

# TSCA reform legislation: Highlights and comparisons

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# ***U.S. Legislation: Current and Proposed***

- Toxic Substances Control Act of 1976 (TSCA)
  - Covers most chemicals used in industry and in commercial/consumer products
  - Excludes:
    - uses in drugs, cosmetics, food packaging regulated by FDA
    - uses in pesticides covered by EPA under FIFRA
- 2010 Reform legislation
  - *Safe Chemicals Act* (S. 3209) introduced by Senator Lautenberg
  - *Toxic Chemicals Safety Act* (H.R. 5820) introduced by Chairmen Rush and Waxman

# TSCA vs. new proposals: Overview

Currently under TSCA	Under Reform 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 are required. A minimum data set (MDS) on all new and existing chemicals sufficient to determine safety is 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 its 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, are to be subject to a full safety determination (for certain new chemicals, at some point after entry into commerce).</p>

# TSCA vs. new proposals: Overview

Currently under TSCA	Under Reform Proposals
<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>Safety determination is based on <i>aggregate</i> exposure to all uses and sources, and must ensure protection of vulnerable populations. Full lifecycle of a chemical must be considered.</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, with deadlines for decisions. EPA can restrict or place any conditions on use of a chemical needed to ensure safety. Chemicals with high hazard, exposure or risk are first to undergo safety determinations.</p>

# TSCA vs. new proposals: Overview

<b>Currently under TSCA</b>	<b>Under Reform Proposals</b>
<p><u>CHEMICALS AND EXPOSURES OF HIGH CONCERN</u>: 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 is to expedite action to reduce use of and exposure to toxic chemicals that persist and build up in the environment and people. “Hot spots” where people are subject to high exposures are to be identified and addressed.</p>
<p><u>INFORMATION ACCESS</u>: Companies can claim, often without providing any justification, most of what they submit to be confidential business information (CBI), denying access to the public and state governments. EPA is not required to review such claims, and the claims never expire.</p>	<p>All CBI claims are to be justified up front. EPA is required to review at least a representative sample of claims. Claims are to expire after a period of time unless renewed. Other levels of government are to have access to CBI.</p>

# TSCA vs. new proposals: Overview

Currently under TSCA	Under Reform Proposals
<p><u>RULEMAKING REQUIREMENTS</u>: 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 in order to require testing, a <i>Catch-22</i>.</p>	<p>In addition to the MDS requirement, EPA has authority to issue an order rather than a regulation to require existing data to be reported or additional testing to be done, and need not first show evidence of harm.</p>

# Data reporting and testing

<b>S. 3209:</b> <b><i>Safe Chemicals Act of 2010</i></b>	<b>H.R. 5820:</b> <b><i>Toxic Chemicals Safety Act of 2010</i></b>
<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"> <li>• resets TSCA inventory; “ceased” chemicals if returned would be new chemicals</li> <li>• updated every 3 years or when significant change in info/production/use occur</li> </ul>	
<p><u>Minimum data set (MDS)</u>: Required for all new and existing chemicals</p> <ul style="list-style-type: none"> <li>• New chemicals: w/ pre-mfctre notice</li> <li>• Existing chemicals:               <ul style="list-style-type: none"> <li>• for priority chemicals, within 18 months of listing</li> <li>• for other chemicals, within 30 months of placement on safety determination list or 14 years after enactment, whichever comes first</li> </ul> </li> <li>• MDS not specified, can be tiered or varied by chemical group/type</li> </ul>	<p>Same, except:</p> <ul style="list-style-type: none"> <li>• Existing chemicals:               <ul style="list-style-type: none"> <li>• for priority chemicals, within 18 months</li> <li>• for all other chemicals, within 5 years of enactment                   <ul style="list-style-type: none"> <li>• High-volume: 3 years</li> <li>• Medium-volume: 4 years</li> <li>• Low-volume: 5 years</li> </ul> </li> </ul> </li> </ul>
<p><u>Omnibus authority</u> for EPA to call in data or require more testing</p> <ul style="list-style-type: none"> <li>• May be done by order rather than rulemaking</li> </ul>	

# Expedited action

## **S. 3209:**

### ***Safe Chemicals Act of 2010***

Single sentence: “The Administrator shall act quickly to manage risks from chemical substances that clearly pose the highest risks to human health or the environment.”

