

# TSCA Implementation: A Focus on New Approach Methodologies

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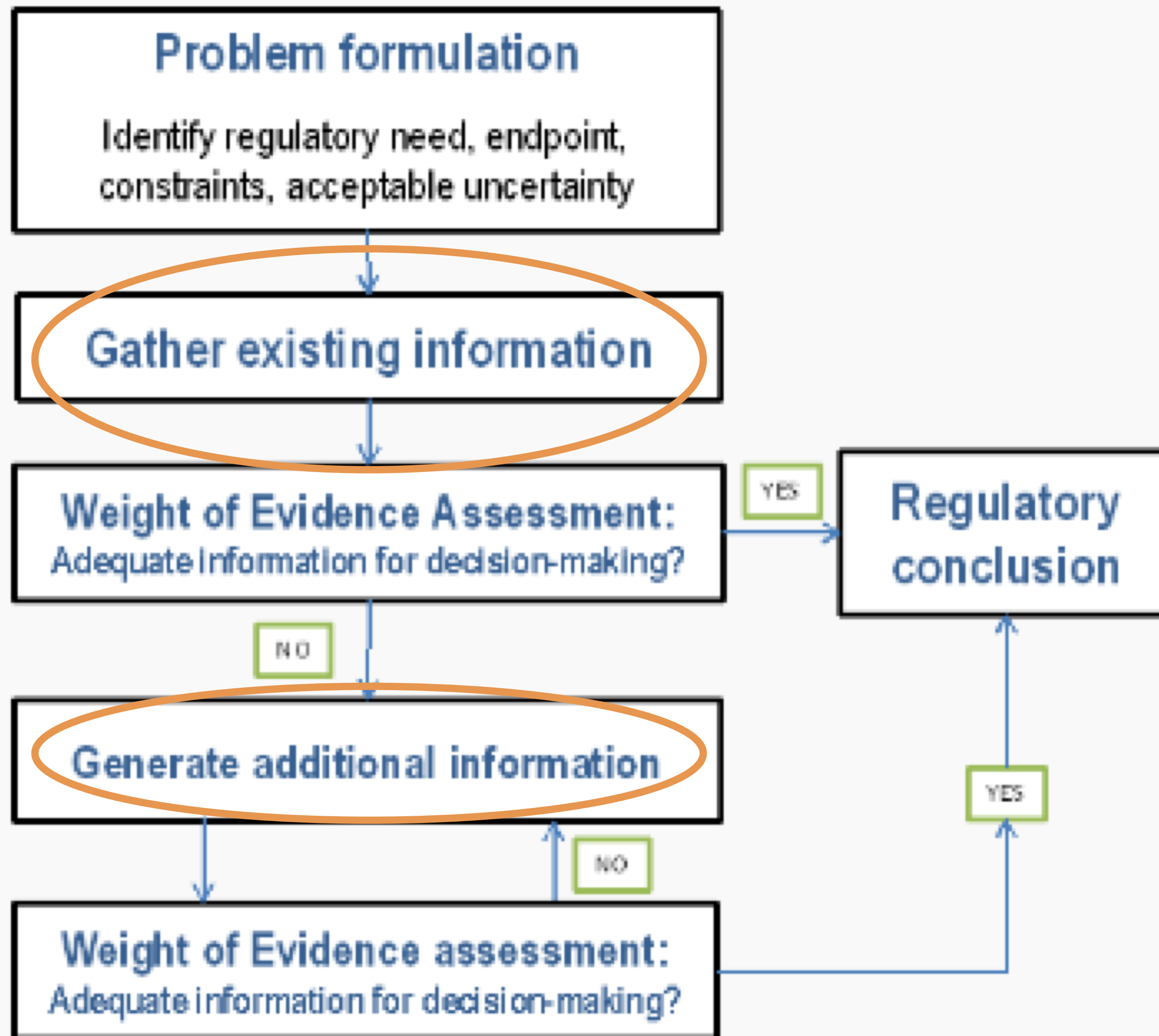


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# Setting the Stage



# “IATA”



- Test Guidelines
- “Non-guideline” methods
- Integrated Testing Strategies
- QSARs
- Defined Approaches

<http://www.oecd.org/chemicalsafety/risk-assessment/iata-integrated-approaches-to-testing-and-assessment.htm>



# New Approach Methodologies in Regulatory Science

Proceedings of a scientific workshop

Helsinki, 19–20 April 2016

# “NAMs”

“NAMs were taken in a broad context 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. They also include a variety of new testing tools, such as “high-throughput screening” and “high-content methods” e.g. genomics, proteomics, metabolomics; as well as some “conventional” methods that aim to improve understanding of toxic effects, either through improving toxicokinetic or toxicodynamic knowledge for substances.”



# NAMs build IATAs

“For the purposes of TSCA, EPA recognizes this new term (i.e., NAMs) as encompassing any ‘alternative test methods and strategies to reduce, refine or replace vertebrate animals.’”

