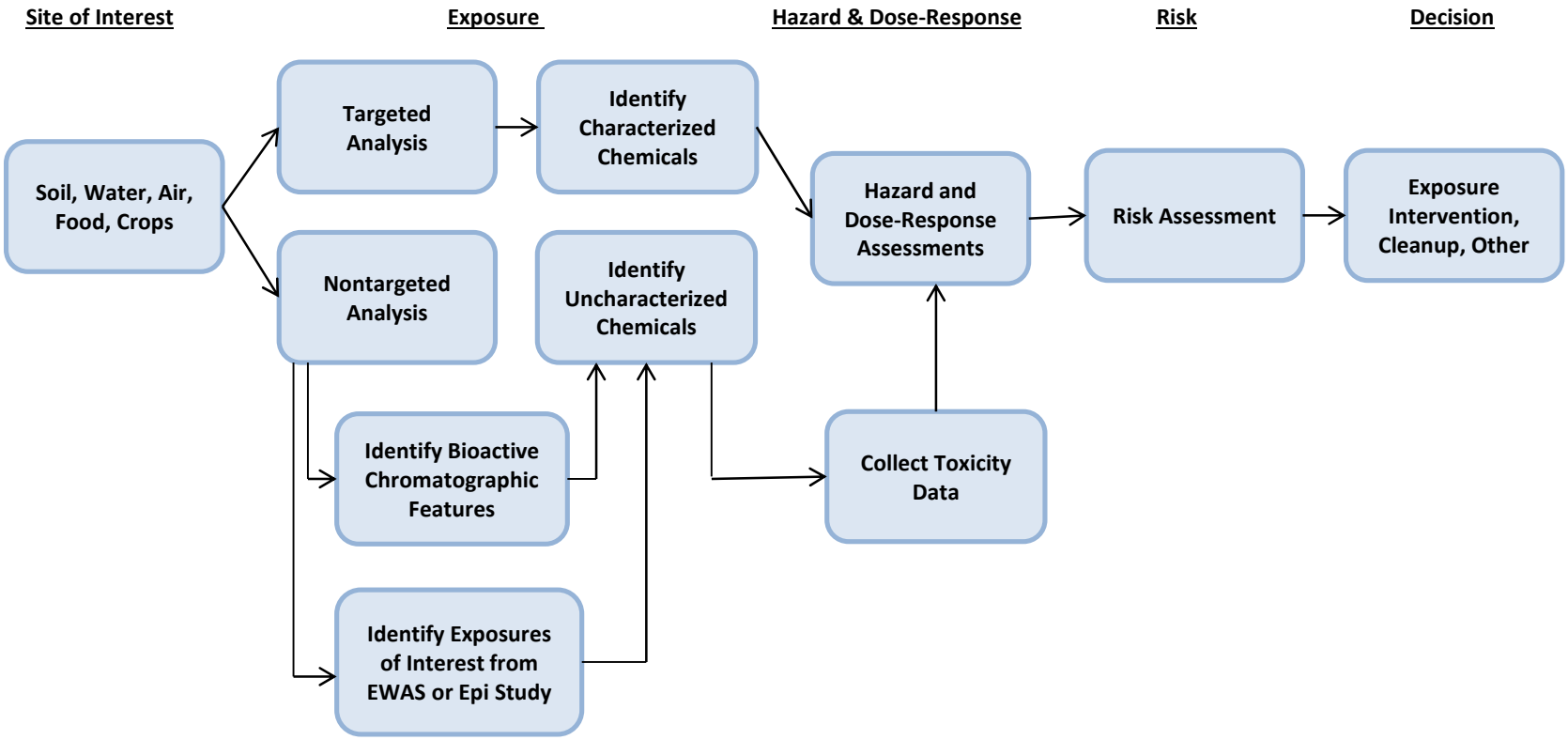
Site-Specific Assessment



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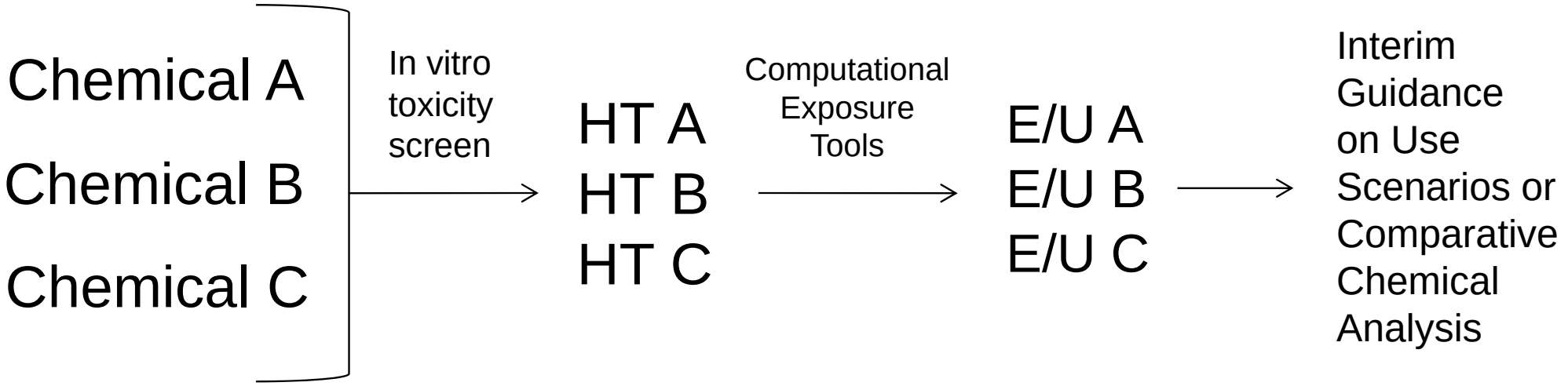
Assessment of New Chemistries



HT = Hazard Threshold
E/U = Emission or Use Rate

Example Applications

- Endocrine Disruptor Screening Program
- Pesticide registration
- Chemical spill on the Elk River in Charleston, West Virginia

CHALLENGES

Validation

"Current processes for validation cannot match the pace of development of new assays, models, and test systems, and … validation processes need to evolve."

Elements That Need to Be Addressed

- Identify appropriate comparators.
- Define assay utility.
- Establish performance and reporting standards.
- Determine methods for validating batteries of assays.

Communication

"Communicating the strengths and limitations of the approaches in a transparent and understandable way will be necessary if the results are to be applied appropriately and will be critical for ultimate acceptance of the approaches."

Data Analysis, Interpretation, and Integration

"Insufficient attention has been given to analysis, interpretation, and integration of various data streams from exposure science, toxicology, and epidemiology."

Research Agenda

- Develop case studies of decision-making and data-availability scenarios.
- Test case studies with multidisciplinary panels.
- Catalogue evidence evaluations and decisions.
- Determine best use of statistically based tools for evidence integration.

Multidisciplinary Approaches

"Exposure scientists, toxicologists, epidemiologists, and scientists in other disciplines need to collaborate closely to ensure that the full potential of 21st century science is realized."

Acknowledgement

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Upcoming Workshop

Informing Environmental Health Decisions through Data Integration – February 20-21, 2018, in Washington, DC.

For more information:

http://nas-sites.org/emergingscience/

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