Implementation of TSCA Amendments

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Lautenberg Chemical Safety Act

In June of 2016, a bipartisan majority of Congress passed and President Obama signed the Lautenberg Chemical Safety Act (LCSA).

LCSA significantly amended the U.S. Toxic Substances Control Act (TSCA), which was originally enacted in 1976.

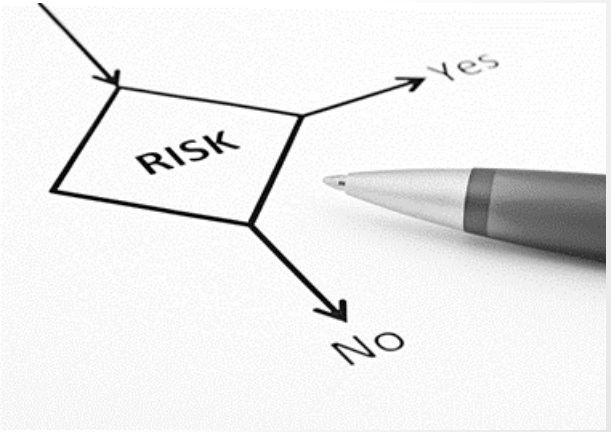
Amended TSCA: Existing Chemicals

Re-set the TSCA Inventory of chemicals in commerce

Identify high priorities and low priorities for risk evaluations

Conduct risk evaluations of high priority chemicals

If chemical presents unreasonable risk under conditions of use, develop risk management rule



Amended TSCA: New Chemicals

- Pre-manufacture notification
- Risk-based review
- Affirmative determination of safety

https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca

A More Efficient System with Deadlines

EPA identifies first 10 chemicals to undergo risk evaluations

December 2016

June 2017

EPA must have risk evaluations underway for at least 20 chemicals

December 2019

EPA establishes rules for:

- Chemical manufacturers to notify EPA of active chemicals
- Identification of low and high priority chemicals
- Risk evaluation process for high priority chemicals
- Establishment of Science Advisory Committee on Chemicals

More Statutory Deadlines

90 days: Once manufacturer submits info about a new chemical to EPA, within 90 days the Agency must determine safety or that information is insufficient (EPA can request more information)

3.5 Years: Once EPA begins risk evaluation of a high priority chemical, it must complete the evaluation within 3.5 years

2 Years: Once EPA determines chemical presents unreasonable risk, it must finalize risk management measures within 2 years (with possibility for extension)

