Comparing the Toxic Substances Control Act, the Frank R. Lautenberg Chemical Safety for the 21st Century Act (S. 697), and the TSCA Modernization Act of 2015 (H.R. 2576)

June 30, 2015

This table compares the Toxic Substances Control Act (TSCA) of 1976 to S. 697 as reported out by the Senate Environment and Public Works Committee on April 28, 2015, and H.R. 2576 as passed by the House of Representatives on June 23, 2015. Our analysis focuses on 12 major issues that fall within the scope of the legislation.

	Current TSCA	Chemical Safety for 21st Century Act (S 697)	TSCA Modernization Act (HR 2576)
1. Safety standard	• "Unreasonable risk" requires cost-benefit analysis and balancing.	• Explicitly precludes EPA from considering costs and other non-risk factors in making safety determinations. • Clarification is made throughout TSCA where "unreasonable risk" is used that it excludes consideration of costs, either by striking "unreasonable" or adding "without taking into account cost or other non-risk factors."	• Prohibits EPA from considering costs in risk evaluations (though it does not clearly state that the unreasonable risk determination is to exclude costs or other non-risk factors). • Does not address other instances of the term "unreasonable risk" in TSCA.
2. Protection of vulnerable populations	• No special consideration.	• Defines "potentially exposed or susceptible population" to include vulnerability due either to elevated chemical exposures or to heightened susceptibility to their effects. • Specifies such populations include (but are not limited to) infants, children, pregnant women, workers, the elderly. • Expressly requires protection of such populations.	• Defines "potentially exposed population" to include vulnerability due either to elevated chemical exposures or to heightened susceptibility to their effects. • Definition does not specify which populations can be included. • EPA cannot conclude a chemical will not present an unreasonable risk if one or more potentially exposed populations are subject to such a risk.

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3. Adequacy of restrictions for chemicals found not to meet safety standard	• Authority but no mandate to restrict chemicals found to present an unreasonable risk. • No provision to ensure the sufficiency of restrictions.	• Explicitly requires that restrictions must either phase out or ban the chemical, or be sufficient to ensure the chemical meets the safety standard. • For PBTs that do not meet the safety standard, EPA is to reduce exposure to the maximum extent practicable. • EPA is to restrict articles "only to the extent necessary for the chemical substance to meet the safety standard." • EPA "shall exempt replacement parts manufactured prior to the effective date of the rule for articles that are first manufactured prior to the effective date of the rule" unless EPA finds they "contribute significantly to the identified risk." • Compliance deadlines for bans or phase-outs are to be "as short as practicable."	• Restrictions must be imposed "to the extent necessary so that the chemical substance no longer presents or will present an unreasonable risk, including an identified unreasonable risk to a potentially exposed subpopulation." • EPA is to restrict articles "only to the extent necessary to protect against the identified risk." • EPA shall exempt replacement parts "designed prior to the date of promulgation of the rule" unless EPA finds they contribute significantly to the risk, "including identified risk to identified potentially exposed subpopulations." • Any restriction imposed "shall provide for a reasonable transition period."
4. Regulation and consideration of costs and other nonrisk factors	• EPA must conduct a formal analysis and show benefits of any proposed restriction outweigh costs. EPA must consider: o benefits of the substance; o availability of substitutes for each use; and o reasonably ascertainable economic consequences of the rule, including on the	• Strikes "least burdensome" requirement. • Makes clear that cost considerations cannot override requirement for restrictions to ensure chemical safety. • Balancing of costs and benefits is not required, is to be considered only "to the extent practicable based on reasonably available information." • Bans and phase-outs must be based on consideration of costs and benefits of relevant alternatives to the chemical. • Only alternatives deemed relevant and technically and economically feasible by EPA need to be considered.	• Strikes "least burdensome" requirement. • Retains TSCA requirements that, in issuing a rule, EPA must consider: o benefits of the substance; and o reasonably ascertainable economic consequences of the rule, including on the national economy, small business and innovation. • Adds two mandatory cost-related requirements not in current TSCA: o EPA must show any requirements are "cost-effective, except where the Administrator determines that

