

TSCA reform legislation: Highlights and comparisons

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TSCA vs. Safe Chemicals Act



TSCA vs. Safe Chemicals Act - 1

Currently under TSCA	Under Safe Chemicals Act
SAFETY DATA	
<p>Few data call-ins are issued, even fewer chemicals are required to be tested and no minimum data set is required even for new chemicals.</p>	<p>Reporting of existing information and minimum information sets (MIS) on new and existing chemicals would be required as they reach various stages of the evaluation process sufficient to categorize, prioritize and assess the chemicals' safety.</p> <p>A new processor use reporting system would be established.</p>
RULEMAKING REQUIREMENTS	
<p>To require testing or take other actions, EPA must promulgate regulations that take many years and resources to develop. EPA must show potential for a chemical to cause harm or widespread exposure in order to require testing, a Catch-22.</p>	<p>In addition to the MIS requirement, EPA would have authority to issue an order rather than a regulation to require reporting of existing data or additional testing, and need not first show evidence of harm.</p>

TSCA vs. Safe Chemicals Act - 2

Currently under TSCA	Under Safe Chemicals Act
BURDEN OF PROOF	
EPA is required to prove harm before it can regulate a chemical.	Industry bears the legal burden of proving its chemicals are safe.
ASSESSMENT OF SAFETY	
No mandate exists to assess the safety of existing chemicals. New chemicals undergo a severely time-limited and highly data-constrained review.	New and existing chemicals would generally be subject to safety determinations as a condition of remaining on the market, using the best available science that relies on the advice of the National Academy of Sciences. Chemicals designated by EPA to be of very low concern or intrinsically safe would not require assessment or further action unless new information altered their designation.

TSCA vs. Safe Chemicals Act - 3

Currently under TSCA	Under Safe Chemicals Act
SCOPE OF ASSESSMENT	
<p>Where the rare chemical assessment is undertaken, there is no requirement to assess exposure to all sources of exposure to a chemical, or to assess risk to vulnerable populations.</p> <p>No guidance is provided on how to determine whether a chemical presents an "unreasonable risk."</p>	<p>A health-based safety standard based on a finding of "reasonable certainty of no harm to human health or the environment" would require EPA to account for aggregate exposures to all uses and sources of a chemical, and to ensure protection of vulnerable populations that may be especially susceptible to chemical effects (e.g., children, the developing fetus) or subject to disproportionately high exposure (e.g., low-income communities living near contaminated sites or chemical production facilities).</p> <p>Cumulative exposures to multiple chemicals contributing to the same or a similar adverse effect would be considered to the extent practicable.</p>

TSCA vs. Safe Chemicals Act - 4

Currently under TSCA	Under Safe Chemicals Act
CHEMICALS AND EXPOSURES OF HIGH CONCERN	
<p>No criteria are provided for EPA to use to identify and prioritize chemicals or exposures of greatest concern, leaving such decisions to case-by-case judgments.</p>	<p>EPA would be required to develop and apply criteria to identify toxic chemicals to which people are exposed that persist and build up in the environment and people (PBTs). “Hot spots” where people are subject to disproportionately high exposures would be specifically identified and addressed.</p>
REGULATORY ACTION	
<p>Even chemicals of highest concern, such as asbestos, have not been able to be regulated under TSCA’s “unreasonable risk” cost-benefit standard. Instead, assessments often drag on indefinitely without conclusion or decision.</p>	<p>PBTs to which people are exposed would be moved directly to mandatory exposure reduction. The remaining chemicals would be prioritized for assessment against a health-based standard, and deadlines for decisions would be specified. EPA would have authority to restrict production and use or place conditions on any stage of the lifecycle of a chemical needed to ensure safety.</p>

TSCA vs. Safe Chemicals Act - 5

Currently under TSCA	Under Safe Chemicals Act
INFORMATION PROTECTION AND DISCLOSURE	
<p>Companies are free to claim, often without providing justification, most information they submit to EPA to be confidential business information (CBI), denying access to the public and even to state and local government. EPA is not required to review such claims, and the claims never expire.</p>	<p>Types of information always and never eligible for CBI protection are designated. CBI claims would have to be justified up front, and EPA is required to review at least a representative subset. Most claims would expire in five years unless renewed. Identity of new chemicals could be protected for a period chosen to reflect market conditions. State governments would have access to CBI.</p>
INFORMATION ACCESS	
<p>Little information is required to be made public even if it is not confidential. The public must often request information using cumbersome procedures (e.g., FOIA).</p>	<p>All significant information on chemicals and associated EPA decisions that is not confidential is to be made publicly available through an Internet-accessible database.</p>

Safe Chemicals Act of 2011 vs. 2013: What's changed?



