

Inside the EPA's TSCA New Chemicals Program

Understanding How EPA Prioritizes New Chemicals Submissions Supporting Data Center Projects

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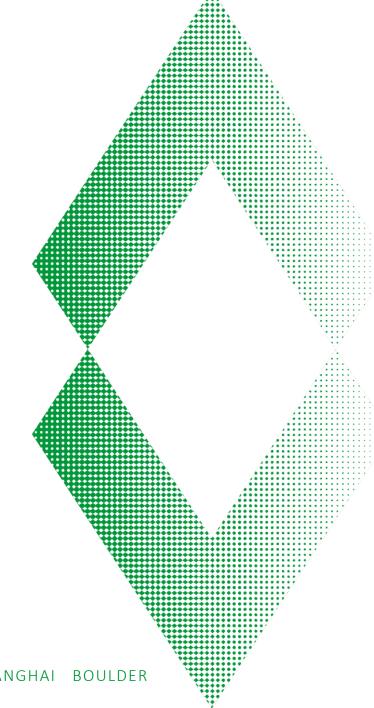
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Gregory A. Clark

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- Gregory (Greg) Clark counsels clients on regulatory and environmental issues, focusing on TSCA, the Clean Air Act (CAA), state volatile organic compound (VOC) regulations, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the Clean Water Act (CWA), and the Resource Conservation and Recovery Act (RCRA).
- He assists clients needing approval of new chemical substances, genetically modified organisms (GMOs), and pesticides under TSCA, FIFRA, and similar laws abroad. Clients value his extensive experience guiding them through the PMN, Low Volume Exemption, Microbial Commercial Activity Notice (MCAN), and TSCA Environmental Release Application (TERA) review processes.
- Greg's extensive background enables him to provide guidance to companies and trade associations on the prioritization, risk evaluation, and risk management of existing chemicals, including chemicals on the 2014 TSCA Work Plan, following the Lautenberg Act amendments to TSCA. He assists companies with periodic reporting under the TSCA Chemical Data Reporting Rule and other agency reporting programs. He also designs, conducts, and coordinates comprehensive internal audits of TSCA compliance for existing operations under EPA's "Audit Policy," as well as under other penalty mitigation policies.



Iris Camacho-Ramos, Ph.D.

- Iris Camacho-Ramos, Ph.D., is a toxicologist specializing in human health risk assessments conducted to support the safety of chemicals in foods, food packaging, and other chemical uses requiring regulatory review.
- Iris assists clients in gathering, evaluating, and interpreting hazard, exposure, and risk information for both novel and existing chemicals in products that require review for regulatory acceptance. She develops risk assessment methods and approaches that are scientifically defensible to regulatory programs, ultimately ensuring the safety of the clients' products.
- Iris has extensive experience in hazard identification/dose-response assessments, exposure assessment, and risk characterization of both new and existing chemicals, including nanomaterials and biotechnology products. Her scientific evaluations provide insight to our attorneys and their clients related to compliance with the technical requirements of national, regional, international, and global regulations, including those of the U.S. Food and Drug Administration (FDA), the U.S. Environmental Protection Agency (EPA), the California Environmental Protection Agency (CalEPA), and other comparable international agencies.





Justin Roberts, Ph.D.

- ◆ Justin Roberts, Ph.D., specializes in pesticides and related regulatory issues. He works closely with our attorneys to assist clients with new and existing pesticide products under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as well as new and existing chemical substances under the Toxic Substances Control Act (TSCA).
- ◆ Justin's extensive TSCA experience includes premanufacturing notices and exemptions, determining the potential for existing chemical substances to cause unreasonable risk to human health and the environment, risk assessment and risk management of nanomaterials, and Civil Enforcement. His FIFRA experience includes characterization between industrial and pesticidal chemicals, and later with criminal enforcement of misuse and mislabeled pesticides.





September 18—EPA Press Release on New Chemicals Supporting Data Center Projects





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EPA Prioritizes Review of New Chemicals Used in Data Center Projects, Supporting American Manufacturing and Technological Advancement

September 18, 2025

Contact Information

EPA Press Office (press@epa.gov)

WASHINGTON – Following a <u>roundtable</u> with AI and data center leaders at the White House on Monday, U.S. Environmental Protection Agency (EPA) Administrator Lee Zeldin announced that it will be prioritizing the review of new chemicals under the Toxic Substances Control Act (TSCA) that are intended for use in data center projects or for the manufacturing of covered components, as defined by Executive Order 14318, "Accelerating Federal Permitting of Data Center Infrastructure." This prioritization of reviews will start with submissions received on or after September 29, 2025.

"We inherited a massive backlog of new chemical reviews from the Biden Administration which is getting in the way of projects as it pertains to data center and artificial intelligence projects. The Trump EPA wants to get out of the way and help speed up progress on these critical developments, as opposed to gumming up the works. We are taking every step possible to make America the artificial intelligence capital of the world. The American people demand it. President Trump and his team are getting it done," said EPA Administrator Zeldin.

