



# **Developing the Strategic Plan to Reduce, Refine or Replace Vertebrate Animal Testing Under the Amended TSCA**

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# Topics Covered

- General Overview of New Law
- Section 4(h) of New TSCA - Alternative Testing Methods
- Developing the Strategic Plan

# The New Law

- “The Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act”
  - Amends and updates the Toxic Substances Control Act (TSCA)
  - Signed by the President on June 22, 2016
  - Effective immediately
- Significance
  - First update to TSCA in 40 years (1976)
  - Passed with overwhelming bipartisan support in both the U.S. House (403 to 12) and Senate (unanimous)
  - Received support from chemical industry and downstream users of chemicals, NGOs, and other stakeholders

# Some Changes Related to...

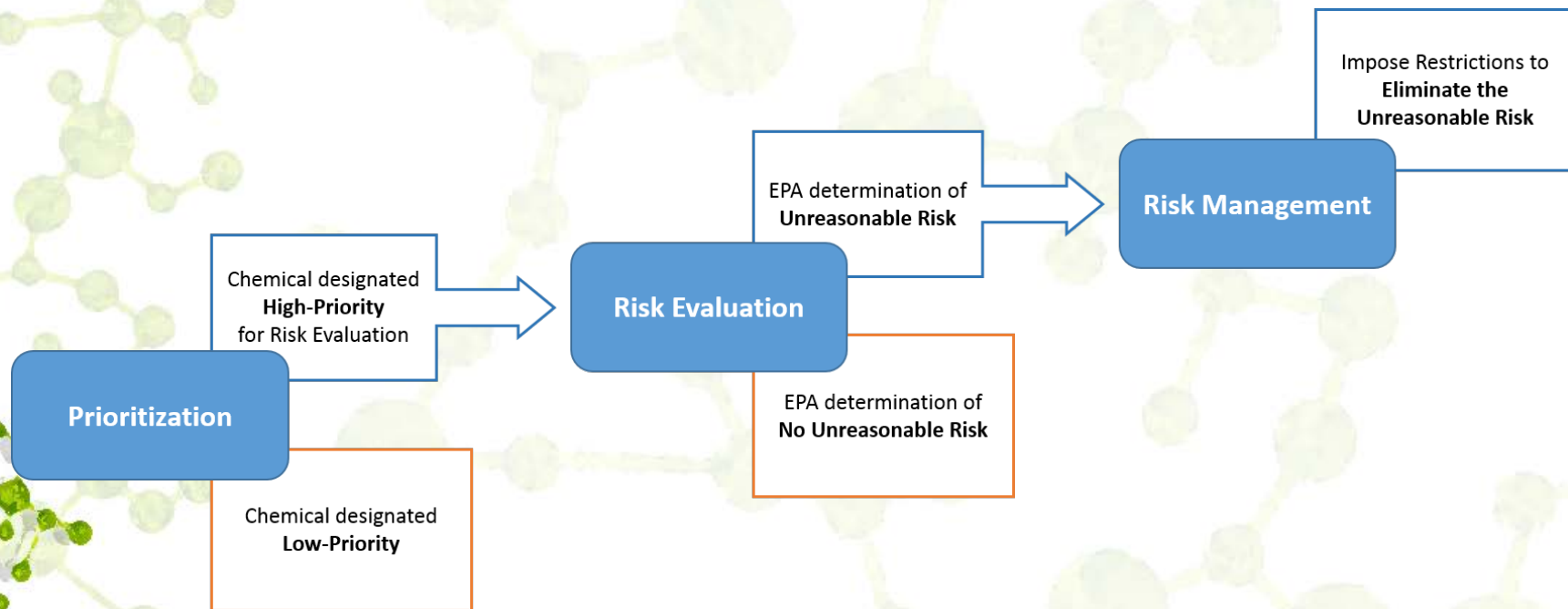
- NEW CHEMICALS:
  - Requires EPA to review and make a determination regarding risk of injury to health or the environment for new chemicals or significant new uses of existing chemicals
- EXISTING CHEMICALS:
  - Mandatory duty on EPA to evaluate existing chemicals – clear and enforceable deadlines
  - Chemicals assessed without consideration of costs or other non-risk factors
  - Must consider risks to potentially exposed or susceptible subpopulation



# Evaluating Risks of New Chemicals

- Premanufacture Notice (PMN) submitted
  - No data requirements
- If no hazard information provided:
  - Use analog(s), category/read-across analyses, In silico predictions (e.g., OncoLogic for cancer in humans and ECOSAR for ecological receptors)
- Determine exposure pathways and scenarios
- Make one of the following findings pertaining to risk of injury to human health or the environment (TSCA Section 5(a)(3)):
  - Presents a risk
  - Insufficient information to make a risk finding
  - Not likely to present a risk
- May ask for hazard information...

# Evaluating Risks of Existing Chemicals



# Section 4(h) and Amended TSCA

Section 4(h)(1) - “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...”

