

Are the Chemicals Your Business Needs in EPA's Regulatory Sights?

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The United States Environmental Protection Agency (EPA) is working under aggressive statutory deadlines to assess chemicals commonly used by manufacturers across a range of industries. EPA will then enact new regulations to manage risks to public health and the environment. Many business owners and executives are unaware of the potential implications of what EPA is doing, and the impact EPA's new regulations may have on businesses and current manufacturing processes. And regulatory compliance, along with certain of EPA's risk evaluations and assessments, may create litigation risks.

Background

The Biden administration is revisiting the Toxic Substances and Control Act (TSCA) risk evaluations for the first 10 high-priority chemicals called for by the Frank R. Lautenberg Chemical Safety for the 21st Century Act.^[1] This act significantly amended TSCA in 2016. EPA plans to revise all 10 risk evaluations finalized during the previous administration. EPA's new approach will be to (1) make a whole-chemical risk determination and (2) no longer assume the appropriate use of personal protective equipment by workers. Most recently, EPA announced that seven of the 10 priority chemicals will undergo a more intensive reevaluation. EPA will consider new exposure pathways (including air and water) and impacts to "fenceline" communities for 1,4-dioxane, methylene chloride, carbon tetrachloride, trichloroethylene (TCE), perchloroethylene (PCE or perc), 1-bromopropane (1-BP), and n-methylpyrrolidone (NMP).^[2]

EPA risk assessments for commonly used chemicals such as ethylene oxide and formaldehyde were controversial. These risk assessments continue to drive litigation, as seen most recently with chemicals lawsuits filed against medical equipment sterilization companies in Georgia. While the risk evaluation procedures under TSCA differ from those of EPA's Integrated Risk Information System (IRIS), regulatory compliance and future litigation risks remain. Litigation risks will be particularly acute should EPA assert impacts to "fenceline" communities.

High-Priority Chemicals Undergoing Substantive Re-Review

On December 19, 2016, EPA announced the first 10 chemicals for TSCA risk evaluation. The risk evaluations for the chemicals asbestos (part 1: chrysotile asbestos), C.I. Pigment Violet 29 (PV29), and cyclic aliphatic bromide cluster (HBCD) are now complete. The new administration announced that the following seven chemicals are subject to re-review.

1. 1,4-Dioxane

- **Uses and Sectors:** 1,4-dioxane is a synthetic industrial chemical that is a by-product in various goods including paint strippers, dyes, greases, antifreeze, and aircraft deicing fluids, as well as some deodorants, shampoos, and cosmetics. It is a by-product in the manufacture of polyethylene terephthalate plastic. 1,4-dioxane is also used as a purifying agent in the manufacture of pharmaceuticals.^[3]
- **Status of Risk Assessment:** In December 2020, EPA released the final risk evaluation for 1,4-dioxane. It concluded that there are unreasonable risks to workers and occupational nonusers from 13 conditions of use, and no unreasonable risks to the environment, consumers, bystanders, or the general population.^[4] Last month, EPA announced that it will undergo an intensive update to the final evaluation for 1,4-dioxane. In addition to evaluating the ambient-air and drinking-water exposure pathways, EPA will examine 1,4-dioxane's existence as a by-product in goods like those listed above. These additional exposure pathways and the by-product analysis were not part of the Trump administration's evaluation.^[5]
- **Status of Litigation:** The final risk evaluation from December 2020 was challenged by advocacy groups and certain states. The petitions for review were consolidated in the Ninth Circuit.^[6] To date, there are no intervenors defending the 1,4-dioxane risk evaluation.

