Comparing the 1976 Toxic Substances Control Act to the Frank R. Lautenberg Chemical Safety for the 21st Century Act (H.R. 2576)

June 22, 2016

This table compares the original Toxic Substances Control Act (TSCA) of 1976 to H.R. 2576 as passed by the full House on May 24, 2016, and the full Senate on June 7, 2016, and signed into law by the President on June 22, 2016. Our analysis focuses on 12 major issues that fall within the scope of the legislation.

[Brackets] following provisions indicate the relevant section(s) of original TSCA as amended by the new bill.

	Old TSCA	Chemical Safety for 21st Century Act (HR 2576)
1. Safety standard	• "Unreasonable risk" requires cost-benefit analysis and balancing.	• Clarification is made throughout TSCA where "unreasonable risk" is used that it excludes consideration of costs and other nonrisk factors, either by striking "unreasonable" or adding "without taking into account cost or other non-risk factors." *[various]* • Applies the same degree of judicial scrutiny to an EPA determination that a chemical does not present an unreasonable risk as is applied to an EPA determination that a chemical does present an unreasonable risk. *[19(c)(1)(B)(i)]*
2. Protection of vulnerable populations	• No special consideration.	• Defines "potentially exposed or susceptible subpopulation" to include vulnerability due either to elevated chemical exposures or to heightened susceptibility to their effects. *[3(12)]* • Specifies such populations may include (but are not limited to) infants, children, pregnant women, workers, the elderly. *[3(12)]* • Expressly requires that restrictions imposed be sufficient to ensure protection of such populations. *[5(e)(1)(A), 5(f)(1), 6(a), 6(b)(4)(A)]*
3. Adequacy of restrictions for chemicals that do not meet safety standard; articles; compliance deadlines	***RESTRICTIONS***: • Authority but no mandate to restrict chemicals found to present an unreasonable risk. • No provision to ensure the sufficiency of restrictions.	***RESTRICTIONS***: • Restrictions must be imposed, up to and including a phase-out or ban of the chemical or specific uses, "to the extent necessary so that the chemical no longer present such [unreasonable] risk." *[6(a)]* • For PBTs, EPA is to impose restrictions that reduce exposure to the extent practicable. *[6(h)(4)]*

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	ARTICLES: • General authority is provided to regulate chemicals in articles. ***COMPLIANCE DEADLINES***: • Compliance deadlines "shall be as soon as feasible."	***ARTICLES***: • EPA is to restrict articles "only to the extent necessary to address the identified risks from exposure to the chemical substance or mixture from the article or category of articles so that the chemical substance or mixture does not present an unreasonable risk." *[6(c)(2)(E)]* • EPA "shall exempt replacement parts for complex durable goods and complex consumer goods that are designed prior to the date of publication of the rule" unless EPA finds they "contribute significantly to the identified risk." *[6(c)(2)(D)]* ***COMPLIANCE DEADLINES***: • Compliance deadlines can be no longer than 5 years. *[6(d)(2)(A)(ii)(I)]* • Compliance deadlines for bans or phase-outs are to be "as soon as practicable" and the ban or phase-out is to start not later than 5 years after the rule is finalized *[6(d)(1)]*
4. Regulation and consideration of costs and other nonrisk factors; other Federal laws	***LEAST BURDENSOME***: • Restrictions must be "least burdensome" among those able to address identified risks. ***COSTS, ALTERNATIVES***: • 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 national economy, small business and innovation.	***LEAST BURDENSOME***: • Strikes "least burdensome" requirement. *[6(a)]* ***COSTS, ALTERNATIVES***: • Retains TSCA requirements that, in issuing a rule, EPA must consider, "to the extent practicable": o benefits of the substance; and o reasonably ascertainable economic consequences of the rule, including on the national economy, small business and innovation. *[6(c)(2)(A)]* • EPA must also consider, to the extent practicable: o the costs and benefits and cost-effectiveness of its proposed regulatory action and of the 1 or more primary alternative regulatory actions it considered *[6(c)(2)(A)];* and o 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 so proposed to be prohibited or restricted, will be reasonably available as a substitute." *[6(c)(2)(C)]* • Required considerations do not override requirement for restrictions to the extent necessary so that the chemical no longer presents an unreasonable risk, without consideration of costs and other nonrisk factors. *[6(a)]*

