

TSCA reform legislation: Highlights and comparisons

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Safer Chemicals Policy Reform
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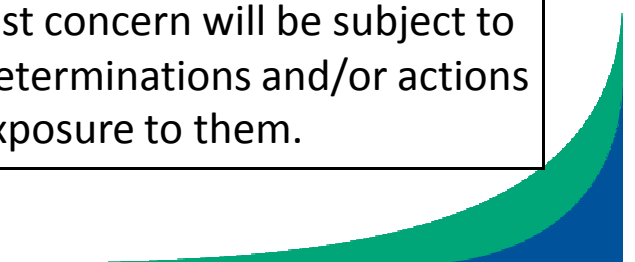
TSCA vs. new proposals: Overview

Currently under TSCA	Under the Senate and House proposals
<p><u>DATA</u>: 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>Up-front data call-ins for all chemicals would be required. A minimum data set (MDS) on all new and existing chemicals sufficient to determine safety would be required to be developed and made public.</p>
<p><u>BURDEN OF PROOF</u>: EPA is required to prove harm before it can regulate a chemical.</p>	<p>Industry bears the legal burden of proving their chemicals are safe.</p>
<p><u>SAFETY ASSESSMENT</u>: No mandate exists to assess the safety of existing chemicals. New chemicals undergo a severely time-limited and highly data-constrained review.</p>	<p>All chemicals, new and existing, would be subject to safety determinations (in the case of certain new chemicals, at some point after entry into commerce).</p>



TSCA vs. new proposals: Overview

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<p><u>SCOPE OF ASSESSMENT:</u> 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>The safety standard requires the assessment of a chemical to account for <i>aggregate</i> and <i>cumulative</i> exposures to all uses and sources, 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 site or chemical production facilities). “Hot spots” would have to be specifically identified and addressed.</p>
<p><u>REGULATORY ACTION:</u> 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>Chemicals are assessed against a health-based standard, and deadlines for decisions are specified. Chemicals of highest concern will be subject to expedited safety determinations and/or actions to reduce use or exposure to them.</p>



TSCA vs. new proposals: Overview

Currently under TSCA	Under the Senate and House proposals
<p><u>INFORMATION ACCESS</u>: Companies are free to claim, often without providing any 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>All CBI claims would have to be justified up front. EPA would be required to review them, and only approved claims would stand. Approved claims would expire after a period of time. Other levels of government would have access to CBI.</p>
<p><u>RULEMAKING REQUIREMENTS</u>: To require testing or take other actions, EPA must promulgate regulations that take many years and resources to develop.</p>	<p>In addition to the MDS requirement, EPA would have authority to issue an order rather than a regulation to require existing data to be reported or additional testing to be done.</p>



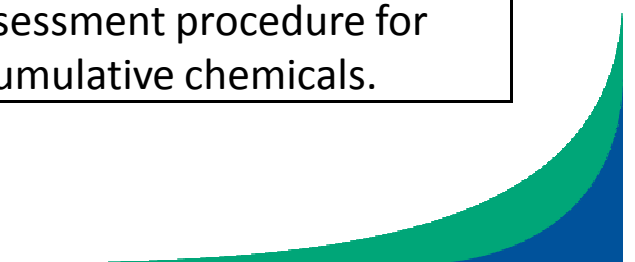
Data reporting and testing

S. 3209: <i>Safe Chemicals Act of 2010</i>	<i>House Discussion Draft:</i> <i>Toxic Chemicals Safety Act of 2010</i>
<p><u>Declarations</u>: Within 1 year, companies to identify all chemicals they make, provide available EHS data</p> <ul style="list-style-type: none"> • resets TSCA inventory; “ceased” chemicals if returned would be new chemicals • updated every 3 years or when significant change in info/production/use occur 	
<p><u>Minimum data set (MDS)</u>: Required for all new and existing chemicals</p> <ul style="list-style-type: none"> • New chemicals: w/ pre-mfctre notice • Existing chemicals: <ul style="list-style-type: none"> • for priority chemicals, within 18 months of listing • for other chemicals, within 30 months of placement on safety determination list or 14 years after enactment, whichever comes first • MDS not specified, can be tiered or varied by chemical group/type 	<p>Same, except:</p> <ul style="list-style-type: none"> • Existing chemicals: <ul style="list-style-type: none"> • for priority chemicals, within 18 months • for all other chemicals, within 5 years of enactment
<p><u>Omnibus authority</u> for EPA to call in data or require more testing</p> <ul style="list-style-type: none"> • May be done by order rather than rulemaking 	



