COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

HEARING CHARTER

"*Chemistry Competitiveness: Fueling Innovation and Streamlining Processes to Ensure Safety and Security"*

Thursday, January 8, 2026
10:00 a.m.
2318 Rayburn House Office Building

Purpose

The purpose of this hearing is to examine chemical research and development (R&D) and innovation in the United States, including the creation of new chemicals and new uses for existing chemistries. The hearing will highlight the essential role chemicals play across virtually every sector of the economy, including building materials, household products, medical devices, pharmaceuticals, space, energy, transportation, semiconductors, defense, and advanced technologies.

The discussion will provide an overview of the current state of chemical R&D and examine how the regulatory environment directly impacts progress. It will also assess U.S. chemical leadership relative to global competitors and explore how greater regulatory certainty for R&D can spur innovation, strengthen supply chains and critical infrastructure, and enhance national security.

Witnesses

- **Ms. Charlotte Bertrand**, Senior Director, Chemical Management, Regulatory Policy and Strategy, American Chemistry Council
- **Dr. Stan Meiburg**, Former Acting Deputy Administrator, United States Environmental Protection Agency
- **Dr. Gwen Gross, Ph.D.**, Senior Technical Fellow, The Boeing Company
- **Mr. Keith Corkwell**, Senior Vice President and President of Lubrizol Additives, the Lubrizol Corporation

Overarching Questions

- What actions are necessary to strengthen chemical R&D in the United States and maintain global competitiveness?
- What factors most influence private-sector investment decisions in chemical R&D?
- How can regulatory certainty support sustained investment in chemical R&D that bolsters supply chain resilience and contributes to national security?

Introduction

This hearing will feature testimony from private sector witnesses with expertise in chemical R&D and regulations as producers, downstream users and industry representatives. As the

Committee examines its role in understanding the domestic R&D landscape for new chemistries and technologies, this discussion will provide valuable insights to help inform future policymaking.

The Toxic Substances Control Act of 1976

The Toxic Substances Control Act (TSCA) of 1976 directs the Environmental Protection Agency (EPA) to evaluate the entire lifecycle of both existing and new chemical substances, including manufacturing, importation, processing, distribution, use, and disposal, to ensure they do not pose "unreasonable risks" to human health or the environment. Under TSCA, EPA has the authority to regulate chemicals and require reporting, recordkeeping, testing, and other restrictions on chemical substances and mixtures.

Covered Chemicals

The term "chemical substance" means any organic or inorganic substance of a "particular molecular identity," including combinations of substances occurring naturally or resulting from a chemical reaction, as well as any element or uncombined radical.[1]

TSCA includes several specific provisions, some added over time[2], that mandate the regulation of polychlorinated biphenyls (PCBs), asbestos, radon, and lead-based paint.[3] The statute also applies to polymers and other chemicals that may appear in R&D pipelines.

Exclusions

Certain substances are generally excluded from TSCA based on their uses, including food and food additives, drugs, cosmetics, medical devices, tobacco, nuclear and radioactive materials, and pesticides, as they are regulated under other laws.[4]

TSCA Inventory

EPA maintains the TSCA Inventory, which lists chemical substances manufactured or processed for commercial purposes in the United States.[5] The Inventory currently contains 86,847 chemicals, of which 42,495 are known to be active in commerce.[6] Under the TSCA Inventory Reset Rule, "active" substances are those that were manufactured, imported, or processed between June 21, 2006, and June 21, 2016.[7] "Inactive" substances are those not currently in commerce but that remain listed and would require notification to the EPA prior to resuming use.[8] The original Inventory included approximately 62,000 chemical substances identified as

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[1] 15 U.S.C. § 2602(2)(A)
[2] The Toxic Substances Control Act (TSCA): A Summary of the Act and Its Major Requirements. (2025, December 18). https://www.congress.gov/crs-product/RL31905
[3] Summary of the Toxic Substances Control Act | US EPA. (2025, August 25). US EPA. https://www.epa.gov/laws-regulations/summary-toxic-substances-control-act
[4] Ibid.
[5] About the TSCA chemical substance inventory | US EPA. (2025, June 2). US EPA. https://www.epa.gov/tsca-inventory/about-tsca-chemical-substance-inventory
[6] Now available: Latest update to the TSCA inventory | US EPA. (2025, January 21). US EPA. https://www.epa.gov/chemicals-under-tsca/now-available-latest-update-tsca-inventory-7
[7] TSCA Inventory Notification (Active-Inactive) Rule | US EPA. (2025, March 13). US EPA. https://www.epa.gov/tsca-inventory/tsca-inventory-notification-active-inactive-rule
[8] Ibid, 6.

being in commerce in 1979, when the first statutorily mandated list was compiled, with the rest being added since.[9]

R&D Under TSCA

R&D under TSCA focuses on the analysis of the chemical or physical characteristics, the performance of a chemical, or the production characteristics of a chemical substance, a mixture containing the substance, or an article. EPA states that legitimate R&D activity generally includes specific, monitored tests conducted as part of a planned program of activity.[10]

Premanufacture Notice (PMN)

Under Section 5(h)(3) of TSCA, certain R&D activities related to the development and use of new chemistries may qualify for conditional exemptions from Premanufacture Notice (PMN) requirements while substances remain in the R&D pipeline and prior to their introduction into commerce.

