

## [Frank R. Lautenberg Chemical Safety for the 21st Century Act \(Public Law 114-182\)](#)

Updates the 1976 Toxic Substances Control Act, which impacts the oversight of nanomaterials.

Updated last **March 14, 2017**  
for Public Law 114-182.



### WHAT IT DOES

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[Public Law 114-182](#), [The Frank R. Lautenberg Chemical Safety for the 21st Century Act](#), also known as the Toxic Substances Control Act (TSCA; [15 U.S.C. 2601 et seq.](#)), was updated on June 22, 2016 from the original, 1976 TSCA ([Public Law 94-469](#)). The update provides the Environmental Protection Agency (EPA) with authority to require reporting, record-keeping and testing requirements, and restrictions relating to chemical substances and/or mixtures. TSCA addresses the production, importation, use, and disposal of specific chemicals, but certain substances are generally excluded from TSCA, including, among others, food, drugs, cosmetics and pesticides.

Previous versions of TSCA did not include specific language that targeted nanomaterials, but the 2016 TSCA provided EPA with new authorities to regulate all industrial chemicals regardless of any material definition, nanoscale or otherwise. Although the term 'nano' does not appear in this legislation, the EPA is using this authority to generate new regulations related to nanoscale materials, the first being a new reporting requirement for nanomaterials ([SciPol brief available](#)).

The EPA offers [highlights of key provisions](#) in the act, related to existing and new chemicals, confidential business information, sources of sustained funding, federal-state partnership, and mercury export and disposal, including:

#### Existing Chemicals

- [Chemical Assessments](#)
  - Prioritization
    - EPA must establish a risk-based process to determine which chemicals it will prioritize for assessment, identifying them as either "high" or low" priority substances.
      - High priority - the chemical may present an unreasonable risk of injury to health or the environment due to potential hazard and route of exposure, including to susceptible subpopulations.
      - Low priority - the chemical use does not meet the standard for high-priority.
  - Risk Evaluations
    - High priority designation triggers a requirement and deadline for EPA to complete a risk evaluation on that chemical to determine its safety.
    - Low priority designation does not require further action, although the chemical can move to high-priority based on new information.
    - Assessment pipeline
      - First 180 days - EPA must have [ten](#) ongoing [risk evaluations](#).
      - Within 3.5 years - EPA must have twenty ongoing risk evaluations.

- New Risk-Based Safety Standard
  - Chemicals are evaluated against a new risk-based safety standard to determine whether a chemical use poses an “unreasonable risk”.
    - Risk evaluation excludes consideration of costs or non-risk factors.
    - Must consider risks to susceptible and highly exposed populations.
- Action to address unreasonable risks
  - When unreasonable risks are identified, EPA must take final risk management action within two years, or four years if extension is needed.
  - Costs and availability of alternatives considered when determining appropriate action to address risks.
  - Action, including bans and phaseouts, must begin as quickly as possible but no later than five years after the final regulation.
- Manufacturer-requested assessments
  - Manufacturers can request that EPA evaluate specific chemicals, and pay the associated costs as follows:
    - If on the [TSCA Workplan](#), manufacturers pay 50% of costs.
    - If not on the TSCA Workplan, manufacturers pay 100% of costs.
  - These assessments must account for between 25-50% of the number of ongoing risk evaluations for high-priority chemicals, but do not count towards the minimum 20 ongoing risk evaluation requirement.
- Chemical Testing Authority
  - Expands authority to obtain testing information for prioritizing or conducting risk evaluations on a chemical, and expedites the process with new order and consent agreement authorities.
  - Promotes the use of non-animal alternative testing methodologies.
- Persistent, Bioaccumulative, and Toxic ([PBT](#)) Chemicals
  - New [fast-track process](#) to address certain PBT chemicals on the TSCA Workplan.
    - Risk evaluation not needed; only use and exposure to chemical needed.
    - Action to reduce exposure to extent practicable must be proposed no later than three years after the new law and finalized 18 months later.
    - Additional requirements for PBTs in the prioritization process for assessments.

## New Chemicals

- [Pre-Market Review of New Chemicals](#)
  - New requirement that EPA must make an affirmative finding on the safety of a [new chemical](#) or significant new use of an existing chemical before it is allowed into the marketplace.
    - EPA can still take a range of actions to address potential concerns including a ban, limitations, and additional testing on the chemical.

