



FoodIndustry
COUNSEL LLC

WHITE PAPER

FDA's WAR ON PATHOGENS

Criminal Charges for Food Company Executives and Quality Assurance Managers

Shawn K. Stevens, Esq.¹
Global Food Safety Attorney

Food Industry Counsel, LLC
www.foodindustrycounsel.com
920.698.2561

Table of Contents

1.	Overview.....	3
2.	FDA’s War on Pathogens: The Federal Government’s New Regulatory and Criminal Offensive Against the Food Industry.....	3
	A. FDA’s Surveillance Capabilities (PulseNet) Used to Link Foodborne Illnesses to a Specific Food Product or Company.....	4
	B. FDA’s Response to Lessen the Number of Outbreaks and Recalls (New Regulations, Microbiological Profiling and Criminal Sanctions).....	4
	(a) FDA’s Regulatory Offensive Against Industry: FDA Microbiological Sampling of Food Products Collected from <u>RETAIL STORES</u>	6
	(b) FDA’s Regulatory Offensive Against Industry: FDA Microbiological Environmental Sampling in <u>FOOD PRODUCTION FACILITIES</u>	7
	(c) FDA’s Criminal Offensive Against Industry: Commencement of Federal Criminal Investigations in Cases Involving Positive Food or Environmental Samples Linked to Human Illness.....	7
	i. The Park Doctrine.....	8
	ii. Peanut Corporation of America.....	8
	iii. Quality Egg.....	8
	iv. Jensen Farms.....	9
	v. ConAgra.....	9
	vi. Blue Bell.....	9
	vii. Chipotle Mexican Grill.....	10
	viii. Multiple Additional Non-public cases.....	11
	C. Strategies to Determine the Extent of Contamination in the Environment, Reduce Environmental Pathogens, and Decrease Criminal Liability.....	11
	(a) Microbiological Profiling Studies.....	13
	(b) Pathogen Reduction Technologies.....	13
	(c) Criminal Protection Audits.....	14
3.	Conclusion.....	15

1. Overview.

In recent years, the food industry has witnessed an alarming increase in the numbers of foodborne illness outbreaks and food product recalls. Last year alone, there were over 500 food product recalls.² Many of these were triggered by the presence of harmful pathogens in the food products or resulting outbreaks. In response to these alarming trends, Congress ordered the Federal Food and Drug Administration (“FDA”) to overhaul the safety of the food supply when it passed the Food Safety Modernization Act (“FSMA”).³

To execute this mandate, FDA is executing numerous policy changes. The agency is now conducting microbiological profiling inside food processing facilities during routine inspections and testing vast amounts of food at retail. FDA is also initiating criminal investigations against food companies (and their executives) who distribute food products that have the potential to cause human illness. These investigations involve multiple cases where food company executives had no direct knowledge that their food products were causing illness or had the potential to cause illness.

Many of these criminal investigations involve *Listeria monocytogenes* (“LM”) found either: (1) in food processing environments; or (2) in food products in commerce. Although previously FDA permitted food companies to occasionally detect LM in the processing environment (so long as the LM was controlled and did not contaminate food contact surfaces or products), under FDA’s new approach, the failure to eliminate sporadic LM findings in the environment may now subject companies to criminal liability. FDA’s aggressive enforcement initiatives targeting harmful bacteria can be reasonably characterized as “the FDA’s War on Pathogens.” These policies will continue to intensify.

The immediate challenge to the food industry is to find a more effective solution to identify and reduce ubiquitous pathogens like LM in the processing environment through the use of emerging pathogen-reduction technologies, while at the same time implementing written food safety protocols which, if followed, provide additional protections against criminal sanctions. The following sections further detail the emerging challenges confronting the food industry, as well as recommended solutions designed to determine the extent of any environmental contamination in the environment, to reduce any pathogens that may be present, and to decrease through written protocols potential criminal liability.

2. FDA’s War on Pathogens: The Federal Government’s New Regulatory and Criminal Offensive Against the Food Industry.

FDA has the capability to effectively link any foodborne illness to a specific food product or company, and is using its powers to microbiologically sample food products at retail and the environment in food processing facilities. In turn, FDA’s policy is to initiate a criminal investigation if it links a positive retail or environmental sample to any human illness.