## **H.R. 5820:**

### ***Toxic Chemicals Safety Act of 2010***

- Sec. 6 lists 19 chemicals for which safety determinations are to be done first.
- Sec. 32 requires EPA to develop and apply criteria to identify chemicals that are persistent, bioaccumulative and toxic.
  - EPA to impose conditions on production use and disposal “necessary to achieve the greatest practicable reductions in exposure.”
  - After conditions are implemented, PBTs are to undergo safety determinations to determine and if necessary control residual risks.
- Sec. 36 lists 5 chemicals/groups banned under international treaties, to be banned under TSCA after 3 years unless made, used or disposed of “in a manner determined by the Administrator to be protective of human health and the environment.”



# Safety standard, determinations

<b>S. 3209:</b> <b><i>Safe Chemicals Act of 2010</i></b>	<b>H.R. 5820:</b> <b><i>Toxic Chemicals Safety Act of 2010</i></b>
<p><u>Safety standard:</u> Health-based standard of “reasonable certainty of no harm”</p> <ul style="list-style-type: none"> <li>• adapted from FQPA; applied via risk assessment; EPA shall “rely on” (House) or “consider” (Senate) NAS recommendations</li> <li>• based on aggregate and cumulative exposure assessment</li> <li>• House only: determination based on “intended uses;” EPA may consider unintended exposures, and may group uses into use categories where exposure is similar</li> <li>• must protect vulnerable subpopulations, consider full lifecycle</li> <li>• Senate: “negligible risk”; House: “protects public welfare” from environmental effects</li> </ul>	
<p><u>Priority list:</u></p> <ul style="list-style-type: none"> <li>• Maintain list of <math>\geq 300</math> chemicals (including 19 named in Sec. 6) chosen based on “relative risk” (House only: “or hazard/exposure”) to determine order of safety determinations.</li> </ul>	
<p><u>Safety determinations:</u></p> <ul style="list-style-type: none"> <li>• New chemicals: Before manufacture unless EPA finds no “red flags”</li> <li>• Existing chemicals:               <ul style="list-style-type: none"> <li>• 6 months after data received, maximum 36 months after listing</li> <li>• Redeterminations after 15 years or significant changes</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• New chemicals: Before manufacture unless EPA finds use is critical, or chemical is inherently safe or is safer than existing chemicals for particular use(s)</li> <li>• Existing chemicals:               <ul style="list-style-type: none"> <li>• 6 months after MDS or any other requested data are received</li> <li>• Same</li> </ul> </li> </ul>

# Safety determinations, continued

<b>S. 3209:</b> <b><i>Safe Chemicals Act of 2010</i></b>	<b>H.R. 5820:</b> <b><i>Toxic Chemicals Safety Act of 2010</i></b>
<ul style="list-style-type: none"><li>• Existing chemicals:<ul style="list-style-type: none"><li>• <u>Fail</u> safety determination: phase-out within 1 year, except for uses granted critical use exemptions.</li><li>• <u>Pass</u> safety determination: production and use limited to those uses and conditions specified in determination.</li></ul></li><li>• New chemicals:<ul style="list-style-type: none"><li>• <u>No 'red flag' criteria met</u>: can enter commerce, eventually undergoes safety determination. Otherwise:</li><li>• <u>Pass</u> safety determination: production and use limited to those uses and conditions specified in determination.</li><li>• <u>Fail</u> safety determination: cannot enter commerce except for uses granted critical use exemptions.</li></ul></li></ul>	<ul style="list-style-type: none"><li>• Existing chemicals:<ul style="list-style-type: none"><li>• <u>Fail</u> safety determination: phase-out within 1-3 years, except for critical uses.</li><li>• <u>Pass with conditions</u>: Limited to uses, conditions specified in determination.</li><li>• <u>Pass without conditions</u>: Can be produced and used for specified uses (EPA may maintain current conditions).</li></ul></li><li>• New chemicals:<ul style="list-style-type: none"><li>• <u>"Intrinsic properties indicate no risk" or safer alternative to existing chemical</u>: can enter commerce, eventually undergoes safety determination.</li><li>• <u>Meets safety standard</u>: can be produced and used for allowed uses under specified conditions.</li><li>• <u>If not</u>: cannot enter commerce except for critical uses.</li></ul></li></ul>

