

S 697

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

Congress: 114 (2015–2017, Ended)

Chamber: Senate

Policy Area: Environmental Protection

Introduced: Mar 10, 2015

Current Status: By Senator Inhofe from Committee on Environment and Public Works filed written report. Report No. 11

Latest Action: By Senator Inhofe from Committee on Environment and Public Works filed written report. Report No. 114-67. Minority views filed. (Jun 18, 2015)

Official Text: <https://www.congress.gov/bill/114th-congress/senate-bill/697>

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Name: Sen. Udall, Tom [D-NM]

Party: Democratic • **State:** NM • **Chamber:** Senate

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Sen. Markey, Edward J. [D-MA]	D · MA		Dec 18, 2015
Sen. Tester, Jon [D-MT]	D · MT		Jan 12, 2016

Committee Activity

Committee	Chamber	Activity	Date
Environment and Public Works Committee	Senate	Reported By	Jun 17, 2015

Subjects & Policy Tags

Policy Area:

Environmental Protection

Related Bills

Bill	Relationship	Last Action
114 HR 2576	Related bill	Jun 22, 2016: Became Public Law No: 114-182.
114 S 725	Related bill	Mar 12, 2015: Read twice and referred to the Committee on Environment and Public Works.

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

This bill revises the standard under the Toxic Substances Control Act (TSCA) used to determine whether regulatory control of a certain chemical is warranted. If a chemical presents an unreasonable risk of injury to health or the environment, the TSCA requires the Environmental Protection Agency (EPA) to initiate rulemaking to reduce risks to a reasonable level. The bill requires that standard to be based on exposure to a chemical under its conditions of use. The conditions of use are the intended, known, or reasonably foreseeable circumstances under which a chemical is manufactured, processed, distributed, disposed of, or used. The safety standard must also protect potentially exposed or susceptible populations, not just the general population, from unreasonable risks. Further, costs or other nonrisk factors may not be considered in developing the safety standard.

(Sec. 4) Within two years, the EPA must develop any policies, procedures, and guidance necessary to carry out the bill's requirements with respect to: (1) requesting safety data from manufacturers or processors, (2) prioritizing existing chemicals for evaluation of their risks, (3) reviewing new chemicals or significant new uses of existing chemicals, and (4) conducting safety assessments and safety determinations on whether a chemical meets the safety standard. Those policies, procedures, and guidances must be reviewed every five years and revised as necessary to reflect new scientific developments or understandings. In carrying out those requirements, the EPA must take into consideration information relating to chemicals that is reasonably available.

The EPA must also establish policies and procedures for the testing of chemicals. The EPA may not interpret the lack of exposure information as a lack of exposure to a chemical.

The EPA must inform the public of the schedule for the completion of each safety assessment and safety determination as soon as practicable after designating a chemical as a high-priority chemical for risk evaluation purposes. A safety assessment is an assessment of the risk posed by a chemical under the conditions of use, integrating hazard, use, and exposure information regarding the chemical. A safety determination is a decision made by the EPA as to whether a chemical meets the safety standard under the conditions of use.

At the beginning of each year, the EPA must identify the chemical safety assessments and determinations to be completed that year. The EPA must make available to the public a summary, and the final version, of each safety assessment and determination. The public must be given an opportunity to comment on each proposed assessment and determination.

The EPA must establish the Science Advisory Committee on Chemicals to provide independent advice to the EPA with respect to the scientific and technical aspects of issues relating to the implementation of this bill.

(Sec. 5) The bill revises requirements on testing chemicals to evaluate their risks.

The bill eliminates a requirement that the EPA must first make a preliminary finding about risks before the EPA can require testing by manufacturers or processors. Instead, the EPA may now require the development of information on chemicals for certain purposes, including the development of information that is necessary for reviewing new chemicals, performing safety assessments or determinations, implementing certain control actions on chemicals, and establishing the priority of a chemical.

Currently, the EPA is limited to requiring the development of information through a rule. This bill allows the EPA to require

the development of information through a consent agreement or an order as well.

In determining testing procedures and related deadlines that must be required under those rules, agreements, or orders, the EPA must take into consideration: (1) the relative costs of the test protocols and methodologies that may be required, and (2) the reasonably foreseeable availability of facilities and personnel required to perform the testing.

