Eight months have now passed since President Obama signed into law the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA), Pub. Law 114-182, on June 22, 2016. This historic legislation overhauled the Toxic Substances Control Act (TSCA) for the first time in 40 years. Attention has now switched to EPA implementation of the new TSCA. This alert summarizes EPA’s implementation activities and challenges since June 2016 and highlights upcoming milestones.

Early Developments

On June 29, 2016, EPA released its First Year Implementation Plan for complying with its initial round of TSCA obligations. EPA announced that it would meet its statutory obligations to continue reviewing premanufacture notices (PMNs) and significant new use notices (SNUNs), but, for previously submitted PMNs, the new law would effectively reset the 90-day review period. EPA also announced it would comply with its statutory deadline to make determinations within 90 days on all confidential business information (CBI) claims. In addition, the Agency announced that, for existing chemicals with risk assessments completed before the date of enactment, it would continue to publish proposed and final rules consistent with the scope of those assessments. Specifically, EPA announced that it planned to finalize rules for trichloroethylene (TCE), methylene chloride, and N-methylpyrrolidone (NMP) by late 2017. EPA’s announcements about framework actions under the new law included:

- A plan to meet its statutory obligation to announce the first ten Work Plan chemicals to undergo risk evaluation by December 2016, with scoping complete by June 2017.
- A plan to propose rules on the prioritization process, risk evaluation process, and inventory reset process by December 2016, in order to meet the statutory deadlines to finalize the rule by June 2017.
- A plan to finalize a rule for the implementation of fee collection provisions under the statute by June 2017, with a proposed rule by December 2016. EPA noted there was no deadline to promulgate such a rule under the LCSA.
- A plan to establish a Science Advisory Committee on Chemicals by December 2016 – six months before the statutory deadline.

EPA also held two public meetings, on August 9 and 10, 2016, regarding its upcoming proposals to establish procedures to prioritize chemicals and conduct risk assessments under section 6. As discussed below, these rules were proposed in January 2017. At each of the public meetings, EPA made a presentation and solicited oral comments. Following the meetings, EPA accepted written comments.

On October 24, 2016, EPA issued a FAQ document regarding the LCSA and its implementation. The document announced, among other things, the five chemicals, regarded by EPA as persistent, bioaccumulative, and toxic (PBT) that will receive expedited action under TSCA section 6(h). The chemicals are:

- Decabromodiphenyl ethers (decaBDE), used as a flame retardant in textiles, plastics, wiring insulation, and
building and construction materials;

- Hexachlorobutadiene (HCBD), used as a solvent in the manufacture of rubber compounds and as hydraulic, heat transfer or transformer fluid;
- Pentachlorothiophenol (PCTP), used as a mercaptan (sulfur) cross-linking agent to make rubber more pliable in industrial uses;
- Tris(4-isopropylphenyl) phosphate, used as a flame retardant in consumer products and as lubricant, hydraulic fluid, and other industrial uses; and
- 2,4,6-Tris(tert-butyl) phenol, an antioxidant that can be used as a fuel, oil, gasoline or lubricant additive.

Section 6(h) requires EPA to propose rules within three years to reduce risks and exposures to PBT chemicals to the extent practicable. Prior to proposing the rule, section 6(h)(1)(B) requires EPA to conduct an exposure and use assessment. TSCA does not prescribe a timetable or procedure for such an assessment, nor has EPA announced one.

On December 19, 2016, EPA published in the Federal Register a list of the first ten Work Plan chemicals that would undergo a risk evaluation under the updated statute. The chemicals selected by EPA are:

- 1,4-Dioxane;
- 1-Bromopropane;
- Asbestos;
- Carbon tetrachloride;
- Cyclic aliphatic bromide cluster (HBCD);
- Methylene chloride;
- N-Methylpyrrolidone (NMP);
- Pigment Violet 29 (Anthra[2,1,9-def:6,5,10-d‘e’f]diisoquinoline-1,3,8,10(2H,9H)-tetrone);
- Trichloroethylene (TCE); and
- Tetrachloroethylene (also known as perchloroethylene).