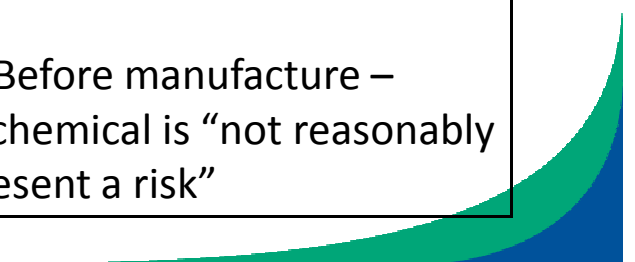
Expedited action

S. 3209: <i>Safe Chemicals Act of 2010</i>	<i>House Discussion Draft: Toxic Chemicals Safety Act of 2010</i>
<p><u>Single sentence</u>: “The Administrator shall act quickly to manage risks from chemical substances that clearly pose the highest risks to human health or the environment.”</p>	<ul style="list-style-type: none">• Sec. 33 lists known PBTs and other high-concern chemicals identified by authoritative bodies; the list is static and is not intended to be added to.<ul style="list-style-type: none">• subject to expedited safety determinations within 1 year.• Sec. 37 lists chemicals banned under the international treaties, to be banned under TSCA after 5 years unless—<ol style="list-style-type: none">(a) made, used or disposed of “in a manner determined by the Administrator to be protective of human health and the environment” or(b) a use gets a critical use exemption.• Sec. 32 requires EPA to develop and apply a specialized risk assessment procedure for persistent, bioaccumulative chemicals.



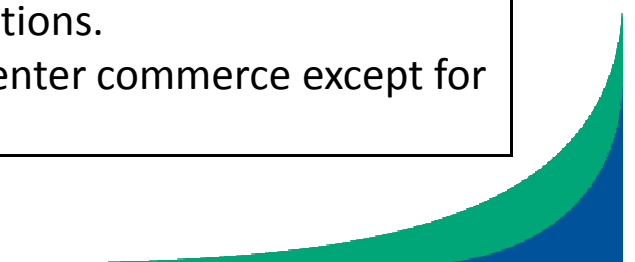
Safety standard, determinations

S. 3209: <i>Safe Chemicals Act of 2010</i>	<i>House Discussion Draft:</i> <i>Toxic Chemicals Safety Act of 2010</i>
<p><u>Safety standard</u>: Health-based standard of “reasonable certainty of no harm”</p> <ul style="list-style-type: none"> • borrowed from FQPA; applied via risk assessment using “best available science” (Senate only: EPA shall “consider” NAS recommendations) • based on aggregate and cumulative exposure assessment • must protect vulnerable subpopulations • “negligible risk” (Senate only) • for environmental effects: “protects public welfare” (House only) 	
<p><u>Priority list</u>:</p> <ul style="list-style-type: none"> • 300 chemicals listed within 18 months of enactment based on “relative risk” • added to as EPA completes safety determinations to maintain list of ≥300 	
<p><u>Safety determinations</u>:</p> <ul style="list-style-type: none"> • Existing chemicals: <ul style="list-style-type: none"> • 6 months after data received, maximum 36 months after listing • Redeterminations after 15 years or significant changes • New chemicals: Before manufacture – unless EPA finds none of several “red flag” criteria are triggered 	<p>Same, except:</p> <ul style="list-style-type: none"> • Existing chemicals: <ul style="list-style-type: none"> • 6 months after MDS or any other requested data are received • New chemicals: Before manufacture – unless EPA finds chemical is “not reasonably anticipated to present a risk”



Safety determinations, continued

S. 3209: <i>Safe Chemicals Act of 2010</i>	<i>House Discussion Draft:</i> <i>Toxic Chemicals Safety Act of 2010</i>
<ul style="list-style-type: none"> • Existing chemicals: <ul style="list-style-type: none"> • <u>Fail</u> safety determination: phase-out within 1 year, except for uses granted critical use exemptions. • <u>Pass</u> safety determination: production and use limited to those uses and conditions specified in determination. • New chemicals: <ul style="list-style-type: none"> • <u>No 'red flag' criteria met</u>: can enter commerce, eventually undergoes safety determination. Otherwise: • <u>Pass</u> safety determination: production and use limited to those uses and conditions specified in determination. • <u>Fail</u> safety determination: cannot enter commerce except for uses granted critical use exemptions. 	<ul style="list-style-type: none"> • Existing chemicals: <ul style="list-style-type: none"> • <u>Fail</u> safety determination: phase-out within 1 year, except for critical uses. • <u>Pass with conditions</u>: Limited to uses, conditions specified in determination. • <u>Pass without conditions</u>: Can be produced and used for allowed uses (using current conditions is implied). • New chemicals: <ul style="list-style-type: none"> • <u>"Not reasonably anticipated to present a risk"</u>: can enter commerce, eventually undergoes safety determination. Otherwise: • <u>"Anticipated use meets safety standard"</u>: can be produced and used for allowed uses and conditions. • <u>If not</u>: cannot enter commerce except for critical uses.



