

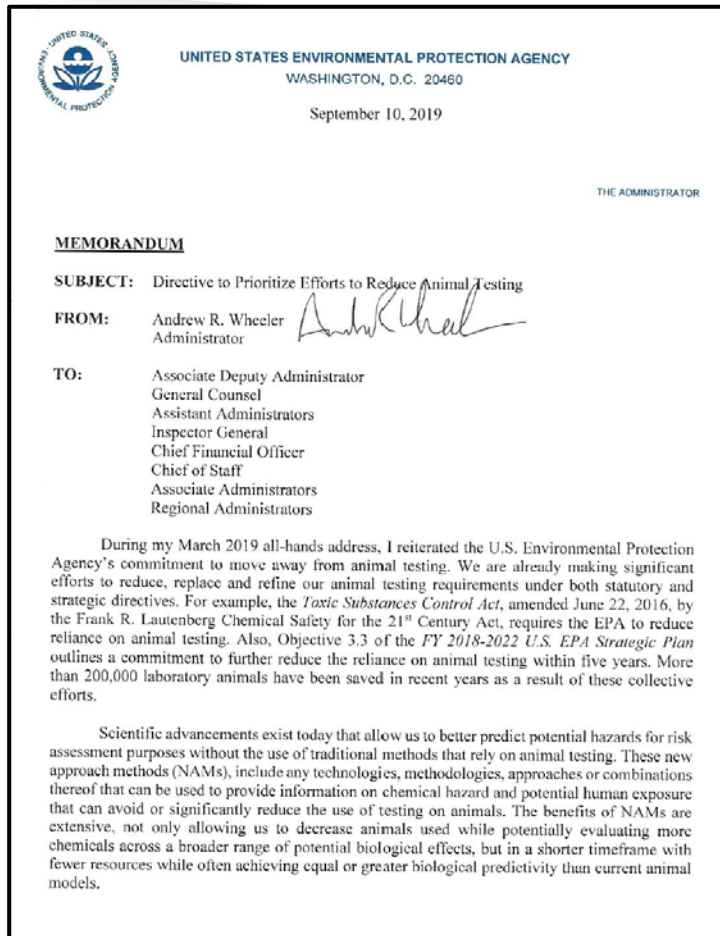


# Introduction to the EPA New Approach Methods Work Plan

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Second Annual EPA NAM Conference  
October 19, 2020

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



- 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 OCSP 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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		Samantha Jones (ORD)		
		Stiven Foster (OLEM)		

\*Subgroup lead

# 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



Develop baselines and metrics for assessing progress



Establish scientific confidence and demonstrate application



Develop NAMs that fill critical information gaps



Engage and communicate with stakeholders

# 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 OCSP 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 ([www.epa.gov/nam](http://www.epa.gov/nam)). 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.*





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## 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

