Lawyer Insights

Formaldehyde Status Increases Litigation Risk

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Companies will soon face increased litigation risk involving formaldehyde, a common chemical found in consumer products like carpeting, flooring, foam insulation, paints, wood glue, cosmetics and fragrances. Following years of criticism over its handling of formaldehyde, on December 20, 2019, the U.S. Environmental Protection Agency identified it as a "high-priority" chemical for risk evaluation and potential regulation under the Toxic Substances Control Act (TSCA). This means the EPA will conduct a comprehensive public evaluation of the risks formaldehyde may pose to the environment and human health. If unreasonable risks are found, TSCA requires the EPA to issue protective regulations.

The most pressing question for the EPA's upcoming TSCA risk evaluation is whether the agency will make a final determination as to whether formaldehyde exposure causes leukemia. The agency reached this conclusion in a previous draft risk assessment prepared by its Integrated Risk Information System (IRIS), but the finding was met with widespread criticism, prompting a re-evaluation.

As the EPA releases information and solicits input from the public during its risk evaluation, litigation risk will increase as consumer groups push the agency to link formaldehyde and leukemia, advocate for tougher regulations, and attempt to build public support by putting pressure on companies. The uncertainty over what the EPA will conclude in its risk evaluation has implications for companies whose products contain formaldehyde as they work to anticipate regulations and face potential lawsuits.

Pressure from Consumers

Consumer groups have long called for stricter formaldehyde regulation and the EPA's decision to evaluate formaldehyde under TSCA has only added fuel to the long-running debate over the EPA's IRIS risk assessment for the chemical. IRIS first classified formaldehyde as a "probable human carcinogen" in 1991, identifying exposure as a potential cause of nasal cancer. In 2010, the agency released a new draft risk assessment, proposing to revise formaldehyde's classification to "carcinogenic to humans" and linking formaldehyde exposure to leukemia for the first time.
However, following widespread criticism of the scientific data and methodology underlying this new risk assessment, the EPA began revisiting its conclusion about the formaldehyde-leukemia link. Despite reports that it was completed in 2017, an updated assessment has still not been released.

Calls for the release of the updated IRIS assessment intensified in 2018 after the EPA delayed enforcement of its final rule, which regulated formaldehyde emissions from composite wood products (often used in furniture, flooring and construction) and imposed a number of testing and recordkeeping requirements on companies in the supply chain. The agency said that it wanted to give companies more time to prepare for compliance, but consumer groups successfully challenged this delay in federal court.

The EPA was ultimately required to enforce the rule six months earlier than planned, which came at great cost to affected companies that had only weeks to design and implement compliance programs as a result.

Most recently, in November 2019, Congress subpoenaed the EPA for documents and information concerning the unreleased IRIS report following the agency's decision to transition analysis of formaldehyde from its IRIS program to TSCA. That transition effectively put the IRIS assessment on an indefinite hold and it is not clear whether the EPA will consider its conclusions regarding leukemia in determining whether formaldehyde poses unreasonable risks under TSCA.

The litigation over the formaldehyde final rule made clear that challenges to regulations can lead to unpredictable results and create compliance difficulties for even the most proactive companies. Notably, although the EPA had sought to delay enforcement to allow companies additional time to comply, it has shown no leniency in assessing penalties. In August 2019, for example, it announced a $544,064 penalty against a company that had imported just 17 noncompliant products and self-disclosed its violations. The EPA's enforcement of the formaldehyde final rule should send a clear message that any unpredictability associated with its regulations is no excuse for noncompliance.

Potential Risks Ahead

With formaldehyde's high-priority designation now finalized, the EPA must begin the TSCA risk evaluation process and meet certain deadlines for disclosing information to the public. Public comments on a draft scope of its formaldehyde risk evaluation will be solicited and considered ahead of a June 2020 deadline for the final scope document. From that point, the EPA will conduct hazard and exposure assessments, risk characterization and risk determination. Once complete, it will release a draft risk evaluation that will be available for public comment and will be peer reviewed prior to finalization by December 2022.

With the TSCA risk evaluation process now underway, consumer groups will scrutinize the decisions the agency makes in defining the scope of its evaluation and choosing the science to support its conclusions—and will not hesitate to challenge those decisions, especially if it does not link leukemia to formaldehyde.

Challenges to the processes and scientific conclusions underlying any future formaldehyde regulations could create significant compliance difficulties while regulations are tied up in unpredictable litigation. And as the controversy over formaldehyde's potential link to leukemia heats up, plaintiff's lawyers searching for the "next wave" of toxic tort and product liability litigation may look to get out ahead of the TSCA risk evaluation, filing lawsuits early and banking on the science underlying the IRIS report's conclusions regarding leukemia. Likewise, the heightened public interest in formaldehyde means that companies may face lawsuits and have to defend their products in the court of public opinion—even if the EPA concludes that formaldehyde does not cause leukemia.

To further garner public support for regulations addressing formaldehyde's alleged link to leukemia, consumer groups may also pressure companies by conducting their own studies of popular consumer products and publicizing reports that those products contain traces of formaldehyde. Several groups have recently employed this strategy in their efforts to call attention to glyphosate, an herbicide allegedly linked to non-Hodgkin's lymphoma and at the center of multimillion-dollar verdicts involving Monsanto's Roundup weed killer. The groups' self-published studies claiming to have found traces of glyphosate in popular consumer products have made national headlines and fueled class action lawsuits filed by

consumers who claim to have been misled by glyphosate-containing products labeled as “natural” or “clean.”

Companies whose products or manufacturing processes use formaldehyde should take steps now to evaluate their products, supply chains, risk-shifting provisions and compliance programs. Though regulations can take years to become final—especially if they are challenged in court—anticipation and preparation are key to positioning a company for success both in terms of compliance and in addressing potentially high-profile product liability litigation that could significantly disrupt its business.

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