Protecting Stakeholder Interests Under the New Section 6 of TSCA

Mark N. Duvall
Ryan J. Carra
Timothy M. Serie
Beveridge & Diamond, P.C.
1350 I Street, N.W., Suite 700
Washington, DC 20005

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ABSTRACT

Stakeholders face radically changed requirements for identifying, evaluating, and regulating chemical substances under section 6 of the amended Toxic Substances Control Act (TSCA), 15 U.S.C. § 2601 et seq. Now manufacturers, processors, and end users of specific chemical substances, as well as others with an interest in those substances, must confront the challenges posed by a newly invigorated TSCA. The Environmental Protection Agency (EPA) can regulate, is regulating, and will regulate chemical substances as never before. Stakeholders should take advantage of the opportunities available to influence potential EPA decisions that may determine the future commercial viability of those substances.

This paper explores those challenges and opportunities. After a brief review of the regulatory scheme under the amended section 6, it suggests answers to the following questions faced by stakeholders under section 6:

- Why should I care if EPA reviews my chemical substance?
- Is EPA already reviewing my chemical substance?
- When will EPA take actions for additional chemical substances?
- Is EPA likely to take action on my chemical substance?
- Is my chemical substance a good candidate for designation as a low-priority substance?
- How can I influence whether EPA decides to conduct a risk evaluation for my chemical substance?
- Once EPA designates my chemical substance for a risk evaluation, how can I protect my interests?
- Once EPA determines that my chemical presents an unreasonable risk, how can I protect my interests?

DISCUSSION

1. The New Section 6

TSCA reform legislation, the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA), was enacted on June 22, 2016.[1] The most fundamental changes to TSCA were to section 6. Originally, section 6 did not charge EPA with any particular mission or a timetable for completing work on those chemical substances that it did consider regulating. In contrast, section 6 now directs EPA to take three key steps while meeting deadlines for completing action.

[1] Pub. L. 114-182 (June 22, 2017). The LCSA is available at https://www.congress.gov/114/plaws/publ182/PLAW-114publ182.pdf. The current text of TSCA (all titles) is available at https://legcounsel.house.gov/Comps/Toxic%20Substances%20Control%20Act.pdf. The U.S. Code version of TSCA as amended is available at http://uscode.house.gov/view.xhtml?path=/prelim@title15/chapter53&edition=prelim. Redlined changes to the original TSCA made by the LCSA as prepared by the Environmental Defense Fund are available at http://blogs.edf.org/health/files/2016/06/TSCA-as-amended-by-final-bill-6-22-16.pdf. References to sections of TSCA in this paper are to TSCA as amended by the LCSA unless otherwise indicated.

The first step, described in amended section 6(b)(1), is for EPA to designate chemical substances[2] as high or low priorities for risk evaluation. This step is known as prioritization. EPA must complete the prioritization process in nine to twelve months after initiating the process for a particular chemical substance. EPA must meet prescribed quotas for designating high- and low-priority substances for the first few years after enactment.[3]

The second step, described in amended section 6(b)(2)-(4), is for EPA to conduct risk evaluations of high-priority substances; the ten chemical substances or categories selected for initial risk evaluations; and chemical substances for which EPA has granted manufacturer requests for a risk evaluation. Through the risk evaluation, EPA must:

> determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use.[4]

The important term "conditions of use" is defined to mean:

> the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.[5]

EPA has three years after initiating the risk evaluation in which to complete this step, subject to a possible six-month extension.[6]

The third step, under section 6(c), is for EPA to regulate those chemical substances found to present an unreasonable risk through rulemaking. EPA has two years after making an "unreasonable risk" determination to complete the rulemaking, subject to possible extension.[7]

Section 6 gave EPA one year to adopt final procedural rules for implementing the prioritization and risk evaluation steps.[8] EPA met that deadline by releasing prepublication versions of those final rules on June 22, 2017. The rules were later published in the Federal Register.[9]

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[2] The term "chemical substance" is defined in TSCA § 3(2)(B) to exclude pesticides and FDA-regulated materials, among other things. Under TSCA § 26(c)(1), EPA may take actions with respect to categories of chemical substances, and EPA has already done so since enactment of the LCSA.
[3] TSCA § 6(b)(2).
[4] TSCA § 6(b)(4)(A).
[5] TSCA § 3(4).
[6] TSCA § 6(b)(4)(G).
[7] TSCA § 6(c)(1).
[8] TSCA § 6(b)(1)(A), 6(b)(4)(B).
[9] The prioritization rule, 40 C.F.R. Part 702, Subpart A, appeared at 82 Fed. Reg. 33753 (July 20, 2017). The risk evaluation rule, 40 C.F.R. Part 702, Subpart B, appeared at 82 Fed. Reg. 33726 (July 20, 2017). See Beveridge & Diamond, EPA Releases TSCA Final Rule on Prioritization of High-Priority and Low-Priority Chemical Substances (July 20, 2017), http://www.bdlaw.com/news-2112.html; Beveridge & Diamond, EPA's Risk Evaluation Framework Rule Incorporates Key Industry Suggestions (July 20, 2017), http://www.bdlaw.com/news-2104.html.

2. Why Should I Care if EPA Reviews My Chemical Substance?

Stakeholders may be impacted if EPA were to take regulatory action under TSCA under section 6 with respect to a particular chemical substance. That impact could come in several forms:

- EPA may require testing of chemical substances under consideration for prioritization in order to close data gaps before making a prioritization decision. EPA now has the authority to issue orders to manufacturers and processors of chemical substances "for the development of new information for the purposes of prioritizing a chemical substance under section 6(b)."[10] Such testing could cost millions of dollars.

