TOXIC SUBSTANCES CONTROL ACT:
EPA IMPLEMENTATON

Society for Chemical Hazard Communication
September 25, 2018

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The New Law

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

The New Law

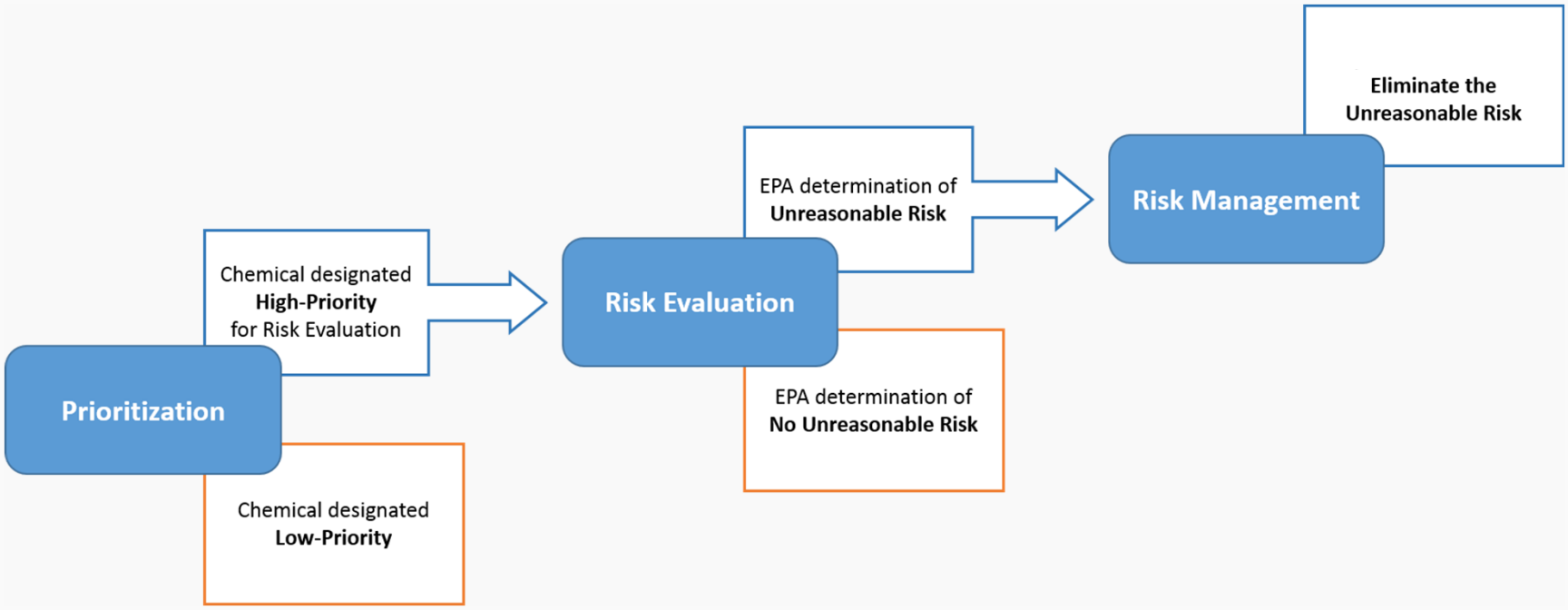
- Requires EPA to promulgate a number of rules (collectively, the “Framework Rules”) to set up the procedures EPA will use to implement, and otherwise align, EPA’s chemical management program with the new requirements and responsibilities in the law:
    - Fees Rule*
    - Active/Inactive Inventory Reporting Rule
    - Prioritization Rule
    - Risk Evaluation Rule

*No statutory deadline for Fees Rule

TSCA Inventory for Active/Inactive Chemicals

- Industry must report on the chemicals they manufactured, and may report on chemicals they processed, in previous 10 years
    - Chemicals will be designated as *active* or *inactive*
- Final rule signed June 22, 2017
- The reporting period for manufacturers (includes importers) ended on February 7, 2018.
- The reporting period for processors ends on October 5, 2018.

