

Food Microbiology and Food Safety
Practical Approaches

John W. Spink

Food Fraud Prevention

Introduction, Implementation, and
Management

Food Microbiology and Food Safety

Practical Approaches

Series Editor:

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Food Microbiology and Food Safety Series

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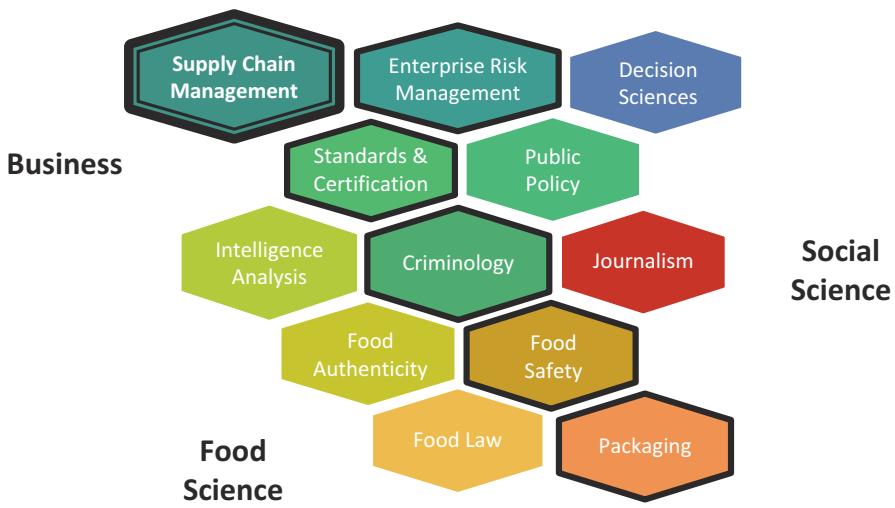
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Dedication

First, this is dedicated to my family who has been patient and supportive throughout the overall journey during the development of this book and also of my overall research path. Second, this is dedicated to the many colleagues I've worked with over the years. While this is a job that provides the finances for us to survive, I absolutely love the topic and working through the challenges of clarifying an implementation of the concepts and working with a wide range of colleagues from all over the world.

This book is also dedicated in remembrance of several key scholar mentors:

Ed Mather (1937–2010)

My first opportunity to return to academia was when in 2003, he asked me to develop an online graduate course for the Master of Science in Food Safety Program. Along the way, he helped me see the opportunity in academia and navigate through Michigan State University. His encouragement and guidance were critical to me, getting through my Ph.D. and providing a realistic perspective on what I could expect from my

appointments. He served as one of my Ph.D. committee members and my first supervisor in the MSU Master of Science in Food Safety Program. Previously, he was chair of the Department of Large Animal Clinical Sciences, associate dean for Research and Graduate Studies, director of the National Food Safety and Toxicology Center, and director of the Master of Science in Food Safety Program.

Don DeKieffer (1946–2011)

After meeting at an Anti-counterfeiting Conference, he was an early mentor that provided tremendous insight into the very first prevention strategies. A key point was “don’t start with trying to stop all counterfeiting, get them to stop knocking you off!” His wide range of Washington experiences were especially insightful and valuable including having served on the professional staff of the US Senate Republican Policy Committee, as general counsel to the Office of the US Trade Representative, and then as a founding partner of deKieffer & Horgan law firm. In parallel, he led the EDDI, Inc., working on databases relating to counterfeiters and diverters.

Foreword

This book deals with a crucial matter regarding food. The problem of food fraud, unfortunately, has been with us as long as the history of food trade. The oldest recorded food laws attempt to deter it. In Babylon, you might be thrown into the Euphrates with a millstone around your neck for the adulteration of flour. In the fourth century BC, the Greek Theophrastus reported on the use of food adulterants for economic reasons in *Enquiry into Plants*. Pliny the Elder in *Natural History* provides evidence of widespread adulteration, such as bread adulterated with chalk to make it whiter and pepper adulterated with juniper berries in economic fraud.

John Spink brings an important perspective to this field. Food lawyers tend to look at food fraud from a legal liability viewpoint. Yet, reputational damage can far exceed the penalties in the laws. Food safety experts tend to approach the topic as health and safety risks. Yet, the clever fraudsters seek economic advantage and may present to health risk. Food scientists see the challenges in standards, detection, and testing. Yet, there can be adulterated food that contains no adulterant. Criminologists see motive and opportunity. Yet, the nature of supply chains can muddle such analysis. To deal with these seeming contradictions, John Spink brings a multidisciplinary approach to the topic.

The problem of food fraud is global in nature. Food fraud concerns public health but goes beyond to economic loss and harm to consumer confidence in individual companies and also loss of confidence in the integrity of the food supply. This has been with us since the beginning of food trade and will be with us as long as there is a trade in food. Knowledge is the key to food fraud prevention. And there has never been a better time for this book.

John Spink's footprints on the field of food fraud circle the globe. He is in such demand as a speaker; it can be hard to catch up with him even while working at the same university. Fortunately, we have his book.

Neal D. Fortin, J.D.
Director, Institute for Food Laws and Regulations (IFLR)
Professor, Food Science and Human Nutrition, College of Agriculture and Natural Resources
Michigan State University

Foreword

Food fraud has emerged as a serious food safety risk that ranks as one of the biggest concerns for both the food industry and government regulators. Food fraud, including economically motivated adulteration, is also a top concern with consumers. Food fraud is the intentional adulteration for economic gain, a food defense incident is intentional adulteration to cause harm, and a food safety incident is unintentional adulteration resulting in unintentional harm. However, in the case of food fraud, even though the motivation is economic gain, it can result in public health harm. The threat of food fraud is not addressed in conventional food safety and food defense management systems and need to be considered separately.

Dr. John Spink has been a leading researcher in the area of food fraud and has worked closely with the industry to develop vulnerability assessments. His work has helped the industry and governments to more effectively identify and manage the root cause of this criminal activity. There is a necessity to continue to address the core problem behind food fraud and develop a preventative system approach to combatting food fraud.

As the former Cargill Incorporated Vice President of Corporate Food Safety, Quality and Regulatory Affairs and the current Chairman of the Global Food Safety Initiative Board of Directors, I am keenly aware of the importance and challenges of dealing with food fraud. I lived through the melamine crisis as it impacted the industry in China and the United States. Food fraud undermines all of our efforts around food safety and food defense, and we must be able to impart trust in the integrity of our supply networks around the world.

This book focuses on tools that enable solutions to more effectively identify and manage the risks of food fraud. It covers all the activities focused on prevention starting with the criminal motivation through the responsibility of companies, from the boardroom to the factory floor to the farm. This groundbreaking textbook provides a full picture of food fraud and is filled with tools that companies can use to establish preventative systems and train employees to deal with this real threat to the integrity and safety of our food supply around the world.

Mike Robach

Chairman, Board of Directors, Global Food Safety Initiative (GFSI)

Former VP of Food Safety, Quality and Regulatory, Cargill Incorporated

Foreword

Food fraud is an extremely important and challenging problem for the food industry and for national administrations worldwide. It is an issue that has received particular focus in the European Union—following some high profile, high visibility, highly disruptive incidents—such as the presence of horse meat in internationally available, commercially recognizable meatballs.

While the horsemeat incident is often thought of as the first major international food fraud event, there have been an increasing series of concerns in recent years. There are a wide range of food fraud incidents that deceive the consumer and are injurious to public health. These can range from counterfeit alcoholic beverages, to species swapping and adulteration of meat products, and to counterfeit country of origin products. These pose many problems that not only have the potential to cause harm to consumers but may also result in reputational damage to a company or food sector, cause loss of profits and market share, lead to the fall or collapse of a share price, result in loss of market access, and can have political and economy-wide impacts.

In my regulatory role, over the past 35 years—more recently as Executive Chairman of the Sea Fisheries Protection Authority, and now in my current role as Director of Audit and Investigations with the Food Safety Authority of Ireland (FSAI)—I have witnessed the increasing sophistication and dangers of food fraud. The FSAI has recognized the need for multi-disciplinary multi-agency coordinated enforcement action in tackling food crime.

In order to lead the fight against fraudsters that operate within our food supply chains, we have engaged in many collaborative international networks such as the EU Food Integrity Project, the Interpol Intellectual Property Crime College (where I first met the author Dr. Spink at the 2013 conference in Dublin), INTERPOL/Europol Operation Opson, and in the EU Food Fraud Network. This broad set of experiences has led us to understand the complexity and challenge of not only detecting and deterring food fraud but also of preventing it from occurring.

This publication will be a benefit to and support for those involved as practitioners in the areas of food safety control, to the investigators of food fraud, and to the prosecutors of apparent wrongdoing. This book provides access to the concept and

breadth of what is defined as food fraud, and it applies its usefulness as a tool of insight as much to the seasoned practitioner as to the student of a number of codes.

Food fraud is not a new problem, but tackling it is a new discipline. This book makes it clear that it involves cooperation across a multitude of codes and professions, across industries, and across borders. As a concept which is evolved and understood, food fraud is given a solid foundation in this publication—this book uses a bedrock of established principles to guide us through the complex areas of understanding and strategy to tackle food fraud—for the danger, menace, and crime that it is.

Dr. Spink tells us that prevention is as important as the pursuit of the wrongdoers, when in pursuit the investigator needs to be as strategic as a chess player, and that targeting the reduction of opportunities for such fraud to exist is a paramount focus—with significant emphasis being placed by the author on the ‘who is likely to commit it’ pattern of thought, which investigators and lawmakers must focus on.

Traceability within and a transparency of the supply chain are deemed important and vital in the narrative of this book. In that regard, international relationships are deemed vital, as is a tailored risk assessment model for this area—rather than an imported model from other food control areas.

In recent years, food fraud has received increasing public and media attention and has been the focus of many academic articles and books. Dr. John Spink is a leading author in this field and has contributed enormously to the area of food fraud detection, management, and prevention. There is an increasing awareness of the need for a more wide-ranging and comprehensive consideration of the root causes of food fraud. This book examines the essential areas of food fraud prevention; demonstrates the need for advanced decision-making in the public and private sectors; addresses the need for industry to have processes in place to identify, assess, and control vulnerabilities, and discusses the application of criminological theory and the necessity to map and understand food supply chains.

The distinction is clearly made between the use of risk analysis in the management of food safety and the evaluation and control of vulnerabilities in the management of food fraud. All these areas are brought together in this book to provide an excellent text for understanding food fraud prevention and will act as a valuable resource for regulators, the food industry, the academic community, researchers, and students alike.

Over the years, Dr. Spink has been a leader and partner for a wide range of food fraud-related groups, and this textbook is the summary of those interactions and insights. This book advances food fraud prevention as a specific area of study and will support the development of a more strategic approach in the fight against food crime. This book provides useful tools for those wishing to reduce the food fraud opportunity and to protect consumer health and interests.

Peter Whelan

Director of Audit and Investigations, Food Safety Authority of Ireland (FSAI)

Irish Food Fraud Contact Point, Food Fraud Network, European Union

Irish Representative, Operation OPSON, INTERPOL/Europol

Advisory Board Member, EU Food Integrity Project

Advisory Board Member, EU Food Smartphone Project

FSAI lead for the Codex e-Working Group on Food Fraud

FSAI representative on the Food Industry Intelligence Network (FIIN)

Preface

Summary

This book is the culmination of a wide range of activities from outreach, research, and teaching. It provides a broad “education” foundation on the topics with practical application “training” to implement a practical Food Fraud Prevention Strategy, lays out an extremely interdisciplinary foundation to help address food fraud prevention, and presents a rational approach that applies sound science to evaluate the solution, understand how the countermeasures and control systems work, establish a first financial and accounting base in enterprise risk management, explore the efficiency of those activities, and then help decide on the course of action that best protects consumers. We’ve only just begun the journey to address food fraud prevention—we’re only at the starting line—getting here was the easy part, and now the hard work begins. This book is one tool for understanding a holistic and all-encompassing perspective on the multidisciplinary Food Fraud Prevention Strategy.

Food Fraud Prevention Research Development

The research on food fraud has constantly been evolving, and until recently an interdisciplinary, holistic, and all-encompassing book—let alone a textbook—on the topic was not warranted since it would be out of date as soon as it was written. Over time, there has been enough research and publication on establishing a broad and theoretically sound foundation that a textbook is now appropriate. This book will cover the foundational principles and theories, not the current trends or hot topics. To be clear, our previous MSU research did *not* create the food fraud term or research area but did help formalize this as a holistic and all-encompassing discipline. When conducting various projects, our team found that there had not been research on defining the topic or publishing the details of the problem. Those findings provided the motivation for our 2011 journal article “Defining the Public

Health Threat of Food Fraud,” which was the first research project and article focused on examining and publishing an explicit definition. While there were previously published uses of the food fraud term, critically reviewing the definition and scope was not the focus of a research project but were included as an assumption in the background or introduction section of a scholarly publication.

Our research and experience at the Food Fraud Initiative (FFI) at Michigan State University (MSU) has provided a unique opportunity to be involved in some of the very first food fraud prevention activities, such as with GFSI, ISO, Codex Alimentarius, FDA, INTERPOL, European Union, other Universities, associations, and others. Over time, our position as scientists “representing the discipline of Food Fraud Prevention” has enabled us to collaborate with many of the US and international thought leaders and committee or advisory group activities.

This MSU research began in 2005 with a focus on intellectual property rights product counterfeiting in my 2009 Ph.D. dissertation “Introducing the Counterfeit Product Risk Model (CPRM)” (see the Risk Assessment Application chapter) (Spink 2009). In parallel, I was teaching graduate courses in food safety starting in 2004. That early dissertation research—combined with graduate course development and teaching in the MSU Food Safety Program, MSU School of Packaging, and the MSU School of Criminal Justice—led to a focus on a wide range of products such as pharmaceuticals, consumer electronics, luxury goods, and food. Specific activities included developing and teaching graduate courses such as “Packaging for Food Safety” in 2005 and “Anti-Counterfeit and Product Protection” in 2008, which covers all products and intellectual property rights infringement. This wide range of activities brought to light an unmet need in prevention of “food counterfeiting” which evolved into “Food Fraud Prevention.”

In 2013, there was an opportunity to shift the FFI activities from the School of Criminal Justice in the College of Social Science back to its original academic home of the Master of Science in Food Safety Program and the College of Veterinary Medicine (CVM), where we were able to focus completely on food fraud and prevention. During that transition, the MSUglobal team provided critical insight and support by supporting the development of the Massive Open Online Course (MOOC) concept, leading to the development of the www.FoodFraud.msu.edu website, and encouraging and supporting the blog posts. The shift back to CVM was an incredibly important opportunity since there were fewer distractions from commitments to address other products or industries. Also, in hindsight, this was also an important reposition to support the more holistic and all-encompassing implementation of the theories since the food industry is very coordinated and collaborative under food safety efforts. Food safety is truly *not* considered a competitive advantage among companies, and the relationships enabled the harmonized and coordinated focus on prevention.

In 2019, I was enabled to shift to the Department of Supply Chain Management (SCM) within the MSU Eli Broad College of Business (BUS). This move to within the business discipline was logical and efficient since, over time, the decision-making and problem assessment research kept narrowing to the COSO-based enterprise risk management practices. This research focus has included the monitoring and

control of both supply chains and operations and also specifically to procurement. While the ongoing research and activities continue, there is a new focus on how the general supply chain management threat of food fraud—and overall product fraud or related issues—would most optimally be assessed and managed. The opportunity in 2019 to shift to SCM has created a more intense focus on the basic business functions from within—rather than trying to influence from outside—business operations, logistics, and procurement.

Building the scholarly foundation helped create opportunities to collaborate with some of the key food fraud-related committee membership or project leadership activities including:

- **US FDA Open Meeting on Economically Motivated Adulteration:** Presented as the first nongovernmental presenter on the topic “Defining Food Fraud and the Chemistry of the Crime”
- **EU Food Integrity Project:** Researcher and former advisory board member
- **Queen’s University Belfast:** Visiting researcher with professor Christopher Elliott, the lead researcher for the UK Defra Elliott Review of Food Crime
- **ISO Technical Committee 292 Security Management (TC292) and Work Group 4 on Product Fraud and Authenticity:** Founding chair of the US Technical Advisory Group
- **ISO Technical Committee 34 Food Products, Subcommittee 17 Management Systems for Food Safety, Work Group 8 Food Safety Management—Requirement (ISO TC34/SC17/WG8)—Management Systems for Food Safety (ISO 22000):** Observer status
- **Grocery Manufacturers Association (GMA)—Work Group on Economic Adulteration as well as Various Brand Protection Advisory Groups:** Committee or share group member
- **Chinese National Center for Food Safety Risk Assessment (CFSAN):** Foreign subject matter expert and researcher
- **US Pharmacopeia’s Original Food Ingredient Intentional Adulteration Expert Panel:** Volunteer member (2009–2018)
- **INFOSAN the WHO and FAO-UN Food Safety Information Sharing Network:** Presenter and researcher
- **Codex Alimentarius Electronic Work Group on Food Integrity and Food Authenticity:** Supporting the US delegation and also as a contributing scientist to the EWG
- **Global Food Safety Initiative (GFSI) Food Fraud Think Tank:** Member (Note: Due to the development and publication of certification requirements—combined with our continued engagement with a broad range of stakeholders—this is the most important and impactful activity.)
- **Canadian Food Fraud Work Group (FFWG):** Ex-officio member supporting the Canadian Food Inspection Agency (CFIA) with the goal of implementing steps to combat and prevent food fraud in Canada
- **ISLI Food Authenticity Project and Task Force:** Member
- **AOAC Presidential Taskforce on Food Authenticity:** Member.

These many research projects and engagements since 2005 are the foundation for this book. While the science of food fraud prevention is continuing to evolve, there is now a need to clearly understand the basic fundamental terms, concepts, theories, tools, methods, and processes. Even if the concepts are not yet universally known or implemented, the base concepts are published in peer-reviewed journals and, usually at least, outlined in standards, certifications, and common practice.

This book is the culmination of those activities.

Personal Insight: Developing Food Fraud

If anything, over time, the food fraud concepts have just become more ingrained and more formally recognized. If anything, they have matured from “what is it?” to “how to deal with it?” and on the way to “how much is enough?” On the GFSI Food Fraud Think Tank, this was referred to as “shifting from “what” to “how.” We find that we have shifted from talking about “Defining Food Fraud and the Chemistry of the Crime” to “Food Fraud Prevention and Global Trends.”

Our original 2011 research paper on “Defining the Public Health Threat of Food Fraud” was conceived during the FDA Public Meeting on EMA in May 2009. The conference was held near Washington, DC, at the FDA Center of Food Safety and Nutrition (CFSAN) in College Park, Maryland, which ended late on a Friday afternoon, and I decided not to hurry to the airport for a late flight. This allowed an opportunity for possible debriefs after the meeting. I decided to stay with friends who lived north of Baltimore and then fly back to Michigan on Saturday morning. I had some important time to decompress and allow time to reflect after the day of presentations. I had a long slow travel time driving through the rush hour that night then the drive and flight the next Saturday morning. I kept thinking about how we could do a better job of explaining the food fraud concepts. The base of that article was conceived during that trip.

The invitation to present at the FDA EMA meeting in 2009 came from David Acheson who was the FDA deputy commissioner for Food Protection. We had met earlier in 2007 at the Association of Food and Drug Officials (AFDO) annual conference and had started conversing about food fraud. (I will admit that I was new to these types of sessions and thought I had been invited to present to David and his team.) Fortunately, earlier in that week while at the Food Safety Summit, Gale Prince, the former vice president of Regulatory Affairs for Kroger, mentioned that he heard I was testifying later that week. “Testifying...?” I did a bit of research and figured out this was a formal public meeting that was on the record and would have a published transcript. I did quite a bit more preparation after hearing this. I am grateful to David for recommending me as a speaker and to Gale for giving me a heads-up to one of the most important events of my career.

After responding to all those insights, taking on an unsolicited project to define a new topic and area of study would seem like a bit of a bold activity since, technically, I was just a “grad student” and not even a “postdoc.” Later that month, I

submitted my Michigan State University Packaging Dissertation, graduated, and, the next month, started at MSU as an assistant professor faculty member in the School of Criminal Justice. Academic publications are important, so I started thinking about how I would write this up to submit to a journal. I was excited about the topic and the opportunity to contribute to the innovation, so I didn't think about funding or a publication outlet—yet.

In July 2009, the National Center for Food Protection and Defense (NCFPD), housed at the University of Minnesota, had a call for projects. I remember hearing about this grant from my MSU SCJ colleague, assistant professor Dr. Robyn Mace, only a few days before it was due. I remember staying in the office late on a Friday to put this proposal together just before the deadline later that night.

I was fortunate in June 2009 to be awarded the grant just a month into my “soft money”—funded MSU fixed-term appointment that covered my annual salary—so this grant helped me get off to a running start. I was very fortunate to enlist a graduate student to help, the now Dr. Douglas C Moyer—and in 2014, now an assistant professor focusing on Public Health Administration and Counterfeit Medicines in the MSU Program in Public Health. He had 25 years of work experience with Ford Motor Company before coming back to MSU to pursue his Packaging Ph.D. and was focusing on operational management but was interested in collaborating on this food project.

We finished the deliverable for the NCFPD grant and then sought a publication outlet. We kept finding that food journals thought this was more of a criminology concept. The criminology journals thought it would be better suited in a food journal. The business and public health journals had not heard of the topic, and we did not yet have empirical research or a reputation that would encourage the defining of a new concept. All the while, both food and criminology journals said it was outside their aim and scope because they had never covered the concept before. There was still a general belief that this was more of a corporate crime or only a financial crime. Food fraud wasn't yet defined as a “thing,” and it was not in the “aim and scope” of *any* discipline—yet.

Eventually, while Doug and I were talking out loud about this while having a beer during a chilly Fall evening around an outdoor fire pit at the 2010 NCFPD conference, a colleague mentioned interest in the article. Dr. Jennifer McEntire was the research director for the Institute of Food Technologists (IFT). We had presented on several panels for her IFT workshops. She chaired a USDA/FDA Public Meeting on food traceability where I submitted public comments on food fraud. She had seen the reaction from industry and understood this was an emerging and important topic. She asked us to forward the manuscript to the editor of the *Journal of Food Science* and to “cc” her. After several discussions, they took the article into the peer-reviewed process; then with quite a bit of effort to find reviewers—and some very challenging rounds of edits—finally our article was accepted. “Defining Food Fraud” was now a published topic. Food fraud was now a topic that had been defined in a scholarly journal. Food fraud was now a “thing.”