The expeditious review of new chemicals, especially those needed to support our nation's investment, advances innovation and helps to grow our nation's economy. This effort advances Administrator Zeldin's Powering the Great American Comeback initiative by streamlining the review of critically needed chemicals and ensuring data centers and related facilities can be powered and operated in a clean manner to make the U.S. the AI capital of the world.

TSCA Submissions Supporting Data Center Projects





- Submitters need to provide documentation to the EPA showing that the submission supports a "qualifying project".
- A "qualifying project" is defined in the Executive Order as:
 - A data center project or covered component project for which the Project Sponsor has committed at least \$500 million in capital expenditures as determined by the Secretary of Commerce;
 - ♦ A data center project or covered component project involving an incremental electric load addition of greater than 100 MW;
 - A data center project or covered component project that protects national security; or
 - A data center or covered component project that has otherwise been designated by the Secretary of Defense, the Secretary of the Interior, the Secretary of Commerce, or the Secretary of Energy as a "qualifying project."

Source: https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/filing-pre-manufacture-notice-epa

TSCA New Chemical Review Workflow



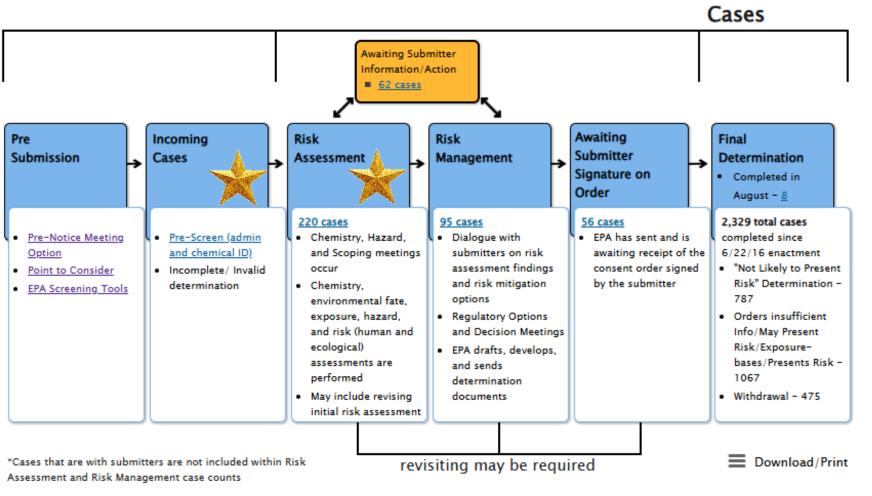
Pre-Screen

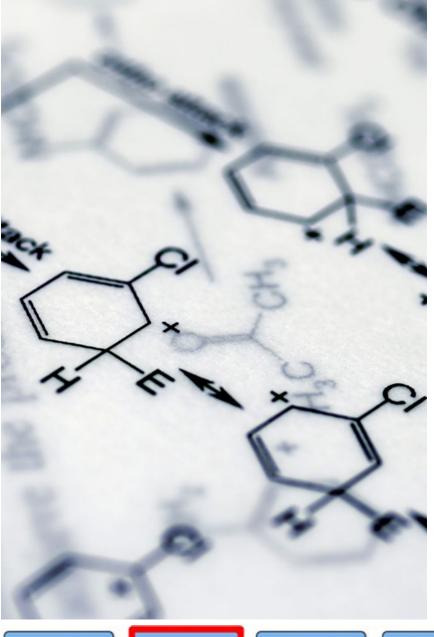
Active Cases (433 Total, including 118 with submitters*)

Completed



= Steps in the workflow where case prioritization is likely to occur





Incoming Cases: Pre-Screen

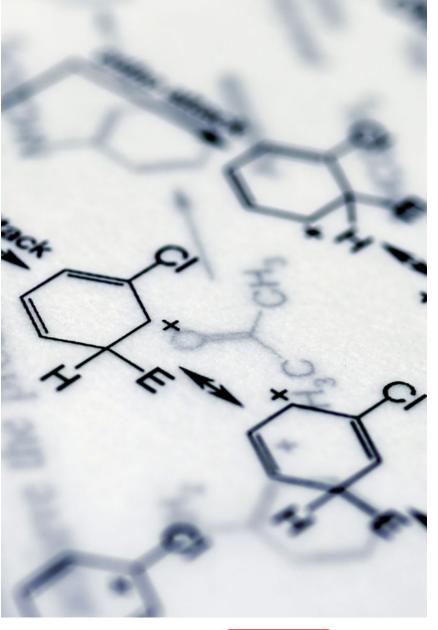


- Initial Admin/CBI Pre-Screen
 - Approved cases move to the risk assessment phase
- Risk Assessment Prescreen
 - Initial review of new cases (e.g., PMN, LVE, LoREx, SNUN) for completeness, basic consistency, and obvious errors
 - Chemistry prescreen
 - Check chemical ID, chemical class, structure diagram, manufacturing diagram, intended use, generic name.
 - ♦ Engineering prescreen
 - Review manufacturing, processing, worker exposure, customer/ submitter sites
 - Rejected cases go back to the submitter for revisions



