
FSMA Compliant in One Week

Be the FSMA Expert in Your Organization

Rob Kooijmans

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Published by Best Seller Publishing®, Pasadena, CA
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Printed in the United States of America.
ISBN: 978-1-949535-17-4

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Introduction

The Food Safety Modernization Act in the United States of America (or in short FSMA) has been the biggest change in food safety legislation in decades. And not only in the USA! This framework of several rule has a global impact as all food producing companies exporting food stuff to the USA are impacted by FSMA as well.

We have been following the creation of FSMA over several years as from the onset it was clear that this new legislation would have a major impact. By the same token we have helped many companies to successfully become complaint to the various rules within FSMA over the last couple of years.

Naturally, the US FDA has created formal training on various parts of FSMA. While this training does result in a certified, qualified individual status for the students, it does not give a hands-on structure for implementing all the requirements of FSMA. Nor does the formal training dive into the level of detail at which processes must be defined. A large part of FSMA does leave room for interpretation and with the

right information companies can come to an effective and efficient implementation of all the requirements.

This book is not just going to cover a lot of boring theory or just the legal requirements. No – this book is hands-on and will deliver the information to you in a very clear and understandable format. Next to this you will get easy to implement tools which are included as downloads via QR codes throughout the book. Every second chapter of this book (except for the introduction of course) is followed by a so-called “working chapter”. In these chapters you will find guidance on the actions you need to take to get FSMA compliant in your company.

An important thing to note here is that even for a Qualified Individual, receiving formal, FDA certified training is not a mandatory requirement in FSMA. Any Qualified Individual can be qualified by a combination of education, training and experience. As long as you properly document this you are OK. That’s why you will get a certificate at completion of the FSMA Masterclass. And you can use this together with any other training, education or experiences to prove that you are a Qualified Individual in relation to FSMA.

So instead of spending at least two days per relevant FSMA rule in a boring classroom training and getting little to no guidance on how to implement things – you can now learn all you need to know, create your own implementation plan in the working chapters and get easy to implement tools from this book.

We are sure this book is going to be a strong starting point for FSMA compliance in your company. For those of you who wish to have even more guidance, we also have an on-

line FSMA Masterclass and we even host a combined FSMA Masterclass / PCQI Training (with official FDA approved certificate) both in the USA and in Europe. For more information have a look at our website: <https://foodsafety-university.thinkific.com/courses/fsma-masterclass>

Together we continue to improve food safety everywhere.
Rob Kooijmans & Kitty Appels
Food Safety Experts

CHAPTER 1

Introduction

I. WHY THIS BOOK

The *FDA Food Safety Modernization Act to amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of the food supply* (or in short FSMA) has been the biggest change in food safety legislation in decades, and not only in the US.

We have been following the creation of FSMA over several years. From the onset, it was clear that its framework would also have a major impact on all companies producing and exporting foodstuff to the US. By the same token, since FSMA has been introduced, we have helped many companies to successfully become compliant with its various rules.

Naturally, the US FDA has created formal training on various parts of FSMA. While this training does result in a certified, “Qualified Individual” status for the students, it

does not give a hands-on structure for implementing all of the requirements of FSMA. Nor does the formal training dive into the level of detail at which processes must be defined. A large part of FSMA leaves room for interpretation, and with the right information, companies can achieve an effective and efficient implementation of all of the requirements.

This book is not just going to cover a lot of boring theory or legal requirements. No – this book is hands-on and will deliver the information to you in a very clear and understandable format. In addition to this, you will get easy-to-implement tools, which are included as downloads via QR codes throughout the book. Every second chapter of this book (the introduction) is followed by a “working chapter”. In these chapters you will find guidance on the actions you need to take to become FSMA-compliant within your company.

We are sure this book is going to be a strong starting point for FSMA compliance in your company. For those of you who wish to receive further guidance, we also have an online FSMA Masterclass and we even host a combined FSMA Masterclass / PCQI Training (with official FDA-approved certificate) both in the US and in Europe.