The EPA must minimize, to the extent practicable, the use of vertebrate animals in testing chemicals. To promote the development and timely incorporation of new testing methods that are not based on vertebrate animals, the EPA must: (1) develop a strategic plan to promote the development and implementation of alternative test methods and testing strategies to generate information under the TSCA that can reduce, refine, or replace the use of vertebrate animals; and (2) fund and carry out research, development, performance assessment, and translational studies to accelerate the development of those alternative test methods and strategies. The EPA must ensure that the elements in the strategic plan are reflected in the development of testing requirements. Any person who voluntarily develops information under the TSCA must first attempt to develop the information by an alternative or nonanimal test method or testing strategy before conducting new animal testing.

The EPA may require the development of information by manufacturers and processors of chemicals.

The EPA must employ a tiered screening and testing process that uses the results of screening-level tests or assessments of available information to inform the decision as to whether additional tests are necessary. The EPA may require more advanced testing without conducting screening-level testing when other information available to the EPA justifies the advanced testing.

Testing information that is not confidential must be made publicly available.

(Sec. 6) Within a year, the EPA must establish a risk-based screening process and explicit criteria for identifying existing chemicals that are a high or low priority for a safety assessment and safety determination.

Within 180 days, the EPA must publish an initial list of high- and low- priority chemicals. The list must contain at least 10 high-priority chemicals as well as 10 low-priority chemicals. At least five of the high-priority chemicals must be drawn from the October 2014 TSCA Work Plan (i.e. existing chemicals that the EPA has already prioritized for review). Insofar as possible, at least 50% of all chemicals subsequently identified as high-priority chemicals must be from the Work Plan until all Work Plan chemicals have been designated.

In developing the initial list and in identifying additional high-priority chemicals, the EPA must give preference to chemicals scored as high for persistence and bioaccumulation in the Work Plan.

Within three years, the EPA must add to the list additional high-priority chemicals sufficient to ensure that at least 20 high-priority chemicals have undergone or are undergoing the safety assessments and determination process, and additional low-priority chemicals sufficient to ensure that at least 20 low-priority chemicals have been designated. Within five years, those numbers must increase to at least 25 high-priority chemicals and 25 and low-priority chemicals.

In carrying out the prioritization screening process, the EPA must consider chemicals active in commerce during the last 10 years. The EPA may take into consideration inactive chemicals if they: (1) have not been subject to enforceable actions by the EPA to ban or phase out the chemicals and have the potential for high hazard and widespread exposure, or (2) have been subject to enforceable actions by the EPA to ban or phase out the chemicals and there is the potential for residual high hazards or widespread exposures not otherwise addressed by the actions.

Once a safety assessment and determination process is completed for a high-priority chemical, it must be replaced on the high-priority list by another chemical until a safety assessment and determination is completed for all high-priority chemicals.

The EPA must complete the designation of all active substances as high- or low-priority chemicals in a timely manner.

The EPA must publish an annual goal for the number of chemicals to be subject to the prioritization screening process. The EPA must also keep current and publish a list of chemicals: (1) that are being considered in the prioritization screening process, and (2) that are designed as high- or low-priority chemicals.

The EPA may screen categories of chemicals to ensure an efficient prioritization screening process.

The prioritization screening decision regarding a chemical must integrate any hazard and exposure information relating to the chemical that is available to the EPA.

The EPA must identify a chemical as a high-priority chemical if it has the potential for significant hazard and significant exposure. The EPA may identify a chemical as high-priority if it has the potential for either a significant hazard or significant exposure. A chemical must be identified as a low-priority chemical if the EPA has information sufficient to establish that the chemical is likely to meet the safety standard.

Prioritization screening decisions may be deferred for a reasonable period if additional information is required to establish the priority of a chemical.

If the EPA requests the development or submission of information under the prioritization screening process, the EPA must establish a deadline for submission of the information.

Prioritization screening decisions are subject to public notice and comment.

The EPA may revise a priority designation based on information available to the EPA after the date of the determination. If limited availability of relevant information was a basis in the designation of a chemical as a high-priority chemical, the EPA must reevaluate the prioritization screening of the chemical on receiving that information.

