

Enterprise Wide Risk Assessment ***How to Prepare Your Business for the New Demands of FSMA***

As the CEO or Board Member for a food company, what I am sharing with you in this white paper could be some of the most important information you will learn this year. It will help you protect your brand and increase your organization's efficiency.

The concept I'm going to introduce today is a new process known as Enterprise-wide Risk Assessment. This is a proprietary tool that my company developed to look inside your company and help you prepare for the new challenges of the Food Safety Modernization Act.

The food industry as we all know, is changing rapidly, providing us with new challenges to our business and profitability. Every single day as the CEO you are aware of the threat occurring now with Amazon and the acquisition of Whole Foods. This is a game changer. It's something that we are all paying very, very close attention to. It's going to impact how we manage our businesses for years to come.

In addition, the FDA with their new authority under the Food Safety Modernization Act, are using aggressive new tactics in how they deal with food companies - and you need to be aware of these actions.

I'm Bryan Armentrout and I'm the CEO of the Food Leadership Group.

- I'm a food industry veteran with over 20 years of experience in CPG companies managing the quality function at multi-billion dollar companies.
- In addition to that, I'm the number-one bestselling author of *The New Manager Mindset*. I wrote this book to help new managers transition from their old role as single contributors into active team leaders in companies. It helps them identify how they can best contribute to the success of their organization.
- I also had the honor of serving as the vice chair of the Safe Quality Foods Technical Advisory Council, one of the leading international food safety standards under the Global Food Safety Initiative.



I want to talk a little about something that as a quality professional we all fear.

It's a phone call that no one ever wants to get. My call happened on Thursday, December 21st.



The call came from the Florida State Department of Health. They had gone into a Publix supermarket and pulled some of my products from store shelves for analysis. The product was a Brie cheese and they had tested it for Listeria - and they said it was positive. I was in shock when I heard that. I didn't believe it - it didn't make any sense to me. I put down the phone and sat there for a moment in stunned silence.

Given the right circumstances, Listeria is a pathogen that can easily cause illness or even death. This was a serious thing. But the plant that manufactured this cheese was one of my best plants and it just didn't make sense to me.

We contacted FDA and told them what was going on, started the necessary recall procedures and the next day I was on a plane to California to go visit the plant. That plant became my home for the next two months.

The plant was shut down during that period of time. There were press releases. There was media. People were out of work. The public needed answers and it was costing the company millions and millions of dollars. Our loyal consumers wanted to make sure that our products were safe. It was my job to make sure they were.

We tore that plant apart. We looked everywhere trying to find the problem. At first, we didn't find anything. It was hard to find because the contamination was sporadic. Only a very few were positive, but we did find it. It was all true. We had Listeria in our plant.

There was something going on - but what was it? What was the culprit in the plant?

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After a while, we found it. It was an old packaging machine. This machine wraps the paper around the outside of the Brie, and hidden down inside that machine in the very bottom was a tiny little area hiding a bit of old cheese that wasn't getting cleaned out. No one could see it. No one knew it was there. It was really easy to miss.

The cheese wedges went on a belt around that machine, and those pieces would touch that contamination source every now and then. We found where the Listeria was growing and our company did the right thing. We returned the product from the markets and luckily no one got sick - or worse. I was very thankful for that, no one wants people to get sick under any circumstances.

I went back to Corporate and I was never the same again.



This recall was a turning point in my career and I went through a lot of reflection about what happened.

However, the bottom line is that you want everything to go to plan. That's why you put together programs. And training and audits and certifications and you test. You do it all, but sometimes that's not enough.

I have seen good people with similar problems have their careers ruined because of it. It really gets at you about why you failed. You didn't protect the public. You had a recall. Why? Why did this happen? You had everything in place and yet it still happened.

What was missing? I realized that you need much more than just QA systems and Programs.



The costs of recalls to food companies are extremely expensive.

Forbes Magazine recently partnered with the Grocery Manufacturers Association to look at the average cost of a recall.

Do you know what it is? *The average direct cost of a recall is now over 30 million dollars.* That's just the average. A lot of companies pay significantly more.

Recently, Fonterra the large cooperative in New Zealand, sold milk powders to Groupe Danone, a large French dairy company in Europe. Fonterra sold them milk powder which they thought had botulism. It triggered a huge recall. Fonterra recently settled the court case over this.

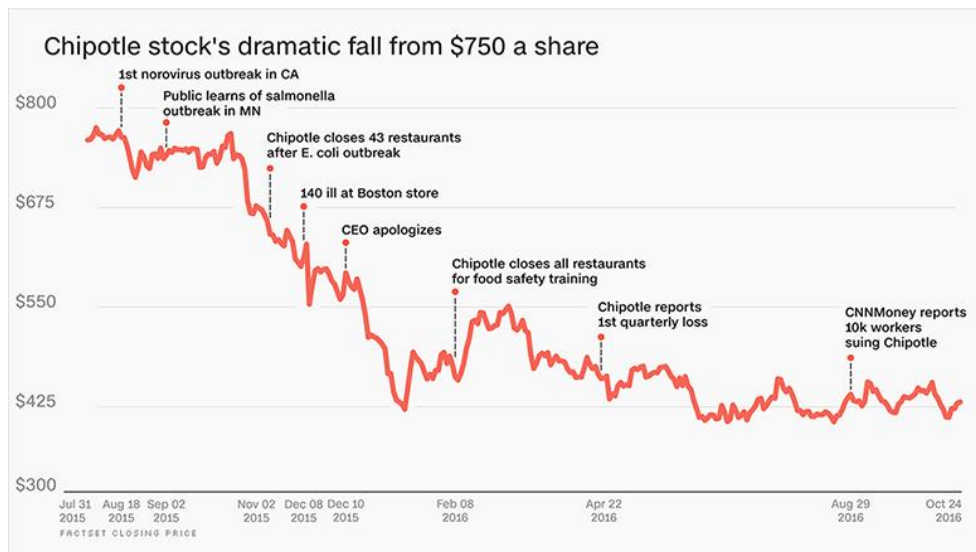
This cost Fonterra 125 million dollars right off their bottom line. Now, I don't care how big your company is. That's a really difficult hit to come back from. Not to mention the damage to your brand and your reputation.

In 2016, in the U.S, there were 762 recalls for food safety. That was up 15 percent from the prior year. The Food Safety Modernization Act, which was passed under President Obama, was supposed to help reduce the number of recalls and the grief and trauma that people go through and I went through with my company. But it hasn't.

They're expecting it to be going up again in 2017 when the data comes out. Forty percent of those issues in 2016 were related to allergens. That's bad systems within companies causing those issues. The likely cause of those failures are not in sanitation, but in the process of managing allergen containing products.

Let's look at a well-known food safety crisis here in the US – Chipotle Mexican Grill (CMG).

The red line on this graph represents their stock price during the worst part of the crisis. It has yet to recover.



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When Chipotle first started having issues in August of 2015, the market capitalization of their company was 23.2 billion dollars and a stock price of \$750 per share. Then you had food safety crisis after crisis as shown on the graph. Their stock price is currently around \$300. Market capitalization is now at \$8.8 billion dollars.

Chipotle Mexican Grill lost \$14.4 billion dollars in shareholder value as the result of food safety failures.

The Founder and CEO recently announced that he's going to step down as CEO. Now, imagine this is your name at the top of this chart. This is your company and it's your stock price going down.

Remember, we don't just sell food, we sell trust.



You and your family practice this trust every day. When you ate breakfast this morning, did you go to the kitchen and say, "Good morning! Before I eat, I'd like to see your sanitation procedures and I would like to see how you safely cook my food?" Of course not!

It's assumed in the U.S. that the food we eat is safe. Now, we get a sense of what it's like sometimes when we travel internationally and we get a little more suspicious. But the level of trust in the U.S. is extremely high for our food supply - as it should be. We work really hard to make it safe. But, when that trust is damaged, companies are penalized severely.

The Food Safety Modernization Act was a direct result of that failure in trust. As a friend of mine, Joe Levitt at Hogan Lovells – former FDA Commissioner at FDA once famously said: "The rules of the game have changed." As CEO, you need to be aware of those rules and how those changes impact you directly.

FDA is there to enforce, and because of those statistics I gave earlier on the number of recalls, they're under immense pressure to deliver lower numbers and make sure that food companies aren't producing unsafe products. So, if there's a doubt in their minds, they're going to come in with guns blazing.

FDA under FSMA has unprecedented access within your company to all your records and all your systems and, even all your people are fair game now for FDA.

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Now imagine this scenario...

You're at corporate, in your office on a Friday afternoon, casually talking with a member of your Board of Directors.

All of a sudden you get a panicked call from the Receptionist at the front desk. FDA is at the door! All your operational people and your VP of QA are off in the field doing what they need to do. No one else is here.

She tells you that there are five Investigators at the front desk and they want to come in and meet with you. They flash their badges and say they want a conference room and a meeting with the CEO in 15 minutes. They say they have reports of complaints and illnesses from your products. They want an explanation now or they are shutting you down.

How do you react to that? Are you personally prepared for that discussion?

You need a plan because this has been a recent development, and this gets back to what I was saying around the aggressiveness of FDA. They're coming to your corporate headquarters and this is not theory anymore. They are doing this right now. They have recently gone to the headquarters of a multibillion dollar retailer and they've done exactly this. You need to be ready for that. You need to protect your brand and your equity.

I've been thinking about this possibility for about a year and a half and seeing this trend, I predicted that this would be coming from FDA.

Based on my decades of industry experience, I have developed a proprietary product called the Enterprise Risk Assessment. This is the evolution of corporate compliance. It's the next step and this is what Sarbanes-Oxley was to finance. This is just as significant and you need to be just as ready.

You need to understand that compliance to FSMA is not something that's just the responsibility of your quality department. This is your personal responsibility as the CEO. Under the Park Doctrine, an obscure Supreme Court ruling from the 70s, you can now be prosecuted by the Department of Justice under FSMA. This is what happened at Blue Bell Ice Cream and the case is still ongoing.

What exactly is the Enterprise Risk Assessment process? This is a state of the art evaluation of your business systems and how they interact based on state of the art practices. This is not an audit. This is a team of world class experts working on your behalf - not former QA managers who have retired and are now doing some auditing on the side. These are former vice presidents of Operations, Senior Vice Presidents of Quality Assurance, and other Executives who understand what world class looks like, and they can come into your company and look at your departments and see if that's how they're operating.

This process will not only show where you have gaps, it will show you how to run your business more efficiently as well. Because as you know, it's not necessarily how well departments do their job, but how well they do their job when working with others.

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Because let's face it, you're the CEO and if you head down to the office of your Vice President of Quality and you go in there and you shut the door, lean over his desk and say, "I just read this article from Bryan on FSMA and I want to make sure we're okay - are we ok?" What's he going to tell you? Is he going to say, "Oh my God, no! We are a mess! We are in serious trouble and I am already working on my resume. Of course not! He's going to look you in the eye and say, "Boss, I've got it." But does he really?

You need a plan with a strategic overview so you can objectively see where the gaps are in your company so you can go in and fix those things. Here's the thing. We need to put capital and the necessary tactical plan associated with who is doing what, when, why and how so you can track the project and ensure that your team is doing what they need to do. You need reporting and accountability. You need to pressure test integrity and vulnerability of your system. Because if you don't, the FDA is going to do it for you - and you're not going to like that. You need an independent objective assessment of your corporate and plant systems and how they interact with each other.

You need due diligence because if something does happen, you will need to avoid a visit from this guy.



This is Bill Marler from the law firm of Marler Clark in Washington state. He made his reputation in the food industry for suing food companies. He made his career on the E. coli issue at Jack in the Box where children died. Now, that's all he does and he makes a really good living at it. He sues food companies who have recalls. He represents plaintiffs and has it down to an art. If something does happen, you want to show that you've done in your company what needs to be done to protect the public – and more. Or like Fonterra, you're going to be paying a very large amount of money – if you don't go bankrupt first.

You need something that's confidential and internal and covered by attorney client privilege. This is for you. This is not for customers, this is not for anyone else. This is how you improve your processes in your facility.

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What are your next steps?

So, what do you do at this point? Don't wait. You need to sit down with me right away.

Let's schedule a free consultation and we'll start mapping out a custom plan of what it is that you need to do at your company based on your risk profile and needs.

We will figure out what resources are required and we'll put together a proposal and then we'll move forward from there. This is not an option, it is a requirement of business under FSMA.

I look forward to hearing from you.



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