- EPA may designate a chemical substance as one which "may present an unreasonable risk." That is the standard for qualifying as a high-priority substance under section 6(b)(1)(B)(i), meaning that EPA will conduct a risk evaluation to determine whether the substance presents an unreasonable risk. In the final prioritization regulations, EPA emphasized that designation as a high-priority substance "is not a finding that the chemical substance presents an unreasonable risk."[11] Nevertheless, stakeholders interested in a chemical substance for which EPA has made a "may present" finding may observe a negative reaction to the substance by the marketplace, since it indicates that EPA is sufficiently concerned about the substance that it has placed it on the track toward possible regulation. The "may present" standard is available to EPA for imposing a section 5(e) order to ban or restrict a new chemical substance that is the subject of a premanufacture notice (PMN).[12] Prior to enactment of the LCSA, EPA issued 1,729 section 5(e) orders and 739 significant new use rules (SNURs) under section 5(a)(2) following issuance of a section 5(e) order. In most cases, EPA issued those section 5(e) orders based solely on a "may present" finding.[13] Those SNURs extended most of the restrictions of the section 5(e) orders to all manufacturers and processors of those substances.[14] At least under section 5, then, EPA has extensively relied on a "may present" finding to restrict chemical substances. Designation of a chemical substance as a high-priority substance based on a "may present" finding thus arguably creates the expectation that EPA is likely to restrict that substance also, notwithstanding EPA's cautionary statement in the prioritization regulations. This is particularly the case since EPA has declared that if a single category of use for a chemical substance is found in the risk evaluation to "present" an unreasonable risk, it must regulate the substance even though all other conditions of use do not present an unreasonable risk.[15] Thus, the designation of a chemical substance as a high-priority substance may have adverse commercial repercussions well before EPA conducts a risk evaluation or regulates it.

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[10] TSCA § 4(a)(2)(B).
[11] 40 C.F.R. § 702.17, 82 Fed. Reg. 33753, 33764 (July 20, 2017).
[12] TSCA § 5(a)(3)(B)(ii)(I).
[13] While pre- and post-enactment "may present" findings differ in some ways, they are still similar.
[14] EPA, Statistics for the New Chemicals Review Program under TSCA (last updated Aug. 24, 2017), https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review.
[15] 40 C.F.R. § 702.49(c), 82 Fed. Reg. at 33753.

- EPA may determine that a chemical substance "presents an unreasonable risk." Under section 6(b)(4)(A), that is one of two possible outcomes of a risk evaluation; the other is that the substance does not present an unreasonable risk. A "presents an unreasonable risk" determination may be commercially devastating for a chemical substance, even before EPA promulgates a rule imposing a ban or restrictions. The marketplace may be expected to deselect products containing such a substance, at least for the conditions of use determined by EPA to present the unreasonable risk. That designation may also place manufacturers, processors, and end users of chemical substances so designated in danger of increased tort liability. Section 18(g) now provides that the LCSA amendments do not affect tort liability. Nevertheless, under a "reasonable person" standard, plaintiffs' lawyers may be expect to argue that the EPA determination that a chemical substance "presents an unreasonable risk" is evidence of negligence by those who manufacture, process, or use that substance, at least for the conditions of use for which EPA makes that determination.

- EPA may ban or restrict future manufacture, processing, distribution, use, and disposal of a chemical substance. Under section 6(c), once it has made a determination that a chemical substance presents an unreasonable risk, EPA must adopt a risk management rule either banning or restricting the substance. As explained below, EPA has already issued proposed rules banning particular uses of three chemical substances (methylene chloride, n-methylpyrrolidone, and trichloroethylene), and it has begun work on risk evaluations that could lead to bans or restrictions on other uses of those substances as well. EPA is directed by section 6(a) to impose bans or restrictions "to the extent necessary so that the chemical substance or mixture no longer presents such a risk." In addition, for certain persistent, bioaccumulative, and toxic chemical substances (PBTs), section 6(h)(4) and (h)(5) direct EPA to "reduce exposure to the substance to the extent practicable." EPA has already begun work on several PBTs under section 6(h)(4).

Thus, even before EPA imposes a ban or restriction, EPA actions under section 6 with respect to a chemical substance could adversely affect the manufacturer, processor, or end user of the substance.

EPA may also take action under section 6 with respect to a chemical substance in ways that may help manufacturers, processors, and end users of the substance:

- EPA may designate the chemical substance as low priority for receiving a risk evaluation. The standard for a low-priority designation is that EPA must find that the substance "does not meet" the standard for a high-priority substance,[16] i.e., that the substance does not meet the "may present" standard. Section 6(b)(2)(B) directs EPA to designate at least 20 low-priority substances by December 22, 2019.[17] Having a low-priority designation for a

[16] TSCA § 6(b)(1)(B)(ii).

[17] Notably, TSCA does not call for EPA to designate additional low-priority substances after the initial 20. Nevertheless, EPA has decided that "[a]s a policy matter, EPA is committed to making Low-Priority designations on an ongoing basis beyond the statutory minimum." 82 Fed. Reg. at 33755.

chemical substance may provide at least some help in the marketplace and with tort suits for manufacturers, processors, and end users of the substance.[18]

- EPA may determine that the substance does not present an unreasonable risk under any of the conditions of use within the scope of the risk evaluation. That determination could come after EPA completes its risk evaluation for a chemical substance. The determination may have the effect of preempting both existing and future state or local statutes, criminal penalties, and administrative actions applicable to that substance.[19]

- Alternatively, the risk evaluation may conclude that the conditions of use of importance to the stakeholder do not present an unreasonable risk, even though other conditions do present an unreasonable risk.[20] Such a determination could prove helpful in the marketplace and in tort litigation.

- EPA may adopt a reasonable risk management rule that preempts both existing and future state and local statutes, criminal penalties, and administrative actions for the chemical substance.[21] Furthermore, compliance with the restrictions in a risk management rule may help with potential tort liability. Since EPA must adopt restrictions for chemical substances found to present an unreasonable risk "to the extent necessary so that the chemical substance or mixture no longer presents such a risk," compliance with those restrictions may be evidence that a manufacturer, processor, or end user of the substance acted reasonably.

In short, there may be compelling reasons why a stakeholder may, or may not, want to have EPA take action under section 6 with respect to a particular substance.

3. Is EPA already reviewing my chemical substance?

Since enactment of the LCSA in June 2016, EPA has identified at least 27 chemical substances for which it has taken or may take action under section 6. Stakeholders should know whether or not substances of importance to them are included.