Our NCFPD grant was funded from October 2009 to September 2010 with the final report published on April 30, 2011. At that time, we began working on the full

manuscript and then first submitted our journal article on November 10, 2010; had a review process for 9 months before it gets accepted on August 24, 2011; and finally published 3 months later on November 9, 2011. The formal research projects spanned 25 months from October 2009 to publication in November 2011. The process seems lengthy, but the peer-reviewed, refereed review process is important and critical to advance the science.

Over the years, patience and persistence have been critical because we often experienced extensive peer-reviewed comments that challenged the very essence of “food fraud” as a “thing.” Fortunately, the intense feedback and lengthy review process was *not* a surprise—it was actually to be expected. Many of our senior mentors predicted the intense scrutiny and helped us to understand this was important. The intense feedback—and our active and thorough responses—was a vital insight into what was misunderstood and where we needed to address more of the basic foundation.

I have mentioned that many of our colleagues had been publishing on related concepts—the basics of food fraud were not the focus of those previous articles. We had now published a peer-reviewed, refereed article on the definition of food fraud and of the public health impact. Scholarly articles are influential because they do go through a peer-reviewed, refereed process. In a top journal, you can’t get away with “junk science” or making “flippant” statements. This rigorous process is important and valuable. The final product stands the test of time. This article allowed future researchers—and us—to be able to reference this article rather than continue to argue about the definition of the term and of the threat. Over time, and through 2019, the definition published in 2011 is referenced as the foundation of almost every definition of food fraud.

Later, we realized that “no wonder” we were having so much trouble getting traction when talking about food fraud because it had not been defined and widely understood to be an actual “thing.” While there have been publications about specific incidents or test methods, there was no scholarly publication citation that explained food fraud was really a problem. While here, in 2019, we’re approaching 8 years since the article published, we’re just starting to see grants soliciting work specifically in food fraud.

Personal Insight: Defining Food Fraud—Exploring a Foundation

Much of the foundation of the food fraud prevention research began earlier at the start of my 2005—2009 Ph.D. research on product counterfeiting risk modeling within the Michigan State University School of Packaging, College of Agriculture and Natural Resources. The Ph.D. dissertation was entitled “Analysis of Counterfeit Risks and Development of a Counterfeit Product Risk Model – CPRM” (Spink 2009). During that time, I was an adjunct graduate course instructor in the MSU

Master of Science in Food Safety Program (MSFS) within the College of Veterinary Medicines. The graduate classes created in 2006 and still taught include “Packaging for Food Safety” (co-listed in the School of Packaging (SOP), College of Agriculture and Natural Resources; VM/PKG 814) and modules in courses such as “Food Protection and Defense” (co-listed in the School of Criminal Justice (SCJ), College of Social Science; VM/CJ 821). Later in 2008, based on my Ph.D. dissertation and before joining the School of Criminal Justice, I developed and still teach “Anti-Counterfeiting and Product Protection” (co-listed in SCJ and SOP; VM/PKG/CJ 840). From the beginning, the broad scope of “all products” focus on intellectual property rights infringement combined with my food safety research applied to the concept of “food counterfeiting” to eventually adapt to policy and strategy issues for food fraud prevention.

As I was getting close to the end of my Ph.D. in early 2008, I approached SCJ director Dr. Edmund McGarrell to propose creating a new assistant professor position in the School of Criminal Justice. I helped develop that proposal and started in June 2009 reporting to him as a faculty member for 4 years before I was enabled to broaden my focus to all fraud while narrowing the scope to only food products. This refinement of focus enabled a much deeper immersion and engagement with a single industry. This immersion has been critical in building trust, increasing insight, and being afforded the time to not only research the topic but also to participate in a meaningful policy and strategy evolution.

Over time, while interacting with the food industry, around 2007, a leader said: “I’m not just worried about counterfeiting we’ve got a wider range of problems.” Also, they stated, “I need to figure how to manage all these problems not just one at a time.” During this period, around 2009, the US FDA defined economically motivated adulteration (EMA) as a “substance” for “economic gain” with a “hazard” (FDA 2009). We became aware of other related concerns such as in the pharmaceutical industry regarding regulations for stolen, diverted, and smuggled goods (RX-360.com, FDA 2004; WHO 2007). Our response was to combine the different intentional acts under a common topic that became “food fraud prevention.” We did not create the food fraud term, but we provided a more rigorous definition and a peer-reviewed, scholarly journal citation.

In an effort to pursue related activities, since 2009, I was the founding chair of the US delegation to the International Organization for Standardization (ISO) Technical Committee 247 on Fraud Countermeasures and Controls (TC247; this shifted to under TC 292 Security Management and Resilience) (ISO 2010, 2017). It was interesting, and timely, to attend that first meeting. I remember talking to MSU colleagues that I could either wait for the results and write about them or actually attend the meeting. While at the meeting, I was approached and convinced to become the chair. This ISO activity was very important and had an influence on our research on the concept of product fraud, counterfeiting, and eventually food fraud. A key need was to define the terms, and eventually a “product fraud” definition was published in ISO standard 22380 Security and resilience—authenticity, integrity, and trust for products and documents—general principles for product fraud risk and

countermeasures (ISO 2018). This ISO standard codified our 2016 published Product Counterfeit Incident Clustering Tool (PCICT).

The evolution of the research continued when, in July 2012, the Global Food Safety Initiative (GFSI), under recommendation by then Chair Yves Rey of Danone and Co-Chair Frank Yiannas of Wal-Mart, convened a “Think Tank.” The mission was to review the concept and consider the application under the GFSI Food Safety Management System. The group was originally entitled the “Economic Adulteration Think Tank,” but based in part on the ISO precedence of referring to this as “product fraud,” the name shifted to “Food Fraud Think Tank.” A key for GFSI was that, although health hazards are the highest priority, companies needed a system to assess and manage all types of food risks. GFSI—and the base functionality of HACCP—is essentially a total quality management system, so it focuses not only on the highest risks but also on the underlying system variability that can lead to nonconformity. The GFSI-FFT shifted a focus from risk to vulnerability and also first conceived the Vulnerability assessment and Critical Control Point plan (VACCP) content. VACCP was first formally presented at the 2013 GFSI Annual Conference in Barcelona.

Here in 2019, the GFSI food fraud requirement should not be a surprise for the industry since; in December 2014, the GFSI Board published their position paper on food fraud that stated the concept would be required in the next GFSI guidance document. The GFSI Issue 7 published in 2017 and implemented as of January 2018 includes requirements for the following: (1) a specific Food Fraud Vulnerability Assessment, (2) Food Fraud Prevention Strategy (Food Fraud Mitigation Plan), and (3) an emphasis on covering the “relevant GFSI scope” which is all types of fraud (e.g., from adulterant substances to stolen goods and counterfeits) and for all products (e.g., from raw materials through finished goods in the market) (GFSI 2014, 2017). In May 2018, the GFSI Board published a Food Fraud Technical Document that further clarified and refined what had been published back in the 2014 Position Paper and what was in the Guidance Document (GFSI 2018).

Over time, the “all types of fraud” and “all products” broad scope of food fraud has been widely adopted by the EC, UK, FSAI, China, INTERPOL-Europol, and others (ISO 2011; Spink and Moyer 2011; GFSI 2012; SSAFE 2012; CRS 2014; DEFRA 2014; EC 2014; CFSI 2015; CFSI 2015; Manning and Soon 2016; CODEX 2017; GFSI 2017; NFCU 2017; van Ruth, Huisman et al. 2017; CEN 2018). It is efficient that the food fraud term has a common definition because users or assessors can clearly state whether they are addressing all types or just a specific area such as adulterant substances.

Over time, food fraud has become a “thing” and is not only a requirement for compliance, but it is beginning to be understood to be a critical component of a competent Food Safety Management System—and just good business practice. The global food supply chain is safer—the global food security is improving.

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There have been so many incredibly important colleagues through the years during my return from industry to academia starting at MSU. Originally in 2003, Ed Mather, MSU CVM Associate Dean and Director of the Food Safety Program, was the first person to recruit me into academia as an adjunct instructor to develop the “Packaging for Food Safety” graduate course. Next, in 2008 Ed McGarrell, MSU SSC Director of the School of Criminal Justice, was the first person to offer me a full-time MSU faculty assistant professor appointment. Then another critical step was in 2013 when Chris Brown, MSU CVM Dean, recruited me to focus on food fraud research. The support of the College of Veterinary Medicine (CVM) allowed and encouraged us to follow wherever the unmet research needs led. It is very unique not only to collaborate across departments within the university but to move a faculty appointment between different departments and colleges is extremely rare. Further, we were wholeheartedly encouraged by CVM to publish in journals from outside our core veterinary medicine area even though it did not bring direct accolades to CVM. I am especially grateful to J. Ian Gray, MSU Vice President for Research and Graduate Studies, who worked with Provost June Youatt to secure a 5-year appointment in 2014. This appointment enabled the priority to shift to developing the research and scholarly foundation that included the top deliverable, which was this food fraud textbook. More recently, I am grateful for the research and co-author collaboration with Dr. Cheri Speier-Pero, Chair of the Department of Supply Chain Management (SCM) within the MSU Eli Broad College of Business (BUS).

Also, over time there have been many valuable colleagues.

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I had an incredibly enlightening experience coauthoring a chapter on food fraud in the book *Food Safety in China: Past, Present, and Future* (Chinese). Drs. Junshi Chen and Joseph Jwu-shan Jen have been important mentors and editors for this book (Fig. 1).

Throughout my experiences working in China, Dr. Yongning Wu has been my primary contact and champion (Fig. 2). We first met in the USA during a US Pharmacopeia Expert Panel Meeting. I mentioned I was researching food fraud prevention and was going to be in Beijing a month later—he immediately extended an invitation to present at a conference, which I accepted. That conference in Beijing was important because I met my Moscow State University for Food Production colleagues and subsequently was invited to one of their conferences in Moscow.

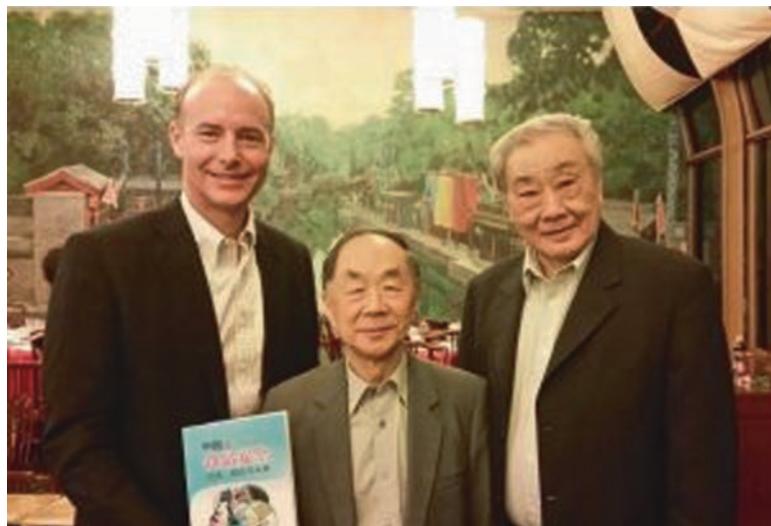


Fig. 1 Dr. Spink with book editors Dr. Junshi Chen and Dr. Joseph Jwu-shan Jen



Fig. 2 Dr. Spink Presenting the Valued Partner award to Dr. Wu and CFSAN

During my trips to China, I was hosted and guided by Dr. Miao Hong (Fig. 3). We originally met a year earlier at a food safety conference in Korea. She is a coauthor on our Food Chemistry article, and we have been constant collaborators on a number of projects. At CFSAN, she is the deputy director of the Food Chemistry Laboratory. My other CFSAN colleague is Dr. Zu Ru who hosted me during a large group presentation. She is the CFSAN deputy director in the Division of Science, Education, and International Cooperation.



Fig. 3 Dr. Spink Presenting the Valued Partner award to Dr. Xu and Hong



Fig. 4 Dr. Spink Presenting the Valued Partner award to Dr. Quiding and China National Research Institute of Food and Fermentation Industries (CNRIFI)

During my trips to China, and more often meeting at events around the world, Dr. Zhong Quiding has been providing important insight and support (Fig. 4).

Throughout my shift from “all products” and IPR counterfeiting to food, the Global Food Safety Initiative (GFSI) has been an extremely influential and the most impactful organization (Fig. 5).

Specifically, I am indebted to my now MSU adjunct faculty colleague Frank Yiannas (Fig. 6). He has provided insight and experience from early days as one of the GFSI board executive champions for the GFSI Food Fraud Think Tank through activities related to Wal-Mart as well as international food fraud and food protection activities.

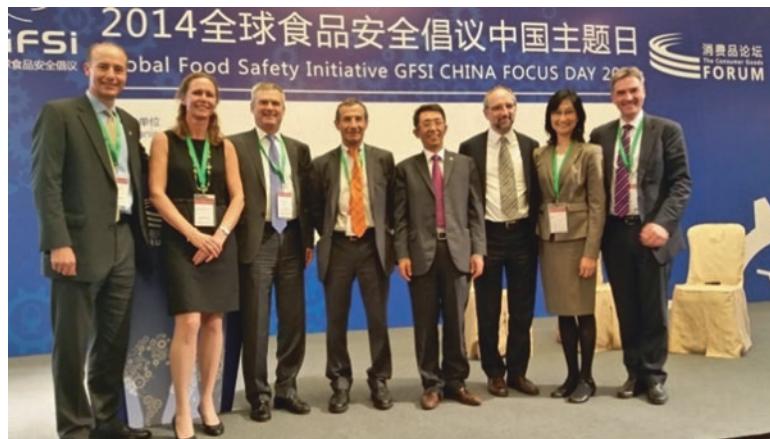


Fig. 5 GFSI China Focus Day Speakers (left to right): John Spink, MSU & Member of the GFSI Food Fraud Task Force; Petra Wissenburg, Director Danone & Chair of the GFSI Food Fraud Task Force; Mike Robach, VP Cargill & GFSI Chairperson; Yves Rey, Gen Manager Danone & GFSI Board Member; Zaotian Wan, VP COFCO (China) & GFSI Board Member; Anthony Hugget, VP Nestle & GFSI Board Member; Cindy Jiang, Sr Director McDonald's & GFSI Board Member; and John Carter, VP Metro Group & GFSI Board Member



Fig. 6 Dr. Spink with Frank Yiannas, VP of Food Safety at Wal-Mart, at the 2013 GFSI China Focus Day (Beijing)

About the Book

This section reviews the organization of the content in the book. The research is presented in a “cloverleaf” structure where several very different concepts will be reviewed in detail before the presentation down the narrow stem of the more specific application. This is different from the more traditional “keyhole” structure of academic research that is usually focused on a very specific small center of a concept explored in detail before the presentation of the broader application. In addition, the content of the book and within each chapter is based on a hierarchy of Key Learning Objectives (KLOs).

This book is organized by thematic areas which start with the core food fraud definitions and scope. Since this is an interdisciplinary and complex problem, then there is no logical, linear path of topics. The information is structured by Key Learning Objectives (KLOs) which are statements about what skills and knowledge are delivered and why. The hierarchy approach allows a review of what topics are important or critical to include, if they have been included, and to explain how the learning objective is to be successfully achieved. The KLO hierarchy includes the following: (1) book, (2) chapters, (3) three per chapter, and, finally, (4) three sub-objectives. Each chapter includes a statement of “What’s In It for Me (WIIFM)” and discussion questions.

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About the Author

Since 2013, Dr. John Spink (www.FoodFraudPrevention.com) has been the director of the Food Fraud Initiative (FFI) at Michigan State University (MSU). The Food Fraud Initiative is an interdisciplinary activity focused on detecting and deterring this public health and economic threat. The research focus is on policy and strategy starting with Criminology and through to the application of business decision-making and COSO/Enterprise Risk Management. His leadership positions include product fraud-related activities with “ISO 22000 Food Safety” and “TC292 Security Management/Fraud Countermeasures,” WHO, FAO/UN, GFSI Food Fraud Think Tank, and US Pharmacopeia (USP). Global activities include engagements with the European Commission, INTERPOL/ Europol Operation Opson, New Zealand MPI, Codex Alimentarius, WHO/FAO, Food Safety Authority of Ireland (FSAI), Canadian Food Fraud Work Group, Trinidad and Tobago Parliamentary Inquiry on Food Fraud, and served as an advisor on food fraud to the Chinese National Center for Food Safety Risk Assessment (CFSA).

Dr. Spink has been focused on product fraud prevention since his 2005–2009 MSU School of Packaging Ph.D. research in the College of Agriculture and Natural Resources (CANR). This work was coordinated with his adjunct instructor activity within the Master of Science in Food Safety Program in the College of Veterinary Medicine (CVM). His Ph.D. dissertation research was focused on Anti-Counterfeit Strategy and risk assessment. Before he completed with his Packaging Dissertation, this research was the foundation for a CVM Food Safety administered graduate course on “Anti-Counterfeiting and Product Protection” (VM840 that was eventually accepted by the School of Packaging as PKG840 and also by the School of Criminal Justice as CJ840). This research formalized into a CVM-based initiative. From 2009 to 2013, he was an assistant professor in the School of Criminal Justice in the College of Social Science at MSU where his work research evolved from an Initiative to a Program. From 2013 to 2019, he was an assistant professor in the College of Veterinary Medicines where he founded the Food Fraud Initiative (FFI). This position was supported by a 5-year research appointment funded primarily by the MSU Provost. More recently, in 2019, he is an assistant professor in the

Department of Supply Chain Management in the Eli Broad College of Business at MSU.

While conducting his full-time faculty member requirements of research and outreach, he has had a full teaching load with graduate courses such as “Packaging for Food Safety,” “Anti-Counterfeiting and Product Protection,” and “Quantifying Food Risk.” This program included a Graduate Certificate in Food Fraud Prevention. This research evolution to business decision-making and supply chain controls is supported by a focus on undergraduate student course development and teaching including “Introduction to Supply Chain Management” and “Procurement and Supply Chain Management.”

He is widely published in leading academic journals with important works such as “Defining the Public Health Threat of Food Fraud,” “Defining the Types of Counterfeeters, Counterfeiting, and Offender Organizations,” “Introduction of the Food Fraud Initial Screening Method (FFIS),” and “Introducing the Food Fraud Prevention Cycle (FFPC).” Before returning to academia in 2009, he worked for over 11 years at Chevron Corporation, then at a high growth \$100 million consumer products company, and 3 years in general management consulting. Outreach includes a series of food-related free, online courses presented in a MOOC (free, Massive Open Online Course) format. Please see www.FoodFraudPrevention.com

Disclosure

This book was created without any additional support other than within the key job responsibilities and commitment of personal time. The topic of food fraud—and especially the interdisciplinary criminology and business decision-making theories—is new, and since this was not a funded project, many other researchers and colleagues were interested but could not justify the time and effort to contribute. Hopefully, the innovative interdisciplinary approach, which is extremely practical and applied, will demonstrate the value of food fraud prevention and begin to support more extensive public and private funding.

There is no intellectual property to protect other than the copyright of the manuscript. The only intellectual property rights protected are those under copyright which allow for fair use and application as long as there is a proper citation. All the concepts, models, or tools are published in journal articles, books or chapters, MSU FFIR reports, primers, blog posts, presentations, video lectures, or other public documents.

Note: This book specifically does not mention or address private or commercial products or services. There are many excellent options, but they will not be covered within.

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Chapter 1

Introduction (Part 1 of 2): Food Fraud Definitions and Scope



Summary

This chapter presents the introduction to the scope and definitions related to food fraud. The next chapter introduces many of the fundamental concepts. Before getting into a structured review of the definitions and related terms, there will be a foundation setting task that considers the end goal such as why do you care, how to start, how much is enough, and is the government doing enough.

The Key Learning Objectives of this chapter are

- (1) **Preface to Introduction:** before reviewing the concepts, there will be a consideration of why this is a worthwhile effort for the ultimate questions such as “how to start?” and “how much is enough?”
- (2) **Definitions:** to review the types of food fraud and also related terms such as food defense, food authenticity, food security, and others. This also considers related terms including some common terms such as adulteration, authenticity, and integrity.
- (3) **Relationship of Food Risk Concepts:** the relation between food quality, food safety, food fraud, and food defense is presented in the Food Risk Matrix.

On the Food Fraud Prevention Cycle (FFPC), this chapter addresses the theoretical foundation concepts related to criminology and the fraudster “(A) Theoretical Foundation” (Fig. 1.1).

Introduction

This chapter covers the basics of food fraud prevention. Food fraud and the focus on prevention have matured as a discipline—and possibly as a science—enough to present a full book and more than “what is it” or “someone should do more.” A set of unique terms and methods are being developed and updated. The research has started in food science and food authenticity before expanding to law and

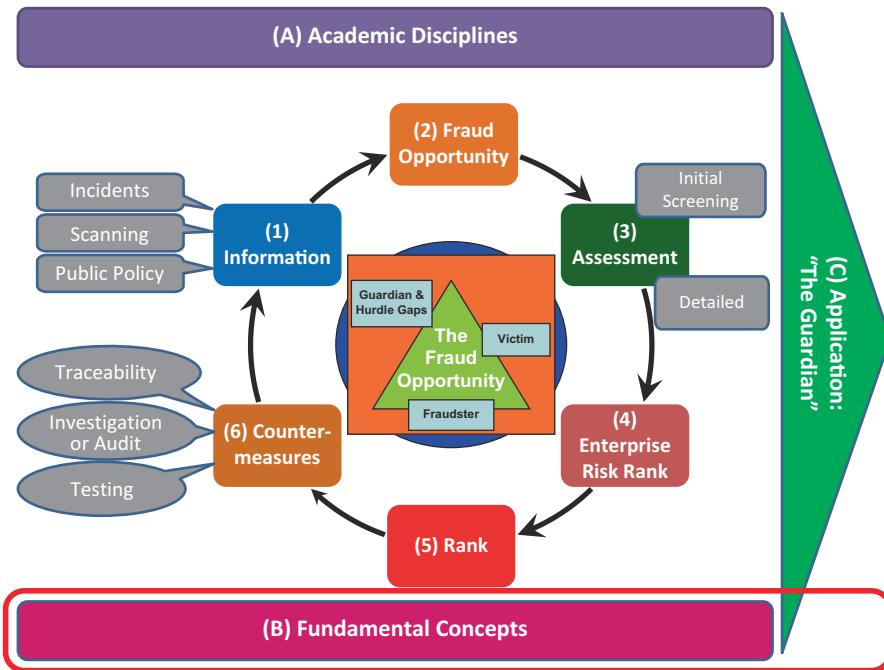


Fig. 1.1 Food Fraud Prevention Cycle—where this chapter applies to the overall concept: “(B) Fundamental Concepts”. (Copyright Permission Granted) (Spink 2014a, b; Spink et al. 2019)

criminology through business and supply chain management to a unique, hybrid, interdisciplinary approach. Overall there is a body of work focused on policy and strategy development. This book represents that broad, interdisciplinary approach to one central system that is presented as the Food Fraud Prevention Cycle (FFPC).