This regulatory exemption is permitted for substances manufactured or processed "only in small quantities solely for the purposes of scientific experimentation or analysis, or chemical research on, or analysis of such substance, or another substance, including such research or analysis for the development of a product."[11] The term "small quantities" is not numerically defined by EPA and is evaluated on a case-by-case basis, depending on the nature and scale of the R&D activity.

The R&D exemption may include the production of a chemical substance for use by others conducting R&D; however, substances operating under the exemption may not be distributed to consumers or used in commerce without EPA approval. The burden of proof for claiming the R&D exemption rests entirely with the entity asserting it, and no formal application process is required by EPA to operate under the exemption.

Distribution of R&D Substances

Current regulations require that if a company distributes an R&D substance externally, it must clearly notify users that the substance is intended for R&D use only, provide adequate notice of certain risks, and comply with all corresponding regulations.[12]

EPA requires manufacturers to notify users through appropriate means, such as container labeling, visible notices in areas where exposure may occur, written notification to each potentially exposed individual, or other methods that adequately inform persons of health risks

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[9] https://www.epa.gov/tsca-inventory/about-tsca-chemical-substance-inventory?utm_source=chatgpt.com

[10] Research and Development Exemption for New Chemical Review under TSCA | US EPA. (2024, December 31). US EPA. https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/research-and-development-exemption

[11] Research and Development Exemption for New Chemical Review under TSCA | US EPA. (2024b, December 31). US EPA. https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/research-and-development-exemption

[12] https://www.ecfr.gov/current/title-40/part-720/section-720.36 , 40 CFR 720.36
Agency, Environmental Protection Agency 40 CFR 720.36

reasonably associated with the substance. [13] Manufacturers must also take steps to prevent unreasonable risks to human health or the environment.[14]

Companies may receive payment for R&D substances, provided the end user uses the substance solely for R&D purposes and does not distribute it for use in commerce.[15]

Significant New Use Rules (SNURs)

Chemical substances and mixtures already in commerce must notify EPA of any new uses through a Significant New Use Rule (SNUR) issued under Section 5(a)(2) of TSCA. In determining whether a use qualifies as a significant new use, EPA considers all relevant factors, including projected manufacturing and processing volumes; the extent to which a use changes the type, magnitude, or duration of human or environmental exposure; and the reasonably anticipated methods of manufacturing, processing, distribution in commerce, and disposal.[16]

Once EPA determines that the use of a chemical substance is a significant new use, a Significant New Use Notice (SNUN) must be submitted to EPA at least 90 days before manufacturing (including importation) or processing for that use. EPA then assesses the potential risks associated with the proposed use, including risks to exposed or susceptible subpopulations, makes a determination, and, if appropriate, regulates the use before it occurs.

R&D activities are not automatically exempt from SNUR requirements. If a substance is subject to a SNUR, the specific R&D conditions in the rule must be met, or a SNUN must be submitted prior to the R&D activity.

Completed R&D

Once R&D is complete, a company must notify EPA in advance of manufacturing a new chemical substance for commercial distribution, as required under Section 5. Distribution may not occur until EPA reviews the chemical substance and determines that it complies with all applicable regulatory requirements, including PMN obligations, SNURs, and other relevant TSCA provisions.

The Frank R. Lautenberg Chemical Safety for the 21st Century Act

The Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA), enacted in 2016, amended primarily Title I of the original statute to modernize chemical regulation at EPA and expand the Agency's ability to collect data, evaluate new and existing chemicals, and issue regulations.[17] Key provisions include mandatory risk-based evaluations of existing chemicals,

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[13] 40 CFR 720.36(c)

[14] Actions under TSCA Section 5 | US EPA. (2025, September 16). US EPA. https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/actions-under-tsca-section-5#SNURs

[15] Research and Development Exemption for New Chemical Review under TSCA | US EPA. (2024c, December 31). US EPA. https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/research-and-development-exemption

[16] Actions under TSCA Section 5 | US EPA. (2025b, September 16). US EPA. https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/actions-under-tsca-section-5#SNURs

[17] Highlights of key provisions in the Frank R. Lautenberg Chemical Safety for the 21st Century Act | US EPA. (2025, March 6). US EPA. https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/highlights-key-provisions-frank-r-lautenberg-chemical?utm_source=chatgpt.com

affirmative safety determinations for new chemicals, increased authority to require data and testing, the establishment of a new user fee system, revisions to confidential business information protections, and clarification of state and federal regulatory roles.[18]

Impact on R&D

The Lautenberg amendments did not alter the existing R&D exemptions under Section 5(h)(3) of TSCA, but they clarified EPA's authority to review chemicals, including those developed under the R&D exemption, and expanded the Agency's ability to collect data and apply risk evaluation and mitigation standards.