2. Methylene Chloride

- **Uses and Sectors:** Methylene chloride is used in a variety of industrial, commercial, and consumer applications. It is used as a solvent in vapor degreasing and metal cleaning, as a paint stripper, in the production of refrigerant chemicals, and as an ingredient in sealants and adhesive removers. Consumers will find methylene chloride in adhesives, sealants, degreasers, cleaners, and automobile care products.^[7]
- **Status of Risk Assessment:** The final risk evaluation for methylene chloride was the first to be completed by the EPA in June 2020.^[8] The final evaluation found that methylene chloride does not present an unreasonable risk of injury to health or the environment under six out of 53 conditions of use. Methylene chloride is one of the six chemicals for which EPA is developing a screening-level approach to conduct assessments for ambient-air and surface-water exposure. This is to determine whether the chemical poses an unreasonable risk to fenceline communities. In the event this screening-level approach shows there is an unreasonable risk to communities living near industrial facilities, the Biden administration will supplement the existing risk analysis. Where no unreasonable risks to fenceline communities are identified and the existing analysis is considered sufficient, EPA will move forward with proposing risk management rules as required under TSCA.^[9] EPA has indicated that the screening-level approach will likely be released for public comment sometime this year. Outside the TSCA risk evaluations, EPA has taken other actions to regulate methylene chloride. As of November 2019, it is unlawful for any person or retailer to sell or distribute paint-removal products containing methylene chloride for consumer use.^[10]
- **Status of Litigation:** The final risk evaluation was challenged in the Ninth Circuit.^[11] Noting that methylene chloride is the first risk evaluation completed since the Frank R. Lautenberg Chemical Safety for the 21st Century Act and could have significant precedential value, several industry trade groups intervened.

3. Carbon Tetrachloride

- **Uses and Sectors:** Historically, carbon tetrachloride was used in a wide variety of settings, including in the production of refrigerants and propellants for aerosol cans; as a solvent for oils, fats, lacquers, varnishes, rubber waxes, and resins; as a fumigant to kill insects in grain; and as a dry-cleaning agent. However, the consumer and fumigant uses have since been discontinued. Today, carbon tetrachloride is used only in industrial settings.^[12]

- **Status of Risk Assessment:** EPA published the final risk evaluation for carbon tetrachloride in November 2020. The final risk evaluation found unreasonable risks to workers and occupational nonusers for 13 conditions of use, and no unreasonable risks to the environment.^[13] The screening-level approach for ambient air and surface water discussed above will be applied to carbon tetrachloride as part of the Biden administration's reevaluation.

4. Trichloroethylene (TCE)

- **Uses and Sectors:** TCE is a volatile organic compound primarily used in industrial and commercial processes, as well as some consumer uses. In an industrial/commercial setting, TCE is widely used for vapor degreasing of metal parts and as an intermediate in the manufacturing of refrigerants.^[14] TCE is also found in certain consumer goods such as cleaning and furniture care products, arts-and-crafts spray coatings, and automotive-care products like brake cleaners.
- **Status of Risk Assessment:** In November 2020, EPA published the final risk evaluation for TCE. It found that there are unreasonable risks to workers, occupational nonusers, consumers, and bystanders for 52 out of 54 conditions of use of TCE. EPA found no unreasonable risks to the environment.^[15] The screening-level approach for ambient air and surface water discussed above will also be used for TCE.

5. Perchloroethylene (PCE or perc)

- **Uses and Sectors:** PCE is found and used in industrial settings to produce fluorinated compounds and as a solvent for cleaning and degreasing. PCE is also widely used in dry-cleaning operations and textile processing. PCE is not utilized in many settings by consumers, though it is found in arts-and-crafts adhesives and stainless-steel polish.^[16]
- **Status of Risk Assessment:** The Trump administration's final risk evaluation for PCE was released in December 2020. The risk evaluation identified unreasonable risks to workers, occupational nonusers, consumers, and bystanders from 59 conditions of use. EPA found no unreasonable risks to the environment.^[17] In its reevaluation, EPA will likewise use the screening-level approach for ambient air and surface water discussed above for PCE.