A first question is whether the focus should be problem-based or solution-based. Prevention starts with understanding the root cause or the problem, and then this is a problem-based approach. If a technology is found and then followed by a search for applications, then this is a solution-based approach. The overall food fraud prevention research—consistent with previous product counterfeiting research—is “problem-based” not “solution-based.” This means the activity starts with a focus on the “problem” and then seeks the most efficient and effective “solutions” (Fig. 1.2). Many times there is a backward process of a “solution looking for a problem.” When starting with the problem, the specific problem can be clearly and explicitly defined using specific incident factors. Often there are a series of root cause factors that create the fraud opportunity. Each root cause factor may require a separate—though often very simple and low or no cost—risk treatment. Then, a solution can be sought that directly and efficiently solves specific aspects of the problem.

The best place to start this Introduction chapter and the book is to review the definition and scope. Using ISO 31000 Risk Management standards, this would identify



Fig. 1.2 Example of identifying the fraud opportunity, the defining specific problems before seeking precise solutions

the very first step of “Establishing the context” (ISO 2009). While a specific department or agency may be accountable or responsible for one type of problem, the companies or countries need to address *all* food risks not just public health hazards. Any starting point that does *not* begin with the “all risks approach” will likely face resource-allocation challenges due to an incomplete proposal that does not calibrate this risk with all other risks.

Key Learning Objective 1: Preface to Introduction—Why Act? Do I Need to Act?

This section reviews a few foundational concepts that should be considered through to the review and management of food fraud prevention. These may seem overly simplistic reviews, but they are essential. The focus is on supporting efficient and effective resource allocation to maximize the ultimate goal which is to protect customers from harm by reducing the fraud opportunity. These key questions will not be answered yet since the first step is “Establishing the context.”

The Key Learning Objectives of this section are

- (1) “How to start?” and “how much is enough?”
- (2) “Who cares?” and “why do I care?”
- (3) Then, is the government doing “enough”?

Do I Need to Act? How Much Is Enough? How to Start?

Yes, “food fraud” is bad. Yes, “more” should be done. Ok, now what? Is food fraud the top priority for your entire enterprise? Is it a top-10 priority? Should you drop everything right now and call the president of your company? Should you stop reading and send a note to your crisis management team? Can you wait until you get done reading this chapter? Can you wait until tomorrow? Do you have a process to prescribe your activity?

Then, to address “how much is enough,” “I need more funding” is a desperate plea and not a strategic proposal. Stating “we don’t have any more budget money” is not a tactical position and not risk-based justification. If your company has \$1 million to spend on *one* project, should it be to address food fraud? Can it identify competing projects that are outside the scope of food fraud, food safety, or all food risks? What specific food fraud prevention project would you propose, *and* could you defend that as the #1 project for all the possible food fraud prevention counter-measures and control systems? Very few people or companies can answer “yes.” Some people even become belligerent when pressed on these questions that they now realize they cannot answer.

The lack of a clear method is the fault and responsibility of the theorists including academics. It is *our* fault that a question exists and *our* collective responsibility to address this unmet need.

The first step in recovery is admitting there is a problem.¹ The next step is to understand the root cause of the dysfunction, and ISO 31000 Risk Management identifies this in “Establishing the context” (ISO 2009).

The food fraud problem is based on the following general risk analysis concepts such as ISO31000, Six Sigma, or others; the steps to address food fraud include (Spink et al. 2019):

1) Establishing the context

a) What is food fraud?

- There are many publications that define the concept and provide examples of incidents.

b) Is it a problem?

- Next, the publications expanded to discuss incidents and to define the public health and economic harms. This also includes examples of how and why incidents occurred. It sometimes also includes reviews of laws and regulations.

¹The term “problem” is used in criminology. **Problem:** “...the basic unit of police works rather than a crime, a case, calls, or incidents. A problem is something that concerns or causes harm to citizens, not just the police. [...] Addressing problems means more than quick fixes: it means dealing with conditions that create problems” (Clarke and Eck 2005) Clarke, Ronald V and John E Eck (2005). “Crime analysis for problem solvers in 60 Small Steps.” Washington, DC: Center for Problem Oriented Policing.

c) **How to detect specific fraud acts, are new tests needed, and then validate the test methods?**

- The vast majority of food fraud published research is related to test methods, results, and either validation or verification of both.

2) **Do I need to act?**

- As the basics are becoming more clearly defined or defended, there is beginning to be a research focus on decision-making and specific regulatory or commercial requirements. For example, is there a law, a company compliance requirement, or a direct order from your superior that requires the activity? Alternatively, is it just something you “should do?”

3) **How to start food fraud?**

a) **What to do?**

- This is covered, in part, above in the research on detection tests.

b) **How to measure success?**

- This is probably one of the currently most under-researched areas. It appears that quality management concepts will present the best opportunity for effective and efficient success metrics. Utilizing quality management principles such as critical control points is well known. For public policy or law enforcement agencies, this will be a bigger challenge since the agencies have really been set up to respond to incidents or current problems rather than strategic prevention.

c) **How much is enough?**

- This question applies to immediate activity or longer-term resource allocation. There is often a gut feel for how much you should do (or is really how little do you dare *not* to do?). A first judgment is if there is a regulatory definition of compliance. Is there a food safety audit nonconformity that needs to be rectified? Is there an internal control or COSO type audit nonconformity that need to be rectified? The next judgment is if there is an enterprise-wide risk or vulnerability compliance system such as COSO type Enterprise Risk Management. For a new or recently defined problem type, it is logical that there is not yet a structure or process for decision-making for “how much is enough.”

4) **Continuous review and process improvement.**

- Identify critical factors that can be assessed and monitored.

Next, the objective is to explore these questions and present insight into the underlying factors. Addressing these questions will help inform resource-allocation decision-making.

Who Cares? Why Do I Care? Why Does Anyone Care?

These are conceptual questions at the core of the problem and challenge. ““Someone” in the enterprise must be responsible for food fraud prevention, right?” The response is “Ok then who? Tell me a name.” What often follows is a blank stare or even an increased agitation.

“Who cares?” This is more a question of “who acts?” and “who has a budget?” This is a challenging question for countries as well as companies. There is a belief that “more” should be done, but at least at the start, there is no budget and no free resources (Spink 2014a, b). There is a gap, and without clear assignment of the problem to someone specific—such as when using the Food Risk Matrix—then often nothing gets done. “That’s bad, but it’s not my job.” When nothing gets done, then incidents such as melamine or horsemeat are fraud opportunities that could become food fraud incidents. The answer to this question is based on strategy or policy commitments and then defined by the prevention strategy assigned in “key job responsibilities.”

“Why do I care?” You have a set of key job responsibilities or success metrics. Food fraud is probably not specifically listed... at least not yet. I’ve heard something like “I’m responsible for food ingredient contamination, so I’m not concerned with all types of fraud.” Ok, understood. However, by stating this, you individually and personally have knowledge that food fraud is probably not being completely addressed at your company. You have knowledge of a regulatory violation. You probably have a role as a “mandatory reporter” of violations—this is especially true and could be literally criminal if you have knowledge that a law is being broken. If there is a death from food fraud, your knowledge and lack of activity could be criminal. Will criminal prosecution always follow, of course not, but it is possible, and do you want to take that chance? Also if you know of smuggling or a criminal act—such as the weights of fish being not accurately listed on a label or manifest—your lack of activity could be criminal. If that fish was imported and sold in the USA, you would have knowledge of “smuggling,” and each incident carries a maximum penalty of 20 years in prison (see keyword “smuggling” in later sections on laws and regulations).

“Why does anyone care?” This is an important question to understand the priority for governments or consumers. Do they understand food fraud? Are they outraged when it occurs? What type of food fraud outrages them the most that leads to more enforcement or prosecution? The bottom line for a company is that food fraud is *illegal* and could lead to a product recall at “best” and criminal prosecution and incarceration “at worst” especially if the incident led to a death or deaths. Regardless of the level of enforcement and prosecution, food fraud must be addressed. Following upon this, the first steps and countermeasures and control systems are often *not* costly or time-consuming; the only reason to *not* start would be a lack of a plan.

Over time, the needs and the challenges have been more clearly identified, and the way forward is now more apparent. These questions are addressed through an interdisciplinary, holistic, all-encompassing focus on food fraud prevention.

Is the Government Doing “Enough”?

In the past food fraud was a known problem, but there was not enough information to really establish a common, practical, preventative approach. In a 2010 government public meeting, I was asked if I thought “industry was doing enough to address food fraud,” and I responded with “based on the way we academics and the laws have defined food fraud and prevention, I think industry and agencies are doing a fine job.” The key is how food fraud is defined and addressed in the laws and regulations. The focus should be on who is assigned the task. With the awareness of the enterprise-wide risk, the leadership is presented with a clear path forward. The leadership is “accountable” for this “inherent risk” and assuring that food fraud prevention is explicitly addressed. There are great strides being made considering how little is really known about food fraud prevention.

Key Learning Objective 2: Definitions

This section reviews the interdisciplinary nature of prevention by considering how the “fraud opportunity” is created and the many academic disciplines that help understand the optimal countermeasures and control systems.

The Key Learning Objectives for this section are

- (1) To review the underlying concepts of framing a problem
- (2) To review the definition and scope of food fraud
- (3) To review the types of food fraud

General Concepts

Over time there has been more and more clarity of the need to continually explore and present definitions of key terms. It is fascinating how often there is confusion or debate on even the most basic terms or concepts. Over time there has been a collective embrace of the food fraud term as well as the focus on prevention. More recently there is an awareness that the root cause is a human adversary so the research must include social science and criminology. The diagnosis of the problem includes a root cause that is understood by applying criminology. Also, as programs are developed, there is an identification of the need to focus on resource-allocation decision-making to address the question of “how much is enough.”

This book will begin with a brief statement of the definitions and scope before moving to the general food fraud prevention concepts.

Undoubtedly product fraud has been conducted since the start of all commerce, and food fraud has been recorded in history since at least 960 BCE during the Song dynasty in China (Wu et al. 2017). What starts as a savvy negotiation can evolve into deception.

Before reviewing the definition and scope of food fraud, it is important to start with the base terms of food and fraud:

- *Food (Codex)*: “... means any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drink, chewing gum and any substance which has been used in the manufacture, preparation or treatment of “food” but does not include cosmetics or tobacco or substances used only as drugs.”
- *Fraud (COSO)*: “...is any intentional act or omission designed to deceive others, resulting in the victim suffering a loss and/or the perpetrator achieving a gain” (COSO 2016).
- *Fraud (Codex)*: *Codex Alimentarius* does *not* seem to have defined this basic term.

Combining the basic terms and the modern application, a simple, holistic definition is:

- *Food fraud* (basic short version): intentional deception for economic gain using food

There is a hesitance in providing a reference for this definition here since this is such a general concept. What is important is the broad definition which covers all food-related product fraud. The broad definition covering all types of fraud and for all products is often a new perspective since there has usually previously been a focus on the most prevalent public health threat which is from a dangerous ingredient intentionally added to the product. It is generally considered that the most dangerous—but by no means, the only—acts are from an adulterant, and the act is adulterant-substances and product counterfeiting.

The research and development of a more detailed definition of food fraud were published in a peer-reviewed, scholarly 2011 article “Defining the Public Health Threat of Food Fraud” (Spink and Moyer 2011a, b). This research activity began by reviewing laws, regulations, standards, and certifications. This then reviewed scholarly articles for food fraud and related topics. Through this research, the broad definition was developed and published. This definition has been quoted and references for the industry standard developed by the Global Food Safety Initiative (GFSI),² the European Commission’s Referendum on Food Fraud, the UK DEFRA Elliott Review, the US Congressional Research Service, the CODEX Electronic Working

²GFSI may not be as recognized by some as the standards from BRC, IFS, FSSC 22000, SGS, or others. GFSI is a major emphasis in this report since the requirements are widely adopted. GFSI will be covered in more detail later. It is important to note that GFSI establishes the expectation or benchmark for what should be in a Food Safety Management System (FSMS). GFSI does not create standards but “recognizes” or endorses standard organizations that are referred to as Certification Program Organizations (CPOs—formerly referred to as scheme owners). The manufacturers that would be certified to an FSMS are from FSSC 22000, BRC, and IFS or others. The standards are audited by Certification Bodies (CBs). The CBs are recognized or endorsed by the CPOs to conduct the audits. Not every auditor or CB can provide an officially certification for every CPO.

Group on Food Integrity and Food Authenticity, and ISO 22380 on product fraud prevention (among others see: EC 2014; CODEX 2017; GFSI 2017; ISO 2018). It has been adopted as a de facto definition of food fraud and the related deceptive economically motivated acts. From the original NCFPD backgrounder report, that was the core research for the later Journal of Food Science publication:

- **Food Fraud:** “Is a collective term used to encompass 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. Food fraud is a broader term than either the economically motivated adulteration (EMA) defined by the Food and Drug Administration (FDA) or the more specific general concept of food counterfeiting” (Spink and Moyer 2011a, b).
 - **Product Fraud:** Wrongful or criminal deception that utilizes material goods for financial or personal gain Note 1 to entry: Fraud means wrongful or criminal deception intended to result in financial or personal gain that creates social or economic harm; Note 2 to entry: Products include electronic media carried on material goods; Note 3 to entry: Fraud related to digitally transmitted electronic media shall be considered separately” (ISO 2018).

A longer, more comprehensive definition is:

- **Food Fraud (basic long version):** “Is a collective term used to encompass the deliberate and intentional substitution, addition, tampering, or misrepresentation of food, food ingredients or food packaging, or statements about the product for economic gain. Food fraud is a broader term than both the Food and Drug Administration’s (FDA) definition of economically motivated adulteration (EMA) or the more specific general concept of food counterfeiting” (Spink and Moyer 2011a, b).

For review, two Global Food Safety Initiative (GFSI) definitions are presented here and demonstrate the evolution of the concept and similarity of scope (GFSI 2014, 2017).

- **Food Fraud (GFSI 2014):** “Including the subcategory of economically motivated adulteration, is of growing concern. It is deception of consumers using food products, ingredients and packaging for economic gain and includes substitution, unapproved enhancements, misbranding, counterfeiting, stolen goods, or others” (GFSI 2014).
- **Food Fraud (GFSI 2017):** “A collective term encompassing the deliberate and intentional substitution, addition, tampering or misrepresentation of food, food ingredients or food packaging, labeling, product information or false or misleading statements made about a product for economic gain that could impact consumer health” (GFSI 2017).

A closely related—and often confused—term is “economically motivated adulteration.” This term came into prominence when the subject of a US FDA Public Meeting (FDA 2009). The definition was identified as a “working definition” in the meeting invitation was published in the US *Federal Register*. This became and remained the FDA “working definition.” The term has often been incorrectly used as the same as food fraud.

The 2009 FDA Working Definition of EMA—which was confirmed in 2018 by FDA as still current—is provided here and was (emphasis added) (FDA 2009):

- ***Economically Motivated Adulteration*** (FDA) Working Definition (emphasis added): “For purposes of this public meeting, FDA proposes a working definition of EMA as the fraudulent, intentional substitution or addition of a substance in a product for the purpose of increasing the apparent value of the product or reducing the cost of its production, i.e., for economic gain. EMA includes dilution of products with increased quantities of an already-present substance (e.g., increasing inactive ingredients of a drug with a resulting reduction in strength of the finished product, or watering down of juice) to the extent that such dilution poses a known or possible health risk to consumers, as well as the addition or substitution of substances in order to mask dilution” (FDA 2009).
- **Economic Adulteration** is an earlier and related term that many groups were proactively using especially after the melamine in infant formula and pet food. The term “economic adulteration” was a common term. This term seems to be first used in the USA in the 1996 GAO report on fruit juice adulteration (GAO 1995). Regarding the “economic adulteration” incidents in the GAO Fruit Juice report, there was an emphasis on “...they pose little threat to the public’s health and safety.” There are reasons why this is a problematic term to use. First, it insinuates adulteration and not the broader fraud concepts. Second, by the grammatical construction of the phrase, it insinuates that the impact or result is only economic harm. Later, there was a trend in the US to evolve the concept of “economically motivated adulteration.” This still was limited to adulterant-substances but was a notable shift to focus on the motivation or intent.

A close review of the FDA working definition of EMA, it becomes clear that EMA is a “substance” for economic gain so would be a sub-category of food fraud including only the “adulterant-substance” type. It appears from the scope that this definition only applies the EMA term when there is a “known or possible health risk.” If this is a correct interpretation, then it is possible that the horsemeat in the beef incident would not technically be classified as an FDA defined “EMA” incident since there was no known health risk. The debate is futile since any all types of food fraud for all products are illegal under the U.S. Food Drug & Cosmetics Act (FDCA) sections on “Adulterated Foods” and also “Misbranded Foods” (FDA 2015). Also, the U.S. FSMA law section on “Hazard Analysis” requires “a documented hazard analysis regardless of the outcome” and including “intentional acts for economic gain” (FDA 2011, 2015).

Though the basic scope is defined, the definition, challenges, thoughts, and derivation of the definitions will be reviewed in much more detail later.

Types of Food Fraud

Before 2011, the food fraud term has been previously used, such as by the UK Food Standards Agency (UK FSA), but the definition and scope had not been rigorously or thoroughly researched as the subject of project or publication. Other researchers—such as UK FDA Woolfe and Primrose as well as Elliott et al. and van Ruth et al.—widely published on the topic with a focus on authentication and testing not the scoping of the basic problem, root cause, or prevention strategies (Primrose et al. 2010; Huisman and Spapens 2016; Barnard and O'Connor 2017; van Ruth et al. 2017, 2018).

A 2011 research publication presented the definition and scope of food fraud with a list of types of food fraud. This was expanded to include other terms such as are used by the Global Food Safety Initiative (GFSI). This work is correlated to a 2015 article which published the Defining the types of counterfeitors, counterfeiting, and offender organizations (Spink et al. 2013). This work drew heavily upon other research in intellectual property rights counterfeiting of many products including food, medicines, medical devices, automobile parts, luxury goods, consumer electronics, industrial electronics, and others. It was especially important to identify types of fraud, to define where and how intellectual property rights counterfeits fit, and to define that some types of fraud were not a violation of a law. For example, in most cases, diversion is not illegal but could be a violation of the commercial agreement.

The following table is included to provide the types of food fraud examples and the public health vulnerability (Table 1.1) (Spink and Moyer 2011a, b).

The entire research project evolved and expanded to work through several concepts at once including reviewing the food fraud incident types, the food risks, the food protection plan, and in applying the Situational Crime Prevention and the Crime Triangle (Table 1.2). This considered known incidents with more detailed research that would follow later. It was especially important to identify adulterant-substances as only one of the types of food fraud.

Regarding the “adulterant-substance” term, the definition and scope have been codified in 2018 where ISO 22380 includes a table of “Types of Product Fraud” including counterfeiting, IP rights infringement, adulterant-substance, tampering, substitution, simulation, diversion, theft, and overrun (ISO 2018). The description is: “A component of the finished product is fraudulent; example: Adulteration of infant formula by melamine in China, Estimate 300,000 victims including 6 infants dying; potential consequence is low quality or unsafe products leading to human or environmental harm” (ISO 2018).

