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Key Governmental Obligations Under TSCA Reform Legislation

Summary: *This alert summarizes the governmental obligations under the TSCA reform bills passed by the Senate and House of Representatives.*

On December 17, 2015, the Senate unanimously approved legislation to amend the Toxic Substances Control Act (TSCA). The Senate had been considering its own legislation, S. 697, but ultimately did not vote on that bill. Instead, it replaced the text of the bill passed by the House of Representatives, H.R. 2576, on June 23, 2015, with the text of S. 697, then passed H.R. 2576 as amended. All that remains for final enactment of the legislation is reconciliation of the version passed by the Senate with the version passed by the House. This reconciliation is underway.

For more information regarding the recent legislative activity, please see: [TSCA Legislation Passes the Senate, Nears Final Passage](#).

Legislation to amend TSCA, H.R. 2576, would impose a range of duties and deadlines on the Environmental Protection Agency (EPA) and, to a lesser degree, the White House's Office of Science and Technology Policy (OSTP). The attached tables summarize each of those duties and their corresponding deadlines.

Governmental Obligations Under H.R. 2576 - Senate Version

Table 1 outlines the governmental obligations that would be established under H.R. 2576 as passed by the Senate on December 17, 2015. It addresses the following topics:

- Organizational and administrative issues
- Prioritization, safety assessments, safety determinations, and risk management
- Active substances notification
- Confidential business information
- Miscellaneous duties

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Governmental Obligations Under H.R. 2576 - House of Representatives Version

Table 2 outlines the governmental obligations that would be established under H.R. 2576 as passed by the House of Representatives on June 23, 2015. It addresses the following topics:

- Organizational and administrative issues
- Risk evaluations, and regulating hazardous chemicals and mixtures
- Persistent, bioaccumulative, and toxic Chemicals
- Confidential business information

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Key Governmental Obligations Under TSCA Reform

Table 1 – H.R. 2576 as Passed by the Senate on December 17, 2015

Topic	Timing	Duty	Provision of TSCA as it would be amended
Organizational and Administrative			
Small Business	180 days after enactment, and at least once every 10 years thereafter	EPA must consult with the Small Business Administration and review the standards for small businesses under section 8(a)(3)(B) within 180 days of enactment and at least once every 10 years thereafter; As a part of this review, EPA must provide public notice and comment, determine whether a revision of the small business standard is warranted, and revise the standard, if necessary.	Section 8(a)(3)(C).
Sustainable Chemistry	180 days after enactment	The OSTP must convene an entity under the National Science and Technology Council to coordinate federal programs in support of sustainable chemistry within 180 days of enactment.	Section 27(c)(1).
Science Advisory Committee on Chemicals	1 year after enactment	EPA must establish a “Science Advisory Committee on Chemicals” that it must convene no less than once every 2 years.	Section 3A(j)(1).
Fees	1 year after enactment	EPA must establish, by rule, the payment of reasonable fees as a condition of submitting a pre-manufacture notice or requesting an exemption under section 5 and reasonable fees by a manufacturer or processor that: (a) submits a notice for an active chemical; (b) submits a notice to change the status of a chemical from inactive to active; reports information pursuant to section 8(a); or (c) manufactures or processes a chemical substance subject to a safety assessment and safety determination.	Section 26(b)(1).
General Policies, Procedures & Guidance	2 years after enactment	EPA must develop, by rule, any policies, procedures, and guidance the Agency determines is necessary to carry out sections 3A, 4, 4A, 5, and 6.	Section 3A(b).

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Key Governmental Obligations Under TSCA Reform

Topic	Timing	Duty	Provision of TSCA as it would be amended
Alternatives to Vertebrate Testing	2 years after enactment	EPA must develop a strategic plan to promote the development and implementation of alternative test methods and testing strategies to reduce vertebrate animal testing.	Section 5(c)(2)(A).
Chemical Data Reporting	2 years after enactment	EPA must promulgate rules requiring the maintenance of records and the reporting of additional information known or reasonably ascertainable by entities reporting under Chemical Data Reporting rule, including rules applicable to processors.	Section 8(a)(4)(A).
Sustainable Chemistry	2 years after enactment	OSTP must submit a national strategy on sustainable chemistry to the House Committee on Science, Space, and Technology and the House Committee on Energy and Commerce, and to the Senate Committee on Environment and Public Works, and the Senate Committee on Commerce, Science, and Transportation.	Section 27(f).
Sustainable Chemistry	3 years after enactment	OSTP must submit an implementation plan for sustainable chemistry (based on the findings of the national strategy) to the House Committee on Science, Space, and Technology and the House Committee on Energy and Commerce, and to the Senate Committee on Environment and Public Works, and the Senate Committee on Commerce, Science, and Transportation.	Section 27(c)(g).
Fees	Fiscal year 3 years after enactment, and every 3 years thereafter	EPA must increase or decrease the fees as necessary to adjust for inflation and to ensure the funds are sufficient to defray the costs of the program.	Section 26(b)(3)(F).
Alternatives to Vertebrate Testing	5 years after enactment, and every 5 years thereafter	EPA must submit a report to congress regarding the Agency's progress in implementing this subsection regarding vertebrate animal testing.	Section 5(c)(2)(E).
Chemical Testing Guidance	Deadline not defined	EPA must establish policies, procedures, and guidance for the testing of chemical substances under section 4.	Section 3A(g).

