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TSCA Overhaul: EPA Identifies Fifteen Chemicals Slated for Risk Assessments

By Corrie L. Plant, Andrew W. Homer, Kevin Ashe and Rebecca Lee

Under the recently amended TSCA, EPA is now bound by new requirements and enforceable timetables to complete risk assessments for chemicals manufactured, distributed and imported to the United States.

In October, EPA listed the first five chemicals subject to new, expedited risk assessments. On November 29, EPA announced ten other chemicals, bringing the list to fifteen chemicals that the agency must now evaluate for risks to human health and the environment.

In light of these requirements, companies with U.S. operations, and particularly manufacturers, should:

- Evaluate what chemicals are used in their manufacturing processes, as product ingredients or elsewhere in their supply chain; and
- Determine whether those chemicals are likely to be prioritized in EPA's new risk assessment process; and
- Based on when those chemicals are likely to undergo risk assessment, consider possible restrictions and their impacts.

In addition, companies of all types should review the list of chemicals EPA has already designated, determine whether those chemicals are part of their product or process lifecycles, and plan accordingly for future limitations.

Background

On June 22, 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act overhauled the Toxic Substances and Control Act's ("TSCA") risk assessment mechanisms for new and existing chemicals. Now, subject to specific rules on prioritization and specific timetables, the United States Environmental Protection Agency ("EPA") must conduct risk assessments for all chemical substances used in commerce that are not specifically exempted from TSCA.

Under the new TSCA rule, EPA must assess whether chemicals pose a risk to human health and/or the environment, and where a risk is identified to mitigate it with restrictions on use up to and including a ban on the chemical or a specific use. Where TSCA previously required EPA to include cost-benefit analysis in its risk assessment, the revised statute prohibits EPA from doing so. EPA must also consider whether restrictions are necessary to protect susceptible subpopulations (e.g., infants, elderly, and pregnant women). Companies must stay abreast of EPA restrictions on chemicals in both their manufacturing processes and their supply chains. Chemical risk assessments could lead to more stringent regulations that could be costly to companies that use chemicals anywhere in their product or process lifecycles.

In addition to manufacturers, distributors and importers of chemicals, companies of all types should pay special attention to their supply chain to identify potential risk areas, especially if chemicals already designated by EPA for risk assessment are used. While future limitations are currently unknown, it may be prudent for companies to identify feasible alternatives to these targeted chemicals.

I. First Ten Chemicals Slated for Standard Risk Assessments

On November 28, 2016, EPA announced the first ten chemicals to be evaluated for risks to human health and the environment under the revised TSCA's ordinary risk assessment process. The newly listed chemicals are:

- **1,4-Dioxane** – a solvent for adhesives, cellulose esters and inks, and can also be an ingredient in paint strippers, dyes, and waxes. The substance is also contained in antifreeze for automobile and aircraft deicing fluids.

- **1-Bromopropane ("1-BP")** – a solvent in adhesives for aviation equipment maintenance, synthetic fiber production, and in glue that binds cushions together. 1-BP is also a component of vapor sprays that degrease metal surfaces, plastics, electronics and optical components.

- **Cyclic Aliphatic Bromide Cluster** – a flame retardant in extruded polystyrene foam, textiles, and electrical and electronic appliances.

- **Methylene Chloride** – also known as Dichloromethane, this chemical is widely used as a paint stripper and a degreaser, but has also been used in the food and beverage industry to decaffeinate coffee and prepare extracts of hops. It is occasionally used in the process of removing heat-sealed printings on clothing, as well as in the manufacturing of photographic film.

- **N-methylpyrrolidone ("NMP")** – is used as a solvent for paint and coating removal products, and for surface treatment of textiles, resins, and metal coated plastics. It is also recovers hydrocarbons generated in petrochemical processing and is used to absorb hydrogen sulfide from hydrodesulphurization facilities. NMP is also used frequently in lithium ion battery manufacturing.

- **Pigment Violet 29** – an organic compound used in vat dying and in metallic varnish to make a dark red, or "bourdeaux" color.

- **Tetrachloroethylene** – a colorless liquid widely used in dry cleaning products, metal degreasers, paint strippers and some spot remover consumer products.

- **Carbon Tetrachloride** – this chemical was once produced in vast quantities as a CFC refrigerant and used in fire extinguishers. Since the Montreal Protocol, the chemical is now used in small quantities as a degreasing agent and in paint removal products.

