

How the Frank R. Lautenberg Chemical Safety for the 21st Century Act¹ amends the Toxic Substances Control Act of 1976 (TSCA)

and

Reconciling and other changes made since House and Senate bill passage

1. How the Lautenberg Act amends the Toxic Substances Control Act of 1976 (TSCA)

Health-based safety standard: Ensures that only human health and environmental impacts are considered in assessing the risks (based on hazard and exposure) of chemicals, replacing TSCA's cost-benefit balancing standard. Provides that costs and other nonrisk factors are to be considered in deciding *how* to regulate a chemical found not to meet the health-based safety standard, not *whether* to regulate.

Vulnerable populations: Requires EPA to identify groups of individuals potentially at most risk in assessing the safety of a chemical, to assess risks to those populations, and to ensure their protection.

Risk reviews of existing chemicals: Establishes for the first time a mandate for EPA to review the risks posed by chemicals in active commerce, in contrast to TSCA's grandfathering-in of chemicals then in use without any risk review. The key steps in the review process are:

- Companies are to identify all chemicals they are currently making or processing.
- EPA is to establish the priority (high or low) of active chemicals, at a pace commensurate with agency resources and capacity.
 - High-priority chemicals are those EPA determines may present an unreasonable risk, and undergo full risk evaluations against the health-based safety standard.
 - For any chemical found to present an unreasonable risk, EPA must either ban or phase it out, or impose restrictions sufficient for the chemical to no longer present such risk.
 - Low-priority chemicals are those EPA concludes have sufficient information (which EPA must identify) to establish that they do not meet the criteria for being designated a high-priority substance.

¹ Based on May 20, 2016, Rules Committee Print 114-54 as amended by Mr. Shimkus' Manager's Amendment posted on May 23, 2016.

- The criteria and process EPA uses for prioritization decisions, and the procedures it follows for risk evaluations, are to be established through full notice-and-comment rulemaking.
- In identifying high-priority chemicals, EPA is to give preference to chemicals on its Work Plan that are persistent and bioaccumulative and those that are known human carcinogens and have high acute and chronic toxicity, as well as chemicals stored near significant sources of drinking water.
- Companies may request EPA to assess their chemicals; the number of such reviews is capped and they cannot get special treatment, to ensure EPA-identified chemicals remain the primary focus.
- All steps in the review and regulatory process are subject to judicially enforceable deadlines, minimum numbers of chemicals to be reviewed are specified, and the number rises over time as program implementation is completed and experience is gained.

Authority to require testing of chemicals: Eliminates TSCA’s *Catch-22* requirement that EPA first have evidence of risk to require testing.” Provides for EPA to issue an order requiring testing, rather than having to promulgate a rule, which can be a multiyear process. Testing authority applies to both new and existing chemicals and for the purpose of prioritization, but for that purpose EPA cannot require testing as a general means to establish minimum information sets for chemicals. Requires EPA to reduce and replace animal testing where scientifically reliable alternatives exist that would generate equivalent or better information.

Review of new chemicals: Upgrades EPA’s review of new chemicals while retaining a balance with the need not to unduly impede innovation and speed to market. Requires for the first time that EPA make an affirmative safety finding, based on sufficient information, that a new chemical is not likely to present an unreasonable risk, as a condition for market entry. Maintains current TSCA’s 90-day review period for new chemicals in most cases.

Regulation of chemicals presenting significant risks: Strikes TSCA’s mandate that EPA demonstrate its regulations impose the “least burdensome” of possible requirements. In selecting among regulatory options, requires EPA to consider, based on reasonably available information, costs and benefits of its action, its cost-effectiveness, and the availability of alternatives to the chemical to be regulated – but EPA’s regulation must still be sufficient to address the identified risks and EPA can act even where its action is not demonstrated to be cost-effective or the benefits of its action are not demonstrated to outweigh the costs.

Requires EPA to identify a limited number of PBTs from its Work Plan to which exposure is likely, and promulgate risk management rules within 18 months, unless within a set time EPA designates the chemical as high-priority or a company requests a risk evaluation, in which case the chemical is instead to undergo a full risk evaluation and be restricted if found to present an unreasonable risk. Under either path, restrictions must reduce exposure to the substance to the extent practicable.

Requires EPA to address risks it refers to another federal agency if that agency fails to act. Retains TSCA’s requirement that, if EPA could act under another statute to address a risk, it must consider the relevant aspects of the risks and compare the estimated costs and efficiencies of acting under TSCA versus the other law.

Confidential business information (CBI): Requires EPA to review, and approve or deny, all past CBI claims to mask the identities of active chemicals on the TSCA Inventory, which are not currently publicly available. Requires that most CBI claims be substantiated when made, be reviewed by EPA, and expire after 10 years unless re-substantiated. Identifies specific types of clearly proprietary information for which claims do not require substantiation or reassertion. Specifies types of information, including health and safety data, that are not eligible for CBI protection. Requires EPA to review and require substantiation for all CBI claims for chemicals found not to meet the safety standard, and specifies that most claims for uses of a chemical that EPA bans or phases out no longer apply. For the first time, provides that CBI is to be shared with state governments, health and environmental professionals and first responders, subject to nondisclosure agreements.

User fees: Requires EPA to collect fees for both new and existing chemicals, as well as those designated as high-priority, to defray a portion of the costs of implementing the program. Provides that fees go into a “TSCA Implementation Fund” and directly to EPA, not the general treasury. Specifies that fees are to cover approximately 25% of relevant EPA program costs (initially set at up to \$25 million annually), and that companies are to pay 100% of the costs of risk evaluations they request (50% for those already on EPA’s Work Plan).

Federal-State authority: Establishes limited preemption of state authority that is chemical-specific, applies only when EPA takes up a chemical that a state has acted or intends to act on, and is confined to the hazards, exposures, risks, uses and conditions of use of a chemical that are included in EPA’s risk evaluation (and, where required, risk management rule). Preemption applies only to existing, not new, chemicals on which EPA is taking action.

Preemption applies only to state *restrictions* on a chemical, not to reporting, monitoring or other information requirements. States can impose and enforce restrictions that are identical to a Federal requirement, adopted under the authority of a federal law, or adopted under a state air or water quality or waste treatment or disposal law, unless they conflict with federal requirements.

State actions taken on a chemical prior to April 22, 2016, or taken under a state law in effect on August 31, 2003, remain in place regardless of EPA action. After enactment, states can restrict a chemical until and unless EPA initiates a review of that same chemical and addresses the same hazards, exposures and uses.

States can enforce existing restrictions until EPA takes final action on a chemical, but can only impose new restrictions during EPA review of a chemical under a waiver. Alternatively, once EPA identifies a chemical it intends to prioritize, states have a 12-18 month window during which time they can get a waiver that allows any action they have initiated on the chemical to be completed and remain in place until EPA takes final action on that chemical. If EPA finds that a chemical presents an unreasonable risk, states can impose new or continue to enforce existing restrictions on that chemical until EPA issues its regulation.

States can also seek waivers to act after EPA review. EPA decisions on waivers, or its failure to make a decision, can both be challenged by anyone in court.

II. Reconciling and other changes made since House and Senate bill passage

General

- While retaining more of the Senate bill's policy provisions, the new bill, like the House bill, adheres more closely to the structure of and retains more of current TSCA.
- Utilizes the House bill's "risk evaluation" in lieu of the Senate bill's "safety assessment and safety determination" (no substantive change in meaning).
- Reconciliation of key terms used throughout the bill:
 - Senate bill's definition of "safety standard" is struck, but now the bill text uses this formulation for EPA determinations: whether a chemical substance "presents [for existing chemicals] or may present [for new chemicals] an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator, under the conditions of use."
 - "Conditions of use" is used instead of "intended conditions of use" (no substantive change in meaning).
 - "Potentially exposed or susceptible subpopulation" is used instead of "potentially exposed subpopulation" (no substantive change in meaning).

Prioritization

- EPA is to designate chemicals as either high-priority substances for risk evaluations or low-priority substances for which risk evaluations are not warranted at the time.
 - A *high-priority substance* is a chemical EPA "concludes, without consideration of costs or other nonrisk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator."
 - A *low-priority substance* is a chemical EPA "concludes, based on information sufficient to establish, without consideration of costs or other nonrisk factors," does not meet the criteria for being designated a high-priority substance.
- EPA is to identify chemicals to be subject to prioritization, allow for submission of information and public comment, and finalize their designations within 1 year.
 - The deadline may be extended by 6 months if more information is needed; if after that there still is not enough information to designate the chemical as low-priority, it is to be designated as high-priority and subject to a risk evaluation.

Risk Evaluations

- Within 6 months, EPA is to designate at least 10 chemicals from its Work Plan for risk evaluations.
- Within 3.5 years of enactment, EPA shall:
 - be conducting risk evaluations on at least 20 high-priority substances, at least half of which are to be Work Plan chemicals; and
 - have designated at least 20 low-priority substances.
- Thereafter, EPA is to prioritize chemicals and conduct risk evaluations on high-priority substances, at a pace consistent with EPA's ability to complete them in accordance with the applicable deadlines.
 - Priority is to be given to Work Plan chemicals that are PBTs or are known human carcinogens and have high acute and chronic toxicity.

- Industry can nominate chemicals for risk evaluation but the number of such chemicals cannot exceed 50% of the number EPA initiates on high-priority chemicals, and they cannot be expedited or given special treatment relative to EPA-initiated risk evaluations. (These risk evaluations do not have a preemptive effect until EPA takes final action.)
- Deadlines and extensions for risk evaluations remain as in the Senate bill.

Risk Management

- Where EPA finds unreasonable risk, restrictions are to be imposed by rule “so that the chemical substance no longer presents such risk.”
- Deadlines and extensions for promulgating risk management rules remain as in the Senate bill.
- Changes to requirements for risk management rules:
 - Among the additional factors EPA must consider, to the extent practicable based on reasonably available information, are:
 - ◆ the cost-effectiveness of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator, and
 - ◆ in deciding whether to ban or phase out a use of a chemical, whether technically and economically feasible alternatives that benefit health or the environment, compared to the use proposed to be banned or phased out, will be reasonably available as a substitute.
 - Replacement parts for complex durable goods and complex consumer goods designed prior to the rule are to be exempted unless EPA finds such parts contribute significantly to the risk to the general population or to an identified potentially exposed or susceptible subpopulation. Definitions of complex durable and complex consumer goods are added.
 - Limitation on regulating chemicals in articles remains as in Senate bill.
- Deadlines for final compliance with risk management regulations are to be within 5 years, except in the case of a ban or phase-out, which is to start within 5 years and be fully implemented “as soon as practicable.”
- Includes a modified version of the House bill’s provision addressing chemicals that are persistent, bioaccumulative, and toxic (PBTs):
 - Not later than 3 years after enactment, EPA is to propose risk management rules for a limited number of PBTs (excluding metals and metal compounds) from its Work Plan to which exposure is likely, and to finalize those rules within 18 more months, to “reduce exposure to the substance to the extent practicable.”
 - However, if, within 90 days of enactment, EPA designates the chemical as high-priority or a company requests a risk evaluation, the chemical is instead to undergo a full risk evaluation and, if found to present an unreasonable risk, restrictions must both eliminate such risk and reduce exposure to the substance to the extent practicable.
- As in the Senate bill, a final determination that a chemical does not present an unreasonable risk is to be made by order and subject to judicial review under the substantial evidence standard. A risk management rule issued for a chemical EPA determines presents an unreasonable risk is also subject to judicial review under the substantial evidence standard.

New Chemicals

- Largely retains Senate bill’s approach, with some restructuring to more closely mirror TSCA:
 - Provides separate order authority for when EPA finds: a) a new chemical presents an unreasonable risk, or b) information is not sufficient to make a risk determination or a

chemical may present an unreasonable risk. In the first of these cases, TSCA's existing rule authority is also retained. Manufacture can commence only in compliance with restrictions in the order or rule, which must be imposed "to the extent necessary to protect against an unreasonable risk."

- Provides for commencement to begin where EPA finds that a new chemical is not likely to present an unreasonable risk.
- If EPA fails to make a determination on a new chemical notice within the applicable review period, unless the notifier has not provided required information or has otherwise unduly delayed the process, EPA must refund all applicable fees but must still complete its review.
- Articles can be subject to notification requirements via Significant New Use Rules (SNURs) only if EPA finds that a "reasonable potential for exposure" *justifies* requiring notification (had been "warrants" in the Senate bill).

Testing

- Retains TSCA's testing authority where a chemical may present an unreasonable risk or where production and release or exposure is substantial, but now allows that testing to be done by order as well as by rule.
- Includes Senate bill's authority to require testing by rule, order or consent agreement for specified purposes."
- Retains the Interagency Testing Committee (which had been eliminated under the Senate bill), and adds FDA and CPSC to the designated list of members.
- Retains Senate bill's tiered testing provision.
- Adds explicit authority to require development of information needed to assess "exposure or exposure potential to humans or the environment."
- Largely retains Senate bill's animal testing provisions, with changes to emphasize scientific validity of alternative methods and some streamlining.

Information Collection and Reporting

- Retains Senate bill's modifications to section 8, including the Inventory reset and mandated review of past CBI claims for chemical identity of active chemicals.

Relationship to Other Federal Laws

- Mandates EPA to act if another federal agency to which it has referred an unreasonable risk finding does not take required actions within the requisite time periods.

Confidential business Information

- Largely retains Senate bill's provisions with mainly clarifying modifications.
- For chemicals subject to bans or phase-outs, CBI claims are presumed to no longer apply, but exceptions are provided for CBI pertaining to: any uses not subject to the ban or phase-out; uses granted critical use exemptions; and manufacture of chemicals exempted from TSCA because they are produced solely for export.
- If disclosure of the specific chemical identity of a chemical in a health or safety study or underlying data would reveal how the chemical is made or the portion it comprises in a mixture, that specific chemical identity is explicitly identified as not authorized to be disclosed.

State-Federal Relationship

- Largely retains Senate bill's provisions with mainly clarifying modifications.
 - Adds a requirement that at least 12 months must elapse between EPA's identification of a chemical to be subject to prioritization, and EPA's publication of the scope of its

risk evaluation for such a chemical it has designated as high-priority (which triggers “pause preemption”).

- This provision is paired with another that creates a window of at least 12 (up to a maximum of 18) months during which time states can get a waiver that allows any action they have initiated on the chemical to be completed and remain in place until EPA takes final action on that chemical.
- Provides that the first 10 chemicals EPA identifies for risk evaluations, and any chemicals industry requests risk evaluations for that are on EPA’s Work Plan, are not subject to pause preemption.

User Fees

- Largely retains Senate bill’s provisions, with some narrowing of activities subject to and covered by fees.