6. 1-Bromopropane (1-BP)

- **Uses and Sectors:** 1-BP has commercial, industrial, and consumer applications. In the industrial sector, 1-BP is used in the manufacture of other chemicals. Commercially, 1-BP is a solvent used in vapor degreasing, dry cleaning, spot cleaners, stain removers, adhesives, sealants, and automobile-care products. Finally, 1-BP is also found in similar consumer goods such as adhesives, degreasers, cleaners, and automobile care products.^[18]
- **Status of Risk Assessment:** EPA finalized the risk evaluation for 1-BP in August 2020. It identified unreasonable risks to workers, occupational nonusers, consumers, and bystanders from 1-BP exposure under 16 out of 25 conditions of use. EPA did not find unreasonable risks to the environment or the general population from the evaluated uses of this chemical. Once approved, the screening level discussed above will also be used to evaluate potential impacts of 1-BP on fence-line communities.^[19]

7. n-Methylpyrrolidone (NMP)

- **Uses and Sectors:** In the manufacturing setting, NMP is used in the production of electronics, polymers, agrochemicals, and petrochemical products. NMP is also used in paint- and coating-removal products and electronic-cleaning products. These are widely available for retail purchase.
- **Status of Risk Assessment:** In December 2020, EPA issued the final risk evaluation for NMP. The final risk evaluation demonstrated unreasonable risks to workers and consumers from 26 conditions of use. The risk evaluation did not identify any unreasonable risks to the environment, general population, bystanders, or occupational nonusers.^[20] NMP is the last of the six chemicals for which EPA will utilize the screening-level assessments for ambient-air and surface-water exposure.

What Comes Next?

TSCA requires EPA to issue a proposed risk-management rule under TSCA Section 6(a) for a chemical substance presenting an unreasonable risk no later than one year after the date on which the final risk evaluation regarding the chemical substance is published.^[24] A final rule is required no later than two years after the publication date of the final risk evaluation.

There are several actions EPA can take to address unreasonable risks. These actions, alone or in combination, may include:

- prohibiting or otherwise restricting or limiting the manufacture, processing, or distribution in commerce of the substance or mixture;
- prohibiting or otherwise restricting or limiting the manufacture, processing, or distribution in commerce of the substance or mixture for a particular use or above a set concentration for a particular use;
- requiring adequate minimum warnings and instructions with respect to the substance's use, distribution in commerce, and/or disposal;
- requiring record keeping, monitoring, or testing by manufacturers and processors;
- prohibiting or regulating manner or method of commercial use;
- prohibiting or regulating manner or method of disposal; and
- directing manufacturers/processors to give notice of the determination of risk to distributors and users and replace or repurchase.

Any risk-management actions would apply only to the condition(s) of use that EPA found to present an unreasonable risk in the final risk evaluation. Those that EPA found do not present an unreasonable risk will not be subject to risk management.

Regulatory Risk Assessments Generating Private Litigation

Beyond the technical and regulatory-compliance obligations that EPA risk evaluations feed into, EPA's reconsideration of the high-priority TSCA chemical-risk evaluations may generate private-party litigation. This is more likely to occur should EPA modify prior evaluations and conclude that certain chemicals pose unreasonable risks to the fenceline communities, the environment, consumers, or the general population. Government or public-health-agency actions often serve as a catalyst for private-party litigation. For instance:

- Families in California recently filed lawsuits against Dow Chemical successor Corteva, Inc.^[22] They claim that the widely used pesticide chlorpyrifos is linked to adverse health effects in children like cognitive and developmental issues. After publishing a revised human health risk assessment for chlorpyrifos in September 2020, EPA is currently determining next steps in the registration review process.^[23]
- Private litigants sued alleging impacts from the chemical ethylene oxide following the publication of the 2016 IRIS value, including suing medical-sterilization facilities in Illinois and Georgia.^[24] In addition, there is a developing line of formaldehyde litigation. This included class action lawsuits against laminate-flooring retailers.^[25]
- The related World Health Organization International Agency for Research on Cancer issued a monograph classifying glyphosate as "probably carcinogenic to humans" because of "limited" evidence of cancer in humans. On the back of this, various lawsuits sued for billions of dollars in damages from manufacturers of the herbicide. Companies are considering stopping sale of the weed killer to private users for their gardens.^[26]

