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COUNSEL LLC

**Shawn Stevens**
Food Industry Consultant and Lawyer
stevens@foodindustrycounsel.com
920.698.2561

# Avoiding FDA and DOJ Criminal Liability for Routine Food Safety Failures


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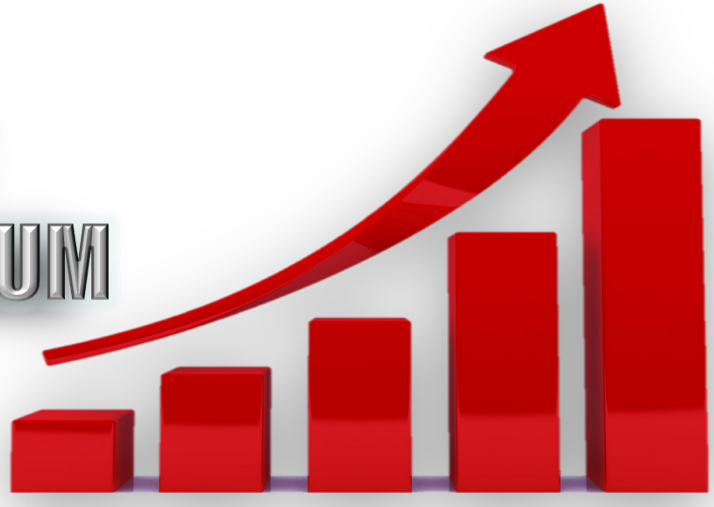
# WHAT IS THE RISK THAT YOUR COMPANY WILL BE INVOLVED IN A RECALL IN THE NEXT 24 MONTHS?

- ☐ HIGH
- ☐ MEDIUM
- ☑ LOW



Bidart Bros. · Blue Bell Ice Cream · Chipotle Mexican Grill · Dole · SunOpta · General Mills · tropical SMOOTHIE CAFE · Sabra go mediterranean

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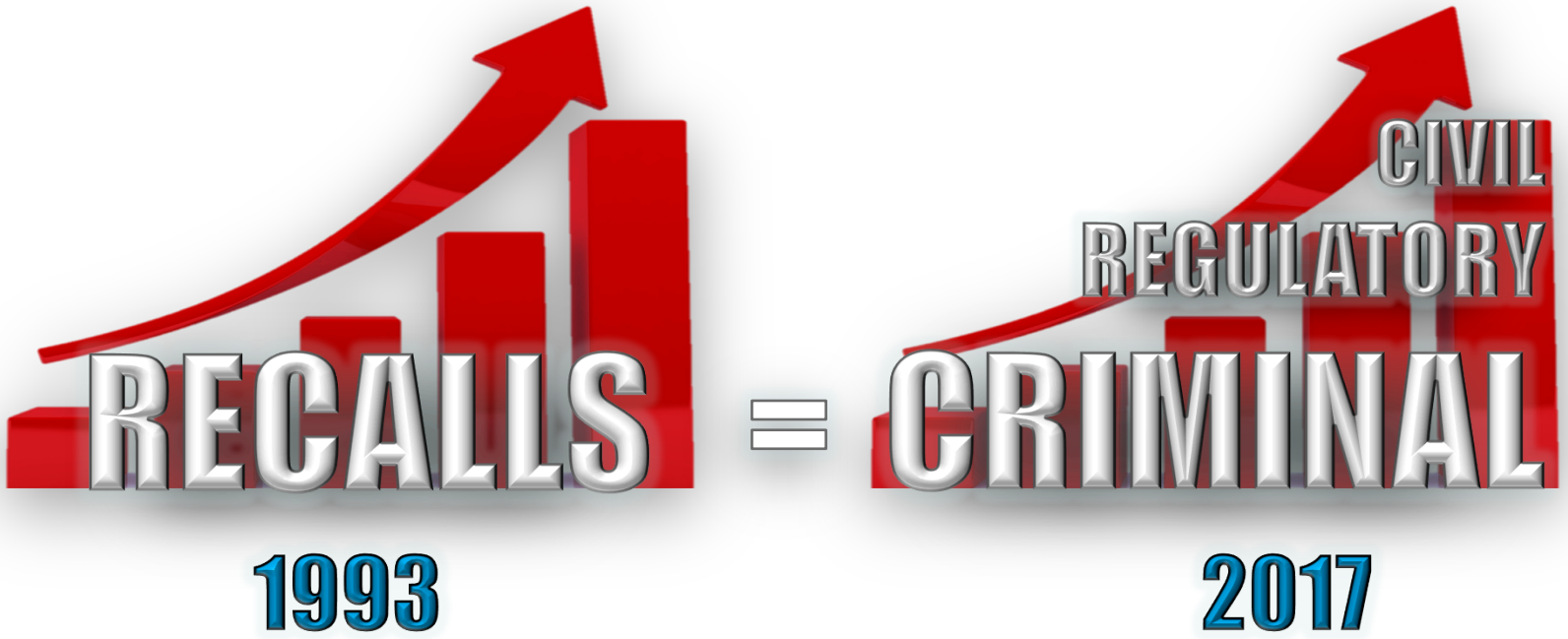
# THE THEME OF EVOLVING INDUSTRY EXPOSURE

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# THE FOOD SAFETY REVOLUTION


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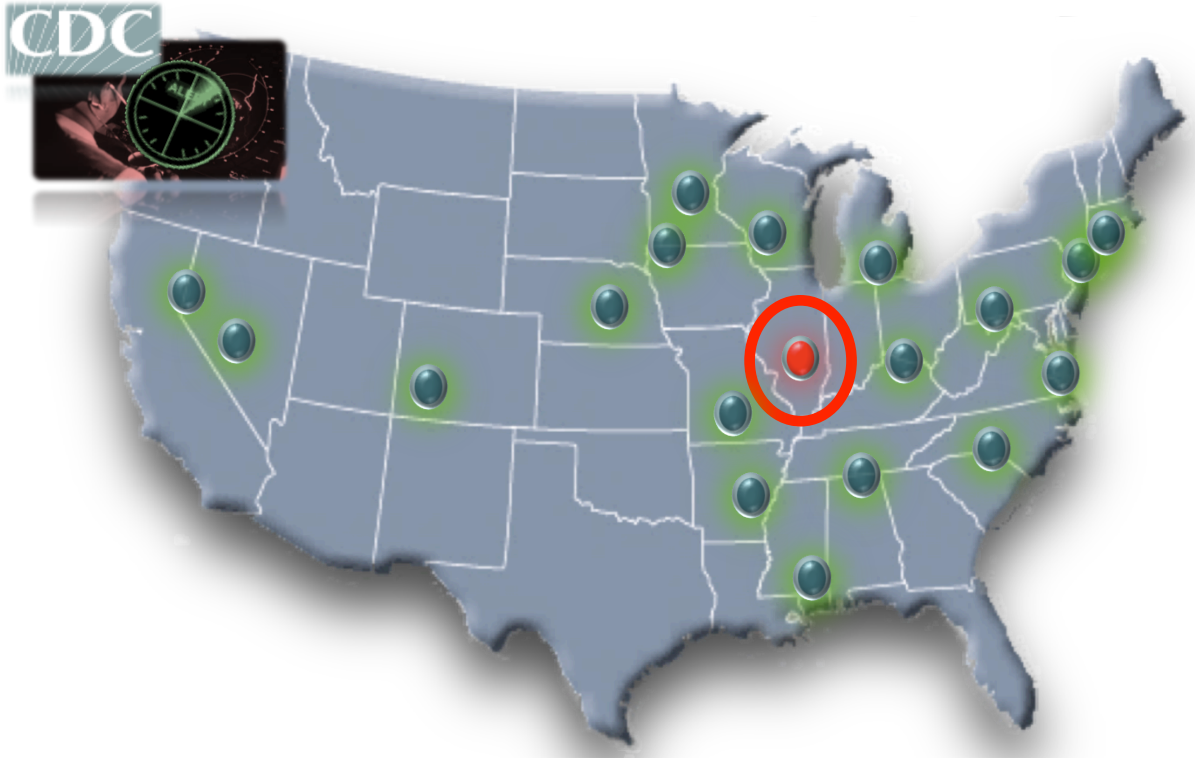
# MANDATORY REPORTING AND PULSENET

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# REPORTABLE FOOD REGISTRY


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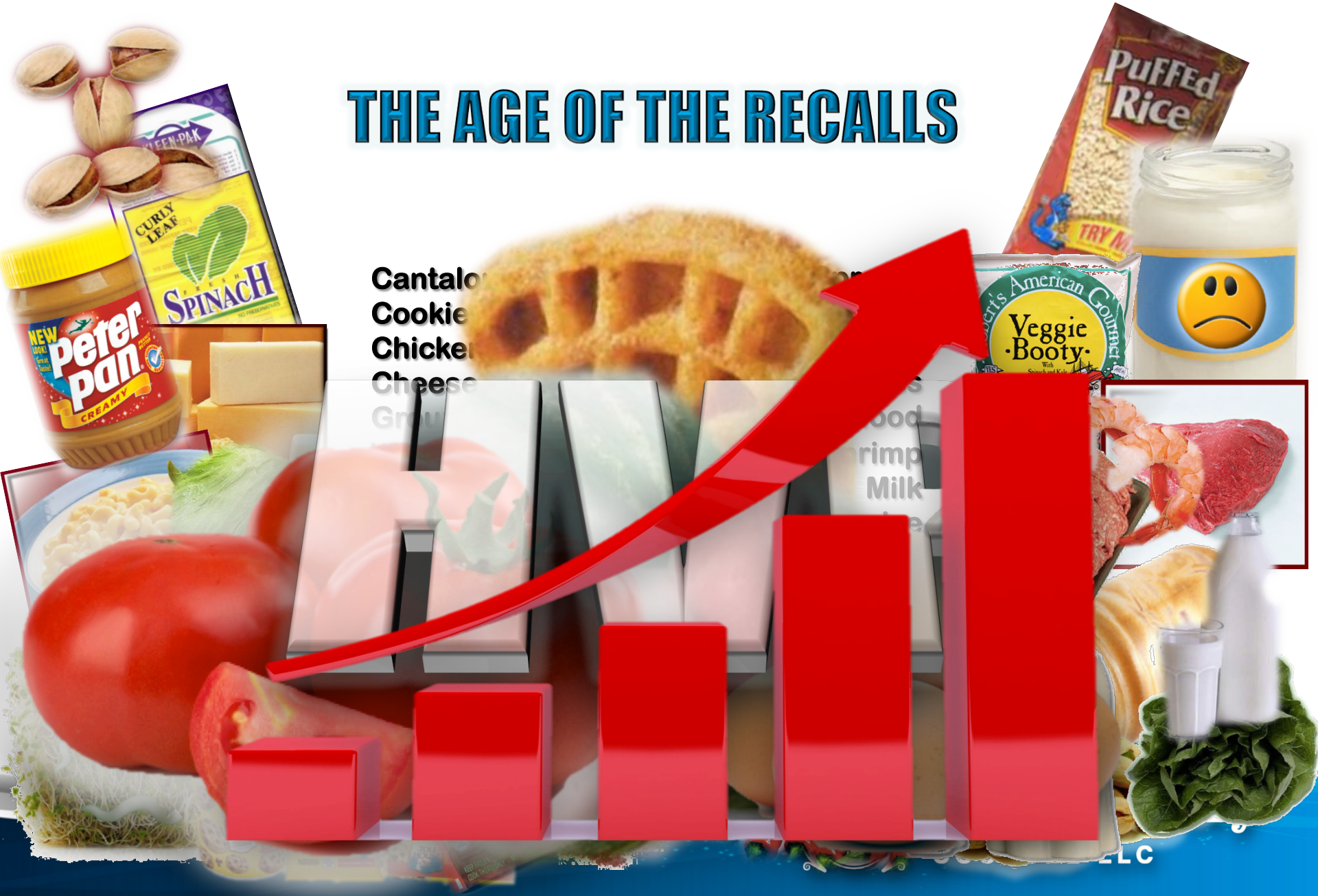
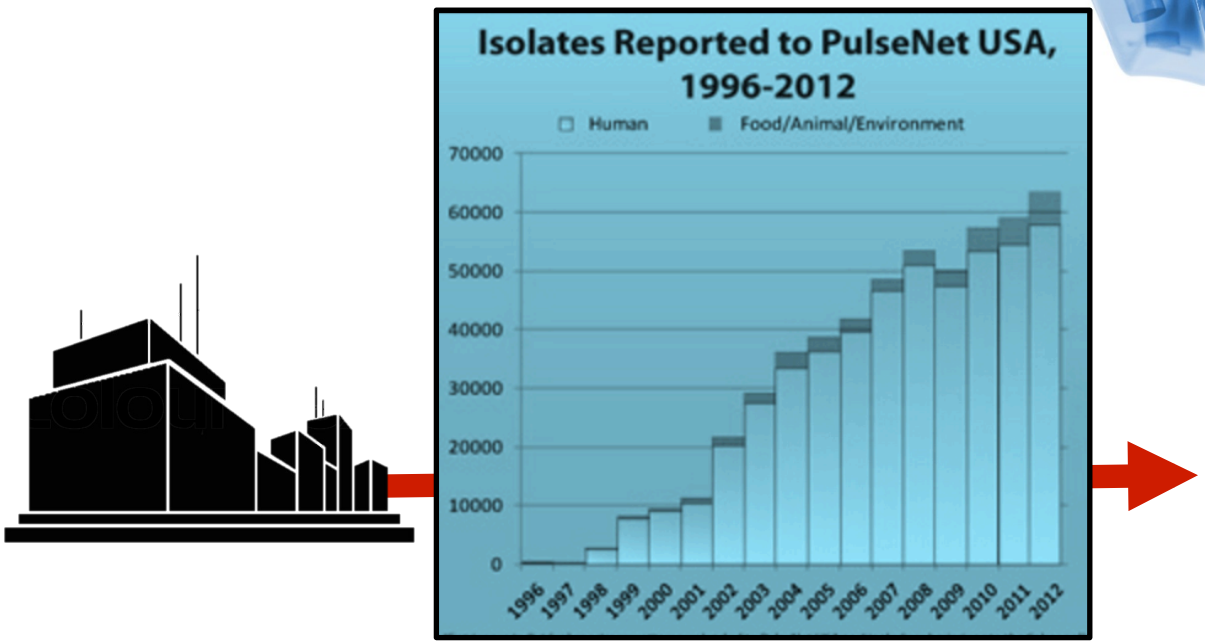
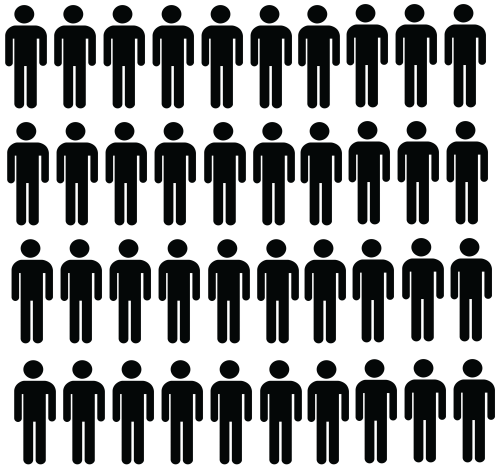
# THE AGE OF THE RECALLS



# >1,000,000 UNSOLVED ILLNESSES



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# THE FDA'S RESPONSE

# FSMA


# TO OVERHAUL THE SAFTEY OF THE U.S. FOOD SUPPLY

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# "THEY'RE COMING..."


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# FOOD SAFETY MODERNIZATION ACT

## RULES AND REGULATIONS


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# THE FDA'S WAR ON PATHOGENS

FoodIndustry COUNSEL LLC

SHAWN K. STEVENS
Direct Dial: 920.698.2561
stevens@foodindustrycounsel.com

WHITE PAPER

FDA WAR ON PATHOGENS – HOW TO PROTECT YOUR COMPANY

National Foodborne Illness Database

In the 1990s, following a high profile foodborne illness outbreak on the West Coast, the national government implemented a system of mandatory reporting for healthcare providers whenever a consumer was cultured positive for a foodborne illness. For nearly two decades, in each of these cases, the government has conducted testing to identify the specific genetic DNA strain of the microorganism making people sick, and then uploaded the DNA signature into a national database called PulseNet. While this system has allowed the government to solve many high-profile outbreaks over the last 20 years (linking consumers sickened by a pathogen sharing a common DNA strain to a single food product), the vast majority of foodborne illnesses uploaded into the PulseNet database remain unsolved. What this means is that there are a large number of food companies that have been unknowingly processing and distributing foods that are contaminated with pathogens and are making American consumers sick

FDA Response and Criminalization of Foodborne Illness

With the passage of the Food Safety Modernization Act (FSMA), the Food and Drug Administration (FDA) was directed by Congress to overhaul the safety of the national food supply and to decrease the numbers of foodborne illnesses and outbreaks. Since the Act was signed by President Obama in 2011, the agency has been working to finalize new regulations requiring food companies to develop comprehensive written food safety programs. In additional to these efforts, FDA has also become increasingly aggressive in its regulatory enforcement activities. The agency has also adopted a number of policy initiatives which create additional and unprecedented risk and exposure for all food companies.

Within the next five years, FDA will visit and inspect every food facility in the nation. To facilitate its goal of preventing the distribution of contaminated foods, FDA's new policy is to conduct extensive microbiological profiling inside of all food facilities during routine visits. While conducting these visits, the agency will execute microbiological swab-a-thons, collecting more than a hundred samples from each food facility and then testing those samples for pathogens such as *Listeria Monocytogenes* or *Salmonella*. No company will be immune from this sampling or scrutiny.

If the FDA finds a positive sample, FDA will immediately compare the DNA from that sample against the PulseNet Database. If the DNA matches a strain that made someone sick during the last 20 years, the FDA will presume that the illness (or, illnesses) were caused by a product distributed from that facility, and may require the company to initiate a recall and likely cease operations until the contamination is isolated and eliminated. In addition, because the company's products caused an illness, FDA will launch (as part of its new policy initiatives) a criminal investigation in cooperation of the U.S. Department of Justice against the company, seeking all emails, documents and records relating in any way to the plant operations and safety of the product. Under FDA legal standards, when a foodborne illness results, a company executive or manager can be charged criminally, even though he or she did not know they were selling a contaminated product. Each charge carries up to a $250,000 fine and a year in prison.

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# THE HUMAN ILLNESS STANDARD

## NEW ENFORCEMENT POLICY


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Roka BIOSCIENCE

# RECORDS REVIEW

## FDA RECORDS ACCESS

If FDA **believes** that there is a reasonable probability that the use of or exposure to [a product] will cause serious adverse health consequences or death . . .

# RECORDS REVIEW

## FDA RECORDS ACCESS

... then FDA shall have access to
the records that are needed
to assist FDA in determining whether there is a reasonable probability that the use of or exposure to [a product] will cause serious adverse health consequences or death.

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# "SWAB-A-THONS"


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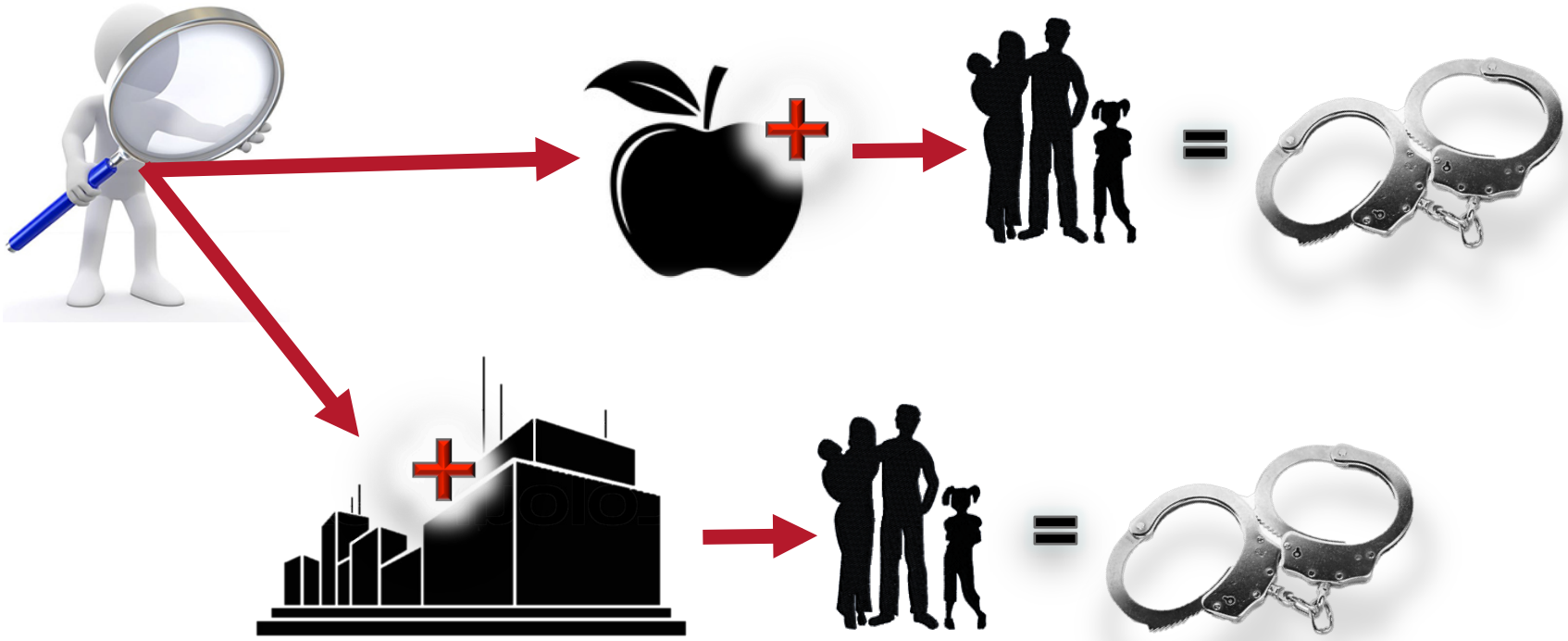
# NEW CONSEQUENCES FOR NONCOMPLIANCE