An important thing to note here is that even for a Qualified Individual, receiving formal FDA-certified training is not a mandatory requirement in FSMA. Any Qualified Individual can be qualified by a combination of education, training and experience. As long as you properly document this, you are OK. That is why you will get a certificate upon completion of the FSMA Masterclass. And you can use this alongside

any other training, education or experiences to prove that you are a Qualified Individual in relation to FSMA.

So instead of spending at least two days on each FSMA rule in a boring classroom training setting and getting little to no guidance on how to implement things – you can now learn all you need to know, create your own implementation plan in the working chapters and get practical tools from this book.

For more information on our online FSMA Masterclass, have a look at our website: <https://foodsafety-university.thinkific.com/courses/fsma-masterclass>

We hope this book provides you with the insights and information you need to come to an effective implementation of all the relevant aspects of FSMA in your organization.

Together we continue to improve food safety everywhere.

Rob Kooijmans & Kitty Appels
Food Safety Experts

II. HOW AND WHY FSMA CAME TO BE

After almost two years in the making, FSMA was signed by President Obama in January 2011. An early version, called the Food Safety Enhancement Act, was approved by the House of Representatives in 2009; then, at the end of 2010, the US Senate approved a revised version under the name of the Food Safety Modernization Act as an amendment of the existing law, the Federal Food, Drug and Cosmetic Act (FFDCA) of 1938.

FSMA's sheer complexity made its implementation quite slow. Public comments on proposed rules opened in 2013, and the first set of final rules were published in 2015. As of today (September 2018), FSMA has been implemented almost in its entirety.

When US Congress chose the word "modernization" instead of "enhancement", it was not simply trying to find a synonym. The previous 1938 law came from a world that no longer existed, so a simple enhancement clearly would not be enough. An upgrade to modern times was necessary.

When lawmakers started to work on a modern food safety law, there were many signs that the food system was getting out of control, and a drastic change was necessary.

Too many people were dying or falling ill due to food poisoning.

While the US Congress was discussing the Food Safety Enhancement Act in 2009, the country was experiencing one of the most serious foodborne illness incidents in the recent years: the Peanut Corporation of America (PCA) *Salmonella* outbreak.

PCA was a peanut-processing business, which sold both raw and processed peanuts. In 2006, when a lab test found *Salmonella* in their products, the company management did not stop sales or warn customers or the authorities. Instead, they kept on doing more tests until they got negative results they could show, and even got to the point of faking sanitary certificates.

Unsurprisingly, a serious *Salmonella* outbreak followed, which caused nine deaths, while at least 714 people in 47 states fell ill and were hospitalised (half of them were

children). The company's owner Stewart Parnell was eventually convicted and sentenced to 28 years (the Federal authorities had recommended life imprisonment) and the company went bankrupt.

The PCA case is an extreme example of large-scale profit-driven food poisoning.

In most cases however, serious foodborne illnesses are unintentional. In 2006 for example, water contaminated with animal faeces likely caused an *E. coli* outbreak in fresh spinach, which killed 3 people and sickened at least 276.