A state must notify the EPA if it proposes or takes administrative action or enacts a law to prohibit or restrict the manufacturing, processing, distribution, or use of a chemical that the EPA has not designated as a high-priority chemical. If certain conditions are met, the EPA must conduct a prioritization screening for that chemical.

The EPA must review the prioritization screening process every five years and modify the process as necessary.

A priority designation for a chemical does not affect the manufacture, processing, distribution, use, or disposal of the chemical or the regulation of those activities.

A manufacturer or processor of an active chemical may request the EPA to prioritize a safety assessment and determination for that chemical upon payment of a fee. A limit is placed on the number of those requests that the EPA may grant.

(Sec. 7) The bill modifies the process of reviewing new chemicals and significant new uses of existing chemicals, including by requiring the EPA to make a determination that a new chemical or use is likely to meet the safety standard before it can be commercially manufactured or processed.

The EPA must: (1) conduct an initial review of a premanufacture notice (PMN) for a new chemical or a significant new use of an existing chemical; (2) develop a profile of the relevant chemical and the potential for exposure to humans and the environment; and (3) make any necessary safety standard determinations. The review must be made within 90 days after receiving the PMN, but the EPA may extend that period for a good cause for up to 90 days. Any relevant information available to the EPA must be considered when the EPA evaluates the PMN.

Before the end of the initial review period, the EPA must determine that: (1) the relevant chemical or significant new use is not likely to meet the safety standard, (2) the new chemical or use is likely to meet the standard, or (3) additional information is necessary in order to make a determination.

The EPA may extend the review period of a PMN to allow for the development and submission of additional information.

In selecting among restrictions for chemicals that rank high for persistence and bioaccumulation to ensure that the chemical is likely to meet the safety standard, the EPA must select a restriction to reduce potential exposure to the chemicals to the maximum extent practicable.

(Sec. 8) The bill outlines requirements and deadlines for conducting safety assessments and determinations, and promulgates control measures on chemicals.

The EPA must conduct a safety assessment and make a safety determination for each high-priority chemical. Both must be completed within three years of a high-priority designation. Within two years of completing a negative safety determination, the EPA must promulgate a rule establishing restrictions necessary to ensure the chemical meets the safety standard. The EPA must ban or phase out the chemical if the safety standard cannot be met with restrictions. A ban or phase-out must be implemented in as short a period as practicable.

If there is adequate public justification, the EPA may extend the deadlines for conducting the assessments and determinations and promulgating those restrictions for a reasonable period of time that does not exceed two years.

The EPA must decide if a chemical meets the safety standard or if additional information is required. If additional information is needed, the EPA must: (1) provide an opportunity for interested persons to submit the additional information, and (2) establish a deadline for the submission of the information when it requests the development of the information.

Restrictions for persistent and bioaccumulative chemicals must reduce exposure to the chemical to the maximum extent practicable.

When establishing restrictions for chemicals that do not meet the safety standard, the EPA must consider the costs and benefits of the proposed regulatory action and the primary alternatives to those actions. That consideration must be given to the extent practicable based on reasonably available information. The bill revokes the requirement that the EPA must apply the least burdensome regulatory option to restrict a chemical that warrants regulation.

Certain exemptions from restrictions, bans, and phase-out on chemicals are established. The EPA may exempt uses of chemicals from restrictions if complying with the restrictions would: (1) harm national security, (2) cause significant disruption in the national economy, or (3) interfere with a critical or essential use for which no technically and economically feasible safer alternative is available. The EPA may also exempt uses of chemicals from restrictions if the chemical provides a substantial benefit to health, the environment, or public safety.

The EPA may declare a proposed rule that outlines restrictions to be effective on publication and until final action is

taken.

(Sec. 10) The bill revises TSCA's reporting requirements, including nomenclature requirements for chemicals.

The EPA must categorize chemicals on the TSCA Inventory (chemicals of concern) list as active or inactive.

Any confidential business information (CBI) claims to protect the specific identities of existing, active chemicals on the list from disclosure would need to be reaffirmed and substantiated. The EPA must maintain both a confidential and non-confidential portion of the Inventory.

