

12 major improvements the UDALL-VITTER DRAFT makes over TSCA and CSIA as introduced¹

September 2014

1. REPLACES COST-BALANCING TEST WITH PURE HEALTH-BASED SAFETY STANDARD: Adopts a safety standard that is based solely on risks to human health or the environment.

Under *current TSCA*, EPA's determination of whether or not a chemical presents an "unreasonable risk" requires the agency to formally balance consideration of costs and other non-risk factors against the potential danger to human health or the environment.

CSIA as introduced retained the term "unreasonable risk" as its safety standard but specified that safety determinations were to be "based solely on considerations of risks to human health and the environment." But other provisions suggested that determination had also to take into consideration costs and other non-risk factors in determining whether a chemical was safe or not.

The UDALL-VITTER DRAFT explicitly precludes EPA from considering costs and other non-risk factors in making safety determinations.

2. PROVIDES EXPLICIT PROTECTION FOR VULNERABLE POPULATIONS: Requires EPA to ensure protection of infants and children, pregnant moms, the elderly, workers, and others more heavily exposed or susceptible to chemicals than the general population.

Under *current TSCA*, there is no provision requiring EPA to account for the increased vulnerability of certain populations to chemical exposures.

CSIA as introduced required EPA to consider "the vulnerability of exposed subpopulations" in conducting a safety assessment of a chemical, but it did not explicitly require EPA to determine risks to such populations or to ensure their protection.

¹ This paper compares the Toxic Substances Control Act (TSCA) of 1976, the Chemical Safety Improvement Act (CSIA, S. 1009) as introduced in May 2013, and the Udall-Vitter redraft of CSIA.

The UDALL-VITTER DRAFT adds a definition for “potentially exposed or susceptible population” addressing vulnerability due both to elevated chemical exposures and to heightened susceptibility to their effects. It specifies that such populations include (but are not limited to) infants, children, pregnant women, workers, and the elderly. In addition, the safety standard definition itself expressly requires protection of “potentially exposed or susceptible populations.”

3. RESTRICTS CHEMICALS THAT DON'T MEET THE SAFETY STANDARD: Requires chemicals not meeting the safety standard be phased out or subject to restrictions sufficient for them to meet the standard.

Under *current TSCA*, EPA has authority but not a mandate to impose restrictions on chemicals found to present an unreasonable risk. Nor is there any provision to ensure the sufficiency of the restrictions imposed on a chemical to address identified risks.

CSIA as introduced mandated that EPA set restrictions on any chemical found not to meet the safety standard. But it did not require that such restrictions be sufficient for the chemical to then *meet* the safety standard.

The UDALL-VITTER DRAFT explicitly requires that restrictions imposed on a chemical found not to meet the safety standard must either phase out or ban the chemical, or be sufficient to ensure the chemical meets the safety standard.

4. ELIMINATES COST-BENEFIT REQUIREMENT FOR REGULATION: Removes the requirement for formal cost-benefit analysis to show that benefits of a restriction on a chemical outweigh its costs.

Under *current TSCA*, EPA is required to conduct a formal analysis of costs and benefits of any proposed restriction of a chemical, and to show that the benefits of the restriction outweigh its costs. It also must demonstrate that any restrictions it chooses to impose are the “least burdensome” among those able to address the identified risks, a showing that in practice has proven excessively onerous. These requirements have proven to be fatal flaws in TSCA, imposing evidentiary and analytic burdens on EPA so severe that it could not meet them even for the deadly human carcinogen asbestos.

CSIA as introduced struck the “least burdensome” requirement and, for most restrictions, would not require formal cost-benefit analysis. But EPA still faced an arduous evidentiary and analytic burden: Any and all potential regulatory and chemical alternatives would have to be identified, and their technical and economic feasibility, costs and benefits, and risks analyzed. And any proposed ban or phase-out still required a cumbersome and costly analysis showing that its benefits outweigh costs.

The UDALL-VITTER DRAFT also strikes the “least burdensome” language and goes further makes clear that cost considerations cannot override the requirement that restrictions be sufficient to ensure chemical safety. A balancing test for costs and benefits is not required, and such factors are to be considered only “to the extent practicable based on reasonably available information.” The new draft also strikes CSIA’s requirement that bans and phase-outs be based on full cost-benefit justification. Finally, only alternatives deemed relevant and technically and economically feasible by EPA need to be considered in imposing restrictions.

