

House Passes Toxic Substance Control Act (TSCA) Reform H.R. 2576 - Senate Vote Slated for Later this Week



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On May 24, 2016, the *U.S. House of Representatives* debated and voted to pass the pending Toxic Substance Control Act (TSCA) reform bill, The "**Frank R. Lautenberg - Chemical Safety for the 21st Century Act**," [H.R. 2576](#). The final vote was 403-12. Three Republicans – Buck (CO-4), Duncan (TN-2), and McClintock (CA-4) – voted against the bill.

H.R. 2576 was the subject of extensive negotiations and has been amended to address competing policy priorities and stakeholder concerns. The Senate is expected to vote on the legislation without amendment. Key supporters of the legislation in the House, including Representatives Shimkus (R-IL), Pallone (D-NJ), Upton (R-MI) and Hoyer (D-MD) characterized the legislation as striking the right balance to protect people, jobs, and the environment.

The legislative agreement negotiated by the House and Senate keeps the framework of the Senate-passed legislation (S. 697) largely intact. Highlights include -

- **Testing.** EPA has new authority to order chemical testing, and is called upon

to use tiered testing, screening approaches, test categories, and encourage alternatives to animal testing. EPA will charge fees to evaluate submitted test results.

- **New chemical reviews.** EPA must take sensitive subpopulations and intended conditions of use into account. If EPA fails to make a timely determination on a new chemical, the Agency is required to refund the submitter's filing fee unless the application is found incomplete. Within 90-days of a finding that the safety standard is not met or that testing is required, EPA must publish a decision on whether to issue a significant new use rule. EPA is required to publish a finding that a new chemical meets the law's safety standard. Commercialization can proceed before publication of EPA's finding. In addition, the 90-day review period can end early if EPA determines before that date that the substance meets the safety standard.
- **Inventory Reset.** Within one year of enactment, EPA will require manufacturers and importers to submit reports within six months on those chemicals listed on the TSCA Chemical Substance Inventory ("Inventory") that they have manufactured or imported for a non-exempt commercial purpose in the previous 10 years ("active" chemicals). In the interim, TSCA section 8(a) Chemical Data Reporting (CDR)-reported substances will serve as the list of active substances. Processors may be asked to report. EPA must publish a list of these active substances, and publish a rule within one year after that to require substantiation for chemical identities claimed as confidential business information (CBI). EPA must complete its review of these CBI claims within five years of issuing the active substance list. Inactive substances will remain on the TSCA Inventory, but EPA must be notified before manufacture, import, or processing can commence.
- **Existing chemicals.** Last minute changes included doubling the number of chemicals previously proposed for EPA to designate and review in the first three and a half years of the existing chemical review program to 20 high-priority and 20 low-priority substances. Preference is given to highly ranked PBTs and known human carcinogens with high acute and chronic toxicity. Metals will be evaluated within the March 2007 Framework for Metals Risk Assessment. EPA will prioritize and evaluate existing chemicals that may present an unreasonable risk of injury to health or the environment without considering costs or other nonrisk factors. EPA must consider intended conditions of use and include an evaluation of unreasonable risk to potentially exposed or susceptible subpopulations. Industry-requested risk assessments may comprise 25% - 50% of the Agency's risk evaluation workload.
- **Regulatory controls.** To restrict, phase-out, or ban an existing chemical, EPA must consider effects on health and the magnitude of the exposure, the benefits of the chemical substance or mixture for various uses, the reasonably ascertainable economic consequences of the rule, the costs and benefits of the regulatory action, and consider alternatives. However, EPA will no longer be required to select the least burdensome regulatory alternative. Exemptions may be granted for critical or essential uses; disruption of national economy, security or critical infrastructure, and beneficial uses. EPA cannot impose a

regulation that duplicates a regulation issued by the Agency or another agency under a different statute.