Within five years of compiling that list of active chemicals, the EPA must establish a plan to review all CBI claims.

(Sec. 13) The bill revises exemption and notice provisions for the exports of chemicals that are not likely to meet, or do not meet, the safety standard.

(Sec. 14) The bill revises provisions concerning the protection of CBI under the TSCA.

The bill enumerates certain categories of information that are presumed to be protected from disclosure. It also specifies certain CBI that is not protected, including information relating to safety assessments and safety determinations and banned or phased-out chemicals. The bill provides exceptions from CBI protection, including an exemption for sharing CBI information with public health or environmental officials in emergencies.

EPA approvals of CBI claims are limited to 10 years. The EPA may grant a 10-year extension.

(Sec. 16) The penalty amounts for violations of the TSCA are increased. A new criminal penalty is established for violators that knowingly place parties in imminent danger of death or serious bodily injury.

(Sec. 17) The bill amends TSCA to revise requirements related to federal preemption of state statutes or administrative actions to manage risks from chemicals. Subject to exemptions, states may not establish or continue to enforce statutes or administrative actions concerning: (1) testing information on chemicals that is likely to produce the same information required by the EPA; (2) restrictions on the manufacture, processing, or distribution in commerce or use of a chemical, and (3) significant new uses of chemicals.

Federal preemption applies only to: (1) the chemical or categories of chemicals subject to a rule, order, or consent agreement; (2) the uses or conditions of use of chemicals that are identified by the EPA as subject to review in a safety assessment and included in the scope of the safety determination, or of any rule establishing restrictions necessary to ensure that the chemical meets the safety standard; and (3) the uses of those chemicals that the EPA has specified as significant new uses and for which the EPA has required a significant new use notification.

States are prohibited from adopting new restrictions for a high-priority chemical between the time the EPA defines the scope of a safety assessment and determination for a chemical and the time the safety determination is published.

The bill caps the penalties and sanctions available to states at the level available to the EPA. The EPA may not assess a penalty for a violation for which a state has already assessed a penalty.

The bill preserves certain state requirements, rights, causes of actions, and remedies from being preempted by EPA actions under TSCA. State actions taken before August 1, 2015, or taken under laws in effect on August 31, 2003, are exempted from preemption.

(Sec. 21) The bill repeals a requirement for the EPA to conduct an indemnification study and a study on classifying, storing, and retrieving information on chemicals.

(Sec. 22) The bill expands the EPA's authority under TSCA to access fees on chemical manufacturers, importers, or processors.

The EPA must establish a fee on manufactures or processors of certain chemicals to defray approximately 25% the cost of implementing certain requirements of the bill. The bill caps the total amount that may be collected from those fees to \$18 million. The amounts generated by the fee must be deposited in the TSCA Implementation Fund that is established by the bill.

The authority to access fees is conditioned on continued federal appropriations at a certain level. Fees may not be assessed for a fiscal year unless the amount of appropriations, excluding fees, is at least equal to the amount of appropriations for FY2015.

The EPA's authority to access fees is terminated after 10 years.

(Sec. 23) The President must establish: (1) an interagency Sustainable Chemistry Program to promote and coordinate federal sustainable chemistry research, development, demonstration, technology transfer, commercialization, education, and training activities; and (2) an interagency working group to oversee the planning, management, and coordination of the program.

Actions Timeline

- **Jun 18, 2015:** By Senator Inhofe from Committee on Environment and Public Works filed written report. Report No. 114-67. Minority views filed.
- **Jun 17, 2015:** Committee on Environment and Public Works. Reported by Senator Inhofe with an amendment in the nature of a substitute. Without written report.
- **Jun 17, 2015:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 121.
- **Apr 28, 2015:** Committee on Environment and Public Works. Ordered to be reported with an amendment in the nature of a substitute favorably.
- **Mar 18, 2015:** Committee on Environment and Public Works. Hearings held. Hearings printed: S.Hrg. 114-25.
- **Mar 10, 2015:** Introduced in Senate
- **Mar 10, 2015:** Read twice and referred to the Committee on Environment and Public Works.