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A METICULOUS FOOD SAFETY PLAN TODAY
AVOIDS HANDCUFFS TOMORROW

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A Meticulous Food Safety Plan Today Avoids Handcuffs Tomorrow

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In August 2010, thousands of people across the United States were poisoned by eating eggs unknowingly tainted with Salmonella enteritidis bacteria.1 Following a lengthy investigation, the owners of the facility where the outbreak began were sentenced to three months in prison.2 This is not a one-off case; poor food safety practices are responsible for several outbreaks and often end in incarceration.3 Filthy hen houses, diseased fruit storage, and negligent food processing may be the last thing we want to imagine, but these practices have much to teach today’s food producers.

This article first examines how poor food production practices can lead to an environment ripe for spread of disease and an unacceptable level of contamination. Then, it explores what companies

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can do to prevent such unacceptable conditions, decrease the likelihood and severity of an outbreak and, of course, avoid incarceration.

The Salmonella That Sickened America

A Salmonella infection, or salmonellosis, is a dangerous and potentially fatal disease. Most people with salmonellosis experience diarrhea, stomach cramps, and fever for several days. The diarrhea can be so severe that some people need to be hospitalized. If the infection spreads to the bloodstream — which is more common in people with compromised immune systems — the victim may succumb to the illness and die. According to some reports, as many as 56,000 Americans were sickened during the 2010 tainted egg outbreak.

The Salmonella outbreak was traced back to eggs produced by a single company based in Iowa notorious for its scoff-law tactics: Quality Eggs, LLC. Faced with information tracing the contamination back to its facilities — courtesy of sleuthing regulators — Quality Egg recalled over 500 million eggs, one of the largest egg recalls in U.S. history. Quality Egg pled guilty to: (1) felony bribing of a USDA inspector; (2) felony introduction of misbranded eggs into interstate commerce with intent to defraud and mislead, and; (3) misdemeanor introduction of adulterated eggs into interstate commerce.

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5 Id.
6 Id.
7 Id.
10 Quality Egg, 99 F. Supp 3d at 923 (“After the U.S. Food and Drug Administration (FDA) presented epidemiologic information to Quality Egg, the defendants voluntarily recalled millions of dozens of eggs in 2010.”).
The Crimes That Spread the Salmonella

The Quality Egg outbreak story is truly sensational for a number of reasons, but especially for the company’s blatant disregard for cleanliness and the horrid conditions of the egg-laying facilities discovered during the FDA’s inspection. However, the case is often only discussed from the perspective of a corporate officer wondering if they are next to face prosecution for a food safety violation. Those concerns are justified. Jack and Peter DeCoster, the father and son duo who owned and managed Quality Egg, were prosecuted under a provision of the Federal Food, Drug and Cosmetics Act providing strict liability for introducing adulterated food in interstate commerce. 21 U.S.C. §331(a).13 Other corporate officers, though not many, have also been prosecuted under this provision as “responsible corporate officers” of food companies.14

Following a plea deal, the DeCosters paid hefty fines and eventually spent three months in prison.15 They were shocked by their prison sentences (issued by Mark Bennett, District Judge for the Northern District of Iowa) and appealed to the Eighth Circuit for relief. The Eighth Circuit upheld the prison sentences even though the DeCosters did not have personal knowledge that Quality Egg had shipped adulterated eggs.16 The Eighth Circuit held the sentences did not violate Due Process even though there was no intent element of their misdemeanor crimes. As the court explained: “[t]he elimination of a mens rea requirement does not violate the Due Process Clause for a public welfare offense where the penalty is ‘relatively small,’ the conviction does not gravely damage the defendant’s reputation, and congressional intent supports the imposition of the penalty.”17

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13 Quality Egg, 99 F. Supp. 3d at 923 (“Austin “Jack” DeCoster owned and controlled the activities of Quality Egg. Peter DeCoster, Austin DeCoster’s son, was the Chief Operating Officer of Quality Egg.”).
14 See id. at 937 (detailing two instances in which other corporate officers have been prosecuted as “reasonable corporate officers” under 21 U.S.C. § 331(a)).
15 DeCoster, 828 F.3d at 631.
16 Id. at 642.
17 Id. at 633.
Moreover, the defendants were not convicted for the wrongs of their subordinates; they were guilty for allowing FDCA violations when they knew or should have known of the unsanitary conditions that directly led to the violations.\textsuperscript{18} Though the DeCosters’ plea agreements claimed they did not know the eggs were contaminated, they admitted they were in positions of sufficient authority to detect, prevent, and correct the sale of contaminated eggs had they known about the contamination.\textsuperscript{19} Under the FDCA, this was sufficient to make them guilty of misdemeanor crimes as responsible corporate officers.\textsuperscript{20}