Evaluating Risks of Existing Chemicals



The New Law
Changes Related to Existing Chemicals

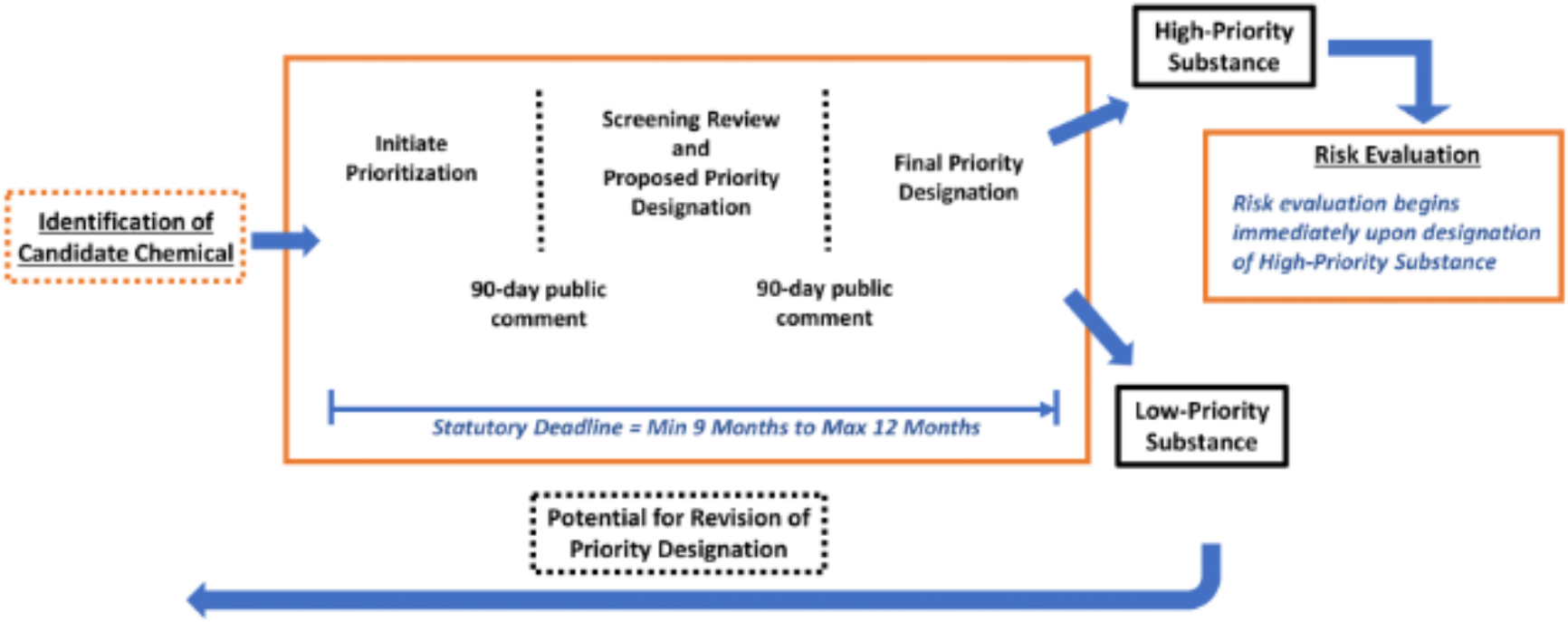
- Mandatory duty on EPA to evaluate existing chemicals – clear and enforceable deadlines
- Chemical assessment is risk-based; without consideration of costs or other non-risk factors
- Persistent, Bioaccumulative and Toxic Chemicals: Fast-track to address certain PBT chemicals already on TSCA Work Plan
- Must consider risks to potentially exposed or susceptible subpopulations identified as relevant to the evaluation
- Unreasonable risks identified in risk evaluation must be addressed
- Expanded authority to more quickly require development of chemical information when needed

Prioritization

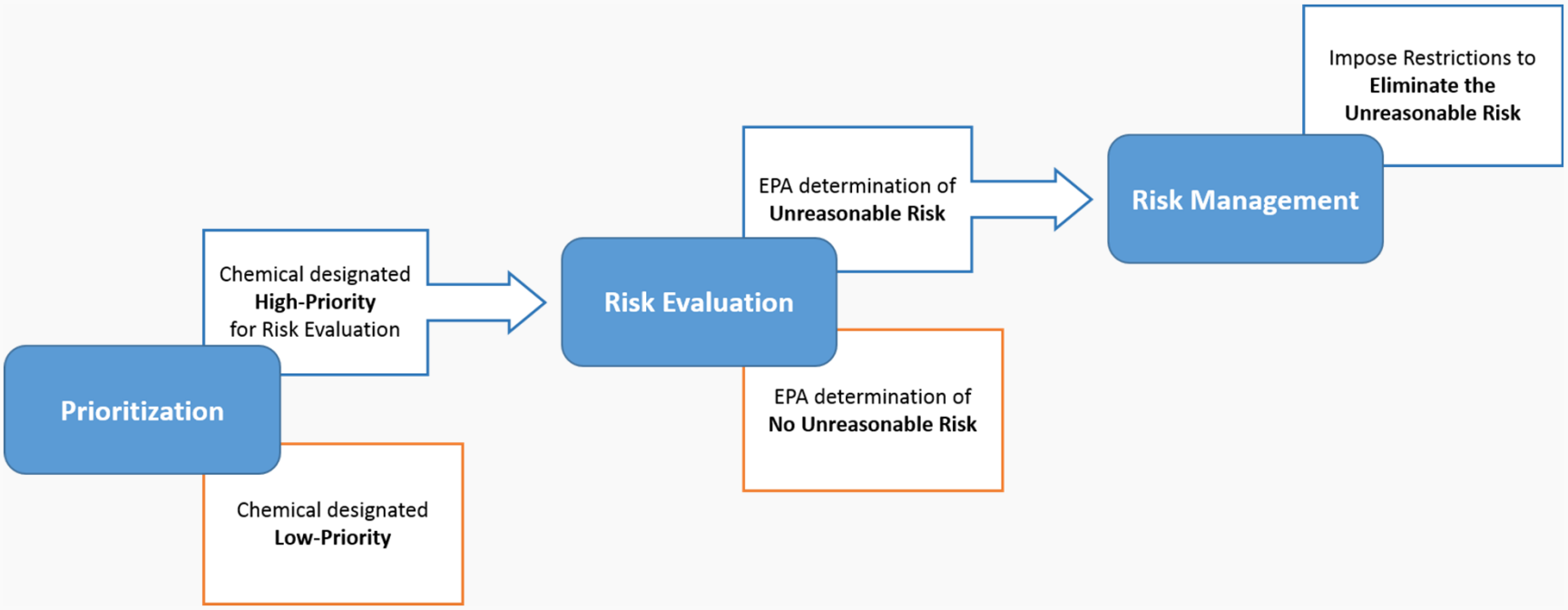
Statutory Requirements

- EPA must establish a risk-based screening process and criteria for designating a chemical substance as either:
  - High-Priority Substance, OR
  - Low-Priority Substance
- Some parts of process and criteria specified in TSCA:
  - Steps and timeframes in the process
  - Definitions for High- and Low-Priority Substances
  - Preferences for certain TSCA Work Plan chemicals
  - Criteria against which chemicals must be screened (e.g., Hazard, Exposure, Persistence, Bioaccumulation, Toxicity, Cancer)