New Chemical Review

Under LSCA, EPA is required to make an affirmative determination as to whether each new chemical substance for which it receives notice under Section 5(1)(a) of TSCA presents an unreasonable risk to human health or the environment under known, intended, or reasonably foreseen conditions of use. These determinations are made using a standardized approach to identify and evaluate potential health and environmental effects, as well as exposure and release pathways.[19]

EPA must base its determinations on scientific methods, databases, and predictive tools that assess how chemicals behave under varying conditions of use.[20] This process is distinct from, and separate from, EPA's review process for existing chemicals.

Prioritization and Risk Evaluation

Under the LSCA, the first step in EPA's process for evaluating the safety of existing chemicals is prioritization. This involves a risk-based screening process to designate chemical substances as either high-priority substances for risk evaluation or low-priority substances that may not warrant further evaluation. High-priority substances undergo evaluation assessing both hazards and human and environmental exposures. During prioritization, EPA may not consider non-risk factors, such as costs or benefits.[21]

There are four parts to EPA's process for evaluating human health risk:

1. Hazard identification – determining whether exposure to a chemical substance causes adverse health effects in humans.
2. Dose-Response Assessment – analyzing the likelihood and severity of adverse health effects in relation to a specific dose or concentration of a chemical substance. These analyses are then used to derive toxicity values.
3. Exposure Assessment – measuring or estimating the magnitude, frequency, and duration of human exposure to a chemical substance.

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[18] Ibid.18

[19] EPA's review process for new chemicals | US EPA. (2025, October 8). US EPA. https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/epas-review-process-new-chemicals?utm_source=chatgpt.com

[20] Ibid. 20

[21] How EPA evaluates the safety of existing chemicals | US EPA. (2025, August 4). US EPA. https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/how-epa-evaluates-safety-existing-chemicals?utm_source=chatgpt.com

4. Risk Characterization – integrating exposure assessment results with the hazard information and toxicity values derived from the dose-response assessment to characterize potential public health risks.[22]

In conducting risk evaluations, EPA must evaluate both hazard and exposure, use scientific information and approaches consistent with TSCA's best available science standards, and base decisions on the weight of scientific evidence.[23] As with prioritization, EPA may not consider non-risk factors, such as costs or benefits, during the risk evaluation process.

If EPA determines at the conclusion of a risk evaluation that a chemical presents an unreasonable risk to human health or the environment, the chemical proceeds to risk management. At that stage, EPA is required to implement regulatory restrictions on the manufacture, processing, distribution, use, or disposal of the chemical to eliminate the unreasonable risk. Risk management actions may include labeling, recordkeeping, or notice requirements; measures to reduce human exposure or environmental release; or, where appropriate, bans on certain chemical uses or the chemical itself.[24]

EPA is also required to publish an Annual Plan each calendar year identifying chemical substances for which risk evaluations are expected to be initiated or completed during that year. The plan must describe the status of ongoing risk evaluations and include updated schedules for their completion.[25]

Integrated Risk Information System

The Integrated Risk Information System (IRIS) was established in the mid-1980s as an internal database of human health assessments for chemicals found in the environment. Its original purpose was to provide toxicity values for acute and chronic exposures to chemicals associated with adverse human health effects and to promote consistency in evaluations across environmental media (e.g. water, air, and soil) and across EPA programs.[26] IRIS later became a publicly available database and is currently housed within EPA's Office of Research and Development.

IRIS applies only to the first two steps of the risk assessment process: hazard identification and dose-response assessments. It serves as a mechanism for examining available scientific data for a given chemical and developing a weight of evidence to characterize the quantitative link between

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[22] *Conducting a human health risk assessment | US EPA. (2025, January 31). US EPA. https://www.epa.gov/risk/conducting-human-health-risk-assessment*

[23] Risk Evaluations for Existing Chemicals under TSCA | US EPA. (2025, September 22). US EPA. https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca?utm_source=chatgpt.com

