Back to Basics: Overhauling Food Safety from the Ground Up.

Introduction

Since the discovery of microbes nearly two centuries ago, humanity has waged an endless war against dangerous pathogens. Pathogens, for their part, have proved to be a formidable adversary. They are ubiquitous in the environment, microscopic, and have spent eons developing elaborate defensive capabilities. Nevertheless, the ingenuity, sacrifice, and dedication of generations of doctors, scientists, and engineers have allowed humanity to make extraordinary inroads in the war against disease. The war is fought in hospitals and laboratories, remote jungles, distant warzones, and even in space. But perhaps more than anywhere else, the war is fought in food processing environments.

Consistently producing a product that is safe and free from harmful pathogens or other contaminants remains an elusive challenge for the food industry. In large part, this is because pathogens are invisible, ubiquitous, and adept at establishing harborages within food processing environments. Moreover, pathogens can be introduced into a food production facility through a multitude of vectors, including incoming ingredients, employees, and equipment. Once introduced, pathogens can rapidly spread throughout a facility. If sanitation practices are ineffective, pathogens can colonize, leading to the intermittent discharge of pathogenic bacteria into the processing environment and ultimately into finished products.

From the standpoint of exposure to legal liability, manufacturing food is an enormously risky endeavor. In simple terms, food production involves removing vast quantities of plants and animals from the dirt or the pasture, transporting them to manufacturing facilities, and turning them into safe, edible products that are

completely free of pathogens. Because food products are manufactured for public consumption, food manufactures are subject to a heightened legal standard. Thus, it is not enough for manufacturers to ensure that their food safety programs are capable of consistently producing a safe and wholesome product. Every product they sell must in fact be safe to consume and free of microscopic pathogens.

Notwithstanding the manifest difficulty of eradicating all foodborne pathogens from all food products at all times, the food industry has made enormous progress toward improving food safety. This progress is principally the product of a better understanding of how foodborne pathogens propagate through food processing environments.

Put differently, carefully studying the behavior of foodborne pathogens has significantly advanced and fundamentally altered our understanding of how pathogens reach consumers. The advances in our understanding have given way to some surprising lessons. For instance, expensive, state of the art, interventions are not necessarily the best interventions. To the contrary, ***we have found that, increasingly, the best interventions are often about getting back to basics***.

Pathogen Persistence
A Microscopic Problem with Monumental Consequences

Historically, the consensus view was that foodborne illness outbreaks were caused by small amounts of pathogenic contamination transiting the entire supply chain from harvest to consumer. Advances in technological, genomic, and surveillance capabilities, however, have led to vast improvements in traceability, which, in turn, have upended the historical consensus and led to revelations which require the food industry to completely rethink its approach to food safety. These revelations are manifested in a ***New Recall Paradigm*** which, because it has gone unnoticed, has devastated many companies in the food industry.

Paradoxically, although food is now safer than ever before, the numbers of recalls and outbreaks have continued to increase. Moreover, recalls are not only more frequent, but also more damaging than ever before because they increasingly implicate months or even years of production.

Pathogens are More Prevalent and Persistent Than Once Believed

In the past, recalls were typically confined to products produced during a narrow, well-defined, period (*i.e.*, a single shift of production). This is because national foodborne illness outbreak surveillance operated at a lower resolution than today. While early genetic typing methods, *e.g.,* Pulse Field Gel Electrophoresis, when coupled with bootstrap epidemiology, were effective in identifying large outbreaks, the technology was not good enough to identify the smaller and more subtle outbreaks that were occurring. Discovering the occurrence of an outbreak—much less the specific source—often required a significant number of foodborne illness outbreak cases occurring in close temporal and geographic proximity. Only then could investigators gather enough information to identify a food product source and a likely production window.

Today, enhanced surveillance and high-fidelity genetic typing capabilities, such as Whole Genome Sequencing ("WGS"), allow investigators to identify and trace illnesses with extraordinary precision and efficiency. Databases like GenomeTrakr, which contain a growing number of clinical and environmental isolates, allow regulators to instantly identify genetic matches between positive samples collected from inside food facilities and human illnesses. Now, with the use of WGS, the source of low-profile foodborne illness outbreaks can often be determined even where there are only a handful of clinical or environmental samples, and even when the positive samples are separated by months or years.

Employing modern tools and technologies, food industry stakeholders have learned some very important lessons. Key among them is that outbreaks are frequently caused by resident (as opposed to transient) pathogens intermittently contaminating food products, thus resulting in isolated illnesses occurring over periods of weeks, months, or years. In these outbreaks, a pathogenic organism (often a single strain) will persist in dark, difficult to clean and sanitize parts of facilities or equipment. Perplexingly, these pathogens manage to survive routine cleaning and sanitation, but are still able to intermittently transfer to food contact surfaces and finished products for days, weeks, months and, sometimes, years.

To conceptualize the scope of the threat, one might consider that while only 10 *E. coli* O157:H7 organisms can cause illness, more than 100,000 cells can fit on the head of a pin. Even in the cleanest food processing facilities, there are literally countless nooks and crannies, both on and around food contact surfaces, that can conceal a pinhead. Consequently, most food processing environments

remain dangerously susceptible to what we have only recently discovered is one of the gravest threats: pathogenic harborage sites.

