

Introduction to the EPA New Approach Methods Work Plan

Second Annual EPA NAM Conference October 19, 2020

The Administrator's September 2019 Memo to Prioritize EPA's Efforts to Reduce Animal Testing



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

September 10, 2019

HE ADMINISTRATOR

MEMORANDUM

SUBJECT: Directive to Prioritize Efforts to Reduce Animal Testing

Andrew R. Who

FO: Associate Deputy Administrator

General Counsel Assistant Administrators Inspector General Chief Financial Officer Chief of Staff

Associate Administrators Regional Administrators

During my March 2019 all-hands address, I reiterated the U.S. Environmental Protection Agency's commitment to move away from animal testing. We are already making significant efforts to reduce, replace and refine our animal testing requirements under both statutory and strategic directives. For example, the Toxic Substances Control Act, amended June 22, 2016, by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, requires the EPA to reduce reliance on animal testing. Also, Objective 3.3 of the FY 2018-2022 U.S. EPA Strategic Plan outlines a commitment to further reduce the reliance on animal testing within five years. More than 200,000 laboratory animals have been saved in recent years as a result of these collective efforts.

Scientific advancements exist today that allow us to better predict potential hazards for risk assessment purposes without the use of traditional methods that rely on animal testing. These new approach methods (NAMs), include any technologies, methodologies, approaches or combinations thereof that can be used to provide information on chemical hazard and potential human exposure that can avoid or significantly reduce the use of testing on animals. The benefits of NAMs are extensive, not only allowing us to decrease animals used while potentially evaluating more chemicals across a broader range of potential biological effects, but in a shorter timeframe with fewer resources while often achieving equal or greater biological predictivity than current animal models.

- The goals in the memo:
 - Reduce its requests for, and funding of, mammalian studies by 30 percent by 2025
 - Eliminate all mammalian study requests and funding by 2035
 - Come as close as possible to excluding reliance on mammalian studies from its approval process (subject to applicable legal requirements)
- Accomplish goals through the development and application of new approach methodologies (NAMs)
 - Any technology, methodology, approach, or combination that can provide information on chemical hazard and risk assessment to avoid the use of animal testing
- ORD and OCSPP were tasked with forming a group of Agency experts to develop a work plan

Development of the EPA NAMs Work Plan

- Formed a cross-Agency group of 34 experts with representatives from OCSPP, ORD, OAR, OW, OLEM, and OGC
- Distributed experts into five subgroups
 - Regulatory Flexibility and Existing Statutes
 - Baselines and Metrics
 - Scientific Confidence and Demonstration
 - NAM Development and Scientific Gaps
 - Communication and Outreach
- Held an internal EPA workshop in January 2020
 - Reviewed presentations and breakout group discussions from December 2019 EPA NAM Conference
 - Outlined and discussed work plan structure and components
- Released final EPA NAMs Work Plan June 22, 2020 (https://www.epa.gov/nam)

EPA NAM Work Plan Leadership and Writing Team

EPA NAM Work Plan Leadership Team					
Sarah Stillman	Anna Lowit	Gino Scarano			
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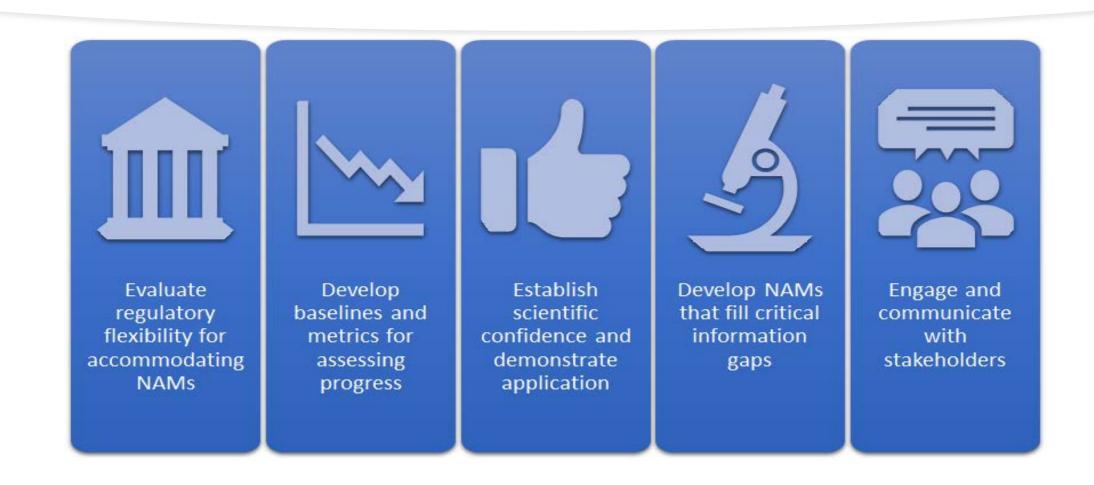
EPA NAM Work Plan Development and Writing Team Subgroups						
Regulatory Flexibility and Existing Statutes	Baselines and Metrics	Scientific Confidence and Demonstration	NAM Development and Scientific Gaps	Communication and Outreach		
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Content of the EPA NAMs Work Plan