5. SETS REAL, MEANINGFUL DEADLINES: Provides concrete deadlines for all major rulemakings and for the key steps of chemical prioritization, safety assessment and determination, and regulation.

Under *current TSCA*, EPA has no mandate to review the safety of existing chemicals. Assessments are rarely undertaken, and often consume many years (or even decades) – in part because there are no deadlines. Actions to restrict chemicals are even rarer, and receive low priority due to the absence of any statutory deadlines.

CSIA as introduced required EPA to prioritize *all* chemicals in active commerce, and to set general schedules for conducting assessments of those designated high-priority. However, while numerous rules and procedures were required, very few deadlines were set for their establishment or for the evaluations of chemicals.

The UDALL-VITTER DRAFT specifies concrete deadlines for all major steps: prioritization, safety assessment & determination, and regulation. A 2-year deadline by which all rules to establish the new requirements and procedures must be issued is also specified. EPA must also specify a deadline for companies to submit any information it requests. EPA can designate its current “work plan chemicals” as high-priority chemicals, and must include at least 10 on the initial high-priority list.

6. STREAMLINES PROCEDURAL AND SCIENTIFIC REQUIREMENTS: Streamlines and reduces overly prescriptive procedural and scientific requirements for chemical prioritization and safety assessments and determinations.

Under *current TSCA*, virtually no procedures or criteria are specified by which EPA is to assess information quality, identify chemicals warranting further scrutiny, or determine the extent of risk posed by a chemical.

CSIA as introduced went to the opposite extreme, prescribing highly-specific, and in some cases biased, scientific methodologies to be used. It required EPA to develop from scratch extensive procedures and criteria before even starting to prioritize or assess chemicals. Coupled with a lack of deadlines, merely getting the new system up and running would have taken many years.

The UDALL-VITTER DRAFT provides a balanced approach that consolidates and streamlines procedural requirements and eliminates prescriptions to use controversial risk assessment methodologies. The new draft also simplifies transition to the new system by, for example, allowing EPA to continue ongoing work, adapt existing procedures, and use current chemical designations and prioritization decisions as new procedures are put in place. It also sets a two-year deadline for establishing all policies, procedures and guidance.

7. EXPANDS TESTING AUTHORITY: Restores EPA authority to require testing for new chemicals and to inform prioritization decisions.

Under *current TSCA*, EPA must go through notice-and-comment rulemaking (typically a multiyear process) before it can require testing. It must also show evidence of potential risk, a *Catch-22*.

CSIA as introduced eliminated EPA's ability to require testing of new chemicals, and expressly prohibited EPA from requiring testing to inform prioritization decisions. But it did allow EPA simply to issue orders to require testing instead of going through full notice-and-comment rulemaking (though it had to justify why it was using an order rather than a rule). It also struck the requirement that EPA find potential risk in order to require testing.

The UDALL-VITTER DRAFT retains CSIA's authority for EPA to use orders to require testing (with justification) and elimination of TSCA's risk findings requirement. Importantly, it also restores full testing authority for new chemicals and to inform prioritization decisions. But 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.

8. DELIMITS LOW-PRIORITY DESIGNATIONS: Ensures low-priority designations are based on sufficient information and are subject to judicial challenge.

Under *current TSCA*, 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.

CSIA as introduced mandated that EPA prioritize all active chemicals as either high- or low-priority. Low-priority designations were to be based on available information, raising the specter of data-poor chemicals being designated low-priority and set aside indefinitely and with no authority to require they be tested. Lack of data could be a factor in designating a chemical as high-priority, which would provide the only means by which EPA could require testing of a data-deficient chemical. Governors or state agencies could recommend that EPA prioritize or reprioritize a chemical, but the

resulting decisions were not judicially reviewable, meaning a decision to set aside a chemical indefinitely as low-priority could not be challenged.

