

**From:** Metcalf, Lynn  
**Sent:** Wednesday, March 16, 2016 10:58 AM  
**To:** Greenwood, Kim  
**Subject:** FW: TSCA Reform issues for governors' letter  
**Attachments:** NEWMOA\_TSCA Comments Table 1-7-2016.pdf; EPA\_TSCAReformView\_Jan2016.pdf; CRS\_R44024.pdf; factsheet\_contaminant\_pfos\_pfoa\_march2014.pdf; 2016Jan AG letter on TSCA Reform.pdf

**Categories:** PFOA

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**From:** Metcalf, Lynn  
**Sent:** Tuesday, March 15, 2016 5:47 PM  
**To:** Martin, Trey <Trey.Martin@vermont.gov>  
**Subject:** TSCA Reform issues for governors' letter

**Trey –**

Here are some notes on the TSCA reform topics that we discussed yesterday. Both the House (H.R. 2576) and Senate (S. 697) bills have merit – each one gets some things right and some things wrong from the state’s perspective. I wanted to get you something this afternoon and I didn’t know if you wanted to go in the direction of which bill’s approach we would prefer for each topic. If you want this level of detail, let me know and I can add it to the extent we know it.

Note that the state’s earlier focus ( and you likely remember this from S.1009) was on preemption and what that might do to states’ ability to regulate chemicals. In the wake of the discovery of widespread PFOA contamination, we (and maybe NY and NH as well) have shifted our emphasis the need to get for TSCA reform passed period. This is a reasonable evolution.

**TSCA REFORM TOPICS:**

**Safety Standard and Vulnerable Populations -**

- The safety standard is the regulatory threshold for restricting a chemical substance.
- The current TSCA uses as a standard "that the chemical substance presents or will present an unreasonable risk of injury to health or the environment," however "unreasonable risk" is not defined in statute and has been interpreted by the courts (in the Corrosion Proof Fittings v. EPA case) to require a balancing of costs and benefits.
- The safety standard should be “no unreasonable risk to health or the environment without consideration of cost or other non-risk factors.” The safety standard should also be protective of potentially-exposed and vulnerable populations including workers, children, pregnant women and those with compromised immune systems.
- When EPA has found that a chemical substance does not meet the safety standard and should be subject to restrictions, EPA should not be required to choose the least burdensome option or to do extensive economic analysis /evaluate an indeterminate number of alternatives to show that it has chosen the option that has the least economic impact.

**Deadlines**

There must be clear and feasible deadlines for:

- starting safety assessments of existing chemicals;
- completing safety assessments; and
- acting on chemicals when they have been found to be unsafe
- TSCA Reform Options:

**Testing**

- Under current TSCA, in order to require testing, EPA must find (based on the available information) that a chemical

substance either (1) may present unreasonable risks, or (2) that substantial quantities are produced either in a way that enters or may be anticipated to enter the environment, or in a way that there is or may be significant or substantial human exposures.

In other words, EPA must show risk in order to require testing to evaluate risk.

- New chemicals: there should be requirements for industry to submit sufficient test data when they submit their pre-manufacture notices so that EPA can quickly make determination of whether or not the chemicals meet the safety standard;
- Existing chemicals: For chemicals already on the TSCA inventory, EPA should be able to require testing for safety assessments of existing chemicals with orders rather than by rulemaking.

**Preemption** - states should not be preempted from taking action on specific chemicals until EPA acts on those chemicals. The NEWMOA summary table entitled Toxic Substances Control Act (TSCA) Reform: Key Issues and Comments - January 7, 2016 (attached as NEWMOA TSCA Comments...) summarizes the many facets of state concern with preemption including timing, scope, grandfathering and waivers. Here are the general points:

- States shouldn't be preempted until EPA takes final action.
- Once EPA has taken final action, the scope of state preemption should not be broader than the scope of EPA's action.
- State chemical programs that exist at the time should not be preempted.
- States should be able to enforce state laws.
- States should be able to get waiver if they have stricter laws as long as the laws don't burden interstate commerce.

**I have attached the following:**

- **NEWMOA\_TSCA\_Comments\_Table 1-7-2016** – Table prepared by Rachel Massey at MA Toxics Use Reduction Institute and reviewed by NEWMOA and ECOS members. Along with EPA's January letter, it is the most up-to-date side-by-side comparison though it focuses primarily on preemption.
- **EPA TSCAReformView\_Jan2016** – EPA's comments on the House and Senate bills and how they address EPA's principals for TSCA reform
- **CRS\_R44024** – This is from July 2015 so a little outdated but I like it because very comprehensively lays out the problems with current TSCA and how each of the bills (including a second senate bill S. 725 which I think got partially folded into S. 697) at that time addressed the issues. I wish we could have the Congressional Research Service write summaries for us.
- **2016Jan AG letter on TSCA reform** - Attorneys General (Including VT)Letter on TSCA reform
- **EPA Factsheet on PFOS and PFOA**
- EDF also posted a house and senate bill comparison after the House bill passed in June (so it is a little outdated re: the Senate bill) but may be useful background for what is wrong with TSCA through another filter:  
<http://blogs.edf.org/health/files/2015/06/TSCA-Lautenberg-Act-House-bill-6-29-15.pdf>

I couldn't find a similarly helpful analysis from the American Chemistry Council but I'll keep looking.

I hope this information is helpful. Let me know if you have questions or want me to find additional information.

Thanks.

Lynn

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## Toxic Substances Control Act (TSCA) Reform: Key Issues and Comments

### January 7, 2016

The following table analyzes the bill adopted by the House on June 23, 2015 (The TSCA Modernization Act of 2015, referred to here as “the House bill”) and the bill adopted by the Senate on December 17, 2015 (the Frank R. Lautenberg Chemical Safety for the 21st Century Act, referred to here as “the Senate bill”).<sup>1</sup> The table presents a compilation of selected points that are of interest to a number of state agencies as well as local authorities. For the sake of brevity, the table makes reference primarily to “states,” but similar concerns generally apply both to state and to local authorities.

The table does not represent a formal consensus and legislation can be subject to varying interpretations; individual stakeholders and authorities may have differing views on points discussed here. The table also does not represent an exhaustive analysis of the elements of the bills that are of interest or concern, and may be revised or expanded based on additional discussion among interested parties. In short, the table is designed as a guide to selected issues of interest.

Points presented here were developed in part through discussions convened by the Northeast Waste Management Officials’ Association (NEWMOA). Background research and analysis was provided by the Massachusetts Toxics Use Reduction Institute in collaboration with the Washington Department of Ecology and agencies in other states.

This document does not represent a legal position or the official position of any entity. Individuals or agencies needing legal information or opinions should consult appropriate experts. Any comments or suggestions are welcomed, and can be sent to [ecos@ecos.org](mailto:ecos@ecos.org) which will collect and share input with the document’s collaborators.

### 1. PREEMPTION

	Summary	Senate Bill	House Bill	Comments
<b>Preemption: General points</b>	<ul style="list-style-type: none"> <li>Many states feel strongly about retaining the ability to act to protect citizens after federal legislation is enacted. Preemption of state authorities reduces the states’ capacity to spur innovation and provide a level of protection that may go beyond federal requirements. The comments below are offered regarding the preemption provisions currently found in the Senate and House bills.</li> </ul>			
<b>Timing of Preemption</b>	<ul style="list-style-type: none"> <li>Many states believe the regulatory pause (or pause preemption) in the Senate bill during EPA’s Safety Determination creates an unnecessary and</li> </ul>	<ul style="list-style-type: none"> <li><i>Permanent federal preemption:</i> For a substance that does not meet the safety standard, preemption is effective as of the effective date of the rule issued by EPA. The rule itself must be complied with within 4 years,</li> </ul>	<ul style="list-style-type: none"> <li>Preemption occurs when EPA takes final action on the chemical in a rule. There is no expressed statutory deadline for industry to comply with a rule.</li> </ul>	<ul style="list-style-type: none"> <li>Eliminating the regulatory pause in the Senate bill would make it possible for states to take action to protect their citizens while EPA analyses are under way. From this perspective, the timing of preemption under the House bill is preferable to the approach taken in the</li> </ul>

	Summary	Senate Bill	House Bill	Comments
	<p>counterproductive barrier to state actions to protect people and the environment from high priority chemicals.</p> <ul style="list-style-type: none"> <li>From the perspective of many states, any preemption of state action should be triggered no earlier than when any EPA final rule is fully implemented.</li> </ul>	<p>with the possibility of an 18 month extension.</p> <ul style="list-style-type: none"> <li><i>Pause preemption:</i> New state prohibitions or restrictions are preempted, starting on the date when EPA publishes the scope of a safety assessment and safety determination, and ending when EPA either publishes a determination or reaches the statutory deadline for publication of the safety determination (a maximum of 3 to 4 years). During this time period, states would be prevented from taking action on high priority chemicals, unless they receive a waiver, even though EPA itself would not yet have taken action.</li> </ul>		<p>Senate bill.</p> <ul style="list-style-type: none"> <li>However, setting a deadline for <i>implementation</i> as in the Senate bill is preferable to the approach under the House bill.</li> <li>To ensure no regulatory gaps, many states believe that preferably, any preemption should occur only when compliance with EPA safety requirements takes effect.</li> <li>In summary, from the perspective of states interested in taking prompt action on chemical hazards, it would be preferable to eliminate the pause preemption that appears in the Senate bill, but include an appropriate, limited statutory time frame for compliance.</li> </ul>
<b>State actions related to monitoring, disclosure, and related activities</b>	<ul style="list-style-type: none"> <li>Many states have reporting, monitoring, disclosure, labeling, options evaluation, assessment, planning, pollution prevention, and technical assistance programs and requirements, as well as other requirements and programs of this kind, and associated fees. It is important to many states that all of these requirements be clearly protected from preemption.</li> </ul>	<ul style="list-style-type: none"> <li>The Senate bill specifies protection from preemption for a “reporting, monitoring, disclosure, or other information obligation.”</li> </ul>	<ul style="list-style-type: none"> <li>The House bill does not specify this exemption as clearly as the Senate bill, although there is discussion of the issue in the House committee report.</li> </ul>	<ul style="list-style-type: none"> <li>Retaining the language in the Senate bill is important to make these protections clear.</li> </ul>

	<b>Summary</b>	<b>Senate Bill</b>	<b>House Bill</b>	<b>Comments</b>
<b>State actions related to clean air and water and related activities</b>	<ul style="list-style-type: none"> <li>It is important to many states that action taken under other federal laws, as well as actions related to water quality, air quality, or waste management, be clearly protected from preemption. Both bills include some protections of this kind.</li> </ul>	<ul style="list-style-type: none"> <li>The Senate bill specifies that there is no preemption of actions undertaken under the authority of another Federal law, or adopted “pursuant to authority under a law of the State or political subdivision of the State related to water quality, air quality, or waste treatment or disposal, except to the extent that the action (I) imposes a restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance; and (II) addresses the same hazards and exposures, with respect to the same conditions of use as are included in the scope of the safety determination ... but is inconsistent with the action of the Administrator; or would cause a violation of the applicable action by the Administrator ...”</li> </ul>	<ul style="list-style-type: none"> <li>The House bill specifies that there is no preemption of actions taken under the authority of another Federal law, or of a requirement that “is adopted to protect air or water quality or is related to waste treatment or disposal,” unless the requirement “actually conflicts” with EPA’s action.</li> </ul>	<ul style="list-style-type: none"> <li>The wording of each provision should be examined carefully as there are differences between the bills that could have implications for implementation.</li> </ul>
<b>Wording used to describe state actions</b>	<ul style="list-style-type: none"> <li>Many states are concerned about ensuring clarity about the actions to which preemption applies.</li> </ul>	<ul style="list-style-type: none"> <li>In the Senate bill, the preemption language refers to “a statute or administrative action to require” development of information, or “a statute or administrative action to prohibit or otherwise restrict the manufacture, processing, or distribution in commerce or use of a chemical substance”</li> </ul>	<ul style="list-style-type: none"> <li>In the House bill, preemption applies to “any requirement that applies to such chemical substance...”</li> </ul>	<ul style="list-style-type: none"> <li>Many states believe this language in the House bill is too broad, and consider the wording in the Senate bill to be clearer.</li> </ul>
<b>Scope of preemption</b>	<ul style="list-style-type: none"> <li><i>Issues related to uses &amp; health effects.</i> Many states believe that it is important that</li> </ul>	<ul style="list-style-type: none"> <li>The Senate bill specifies that preemption applies only to “the hazards, exposure, risks, and uses or conditions of use”</li> </ul>	<ul style="list-style-type: none"> <li>The House bill specifies that preemption applies to “any requirement that applies to such substance</li> </ul>	<ul style="list-style-type: none"> <li>The language in the Senate bill is clearer than that of the House bill in limiting the scope of preemption for existing chemicals both to the uses and to the</li> </ul>

	Summary	Senate Bill	House Bill	Comments
	<p>preemption be limited to both the uses and the health effects that have been considered by EPA and that states should be able to act on newly emerging science.</p> <ul style="list-style-type: none"> <li>Some state agencies have pointed out that if new scientific findings or assessment methods emerge that indicate a new or higher risk than was previously recognized, and EPA has not yet reviewed this new science, it is particularly important that states be able to take action.</li> <li><i>Issues related to new chemicals &amp; significant new uses.</i> Many states believe it is important to preserve the ability to regulate a chemical that EPA has not yet analyzed in detail. This includes chemicals for which a significant new use rule may have been issued.</li> </ul>	<p>considered in the safety assessment and determination.</p> <ul style="list-style-type: none"> <li><i>Significant new uses.</i> The Senate bill specifies that states are preempted from requiring notification of a use of a chemical that EPA has designated as a significant new use and for which EPA has required notification.</li> </ul>	<p>or mixture...and is designed to protect against exposure to the chemical substance or mixture either under the intended conditions of use considered by the Administrator in the risk evaluation...”</p> <ul style="list-style-type: none"> <li><i>New chemicals or significant new uses.</i> Under the House bill, broad state preemption can result if EPA imposes a requirement related to a new chemical or a significant new use. Thus, under the approach of the House bill, when EPA acts to regulate a new chemical or a significant new use of an existing chemical, state regulations may be preempted without EPA having conducted a full analysis.</li> </ul>	<p>health and environmental concerns that have been considered by EPA.</p> <ul style="list-style-type: none"> <li><i>New chemicals &amp; significant new uses.</i> The scope of preemption for new chemicals is considerably broader in the House bill than that in the Senate bill. Many states believe the more limited approach in the Senate bill is preferable, based on the principle that the scope of preemption should correspond to the scope of the action taken by EPA.</li> </ul>
<b>Grand-fathering</b>	<ul style="list-style-type: none"> <li>Many states urge that all state and local laws, statutes, rules,</li> </ul>	<ul style="list-style-type: none"> <li>The Senate bill specifies that nothing in the Act shall“(A) be construed to preempt or</li> </ul>	<ul style="list-style-type: none"> <li>The House bill specifies that none of the bill’s provisions “shall be</li> </ul>	<ul style="list-style-type: none"> <li>Many states believe strongly that all existing statutes, rules, regulations and other actions or requirements that are in</li> </ul>

	Summary	Senate Bill	House Bill	Comments
	regulations, orders and other actions and requirements adopted before any revised TSCA takes effect be grandfathered so that the states can continue to implement and enforce them.	otherwise affect the authority of a State or political subdivision of a State to continue to enforce any action taken before August 1, 2015, under the authority of a law of the State or political subdivision of the State that prohibits or otherwise restricts manufacturing, processing, distribution in commerce, use, or disposal of a chemical substance; or (B) be construed to preempt or otherwise affect any action taken pursuant to a State law that was in effect on August 31, 2003.”	construed to preempt or otherwise affect the authority of a State or political subdivision of a State to continue to enforce any action taken or requirement that has taken effect— (A) before August 1, 2015, under the authority of a State law that prohibits or otherwise restricts the manufacturing, processing, distribution in commerce, use, or disposal of a chemical substance; or (B) pursuant to a State law that was in effect on August 31, 2003, unless an action or determination made by the Administrator under this title actually conflicts with the action taken or requirement that has taken effect pursuant to such a State law.”	place at the time of the bill’s adoption, including authority to undertake future actions under all existing laws and regulations, should be fully preserved. <ul style="list-style-type: none"> <li>At a minimum, this goal can be supported by retaining the Senate language on grandfathering, with the addition of the words “or requirement imposed” after the words “action taken” in both places where these words appear.</li> </ul>
<b>Waivers</b>	<ul style="list-style-type: none"> <li>Predictability is a priority for many states. From the perspective of these states, it is important to have the ability to receive a waiver from preemption when needed. The waiver process should be straightforward and predictable.</li> </ul>	<ul style="list-style-type: none"> <li>The Senate bill includes two waiver processes.</li> <li>For <i>discretionary waivers</i> from permanent federal preemption, EPA is to make decisions based on factors including “compelling conditions” related to health or environment and an EPA evaluation of the state’s use of science in decision making. These conditions are more burdensome to meet than those in existing TSCA.</li> <li>For <i>required waivers</i> from pause</li> </ul>	<ul style="list-style-type: none"> <li>The House bill retains the existing TSCA language regarding waivers from permanent federal preemption.</li> <li>The House bill does not include deadlines for EPA to act on a waiver request.</li> </ul>	<ul style="list-style-type: none"> <li>Many states feel the final language regarding waivers from permanent federal preemption should retain the existing TSCA approach to waivers, and should also include a requirement and deadline for EPA to act on a waiver request.</li> <li><i>Comments on Senate approach to waivers.</i> In the Senate bill, EPA’s evaluation of a state’s use of science is more straightforward for required waivers than it is for discretionary waivers. Many states believe the expressed standard for required waivers</li> </ul>