Prioritization Process and Timeline



Evaluating Risks of Existing Chemicals



Risk Evaluation
Statutory Requirements

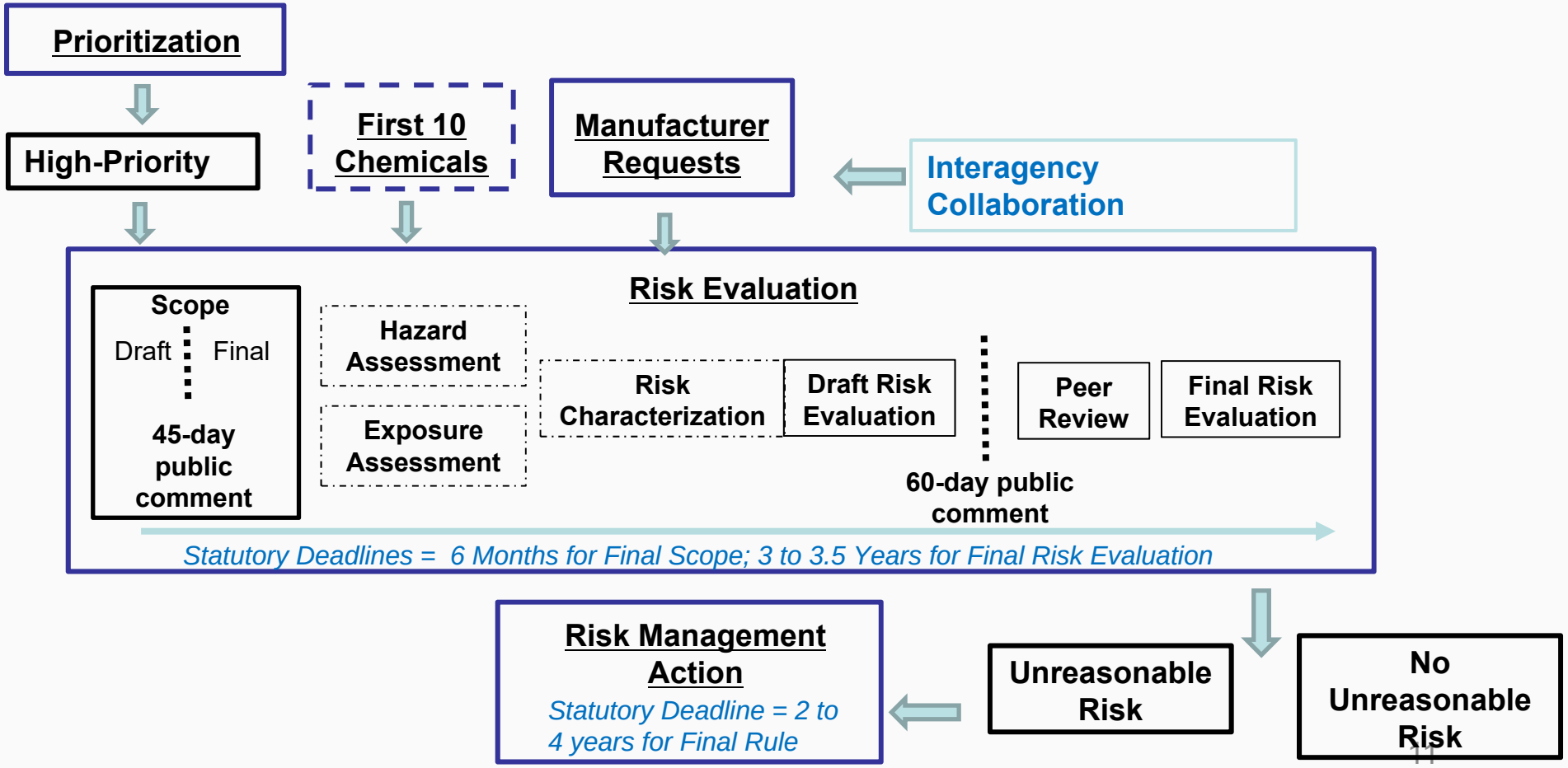
- **First 10** Chemicals for Risk Evaluation – Announced December 19, 2016

- **Scope** –Publish within 6 months of initiation – Published June 22, 2017
  - Must identify hazards, exposure, conditions of use, potentially exposed or susceptible subpopulation(s) the EPA expects to consider