Table 1.1 Food fraud incident types (in (Spink and Moyer 2011a, b)

Term	Definition	Example	Potential public health threat that may lead to illness or death
Adulterant-substance (adulterate, adulterated, etc.)	A component of the finished product is fraudulent	Melamine added to milk	Fraudulent component
Tamper	Legitimate product and packaging are used in a fraudulent way	Changed expiry information, product up-labeling, etc.	Fraudulent packaging information
Overrun	Legitimate product is made in excess of production agreements	Underreporting of production	Fraudulent product is distributed outside of regulated or controlled supply chain
Theft	Legitimate product is stolen and passed off as legitimately procured	Stolen products are comingled with legitimate products	Fraudulent product is distributed outside of regulated or controlled supply chain
Diversion	The sale or distribution of legitimate products outside of intended markets	Relief food redirected to markets where aid is not required	Shortages or delays of relief food to needy populations
Simulation	Illegitimate product is designed to look like but not exactly copy the legitimate product	“Knock-offs” of popular foods not produced with same food safety assurances	Fraudulent product of lesser quality
Counterfeit	All aspects of the fraudulent product and packaging are fully replicated	Copies of popular foods not produced with same food safety assurances	Fraudulent product

Adapted from Spink (2007, 2009a, b)

Note: In each case, fraudsters may not be following Good Manufacturing Practices (GMPs), Good Agricultural Practices (GAPs), or Good Hygiene Practices (GHPs)

Table 1.2 Food fraud types, definitions, and examples (as published in (GFSI 2018) which references (Spink and Moyer 2011a, b; GFSI 2014; SSAFE 2015; PWC 2016; Spink et al. 2016a, b; GFSI 2017))

GFSI ^a type of food fraud	Definition from SSAFE ^b	Examples from GFSI FFTT ^c	General type of food fraud
Dilution	The process of mixing a liquid ingredient with high value with a liquid of lower value	Watered-down products using non-potable/unsafe water Olive oil diluted with potentially toxic tea tree oil	Adulterant-substance (adulterant)
Substitution	The process of replacing an ingredient or part of the product of high value with another ingredient or part of the product of lower value	Sunflower oil partially substituted with mineral oil Hydrolyzed leather protein in milk	Adulterant-substance or tampering
Concealment	The process of hiding the low quality of food ingredients or product	Poultry injected with hormones to conceal disease Harmful food colouring applied to fresh fruit to cover defects	Adulterant-substance or tampering
Unapproved enhancements	The process of adding unknown and undeclared materials to food products in order to enhance their quality attributes	Melamine added to enhance protein value Use of unauthorized additives (Sudan dyes in spices)	Adulterant-substance or tampering
Mislabelling	The process of placing false claims on packaging for economic gain	Expiry, provenance (unsafe origin) Toxic Japanese star anise labeled as Chinese star anise Mislabeled recycled cooking oil	Tampering
Grey market ^d production/ theft/ diversion	Grey market production/ theft/ diversion are out of scope for this tool. However, it may be picked up anyway	Sale of excess unreported product Product allocated for the US market appearing in another country	Overrun, theft, or diversion ^e
Counterfeiting	The process of copying the brand name, packaging concept, recipe, processing method, etc. of food products for economic gain	Copies of popular foods not produced with acceptable safety assurances Counterfeit chocolate bars	Counterfeiting

Notes:

^aGFSI—Global Food Safety Initiative

^bSSAFE—Safe Secure and Affordable Food For Everyone

^cGFSI FFTT—Global Food Safety Initiative: Food Fraud Think Tank

^dGray market—a market employing irregular but not illegal methods; theft, something stolen

^eDiversion/parallel trade—the act or an instance of diverting straying from a course, activity, or use

Comment: This table is used as the types of fraud list and definitions in the GFSI Food Fraud Technical Document published in 2018. That report is the reference used for GFSI compliance

Sidebar: Types of Fraud Defined—Why Include Diversion and Simulations

The book *Counterfeiting Exposed* (2003) was a very important influence on my thinking because it is one of the most thorough and practical presentations of the problem and how to address it (Hopkins et al. 2003). The authors were very realistic—based on experience—in the role of government, the role of consumers, and what really can be done to reduce counterfeiting. They expanded from “counterfeiting is bad” and “what wasn’t being done” to a presentation of fundamental concepts and a practitioner-based focus on implementing strategies. They specifically refer to “detect, deter, and control” which our MSU research evolved from “control” to “prevention.” Also, they build upon the general concept of “no product is too cheap to counterfeit” and “if you can make it, they can fake it”—which for me evolved to a focus on the overall fraud opportunity.

An important foundational concept covered in the book was addressing the types of counterfeiting which our MSU research evolved to more broadly cover all the types of fraud. If product fraud is occurring, then there is a supply chain lack of control that could be a vulnerability for counterfeits to enter the market. They define:

- **Counterfeiting:** “the knowing duplication of a product by a party who wishes to usurp the brand or trademark of another” (Hopkins et al. 2003).
- **Simulation or Copycat:** “By contrast [and different than counterfeiting], is a copy of a product in form or substance with no attempt to actually duplicate the brand name” (Hopkins et al. 2003). Though the trademarked name is not used, this may be a violation of other intellectual property laws such as “trade dress” or “patent.” “They are attempting to profit from association with the brand and may face other legal challenges.” The presence of simulations signals an unmet market need and is a possible indicator that counterfeits may also be in this supply chain.
- **Overruns/production-overruns:** “Although often of identical quality to the legitimate product, are produced in violation of the brand owners’ rights” (Hopkins et al. 2003). This is conducted by an authorized and legitimate co-manufacturer or partner who produces the product without the authorization of the right holder. The right holder does not get paid for the sales of this branded product. This is sometimes referred to as a “ghost shift” or “fourth shift”—there are three, 8-hour shifts per day. In some cases, the “unauthorized overrun” could be identical or a clone of the genuine product. If this is food, then it would be considered illegal under the “Adulterated Foods” section of the US Food, Drug, and Cosmetics Act because it was manufactured outside the control of the company. Other times the substandard product is reclaimed (not properly disposed of) and sold. As with the other definitions, the presence of overruns signals a lack of control of supply chains—or in this case the production—which is a

possible indicator that counterfeit products may be in this supply chain. Also, from the US Department of Justice guidance for prosecuting IP cases, “As with overrun goods, the marks on gray market goods are placed there with the mark-holder’s authorization. What the mark-holder has not authorized is the sale of those foreign goods within the United States” (DOJ 2013).

Regarding overruns, a unique situation with designer apparel is that often the brand name is trademarked, but the design or patent is not. Thus, a contract manufacturer of a designer brand leather jacket could legally sell the exact same jacket if the brand label was not used. There may be commercial agreements that control these sales, but without the design or patent, then this would not be illegal and not a criminal act.

- **Gray Market or Diversion (or Parallel Trade):** “When products which are shipped into specific distribution channels are shipped out of those channels into others, often in violation of distribution or sales contracts” (Hopkins et al. 2003). Also see US Department of Justice guidance for prosecuting IP cases, section on “Authorized-Use Defense: Gray Market Goods.” From Black’s Law Dictionary, “A market in which the seller uses legal but sometimes unethical methods to avoid a manufacturer’s distribution chain and thereby sell goods (especially imported goods) at prices lower than those envisions by the manufacturer. See Parallel Imports.”
- **Illegal Diversion—First-Sale Doctrine:** They clarify legal or illegal diversion based on the first-sale doctrine which defined who legally controls the product after a legitimate first sale, based on the first-sale doctrine. This would be illegal after a legitimate first sale, and this would only if the export to a specific country is illegal and if the sales in the new country would be a violation of a different law, for example, sales of controlled substances of some medicines that are not approved in a country or their distribution is tightly controlled. A violation, such as commercial geographic distribution agreements, could be subject to a civil lawsuit but not prosecution in a criminal proceeding.
- **Black Market** (Black’s Law): An illegal market for goods that are controlled or prohibited by the government, such as the underground market for prescription drugs. Also Shadow Economy or Underground Economy.
- **Parallel Imports** (Black’s Law): Goods bearing valid trademarks that are manufactured abroad and imported into the US to compete with domestically manufactured goods bearing the same valid trademarks. Domestic parties commonly complain that parallel imports compete unfairly in the US market. But US trademark law does not prohibit the sale of most parallel imports. Also termed “gray-market goods.” See “Gray Market” under “Market.”

(continued)

- **Parallel Imports/Parallel Trade** (WTO): “When a product made legally (i.e., not pirated) abroad is imported without the permission of the intellectual property right-holder (e.g., the trademark or patent owner). Some countries allow this; others do not.”
- **Shadow Economy** (Black’s Law): Collectively, the unregistered economic activities that contribute to a country’s gross national product. A shadow economy may involve legal or illegal production of goods and services, including gambling, prostitution, and drug-dealing, as well as barter transactions and unreported incomes. Also termed “black economy,” “black market,” and “underground economy.”

Regarding diversion, the activity signifies a supply chain may be “porous” which is a possible indicator that counterfeit product may be in this supply chain. “Furthermore, global supply chains have become increasingly fragmented and indirect. It is therefore relatively easy to blend fake product with the legitimate product in the gray market or to find unauthorized dealers over the internet” (Hopkins et al. 2003). A concerning situation since this lack of transparency can create an opportunity for stolen goods to reenter the legitimate supply chain, products “decoded” with their traceability or authenticity features removed or others. Also “criminals also use [parallel trade] as a channel for mixing of real with fakes and for the importation of counterfeits” (Hopkins et al. 2003).

- **Illegal Diversion—Stolen, Decoded, Substandard:** these products are illegal for those reasons such as stolen goods represented as legal, products “decoded” with their traceability or authenticity features removed, or products that may be substandard based on local laws or regulations.

The book *Counterfeiting Exposed* presented a practical approach to prevention and presented an obvious need to focus on the criminal motivation for any and all types of fraud. This book helped the research expand from counterfeiting to all types of fraud.

Sidebar: Expanded Review of the First-Sale Doctrine—The Right to Resell Legitimately Purchased Products

From the US Department of Justice’s Criminal Resource Manual, CRM 1500–1999, Criminal Resource Manual 1801–1899 (DOJ 2019):

- 1854. COPYRIGHT INFRINGEMENT—FIRST-SALE DOCTRINE
- “Few issues have created greater confusion in criminal copyright prosecutions than the ‘first sale doctrine.’ The doctrine is one of the specific statutory restrictions which Congress has placed on the exclusive rights of copyright owners. Criminal defendants frequently resist prosecution by

claiming that they believed that the works they were selling had been the subject of a legitimate first sale. Moreover, several criminal copyright convictions have been overturned because of inadequacies in the government's proof on this issue."

- "'The first sale doctrine,' codified at 17 U.S.C. § 109, provides that an individual who knowingly purchases a copy of a copyrighted work from the copyright holder receives the right to sell, display or otherwise dispose of that particular copy, notwithstanding the interests of the copyright owner. The right to distribute ends, however, once the owner has sold that particular copy."

The first-sale Doctrine is related to the exhaustion rule:

- **Exhaustion** (sales exhaustion rule) (WTO): In intellectual property protection, the principle that once a product has been sold on a market, the intellectual property owner no longer has any rights over it. (A debate among WTO member governments is whether this applies to products put on the market under compulsory licenses.) Countries' laws vary as to whether the right continues to be exhausted if the product is imported from one market into another, which affects the owner's rights over trade in the protected product. See also parallel imports or first-sale doctrine (WTO 1994).

For food fraud prevention, there are a couple of situations where this may apply. First is selling product outside an authorized distribution area. For example, consider a distributor who is contracted to be the authorized seller of your product in Michigan who decides to sell the product in Ohio. This act may be a violation of a contractual agreement, prosecutable in civil court, but may not be a violation of a specific criminal law. Second, a short-dated product (product near the expiration date) may be sold at a deep discount to an exporter for sale in another country. This would provide a benefit of receiving some revenue for that product before it would need to be destroyed and also to be sold in a faraway market that would not impact the local market price. Considering the first-sale doctrine, this is a legal sale of a genuine product so the buyer could legally resell that product to the first market. This would not be a violation of the criminal law but could be subject to a contractual violation and possibly prosecuted under civil law. The best option is to have a strong contractual agreement and understanding of where this product is allowed to be sold. There is another example of a product where the labeling or recipe is legal in one country and not another. The sale of the diverted product into an illegal market would not be a specific violation of the first sale doctrine but would be illegal under possibly many other laws such as smuggling or food labeling.

Sidebar: The Special Problem of Overruns

Several of the types of food fraud may seem to be determined by casual or unsophisticated decisions, but there is often case law to support the inclusion. For example, product overruns are defined in US law and include guidance for prosecutors (DOJ 2013). For example, here is text from a legal defense:

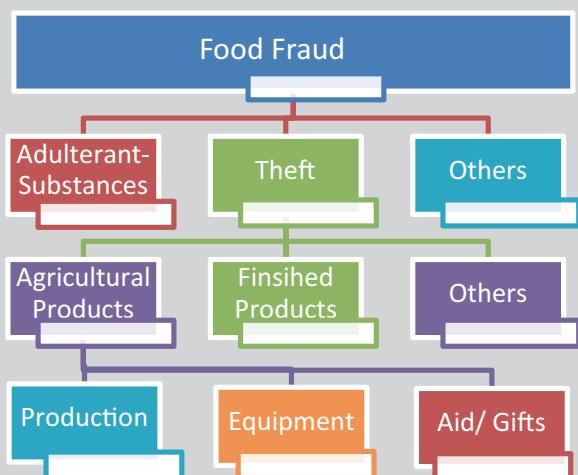
- **“Overrun:** goods or services, that is, goods or services that an otherwise authorized manufacturer or producer makes and sells on the side without the mark-holder or licensor’s knowledge or approval.”

It is important to note that some of the overruns are not considered technically “counterfeits.” “If a licensee manufactures overruns during the course of the valid license, the marks on those goods will remain non-counterfeit for purposes of this act.”

Examples of the types of overruns are:

- **Overproduction:** “For instance, consider a trademark licensee who is authorized to make 500,000 umbrellas bearing the licensor’s trademark but who manufactures without authorization an additional 500,000 umbrellas bearing that mark during the course of the license. *Joint Statement*, 130 Cong. Rec. 31,676 (1984). Because the trademark owner in this situation can protect himself through “contractual and other civil remedies,” Congress felt that it was “inappropriate to criminalize such practices.” *Id.* Thus, “[if] a licensee manufactures overruns during the course of the valid license, the marks on those goods will remain non-counterfeit for purposes of this act.” *Id.*
- **Expanded Product Line:** “a licensee produces a type of goods in connection with which he or she was not authorized to use the trademark in question.” ... For example, “if a licensee is authorized to produce ‘Zephyr’ trench coats, but without permission manufactures ‘Zephyr’ wallets, the overrun exception would not apply.” In this example, the licensee could be prosecuted for producing the wallets only if the ‘Zephyr’ mark was registered for use on wallets as well as trench coats.”
- **Production After Authorization Ends:** “limited to goods or services for which authorization existed “during the *entire* period of production or manufacture.”
- **Sales of Rejected or Substandard Production:** “The use of a licensee’s rejected irregular goods.”

Fig. 1.3 Praedial larceny hierarchy from food fraud to theft to theft of agricultural products including the types of products



Sidebar: FAO and Praedial Larceny Including Agricultural Theft

The food fraud prevention concepts apply to a wide range of food supply problems, including theft, which is one of the types of food fraud. Within food fraud/theft, there are many different “hot products” and “hot spots” that can efficiently and effectively adapt the general prevention concepts to specific problems (Lam and Spink 2018; Spink 2019)—in this case to a very specific problem of the theft of agricultural products and related production and processing equipment (Fig. 1.3).

While possibly not a well-known term or widely understood problem, praedial larceny has been identified as one of the most critical food security and criminal activities in many regions of the world. The cost and public health harm are also probably vastly underestimated around the world and in the USA because the many types of incidents are reported under a wide range of laws such as motor vehicle theft, grand larceny, smuggling, food adulteration, food misbranding, or others (FAO 2013).

The Food and Agriculture Organization (FAO) of the United Nations has had an ongoing focus on addressing the challenges of praedial larceny or what is also categorized as a wide range of agriculture-related thefts (FAO 2013):

- **Praedial** (prēdēēl): Being or made up of land or immovable property or the profits therefrom (Roman law) (Black’s 2014).
- **Larceny**: “The unlawful taking of property other than a motor vehicle from the possession of another, by stealth, without force or deceit. Includes pocket picking, non-forcible purse snatching, shoplifting, and thefts from motor vehicles. Excludes receiving and/or reselling stolen property (fencing) and thefts through fraud or deceit” (US DOJ 2017).

(continued)

- **Praedial Larceny:** The theft of agriculture products [...] to include the theft of agricultural equipment, agriculture inputs and secondary products such as feed and fodder (FAO 2013).

From the FAO Issue Brief on Praedial Larceny in the Caribbean (FAO 2013):

- ***The most extensive among all crimes committed in the [Caribbean] sub-region*** in terms of the number of persons and families affected.
- ***98% of all producers surveyed have experienced this type of loss.***
- ***The single greatest disincentive to investment in the sector.***
- Estimates are that ***18% of the value of farm output regionally*** is taken by thieves.

The FAO report differentiated between a thief who steals product for their own consumption and criminals who steal to resell or trade the products. It is documented that, in some cases, criminals or gangs convert the livestock into cash to buy drugs or guns which creates a national security threat. There is also ongoing research on the different types of victims, including the farmers, processors, producers, and retailers. A specific type of Praedial Larceny or Agricultural Theft (PLAT) includes losses of food aid and humanitarian aid which could include food or related food security contributions such as seeds, fertilizer, feed, agricultural equipment, or even products such as gifts of animals used for breeding or food production.

So, the victims are identified, and the consequence or result of the fraud act is well documented. A next step is to understand how this problem fits into other broader problems and overall global priority-setting. When the agricultural products are stolen, it reduces the food available for the producer to sell or the aid organization to distribute. The ultimate impact is that food fraud—and Praedial Larceny or Agricultural Theft—negatively impacts food security.

While the impact on food security may seem intuitive at first, it is important to note that the ultimate goal of food security is to create and sustain continuous food production and prosperity. Specifically, the food security priorities for the WHO include (emphasis added):

From the World Health Organization—Goals for Food Security:

- Eradicating poverty and promoting prosperity for a changing world prioritizes the following goals (WHO 2009):
 - Goal 2. End hunger, achieve food security and improved nutrition and promote sustainable agriculture
 - Goal 9. Build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation

For food fraud prevention, there are clear applications deep into problems that can have broad impacts beyond the immediate victim to entire markets such as increasing global food security.

Definitions of Food Risks: Food Quality Food Safety, Food Fraud, and Food Defense

To consider food fraud in relation to the bigger picture, the other food risk types are defined (Spink and Moyer 2011a, b):

- *Food Quality*: Product meets the specification. This is an unintentional act with no intent to harm.
 - *Food Quality (CODEX)*: “Quality includes all the attributes that influence a product’s value to the consumer. This includes negative attributes such as spoilage, contamination with filth, discolouration, off-odours and positive attributes such as the origin, colour, flavour, texture and processing method of the food” (CODEX 2014). Note: it is interesting that the 2014 Codex definition includes “the origin” and “processing method”—thus, a fraudulent act could violate that part of the definition and define a lack of quality.
 - *Quality Assurance (CODEX CCFICS)*: “all those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality (ISO-8402 Quality – Vocabulary).”
- *Food Safety*: Product causes a health hazard. This is an unintentional act with a health hazard.
 - *Food Safety (Codex)*: “The assurance that food will not cause harm to the consumer when prepared and/or eaten according to its intended use” (CODEX 2014).
- *Food Fraud* (basic short version): Illegal deception for economic gain using food.
- *Food Defense*: An intentional act with the intent to harm as defined in terms of psychological terror, economic harm, or a public health threat.
 - *Food Defense (FSMA-IA)*: The US Food Safety Modernization Act includes an Intentional Adulteration Final Rule that narrows a focus of Food Defense to “wide-scale human health harms” (FDA 2016). When addressing food defense, it is *critical* to state the definition and scope of the project to avoid confusion related to regulatory or certification compliance.

It is understood that food fraud is a description of the unacceptable act, not the prevention activity. Over time, it seemed that there was no more efficient term to use. Of course, food safety is protecting the food from health harms, food defense is to protect the food from an intentional act intended to harm, and so food fraud prevention is protecting the food from fraudulent acts.

The food risk definitions and examples are expanded (Table 1.3) (Spink and Moyer 2011a, b):

Table 1.3 Types of food risks with examples, the cause and motivation, the effect, the public health risk type, and secondary effect

Discipline risk type	Example	Cause and motivation	Effect	Public health risk type	Secondary effect
Food quality	Accidental bruising of fruit	Mishandling	Unsalable product or possible additional contamination with <i>E. coli</i> O157:H7	None or food safety	Reduced brand equity or food safety incident
Food fraud	Intentional adulteration of milk with melamine	Increased margin	Toxic poisonings	Food safety	Public fear and possibly lower prices industry-wide
Food safety	Unintentional contamination of raw vegetables with <i>E. coli</i> O157:H7	Limited field protection and control during harvesting and processing	Illnesses and/or deaths	Food safety	Damaged industry, product recall expense, and public fear
Food defense	Intentional contamination of ground beef with nicotine	Revenge intent against the store/manager through injury to consumers	Nonlethal poisonings	Food defense	Adulterated product, damaged industry, product recall expense, and public fear

Adapted from Spink and Moyer (2011a, b)

Sidebar: Common Dictionary Definitions of Food Fraud-Related Terms

The product fraud, product anti-counterfeiting, and food fraud literature and application are rapidly changing. There are many terms that have been—or are—using common practice but possibly not based on formal review or intent. Several dictionary definitions are noted here (Merriam-Webster 2004) Webster's):

- **Counterfeit:** “To copy, with the intent to deceive” and “made in imitation of the genuine so as to deceive”
- **Diversion:** “A turning aside from a course, activity, or use”
- **Simulation:** “1: The act or process of simulating 2: an object that is not genuine 3: imitation by one system or process of the way in which another system or process works”—“simulate: to give or create the effect or appearance of”
- **Tamper:** “1: to carry on underhand negotiations (as by bribery) <~with a witness>2: to interfere so as to weaken or change for the worse <~ with a document>3: to try foolish or dangerous experiments”
- **Knockoff:** “noun: a copy or imitation of someone or something popular”

- **Knock off:** “verb: 1 to stop doing something 2: to do quickly, or carelessly”
- **Replica:** “noun 1: an exact reproduction (as of a painting) executed by the original artist 2: a copy exact in all details: duplicate”

Definition of Contaminant and Contamination

Before moving on, to cover the related topics, we will review contaminants and contamination. Adulterant/adulteration and contaminant/contamination are closely related terms that are often incorrectly interchanged. The most official and direct definition of a contaminant is by the *Codex Alimentarius* (CODEX) (CODEX 2014):

- **Contaminant (Codex):** Contaminant (CODEX, Procedural Manual). *Codex Alimentarius* defines a contaminant as follows: “Any substance not intentionally added to food, which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or as a result of environmental contamination. The term does not include insect fragments, rodent hairs, and other extraneous matter” (CODEX 1995).

CODEX does not define an acceptable amount of the contaminant only that it is “any” “substance” that is “not intentionally” “added.” CODEX does not define deliberate contamination, but a definition can be inferred. An adulterant is not defined so the definition of the term “adulteration” cannot be inferred.

Definition of Food Counterfeiting and Food Crime

The term “crime” and “counterfeiting” has been applied to food. Both are applicable in specific situations. When there is a shift of focus from the “effect” to the “cause”—and to build on our 2005–2012 research focus on IP violations and counterfeiting—we first used the term “food counterfeiting.”

There is a challenge of using the term “counterfeit” because although the dictionary definition applies to deception and fraud, there is an insinuation that the term applies to only intellectual property rights. On several occasions, food industry managers stated that they didn’t have a “counterfeit” problem, but they did have broader “fraud” problems. Food fraud was a more widely applicable and understood term than food counterfeiting. This is a term emphasized in the UK and in the UK DEFRA Elliott Review.