## [Confidential Business Information](#)

- Establishes new substantiation requirements for certain types of confidentiality claims from companies.
- Requires that EPA review and make determinations on all new confidentiality claims for the identity of chemicals and a subset of other types of confidentiality claims.
- EPA must review past confidentiality claims for chemical identity to determine if still warranted.

## Source of Sustained Funding

- Allows EPA to collect up to \$25 million annually in [user fees](#) from chemical manufacturers and processors when they:
  - Submit test data for EPA review;
  - Submit a premanufacture notice for a new chemical or a notice of new use;
  - Manufacture or process a chemical substance that is the subject of a risk evaluation; or
  - Request that EPA conduct a chemical risk evaluation.
- New fees will defray costs for new chemical reviews and a range of TSCA implementation activities for existing chemicals.

## Federal-State Partnership

- Preservation of State Laws
  - States can continue to act on any chemical, or particular uses or risks from a chemical, that EPA has not yet addressed.
  - Existing state requirements (prior to April 22, 2016) are grandfathered.
  - Existing and new state requirements under state laws in effect on August 31, 2003, are preserved.
  - Preserves states environmental authorities related to air, water, waste disposal and treatment.
  - States and federal government can co-enforce identical regulations.
- Preemption of State Laws
  - State action on a chemical is preempted when:
    - EPA finds (through a risk evaluation) that the chemical is safe; or
    - EPA takes final action to address the chemical's risks.
  - State action on a chemical is temporarily "paused" when EPA's risk evaluation on the chemical is underway, but lifted when EPA:
    - Completes the risk evaluation; or
    - Misses the deadline to complete the risk evaluation.
- Exemptions
  - States can apply for waivers from both general and "pause" preemption.
  - If certain conditions are met, EPA *may* grant an exemption from general preemption, and *must* grant an exemption from pause preemption.

## Mercury Export and Disposal

- Amends requirements of the Mercury Export Ban Act (MEBA; [Public Law 110-414](#)) and addresses the responsibility of the Department of Energy (DOE) to designate a long-term storage facility.
  - If the facility is not operational by January 1, 2020, DOE must accept title to and pay for permitting and storage costs for mercury accumulated in accordance with MEBA prior to that date.
- Requires that EPA create an inventory of supply, use, and trade of mercury and mercury compounds; and prohibits export of certain mercury compounds.

## Trevor's Law

- Provides appropriate authority and enables coordination between federal, state, and local agencies, institutes of higher education, and the public to help conduct investigations into potential cancer clusters.
  - The term 'cancer cluster' is defined as the incidence of a particular cancer within a population group (for purposes of calculating cancer rates, defined by factors such as race, ethnicity, age, or gender), a geographical area, and a period of time that is greater than expected.

## RELEVANT SCIENCE

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The Frank R. Lautenberg Chemical Safety for the 21st Century Act, or the Toxic Substances Control Act (TSCA), encompasses regulation and testing of "chemical substances or mixtures" used for commercial purposes, to protect the health of humans as well as the environment. A chemical is an organized arrangement of elemental components known as atoms. For example, water is a chemical (H<sub>2</sub>O, which is composed of hydrogen, H, and oxygen, O, atoms), as is SiO<sub>2</sub>, which commonly is known as sand. Chemical substances are the pure form of a single type of chemical. Chemical mixtures are comprised of more than one pure chemical substance mixed together.

Some chemicals can be taken up by biological organisms and remain for a period of time, which is known as bioaccumulation. Chemicals that can accumulate and persist in the environment may exert toxic influence on the local environmental as well as biological systems. Thus, Congress has determined that it is important for EPA to regulate and track such chemicals, many of which

are active at the nanoscale.

All nanoscale materials are comprised of "chemical substances or mixtures", however not all chemical substances or mixtures are defined as nanomaterials. A definition for what constitutes a nanomaterial has not yet been agreed upon either [nationally](#) nor [internationally](#). Likewise, a recent EPA final rule ([SciPol brief available](#)) states that the agency does not attempt to define nanomaterials; its purpose is to require reporting of nanomaterial products that are created for commercial purposes for an agency inventory/database of chemical substances and mixtures.

Technically speaking, most chemical substances could be classified as nanomaterials. However, very likely, what constitutes a nanomaterial will eventually be defined in terms of the [unique characteristics](#) found at the nanoscale. Nanoscale materials are thousands of times smaller than the human eye can see. Nanoscale chemical substances typically have properties different than the same chemical substances with structures at a larger scale (also known as the bulk scale), such as greater strength, lighter weight, and greater chemical reactivity.