	Summary	Senate Bill	House Bill	Comments
		<p>preemption, considerations include an EPA determination that the state “has a concern” about the chemical “based in peer-reviewed science.” This appears to be more straightforward than the conditions for discretionary waivers.</p> <ul style="list-style-type: none"> <li>For both processes, the Senate bill includes a requirement and deadline for EPA to act on a waiver request.</li> </ul>		is the more appropriate standard for states to meet for securing either type of waiver under the statute.
<b>Savings clause - statutory &amp; common law claims for damages</b>	<ul style="list-style-type: none"> <li>From the perspective of some states, it is important to ensure no preemption of the application of state statutory and common law claims for damages.</li> </ul>	<ul style="list-style-type: none"> <li>The Senate bill states explicitly that nothing in the bill is intended to preempt the application of state statutory or common law claims in any way, including damage suits.</li> </ul>	<ul style="list-style-type: none"> <li>The savings language in the House bill is not as clear in protecting remedies currently available to states, municipalities, and members of the public.</li> </ul>	<ul style="list-style-type: none"> <li>From the perspective of some states, the tort savings language in the Senate bill is preferable.</li> </ul>

## 2. OTHER POINTS RELATED TO STATE-FEDERAL RELATIONSHIP

	Summary	Senate Bill	House Bill	Comments
<b>State action on low priority chemicals</b>		<ul style="list-style-type: none"> <li>If two or more states take action on a low priority chemical, then the Senate bill requires EPA to conduct a prioritization screening for that chemical.</li> </ul>		<ul style="list-style-type: none"> <li>This provision increases administrative burden for states somewhat.</li> <li>If EPA were to decide to prioritize the chemical for a Safety Assessment, then new state actions could be preempted.</li> <li>From the perspective of some states, it may be preferable to remove this language.</li> </ul>
<b>Confidential business information</b>	<ul style="list-style-type: none"> <li>Both bills include a number of changes related to management of Confidential</li> </ul>	<ul style="list-style-type: none"> <li>The Senate bill <i>requires</i> EPA to share data with the states for use related to development, administration or enforcement of</li> </ul>	<ul style="list-style-type: none"> <li>The House bill <i>allows</i> EPA to share data with the states for use related to administration or</li> </ul>	<ul style="list-style-type: none"> <li>States’ ability to address chemical hazards within their borders is enhanced by access to CBI data. Requiring EPA to share CBI data with state environmental</li> </ul>

	<b>Summary</b>	<b>Senate Bill</b>	<b>House Bill</b>	<b>Comments</b>
	<p>Business Information (CBI) claims.</p> <ul style="list-style-type: none"> <li>Please note that this table does NOT cover CBI-related issues exhaustively. Only selected points are discussed here.</li> </ul>	<p>a law under specific circumstances.</p> <ul style="list-style-type: none"> <li>The Senate bill requires EPA to share data with a government health or environmental professional, or a health care professional, under certain circumstances, subject to that individual signing a confidentiality agreement.</li> <li>The Senate bill requires substantiation of most CBI claims, and provides a time frame for expiration of these claims unless they are resubstantiated. It also requires resubstantiation of all CBI claims filed to date for active chemicals.</li> <li>The Senate bill designates specific types of information, including health and safety data, that are not eligible for CBI protection.</li> <li>The Senate bill requires EPA to review and approve, modify or deny CBI claims, with some exceptions.</li> </ul>	<p>enforcement of a law.</p> <ul style="list-style-type: none"> <li>The House bill requires EPA to share data with a government health or environmental professional or health care professional, under certain circumstances, subject to statutory restrictions on that individual's ability to disclose the information to others.</li> <li>The House bill expands upon existing CBI provisions related to health and safety studies to explicitly protect from disclosure chemical formulas, including molecular structures, used in manufacturing or processing a chemical or mixture.</li> <li>The House bill does not require resubstantiation of past CBI claims filed.</li> </ul>	<p>and public health authorities, and ensuring funding to do so, supports this state function. Many states believe the approach to data sharing in the Senate bill is preferable to that in the House bill.</p> <ul style="list-style-type: none"> <li>It could also be useful to authorize EPA to share CBI with interstate organizations, such as the Interstate Chemicals Clearinghouse, in order to avoid inefficient duplication of efforts. Neither bill includes this provision.</li> <li>The Senate and House bills differ with regard to the specific circumstances that trigger a release of information to a health or environmental professional. These differences should be examined carefully as they are likely to affect the ability of states to respond to public health and environmental issues within their borders. The bills also take different approaches to limiting the ability of these professionals to communicate with others about key information on chemicals. Again, the specifics of these provisions could have important consequences for states' ability to protect their citizens.</li> <li>Resubstantiation of CBI claims, as provided for in the Senate bill, is preferable from the perspective of states that may wish to take action on any of these chemicals, as important information may be unavailable due to CBI claims that have not been fully evaluated for validity.</li> </ul>
<b>Industry requests for safety determinations</b>	<ul style="list-style-type: none"> <li>Many states are concerned that significant amounts of EPA staff time could</li> </ul>	<ul style="list-style-type: none"> <li>The Senate bill specifies that these industry-requested safety determinations are to account for a minimum of 25% and a</li> </ul>	<ul style="list-style-type: none"> <li>The House bill does not specify a maximum.</li> <li>The House bill provides a time frame of 2 years for</li> </ul>	<ul style="list-style-type: none"> <li>To ensure that EPA staff time is not consumed by responding to industry requests, it would be preferable to many states if the provision allowing industry</li> </ul>

	<b>Summary</b>	<b>Senate Bill</b>	<b>House Bill</b>	<b>Comments</b>
	be consumed by responding to industry requests for safety determinations, rather than focusing on EPA-identified critical priorities to protect public health and the environment.	maximum of 30% of the substances assessed by EPA.	EPA to complete an assessment of a manufacturer-requested substance, and a time frame of 3 years for a chemical that EPA has selected as a priority.	<p>requests for safety determinations were removed.</p> <ul style="list-style-type: none"> <li>• If the provision is retained, retaining the maximum specified in the Senate bill would help to limit potential negative effects from this provision.</li> <li>• The different time frames for manufacturer-requested and EPA-prioritized substances under the House bill could exacerbate resource constraint problems, making it difficult for EPA to act promptly on high priority chemicals.</li> </ul>
<b>State Grants</b>	<ul style="list-style-type: none"> <li>• Federal support for state activities would help build and strengthen a federal – state partnership on TSCA issues such as co-enforcement, outreach to stakeholders, and other areas.</li> </ul>			<ul style="list-style-type: none"> <li>• Some states have suggested that it may be useful to direct EPA to use a portion of the fees collected from industry to provide chemical safety grants for the states and their representatives. These funds could be used for compliance and enforcement, technical assistance, pollution prevention programs, and sector and public education.</li> </ul>
<b>Safer Choice</b>		<ul style="list-style-type: none"> <li>• In its commentary on S. 697, the Senate committee questioned whether EPA’s Safer Choice program should be maintained.</li> </ul>		<ul style="list-style-type: none"> <li>• EPA’s Safer Choice program has been a useful program. Retaining the program without changes, including the alternatives assessment program, would enable on-going work to recognize the safest products on the market, helping businesses and consumers to differentiate among products and fostering continuous improvement.</li> </ul>

### 3. POINTS RELATED TO EPA AUTHORITIES

Selected additional comments include the following. Please note this is not a comprehensive review.

	<b>Summary</b>	<b>Senate Bill</b>	<b>House Bill</b>	<b>Comments</b>
<b>Safety standard &amp; determination of “unreasonable risk”</b>	<ul style="list-style-type: none"> <li>To the extent that state actions on chemicals will be preempted, it is particularly important to many states that EPA apply a safety standard that is adequate to protect public health.</li> </ul>	<ul style="list-style-type: none"> <li>The Senate bill explicitly states within the definition of the safety standard that cost is not to be considered, and also clarifies that cost is not to be considered in all instances where the phrase “unreasonable risk” is used.</li> </ul>	<ul style="list-style-type: none"> <li>The House bill states that the risk evaluation is to be conducted without consideration of cost, but does not make conforming changes to the entire underlying TSCA statute.</li> </ul>	<ul style="list-style-type: none"> <li>For the use of the unreasonable risk standard, many states believe that a comprehensive approach to clarifying every regulatory provision in the TSCA statute should be adopted, making clear that cost is not taken into account in this process. This is done in the Senate bill.</li> <li>The experience of many states has shown that in making decisions about chemicals it is important to use a standard that is protective of the most sensitive and vulnerable populations, and to employ an adequate margin of safety.</li> <li>A standard of “reasonable certainty of no harm” would be more protective of public health than a standard of “unreasonable risk.”</li> </ul>
<b>Role of cost analysis in decision making about regulations</b>	<ul style="list-style-type: none"> <li>Many states feel that EPA’s ability to regulate chemicals and articles should not be subject to limitations related to analysis of costs.</li> </ul>	<ul style="list-style-type: none"> <li>The Senate bill directs EPA, in making decisions about restrictions, to “take into consideration” information on costs and benefits of regulatory actions.</li> </ul>	<ul style="list-style-type: none"> <li>The House bill directs EPA to impose requirements that are “cost-effective, except where the Administrator determines that additional or different requirements ... are necessary to protect against the identified risk”</li> </ul>	<ul style="list-style-type: none"> <li>Based on the experience of many states, it would be preferable not to require EPA to justify its regulatory decisions with extensive economic analyses. The approach of the Senate bill noted here is preferable to the House bill’s requirement noted here related to cost effectiveness.</li> </ul>

	<b>Summary</b>	<b>Senate Bill</b>	<b>House Bill</b>	<b>Comments</b>
<b>Breadth of EPA authority</b>	<ul style="list-style-type: none"> <li>Many states feel that it is important that EPA have broad authority to take action on chemicals that do not meet the safety standard.</li> </ul>	<ul style="list-style-type: none"> <li>For chemicals that do not meet the safety standard, the Senate bill provides EPA with the authority to “impose restrictions necessary to ensure that the chemical substance meets the safety standard under the conditions of use...” or to ban or phase out the chemical if the safety standard cannot be met.</li> </ul>	<ul style="list-style-type: none"> <li>The House bill directs EPA to adopt a rule “so that the chemical substance or mixture no longer presents or will present an unreasonable risk, including an identified unreasonable risk to a potentially exposed subpopulation”</li> </ul>	<ul style="list-style-type: none"> <li>To the extent that EPA actions will preempt those of states, it is important to provide EPA with broad authority to regulate chemicals that do not meet the safety standard, with an adequate safety margin, including consideration of potential future uses of the chemical.</li> </ul>
<b>Articles</b>	<ul style="list-style-type: none"> <li>A key goal for many states has been improved regulation of articles containing chemicals. Combined with the preemption of state authorities, both bills could potentially have the effect of limiting regulation of articles nationwide.</li> </ul>	<ul style="list-style-type: none"> <li>The Senate bill provides that EPA may restrict articles “only to the extent necessary to address the identified risks in order to determine that the chemical substance meets the safety standard.”</li> <li>The Senate bill provides an exemption for replacement parts that were manufactured prior to the effective date of a restriction.</li> </ul>	<ul style="list-style-type: none"> <li>The House bill provides for EPA to restrict articles “only to the extent necessary to protect against the identified risk.”</li> <li>The House bill exempts replacement parts that were designed prior to the publication date of a rule.</li> </ul>	<ul style="list-style-type: none"> <li>Many states believe it is important to provide EPA with broad authority to regulate articles with an adequate safety margin. EPA should not be limited in the range of options available to it in regulating articles that contain chemicals found not to meet the safety standard or pose other risks to health or the environment.</li> <li>It is important to note that an article may contain multiple chemicals, and may pose a threat to health or the environment based on the cumulative effects of those chemicals.</li> <li>Regarding replacement parts, any automatic exemption should apply to parts manufactured, not designed, prior to the date in question.</li> </ul>
<b>Fees</b>	<ul style="list-style-type: none"> <li>From the perspective of many states, it is essential to fund EPA’s work on chemicals adequately.</li> </ul>	<ul style="list-style-type: none"> <li>The Senate bill requires EPA to establish certain fees.</li> <li>These include fees related to manufacturer-requested safety assessments.</li> <li>The remaining fees are to be set at levels that will meet the lower of: 25% of specified implementation costs, or \$25 million.</li> </ul>	<ul style="list-style-type: none"> <li>The House bill retains the approach of current TSCA, which allows, but does not require, EPA to establish fees to defray costs of administering the act. It does not specify a percentage or a dollar amount to be raised through the fees.</li> </ul>	<ul style="list-style-type: none"> <li>Neither bill provides a mechanism for fully funding the new activities envisioned in the bills.</li> <li>The approach in the Senate bill is preferable from the perspective of increasing the likelihood that EPA’s work will be adequately funded.</li> </ul>

	<b>Summary</b>	<b>Senate Bill</b>	<b>House Bill</b>	<b>Comments</b>
		<ul style="list-style-type: none"> <li>EPA's ability to assess fees is contingent upon a specified amount of funding being appropriated to EPA for the relevant fiscal year.</li> </ul>		

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<sup>1</sup>Note: As a procedural matter, the Senate substituted the content of S. 697 into the House bill, so that the Senate bill was technically adopted as an amendment to H.R. 2576. This affects only the nomenclature, not the content, of the two bills.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

JAN 20 2016

THE ADMINISTRATOR

The Honorable Barbara Boxer  
Ranking Member  
Committee on Environment and Public Works  
United States Senate  
Washington, DC 20510

Dear Senator Boxer:

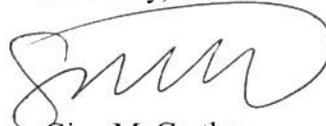
The Administration commends the Senate Environment and Public Works Committee and the House Energy and Commerce Committee on their bipartisan efforts to pass Toxic Substances Control Act (TSCA) reform legislation. In 2009, the Administration released Essential Principles for Reform of Chemicals Management Legislation (Principles) to help inform Congressional efforts on TSCA. The Administration is pleased to share the additional views in this letter, and would welcome the opportunity to work with Congress on more technical drafting issues during the reconciliation process.

Under TSCA, insufficient progress has been made in determining whether the tens of thousands of chemicals in commerce today are safe for the American people and the environment. When TSCA was enacted, it grandfathered in, without any evaluation, over 60,000 chemicals that were in commerce at the time. TSCA did not impose any requirement or schedule for the EPA to review these chemicals for safety. Even for chemicals with known risks, TSCA's "unreasonable risk" standard and "least burdensome" regulatory requirement have generally prevented the EPA from taking necessary and timely actions to protect human health and the environment.

The Administration appreciates that Congress took a comprehensive look at TSCA when it developed its reform bills. While there are many aspects to overhauling TSCA, the Administration encourages Congress to ensure several important issues are addressed sufficiently in any legislation to emerge from the reconciliation process. The views provided in the attachment are intended to assist Congress in reconciling the two pieces of legislation. The lack of a workable safety standard, deadlines to review and act on existing chemicals, and a consistent source of funding are all fundamental flaws in TSCA that should be addressed.

The Administration strongly supports Congress's efforts to strengthen TSCA to provide the EPA with the necessary tools and authorities to target and assess chemicals, and effectively regulate risks. Chemicals are vital to our nation's economy, but safety should continue to be of paramount importance. We need to restore confidence that chemicals used in commerce will not endanger the health and welfare of the American people. The Administration looks forward to continuing to work with Congress toward these goals.

Sincerely,



Gina McCarthy

Enclosure

Identical letters sent to the Honorable James M. Inhofe, The Honorable Barbara Boxer, The Honorable Fred Upton, and the Honorable Frank Pallone Jr.

## Administration Views on the TSCA Reform Bills (H.R. 2576 and S. 697)

### **Deadlines for Action**

Essential to a reformed TSCA are statutory mechanisms that drive EPA action to review chemicals and regulate those that are unsafe. In its Principles, the Administration calls for “clear, enforceable and practicable deadlines.”

On this point, the Senate bill is preferable. It provides certainty about the progress that the EPA is required to make reviewing chemicals. The Senate bill imposes an absolute requirement to have completed or at least begun a certain number of assessments (20 high-priority assessments within 3 years, and 25 high-priority assessments within 5 years), and imposes a requirement to repopulate the high-priority list as each assessment is completed until all chemicals on the TSCA inventory have been evaluated.

### **Elimination of the “Least Burdensome” Requirement**

The Administration supports the elimination of current TSCA’s “least burdensome” requirement, which the court in *Corrosion Proof Fittings* – an often-cited TSCA case – has interpreted to impose a tremendous analytical burden on the agency. The EPA’s failure to meet this requirement – after over a decade of rulemaking and thousands of pages of analytical record – resulted in the overturning of the asbestos rule. Both the House and Senate bills include new, different considerations for the EPA when selecting among risk management measures (“Analysis for Rulemaking” in Section 6(d)(4) of TSCA as amended by the Senate bill and “Requirements for Rule” at Section 6(c)(1)(B) of TSCA as amended by the House bill).

Whatever the resolution, the Administration urges Congress to establish considerations that are sufficiently circumscribed so that the EPA will not be required to assess the costs and benefits of an indefinite number of regulatory alternatives, or otherwise be obligated to pursue alternatives analyses beyond the realm of analytic practicability. Such requirements would likely undermine the operation of a revised law even if it contains a clear safety standard and practicable deadlines.

The Administration prefers the consideration requirements under the Senate bill because they expressly provide that they do not extend the EPA’s analytical burden beyond what can be practicably accomplished, based on reasonably available information. Subject to these bounds, the EPA would be required to consider the costs and benefits of alternative methods to achieve the safety standard for a particular chemical substance. The EPA would also be required to incorporate such consideration into a statement accompanying each risk management rule, which would then be part of the administrative record for the rule, and thus allow for judicial review of the adequacy of the agency’s reasoning.

By contrast, the House bill requires the EPA to defend one of two affirmative alternative findings in order to issue a risk management rule: either that the rule is cost effective or that a non-cost effective alternative is necessary. The scope of analysis required for making these findings may be bounded by the information that is “reasonably ascertainable,” under section

6(c)(1)(A). Even if the analysis is so bounded, this provision leaves uncertainty about how many cost effective options the EPA would have to analyze and reject as inadequate before selecting a non-cost effective option.

