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FOOD SAFETY RISK

The Top Food Safety Exposures Which Corporate Leaders Most Often Overlook.

MITIGATING RISK AND EXPOSURE THROUGH MANAGING VISIBLE AND INVISIBLE FOOD SAFETY RISKS

About the Author

Shawn K. Stevens is the founding member of Food Industry Counsel LLC, the only law firm in the U.S. that represents food industry clients exclusively. Mr. Stevens works throughout the country and abroad with food industry clients (including the world's largest growers, food processors, national restaurant chains, and food distributors and grocery chains) helping them protect their brand by reducing food safety risk, complying with FDA and USDA food safety regulations, managing recalls, and defending high-profile foodborne illness claims.

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Introduction

Manufacturing food products is accompanied by enormous risk. Because food products are intended to be consumed by the public, food manufactures are held to a heightened duty of care. Not only must manufacturers ensure that they are taking the appropriate steps to consistently produce a safe and wholesome product, they must also ensure that the product they are selling is safe and free from any contamination that could harm or sicken consumers.

Consistently producing safe products that are free of pathogens and other contaminants has always been a challenge. In large part, this is because pathogens are invisible and difficult to detect. Moreover, there are countless modalities for pathogens to be introduced to food production facilities. For instance, pathogens may be introduced through incoming ingredients, packaging, employees, equipment, traffic, or product flow. Likewise, pathogens may also be introduced or transferred throughout a facility by rodent or pest activity, which mostly occurs overnight when nobody is around. If this activity is not appropriately controlled, pathogens can be reintroduced following routine cleaning and sanitation by the migration of rodents through a facility. Once spread, pathogens can—unbeknownst to the company—contaminate equipment or finished products destined for consumer's homes.

When contamination slips through a facility's defenses and food products become compromised, consumers can become sick or worse. Of the more than 700 food recalls last year, about one-third (approximately 250) involved the presence of harmful pathogens. Notably, as few as 10 *E. coli* O157:H7 cells can cause illness. Symptoms include severe stomach cramps, diarrhea (often bloody), and vomiting. Some people also develop a potentially lethal condition called hemolytic uremic syndrome (HUS), which can result in kidney failure and stroke. And, *E. coli* is not the only foodborne pathogen that can cause life-threatening illness. *Listeria monocytogenes* can also be a prolific pathogen in food facilities and the food processing environment. Historically, nearly one-third of confirmed *Listeria monocytogenes* illnesses were fatal.

As a result, in recent years, the Food and Drug Administration (FDA), Food Safety Inspection Service (FSIS) and the federal Department of Justice (DOJ)

have publicly announced that if a food company sells food that makes people sick, the company will be scrutinized to determine whether the contamination was preventable and, if so, whether enhanced civil or even criminal penalties are appropriate. Thus, when developing, implementing or assessing food safety programs, it is critical for company leadership to identify and address every risk.

The U.S. Supreme Court "Park Doctrine:" Personal criminal exposure for food safety failures

The Responsible Corporate Officer Doctrine (RCOD), colloquially known as the "Park Doctrine," is a controversial legal doctrine under which both companies and their corporate executives may be prosecuted for violations of the Federal Food Drug and Cosmetic Act (FDCA), even without any prior knowledge of wrongdoing. In turn, many food company executives have found themselves under criminal investigation by FDA and DOJ in recent years for unknowingly distributing products responsible for causing foodborne illness outbreaks.

In *U.S. v. Dotterweich*, the U.S. Supreme Court explained that FDCA prosecutions dispense "with the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger." Thus, corporate officers can be criminally prosecuted if the company they are employed by ships adulterated product into commerce, regardless of whether they had any foreknowledge. Thus, under current law, even if there is no affirmative wrongdoing, the officer of a corporation can be prosecuted under the Federal Food, Drug, and Cosmetic Act for shipping adulterated product.

Since *Dotterweich*, federal prosecutors have routinely used the RCOD to prosecute corporations and officers for FDCA violations. To obtain a conviction for an FDCA violation, prosecutors must prove each of the following beyond a reasonable doubt:

1. The corporate officer was in a position of responsibility relevant to the violation;
2. The corporate officer was able or authorized to prevent or correct the violation; and
3. The corporate officer failed to prevent the violation.

Though every executive understands that delivering adulterated food into interstate commerce is a violation of federal law, few understand the risk they face. Consider what befell John Park, who, absent any intentional wrongdoing, was tried, convicted, and now has a criminal legal doctrine (the "Park Doctrine") named after him.