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	OTHER LAWS: • Requires EPA to refer risks where another federal agency could address the concern, but does not require EPA to act if that agency fails to act. • Before acting under TSCA to address a risk, EPA must compare the relevant risks, costs and efficiencies of acting under TSCA vs. acting under another law administered by EPA.	***OTHER LAWS***: • Requires EPA to address risks it refers to another federal agency if that agency fails to act. *[9(a)(4)]* • Retains the requirement for EPA to consider the relevant aspects of the risk and compare costs and efficiencies of acting under TSCA vs. acting under another law administered by EPA, but qualifies this to be based on information reasonably available to EPA. *[9(b)(2)]*
5. Deadlines; mandates and pace of chemical reviews	***DEADLINES***: • No deadline for completing initiated assessments or imposing restrictions. ***REVIEW MANDATES***: • No mandate to review the safety of existing chemicals.	***DEADLINES***: • Sets a 3-year deadline for all risk evaluations. *[6(b)(4)(G)(i)]* • Allows up to a 6-month extension of the deadline. *[6(b)(4)(G)(ii)]* • Sets a 2-year deadline for any needed regulations. *[6(c)(1)]* • Allows deadlines for risk evaluations and any required regulations to be extended in the aggregate by up to 2 years, with cause. *[6(c)(1)(C)]* • Deadlines for chemicals on EPA's work plan cannot be extended unless EPA demonstrates that additional information is needed to complete the risk evaluation or regulation. *[6(c)(1)(C)]* ***REVIEW MANDATES***: • Risk evaluations are to be conducted on each chemical EPA designates as a high-priority substance. *[6(b)(3)]* • Six months after enactment, EPA must be conducting risk evaluations for 10 chemicals drawn from its Work Plan. *[6(b)(2)(A)]* o By 3.5 years after enactment, at least 20 high-priority chemicals must be undergoing risk evaluations (at least half drawn from the Work Plan), and at least 20-low-priority chemicals must have been designated. *[6(b)(2)(B)]* • Storage near significant sources of drinking water is a prioritization criterion. *[6(b)(1)(A)]* • Preference in prioritization is to be given to Work Plan chemicals that are persistent and bioaccumulative and those that are carcinogens and have high acute and chronic toxicity. *[6(b)(2)(D)]*

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	COMPANY-REQUESTED REVIEWS: Not applicable.	***COMPANY-REQUESTED REVIEWS***: • Companies can request EPA to conduct a risk evaluation on 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 50% 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. *[6(b)(4)(C)(ii), 6(b)(4)(E)]* • Company requests for EPA to conduct a risk evaluation of a Work Plan chemical it has not yet designated high-priority are not subject to the 50% cap. *[6(b)(4)(E)(iv)(II)]* • Companies must pay 100% of the costs of risk evaluations they request (50% for chemicals already on EPA's Work Plan). *[26(b)(4)(D)]*
6. Procedural and scientific requirements; transition	***REQUIREMENTS***: • Virtually no procedures or criteria specified to assess information quality, identify chemicals warranting further scrutiny, or determine risk. ***TRANSITION***: Not applicable.	***REQUIREMENTS***: • Requires EPA to establish any policies, procedures and guidance it needs to carry out the amended law within 2 years of enactment. *[26(l)(1)]* • Requires EPA to base decisions on best available science and on the weight of the scientific evidence. *[26(h), (i)]* • Risk evaluations must identify relevant vulnerable populations and the basis for considering either aggregate or sentinel exposures. *[6(b)(4)(F)]* ***TRANSITION***: • Eases transition to new system by, for example, allowing EPA to continue or initiate risk evaluations or rules, as new procedures are put in place. *[6(l)(4), 6(p)]*
7. Testing	• EPA must go through notice-and-comment rulemaking (typically a multiyear process) to require testing. • EPA must also show evidence of potential risk or high exposure, a *Catch-22*.	• Eliminates TSCA's requirement to first show potential risk or high exposure in order to require testing. *[4(a)]* • Provides authority for EPA to use orders to require testing, either (a) where EPA determines a chemical may present an unreasonable risk *[4(a)(1)]*, or (b) for specified purposes, with explanation as to why an order is warranted rather than a test rule or consent agreement *[4(a)(3)]* • For purposes of prioritization, EPA cannot require testing as a means to establish minimum information sets for chemicals generally. *[4(a)(2)(B)(ii)]*
8. High- and low-priority designations	• EPA has no mandate to prioritize chemicals, the result being that a	• EPA is to designate as a high priority any chemical that EPA finds may present an unreasonable risk. *[6(b)(1)(B)(i)]*

