U.S. EPA TSCA Update

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Amended Law

- The Frank R. Lautenberg Chemical Safety for the 21st Century Act
  - Amended and updated the Toxic Substances Control Act (TSCA)
  - Signed on June 22, 2016
  - Went into immediate effect
  - Many deadlines now approaching on prioritization and risk evaluation
- 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

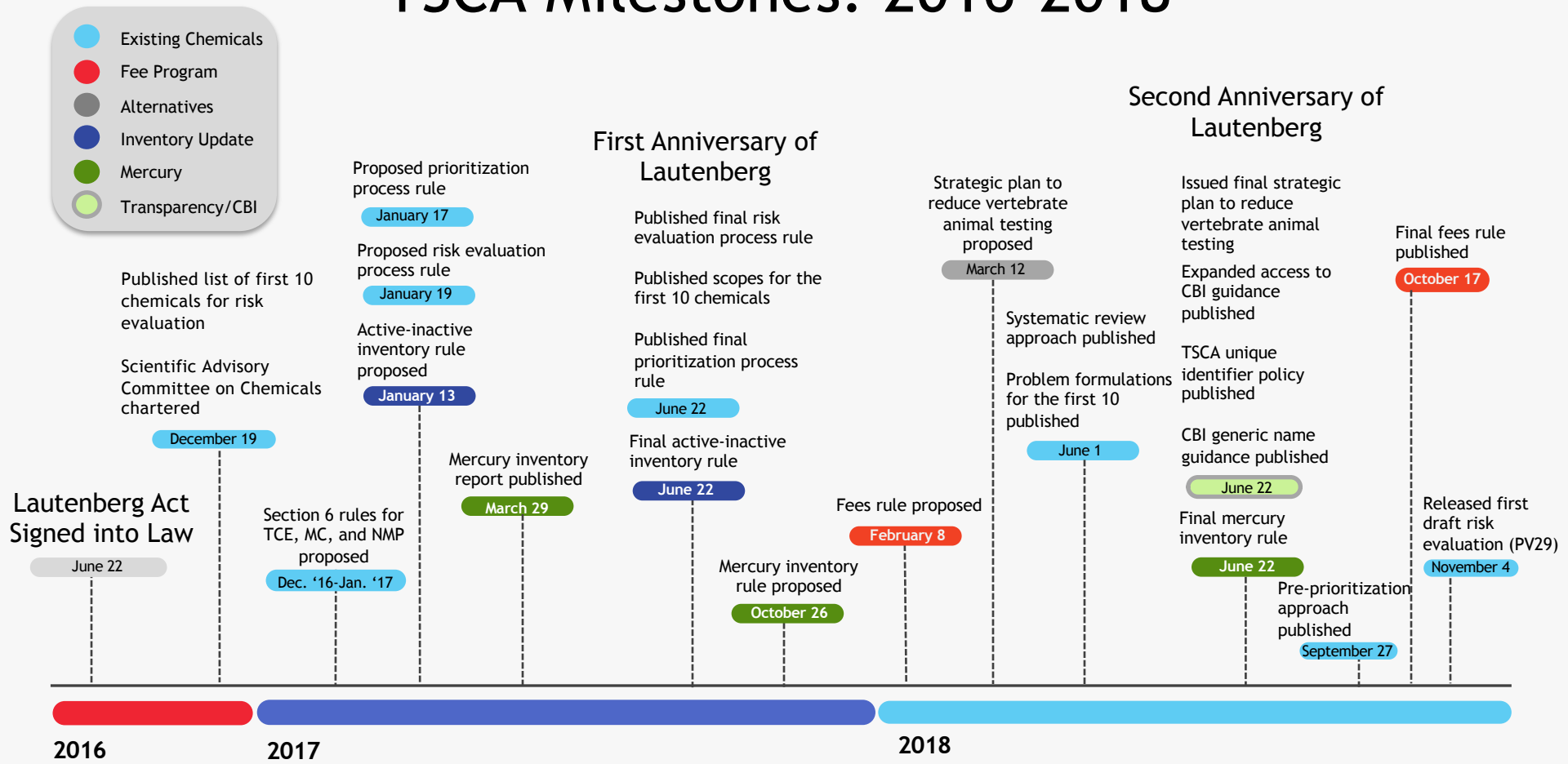
Pre-TSCA Reform

- Stakeholder Concerns:
  - No requirement that EPA review existing chemicals.
  - No requirement that EPA make affirmative determinations on new chemical notifications
  - Little EPA review of CBI claims
  - Patchwork of state actions in absence of Federal action
  - Slow progress moving non-animal tests from laboratory to TSCA decision-making