Key Governmental Obligations Under TSCA Reform

Topic	Timing	Duty	Provision of TSCA as it would be amended
Prioritization, Safety Assessments, Safety Determinations, and Risk Management			
Prioritization Screening	180 days after enactment and before the date of promulgation of the rule under section 4A(a)(1) establishing a risk-based screening process and criteria for identifying existing chemical substances that are high and low priorities	EPA must publish an initial list of at least 10 high-priority substances (at least 5 from the TSCA Work Plan) and 10 low-priority substances.	Section 4A(a)(2)(A).
Prioritization Screening	180 days after EPA establishes the prioritization screening process within 1 year of enactment	EPA must begin the prioritization screening process.	Section 4A(a)(3)(B)(i)(I).
Prioritization Screening	1 year after enactment	EPA must establish, by rule, a risk-based screening process and criteria for identifying existing chemical substances that are high and low priorities.	Section 4A(a)(1).
Prioritization Screening	As soon as practicable, but not later than 3 years after enactment	EPA must add additional substances to the priority lists sufficient to ensure at least 20 high-priority substances have undergone or are undergoing the process established in section 6(a) and 20 low-priority substances have been designated.	Section 4A(a)(2)(C)(i).
Prioritization Screening	As soon as practicable, but not later than 5 years after enactment	EPA must add additional substances to the priority lists sufficient to ensure at least 25 high-priority have undergone or are undergoing a safety assessment and 25 low-priority substances have been designated.	Section 4A(a)(2)(C)(ii).

Key Governmental Obligations Under TSCA Reform

Topic	Timing	Duty	Provision of TSCA as it would be amended
Prioritization Screening	At least every 5 years after EPA promulgates the final rule under section 4A(a)(1) establishing a risk-based screening process and criteria for identifying existing chemical substances that are high and low priorities	EPA must review the prioritization screening process and modify it, if necessary.	Section 4A(b)(10).
Prioritization Screening	Annually	EPA must publish an annual goal for the number of chemical substances that will be subject to the prioritization screening process.	Section 4A(a)(3)(B)(iii)(II).
Prioritization Screening	Ongoing	EPA must publish and keep current a list of chemical substances being considered in the prioritization screening process (including prioritization decisions that have been postponed) and which substances have been designated as a high-priority or low-priority substances.	Section 4A(a)(3)(D).
Prioritization Screening	90 days after receiving information regarding a chemical substance complying with a rule, consent agreement, or order	EPA must designate a substance as a high-priority or low-priority.	Section 4A(a)(3)(B)(ii).
Safety Assessments & Determinations	180 days after receiving a request	EPA must decide whether or not to grant a request by a manufacturer or processor to prioritize a substance for a safety assessment or safety determination.	Section 4A(c)(4)(B).
Safety Assessment Guidance	1 year after enactment	EPA must develop guidance to assist interested persons in developing their own draft safety assessments and other information for submission to EPA.	Section 3A(h)(2)(D).
Safety Assessments & Determinations	6 months after a chemical substance is designated as a high-priority substance	EPA must define and publish the scope of the safety assessment and safety determination, including the hazards, exposures, conditions of use, and potentially exposed or susceptible populations EPA expects to consider.	Section 6(a)(2).

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Topic	Timing	Duty	Provision of TSCA as it would be amended
Safety Assessments & Determinations	3 years after a substance is designated as a high-priority substance	EPA must complete and publish a safety assessment and safety determination; EPA may extend this deadline up to 1 year if additional information is needed.	Section 6(a)(4),(6).
Safety Assessments & Determinations	At the beginning of each year	At the beginning of each year, EPA must publish an annual plan: <ul style="list-style-type: none"> • Identifying the substances subject to safety assessments and safety determinations to be completed that year; • Describing the status of each ongoing safety assessment and safety determination; and • Including an updated schedule if the schedule for the completion of a safety assessment or safety determination has changed. 	Section 3A(h)(1)(C).
Safety Assessments & Determinations	Deadline not defined	EPA must inform the public regarding the schedule and resources necessary for the completion of each safety assessment and safety determination as soon as practicable after designation as a high-priority substance under section 6.	Section 3A(h)(1)(A).
Safety Assessments & Determinations	Deadline not defined	EPA must establish, by rule, policies and procedures regarding the manner in which EPA must carry out section 6 regarding safety assessments and determinations.	Section 3A(h)(2)(A).
Risk Management	2 years after a safety determination is completed	EPA must promulgate any necessary final rule pursuant to section 6(d).	Section 6(a)(5).