This publication triggered a statutory deadline to complete risk evaluations for the chemicals by December 19, 2019 and for a scoping document for each chemical to be published by June 19, 2017. EPA has established dockets and announced agency contacts for each of the ten chemicals. Each of the dockets contain a document containing EPA’s preliminary evaluation about the domestic manufacturing, processing, distribution, use, and disposal of the chemical. EPA also held a public meeting on scoping efforts for these first ten risk evaluations on February 14, 2017. EPA will accept written public comments on the scope of these risk evaluations until March 15, 2017.

**Significant New Use Rules**

EPA has continued to issue significant new use rules (SNURs) under TSCA since the passage of the LCSA in 2016, and has proposed updates to the SNUR framework. On July 28, 2016, EPA proposed changes to the existing regulations governing significant new uses of chemical substances to align these regulations under TSCA with revisions to the Occupational Safety and Health Administration’s hazard communication standard, and with changes to the OSHA respiratory protection standard and the National Institute for Occupational Safety and Health respirator certification requirements. EPA has also continued to move forward with a series of proposed and final SNURs, which include the following:

- August 24, 2016 – EPA issued a proposed SNUR for two intermediate chemical substances, hydrochlorofluoropropane and hydrochlorofluoropropene, that were the subject of PMNs.
- October 27, 2016 – EPA issued proposed SNURs for three chemical substances – two isocyanates and one for functionalized carbon nanotubes. On January 3, 2017, EPA reopened the comment period on the proposed SNUR for 60 days, and is accepting additional comments until March 6, 2017.
November 17, 2016 – EPA issued direct final SNURs for 57 chemical substances.\[20]\n
November 28, 2016 – EPA issued a proposed SNUR for two alkylpyrrolidones: n-ethylpyrrolidone (NEP) and n-isopropylpyrrolidone (NiPP).\[21]\n
As EPA reviews and approves new chemicals under the PMN process, it will likely continue to rely on SNURs as a powerful tool to restrict the use of chemicals to those uses specified by the PMN submitter.

**PMN Review Since Enactment of the LCSA**

Amended TSCA section 5 largely retains the structure of the original section. For instance, the revised provision retains the requirement that manufacturers submit a PMN prior to manufacturing a chemical that is not on the TSCA Inventory. However, new section 5(a)(3)(C) now requires EPA to make an affirmative finding that a PMN substance “is not likely to present an unreasonable risk of injury to health or the environment” before the manufacture may commence. Following enactment of the LCSA, EPA announced that any pending PMNs would be considered under the new section 5 and that EPA’s 90-day clock to review PMNs would be reset to the date of enactment.\[22]\n
EPA’s website shows that, since enactment of the LCSA, the Agency has made final determinations for 39 PMNs that the subject chemicals did not present an unreasonable risk.\[23\] Other PMN submissions are pending.\[24\] Industry has raised concerns that, under amended TSCA, EPA review of PMNs is falling behind submissions. EPA held a public meeting on December 14, 2016 to address those concerns and to receive public comments.\[25\]

**Negotiated Rulemaking for Inorganic Byproducts**

On December 15, 2016, EPA issued a notice of intent to establish a Negotiated Rulemaking Committee to negotiate a proposed rule that would limit chemical data reporting requirements under section 8(a) for manufacturers of inorganic byproduct chemical substances when the byproducts are ultimately recycled, reused, or reprocessed.\[26\] EPA accepted public comments on the notice until January 17, 2017, and is now proceeding to convene the Negotiated Rulemaking Committee, which will be comprised of approximately 10-25 stakeholders representing significantly affected interests. EPA intends to hold the Committee’s first meeting in March 2017, and expects the Negotiated Rulemaking Committee to conclude its work by September 2017. Section 8(a)(6) requires EPA to publish a proposed rule that limits the reporting requirements for inorganic byproducts that are recycled, reused, or reprocessed that is based on the outcome of the negotiated rulemaking, by June 22, 2019, and issue a final rule by December 23, 2019.