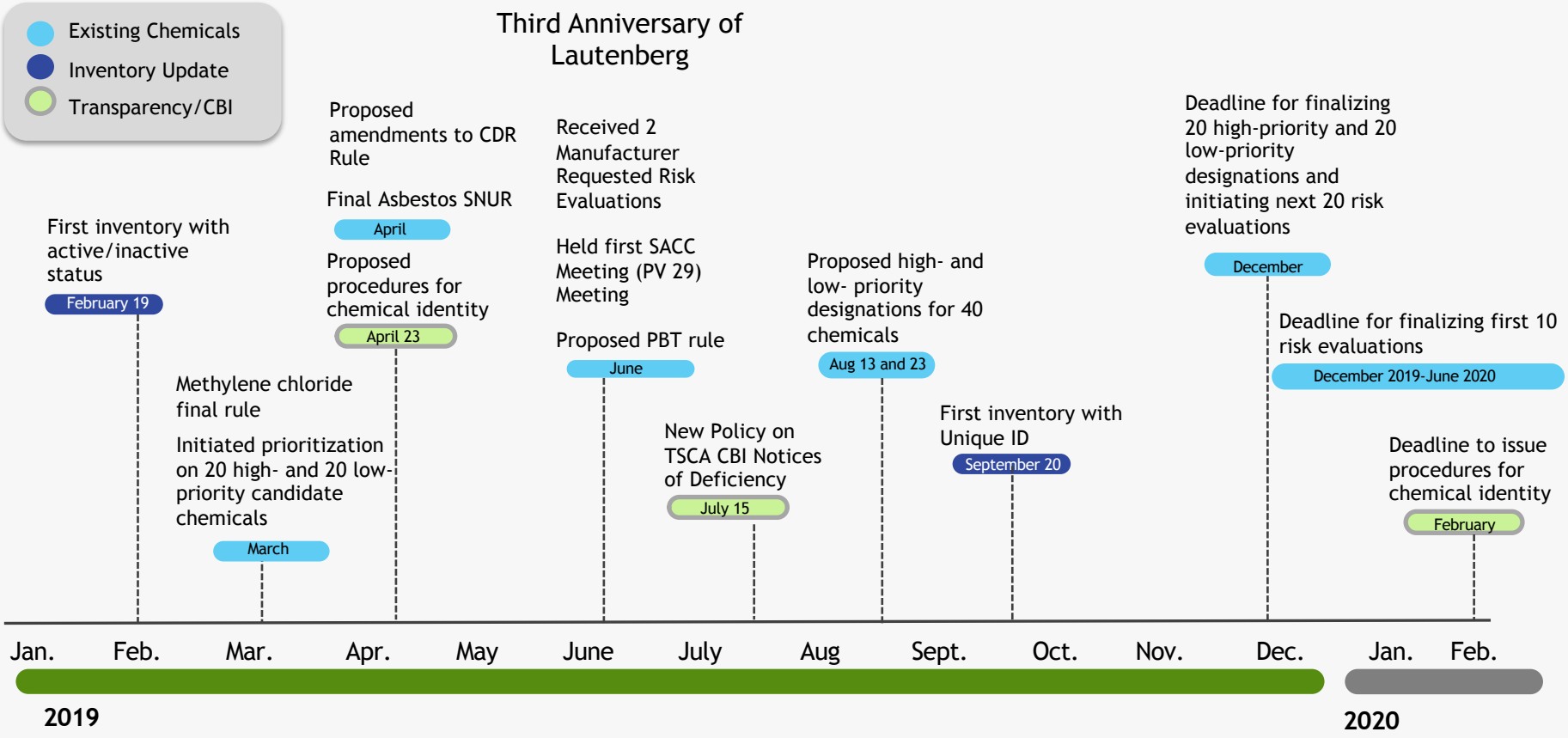
Amended TSCA
Changes Related to Existing Chemicals

- 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
- EPA must consider risks to potentially exposed or susceptible subpopulations determined to be 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