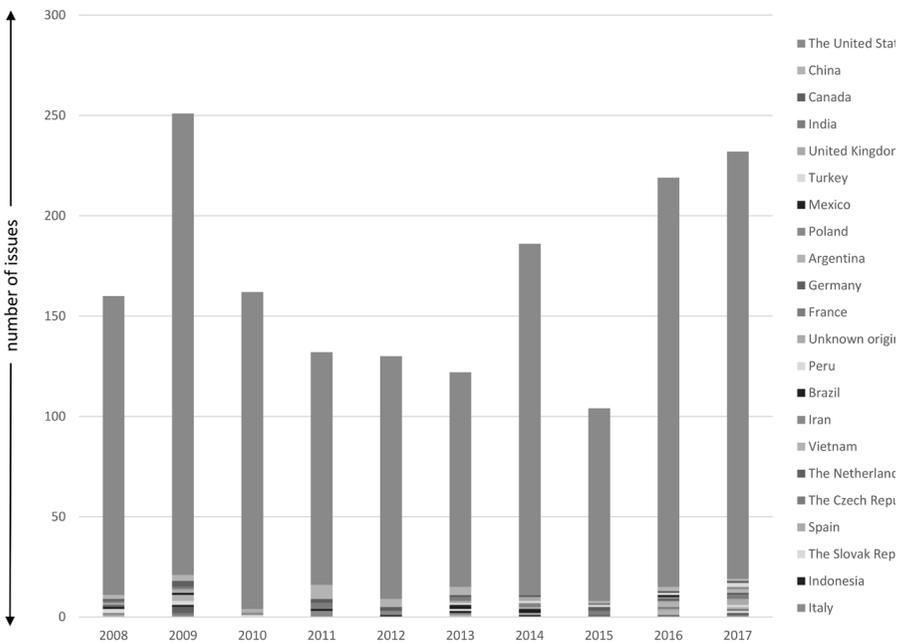
The PCA and *E. coli* cases above were not serious incidents in an otherwise healthy food system. Rather, they were the tip of the iceberg of many food safety incidents that were killing thousands of people every year. Data published by CDC (the Centre for Disease Control and Prevention) in 2011 estimated that "each year roughly 1 in 6 Americans (or 48 million people) gets sick, 128,000 are hospitalized, and 3,000 die of foodborne diseases." That data is often used as an introduction to FSMA. The same report however, has a much more worrying part: 56% of those deaths were caused by "unspecified agents transmitted through food." Poisoned food was killing people, but in most cases no one knew exactly how.

Food safety incidents are also a significant cost for the healthcare system. A 2015 study by Ohio State University, estimated that the average national cost of foodborne illness is between \$55.5 billion \$93.2 billion

Data provided by HorizonScan gives a more detailed picture of the state of food safety in the US in the last ten

years. From 2008 to 2017, there were 6,836 reported food safety incidents, which were caused by 111 different types of contaminations. Five of them were responsible for 80% of total incidents:

- Aflatoxins
- Listeria
- Salmonella
- Unauthorised additives
- Undeclared allergens



Total number of USA related food safety issues by country of origin.

As we can see from the chart above with data from HorizonScan, the progression of food incidents in the USA is not linear from year to year. The trend, however, is undoubtedly upward. A higher number of incidents

does not necessarily mean that the food protection system has gotten worse. In fact, it can also mean that it is more capable of detecting food safety issues.

Food recalls cost the food industry millions of dollars every year.

Food safety incidents have a high social cost but are also a financial issue for the food industry. A product recall is both a sanitary and a PR crisis with repercussions at many levels: the cost of the recall itself, lost sales, damaged reputation, etc.

Comprehensive and updated data on the financial burden of food recalls is scarce, but there are two recent studies we can quote.

An analysis of more than 100,000 insurance industry claims for product recalls by Allianz Global Corporate & Specialty. Key findings:

- The F&B sector is the second most affected by food recalls
- The average claim value is €1.31m
- The average claim value for a large recall is €7.92m

A 2011 report by the Grocery Manufacturers Association, based on a survey with 36 members. Key findings:

- 81% of respondents deem financial risk from recalls as significant to catastrophic
- 58% have been affected by a product recall event in the last five years
- 77% of them experienced recalls that had a financial impact of up to \$30 million.

For large food companies, the financial impact of food recalls can be much higher than \$30 million. Two notable examples are the Maggi instant noodle recall in India, which cost Nestle half-billion dollars and a milk recall which cost New Zealand's milk giant Fonterra over €100 million.