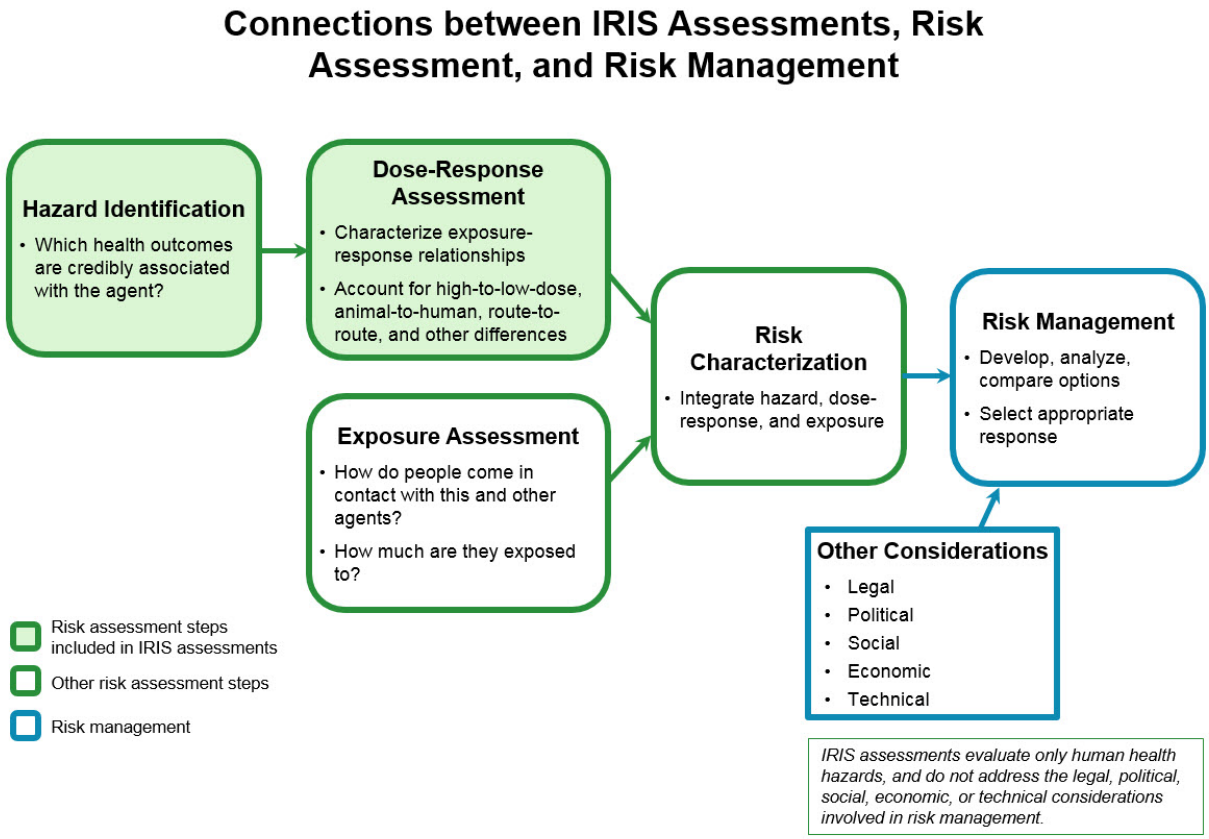
[24] How EPA evaluates the safety of existing chemicals | US EPA. (2025b, August 4). US EPA. https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/how-epa-evaluates-safety-existing-chemicals?utm_source=chatgpt.com

[25] EPAIbid.

[26] *Basic Information about the Integrated Risk Information System | US EPA*. (2025b, October 1). US EPA. https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system#history

potential adverse human health effects and the chemical under review. This process involves identifying relevant studies and evaluating their methodologies and scientific quality.[27]

Epidemiological and animal studies tend to comprise the bulk of the scientific evidence used for hazard identification. Epidemiological studies rely on statistical analyses of human populations to determine associations between exposure to a substance and adverse health effects; however, they often lack precise exposure information, making it difficult to isolate causation. Statistically controlled human clinical studies provide the strongest evidence of a causal relationship between a substance and adverse effects, but such studies are frequently unavailable.



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IRIS assessments also characterize exposure-response relationships as part of the dose-response assessment, which is based on existing scientific studies. As with the hazard identification, the dose-response assessment is best informed by data from controlled human clinical studies that identify the lowest dose associated with an adverse effect. However, the frequent lack of direct human data requires EPA to infer dose-response curves from studies involving higher exposure

[27] Conducting a human health risk assessment | US EPA. (2025, January 31). US EPA. https://www.epa.gov/risk/conducting-human-health-risk-assessment

[28] *Basic Information about the Integrated Risk Information System | US EPA*. (2025a, October 1). US EPA. https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system

levels, alternative observed health effects or animal subjects.[29] IRIS assessments then use the quantitative relationships determined by the dose-response assessment to derive toxicity values, such as reference concentrations and reference doses.[30] These values have been used by both EPA and states to inform regulatory decisions.

[29] Conducting a human health risk assessment | US EPA. (2025, January 31). US EPA. https://www.epa.gov/risk/conducting-human-health-risk-assessment

[30] Basic Information about the Integrated Risk Information System | US EPA. (2025, October 1). US EPA. https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system#process