Key Takeaways

- The Biden administration is adopting a new and broader approach to TSCA risk evaluations, including:
 - no longer assuming the appropriate use of PPE by workers;

- taking a “whole chemical” determination approach, rather than making a separate unreasonable-risk determination for every condition of use of a chemical;
- considering new exposure routes that are already the subject of other statutes, including the Clean Air Act, Clean Water Act, and the Safe Drinking Water Act; and
- considering impacts on vulnerable populations, including communities living near industrial facilities.
- EPA plans to substantively revisit the risk evaluations for seven of the 10 high-priority chemicals. In the meantime, regulated entities are likely to see proposed rules for HBCD, PV29, and asbestos (part 1: chrysotile asbestos) first.
- Regulated entities should follow the reevaluation process for the high-priority chemicals of relevance to their businesses. Interested parties that manufacture and use these chemicals should look for opportunities to comment on EPA’s risk evaluations, not simply EPA’s later risk-management regulations.
- Regulated entities should ensure that EPA’s risk evaluations reflect the best-possible science and are appropriately tailored to material risks. EPA’s risk evaluations may generate private-party litigation, as has occurred with other chemicals like ethylene oxide, chlorpyrifos, formaldehyde, and glyphosate.

For further information or questions about how TSCA risk evaluations or other regulatory actions on chemicals may impact your business, compliance obligations, and risk, please contact Jonathan D. Brightbill (Partner, White Collar, Regulatory Defense & Investigations/Environmental Litigation), Madalyn Brown (Associate, Environmental), or your Winston relationship attorney.

We note that government orders on the federal, state, and local level are changing every day, and the information contained herein is accurate only as of the date set forth above.

¹¹ Updates on Chemical Safety Actions, available at <https://www.epa.gov/chemicals-under-tsca/updates-chemical-safety-actions>.

¹² EPA Announces Path Forward for TSCA Chemical Risk Evaluations (June 30, 2021), available at <https://insideepa.com/daily-news/epa-sets-timeline-revisiting-trump-era-tsca-chemical-evaluations>.

¹³ Technical Fact Sheet – 1,4-Dioxane, available at https://www.epa.gov/sites/production/files/2014-03/documents/ffrro_factsheet_contaminant_14-dioxane_january2014_final.pdf.

¹⁴ Risk Evaluation for 1,4-Dioxane, available at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-14-dioxane>.

¹⁵ EPA Announces Path Forward for TSCA Chemical Risk Evaluations (June 30, 2021), available at <https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations>; EPA Sets Timeline For Revisiting Trump-Era TSCA Chemical Evaluations, Inside EPA (June 30, 2021), available at <https://insideepa.com/daily-news/epa-sets-timeline-revisiting-trump-era-tsca-chemical-evaluations>.

¹⁶ *Environmental Defense Fund v. EPA*, Case No. 21-70162 (9th Cir.).

¹⁷ Risk Evaluation for Methylene Chloride, available at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-methylene-chloride-0>.

¹⁸ EPA Releases First Final Chemical Risk Evaluation, available at <https://www.epa.gov/newsreleases/epa-releases-first-final-chemical-risk-evaluation>.

¹⁹ News Release, EPA Announces Path Forward for TSCA Chemical Risk Evaluations (June 30, 2021), available at <https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations>.

²⁰ EPA Bans All Retail Distribution of Methylene Chloride to Consumers for Paint and Coating Removal, available at <https://www.epa.gov/newsreleases/epa-bans-all-retail-distribution-methylene-chloride-consumers-paint-and-coating-removal>.