- **Preemption.** Federal preemption of new and existing state laws applies when EPA finds that a high priority chemical meets the safety standard and when EPA enacts a rule to regulate a chemical that does not meet the safety standard. Any state statute or regulation in existence before April 22, 2016, however, is grandfathered and not subject to preemption. There is no preemption of common law tort claim actions. Between the time EPA publishes the scope of a chemical risk assessment and up to three and a half years while it conducts the assessment, states generally may not enact new laws and regulations regulating the chemical. However, states may submit waiver requests to EPA to regulate a chemical during this period. States also are given up to 18 months after EPA has initiated the prioritization process or published the scope of the risk evaluation, whichever is sooner, to (i) enact a statute or (ii) propose or finalize an administrative action without any preemption while EPA evaluates the chemical. Exemptions from federal preemption include state law adopted pursuant to federal law; reporting, monitoring, or information obligations not otherwise adopted by EPA; and air, water quality, and hazardous waste laws absent a direct conflict with a TSCA regulation.
- **Confidential Business Information (CBI).** The legislation establishes processes for protecting CBI and requires written support for claiming protection from disclosure for chemical identity and other information. Only specific manufacturing and processing descriptions, specific volumes, the composition of a mixture, a chemical's use and function, and sales and marketing information will not require substantiation. There is a ten year time limit on confidentiality claims. Extensions of CBI protection are available for additional ten year terms. There is a presumption that information on uses of chemicals to be banned or phased-out will be fully disclosed to the public.
- **Fees and Penalties.** EPA is tasked to update fees for PMN submissions and impose new fees for reviews of test data and risk assessments for existing chemicals. The fees must support 25% of the operating costs of these programs. Small businesses will pay lower fees. The maximum civil penalty for TSCA violations is increased to \$37,500, and maximum criminal penalties are increased to \$50,000. Individuals may be fined \$250,000 as well as up to 15 years imprisonment for willful, imminent endangerment. Organizations may be fined up to \$1 million in such case.
- **Articles.** EPA may require a premanufacture notification (PMN) for a chemical substance imported as part of an "article" after issuing a rule finding that there is reasonable potential for exposure that justifies notification. EPA can impose prohibitions or restrictions on articles containing chemicals that do not meet the safety standard to the extent necessary to address the identified risks from exposure.
- **Advisory Committee.** EPA is instructed to have an advisory committee with representation from government, industry, nongovernmental organizations and academia to advise the Agency on new and existing chemical reviews.

- **Best Science.** EPA must use the “best available science” to review chemicals and develop policies and procedures necessary for implementation within two years.
- **Retroactivity.** The new law does not modify any rule or order promulgated or issued under TSCA before its effective date.
- **Judicial review.** A determination that the safety standard is met is a final Agency action. A determination that the safety standard is not met is not reviewable until EPA issues a final rule regulating the chemical substance.
- **Miscellaneous:** Other provisions further regulate export and disposal of mercury compounds, require negotiated reporting for inorganic byproducts, and provide authority to investigate potential cancer clusters. A section in the earlier Senate bill (S. 697) assessing federal resources dedicated to the use of sustainable chemistry was removed. Previously agreed-on provisions providing greater federal seizure authority and changes to export requirements were dropped from the legislation.

During consideration by the House of Representatives, Representative Tonko (D-NY), an earlier supporter of the legislation, expressed his concern that the negotiated agreement had weakened the Agency’s ability to impose significant new use rules and track chemicals in imported products. Other provisions that he listed as bases for his decision to vote against the legislation include provisions to limit reporting on inorganic byproducts and the ability of states to ban chemicals. Representative Tonko noted the precedent setting nature of the preemption pause and his view that the negotiated 18 month period for states to enact new legislation before the pause goes into effect is insufficient. In their remarks on the House Floor, Representatives Blackburn (R-TN) and Pittinger (R-NC) expressed support for section 9(b)(2), which will prevent EPA from restricting the use of a chemical if it is already regulated by EPA or another agency under a different statute in a manner that protects against the identified risks associated with the chemical. Representative Shimkus closed the bipartisan discussion leading up to the vote by noting the broad support for the legislation among industry, labor, and nongovernmental organizations. H.R. 2576 is expected to be fast-tracked for Senate consideration later this week on Wednesday or Thursday and the White House has announced the President’s intention to sign the legislation into law.

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