### **Prioritizing Chemicals for Review**

The Administration's Principles make clear that the EPA should have the authority to prioritize chemicals for review based on relevant risk and exposure considerations. Both the House and Senate bills also include provisions that would allow manufacturers to identify their own priority chemicals for review by the EPA. If a similar mechanism is included in a final bill, it is essential that it not overrun the EPA's ability to prioritize chemical reviews. For this reason, the Administration strongly prefers the Senate version since that bill explicitly caps the number of risk evaluations that can be initiated based solely on manufacturers' interest and it requires both full payment of the costs of the assessment and, if necessary, defrayment of the ensuing costs to develop risk management regulation. Without a meaningful cap or similar measures, manufacturer priorities have the potential to overrun the EPA's chemicals management program and prevent the agency from addressing chemicals with greater potential risks. Without appropriate funding for risk management costs, the EPA may not be able to complete work on manufacturer priorities as Congress presumably intended. The House bill has no cap on manufacturer initiated risk evaluations, and no requirement for industry to pay for the risk management actions that the EPA may find itself legally obligated to undertake after completing the requested risk evaluations. The House language would allow the EPA to put risk evaluations on hold if it receives more industry requests than it has resources to handle, but this provision could be interpreted to allow the EPA to put on hold *EPA initiated evaluations* as well as manufacturer initiated evaluations.

### **Sustained Source of Funding**

The Administration's Principles state that the EPA work under TSCA should be "adequately and consistently funded" and that manufacturers should "support the costs of Agency implementation." The Administration is pleased that both the House and Senate modify Section 26 to establish a dedicated TSCA implementation fund and expand fee collection authority.

The House bill's fee provisions would not defray the EPA's costs of reviewing existing chemicals (aside from those initiated by industry) or any of the costs associated with regulatory risk management actions. It could also be argued that the fees that the EPA could collect for the submission of test data would not cover the EPA's costs to assess the data as part of a chemical risk evaluation.

The Administration prefers the Senate bill's funding provisions, which explicitly add new fee collection authority for the costs of reviewing confidential business information (CBI) claims, reviewing notices under section 5, making prioritization decisions, conducting and completing safety assessments, and conducting rulemakings.

The EPA should have broad authority to use its fees to cover the costs of agency implementation. Giving the EPA this authority generally would avoid the concerns raised above about the EPA's spending authority in specific scenarios. Further, imposing spending caps and the Senate bill's minimum appropriations requirements for assessing fees could still create implementation challenges.

### **Implementation Challenges**

The Administration encourages Congress not to impose on the EPA extensive, prescriptive requirements to develop policy and procedure documents. The dedication of resources to meeting these process development expectations could frustrate the EPA's efforts to timely and directly implement the substantive requirements of TSCA.

The Senate bill, particularly in sections 3A and 4A, establishes pressing deadlines for the EPA to develop various policy and procedure documents, and prescribes numerous specifications for the content of such documents. Meeting these document generation requirements may unnecessarily slow progress on more substantive issues, limit the EPA's flexibility to allocate resources appropriately, and lead to burdensome litigation regarding the process development requirements.

The EPA has already developed and promulgated numerous policies, procedures, and scientific guidances. The EPA continues to invest resources in hosting open public debate on pressing scientific issues and the development of policies and guidances, and does so in accordance with existing objectivity and transparency requirements. For highly impactful or controversial issues, the EPA continues to engage the National Academies of Science, Engineering and Medicine to ensure the development of robust policies and procedures.

The Administration strongly prefers the House bill on this matter since it only requires the EPA to develop new policies, procedures, and guidelines to the extent necessary. If the detailed procedural specifications of the Senate bill are retained, the Administration supports also retaining the accompanying savings provisions that the Senate bill adds to TSCA Section 6(b), which allow the EPA to continue its ongoing work to protect public health and the environment while the required policies, procedures and guideline are under development.

### **Safety Standard**

The Administration's Principles call for a new safety standard that is "based on sound science and reflect[s] risk-based criteria protective of human health." The Administration encourages Congress to apply the new safety standard consistently throughout the revised statute.

If a clear directive for the EPA to apply the new safety standard is expressed only with respect to section 6, as is the case in the House bill, that could create uncertainty as to what standard would apply to EPA actions under other provisions of TSCA where the phrase "unreasonable risk" appears (for example, under sections 4, 5, 7, 12 and 14). Providing an upfront definition of the safety standard, as in the Senate bill, is one way to better ensure uniform

application of the new standard to all actions under TSCA. Alternatively, “unreasonable risk” could be redefined in each instance it appears.

On a related point, there are several provisions in section 6 of the House bill that could possibly be read to suggest that different standards apply in section 6(a) rulemakings in different scenarios. For example, the EPA is authorized to promulgate non-cost-effective requirements if “necessary to protect against the identified risk” (section 6(c)(1)(B)). It might be argued that this language provides a different risk management standard from section 6(a) (regulation must ensure that a chemical substance “no longer presents or will present an unreasonable risk”). A similar issue appears with respect to regulation of replacement parts (section 6(c)(1)(D)) and articles (section 6(c)(1)(E)).

In general, the Administration appreciates that both the House and Senate bills allow for exemptions to otherwise applicable risk management requirements where necessary to maintain a critical use, or to protect national security or avoid disruption to the national economy. This is consistent with Administration Principle 3, which states that risk management decisions should take into account sensitive subpopulations, cost, availability of substitutes and other relevant considerations. This principle should be consistent across the relevant risk management provisions of the bills.

Finally, some confusion might be caused by the House bill provision that requires rulemaking for persistent, bioaccumulative and toxic (PBT) chemicals under section 6(a) to reduce likely exposure to the extent practicable (section 6(i)(3)). Sections 6(a) and 6(i) actually impose different rulemaking standards. Both the section 6(a) rulemaking standard and several of the considerations required in promulgating section 6(a) rules (which appear in section 6(c)) assume that the EPA has identified specific risks as unreasonable. However, the EPA may not have actually performed a risk evaluation for a particular PBT which is required (under section 6(i)) to be the subject of a 6(a) risk management rulemaking.

### **Regulatory Flexibility**

The House bill retains the current TSCA section 6(a) menu of requirements the EPA can impose in section 6 rulemakings. Although this menu is extensive, it is not comprehensive. Specifically, the menu expressly authorizes the EPA to regulate the manufacture, processing and distribution in commerce of a chemical substance only through a complete ban or ban for specific uses, or through quantity or concentration limitations. In contrast, with respect to commercial use, section 6(a) gives the EPA broader authority to impose requirements “prohibiting *or otherwise regulating*” the use (section 6(a)(5)). In operation, this menu may drive regulation that is more burdensome than necessary. The Administration prefers the approach in section 6(d) of the Senate bill, which includes “catch-all” regulatory authorities.

### **Safety of New Chemicals**

Under current TSCA, manufacturing and processing of new chemicals can commence upon expiration of the premanufacture notice review period without the EPA determining whether or not those chemicals are safe. As stated in the Administration’s Principles 2 and 4, the

EPA should conclude whether or not new chemicals meet the safety standard before those chemicals are allowed to enter the market. As such, the Administration supports the Senate bill requirement that the EPA make an affirmative safety determination regarding new chemicals.

### **Transparency and Confidential Business Information**

The Administration's Principles outline certain improvements regarding the transparency of chemical information. The Administration is pleased that both the House and Senate make improvements to substantiation requirements for CBI claims. The House bill requires substantiation of new CBI claims, while the Senate bill requires substantiation of both new and existing claims. The Administration also supports new authority in both bills for the EPA to appropriately share CBI with others when necessary to protect public health and safety.

However, the Administration is concerned with a provision in the House bill that would allow "formulas (including molecular structures)" of a chemical substance to be withheld as CBI in health and safety studies. Under current section 14, formula information in health and safety studies can be protected as CBI only if it discloses process information. Thus, the House provision would decrease transparency and shield from the public relevant chemical information (in some cases, the specific identity of a chemical that is the subject of a health and safety study).

### **Authority to Require Development of Information**

Another significant problem under current TSCA is the difficulty of requiring the development of information on chemicals for which information is lacking. Both bills address a major contributor to this problem: the lack of authority to require testing by order. The other contributor is substantive: section 4 of TSCA currently requires the EPA to either demonstrate that a chemical "may present an unreasonable risk," before it can require testing, or else that there is already substantial production and substantial release of or exposure to the chemical substance. The obligation to make these demonstrations has created difficulties for the EPA in requiring testing necessary to assess the safety of chemicals.

Both the House and Senate bills give the EPA new authority to require testing for specific purposes, including during risk evaluations. Under the new House authority, however, the EPA must first make a risk-based finding before initiating a risk evaluation. Although the bar is fairly low ("may present an unreasonable risk...because of potential hazard and a potential route of exposure..."), it could have the effect of perpetuating the difficulties the EPA has encountered under current TSCA. Outside of the risk evaluation context, the House bill could still require the EPA to make a "may present an unreasonable risk" finding before requiring testing under section 4. The Administration encourages Congress to ensure that the EPA is given the necessary authority and tools to obtain information relevant to determining the safety of chemicals.

### **Chemicals in Articles**

The Administration encourages Congress to look closely at provisions in both the Senate and House bills that may make it more difficult for the EPA to review and regulate risks from chemicals contained in articles. Under current TSCA, the EPA has used its authority under

section 5 to establish notification requirements for new uses of a chemical for which the EPA has concerns, including chemicals in imported articles. Section 5 does not require the EPA to make any particular exposure or hazard finding to use this authority, presumably since the function of these significant new use rules is simply to allow the EPA to review, and regulate as necessary, new uses of existing chemicals on the same basis as new chemicals. The Senate bill imposes a new requirement: the EPA must first find the notification requirement for the article is warranted based on “the reasonable potential for exposure through the article or category of articles.” This new requirement may make it harder for the EPA to require notification for uses that are not currently foreseen. Even for currently envisioned uses, it may generate litigation over an EPA finding that the potential for exposure through an article or category of articles is “reasonable”. The House bill exempts from regulation all “replacement parts designed prior to” the publication of a risk management rule, unless the replacement parts “contribute significantly to the identified risk.” This provision would make it more difficult for the EPA to define the scope of regulations given the likely challenges of determining when particular replacement parts were designed.

### **Enforcement Improvements**

While the Administration’s Principles do not discuss civil and criminal enforcement of TSCA, the Administration supports the decision to include provisions in the Senate bill that would strengthen civil and criminal enforcement authorities. We look forward to continuing to work with Congress on these provisions.

### **Federal-State Relationship**

The EPA’s limited ability to regulate under TSCA has encouraged states to step in, resulting in varying chemical regulations across the country. Assuming the flaws in TSCA that have prevented effective federal action are addressed in reform legislation, the Administration supports an approach to preemption that provides a consistent regulatory regime for industry while allowing appropriate additional actions by the states. These comments are intended to note provisions that could benefit from drafting changes to reflect Congress’s presumed intent, as well as provisions that could result in permanent preemption of state actions to address risks not addressed by federal regulation.

The Administration supports Congress’s intent to preserve existing state laws like California’s Proposition 65, and other state environmental laws related to the protection of air and water, and to waste. Respecting the preservation of such laws, both the Senate and House bills would benefit from further work to reflect the drafters’ intent. For example, the Senate bill should better reflect its apparent intent to preserve state regulations adopted prior to August 1, 2015, not merely to enforce actions initiated prior to August 1, 2015. Similarly, the House bill should clarify that it is wholly preserving the identified laws, not just State efforts “to continue to enforce” those laws, and also that any state requirement enacted under a law that was in effect on August 31, 2003, is saved from preemption, even if the specific requirement is promulgated after the date of the TSCA Modernization Act.

The House bill should also clarify the scope of potential preemption of state environmental laws that “actually conflict[]” with an EPA “action or determination.” While two

laws might be said to actually conflict if they impose incompatible obligations or one purports to abrogate the other, it is far less clear when a state law could be said to be in actual conflict with an EPA determination that is not an action, or with an EPA action that does not impose requirements.

Respecting the preservation of state laws adopted under the authority of federal law, the Administration supports the Senate bill's clarification of the types of state laws that are intended to receive such protection from preemption. Specifically, the Senate bill makes clear that this protection also extends to laws that a state adopts using its own legal authority, but that are nonetheless authorized under federal law, or adopted to satisfy or obtain authorization or approval under federal law. This clarification furthers a common sense objective: to ensure that TSCA actions do not block the purposes of the many other federal environmental statutes (e.g., the Clean Air Act) that are implemented through a system of cooperative federalism. The Senate bill's clarification is also consistent with evidence of original Congressional intent, found in TSCA's legislative history.

Furthermore, the Administration supports an approach in which any preemption resulting from a completed EPA safety assessment or risk management rule is appropriately limited to the particular risks that the agency actually considered in the scope of that assessment or rulemaking. The Administration prefers the Senate bill's clarity on this issue. On a related issue, the House bill, which does not require an affirmative safety determination for new chemicals, nonetheless would lead to preemption of state regulation for all uses of a new chemical substance identified in a pre-manufacture notification, if the agency took action merely to address a subset of those uses.





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# **Proposed Amendments to the Toxic Substances Control Act (TSCA) in the 114<sup>th</sup> Congress: S. 697, S. 725, and H.R. 2576**

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July 8, 2015

**Congressional Research Service**

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## Summary

Enacted in 1976, the Toxic Substances Control Act (TSCA) is the primary federal law that governs the regulation of chemicals in commerce. TSCA authorizes the Environmental Protection Agency (EPA) to determine whether regulatory control of a chemical substance is necessary to provide protection against “unreasonable risks” to those who are potentially exposed or to the environment. For several years leading up to the 114<sup>th</sup> Congress, there have been various legislative proposals to amend Title I of TSCA to revise the chemical evaluation process and the criteria by which chemical substances would be regulated and to address certain other related purposes.

On June 23, 2015, the TSCA Modernization Act of 2015 (H.R. 2576) was passed by the House under suspension of the rules on a 398-1 vote. The House Committee on Energy and Commerce had previously reported the bill. The report is H.Rept. 114-176. On April 28, 2015, the Senate Committee on Environment and Public Works (Senate EPW) ordered that the Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act (S. 697) be reported for Senate floor consideration on a 15-5 vote. On June 18, 2015, the Senate EPW filed the report (S.Rept. 114-67). Another bill introduced in the Senate, the Alan Reinstein and Trevor Schaefer Toxic Chemical Protection Act (S. 725), has not been reported out of committee. The Senate bills present fairly broad approaches to revising the evaluation process of chemical substances to determine whether regulatory control is warranted and propose various other changes to the TSCA framework, while H.R. 2576 takes a more targeted approach in amending specific provisions of Title I of TSCA.

All three bills would address many key issues regarding the federal role in regulating chemical substances. This report discusses selected issues that have received considerable attention and provides a comparison of the current proposals’ differing approaches to revise Title I of TSCA. This report does not present a comprehensive analysis of all provisions of relevant legislation, nor is this report intended to provide a detailed analysis of specific language and its legal or regulatory interpretation.

The following selected issues are described in more detail in the report and in the context of current TSCA and the three bills:

- The prioritization of existing chemical substances for the evaluation of risks;
- The regulatory threshold criteria under which EPA would be authorized to restrict a chemical substance;
- The regulatory options available to EPA in restricting a chemical substance found to warrant regulation;
- The authority of EPA to require the development of new information regarding a chemical substance;
- The preemption of state laws concerning the regulation of chemicals;
- The disclosure and protection from disclosure of information submitted to EPA; and
- The resources that may be available for EPA to administer the act.

This report was updated to reflect legislative actions in Congress as of July 7, 2015. The report will be updated as necessary as the debate and consideration of legislation continues.

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## Introduction

In 1976, President Gerald Ford signed into law the Toxic Substances Control Act (TSCA; P.L. 94-469), which authorized the U.S. Environmental Protection Agency (EPA) to identify and regulate toxic chemicals in U.S. commerce to prevent “unreasonable risk of injury to human health or the environment.”<sup>1</sup> In order to determine which chemicals warrant regulation under TSCA, EPA is authorized to evaluate risks that may arise from the entire commercial life-cycle of chemicals, including their production, importation,<sup>2</sup> processing, distribution, use, and disposal. EPA has authority to pursue a range of regulatory options to address risks from chemicals. Since 1976, Congress has added five other titles to TSCA and has also amended the original law, referred to as Title I, to target specific chemical concerns.<sup>3</sup> None of these additions and amendments addresses the core program under Title I of TSCA. Since 2005, a number of bills have been introduced to revise the chemical evaluation process for determining whether regulatory controls are warranted and to address certain other related purposes.<sup>4</sup> These bills were not enacted, as there was and continues to be legislative debate on whether and how to amend the evaluation process, regulatory criteria, and other elements of the law.<sup>5</sup>

Since the enactment of TSCA in 1976, more chemicals have continued to enter the U.S. market. A greater number of studies on chemical risks have been published, and scientific understanding of chemical risks has continued to evolve.<sup>6</sup> Because relatively few chemicals have been evaluated and even fewer regulated under TSCA’s risk management provisions, proponents of amending Title I of TSCA argue that the current regulatory framework for chemicals is not sufficiently

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<sup>1</sup> 15 U.S.C. §§2601-2629. For a summary of TSCA provisions and history, see CRS Report RL31905, *The Toxic Substances Control Act (TSCA): A Summary of the Act and Its Major Requirements*, by Jerry H. Yen.

Section 3(2) of TSCA (15 U.S.C. § 2602(2)) excludes certain chemical substances from regulation, including pesticides, tobacco and tobacco products, certain radioactive materials, pistols, revolvers, firearms, shells, cartridges, food, food additives (including food contact substances, such as container components, that may be indirect food additives), drugs, cosmetics and personal care products, and medical devices. Additionally, §9 of TSCA (15 U.S.C. §2608) limits EPA’s authority to address unreasonable risks of chemical substances by directing the agency to determine, if unreasonable risks are identified, whether other statutes administered by EPA or another federal agency may adequately address such risks.

<sup>2</sup> Section 3(7) of TSCA (15 U.S.C. §2602(7)) defines the term *manufacture* to include production and importation.

<sup>3</sup> The other specific chemical concerns include asbestos (Title II), indoor radon (Title III), lead (Title IV), environmental exposures in schools (Title V), and formaldehyde in composite wood products (Title VI). Title I was amended in 2008 to address elemental mercury. 15 U.S.C. §§2605(f), 2611(c).

<sup>4</sup> Legislation to revise the chemical evaluation process under TSCA and for certain other related purposes dates back at least to the 109<sup>th</sup> Congress. S. 1391 and H.R. 4308, both introduced in 2005 under the short title “Kid Safe Chemicals Act,” are examples of such legislation.