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	chemical unexamined by EPA is effectively set aside indefinitely, with lack of data presumed to indicate lack of risk.	• A chemical is to be designated low-priority only if EPA concludes based on sufficient information that it is not a high-priority substance. *[6(b)(1)(B)(ii)]* • Requires EPA to identify the basis for high- and low-priority designations, including the information on which they are based. *[6(b)(1)(C)(ii)]* • Criteria and process for designating high- and low-priority chemicals must be developed by notice-and-comment rulemaking. *[6(b)(1)(A)]* • Lack of adequate information following a request for information results in designation of a chemical as high-priority. *[6(b)(1)(C)(iii)]* • EPA has authority to require testing to inform prioritization decisions where data are lacking.*[4(a)(2)(B)]* • Anyone can judicially challenge an EPA designation of a chemical as low-priority. *[19(a)(1)(C)]* • States can impose restrictions on low-priority chemicals (see item 12a below). *[18]*
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.	• Mandates EPA review of and a risk determination for all new chemicals. *[5(a)(3)]* • If EPA determines that a new chemical a) presents an unreasonable risk, b) lacks sufficient information to make a reasoned evaluation, c) may present an unreasonable risk, or d) is produced in large amounts and results in large releases or exposures, EPA must impose restrictions to the extent necessary to protect against any such risk. *[5(e), 5(f)]* • Manufacture of a new chemical can only start in compliance with such restrictions or if EPA affirmatively finds it is not likely to present an unreasonable risk. *[5(a)(1)(B), 5(g)]* • Whenever EPA imposes a restriction on the submitter of a notice for a new chemical or a significant new use of a chemical, it must within 90 days either initiate promulgation of a significant new use rule or publish an explanation for why such a rule is not needed. *[5(f)(4)]* • To require notification of articles as a significant new use, EPA needs to make an affirmative regulatory finding that there is a "reasonable potential for exposure" to a chemical from the article. *[5(a)(5)]*
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	• 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. *[14(c)(2)(G), 14(c)(3)]*

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	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 and rarely mounts challenges because of the resources required.	• 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 (extendable by up to 2 years if EPA can show cause), and for any inactive chemical at the time it is moved to active status. *[8(b)(4)]* • Chemical identities not already on the confidential portion of the inventory or added to it per prescribed procedures cannot be claimed confidential. *[8(b)(8)]*
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. *[14(b)(2)]* • Does *not* affect current EPA policy that generally disallows masking of the identities of chemicals in health and safety studies. o Retains TSCA's two exceptions to the general allowance for disclosing health and safety information: Disclosure is not authorized under this provision of information if its disclosure would disclose processes used in manufacturing or processing of a chemical mixture, and in the case of a mixture, information that would disclose the portion of the mixture comprised by a chemical. A clarification is added to make explicit that disclosure of a specific chemical identity that would disclose such process or mixture portionality information is not authorized by this provision. *[14(b)(2)]*
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. *[14(c)(3), 14(g)(1)(A)]* • Approved claims expire after 10 years unless resubstantiated and reapproved. *[8(b)(4)(D)(ii)(III)), 8(b)(5)(B)(iii)(III), 14(e)(1)(B)(i), 14(f)(3)]* • 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. *[14(f)(1)]* • 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 to present an unreasonable risk. *[14(f)(2)]* • Most CBI claims for a chemical that EPA bans or phases out automatically expire, and CBI disclosure in