Another related concept is “food crime.” There are two definitions (Manning and Soon 2016; van Ruth et al. 2017):

- **Food Crime (UK DEFRA):** All types of food fraud that is conducted on a large scale (NFCU 2017). Long Definition: “Dishonesty relating to the production or supply of food that is either complex or likely to be seriously detrimental to consumers, businesses or the overall public interest. Food fraud becomes a food

crime when the scale and potential impact of the activity is considered to be serious. This might mean that the criminal activity has cross-regional, national or international reach, that there is a significant risk to public safety, or that there is a substantial financial loss to consumers or businesses. Clearly, the full extent and impact of food criminality may not be immediately apparent when information is first received” (NFCU 2017).

- *Food Crime* (general): Incidents involving food that is a violation of a criminal statute. Long definition: None.

The food crime term is confusing for two reasons: (1) crimes are sometimes defined only as a violation of a criminal statute, and some food fraud is outside this scope, and (2) any crime using food could include activities beyond the economic motivation to the scope of food defense (intent to harm) or food quality (legal violation or criminal negligence).

Every crime may be a fraud, but every fraud may not be a crime. In most cases, the term food crime does apply. That said, food crime is a term that is understandable to many. The first goal is clear communication of the message. If food crime is the term that gets attention, then use the term but be clear about the definition and scope.

Key Learning Objective 3: The Food Risk Matrix—Food Quality, Food Safety, Food Fraud, and Food Defense

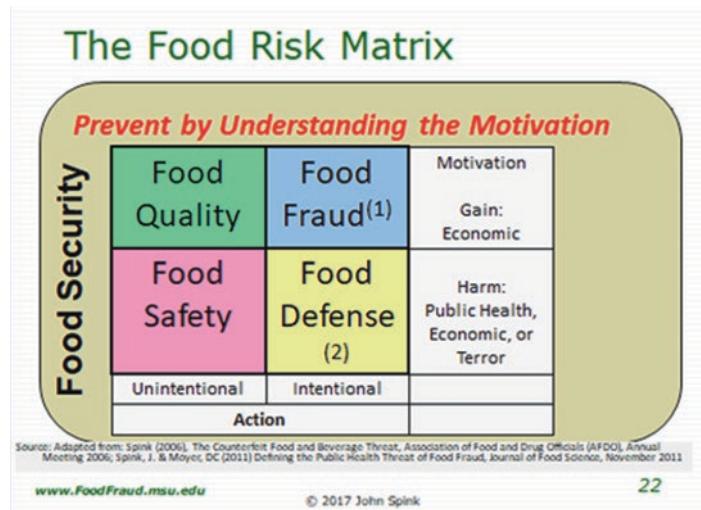
This section reviews the relationship between the food risks including the presentation in the Food Risk Matrix. The relationship of these food risks, in addition to a wider set of related terms, helps clarify the wide range of prevention activities. To understand the currently applied definitions, it is helpful to examine the origin of several of the key terms.

The Key Learning Objectives of this section are

- (1) Review of the Food Risk Matrix
- (2) Consideration of the relationship of other food fraud terms
- (3) Then a consideration of the foundation of related terms such as adulterated, misbranded, and economically motivated adulteration

The Food Risk Matrix

One way to review and organize all food risks is by using the Food Risk Matrix (Fig. 1.4) (Spink and Moyer 2011a, b). The Food Risk Matrix is a way to review the food risks and how they relate to each other. To start the definitions are (Spink and Moyer 2011a, b). The Food Risk Matrix was developed to focus on prevention which is the cause—not the effect—of an incident. This is an important concept because it covers all types of food risks that are the responsibility of an entire enterprise which could be a company or a country.



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Fig. 1.4 Food Risk Matrix. (Copyright Permission Granted) (Spink 2007; Spink and Moyer 2011a, b)

Definitions of Additional Related Terms

There are several additional related terms that will be reviewed here. One separate concept that is often confused is food defense and food security. *Food defense* is protection from an attack with the intent to harm, and food security is the continuous supply of enough food. As defined by the World Health Organization (WHO) and widely adopted, it is to ensure the supply of food, not protecting food from attack.

- **Food Security** (WHO): “...exists when all people, at all times, have physical, social and economic access to sufficient, safe and nutritious food which meets their dietary needs and food preferences for an active and healthy life. Household food security is the application of this concept to the family level, with individuals within households as the focus of concern” (WHO 2009).

In addition, other food fraud-related terms are included. Currently, the definitions of both terms are being evaluated and edited by groups including *Codex Alimentarius*. The definition and reference will probably change in the future.

- **Food Authenticity** (Elliott Review): Food is what it says it is (DEFRA 2014). The long definition “... is about ensuring that food offered for sale or sold is of the nature, substance, and quality expected by the purchaser (Section 14 Food Safety Act 1990). Authenticity can be a particular issue for faith groups or consumers with particular food preferences who do not want to purchase products containing certain ingredients” (DEFRA 2014).
- **Food Integrity** (EC, FIP): The product is of the specification defined such as quality and label claims (EU FIP 2017). “The long definition is “the state of being whole, entire, or undiminished or in perfect condition.” Providing assurance to consumers and other stakeholders about the safety, authenticity, and quality of

European food (integrity) is of prime importance in adding value to the European Agri-food economy. The integrity of European foods is under constant threat from fraudulently labeled imitations that try to exploit that added value" (EU FIP 2017).

The final definition is for the term food protection. There have been several informal definitions that are based on the previous food defense definition of protecting against intentional acts, and some others include protection from any type of harm including food safety incidents.

- *Food Protection* (FDA 2007): Address food safety and food defense (including food fraud/ EMA) (FDA 2007) and in (Petrova Dickenson and Spink 2019). A long definition from FDA is: "A Food Protection Plan (the Plan) that addresses both food safety and food defense for domestic and imported products. ... Address both unintentional and deliberate contamination" (FDA 2007).

Together, these are all terms related to food fraud as well as all food risks.

Food Risk Terminology Relationship Matrix

To provide clarity on the relationship between the terms, the figure was created (Fig. 1.5).

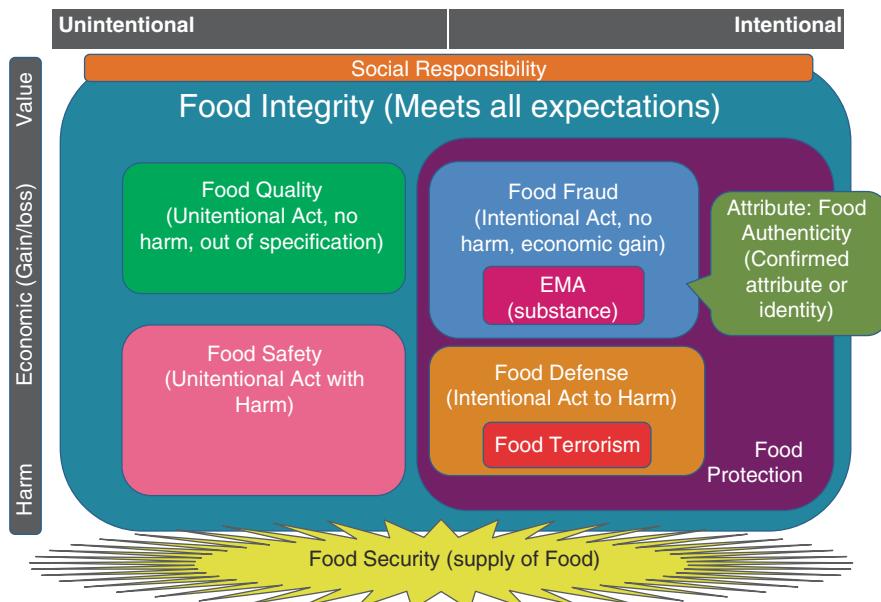


Fig. 1.5 Hierarchy and relationship of food fraud-related terms with the addition of food protection, food integrity, food authenticity, social responsibility, and food security

Sidebar: The Importance of Clear Definitions: The Four Definitions of “Food Quality” (MSU FFI 2018)

Title: The Importance of Clear Definitions: The Four Definitions of “Food Quality”

By John Spink • February 24, 2014 • Blog

“Argh... are those academics crazy for being such sticklers about definitions?” Not at all! So far — with scholarly articles to quote and reference — we’re all creating a harmonized starting point for food fraud prevention the important work is to just start defining and clarifying even the most basic terms. We all need to stay focused because the laws, regulations, and industry certifications are just now being finalized.

Our definition of food fraud is getting quite a bit of attention, being quoted in the many US and global regulations or reports. As we’re all developing our responses to FDA’s formal request for comments on the Food Safety Modernization Act (FSMA), another concept that’s important to review is “food quality.”

While we have presented food quality in presentations or in our MOOC, we haven’t directly addressed it in a publication. This discussion is essential to demonstrate why accurate definitions are so critical... moreover, how we can get on the wrong track with inaccurate ones.

When we were researching our NCFPD backgrounder on Food Fraud recently (Spink and Moyer 2011a, b), we found these varying definitions of “food quality” or “Quality Food”:

- Public Health Professional: doesn’t make people sick
- Food Manufacturing Manager: product attributes that lead to consistent end product and manufacturing operations
- Food Standards and Certification Leader: meets the defined specifications such as viscosity, density, color, texture, etc.
- Consumer: a high quality or premium

While you may not agree on every aspect of the definitions, an understanding of the different assumptions is essential. If the four stakeholders in those bullet points were working together on a project, without clear definitions, they could all start arguing about project details that might actually be the same. Right or wrong, different groups can have different understandings of the meaning of what seems to be the most rudimentary of terms. This challenge becomes even more of an issue when translating and interpreting between languages and alphabets. On a current food fraud prevention project involving the US, Russia, and Korea we were taking a proactive approach of first creating a background document with the definitions – translated into each language. We’re also engaging linguistics scholars to help study the process of translating between languages. As with other food fraud research, this is helping establish a very firm foundation for future work.

(continued)

While the world is developing the first food fraud prevention laws, regulations, and industry standards, it is critical that we continue to focus on defining and explaining the foundational concepts. This is important whether it is for FSMA Intentional Adulteration, the European Parliament/ European Commission/ European Union draft regulation on food fraud, the UK Elliott Review of food fraud, the Global Food Safety Initiative (GFSI) guidance documents, or the International Standards Organization activities.

So, pay attention, engage, and stay involved when these laws, regulations, and industry standards are being defined. If we all engage early and often, we have a better chance of all getting on the same page and reducing confusion. Hopefully, these efforts help to support the implementation of efficient and effective countermeasures and control systems. We will continue to present those key reports in this blog series. Stay tuned. MSU-FFI.

Adulterant, Adulteration, and Adulterated Foods

A source of confusion has been the use of the term economically motivated adulteration which is abbreviated as “EMA.” Initially, adulteration was the subject of an 1820 book by Frederick Accum on *A Treatise on Adulteration of Food and Culinary Poisons* (Accum 1820) (for more on Accum, see later section). The key challenges from Accum’s work are (1) no definition of adulteration and (2) no definition of adulterant. The book focuses on methods to detect “counterfeiting and adulteration” of either substituted or lower quality substances. Later the term “economic adulteration” was introduced seemingly from the 1996 US Government Accountability Office (GAO) report on “fruit juice adulteration.” This report stated, “Although these types of adulteration provide an economic advantage (and are therefore referred to as economic adulteration), they pose little threat to the public’s health and safety” (GAO 1995). That report repeatedly emphasized there was “little threat to the public’s health.” To note, a 2018 internet keyword search using Google did not find any mentions of “economic adulteration” before the GAO report published on November 5, 1995. Another search in 2018 on “economically motivated adulteration” did not find any results for that term before 2000.

From the *Federal Register* published meeting invitation (emphasis added),³ expanding on the FDA EMA definition quoted above, FDA did not exactly define adulteration or adulterant:

The Food and Drug Administration (FDA) is announcing a public meeting pertaining to economically motivated adulteration (EMA). The purpose of the meeting is to stimulate and focus a discussion about ways in which the food (including dietary supplements and animal food), drug, medical device, and cosmetic industries, regulatory agencies, and other parties

³ Note: See the glossary for re-specific and formally published definitions of key words such as interested parties, organization, management, top management, management system, documented/ documented information, test, exercise, and others.]

can better predict and prevent economically motivated adulteration with a focus on situations that pose the greatest public health risk. FDA invites interested individuals, organizations, and other stakeholders, including industry representatives, to present information pertaining to predicting and preventing EMA of food (including dietary supplements and animal food), drugs, medical devices, and cosmetics. The agency also requests interested parties to submit comments on this issue to the public docket.

Remember, as quoted earlier in this document, the FDA Public Meeting on Economically Motivated Adulteration Invitation was published officially and publicly in the *Federal Register* and included a “working definition” of EMA as (emphasis added):

Fraudulent, intentional substitution or addition of a substance in a product for the purpose of increasing the apparent value of the product or reducing the cost of its production, i.e., for economic gain. (FDA 2009)

It is important to note that although this is a formal publication, it is a meeting invitation and not a researched publication or a final agency conclusion. FDA has continued to use this as a working definition. FDA has had no reason or requirement to review or update this term.

An especially confusing aspect of this working definition of EMA is that the “adulteration” term is defined in conflict with the “Adulterated Foods” Section of the US Food Drug and Cosmetics Act (FDCA) of 1938 (FDA 2015). The FDCA defines “Adulterated Foods” as anything that compromises the product including a genuine product that spoils and a product where the Good Manufacturing Practices cannot be confirmed such as stolen goods that have been outside the control of the owner. The FDCA has a separate section on “Misbranded Foods” which refers to labeling and claims.

The confusion is that the working definition of economically motivated adulteration requires a “substance”—or adulterant—but the FDCA “Adulterated Foods” section does not. (Consider the challenge of trying to explain to a foreign language translator that an “adulterated product” is not necessarily required to include an “adulterant.”)

Later the US Food Safety Modernization Act (FSMA) of 2011 added more confusion—but maybe some clarity if the ambiguity is considered intentional text and interpreted literally—in the Preventive Controls (FSMA-PC) Final Rule. The original FSMA law does not mention or cite the term EMA (so economically motivated adulteration is not a term that the FDA legally must use). FSMA-PC refers to economically motivated adulteration but not “EMA” and does not include any mention to the working definition of EMA or the previous public meeting (there are no mentions of “EMA” and 33 uses of the phrase “economically motivated adulteration”). Later the FSMA-PC for Human Foods Qualified Individual training (PCHF-QI) also does not define the term or use “EMA” while introducing new terms including “economically motivated hazard” and “economically motivated food safety hazard.” There would have been no confusion if either of those two terms was used in the 2009 public meeting.

The result is that globally the problem has been referred to as food fraud. Occasionally economically motivated adulteration is still used to refer to food fraud that occurs with and adulterant-substance. The food fraud term is short and easy to say as well as correlates with the related terms of food quality, food safety, and food defense.

Due to all this confusion, when even referring to a substance that was intentionally added for economic gain, there has been a trend to shift from EMA or adulteration to “adulterant-substance.” Adulterant-substance is used in this research and more often by other scholars.

Sidebar: Regulatory Definition of “Adulterated Foods”—A US Example

The general concept of an “adulterant” and “adulteration” should not be confused with the US-centric “Adulterated Foods” concept. In the Food and Drug Cosmetics Act of 1938 (FDCA), adulteration is defined and explained in a section on Adulterated Food (21 USC §342, 2007) which is separate from misbranding, which is defined in a separate “Misbranded Foods” section (21 USC §343, 2004). Reviews of this FDCA section usually focus on the health hazard and not the violations for lack of control or the ability to verify that Good Manufacturing Practices have been attained and maintained.

Details of the sections on “Adulterated Food” and “Misbranded Food” are presented with a listing of each subsection and details needed. For a product to be a regulatory violation of “Adulterated Food” section, there must be an actual hazard which is not required and just a concern that “whereby it may have become contaminated.” The FDCA definition of “Adulterated Foods” is (only applicable sections are included) (FDA 2015):

- **‘§ 342. Adulterated food**
- A food shall be deemed to be adulterated—
 - ‘(a) Poisonous, insanitary, etc., ingredients
 - ‘(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health.
 - ‘(2) if it bears or contains any added poisonous or added deleterious substance (other than a substance that is a pesticide chemical residue in or on a raw agricultural commodity or processed food, a food additive, a color additive, or a new animal drug) that is unsafe...
 - ‘(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; ...
 - ‘(4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; ...
 - ‘(5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or

- ‘(6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; ...
- ‘(7) if it has been intentionally subjected to radiation, ...
 - ‘(b) Absence, substitution, or addition of constituents
- ‘(1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom;
- ‘(3) if damage or inferiority has been concealed in any manner; or
- ‘(4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.
- ‘(c) Color additives
- ‘ If it is, or it bears or contains, a color additive which is unsafe within the meaning of section 379e(a) of this title.
 - ‘(d) Confectionery containing alcohol or nonnutritive substance
 - ‘(e) Oleomargarine (or margarine or butter) containing filthy, putrid, etc., matter
 - ‘(f) Dietary supplement or ingredient: safety (unsafe or unapproved)
 - ‘(g) Dietary supplement: manufacturing practices (same as for “(a)”)
 - ‘(h) Reoffer of food previously denied admission
- ‘ If it is an article of food imported or offered for import into the United States and the article of food has previously been refused admission under section 381(a) of this title, ...
 - ‘(i) Noncompliance with sanitary transportation practices

There are also often sections applying to specific products such as infant formula:

- ‘**§ 350a. Infant formulas**
- ‘(a) Adulteration
- An infant formula, including an infant formula powder, shall be deemed to be adulterated if—
 - ‘(1) such infant formula does not provide nutrients as required by sub-section (i) of this section,
 - ‘(2) such infant formula does not meet the quality factor requirements prescribed by the Secretary under subsection (b)(1) of this section, or
 - ‘(3) the processing of such infant formula is not in compliance with the Good Manufacturing Practices and the quality control procedures prescribed by the Secretary under subsection (b)(2) of this section.

(continued)

The FDCA is focused on public health threats, and the definitions define the *effect* not the *cause*. For example, a genuine product that has spoiled would be defined by the FDCA as an “Adulterated Food,” but clearly there is not “adulteration”—at least not in line with the intentional adulteration or economically motivated adulteration concepts.

Thus, when looking at the definitions, a product that meets the definition of an “Adulterated Food” might *not* require an adulterant.

Sidebar: Regulatory Definition of “Misbranded Foods”—A US Example

Since the terms adulteration and misbranding are often mentioned together—including in the Food Safety Modernization Act—it is essential to review the FD&C definition of “misbranding” (FDA 2015):

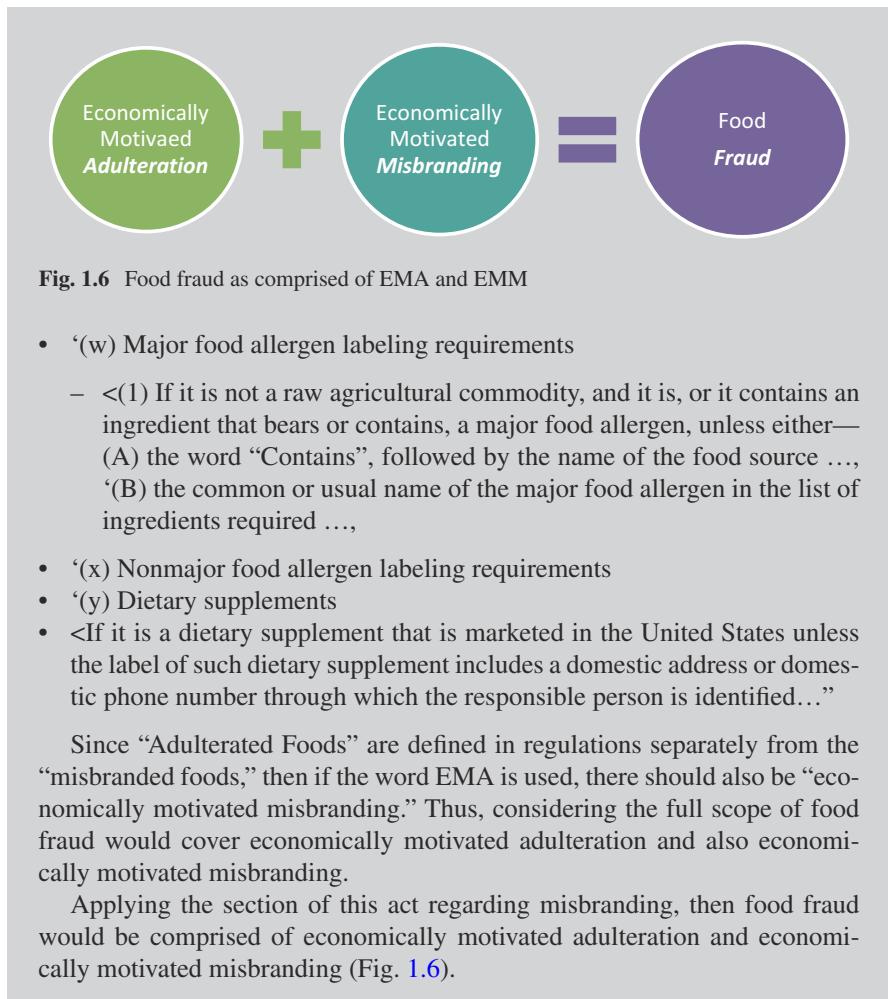
§ 343. Misbranded food

A food shall be deemed to be misbranded—

- ‘(a) False or misleading label
 - < If (1) its labeling is false or misleading in any particular, or (2) in the case of a food to which section 350 of this title applies, its advertising is false or misleading in a material respect or its labeling is in violation of section 350(b)(2) of this title.
- ‘(b) Offer for sale under another name (of another food)
- ‘(c) Imitation of another food
 - < If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word “imitation” and, immediately thereafter, the name of the food imitated.
- ‘(d) Misleading container
 - If its container is so made, formed, or filled as to be misleading.
- ‘(e) Package form
 - If in package form unless it bears a label containing
 - <(1) the name and place of business of the manufacturer, packer, or distributor; [...]
 - <(2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count, [...]
- ‘(f) Prominence of information on label
- ‘(g) Representation as to definition and standard of identity
- ‘(h) Representation as to standards of quality and fill of container
- ‘(i) Label where no representation as to definition and standard of identity