# Exposure of vulnerable populations

**S. 3209:**

***Safe Chemicals Act of 2010***

**H.R. 5820:**

***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***

**H.R. 5820:**

***Toxic Chemicals Safety Act of 2010***

EPA requirement to assess aggregate exposure to chemicals includes:

- uses of a chemical subject to current TSCA, AND
- uses and sources of the same chemical that fall under other laws/agencies, e.g., use in cosmetics, food packaging (House only: eliminates exemption of such uses from TSCA's definition of "chemical substance" but redefines "manufacture," "process" and "distribute in commerce" to exclude them)

If EPA finds:

- a chemical fails the safety standard (Senate only: or 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, and the other agency must report back; EPA's and other agency reports must be made public.

- House only: Other agency must report back within 6 months; if it agrees to act, EPA cannot.
- Senate only: EPA can act if the other agency:
  - says it cannot or will not act,
  - does not initiate or complete sufficient action to ensure safety standard is met, or
  - fails to respond.

# Information disclosure

## ***S. 3209:***

### ***Safe Chemicals Act of 2010***

## ***H.R. 5820:***

### ***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 CBI claims (Senate: all claims; House: “representative sample”)
  - disclosure of information found ineligible or not legitimately CBI; and
  - expiration of CBI claims after 5 years (House only: unless renewed);
- 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 (House only: or mixture composition)
  - chemical identity except for new chemicals under certain conditions,
  - safety determinations, and
  - presence of a chemical in products to which children may be exposed.
- House only: Penalties provided for wrongful designation of information as CBI.

# Other notable provisions

## ***S. 3209:***

### ***Safe Chemicals Act of 2010***

## ***H.R. 5820:***

### ***Toxic Chemicals Safety Act of 2010***

Green chemistry: Establishes programs, policies and research programs promoting green chemistry and the development and implementation of safer alternatives.

Reduction in animal testing: Promotes development and use of non-animal tests where scientifically valid.

International treaties: Intended to provide implementing language toward US ratification of Stockholm and Rotterdam Conventions and LRTAP POPs Protocol.

Exports: Eliminates blanket exemption of chemicals made solely for export from TSCA requirements.

Imports: House only: Extends TSCA to imported articles containing chemical substances.

Judicial review: Replaces TSCA's "substantial evidence" standard with conventional standard or "arbitrary or capricious."

Data quality: 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).

Failure to meet deadlines: If EPA fails to meet deadline for safety determinations:

- EPA would have to inform the public, and manufacturers would have to inform the public, their workers and customers, that a safety determination is pending.
- House only: No new manufacturer or processor and no new use of the chemical can enter the market until the determination is published.

# Other notable provisions

<b>S. 3209:</b> <b><i>Safe Chemicals Act of 2010</i></b>	<b>H.R. 5820:</b> <b><i>Toxic Chemicals Safety Act of 2010</i></b>
<u>Fees</u> : EPA authorized (Senate) or mandated (House) to impose a fee on industry to cover the costs of administering the law.	
<u>Order authority</u> : EPA authorized to use orders rather than rulemaking in carrying out chemical-specific actions.	
<u>Federal preemption</u> : <ul style="list-style-type: none"> <li>State requirements or actions on chemicals <u>more stringent</u> than federal requirements are not preempted.</li> </ul>	<ul style="list-style-type: none"> <li>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.</li> </ul>
	<u>Employee protection</u> : Significantly expands protections available to employees under current Section 23 of TSCA.
	<u>Supply chain communication</u> : Chemical producers must disclose chemical identity (subject to CBI allowances) and hazard information to their downstream commercial purchasers.
	<u>Safer alternatives</u> : Establishes process and data requirements for approval of safer alternatives to existing chemical substances.

# ***For more information***

TSCA, REACH & CEPA: *Not That Innocent*

[www.edf.org/chempolicyreport](http://www.edf.org/chempolicyreport)

TSCA Reform: Policy Papers and Reports,  
Congressional Testimony

[www.edf.org/page.cfm?tagID=12814](http://www.edf.org/page.cfm?tagID=12814)

EDF Chemicals & Nanomaterials Blog

[www.edf.org/chemandnano](http://www.edf.org/chemandnano)

*Safer Chemicals Healthy Families* coalition

[www.saferchemicals.org](http://www.saferchemicals.org)