- **Trichloroethylene ("TCE")** – TCE is used in metal degreasers and paint removers, and commonly used in products that clean kerosene-fueled rocket engines. The chemical is also a main component in the manufacturing of fluorocarbon refrigerants.

- **Asbestos** – this silicate mineral comes in various forms and was used in everything from fire-proof clothing to commercial construction due to its resistance to heat and its insulating properties.

By mid-June 2017, EPA must issue a scoping memorandum for each listed chemical detailing their respective hazards, exposures, conditions of use, and any susceptible subpopulations the agency plans to consider for the evaluation. Interestingly, EPA has already completed risk assessments for three of the listed chemicals (TCE, NMP and methylene chloride). Even so, the 2016 revisions to TSCA permit EPA to issue final rules with limitations for chemicals for which risk assessments were completed *prior* to the TSCA amendments.

II. Five Previously Designated Fast Track Chemicals: Emphasis on Flame Retardants

On October 11, 2016, EPA announced the first five persistent, bioaccumulative and toxic chemicals ("PBTs") that will receive expedited risk evaluations. The targeted chemicals are Decabromodiphenyl ethers (DecaBDE), Hexachlorobutadiene (HCBD), Pentachlorothio-phenol (PCTP), Tris (4-isopropylphenyl) phosphate and 2,4,6-Tris(tert-butyl)phenol. PBTs have been prioritized due to their reported resistance to environmental degradation and potential to accumulate in soil and aquatic environments. EPA must take expedited action by identifying where PBT chemicals are used and how people are exposed to them, and if necessary, place limitations on their use.

Of these, DecaBDE and Tris (4-isopropylphenyl) phosphate are routinely used as flame retardants in textiles and plastics. DecaBDE is used by the television industry to create cabinet backs, and is a common component in drapery and upholstery fabrics. Both DecaBDE and Tris(isopropylphenyl) phosphate are used in polyurethane foam — a common ingredient in infant walkers, changing pads, and play mats. The chemicals are not bound to foam, but are emitted as gas off of the foam that settles into dust, which potentially can be ingested through hand-to-mouth contact.

For those considering alternatives, EPA has on occasion released informational reports to help identify substitutes for flame retardants in certain commercial uses. Moreover, in 2014, EPA released a final report identifying twenty nine potentially functional alternatives for DecaBDE.

III. Looking Forward: Expectations Under the Trump Administration

By December 2019, EPA must have twenty risk evaluations ongoing for high priority chemicals *and* must make "low priority" designations for another twenty chemicals. On December 14, 2016, EPA is holding a workshop to update the public on changes under new TSCA related to pre-manufacture notices and significant new use notices. Agency and industry participants are expected to discuss issues and opportunities discovered within the first months of implementation.

It remains unknown whether the Trump administration will embrace future EPA action under the amended TSCA. While the President-elect has not mentioned TSCA specifically, he has expressed concern about other EPA regulations and their impact on industry. The lengthy effort to finalize and enact the 2016 revisions to TSCA was an overwhelmingly bipartisan effort, and largely supported by the chemical industry and environmental groups, so it seems unlikely to draw attention for further changes. Since the election, both the American Chemical Council and the Society of Chemical Manufacturers and Affiliates have issued

statements pronouncing their continued support of amended TSCA and enthusiasm to work with the new administration on effective implementation.

Pillsbury is monitoring EPA's widespread activity on risk assessment and prioritization of chemical substances under the revised TSCA and related regulations. We urge clients to take a close look at key chemical substances in their processes and product life cycle, to determine when EPA is likely to consider them for risk assessment, and to determine if contingency plans are required for possible restrictions on use.

If you have any questions about the content of this alert, please contact the Pillsbury attorney with whom you regularly work, or the attorneys below.

Corrie L. Plant (bio)
Los Angeles
+1.213.488.7494
corrie.plant@pillsburylaw.com

Andrew W. Homer (bio)
San Diego
+1.619.544.3155
andrew.homer@pillsburylaw.com

Kevin Ashe (bio)
San Francisco
+1.415.983.7498
kevin.ashe@pillsburylaw.com

Rebecca M. Lee (bio)
Los Angeles
+1.213.488.7208
rebecca.lee@pillsburylaw.com