- Unless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient and if the food purports to be a beverage containing vegetable or fruit juice, a statement with appropriate prominence on the information panel of the total percentage of such fruit or vegetable juice contained in the food; ...
- ‘(j) Representation for special dietary use
- ‘(k) Artificial flavoring, artificial coloring, or chemical preservatives
 - If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact, except that to the extent that compliance with the requirements of this paragraph is impracticable,
- ‘(l) Pesticide chemicals on raw agricultural commodities
- <If it is a raw agricultural commodity which is the product of the soil, bearing or containing a pesticide chemical applied after harvest, unless the shipping container of such commodity bears labeling which declares the presence of such chemical in or on such commodity [...]
- ‘(m) Color additives
- ‘(n) Packaging or labeling of drugs in violation of regulations
- ‘(q) Nutrition information
 - <label or labeling bears nutrition information that provides— (A)(i) the serving size which is an amount customarily consumed and which is expressed in a common household measure that is appropriate to the food, or
 - <(B) the number of servings or other units of measure per container,
 - <(C) the total number of calories—
 - <(D) the amount of the following nutrients: ...
 - <(E) any vitamin, mineral, or other nutrient ...
- ‘(r) Nutrition levels and health-related claims
- ‘(s) Dietary supplements (other requirements apply)
- ‘(t) Catfish
 - < If it purports to be or is represented as catfish, unless it is fish classified within the family Ictaluridae.
- ‘(u) Ginseng
 - <If it purports to be or is represented as ginseng unless it is an herb or herbal ingredient derived from a plant classified within the genus Panax.
- ‘(v) Failure to label; health threat

(continued)



FDA Historical Foundation of the “Economically Motivated Adulteration” Term

The term “economically motivated adulteration” (EMA) was brought to the forefront when the US Food and Drug Administration (US FDA) announced a public meeting on EMA. The meeting addressed all FDA-regulated products including pharmaceuticals, medical devices, dietary supplements, and not just food. Led by Randall Lutter, the former Deputy Commissioner for Policy (currently Senior Science and Regulatory Advisor in the Immediate Office of the Commissioner reporting directly to FDA Commissioner Scott Gottlieb) 2009, the US FDA posted a *Federal Register* notice of a Public Meeting on EMA that was held in May 2009

(FDA 2009). While EMA has been a term mainly used since then by the food industry, the public meeting covered all FDA products. Specific examples of incidents published in the notice included (FDA 2009):

- **Melamine in pet food:** “In March 2007, FDA received reports of kidney failure among cats and dogs and a report that cats died during taste tests of certain brands of pet food. ... Over 150 brands of pet food and 1000 products were voluntarily recalled by a number of companies.”
- **Heparin in kidney dialysis medicine:** “In January 2008, FDA received reports of adverse reactions in pediatric dialysis patients ... associated with heparin manufactured by Baxter Healthcare Corp. that was administered during the dialysis procedures.”
 - Impact: “FDA’s investigation ultimately identified almost 150 U.S. deaths occurring between January 1, 2007, and May 31, 2008, that appeared to be associated with the use of these heparin products.”
- **Melamine in milk powder and infant formula:** “In September 2008, FDA issued a Health Information Advisory in response to reports of melamine-contaminated milk-based infant formula manufactured in China. Melamine was apparently added to diluted milk in order to increase measured nitrogen levels (indicators of protein content) and thereby inflate the apparent protein content found in the product.”
 - Impact: “To date, official reports from the Chinese Ministry of Health state that nearly 300,000 Chinese infants were sickened by the contaminated infant formula, and that six infant deaths were likely due to the contamination.”
- **Diethylene Glycol (DEG) in various medicine products:** “Adulteration of glycerin, an ingredient in cough syrup and other drugs, with diethylene glycol (DEG) has resulted in several mass poisonings around the world in the past two decades.”
 - Impact: “In 1996, contaminated acetaminophen syrup was responsible for the deaths of more than 70 children in Haiti. In 2006, tainted cough syrup resulted in dozens of deaths in Panama. In Nigeria, between 2008 and 2009, more than 50 children died after ingesting contaminated teething syrup. Incidents of DEG contamination in these two decades have not resulted in any reported U.S. deaths or illnesses, but in 2007, foreign-made toothpaste contaminated with DEG was reported in the United States resulting in recalls and restriction on imports of suspect toothpaste.”

The day-long FDA public meeting included presentations from many industry leaders from beyond the food industry. The presenters are listed here in order of the presentations on the meeting website (there were additional members listed on the agenda) (Table 1.4).

Table 1.4 Organizations and links to presentations at the FDA EMA public meeting in agenda order (Note: as listed on the FDA website in September 2018—additional presenters were listed on the agenda but not included in this set of links to the presentations) (FDA 2009)

Organizations who presented at the FDA EMA public meeting in order of presentation (as listed on the FDA website in September 2018—additional presenters were on the agenda)
1. Michigan State University (Defining Food Fraud & The Chemistry of the Crime. Presenter: John Spink, Ph.D., Associate Director Anti-Counterfeiting and Product Protection Program (A-CAPP), School of Criminal Justice)
2. US Pharmacopeia (Economically Motivated Adulteration, Roger L. Williams, M.D., Chief Executive Officer Chair, Council of Experts, US Pharmacopeia)
3. IPEC (International Pharmaceutical Excipients Council) (Efforts to Ensure Excipient Safety, Irwin Silverstein)
4. Amgen Incorporated (Economically Motivated Adulteration, Martin VanTrieste, Vice President Quality; Commercial Operations, Amgen)
5. National Fisheries Institute (Summary of Comments: Economically Motivated Adulteration, Lisa Weddig, National Fisheries Institute)
6. Science Personal Care Products Council (Suspected Economically Motivated Adulteration of FDA-Regulated Products, John E. Bailey, Executive Vice President – Science Personal Care Products Council)
7. Natural Products Association (Economically Motivated Adulteration, Daniel Fabricant, Ph.D. Vice President, Scientific & Regulatory Affairs)
8. American Herbal Products Association (Simple Authentication Methods for Herbal Ingredient Integrity in the face of EMA, Steven Dentali, Ph.D., Chief Science Officer)
9. Council for Responsible Nutrition (Avoiding economic adulteration of dietary supplements: The need for ingredient supplier qualification guidelines, Andrew Shao, Ph.D., Vice President, Scientific & Regulatory Affairs)
10. ConsumerLab.com (Economically Motivated Adulteration in the Dietary Supplement Market Place, William Obermeyer Ph.D., VP Research)
11. The Pew Charitable Trusts (Protecting Consumers from Adulterated Drugs, Allan Coukell, Director, Pew Prescription Project)
12. Center for Science in the Public Interest (Comments on Economically Motivated Adulteration, Xuman Amanda Tian, Research Associate, Food Safety Program)
13. Grocery Manufacturers Association (GMA) (Economically Motivated Adulteration, Craig W. Henry Ph.D., Senior Vice President, and Chief Operating Officer, Scientific and Regulatory Affairs)

Everything might have been different if that first working definition of EMA referred broadly to “adulteration” as specified in the FDCA. Nevertheless, terms that are now used in FSMA guidance such as the qualified individual training are “economically motivated food safety hazard” and “economically motivated hazard.”

Sidebar: A Treatise on Adulteration of Food in 1820 by Frederick Accum

An appropriate end to this Introduction chapter on definitions is to review the very earliest research on food fraud. The food fraud concept has been confusing from the start. Accum's book published in 1820 was apparently the first citation for the use of the term "food adulteration." Frederick Accum published *A Treatise on Adulteration of Food* (Accum 1820). The full title is "A Treatise on Adulteration of Food and Culinary Poisons exhibiting the Fraudulent Sophistications of [various products] and the Methods of Detecting Them." There are no definitions of adulteration, adulterated, adulterant, counterfeit, or contaminant, and he does not use the term "substance."

Accum's statement is (emphasis added):

- "This treatise, as its title expresses, is intended to exhibit easy methods of detecting the fraudulent adulterations of food, and of other articles, classed either among the necessaries or luxuries of the table; and to put the unwary on their guard against the use of such commodities as are contaminated with substances deleterious to health."

But, what exactly does he think is adulteration?

Accum did mention "the fraudulent adulterations of food," "the detection of frauds," and "counterfeit" products then shifted the focus of the research to test methods for "detection of the adulteration of foods." He refers to "the adulteration of food" (interpreted as the intentional deception of usually a lower quality version of the product) and "counterfeit" (interpreted as the intentional deception of substituting a different product) though here he does not use the phrase "food adulteration" or "adulterant."

Thus, Accum appears to consider that of the many types of adulteration of food, one type is fraudulent adulteration using a lower quality substance, and another is counterfeiting by substituting another product. The lack of a clear definition has created confusion from the very start of attempting to prevent food fraud.

Conclusion

This Introductory Chapter—and the starting point for the book—began at the most logical starting point which is reviewing the definition and scope of food fraud. Considering the definition of this and related terms—including a consideration of the prevention-focused objective—helps set the direction of the research. The direction from the 2018 CODEX CCFICS Chairman directed the Electronic Working Group on Food Integrity and Food Authenticity food fraud and was consistent with this idea that definition clarity would self-direct the next steps. *The first conclusion is that the most logical starting point to review the Food Fraud Prevention Strategy*

is, to begin with, the definition of the term. As a series of incidents have become more and more impactful, the problem has been more clarified from covering adulterant-substances to mislabeling and then counterfeiting and a realization that a holistic, all-encompassing approach is to address all types of fraud. *The second conclusion is* that food fraud prevention follows the saying that “common sense is neither common nor sense.” It might seem that “everyone knows what that means” is not always so and when applied to food fraud is often *not* the case. A simple first step is to clarify the definition and scope of the research question and then confirm the end use of the information. *General* information *generally* helps, and *specific* information *specifically* helps. Without a clear definition and scope, combined with a clear specification of what decision is being addressed, the projects often end in confusion or a report that is not useable. *The final conclusion is* that to understand the current state and focus, it is important to review the applicability of the core source documents such as Accum’s treatise on food adulterations or the FDA working definition of economically motivated adulteration. Over time, as the scope of food fraud is clarified and the prevention priority, some of the original concepts may adapt to be more appropriate.

There is a saying:

We're not trying to catch bad product but to prevent food fraud from occurring in the first place.

The next chapter on an introduction to the concepts will expand on the introduction to the concept before a deeper dive into the specific topics (Fig. 1.7).

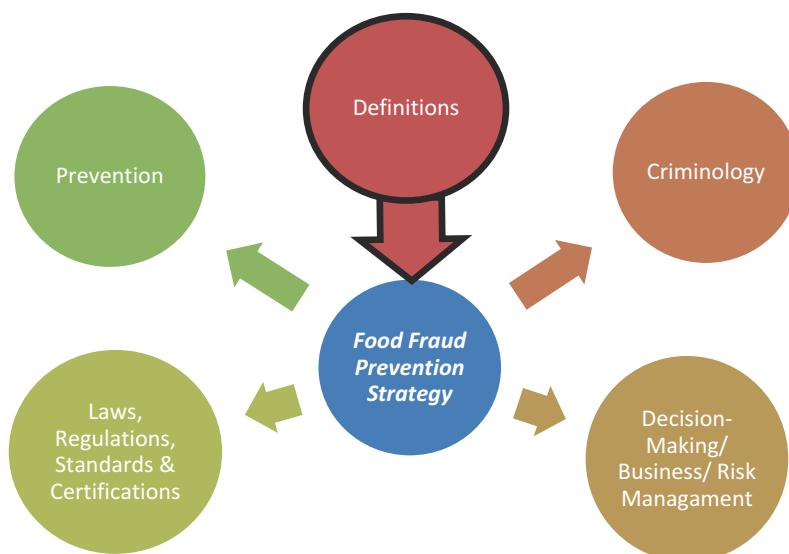


Fig. 1.7 Example of confirming definitions and scope before beginning to create the Food Fraud Prevention Strategy that is comprised of specific disciplines

Appendix: WIIFM Chapter on Introduction and Definitions

This “What’s In It For Me” (WIIFM) section explains why this chapter is important to you.

Business functional group	Application of this chapter
WIIFM all	Food fraud is a new topic, and this chapter provides a very thorough review and foundation of the definition and scope—just follow the recommendation
Quality team	Use this to identify where to expand your focus from traditional food safety to food fraud prevention—from biological sciences to criminology and business risk assessment
Auditors	This supports your awareness of “what is food fraud?”
Management	This is scholarly support for the broader foundation that is usually addressed by a food quality team
Corp. Decision-makers	The employees have a process that is based on a theoretically sound and widely researched foundation

Appendix: Study Questions

This section includes study questions based on the key Learning Objectives in this chapter.

1. Discussion Question

- (a) Why must FF be addressed by a company or country?
- (b) What are the major challenges to creating and then implementing an FFPS?
- (c) How does a government FFPS differ from a company strategy?

2. Key Learning Objective 1

- (a) What is the definition of a “problem”?
- (b) Why is “Establishing the context” critical?
- (c) How is “success” measured?

3. Key Learning Objective 2

- (a) What is the definition of “food fraud”?
- (b) Explain EMA in relation to food fraud?
- (c) What is the relationship between food authenticity and food integrity?

4. Key Learning Objective 3

- (a) What is the “Food Risk Matrix”?
- (b) How is food fraud different from food defense?
- (c) Where is a “disgruntled employee” applied in the Food Risk Matrix?

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Chapter 2

Introduction (Part 2 of 2): Basic Prevention Concepts



Summary

This chapter presents the introduction to the fundamentals of product fraud prevention and the application to food fraud. To start, the basic concepts are reviewed, then the risks or vulnerabilities, and finally the difficulties and issues that have hindered the focus on prevention. The interdisciplinary nature of prevention is reviewed by considering how the fraud opportunity is created and the many academic disciplines that help understand the optimal countermeasures and control systems.

The Key Learning Objectives of this chapter are

- (1) **Product Fraud Attributes:** This section will present the basic details that define the fraud opportunity as well as the key focus areas for prevention.
- (2) **Types of Harms and Identifying the Root Cause or Types of Food Risks and Vulnerability:** To identify these concepts, there is a need to step back and review the terms and how they relate to each other.
- (3) **Prevention and Problem-Focused Research:** After holistically reviewing the reaction or tactical responses through reducing the fraud opportunity, there is an obvious need to focus on and prioritize multidisciplinary-based prevention countermeasures.

This chapter reviews the “(0) Fundamental Concepts” and “(A) Academic Disciplines” in the Food Fraud Prevention Cycle (Fig. 2.1).

Introduction

Beyond definitions of terms, there are some key concepts that provide insight to address food fraud prevention. The concepts are both about the fraud opportunity and also about how to think to address the problem. This chapter addresses a wide range of topics that are fundamental concepts.

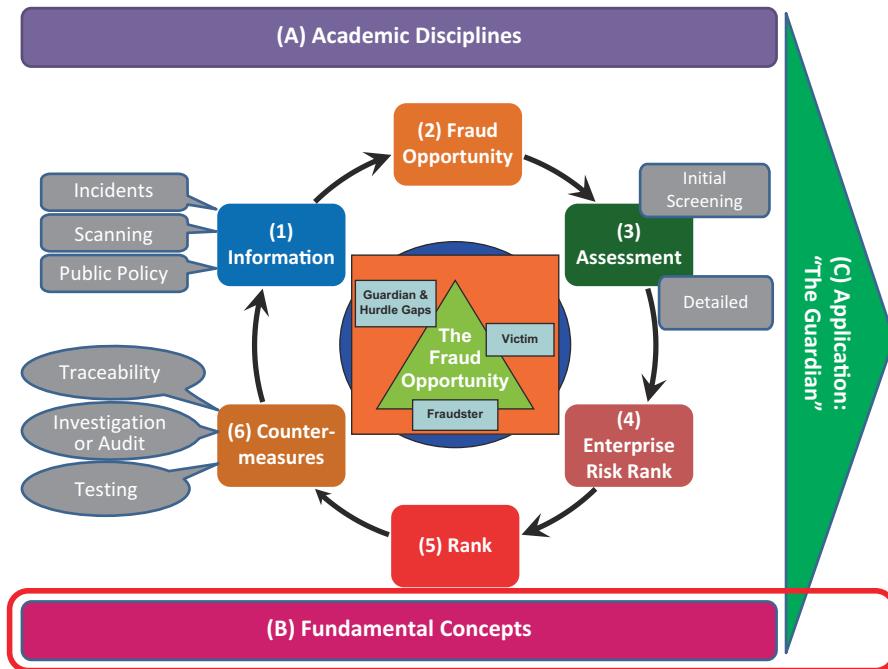


Fig. 2.1 Food Fraud Prevention Cycle—where this chapter applies to the overall concept: “(B) Fundamental Concepts” (Copyright Permission Granted) (Spink 2014; Spink et al. 2019)

Key Learning Objective 1: Product Fraud Attributes

This section reviews the basic details that define the fraud opportunity as well as the key focus area for prevention. This expands from the basic attributes of the product fraud risk to the beginning of organizing the response plan.

The Key Learning Objectives of this section are

- (1) The types of food fraud risks
- (2) The types of deceptive and non-deceptive counterfeits
- (3) The goals of the countermeasures and control systems

Types of Food Fraud Risks: Direct, Indirect, and Technical

A consideration when classifying food fraud incidents is the type of risk that occurs. From “Introducing the Public Health Threat of Food fraud,” there are three basic types of food risks including direct or acute, indirect or chronic, and then technical or nonmaterial (Spink and Moyer 2011).

“This research identified three types of food fraud risks for public health: direct, indirect, and technical. It is important to note that for all three types, these are the effects, not the fraudster motivation.

- **Direct food fraud risk** occurs when the consumer is put at immediate or imminent risk, such as the inclusion of an acutely toxic or lethal contaminant; that is, one exposure can cause adverse effects in the whole or a smaller at-risk population.
- **Indirect food fraud risk** occurs when the consumer is put at risk through long-term exposure, such as the buildup of a chronically toxic contaminant in the body, through the ingestion of low doses. Indirect risk also includes the omission of beneficial ingredients, such as preservatives or vitamins.
- **Technical food fraud risk** is nonmaterial in nature. For example, food documentation fraud occurs when product content or country-of-origin information is deliberately misrepresented.”

In reality, a food fraud incident probably has aspects that are in each category. For example, melamine in infant formula did include direct food fraud risk from the lethal response in some infants, an indirect food fraud risk due to lower nutritional content, and also a technical food fraud risk of the mislabeling. On the other hand, a genuine, food product that was manufactured under confirmed Good Manufacturing Practices in an authorized facility that has a fraudulent country of origin to avoid a high tariff would be only a technical food fraud risk (as long as there was still supply chain traceability).

Types of Fraudulent Deception: Deceptive Versus Non-deceptive Product and Primary and Secondary Markets

While it is not usually a debate for food products, generally product fraud includes deceptive and non-deceptive products (OECD 2008; Moyer et al. 2017):

- **Deceptive Products** (counterfeits) are products that are placed into supply chains with the intent to deceive the consumer into believing that the product is genuine in every way.
- **Non-deceptive Products** (counterfeits) are products that do not position to deceive the consumer into believing the products are genuine by their positioning in the market whether through the type of retail outlet in which they are sold (flea market, etc.), the price (exponentially low), or the quality (poor).

In addition to the deceptive and non-deceptive description, another consideration is the type of market including primary and secondary markets. While there is an academic definition of two extremes, the actual marketplace includes variations along a continuum.

- **Primary market** is through authorized resellers which are for “Consumers who demand goods of genuine, non-infringing origin establish a market that is referred to in this report as the primary market (Spink 2019). For a fraudster to penetrate this market, to maintain the price and continued sales, the product must be able to deceive consumers into thinking they are buying genuine products (deceptive counterfeits)” (Spink 2019).
- **Secondary market** (possibly to the clearly illegal and clandestine black market): “Under certain conditions, consumers are often willing to purchase products they know are not legitimate” (Spink 2019). In this situation, the consumers usually understand something is not right or proper about the product whether it is stolen, counterfeit, or otherwise substandard (non-deceptive counterfeits). “There are other markets in between such as products not sold through authorized resellers, legal diverted product, or other types of ‘gray markets’”(Spink 2019).

There are many important considerations both for how consumers are deceived (or not) and how to successfully implement risk treatments (from (Moyer et al. 2017):

Food fraud can usually be categorized as a deceptive product since consumers generally would not purposefully choose to purchase a counterfeit food. Consumers might seek lower prices, a generic version, or discounted sale products, but they would not purchase an outright fake food. This distinction actually aids in combatting food fraud as it deemphasizes non-deceptive fraudsters who do not have access to food value chains including retailers. (Moyer et al. 2017)

Also,

When considering all product fraud, there are deceptive products designed to convince the victim that the product is genuine in every way (e.g., branded food, pharmaceuticals, and products sold at traditional retail outlets, etc.) (OECD 2008). Conversely there are non-deceptive products that do not try to hide the fact that they are counterfeit or fraudulent (e.g., luxury goods offered at a fraction of typical market price and sold at non-traditional outlets such as flea markets, products that are insinuated to be stolen goods that could be counterfeits, etc.). (Spink et al. 2013)

This classification is an important insight when selecting countermeasures:

When selecting countermeasures, it is important to understand the difference and to know whether consumers are seeking genuine or counterfeit product since this will affect the countermeasures chosen. With deceptive counterfeits, the consumer may not be aware there are counterfeit products in the marketplace; increasing awareness through publicity may lead the consumer not to buy the genuine brand or product which would not satisfy the brand owner. With non-deceptive counterfeits, the consumer is seeking illegal product, so identifying a product as ‘fake’ would not deter the sale. (Spink et al. 2013)

Thus, it is important to understand whether the customer is seeking a counterfeit product or if they are even aware that there may be fraudulent products in the marketplace.

Countermeasures and Control Systems: Detect, Deter, and Prevent

Based on criminology theory, there are three goals of countermeasures and control systems including detect, deter, and prevent. The prevent concept is admittedly aspirational, but the ultimate goal is not only to reduce the criminal act but eliminate it from even occurring at all (Spink et al. 2016a, b):

- “***Detection (detect)*** is finding a specific adulterant-substance or product anomaly.”
- “***Deterrence (deter)*** is a targeted countermeasure to stop one specific type of food fraud or fraudster.”
- “***Prevention (prevent)*** is the application of countermeasures that reduce the fraud opportunity.”