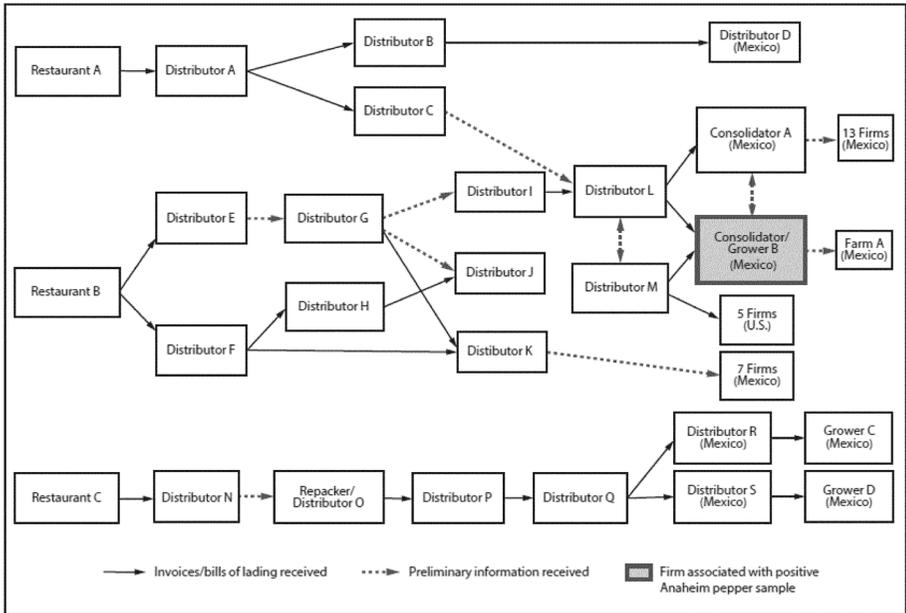
These cases are also important cautionary tales, and for two reasons. First: they prove that they can happen even to companies with the highest budgets to spend on food safety standards. Second: both recalls were precautionary, meaning they were issued over a *potential* food safety risk. Eventually, there were no consequences on public health and while this is certainly a positive outcome, it makes food safety an even greater liability for food companies.

Keeping track of food origins was becoming more and more difficult.

Food safety incidents are unfortunate events, but they could also serve as case studies for health authorities and food companies to make sure they do not happen again. Unfortunately, a globalised and incredibly complex food supply chain is making that task very difficult.

A good example of this is a 2016 Salmonella outbreak linked to hot peppers imported from Mexico and sold to restaurants.

In the investigation that followed, the CDC tried to find out exactly at what point between the farms and the restaurants the hot peppers were contaminated. However, the intricate web of intermediaries in the farm-to-table journey of the contaminated food – pictured below - made that search unsuccessful.