<sup>5</sup> For recent examples of debate, see U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Environment and the Economy, *H.R. \_\_\_\_, the TSCA Modernization Act of 2015*, 114<sup>th</sup> Cong., 1<sup>st</sup> sess., April 14, 2015, <http://energycommerce.house.gov/hearing/hr-tsca-modernization-act-2015> (hereinafter “House discussion draft hearing”); and U.S. Congress, Senate Committee on Environment and Public Works, *Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act*, 114<sup>th</sup> Cong., 1<sup>st</sup> sess., March 18, 2015, <http://www.epw.senate.gov/public/index.cfm/hearings?ID=60D1E265-CDAC-7629-3385-2D72DD8FE3EB> (hereinafter “S. 697 hearing”).

<sup>6</sup> For example, there is greater scientific understanding of the properties of chemicals, the toxicological effects of chemicals, routes of exposure, and methods for assessing risk.

protective of the public or the environment.<sup>7</sup> EPA's evaluation of risks is ultimately dependent on the resources the agency has available.

As states have enacted statutes to address specific chemical concerns not addressed by EPA under TSCA, there has been greater potential for the same chemical to be regulated differently among states.<sup>8</sup> Manufacturers and processors of chemicals have argued that compliance with different state regulations regarding the same chemical is not efficient given chemicals' movement through interstate commerce. Proponents of state regulations that differ from federal requirements for the same chemicals, in turn, have argued that states can lead the way in trying alternative approaches and that states should be allowed to do so to protect their citizens. Non-governmental programs, such as voluntary measures to label products as "sustainable" or "non-toxic," have also emerged as an alternative approach to regulation.<sup>9</sup>

This report tracks the legislative status in the 114<sup>th</sup> Congress of bills that would amend Title I of TSCA and includes a discussion of selected issues that have received more attention. This report does not present a comprehensive analysis of all provisions of relevant legislation, nor is this report intended to provide a detailed analysis of specific language and its legal or regulatory interpretation.

## Legislative Status in the 114<sup>th</sup> Congress

In the 114<sup>th</sup> Congress, bills have been introduced in both chambers to amend Title I of TSCA.<sup>10</sup> On March 10, 2015, the Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act (S. 697) was introduced and referred to the Senate Committee on Environment and Public Works (Senate EPW). Two days later, the Alan Reinstein and Trevor Schaefer Toxic Chemical Protection Act (S. 725) was introduced and also referred to Senate EPW. On March 18, 2015, Senate EPW held a hearing regarding S. 697.<sup>11</sup> On April 28, 2015, Senate EPW marked up an amendment in the nature of a substitute for S. 697, which was ordered to be reported out of the committee for

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<sup>7</sup> For example, EPA has regulated six chemical substances under §6 of TSCA (15 U.S.C. §2605). These substances include chlorofluorocarbons, nitrosamines in metalworking fluids, hexavalent chromium in certain water cooling towers, new uses of asbestos, dioxin-contaminated wastes, and polychlorinated biphenyls.

<sup>8</sup> For example, states including California, Maine, and Washington have enacted "green chemistry" statutes that authorize the regulation of chemical substances based on various criteria and regulatory processes. Also, many states have enacted chemical-specific restrictions.

<sup>9</sup> EPA lists, but does not necessarily endorse, a variety of non-governmental eco-labeling programs and voluntary standards at its Greener Products website. U.S. EPA, "Greener Products: Related Links," April 27, 2015, <http://www.epa.gov/greenerproducts/related/>. Note that some groups have expressed concerns regarding some voluntary labels; for example, Consumers Union, publisher of *Consumer Reports*, has described the label "Non-Toxic" on products as generally lacking in independent verification. Consumers Union of the United States, "Greener Choices Eco-Labels Center," <http://www.greenerchoices.org/eco-labels/label.cfm?LabelID=131>.

<sup>10</sup> S. 725 also proposes additional titles on the topic of "disease clusters," which are not discussed in this report.

<sup>11</sup> S. 697 hearing in footnote 5.

Senate floor consideration on a 15-5 vote.<sup>12</sup> On June 18, 2015, Senate EPW filed the report (S.Rept. 114-67) for S. 697.<sup>13</sup>

On April 7, 2015, the House Committee on Energy and Commerce, Subcommittee on Environment and the Economy, announced a discussion draft that takes a more targeted approach to amending Title I of TSCA than either Senate bill.<sup>14</sup> The discussion draft is called the TSCA Modernization Act of 2015 and hereinafter is referred to as the House discussion draft.<sup>15</sup> On April 14, 2015, the subcommittee held a hearing regarding the discussion draft.<sup>16</sup> On May 14, 2015, the subcommittee ordered the revised House discussion draft to be forwarded with an amendment to the full House Committee on Energy and Commerce for its consideration on a 21-0 vote.<sup>17</sup> On May 26, 2015, H.R. 2576, also titled the TSCA Modernization Act of 2015, was introduced. The bill is based on the version of the House discussion draft that was ordered to be forwarded by the subcommittee for full committee consideration. On June 3, 2015, the House Committee on Energy and Commerce approved the bill with technical amendments on a 47-0 vote (with one abstention).<sup>18</sup> The committee's report for the bill is H.Rept. 114-176.<sup>19</sup> On June 23, 2015, the House passed H.R. 2576, as amended, under suspension of the rules on a 398-1 vote.<sup>20</sup>

## Selected Issues for Congress

Among the various issues regarding the federal role in regulating chemical substances under Title I of TSCA, the following topic areas are among the more debated:

- The prioritization of existing chemical substances for the evaluation of risks;
- The regulatory threshold criteria under which EPA would be authorized to restrict a chemical substance;

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<sup>12</sup> U.S. Congress, Senate Committee on Environment and Public Works, *Markup, Nomination, Consideration of GSA Resolutions*, 114<sup>th</sup> Cong., 1<sup>st</sup> sess., April 28, 2015, <http://www.epw.senate.gov/public/index.cfm/hearings?ID=3EAE7787-B182-BE85-C483-BDD391E4302B>; and *S. 697 Compromise Amendment*, released April 28, 2015, <http://www.scribd.com/doc/263408687/S-697-Compromise-Amendment>.

<sup>13</sup> U.S. Congress, Senate Committee on Environment and Public Works, *Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act*, report together with minority views to accompany S. 697, 114<sup>th</sup> Cong., 1<sup>st</sup> sess., June 18, 2015, S.Rept. 114-67 (Washington: GPO, 2015).

<sup>14</sup> U.S. Congress, House Committee on Energy and Commerce, "Subcommittee to Review Bipartisan Draft of the TSCA Modernization Act," press release, April 7, 2015, <http://energycommerce.house.gov/press-release/shimkus-upton-pallone-back-effort-improve-chemical-safety>.

<sup>15</sup> U.S. Congress, House Committee on Energy and Commerce, Subcommittee on Environment and the Economy, *H.R. \_\_\_\_, the TSCA Modernization Act of 2015*, 114<sup>th</sup> Cong., 1<sup>st</sup> sess., April 7, 2015, [http://docs.house.gov/meetings/IF/IF18/20150414/103313/BILLS-114pih-HR\\_\\_TSCAModernizationActof2015.pdf](http://docs.house.gov/meetings/IF/IF18/20150414/103313/BILLS-114pih-HR__TSCAModernizationActof2015.pdf).

<sup>16</sup> House discussion draft hearing in footnote 5 above.

<sup>17</sup> U.S. Congress, House Committee on Energy and Commerce, "Subcommittee Unanimously Approves TSCA Modernization Act," press release, May 14, 2015, <http://energycommerce.house.gov/press-release/subcommittee-unanimously-approves-tsc-modernization-act>.

<sup>18</sup> U.S. Congress, House Committee on Energy and Commerce, "Committee Advances Bipartisan Breakthrough to Bring Chemical Safety Law into 21<sup>st</sup> Century," press release, June 3, 2015, <http://energycommerce.house.gov/press-release/committee-advances-bipartisan-breakthrough-bring-chemical-safety-law-21st-century>.

<sup>19</sup> U.S. Congress, House Committee on Energy and Commerce, *TSCA Modernization Act of 2015*, report to accompany H.R. 2576, 114<sup>th</sup> Cong., 1<sup>st</sup> sess., June 23, 2015, H.Rept. 114-176 (Washington: GPO, 2015).

<sup>20</sup> U.S. Congress, House Office of the Clerk, "Final Vote Results for Roll Call 378," <http://clerk.house.gov/evs/2015/roll378.xml>.

- The regulatory options available to EPA in restricting a chemical substance found to warrant regulation;
- The authority of EPA to require the development of new information regarding a chemical substance;
- The preemption of state laws concerning the regulation of chemicals;
- The disclosure and protection from disclosure of information submitted to EPA; and
- The resources that may be available for EPA to administer the act.

This report compares approaches among S. 697, as reported, S. 725, and H.R. 2576, as passed by the House, in amending Title I of TSCA to address these key issues.

## Prioritization of Chemical Substances for the Evaluation of Risks

Given that the evaluation of risks for the large number of chemicals in the marketplace is limited by finite resources, determining what criteria to use in selecting which chemicals to evaluate has been a perennial issue. Under the current TSCA, EPA has discretion regarding which chemical substances to evaluate for risks and no mandate to review or evaluate chemicals.

The substances that the agency may evaluate for risks include those on the initial inventory of known chemical substances reported to EPA under Section 8(a) of TSCA after enactment of the law<sup>21</sup> and those that manufacturers subsequently report to EPA in premanufacture notices (PMNs) under Section 5 of TSCA.<sup>22</sup> These substances all together number over 83,000 chemical substances, although not all of them are necessarily still in U.S. commerce.<sup>23</sup> In 2012, as part of EPA's TSCA Work Plan, the agency identified more than 1,200 substances that possibly warranted an evaluation based on certain prioritization criteria.<sup>24</sup> These substances were further screened based on hazard, exposure, and bioaccumulation potential, which led EPA to prioritize 90 substances for an evaluation of risks to human health or the environment.<sup>25</sup> Of the 90 prioritized chemical substances, EPA has assessed five, three of which were determined to present risks.<sup>26</sup>

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<sup>21</sup> 15 U.S.C. §2607(a). The initial inventory included approximately 62,000 chemicals that were not subject to the 90-day prior notice requirement for new chemicals. See EPA, "TSCA Chemical Substance Inventory: Basic Information," updated March 13, 2014, <http://www.epa.gov/oppt/existingchemicals/pubs/tscainventory/basic.html>.

<sup>22</sup> 15 U.S.C. §2604. Section 3(7) of TSCA (15 U.S.C. §2602(7)) defines the term *manufacture* to include production and importation. PMNs are therefore required for chemical substances not on the TSCA inventory that are to be imported into the United States.

<sup>23</sup> EPA, "Summary of the Toxic Substances Control Act," updated March 9, 2015, <http://www2.epa.gov/laws-regulations/summary-toxic-substances-control-act>.

<sup>24</sup> EPA, Office of Pollution Prevention and Toxics, *TSCA Work Plan for Chemical Assessments: 2014 Update*, October 2014, p. 3, [http://www.epa.gov/oppt/existingchemicals/pubs/TSCA\\_Work\\_Plan\\_Chemicals\\_2014\\_Update-final.pdf](http://www.epa.gov/oppt/existingchemicals/pubs/TSCA_Work_Plan_Chemicals_2014_Update-final.pdf).

<sup>25</sup> Ibid.

<sup>26</sup> EPA, "Assessments for TSCA Work Plan Chemicals," updated May 27, 2015, <http://www.epa.gov/oppt/existingchemicals/pubs/riskassess.html>. EPA completed assessments for N-methylpyrrolidone (NMP) in paint and coating removal products; antimony trioxide as a synergist in halogenated flame retardants; 1,3,4,6,7,8-hexahydro-4,6,6,7,8,8-hexamethylcyclopenta[γ]-2-benzopyran as a fragrance ingredient in commercial and consumer products; methylene chloride in paint and coating removal products; and trichloroethylene (TCE) as a degreaser, a spot-cleaner in dry cleaning, and a spray-on protective coating. The NMP, methylene chloride, and TCE assessments identified risks.

For new chemicals, Section 5 of TSCA requires manufacturers to submit a PMN to EPA 90 days prior to manufacturing the chemical substance, subject to certain exemptions.<sup>27</sup> During this time period, EPA has the opportunity to evaluate risks of the new chemical substance and determine whether regulation may be warranted based on the PMN and any existing data concerning the environmental and health effects of the substance. According to EPA, from July 1979 to September 2010, the agency has received more than 36,000 PMNs and more than 13,000 PMN exemption applications.<sup>28</sup>

S. 697 and S. 725 would direct EPA to prioritize existing chemical substances in multiple steps for evaluation of risks, whereas H.R. 2576 would direct the agency to evaluate chemicals based on specific criteria.<sup>29</sup> H.R. 2576 would give EPA the discretion to evaluate chemicals that the agency identifies as having potential for unreasonable risk arising from the combination of hazards and exposures under the intended conditions of use for the chemical. S. 697 and S. 725 differ in the factors and criteria used to prioritize substances. Both Senate bills would establish a process that includes dividing the inventory of existing chemical substances into those that are reported to be currently in the marketplace (i.e., active substances) and those that are not (i.e., inactive substances), prioritizing the inventory of substances for evaluations based on various factors, conducting risk-based safety evaluations, and taking regulatory action based on the result of each evaluation. All three bills would also address prioritization of persistent, bioaccumulative and toxic (PBT) substances, albeit in slightly different ways.

S. 697 and H.R. 2576 would establish a process by which manufacturers (and, under S. 697, processors) may request EPA to prioritize certain substances for an evaluation upon payment of a fee. Under S. 697, EPA would have discretion to grant only a limited number of requests, subject to public notice and opportunity for comment.<sup>30</sup> Under H.R. 2576, EPA would be required to evaluate risks for every substance for which a manufacturer makes a request so long as the manufacturer has paid the costs of the evaluation to the agency.

S. 697 and S. 725 would establish the prioritization process with varying deadlines for evaluating chemical substances and, if necessary, for taking regulatory actions. Under S. 697, EPA would be required to “make every effort to complete the designation of all active substances as high-priority substances or low-priority substances in a timely manner” and to publish an annual goal. EPA would be required to designate at least 25 chemicals as high priority and begin safety assessment on them within five years after enactment of S. 697.<sup>31</sup> Safety assessments and determinations would have to be completed within three years after a chemical’s designation as a high-priority substance and a rule promulgated within two years after a negative safety determination, subject to limited extensions. The prioritization and safety assessment procedures

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<sup>27</sup> 15 U.S.C. § 2604. Section 5(h) of TSCA authorizes certain exemptions from the requirements of all or parts of Section 5 of TSCA.

<sup>28</sup> EPA, “Summary of Accomplishments,” updated April 3, 2013, <http://www.epa.gov/oppt/newchems/pubs/accomplishments.htm>.

<sup>29</sup> See generally §6 of S. 697, §105 of S. 725, and §4 of H.R. 2576.

<sup>30</sup> S. 725 also does not include any provision for manufacturers to request prioritization or assessment.

<sup>31</sup> Section 6 of S. 697 would require an initial high- and low-priority list each containing at least 10 substances. By three years after enactment, additional substances would have to be added to each list to ensure at least 20 had undergone or were undergoing safety assessment and, by five years, at least 25.

proposed by S. 725 are generally comparable to those under S. 697, with tighter deadlines on EPA<sup>32</sup> and certain other differing conditions and procedures for prioritization and assessment.

In contrast, H.R. 2576 would require risk evaluations to be published within three years after a manufacturer's request for an evaluation or within three years following an EPA finding of potential for unreasonable risk.<sup>33</sup> H.R. 2576 would require EPA to initiate at least 10 risk evaluations (not including manufacturer-requested evaluations) per year, subject to the availability of appropriations. H.R. 2576 would not set a limit on manufacturer requests, except that the requested evaluation be paid for fully by the requesters.

For new chemical substances and significant new uses,<sup>34</sup> S. 697 and S. 725 would amend TSCA Section 5 to establish a process for EPA to review a notice and information submitted by manufacturers and processors.<sup>35</sup> H.R. 2576 would not amend TSCA Section 5, leaving in place the current process for EPA to have the initial opportunity to evaluate risks of new chemicals based on when a notice is submitted. Under the Senate bills, EPA would be required to make a determination of whether regulatory action is warranted for new chemicals following the submission of a PMN.<sup>36</sup> For new chemicals, both Senate bills would direct EPA to conduct an initial review and render a determination within 90 days of receiving a PMN (and accompanying information) and information that the substance is likely or not likely to attain the safety standard or that additional information is necessary to make such a determination. Once the manufacture of a new chemical has commenced and that chemical is added to the TSCA Inventory, it would presumably be subject to the same prioritization, safety assessment, and safety determination procedures and conditions for existing chemical substances as proposed by S. 697 and S. 725.

## **Regulatory Threshold for Restricting a Chemical Substance**

The current TSCA establishes as a standard for regulation of chemical substances that the chemical presents or will present “an unreasonable risk of injury to [human] health or the environment.” This phrase is used in multiple provisions of TSCA as the basis of whether certain actions may be warranted, particularly with respect to various regulatory controls under Section 5 regarding new chemicals<sup>37</sup> and Section 6 regarding existing chemicals.<sup>38</sup> Some have argued that the existing regulatory threshold for restricting a chemical substance in TSCA—that the chemical presents or will present risks that are unreasonable—is difficult for EPA to show and subject to

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<sup>32</sup> For example, EPA would have to designate at least 90 chemicals as high priority and begin safety assessment on them by five and a half years after enactment. Section 105 of S. 725 would require EPA to develop an initial high-priority list within six months of enactment containing at least 15 substances and to add at least an additional 15 within one year after the initial list, plus at least an additional 15 for each of the following four years. Upon removing a substance from the high-priority list after its safety determination, EPA would be required to add at least three substances to repopulate the list when fees are in place. In addition, safety evaluations and determinations would also have to be completed within two years, rather than three, after a chemical's designation as a high-priority substance.

<sup>33</sup> See generally §4 of H.R. 2576.