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		such cases is presumed to be in the public interest. *[14(b)(4), 14(g)(1)(E)]*
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 environmental professionals, or even to first responders.	• Explicit requirements are included for EPA to make public information it receives, and decisions it makes and the basis for them. *[26(j)]* • EPA shall disclose CBI upon request to a state or local government. *[14(d)(4)]* • EPA shall disclose CBI upon request to health or environmental professionals employed by federal or state agencies or treating physicians or other health care professionals in response to an environmental release or to assist in diagnosis or treatment. *[14(d)(5)]* • EPA shall also disclose CBI upon request to poison control centers or first responders in emergency situations. *[14(d)(6)]* • Disclosures require statement of need and a confidentiality agreement with EPA to keep the information confidential. *[14(d)(4), 14(d)(5), 14(d)(6)]* • 15-day advance notification is required prior to CBI release to state or local governments; while appeal is provided for, release of CBI can proceed while the appeal is pending. *[14(g)(2)(C)(i), 14(g)(2)(D)]* • 15-day advance notification is required prior to disclosure to health or environmental professionals or heath care professionals, except in emergency situations. *[14(g)(2)(C)(i), [14(g)(2)(C)(ii)]*] • EPA is to institute a system to expedite and facilitate access to confidential information allowed to be disclosed to health and environmental professionals. *[14(g)(3)]*
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>may</u> collect fees for both new and existing chemicals, as well as those designated as high-priority. *[26(b)(1)]* • Fees can be used to defray the costs of: new chemical reviews; prioritization screening; risk evaluations and any needed regulation of new and existing chemicals; and the collection, processing, review, and provision of public access to information, as well as protection of information found to warrant it. *[26(b)(1)]* • Fees go into a "TSCA Service Fee Fund" and directly to EPA, not the general treasury. *[26(b)(3)(A)]* • Fees are contingent on Congress providing sufficient funds through normal appropriations, to seek to ensure collection of fees does not lead to a reduction in EPA's budget. *[26(b)(5)]* • The level of fees is to be set to cover approximately

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	are not available to directly cover EPA's costs.	25% of relevant EPA program costs, initially capped at $25 million/year but subject to adjustment over time to ensure 25% of costs are defrayed. *[26(b)(4)(B), 26(b)(4)(F)]* • Companies must pay 100% of the costs of risk evaluations they request (50% for chemicals already on EPA's work plan). *[26(b)(4)(D)(i)]*
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 <u>restrictions</u> on a chemical, not to requirements for reporting, monitoring or disclosure. *[18(a)(1)(B), 18(b)(1), 18(d)(1)(A)(ii)]* • Preemption is explicitly limited to restrictions relating to the hazards, exposures, risks, and uses or conditions of use that are included in the scope of EPA's risk evaluation, which EPA must set within 6 months of designating a chemical as high-priority, and final action. *[6(b)(4)(D), 18(c)(2), 18(c)(3), 18(d)(1)(A)(iii)(II)(aa)]* • 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). *[18(c)(2) , 18(c)(3), 18(d)(1)(A)(iii)]* • 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 law, unless they conflict with federal requirements. *[18(d)(1)(A)]* • A state cannot prohibit all use of the chemical in the state, except via co-enforcement or getting a waiver. *[18(a)(1)]* • Preemption is not triggered by a low-priority designation, so states can continue to act on such a chemical.
12b. State preemption – grandfathering; savings clauses	***<u>GRANDFATHERING</u>***: Not applicable ***<u>SAVINGS CLAUSE</u>***: None	***<u>GRANDFATHERING</u>***: • Any state action taken on a chemical prior to April 22, 2016, or taken under a law in effect on August 31, 2003, remains in place regardless of EPA action. *[18(e)]* • California's Proposition 65 and Massachusetts' Toxics Use Reduction Act are excluded from the scope of preemption. *[18(e)]* ***<u>SAVINGS CLAUSE</u>***: • A savings clause preserves rights of action under common law or statutory causes of action for civil relief or penalties for criminal conduct. *[18(g)(1)]*

