As 2019 moves into its closing months, US EPA activity under the amended Toxic Substances Control Act (TSCA) remains front and center. As part of US EPA’s three-step process of prioritization, risk evaluation and risk management for existing chemicals, as we previously reported, EPA began in 2016 by identifying the first ten chemicals for risk evaluation under TSCA, which set forth a three-year deadline for completing the evaluations that is supposed to come to a close this December under the statute. TSCA gives US EPA the ability to extend the deadline for finishing the risk evaluations by up to six months if needed, and the Agency has indicated that it likely will do so.

Over the last three years, US EPA has taken action under the amended TSCA in a number of ways, including the following:

- Releasing scope documents providing information on the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations EPA expects to consider in its risk evaluations;

- Releasing problem formulation documents refining the scope of the risk evaluations for the first 10 chemicals;

- Finalizing a rule requiring industry reporting of chemicals manufactured, imported or processed in the US during the ten years prior to June 21, 2016, in order to “reset” the TSCA Inventory;
• Issuing draft risk evaluations for several substances: Pigment Violet 29, HBCD, 1,4-Dioxane, and 1-Bromopropane.

Activity continued earlier this month, as US EPA proposed in two separate actions to designate an additional twenty “low priority” substances for risk evaluation, as well as twenty “high priority” substances for risk evaluation, including common chemicals such as formaldehyde, certain phthalates, flame retardants and chlorinated solvents. Each of these actions has generated significant attention from interested stakeholders as the Agency attempts to define the criteria and stringency of potential regulations of those substances, including a few skirmishes over higher profile substances such as TCE, for example.

In July, the Agency for Toxic Substances and Disease Registry (ASTDR) released its toxicological profile for trichloroethene/trichloroethylene (TCE) as required under Section 104 of CERCLA, which summarizes the characteristics, exposure risks and possible adverse health effects. The profile notably backs the findings of a prior 2011 assessment performed by US EPA’s Integrated Risk Information System (IRIS), which set relatively strict risk values for TCE using a so-called Johnson study performed in 2003 that found a correlation between TCE and increased fetal heart defects. Reliance on the profile comes over the objections of the chemical manufacturing industry, calling the Johnson study “flawed,” and arguing in favor of an alternative study prepared earlier this year that did not show such fetal heart defects.

In addition, back in January 2017, US EPA proposed under Section 6 of TSCA to prohibit the manufacture (including import), processing, and distribution in commerce of TCE for use in vapor degreasing; to prohibit commercial use of TCE in vapor degreasing; to require manufacturers, processors, and distributors, except for retailers of TCE for any use, to provide downstream notification of these prohibitions throughout the supply chain; and to require limited recordkeeping. However, the Trump Administration has effectively halted the imposition of the ban, and as of December 2017, US EPA had “indefinitely postponed” the ban on TCE. Because TCE is one of the “first ten” substances currently undergoing risk evaluation, the soon-to-be-released draft risk evaluation for the substance should indicate the extent to which US EPA believes that restrictions may need to be imposed upon it.

Consequently, these battles continue to shape the regulatory dialogue that will carry on throughout the year. Interested parties should remain vigilant as there continue to be opportunities to engage in the regulatory process. Presently, US EPA’s rulemakings regarding the proposed “low priority” and “high priority” substances have open comment periods of November 13, 2019 and November 21, 2019, respectively. US EPA must finalize the designation of these substances as either low priority or high priority by December 22, 2019, and then must initiate risk evaluations for the high priority substances. In addition, US EPA’s Toxic Substances Control Act Science Advisory Committee on Chemicals held a peer review meeting on September 10-12, 2019 in Arlington, Virginia to discuss the risk evaluation for 1-Bromopropane, and will continue to accept comments through October 11, 2019. Interested stakeholders should be working with their technical and legal experts to engage in these participation opportunities.

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