# Section 4(h) and Amended TSCA

Section 4(h)(1) goes on to say that

“...prior to making a request or adopting a requirement for testing using vertebrate animals.....taking into consideration ....reasonably available existing information, including:

- i. Toxicity information;
- ii. Computational toxicology and bioinformatics; and
- iii. High-throughput screening methods and the prediction models of those methods; and

Encouraging and facilitating –

- i. The use of scientifically valid test methods and strategies that reduce or replace the use of vertebrate animals while providing information of equivalent or better scientific quality.....;
- ii. The grouping of 2 or more chemical substances into scientifically appropriate categories.....; and
- iii. The formation of industry consortia to jointly conduct testing to avoid unnecessary duplication of tests...”



# Section 4(h) and Amended TSCA

*And, for voluntary testing (that is, not asked for or required by the Administrator) –*

Section 4(h)(3)(A) – “Any person developing information for submission...shall first attempt to develop the information by means of an alternative test method or strategy...”

*Thus, whether EPA asks for information or someone volunteers the information, the 3Rs need to be considered*

# Requirement for Development of a Strategic Plan Under Section 4(h) of Amended TSCA

Section 4(h)(2)(A) – “...not later than 2 years after the date of enactment....develop a strategic plan to **promote the development and implementation of alternative test methods and strategies** to reduce, refine, or replace vertebrate animal testing **and provide information of equivalent or better scientific quality and relevance for assessing risks of injury to health or the environment...**” (by June of 2018)

# The Next Few Slides will be on the Approach to the Strategic Plan

*The intent of Section 4(h) is clear – to develop and use methods and strategies that will not require the use of vertebrate animal testing to evaluate chemical substances or mixtures in the United States under TSCA.*

Goals, Objectives, Other Points...

# DRAFT Goals

The following four goals have been identified to meet both the requirements and the intent of the amended TSCA:

1. To *reduce and replace the use of vertebrate animals* in testing chemical substances or mixtures under TSCA.
2. To *use Integrated Approaches to Testing and Assessment (IATA) as the principle method* for evaluating and regulating new and existing chemicals under TSCA.
3. To *collaborate* with stakeholders inside and outside government, and domestically and internationally, *to develop and implement alternative methods and strategies that will increase the efficiency* of evaluating and regulating new and existing chemicals under TSCA.
4. To *inspire industry scientists and regulators* to develop and use alternative test methods and strategies *with confidence to protect public health and the environment.*



# DRAFT Objectives

To meet these goals, the following objectives have been identified:

1. *Engage with stakeholders and the public as the Strategic Plan is being developed, and to overcome challenges and use available opportunities to achieve the objectives further outlined below.*
2. *Meet the requirements of the law by collaborating with stakeholders and domestic/international partners to:*
  - a. *Compile a list of alternative methods and strategies to assess the safety of chemicals in the U.S. (Section 4(h)(2)(C)). There are several lists available to use as a starting point.*
  - b. *Develop criteria for the scientific reliability and relevance of the alternative methods and strategies in 2(a) above (Section 4(h)(2)(D)).*
  - c. *Accelerate the development of alternative methods and strategies (Section 4(h)(2)(F)).*
  - d. *Accelerate the use/application of the alternative methods and strategies..*

# DRAFT Objectives

3. *Enhance EPA staff training* to understand and use alternative methods and strategies identified and presented in the Strategic Plan.
4. *Identify measures of success* for meeting the objectives/goals outlined herein.
5. *Communicate* with stakeholders and the public throughout the process.

# Legal Requirements for Developing Strategic Plan

- Requirement for list of methods and strategies (Section 4(h)(2)(C))
- Criteria for considering scientific reliability and relevance (Section 4(h)(2)(D))
- Prioritize and carry out performance assessment, validation and translational studies to accelerate the development of alternative methods/strategies (Section 4(h)(2)(F))

# Other Points for Developing Strategic Plan

- Context – new vs. existing chemicals (i.e., data-poor vs. data rich)
  - New Chemical Assessments, Prioritization, Risk Evaluation
- Vertebrate animals
  - Would include ecological test species (i.e., fish, birds)
- “...provide information of equivalent or better quality and relevance for assessing risk of injury...”
- Develop new scientifically valid methods and strategies



# Draft Timeline for Development of Strategic Plan

June – November, 2017  
Create draft, solicit Ideas

November, 2017  
Information-Gathering Discussions,  
Public Meeting

December, 2017 – April, 2018  
Complete first draft

April – May, 2018  
Finalize Plan

Post by June 22, 2018

# Collaboration

## *In the US Government:*

- **Within EPA** – Office of Research and Development, Office of Pesticide Programs, Office of Science Coordination and Policy (Endocrine Program)
- **EPA Grants** – NCER program/STAR grants on alternative methods (awarded before the new law)
- **Interagency Coordinating Committee for Validation of Alternative Methods (ICCVAM): Sixteen federal agencies**
- **Other** – NIH (including NTP, NICEATM, Tox21)

# Collaboration

## Outside of US Government:

- **Industry** – Regulated community, CROs,
- **NGOs** - “traditional”, think tanks, animal welfare organizations
- **International** – EU, Canada, OECD, others
- **Academics**
- **Professional organizations** – SOT, ASCCT

# Importance of Collaboration

*With the amended TSCA requirement to develop and implement the use of alternative test methods in risk assessments, EPA is reaching out – and considering – all ideas/stakeholders as it builds this new paradigm...*

THANK YOU!