TSCA Milestones: 2016-2018



TSCA Milestones: 2019 and Beyond



Going Forward

Importance of Information and Dialogue on TSCA Chemicals

- Manufacture (including import), processing, distribution, use, disposal, and release information is important for understanding conditions of use.
- Conditions of use means the circumstances where a chemical substance is intended, known or reasonably foreseen to be manufactured, processed, distributed, in commerce, used, or disposed of.
- Detailed use information helps EPA understand how the chemical is used, the amounts of a chemical used, how the chemical is distributed in commerce, and the exposure scenarios for the use.
- Risk evaluations require complex decisions that are best informed by complete and high quality information.

Importance of Information (continued)

- Receiving information early in the prioritization and risk evaluation processes is most helpful to ensuring an expeditious evaluation that does not require analytical rework.
- Comprehensive hazard and exposure information, information on potentially exposed or susceptible subpopulations, and information that is relevant to specific risks of injury to health or the environment, improves accuracy of risk evaluations.
- See Submitting Information to Inform Prioritization and Risk Evaluation

Draft Risk Evaluations for First 10 Chemicals

- The Agency will use the scientific advice, information and recommendations from the SACC, as well as public comments, to inform the final risk evaluations.
- **PV-29**
  - SACC report submitted on September 20, 2019
- **HBCD and 1,4-Dioxane**
  - SACC report submitted on November 5, 2019
- **1-Bromopropane**
  - SACC Meeting September 10-12, 2019.
  - Public comment period ended October 11, 2019.
- **Methylene Chloride**
  - Draft risk evaluation released on October 29
  - SACC meeting week of December 2
- **N-methylpyrrolidone (NMP)**
  - Draft risk evaluation released on November 4
  - SACC meeting week of December 2

Prioritization for Risk Evaluation

- EPA must begin risk evaluations on 20 high priority chemicals and designate 20 chemicals as low priority by December 22, 2019.
- Draft dossiers for substances designated as a high- and low-priority published in the Federal Register for 90-day public comment.
  - Low-Priority: August 15, 2019 → November 13, 2019
  - High-Priority: August 23, 2019 → November 21, 2019
  - Also published Approach Document for Screening Hazard Information for both Low- and High-Priority Substances Under TSCA
- Once substances receive final designation as a high priority, risk evaluation process begins. EPA will issue draft scopes for public comment prior to issuing the statutorily required final scopes 6 months after initiating the risk evaluation.
- Issuance of scopes triggers “pause” preemption.

Risk Management

- Under TSCA, EPA is authorized to take action to address chemicals that pose potentially unreasonable risks to human health or the environment.
- The Frank R. Lautenberg Chemical Safety for the 21st Century Act enhanced EPA's authority to take action on certain PBT chemicals and to address risks from existing chemicals following risk evaluation.
- Risk management under section 6 includes the final rule to address the unreasonable risks presented by methylene chloride in paint and coating removal for consumer use.
  - Issued March 15, 2019
  - After November 22, 2019, prohibitions on retailer distribution take effect

