
Toxic Substances Control Act

EPA Identifies Additional 10 Chemicals Slated for Risk Assessments

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Under the recently amended Toxic Substances Control Act (TSCA), EPA is 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 10 other chemicals, bringing the list to 15 chemicals that the agency must now evaluate for risks to human health and the environment. The 10 chemicals are drawn from EPA's TSCA Work Plan list of 90 chemicals prioritized for heightened Agency review, and EPA is required to consider additional chemicals from the Work Plan list.

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;
- Determine whether those chemicals are likely to be prioritized in EPA's new risk assessment process;
- Based on when those chemicals are likely to undergo risk assessment, participate in the risk assessment process by submitting comments and information for EPA consideration; and
- Consider the potential impacts of restrictions on supply chains and manufacturing processes.

In addition, companies of all types should review the list of chemicals in EPA's TSCA Work Plan, determine whether those chemicals are part of their product or process lifecycles, and plan accordingly for future Agency actions.

Background

On June 22, 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act overhauled TSCA's risk assessment mechanisms for new and existing chemicals. Now, subject to specific rules on prioritization and specific timetables, the U.S. Environmental Protection Agency must conduct risk

assessments for all chemical substances used in commerce that are not specifically exempted from TSCA. In 2014, EPA published a Work Plan¹, which listed 90 chemicals that it wished to prioritize for purposes of risk assessment, and under the amended TSCA, EPA is required to perform additional risk assessments of chemicals from the Work Plan.

Under the revised statute, 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). Under the revised statute, third-parties, including industry members, environmental groups, and non-governmental organizations, may submit comments and information for EPA consideration during the risk evaluation process.

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. As a result, 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 10 Chemicals Slated for Standard Risk Assessments

On November 29, 2016, EPA announced the first 10 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. The selection of this chemical is consistent with the increased attention given to this chemical ever since EPA's 2012 cancer risk assessment classified it as a likely human carcinogen.
- **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



¹ https://www.epa.gov/sites/production/files/2016-02/documents/tsca_work_plan_2014_update_tables.pdf.

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 dyeing 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.

Interestingly, EPA has already completed risk assessments for three of the listed chemicals (TCE, NMP and methylene chloride), as the 2016 revisions to TSCA permit EPA to issue final rules under Section 6(a) restricting the use of chemicals for which risk assessments were completed *prior* to the TSCA amendments. Even so, EPA is not prohibited from broadening the risk evaluations to include use scenarios beyond those set forth in the completed assessments.

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. By statute, the risk assessments must be completed within three years. If sound science demonstrates that a chemical presents an unreasonable risk, EPA must mitigate that risk within two years through further rulemaking.

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), Pentachloro-thio-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. Under the revised statute, 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 29 potentially functional alternatives for DecaBDE.

III. Looking Forward: Expectations Under the Trump Administration

By December 2019, EPA must have 20 risk evaluations ongoing for high priority chemicals *and* must make “low priority” designations for another 20 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 participate in the risk assessment process and to take a close look at key chemical substances used or produced in their operations and to develop contingency plans that address the potential impacts of possible use restrictions.

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.

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