The Questions We Should Be Asking to Prevent Criminal FDCA Violations

Given these types of cases, corporate officers have reason to be concerned about the liability risks of running and owning a food business. Criminal strict liability for FDCA violations is a real possibility. However, while criminal liability for c-suite executives and quality control officers is an important concern, preventing death and severe illness from the shipment and sale of adulterated food is a much more important matter. The mental and physical harm incurred from a foodborne illness can be debilitating and impose a sentence much more severe than the three-month prison terms the DeCoster served.

Fortunately, the goals of avoiding criminal liability and preventing foodborne illness go hand in hand. I would suggest, however, instead of focusing on how food executives can avoid prosecution, food companies should ask the following question: How can we create a culture and environment that makes food safety a top priority?

\textsuperscript{18} Id. ("Under the FDCA… a Corporate officer is held accountable not for the acts or omissions of others, but rather for his own failure to prevent or remedy 'the condition which gave rise to the charges against him.'" (quoting United States v. Park, 421 U.S. 658, 675 (1975))).

\textsuperscript{19} Id. at 631.

\textsuperscript{20} Id. at 632.
priority and encourages employees to express food safety concerns and follow established food safety protocol?

What Practices Have Led to Outbreaks Resulting in Criminal Liability?

We can examine a handful of cases involving criminal food safety violations in pursuit of creating a better food safety culture. One is the case of Quality Egg LLC, mentioned above. Quality Egg’s massive egg laying system housed upwards of 7 million chickens which produced 5.5 million eggs a day. Large facilities containing millions of live animals provide excellent conditions for the introduction and spread of illness. Preventing disease calls for extreme care.

Quality Egg engaged in the opposite. The company allowed and created conditions that fostered the growth and spread of disease by: (1) failing to keep live and dead rodents, frogs, and flying insects out of their facilities; (2) failing to remove manure from the egg laying facilities such that it filled entire rooms and burst through facility doors; (3) failing to clean and sanitize equipment; and (4) failing to comply with written food safety plans. As a result, the Salmonella contamination spread throughout the company’s entire facilities and pushed the company’s Salmonella presence rate nearly 40 times higher than the national rate. Following the criminal investigation, the government discovered Quality Egg had also covered up its food safety problems, thereby prolonging and intensifying the outbreak. Quality Egg had falsified food safety records, lied to its customer’s auditors about food safety measures,

24 DeCoster, 828 F.3d at 630.
falsified packing dates on pallets of eggs, and bribed USDA officials so it could sell inferior eggs.\textsuperscript{26}

Another notorious case involves Peanut Corporation of America (PCA). Stewart Parnell, company president, and Michael Parnell, corporate officer, of PCA stood trial in 2014 for multiple federal crimes stemming from shipping adulterated peanut butter and peanut paste into interstate commerce.\textsuperscript{27} Shipping peanut products knowingly tainted with Salmonella typhimurium earned them felony convictions, and two decades each in prison.\textsuperscript{28} At least 714 people were sickened by the Salmonella; at least nine people lost their lives fighting salmonellosis infections caused by the negligent and intentional conduct of the Parnells and PCA.\textsuperscript{29}

What went wrong? Because they are grown on the ground, peanuts are generally more susceptible to encountering pathogenic bacteria than certain other foods.\textsuperscript{30} As such, peanut producers should be acutely aware of the higher potential for contamination and strive to eliminate the risk of contaminated peanuts entering commerce, something PCA ignored. Further, since PCA was a large peanut producer, their products were essentially everywhere. They also supplied large amounts of product to many vulnerable populations, including products used in school lunches, children’s snack products, nursing homes, and hospitals.\textsuperscript{31} PCA’s process also mixed together