- **Draft Risk Evaluation** – Integrate and assess available information on hazards and exposures for the conditions of use
  - Hazard Assessment – identification of types of hazards to human health and/or the environment
  - Exposure Assessment – account for the duration, intensity, frequency, and number of exposures under the conditions of use; Describe whether aggregate or sentinel exposures were considered, and the basis
  - Risk Characterization – integration of hazards and exposure into estimates of risk
  - Determination of Unreasonable Risk – does or does not present an unreasonable risk
  - Peer review – all evaluations will be peer reviewed
  - Publish in Federal Register and 30 day public comment period

- **Final Risk Evaluation**
  - Complete within 3 years of initiation; with potential 6 month extension
  - Publish in Federal Register

Risk Evaluation Process and Timeline



Condition of Use

- Means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, use, or disposed of.
    - EPA generally does not view uses that are legacy uses and intentional misuse (e.g., purposeful inhalation) as conditions of use
- Statutory language for scope includes "that the Administrator expects to consider"
    - EPA may exclude from an individual risk evaluation some activities that are conditions of use (e.g., *de minimis* use that presents low risk)
- Risk determinations – A risk determination will be made for each use EPA includes in the risk evaluation
    - EPA may make early determinations on use(s) once statutory and regulatory requirements for a risk evaluation, including a peer review, are fulfilled

Best Available Science

- ***Best available science*** – science that is reliable and unbiased. Use of best available science involves the use of supporting studies conducted in accordance with sound and objective science practices, including, when available, peer reviewed science and supporting studies and data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data)
  - Additionally, EPA will consider as applicable:
    - The extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are **reasonable for and consistent with the intended use of the information**
    - The extent to which the information is **relevant for the Administrator's use in making a decision** about a chemical substance or mixture
    - The degree of **clarity and completeness** with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented
    - The extent to which the **variability and uncertainty** in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized
    - The extent of **independent verification or peer review** of the information or of the procedures, measures, methods, protocols, methodologies, or models

Weight of the Scientific Evidence

- Means a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance
  - Consistent with legislative history
  - EPA did not codify definition of “systematic review”

Systematic Review

"is a scientific investigation that focuses on a specific question and uses explicit, pre-specified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. The goal of systematic review methods is to ensure that the review is complete, unbiased, reproducible, and transparent" (Institute of Medicine)

Key Elements of a systematic review:

- A clearly stated set of objectives (defining the question);
- Developing a protocol which describes the specific criteria and approaches that will be used throughout the process;
- Applying the search strategy criteria in a literature search;
- Selecting the relevant papers using predefined criteria;
- Assessing the quality of the studies using predefined criteria;
- Analyzing and synthesizing the data using the predefined methodology;
- Interpreting the results and presenting a summary of findings

Initial 10 Risk Evaluations

- The list of the initial 10 chemicals was published on Dec. 19, 2016

1, 4 Dioxane
1-Bromopropane
Asbestos
Carbon Tetrachloride
Cyclic Aliphatic Bromide Cluster (HBCD)
Methylene Chloride
N-Methylpyrolidone
Pigment Violet 29
Trichloroethylene
Tetrachloroethylene

- Scope documents published June 22, 2017
- Problem Formulation documents published June, 2018
- Risk evaluations must be final by December 2019

Next-Phase of Implementation Actions
(Through Jan., 2020)

Risk Evaluations

- November 2018 – Spring 2019 – EPA will publish draft risk evaluations for the first 10 chemicals
  - Public Comment
  - Peer Review
- December 2019 – EPA will have completed the risk evaluations on the first 10 chemicals

Prioritization

- By December 2019 – EPA must
  - Have 20 chemicals designated as high-priority undergoing risk evaluation
  - Have 20 chemicals designated as low-priority (no risk evaluation at this time)

Manufacturer Requests

"The Administrator shall conduct and publish risk evaluations […] that a manufacturer of the chemical substance has requested, in a **form and manner** and using the **criteria** prescribed by the Administrator"

- **Conditions of use** – Manufacturers may request a risk evaluation for only uses of interest. EPA will identify other conditions of use that warrant inclusion in the risk evaluation.

Persistent, Bioaccumulative, and Toxic Chemicals

- Statute requires a fast-track process for certain PBT chemicals
- Use and exposure assessment required; No formal risk evaluation
- Rules to reduce exposure, to the extent practicable, must be proposed by June 2019 and finalized 18 months later
- Status
  - 5 chemicals will get expedited action based on use and exposure assessments for these chemicals.
    - Decabromodiphenyl ether (DecaBDE)
    - Hexachlorobutadiene (HCBD
    - Pentachlorothiophenol (PCTP)
    - Phenol, isopropylated, phosphate (3:1)
    - 2,4,6-Tris(tert-butyl) phenol

TSCA: New Chemicals

TSCA Section 2(b)(3):

- Authority over chemical substances and mixtures should be exercised in such a manner ***as not to impede unduly or create unnecessary economic barriers to technological innovation***

- While fulfilling the primary purpose of this Act to assure that such innovation and commerce in such chemical substances and mixtures ***do not present an unreasonable risk of injury to health or the environment.***

The New Law

Changes Related to New Chemicals

- New law requires EPA to make an *affirmative finding* on new chemicals or significant new uses of existing chemicals, before those chemicals can enter the market

- Chemicals under review at time of enactment were considered "resubmitted" and review period restarted; additional notices continued to come in, resulting in the need to re-review and "backlog"

- Current focus is to continue to improve processes to meet new requirements in law

Overview of New Chemicals Program

TSCA Section 5:

New Chemicals program functions as a “gatekeeper” to help manage the potential risk to human health and the environment from chemicals new to the marketplace

- Anyone who plans to manufacture (or import) a new chemical substance must provide EPA with notice - a Premanufacture Notice (PMN)
- EPA must review and evaluate new chemicals (or significant new uses of existing chemicals) and make an affirmative finding before those chemicals can enter the market
- Review must be completed within 90 days, with ability to extend 90 days
- If risks are identified, EPA must impose restrictions or prohibitions on the manufacturing, processing or use of the chemical to ensure the risks are mitigated

New Chemical Assessments

- New chemicals determinations are made using a risk-based approach, taking into account both hazard and exposure, under the substance's conditions of use (intended, known and reasonably foreseen).