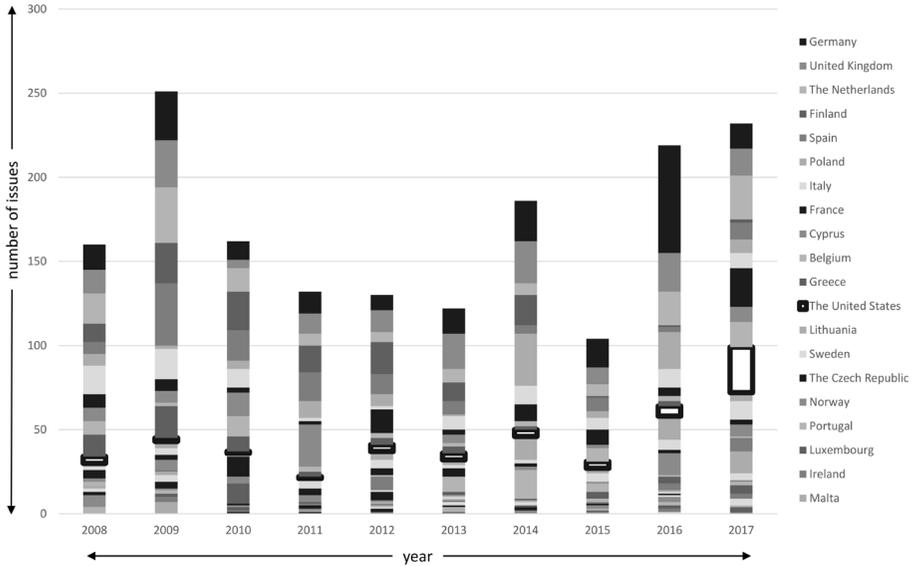


The chart above illustrates what can happen when a contaminated ingredient is at least identified. With processed multi-ingredient foods, things can get even more complicated. During the investigations following the horsemeat scandal in 2013, the National Audit Office in the UK reported that a pizza was in fact made with 35 ingredients that passed through 60 different countries, although on the label its country of origin was Ireland.

It was therefore clear that in a system where food travels the world with multiple stops, FSMA had to focus also on the food coming from foreign suppliers, not only on the domestic side.

Indeed, that shift in focus started to show some positive effects. Available data from HorizonScan as shown in the chart below, indicates that the situation improved in terms

of the FDA consistently being the first food safety authority to pick up more food safety issues over the last years.



Total number of USA related food safety issues notified by various counties

Consumers were losing trust in food brands.

Finally, what made a new food safety law necessary was that consumers were losing trust in how genuinely food brands were trying to produce healthy food without unnecessary chemicals.

A survey conducted by Edelman in 2012 highlighted a growing concern in consumers about the sources of their food: 22% of respondents cited safety and production as one of the reasons why food production in America “is on the wrong track.” 81% said they prefer US-grown foods, while 69% wanted to know where their food comes from.

III. THE PROTECTIVE NET OF FSMA

At its core, the purpose of FSMA is to cast a wider and tighter food protection net around consumers and the food industry in the US.

Food protection can take many forms. A useful way to represent it is the food risk matrix, which is divided into four quadrants: food fraud, food safety, food quality and food defence.

https://www.foodsafetystrategies.com/ext/resources/FSS_Event/2017/2017_Presentations/Food-Fraud-and-Vulnerability-Assessment.pdf?1515701161

Food Quality	Food Fraud	Motivation Gain: Economic
Food Safety	Food Defence	Harm: Public Health, Economic, or Terror
Unintentional	Intentional	
Action		

Food fraud

A common definition of food fraud is the “deliberate and intentional substitution, addition, tampering, or misrepresentation of food, food ingredients, or food packaging; or false or misleading statements made about a product for economic gain.”

The most important part in this definition is “economic gain.” Because profit is the primary goal of food fraud, in most cases there is no eventual risk for public health.

The EU horsemeat scandal is an example of a large-scale food fraud where not a single person was reported sick. Also, food fraud is not limited to food adulteration, but includes conducts outside the food risk matrix, such as misbranding and theft.

However, food fraud is also a health risk, as the negligent conduct of the fraudster may unintentionally harm people. The 2008 melamine milk scandal in China, where six infants died and an estimated 54,000 were hospitalised, remains one of the worst examples of the unintentional consequences of food fraud. That incident was one of the lowest points in the history of food safety and a major turning point towards a tighter food protection system worldwide.

Food fraud is a very common crime around the world. What makes it so appealing to fraudsters is the opportunity to obtain maximum profit with minimum risk. The most targeted foods are also the most expensive ones. Here we will provide a few examples, although the list is by no means exhaustive.

Meat. In the above-mentioned 2013 horsemeat scandal, beef meat was mixed with considerable amounts of horse meat to lower its production cost and increase profits. The response of the authorities was tighter controls and the creation of the Food Fraud Network. That wouldn't be enough to stop fraudsters, though: still today, criminals are being arrested for the same type of fraud.

Olive oil. The adulteration of olive oil is almost as old as olive oil itself. Very frequent ways this is done is by selling further processed olive oil as extra virgin olive oil or mixing different oils without declaring it on the label.