A. FDA's Surveillance Capabilities (PulseNet) Used to Link Foodborne Illnesses to a Specific Food Product or Company.

Prior to the Jack-In-The Box Outbreak in 1993, which sickened 600 people and killed four, there was no national system in place to track foodborne illness outbreaks as they occurred. The source of the Jack-In-The-Box Outbreak (undercooked hamburgers served to customers) was only discovered because the victims were located in a relatively limited geographical area, and were in many cases treated in the same hospitals and in some cases by the same doctors. As a result, the existence of an emerging outbreak was eventually identified, and healthcare providers worked closely with public health officials to determine the ultimate source.

Following the conclusion of that outbreak, the federal government recognized that similar outbreaks were likely occurring throughout the nation without any means to detect them. To enhance its ability to detect outbreaks real-time as they occurred, the government implemented a system of mandatory foodborne illness reporting.

As a result, beginning in the late 1990s, whenever a doctor in any of the 50 states discovered that a patient was positive with a pathogen of concern (such as *Listeria Monocytogenes*, *Salmonella* or *E. coli* O157:H7), he or she was (and remains) required to report that finding to the relevant state health department. The individual states then request copies of the isolates and test them for the specific genetic DNA fingerprint of the pathogen making the patient sick.

Those genetic DNA fingerprints are then uploaded to PulseNet, the system designed by the Centers for Disease Control ("CDC") to track emerging foodborne illness outbreaks. When indistinguishable genetic DNA fingerprints are uploaded from multiple victims, the CDC knows that a foodborne outbreak is emerging, and will then share that information with FDA and other federal, state and local health departments as they work collaboratively to determine a common source. Although the specific causes of the vast majority of illnesses uploaded to the PulseNet database over the last 20 years remain unsolved, the system has enabled CDC and FDA to solve hundreds of foodborne illness outbreaks involving thousands of victims.

B. FDA's Response to Lessen the Number of Outbreaks and Recalls (New Regulations, Microbiological Profiling and Criminal Sanctions).

When PulseNet first came online in the late-1990s, numerous overlapping outbreaks were almost immediately identified. Over the next ten years, as the system became more effective and capable, more and more outbreaks were identified at an increasing rate. As the national surveillance system matured, it also became clear that many of the food products sold in commerce, and many of the ingredients used to produce those food products, were at risk from contamination with pathogens of concern. In many cases, product from a single lot or batch of contaminated ingredients might be sold by a single supplier to dozens of customers and then used

to produce hundreds of products which would be distributed into thousands of retail stores.

In 2009, in an effort to contain the consequences associated with shipments of contaminated ingredients into the food supply, FDA created the Reportable Food Registry (“RFR”). Prior to the RFR, if a food company sampled the ingredients received from a supplier, and those ingredients tested positive for a pathogen, the company would simply reject the shipment and it would be returned to the supplier. Once the RFR became a requirement, any food company finding that the ingredients or products it received tested positive was (and remains) required to inform FDA of those findings. The agency then used these reports to take regulatory action against the original supplier, and require that all ingredients or products from all potentially affected lots be recalled from commerce. Because the RFR allowed FDA to immediately begin tracking and containing ingredients testing positive for pathogens, the introduction of the RFR caused an immediate and massive spike in the numbers of recalls being announced.

Driven initially by the large numbers of outbreaks and recalls triggered by PulseNet, and then reinforced further by the increasing numbers of recalls triggered by the RFR, a national perception that the country’s food supply was extremely unsafe began to emerge. As a result, members of the public and media began calling upon Congress to do more to protect the safety of the national food supply.

Congress responded by beginning work on the Food Safety Modernization Act (“FSMA”), which was signed into law on January 4, 2011. Although the law was enacted over 5 years ago, the regulations giving FDA the tools to enforce the new law took years to finalize and do not begin go into effect until September 2016. With that said, FSMA gives FDA extremely broad new powers to overhaul the safety of the food supply. In essence, the new regulations require all FDA-regulated food companies to develop and implement written preventative control programs designed to control pathogens and other hazards in food. As the FDA begins enforcing these rules, all food companies will face increasing regulatory risk, scrutiny and exposure.

In addition to the RFR and the new tools FDA has under FSMA, the agency is pursuing additional regulatory enforcement initiatives in its efforts to decrease the numbers of outbreaks and recalls. These initiatives include the FDA’s recent initiatives: (a) to sample and test vast amounts of food products at retail for the presence of pathogens; (b) to conduct microbiological profiling of food processing facilities during routine inspections; and (c) to look for the justification to bring criminal sanctions against a food company any time positive samples from its food products or production facilities are linked to an outbreak or connected to a foodborne illness.