United States v. Park, 421 U.S. 658 (1975)

In the early 1970s, Acme Markets, Inc. operated a large national retail grocery chain with 874 stores, 16 warehouses, and approximately 36,000 employees. John Park, the company's CEO, had broad operational oversight responsibility, but little involvement in the day-to-day operational happenings, which he delegated to qualified division heads who, in turn, had their own staffs and departments under them.

In late 1971, during a 12-day inspection at an Acme warehouse in Baltimore, Maryland, FDA inspectors discovered evidence of rodent activity (i.e., rodent droppings on the warehouse floor near a pallet of cased product). Park first became aware of the violations a month after the fact, when FDA issued the company a FORM 483 (itemization of FDCA violations), at which point he immediately contacted Acme's Vice President for Legal Affairs, who assured Park that the head of the respective division was investigating the situation and would be taking corrective action.

During a follow-up inspection three months later, FDA inspectors noted improvement in the evidence of rodent activity, but not complete abatement. Soon after, Park and Acme were charged by FDA and DOJ with multiple misdemeanor violations of the FDCA. Park, who had no personal involvement or knowledge in the matter until after the violations were discovered, pleaded not guilty. At trial, Park acknowledged that, as Acme's CEO, he was ultimately responsible for the company's conduct. Consequently, he was found guilty for failing to abate continued evidence of rodent activity.

Park stands for the proposition that FDCA violations are chargeable against anyone and everyone with a share of the responsibility for preventing FDCA violations. In other words, criminal liability for a violation of the FDCA attaches not only to individuals directly responsible for violations, ***but also any management personnel responsible for taking affirmative steps to prevent violations.*** Upon conviction, defendants may face significant fines and even jail time.

United States v. DeCoster, 828 F.3d 626 (8th Cir. 2016)

Austin "Jack" DeCoster owned Quality Egg, an Iowa company that operated a processing facility, six farms, and 97 barns housing chickens and hens. His son, Peter DeCoster, was Quality Egg's COO. The DeCosters also owned and operated several egg production companies in Maine.

In August 2010, Quality Egg was allegedly responsible for an outbreak of *Salmonella enteritidis*. During the subsequent investigation, FDA inspectors identified numerous sanitation problems at Quality Egg's chicken farms. Following a criminal investigation stemming from the outbreak, Jack and his son were charged with misdemeanor violations of the FDCA under the RCOD. After pleading guilty, they were each fined $100,000 and sentenced to three months in jail.

The DeCosters appealed the sentence, arguing that, because they did not know that the eggs were adulterated, imprisonment was unconstitutional. The Court disagreed, succinctly summarizing the law as follows:

> The FDCA punishes neglect where the law requires care, or inaction where it imposes a duty because according to Congress, the public interest in the purity of its food is so great as to warrant the imposition of the highest standard of care on distributors.

Thus, whenever a food company ships an adulterated product into commerce, the company and its corporate leadership face the specter of a criminal investigation, and potential criminal charges or fines.

Administrative Orders Halting Production

It can take hundreds-of-thousands, or even millions of dollars, to reopen – an ounce of prevention is better than a pound of cure.

There are numerous direct and immediate costs associated with any food product recall. They include: (1) issuing notifications to the public, regulators, and your customers in the supply chain; (2) removing implicated product from commerce; (3) storage and disposal of the recalled product; (4) assembling a crisis team, which includes the often costly services of regulatory lawyers and Public Relations consultants; and (5) conducting a comprehensive root cause analysis.

In addition to the immediate reactionary costs, companies faced with a recall will suffer other financial losses as well. According to a study by the Food

Marketing Institute and the Grocery Manufacturers Association, recalls cost companies an average of $10 million in direct costs alone. These costs do not include indirect costs, which can exceed direct costs and include lost future sales, business disruption, fines or regulatory costs, litigation, and lost share value.

To determine the value of the various components of losses in a recall, companies can use available data to predict what their losses might be. One of the tools available to accomplish this goal is historic recall data. In 2018, for instance, the average weight of a food product recall equated to 269,572 pounds.

Thus, if a company wanted to forecast the likely financial impact of a food product recall, it need only to multiply the company's Sale Price to customers for each pound of product produced times 269,572 pounds:

_____	X	269,572	.
Sale Price to customers (per pound)		Average Recall (in pounds)	

Thus, in our simple example, if the per pound Sales Price to customers is $2.50, then the recall will likely cost the company **$673,930** in lost revenue. These costs can vary significantly, however, depending upon the product or commodity involved. As noted above, one of the larger recalls in 2018 involved a total of 17,249,347 pounds of product. Using the estimated price above, the recall would have cost a staggering **$43,123,367.50**.