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



# NAMs and Chemical Evaluation

OECD implementing IATA and Defined Approaches into  
Test Guidelines Programme

NAMs integral to achieving goals of the Lautenberg Act



# NAMs and Chemical Evaluation

TSCA Sec 4(h): “IN GENERAL —The *Administrator shall reduce and replace*, to the extent practicable, scientifically justified, and consistent with the policies of this title, *the use of vertebrate animals in the testing of chemical substances or mixtures under this title*”

15 U.S.C. §2603(h)

# Other Key Principles

Language regarding reducing and replacing vertebrate testing applies to *required* and *voluntary* testing

Flexible, risk-based process

Exposure considerations should inform testing

“Data” has become “information”

Methods and approaches not limited to validated OECD Test Guidelines or to methods on list EPA develops with strategic plan



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# Implementation





**United States  
Environmental Protection Agency**

**EPA Document# EPA-740-R1-8004**

**June 22, 2018**

**Office of Chemical Safety and  
Pollution Prevention**

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

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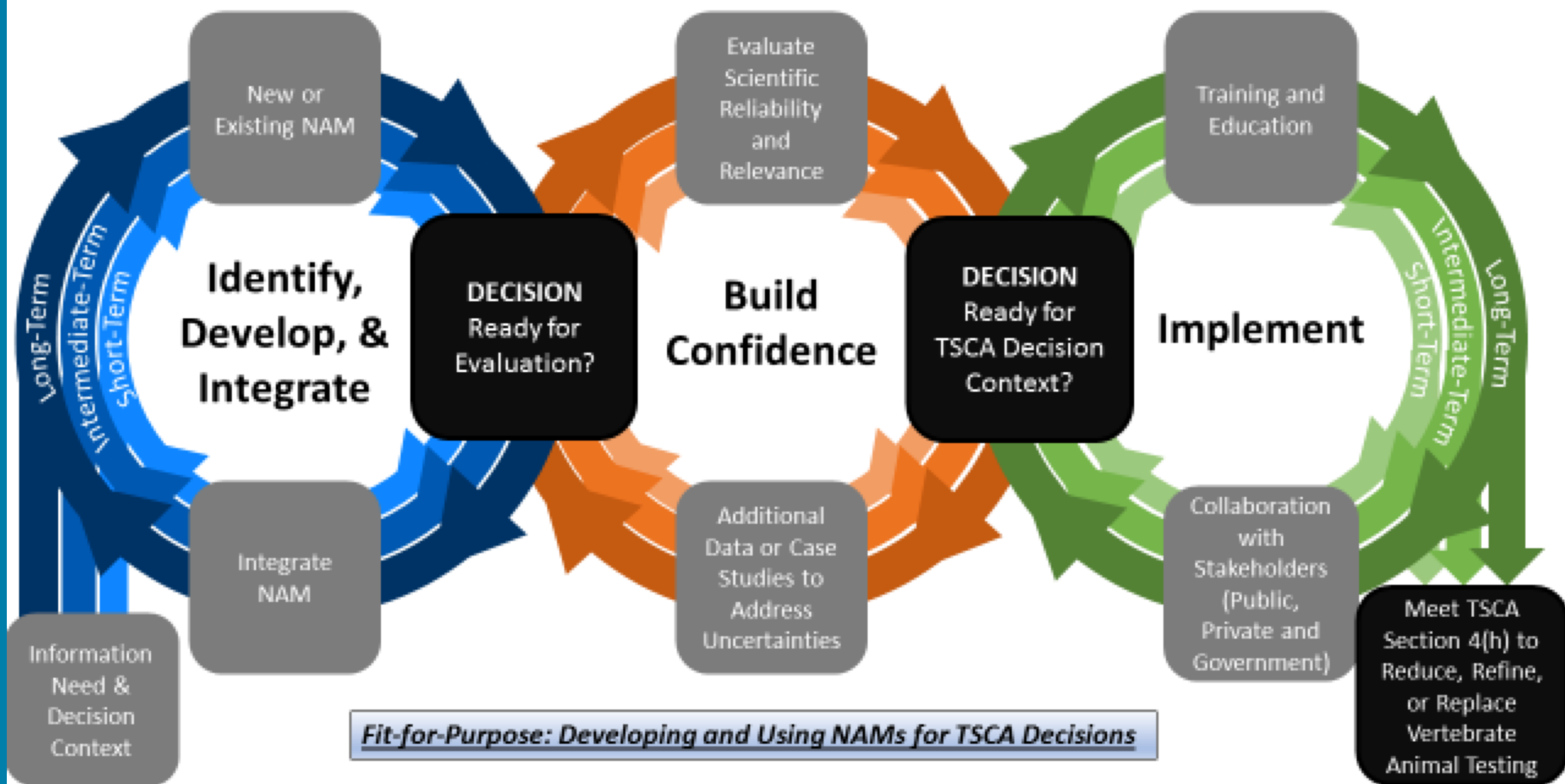
## **List of Alternative Test Methods and Strategies (or New Approach Methodologies [NAMs])**

**June 22, 2018**

<https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/strategic-plan-reduce-use-vertebrate-animals-chemical>



Fig. 1 Core Components of EPA Strategic Plan to Develop and Implement New Approach Methodologies (NAMs) in TSCA



# Policies & Activities Impact NAMs

Use and exposure:

- Potential use scenarios
- Biological exposure?

Statement of need

OPPT partnering with ICCVAM and EPA OPP to apply NAMs for skin sensitization, inhalation



# External Factors

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- Funding, involvement of scientific community, funding agencies
- Application by industry
- Budgetary considerations
- Public engagement
- Agencies in other regions or the states—  
data availability, NAM acceptance, in vivo requirements



# NGO Contributions

- Training and Workshops
- Funding for AOP and method development
- Information sharing, scientific support
- Public Comments
- Engagement/Education of public





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Looking Ahead



# Transparency & Information

- ChemView or similar systems
- EPA information needs
- EPA and Industry successes and challenges



# Research and Development

- Government incentivizes targeted AOP Development
- Agency clear about what it needs and where development energy is best spent
- Academia develops science with application in mind; adds data to AOP Wiki; trains toxicology students

# Uptake and application

- Industry truly prioritizes uptake of NAMs
- Agency incentivizes exploration and application of NAMs
- Cooperative and open case studies



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