Safe Chemicals Act of 2011 vs. 2013 – 1

Safe Chemicals Act of 2011	Safe Chemicals Act of 2013
SEC. 4: MINIMUM INFORMATION SETS AND TESTING OF CHEMICAL SUBSTANCES	
<p>“The rule shall provide for varied or tiered testing for different chemical substances, mixtures or categories of chemical substances and mixtures.”</p>	<p>The tiering requirement is retained but more specific description of potential tiers is provided, reflecting the revamped process for screening and evaluating chemicals (see Secs. 5 and 6 below).</p> <p>“Data” is changed to “information” to acknowledge that a range of types of information, not just test data, may be sufficient to meet an information requirement.</p>
<p>Minimum data sets [MDSs] are due within the earlier of 18 months of assignment to a priority class (see Sec. 6 below) or 5 years of enactment, for existing chemicals; and at the time of filing notifications, for new chemicals.</p>	<p>Minimum information sets [MISs] are only required for some existing chemicals, and timing is as specified in Sec. 6 (see below). MISs for new chemicals are limited to that sufficient to support categorization (see Sec. 5 below) and are still due at the time of filing notifications for new chemicals.</p>

Safe Chemicals Act of 2011 vs. 2013 - 2

Safe Chemicals Act of 2011	Safe Chemicals Act of 2013
SEC. 5: NEW CHEMICALS	
<p>New chemicals can enter the market only if (a) they are shown to meet the safety standard, or (b) they do not exhibit significant hazard properties, are not persistent and bioaccumulative and are not detected in biomonitoring or environmental monitoring.</p>	<p>New chemicals can enter the market if (a) EPA finds it is “likely to meet the safety standard” or (b) it serves a critical or essential use for which there are no viable alternatives.</p> <p>EPA categorizes new chemicals as substances:</p> <ul style="list-style-type: none">(a) of very high concern, which can enter the market only for critical uses;(b) likely to meet the safety standard, including:<ul style="list-style-type: none">• substances of very low concern, which are set aside, or• substances to undergo safety determinations, which get in line for a determination after market entry;(c) with insufficient information, which must meet MIS requirements to be recategorized; or(d) unlikely to meet the safety standard, which can be used only for critical uses.

Safe Chemicals Act of 2011 vs. 2013 - 3

Safe Chemicals Act of 2011	Safe Chemicals Act of 2013
SEC. 6: BATCHING, CATEGORIZATION	
<p>Chemicals are categorized as:</p> <ul style="list-style-type: none">• Priority Class 1: Chemicals requiring immediate risk management (PBTs with expected widespread exposure; list to include 20-30 such PBTs);• Priority Class 2: Chemicals requiring safety determinations (those for which “more than a theoretical concern” exists as to whether it would meet the safety standard); or• Priority Class 3: Chemicals requiring no immediate action (chemicals with inherent properties indicating no risk based on robust data).	<p>Chemicals are evaluated in <u>batches</u> of ca. 6,000 chemicals, starting with CDR-reported chemicals.</p> <p>Using existing information, chemicals in each batch are <u>categorized</u> as substances:</p> <ul style="list-style-type: none">(a) of very high concern (SVHCs), which are subject to expedited exposure reduction measures<ul style="list-style-type: none">• no MIS needed, and• measures to be applied in 3 years;(b) of very low concern, to be set aside;(c) to undergo safety determinations, which are <u>prioritized</u> for a determination (see next slide);(d) with insufficient information, which must have MIS supplied within 5 years. <p>Subsequent batches designated until all chemicals have been evaluated.</p>

Safe Chemicals Act of 2011 vs. 2013 - 4

Safe Chemicals Act of 2011	Safe Chemicals Act of 2013
SEC. 6: PRIORITIZATION AND SAFETY STANDARD DETERMINATION	
<p>Priority Class 1 chemicals are subject to actions “to achieve the greatest practicable reductions in human or environmental exposure.” A safety determination for remaining uses subsequently conducted.</p> <p>Priority Class 2 chemicals are prioritized for safety determinations. The number of substances assigned to this class at a given time is based on EPA’s capacity to expeditiously conduct safety determinations.</p> <p>Priority Class 3 chemicals are subject to a safety determination if new information is developed that calls into question or changes their prioritization.</p>	<p>Chemicals to undergo safety determinations are prioritized as:</p> <ul style="list-style-type: none">(a) Priority Class 1: Safety determinations to be completed within 5 years, based on full MISs and any other data EPA needs(b) Priority Class 2: MIS for safety determination to be supplied in 5 years, used to reprioritize(c) Priority Class 3: set aside from further assessment until Class 1 and 2 safety determinations are completed<ul style="list-style-type: none">• MIS not required until reprioritized

