



FIRM NEWS

## Former FDA Legal Counsel Moves to Shook

Former U.S. Food & Drug Administration (FDA) Associate Chief Counsel [Kristin Kaplan](#) joins Shook, Hardy & Bacon, further expanding the firm’s regulatory capabilities. Kaplan has a deep understanding of regulatory issues and the nuances of the government agency after advising FDA for eight years and serving an in-house role at a global leader in animal health.

“Her combined FDA insight and in-house experience make Kristin invaluable as we deepen our regulatory capabilities,” said Shook Chair [Madeleine McDonough](#). “It is critical for our clients facing litigation to align with our regulatory team to anticipate and address developing legal developments.”

Kaplan counseled FDA on a variety of issues, including new animal drug applications stemming from biotechnology and recalls of foods, animal foods and drugs. She later became Deputy General Counsel for one of the world’s largest animal health leaders, where she provided strategic insight on various issues including regulatory, compliance, and health, safety and environment matters. In addition, she provided direct global legal support for the company’s COVID-19 response.

“Given the new Administration and pending announcement of a new commissioner, it’s extremely important that businesses recognize priorities may shift whether that’s enforcement or COVID,” said Kaplan. “I am well-positioned to impart the lessons learned on what resonates with the FDA and what does not.”

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Shook offers expert, efficient and innovative representation to clients targeted by food lawyers and regulators. We know that the successful resolution of food-related matters requires a comprehensive strategy developed in partnership with our clients.

For additional information about Shook’s capabilities, please contact



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## FDA Announces Actions on Metals in Baby Food

The U.S. Food and Drug Administration (FDA) has responded to the [House report on levels of heavy metals in baby food](#) with the promise of additional action. The [FDA statement](#) notes, “First, today we issued a [letter to industry](#) reminding manufacturers of these types of foods of their existing responsibilities related to these efforts. Secondly, the agency is announcing that we’ll soon be putting into action a plan aimed at reducing toxic elements in foods for babies and young children to levels as low as is reasonably achievable.” The industry letter asserts that the agency will take action to remove foods from the market “when the levels of toxic elements or other chemicals in foods do pose a health risk,” citing as an example a [consent decree](#) the agency obtained in January 2021 to stop [Valley Processing Inc.](#) from selling adulterated juice.

The agency’s plan includes finalizing an action level on inorganic arsenic on infant rice and developing additional action levels. FDA also cited four areas to address: (i) “issuing guidance to identify action levels for contaminants in key foods, with plans to revisit those levels on a regular basis and lower them if appropriate, as well as providing guidance to industry on how to meet their obligations under current regulations”; (ii) increasing inspections and taking compliance and enforcement actions; (iii) boosting sampling for infant and toddler foods and sharing the results; and (iv) “working with government, academia and industry to support research and development of additional safety information on toxic elements in foods for babies and young children and additional steps that industry can take to further reduce levels.” The agency also indicated it will hold a public workshop on “the science surrounding levels of exposure that result in developmental impacts, and the foods that may contribute to those exposures.”

## USDA Reviewing Agency Inspections of Meatpacking Plants During COVID-19 Pandemic

The U.S. Department of Agriculture’s (USDA’s) inspector general will reportedly review how the agency handled inspections during the COVID-19 pandemic, according to [The Washington Post](#). The



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### ABOUT SHOOK

Shook, Hardy & Bacon is widely recognized as a premier litigation firm in the United States and abroad. For more than a century, the firm has defended clients in some of the most substantial national and international product liability and mass tort litigations.

Shook attorneys are experienced at assisting food industry clients develop early assessment procedures that allow for quick evaluation of potential liability and the most appropriate response in the event of suspected product contamination or an alleged food-borne safety outbreak. The firm also counsels food producers on labeling audits and other compliance issues, ranging from recalls to facility

probe will review how the Food Safety and Inspection Service spent \$33 million in extra funding provided by Congress in March 2020, including what precautions were taken to protect the health of inspectors.

The probe comes amid elevated scrutiny on how meatpacking plants have handled the pandemic, including lawsuits targeting meat companies. A Nebraska court dismissed a lawsuit brought by former employees of a Noah's Ark Processors plant alleging the company failed to implement proper precautions to stop the spread of the virus, holding that the employees lacked standing because they no longer work at the plant. *Alma v. Noah's Ark Processors LLC*, No. 20-3141 (D. Neb., entered March 1, 2021).

inspections, subject to FDA, USDA and FTC regulation.



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## LITIGATION

### Pennsylvania Cities Sue State over Ban on Plastic Bag Restrictions

Philadelphia and three other municipalities have filed a lawsuit challenging Pennsylvania's prohibition of bans on plastic or single-use bags. *Philadelphia v. Penn.*, No. 42 MD 2021 (Penn. Commw. Ct., filed March 3, 2021). "To combat the destructive environmental impact of single use plastic bags, states and cities across the country have enacted laws restricting distribution of single-use plastic bags by retailers," the complaint argues. The plaintiff cities assert that Pennsylvania has prevented them from taking action on limiting plastic bags. "In both 2019 and 2020, the Pennsylvania General Assembly used the annual fiscal code amendment – a must-pass omnibus-style bill that implements the state's budget – to sneak in a provision prohibiting plastics legislation by Pennsylvania municipalities into state law," they allege. "Petitioners are now indefinitely barred from enacting or enforcing local single-use plastics ordinances. Petitioners Philadelphia, West Chester, and Narberth wish to move forward with enforcement of their ordinances, but enforcement is not possible due to the unlawful plastics preemption provision. Petitioner Lower Merion is interested in considering a single-use plastics ordinance, but the plastics preemption provision bars not only enforcement but also enactment of new legislation."

The plaintiffs argue that the ban on plastic-bag restrictions violates the Pennsylvania Constitution in multiple ways, including a limit on bills "containing more than one subject" and an amendment providing that the "people of have a right to clean air,

pure water, and to the preservation of the natural, scenic, historic and esthetic values of the environment.”

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