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	national economy, small business and innovation. • Restrictions must be "least burdensome" among those able to address identified risks.		"additional or different requirements ... are necessary." o For a ban or effective ban, and in setting compliance dates, EPA must determine whether viable and safer alternatives are available. • EPA is to identify PBTs – *excluding any metal or metal compound* – to which there is likely exposure and, without first having to conduct a risk evaluation, promulgate rules "to reduce likely exposure to the extent practicable" – but "subject to the availability of appropriations." o But if EPA initiates a risk evaluation or a company requests one, this expedited action does not apply. • Before acting under TSCA to address a risk, EPA must compare the relative risks, costs and efficiencies of acting under TSCA vs. acting under another law administered by EPA. This new requirement is in addition to TSCA's existing requirement that EPA show that acting under TSCA is "in the public interest" (determined wholly at the Administrator's discretion).
5. Pace of reviews and deadlines	• No mandate to review the safety of existing chemicals. • No deadline for completing initiated assessments or imposing restrictions.	• Specifies concrete deadlines for all major steps: prioritization, safety assessment and determination (3 years), and regulation (2 years), extendable in the aggregate up to 2 years with cause. • Sets a 2-year deadline by which all rules to	• Sets a 3-year deadline for EPA-initiated risk evaluations and a 2-year deadline for industry-requested ones (each extendable up to 2 years if additional information is needed) and a 2-year deadline for any regulations.

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		establish requirements and procedures must be issued. • EPA must also specify a deadline for companies to submit any information it requests. • EPA must include at least 10 chemicals on the initial high-priority list, as well as at least 10 on the low-priority list. o By 3 years after enactment, at least 20 high-priority and 20-low-priority chemicals must have been listed. o By 5 years after enactment, at least 25 high-priority and 25-low-priority chemicals must have been listed. • At least 50% of chemicals are to be work plan chemicals until all of them have been listed, with preference given to chemicals ranking high for persistence and bioaccumulation. • Companies can request EPA to assess a chemical; at EPA's discretion, using criteria it must develop by rule, EPA can grant such requests. If sufficient requests meeting the criteria are made, EPA must grant requests totaling not less than 25% and not more than 30% of the number of high-priority assessments, but cannot give them preference over high-priority chemicals, and initiation of such assessments does not trigger preemption. • Companies can request EPA to assess a work plan chemical it has not yet designated high-priority (and if EPA starts	• EPA is to conduct risk evaluations for any chemicals it determines "may present unreasonable risk of injury to health or the environment because of potential hazard and a potential route of exposure under the intended conditions of use," but: o there is no prioritization or other process for identifying such chemicals, and o EPA needs to make a potential risk finding in order to initiate a risk evaluation. • For chemicals with insufficient information to determine whether they may present an unreasonable risk: o there is no mechanism provided to spur their review; and o as noted below, EPA could not require testing without first showing potential risk or substantial production/exposure. • Specifies EPA is to initiate at least 10 risk evaluations each year for chemicals it selects – "subject to the availability of appropriations." • EPA may initiate a risk evaluation on any chemical listed on its work plan without having to make a risk finding. • EPA must conduct a risk evaluation of any chemical that any manufacturer requests it conduct. EPA can