(a) FDA's Regulatory Offensive Against Industry: FDA Microbiological Sampling of Food Products Collected from RETAIL STORES.

As part of its policy initiatives, FDA is now collecting vast amounts of food products from retail stores, and testing those products for the presence of pathogens. The agency is sampling both products intended for human consumption and food intended for animal consumption. In June 2015, for instance, FDA announced that between June 1, 2015 and August 31, 2015, it would commence a nationwide initiative to collect and test samples of pet food at retail for the presence of pathogens.⁴ As a result of that offensive, FDA discovered contamination in multiple products, and forced all of the companies that were targeted to recall all of their affected products.

As FDA continues to collect and test food products from retail stores, there is an increasing likelihood that an increasing number of food products will test positive for the presence of pathogens. In the event of any positive product sample, FDA will take immediate action against the company that processed the product. Initially, the agency will require the company to recall all affected product.

In addition to mandating a recall of the affected product, FDA will also demand entrance into the production facility at issue, and begin sampling the environment extensively (taking hundreds of samples from the drains, floors, walls, production equipment, and finished products) to find the same strain as the sample testing positive at retail. In these circumstances, it is likely that FDA will identify additional positives, and any recall will broaden accordingly.

Additionally, in the event that any product or environmental samples test positive, FDA will perform genetic DNA testing on the isolates collected from those samples, and compare the DNA fingerprints of those samples against the DNA fingerprints of the isolates collected from sick case patients over the last 15-years and uploaded into the PulseNet database. If FDA discovers that the DNA fingerprint from any of those samples matches an illness (or illnesses) in the PulseNet database, FDA will immediately presume that all of the illnesses were caused by product that originated from that facility. This is the same scenario which unfolded in advance of the recent Blue Bell outbreak and recall, which is discussed in greater detail below.

At the same time FDA is conducting extensive microbiological profiling in the food production facility at issue, FDA will also demand full access to all food production and microbiological testing records for the previous months (or, even, years) and begin to critique those records. Additionally, pursuant to FDA's new enforcement initiatives, we predict that in the event any sample is

linked to an illness, the FDA will commence a broader criminal investigation, as discussed in more detail below.

(b) FDA’s Regulatory Offensive Against Industry: FDA Environmental Microbiological Sampling in FOOD PRODUCTION FACILITIES.

Pursuant to FSMA, FDA is also required to inspect all food production facilities that process higher-risk ingredients or food products within the next three years. In the example noted above, FDA demanded access to the food production facility at issue, and then performed microbiological sampling of the processing environment, only after the company’s product tested positive at retail. As part of its new policy initiatives, FDA is now performing extensive microbiological profiling of the food processing environment in all food production facilities it visits **during routine FDA inspections**.

Thus, when FDA visits any of these facilities over the course of the next three years (and lower-risk facilities over the course of the next five years), the agency will as a matter of course perform microbiological sampling of the food processing environment (sampling drains, floors, walls, food processing equipment, and finished products). The level and intensity of sampling will likely increase in the coming months and years as FDA continues to inspect food production facilities while carrying out its mandates under FSMA. In the event any environmental sample tests positive, depending upon the location of the sample and the circumstances surrounding its collection, the agency may require the company to recall potentially affected product.

In the event this occurs, recall exposure is not the only exposure facing the companies at issue. As FDA continues to perform extensive microbiological sampling in food production facilities, the agency will continue to perform genetic DNA testing on any positive samples collected from those facilities, and compare the DNA fingerprints of those samples against the DNA fingerprints of sick case patients over the last 20-years. If FDA discovers that the DNA fingerprint from any of those samples matches an illness (or illnesses) in the PulseNet database, FDA will immediately presume that all of the illnesses were caused by a food product that originated from that facility.

(c) FDA’s Criminal Offensive Against Industry: Commencement of Federal Criminal Investigations in Cases Involving Positive Food or Environmental Samples Linked to Human Illness.