When contamination slips through defenses and food products become compromised, consumers can become sick or worse. Of the over 700 recalls last year, nearly one-third (approximately 250) involved the presence of harmful pathogens. Again, 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 serious type of illness called hemolytic uremic syndrome ("HUS"), which can result in kidney failure, stroke, and even death. And, *E. coli* is not the only pathogen that can cause severe life-threatening disease. *Listeria monocytogenes* can also be a prolific pathogen in food facilities and the food processing environment. Notably, nearly one-third of all patients who become sick from *Listeria monocytogenes* will also die. And, from an environmental control standpoint, *Listeria* remains one of the food industry's most significant challenges.

The FDA and USDA Response

Further enhancing the threat to food companies, USDA and FDA have begun aggressively pursuing enforcement initiatives intended to reduce outbreaks and hold companies accountable, regardless of whether the company knowingly 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) pursuing criminal investigations against regulated-entities, including targeting executives, whose products are implicated in outbreaks of foodborne illness. USDA has also increased the level of sampling conducted in food processing environments and on products.

Given this background, it is difficult to overstate the monumental risk facing food companies. Suffice it to say that very few American food companies are positioned to survive a multi-year product recall, especially one involving illnesses. The costs associated with regulatory investigations and fines, civil liability, lost business, legal fees, and public relations are often astronomical and rarely compensable by insurance.

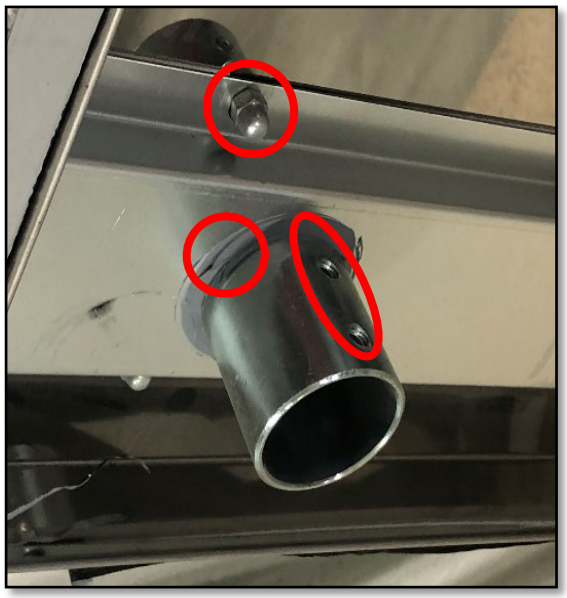
Fortunately, there is a relatively simple, straightforward, and cost-effective measure companies can take to immediately and drastically reduce the ability of pathogens to establish harborages, and thus reduce risk. The simplest answer is to utilize clean design equipment.

Clean Design Equipment
A Brilliant Engineering Solution to a Persistent Problem

A simple but brilliant engineering approach can be used to eliminate and eradicate pathogenic harborage sites in food processing facilities. From a sanitation standpoint, most tables, racks, and other types of industrial equipment widely used in food processing facilities are very poorly designed. Such equipment often uses hollow tubing, nuts, bolts, and sealants, all of which are difficult to clean and sanitize and thus provide ample hiding places for microscopic organisms. Moreover, hollow tubes, screw holes and other voids can collect and store water, further enhancing conditions conducive to microbial growth.

Processing Table or Trojan Horse?
The Growing Risk Created by Non-Sanitary Design in Food Processing

The photographs below provide illustrative examples of insanitary design aspects common to traditional non-sanitary tables, which are conducive to the creation of pathogenic harborages:



Traditional designs—although problematic in terms of sanitization—are designed to reduce manufacturing costs. In food processing operations, however, ***the use of traditional equipment, which cannot be effectively cleaned and sanitized, can introduce tremendous risk and unanticipated cost. Thus, the cost reductive design aspects of traditional non-sanitary equipment***

significantly increase the downstream risk of persistent microbiological contamination as well as increasing sanitation time and costs. Consequently, any savings realized by purchasing poorly designed and inferior equipment are more than offset by the substantial risk and additional costs added from substantially increased risk.

Clean Design Tables

Clean Design Equipment, on the other hand, is specifically designed and constructed for environments where sanitation matters. Clean design tables are purposefully designed to mitigate or eliminate harborage points and to reduce cleaning time and costs. Clean design products facilitate effective sanitization by utilizing only formed components and complete clean welds with no hollow tubes or other pathogen harboring cavities.

The following photographs depict the sanitary design aspects of such tables:

Steel Top Table SSL-1001

Tab Top Table SSL-1002

The following photograph demonstrates that there are no seams or attachment points where pathogens could find harborage or residence:

This design is easy to quickly and effectively clean and sanitize. Thus, the design not only reduces the risks associated with pathogenic harborages, it also reduces cleaning time and thus significantly reduces both labor and water, which further offsets any cost differential between traditional and clean design products.

