

Translation and Implementation of New Approach Methodologies (NAMs)

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

Sepa Outline

- NAS Using 21st Century Science
- NAMs (ECHA/EPA definitions)
- EPA-specific Drivers
- What is needed to expand translation/implementation for NAMs?

Conclusions

Toxicology Moving to Embrace 21st Century Methods



EPA

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

New Approach Methodologies (NAMs)



SEPA

- 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 assessment.
- Recently 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-strategiesreduce

EPA-Specific Drivers



EPA

USEPA Administrator Memo Prioritizing Efforts to Reduce Animal Testing, September 10, 2019

- EPA will reduce its requests for, and our funding of, mammal studies by 30 percent by 2025
- EPA will eliminate all mammal study requests and funding by 2035. Any mammal studies requested or funded by the EPA after 2035 will require Administrator approval on a case-bycase basis.
- Form a working group of agency experts in this field who will provide a work plan within six months.
- https://www.epa.gov/environmentaltopics/administrator-memo-prioritizing-effortsreduce-animal-testing-september-10-2019

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EPA-Specific Drivers

Letter to Stakeholders on OPP's Goal to Reduce Animal Testing from Jack E. Housenger, Director

- https://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2016-0093-0003
- Working in partnership with other governmental entities, industry and non-governmental organizations (NGOs) and need continued robust participation and support to achieve our mutual goal.
- Activities fall under three main objectives
 - Critically evaluating which studies form the basis of OPP decisions;
 - Expanding acceptance of alternative methods and;
 - Reducing barriers such as challenges of data sharing among companies and international harmonization to adopting alternative methods in the U.S. and internationally.

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EPA-Specific Drivers

Toxic Substances Control Act (TSCA)

- The Toxic Substances Control Act (TSCA) regulates the introduction of new and existing chemicals.
- TSCA was amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (June 22, 2016):
 - Large bipartisan support in both House and Senate;
 - Broad stakeholder support;
 - First major update to an environmental statute in about 20 years.
- Implementation of TSCA is the responsibility of the Office of Chemical Safety and Pollution Prevention (OCSPP), specifically, the Office of Pollution Prevention and Toxics (OPPT).
- EPA required to make determination if chemical substance presents an unreasonable risk of injury to human health or the environment.
 Determinations are risk-based.

TSCA Section 6 (Existing Chemicals)

\$epa	United States Environmental Protection Agency	September 27, 2018 Office of Chemical Safety and Pollution Prevention
A Working Approa	ch for Identifying Potential Candidate	Chemicals for Prioritization
	September 2018	

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https://www.epa.gov/sites/prod uction/files/2018-09/documents/preprioritizatio n_white_paper_9272018.pdf

- Under Lautenberg, EPA must identify 20 highand 20 low-priority chemicals (TSCA Section 6).
- EPA developed a document describing two approaches on how EPA may identify candidate chemicals to enter the prioritization process:
 - Short-term approach may be used to identify high-priority chemicals (likely) from the TSCA 2014 Workplan and low-priority chemicals from the Safer Chemicals Ingredients List;
 - Long-term approach proposed an approach to review chemicals in the TSCA active list (about 40K chemicals) based upon risk-related scoring and information availability
- On March 20, 2019, EPA initiated the prioritization process by issues a list of 40 chemical substances and began effort to designate 20 as high-priority and 20 low-priority substances.

EPA-Specific Drivers

 The US Environmental Protection Agency's (EPA) Endocrine Disrupting Screening Program (EDSP)

SEPA

- established in response to Congressional mandates in the Federal Food Quality Protection and Safe Water Drinking Acts
- evaluating potential risk of endocrine disruption in humans and wildlife from exposure to pesticide chemicals and drinking water contaminants
- recommendations from an expert advisory committee established a two tiered system
 - Tier I screening for *potential* to interact with the estrogen, androgen or thyroid hormone systems
 - Tier 2 testing to verify interaction and quantify dose-response relationship
- In 2011, EPA began a multiyear transition to prioritize and screen thousands of EDSP chemicals using high-throughput in vitro assays and computational modeling approaches

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What is needed to expand translation and implementation of NAMs?

- Integration of NAM data with traditional data
- Fit-for-purpose applications
- Build confidence and understanding
- Engage stakeholders

Sepa



- Incorporating new technologies and innovations in toxicology can more rapidly and inexpensively screen chemicals for potential adverse biological effects.
- EPA has made great advances in the development of NAMs for filling information gaps for decision-making and integrating those tools and data streams into chemical risk assessment.
- Building confidence in the use of NAMs for regulatory decision-making is key to the increased implementation of these methods.



