Systematic Review Community of Practice

NAMs 101 webinars - Introduction

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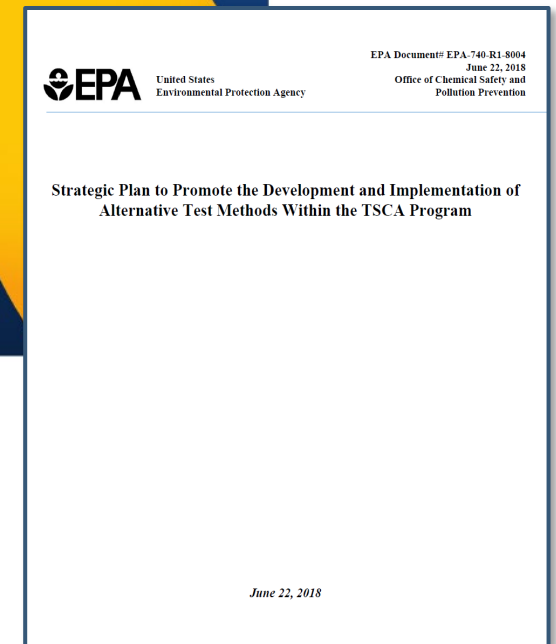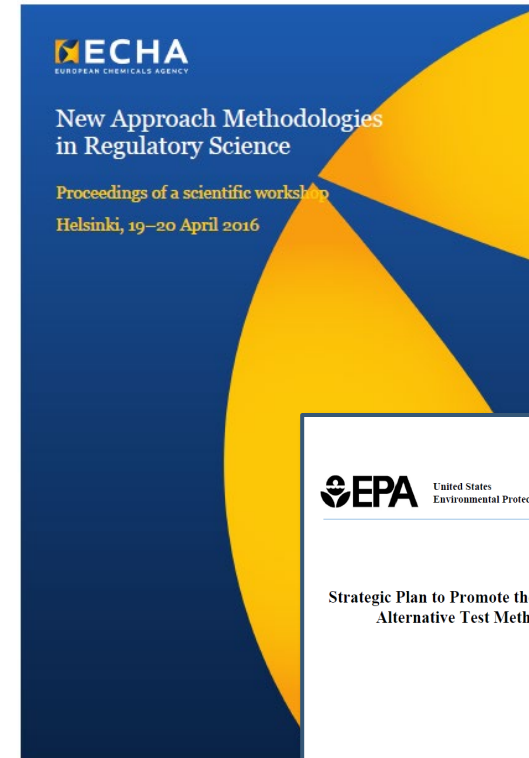Office of Research and Development

US Environmental Protection Agency

April 13th, 2021

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

ECHA
EUROPEAN CHEMICALS AGENCY

New Approach Methodologies
in Regulatory Science

Proceedings of a scientific workshop
Helsinki, 19–20 April 2016

EPA Document# EPA-740-R1-8004
June 22, 2018
Office of Chemical Safety and
Pollution Prevention

EPA United States
Environmental Protection Agency

Strategic Plan to Promote the Development and Implementation of
Alternative Test Methods Within the TSCA Program

June 22, 2018

Examples of New Approach Methodologies

- In silico (e.g. QSAR and Read-across)
  - Estimate effects and doses
  - Consensus exposure modeling
- In vitro assays
  - Broad / screening (transcriptomics, cell painting)
  - Targeted (receptors, enzymes)
  - In vitro PODs, modes / mechanisms of action
- In vitro Toxicokinetics
  - Allow conversion of an in vitro POD to in vivo (IVIVE)
- High-throughput Exposure Measurements
  - To fill data gaps in monitoring data
- Computer models
  - Hazard models to integrate multiple in silico and in vitro data streams
  - Exposure models to increase information on different pathways of exposure
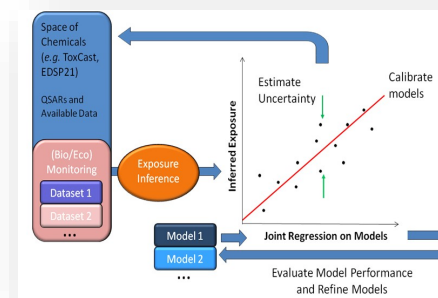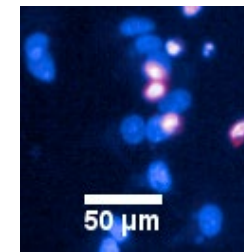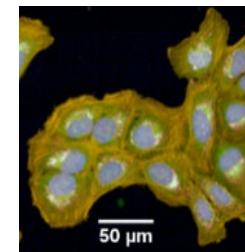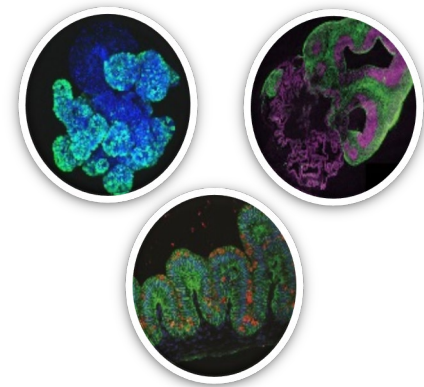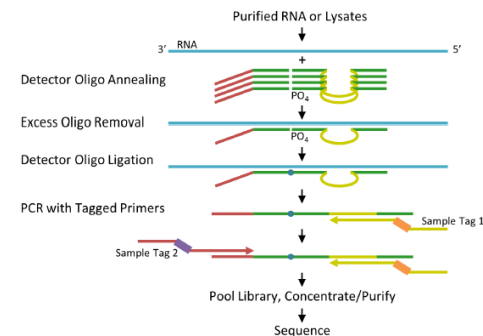
Goals for today

- General introduction to NAMs – key concepts and examples, but not comprehensive

  - Katie Paul Friedman – Targeted New Approach Methodologies: Current ToxCast Tools for Users
  - John Wambaugh – New Approach Methodologies for Exposure
  - Ann Richard – "What's in a NAM: Why chemistry, of course!"

- Demonstration of tools and resources

  - Tony Williams – The CompTox Chemicals Dashboard as an Access Point to NAMS-related Data

- Outcomes

  - Starting point discussions

  - Collaborative development

  - Application of tools