Pursuant to section 6(b)(2)(A), EPA has identified the first ten chemical substances or categories of chemical substances to receive risk evaluations. They include the following:

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[18] The preamble to the prioritization rule explained, "Chemical substances with low hazard and/or exposure potential that meet the definition of Low-Priority Substances are taken out of consideration for further assessment. This gives the public notice of chemical substances for which the hazard and/or exposure potential is anticipated to be low or nonexistent, and provides some insight into which chemical substances are likely not to need additional evaluation and risk management under TSCA." 82 Fed. Reg. at 33755.

[19] TSCA § 18(a)(1)(B)(i). However, note that this potential for preemption is limited by section 18(c)-(g).

[20] Under 40 C.F.R. § 702.47, "As part of the risk evaluation, EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under each condition of uses within the scope of the risk evaluation, either in a single decision document or in multiple decision documents."

[21] TSCA § 18(a)(1)(B)(ii). However, note that this potential for preemption is limited by section 18(c)-(g).

- Asbestos (a category of six chemical substances)[22]
- 1-Bromopropane, CAS No. 106-94-5
- 1,4-Dioxane, CAS No. 123-91-1
- Carbon tetrachloride, CAS No. 56-23-5
- Cyclic aliphatic bromide cluster (a category of three flame retardants)[23]
- Methylene chloride, CAS No. 75-09-2
- N-methylpyrrolidone (NMP), CAS No. 872-50-4
- Pigment Violet 29 (Anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-1,3,8,10(2H,9H)-tetrone), CAS No. 81-33-4
- Tetrachloroethylene (perchloroethylene), CAS No. 127-18-4
- Trichloroethylene (TCE), CAS No. 79-01-6

Since naming these initial chemical substances, EPA has developed scoping documents for their risk evaluations. [24] Separately, EPA has also issued proposed bans under section 6(a) of certain narrow uses of three of these chemical substances (methylene chloride, n-methylpyrrolidone, and trichloroethylene).[25]

EPA has also identified the following chemical substances for regulation as PBTs under section 6(h):

- Decabromodiphenyl ethers (decaBDE), CAS No. 1163-19-5
- Hexachlorobutadiene (HCBD), CAS No. 87-68-3
- Pentachlorothiophenol (PCTP), CAS No. 133-49-3
- Phenol, isopropylated, phosphate (3:1) (a structural grouping of at least three chemical substances)[26]

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[22] In the scoping document for the risk evaluation for asbestos, EPA explained that it "has adopted the definition of asbestos as defined by TSCA Title II (added to TSCA in 1986), Section 202 as the 'asbestiform varieties of six fiber types – chrysotile (serpentine), crocidolite (riebeckite), amosite (cummingtonite-grunerite), anthophyllite, tremolite or actinolite.' The latter five fiber types are amphibole varieties. The general CAS Registry Number (CASRN) of asbestos is 1332-21-4; this is the only asbestos on the TSCA Inventory. However, CASRNs are also available for specific fiber types." EPA, Scope of the Risk Evaluation for Asbestos (June 2017) at 9, https://www.epa.gov/sites/production/files/2017-06/documents/asbestos_scope_06-22-17.pdf. The six fiber types thus are chrysotile (serpentine), CAS No. 12001-29-5; crocidolite (riebeckite), CAS No. 12001-28-4; amosite (cummingtonite-grunerite), CAS No. 12172-73-5; anthophyllite, CAS No. 17068-78-9; tremolite, CAS No. 14567-73-8; and actinolite, CAS No. 12172-67-7.

[23] In the scoping document for the cyclic aliphatic bromide cluster, EPA explained that the cluster includes hexabromocyclododecane (HBCD), CAS No. 25637-99-4; 1,2,5,6,9,10-hexabromocyclododecane (1,2,5,6,9,10-HBCD, CAS No. 3194-55-6; and 1,2,5,6-tetrabromocyclooctane, CAS No. 3195-57-8. EPA, Scope of the Risk Evaluation for Cyclic Aliphatic Bromides Cluster (June 2017) at 8, https://www.epa.gov/sites/production/files/2017-06/documents/hbcd_scope_06-22-17_0.pdf.

[24] 81 Fed. Reg. 91927 (Dec. 19, 2016). See Beveridge & Diamond, EPA Unveils Scoping Analysis for Risk Evaluations under Amended TSCA, Requests Comments on the First Ten Chemicals (July 5, 2017), http://www.bdlaw.com/news-2098.html.

[25] The proposed rule for methylene chloride and n-methylpyrrolidone appeared at 82 Fed. Reg. 7464 (Jan. 19, 2017). EPA issued two proposed rules for trichloroethylene, which appeared at 81 Fed. Reg. 91592 (Dec. 16, 2016) and 82 Fed. Reg. 7432 (Jan. 19, 2017).

[26] According to EPA, this name applies to "a family of structures in which each of the three aryl groups have at least one isopropyl group." The document identifies three chemical substances that meet that structure: tris(3-isopropylphenyl) phosphate, CAS No. 72668-27-0; tri(isopropylphenyl) phosphate, CAS No. 26967-76-0; and tri(4-

- 2,4,6-Tris(tert-butyl) phenol, CAS No. 732-26-3

EPA has developed a background document for each of these chemical substances or categories that provides preliminary information on their manufacturing, processing, distribution, use, and disposal as first step toward developing an exposure and use assessment for them under section 6(h)(1)(B).[27]

Also, EPA has announced two chemical substances that are the subject of manufacturer requests that EPA conduct risk evaluations.[28] The two announced chemical substances are ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,5,5-tetramethyl-2-naphthalenyl), CAS No. 54464-59-4, and ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl), CAS No. 55464-57-2. According to EPA, these two would have been included with the section 6(h) chemical substances but for the manufacturer requests. EPA has indicated that it will evaluate these two substances, with the evaluations to be completed in fiscal year 2020.[29]

Clearly, EPA has approached its responsibilities under section 6 with vigor since enactment of the LCSA. Stakeholders interested in these 27 chemical substances already selected for review under section 6 should be aware of EPA's focus on them.