Pre-screen is where high-priority cases are flagged





Risk Assessment: Chemistry Evaluation



Chemical Identity Check

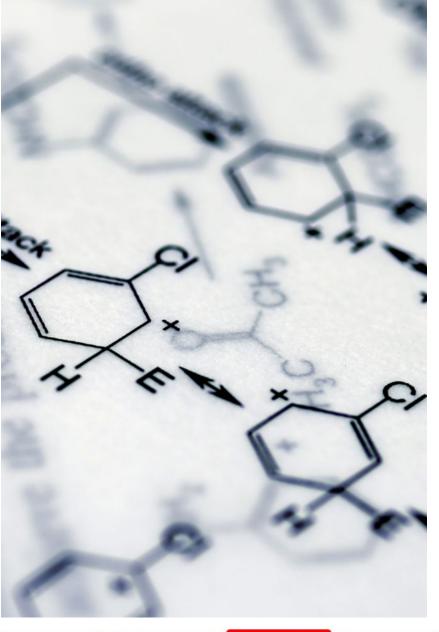
- Confirm the accuracy and completeness of substance name and structure
- Determine whether it matches existing chemicals on the TSCA Inventory

Chemistry Report

- Compile and assess physicochemical properties (measured or estimated)
- Review synthesis processes, including byproducts and impurities
- Identify structural analogs, potential chemical categories, structural alerts
- Review intended and foreseeable uses and pollutionprevention information
- Recommendations for next steps (e.g., further review, exemption, or exclusion if already on Inventory or not within TSCA purview)



Case prioritizing may occur at the chemistry meetings



Risk Assessment: Hazard, Exposure, and Risk



- Technical teams develop risk assessment (RA)
 - ♦ Fate Review: environmental behavior
 - Hazard Review: integrate data and define human health and environmental hazard endpoints
 - Exposure Assessment: evaluate exposure in workers, general population, consumers and environmental receptors
 - Risk Characterization: combine hazard and exposure to determine potential risks
- Role of Hazard & Scoping Meetings
 - Hazard Review Meeting: brings together initial evidence (chemistry, fate, toxicology) to identify hazards, uncertainties, and communication of preliminary concerns.
 - Scoping Meeting: determines the risk assessment approach (quantitative or qualitative; streamlined vs. conventional RA), and risk managers participate to ensure the right information is available for regulatory decisions



- Can further prioritize chemicals at these meetings
- Focused Teams: can be formed to evaluate high-priority chemicals





Incoming

Submission

Risk

Assessment

Management

Risk Management



- Risk managers act as the case managers
 - Track cases and communicate with submitters
- Risk assessment outcomes support regulatory decisions and legal instruments
 - Personal protective equipment
 - ♦ Hazard communication
 - Restricting uses or releases to the environment
 - Required testing
 - ♦ Consent orders
- Issue Significant New Use Rules (SNUR)
 - Require notification to EPA for review before commencing significant new uses
 - Apply to all manufacturers, processors, and industrial/commercial users
 - Designate certain releases/exposures/uses as "significant new uses"

TSCA Submissions Supporting Data Center Projects





- Seeking priority review requires evidence that submission meets the qualification criteria
- Documents must be submitted to EPA via CDX
- Submitters are encouraged to confirm priority status with the assigned EPA new Chemicals Program Manager



DISCUSSION

Upcoming Seminar: Navigating TSCA Basics and Beyond 2025



- ★ Keller and Heckman is pleased to announce our annual course, Navigating TSCA: Basics and Beyond 2025, taking place November 4 — 5, in Arlington, VA. This seminar is designed to provide comprehensive insights into the basics as well as advanced topics relating to understanding and complying with the Toxic Substances Control Act (TSCA). The course will be held over two days, with the first day dedicated to covering fundamental concepts and the second day delving into more advanced topics.
- Learn more, including how to register: <u>Navigating</u> <u>TSCA: Basics and Beyond 2025 | Keller and</u> <u>Heckman</u>



Upcoming Webinars





Please join us at 10:00 AM Eastern U.S. Wednesday, 10 December 2025 www.khlaw.com/REACH-3030



Please join us at 1:00 PM Eastern U.S. Wednesday, October 22, 2025 www.khlaw.com/OSHA3030



Please join us at 1:00 PM Eastern U.S. Wednesday, December 10, 2025 www.khlaw.com/TSCA-3030





Any questions?

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