Key Governmental Obligations Under TSCA Reform

Topic	Timing	Duty	Provision of TSCA as it would be amended
Active Substances Notification			
Active Substances Notification	1 year after enactment	EPA, by rule, must require manufacturers and processors to notify EPA within 180 days of the final rule regarding each chemical substance on the Inventory that it has manufactured or processed for nonexempt commercial purposes during the 10-year period prior to the day of enactment. Prior to promulgating the rule under section 8(b)(4)(A) above, EPA must designate chemical substances reported under 40 C.F.R. Part 711 (the Chemical Data Reporting rule) during the reporting period that most closely preceded the date of enactment as the interim list of active substances for purposes of the section 4A prioritization screening process.	Section 8(b)(4)(A)(i). Section 8(b)(6).
Confidential Claims	1 year after EPA compiles the list of active substances	EPA must establish a plan to review all claims to protect the specific identities of chemical substances on the confidential portion of the list.	Section 8(b)(4)(C).
Confidential Claims	5 years after EPA compiles the list of active substances	EPA must complete implementation of the review; EPA may extend this timeline for up to 2 years based on an adequate public justification.	Section 8(b)(4)(E)(i)(I).
Confidential Claims	Annually	At the beginning of each year, EPA must publish an annual goal and the number of reviews completed in the prior year.	Section 8(b)(4)(E)(i)(II).
Confidential Business Information			
Confidentiality Claim	90 days after receipt of a confidentiality claim and 30 days after receipt of a request for an extension	EPA must review and approve, modify, or deny a confidentiality claim.	Section 14(g)(1)(A).
Public Disclosure	15 days after EPA provides notice to the claimant	EPA cannot release information under section 14(e)(3) and 14(e)(8) until 15 days after EPA provides notice to the claimant, unless the information is necessary to protect against an imminent and substantial harm to health or the environment.	Section 14(g)(1)(C)(i).

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Public Disclosure	60 days before the protection period ends for confidential information	EPA must provide to the person that asserted the claim a notice of the impending expiration of the confidentiality claim period.	Section 14(f)(1)(C)(i).
Public Disclosure	30 days after documentation is received	EPA must consider documentation provided by a person trying to rebut the presumption that confidential information should be publically disclosed, and make a determination; EPA must publically release the information if it determines that the information is not protected from disclosure.	Section 14(g)(3)(C).
Miscellaneous Duties			
Pre-manufacture Notices	90 days after receiving a new chemical notice	EPA must review a new chemical notice and make a determination within 90 days, which can be extended up to 90 days.	Section 5(d)(1).
Significant New Use Rules (SNURs)	90 days after issuing a consent agreement or order	Within 90 days of issuing a consent agreement or order regarding a new chemical, EPA must consider whether to promulgate a rule identifying significant new uses that do not conform to the agreement or order, or publish the basis for not initiating a rulemaking.	Section 5(d)(4)(B).
State Preemption Waivers	180 days after receiving a discretionary exemption application and 110 days after receiving a nondiscretionary exemption application	With regard to preemption waivers, EPA must make a determination regarding a discretionary exemption application within 180 days and a nondiscretionary exemption application within 110 days.	Section 18(f)(3).

Key Governmental Obligations Under TSCA Reform

Table 2 – H.R. 2576 as Passed by the House of Representatives on June 23, 2015

Topic	Timing	Duty	Provision of TSCA as it would be amended
Organizational and Administrative			
Congressional Reports	6 months after enactment and every 5 years thereafter	<p>EPA must submit a report that includes an estimation of EPA’s capacity to conduct and publish risk evaluations, and EPA’s capacity to promulgate rules under section 6(a) to the Senate Committee on Environment and Public Works, and the House Committee on Energy and Commerce.</p> <p>EPA must update and resubmit the report at least every 5 years.</p>	<p>Section 26(l)(1).</p> <p>Section 26(l)(2).</p>
Congressional Reports	Every 2 years	EPA must prepare and submit a report to the Senate Committee on Environment and Public Works, and the House Committee on Energy and Commerce that includes an accounting of fees paid to EPA and amounts disbursed from the treasury Fund to EPA.	Section 26(b)(3)(E)(i).
General Policies, Procedures & Guidance	2 years after enactment	EPA must develop policies, procedures, and guidance as necessary to carry out the amendments to TSCA.	Section 26(k)(1).
General Policies, Procedures & Guidance	5 years after enactment and at least every 5 years thereafter	EPA must review the adequacy of its policies, procedures, and guidance, and revise such policies, procedures, and guidance as necessary.	Section 26(k)(2).
Risk Evaluations, and Regulating Hazardous Chemicals and Mixtures			
Risk Evaluation	Beginning in the first fiscal year after enactment and every fiscal year thereafter	EPA must initiate 10 or more risk evaluations.	Section 6(b)(7).

