



# **Focus Topic 2 - New Approach Methods (Problem formulation using NAMs as a tool and Case Study)**

Risk Assessment Forum Colloquium

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*Disclaimer: The views presented are those of the author and do not necessarily reflect the views of the US EPA.*

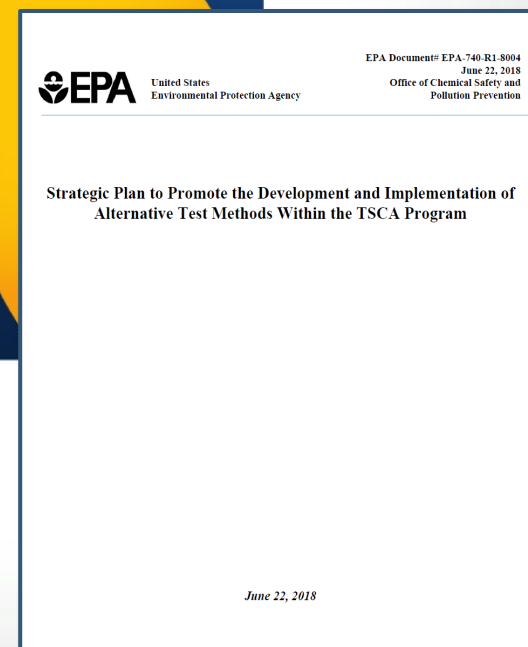
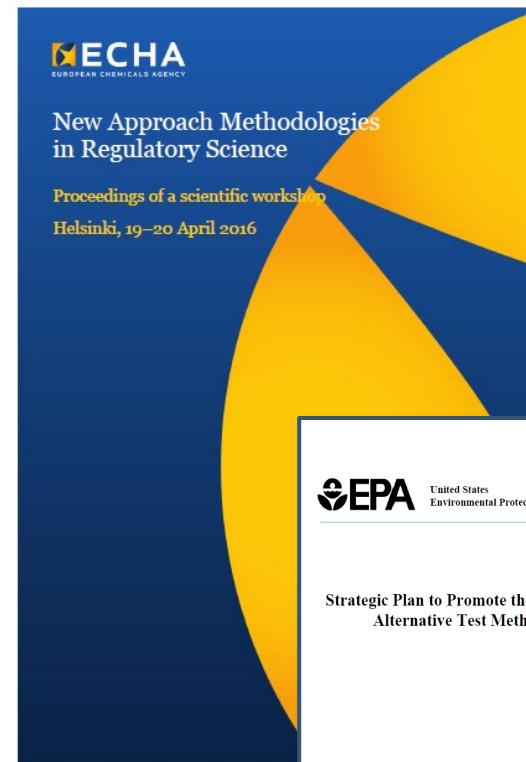


## What's a NAM?

- NAM = New Approach Methodologies
- Commonly defined to include in silico approaches, in chemico and in vitro assays, as well as the inclusion of information from the exposure of chemicals in the context of hazard and exposure assessment.
- Defined in the EPA's TSCA Alternative Toxicity Strategy as:
  - a broadly descriptive reference to any technology, methodology, approach, or combination thereof that can be used to provide information on chemical hazard and risk assessment that avoids the use of intact animals.

[https://echa.europa.eu/documents/10162/22816069/scientific\\_ws\\_proceedings\\_en.pdf](https://echa.europa.eu/documents/10162/22816069/scientific_ws_proceedings_en.pdf)

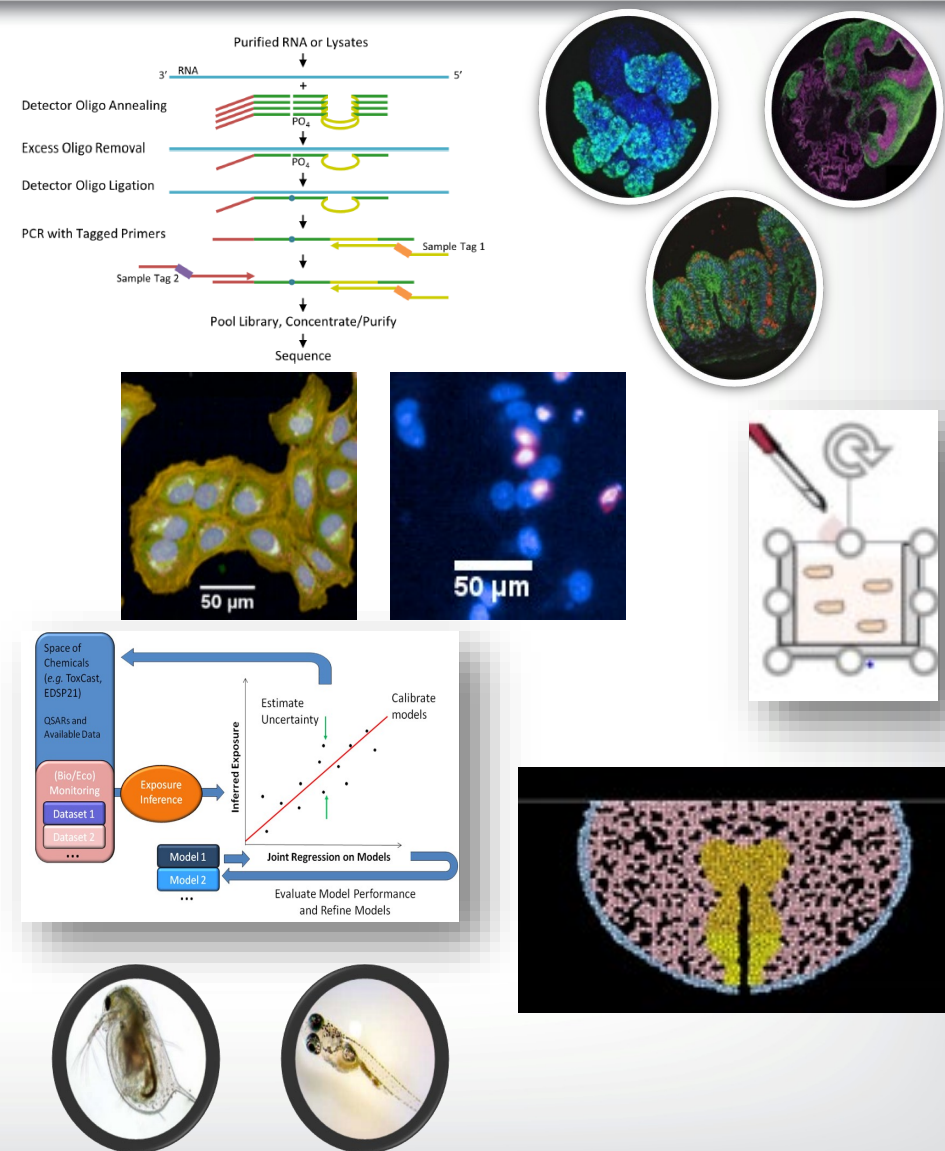
<https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/alternative-test-methods-and-strategies-reduce>





# Examples of NAMs

- **In silico (e.g. QSAR and Read-across)**
  - Estimate effects, doses, and chemical parameters
  - Consensus exposure modeling
- **High-throughput/In vitro assays**
  - Broad / screening (transcriptomics, cell painting)
  - Targeted (receptors, enzymes)
  - In vitro PODs, modes / mechanisms of action
  - Developing higher throughput aquatic toxicity tests for ecotoxicity
- **In vitro Toxicokinetics**
  - Allow conversion of an in vitro POD to in vivo (IVIVE)
- **High-throughput Exposure Measurements/NTA**
  - To fill data gaps in monitoring data
- **Computer models/Systems biology**
  - Hazard models to integrate multiple in silico and in vitro data streams
  - Exposure models to increase information on different pathways of exposure
  - Sequence alignment to predict cross-species differences





## Examples of NAMs (Problem formulation)

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**Populations**

**Exposures**

**Comparators**

**Outcomes**



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- **Key risk assessment considerations: relevance, uncertainty, predictivity, dosimetry**
- **Increase understanding of benchmarks for NAM performance in different regulatory contexts.**
- **Increase engagement and commitment to development and sharing of case studies of mutual interest.**
- **Increase collaboration to strategically address barriers and limitations of use of NAMs in a regulatory context.**





**Thank you!**