- EPA assesses health and environmental hazards and exposures to:
  - multiple populations of humans: workers, consumers and general population, including susceptible subpopulations, e.g. different age groups of the general population)
  - the environment (e.g., primarily aquatic environment).

- Data required to be submitted with a new chemical (PMN) under TSCA is limited:
  - Details about how the chemical with be manufactured, processed and used
  - Only test data (e.g., fate tests, toxicity tests, etc.) that already exists; no new testing is required to be conducted for the submission.

- Therefore, EPA relies on predictive assessment methods, databases, and tools and models to evaluate chemicals throughout their lifecycle, i.e., manufacture, processing, distribution, use and disposal.

Computational Tools Used Routinely

Analogs & Categories

P-Chem and Fate

Aquatic Toxicity

Carcinogenicty

Non-Cancer Effects

Exposure Potential

AIM/ChemACE

EPISuite

PBT Profiler

ECOSAR

OncoLogic

Analogs

E-FAST

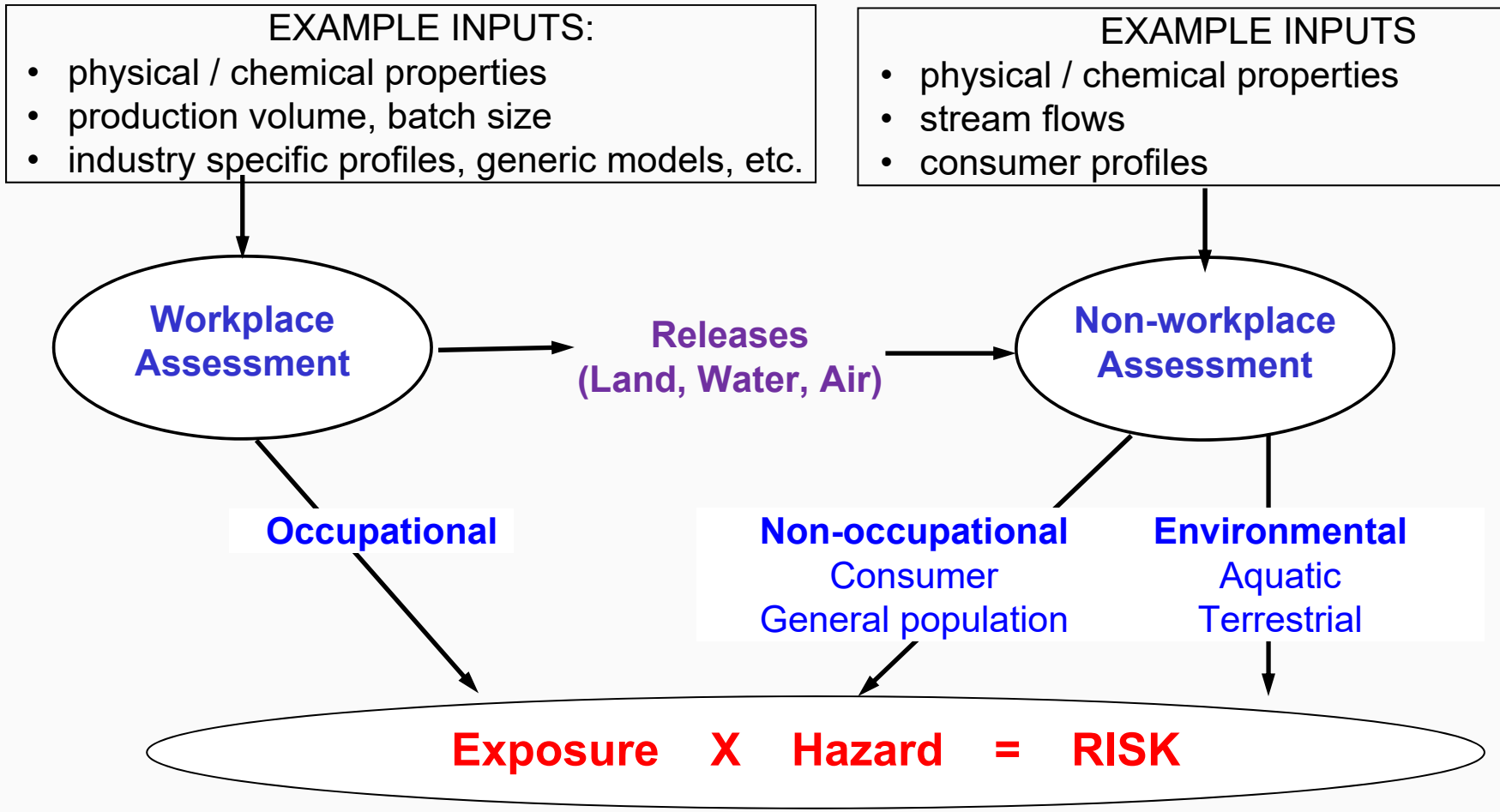
ChemSTEER

Chemical Assessment

New Chemical Submission Review

- Chemical Review/Search Strategy
  - Physical Chemical Properties
  - Conditions of Use Identified
- Structure Activity Team (SAT)
  - Conditions of use, p-chem, fate, health hazard, eco hazard information considered
  - Determine whether/what scope of exposure assessment to conduct (e.g., occupational, general population, consumers, environment)
- Develop Exposure/Release Assessments
  - Based on modeling using well known/publicly available models
  - Exposure scenarios for occupational (ESDs), general population, and consumer exposures
  - Both default (reasonable worst-case; upper-end; typical) and case-specific (if provided in PMN) input parameters
  - All exposure pathways/routes may not be assessed quantitatively