**Risk Management Rulemaking for TCE, NMP, and Methylene Chloride**

Since enactment of the LCSA, EPA has published proposed section 6 rules seeking to restrict and prohibit certain uses of TCE, NMP, and methylene chloride based on the Agency’s prior risk assessments for these chemicals. A proposed rule to prohibit the manufacture, processing, distribution, and use of TCE for aerosol degreasing and in spot cleaning in dry cleaning facilities was published on December 16, 2016,\[27\] and a companion proposed rule to prohibit the manufacture, import, processing, distribution, and use of TCE in vapor degreasing was published on January 19, 2017.\[28\] Both proposed rules would require manufacturers, processors, and distributors, except for retailers, of TCE to provide downstream notification of these prohibitions throughout the supply chain, and keep records. EPA recently extended the deadlines for commenting on these proposed rules by 30 days. It is accepting comments on the TCE aerosol degreasing and spot cleaning proposed rule until March 16, 2017, and the TCE vapor degreasing proposed rule until April 19, 2017.\[29\]

On January 17, 2017, EPA issued a proposed section 6 rule seeking to regulate certain uses of NMP and methylene chloride in paint and coatings removers based on a proposed determination that such uses pose an unreasonable risk.\[30\] The proposal would prohibit the manufacture, import, processing, and distribution of methylene chloride and NMP for all consumer uses and most types of commercial paint and coating removal (e.g., paint stripping). It would also require manufacturers, importers, processors, and distributors, except for retailers, of methylene chloride and NMP to provide downstream notification of these prohibitions throughout the supply chain. With respect to NMP, EPA is proposing an alternative option that would impose worker health and safety requirements on commercial users of NMP, and institute a 35 percent by weight limit on NMP in products. EPA is accepting comments on the proposed methylene chloride and NMP restrictions until April 19, 2017.

**TSCA Inventory Reset**

On January 13, 2017, EPA published a proposed rule to establish a process to designate substances on the TSCA
Inventory as “active” or “inactive” (known as the TSCA Inventory Reset). There are currently approximately 85,000 chemicals on the TSCA Inventory, many of which are no longer in use. EPA is required by section 8(b)(4) to determine which chemicals substances on the Inventory are still in commerce today. To achieve this end, EPA is proposing to require manufacturers (including importers) to notify EPA regarding the manufacture or import of chemical substances for non-exempt commercial purposes during the 10 years prior to enactment of the LCSA (from June 21, 2006 to June 21, 2016) within 180 days of the final rule. EPA is proposing to allow, but not require, processors to notify EPA regarding chemical substances that were processed for non-exempt commercial purposes during this 10-year period as well. Processors would have 360 days to report, meaning that they may decide whether or not to report after reviewing an interim list of active substances. The proposed rule would require information regarding “the chemical identity, type of commercial activity (i.e., whether it is domestic manufacture and/or import), date range of manufacture for nonexempt commercial purpose during the 10-year reporting period ending on June 21, 2016, and whether they seek to maintain an existing claim for protection against disclosure of a confidential chemical identity.” The proposed rule includes exemptions from the notification requirements, including a specific exemption for importers of articles containing chemical substances.

After the initial reporting period, EPA would designate all chemicals on the TSCA Inventory as either active or inactive based on the notifications it receives from manufacturers and processors. Once the TSCA Inventory has been “reset,” no one would be permitted to manufacture or process an inactive chemical substance without first submitting a notification to EPA within 30 days of manufacturing or processing the substance. Upon notice, EPA would change the designation of the chemical substance from inactive to active, and manufacturing and processing could commence. Comments on the proposed TSCA Inventory notification proposed rule are due by March 14, 2017.

Prioritization

On January 17, 2017, EPA published a proposed rule under section 6 to establish “a risk-based screening process and criteria that EPA will use to identify chemical substances as either high-priority substances for risk evaluation, or low-priority Substances for which risk evaluations are not warranted at the time.” EPA is accepting comments on the proposed process until March 20, 2017.