The UDALL-VITTER DRAFT 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.” Lack of data can now be a sufficient basis in itself (not just a factor) for designating a chemical as high-priority. The new draft also restores EPA authority to require testing to inform prioritization decisions where data are lacking. Finally, a Governor or state agency that recommended EPA prioritize or reprioritize a chemical can challenge a low-priority designation in court.

9. REQUIRES SAFETY FINDING FOR NEW CHEMICALS BEFORE THEY ENTER THE MARKET: Allows new chemicals to enter the market only where EPA affirmatively finds they are likely to meet the safety standard.

Under *current TSCA*, 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.” That is, no affirmative safety decision is required, and the burden is on EPA to find a concern even when safety data are wholly lacking.

CSIA as introduced mandated that EPA make a safety determination for each new chemical, and that EPA impose “appropriate” restrictions if it determined the chemical was not likely to meet the safety standard. But the bill did not require that such restrictions be sufficient for EPA then to find the chemical was likely to meet the safety standard. Moreover, the bill was unclear as to whether companies could start producing a new chemical if EPA had insufficient information to determine whether it was likely to meet the safety standard. Finally, the bill barred EPA from requiring development of the needed information.

The UDALL-VITTER DRAFT makes clear 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 find the chemical is likely to meet the safety standard. If EPA finds it 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.

10. RAISES THE BAR FOR HIDING CHEMICAL IDENTITIES: Requires EPA to review and approve any claims – whether past or future – to protect from disclosure the identities of chemicals in commerce.

Under *current TSCA*, 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 confidential business information (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.

CSIA as introduced authorized EPA to review CBI claims for chemical identity at any time, but did not mandate any review of such claims. Chemical identities were generally to be presumed protected from disclosure, both before and after they entered the market. Such protection was time-limited, however, for a period set by the claimant if found reasonable by EPA. And such a claim was not allowed if the identity could be readily discovered through reverse engineering.

The UDALL-VITTER DRAFT 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 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 in any context.

11. EXPANDS ACCESS TO HEALTH AND SAFETY INFORMATION: Provides state officials, medical experts and the public with greater access to information on the health and environmental effects of chemicals.

Under *current TSCA*, companies are free to claim virtually any information they submit to EPA is CBI. EPA cannot disclose information claimed CBI to the public, to state and local agencies or even to first responders. 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.

Under *CSIA as introduced*, health and safety information remained ineligible for CBI secrecy, as under current TSCA. However, chemical identities were presumed protected from disclosure even in the context of health and safety information. The bill also severely limited EPA's authority to question past CBI claims. For the first time, however, state and local governments as well as health professionals would have access to CBI, per agreements that they keep the information confidential.

The UDALL-VITTER DRAFT retains current TSCA's exclusion of health and safety studies and their underlying data from being claimed CBI. Unlike CSIA as introduced, it

does *not* affect current EPA policy that disallows masking of the identities of chemicals in those health and safety studies. The new draft 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 12 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 standard, EPA is required to review all CBI claims and require their substantiation. All CBI claims for a chemical that EPA bans or phases out automatically expire.

12. SETS TIME LIMITS ON SECRECY: Limits confidential business information claims to 10 years, after which they expire unless renewed.

Under *current TSCA*, CBI claims are not subject to time limits and remain in place until and unless challenged by EPA.

CSIA as introduced required that many CBI claims be substantiated, and that EPA review a representative subset. Claims for chemical identities would be time-limited for a period found reasonable by EPA, but other types of claims would not be time-limited and EPA could not subject them to routine periodic review or resubstantiation. Except for chemical identity claims, EPA could not require substantiation of past claims unless EPA designated a chemical as high-priority.

Under the UDALL-VITTER DRAFT, 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 has authority to review and require resubstantiation of CBI claims under a range of circumstances, including for high-priority chemicals; for chemicals found not to have sufficient information for a safety determination; inactive chemicals; or where EPA finds that disclosure of information claimed CBI, if found not to warrant protection, would assist the agency in conducting safety assessments and determinations or developing risk management rules. EPA is mandated to review a CBI claim and require resubstantiation if necessary to comply with a FOIA request; if EPA has reason to believe the claim is not valid; or for chemicals found not to meet the safety standard. All CBI claims for a chemical that EPA bans or phases out automatically expire.