<sup>34</sup> Under §5(a)(2) of TSCA (15 U.S.C. §2604(a)(2)), EPA may determine that a use of a chemical substance constitutes a significant new use following consideration of all relevant factors. The manufacture and processing of a substance for a use that is considered a significant new use are subject to notice requirements 90 days prior to manufacture or processing of a substance for that use. S. 697 and S. 725 would not amend this provision.

<sup>35</sup> 15 U.S.C. §2604.

<sup>36</sup> See generally §7 of S. 697 and §106 of S. 725.

<sup>37</sup> 15 U.S.C. §2604.

<sup>38</sup> 15 U.S.C. §2605.

interpretation. A recurring issue of concern in the TSCA debate has been whether or how to amend the regulatory threshold to clarify the criteria and factors to be considered for determining whether certain substances warrant regulatory control.

Under current TSCA, the “unreasonable risk” standard is not defined in statute.<sup>39</sup> However, the “unreasonable risk” standard of TSCA has been interpreted at the circuit court level as, essentially, a multi-factor balancing test. In its influential 1991 decision, *Corrosion Proof Fittings v. EPA*, which struck down large parts of an asbestos ban under TSCA, the Fifth Circuit interpreted TSCA’s “unreasonable risk” standard, stating that “[i]n evaluating what is ‘unreasonable,’ the EPA is required to consider the costs of any proposed actions and to ‘carry out this chapter in a reasonable and prudent manner [after considering] the environmental, economic, and social impact of any action.’”<sup>40</sup> The court also quoted a Supreme Court case regarding “unreasonable risk” language in general, saying that “‘unreasonable risk’ statutes require ‘a generalized balancing of costs and benefits.’”<sup>41</sup> The Fifth Circuit ruled that in its asbestos ban, EPA had “basically ignored the cost side of the TSCA equation” and that potentially “spending \$200-\$300 million to save approximately seven lives (approximately \$30-\$40 million per life) over thirteen years” was not reasonable under the “unreasonable risk” standard.<sup>42</sup> Thus, under the “unreasonable risk” standard in current TSCA, whether regulation of a substance is warranted depends on not only the hazards of the chemical and the extent or likelihood of exposure to the chemical but also the costs of risk management and the benefits of the chemical for various uses.

S. 697 would establish a statutory definition for the term “safety standard” that uses the regulatory threshold of “unreasonable risk of injury to health or the environment” in current TSCA and adds some qualifiers.<sup>43</sup> First, S. 697 would establish the regulatory threshold to be whether the “conditions of use” of a chemical substance would attain the safety standard.<sup>44</sup> Additionally, S. 697 would explicitly include “potentially exposed or susceptible populations” among the general population with respect to an evaluation of risks.<sup>45</sup> Also, in the qualifier departing most significantly from current TSCA, S. 697 would expressly prohibit the consideration of “cost and other nonrisk factors” in evaluating risks.

Similar to S. 697, S. 725 would define a “safety standard” against which chemical risks would be measured.<sup>46</sup> However, under S. 725, the safety standard would be one that “ensures with

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<sup>39</sup> The interpretation of “unreasonable risk” is also influenced by the regulatory conditions for restricting a chemical substance, discussed below. In issuing rules to protect against unreasonable risk, EPA is directed to consider not only the hazards and exposures, but also the benefits of the chemical, available alternatives to the chemical, and the economic costs of restrictions. 15 U.S.C. §2605(c)(1).

<sup>40</sup> 947 F.2d 1201, 1222 (5<sup>th</sup> Cir. 1991) (quoting 15 U.S.C. §2601(c)).

<sup>41</sup> *Ibid.* (quoting *American Textile Mfrs. Inst. v. Donovan*, 452 U.S. 490, 510 n.30 (1981)).

<sup>42</sup> *Ibid.* at 1223.

<sup>43</sup> Section 3 of S. 697.

<sup>44</sup> Section 3 of S. 697 would add a definition to TSCA for “conditions of use,” which is defined as the “intended, known, or reasonably foreseeable circumstances the [EPA] Administrator determines a chemical substance is manufactured, processed, distributed in commerce, used, or disposed of.”

<sup>45</sup> Section 3 of S. 697 would add a definition to TSCA for “potentially exposed or susceptible population,” which is defined as “1 or more groups (A) of individuals within the general population who may be (i) differentially exposed to chemical substances under the conditions of use; or (ii) susceptible to greater adverse health consequences from chemical exposures than the general population;” and (B) that when identified by the [EPA] Administrator may include such groups as infants, children, pregnant women, workers, and the elderly.”

<sup>46</sup> Section 102 of S. 725.

reasonable certainty, without taking into consideration cost or other non-risk factors, that no harm to human health or the environment will result from exposure to a chemical substance under the intended or reasonably foreseeable conditions of use, including no harm to the general population or to any potentially exposed or susceptible subpopulation.”<sup>47</sup> This “reasonable certainty [of] no harm” language parallels the standard used to evaluate, for example, pesticide residues in or on food.<sup>48</sup>

In contrast to S. 697 and S. 725, H.R. 2576 would not define a “safety standard.” It would retain the language of the regulatory threshold based on “unreasonable risk” in current TSCA but would add certain requirements for EPA’s risk evaluation process to determine risks. Some examples of the requirements for evaluating risks include assessing risks to “potentially exposed populations” and not considering information on “cost and other factors not directly related to health or the environment” in evaluating risks.<sup>49</sup> Furthermore, H.R. 2576 would explicitly prohibit EPA from considering “costs or other non-risk factors” when deciding whether to initiate a rulemaking under Section 6(a) of TSCA to address unreasonable risks.

## Regulatory Options for Restricting a Chemical Substance

Some statutes that authorize regulatory controls such as TSCA include the concept of balancing costs and benefits. Title I of TSCA acknowledges this balance through various references. As an example, if EPA were to determine that a chemical substance presents or will present “an unreasonable risk of injury to health or the environment,” Section 6 of TSCA directs the agency to promulgate a requirement to protect adequately against such risks using the least burdensome requirement while considering certain other factors: for example, the approximate costs of the proposed regulation and the availability of alternatives to the chemical subject to regulatory control.<sup>50</sup> The regulatory requirements that EPA may choose vary in severity from a complete ban to a requirement that manufacturers notify distributors of unreasonable risks. Some have argued that the limit on EPA to choose the least burdensome regulatory requirement that still adequately protects from unreasonable risk requires the agency to do lengthy analyses.

In *Corrosion Proof Fittings v. EPA*, the Fifth Circuit stated that EPA had not shown substantial evidence<sup>51</sup> that its total ban on most ongoing uses of asbestos was the least burdensome adequate

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<sup>47</sup> Section 102 of S. 725 would add a definition to TSCA for “intended or reasonably foreseeable conditions of use,” which is defined as “circumstances under which a chemical substance is intended, reasonably known, or reasonably anticipated to be manufactured, processed, distributed in commerce, used, disposed of, and released into the environment, including reasonably foreseeable but unintended exposure conditions from unplanned releases into the environment.”

Additionally, §102 of S. 725 would add a definition to TSCA for “potentially exposed or susceptible population,” which means “a group or groups of individuals within the general population who may be (A) differentially exposed to chemical substances under the intended or reasonably foreseeable conditions of use; or (B) more susceptible to adverse health consequences from chemical exposures than the general population, which when identified by the [EPA] Administrator may include such groups as infants, children, pregnant women, workers, and the elderly.”

<sup>48</sup> Federal Food, Drug, and Cosmetic Act §408(b)(2)(A)(ii), (b)(2)(C)(ii), 21 U.S.C. §346a(b)(2)(A)(ii), (b)(2)(C)(ii) (“As used in this section, the term ‘safe’, with respect to a tolerance for a pesticide chemical residue, means that the [EPA] Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue,” including “no harm . . . to infants and children”).

<sup>49</sup> See generally §4 of H.R. 2576.

<sup>50</sup> 15 U.S.C. §2605.

<sup>51</sup> Section 19 of TSCA (15 U.S.C. §2618(c)(1)(B)) provides that the standard of review for certain rules issued by EPA, (continued...)

alternative for all circumstances and product categories.<sup>52</sup> Thus, in practice, the “least burdensome” requirement imposes an additional standard on EPA beyond that imposed by the requirement that EPA conduct a cost-benefit analysis of the chosen alternative, because a rule cannot be upheld based only on its benefits outweighing its costs. In order to reject a less burdensome requirement in favor of a more burdensome one, the Fifth Circuit required EPA to show that each less burdensome requirement would not adequately protect against the unreasonable risk.<sup>53</sup>

S. 697, S. 725, and H.R. 2576 would eliminate the requirement that EPA choose the least burdensome regulatory option to restrict a chemical substance that warrants regulation.<sup>54</sup> Rather, S. 697 and S. 725 would direct EPA to choose a regulatory option that is “necessary” for the chemical substance to meet the safety standard, subject to consideration of other factors such as costs and alternative regulations. In contrast, H.R. 2576 would require that EPA promulgate a rule that adequately protects against risks including those to potentially exposed subpopulations. Additionally, H.R. 2576 would amend the factors that EPA would be required to consider to promulgate a restriction on a chemical substance and would require rules to be, by EPA’s determination, “cost-effective,” except where it is determined not practicable to protect against the identified risk using cost-effective requirements.

All three bills would include a provision authorizing EPA to exempt certain uses of chemical substances from any restrictions if certain circumstances are found. S. 697 and S. 725 would authorize EPA to exempt uses if a restriction cannot be complied with without harming national security, causing significant disruption in the national economy, or interfering with a critical or essential use for which no technically and economically feasible safer alternative is available. H.R. 2576 would also authorize EPA to grant “critical use exemptions” for specific uses of a chemical substance if the agency determines that a requirement is not “cost-effective” and finds that the specific use is a critical or essential use or that the requirement would significantly disrupt the national economy, national security, or critical infrastructure. EPA would be authorized only to grant critical use exemptions to reduce risk to the greatest extent feasible. Critical use exemptions under H.R. 2576 would initially be in effect for a maximum period of five years, and the exemption may be renewed for one or more additional five-year periods if the agency finds that the requirements for granting the exemption continue to be met.

## **Requirement for the Development of Test Information**

EPA relies on scientific and technical information regarding chemical substances to evaluate risks and determine if any risks are unreasonable. In order to obtain such information, Section 8 of TSCA authorizes EPA to require reporting and record keeping of existing information on

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(...continued)

including restrictions on new or existing chemicals, is that a reviewing court shall set aside such rules if it finds that the rule is not supported by substantial evidence in the rulemaking record. This standard applies in lieu of the standard under the Administrative Procedure Act (APA), which provides that a reviewing court shall set aside agency action that is arbitrary, capricious, an abuse of discretion, etc. 5 U.S.C. §706. Neither S. 697 nor H.R. 2576 would substantively change this standard of review, but S. 725 would apply the APA standard for judicial review.

<sup>52</sup> 947 F.2d 1201 (5<sup>th</sup> Cir. 1991). The Fifth Circuit did not strike down restrictions on new uses of asbestos.

<sup>53</sup> *Ibid.* at 1226, 1229. This interpretation of the “least burdensome” requirement has not been applied in other significant TSCA litigation challenging risk management rules since *Corrosion Proof Fittings v. EPA*.

<sup>54</sup> See generally §8 of S. 697, §107 of S. 725, and §4 of H.R. 2576.

chemicals by manufacturers, processors, and distributors of chemical substances.<sup>55</sup> If the risks are insufficiently known from existing information and testing is necessary to develop new information about the risks, Section 4 of TSCA mandates that EPA promulgate a rule to require manufacturers and processors to conduct testing if the agency is able to render one of the following two threshold findings.<sup>56</sup> The threshold findings are either (1) that the chemical substance may present unreasonable risks,<sup>57</sup> or (2) that “substantial quantities” are or will be produced either in a way that enters or may reasonably be anticipated to enter the environment, or in a way that “there is or may be significant or substantial human exposures.”<sup>58</sup> To date, EPA has required additional testing for over 200 chemical substances.<sup>59</sup>

Some have argued that limits on EPA’s authority under TSCA to require the development of new information regarding the health and environmental effects of chemicals have limited EPA’s ability to assess the risks of chemicals.<sup>60</sup> EPA has argued that finding a chemical substance “may present an unreasonable risk of injury to health or the environment” in order to require the development of new information to determine whether a chemical substance presents an unreasonable risk is a “possible analytical catch-22.”<sup>61</sup> Instead, EPA has generally made the other finding, which is based on the production volume of a chemical and the likelihood of exposure. However, the development of new information may take a lengthy amount of time and be costly to those who are required to develop the information.

Whereas Section 4 of TSCA currently mandates that EPA require testing based on certain conditions for which the agency renders a finding, S. 697 and S. 725 would give EPA discretion to require testing if the agency were to determine it necessary for specific purposes.<sup>62</sup> In contrast to the Senate bills, H.R. 2576 would still require that EPA render certain findings to require testing under Section 4 of TSCA.<sup>63</sup> However, EPA would also be authorized to require testing if it is “necessary to conduct a risk evaluation” under Section 6 as would be amended. All three bills would authorize EPA to require the development of new information by promulgating a rule, issuing an order, or entering into a testing consent agreement. The Senate bills would further amend procedures for requiring the development of new information, including a provision that would require EPA to minimize animal testing to the extent practicable.

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<sup>55</sup> 15 U.S.C. §2607.

<sup>56</sup> 15 U.S.C. §2603.

<sup>57</sup> This threshold finding has been held to be met when EPA “finds a more-than-theoretical basis for suspecting that the chemical substance in question presents an ‘unreasonable risk of injury....’” *Chemical Mfrs. Ass’n v. U.S. EPA*, 859 F.2d 977, 979 (D.C. Cir. 1988).

<sup>58</sup> This threshold finding has been held to require EPA to “articulate the standards or criteria on the basis of which it found the quantities of [a chemical] entering the environment ... to be ‘substantial’ and the human exposure potentially resulting to be ‘substantial’” on a general or case-specific basis. *Chemical Mfrs. Ass’n v. EPA*, 899 F.2d 344, 360 (5<sup>th</sup> Cir. 1990). EPA thereafter published technical criteria that form the basis for EPA’s policy for making exposure-based findings. EPA, “TSCA Section 4(a)(1)(B) Final Statement of Policy; Criteria for Evaluating Substantial Production, Substantial Release, and Substantial or Significant Human Exposure,” 58 *Federal Register* 28736-28749, May 14, 1993.

<sup>59</sup> Testimony of James Jones, EPA Assistant Administrator for the Office of Chemical Safety and Pollution Prevention, in House discussion draft hearing in footnote 5, <http://docs.house.gov/meetings/IF/IF18/20150414/103313/HHRG-114-IF18-Wstate-JonesJ-20150414.pdf>.

<sup>60</sup> *Ibid.*

<sup>61</sup> *Ibid.*

<sup>62</sup> See generally §5 of S. 697 and §104 of S. 725.

<sup>63</sup> See generally §3 of H.R. 2576.

## Preemption of State Requirements

With an increasing number and diversity of state chemical regulations providing a backdrop for TSCA amendment discussions at the federal level, the scope of TSCA preemption has been a long-standing issue.<sup>64</sup> Under the Supremacy Clause of the U.S. Constitution, conflicting state law and policy must yield to the exercise of Congress's enumerated powers.<sup>65</sup> When it acts, Congress can preempt state action within a field entirely, allow states to take different actions, or permit state action to any degree in between. Current TSCA preemption is not at either extreme of the spectrum; it gives EPA a primary role in management of chemicals but leaves states some ability to set their own chemical requirements under certain circumstances.

Specifically, Section 18 of TSCA provides that states are generally preempted from taking action to manage risk from a chemical if EPA has taken action on a similar risk presented by that chemical, although states may apply for waivers.<sup>66</sup> For state requirements other than duplicative testing requirements, a number of exceptions to preemption apply. State requirements that are identical to federal requirements are not preempted, allowing states to co-enforce the federal requirements by adopting them as their own law.<sup>67</sup> States are also authorized to regulate disposal, establish or continue in effect any chemical requirement adopted under the authority of any other federal law, and prohibit use of a chemical within the state (except for its upstream use in manufacture or processing of other chemicals).<sup>68</sup>

In the TSCA amendment context, advocates for broader federal preemption claim that a uniform national regulatory framework with regard to chemicals can provide sufficient protection from chemical risks. They assert that absent preemption, states may implement varying and even conflicting regulations, leading to increased compliance costs, reduced economies of scale, and economic repercussions across industry supply chains and throughout interstate commerce.<sup>69</sup> On the other hand, opponents of preemption argue that the federal regulation should set a minimum standard but that states should be able to experiment with different policies and implement more stringent requirements than those EPA sets in order to protect the safety and welfare of their citizens.<sup>70</sup>

S. 697 would make a number of changes to TSCA preemption and the state-federal relationship in the field of chemical management. As under current TSCA, states could act without preemption if

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<sup>64</sup> For more information on this topic, see CRS Report R44066, *Preemption in Proposed Amendments to the Toxic Substances Control Act (TSCA): Side-by-Side Analysis of S. 697 and H.R. 2576*, by Alexandra M. Wyatt, and CRS Report WSLG1269, *Toxic Substances Control Act (TSCA) Preemption and State Chemical Regulations Under Current Law*, by Alexandra M. Wyatt

<sup>65</sup> U.S. Constitution, Article VI, clause 2. Note that local as well as state laws are subject to federal preemption. Also, while this report discusses statutory preemption provisions, it should be noted that under the Supremacy Clause, state law can be preempted either because the federal law is intended to be comprehensive and occupies the field or because the state law conflicts with a federal law, even if the federal law does not expressly preempt the state law. Conflict preemption could occur either because compliance with both the state rule and the federal rule would be impossible or because the state rule would stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. Whether a certain state action is preempted by federal law is a question of congressional intent.

<sup>66</sup> 15 U.S.C. §2617.

<sup>67</sup> 15 U.S.C. §2617(a)(2)(B).

<sup>68</sup> *Ibid.*

<sup>69</sup> See, for example, S. 697 hearing in footnote 5 above.