4. When will EPA take actions for additional chemical substances?

By December 22, 2019, EPA must ensure that it is conducting risk evaluations on at least 20 high-priority substances and has designated at least 20 low-priority substances.[30] To date, EPA has not designated any high- or low-priority substances, as the initial ten substances or categories were not considered to be high-priority substances.[31]

Before EPA may officially prioritize a chemical substance as a high- or low-priority substance, it must follow the procedures described in section 6(b)(1)(A), which are codified in the prioritization rule. Following those procedures must take EPA at least nine months and no longer than twelve months.[32] Assuming that EPA begins to conduct a risk evaluation for a high-priority substance on the date that it officially designates the substances as high priority, EPA

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isopropylphenyl) phosphate, CAS No. 2502-15-0. EPA, Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Phenol, isopropylated, phosphate (3:1) (Aug. 2017) at 2, https://www.epa.gov/sites/production/files/2017-08/documents/pip3-1_-_use_information_8-10-17.pdf.

[27] See Beveridge & Diamond, EPA Publishes Background Documents for Five PBT Chemicals, Hosting Webinar in Early September (Aug. 23, 2017), http://www.bdlaw.com/news-2114.html.

[28] EPA, Persistent, Bioaccumulative, and Toxic (PBT) Chemicals under TSCA Section 6(h), https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/persistent-bioaccumulative-and-toxic-pbt-chemicals-under.

[29] EPA, Initial Report to Congress on the EPA's Capacity to Implement Certain Provisions of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Jan. 2017) at 3, 5, https://www.epa.gov/sites/production/files/2017-01/documents/tsca_report_to_congress.pdf.

[30] TSCA § 6(b)(2)(B).

[31] Under TSCA § 6(b)(2)(A), EPA was required to ensure that risk evaluations were being conducted on the first ten chemical substances or categories by December 22, 2016, but it was not required to designate those substances as high-priority, nor did it do so.

[32] TSCA § 6(b)(2)(C).

must begin the official prioritization process no later than March 22, 2019. Of course, the process may begin earlier.

This means that the activities necessary to identify candidates for prioritization is probably already underway. The nine- to twelve-month period for prioritization begins upon publication of a Federal Register notice identifying a chemical substance for prioritization.[33] Before this time, EPA must identify appropriate candidates through what has been referred to as pre-prioritization.

EPA did not adopt a formal pre-prioritization step in its procedural rule, feeling that additional comment was necessary,[34] but in the preamble to the proposed rule it described what it has been considering for pre-prioritization:

> [P]rior to initiating the prioritization process for a chemical substance, EPA will generally review the available hazard and exposure-related information, and evaluate whether that information would be sufficient to allow EPA to complete both prioritization and risk evaluation processes. As part of such an evaluation, EPA expects to consider the quality, objectivity, utility, and integrity of the available information. To the extent the information is not currently available or is insufficient, EPA will determine whether or not information can be developed and collected, reviewed and incorporated into analyses and decisions in a timely manner.[35]

As a result, while EPA has not specifically identified any chemical substances or categories it is considering for prioritization, it is almost certainly already working to identify the candidates for prioritization that it must announce prior to March 2019.

5. Is EPA likely to take action on my chemical substance?

The best approach to projecting whether or not a particular chemical substance will become the subject to EPA action under section 6 is to analyze the substance as EPA would under section 6(b) and the prioritization rule. EPA faces resource constraints in selecting chemical substances for prioritization and risk evaluation. This means that EPA must be quite selective in identifying additional candidates for prioritization.

a. The TSCA Work Plan Chemicals and Categories

An initial reference point is the 2014 update to the TSCA Work Plan list.[36] This list includes 90 chemical substances or chemical categories. At least 50% of the initial 20 high-priority substances must come from this list.[37] Stakeholders should review that list to see if their

[33] 40 C.F.R. § 702.7(c), 82 Fed. Reg. at 33763.
[34] 82 Fed. Reg. at 33757.
[35] 82 Fed. Reg. at 4831.
[36] EPA, TSCA Work Plan for Chemical Assessments: 2014 Update (Oct. 2014), https://www.epa.gov/sites/production/files/2015-01/documents/tsca_work_plan_chemicals_2014_update-final.pdf.
[37] TSCA § 6(b)(2)(B).

important chemical substances are included, since being listed increases the likelihood of becoming subject to section 6 action.

All of the initial ten chemical substances and categories were required to come from that list as well,[38] as were the five PBT chemical substances or categories designated under section 6(h) and the two chemical substances for which manufacturer requests are known to have been made.[39] This leaves 73 chemical substances or categories from the 2014 update remaining to be designated for risk evaluations.

Of those, EPA is directed to give preference to those on the list that have a Persistence and Bioaccumulation Score of 3 (as indicated on that list) and to those that are known human carcinogens and have high acute and chronic toxicity (as indicated on that list).[40] The chemical substances meeting those criteria not already designated for risk evaluations are the following:

- Arsenic and arsenic compounds (acute and chronic toxicity from inhalation exposures)
- Cadmium and cadmium compounds (acute and chronic toxicity from inhalation exposures)
- Chromium and chromium compounds (acute and chronic toxicity from inhalation exposures)
- Cobalt and cobalt compounds (Persistence & Bioaccumulation Score of 3)
- Lead and lead compounds (Persistence & Bioaccumulation Score of 3)
- Long-chain chlorinated paraffins ($C_{18\text{-}20}$) (Persistence & Bioaccumulation Score of 3)
- Medium-chain chlorinated paraffins ($C_{14\text{-}17}$) (Persistence & Bioaccumulation Score of 3)
- Molybdenum and molybdenum compounds (acute and chronic toxicity from inhalation exposures)
- Nickel and nickel compounds (acute and chronic toxicity from inhalation exposures)
- Octamethylcyclotetrasiloxane (D4), CAS No. 556-67-2 (Persistence & Bioaccumulation Score of 3)
- Pigment Yellow 83 (Butanamide, 2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)biz(azo)bis[N-(4-chloro-2, 5- dimethoxyphenyl)-3-oxo-), CAS No. 5565,15-7 (Persistence & Bioaccumulation Score of 3)

Seven of these listings are categories of metals or metal compounds.[41] In identifying priorities for risk evaluations and conducting risk evaluations on metals and metal compounds, EPA must use the 2007 Framework for Metals Risk Assessment or a future successor