- Initial Risk Management Preliminary Decision Meeting
  - Conditions of use, environmental fate, exposure, health & eco hazard and initial risk estimates presented
  - Assessment adequate or “Standard Review” Needed?
- Further Assessment (if needed) – “Standard Review”
  - Full Life-cycle assessment – all exposure pathways/populations scoped at SAT
- Final Risk Management Decision

New Chemical Risk Assessment



Approach to Making Determinations

- "Intended Conditions of Use"
  - The circumstances of manufacture, processing, distribution in commerce, use, or disposal, as stated in the submission, including any identified conditions or controls
  - Timely written amendments from submitter become the intended conditions of use
- "Reasonably Foreseen Conditions of Use"
  - Identification is fact- or knowledge-specific
  - Based on evidence, knowledge, or experience leading EPA to foresee conditions of use different from those described in the submission
  - If EPA identifies potential concerns with reasonably foreseen conditions of use, but not with the intended conditions as described in the submission, EPA may assess whether those concerns can be addressed through significant new use rules (SNURs)

New Chemicals Determinations

Presents an unreasonable risk

- Section 5(f) order
- Section 6(a) proposed rule
- Restriction/prohibition of manufacturing, processing, distribution, or disposal

Not likely to present an unreasonable risk

- Commercialization can commence after the determination is made
- Section 5(g) – Statement in the Federal Register

Information is insufficient to permit a reasoned evaluation of the risk

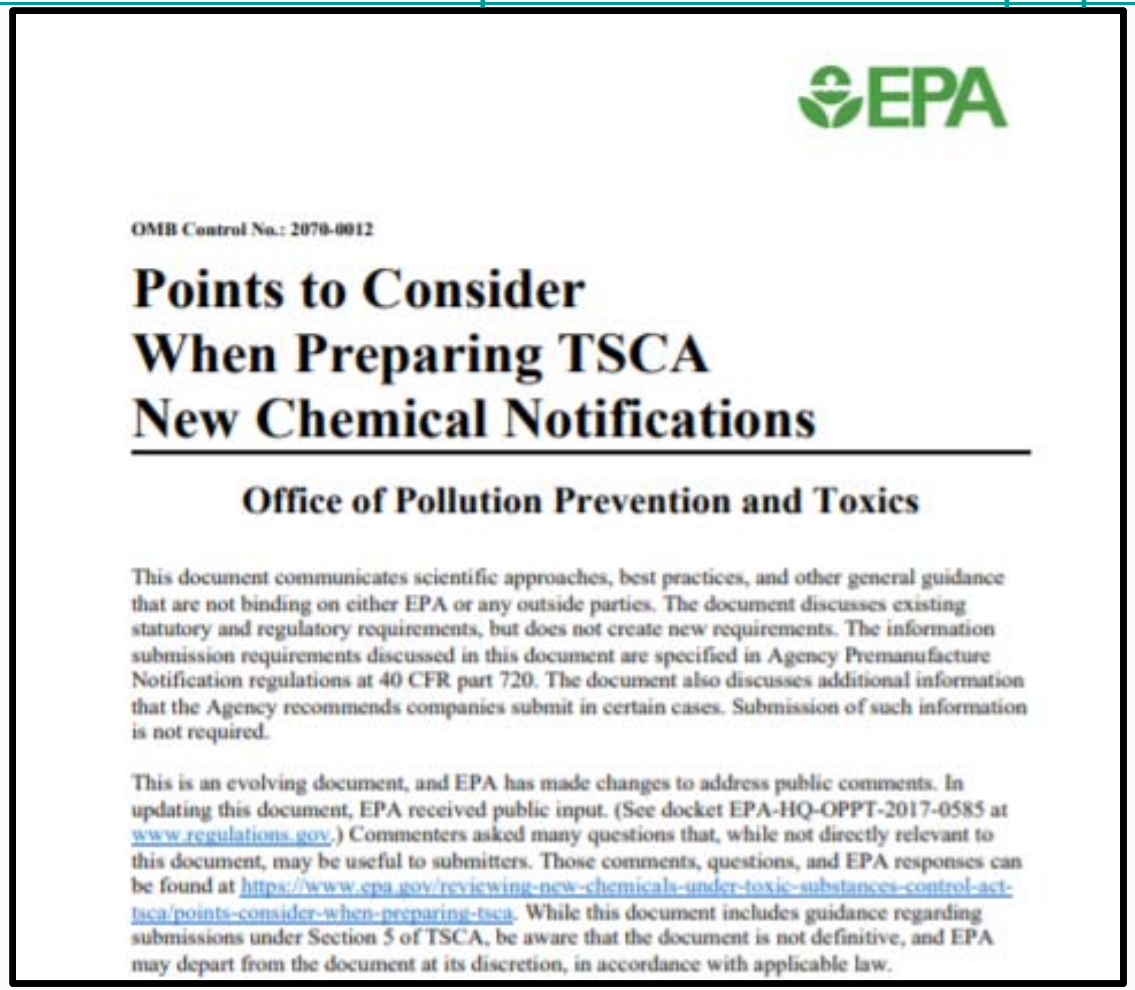
- Section 5(e) – Regulation pending more information
- Section 5(e) order
- Testing generally required