Key Governmental Obligations Under TSCA Reform

Topic	Timing	Duty	Provision of TSCA as it would be amended
Risk Evaluation	3 years after EPA determines that a chemical substances may present an unreasonable risk or begins the risk evaluation process for a chemical on the TSCA Work Plan	EPA must conduct and publish a risk evaluation. EPA may extend this timeframe if the Agency determines that additional information is necessary to make a risk evaluation determination; The timing may only be extended by 2 years, and EPA must complete the evaluation within 90 days of receiving additional information.	Section 6(b)(5)(A)(i). Section 6(b)(5)(D)(ii).
Risk Evaluation	2 years after a manufacturer requests a risk evaluation	EPA must conduct and publish a risk evaluation within 2 years after a manufacturer requests a risk evaluation (or within 2 years after the Agency has the resources to conduct further risk evaluations). EPA may extend this timeframe if the Agency determines that additional information is necessary to make a risk evaluation determination; the timing may only be extended by 2 years, and EPA must complete the evaluation within 90 days after receiving additional information.	Section 6(b)(5)(A)(ii). Section 6(b)(5)(D)(ii).
Risk Evaluation	30 days before EPA publishes a final determination that a chemical substance does not pose an unreasonable risk	EPA must make a preliminary risk evaluation determination that a chemical substance does not present an unreasonable risk, and provide public notice and an opportunity to comment on the preliminary determination prior to publishing the final determination.	Section 6(b)(6)(A).
Section 6(a) Rules	1 year after a risk evaluation is published	EPA must propose a rule under section 6(a) regulating the hazardous substance or mixture.	Section 6(b)(5)(C)(i).
Section 6(a) Rules	2 years after a risk evaluation is published	EPA must finalize a rule under section 6(a) regulating the hazardous substance or mixture.	Section 6(b)(5)(C)(ii).

Key Governmental Obligations Under TSCA Reform

Topic	Timing	Duty	Provision of TSCA as it would be amended
Critical Use Exemption	5 years after an exemption is granted	An exemption for a specific critical use of a chemical substance or mixture from a requirement established under section 6(a) expires after 5 years, but may be renewed for one or more additional 5-year periods.	Section 6(h)(3).
Persistent, Bioaccumulative, and Toxic Chemicals			
PBT List	9 months after enactment	EPA must publish a list of persistent, bioaccumulative, and toxic chemical substances.	Section 6(i)(1).
PBT List	2 years after enactment	EPA must designate chemical substances from the PBT list as “PBT chemicals of concern” if: <ul style="list-style-type: none"> • The chemical substance scores high with respect to either persistence or bioaccumulation, and high or moderate for the other category (based on the 2012 TSCA Work Plan Chemicals Method Document); and • Exposure of the general population or a potentially exposed subpopulation to the chemical substance is likely. 	Section 6(i)(2).
Section 6(a) Rules	2 years after designating a chemical substance as a PBT chemical of concern	EPA must promulgate a rule under section 6(a) to reduce likely exposure to a chemical substance that has been designated as a PBT chemical of concern under section 6(i)(2).	Section 6(i)(3).
Exclusion from PBT Subsection	Prior to 90 days after EPA publishes the PBT list under section 6(i)(1)	Chemical substances that EPA has determined may present an unreasonable risk under section 6(b)(3)(A)(i) or for which a manufacturer requests a risk evaluation under section (6)(b)(3)(A)(ii) prior to 90 days after EPA publishes the PBT list are not subject to the PBT provisions under section 6(i).	Section 6(i)(4).

Key Governmental Obligations Under TSCA Reform

Topic	Timing	Duty	Provision of TSCA as it would be amended
Confidential Business Information			
Confidentiality Claim	10 years after designation	Confidentiality claims expire after 10 years, at which time the information is publically disclosed.	Section 14(c)(1)(B).
Public disclosure	60 days prior to making the information public	EPA must notify the manufacturer, processor, or distributor who designated the information as confidential of the date on which the information will be made public.	Section 14(c)(1)(C).