[38] TSCA § 6(b)(2)(A).
[39] TSCA § 6(h)(1).
[40] TSCA § 6(b)(2)(D).
[41] The 2014 update included one additional metals category, antimony and antimony compounds. EPA completed a risk assessment on antimony trioxide (ATO) in 2014 focused on ecological risks from the use of ATO as a synergist in halogenated flame retardants. It found no concern for this use of ATO. The risk assessment noted that "ATO is the most widely used antimony compound, accounting for roughly 80 percent of primary (*i.e.*, mined) antimony consumption in the US." EPA, TSCA Work Plan Chemical Risk Assessment Antimony Trioxide (Aug. 2014), https://www.epa.gov/sites/production/files/2015-09/documents/ato_ra_8-28-14_final.pdf. Accordingly, it is unlikely that EPA will prioritize antimony and antimony compounds as a high priority for many years.

document.[42] That document recognizes that "metals present unique risk assessment issues." These issues may cause EPA to defer identifying the metals and metal compounds listed in the 2014 update as candidates for prioritization.

Long-chain and medium-chain chlorinated paraffins were the subject of risk assessments conducted under section 5.[43] EPA might be taking the position that it does not have to designate them as high-priority substances at this point and can instead proceed to rulemaking under section 6(a).[44]

Octamethylcyclotetrasiloxane (D4) was the subject of a 2014 testing consent agreement "to conduct environmental monitoring to characterize specified sources and pathways of release of D4 to the environment and resulting exposure of aquatic and sediment dwelling organisms to D4."[45] EPA will have to evaluate the voluminous testing results submitted under that testing agreement to determine whether or not it can make the "may present an unreasonable risk" finding for D4 necessary for designation as a high-priority substance.

How will EPA select among the remaining TSCA Work Plan chemicals? It has statutory and regulatory priorities (described below), but additional factors may also be considered, such as the extent to which other federal agencies are addressing the chemicals. For example, the 2014 update added a group of seven phthalates[46] and bisphenol A (BPA).[47] However, the

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[42] TSCA § 6(b)(2)(E). The Framework for Metals Risk Assessment (Mar. 2007) is available at https://www.epa.gov/sites/production/files/2013-09/documents/metals-risk-assessment-final.pdf. It notes that "data may not be available to implement all the steps in a metals risk assessment (e.g., lack of information about metal speciation in some environmental media), requiring use of assumptions and a discussion of how such uncertainty influences the risk outcome;" and that "the latest scientific data on bioaccumulation do not currently support the use of bioconcentration factors and bioaccumulation factors when applied as generic threshold criteria for the hazard potential of metals." The ATO risk assessment cited the Framework for Metals Risk Assessment for the assertion that "[c]onsiderable uncertainty may be associated with the application of metal bioaccumulation (or bioconcentration) factors," but did not otherwise appear to rely on it.

[43] EPA, Standard Review Risk Assessment of Medium-chain and Long-chain Chlorinated paraffins submitted as PMNs by INEOS (Dec. 22, 2015), https://www.epa.gov/sites/production/files/2015-12/documents/standard_review_risk_assessment_ineos_p-12-0433-0453_docket.pdf; EPA, TSCA New Chemicals Review Program Standard Review Risk Assessment on Medium-Chain Chlorinated Paraffins (PMN P-12-0282, P-12-0283) and Long-Chain Chlorinated Paraffins (PMN P-12-0284) (2015), https://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OPPT-2015-0789-0016&contentType=pdf. It is not clear if EPA regards these documents as final, as it was considering obtaining peer review for them.

[44] TSCA § 26(l)(4) provides, "With respect to a chemical substance listed in the 2014 update to the TSCA Work Plan for Chemical Assessments for which the Administrator has published a completed risk assessment prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator may publish proposed and final rules under section 6(a) that are consistent with the scope of the completed risk assessment for the chemical substance and consistent with other applicable requirements of section 6." It is not clear that these risk assessments were "completed" prior to June 22, 2016, however, since upon issuance of the risk assessments EPA "requested new available data on certain chlorinated paraffins in different industries and for different uses, to inform the risk assessments for chlorinated paraffins." 80 Fed. Reg. 79886 (Dec. 23, 2015). It subsequently indicated that it would seek peer review of those risk assessments.

[45] Enforceable Consent Agreement for Environmental Testing for Octamethylcyclotetrasiloxane (D4) (CASRN 556-67-2) (Feb. 6, 2014), Docket No. EPA-HQ-OPPT-2012-0209. The agreement is referenced at 40 C.F.R. § 799.5000.

[46] The group of phthalates includes: dibutyl phthalate (DBP), CAS No. 84-74-2; butyl benzyl phthalate (BBP), CAS No. 85-68-7; di-(2-ethylhexyl) phthalate (DEHP), CAS No 117-81-7; di-*n*-octyl phthalate (DnOP), CAS No. 1117-84-0; di-isononyl phthalate (DINP), CAS No. 28553-12-0; di-isodecyl phthalate (DIDP), CAS No. 26761-40-0; di-isobutyl phthalate (DIBP), CAS No. 84-69-5.

phthalates, along with a previously-listed phthalate,[48] are being addressed for certain applications by the Consumer Product Safety Commission.[49] In the 2014 update, EPA said that all of these phthalates "will also be evaluated by EPA to determine if there are TSCA-specific scenarios that should be assessed." EPA has not publicly provided further information about its evaluation of such scenarios. Similarly, many uses of BPA are subject to FDA jurisdiction, and FDA continues to evaluate the safety of BPA for those uses.[50] EPA has released an alternatives analysis for the use of BPA in thermal paper, an application subject to TSCA.[51]

More likely to be named high-priority substances are three clusters of flame retardants for which EPA had begun work under the TSCA Work Plan:[52]

- The brominated phthalate cluster[53]
- The chlorinated phosphate esters cluster[54]
- The tetrabromobisphenol A and related chemicals cluster[55]

The fourth cluster from the TSCA Work Plan, the cyclic aliphatic bromide cluster, was included in the initial ten chemicals and categories.

b. Other Criteria for Identifying Chemical Substances

EPA may select chemicals and categories other than those on the TSCA Work Plan list as high-priority substances. Accordingly, stakeholders should consider evaluating the chemical substances of importance to them against the criteria EPA will use in selecting candidates or selecting among candidates for prioritization.

