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$19 Million Criminal Penalty Levied Against Food Manufacturer Serves as a Stark Reminder of the Importance of Food Safety Obligations

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Kerry Inc. Guilty Plea Follows Salmonella Outbreak

On February 3, 2023, Kerry Inc. pleaded guilty to a misdemeanor count of distributing adulterated cereal branded as Kellogg's Honey Smacks at its Gridley, Illinois, facility in violation of the Federal Food, Drug, and Cosmetic Act (FDCA). According to the unsealed criminal information, over the course of a two-year period, Kerry caused the introduction of adulterated food into interstate commerce that was prepared under insanitary conditions. This conduct was linked to Kellogg's June 2018 voluntary recall of Honey Smacks cereal following the U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention's (CDC) announcement of a multistate outbreak of salmonella linked to the cereal at Kerry's Gridley facility. According to the CDC, 135 people in 36 states were infected, resulting in 34 hospitalizations.

In its press release announcing Kerry's guilty plea, the U.S. Department of Justice (DOJ) stated that Kerry had detected salmonella at its Gridley facility via routine environmental tests approximately 81 times between June 2016 and June 2018. Despite this, Kerry's employees had "routinely failed to implement corrective and preventative [*sic*] actions (CAPAs) to address positive Salmonella tests." Kerry's guilty plea follows a July 2018 FDA warning letter issued to Kerry detailing "serious violations" of FDA regulations.

Kerry agreed to pay a criminal fine and forfeiture totaling $19,228,000, which is pending acceptance by the court. Kerry is scheduled to be sentenced on March 14.

Kerry's former director of quality assurance, Ravi Chermala, previously pleaded guilty to three misdemeanor counts of causing the introduction of adulterated food into interstate commerce. Chermala, who oversaw Kerry's sanitation program, admitted that he directed employees to not report certain information to Kellogg's about conditions at the Gridley facility. He also admitted to directing employees to alter the facility's program for pathogen monitoring, which effectively limited the facility's ability to accurately detect insanitary conditions. Chermala is scheduled to be sentenced on February 16.

Basic Food Safety Regulatory Obligations Implicated in Kerry Action

Food manufacturers are subject to a plethora of regulatory requirements at both the federal and state levels, depending on the specific type of operation and the products being manufactured. Manufacturing facilities like Kerry's Gridley facility are regulated by the FDA and must comply with the FDA's Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food regulation (CGMP & PC rule).

Broadly, the FDA's CGMP regulations require food to be produced under safe and sanitary conditions and set forth basic standards related to sanitary operations, facility sanitation, production, and process controls, among other things. The PC regulations require identifying "known or reasonably foreseeable" biological, chemical, and physical hazards; identifying and implementing preventive controls to minimize or prevent such hazards; and implementing corrective actions. Manufacturers must also comply with applicable reporting requirements when food safety issues arise, such as the FDA's Reportable Food Registry, as well as other potential state or local reporting requirements.

The July 2018 warning letter issued to Kerry details its failure to comply with these basic requirements. A warning letter is only issued, according to the FDA, for violations of "regulatory significance," i.e., "violations that may lead to enforcement action if not promptly and adequately corrected." The July 2018 warning letter covered an inspection of the Gridley facility conducted the previous month. In it, the FDA acknowledged that Kerry provided both verbal and written responses to FDA Form 483 (issued at the conclusion of the inspection listing deviations) with a description of the company's corrective actions.

While the FDA acknowledged it would evaluate the adequacy of Kerry's implementation of corrective actions during the follow-up FDA inspection, the warning letter was issued to detail various "serious violations" of FDA requirements. The violations detailed in the July 2018 warning letter included a failure to identify contamination of the cereal with salmonella as a food safety hazard requiring a preventive control, the failure to identify or implement sanitation controls to minimize or prevent that hazard, the failure to have corrective action plan procedures, and the failure to verify that any sanitation controls were being implemented.

The failures set forth in the July 2018 warning letter ultimately resulted in a referral to the DOJ and its subsequent criminal prosecution of the company and its quality assurance director.

Increasing FDA Action, Civil, and Criminal Enforcement

In its press release announcing the Kerry plea agreement, the DOJ called this fine and forfeiture "the largest-ever criminal penalty following a criminal conviction in a food safety case." At a time when the FDA has proposed to restructure its food safety program in the wake of criticism for how it has handled recent crises, including baby formula shortages and other major foodborne illness outbreaks, Kerry's guilty plea reflects an increase in FDA attention to food safety issues and other recent high-profile criminal and civil cases targeting the food industry.

As the COVID-19 pandemic began to recede in 2022, FDA inspections targeting food facilities dramatically increased. The FDA reports that domestic inspections of facilities in the food and cosmetic category rose from 4,593 in 2021 to 6,939 in 2022, while foreign inspections increased from 80 to 1,351 during the same period. With increased inspection activity, the agency's use of other tools, such as FDA Form 483 observations and warning letters, has also increased.

The Kerry plea deal also comes at a time of increased DOJ activity targeting food companies for violations of the FDCA. For example, in May 2020, ice cream manufacturer Blue Bell Creameries pleaded guilty to two misdemeanor counts of distributing adulterated ice cream in violation of the FDCA and agreed to pay a $17.25 million forfeiture,

as well as an additional $2.1 million to resolve civil False Claims Act allegations involving product sold to federal facilities. Similar to the Kerry matter, those violations involved manufacturing products under insanitary conditions and contaminated with *Listeria monocytogenes*. According to the plea agreement, in 2015, Blue Bell failed to recall product or communicate potential contamination after it received notification of positive *Listeria* tests (and only recalled product after hospitalizations and deaths occurred).

In a related case, Blue Bell's former president, Paul Kruse, was charged with seven felony counts related to allegedly concealing from customers what Blue Bell knew about the *Listeria* contamination. A second criminal trial of Kruse begins in April 2023 after jurors were unable to reach a unanimous verdict in his first trial, resulting in a mistrial.

Others in the food industry, such as Chipotle Mexican Grill Inc., a restaurant chain, have also been targets of the DOJ following foodborne illness outbreaks. In 2020, Chipotle agreed to pay $25 million to resolve criminal charges stemming from outbreaks from 2015 to 2018 linked to the company's systemic food safety failures. According to the three-year deferred prosecution agreement (DPA), Chipotle employees failed to follow food safety protocols, including a policy requiring the exclusion of employees who were sick or recently had been sick. Under the DPA, Chipotle agreed to implement an improved food safety compliance program.

Key Takeaways

With increased FDA and DOJ enforcement targeting the food industry, every food and beverage manufacturer should consider taking the following steps to ensure the product it distributes is safe and not adulterated and to mitigate potential enforcement risk:

- Place compliance with food safety obligations as a top business priority, and instill a culture focused on food safety throughout the organization.
- Prepare for when food safety issues arise by implementing policies and procedures that, for example, set forth obligations relating to conducting a root-cause analysis and corrective and preventive actions, as well as event reporting to regulatory authorities and customers.
- Prepare for regulatory inspections, as well as third-party and customer audits.
- Take responses to FDA Form 483s, untitled letters, warning letters, and other regulatory correspondence seriously to avoid escalation of regulatory enforcement activity or the initiation of civil or criminal investigations.

Our Food, Beverage & Agribusiness and White Collar, Government & Internal Investigations teams help clients navigate FDA compliance issues and respond to DOJ civil and criminal actions in the food and beverage industry and will continue to monitor and report on further developments.

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If you have any questions or would like additional information, please contact your Alston & Bird attorney or a member of the Food, Beverage & Agribusiness and White Collar, Government & Internal Investigations teams.

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