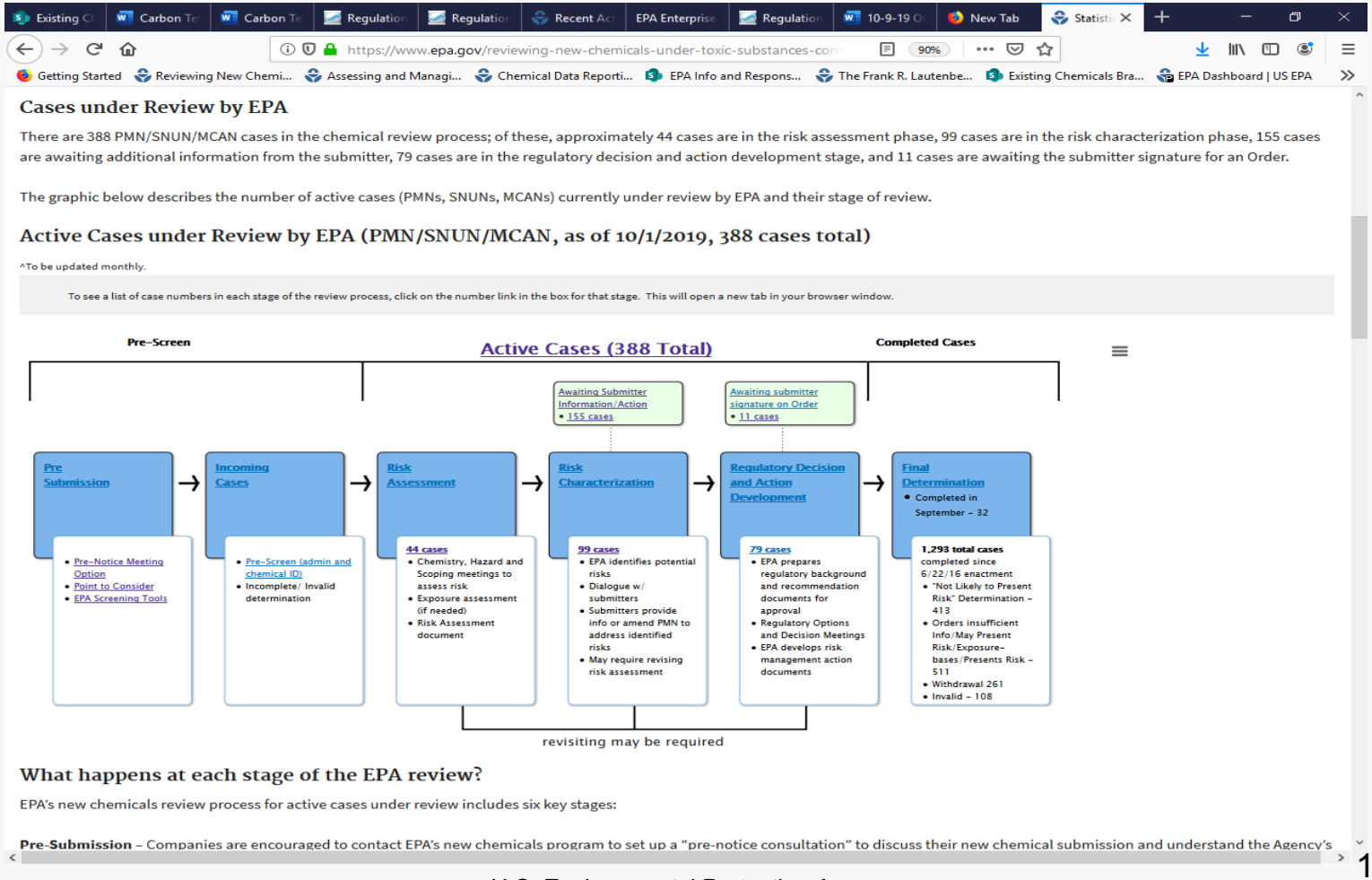
Section 6(h) on Persistence, Bioaccumulative, and Toxic Chemicals

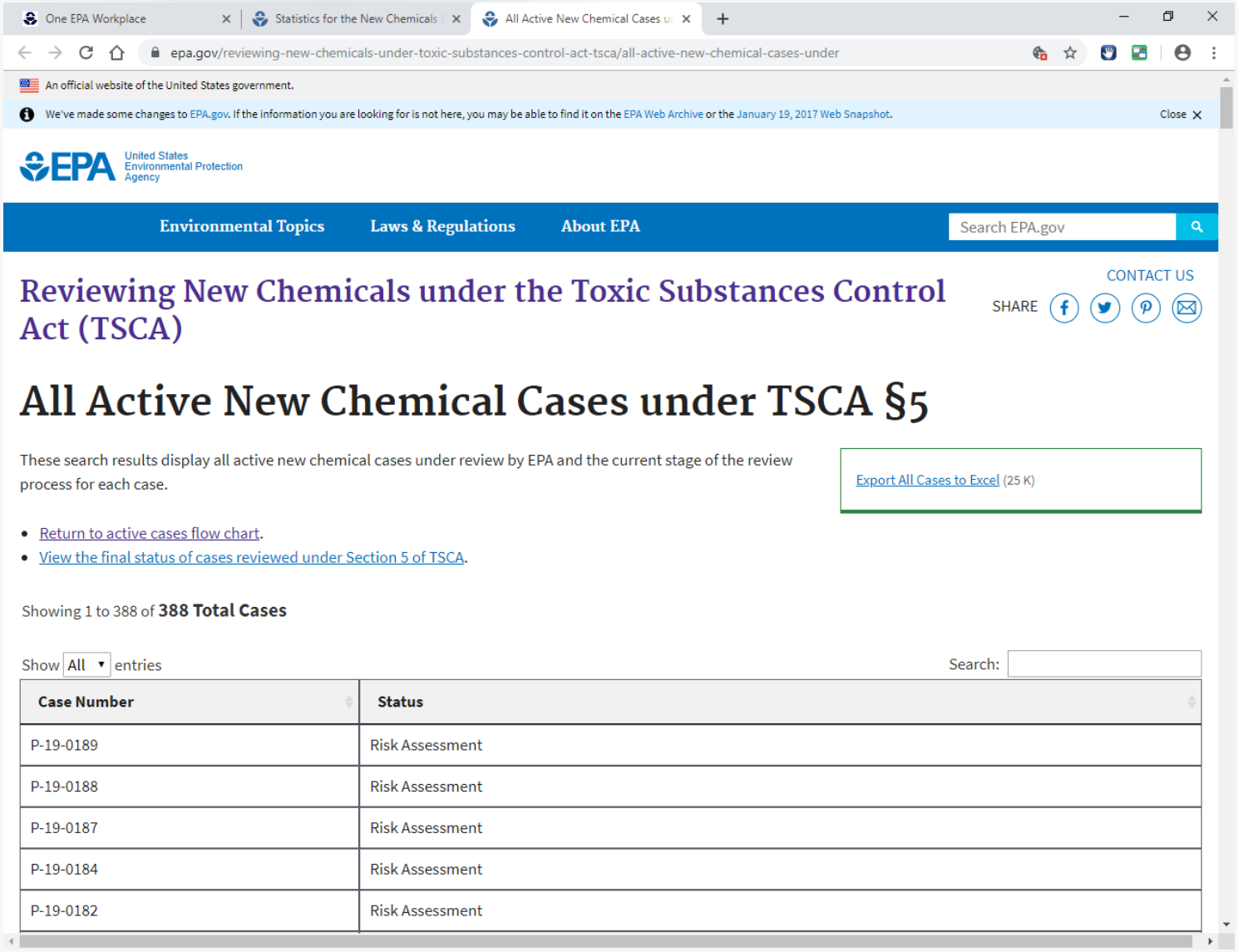
- Section 6(h) requires EPA to take expedited regulatory action to address risks from certain PBT chemicals.
- The provision includes certain criteria and selection restrictions for identifying the PBTs and does not mandate expedited action for PBT chemicals for which timely manufacturer requests for risk evaluations were received.
- The law gave EPA three years to propose rules to address risks and to reduce exposures to the extent practicable. EPA must finalize the rules within 18 months of proposal.
  - Proposed rule on June 21, 2019.
  - Comment period closed October 28; currently reviewing comments.

New Chemicals

- EPA must make an affirmative finding of potential risk on new chemicals or significant new uses of existing chemicals, before those chemicals or significant new uses can enter the market.
- Reviews underway at time of enactment were considered resubmitted and review period restarted; additional notices continued to be received, resulting in a backlog of cases.

Transparency: Active Case Tracker




One EPA Workplace
Statistics for the New Chemicals
All Active New Chemical Cases
epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/all-active-new-chemical-cases-under
An official website of the United States government.
We've made some changes to EPA.gov. If the information you are looking for is not here, you may be able to find it on the EPA Web Archive or the January 19, 2017 Web Snapshot.
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Reviewing New Chemicals under the Toxic Substances Control Act (TSCA)
All Active New Chemical Cases under TSCA §5
These search results display all active new chemical cases under review by EPA and the current stage of the review process for each case.
Export All Cases to Excel (25 K)
Return to active cases flow chart.
View the final status of cases reviewed under Section 5 of TSCA.
Showing 1 to 388 of 388 Total Cases
Show All entries
Search:
Case Number
Status
P-19-0189
Risk Assessment
P-19-0188
Risk Assessment
P-19-0187
Risk Assessment
P-19-0184
Risk Assessment
P-19-0182
Risk Assessment

Social Media

TSCA Overview:

- ***Ensuring the Safety of Chemicals in our Everyday Lives***
- https://www.youtube.com/watch?v=q3khHQytzco

QUESTIONS