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[47] BPA is more formally known as phenol, 4,4'-(1-methylethylidene)bis-, CAS No. 80-05-7.
[48] The previously-listed phthalate is di-cyclohexyl phthalate (DCHP), CAS No. 84-61-7.
[49] 16 C.F.R. Part 1307 (restricting DBP, BBP, DEHP, DINP, DnOP, and DIDP); 79 Fed. Reg. 78324 (Dec. 30, 2014) (proposing to restrict DIBP and DCHP).
[50] See FDA, "Bisphenol A (BPA), https://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/ucm166145.htm.
[51] EPA, Bisphenol A Alternatives in Thermal Paper Final Report (Aug. 2015), https://www.epa.gov/sites/production/files/2015-08/documents/bpa_final.pdf.
[52] See EPA, "Assessments Conducted on TSCA Work Plan Chemicals Prior to June 22, 2016," https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/assessments-conducted-tsca-work-plan-chemicals-prior.
[53] The brominated phthalate cluster includes seven flame retardants: 1,2-benzenedicarboxylic acid, 3,4,5,6-tetrabromo-, 1,2-bis(2-ethylhexyl) esters (TBPH), CAS No. 26040-51-7; benzoic acid, 2,3,4,5-tetrabromo-, 2-ethylhexyl esters (TBB), CAS No. 183658-27-7; 2-(2-hydroxyethoxy)ethyl 2-hydroxypropyl 3,4,5,6-tetrabromobenzenedicaroxylate, CAS No. 77098-07-8; 3,4,5,6-tetrabromo-1,2-benzenedicarboxylic acid, mixed esters with diethylene glycol and propylene glycol, CAS No. 20566-35-2; 1,2- (2,3-dibromopropyl) benzenedicarboxylate, CAS No.7415-86-3; Confidential A, P-96-0965; and Confidential B, P-04-0404.
[54] The chlorinated phosphate esters cluster includes three flame retardants: ethanol, 2-chloro-, phosphate (3:1) (TCEP), CAS No. 115-96-8; 2-propanol, 1-chloro-, 2,2',2"-phosphate (TCPP), CAS No. 13674-84-5; and 2-propanol, 1,3-dichloro-, phosphate (3:1) (TDCPP), CAS No. 13674-87-8.
[55] The tetrabromobisphenol A and related chemicals cluster includes four flame retardants: tetrabromobisphenol A (TBBPA), CAS No. 79-94-7; TBBPA-bis(dibromopropyl ether), (CAS No. 21850-44-2; TBBPA-bis(ally ether), CAS No. 25327-89-3; and TBBPA-bis(methyl ether), CAS No. 37853-61-5.

In the prioritization rule, EPA explained its guiding principles for selecting potential high-priority substances, while also recognizing its obligations with respect to TSCA Work Plan chemicals and the Congressional preferences:

> In selecting candidates for a High-Priority Substance designation, it is EPA's general objective to select those chemical substances with the greatest hazard and exposure potential first, considering reasonably available information on the relative hazard and exposure of potential candidates.[56]

EPA also adopted the criteria in section 6(b)(1)(A):

> EPA will generally use reasonably available information to screen the candidate chemical substance against the following criteria and considerations:
> (1) The chemical substance's hazard and exposure potential;
> (2) The chemical substance's persistence and bioaccumulation;
> (3) Potentially exposed or susceptible subpopulations;
> (4) Storage of the chemical substance near significant sources of drinking water;
> (5) The chemical substance's conditions of use or significant changes in conditions of use;
> (6) The chemical substance's production volume or significant changes in production volume; and
> (7) Other risk-based criteria that EPA determines to be relevant to the designation of the chemical substance's priority.[57]

As a quick reference, EPA has posted its 2012 scoring for the first two items for 344 chemicals, including many substances not on the 2014 update to the TSCA Work Plan list.[58]

Another important factor is the availability of information on the chemical substance or category. Stakeholders may want to evaluate the extent of the information available on their chemicals of interest. Any EPA request or requirement for additional information on a chemical substance may be an indication of EPA's interest in the substance during the current pre-prioritization activities.

6. Is my chemical substance a good candidate for designation as a low-priority substance?

A low-priority substance is one for which "the Administrator concludes, based on information sufficient to establish, without consideration of costs or other nonrisk factors, that such substance does not meet the standard ... for designating a chemical substance a high-priority

[56] 40 C.F.R. § 702.5(a), 82 Fed. Reg. at 33763.
[57] 40 C.F.R. § 702.5(c), 82 Fed. Reg. at 33763.
[58] EPA, TSCA Work Plan: 2012 Scoring of Potential Candidate Chemicals Entering Step 2 (posted Aug. 2016), https://www.epa.gov/sites/production/files/2016-08/documents/2012_workplan_step_2_chemicals-for_web-final.pdf.

substance."[59] In other words, EPA must have sufficient information to conclude that the substance does not qualify for a "may present an unreasonable risk" finding.

In the preamble to the proposed prioritization rule, EPA emphasized the difficulty of qualifying as a low-priority substance:

> TSCA's definition of Low-Priority Substance … is fairly rigorous, and effectively requires EPA to determine that under no condition of use does the chemical meet the High-Priority Substance standard. Consequently, EPA expects it will be more difficult to support such designations.[60]

The preamble advised that "[w]hile not determinative, EPA believes that its Safer Chemicals Ingredients List (SCIL) (Ref. 6) will be a good starting point for identifying potential candidates for Low-Priority Substance designations."[61]

A stakeholder interested in establishing that a substance should be designated as low-priority may want to do the following:

- Check the Safer Chemicals Ingredients List to see if the substance is listed there. [62]
- Review the available hazard and exposure information to see if a "may present" finding is quite unlikely for any condition of use for the substance.
- Assess the completeness of the information available to EPA on the substance.
- Supplement the information available to EPA with submissions to the Agency if appropriate.
- Advocate to EPA that it should select the chemical as a candidate for low-priority designation.