The proposed rule outlines a prioritization process with four phases: (1) pre-prioritization/screening, (2) initiation, (3) proposed designation, and (4) final designation. EPA is proposing to identify and screen candidates chemicals against the criteria in the statute during the pre-prioritization phase. Those criteria include considerations regarding “the hazard and exposure potential of the chemical substance (e.g., persistence and bioaccumulation, potentially exposed or susceptible subpopulations, and storage near significant sources of drinking water), the conditions of use or significant changes in the conditions of use of the chemical substance, and the volume or significant changes in the volume of the chemical substance manufactured or processed.” After the initial screening, EPA would select substances from the pool of candidates, and initiate the prioritization process. EPA must complete the prioritization process for a chemical substance within nine months to one year following initiation of the prioritization process, with two 90-day public comment periods built into the process (after the initiation and after the proposed designation). A high-priority substance designation at the conclusion of the process would immediately lead to a risk evaluation for the substance. A low-priority substance designation would not lead to any further action.

Risk Evaluation

On January 19, 2017, EPA published a proposed rule for establishing a procedure for risk evaluations under section 6. EPA is accepting written comments on the proposed rule until March 20, 2017. Under EPA’s proposal, the first step of a risk evaluation would be a scoping analysis regarding conditions of use. This would involve publication of a draft analysis, with public comment. EPA announced in the proposed rule preamble that “a risk evaluation must encompass all known, intended, and reasonably foreseen activities associated with the subject chemical substance.” This interpretation is at odds with industry’s position that EPA should use its discretion to only consider uses that would present the highest risks. EPA also announced that any objections to the draft scope document would be waived if not raised during the scoping portion of the analysis. The subsequent steps of a risk evaluation, under EPA’s proposal, would be a hazard assessment, exposure assessment, risk characterization and a risk determination.

What’s in Store for TSCA Under the Trump Administration

President Trump’s nominee to serve as EPA Administrator, Scott Pruitt, was confirmed by the Senate on February 17, 2017. With the change of administrations, Jim Jones, who had served as Assistant Administrator of EPA’s Office
of Chemical Safety and Pollution Prevention (OCSPP), has stepped down. The new Acting Assistant Administrator is Wendy Cleland-Hamnett, who had previously reported to Jones.[38] A new Assistant Administrator of OCSPP is expected to be nominated by President Trump in the coming months.

The new Administration’s policies could have an impact on TSCA reform implementation and the TSCA program in general. The Trump Administration’s Regulatory Freeze Pending Review Memorandum issued on January 20, 2017[39] may not have a direct effect on TSCA reform implementation since there is a specific carve-out for regulations subject to statutory deadlines (of which TSCA has many under the LCSA). However, resource and budgetary constraints under the new Administration could have an impact on EPA’s ability to effectuate the significant changes to TSCA called for by the LCSA. For example, the Trump Administration’s blanket hiring freeze[40] on federal civilian employees across the executive branch could limit EPA’s ability to allocate sufficient staff resources to meet its obligations under revised TSCA. Furthermore, the Trump Administration has signaled that it may cut EPA’s budget, which would hinder the Agency’s ability to implement TSCA reform and efficiently and effectively operate the TSCA program.

On the other hand, new Administrator Scott Pruitt could ensure continuation of EPA’s implementation of the amended TSCA. During his confirmation process, he declared that “I am committed to implementing the Lautenberg Act as required by law including meeting the statutory deadlines enumerated in the law including the required rulemakings, risk evaluations, and future chemical prioritizations.”[41]


[4] TSCA § 26(l)(4); 15 U.S.C. § 2625(l)(4). All references to TSCA provisions in this alert are to TSCA as amended, rather than to the LCSA.


EPA is proposing to identify candidate chemicals for prioritization if they meet one of the following exposure or hazard considerations: (1) persistent, bioaccumulative, and toxic; (2) used in children’s products; (3) used in consumer products; (4) detected in human and/or ecological biomonitoring programs; (5) potentially of concern for children’s health; (6) high acute and chronic toxicity; (7) probable or known carcinogen; (8) neurotoxicity; or (9) other emerging exposure and hazard concerns to human health or the environment, as determined by the Agency.

TSCA Section 6(b)(1)(A); U.S.C. § 2605(b)(1)(A).

TSCA § 6(b)(1)(C); U.S.C. § 2605(b)(1)(C).


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