Insufficient Information to permit a reasoned evaluation **and may present** unreasonable risk

- Section 5(e) – Regulation pending more information
- Section 5(e) order
- Testing generally required

New Chemicals: Points to Consider

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



EPA

OMB Control No.: 2070-0012

Points to Consider When Preparing TSCA New Chemical Notifications

Office of Pollution Prevention and Toxics

This document communicates scientific approaches, best practices, and other general guidance that are not binding on either EPA or any outside parties. The document discusses existing statutory and regulatory requirements, but does not create new requirements. The information submission requirements discussed in this document are specified in Agency Premanufacture Notification regulations at 40 CFR part 720. The document also discusses additional information that the Agency recommends companies submit in certain cases. Submission of such information is not required.

This is an evolving document, and EPA has made changes to address public comments. In updating this document, EPA received public input. (See docket EPA-HQ-OPPT-2017-0585 at www.regulations.gov.) Commenters asked many questions that, while not directly relevant to this document, may be useful to submitters. Those comments, questions, and EPA responses can be found at https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/points-consider-when-preparing-tsca. While this document includes guidance regarding submissions under Section 5 of TSCA, be aware that the document is not definitive, and EPA may depart from the document at its discretion, in accordance with applicable law.

Points to Consider When Preparing TSCA New Chemical Notifications

- Two common observations in submissions:
  - Provided information does not allow for refinement of risk assessment
  - Useful information that is in the submitter's possession is not always provided; e.g., analog data
- EPA developed *Points to Consider* to
  - provide concise guidance to improve PMN submissions – largely based on existing documentation, e.g., Sustainable Futures
  - reduce delays caused by rounds of discussion/data submission submitters
- Provides guidance on:
  - General information requirements
  - EPA's new chemical review process, procedures & assumptions
  - Specific information that aids and expedites review (e.g., pchem properties, process information, exposure information, PMN chemical or analog data)

Promoting Transparency

- Tracking of new chemical cases in progress – updated weekly

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

- Search status of TSCA section 5 notices or exemptions, by case type, by case number, status, final determination, or date

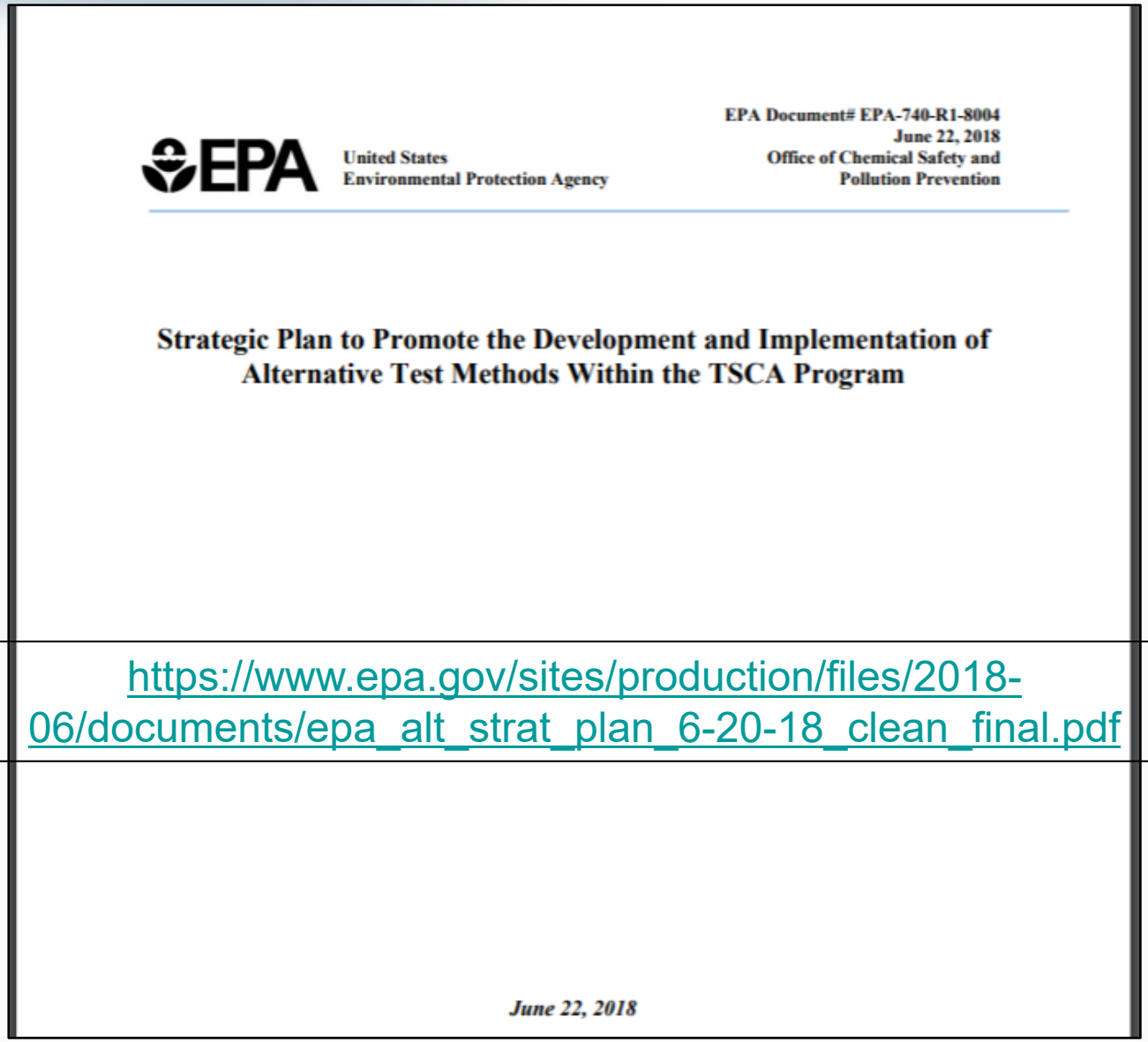
  https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/status-pre-manufacture-notices

