

Unpredictability of TSCA chemical risk evaluation process increases litigation risk for companies

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A challenge to the Environmental Protection Agency's chemical risk evaluation methodology has created an uncertain regulatory and litigation landscape for companies manufacturing, distributing or selling products containing common chemicals.

Since December 2016, the EPA has been reviewing 10 chemicals it designated as "high priority" for risk evaluation and possible regulation under the Toxic Substances Control Act, 15 U.S.C.A. § 2601.

In November 2019, consumer groups successfully challenged the agency's decision to exclude certain chemical uses from the evaluations.

The challenge has left the first 10 risk evaluations — and the associated impact on affected companies — in limbo ahead of the June 2020 completion deadline set by the statute.

Meanwhile, the EPA has identified the next 20 high-priority chemicals it will evaluate — many of which are found in popular consumer products. The agency is scheduled to begin reviewing these additional chemicals this year.

Significantly, these risk evaluations are the first to be conducted since Congress amended the TSCA in 2016 to give the EPA new powers to review and regulate chemicals. Under the statute, if the agency determines via these evaluations that a particular use of a chemical poses an unreasonable risk to the environment or to human health, it must regulate the chemical.

The novelty and unpredictability of the TSCA process mean that companies are navigating uncharted territory as they work to anticipate the EPA's conclusions and potential regulations.

And with a new set of chemicals coming under EPA scrutiny in 2020, companies with products containing an identified chemical will face increased litigation risk long before the EPA officially speaks on the chemical's risks or proposes regulations.

DEADLINE FOR FIRST 10 EVALUATIONS APPROACHING

By June 2020, the EPA must finalize risk evaluations for these first 10 high-priority chemicals:

- Asbestos (used in the chlor-alkali industry and some imported products like gaskets, friction products, adhesives and sealants).

- 1-Bromopropane (used in adhesives, sealants, cleaning and furniture care products, dry cleaning, arts and crafts products, automotive care products and mold cleaning products).
- Carbon tetrachloride (used in degreasers and cleaning products, adhesives, sealants, paints and coatings, rubber, and cement and asphalt formulations).
- 1, 4-Dioxane (used in laboratory chemicals, adhesives, sealants, professional film cement, dry film lubricant, printing and printing compositions, and spray polyurethane foam).
- Cyclic aliphatic bromide cluster (HBCD) (used in the processing of flame retardants, recycling of foam and resin panels, building and construction materials, automobile replacement parts, recycled plastics, and the disposal of construction and demolition waste).
- Methylene chloride (used in cleaning and degreasing solvents, adhesives, sealants, paint and coating removers, fabric and textile surface treatments, and lubricants and greases).
- N-Methylpyrrolidone (used in cleaning and degreasing solvents, adhesives, sealants, lubricants, paint and coating removers, and petrochemical manufacturing).
- Perchloroethylene (used in dry cleaning, automotive care products, cleaning and furniture care products, lubricants and greases, adhesives, sealants, and paints and coatings).
- Pigment violet 29 (used in automotive paints and coatings, automobile and industrial carpeting, merchant inks for printing and packaging, odor agents, cleaning and washing agents, pharmaceuticals, solar cells, paper, polyester fibers, sporting goods, appliances, agricultural equipment, and watercolors and acrylic paints); and
- Trichloroethylene (used in the manufacturing of hydrofluorocarbon, degreasing solvents, spotting agents for dry cleaning, adhesives, sealants, carpet cleaning and furniture care products, paints and coatings, hoof polish, pepper spray and toner).

The EPA began releasing draft risk evaluations on a rolling basis in November 2018. Eight of the first 10 draft risk evaluations have been released.

Of those eight chemicals, the EPA has made preliminary determinations that six (1-bromopropane, 1,4-dioxane, methylene chloride, n-methylpyrrolidone, carbon tetrachloride and trichlorethylene) pose at least some unreasonable risks to human health.

If those conclusions hold in the final risk evaluations, the agency must issue appropriate regulations to address those concerns.

The EPA also made preliminary determinations that neither HBCD nor pigment violet 29 pose unreasonable risks to human health or the environment — decisions that, should they become final, may spark challenges from various consumer groups that believe those chemicals are dangerous.

The agency has yet to release draft risk evaluations for asbestos or perchloroethylene. Those drafts are expected to be completed by April 2020.

9TH CIRCUIT SIDES WITH CONSUMER GROUPS

As the EPA finalizes the first 10 risk evaluations before the June 2020 deadline, it must also grapple with a decision by the 9th U.S. Circuit Court of Appeals in *Safer Chemicals, Healthy Families et al. v. U.S. Environmental Protection Agency et al.*, 943 F.3d 397 (9th Cir. 2019).

The decision rejected critical elements of the EPA's risk evaluation process and set the stage for future challenges to the agency's final risk determinations.