\textsuperscript{26} Id.
\textsuperscript{30} \textit{See How Peanuts Grow}, NAT’L PEANUT BOARD, http://www.nationalpeanutboard.org/peanut-info/how-peanuts-grow.htm (“Unlike most plants, the peanut plant flowers above the ground, but fruits below ground.”) (last visited Sept. 19, 2018); \textit{see also} K. Annabelle Smith, \textit{Why Peanut Butter is the Perfect Home for Salmonella}, SMITHSONIAN, https://www.smithsonianmag.com/arts-culture/why-peanut-butter-is-the-perfect-home-for-salmonella-149834812/ (explaining that because peanuts grow on the ground, they “can be contaminated from a variety of sources: manure, water, wild animals—even the soil.”).
many peanuts in its facility, so contamination on one peanut could easily be spread to other peanuts, especially if equipment was not sanitized after each lot of product produced (which, in PCA’s case, it was not).

These facts — which are not in themselves FDCA violations — combined together allowed the following potentially dangerous food safety conditions: (1) initial contamination of the peanuts was possible before harvest because of the peanuts’ contact with soil, water and rodents;\(^{32}\) (2) cross-contamination in the facility was almost assured because the peanuts were mixed together and blended into pastes and butter;\(^{33}\) and (3) because much of the product was sold to entities making product for schools, the sick, and the elderly,\(^{34}\) there was a greater possibility for more severe illnesses. Like the DeCosters, however, the Parnells ignored these heightened risks and did the exact opposite of what they should have done: they created conditions that led to a widespread outbreak of foodborne illness.

Beyond these conditions, the Parnells’ negligence also included: (1) failing to fix leaky roofs that allowed potentially contaminated water to enter production facilities;\(^{35}\) (2) failing to validate roasting conditions to properly conduct the bacteria kill step;\(^{36}\) (3) failing to ensure adequate pest control, allowing for rodents and other pests to enter the facility and spread disease;\(^{37}\) (4) failing to use proper cleaning devices and failing to sanitize equipment;\(^{38}\) and (5) leaving product uncovered in facilities, among other regulatory misconduct.\(^{39}\)

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32 Smith, supra note 30.


34 Weise, supra note 31.


36 Id. at 80.

37 Id.


39 Id. at 3.
PCA and the Parnells also engaged in a cover-up conspiracy that prolonged the outbreak and prevented customers and the government from taking action to halt its spread. The cover-up included: (1) instructing company employees to ship product before the Salmonella test results were received by the company; (2) knowingly shipping Salmonella tainted peanut product to customers; (3) shipping numerous lots of peanut product with falsified certificates of analysis so customers believed they were receiving product that met their microbial specifications when, in fact, they were not; (4) failing to inform customers of positive test results received after the product had shipped; (5) shipping product without conducting any microbial testing at all, yet representing that testing had been completed; (6) re-testing a product that had tested positive for Salmonella until that product tested negative, then shipping the product with only the negative test report; and (7) continuing to produce product in a plant that PCA knew had produced contaminated product every year dating back to 2003. Given this background, it is easy to see how the Parnells earned their prison sentences.

Another cautionary tale involves Jensen Farms. The Jensen Brothers, owners and operators of Jensen Farms, set the record for the deadliest foodborne illness outbreak in the U.S. since the early 1900s. Not an easy feat. All told 33 people died and approximately 150 were sickened from eating cantaloupe tainted with Listeria monocytogenes

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40 See Basu, supra note 27.
42 United States v. Parnell, 723 F. App’x 745, 747 (11th Cir. 2018).
43 Id.
44 Id.
45 Id.
46 Id.
produced and sold by the Jensens in late 2011.\textsuperscript{49} Listeria is one of the most virulent foodborne pathogens and is particularly dangerous for the immune-compromised and developing fetuses.\textsuperscript{50} According to the CDC, the fatality rate for people who develop listeriosis as a result of infection with Listeria is 21%.\textsuperscript{51}

What caused this cantaloupe outbreak? Listeria bacteria is found in soil, water, and some animals.\textsuperscript{52} Cantaloupes are more susceptible to Listeria contamination than fruits growing off the ground because they grow on the ground and have significant contact with soil and water.\textsuperscript{53} Listeria can also live in processing plants, as a resident bacteria.\textsuperscript{54} The Jensens failed to take this heightened risk into account by not properly preparing their packing and storage facilities to address potential contamination. The primary culprit in spreading the Listeria bacteria was one piece of equipment — a used potato washing machine bought immediately before the outbreak.\textsuperscript{55} It was not thoroughly cleaned and thus harbored the Listeria bacteria.\textsuperscript{56} Further, the manner in which the cantaloupes were cooled, stored, and transported after harvest may have contributed to the Listeria growth.\textsuperscript{57} The Jensens were convicted of the same crime as the DeCosters, but