- Links to consent orders (non-CBI versions) generally available within two weeks of the order's effective date

  https://chemview.epa.gov/chemview

Non-animal Testing Strategy

To promote the development and timely incorporation of the new scientifically valid test methods and strategies that are not based on vertebrate animals – not later than 2 years after the day 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 fro assessing risk of injury to health or the environment of chemical substances or mixtures.



EPA Document# EPA-740-R1-8004
June 22, 2018
Office of Chemical Safety and
Pollution Prevention

EPA United States Environmental Protection Agency

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

June 22, 2018

https://www.epa.gov/sites/production/files/2018-06/documents/epa_alt_strat_plan_6-20-18_clean_final.pdf

Draft Interim Science Policy: Use of Alternative Approaches for Skin Sensitization as a Replacement for Laboratory Animal Testing

- Announced April 10, 2018: describes the science that supports a policy to accept alternative (in vitro, in silico, in chemico) approaches for identifying skin sensitization hazard in place of animal studies

- EPA's OPP & OPPT began accepting these approaches immediately under conditions described in the interim policy.
  - Existing OECD guidelines for determining hazard (only)
  - Approaches for combining results of 2 or 3 assays described
  - Active or inert ingredients (not formulations yet)

- Public comments accepted on the draft skin sensitization policy (June 9, 2018)

- Result of collaboration between:
  - Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM);
  - NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM);
  - European Union Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM);
  - Health Canada (PMRA)

TSCA Implementation Milestones

Day 1 (June 22, 2016)

- ✓ New chemicals – implement all new requirements, including affirmative determinations
- ✓ Existing Chemicals – apply new risk-based approach and scientific standards for evaluations and risk management rules
- ✓ CBI – review chem ID claims (and subset of other claims) within 90 days

By 6 months (December 2016)

- ✓ Propose TSCA Framework rules (prioritization, risk evaluation, and active/inactive inventory rules)
- ✓ Publish list of first 10 chemicals for risk evaluation
- ✓ Publish annual risk evaluation plan
- ✓ Determine whether “small business” definition warrants revision
- ✓ Report to Congress on capacity to implement

By 1 Year (June 2017)

- ✓ Finalize TSCA Framework rules
- ✓ Finalize scopes for first 10 risk evaluations
- ✓ Publish Guidance to Assist Interested Persons in Developing and Submitting Draft Risk Evaluations
- ✓ Establish Science Advisory Committee on Chemicals

TSCA Implementation Milestones

By 2 Years (June 2018)

- ✓ Publish strategic plan for non-animal testing methodologies
- ✓ Finalize all necessary policies, procedures and guidance for TSCA implementation
- ✓ Publish guidance re: generic names for chem ID
- ✓ Receive active/inactive notices from manufacturers and processors (Oct 2018) and update inventory listings (Nov 2018)
- ✓ Propose rule for reviewing all chem ID claims (Nov 2018)
- ✓ Propose rule for TSCA user fees (target date early 2018)

By 3.5 Years (late 2019)

- ❑ Finalize first 10 risk evaluations; initiate risk management if warranted
- ❑ Finalize rule for reviewing chem ID claims for active chems (Nov 2019)
- ❑ Designate 20 High-Priority and 20 Low-Priority chemicals (Dec 2019)
- ❑ Propose risk management rule for certain PBT chemicals (Dec 2019)

By 5 Years (June 2021)

- ❑ Complete review of CBI claims for chem ID
- ❑ Report to Congress on implementation of non-animal testing plan
- ❑ Finalize PBT rule (~December 2020)

For More Information

- *General TSCA:* https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act
- *Evaluating Existing Chemicals:* https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/how-epa-evaluates-safety-existing-chemicals
- *Reviewing New Chemicals:* https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca
- *Contact EPA at:* https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/forms/assessing-and-managing-chemicals-under-tsca