



Hand Sanitizer Production Cleans Up—Are Companies Ready?

Companies That Pivot to Hand Sanitizer Production Should Heed Varying Rules

Global product liability leader Shook, Hardy & Bacon creates easy-to-read infographics of regulations and requirements for companies entering into complex industry.

Washington, D.C. (July 14, 2020) *Business Wire* reports that global sales of hand sanitizer will soar to \$3.65 billion by 2025. Economists attribute the spike to the global COVID-19 pandemic that has people all over the world bettering their hygiene practices in an effort to ward off the virus. Even businesses who focus on other industries are pivoting to meet the demand including distilleries, breweries, personal care, and chemical and household product manufacturers according to media reports.

“Manufacturers moving to a new business line need to understand strict FDA regulations for hand sanitizers, which are regulated by FDA as a drug,” said John Johnson III, who has represented companies before the FDA and practices nationally from Washington, D.C. “Against those pathways to market requirements, manufacturers need to weigh the liability considerations against the PREP Act (Public Readiness and Emergency Preparedness Act).”

Regulations and requirements vary from country to country. In the UK and EU, hand sanitizers are regulated in various ways: as a cosmetic, a biocide or a pharmaceutical product. Each has its own regulatory requirements. Failure to comply with regulations may result in enforcement action; competitor complaints; and consumer claims. The FDA recently issued a warning to consumers and health professionals about manufacturers using methanol in hand sanitizer that can be toxic if absorbed through the skin or life threatening if ingested. Shook has created a series of [infographics](#) to easily explain some of the necessary requirements for manufacturing hand sanitizer in various jurisdictions.

“Understanding and following the rules at the outset helps companies avoid risk and develop potentially long term products,” said Shook Partner Eva Weiler, who focuses on a variety of industries including cosmetics and personal care and leads the firm’s Orange County office. “And coming up with a good quality and trustworthy product that consumers want—vs. throwing something together that results in regulatory action or lawsuit—could enable a new player to stay in the space even after the pandemic ends.”

Shook, Hardy & Bacon is known globally for its representation of some of the world's leading brands. In 2020, [Lex Machina](#) recognized Shook as the “most active defendants’ firm for product liability in the last five years” based on court records. [Chambers](#) ranked Shook nationally in the highest tier (Tier 1) for Product Liability and Mass Torts. The firm added offices in Atlanta, Boston and Los Angeles in 2019 and its premiere trial lawyers represent clients around the world in product regulatory and liability matters.

For the media

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About Shook, Hardy & Bacon

Founded in 1889, Shook, Hardy & Bacon L.L.P. has 15 offices in the United States and London, with attorneys and professional staff serving clients in the health, science and technology sectors in areas ranging from product liability defense and commercial litigation to intellectual property prosecution and litigation, environmental and toxic tort, privacy and data security and regulatory counseling.