7. How can I influence whether EPA decides to conduct a risk evaluation for my chemical substance?

There are two routes to an EPA decision to conduct a risk evaluation on a chemical. One is through a manufacturer request. The other is through the prioritization process. Both provide opportunities for stakeholder advocacy which may influence the EPA decision.

a. Manufacturer requests

A manufacturer may request EPA to conduct a risk evaluation on its chemical.[63] EPA must grant qualifying petitions to the extent that they represent between 25% and 50% of all risk

[59] TSCA § 6(b)(1)(B)(ii).
[60] 82 Fed. Reg. 4825, 4830 (Jan. 17, 2017).
[61] Id. at 4830. According to EPA, https://www.epa.gov/saferchoice/learn-about-safer-choice-label, "Products with the Safer Choice label help consumers and commercial buyers identify products with safer chemical ingredients, without sacrificing quality or performance."
[62] The Safer Chemical Ingredients List is available at https://www.epa.gov/saferchoice/safer-ingredients.
[63] TSCA § 6(b)(4)(C)(ii).

evaluations,[64] although it has discretion not to accept a manufacturer request for a chemical on the TSCA Work Plan list.[65]

A manufacturer may request that EPA conduct a risk evaluation on its chemical substance. However, the up-front requirements are substantial, as is the fee that the manufacturer incurs by making a request. The up-front requirements include the following, among others:

> The request must also include a list of all the existing information that is relevant to whether the chemical substance, under the circumstances identified by the manufacturer(s), presents an unreasonable risk, of injury to health or the environment ....
>
> The request must include or reference all available information on the health and environmental hazard(s) of the chemical substance, human and environmental exposure(s), and exposed population(s), as relevant to the circumstances identified in the request.[66]

If the chemical substance is on the 2014 update to the TSCA Work Plan list, the manufacturer must pay 50% of EPA's cost of conducting the requested risk evaluation. If the chemical substance is not a TSCA Work Plan chemical substance, the manufacturer must pay 100% of that cost.[67] While EPA has not formally determined the cost of a risk evaluation, it has estimated that cost at $3.7 million.[68] The fee feature alone constitutes a substantial disincentive for manufacturer requests.

Stakeholders may want to comment on manufacturer requests.[69] For example, they may supplement the information provided in the request or focus on different conditions of use.

b. Using the Prioritization Process

The most effective time for influencing EPA's decision to list or not to list a chemical substance as a high-priority substance may be during the pre-prioritization step, which remains to be defined. After this step, EPA will publish a list of candidate chemical substances for high-priority designation.[70] The remaining process will focus on whether EPA should confirm or change those listings, with EPA likely oriented toward confirming them.

Accordingly, stakeholders may want to submit information and advocacy about a chemical substance to EPA proactively, prior to EPA formally identifying the substance as a candidate for prioritization. The information should address the criteria EPA plans to use,

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[64] TSCA § 6(b)(4)(E)(i).
[65] TSCA § 6(b)(4)(E)(iv)(II).
[66] 40 C.F.R. § 702.37(b)(4), 82 Fed. Reg. at 33749.
[67] TSCA §§ 6(b)(4)(E)(ii), 26(b)(4)(D).
[68] EPA, Initial Report to Congress on the EPA's Capacity to Implement Certain Provisions of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Jan. 2017) at 4, 5, https://www.epa.gov/sites/production/files/2017-01/documents/tsca_report_to_congress.pdf.
[69] 40 C.F.R. § 702.37(e)(4), 82 Fed. Reg. at 33750.
[70] 40 C.F.R. § 702.7(b), 82 Fed. Reg. at 33763.

identified above. Developing that information may take months or years, so planning ahead can be critical. Planning often involves development of a coordinated strategy that identifies potential allies in the process, allocates sufficient budget, identifies information needs, and establishes a timetable for information development.

Exposure information is likely to be particularly important to EPA, since it is the hardest information for EPA to collect, other than through the Chemical Data Reporting rule.[71] For occupational exposure, typical engineering controls and personal protective equipment used to prevent or limit exposure may be helpful. Industrial hygiene monitoring results and measurements of environmental releases or concentrations in environmental media can provide real-world data on actual exposure conditions. Since this data may not be readily available in a form that would be useful to EPA, stakeholders may want to plan to develop data that is useful to EPA.

Hazard data may also be important. For example, acute and chronic toxicity studies in fish, invertebrates, and algae can supplant modeling for ecotoxicity endpoints on which EPA might otherwise rely. If a flawed study indicating a significant hazard is available to EPA, stakeholders may want to point out those flaws, since EPA must regulate on the basis of the best available science and the weight of the scientific evidence.[72] Even better would be conducting a more reliable study on that endpoint and submitting it to EPA.

EPA encourages stakeholders planning to develop exposure or hazard information to discuss their plans with the Agency, since it may have opinions on which tests would be most useful and the protocols for those tests.

It is important to submit full studies wherever possible, because brief summaries are unlikely to be convincing to EPA. Robust summaries of studies cited in REACH registration dossiers are helpful, but submitting the full studies will be more useful to EPA. Note, however, that confidentiality agreements related to REACH dossiers may limit the ability of stakeholders to submit full studies covered by those agreements.

Once EPA identifies a chemical as a candidate for a high-priority designation, stakeholders will have opportunities for additional input:

- Publication of the list of candidates for high- or low-priority designation will trigger a 90-day comment period.[73]
- After further review, EPA will publish a list of proposed designations of high- and low-priority substances, triggering a second 90-day comment period.[74]

Stakeholders should take advantage of these opportunities, even if only to reiterate previous comments and to respond to comments by EPA and other stakeholders.

[71] 40 C.F.R. Part 711.
[72] TSCA § 26(h), (i).
[73] 40 C.F.R. § 702.7(d), 82 Fed. Reg. at 33763.
[74] 40 C.F.R. § 702.9(g), 82 Fed. Reg. at 33764.

8. Once EPA designates my chemical substance for a risk evaluation, how can I protect my interests?

Once EPA designates a chemical substance or category as high priority, or accepts a manufacturer request, it will conduct a risk evaluation for that substance or category. The risk evaluation rule provides multiple opportunities for comment at key points during the risk evaluation process. Manufacturer requests will be subject to at least a 45-day comment period.[75] EPA will publish a draft scope for each risk evaluation, with at least a 45-day comment period.[76] EPA will publish a draft risk evaluation for comment, with at least a 60-day comment period.[77]

Stakeholder comments on the proposed scope of a risk evaluation may be critical, since the scope determines which conditions of use (potentially, less than all) will be evaluated. Stakeholder comments on the draft risk evaluation may have much less impact, since by then EPA will have completed virtually the entire risk evaluation process.

Stakeholder comments should not only react to EPA drafts, but also provide additional information not cited by EPA that may help provide a more balanced assessment. In addition, stakeholders may want to act proactively to attempt to influence EPA's final risk evaluation by submitting a risk evaluation of their own. EPA has published guidance for developing such risk evaluations.[78] The guidance notes that "EPA's vision is to have a sustainable TSCA program that is meaningfully informed by high quality risk evaluations conducted by external parties." Development of a risk evaluation that meets the scientific standards to which EPA's risk evaluation is subject will require a significant investment of time and resources. However, it will be most effective the earlier EPA receives it, so stakeholders may want to provide their own risk evaluations as early as the pre-prioritization period.

Stakeholders may want to focus their comments on the one or few conditions of use of importance to them. EPA will make a determination that a chemical substance presents a significant risk if a single condition of use merits that determination, but it will also make determinations for the other conditions of use within the scope of the risk evaluation as well,[79] and those may be of greater importance to the stakeholder.

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[75] 40 C.F.R. § 702.37(e)(4), 82 Fed. Reg. at 33750. That provision advises, "in particular, commenters are encouraged to identify any information not included in the request or the proposed determinations that the commenters believe would be needed to conduct a risk evaluation, and to provide any other information relevant to EPA's proposed determinations of the conditions of use, such as information on other conditions of use of the chemical than those included in the request or in EPA's proposed determinations."

[76] 40 C.F.R. § 702.41(c)(7)(iii), 82 Fed. Reg. at 33751.

[77] 40 C.F.R. § 702.49(a), 82 Fed. Reg. at 337552-53.

[78] EPA, Guidance to Assist Interested Persons in Developing and Submitting Draft Risk Evaluations Under the Toxic Substances Control Act (June 2017), https://www.epa.gov/sites/production/files/2017-06/documents/tsca_ra_guidance_final.pdf. A notice of availability for this guidance appeared at 82 Fed. Reg. 33765 (July 20, 2017).

[79] 40 C.F.R. §§ 702.47, 702.49(c), 82 Fed. Reg. at 33752-53.

9. Once EPA determines that my chemical presents an unreasonable risk, how can I protect my interests?

EPA must publish a proposed risk management rule under section 6(a) banning or restricting a chemical substance that it determines presents an unreasonable risk.[80] Stakeholders will have an opportunity to comment on the proposed rule. In addition, they may want to submit information and arguments before then in an effort to influence the proposed rule. Stakeholders will have a variety of important issues to address in their advocacy to EPA, including the risk management measures to be selected and their compliance dates.

Section 6(a) presents an array of possible risk management measures, ranging from labeling requirements to outright bans. EPA's selection may determine whether or not the chemical substance will remain commercially viable.

If the risk evaluation determines that a chemical substance presents an unreasonable risk with respect to one or more conditions of use, EPA considers that the substance itself presents an unreasonable risk and that it must ban or restrict that substance "to the extent necessary so that the chemical substance or mixture no longer presents such risk."[81] Stakeholders affected by the condition or conditions of use determined to present an unreasonable risk will want to comment to EPA on how restrictive the risk management measures need to be.

This language leaves open questions about the extent to which conditions of use for the substance determined not to present an unreasonable risk should or should not be impacted by the ban or restrictions for those that do. Stakeholders affected by conditions of use that do not present an unreasonable risk should also plan to comment to EPA on the appropriate remedies.

In selecting risk management measures, EPA must consider some non-risk factors that were excluded from the prioritization and risk evaluation steps. These include the benefits of the chemical substance for various uses; the reasonably ascertainable economic consequences of the rule, such as the likely effect of the rule on the national economy, small business, and technological innovation; the costs and benefits of the rule and at least one alternative regulatory action; and the cost-effectiveness of the rule and at least one alternative.[82] Stakeholders will want to present their views on these issues to EPA, since EPA's selection of risk management measures must factor in these issues to the extent practicable.[83]

In addition, stakeholders may want to address other issues that EPA may have to consider, such as possible exemptions for replacement parts[84] and articles[85] containing the chemical substance being restricted. Also, if EPA plans to propose restrictions that would effectively preclude a condition of use, it must also consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment,

[80] TSCA § 6(c)(3)(A).
[81] TSCA § 6(a).
[82] TSCA § 6(c)(2)(A).
[83] TSCA § 6(c)(2)(B).
[84] TSCA § 6(c)(2)(D).
[85] TSCA § 6(c)(2)(E).

compared to the use so proposed to be prohibited or restricted will be reasonably available as a substitute when the restrictions take effect.[86] Stakeholder information and advocacy will be important.

Compliance dates may also be issues for comment. EPA must adopt compliance dates that are as soon as practicable and no more than five years after promulgation of the rule,[87] but they may vary for different persons.[88] The timing can be crucial to stakeholders.

CONCLUSION

The 2016 amendments to section 6 of TSCA mean that EPA will be much more active than previously in identifying, evaluating, and regulating chemical substances. Its many section 6 actions since enactment of the LCSA demonstrate that new reality. Stakeholders have many opportunities to take part in the different steps and even more incentives to be involved.

Stakeholder involvement will be more effective the earlier it occurs in the section 6 process. Stakeholders are encouraged to develop and implement far-sighted strategies concerning the chemical substances of importance to them, without waiting for EPA to make critical decisions that may influence the remainder of the process. Once EPA does initiate actions on those substances, stakeholders should plan to stay involved until the entire process is completed.

[86] TSCA § 6(c)(2)(C).
[87] TSCA § 6(d)(1)(B).
[88] TSCA § 6(d)(2).