As demonstrated in the recent *Jensen Farms*, *Quality Egg*, *ConAgra*, *Blue Bell*, *Chipotle* and other ongoing incidents, FDA has demonstrated its intent to initiate a criminal investigation against any food company executives or Quality Assurance (“QA”) managers involved in a case where a positive sample collected by FDA from their food facility or product is linked to a

foodborne illness. The FDA is using this power while, at the same time, exercising nearly limitless authority to access company records during the course of an inspection and investigation – without a warrant.

i. The Park Doctrine

The FDA's power to bring criminal charges against corporate executives and high-level managers was solidified in 1975, under the "Park Doctrine," when the Supreme Court upheld the conviction of the president of a major grocery chain. In that case, the president was found to be criminally liable for the insanitary conditions existing in a company distribution center, notwithstanding the argument that he had delegated the responsibility for maintaining the cleanliness of the distribution center to his subordinates.

The Supreme Court concluded that if a company ships adulterated food, the management of that company can be charged, even if they have no direct knowledge or intent. Under this standard, a food industry executive or QA manager can be sentenced to prison if he or she is aware of a circumstance or condition within his or her facility that could lead to a foodborne illness and fails to take action to correct it. If charged with this type of misdemeanor, the executive could be sentenced to up to a year in prison and a \$250,000 fine for each count. In each case, FDA will consider the individual's position within the company, his or her relationship to the violation, and whether in fact he or she was in a position (or, had the authority) to correct the violation.

ii. Peanut Corporation of America

Recent examples show that the government intends to use these types of criminal sanctions as a tool to compel compliance and to create a deterrent. The most notable involves a *Salmonella* outbreak caused by Peanut Corporation of America ("PCA") in 2008. Stewart Parnell, 61, PCA's owner, was sentenced to 28 years in prison for knowingly selling peanut products contaminated with *Salmonella*. Parnell's brother, a peanut broker, was sentenced to 20 years. Parnell's QA manager was sentenced to five years.

iii. Quality Egg

In 2010, Quality Egg distributed products that were linked to human illness. The company's eggs were blamed for causing a *Salmonella* outbreak that sickened over one-thousand people. In this case, company executives did not know that their products were sickening consumers. Nevertheless, the company was cited by FDA for failing to control *Salmonella* in the growing and processing environment. Following the conclusion of the outbreak, FDA

launched a criminal investigation, and company executives were sentenced to three months in jail and given significant fines for their food safety violations.

iv. Jensen Farms

In 2011, Jensen Farms distributed cantaloupe contaminated with LM. Over a two-month period, the tainted cantaloupe sickened nearly 150 people and killed over 30. Although the owners of the company did not know that their products were contaminated, federal prosecutors brought criminal charges arguing that the company failed to take appropriate steps to reduce LM contamination in their facility. While the owners were not imprisoned, they were sentenced to five years' probation, six months' home detention, 100 hours of community service and assessed individual fines of \$150,000.

v. ConAgra

More recently, in 2014, FDA urged that criminal charges be brought against ConAgra for distributing *Salmonella*-contaminated peanut butter in 2006 and 2007 which sickened approximately 700 people. The company pled guilty to the charges and paid over \$11 million in fines. The decision followed the FDA's pronouncement on May 2, 2014 that the agency intends to pursue "[c]riminal prosecution for falsifying records, lying to FDA, knowingly putting consumers at risk, or in other appropriate cases."⁵ Especially telling is the agency's use of the words "... or in other appropriate cases," which in essence describes the new FDA policy of initiating criminal investigations whenever a positive sample from a product or facility is linked to a human illness.

vi. Blue Bell

The following year, in 2015, Blue Bell ice cream was linked to an outbreak spanning five years. In the Blue Bell investigation, FDA sampled Blue Bell's ice cream at retail, and then sampled Blue Bell's production facilities, and linked positive samples from that investigation to a total of seven case patients in the CDC database who carried the same strain of LM. What makes the investigation most concerning for industry is that the first people who became sick in the outbreak became ill more than five years ago. Indeed, the first illness was reported in January 2010. Two more illnesses were recorded in 2011. There was only one illness 2012, and three in 2014. The final illness was reported in January 2015.

Once FDA found the same strain in Blue Bell's facilities that sickened these people, the agency urged the company to recall all of its products. Although we will never know how many finished products that Blue Bell shipped were ultimately contaminated, what remains clear is that a large

amount of product was unknowingly becoming contaminated within Blue Bell's facilities over a long period of time.