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		such an assessment, it triggers preemption of new state restrictions).	modulate the number of industry-requested risk evaluations it conducts if it is unable to meet the deadlines for *those* risk evaluations – but not the deadlines for EPA-initiated risk evaluations. The full costs of industry requested risk evaluations are to be borne by the manufacturer.
6. Procedural and scientific requirements; transition	• Virtually no procedures or criteria specified to assess information quality, identify chemicals warranting further scrutiny, or determine risk.	• Requires EPA to establish policies, procedures and guidance addressing: use of science; information sources; testing; prioritization screening; and safety assessments and safety determinations. • Sets a two-year deadline for EPA to establish all policies, procedures and guidance. • Requires EPA to base decisions on best available science and on the weight of the scientific evidence, and consider recommendations of the National Academy of Sciences. • Safety assessments and determinations must identify relevant vulnerable populations and the basis for considering either aggregate exposure or significant subsets of exposures. • Eases transition to new system by, for example, allowing EPA to continue or initiate assessments on Work Plan chemicals, and adapt current procedures, as new procedures are put in place.	• Risk evaluations are to integrate hazard and exposure information for all intended conditions of use of a chemical; consider information on vulnerable populations; describe the weight of the scientific evidence; and consider whether threshold doses exist below which no adverse effects are expected. • EPA may subject chemicals identified in its Work Plan to risk evaluations. • No other specific provisions are included to indicate how EPA is to transition from its current processes and activities to the new ones called for under the bill.

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7. Testing	• EPA must go through notice-and-comment rulemaking (typically a multiyear process) to require testing. • It must also show evidence of potential risk or high exposure, a *Catch-22*.	• Provides authority for EPA to use orders to require testing (with justification) and eliminates TSCA's requirement to first show risk or high exposure. • EPA must first request submission of the needed information before requiring testing; and it cannot require testing as a means to establish minimum information sets for chemicals generally.	• Provides order authority to require testing; no specific justification for using an order is required. • Retains TSCA's requirement for EPA to first show risk or high exposure before requiring testing unless the testing is "necessary to conduct a risk evaluation." o Making the risk finding necessary to initiate a risk evaluation may be difficult or impossible absent the information testing would yield.
8. Low-priority designations	• EPA has no mandate to prioritize chemicals, the result being that a chemical unexamined by EPA is effectively a low priority, with a lack of data presumed to indicate lack of risk.	• States explicitly that a chemical cannot be designated as low-priority unless EPA concludes that there is "information sufficient to establish it is likely to meet the safety standard". • Criteria and process for designating low- (and high-) priority chemicals must be developed by notice-and-comment rulemaking. • Lack of data can be a sufficient basis in itself (not just a factor) for designating a chemical as high-priority. • EPA has authority to require testing to inform prioritization decisions where data are lacking. • Anyone can judicially challenge an EPA designation of a chemical as low-priority. • States can impose restrictions on low-priority chemicals (see item 12a below).	• Not applicable: no prioritization process is included. • As under current TSCA, chemicals for which EPA does not or cannot make the risk finding needed to initiate a risk evaluation are effectively set aside and not subject to any review.

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9. New chemicals	• A company is generally free to start making and selling a new chemical at the end of a 90-day review period, unless EPA finds the chemical "may present an unreasonable risk". • No affirmative safety decision is required, and the burden is on EPA to find a concern even when safety data are wholly lacking.	• Clarifies that manufacture of a new chemical can only start if EPA affirmatively finds it is likely to meet the safety standard. • Where EPA determines the chemical is *not* likely to meet the safety standard, it must preclude manufacture or impose restrictions sufficient for EPA then to make the likely-safe finding. • If EPA has insufficient information to make a determination, it can suspend the review pending receipt of the information, or impose restrictions sufficient for it to make the likely-safe determination even in the absence of the information. • To require notification of articles as a significant new use, EPA needs to make an affirmative finding of "reasonable potential for exposure."	• Makes no changes to TSCA's new chemicals provisions.
10. Confidential business information (CBI)			
10a. CBI claims – Chemical identity	• The identities of about 17,000 chemicals (out of the 85,000) on the TSCA Inventory are hidden from public view, having been claimed by their makers to be CBI. • EPA can challenge such CBI claims on a case-by-case basis, but it has no mandate to review them	• Limits any presumption of protection from disclosure of chemical identities to the period before they enter the market; and any such claim for a chemical after market entry has to be substantiated and reviewed by EPA. • EPA is also required to review and require substantiation of past chemical identity claims for all active chemicals now on the confidential portion of the TSCA Inventory within five years of enactment, and for any	• CBI claims made before enactment are not subject to any review, do not expire and are not subject to justification requirements, so confidential chemicals on the TSCA Inventory will remain so. • No requirement for EPA to review any past chemical identity CBI claims (17,000 of the 85,000 chemicals on the TSCA Inventory), but retains EPA authority to challenge claims on a