\textsuperscript{49} Multistate Outbreak of Listeriosis Linked to Whole Cantaloupes from Jensen Farms, Colorado (FINAL UPDATE), C\textsc{tr.} F\textsc{or} D\textsc{isease} C\textsc{ontrol} and P\textsc{revention} (Aug. 27, 2012), https://www.cdc.gov/listeria/outbreaks/cantaloupes-jensen-farms/index.html.

\textsuperscript{50} See generally Listeria (Listeriosis), C\textsc{tr.} F\textsc{or} D\textsc{isease} C\textsc{ontrol} and P\textsc{revention}, https://www.cdc.gov/listeria/ (providing information on Listeria and how the illness it causes, listeriosis, affects the United States’ population) (last updated June 29, 2017).


\textsuperscript{54} Listeria—DHHS, supra note 52.


\textsuperscript{56} Id.

\textsuperscript{57} Id.
for clearly less egregious conduct. The Jensens were ordered to pay restitution, perform community service, were sentenced to five years’ probation and six months home detention.

The lessons

What are the lessons corporate officers can learn from these cases? The primary point, according to the foremost expert in food safety litigation, Bill Marler, is: “there was always an opportunity to fix the problem before it blew up.” This is true in all of the outbreaks explored in this article and likely true of every other major foodborne illness outbreak in the United States. The lesson should be to have a food safety system in place for finding and maximizing on those opportunities. On a more microscopic level, the primary lessons from these criminal cases are fairly obvious:

- Don’t engage in fraudulent conduct (e.g., falsifying testing reports or changing production date stamps) and don’t tacitly encourages others to do so.
- Don't knowingly ship or sell contaminated product.
- Don’t bribe or otherwise attempt to manipulate regulators.
- Don’t create conditions that foster spread of disease by, for example, storing product in open containers or allowing rodents and other vermin easy access to your facility.
- Create, and then follow, a FSMA-compliant food safety plan.
- Immediately fix a food safety violation when you uncover it.

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58 Compare Plea Agreement for Eric Jensen, United States v. Jensen, No. 13-mj-01138 (D. Colo. Oct. 22, 2013) (finding Eric and Ryan Jensen knowingly distributed adulterated cantelope in interstate commerce), with United States v. DeCoster, 828 F.3d 626, 631 (8th Cir. 2016) (showing Mr. Decoster plead guilty to: (1) bribing a USDA inspector, (2) intentionally introducing misbran ded eggs into interstate commerce, and (3) introducing adulterated eggs into commerce).
60 Bill Marler, Managing Partner, Marler Clark, Lecture in Food Safety Litigation Course at the Univ. of Ark. Sch. of Law (Spring 2017).
However, these measures are no-brainers and things your company is hopefully already doing. So what else can we discern from these cases about foodborne illness prevention that is not immediately obvious and may help create a more meaningful food safety program? Here are some ideas:

1. Create a food safety first culture. A food safety first culture can make all the difference in preventing or lessening the severity of an outbreak. Food safety was not part of PCA’s company culture. Employees were routinely instructed to ship contaminated product and to “just ship” product without receiving test results because the Parnells did not want to lose a customer. The Parnells maintained a company-wide culture of indifference and indignation to food safety measures. In contrast to the Parnells, food companies should ensure the company culture has a strong, primary focus on food safety which includes ensuring all employees feel comfortable reporting potential food safety violations, no matter how trivial they may appear. Companies should consider incentives and rewards for employees who identify and fix food safety errors. Moreover, company policy should instruct that each employee is responsible for, and must take ownership of, the safety of all food products under his or her control. Management should likewise take responsibility for, and ownership of, food safety products under control of his or her subordinates. Food safety should be a source of company and employee pride.