Summary of EPA Implementation Actions

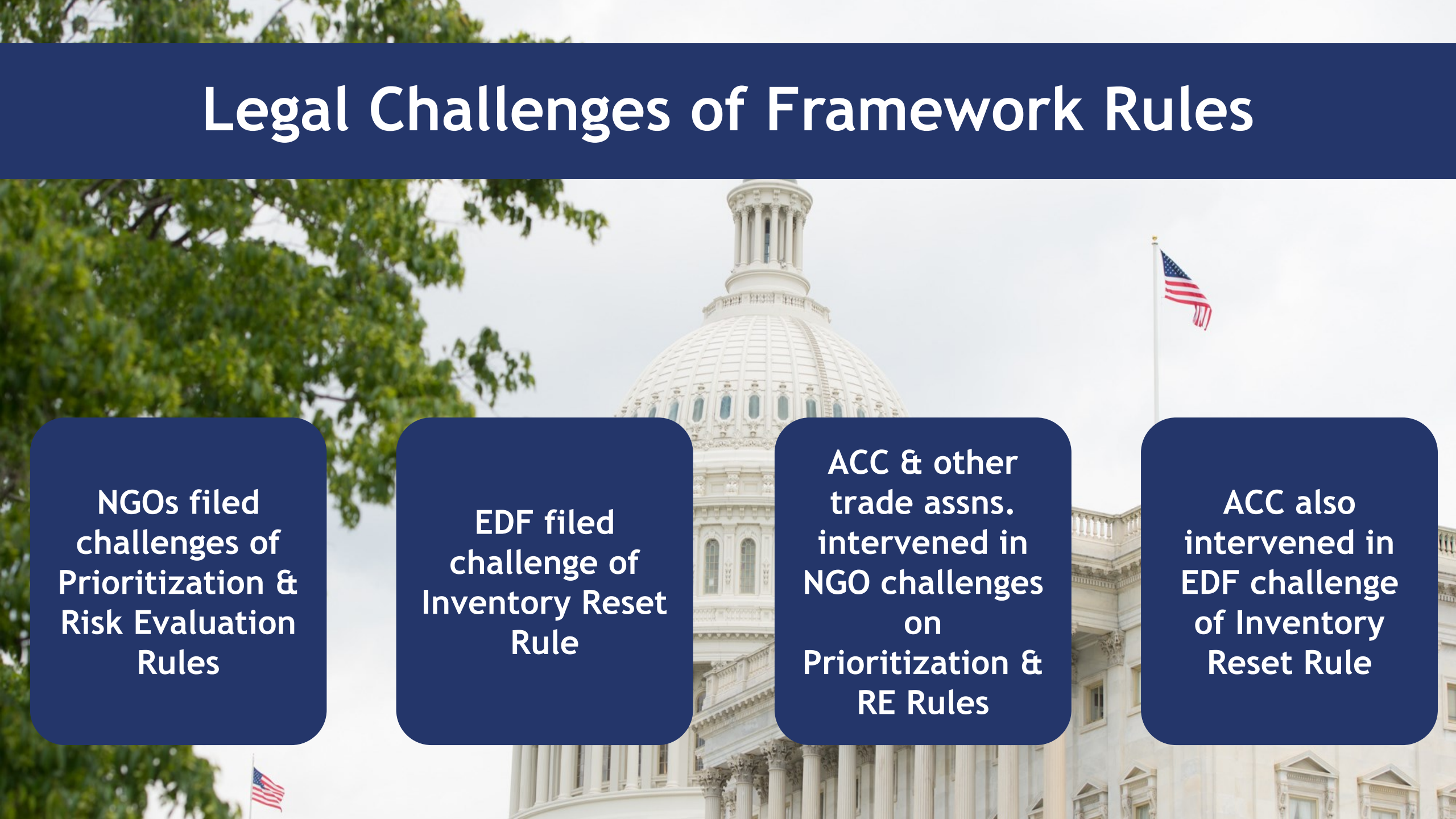
- ✓ Final Inventory Reset, Prioritization, and Risk Evaluation Rule
- ✓ Risk evaluation guidance
- ✓ Scopes of 1st 10 Risk Evaluations
- ✓ New Chemicals backlog substantially reduced
- ✓ New Chemicals “not likely to present unreasonable risk” website
- ✓ CBI substantiation requirements
- ✓ Risk management rulemakings in progress
- ✓ Inventory re-set process underway (Feb. 8 and Oct. 5 deadlines)


What’s Next?

On the Horizon

- ✓ Strategy for Alternatives to Animal Tests
- ✓ Science Advisory Committee on Chemicals (SACC)
- ✓ Fees Rule
- ✓ Nomenclature
- ✓ Mercury Export Ban
- ✓ PBTs: Expedited Action

Legal Challenges of Framework Rules



NGOs filed challenges of Prioritization & Risk Evaluation Rules

EDF filed challenge of Inventory Reset Rule

ACC & other trade assns. intervened in NGO challenges on Prioritization & RE Rules

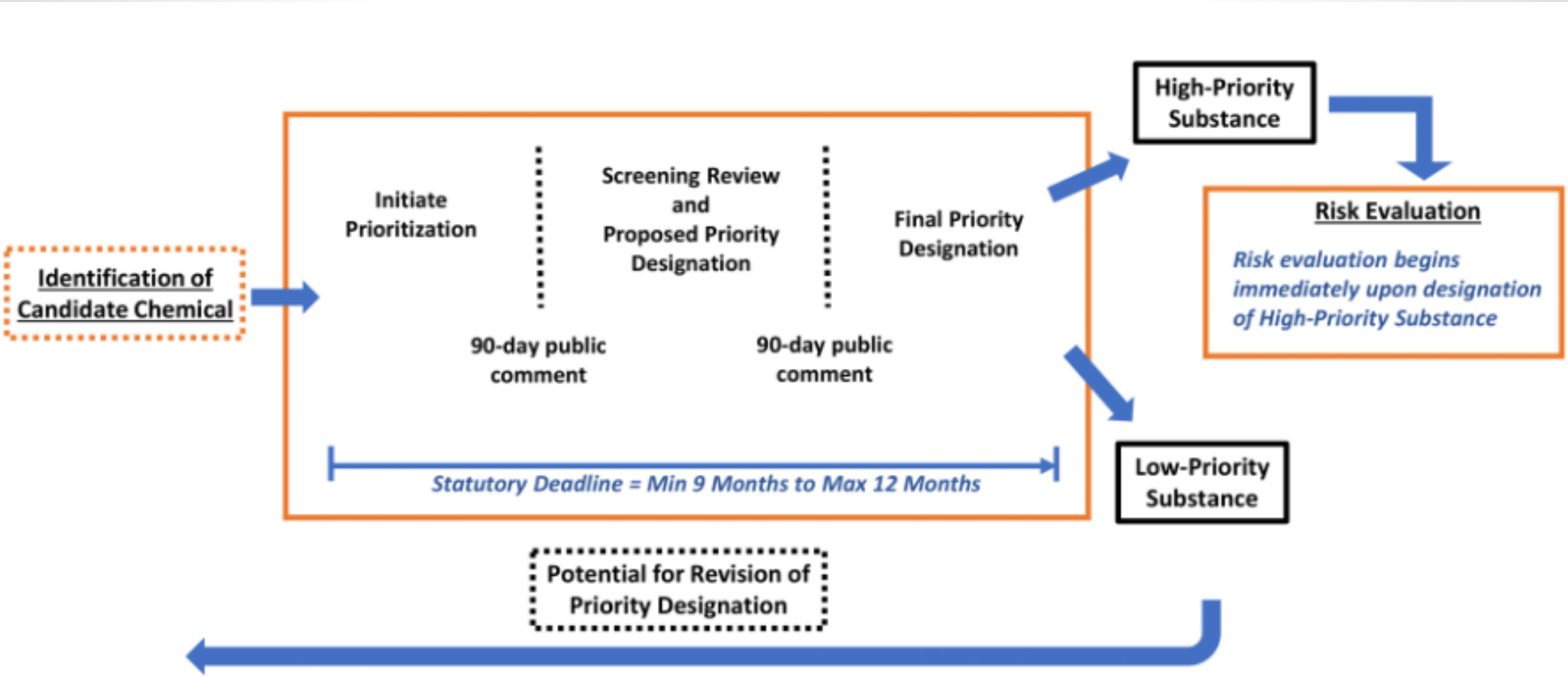
ACC also intervened in EDF challenge of Inventory Reset Rule

New Chemicals

- Pilot project on pre-submission consultation
- New ACC consortium to provide input on EPA's development of category approaches to certain Pre-Manufacture Notification (PMN) submissions
- Possible NGO challenge to implementation of new chemical review program?

https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/chemicals-determined-not-likely

Prioritization Process



https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/prioritizing-existing-chemicals-risk-evaluation

Risk Evaluations

- Initial 10 chemicals will be first risk evaluations conducted
- EPA will identify conditions of use for the risk evaluations on case-by-case basis
- In initial 10, conditions of use will be addressed in problem formulations for each risk evaluation
- Reasonably foreseen conditions of use: probable, not “possible”
- Importance of information on uses and potential exposures from downstream value chain

Lautenberg Chemical Safety Act

A More Effective Way to Regulate Chemicals

EXISTING CHEMICALS

EPA will conduct risk-based reviews of chemicals in commerce

Inventory Reset

EPA maintains an inventory of chemicals, but it is difficult to tell which are used today and which are no longer in use

LCSA requires the inventory be updated so EPA can focus on chemicals actually in use today

Prioritization

EPA will screen all chemicals in active use to identify low and high priorities for risk evaluation. Prioritization will be based on factors including hazards, uses and exposures to people and the environment, including vulnerable groups like infants, children, pregnant women and the elderly

Low Priority Chemicals

Chemicals can remain in use but can be reprioritized based on new information

High Priority Chemicals

EPA will conduct a thorough risk evaluation

The first 10 high priorities must be drawn from EPA's existing TSCA Chemical Work Plan list

Risk Evaluation

EPA Risk Evaluations will:

- Be based solely on health and environmental information
- Consider a chemical's conditions of use
- Rely on the best available studies and weight of scientific evidence
- Consider risks to vulnerable groups

LCSA makes it easier for EPA to request more testing and data from producers when needed

20 risk evaluations must be underway within 3.5 years

Safety Determination

EPA will determine if a chemical meets the law's safety standard or requires risk management

Chemical Meets Safety Standard

Chemical may be used for its intended uses

Chemical Needs Risk Management

EPA's options include:

- Labeling Requirements
- Use Restrictions
- Phase Outs
- Bans

NEW CHEMICALS

EPA must conduct a risk-based review and make an affirmative safety determination before a new chemical can come to market

Information Submitted to EPA

Manufacturers provide information about new chemicals and new chemical uses to EPA

Risk-Based Review

EPA reviews information including chemical characteristics, available testing and exposure data and intended uses

EPA can request more information if needed

Safety Determination

If EPA finds the chemical is not likely to present an unreasonable risk, it proceeds to market
If the chemical presents an unreasonable risk, EPA may apply risk management measures

Resources

LCSA Language (link)

LCSA Fact Sheet (link)

Frequently Asked Questions (link)

LCSA Video (link)

Infographic of Chemical Review Process (link)

ACC's Principles for Improving Chemical Hazard and Risk Assessment (link)