It is also important to note that, in addition to the losses detailed above, many retailers will also charge additional fees (such as administrative costs) back to their suppliers. While difficult to quantify given the wide-range of product recalls and the varying scope of recalls, these fees are almost always substantial.

In addition to chargebacks, most companies faced with these types of recalls will also be forced to halt production and shutter their doors while they disassemble equipment and production lines to find the root cause of the resident contamination. In many cases, following a large-scale recall, in the absence of compelling evidence that the problem has been identified, contained and corrected, regulators may demand a production stop. In order to resume production, companies will have to make sufficient improvements and pass numerous re-inspections from state and local regulators.

This process often involves considerable assistance from experts and additional facility and equipment investment to persuade state and federal

regulatory officials that the pathogen has been eliminated and that production should be allowed to resume. In many cases, this process can last weeks or even months. Here too, these costs can easily climb into the hundreds of thousands, or even millions, of dollars.

Finally, none of these costs take into account the losses that will be suffered from brand damage. Whenever a recall occurs, commercial customers and consumers alike will hear the negative publicity and begin to question the brand. If the facility is shut down, customers will likely begin buying a competing product elsewhere. In some cases, regardless of whether the company is forced to halt production, entire national accounts can be compromised or lost. In turn, remaining orders and sales will likely decline while the company works to slowly regain trust. As a result, in the short-term and long-term aftermath of a recall, the total financial impact can become overwhelming.

Incorporating risk mitigation strategies into the design of your systems is one of the best ways to avoid long production delays when a recall occurs.

Negative Press
Drop in Sales, Share Value, and Sentiment

For years, Chipotle was one of the best performing stocks on the S&P 500. Between 2006 and 2015, Chipotle's share-price rose from $42 to $750. Chipotle's explosive growth came to a crashing halt in the aftermath of multiple foodborne illness outbreaks. By early 2018, Chipotle's share price had plummeted to less than $300. That is more than a 50% drop.

A decrease in share value is far from the worst that can happen from a financial standpoint. Indeed, as outbreaks are more frequently detected and traced to their source, and recalls are more frequently encompassing weeks, months or even years of product, the likelihood of going out of business as a result of a recall is increasing.

For instance, in 2016, a frozen vegetable company had to completely cease operations and recall approximately hundreds of products sold under 42 separate brands that were produced over a period of multiple years. The company ultimately went out of business as a result.

In April 2015, an ice cream company was implicated after an FDA sample from a retail container of ice cream tested positive for *Listeria monocytogenes*.

FDA went to the manufacturer's facility and, among the samples it collected, there was a positive that matched case patients in the CDC database.

The *Listeria* outbreak had sickened just 9 people over a period of more than five years. The significant period of time that elapsed, in contrast with the relatively limited number of illnesses is striking. The first known illness was in January 2010. It was followed by two additional illnesses in 2011, one in 2012, none in 2013, three in 2014, and one in 2015. Once the matching strain was found, the agency urged the company to recall all of its products.

The company ultimately recalled eight million gallons of ice cream, laid off 1,450 workers, and furloughed another 1,400.

Large recalls almost invariably equal bad press. When it occurs, bad press inevitably places additional political and other pressure on regulators to close facilities and resist the resumption of production until it is certain that the underlying problem is fixed. In many cases, the financial strain forces the company to close.

Lost Customers
When They Leave, Many Will Never Come Back

The effect on consumer attitudes is among the most significant factor in terms of the damages associated with recalls. Studies have shown that 15% of consumers claim they would never buy a recalled product again and 21% of people affected by a recall would not buy any product from the same manufacturer. These results are backed by a 2010 U.S. Grocery Supplier survey which found that in the year following the large spinach and peanut butter recalls, almost three-quarters of consumers stopped purchasing those products out of safety concerns.

Despite these alarming numbers, there is another even greater risk of loss associated with recalls. That risk is losing important downstream customers. Losing your best customers can devastate your business. Given that the food industry is among the most competitive of all large industries, losing a customer is often permanent. For many food companies, there are individual customers that make up disproportionate cross-sections of total sales. In such a circumstance, the choice of one customer to go elsewhere can easily result in a permanent loss of 20, 30, or even 40% of total sales.

With the emergence of the "New Recall Model" (referenced above and described in more detail in the next section), recalls can often cover years' worth

of product. With a 24-hour news cycle, and the ease of sensationalizing food issues, food companies are uniquely situated to be devastated by a recall. No matter how great the relationship is with any customer, or how safe your products have historically been, it is a rare customer that will be willing or able to withstand the withering pressure associated with negative press coverage. Indeed, in many cases the only option may be to cut ties.