2. Do not ignore your own internal food safety research. The 1993 Jack-in-the-Box E-coli outbreak could have been prevented if the company had simply followed the advice and research of its own employees. In that case, internal studies showed that increasing cooking time by a couple of minutes would have reduced the

62 Id. at 13.
E-coli colonies in burgers sufficient to ensure they could be safely consumed. Jack-in-the-Box management ignored one employee’s suggestion to increase cook time and, instead, reminded the employee of the obligation to follow the existing company cooking-time policies. Had they taken up the suggestion instead, the outbreak could have been prevented.

3. Have measurable and meaningful pathogen-reduction goals. In ready-to-eat foods, the goal for positive pathogen testing should, of course, be zero. Likewise, for per-se adulterants (e.g., E-coli 0157:H7), zero tolerance is the measure. However, where the USDA or FDA has not declared a pathogen a per se adulterant, companies should set strict and challenging microbial level goals. For example, Wal-Mart has undertaken significant efforts to reduce the presence of Salmonella in its raw chicken by placing strict pathogen requirements on its chicken parts suppliers. Wal-Mart has also implemented a testing regime for the raw chicken it purchases. As a result, the company has had a significant decrease in Salmonella presence in its raw chicken.

4. Know where your skeletons are. That is, understand the risks most likely associated with your product and create — then follow — an individual risk mitigation plan for those specific risks. There are some food products that commonly carry pathogens;

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64 *Id.*

65 See id. (noting the company’s answer to an employee’s concern about undercooked burgers, which stated that “if patties are cooked longer, they become tough.”).


poultry is known to carry Salmonella bacteria,\(^\text{69}\) beef is known to carry E-coli bacteria,\(^\text{70}\) and ready-to-eat deli meat is known to carry Listeria bacteria.\(^\text{71}\) Companies selling these products, therefore, should test for these pathogens and create a pathogen-reduction and control program specific to those risks as a part of FSMA compliance. For example, given the 2017 widespread outbreak of E-coli illness from romaine lettuce grown near Yuma, AZ, food companies planning to source produce from that region should take caution to protect against contamination. The outbreak was traced to an irrigation ditch downstream from a concentrated cattle feeding operation and upstream from the romaine fields; the source of the E-coli, therefore, may still be lingering upstream from the produce fields.\(^\text{72}\)

5. Invest in traceability measures and consider blockchain technology. Food giants like Wal-Mart view blockchain technology as the answer to stopping or slowing down food-related pathogen outbreaks.\(^\text{73}\) Regulations require a one-forward, one-back traceability system, but as we saw in the recent E-coli outbreak, this approach may not be sufficient to initiate a product recall or swiftly trace the source of the pathogen. It took months for the CDC and FDA to

\(^{69}\) *Chicken and food poisoning*, CTR. FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/features/salmonellachicken/index.html (noting that “Chicken can be a nutritious choice, but raw chicken is often contaminated with *Campylobacter* bacteria and sometimes with *Salmonella* and *Clostridium perfringens* bacteria”) (last updated Sept. 20, 2018).


\(^{71}\) *Listeria*, supra note 51.


trace the tainted romaine lettuce back to a grower. In the meantime, grocery stores were pulling all romaine products off their shelves and consumers were avoiding consumption of any and all romaine lettuce. The outbreak could have ended sooner and companies could have wasted fewer resources had the supply chain been better documented through blockchain or other technology. Blockchain technology can assist with more than traceability, it can also help companies identify any weakness in their supply chain since it can be used to automatically track temperatures, shipment dates, delivery dates, currency of safety certificates, and other information critical to maintaining a safe and secure supply chain. As part of your traceability program, conduct mock recalls and audits to ensure your traceability system will function if necessary.

6. Take immediate action to notify customers of a recall. In other words, don’t wait until the close of markets on a Friday afternoon to notify your retailers of a recall. This common practice is a dead giveaway you are putting profits ahead of food safety and may ruin your relationships with business partners.

7. Overtrain employees on food safety and do it in their native language. Research shows people only retain 20% of what they hear. Repetition can significantly increase this number, so employees must be trained and trained again (critically, in their native language) on proper food safety measures.


Conclusions

In sum, following a food safety plan is essential to achieve food safety goals, prevent widespread and lingering outbreaks, ensure regulatory compliance, and avoid incarceration. Going one step further and engaging employees, creating a healthy food safety culture, and installing numerous check points can create brand loyalty, customer loyalty, and hopefully prevent any illness from occurring at all. Simply put, if food companies put food safety first, the results will follow.