²¹ *Neighbors for Env’tl. Justice v. U.S. Env’tl. Protection Agency*, Case No. 20-72091 (9th Cir.).

²² Carbon tetrachloride, available at <https://www.epa.gov/sites/production/files/2016-09/documents/carbon-tetrachloride.pdf>.

²³ Risk Evaluation for Carbon Tetrachloride, available at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-carbon-tetrachloride>.

^[14] *Trichloroethylene*, available at <https://www.epa.gov/sites/production/files/2016-09/documents/trichloroethylene.pdf>.

^[15] *Risk Evaluation for Trichloroethylene (TCE)*, available at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-trichloroethylene-tce-0>.

^[16] *Risk Evaluation for Perchloroethylene*, available at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-perchloroethylene>.

^[17] *Id.*

^[18] *Risk Evaluation for 1-Bromopropane (1-BP)*, available at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-1-bromopropane-1-bp>.

^[19] *Id.*

^[20] *Risk Evaluation for n-Methylpyrrolidone (NMP)*, available at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-n-methylpyrrolidone-nmp-0>.

^[21] *EPA Announces Path Forward for TSCA Chemical Risk Evaluations*, available at <https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations>.

^[22] Don Thompson, *Pesticide caused kids' brain damage, California lawsuits say*, Associated Press (July 12, 2021), available at <https://apnews.com/article/business-science-health-environment-and-nature-lawsuits-e032c7516dcf1404ad3f0b75e09bf743>; cases are *Castillo v. Corteva*, *Mendoza v. Corteva*, *Miranada-Salgado v. Corteva*, and *Montano v. Corteva*, filed July 12, 2021, in four California superior courts.

^[23] *Chlorpyrifos*, available at <https://www.epa.gov/ingredients-used-pesticide-products/chlorpyrifos>.

^[24] *Toxic emissions lawsuits against Sterigenics skyrocket ten-fold from 75 cases to more than 700* (Aug. 21, 2020), available at <https://www.willowbrookcancerlawsuit.com/toxic-emissions-lawsuits-against-sterigenics-skyrocket-ten-fold-from-75-cases-to-more-than-700>; Brett Barrouquere, *Another Ga. Sterilization Plant Sued Over Chemical Emissions*, Law 360 (July 21, 2021), available at https://www.law360.com/environmental/articles/1405193/another-ga-sterilization-plant-sued-over-chemical-emissions?nl_pk=f3385f9c-6298-47a1-9534-a5a035fc0ab1&utm_source=newsletter&utm_medium=email&utm_campaign=environmental.

^[25] See *Formaldehyde Flooring Class Action Lawsuit*, available at <https://formaldehydeflooringlawsuit.com/>; Gibbs Law Group LLP, *Lumber Liquidators Class Action Lawsuit*, available at <https://www.classlawgroup.com/lumber-liquidators-formaldehyde-lawsuit/>.

^[26] Olaf Storbeck, *Bayer to consider ending US retail sales of weedkiller glyphosate*, Financial Times (May 27, 2021), available at <https://www.ft.com/content/f1b3009d-f678-45ab-b028-74ab40d7e1ad>.

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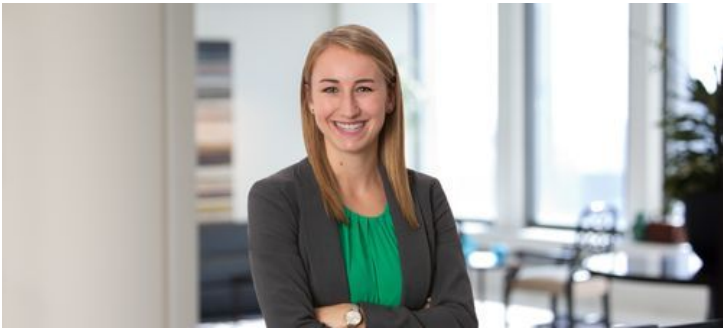
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