Making a Buck vs. Making People Sick

Turning a profit is nearly impossible when your products cause outbreaks

The food industry has made enormous progress toward improving food safety. However, regulators have simultaneously made enormous improvements in traceability. Consequently, although food is safer, the numbers of recalls and outbreaks have continued to increase. Moreover, today's recalls are often more damaging than ever before due to an emerging shift, a new recall model.

In the past, recalls were typically confined to products produced during narrow, well-defined, periods of time. That is no longer the case. Instead, enhanced regulatory sampling capabilities mean recalls increasingly involve weeks, months, or even years of production. New investigative tools allow for the detection of low intensity outbreaks responsible for intermittent illnesses occurring over long periods of time. Such outbreaks are often caused by niche organisms that persist in dark, difficult to reach parts of facilities or equipment. As noted above, these conditions can be created or even exacerbated by unmonitored rodent activity and migration. In addition, databases like Pulsenet and GenomeTrakr, which contain millions of isolates, allow regulators to instantly identify matches between positive samples collected from inside food facilities and illnesses that occurred years ago.

Today, there is at least one PulseNet laboratory in every state, and although the vast majority of illnesses uploaded to the PulseNet database over the last 20 years remain unsolved, the network has enabled CDC and FDA to solve hundreds of foodborne illness outbreaks involving thousands of case-patients. The PulseNet database now has more than a million isolates, and that number will continue to increase.

To make matters even more precarious for food companies, FDA has begun aggressively pursuing enforcement initiatives aimed not only at decreasing the numbers of outbreaks and recalls but holding companies implicated in the

occurrence of illnesses accountable, regardless of whether the company committed any wrongdoing. In pursuit of its objectives, FDA has begun: (a) intensive pathogen sampling at the retail level: (b) conducting microbiological profiling (so-called "swab-a-thons") of food processing facilities during routine inspections; and (c) as noted above, pursuing criminal investigations against regulated-entities, including executives, whose products are implicated in outbreaks of foodborne illness. (*See* above relating to the Park Doctrine).

When FDA collects a sample at retail that tests positive, or when a regulated entity is implicated in an outbreak, FDA personnel are authorized to demand entry into facilities, to urge and then compel product recalls, and to conduct extensive environmental sampling. This means scouring a facility, collecting hundreds of samples from drains, ducts, processing equipment, and finished products. The objective is to hunt down and isolate any pathogens which, if found, are subjected to genetic fingerprinting. Even as FDA is conducting this extensive microbiological profiling in the facility, regulators will demand access to internal food-safety records, including months or years of microbiological testing data, which are critically examined with an eye toward enforcement.

The lesson: Despite incredible progress, companies (and executives) are facing more risk than ever before. Once a company is linked to an illness cluster or outbreak, it becomes nearly impossible to earn a profit.

Supply Chain Risk
Mitigating exposure when its not your warehouse

We live in an increasingly globalized world with increasingly complex supply chains. Mitigating risk requires managing the safety of your product until it reaches its final destination – the consumer. This means that, in addition to managing upstream risks that may be introduced into your facilities by suppliers, companies must also manage the risks introduced by down-stream partners.

Imagine a scenario in which, after your products leave your control, they are stored in a third-party warehouse while awaiting distribution. Imagine further that you begin receiving complaints from your customers that products shipped from that warehouse are showing signs of rodent activity or infestation. When the warehouse is confronted, it claims to have robust pest-management programs, but refuses to share accurate monitoring data. And, instead of shouldering responsibility, the third-party warehouse blames you and claims that the product was damaged while in your control. In the eyes of your customer, you

and your company would be to blame.

This scenario plays out across the U.S. every day. If your downstream partners can be persuaded to invest in effective, real-time, rodent monitoring technologies, however, emerging problems can be quickly identified and corrected. These are the types of proactive initiatives which can help you better protect your brand and image. Transparency throughout the supply chain, which includes your suppliers, your own internal operations, and your downstream partners, will ensure that you are always manufacturing – and delivering – the safest possible product which consumers and customers have increasingly come to expect and demand.

Conclusion

Food companies producing products for the consuming public face enormous risk. Many of these risks are visible and more easily controlled. Others are more nuanced and require a special lens through which to focus. Through the use of real-time monitoring technologies, the once unforeseen and invisible risks created by rodent activity can be identified and controlled.

Once that occurs, the likelihood of a large-scale recall, and the adverse consequences which follow, will likely be reduced dramatically