Safe Chemicals Act of 2011 vs. 2013 - 5

Safe Chemicals Act of 2011	Safe Chemicals Act of 2013
SEC. 8: REPORTING AND RETENTION OF INFORMATION	
<p>Declarations of current manufacture or processing required (or cessation thereof) required within 1 year.</p> <p>Declarations must include all available use, hazard and exposure information.</p>	<p>Declarations (“hand-raising” only; no use, hazard and exposure information required) of:</p> <p>(a) “current commercial interest”:</p> <ul style="list-style-type: none"> • required of manufacturers, in 6 months • optional for processors, in 1 year • placed on “active” inventory; new producers or users must submit their own declarations <p>(b) “potential commercial interest”</p> <ul style="list-style-type: none"> • may be submitted by manufacturers or processors, due within 6 months • only includes substances that “may serve as a reasonable substitute” for a substance for which company has declared a current commercial interest • placed on “inactive” inventory; move to active inventory requires notice and submission of available use, hazard and exposure information <p>Declarations of cessation due in 6 months</p>

Safe Chemicals Act of 2011 vs. 2013 - 6

Safe Chemicals Act of 2011	Safe Chemicals Act of 2013
SEC. 8: REPORTING AND RETENTION OF INFORMATION	
<p>EPA has omnibus authority to require processors to report chemical information in their possession or control.</p>	<p>Omnibus authority is retained, but a new periodic processor use reporting program is also to be established through rulemaking. EPA may exempt small processors or others deemed not needed. Reporting elements include:</p> <ul style="list-style-type: none">• commercial/consumer product categories• annual volume processed• use in children’s products• maximum concentration (in range) for each product category• number of commercial workers (in range) “reasonably likely” to be exposed via processing• other information on processing or use EPA needs to understand exposure potential <p>Updating is required every 4 years or when significant changes occur or new information develops.</p>

Safe Chemicals Act of 2011 vs. 2013 – 7

Safe Chemicals Act of 2011	Safe Chemicals Act of 2013
SEC. 14: DISCLOSURE OF DATA	
<p>Up-front justification and EPA review is required for all confidential business information (CBI) claims.</p>	<p>Three categories of information identified:</p> <ul style="list-style-type: none">• Always eligible for CBI protection (e.g., sales data, customer lists, precise volumes/functions)• Never eligible for CBI protection (e.g., safety determinations, health and safety data, general volume/use/function descriptions)• Case-by-case for other information; requires up-front justification<ul style="list-style-type: none">• EPA to review all chemical identity CBI claims, at least representative 25% of others• <u>new chemical identity</u> may be protected after market entry for period EPA deems reasonable, unless chemical is a known or probable toxicant or PBT, fails its safety determination, or can be readily reverse-engineered• <u>degree of purity or identity of impurities</u> may be protected if it would reveal process

Safe Chemicals Act of 2011 vs. 2013 - 8

Safe Chemicals Act of 2011	Safe Chemicals Act of 2013
SEC. 14: DISCLOSURE OF DATA	
CBI claims would be subject to a five-year expiration except for types of information EPA decides warrant indefinite protection.	Except for new chemical identity CBI claims (see previous slide) and types of information EPA decides warrant indefinite protection, CBI claims would be protected for a period specified by EPA of up to five years, and could renewed upon reassertion, re-justification and EPA approval.
Sharing of confidential business information (CBI) with state, Tribal and municipal governments would be allowed, subject to applicable agreements to maintain confidentiality.	Inter-government sharing of CBI is limited to state and Tribal governments. CBI can be shared under certain conditions with public or environmental health professionals and medical personnel. CBI claimants would be notified of CBI releases to the above parties.
Criminal penalties would apply to knowing wrongful CBI disclosures by government employees or contractors (in current TSCA).	Civil penalties would apply to knowing wrongful CBI disclosures and also to claimants making false claims.