<sup>70</sup> *Ibid.*

EPA had taken no action with respect to a chemical. However, S. 697 would modify the EPA actions triggering preemption of states' chemical-specific requirements, the scope of state laws that would be preempted or excepted from preemption, and the waiver provisions. Subject to exceptions, a state would be prohibited from restricting the manufacture, processing, sale or distribution in commerce, or use of a chemical substance that EPA either had found to meet the safety standard or had restricted by rule on the basis that it did not meet the safety standard within the scope of uses addressed by EPA.<sup>71</sup> Moreover, states would be prohibited from establishing new restrictions on chemical substances listed by EPA as high priority chemicals for safety assessment if the state restrictions fell within the scope of uses or conditions to be considered in EPA's planned safety assessment.<sup>72</sup> Such preemption of new state restrictions would begin upon EPA's defining the scope of the safety assessment: If EPA determined that the chemical substance met the safety standard, preemption would continue, but if EPA determined that the chemical substance did not meet the safety standard, preemption would be lifted until the effective date of the EPA rule restricting the chemical substance.

S. 697 would generally retain the preemption exceptions provided by current TSCA, except for TSCA's current exception allowing states to prohibit use of chemicals, which would be removed. TSCA's exception allowing states to enforce requirements identical to federal requirements would be refined with new provisions to prohibit states from imposing duplicative or more stringent penalties or sanctions. Other exceptions to preemption would be added, including allowing states to establish or enforce some requirements adopted under the authority of state environmental laws.<sup>73</sup> Certain state actions taken before August 1, 2015, and past or future state actions under the authority of state laws that were in effect as of August 31, 2003 (such as California's Proposition 65),<sup>74</sup> would not be subject to preemption.<sup>75</sup> S. 697 would also add savings clauses clarifying that common law or statutory causes of action, private remedies, or evidentiary or other authorities of courts would not be affected.<sup>76</sup> In addition to discretionary waivers similar to current TSCA, states could apply for waivers on the basis of concerns about a chemical based on peer-reviewed science. EPA would have to grant such waivers if the application met statutory requirements; such waivers would also automatically be granted if EPA failed to make a decision on them within 90 days or if EPA missed the applicable deadline for a safety determination on the chemical.

S. 725, in contrast, would eliminate TSCA's current preemption provisions. While state laws could be found to be implicitly preempted if they conflicted with federal requirements, S. 725 would generally allow states to impose and enforce different regulations or requirements for chemicals.<sup>77</sup>

H.R. 2576 would make somewhat smaller substantive changes to TSCA preemption than the Senate bills. As under current TSCA and S. 697, states could impose requirements on chemicals without preemption if EPA had taken no action with respect to a chemical. H.R. 2576 would

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<sup>71</sup> Section 17 of S. 697 would replace subsections (a) and (b) of TSCA §18 with new subsections (a) through (g). The preemption of existing state laws would be set forth in new §18(a).

<sup>72</sup> Section 17 of S. 697 would set forth preemption of new state laws in an amended §18(b) of TSCA.

<sup>73</sup> Section 17 of S. 697 would describe the exceptions in amended subsections (c) through (e) of TSCA §18.

<sup>74</sup> *California Health and Safety Code*, §25249.5-25249.13.

<sup>75</sup> See footnote 73.

<sup>76</sup> Section 17 of S. 697 would add a new subsection (g) to TSCA §18.

<sup>77</sup> Section 117 of S. 725 would replace TSCA §18. See also footnote 65.

provide for the preemption of state laws designed to protect against exposure to a chemical that EPA had determined not to present an unreasonable risk to the extent the state laws applied to the conditions of use considered by EPA in its risk evaluation for that chemical.<sup>78</sup> H.R. 2576 would generally maintain TSCA's preemption of state requirements for chemicals on the basis of EPA risk management actions under Sections 5 or 6 for such chemicals, with some additional language to align preemption with the risk evaluation process under amended Section 6.<sup>79</sup> Unlike the current TSCA, state prohibitions on use of such chemicals would not be excepted from preemption.<sup>80</sup>

H.R. 2576 would also add comparable language to that in S. 697 pertaining to a state's ability to enforce, with penalties and sanctions, a state requirement identical to an EPA requirement.<sup>81</sup> As with S. 697, H.R. 2576 would provide that certain actions taken before August 2015—and past or future state actions under the authority of state laws that were in effect as of 2003—would not be subject to preemption.<sup>82</sup> In addition, all three bills would add several savings clauses regarding the preservation of common law or statutory causes of action under tort or contract law and of court authorities in civil actions, although the wording would differ.<sup>83</sup>

## **Confidentiality and Disclosures of Information**

TSCA requires chemical manufacturers, processors, and distributors to submit certain information to EPA regarding their chemicals.<sup>84</sup> This information can include detailed chemical structures, production volumes, and health and safety data. Thus, another issue of concern in amending TSCA is how to balance the goals of, on the one hand, public access to chemical information and, on the other, protection of information that if disclosed could compromise the submitter's competitiveness.

Section 14 of TSCA prohibits disclosure of information reported to or obtained by EPA that is exempt from disclosure under the Freedom of Information Act (FOIA) as “trade secrets and commercial or financial information obtained from a person and privileged or confidential,”<sup>85</sup> with certain exceptions.<sup>86</sup> Under the terms of TSCA, wrongful disclosure by EPA employees or contractors is a criminal act.<sup>87</sup> Confidential business information (CBI) protection under TSCA does not prohibit disclosure of any health and safety study, but any data within any such study that would disclose manufacturing processes or proprietary mixture compositions would remain protected.<sup>88</sup>

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<sup>78</sup> Section 7(a)(2) of H.R. 2576 would replace TSCA §18(a)(2)(B) with new subparagraphs (B) and (C).

<sup>79</sup> *Ibid.*

<sup>80</sup> *Ibid.*

<sup>81</sup> *Ibid.* (adding new TSCA §18(a)(2)(C)).

<sup>82</sup> Section 7(b) of H.R. 2576 would add new subsections (c) and (d) at the end of TSCA §18.

<sup>83</sup> *Ibid.*

<sup>84</sup> See 15 U.S.C. §§2604(d)(1), 2607(a)(2) (requiring information on new and existing chemicals to the extent such information is known or reasonably ascertainable), 2607(d)-(e) (requiring submission to EPA of health and safety studies and of substantial risk allegations), and 2603 (authorizing EPA to require development of new information).

<sup>85</sup> 5 U.S.C. §552(b)(4).

<sup>86</sup> 15 U.S.C. §2613.

<sup>87</sup> 15 U.S.C. §2613(d).

<sup>88</sup> 15 U.S.C. §2613(b).

Many items of information—including chemical identities—have been protected by EPA as CBI on the TSCA Inventory, in health and safety studies, and in other situations.<sup>89</sup> TSCA Section 14 contains several exceptions requiring disclosure of CBI, including if EPA determines that disclosure is “necessary to protect health or the environment against an unreasonable risk of injury.”<sup>90</sup> If EPA makes this determination, or if EPA finds that information that has been designated as CBI does not meet the standard for protection, EPA must provide notice to the information submitter prior to disclosing the information.<sup>91</sup>

Procedurally, to obtain CBI protection for information that the submitter believes is entitled to confidential treatment, the submitter is required only to designate the information as CBI.<sup>92</sup> Neither substantiation nor EPA review of confidentiality claims is expressly required under current TSCA. CBI protection also continues indefinitely, unless EPA determines that the information no longer qualifies for protection under the FOIA exemption and gives the submitter the required prior notice.<sup>93</sup> Since 2010, EPA has increased its review of confidentiality claims, particularly relating to chemical identities in health and safety studies.<sup>94</sup> The agency has also issued a “CBI Declassification Challenge,” asking industry to withdraw CBI claims voluntarily, and has engaged in other initiatives to increase public access to non-confidential information.<sup>95</sup>

All three bills would retain current TSCA’s basic framework requiring protection of information that falls within the FOIA trade secrets exemption. The three proposals, however, would require or authorize EPA to disclose CBI in additional circumstances, including in response to requests from state, local, or tribal officials for enforcement purposes; requests from certain federal or state professionals in response to an environmental release; or requests from health care professionals to assist in diagnoses or treatments of patients.<sup>96</sup>

The Senate bills would make more extensive revisions and additions to Section 14 of TSCA than H.R. 2576, with more detailed procedural requirements for information submitters and more review requirements for EPA.<sup>97</sup> They would also enumerate certain categories of information presumed protected from disclosure, including specific chemical identity (chemical formula and molecular structure) prior to the date a chemical is first offered for commercial distribution. On the other hand, information on chemicals subject to a ban or phase-out rule under amended Section 6 would be presumed not protected.<sup>98</sup>

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<sup>89</sup> EPA, “Declassifying Confidentiality Claims to Increase Access to Chemical Information,” updated January 8, 2015, <http://www.epa.gov/oppt/existingchemicals/pubs/transparency-charts.html>.

<sup>90</sup> 15 U.S.C. §2613(a)(3).

<sup>91</sup> 15 U.S.C. §2613(c)(2).

<sup>92</sup> 15 U.S.C. §2613(c)(1).

<sup>93</sup> 15 U.S.C. §2613(c)(2).

<sup>94</sup> See footnote 89.

<sup>95</sup> EPA, “Increasing Transparency in TSCA,” updated January 8, 2015, <http://www.epa.gov/oppt/existingchemicals/pubs/transparency.html>.

<sup>96</sup> See generally §14 of S. 697 and §114 of S. 725, which would replace current TSCA §14 and enumerate disclosure circumstances in a new TSCA §14(e), and §6(1) of H.R. 2576, which would add specific new disclosure circumstances to those now contained in TSCA §14(a).

<sup>97</sup> See generally §14 of S. 697 and §114 of S. 725, both of which would replace current TSCA §14(c) with new procedures that would be set forth in new subsections (d) and (f)-(g) of TSCA §14.

<sup>98</sup> See §14 of S. 697 and §114 of S. 725, both of which would revise TSCA §14(b).

In comparison, H.R. 2576 would protect the confidentiality of chemicals' identities in health and safety studies. All three bills would require submitters to substantiate, and resubstantiate after no more than 10 years, their confidentiality claims.<sup>99</sup> In H.R. 2576, however, these substantiation requirements would be limited to confidentiality claims made after enactment. H.R. 2576 would also require EPA to notify submitters before the expiration date of their confidentiality claims.<sup>100</sup>

## **Resources to Administer TSCA**

In implementing Title I of TSCA, the pace and thoroughness with which EPA can evaluate chemical risks often depends on the resources made available to the agency. An issue for Congress is whether to continue funding EPA's activities under TSCA through discretionary appropriations or to establish dedicated sources of funding that are supplemental to and not subject to discretionary appropriations.

Under Section 29 of TSCA, appropriations for Title I were authorized through FY1983. Congress has continued to fund EPA's implementation of TSCA through annual appropriations pursuant to the program or "organic" authorities of TSCA that do not have a sunset date and do not expire unless otherwise amended.<sup>101</sup> Additionally, Section 26(b) of TSCA authorizes EPA to assess fees on chemical manufacturers, importers, or processors.<sup>102</sup> The authorization for EPA to assess these fees does not have a sunset date. EPA's authority to collect fees is statutorily limited to a maximum of \$2,500 for the following actions required under Section 5 of the statute:

- Each PMN that a manufacturer or importer of a new chemical substance is required to submit to EPA, and
- Each notice that a manufacturer, importer, or processor is required to submit to EPA for a significant new use of a chemical substance.<sup>103</sup>

Section 26(b) currently provides an exception for small businesses under which these fees are limited to a maximum of \$100. Furthermore, Section 26(b) authorizes EPA to assess fees within these statutory caps for the costs of evaluating testing data that a manufacturer, importer, or processor of a chemical substance may be required to submit to the agency under Section 4 of the statute.<sup>104</sup>

Under TSCA, there is no dedicated account for fees collected under Section 26(b). As such, these fees are treated as miscellaneous receipts and deposited into the General Fund of the U.S.

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<sup>99</sup> Section 14 of S. 697, §114 of S. 725, and §6(3) of H.R. 2576 would replace TSCA §14(c)(1).

<sup>100</sup> Section 6(3) of H.R. 2576 would add requirements in amended subsection 14(c)(1)(B)-(C) for EPA to notify the designator of CBI at least 60 days prior to releasing it after the expiration of the initial 10-year protection period to allow the designator to submit a request for renewal.

<sup>101</sup> 15 U.S.C. §2628.

<sup>102</sup> 15 U.S.C. §2625(b).

<sup>103</sup> 15 U.S.C. §2604.

<sup>104</sup> 15 U.S.C. §2603. As a matter of implementation, the regulations that EPA has promulgated to assess fees under TSCA apply to PMNs and notices of significant new uses required under §5 of the statute but not to the evaluation of testing data that may be required under §4.

Treasury as required by the Miscellaneous Receipts Act.<sup>105</sup> The availability of fees collected under TSCA for obligation by EPA is subject to annual appropriations.

S. 697 and S. 725 would repeal the expired authorization of appropriations under Section 29 of TSCA, whereas H.R. 2576 would not amend Section 29.<sup>106</sup> With regard to the authority to collect fees under Section 26(b) of TSCA, all three bills would revise this authority to differing degrees.<sup>107</sup> S. 697 would authorize the collection of fees to accompany certain submissions of information to EPA regarding chemicals that the agency would be directed to evaluate, although the authority to collect fees would be conditional on a minimum level of discretionary appropriations made available to the agency.

S. 697 would direct the agency to set fees at levels such that the fees would, in aggregate, provide a sustainable source of funds to partially defray the cost of conducting various activities. S. 697 would cap the total amount collected at \$18 million. The bill does not indicate whether this cap applies annually or indefinitely from the bill's enactment. EPA would be directed to deposit receipts from fees in a dedicated fund. The amounts in the fund would be obligated only to defray the costs of evaluating various submissions of information submitted to the agency. These fees would be made available without fiscal year limitation subject to the availability of appropriations.

In addition to the existing authority to collect fees under TSCA, H.R. 2576 would authorize EPA to collect fees from manufacturers who request a risk evaluation of a chemical substance. The bill would eliminate the current statutory limit for the amount that EPA may collect in fees per notice submission. Instead, the agency would be authorized to collect a fee that is sufficient and not more than reasonably necessary to defray certain costs in administering TSCA. H.R. 2576 and S. 697 would establish a dedicated fund in which receipts from fees would be deposited. The amount of fees would be made available to EPA without fiscal year limitation subject to the availability of discretionary appropriations.

S. 725 would authorize EPA to collect fees from chemical manufacturers for various purposes. Similar to S. 697 and H.R. 2576, S. 725 would also eliminate the current statutory limit that EPA may collect in fees per notice submission under current TSCA and direct the agency to ensure that fees are set at a level sufficient to enable the agency to perform certain responsibilities. As under the current TSCA, S. 725 does not establish a dedicated account for the deposit of fees collected. Receipts from collected fees would be deposited as miscellaneous receipts into the General Fund of the U.S. Treasury pursuant to the Miscellaneous Receipts Act.<sup>108</sup> Funds would be made available subject to discretionary appropriations.

The Congressional Budget Office has published cost estimates for S. 697 and H.R. 2576 that present estimates of the potential budgetary impacts of the bills. The cost estimate for S. 697 is included in S.Rept. 114-67, and the cost estimate for H.R. 2576 is included in H.Rept. 114-176.<sup>109</sup>

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<sup>105</sup> 31 U.S.C. §3302(b).

<sup>106</sup> See generally §25 of S. 697 and §124 of S. 725.

<sup>107</sup> See generally §22 of S. 697, §121 of S. 725, and §8 of H.R. 2576.

<sup>108</sup> 31 U.S.C. §3302(b).

<sup>109</sup> U.S. Congress, Senate Committee on Environment and Public Works, *Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act*, report together with minority views to accompany S. 697, 114<sup>th</sup> Cong., 1<sup>st</sup> sess., June 18, 2015, S.Rept. 114-67 (Washington: GPO, 2015), pp. 32-36, and U.S. Congress, House Committee on Energy and Commerce, (continued...)

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*TSCA Modernization Act of 2015*, report to accompany H.R. 2576, 114<sup>th</sup> Cong., 1<sup>st</sup> sess., June 23, 2015, H.Rept. 114-176 (Washington: GPO, 2015), pp. 17-21.



## EMERGING CONTAMINANTS FACT SHEET – PFOS and PFOA

### At a Glance

- ❖ Fully fluorinated compounds that are human-made substances and are not naturally found in the environment.
- ❖ Used as a surface-active agent and in a variety of products, such as firefighting foams, coating additives and cleaning products.
- ❖ Do not hydrolyze, photolyze or biodegrade under typical environmental conditions and are extremely persistent in the environment.
- ❖ Studies have shown they have the potential to bioaccumulate and biomagnify in wildlife.
- ❖ Readily absorbed after oral exposure and accumulate primarily in the serum, kidney and liver.
- ❖ Toxicological studies on animals indicate potential developmental, reproductive and systemic effects.
- ❖ Health-based advisories or screening levels for PFOS and PFOA have been developed by the EPA and state agencies.
- ❖ Standard detection methods include high-performance liquid chromatography and tandem mass spectrometry.
- ❖ Common ex situ water treatment technologies include activated carbon filters and reverse osmosis units.

### Introduction

An “emerging contaminant” is a chemical or material that is characterized by a perceived, potential, or real threat to human health or the environment or by a lack of published health standards. A contaminant may also be “emerging” because a new source or a new pathway to humans has been discovered or a new detection method or treatment technology has been developed (DoD 2011). This fact sheet, developed by the U.S. Environmental Protection Agency (EPA) Federal Facilities Restoration and Reuse Office (FFRRO), provides a summary of the emerging contaminants perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA), including physical and chemical properties; environmental and health impacts; existing federal and state guidelines; detection and treatment methods; and additional sources of information. This fact sheet is intended for use by site managers who may address PFOS and PFOA at cleanup sites or in drinking water supplies and for those in a position to consider whether these chemicals should be added to the analytical suite for site investigations.

PFOS and PFOA are extremely persistent in the environment and resistant to typical environmental degradation processes. As a result, they are widely distributed across the higher trophic levels and are found in soil, air and groundwater at sites across the United States. The toxicity, mobility and bioaccumulation potential of PFOS and PFOA pose potential adverse effects for the environment and human health.