SSL Industries
The Leading Manufacturer of Clean Design Equipment

SSL Industries, headquartered in Plymouth, Wisconsin, is an industry leader in the design and manufacture of clean design equipment. SSL Industries designs and constructs a vast array of fully customizable products, including clean design tables, for use in a vast array of medical and food processing applications. SSL's patented Clean Design products are USDA approved.

Demand for SSL's products has grown dramatically in recent years (both from existing clients seeking to expand their use of Clean-Design Equipment and a bevy of new clients from across the sector).

SSL's founder and President, Steve Lawrence, has enjoyed utilizing a creative approach to meeting the demand. Because the interest in Clean-Design Equipment has come from such a diverse cross-section of food industry companies, Mr. Lawrence has had the opportunity to invent, design and manufacture entirely new types of equipment that address the specific needs and applications of his clients.

The USDA approval obtained by SSL Industries was based upon comprehensive design reviews and compliance with consensus standards established by NSF/3-A Joint Committee on Food Processing Equipment and the procedures in the USDA Guidelines for the Evaluation of the Sanitary Design and Fabrication of Meat and Poultry Processing Equipment.

In addition to manufacturing clean-design products, SSL also manufacturers clean design shop carts, platforms, benches, racks, conveyors, boot/shoe washers, and many other products. The optional stainless casters and formed acetal pads can also withstand very high temperatures, thus allowing for equipment "cook" or "steam" treatment interventions. Such interventions might include cooking the clean design equipment in an oven, or tenting and steaming to achieve full lethality treatment.

All products come with a DA Finish standard, which exceeds USDA requirements and helps mask fingerprints.

The Costs of Failure
Regulators are Utilizing Enforcement and Criminal Sanctions to Punish Executives, Even Absent Knowledge of Wrongdoing

When FDA or USDA collect a food sample at retail that tests positive for a pathogen, or when a regulated entity is implicated in an outbreak, the agencies are authorized to demand entry into facilities, to urge and then compel product recalls, and to conduct extensive environmental sampling. This means the regulators will scour a facility and collect 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 WGS 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 food safety documents and microbiological testing data, which are critically examined with an eye toward enforcement.

As a result, in recent years, FDA, USDA and the federal Department of Justice ("DOJ") have publicly announced that if a food company sells food which makes people sick, the company and its operations may be carefully scrutinized to determine whether the contamination that sickened consumers could have been prevented and, if so, whether there is any basis for enhanced civil or even *criminal* penalties. Thus, when developing, implementing or assessing food safety programs and the necessary controls (such as sanitary equipment), it is critical for company leadership identify and address all possible risk.

The U.S. Supreme Court "Park Doctrine:" Personal Criminal Liability for Food Safety Failures

The Responsible Corporate Officer Doctrine ("RCOD"), colloquially known as the "Park Doctrine," is a controversial legal doctrine under which both ***food companies and their corporate executives could be prosecuted, when their products make people sick, for Federal Food Drug and Cosmetic Act ("FDCA") violations even without any prior knowledge of wrongdoing.*** In turn, many food company corporate 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 FDCA 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, discussed further below, 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 issues 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 time in jail.

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 and consumers become sick, the company and its corporate leadership face the specter of a criminal investigation, and potential criminal charges or fines.

The Consequences of Outbreaks and Recalls

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

There are numerous direct and immediate costs associated with any outbreak and food product recall. At the most severe, they may include orders from regulatory authorities withdrawing registrations and ordering a food company

to cease production. At the least severe, they may include: (1) issuing notifications to 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 always quite substantial.

As noted, in addition to these losses, some companies faced with these types of recalls may also be required to halt production and shutter their doors while they disassemble equipment and production lines to find the root cause of

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.

The best way to avoid long production delays in the event of a recall is to design your systems to mitigate risks.

Negative Press
Lost Sales, Plummeting Share Value, and Public Mistrust

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 several of foodborne illness outbreak events. 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 sample 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 result in 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 May 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 2007 spinach and peanut butter recalls, almost three-quarters of consumers stopped purchasing certain products out of safety concerns.

Despite the 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), recalls can often affect product produced over the course of many years. With the 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.

Conclusion

In today's day and age, food companies face enormous risk. As previously noted, nearly one-third of all 2018 recalls were caused by food products becoming unknowingly contaminated with dangerous pathogens. We now know that the largest recalls are almost always caused by resident pathogens contaminating food products. These recalls often involve hundreds of thousands—or even millions—of pounds of food products. The larger the recall, the larger the recall-related losses, and the larger the total financial exposure.

To combat the monumental risk arising from resident pathogens, food processors must get back to basics. Here, getting back to basics means eliminating harborage sites from food processing environments. Adopting Clean Design products is the single most effective way to do so.

Clean Design products (tables, chairs, racks, conveyors, etc.)—specifically those manufactured by SSL Industries—are expressly designed to effectuate sanitation by utilizing easily accessible components and stainless steel construction with no hollow tubes or other pathogen harboring cavities. In addition to enhancing safety and sanitation, Clean Design products can lead to significant

reductions in cleaning and sanitation time and effort, decreased water usage, and a lower volume of cleaning and sanitation products.

Collectively, these advantages can result in more production time, more revenue, and more peace of mind for food processors and their customers.