In the event criminal charges are brought against Blue Bell, FDA will likely argue (to support those charges under the "Park Doctrine") that: (1) Blue Bell was periodically finding LM in the environment in its facilities over the course of the previous five-years (thus, it was aware of a condition that could lead to product contamination and resulting human illness); (2) that Blue Bell failed to take action to correct the condition (by eliminating the resident strain of LM from its facility entirely); and (3) that, as demonstrated by the seven matching illnesses in the PulseNet database (that had been uploaded over the course of the previous five-years), human illness did in fact result. Although this seems like an extreme approach, given the ubiquitous nature of LM, it is the approach the agency has adopted and is aggressively pursuing.

While the FDA refrained from comment in the weeks following the discovery of the outbreak whether charges would be brought, DOJ confirmed separately that FDA and DOJ are making the use of criminal sanctions "a priority" when companies "fail to live up to their obligations to protect the safety of the food that all of us eat." Since those public statements were made, we have learned that DOJ, working with FDA, has in fact served federal grand jury subpoenas in the Blue Bell case, likely scanning food company records and executive emails in an effort to justify the criminal charges it intends to bring.

vii. Chipotle Mexican Grill

The most recent high-profile example involves Chipotle Mexican Grill ("Chipotle"). For numerous months in 2015, the national restaurant chain struggled to contain and manage numerous foodborne illness outbreaks linked to its restaurants. Although the source of many of the resulting illnesses remains under investigation, Chipotle confirmed in a public filing that it initially received a federal grand jury subpoena from DOJ in connection with a norovirus outbreak that occurred at a restaurant in California. In that outbreak, over 200 of Chipotle's customers became ill.

According to reports, in August 2015, company executives became aware that numerous employees from the restaurant had reported being sick, and waited a few days before informing the local health department of the illnesses and closing the restaurant. In turn, it appears that FDA and DOJ initiated a criminal investigation and served the grand jury subpoenas in an effort to gain access to corporate emails and to determine whether company executives waited "too long" after learning about the illnesses to take action. Here too, the FDA would likely argue to support charges under the Park Doctrine that: (1) numerous Chipotle employees were sick (thus, corporate executives were aware of a condition that could lead to human illness through

the transfer of disease); (2) Chipotle failed to take action to immediately correct the condition (the company permitted the restaurant to stay open for another 3 or 4 days); and (3) human illness did in fact result (more employees became ill and approximately 200 customers became sick from norovirus). Here too, this seems like an extreme approach to take against a company, given the uncertainty of the etiology of any restaurant employee illness, it is the approach the agency has adopted and is pursuing.

Following the issuance of the initial subpoena, FDA and DOJ recently expanded the investigation. Company officials subsequently confirmed that, on January 28, 2016, Chipotle was served with a subpoena broadening the scope of the previously-announced criminal investigation by the U.S. Attorney's office for the Central District of California. The new subpoena requires Chipotle to produce documents and information related to company-wide food safety matters dating back to January 1, 2013, and supersedes the subpoena served in December 2015 that was limited to the Chipotle restaurant in Simi Valley, California. Here too, it appears that, while the agency is in fact attempting to discover how the recent outbreaks occurred, FDA is also engaged in a broader "fishing expedition" to see if there is any further justification to bring criminal sanctions as a result of any of the company's broader food safety conduct.

viii. Multiple Additional Non-public Cases

In addition to the examples detailed above, there are many more. DOJ in cooperation with FDA is currently pursuing criminal investigations (and serving additional grand jury subpoenas) against numerous other companies connected to other reported illnesses. Because of limitations associated with the ongoing investigations, the underlying facts of these cases cannot be discussed publicly. With that said, while there are many lessons to be learned for the government's pronouncement that it will begin using criminal sanctions more frequently as a tool (and the proof that the government is in fact initiating an alarming number of criminal investigations), the most important lesson is that food companies begin taking steps to better control pathogens in their environment to protect themselves from criminal prosecutions.

C. Strategies to Determine the Extent of Contamination in the Environment, Reduce Environmental Pathogens, and Decrease Criminal Liability.

Within just the past 12 months, a broad array of food products we typically regard as safe, ranging from caramel apples to ice cream, have been unexpectedly recalled because they contained LM. Indeed, these two products sickened dozens of people and killed nearly 10.

What is equally alarming is these products join an already diverse list of common foods that have caused outbreaks, including milk, spinach, sprouts, peanut butter, cheese, cantaloupes, and raw cookie dough. And the broad range of pathogens causing these outbreaks are just as diverse. In addition to the risks associated with LM, *Salmonella*, *E. coli* O157:H7 and other emerging pathogens continue to find their way into food processing facilities, finished food products and customer's homes.