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	and rarely mounts challenges because of the resources required.	inactive chemical at the time it is moved to active status. • Chemical identities not already on the confidential portion of the inventory or added to it per prescribed procedures cannot be claimed confidential.	case-by-case basis.
10b. CBI claims – Health and safety information	• Companies are free to claim virtually any information they submit to EPA is CBI. • Health and safety studies and their underlying data are generally not eligible for CBI protection under TSCA, but, until recently EPA routinely allowed those studies, or the identities of the studied chemicals, to be hidden from public view.	• Retains current TSCA's exclusion of health and safety studies and their underlying data from being claimed CBI. • Retains TSCA's two exceptions to the general allowance for disclosing health and safety information: data that would disclose processes used in manufacturing or processing of a chemical mixture, and in the case of a mixture, data that would disclose the portion of the mixture comprised by a chemical. • Does *not* affect current EPA policy that disallows masking of the identities of chemicals in those health and safety studies. • Restores EPA's authority to review all types of CBI claims made in the past. • For claims made going forward, they generally must be substantiated at the time they are asserted and are time-limited (see item 10c below). • EPA has authority to review the claims under a range of circumstances, including for chemicals designated high-priority or found not to have sufficient information for a safety determination. • For chemicals found not to meet the safety	• Retains current TSCA's exclusion of health and safety studies and their underlying data from being claimed CBI. • But current TSCA's provision for EPA to identify chemicals that are the subject of health and safety information it is making public is effectively eliminated: o Retains TSCA's two exceptions to the general allowance for disclosing health and safety information: data that would disclose processes used in manufacturing or processing of a chemical mixture, and in the case of a mixture, data that would disclose the portion of the mixture comprised by a chemical. o But it adds a third exception: "data that disclose formulas (including molecular structures) of a chemical substance or mixture." This inclusion goes beyond data relating to a chemical formulation and would expressly preclude EPA from identifying a chemical that is the subject of health and safety data it

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		standard, EPA must to review all CBI claims and require substantiation. • CBI disclosure for banned or phased-out chemical presumed in the public interest.	is making public, if claimed CBI.
10c. CBI claims – Substantiation and EPA review requirements, time limits	• No statutory requirement for CBI claims to be substantiated, though EPA has done so in certain cases. • CBI claims are not subject to time limits and remain in place until and unless challenged by EPA.	• Most CBI claims are required to be substantiated at the time they are asserted, promptly reviewed by EPA, and either approved or denied. • Approved claims expire after 10 years unless resubstantiated and reapproved. • Even between 10-year intervals, EPA can review and require resubstantiation of certain CBI claims, including for high-priority chemicals or those lacking sufficient information. • EPA is mandated to review and require resubstantiation of certain CBI claims, including where EPA has reason to believe the claim is not valid; or for chemicals found not to meet the safety standard. • Most CBI claims for a chemical that EPA bans or phases out automatically expire.	• CBI claims are to be substantiated at the time they are asserted (though no requirements are specified). • No mandate for EPA review of CBI claims. • CBI claims made after enactment expire after 10 years unless the claim is reasserted. • Retains EPA authority to challenge claims on a case-by-case basis.
10d. CBI claims – Access to information, including CBI	• TSCA provides few requirements for EPA to make public information it receives or decisions it makes and the basis for them. • EPA cannot disclose information claimed CBI to the public, to state and local agencies, health or	• Explicit requirements are included throughout the bill for EPA to make information it receives, and decisions it makes and the basis for them, available to the public. • EPA <u>shall</u> disclose CBI upon request to a state or local government. • EPA shall disclose CBI upon request to health or environmental professionals employed by federal or state agencies or	• No specific requirements for EPA to make information public are added by the bill to current TSCA. • EPA <u>may</u> disclose CBI upon request to a state, local or tribal government. • EPA shall disclose CBI upon request to: o health or environmental professionals employed by federal or state agencies in response to an environmental release; or

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	environmental professionals, or even to first responders.	treating physicians or other health care professionals in response to an environmental release or to assist in diagnosis or treatment. • EPA shall also disclose CBI upon request to poison control centers or first responders in emergency situations. • Disclosures require statement of need and a confidentiality agreement with EPA to keep the information confidential. • No advance notification is required prior to CBI disclosure to state or local governments. • Advance notification is required prior to disclosure to health or environmental professionals or heath care professionals, except in emergency situations.	o treating physicians or other health care professionals to assist in diagnosis or treatment. • No recipient of CBI may use the information for any other purpose or disclose the information to any non-authorized person. • Advance notification is required prior to CBI disclosure to state or local governments. • No advance notification is required prior to disclosure to health or environmental professionals or heath care professionals.
11. User fees	• EPA can only charge fees to cover testing requirements or new chemicals. • No fees can be charged to defray the typically much higher costs of EPA reviews of existing chemicals or the collection, management or evaluation of information on existing chemicals. • Fees are capped at $2,500 per company ($100 per small company). • Any fees collected go to the general treasury and	• EPA <u>shall</u> collect fees for both new and existing chemicals, as well as those designated as high-priority. • Fees can be used to defray the costs of: new chemical reviews; prioritization screening; safety assessments, safety determinations and any needed regulation of new and existing chemicals; and the collection, review, and provision of public access to information, as well as protection of information found to warrant it. • Fees go into a "TSCA Implementation Fund" and directly to EPA, not the general treasury. • Fees are contingent on Congress providing sufficient funds through normal	• EPA <u>may</u> collect fees for new chemicals and for industry-requested risk evaluations – but <u>not</u> for EPA-initiated risk evaluations. • Fees can only be used to administer the provisions for which they are collected. • Fees go into a "TSCA Service Fee Fund" and directly to EPA, not the general treasury. • No specification as to the level of fees is provided. • Companies must pay 100% of the costs of risk evaluations they request.

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	are not available to directly cover EPA's costs.	appropriations, to seek to ensure collection of fees does not lead to a reduction in EPA's budget. • The level of fees is to be set to cover approximately 25% of relevant EPA program costs up to $18 million/year. • Companies must pay 100% of the costs of safety assessments they request (50% for those already on EPA's work plan).	
12. State preemption			
12a. State preemption – general	• Preemption has rarely if ever been applied because, in practice, EPA has imposed so few restrictions on chemicals under the current law. • EPA actions to protect against risks of new or existing chemicals generally preempt states' existing or new actions. • Exceptions are provided for a state requirement that is identical to the federal requirement (providing for co-enforcement), is adopted under authority of a Federal law, or prohibits all use of the chemical in the state.	• The bill's preemption applies to state restrictions on a chemical, not to requirements for reporting, monitoring or disclosure. • Preemption is explicitly limited to restrictions relating to the uses and conditions of use that are included in the scope of EPA's safety assessment and determination, which EPA must set within 6 months of designating a chemical as high-priority. • States can still act on a chemical to address a different health or environmental concern than EPA considers under TSCA (e.g., VOC restrictions to address ozone formation). • States can continue to impose restrictions that are: o identical to a Federal requirement; o adopted under the authority of a federal law; or o adopted under a state air or water quality or waste treatment or disposal	• The bill's preemption applies to any state requirement "designed to protect against exposure" to a chemical, not just to restrictions, which could preempt state requirements for reporting or disclosure. • Preemption is explicitly limited to requirements relating to the intended conditions of use considered by the Administrator in the risk evaluation. • States could not act on a chemical to address a different health or environmental concern than EPA considered. • States can continue to impose requirements that are: o identical to a Federal requirement; o adopted under the authority of a federal law; or o adopted under a state air or water quality or waste treatment or disposal law,

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		law, unless they conflict with federal requirements. • A state cannot prohibit all use of the chemical in the state, except via co-enforcement or getting a waiver. • Preemption is not triggered by a low-priority designation, so states can continue to act on such a chemical; however: o States are to notify EPA of actions they take on such a chemical and if requested by EPA provide the basis for the action; and EPA is to prioritize the chemical if it has national impact.	unless they conflict with federal requirements. • A state cannot prohibit all use of the chemical in the state, except via co-enforcement or getting a waiver.
12b. State preemption – grandfathering	• Not applicable	• Any state action taken on a chemical prior to August 1, 2015, or taken under a law in effect on August 31, 2003, remain in place regardless of EPA action. • California's Proposition 65 is excluded from the scope of preemption.	• Any state action taken or requirement that has taken effect on a chemical prior to August 1, 2015, or under a state law in effect on August 31, 2003, remain in place regardless of EPA action. • California's Proposition 65 is excluded from the scope of preemption.
12c. State preemption – before final EPA action	• States are not barred from imposing a new requirement on a chemical EPA is reviewing until EPA takes final action on the chemical.	• States are generally barred from imposing a new restriction on a chemical once EPA designates it as high-priority and starts a review, ending when EPA issues a final safety determination; states can impose new restrictions during any required rulemaking. • EPA's initiation of assessments on chemicals that industry requested it to conduct does not trigger preemption, except that initiation of industry-requested	• States are not barred from imposing a new requirement on a chemical EPA is reviewing until EPA takes final action on the chemical.

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		assessments of EPA work plan chemicals does trigger preemption of new state restrictions.	
12d. State preemption – after final EPA action	• EPA actions taken to protect against risks of new or existing chemicals generally preempt states' existing or new actions.	• State restrictions on a chemical imposed after August 1, 2015, are preempted if EPA determines the chemical meets the safety standard; if EPA determines a chemical does not meet the standard, preemption applies when EPA issues a final rule restricting the chemical.	• State requirements on a chemical imposed after August 1, 2015 are preempted if EPA determines the chemical does not present an unreasonable risk; if EPA determines a chemical does present an unreasonable risk, preemption applies when EPA issues a final rule restricting the chemical.
12e. State preemption – new chemicals	• If EPA imposes any requirement on a new chemical designed to protect against risk, no state could impose a requirement on the chemical designed to protect against the risk.	• EPA reviews of new chemicals would have no preemptive effect (unlike under TSCA and the House bill).	• If EPA imposes any requirement on a new chemical designed to protect against risk, no state could impose a requirement on the chemical designed to protect against exposure from the use(s) identified by the company.
12f. State preemption – waivers	• States can obtain waivers from Federal preemption for a requirement that is significantly more protective and does not unduly burden interstate commerce.	• EPA shall grant a waiver for a state to act before a final safety determination if it meets conditions similar to those under current TSCA. o If EPA fails to meet its deadline for issuing a safety determination, or for deciding on a state waiver application, the state waiver is automatically approved. • EPA may grant a state a waiver to act after a final safety determination or risk management rule if certain conditions are met, which are more onerous than under	• EPA may grant a state a waiver to act after a final safety determination or risk management rule, if certain conditions are met, which are the same as those under current TSCA. o If EPA fails to decide on a state waiver application, because it is done at EPA's discretion, no recourse is available to compel a decision. • If EPA grants a state waiver, the decision can be challenged in court. • If EPA denies a state waiver, the

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		current TSCA or the House bill. • If EPA fails to decide on a state waiver application, any person may sue EPA to compel a decision. • If EPA grants or denies a state waiver, the decision can be challenged in court.	decision cannot be challenged in court under TSCA, although a challenge may be possible under the Administrative Procedures Act if the decision is deemed a final agency action.