### What are PFOS and PFOA?

- ❖ PFOS and PFOA are fully fluorinated, organic compounds and are the two perfluorinated chemicals (PFCs) that have been produced in the largest amounts within the United States (ATSDR 2009; EFSA 2008).
- ❖ PFOS is a perfluoroalkyl sulfonate that is commonly used as a simple salt (such as potassium, sodium or ammonium) or is incorporated into larger polymers (EFSA 2008; EPA 2009c).
- ❖ PFOA is a perfluoroalkyl carboxylate that is produced synthetically as a salt. Ammonium salt is the most widely produced form (EFSA 2008; EPA 2009c).

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## What are PFOS and PFOA? (continued)

- ❖ PFOS synonyms include 1-octanesulfonic acid, heptadecafluoro-, 1-perfluorooctanesulfonic acid, heptadecafluoro-1-octanesulfonic acid, perfluoro-n-octanesulfonic acid, perfluorooctanesulfonic acid and perfluorooctylsulfonic acid (ATSDR 2009; UNEP 2005).
- ❖ PFOA synonyms include pentadecafluoro-1-octanoic acid, pentadecafluoro-n-octanoic acid, pentadecafluorooctanoic acid, perfluorocaprylic acid, perfluorooctanoic acid, perfluoroheptanecarboxylic acid and octanoic acid (ATSDR 2009).
- ❖ They are stable chemicals that include long carbon chains. Because of their unique lipid- and water-repellent characteristics, PFOS and PFOA are used as surface-active agents in various high-temperature applications and as a coating on surfaces that contact with strong acids or bases (Schultz and others 2003; UNEP 2005).
- ❖ PFCs are used in a wide variety of industrial and commercial products such as textiles and leather products, metal plating, the photographic industry, photolithography, semi-conductors, paper and packaging, coating additives, cleaning products and pesticides (ATSDR 2009; EPA 2009c; OECD 2002).
- ❖ Through 2001, PFCs were used to manufacture Aqueous Film Forming Foam (AFFF). PFOS-based AFFF is used to extinguish flammable liquid fires (for example, hydrocarbon fueled), such as fires involving gas tankers and oil refineries (EPA 2013a; DoD SERDP 2012).
- ❖ They are human-made compounds and do not occur naturally in the environment (ATSDR 2009; EPA 2009c).
- ❖ PFOS and PFOA can also be formed by environmental microbial degradation or by metabolism in larger organisms from a large group of related substances or precursor compounds (ATSDR 2009; UNEP 2006).
- ❖ The 3M Company, the primary manufacturer of PFOS, completed a voluntary phase-out of PFOS production in 2002 (ATSDR 2009; 3M 2008).

### Exhibit 1: Physical and Chemical Properties of PFOS and PFOA

(ATSDR 2009; Brooke and others 2004; EFSA 2008; Environment Canada 2012; EPA 2002b; OECD 2002; UNEP 2006)

Property	PFOS (Potassium Salt)	PFOA (Free Acid)
Chemical Abstracts Service (CAS) Number	2795-39-3	335-67-1
Physical Description (physical state at room temperature and atmospheric pressure)	White powder	White powder/ waxy white solid
Molecular weight (g/mol)	538	414
Water solubility at 25°C (mg/L)	550 to 570 (purified), 370 (fresh water), 25 (filtered sea water)	9.5 X 10 <sup>3</sup> (purified)
Melting Point (°C)	> 400	45 to 54
Boiling point (°C)	Not measurable	188 to 192
Vapor pressure at 20 °C (mm Hg)	2.48 X10 <sup>-6</sup>	0.017 <sup>1</sup>
Octanol-water partition coefficient (log K <sub>ow</sub> )	Not measurable	Not measurable
Organic-carbon partition coefficient (log K <sub>oc</sub> )	2.57 (Value estimated based on anion and not the salt)	2.06
Henry's law constant (atm-m <sup>3</sup> /mol)	3.05 × 10 <sup>-9</sup>	Not measurable
Half-Life	Atmospheric: 114 days Water: > 41 years (at 25° C)	Atmospheric: 90 days <sup>2</sup> Water: > 92 years (at 25° C)

Abbreviations: g/mol – grams per mole; mg/L – milligrams per liter; °C – degree Celsius; mm Hg – millimeters of mercury; atm-m<sup>3</sup>/mol – atmosphere-cubic meters per mole.

<sup>1</sup> Extrapolation from measurement.

<sup>2</sup> The atmospheric half-life value identified for PFOA is estimated based on available data determined from short study periods.

### What are PFOS and PFOA? (continued)

- ❖ PFOS chemicals are no longer manufactured in the United States; however, EPA significant new use rules (SNURs) allow for the continuation of a few, limited, highly technical applications of PFOS-related substances where no known alternatives are available. In addition, existing stocks of PFC-based chemicals that were manufactured or imported into the United States before the effective date of the SNURs (for example, PFOS-based AFFF produced before the rules took effect in 2002) can still be used (EPA 2009c, 2013a).
- ❖ PFOA as its ammonium salt is manufactured primarily for use as an aqueous dispersion agent and in the manufacture of fluoropolymers (which are used in a wide variety of mechanical and industrial components) such as electrical wire casings, fire- and chemical-resistant tubing and plumbing seal tape. They are also produced unintentionally by the degradation of some fluorotelomers (ATSDR 2009; EPA 2009c).
- ❖ As part of the EPA's PFOA stewardship program, eight companies committed to achieve the following by 2010: (1) reduce global facility emissions of PFOA to all media; (2) reduce precursor chemicals that break down to PFOA and related higher homologue chemicals; and (3) PFOA product content (95 percent). The companies also agreed to work toward eliminating these chemicals from emissions and products by 2015 (EPA 2013a).

### What are the environmental impacts of PFOS and PFOA?

- ❖ During past manufacturing processes, large amounts of PFOS and PFOA were released to the air, water and soil in and around fluorochemical facilities (ATSDR 2009).
- ❖ PFOS and PFOA have been detected in a number of U.S. cities in surface water and sediments downstream of former fluorochemical production facilities and in wastewater treatment plant effluent, sewage sludge and landfill leachate (EPA 2002b; OECD 2002).
- ❖ The environmental release of PFOS-based AFFF may also occur from tank and supply line leaks, use of aircraft hangar fire suppression systems and firefighting training (DoD SERDP 2012).
- ❖ Both PFOS and PFOA are the stable end products resulting from the degradation of precursor substances through a variety of abiotic and biotic transformation pathways (Conder and others 2010).
- ❖ Because of their chemical structure, PFCs, including PFOS and PFOA, are chemically and biologically stable in the environment and resist typical environmental degradation processes, including atmospheric photooxidation, direct photolysis and hydrolysis. As a result, these chemicals are extremely persistent in the environment (OECD 2002; Schultz and others 2003).
- ❖ PFOS and PFOA have very low volatility because of their ionic nature. Therefore, they will be persistent in water and soil (3M 2000; ATSDR 2009).
- ❖ When released directly to the atmosphere, PFCs are expected to adsorb to particles and settle to the ground through wet or dry deposition (Barton and others 2007; Hurley and others 2004).
- ❖ In their anionic forms, PFOA and PFOS are water-soluble and can migrate readily from soil to groundwater, where they can be transported long distances (Davis and others 2007; Post and others 2012).
- ❖ Monitoring data from the Arctic region and at sites remote from known point sources have shown levels of PFOS and PFOA in environmental media and biota, indicating that long-range transport has occurred. For example, PFOA and PFOS have been detected in concentrations from the low- to mid- picograms per liter (pg/L) range in remote regions of the Arctic caps. In addition, PFOS concentrations detected in the liver of the Canadian Arctic polar bear range from 1,700 to more than 4,000 nanograms per gram (ng/g) (Lau and others 2007; Martin and others 2004; Young and others 2007).
- ❖ Causes of long-range PFC transport include (1) atmospheric transport of precursor compounds (such as perfluoroalkyl sulfonamides), followed by degradation to form PFCs and (2) direct, long-range transport of PFCs via ocean currents or in the form of marine aerosols (Armitage and others 2006; Post and others 2012).

### What are the environmental impacts of PFOS and PFOA? (continued)

- ❖ The wide distribution of PFCs increases the potential for bioaccumulation and bioconcentration as they are transferred from low to higher trophic level organisms. Because of their persistence and long-term accumulation, higher trophic level wildlife such as fish, piscivorous birds and other biota can continue to be exposed to PFOS and PFOA (EPA 2006a; UNEP 2006).
- ❖ The bioaccumulation potential of PFCs increases with increasing carbon chain length (ATSDR 2009; Furdui and others 2007).
- ❖ PFOS is the only PFC that has been shown to accumulate to levels of concern in fish tissue. The estimated bioconcentration factor in fish ranges from 1,000 to 4,000 (EFSA 2008; MDH 2011; OECD 2002).
- ❖ As of 2013, the Superfund Information Systems Database indicates PFCs have been reported in the 5-year reviews of 14 hazardous waste sites on the EPA National Priorities List (EPA 2013b).
- ❖ Data gathered in 2008 from the DoD Knowledge Based Corporate Reporting System show that 594 DoD facilities have been categorized as Fire/Crash/Training Sites and, therefore, have the potential for PFC contamination based on historical use of AFFF (DoD 2008; DoD SERDP 2012).

### What are the routes of exposure and the health effects of PFOS and PFOA?

- ❖ Studies have found PFOS and PFOA in the blood samples of the general human population and wildlife nationwide, indicating that exposure to the chemicals is widespread (ATSDR 2009; EPA 2006a).
- ❖ Reported data indicate that serum concentrations of PFOS and PFOA are higher in workers and individuals living near fluorochemical production facilities than for the general population (Calafat and others 2007; EPA 2009c).
- ❖ Potential pathways, which may lead to widespread exposure, include ingestion of food and water, use of commercial products or inhalation from long-range air transport of PFC-containing particulate matter (ATSDR 2009; EPA 2009c).
- ❖ Based on the limited information available, fish and fishery products seem to be one of the primary sources of human exposure to PFOS (EFSA 2008).
- ❖ While a federal screening level or toxicity value for the consumption of fish has not yet been established, the Dutch National Institute for Public Health and the Environment has calculated a maximum permissible concentration for PFOS of 0.65 nanograms per liter (ng/L) for fresh water (based on consumption of fish by humans as the most critical route) (Moermond and others 2010).
- ❖ Studies also indicate that continued exposure to low levels of PFOA in drinking water may result in adverse health effects (Post and others 2012).
- ❖ Toxicology studies show that PFOS and PFOA are readily absorbed after oral exposure and accumulate primarily in the serum, kidney and liver. No further metabolism is expected (EPA 2006a, 2009c).
- ❖ PFOS and PFOA have half-lives in humans ranging from 2 to 9 years, depending on the study. This half-life results in continued exposure that could increase body burdens to levels that would result in adverse outcomes (ATSDR 2009; EPA 2009c; Kärman and others 2006; Olsen and others 2007).
- ❖ Acute- and intermediate-duration oral studies on rodents have raised concerns about potential developmental, reproductive and other systemic effects of PFOS and PFOA (Austin and others 2003; EPA 2006a).
- ❖ The ingestion of PFOA-contaminated water was found to cause adverse effects on mammary gland development in mice (Post and others 2012).
- ❖ One study indicated that exposure to PFOS can affect the neuroendocrine system in rats; however, the mechanism by which PFOS affects brain neurotransmitters is still unclear (Austin and others 2003).
- ❖ Both PFOS and PFOA have a high affinity for binding to B-lipoproteins and liver fatty acid-binding protein. Several studies on animals have shown that these compounds can interfere with fatty acid metabolism and may deregulate metabolism of lipids and lipoproteins (EFSA 2008; EPA 2009c).

### What are the routes of exposure and the health effects of PFOS and PFOA? (continued)

- ❖ In May 2006, the EPA Science Advisory Board suggested that PFOA cancer data are consistent with the EPA guidelines for the Carcinogen Risk Assessment descriptor “likely to be carcinogenic to humans.” EPA is still evaluating this information and additional research pertaining to the carcinogenicity of PFOA (EPA 2006b, 2013a).
- ❖ The American Conference of Governmental Industrial Hygienists (ACGIH) has classified PFOA as a Group A3 carcinogen — confirmed animal carcinogen with unknown relevance to humans (ACGIH 2002).
- ❖ The chronic exposure to PFOS and PFOA can lead to the development of tumors in the liver of rats; however, more research is needed to determine if there are similar cancer risks for humans (ATSDR 2009; OECD 2002).
- ❖ In a retrospective cohort mortality study of more than 6,000 PFOA-exposed employees at one plant, results identified elevated standardized mortality ratios for kidney cancer and a statistically significant increase in diabetes mortality for male workers. The study noted that additional investigations are needed to confirm these findings (DuPont 2006; Lau and others 2007).
- ❖ Studies have shown that PFCs may induce modest effects on reactive oxygen species and deoxyribonucleic acid (DNA) damage in the cells of the human liver (Eriksen and others 2010; Reistad and others 2013).
- ❖ Analysis of U.S. National Health and Nutrition Examination Survey representative study samples indicate that higher concentrations of serum PFOA and PFOS are associated with thyroid disease in the U.S. general adult population. Further analysis is needed to identify the mechanisms underlying this association (Melzer and others 2010).
- ❖ Epidemiologic studies have shown an association between PFOS exposure and bladder cancer; however, further research and analysis are needed to understand this association (Alexander and others 2004; Lau and others 2007).

### Are there any federal and state guidelines and health standards for PFOS and PFOA?

- ❖ In January 2009, the EPA’s Office of Water established a provisional health advisory (PHA) of 0.2 micrograms per liter (µg/L) for PFOS and 0.4 µg/L for PFOA to assess the potential risk from short-term exposure of these chemicals through drinking water. PHAs reflect reasonable, health-based hazard concentrations above which action should be taken to reduce exposure to unregulated contaminants in drinking water (EPA 2009d, 2013a).
- ❖ EPA Region 4 calculated a residential soil screening level of 6 milligrams per kilogram (mg/kg) for PFOS and 16 mg/kg for PFOA (EPA Region 4 2009).
- ❖ Various states have established drinking water and groundwater guidelines, including the following:
  - Minnesota has established a chronic health risk limit of 0.3 µg/L for PFOS and PFOA in drinking water (MDH 2011).
  - New Jersey has established a preliminary health-based guidance value of 0.04 µg/L for PFOA in drinking water (NJDEP 2013).
  - North Carolina has established an interim maximum allowable concentration (IMAC) of 2 µg/L for PFOA in groundwater (NCDENR 2006).
- In 2010, the North Carolina Secretary’s Science Advisory Board (NCSAB) on Toxic Air Pollutants recommended that the IMAC be reduced to 1 µg/L based on a review of the toxicological literature and discussions with scientists conducting research on the health effects associated with exposure to PFOA. As of February 2014, the NCSAB’s recommendation was still pending review by the North Carolina Division of Water Quality (NCSAB 2010).
- ❖ Under the Toxic Substances Control Act (TSCA), the EPA finalized two SNURs in 2002 for 88 PFOS-related substances, which require companies to notify the EPA 90 days before starting to manufacture or importing these substances for a significant new use; this pre-notification allows time to evaluate the new use (EPA 2002a, 2013a).
- ❖ In 2007, the SNURs were amended to include 183 additional PFOS-related substances (EPA 2006a, 2013a).

### Are there any federal and state guidelines and health standards for PFOS and PFOA? (continued)

- ❖ On September 30, 2013, the EPA issued a final SNUR requiring companies to report 90 days in advance of all new uses of long-chain perfluoroalkyl carboxylic (LCPFAC) chemicals (defined as having perfluorinated carbon chain lengths equal to or greater than seven carbons and less than or equal to 20 carbons) for use as part of carpets or to treat carpets, including the import of new carpet containing LCPFACs. In addition, the EPA is amending the existing SNUR to add PFOS-related substances that have completed the TSCA new chemical review process but have not yet commenced production or importation, and to designate processing as a significant new use (EPA 2012, 2013a).
- ❖ The SNURs allow for continued use for a few highly technical applications of PFOS-related substances where no alternatives are available; these specialized uses are characterized by very low volume, low exposure and low releases (EPA 2009c, 2013a).
- ❖ The Agency for Toxic Substances and Disease Registry has not established a minimal risk level (MRL) for PFOS or PFOA; when the draft toxicological profile was published, human studies were insufficient to determine with a sufficient degree of certainty that the effects are either exposure-related or adverse (ATSDR 2009).
- ❖ The EPA has not derived a chronic oral reference dose (RfD) or chronic inhalation reference concentration (RfC) for PFOS or PFOA and has not classified PFOS or PFOA carcinogenicity.
- ❖ The EPA removed PFOS and PFOA from the Integrated Risk Information System (IRIS) agenda in a Federal Register notice released on October 18, 2010. At this time, EPA is not conducting an IRIS assessment for these chemicals (EPA 2010).
- ❖ PFOS and PFOA were included on the third drinking water contaminant candidate list, which is a list of unregulated contaminants that are known to, or anticipated to, occur in public water systems and may require regulation under the Safe Drinking Water Act (EPA 2009a).

### What detection and site characterization methods are available for PFOS and PFOA?

- ❖ PFOS and PFOA are commonly deposited in the environment as discrete particles with strongly heterogeneous spatial distributions. Unless precautions are taken, this distribution causes highly variable soil data that can lead to confusing or contradictory conclusions about the location and degree of contamination. Proper sample collection (using an incremental field sampling approach), sample processing (which includes grinding) and incremental subsampling are required to obtain reliable soil data (EPA 2003, 2013c).
- ❖ PFOS and PFOA in anionic form can be extracted from environmental media by conventional methods using either acidification or ion pairing to obtain a neutral form of the analyte. Sample preparation methods used for PFCs have included solvent extraction, ion-pair extraction, solid-phase extraction and column-switching extraction (Flaherty and others 2005).
- ❖ Precursors and intermediate degradation products can be extracted using solvents (Dasu and others 2012; Ellington and others 2009).
- ❖ Air samples may be collected using high-volume air samplers that employ sampling modules containing glass-fiber filters and glass columns with a polyurethane foam (Jahnke and others 2007a).
- ❖ Detection methods for PFCs are primarily based on high-performance liquid chromatography (HPLC) coupled with tandem mass spectrometry (MS/MS). HPLC-MS/MS has allowed for more sensitive determinations of individual PFOS and PFOA in air, water and soil (EFSA 2008; Jahnke and others 2007b; Washington and others 2008).
- ❖ Both liquid chromatography (LC)-MS/MS and gas chromatography-mass spectrometry (GC-MS) can be used to identify the precursors of PFOS and PFOA (EFSA 2008).
- ❖ EPA Method 537, Version 1.1, is an LC-MS/MS method used to analyze selected perfluorinated alkyl acids in drinking water. While most sampling protocols for organic compounds require sample collection in glass, this method requires plastic sample bottles because PFCs are known to adhere to glass (EPA 2009b).
- ❖ The development of LC - electrospray ionization (ESI) MS and LC-MS/MS has improved the analysis of PFOS and PFOA (EFSA 2008).
- ❖ Reported sensitivities for the available detection methods include low picograms per cubic meter ( $\text{pg}/\text{m}^3$ ) levels in air, high picograms per liter ( $\text{pg}/\text{L}$ ) to low  $\text{ng}/\text{L}$  levels in water and high picogram per gram to low  $\text{ng}/\text{g}$  levels in soil (ATSDR 2009).