It is also important to recognize that no company, no matter how sophisticated or experienced in pathogen control, is immune. Ultimately, this is because many of the foods we eat (or the ingredients we use to make the foods we eat) are grown and harvested in environments where they are susceptible to contamination. Fruits, vegetables and other products, such as spices, can easily become contaminated with LM, *Salmonella* or *E. coli* in the fields where they are grown. In some cases, these products can become contaminated in transit, or in the manufacturing facilities where they are processed. If the industry is not extremely careful about properly sourcing and then appropriately handling fruits, vegetables and similar products, it is extremely easy to put consumers at risk.

Once pathogens like LM are introduced into the processing environment, they can spread and unknowingly contaminate food products such as fruits, vegetables, meats and other ready-to-eat products with lightning speed. Recent studies tell us that in these environments, *Listeria* is, in fact, a significant concern. Of nearly 5,000 randomly collected samples from the food preparation areas of 30 separate retail grocery establishments, approximately 10 percent tested positive for LM. In light of the fact that nearly 16 percent of all people who become infected with LM will die, the numbers are alarming. The lesson for us all is that, once LM is introduced into the processing environment, it can easily spread and contaminate finished products.

Increasingly, under the new FDA standards, FDA will be seeking justification to bring criminal charges anytime a contaminated product causes human illness. This should create a sense of apprehension in the food industry. Any company that sells finished goods into commerce has a risk that its products will be selected for sampling and testing, and that the results will come back positive for a pathogen of concern.

This is especially concerning considering that many companies do not conduct environmental testing in their food processing facilities. As a result, they do not know whether there are any pathogens of concern (whether transient or resident) within their facilities. Thus, as detailed further below, these companies should conduct a microbiological profiling study to determine whether there are any microbiological persistence issues within their facility. Once that study is complete, as detailed further below, those companies should invest in pathogen-reduction technologies to decrease the chances that FDA will find any pathogens in the environment when the agency arrives to conduct its next inspection and performs extensive microbiological profiling. Finally, as discussed below, those companies should also perform a criminal

protection audit to help strengthen their programs and develop protocols which, if followed, will further protect them against criminal exposure.

Indeed, Blue Bell confirms that, once LM is allowed to enter a food processing environment, no food product (not even ice cream) is safe. If food companies do not take extraordinary steps to identify LM in their facilities, perform a comprehensive investigation to find the root cause or source, and then destroy and eliminate it completely, LM will likely continue to persist and, over time, intermittently contaminate their finished products.

(a) Microbiological Profiling Studies

One of the most important lessons from Blue Bell is that a simple environmental monitoring program will never be enough to protect your company from being involved in an outbreak or being the focus of criminal sanctions. All food companies should be aggressively testing for LM (or for other pathogens, depending upon the risk profile of their products) in their facilities. In turn, if food companies are already testing for LM, they cannot (like Blue Bell) continue to take anything less than extremely aggressive action against any sporadic or intermittent positive findings. Although many food companies view an outbreak as something that will be caused by a single operational failure (which will be obvious and limited in scope when it occurs), the reality is that the culprit is in most cases something far more subtle, far more persistent, and far more dangerous. In the past few years, we have witnessed a large number of outbreaks involving LM and antibiotic-resistant *Salmonella* linked to products that had been processed over multiple months.

For this reason, food companies should arrange for and conduct a comprehensive one-time microbiological profile for pathogens in their food processing facilities. Food companies should also arrange for this profile and report the testing results through their lawyer so that the results are protected by the attorney-client privilege. In turn, once the results are reported, the company can address any positive findings, determine the original source of the contamination, employ technologies to completely eliminate, reduce and control the contamination, and then develop a microbiological control and monitoring program to ensure that the pathogen, in fact, remains controlled.

(b) Pathogen Reduction Technologies

The second lesson learned from Blue Bell is that, when LM or any resistant pathogen is found sporadically in the environment, what was once regarded as effective corrective actions (such as re-cleaning, re-sanitizing and re-testing) are no longer adequate. As a result, in addition to their existing cleaning and sanitizing procedures, companies should explore and implement new pathogen reduction technologies to help control the environment.