Also:

Food fraud is opportunistic in nature and represents a significant challenge to both industry and government (Spink 2011). Detection and intervention become more complex when incidences of food fraud seem to be random, isolated, or small. Food fraud incidents do not fall into a statistically normal distribution, based on the widespread prevalence of the same type of fraud. Food fraud risk analysis is further complicated by the fraudsters being intelligent, resilient, clandestine, and good at stealthily avoiding detection. Prevention, through deterrence of *the chemistry of the crime*, is critical because we cannot incarcerate our way to safety. (Spink and Moyer 2011)

Sidebar: Home Burglary Analogy for Detect, Deter, and Prevent

In relation to food fraud prevention, the concepts of detect, deter, and prevent are difficult to understand in relation to the actual application to food fraud prevention. Different stakeholders have different ideas of what the terms mean. A food authenticity scientist understands that a species test does “detect” an incorrect species. That logically does “deter” and thus “prevent.” While this is generally true—of course—there is more to prevention than a general theory. “*General theories generally apply, and specific theories specifically apply.*” We find that using everyday examples helps to explain the topics. For “deter”—and as it is presented in the fraud opportunity—two actions are hurdles that make an act more difficult to conduct and guardians who catch the crime.

To use an everyday example, we refer to protecting a home from a specific act such as a break-in burglary or generally of any type of attack.

For a specific act such as a burglary, we will present how the topics apply:

- ***Detect:*** The goal is to monitor any bad guys *in* your house. “Beep-Beep” the motion detector alarm is sounded since a burglar is in your kitchen and then flees. You are in your bedroom, so it is good that the burglar did not get to you, but it would have been better if they didn’t get into your house at all.

(continued)

- **For food fraud prevention**, an example is conducting a species test on incoming raw materials and therefore removing illegal horsemeat before it gets into your production. If you catch it, it is fortunate that the fraudulent material did not get into your finished product, but it would have been better if you were never even shipped the fraudulent goods. The higher objective is to deter the fraudster.
- **Deter:** The goal is to combat—or deter—a specific type of activity which is entering the house through a window. Considering a “guardian,” “crash” a burglar breaks your kitchen window, but a nearby security office hears the noise and stops the burglar. It is an improvement that the burglar did not get into your kitchen but you’d really rather they didn’t even try to break your window. Considering a “hurdle”—“crash” a burglar breaks your kitchen window but hits security bars that you have put on the window, and they flee—it is an improvement that the burglar did not get into your kitchen but you’d really rather they didn’t even try to break your window.
- **For food fraud prevention**, this is either a very alert incoming goods quality control person noticing a difference in a product or conducting a specific type of authenticity test to reject the product before it is taken into inventory. The higher objective is to prevent, the fraudster from ever even trying to attack you.
- **Prevent:** The goal is to dissuade any burglar from even trying to break into your house. For the general burglar, your home defense does not need to be perfect but just a less attractive target. If your house is locked, lights on, dog barking, alarm on with active blinking, and your neighbor’s house is dark with a window open, then unless there is something very attractive about your house, the bad guy will not rob you.
- **For food fraud prevention**, this is a potential fraudster (a motivated offender who is looking for a victim, see criminology theory chapter below) who does not consider you as a target.

Expanding this home protection from burglary to all fraud, you are concerned about *all* types of attacks on your house, not just break-ins. If you conduct a vulnerability assessment for all crime issues, you might find sometime link cybercrime through Wi-Fi-enabled systems or malware through email. Those are very different from combating a burglar but no less concerning or dangerous. From this perspective, it’s obvious that a different scientific discipline is needed to combat that vulnerability.

Now, to take a strategic approach to reduce the overall home fraud opportunity, once you identify vulnerabilities, you continue to examine the risk. Vulnerabilities are system weaknesses that could be compromised. For example, a window is left unlocked. A risk is the consideration of the vulnerability

in relation to other factors that define likelihood and consequence, for example, the unlocked window after considering how many houses have been burgled in your neighborhood in the last year (likelihood) and how bad it would be for you if you had items stolen (consequence). If there have been many burglaries nearby and you have valuable products, then your “risk treatment” could justify a large investment. In part, you may review what other neighbors have implemented, so you at least have a system in place that is as good as theirs.

In many cases, the food fraud vulnerability assessments identify simple vulnerabilities (such as that window left open) and very easy countermeasures and control systems (make sure to close and lock the window when you leave your house). Closing the window vastly reduces the fraud opportunity regardless of the risk. If there are few burglaries in your neighborhood, your vulnerability would vastly be reduced, but the statistical probability would hardly be reduced at all. From a “risk-based approach,” it would not be warranted to close the window. From a “vulnerability reduction approach,” it is efficient and logical to get into the habit of committing those extra couple seconds always to close the window.

It is important to note that if someone really wants to get into your specific house, it will probably happen. High-security art museums and banks are successfully attacked and robbed. The countermeasures and control systems do not need to be perfect or impenetrable just “unattractive enough” to reduce your fraud opportunity to within your “risk tolerance” (note: “risk appetite” and “risk tolerance” are terms that are formally defined in standards and will be addressed more thoroughly in a later chapter). There is a saying of “how fast do you need to be to outrun a bear? Faster than the person you are running with” (insinuating that the bear will stop and eat your colleague)! For food fraud prevention, there is a sharing of best practices, so everyone is not getting faster but all carrying bear repellent systems. The bear doesn’t try to attack any of you.

Addressing an Incident: Prevention, Intervention, and Response

The Food Protection Plan of prevention, intervention, and response will be reviewed in more detail in later chapters on risk assessment, but here it is important to include with the other basic terms. Based on the FDA Food Protection Plan concept, the series of activities to address an incident are presented here (Fig. 2.2) (FDA 2007):

- **Prevention:** to implement risk treatments or change behaviors in a way that reduces the likelihood of the event occurring again
- **Intervention:** to identify the hazard and find a detection method focusing on an immediate, direct, and tactical response to “intervention” that is absolutely critical and proper during a crisis
- **Response:** to find ways to remove the hazard from the supply chain quickly

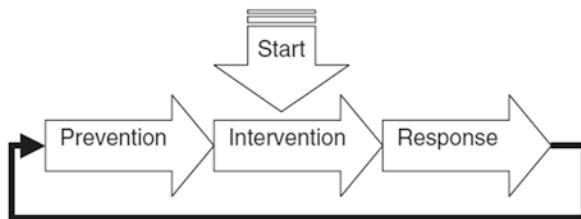


Fig. 2.2 Food Protection Plan series of activities: Prevention-Intervention-Response (PIR) with the starting point after an incident at intervention (Copyright Permission Granted) (Spink and Moyer 2011)

The figure identified that the process starts at intervention because there needs to be awareness and priority-setting before the process starts. A saying is that “We do not prevent everything.”

The Focus on Countermeasures and Control Systems

Throughout this book, the prevention strategies and risk treatment tactics are referred to as ***countermeasures and control systems***. A **countermeasure** is a risk treatment such as an authenticity test or using an authentication code. A **control system** is a monitoring or process control that reduces the fraud opportunity by either seeking anomalies or increasing the transparency of the supply chain through traceability. The term “control system” was carefully selected after starting with “control plans” and also considering a more proactive statement of a “control strategy.” First, a system seems to be more all-encompassing than a plan. “System” was used to make sure to not confuse with other concepts, for example, HACCP is often referred to as a “plan.” “Control plan” was avoided not to confuse the activity with the US FDA-defined regulatory compliance use of the phrase (FDA 2011). For example, “in-process control plan” is a specific focus in the FDCA specifically here referring to 21 CFR 106 D conduct of audits) (FDA 2015a, b; 21CFR106D 2018). The focus of a Food Fraud Prevention Strategy is to create an overall management system that could end up meeting regulatory compliance but only after further review and adjustment. “Control strategy” was not used not to confuse the activity with the CODEX defined the concept of a “National Food Control Strategy” (WHO 2003). For example, that CODEX report states “The attainment of food control system objectives requires knowledge of the current situation and the development of a national food control strategy” (WHO 2003). The Codex use of the term “strategy” is consistent with the Food Fraud Prevention Strategy definition and scope.

Key Learning Objective 2: Types of Harms and Identifying the Root Cause

This section reviews the food risks and vulnerability which provides a foundation for classifying and organizing a response.

The Key Learning Objectives for this section are

- (1) The Food Risk Matrix and relationship between concepts of food quality, food safety, food fraud, food defense, and food security
- (2) The supply chain vulnerabilities by identifying each node whether within or outside the proprietary or legitimate supply chain
- (3) The root cause of the vulnerability which is an economic gain

Food Risk Matrix: Connection of Concepts

Expanding on the brief introduction to the Food Risk Matrix above, before reviewing the types of harms and the root causes, it is important to expand the understanding of the problem, itself further. An important concept is how food fraud connects to other types of food risks—this helps define what is and what is *not* food fraud.

Food fraud risks are already present whether explicitly known or not. A company is accountable and responsible for all food risks. The CEO holds the President accountable who holds the General Manager accountable who holds the VP of Quality Assurance accountable. The VP of Quality Assurance is possibly your boss. If you are assigned the responsibility for addressing food fraud, then you are doing them a disservice if you do not cover all types of fraud and for all products. You could say “that wasn’t my assignment,” but “not my job” is not a wise career move. Of course, scope creep and lack of resources are a challenge, but it is recommended that you *at least* define what you do and don’t cover in your project.

Especially when reviewing food fraud prevention for the first time—whether for GFSI, the Food Safety Modernization Act Preventive Controls Rule, Sarbanes-Oxley Act,¹ or others—it is most efficient, and not that much more work, to address *all* types of fraud and for *all* products. This is also efficient because at some point in the future you—or someone else—will be given this task.

One way to review and organize all food risks is by using the Food Risk Matrix (Fig. 1.4 from above) (Spink and Moyer 2011). The Food Risk Matrix was developed to focus on prevention which is the cause—not the effect—of an incident.

In the past, food agencies such as the US FDA categorized health hazards as (1) unintentional (Food Safety) or (2) intentional (food defense). With these two

¹Throughout this book the US Sarbanes-Oxley Act of 2002 (SOX or Sarbox) is referred to as a primary compliance requirement for implementing Enterprise Risk Management. While SOX is a compliance requirement in the USA for public companies, the basic “ERM” or “ERM-like” systems are a regulatory or general management requirements for virtually all companies. The owners of the company, through the board of directors, require this type of oversight.

categories, of course, food fraud would be classified under food defense. Before the FSMA Intentional Adulteration Rule, the US FDA included food fraud under food defense. In the rule development process and public comment responses, EMA/FF was most efficiently addressed by preventive controls and thus was switched to the FSMA Preventive Controls rule (FSMA-PC).

While reviewing how an agency addresses unintentional or intentional acts, it is opportune to review details of how the FDA addressed the subject. While all hazards are a concern and focus for a public health agency such as the FDA, there was a need to define the scope of final rules to address the overall law.

Before the FSMA final rules, the FSMA law (US Code) included clear and direct compliance requirements that technically required a food fraud vulnerability assessment for all types of fraud and for all products—specifically there is a requirement to assess *all* hazards, of which acts for economic gain are listed (emphasis added) (21CFR117.130 2018):

§ 117.130 - Hazard analysis & Sec. 507.33 Hazard analysis.

'(1) You must conduct a hazard analysis to identify and evaluate, based on experience, illness data, scientific reports, and other information, known or reasonably foreseeable hazards for each type of animal food manufactured, processed, packed, or held at your facility to determine whether there are any hazards requiring a preventive control; and

'(2) The hazard analysis must be written regardless of its outcome.

b) Hazard identification. The hazard identification must consider:

'(1) Known or reasonably foreseeable hazards that include:

'(i) Biological hazards, including microbiological hazards such as parasites, environmental pathogens, and other pathogens;

'(ii) Chemical hazards, including radiological hazards, substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, and food allergens; and

'(iii) Physical hazards (such as stones, glass, and metal fragments); and

'(2) Known or reasonably foreseeable hazards that may be present in the food for any of the following reasons:

'(i) The hazard occurs naturally;

'(ii) The hazard may be unintentionally introduced; or

'(iii) The hazard may be intentionally introduced for purposes of economic gain.

In FSMA-IA, the FDA defined the “intentional adulteration” section scope to be “wide-scale health harms.”

The FSMA Draft Rule provides a table that explained exactly why certain intentional acts were outside the scope including disgruntled employees and economically motivated adulteration (other issues not mentioned are tampering/ malicious tampering, smuggling, stolen goods, port shopping, and others) (Table 2.1) (FDA 2016).

The FSMA-IA Final Rule stated:

We further explained that attacks by disgruntled employees, consumers, or competitors would be consistently ranked as relatively low risk mainly because their public health and economic impact would generally be quite small. We further stated that disgruntled employees are generally understood to be interested primarily in attacking the reputation of the company and otherwise have little interest in public health harm. Typically, acts of disgruntled employees, consumers, or competitors target food and the point(s) in its production

Table 2.1 “Scope of intentional adulteration and proposed exclusions and exemptions (table from the draft rule but confirmed in the final rule)

Type of intentional adulteration	Coverage within the scope of proposed 21 CFR 121	Brief rationale and the relevant corresponding section of the rule
Acts of disgruntled employees, consumers, or competitors intended to attack the reputation of a company, and not to cause public health harm, although public health harm may occur	Not within the scope of intentional adulteration covered under proposed 21 CFR 121	Not considered “high risk” because not intended to cause widespread, significant public health harm. See section IV.E of this document
Economically motivated adulteration (EMA) intended to obtain economic gain, and not to cause public health harm, although public health harm may occur	Not within the scope of intentional adulteration covered under proposed 21 CFR 121	Considering addressing as part of hazard analysis in a preventive controls framework where EMA is “reasonably likely to occur.” See section IV.F of this document
Acts intended to cause massive public health harm, including acts of terrorism	Covered within scope and is the focus of proposed 21 CFR 121	Considered “high risk” because the intent of the act is to cause widespread, significant public health harm

that are convenient (i.e., a point at which they can easily access the food and contaminate it). To minimize or prevent this type of adulteration would require restricting access to nearly all points in the food system. Instead, we proposed to focus on those points in the food system where an attack would be expected to cause massive adverse public health impact. (FDA 2016)

In the absence of a clear FSMA law definition of “adulteration,” this was the FDA interpreted the FSMA law statement of “intentional adulteration, including by acts of terrorism” and “intentionally introduced, including by acts of terrorism” (FDA 2011).

Sidebar: FSMA Regarding Smuggling and also Port Shopping

The FDA Final Rules constantly emphasize they apply to the final rule and not the overall FSMA or US legal compliance requirements. There are some FSMA law requirements topics that are not explicitly addressed in a final rule. The final rules also continue to emphasize that the overarching statutory requirement is still the Food, Drug & Cosmetics Act of 1938. For food fraud prevention, two topics include:

- **Smuggling:** product that is imported into the U.S. through an act of deception. FSMA and Smuggled Foods is illegal under 21 USC 2243 and 21 CFR Sect. 309. Product that has been smuggled would be illegal under various laws including the FDCA Adulterated Foods section.
 - “SEC. 309. <<NOTE: 21 USC 2243.>> SMUGGLED FOOD (a) In General. <<NOTE: Deadline. Strategy.>> --Not later than 180 days

(continued)

- after the enactment of this Act, the Secretary shall, in coordination with the Secretary of Homeland Security, develop and implement a strategy to better identify smuggled food and prevent entry of such food into the United States.
- (b) Notification to Homeland Security. <<NOTE: Deadline.> > --Not later than 10 days after the Secretary identifies a smuggled food that the Secretary believes would cause serious adverse health consequences [[Page 124 STAT. 3967]] or death to humans or animals, the Secretary shall provide to the Secretary of Homeland Security a notification under section 417(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350f(k)) describing the smuggled food and, if available, the names of the individuals or entities that attempted to import such food into the United States.
 - (c) Public Notification.--If the Secretary--
 - (1) identifies a smuggled food;
 - (2) reasonably believes exposure to the food would cause serious adverse health consequences or death to humans or animals; and
 - (3) reasonably believes that the food has entered domestic commerce and is likely to be consumed, the Secretary shall promptly issue a press release describing that food and shall use other emergency communication or recall networks, as appropriate, to warn consumers and vendors about the potential threat.
 - (d) Effect of Section.--Nothing in this section shall affect the authority of the Secretary to issue public notifications under other circumstances.
 - (e) Definition.--In this subsection, the term “smuggled food” means any food that a person introduces into the United States through fraudulent means or with the intent to defraud or mislead.”
- **Port Shopping:** attempting to import products into a US port after had been rejected at another US port. Port shopping is illegal under FSMA 21 USC 381 and 21 CFR Sec. 115 (FDA 2011). Product that has been smuggled would be illegal under various laws including the FDCA Adulterated Foods section.
 - SEC. 115. [NOTE: 21 USC 381 note] PORT SHOPPING.
 - “[NOTE: Notification.] Until the date on which the Secretary promulgates a final rule that implements the amendments made by section 308 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, (Public Law 107-188), the Secretary shall notify the Secretary of Homeland Security of all instances in which the Secretary refuses to admit a food into the United States under section 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(a))

so that the Secretary of Homeland Security, acting through the Commissioner of Customs and Border Protection, may prevent food refused admittance into the United States by a United States port of entry from being admitted by another United States port of entry, through the notification of other such United States ports of entry.”

Sidebar: Applying the Food Risk Matrix to Key Job Responsibilities

Considering the vertical columns in the Food Risk Matrix, food quality and food safety are both “unintentional” acts—there is no intent to create these problems. Then, food fraud and food defense are both “intentional” acts—the actors know what they are doing.

Food fraud is an emerging and often odd type of problem. Melamine in infant formula created a health hazard, so it was initially addressed by the food safety product recall team. The food safety countermeasure and controls were put in place. Once melamine was not found in the product, the problem was considered “resolved” or at least “not a problem anymore.” The food safety team would logically *not* prioritize any further focus on melamine. The food safety team would definitely not expand to consider other types of protein fraud.

For this melamine example, the “effect”—the incident—did have a health hazard and so logically would be addressed by the food safety system. The challenging issue is that the “cause”—or the root-cause motivation—was nothing like any other food safety issue. The problem was not a microbe but a human adversary. The human adversary is intelligent, learns, and can actively seek to avoid detection. Traditional food safety countermeasures and control systems are at best “ill-fitting tools.” Of course, testing for melamine is good and will catch melamine, but “the goal is not to catch bad product but stop fraud from occurring in the first place.”

Once the effect—the incident—is under control, then preventive measures can be considered within the “Food Fraud Cell” of the Food Risk Matrix. To effectively and efficiently protect consumers and the company, there are several important best practices:

1. Each new incident must be assigned to a specific cell.
2. Someone must be clearly defined and recognized as accountable for the management of each cell.
3. A new incident cannot be a switch to another cell until the owner of that other cell accepted the switch.

Food Supply Chain Vulnerabilities

The food risks are present throughout the Food Supply Chain whether within or outside the proprietary channels. To consider the scope of food fraud prevention, the extent of the supply chain risks should be reviewed (Fig. 2.3). The most impactful problems have been adulterant-substances added to the raw materials and mislabeling such as origin or type of processing. Considering these food safety issues, the focus on ingredients is logical. Most of the food fraud incidents are categorized as a food safety hazard and, thus, usually first managed by a food safety workgroup (Moore et al. 2012; Everstine et al. 2013; Strayer et al. 2014; Everstine et al. 2017). The food safety group is focused on their highest risk products and activities that are incoming raw materials. The food safety group is often closely connected to Supplier Quality Assurance. This type of workgroup does not have responsibility for a product after it enters manufacturing—thus, the focus on food fraud prevention often does not expand past the (1) incoming goods and (2) manufacturing steps in the supply chain.

While fraud does occur on the Food Fraud Prevention Cycle at location “(2) Manufacturing,” the controls here are usually a combination of HACCP as well as Corporate Security such as employee theft.

Purchasing, Supplier Quality Control, and Operations usually end their focus after the product leaves the production facility to “(3) Finished Goods.” The control of the supply chain is often the role of a Traffic or Logistics Group.

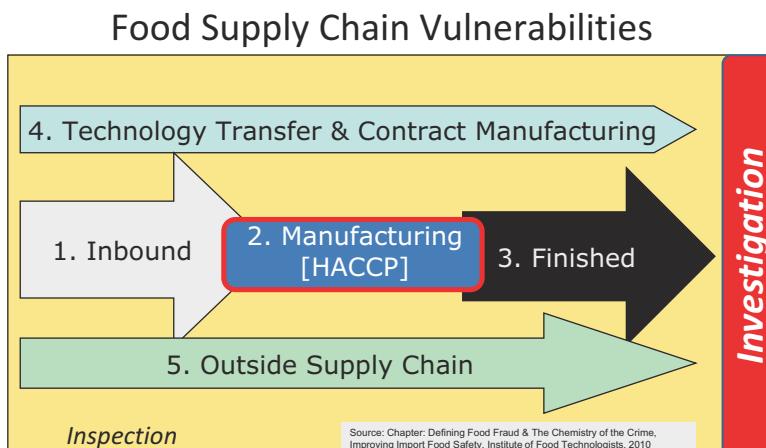


Fig. 2.3 The food supply chain with a focus on vulnerabilities that are identified by either inspection or investigation. (Copyright Permission Granted) (Spink 2012)

There is a fraud opportunity between “(2) Manufacturing” and “(3) Finished Goods” that could be employee theft, reselling of product that was sent for destruction, downgrading “first quality” product to “substandard” in a criminal scheme, or other weights or document fraud.

Of the two segments that are outside the normal operation the first is “(4) Technology Transfer & Contract Manufacturing.” The contract manufacturers are usually more under the control of the usual product quality but not always. The contract manufacturers are outside the day-to-day monitoring, so there is a unique “fraud opportunity.” Another segment is technology transfer where a brand may be licensed by a company in another country or region. This segment is usually administered by a legal group managing the legal contract.

There are other incidents that are also found and assigned to other parts of the corporation. For example, a counterfeit or diverted product that is found in a marketplace are often found during global brand protection audits by Corporate Security located at “(5) Outside the Supply Chain” and more generally “(6) Marketplace.”