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		• Actions taken under the bill are precluded from: o being interpreted as influencing, in either a plaintiff's or defendant's favor, the disposition of any civil action; or o affecting the authority of any court to make a determination with respect to the admissibility of evidence in an adjudicatory proceeding. *[18(g)(2)]*
12c. State preemption – <u>before</u> final EPA action; waivers	• States are not barred from imposing a new requirement on a chemical EPA is reviewing until EPA takes final action on the chemical. ***<u>WAIVERS</u>:*** Not applicable.	• States are generally barred, except via a waiver, from imposing a new restriction on a chemical once EPA designates it as high-priority and publishes the scope of its risk evaluation, ending when EPA publishes a final risk evaluation or misses the deadline for doing so, whichever is earlier; states can impose new restrictions during any required rulemaking. *[18(b)]* • EPA's initiation of risk evaluations on chemicals that industry requested it to conduct does not trigger preemption. *[6(b)(4)(E)(iv)]* ***<u>WAIVERS</u>:*** • EPA <u>shall</u> grant a waiver for a state to act before a final risk evaluation if: o it meets conditions similar to those under current TSCA; or o the state has enacted a statute or proposed or finalized an administrative action prior to EPA's publication of the scope of its risk evaluation. *[18(f)(2)]* • If EPA fails to meet its deadline for deciding on a state waiver application, the state waiver is automatically approved. *[18(f)(9)(A)]* o Such automatic approvals are not subject to judicial review but EPA's failure to decide on a waiver is subject to a citizen's civil action under section 20 of TSCA, because it is a failure of EPA to perform a mandatory duty. *[18(f)(9)(B)]* o Automatically approved waivers stay in effect until EPA completes, or misses its deadline for completing, its risk evaluation, whichever is earlier, unless: a) EPA subsequently denies the waiver, or b) EPA grants it, judicial review of that decision is sought, and EPA denies the waiver in response to a court's ruling. *[(18(f)]* • If EPA fails to decide on a state waiver application, any person may sue EPA to compel a decision. *[18(f)(3), 20]* • If EPA grants or denies a state waiver, the decision can be challenged in court. *[18(f)(6)]*

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12d. State preemption – <u>after</u> final EPA action; waivers	• EPA actions taken to protect against risks of new or existing chemicals generally preempt states' existing or new actions. ***<u>WAIVERS</u>:*** • States can obtain waivers from Federal preemption for a requirement that is significantly more protective and does not unduly burden interstate commerce.	• State restrictions on a chemical imposed after April 22, 2016, are preempted if they fall within the scope of EPA's risk evaluation of that chemical and EPA determines the chemical meets the safety standard; if EPA determines the chemical does not meet the standard, preemption applies when EPA issues a final rule restricting the chemical. *[18(a)(1)(B, 18(a)(2))]* ***<u>WAIVERS</u>:*** • EPA <u>may</u> grant a state a waiver to act after a final risk evaluation or risk management rule if certain conditions are met, two of which are in addition to those under current TSCA: o compelling conditions warrant granting the waiver to protect health or the environment; o in EPA's judgment, the state's proposed requirement is designed to address a risk of a chemical substance, under the conditions of use, that was identified— ▪ consistent with the best available science; ▪ using supporting studies conducted in accordance with sound and objective scientific practices; and ▪ based on the weight of the scientific evidence. *[18(f)(1)]* • If EPA fails to decide on a state waiver application, any person may sue EPA to compel a decision. *[18(f)(3), 20]* • If EPA grants or denies a state waiver, the decision can be challenged in court. *[18(f)(6)]* • A waiver granted by EPA stays in effect unless a court directs EPA to deny the waiver in response to a judicial challenge. *[18(f)(6), 19]*
12e. State preemption – new chemicals	• If EPA imposes any requirement on a new chemical designed to protect against risk, no state can impose a requirement on the chemical designed to protect against the risk.	• EPA reviews of new chemicals have no preemptive effect (unlike under TSCA). *[18(a), 18(b)]* o The only exception is that, if EPA issued a Significant New Use Rule for the chemical, a state could not require notification for the same use of the same chemical identified in the SNUR. *[18(a)(1)(C), 18(c)(4)]*