### What technologies are being used to treat PFOS and PFOA?

- ❖ Because of their unique physicochemical properties (strong fluorine-carbon bond and low vapor pressure), PFOS and PFOA resist most conventional in situ treatment technologies, such as direct oxidation (Hartten 2009; Vectis and others 2009).
- ❖ Factors to consider when selecting a treatment method in all media include: (1) initial concentration of PFCs; (2) the background organic and metal concentration; (3) available degradation time; and (4) other site-specific conditions (Vectis and others 2009).
- ❖ Ex situ treatments including activated carbon filters, nanofiltration and reverse osmosis units have been shown to remove PFCs from water; however, incineration of the concentrated waste would be needed for the complete destruction of PFCs (Hartten 2009; MDH 2008; Vectis and others 2009).
- ❖ Research into a cost-effective treatment approach for PFOS and PFOA is ongoing (DoD SERDP 2012).
- ❖ Alternative technologies studied for PFOS and PFOA degradation in water, soil and solid waste include photochemical oxidation and thermally induced reduction, which have achieved some bench-scale success (Hartten 2009; Vectis and others 2009).
- ❖ Laboratory-scale studies have also evaluated sonochemical degradation (that is, ultrasonic irradiation) to treat PFOS and PFOA in groundwater and have reported a sonochemical degradation half-life less than 30 minutes for both PFOS and PFOA (Cheng and others 2008, 2010).
- ❖ Results from a laboratory-scale study suggested the promising potential of using a double-layer permeable reactive barrier (DL-PRB) system for the in situ containment of PFC-contaminated soil and groundwater. The DL-PRB system is composed of an oxidant-releasing material layer followed by a layer of quartz sands immobilized with humification enzymes. The system drives enzyme-catalyzed oxidative humification reactions to degrade PFCs in the PRB (DoD SERDP 2013).
- ❖ In situ chemical oxidation is being explored as a possible means to treat PFCs in water. Laboratory-scale study results indicate that heat-activated persulfate and permanganate can effectively degrade PFOS and PFOA in water (Liu and others 2012a, b).

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## Contact Information

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**THE ATTORNEYS GENERAL OF  
MASSACHUSETTS, CALIFORNIA, HAWAII, IOWA, MAINE,  
MARYLAND, NEW HAMPSHIRE, NEW YORK, OREGON,  
RHODE ISLAND, VERMONT, AND WASHINGTON**

January 19, 2016

The Honorable James M. Inhofe  
Chairman  
Committee on Environment and Public Works  
U.S. Senate  
410 Dirksen Senate Office Building  
Washington, DC 20510-6175

The Honorable Frederick S. Upton  
Chairman  
Committee on Energy and Commerce  
U.S. House of Representatives  
2183 Rayburn House Office Building  
Washington, DC 20515

The Honorable Barbara Boxer  
Ranking Member  
Committee on Environment and Public Works  
U.S. Senate  
456 Dirksen Senate Office Building  
Washington, DC 20510-6175

The Honorable Frank Pallone, Jr.  
Ranking Member  
Committee on Energy and Commerce  
U.S. House of Representatives  
237 Cannon House Office Building  
Washington, DC 20515

Dear Chairman Inhofe and Ranking Member Boxer, and Chairman Upton  
and Ranking Member Pallone:

We, the undersigned Attorneys General, write to commend Congress on undertaking efforts to reform the Toxic Substances Control Act of 1976, 15 U.S.C. §§ 2601, *et seq.* (“TSCA”) to help TSCA achieve its goal of protecting public health and the environment from toxic chemicals. As the House of Representatives and Senate have both passed TSCA reform bills, and are now working to reconcile them, we would also like to distill our prior comments into seven core principles regarding the federal-state relationship in TSCA reform, and offer recommendations for addressing issues presented by the differing bills regarding the scope of preemption.

We continue to strongly support the shared goal of reforming TSCA to remove obstacles that have prevented the Environmental Protection Agency from playing a more robust role in protecting the public and the environment from toxic chemicals. At the same time, we believe it is important to recognize that state and local regulation of public health and safety, and environmental effects, is consistent with the traditional allocation of responsibilities and powers under our federal system of government, and that this cooperative exercise of regulatory authority has been an important tool for reducing risks to our residents and the environment from toxic chemicals. Accordingly, we strongly believe that preemption of state actions beyond that of existing TSCA is counterproductive.

In prior correspondence and testimony on behalf of our states, we have said that, to the extent that TSCA reform legislation contemplates preemption of state and local regulation, any

such preemption should be as limited as possible and consistent with fundamental principles regarding the vital, complementary roles that the states and the federal government must play, and historically have played, in chemicals regulation. Our recommendations below on limiting the preemption of each state's authority to protect its citizens and the environment in any final bill are guided by those principles.

We appreciate the invitations we have received to testify in Committee, and the dedicated efforts of Congressional staff members to engage our coalition to discuss our concerns and to attempt to find ways to address them. We believe this has resulted in progress on several of the significant concerns we have raised in this legislative process. For example, in their final form, both the TSCA Modernization Act of 2015 (H.R. 2576) as passed by the House in June 2015 (the "House Bill") and the Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act as passed by the Senate in December 2015 (the "Senate Bill;" formerly S. 697, now H.R. 2576, as amended in the Senate December 17, 2015): (i) allow states and political subdivisions (hereafter "states") to co-enforce federal standards through the adoption of identical requirements in state law; (ii) preserve longstanding state chemicals programs from preemption; and (iii) exempt from preemption state water quality, air quality and waste treatment or disposal laws. In other areas, however, such as the timing of preemption and the requirements for obtaining a waiver, the bills differ in the extent to which they have made progress on our core concerns.

Thus, the outcome of the reconciliation process will be crucial in determining whether the new TSCA regimen to a greater extent reflects our goal of having a successful federal-state partnership that both enhances federal authority and protects state interests, and is of deep interest to our states.

### **State Principles**

There are seven core principles regarding the state-federal relationship in TSCA reform reflected in our prior letters and hearing testimony. We believe adherence to these principles is crucial to limit preemption to the greatest extent possible and succeed in spurring an appropriate, beneficial government partnership in chemical regulation – a partnership we resolutely believe is needed to protect the public health and environment both when EPA has access to adequate resources and when the agency does not enjoy such resources:

- 1. States should not be preempted until EPA has taken a final action;**
- 2. Once EPA has taken a final action, the scope of state law preempted should be no broader than the scope of EPA's action;**
- 3. States should not be preempted from continuing to establish requirements on chemicals pursuant to longstanding state laws;**
- 4. States should not be preempted from continuing to enforce existing requirements on chemicals;**
- 5. State laws related to water quality, air quality or waste treatment or disposal should not be preempted;**

6. States should be able to obtain a waiver to adopt requirements that are more protective than EPA's if the requirements do not unduly burden interstate commerce and do not make it impossible to comply with both state and federal law; and
7. States should be able to keep "cops on the beat" to co-enforce requirements that have been adopted by EPA.

We address each state principle in turn below, and make recommendations for reconciling the House Bill and the Senate Bill better to satisfy them.

### **Preemption Only After Final EPA Action**

States should not be preempted until EPA has taken a final action. Existing TSCA<sup>1</sup> and the House Bill<sup>2</sup> take this approach, which avoids problematic "regulatory void preemption," where the federal government has yet to reach a determination and states are nonetheless prevented from taking action. A regulatory void jeopardizes the state and federal government's shared objective of protecting public health and the environment and intrudes unnecessarily on state authority. In short, there are strong reasons not to deviate from the well-established practice of not preempting states prior to final federal government action, and to avoid regulatory lapses states should not be preempted until the federal government requirement is implemented.

### **Preemption Limited to the Scope of EPA's Action**

Once EPA restricts a chemical, the scope of state law preempted should be no broader than the scope of EPA's action. Existing TSCA preempts any state law that is applicable to the same chemical or article containing such chemical and "is designed to protect against" the same "risk" as the Administrator's rule or order.<sup>3</sup> This approach makes good sense. As to most chemicals, the House Bill takes a different approach, arguably broadening the scope of preemption by referring to the "intended conditions of use considered by the Administrator in the risk evaluation . . . [or] a use identified in a notice received by the Administrator."<sup>4</sup> Thus, for example, a hypothetical EPA action with respect to use of a particular cleaning-product chemical on the basis of long-term cancer-causing potential might be asserted to preclude a state from taking regulatory action on the same chemical designed to protect against, e.g., short-term respiratory effects. The Senate Bill appears to avoid this potential infirmity by limiting the scope of preemption to "the hazards, exposures, risks and uses or conditions of use . . . included in the scope of the safety determination . . ."<sup>5</sup> This is similar to the approach the House Bill takes with respect to Persistent Bioaccumulative Toxic chemicals ("PBTs").<sup>6</sup>

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<sup>1</sup> 15 U.S.C. §§ 2617(a)(2)(A) and 2617(a)(2)(B).

<sup>2</sup> The House Bill § 7(a)(2) (revising existing TSCA § 18(a)(2)(B) and adding new TSCA § 18(a)(2)(C)).

<sup>3</sup> 15 U.S.C. § 2617(a)(2)(B).

<sup>4</sup> The House Bill § 7(a)(2) adding new TSCA § 18(a)(2)(C)).

<sup>5</sup> The Senate Bill § 17 (adding new TSCA § 18(c)(2)).

<sup>6</sup> The House Bill § 4(e), amends TSCA, § 6 (15 U.S.C. § 2605), by adding new § 6(i), which requires that within nine months of enactment, EPA publish a list of chemicals the agency has a reasonable basis to conclude are PBTs. Then, with respect to any PBTs identified under the proposed § 6(i), the House Bill § 7(a), amends TSCA § 18(a)

## Preservation of State Authority Under Longstanding State Laws

During the nearly four decades in which EPA has been hamstrung by the limitations TSCA imposes on federal efforts to protect the public from unsafe chemicals, many states have stepped up to take action. In some instances, state laws creating chemical regulatory programs have been in operation for twenty-five years or more. For example, California voters passed the Safe Drinking Water and Toxics Enforcement Act of 1986 (Proposition 65), and in 1989 the Massachusetts legislature passed the Toxics Use Reduction Act (Mass. General Laws Ch. 211). These longstanding programs have been working in conjunction with TSCA and numerous other federal health and safety laws, and there appears to be a clear consensus that TSCA reform should not interfere with the authority of states to continue to establish requirements under such longstanding laws.<sup>7</sup> While the two bills arrive at this result through different phrasing, we prefer wording closely modeled on prior precedent – section 231(b) of the Consumer Product Safety Improvement Act (CPSIA) – as reflected in the new TSCA sections 18(e)(1)(A) and 18(e)(1)(B) set out in the Senate Bill.

## Preservation of Existing State Requirements

Both the House and Senate bills reflect an intent not to undo the good work already done by the states to protect their residents' health and their environment from the hazards presented by toxic chemicals. Both bills provide that states may “continue to enforce any action” that was taken “before August 1, 2015 under the authority of a State law.” See the House Bill § 7(b) (adding new TSCA §18(e)(1)(A)); the Senate Bill § 17 (adding new TSCA § 18(e)(1)(A)). As we understand it, the intent of both houses is to give the word “action” its plain meaning, rather than a narrow legal definition (i.e., a lawsuit). Thus, the word “action” encompasses the adoption of a requirement or regulation implementing state law, so long as those actions were taken prior to August 1, 2015. Thus, for example, pre-August 2015 state laws banning or restricting the use of flame retardant chemicals in upholstered furniture or children's products, or pre-August 2015 regulations implementing those statutes, would not be preempted, and states would not be preempted from “continuing to enforce” those laws. Here, we believe that the use of the phrase “action taken or requirement imposed” would provide greater clarity.

## No Preemption of State Air Quality, Water Quality or Waste Treatment or Disposal Laws

As both bills recognize, in the course of regulating water quality, air quality or waste treatment or disposal, states may have a need to impose requirements on the manufacture, processing, distribution in commerce or use of chemicals. See the House Bill § 7(a) (adding new TSCA § 18(a)(2)(C)(iii)); the Senate Bill § 17 (adding new TSCA § 18(d)(1)(A)(iii)). Both bills attach certain caveats to the preservation of these state requirements on chemicals. Of the different formulations of those caveats, the one we prefer limits preemption to those state requirements that “would cause a violation of the applicable action by the Administrator under section 5 or 6.” If there is to be any further articulation of the caveats – e.g., preempting

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(15 U.S.C. § 2617(a)), by adding §18(a)(2)(C). That section, among others, *limits preemption to the risk of injury considered by EPA*, but only as to PBT assessments under the newly added § 6(i).

<sup>7</sup> See 161 Cong. Rec.—House, H4559 (June 23, 2015) (“Mr. SHIMKUS. Mr. Speaker, that is correct. We do not intend to interfere with the operation of Proposition 65 unless a requirement under that law actually conflicts with a federal requirement under TSCA.”); see also Senate Report 114-67 (June 18, 2015) at 26.

“inconsistent” or “actually conflicting” requirements – we agree that those should be limited to state laws that “address [ ] the same hazards and exposures, with respect to the same conditions of use.” *See* the Senate Bill § 18(d)(1)(A)(iii)(II)(aa). In addition, both houses have indicated that state requirements implementing a reporting, monitoring, disclosure or other information obligation not otherwise required by the Administrator or by Federal law should fall outside the scope of preemption. *See* the Senate Bill § 18(d)(1)(A)(ii); House Report 114-176, at p. 31. For clarity, we prefer that this exemption from preemption be expressly stated in the bill.

### **Conditions for State Waivers Should be Clear and the Process Straightforward**

Existing TSCA permits the Administrator to exempt (i.e., to grant a waiver from preemption for) state requirements that: (1) would not cause a person to be in violation of a federal requirement for the same chemical, (2)(A) provide a significantly higher degree of protection from risk, and (2)(B) do not unduly burden interstate commerce.<sup>8</sup> The House Bill does not alter these conditions. The Senate Bill, however, adds two additional conditions for such waiver: first, that the Administrator find that the state has shown “compelling conditions” and second, that the proposed state requirement 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 available evidence.” The Senate Bill § 17 (adding new § 18(f)(1)). We are concerned that the Senate Bill’s proposed waiver requirement adds unnecessarily to the number of issues that might be litigated in a challenge to either a grant or denial of a state’s waiver application.

In addition, the framework of existing TSCA, left unchanged by the House Bill, does not clearly require the Administrator to make a timely decision on a waiver request. We would prefer that the statute specify a time period within which the Administrator shall make a reviewable decision regarding a state’s waiver request.

### **States Must Be Able to Keep Their “Cops on the Beat”**

Existing TSCA and many other federal environmental statutes, such as the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the CPSIA, permit states to adopt requirements that are identical to the requirements prescribed by the federal government.<sup>9</sup> This enables state Attorneys General and other state agencies to complement the resources of the federal government for enforcement. The current versions of both the House and Senate bills wisely continue to allow states to adopt requirements that are identical to EPA’s, although they place limits on the recovery of penalties that we believe hamper the important deterrent value of the statutory penalty scheme. *See* the House Bill § 7(a)(3) (adding new TSCA § 18(a)(3)); the Senate Bill § 17 (adding new TSCA §§ 18(d)(1)(A)(iv) and 18(d)(1)(B)). In this regard, we prefer the language in the Senate Bill, which would restrict a state’s recovery only if EPA has assessed an adequate penalty.

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<sup>8</sup> 15 U.S.C. § 2617(b).

<sup>9</sup> *See* 15 U.S.C. § 2617(a)(2)(B)(i); 7 U.S.C. § 136w-1; 15 U.S.C. § 2075(a).

Conclusion

The undersigned Attorneys General welcome the opportunity to continue to work with Congress to ensure that this important effort to improve federal regulation of toxic chemicals will not undermine a productive federal-state partnership in protecting the health and welfare of the public and our environment.

Thank you for your continuing consideration of our concerns. Sincerely,



Kamala D. Harris  
California Attorney General



Maura Healey  
Massachusetts Attorney General



Doug S. Chin  
Hawaii Attorney General



Eric T. Schneiderman  
New York State Attorney General



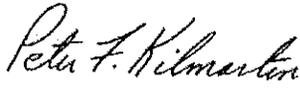
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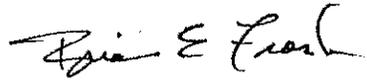
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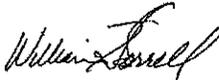
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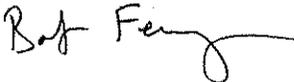
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cc: The Honorable Mitch McConnell, U.S. Senate Majority Leader  
The Honorable Harry Reid, U.S. Senate Minority Leader  
The Honorable Paul Ryan, U.S. House Speaker  
The Honorable Nancy Pelosi, U.S. House Minority Leader  
The Honorable John Cornyn, U.S. Senate Majority Whip  
The Honorable Dick Durbin, U.S. Senate Minority Whip  
The Honorable Kevin McCarthy, U.S. House Majority Leader  
The Honorable Steny Hoyer, U.S. House Minority Whip  
The Honorable Mike Rounds, Chairman, Subcommittee on Superfund,  
Waste Management, and Regulatory Oversight  
The Honorable Edward J. Markey, Ranking Member, Subcommittee on Superfund,  
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The Honorable David Vitter, U.S. Senate