Honey. According to a 2016 EU report, 14.2% of honey is likely to be adulterated. Again, the most expensive ones are a favourite target, like Manuka from New Zealand. In 2014, the leading Manuka association calculated that the consumption of Manuka honey in the UK alone exceeds the total production of New Zealand. That clearly means that a lot of honey that is sold as Manuka is not what consumers expect it to be.

Fish. Last year, a report from non-profit ocean conservation group Oceana revealed how “seafood swaps” is as a global practice. The typical example is Asian catfish, which is mislabelled and sold as eighteen different – and more expensive – types of fish.

Food fraud is a very pervasive crime and still very difficult to fight. Unfortunately, there’s no comprehensive data on the phenomenon, because not all cases are discovered by authorities and food companies are not always keen on reporting that they were victims of food frauds.

Another survey-based report by the GMA from 2010 can help shed some light. Its conclusions are worrying: economic adulteration and counterfeiting cost the food industry between \$10 and \$15 billion per year globally. For a single company, being a victim of food fraud case may cost between 2% and 15% of annual revenues.

Food quality and food safety

While food safety and food quality are both unintentional acts, food quality issues do not necessarily result in food safety issues.

Food safety incidents can be caused by different things: physical contamination (plastic, stones, bones, etc), chemical contamination (pesticides, cleaning agents, etc.) and bacteria or allergens not declared on the packaging.

At a more general level, a food safety issue is also a food quality issue. In the context of the food risk matrix however, food quality has more to do with customers' expectations regarding the appearance and texture of food. A food processing operation that is not investing enough resources in equipment and quality control is more likely to incur food quality issues.

Food defence

Food defence is the protection against intentional food contamination whose specific purpose is to harm people.

Intentional food contamination can happen at different scales. On the small side of the spectrum, we find individual criminal acts, for example when a murderer kills someone by poisoning their food. The real concern of FSMA, however, is to prevent large-scale incidents like food terrorist attacks, industrial sabotage, or other acts with purely criminal intent.

Although no mass-scale food terrorism case has ever occurred, in the post-9/11 era we live in, it's clear that terrorists are constantly looking for new and unconventional ways to perpetrate attacks. A vulnerable food supply

chain could be an effective vehicle for such acts. When he resigned as the secretary of Health and Human Services in 2004, Tommy G. Thompson is often quoted as saying: “For the life of me, I can’t understand why the terrorists have not attacked our food supply because it is so easy to do.”

Even when they do not cause casualties, food defence issues can badly hurt the finances of food companies at any step of the supply chain. Below are a few examples.

Before food or animals leave the farm.

In 1996 in Wisconsin, pesticide was added to an ingredient used by an animal feed plant. The contaminated feed was then distributed to over 4,000 farms, causing several recalls of dairy products. The convicted person was a competitor of the facility.

http://www3.ntu.edu.sg/rsis/cens/publications/reports/RSIS_Food%20Defence_170209.pdf (page 12)

After food has left the farm.

In 1978, Palestinian terrorists injected mercury into Israeli oranges. The contamination probably took place at the Dutch port of Rotterdam. The terrorists later declared that they didn’t intend to cause any harm to people. <https://www.washingtonpost.com/archive/politics/1978/02/02/terrorists-poison-israeli-oranges/5650c62a-7ef2-497d-9b20-c47d4376c908/>

At the store.

In 2000 in Italy, a terrorist known as “the Italian Unabomber,” placed explosives inside several food articles in a large supermarket. No one was ever convicted for those acts.

https://en.wikipedia.org/wiki/Italian_Unabomber

As recently as 2017, a man in Germany contaminated adult and baby food, warning that he would not stop unless he would be paid 11.7m euros. A 53-year old man was later arrested.

<https://news.sky.com/story/blackmailer-who-poisoned-baby-food-in-supermarkets-arrested-11061907>

As a service to the reader we have created an Excel file containing all the hyperlinks which are mentioned in the book. You can download the Excel file via this link: <https://www.foodsafety-experts.com/fsma-book-link/>

Alternatively, you can also scan this QR code:

