



U.S. EPA TSCA Update

Accomplishments and Priorities



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Amended TSCA: Early 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

Amended TSCA: Early Implementation Milestones

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

By 2 Years (June 2018)

- ✓ Propose rule for TSCA user fees (February 2018)
- ✓ Publish strategic plan for non-animal testing methodologies
- ✓ Finalize all necessary policies, procedures and guidance for TSCA implementation
 - ✓ Unique Identifier
 - ✓ Generic Name Guidance
 - ✓ Expanded Access to CBI Guidance
- ✓ Finalize Mercury Reporting Rule

TSCA Year 3 Accomplishments

- **October 2018:** finalized and began implementation of the **TSCA fees rule**.
- **November 2018:** issued the **first draft risk evaluation** (Pigment Violet 29).
- **February 2019:** updated the **TSCA Chemical Substance Inventory** by designating substances as active in commerce.
- **March 2019:** took action to protect consumers from **methylene chloride** by prohibiting the manufacture (including import), processing, and distribution of methylene chloride in all paint removers for consumer use.
- **March 2019:** **initiated prioritization** by identifying 40 chemicals for prioritization for risk evaluation.

TSCA Year 3 Accomplishments

- **April 2019:** issued a final rule to ensure that **asbestos products** that are no longer on the market cannot return to commerce without the Agency evaluating them and putting in place any necessary restrictions or prohibiting use.
- **April 2019:** proposed amendments to **Chemical Data Reporting** rule to make reporting easier, better support data collection efforts, and require that CBI claims be substantiated.
- **April 2019:** proposed rule on certain **confidential business information** claims as required by Section 8(b) of TSCA. The final rule must be established by February 19, 2020, within one year of publishing the updated TSCA Inventory on February 19, 2019.

TSCA Year 3 Accomplishments

- **June 2019:** signed a proposed rule to reduce exposure to four **persistent, bioaccumulative, and toxic chemicals** (PBTs) in order to protect human health and the environment. 60-day comment period ends September 27, 2019.
- **June 2019:** announced new, tighter **standards for lead in dust** on floors and window sills to protect children from the harmful effects of lead exposure. The strengthened standards become effective January 6, 2020.

TSCA Year 3 Accomplishments

- **June 2019:** held **Science Advisory Committee on Chemicals (SACC)** meeting to peer review draft **Risk Evaluation for PV29**
- **July 2019:** released draft risk evaluations for public comment and held **Science Advisory Committee on Chemicals (SACC)** meeting to peer review **draft Risk Evaluations for 1,4-Dioxane and HBCD**
- **August 2019:** released draft **risk evaluation for 1-bromopropane** for public comment and peer review.
- **August 2019:** **proposed priority designation** for 20 chemicals as low-priority and 20 chemicals as high-priority for risk evaluation.

Going Forward



Risk Evaluations

- 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**
 - Public Comment period ended July 10, 2019.
- **HBCD and 1,4-Dioxane**
 - Public comment period ended August 28, 2019.
- **1-Bromopropane**
 - SACC Meeting September 10-12, 2019
 - Public comment period ends October 11, 2019.
- **6 Risk Evaluations**

Prioritization

- 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 high- and low-priority published in the Federal Register for 90-day public comment
 - Low-Priority: August 13, 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*
- EPA will issue draft scopes for public comment prior to issuing the statutorily required final scopes 6 months after initiating the risk evaluation.

Manufacturer- Requested Risk Evaluations (MRREs)

- TSCA allows chemical manufacturers to request an EPA-conducted risk evaluation of a chemical under 40 CFR 702.31.
- A manufacturer may request that EPA conduct a risk evaluation for conditions of use of interest to the manufacturer.
- EPA has received requests for two phthalates.
- EPA published the requests and possible additional conditions of use identified by EPA in the Federal Register, opened public docket, and is taking comment until October 3, 2019.
- After the comment period closes the Agency has 60 calendar days to either grant or deny the request.
- EPA looks forward to hearing from the public on the requests themselves as well as the additional conditions of use EPA proposes for inclusion.

New Chemicals Transparency Efforts

- EPA is now publishing all new chemical notices and their attachments in ChemView
- <https://chemview.epa.gov/chemview>

The screenshot displays the EPA ChemView interface. At the top, there are navigation links for 'CHEMICALS', 'ADVANCED SEARCH', and 'DASHBOARD'. A search bar is visible with the text 'Select Search Criteria'. Below the search bar, there are several filter sections: 'Chemical Information', 'Chemical Name or Chemical Structure', 'Use', 'Significant New Use Notice', 'Chemical Category', 'Effects/Endpoints', and 'Company/Submitter'. A table of search results is shown, with columns for 'Data Submitted to EPA', 'EPA Assessments', 'EPA Actions', and 'Manufacturing, Processing, Use or Release'. A modal window is open, displaying details for a specific New Chemical Notice.

New Chemical Notices [View New Chemical Notice Documents](#)

Chemical Name: Benzofuranone, bis(branched alkyl)-[dialkyl[tetrakis(branched alkyl)-alkyl-dibenzo-substitutedphosphite-yl] phenyl]- (generic)
Chemical Identifier: P-19-0096
Receipt Date of Notice: May 31, 2019

Notice Number: P-19-0096

Type of Notice: Premanufacture Notice (PMN)

Company Name: CBI

Maximum 12-month production volume during the first 3 years(kg/yr): CBI

Type of EPA Review: 90-day

Use(s):

- Additive for plastics industry(generic)

All Versions (including attachments) of this notice from most recent to original:

Latest Version
[+Version Received: 05/31/2019](#) (Download zip)

	Data Submitted to EPA	EPA Assessments	EPA Actions	Manufacturing, Processing, Use or Release
methanolate	<input type="checkbox"/>			
(branched alkyl)-ched alkyl)-alkyl-phosphite-yl]	<input type="checkbox"/>			
benzoic acid, ethyl	<input type="checkbox"/>			
polymer with diol and alkanediol	<input type="checkbox"/>			
benzoic acid, ethyl	<input type="checkbox"/>			
benzoic acid, ethyl	<input type="checkbox"/>			
benzoic acid	<input type="checkbox"/>			
benzoic acid, ethyl	<input type="checkbox"/>			
benzoic acid, ethyl ester	<input type="checkbox"/>			
benzoic acid, ethyl	<input type="checkbox"/>			

TSCA CBI Review Statistics

Since the enactment of the TSCA amendments in June 2016, EPA has established numerous new processes, systems, and procedures to enable submitters to provide the information required when making confidentiality claims and to facilitate EPA's review, and where applicable, determinations on these claims. The statistics provided below show EPA's progress toward meeting the requirements of TSCA section 14(g). A "case" is a submission made under a specific section of TSCA and all subsequent submissions and amendments by the same submitter that relate back to the first submission.

CBI Review Statistics (cases received between June 22, 2016 and June 25, 2019)	
Cases in which the specific chemical identity is subject to CBI review	2,177
Cases in which information other than the specific chemical identity is subject to CBI review	2,305
Cases in which both the specific chemical identity and information other than the specific chemical identity is subject to CBI review	587
Total cases subject to CBI review	5,069

Cases resulting in final CBI determinations	
Cases with all CBI claims subject to review, approved	523
Cases with all CBI claims subject to review, denied	5
Cases with CBI claims subject to review, approved-in-part/denied-in-part	34
Cases with all CBI claims subject to review, denial - appeal period pending*	10
Total cases resulting in final CBI determinations	572

New Chemicals Transparency Efforts

- EPA is now publishing information about TSCA Confidential Business Information (CBI) claim reviews
- <https://www.epa.gov/tscsca-cbi/statistics-tscsca-cbi-review-program>

New Chemicals Transparency Efforts

- EPA has updated its Chemical Review Tool

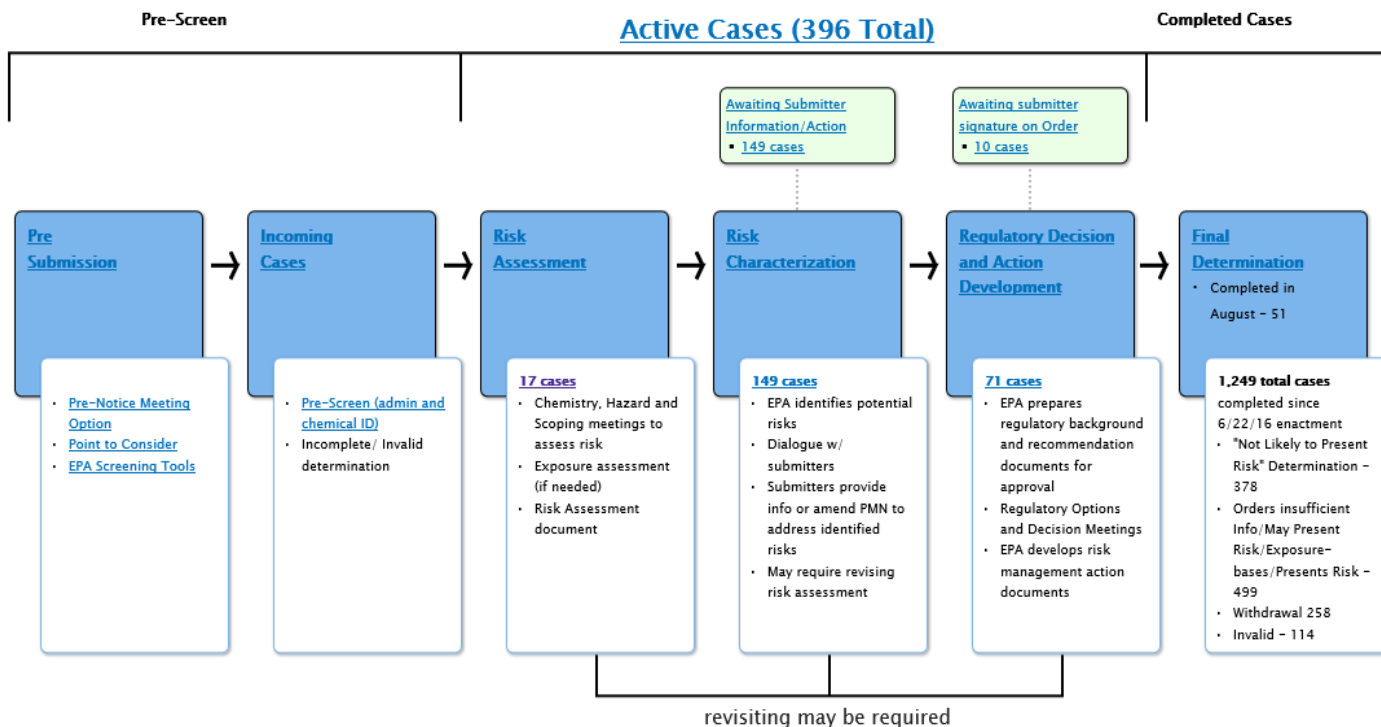
- <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review>

The graphic below describes the number of active cases (PMNs, SNUNs, MCANs) currently under review by EPA and their stage of review.

Active Cases under Review by EPA (PMN/SNUN/MCAN, as of 8/27/2019, 396 cases total)

^To be updated monthly.

To see a list of case numbers in each stage of the review process, click on the number link in the box for that stage. This will open a new tab in your browser window.



Social Media



TSCA Overview: *Ensuring the Safety of Chemicals in our Everyday Lives*



<https://www.youtube.com/watch?v=q3khHQytzco>

QUESTIONS