Currently, a nanomaterial (nm) is often defined as being in the size range of 1 nm - 100 nm in at least one dimension. However, this broad definition excludes some important nanomaterials, which are less than 1 nm in one dimension and vary in size along the other second dimension (e.g., [single walled carbon nanotubes](#), [fullerenes](#), and [graphene flakes](#)).

#### RELEVANT EXPERTS

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[Mark Wiesner, Ph.D.](#), Professor in the Duke University Pratt School of Engineering, Director of the Center for the Environmental Implications of NanoTechnology (CEINT) Duke University.

[Mike Hochella, Ph.D.](#), University Distinguished Professor of the Virginia Tech Department of Geosciences; Director of the Virginia Tech National Center for Earth and Environmental Nanotechnology Infrastructure ([NanoEarth](#)); Affiliate Professor of the Center for the Environmental Implications of NanoTechnology (CEINT) Duke University.

#### BACKGROUND

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The 1976 TSCA was signed into law by President Gerald Ford, on October 11, 1976. All chemicals available for commercial use prior to TSCA's 1976 inception were considered safe. The law's [original purpose](#) was "To regulate commerce and protect human health and the environment by requiring testing and necessary use restrictions on certain chemical substances", for instance, polychlorinated biphenyls (PCBs), lead, mercury, radon, and lead-based paint.

#### ENDORSEMENTS & OPPOSITION

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##### Endorsement

- Some laud the passage of TSCA reform as among the [greatest lobbying victories](#) of 2016. The [American Chemistry Council](#) celebrated: "More effective federal oversight of chemicals will give Americans greater confidence that chemicals in commerce are being used safely and reduce the number of inconsistent state-based chemical initiatives that impede interstate commerce and send mixed messages to consumers." Other groups that lobbied for the passage of this legislation include the National Association of Manufacturers; Environmental Defense Fund; the National Retail Federation; the U.S. Chamber of Commerce; the Alliance of Automobile Manufacturers; the Natural Resources Defense Council; and Safer Chemicals, Healthy Families, a coalition of more than 450 groups, labor unions and individuals.

##### Opposition

- The [Environmental Health Strategy Center celebrates](#) TSCA's passage but also sees cause for concern: "The timetables the new law puts in place mean that EPA action will be disappointingly slow when it comes to evaluating the safety of thousands of chemicals now in commercial use. It is important to note that states still can restrict chemical uses that EPA can't touch or won't address soon. States must continue to act."
- New York's Attorney General, Eric Schneiderman, issued a [statement](#) addressing concerns regarding the law's state preemption provisions: "Generations of New Yorkers have benefited from our state's robust environmental and public health laws. New York is a national leader on these issues and the federal government should not diminish our authority to continue to ensure protections. I am disappointed that the amended Toxics Substances Control Act passed by Congress expands federal preemption, creating new obstacles to the ability of New York and other states to protect their citizens from the hazards of toxic chemicals. I appreciate the hard work of Senator Charles Schumer, Senator Kirsten Gillibrand, and Representative Paul Tonko in opposing this new, expanded preemption, and limiting its scope and extent in the final bill."

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**STATUS**

Signed into law on June 22, 2016 by President Barack Obama.

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**RELATED POLICIES**

Under TSCA's authority, the EPA has issued a final rule, *Reporting and Recordkeeping Requirements of Chemical Substances when Manufactured or Processed as Nanoscale Materials*, that will become effective July 11, 2017 ([SciPol brief available](#)). This rule establishes reporting and recordkeeping requirements for certain chemical substances when they are manufactured or processed at the nanoscale.

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**SPONSORS**

Sponsor:

- [Representative John Shimkus](#) (R-IL-15)

Cosponsors: \*Original Cosponsors

- [Representative Fred Upton](#) (R-MI-6)
- [Representative Frank Pallone, Jr.](#) (D-NJ-6)
- [Representative Paul Tonko](#) (D-NY-20)

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**RECOMMENDED CITATION**

Duke SciPol, "Frank R. Lautenberg Chemical Safety for the 21st Century Act (Public Law Number 114-182)" available at [http://scipol.duke.edu/content/frank-r-lautenberg-chemical-safety-21st-century-act-public-law 114-182](http://scipol.duke.edu/content/frank-r-lautenberg-chemical-safety-21st-century-act-public-law-114-182) (03/14/2017).