Inexpensive, air and surface treatment technology that sanitizes the food processing environment is now available. This type of treatment is approved for use in occupied spaces and continuously treats the environment 24-hours a day. By employing active air and surface treatment, food processing companies can gain a level of control and decrease the possibility that any pathogen, if introduced, will persist or establish a niche.

One company, Puradigm, LLC (www.Puradigm.com) utilizes a multi-patented, NASA based active air and surface sterilization approach to control pathogens in the food processing environment.⁶ The results the technology achieved with LM are notable. In studies performed by Kansas State University, the company obtained a 2.9 Log reduction on environmental food contact surfaces in the first 24 hours. Similar reductions for other pathogens are displayed below.⁷

KANSAS STATE UNIVERSITY

	S. aureus	MRSA	E. coli	E. coli O157:H7	B. globigii	L. Mono	P. aeruginosa	S. pneumonia	C. albicans	S. chartarum
24 Hrs	2.07	2.12	2.23	2.39	2.71	2.90	2.34	1.93	3.87	4.12

*Microbial Reductions on Stainless Steel Associated with 24 Hour Treatment using Puradigm Advanced Oxidation Cell

I make this observation because, given the risk created by the FDA's War on Pathogens, food companies should be looking to invest in technologies to better control pathogens in their food processing environments. Once these preventative technologies are put into place, companies can perform periodic microbiological monitoring to validate that the controls are effective and working as designed. If such solutions are employed, there is a greater likelihood that when FDA arrives to perform microbiological profiling, it will be less likely to find any positive test results from the food processing environment, better shielding food companies who are employing such technologies from additional regulatory or criminal exposure.

(c) Criminal Protection Audits

In addition to commissioning their own microbiological profiling studies in their facilities (to detect and eliminate any resident pathogens), and employing the use of active air and surface sterilization technologies, food companies should also perform internal criminal protection audits. These

audits should be designed to identify gaps in existing company protocols, and develop written programs designed to help the food company navigate the challenges posed by food safety issues discovered within the company.

If developed correctly, the written program should provide the company with a decision-tree to follow in the event of a positive environmental finding, a series of customer complaints relating to the safety of a product, or a notification from a governmental entity of a potential food safety problem. These protocols and programs, if followed in the event of a food safety issue, should be developed to ensure that the conduct of the company in response to any such issues will in all cases be appropriate, and that there will not be any basis upon which FDA or DOJ could support criminal charges.

3. Conclusion.

Through its actions and conduct, the FDA (in cooperation with DOJ) has launched a War on Pathogens. The agency is targeting food products at retail, and engaging in microbiological profiling of all food companies. Unless companies act now to better quantify and control pathogens in the food processing environment, they are exposing themselves to incredible food safety risk, including (in the event of a recall) significant brand damage and (in the event of a link between their product and a human illness) criminal sanctions. Companies should carefully consider the emerging risks facing them, and begin employing measures to decrease and eliminate their exposure.

¹ Shawn K. Stevens is a food safety lawyer and founding member of *Food Industry Counsel LLC*, the only law firm in the world that represents the food industry exclusively. Mr. Stevens works throughout the country and abroad with food industry clients (including the world's largest food processors, national restaurant chains, and food distributors and grocers) helping them protect their brand by proactively eliminating their food safety risk, complying with complex FDA and USDA food safety regulations, managing recall response efforts, and defending high-profile foodborne illness claims. Mr. Stevens speaks regularly to national and international audiences on a wide variety of emerging scientific, regulatory and legal food safety trends, authors dedicated columns for *Meatingplace* and *The National Provisioner*, and is quoted regularly by national media publications such as *TIME Magazine*, the *New York Post*, and *Corporate Counsel Magazine*.

² FDA Recalls, Market Withdrawals, & Safety Alerts: <http://www.fda.gov/Safety/Recalls/>; FSIS Recalls and Public Health Alerts: <http://www.fsis.usda.gov/wps/portal/fsis/topics/recalls-and-public-health-alerts>.

³ Food Safety Modernization Act background: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm239907.htm>.

⁴ CVM Sampling: <http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/Contaminants/ucm449501.htm>.

⁵ FDA Operational Implementation Strategy: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm395105.htm>.

⁶ www.puradigm.com.

⁷ GC/MS Evaluation of Compounds in Air Samples in a Controlled Environmental Chamber Equipped with a Puradigm Advanced Technology Cell, November 5, 2013, Dr. James Marsden, Kansas State University Food Science Institute.