Exposure of vulnerable populations

S. 3209:

Safe Chemicals Act of 2010

House Discussion Draft:

Toxic Chemicals Safety Act of 2010

Prenatal and Infant Exposures:

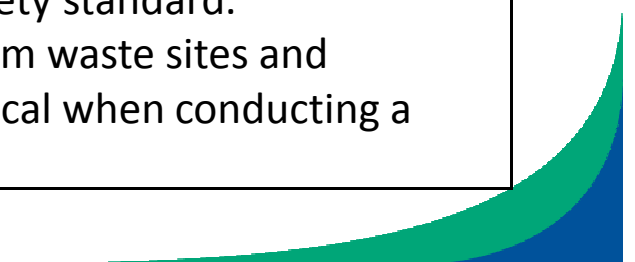
- Applies to chemicals that may be in people and may adversely affect early development.
- CDC to biomonitor such chemicals within 2 years to determine if pregnant women or infants are exposed.
- If so, manufacturers and processors must publicly disclose all known uses of the substance and articles in which it is expected to be present.

Hot spots:

- EPA to identify geographic areas in which resident populations are subject to disproportionately high exposures to toxic chemicals.
 - Based on existing databases and criteria EPA is to develop.
 - Public can nominate localities for inclusion.
- EPA to develop and implement action plans to reduce such exposures.

Other provisions:

- People subject to disproportionately high exposures may be included among vulnerable subpopulations for which protection is called for under the safety standard.
- EPA must consider current releases and “legacy” exposures from waste sites and contaminated sites in assessing aggregate exposure to a chemical when conducting a safety determination.



Interagency coordination

S. 3209:

Safe Chemicals Act of 2010

House Discussion Draft:

Toxic Chemicals Safety Act of 2010

EPA required to assess aggregate exposure to chemicals – includes:

- TSCA regulated uses of a chemical AND
- uses and sources of the same chemical that fall under other laws/agencies (e.g., use in cosmetics, food packaging)

If EPA finds:

- a chemical fails the safety standard (or Senate only: passes it only with new conditions imposed) AND
- action could be taken under another law to address uses or reduce aggregate exposure to the chemical,

THEN:

- EPA must inform the other agency of needed actions,
- the other agency must report back and either:
 - initiate action, in which case EPA cannot, or
 - say it cannot or will not, in which case EPA can act
- EPA can also act if the other agency:
 - does not complete the needed action,
 - takes insufficient action to ensure the safety standard is met, or
 - fails to respond



Information disclosure

S. 3209:

Safe Chemicals Act of 2010

House Discussion Draft:

Toxic Chemicals Safety Act of 2010

- Establishes a public database for both chemical information and EPA decisions made about the safety of chemicals.
- Narrows conditions under which submitted information can be claimed confidential, by requiring:
 - up-front justifications for all CBI claims (based on EPA standards);
 - EPA review and determination of validity of each CBI claim;
 - disclosure of information found ineligible or not legitimately CBI; and
 - expiration of CBI claims after 5 years;
- Requires CBI to be shared with state, Tribal or local (and House only: foreign) governments, subject to an agreement to keep the information confidential.
- EPA to facilitate worker access to information on chemicals they may be exposed to.
- Specifies certain information is ineligible for CBI protection, including:
 - EHS data, including chemical identity
 - chemical identity except for new chemicals under certain conditions,
 - safety determinations, and
 - presence of a chemical in products to which children may be exposed.



Other notable provisions

S. 3209: <i>Safe Chemicals Act of 2010</i>	House Discussion Draft: <i>Toxic Chemicals Safety Act of 2010</i>
<p><u>Green chemistry</u>: Establishes programs, policies and research programs promoting green chemistry and the development and implementation of safer alternatives.</p> <p><u>Reduction in animal testing</u>: Promotes development and use of non-animal tests where scientifically valid.</p> <p><u>International treaties</u>: Intended to provide implementing language toward US ratification of Stockholm and Rotterdam Conventions and LRTAP POPs Protocol.</p> <p><u>Exports</u>: Eliminates blanket exemption of chemicals made solely for export from TSCA requirements.</p> <p><u>Judicial review</u>: Replaces TSCA's "substantial evidence" standard with conventional standard or "arbitrary or capricious."</p> <p><u>Data quality</u>: Requires EPA to conduct lab inspections, audits of data submissions; provides EPA access to private EHS research records; requires funder disclosures for third-party research (and Senate only: establishment of regulatory study registry).</p>	
<p><u>Federal preemption</u>:</p> <ul style="list-style-type: none"> • State requirements or actions on chemicals <u>more stringent</u> than federal requirements are not preempted. 	<p>Same except:</p> <ul style="list-style-type: none"> • State requirements or actions on chemicals <u>different from or in addition to</u> federal requirements or actions are not preempted, <u>unless</u> compliance with both is impossible.