Specifically, in June 2017, the EPA released a set of "framework rules" that established how the agency would conduct its risk evaluations under the Frank R. Lautenberg Chemical Safety for the 21st Century Act, 15 U.S.C.A. § 2601.

Those rules specified that the chemical uses considered by the EPA in risk evaluations would generally not include what are commonly known as "legacy uses" — uses that occurred in the past but are not "ongoing or prospective."

The EPA also announced that it reserved the right to exclude other types of uses from the scope of its risk evaluations, including unintentional inclusion of chemicals in other products (i.e., impurities), de minimis uses or uses that the agency believes are already adequately controlled by other regulatory schemes.

Numerous environmental, public health and consumer advocacy groups disagreed with the EPA's proposed approach, challenging the agency's decision not to analyze certain chemical uses in its risk evaluations.

They argued in a petition to the 9th Circuit that the public and environment continue to be exposed to chemicals already in the marketplace — for example, lead in lead pipes —

even if those chemicals or products are not being currently produced.

In the challengers' view, the EPA's exclusion of those exposures from its analyses would render the risk evaluations incomplete and would understate a chemical's potential danger.

A three-judge panel of the 9th Circuit ruled in November 2019 that the EPA cannot categorically exclude legacy uses, such as legacy uses of asbestos in insulation, or ongoing associated "legacy disposals," such as removal of that insulation from homes, from its risk evaluations.

Though the panel declined to rule on whether the EPA must analyze risks associated with impurities or de minimis uses, it left the door open for future challenges if the agency excludes them from its risk evaluations.

The 9th Circuit's decision puts the EPA in a difficult position, especially because the agency has already invoked a six-month extension allowed by the TSCA to complete the risk evaluations and cannot grant itself any additional time.

The EPA recently indicated that it may proceed with the asbestos risk evaluation in two parts because it may not be able to complete the legacy use and disposal analysis before June. The analysis of other chemicals may be subject to similar time constraints.

The question of whether the TSCA allows the EPA to conduct risk analyses in multiple parts does not have a settled answer. But regardless of the EPA's approach, the additional analyses will require significant work on the agency's part and will be closely watched by interested consumer groups.

WHAT'S COMING IN 2020?

The first half of 2020 will be a busy one for the EPA.

By June, the agency must not only finalize all 10 of its pending risk evaluations, but must also finalize the scope of the risk evaluation for each of its next 20 high-priority chemicals:

- Formaldehyde (commonly used in building products and as a preservative).
- BBP, DBP, DEHP, DIBP and DCHP (phthalates used as plasticizers in products like plastic pipes, toys, food packaging, cosmetics and medical/dental products) and phthalic anhydride (used to make phthalates).
- TBBPA, TCEP and TPP (flame retardants) and ethylene dibromide (sometimes used in the manufacture of flame retardants and fire extinguishers).
- HHCB (galaxolide) (fragrance additive found in perfumes, cosmetics and other consumer products).
- 1,1-dichloroethane, 1,2-dichloropropane, 1,2-dichloroethane, o-dichlorobenzene,

p-dichlorobenzene, trans-1,2-dichloroethylene and 1,1,2-trichloroethane (chlorinated solvents found in products like cleaning solutions, paint thinners and glues); and

- 1,3-butadiene (used to manufacture synthetic rubber).

The EPA also recently granted requests for risk evaluations of two phthalates — diisodecyl phthalate (DIDP) and diisononyl phthalate (DINP) — submitted by manufacturers taking the proactive step of seeking a risk determination from the agency. The risk evaluations for DIDP and DINP will also proceed in 2020.

MITIGATING LITIGATION RISK

As the EPA moves forward with this next set of risk evaluations, it will likely be dealing with challenges to its first 10 risk evaluations while it is simultaneously developing regulations for any chemicals it determines pose unreasonable risks.

With so many moving parts potentially tied up in litigation, companies whose products or manufacturing processes involve the chemicals may face years of uncertainty.

A high-priority designation does not mean that the EPA has determined that a particular chemical poses a hazard. The designation does, however, increase litigation risk as the EPA reviews the chemical and releases information about potential hazards throughout the process.

But the unpredictability of the agency's evaluation process (and any challenges to it) means that companies may not know the scope of that litigation risk for years following its initial identification.

Even if the EPA determines that a chemical poses no unreasonable risk, consumer groups may challenge those conclusions in court, and, if successful, force the agency to revisit the question.

Moreover, even for the chemicals the EPA does determine pose unreasonable risks, consumer groups who believe the agency's proposed regulations do not go far enough may likewise lodge challenges.

The uncertainty surrounding the EPA's TSCA risk evaluation and regulation process underscores the importance of developing strategic plans to deal with the potential disruption to business should identified chemicals be regulated — or even banned.

Companies should take steps to review their products and processes to identify if and where the first 30 high-priority chemicals may be used. Evaluating those uses is an important step toward preparing for regulation and potential litigation should those chemicals ultimately be determined to pose unreasonable risks.

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