- **Five objectives** for achieving the reduction goals while ensuring that Agency decisions remain fully protective of human health and the environment
- Short- and long-term strategies EPA will use to accomplish the objectives
- Specific deliverables and timelines linked with each objective
- Recognition that the EPA NAMs Work Plan represents a snapshot in time and will evolve as EPA's knowledge and experience grows

5 Objectives for Achieving the Goals





Evaluate Regulatory Flexibility for Accommodating NAMs

Strategy:

- Perform a thorough review of existing statutes and programmatic regulations, policies and guidance to identify mammalian testing requirements that may not allow flexibility for the Agency to apply NAMs.
- Consider options for introducing flexibility on implementing and/or using appropriate NAMs for regulatory purposes.

Deliverable: EPA report on findings of the review and options in 2021.

Develop Baselines and Metrics for Assessing Progress

Strategy:

- Build on previously established baselines and metrics for animal use within OCSPP and ORD
- Progressively extend to other EPA offices since baselines and metrics will need to be customized to the specific requirements in each program

Deliverable:

 Progress and summary metrics reported annually through EPA website starting in Q4 of 2021 (associated with the 2021 NAMs conference)





Establish Scientific Confidence in NAMs and Demonstrate Application to Regulatory Decisions

Strategy:

- Characterize the scientific quality and relevance of existing animal tests
- Develop a scientific confidence framework to evaluate the quality, reliability, and relevance of NAMs
- Develop recommended reporting templates
- Demonstrate application of the NAMs to regulatory decisions through case studies

Deliverables (among others):

- NAS report on uncertainties and utility of existing mammalian toxicity tests. Q4 2022.
- Scientific confidence framework to evaluate the quality, reliability, and relevance of NAMs. Q3 2022.
- Approx. one case study every other year beginning in 2022



Develop NAMs to Address Scientific Challenges and Fill Important Information Gaps

Strategy:

- Facilitate joint planning of NAM development by EPA research scientists and regulators
- Encourage development and evaluation of NAMs by external parties

Deliverables:

- Develop EPA Strategic Research Action Plans on a regular
 4-year planning cycle
- Encourage development of NAMs through mechanisms such as the STAR grant program and facilitate partnerships with organizations focused on establishing scientific confidence in alternative methods. Ongoing deliverable.



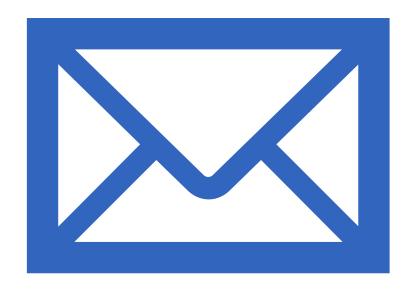
Engage and Communicate with Stakeholders

Strategy:

- Develop centralized portal for releasing EPA-related NAM Information
- Actively solicit comment and feedback associated with deliverables
- Develop training courses, workshops, and conferences for stakeholders on NAMs

Deliverables:

- EPA NAM website (<u>www.epa.gov/nam</u>). Established in Q3 2020.
- Public webinars when deliverables are released.
 Ongoing deliverable.
- Training, opportunities for scientific exchange, and progress updates through Agency sponsored and partners events. Ongoing deliverable.



Email: NAM@epa.gov

Provide Your Feedback

- Feedback and suggestions are compiled quarterly and reviewed by the EPA NAM leadership team.
- Suggestions for changes to the EPA NAM Work Plan will be considered as the plan evolves and matures.

Questions