## PERSONAL LIABILITY



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# NEW CONSEQUENCES FOR NONCOMPLIANCE

## PERSONAL LIABILITY


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# NEW CONSEQUENCES FOR NONCOMPLIANCE

## PERSONAL LIABILITY

## PARK DOCTRINE


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# NEW CONSEQUENCES FOR NONCOMPLIANCE

## PERSONAL LIABILITY

## PARK DOCTRINE

**(1) You are aware of a condition that could lead to product contamination;**
**(2) you are in a position to correct or eliminate the condition; and**
**(3) you fail to correct or eliminate the condition.**

**MISDEMEANOR CHARGE**

**$250,000**
**1 YEAR IN PRISON**

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# NEW CONSEQUENCES FOR NONCOMPLIANCE

## PERSONAL LIABILITY


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# NEW CONSEQUENCES FOR NONCOMPLIANCE

## PERSONAL LIABILITY

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# NEW CONSEQUENCES FOR NONCOMPLIANCE

## PERSONAL LIABILITY




# WHAT CAN YOU DO TO PROTECT YOURSELF AND YOUR COMPANY?

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# "PLAY FDA FOR A DAY"

## CONDUCT YOUR OWN MICROBIOLOGICAL PROFILING OF ZONE 3 AND ZONE 4 AREAS

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# USE RESULTS TO PROTECT YOUR COMPANY

SEEK AND DESTROY HARBORAGES
DEVELOP ADDITIONAL INTERVENTIONS
REFINE MONITORING LOCATIONS AND FREQUENCY
GAIN AN ENHANCED LEVEL OF SECURITY

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# KNOW YOUR SUPPLIERS


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# KNOW YOURSELF

# HOW ARE YOU SAMPLING?
# WHEN ARE YOU SAMPLING?
# WHERE ARE YOU SAMPLING?

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# KNOW YOURSELF

# HO "ROOT CAUSE" v. "ROOT SOURCE"

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# REVIEW THE FDA INSPECTION CHECKLIST

FoodIndustry COUNSEL LLC

SHAWN K. STEVENS
FDA Consultant/Attorney
Direct Dial: 920.698.2561
stevens@foodindustrycounsel.com

**FDA INSPECTION CHECKLIST**

*What to do Before, During, and After Your Next FDA Inspection*

**INTRODUCTION**

**Food Industry Counsel, LLC** is pleased to provide you with the most comprehensive and useful FDA Inspection Checklist available. With the passage of the Food Safety Modernization Act (FSMA), the Food and Drug Administration (FDA) was given the mission of overhauling the safety of the nation's food supply. The new FSMA regulations written by FDA are now coming into effect, and the agency is now aggressively enforcing its new rules during routine inspections. Within the coming years, FDA Investigators will conduct an onsite inspection of every food facility in the U.S.[1]

Here are *FDA's new enforcement priorities* during routine unannounced inspections:

(1) To carefully critique each company's written food safety programs and verification records to ensure they are compliant with the new FSMA requirements;

(2) To conduct extensive Zone 1, Zone 2, Zone 3 and Zone 4 microbiological sampling inside all food facilities to find evidence of pathogenic contamination;

(3) To require recalls if the percentage of FDA samples testing positive for *Listeria Monocytogenes*, *Salmonella* or other pathogens exceeds FDA thresholds;

(4) To compare the DNA fingerprints of any pathogens found in the facility against the >1,000,000 human isolates stored in the CDC's PulseNet database to identify any matches, and then require food product recalls if any matches are found; and

(5) To initiate broader investigations, including criminal investigations, against food companies whose products are found to have caused human illness.

Against this backdrop, all companies should begin taking steps to prepare for their next FDA inspection. Companies can use the following checklists to ensure that they have completed the needed preparations before the FDA Investigators arrive, to help effectively navigate the inspection process once the inspection is underway, and to appropriately respond to any FDA criticisms once the FDA inspection concludes.

[1] The FDA employees performing these routine onsite inspections are not referred to as "FDA Inspectors," but rather as "FDA Investigators." The concern with this terminology is that some FDA Investigators may be more inclined to find violations since their title presumes, in advance of any facility visit, that violations have already occurred.



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