When a problem is identified, it is assigned to the most common or convenient business function. If you find the counterfeit product in a far-away country, it is best to have Corporate Security engage criminal investigators in those countries (MSU-FBI 2018). A food science inspector in your home country would not have the skills or capabilities to conduct the criminal investigation, and they probably aren’t trained to avoid violence and personal security such as avoiding kidnapping. For this situation, the intervention is best led or at least coordinated by the Corporate Security function.

Personal Insight: Technology Transfer and Patent Royalty Payments

I presented at an academic Law School conference where several professors were getting great accolades for their patented crops. They were talking about patent negotiations and writing licensing contracts. It was a very exciting presentation because they were discussing the great financial payments for agricultural production based on the number of plants or trees in use. There was a royalty paid for each plant or tree used.

Considering product fraud, I asked how they monitored the use of their patents. There seemed to be a very high fraud opportunity if the patent buyer was providing the data for defining the amount of the payments.

I got blank stares.

I never got invited back to that conference speaker.

Root-Cause Analysis: Cause and Effect

Now that the type of food risks and the food supply locations of vulnerabilities have been presented, it is important to shift to focus on the root causes. The “cause” aspect is important to consider separately from the “effect.” The “cause”

is the reason why an incident could occur which would have a result of an “effect.” For food safety, there is HACCP to focus on the food safety “cause” and a very active and extensive system to deal with incidents or the “effect” of those potential public health harms. For food defense, there is also a threat assessment and control system methods to deal with contaminated products. For food quality, there are total quality management systems that extensively assess the root cause of possible anomalies. For food fraud, the vast majority of incidents do *not* have a public health harm so they do not trigger the food safety or food defense response systems. Also, the food fraud vulnerabilities would rank very low on a food safety or food defense risk assessment. Likewise, food fraud would be difficult to truly consider in a food quality system since there are so few incidents and usually so little of an economic impact. For all the traditional food risk responses, addressing and prevention of food fraud are just so complex, interdisciplinary, and fundamentally different.

For food safety incidents, there is a focus on the “effect” from “public health harm.”

The food safety vulnerabilities and risks are inherent in the nature of the food production (e.g., vegetables are grown in dirt, animals have produce feces in their bodies, and the food manufacturing operations constantly address these non-sterile challenges).

Based on the food safety paradigm, there is a belief that current control systems or HACCP plans are holistic and all-encompassing for all public health-related food risks. Food safety issues are not the root cause of all food public health hazards. When melamine was detected in infant formula and powdered milk, there seemed to be a food safety industry impression that the early warning systems worked since they detected the product. In reality, melamine was not a substance on the early warning system radar, and the “early warning” was the public health incidents—the detection was a response to human illness and death. Waiting for illness or death is not proactive and not the intent of an early warning system; rather, monitoring for illnesses is an outbreak rapid alert system.

The application to food fraud and prevention is that there is often a belief that the current food safety response systems and HACCP plans already are competently addressing the—and assumed all—food public health hazards.

The root cause of the food fraud incident is fundamentally different than for food quality, food safety, or food defense. Thus, a separate root cause analysis for food fraud would focus on the unique “cause” which is an intelligent, human, criminal adversary who is actively seeking to avoid detection.

For food fraud prevention, really the only practical approach is to consider vulnerabilities and address the root cause. When this focus is implemented, there can be simple and usually cost-effective risk treatment that vastly reduces or eliminates the fraud opportunity and the subsequent costs or illnesses.

Examples of Incident Impacts

To continue to focus on the root causes and to understand the complex challenge, it is important to review incidents. Food fraud incidents are not new, but there is a recent focus on clustering these types of activities and considering holistic, all-encompassing risk treatments.

It is widely documented that food fraud was present in the UK back to the 1800s by Accum, to ancient times by Pliny the Elder in his book *Naturalis Historia*, which was actually not completed at the time of his death in AD 79 during the eruption of Mount Vesuvius), and recorded even back as far as 1046 BCE in the writings of Zhou Dynasty in China (Wu et al. 2017). The first US food laws in 1906 and 1938 mentioned “fraud jokesters” and diethylene-glycol which also was cited as a danger in the US Food Safety Modernization Act of 2011. The same types of food fraud—actually the exact same fraud acts and substances—have continued to be a problem.

Several modern food fraud incidents occurred that escalated the danger and risks for companies, markets, and even countries. Several of the most impactful modern food fraud incidents include (Moore et al. 2012; Everstine et al. 2013; Strayer et al. 2014; Spink et al. 2016a):

- ~2004—Sudan Red carcinogen colorant in paprika and other spices (adulterant-substance)
- 2007—melamine in infant formula and pet food (adulterant-substance)
- 2012—horsemeat in beef (adulterant-substance)
- Continued announcements such as:
 - Peanut Corporation of America selling the product with known bacterial contamination (tampering)
 - Smuggled honey and origin laundering for tax avoidance (diversion)
 - Stolen raw poultry re-introduced to the supply chain (theft)
 - Ground peanut shells used to extend cumin (adulterant-substance)

The seemingly never-ending string of incidents has become more defined and catastrophic as an issue for several reasons including more product traveling farther and faster around the world, that global reach increasing the minimum efficient scale of production (larger manufacturing plants produce more product), a consumer preference for less processed or raw foods, and an increase in both the test precision and the availability of more tests being conducted, plus the more rapid communication of problems once they do occur.

The Economic Impact of a Food Fraud Incident

The economic impact of an incident can be very significant or catastrophic. Beyond the cost of a product recall or regulatory penalty is a possibly bigger loss of sales or loss of market capitalization (the value of a company based on its stock price).

It is estimated by Forbes magazine that McDonald's restaurants lost 0.8% in stock price due to an alleged date code tampering fraud in China. The 0.8% drop for a \$90 billion market capitalization is almost a \$900 million drop in the stock price. While stock prices fluctuate up and down, there is a problem when the fluctuation is based on a specific single incident or vulnerability. While not food fraud, another example is the impact on the entire New Zealand economy when the Fonterra Corporation has a suspected food safety incident. This led to a block of imports of some of their perishable dairy products. Fonterra is a co-op that represents New Zealand dairies and is a major part of the entire economy. It is reported that the New Zealand currency devalued during this crisis.

While in Macro, or enterprise-wide, the impact of the incidents is a result of micro- or fraudster-specific opportunities. The risks can be summarized to an overall impact, but the derivation of the estimates and the understanding of the fraud opportunity are specific to the individual actors. For example, the food fraud profit per truckload can be very high and even more humongous when considering one deal could be many truckloads (Table 2.2) (Moyer et al. 2017).

For more detail on how quickly the food fraud profits can accrue, it is helpful to review the details of an incident (Table 2.3) (Moyer et al. 2017).

Key Learning Objective 3: Prevention and Problem-Oriented Research

This section reviews the root cause of the fraud opportunity which leads to a strategy based on an understanding of the root cause to create prevention focused efforts.

The Key Learning Objectives of this section are to review

- (1) Why prevention is the primary and most efficient and effective response
- (2) Working from identification of the problem to seek solutions (and Envisioning food fraud prevention as similar to managing diabetes not fixing a broken leg)
- (3) Why an interdisciplinary approach is critical and most effecient

Table 2.2 Review of food ingredients, adulterants, estimated economic gain, and the units of one fraud incident

Food ingredient	Adulterant	Economic gain	Units
Wheat gluten	Melamine	\$31,000	Truckload (50k lbs.)
Wheat	Urea	\$11,000	Bin (10k bushels)
Apple juice	High-fructose corn syrup or hydrolyzed chicory syrup	\$18,000	Truckload (50k lbs.)
Tomatoes	Maltodextrin	\$12,000	Truckload (50k lbs.)
Spices (e.g., paprika, curry, chili powder, etc.)	Sudan dyes	Undefined	\$0.06 of dye probably increases profit by \$1+/lb

Adapted from DeVries (2013)

Table 2.3 Ingredient-level review of adulterated melamine in a hypothetical protein bar

Food ingredient	Percent content per bar	Cost per pound (of the raw material)	Genuine product: ingredient cost per 1 lb. bar ^a	Fraudulent ingredient cost in the finished good ^b
Peanuts	30%	\$1.00	\$0.30	\$0.30
Almonds	25%	\$2.40	\$0.60	\$0.60
Wheat gluten	20%	\$1.25	\$0.25	\$0.126 (\$0.25/2+ \$0.001)
Sugars	10%	\$0.20	\$0.02	\$0.02
Vegetable oil	10%	\$0.50	\$0.05	\$0.05
Salt/soda/misc.	5%	\$1.00	\$0.05	
Ingredient total	100%		\$1.27	\$1.146
Processing and packaging		50% of the total cost of goods sold (COGS)	\$0.64	\$0.64
Total cost (per bar)			\$1.91	\$1.786
Food fraud profit (per bar)				\$1.124
Pounds per truckload	50k pounds			
Total profit (per truckload; authentic vs. non-fraudulent)				\$6200
Truckloads per sale	10 truckloads			
Total food fraud profit				\$62,000

Adapted from Moyer et al. (2017)

Note ^afor simplicity, a 1 pound single serve bar was used]

Note ^b10% melamine at \$0.01 per pound

The Efficiency of Prevention: The Only Really Logical Strategy

While it may seem completely logical to state the efficiency of prevention, there are often proposed countermeasures or control systems that do not address the overall concept. When considering the overall food risk focus, the food fraud problem is to address all types of fraud for all products and a proactive, strategic approach. The fraudsters are focused on any criminal act that allows them a high probability of achieving their highest available economic gain, so the response is likewise aligned. Once the assessment of the overall problem and the prevention strategy is in place, only then can detection and deterrence countermeasures and control systems be considered and assessed. The chapter on Risk Analysis and the other on Risk Assessment Application will cover this concept in more detail and with examples.

Shifting to Prevention: Why Hasn't This Been Addressed Proactively Before?

An occasional question is that if food fraud has been around since the beginning of recorded history, then why has it not been directly addressed? There is a question of why a government would “allow” this to continue not to be directly addressed? Also, if there are so many economic harms to a company, why haven’t they addressed this sooner? The answer is based on the complexity of the crime and the extremely interdisciplinary strategy.

Also, later in the Criminology Chapter, there will be a more detailed discussion about the complexity even of classifying product fraud as a “traditional crime” or a “white collar crime.” The research led product fraud identified as a hybrid crime where the preparation is more of a typical “white collar crime” and the activity is more of a typical “traditional crime.” Anytime a problem falls outside of normal and simple categories, there are additional challenges regarding accountability and responsibility.

Regarding the complexity of the detection of the fraud act, to begin there are two parts to the response to the incidents which are detecting the fraud and then prevention countermeasures and control systems. First, there is detecting the food fraud act. Industry and agencies already have systems in place to detect contaminants (regularly occurring, expected “things”). When an incident like melamine occurs, it becomes known, and, if it seems to have a chance of occurring again or in a more harmful, the adulterant could be categorized in an Early Warning System as a “contaminant.” The *reactive* systems start to look for that contaminant.

This is applicable to those contaminants that are known and can be expected to recur under the same general conditions and in the same way. For food fraud, there are a nearly infinite number of adulterants. Also, just because there is a fraud opportunity (e.g., the price of a commodity sky-rocket), this does not mean there is always an incident.

The human fraudster may be a biological organism that does respond to opportunities. But unlike a microorganism, the human fraudster will not always respond the same way each time to the same stimuli or conditions. The human fraudster is often intelligent, creative, resilient, patient, and often very well-funded. Also, the human fraudster may decide for some reason *not* to act. Beyond this generalization, the macroeconomic conditions do not always apply to an individual human fraudster. Each human fraudster is like a separate species of microorganism—or at least a single species that has exhibited a nearly infinite number of mutations or adaptations. Each human fraudster has an extremely varied set of characteristics and motivations.

To explain this analogy, consider that *E. coli*, *Salmonella*, and *Listeria* are three microorganisms. While most *E. coli* (the general genus *Escherichia*) are not only harmless to humans but actually play an important role in gut health, there are pathogenic strains such as *E. coli* H1N1 that pose a very serious public health threat (CDC 2018). That said, all *E. coli* will respond to environmental conditions, in the same way, every time (admittedly, there may be some mutations or abnormal

individual organisms). With the human fraudster, the response to the condition is much more individual. For example, the global change in cocoa pricing will have no effect on a fraudster dealing with tea. Also, that global change in cocoa pricing may have no effect on a fraudster selling hot chocolate to a company that has very strong incoming goods quality control tests—the fraudster may decide it is a “rational choice” *not* to try to commit the fraud act (for more, see the Criminology chapters).

To review the question of whether there is a practical and pragmatic response to address food fraud prevention, in response to that, the blame is on academia (including the authors of this book) for not more fully grappling with the challenge sooner. While the academics have been improving detection, and separately growing criminology concepts such as Situational Crime Prevention, there has been a challenge to develop a paradigm-shifting theory that addresses the challenge of integrating a multiple of disciplines. It is very difficult to apply a complex web of disciplines to respond to a complex problem such as food fraud. The food fraud opportunity has continued to grow because of the very nature of the complexity. The bad guys have been able to evolve to exploit even minuscule new guardian and hurdle gaps—there are capable guardians and hurdles but an even more nimble criminal response.

These all are factors that have led to challenges when focusing on the overall Food Fraud Prevention Strategy.

Food Fraud as a Disease: Managing Diabetes Rather than Fixing a Broken Leg

There is a saying:

Food fraud prevention is like managing diabetes not fixing a broken leg -- for diabetes, the patient may look fine today but without monitoring and treatments but danger could be close at hand.

Another challenge when considering prevention has been the lack of information on the incidents and the general lack of incidents. Let’s consider food fraud to be a new disease. We don’t wake up one day and figure a way to cure or manage a disease. There are many years of patients showing up sick at the hospital. This is the effect, and we don’t yet understand the cause... we don’t even know that it’s a new disease. Along the way—or over possibly the 100s of years—we start to see a pattern, but it is faint. Each doctor, hospital, or country just doesn’t see that many of these specific rare cases. As more information is stored and more readily accessible, and as we have more and better testing, we can learn more about the illness. At some point, we have a lucky break—usually an outbreak or a cluster of incidents—that lead us to identify it is really a new disease.

This is the “eureka” moment when we shift from intervention through response to prevention (Fig. 2.2). We don’t start with prevention, and we don’t even start with a response. Only after those two can we cycle back up to prevention.

For example, in the USA, there was an incident where we started to see many pets dying. We had no idea why they were dying, but we did the best we could to treat them (intervention: the public health system and their healthcare professionals). At some point, we figured the root cause was melamine, found it in the pet food and the pet food was recalled from the marketplace (response: the marketplace and the industry recalling product). Then to focus on prevention, we began to implement testing for melamine in raw ingredients and finished goods (prevention and the industry conducting tests).

So while the system evolved to address melamine, we were aware that the problem wasn't just melamine. The fraud opportunity was not just for melamine but for all types of protein fraud. The food industry, agencies, academics, and others began working together to understand the fraud opportunity better and to implement holistic, all-encompassing countermeasures. This activity is underway, and a first step is improved intervention and detection methods and also establishing a common frame of definitions and a prevention focus.

Personal Insight: Food Fraud Prevention into Action

So, food fraud was known, but there was not enough information to really establish a common, effective, holistic, all-encompassing, preventative approach. I stated in a public forum meeting in 2010 when asked if I thought "industry was doing enough to address food fraud" I responded with "based on the way we academics – and the laws – have defined food fraud and prevention... I think industry – and agencies – are doing a fine job." The key is how food fraud is defined and addressed in the laws. There are great strides being made considering how little is really known about food fraud prevention.

I was told that is it usually at least 5–10 years between an article published in a scholarly article makes an impact in the real world. While I continue to emphasize that there was excellent work in food fraud before our article, our article was the first scholarly article with research focused on the definition of food fraud. So the term was defined in November 2011. Just about 2 years later, food fraud had just entered the mainstream. Several key dates and milestones include:

- February 2017: The GFSI Guidance Document version 7 was published that included food fraud requirements as of January 2018.
- May 2016: The FSMA Intentional Adulteration Final Rule was published with a full implementation date in "three years after the publication of the final rule" (FDA 2016).
- September 2015: The FSMA Preventive Controls Final Rule was published with a full implementation date for large companies "required to be in compliance on September 19, 2016 (two-thousand and sixteen)" (FDA 2015a, b). The term economically motivated adulteration was included and the term "defraud" and "fraudulent" but not specifically "food fraud." This includes addressing any hazard from any source including the act that is for "economic gain" and for any

product—thus, FSMA has essentially required a full Food Fraud Vulnerability Assessment and Food Fraud Prevention Strategy since at least September 2016. The publication date of the final rule was forced by lawsuits to be published by August 31, 2016, so additional changes—such as further addressing EMA or possibly expanding to use the term “food fraud”—was not possible due since new addition edits would require an additional open comment period (Case4:12-cv-04529-PJH [2012](#); CRS [2016](#); Case No.: 3:18-cv-06299 [2018](#)).

- July 2014: The GFSI board of directors published the “GFSI Position Paper on Mitigating the Public Health Risk of Food Fraud” ([GFSI 2014](#)).
- February 2014: The GFSI Food Fraud Think Tank presented their recommendation to include food fraud in their Food Safety Management System (a final report but not a public document)
- February 2014: The GMA published their Brand Protection report ([GMA 2014](#)).
- January 2014: The US Congressional Research Service published their report on food fraud which is a demonstration of congressional interest in a subject ([CRS 2014](#)).
- December 2013: The first draft of the FSMA Intentional Adulteration draft rule was posted on the Federal Register with a request for comments, and it mentioned a shift from economically motivated adulteration to the preventive controls rule. This was a significant shift in focus from a local threat or target-specific food defense-type countermeasures to more preventive controls ([FDA 2013a, b](#)).
- October 2013: The EU proposed a draft referendum on food fraud which proposed a common definition of food fraud ([CRS 2014](#)).
- July 2012: The GFSI convened a Food Fraud Think Tank to review the subject.
- November 2011: Peer-reviewed journal publication of “Defining the Public Health Threat of Food Fraud” ([Spink and Moyer 2011](#)).

Before that publication in November 2011, there was momentum starting on the related topics:

- October 2011: The GMA published their Capturing Recall Costs report (that included fraudulent and criminal acts) ([GMA 2011](#)).
- April 2011: The first draft of the FSMA Preventive Controls draft rule was published on the Federal Register with a request for comments, and it had no mention of economically motivated adulteration or fraud ([FDA 2013a, b](#)). Later, EMA was added to this rule after the Intentional Adulteration draft rule directed the change ([FDA 2013a, b](#)).
- January 2011: The US Food Safety Modernization Act (FSMA) was signed into law and identified actions for “economic gain” but did not mention fraud.
- November 2010: The GMA published their report on Consumer Product Fraud (which featured food fraud) ([GMA 2010](#)).
- May 2009: FDA public meeting on Economically Motivated Adulteration where the “FDA working definition” of that term was first published ([FDA 2009](#)).

So, food fraud prevention is being addressed and implemented. There has been quite a bit of focus on reactive and responsive actions. This seems to be common for

analytical science and also for enforcement organizations. These might seem like two very different types of groups, but the core theory is that when faced with challenges, we, as humans, respond with our current resources, what we know, and what we can implement right away.

So, analytical chemists, faced with the melamine adulteration, naturally approach the problem from their world view—a natural first step is to increase the focus on food authenticity detection. Their focus increases the ability to “detect” fraudulent product.

Also, enforcement organizations, faced with melamine adulteration, naturally approach those problems from their world view—a natural first step is to find, arrest, and prosecute the food fraudsters. Their focus increases the ability to “deter” the fraudsters (at least to some degree, for those who are currently committing fraud, get caught, and are persuaded not to continue committing fraud -- that will be discussed further later).

These linear solutions fit for a linear problem. With food fraud, there are a nearly infinite number of adulterants, and there are a seemingly near an infinite number of fraudsters. (When considering the adulterants, there are also ways to commit fraud that do not include an adulterant at all... such as for genuine but stolen products.) There is a saying that “for food safety that we will not test our way to safety.” Also, we’re not trying to make “food, safe” we’re trying to make “safe food.” For food fraud prevention, we’re not going to arrest our way to safety. We’re not trying to catch food fraud we’re trying to prevent the fraud opportunity in the first place.

Prevention Addresses Problems: “Problem Looking for a Solution” or “Solution Looking for a Problem”

Since food fraud prevention is focused on the fraud opportunity and a strategic prevention approach, to reduce vulnerabilities, there is an obvious need for countermeasures and control systems. The risk manager—brand owner or manufacturer—addresses the overall, enterprise-wide, holistic, and all-encompassing strategic problem and then to tactically address a specific incident. The specific incident is straightforward and a very finite problem and response. On the other hand, the suppliers of the countermeasures and control systems are of course trying to apply their product to the user need. The implementation of the overall Food Fraud Prevention Strategy compliance requirements will help with this conundrum. The more harmonized and standardized the strategy, the more clearly both sides will understand the problem (diagnosis or root cause), optimal countermeasures, and control systems (risk treatment) and understand then “how much is enough” (prognosis that results in decision) (see the section on Diagnosis, Treatment, Prognosis, and Decision).

In the absence of a harmonized and standardized food fraud prevention approach, it was most simple to take a direct, tactical approach to start by considering solutions before there was even the creation of an overall strategic vision. At that point, the strategic problem was not yet clarified which has been a constant challenge for anti-counterfeiting and security products suppliers across all industries.

Product and service providers—admittedly, including academics seeking funding for research or tuition dollars from students—are usually a “solution” looking for a “problem.” Suppliers often present only a factual statement about the new technology or service “feature” and let the customer figure the actual application “benefit” of how it resolves a problem. The problem is that the “features” of the product are usually presented without a clear explanation of the specific “benefit” for the customer. To be fair, it is the job of the supplier to sell their products not to solve the world’s problems.

Sidebar: A Solution Looking for a Problem or a Problem looking for a Solution?

The concept of a “solution looking for a problem” may seem abstract or confusing, so an example will be provided.

During the Silicon Valley Dot-Com era, there were massive innovations in computer technology and online applications. It was referred to as the “dot-com” era because of the Internet websites that ended in “.com” (though later referred to sometimes as “dot-bomb” after many of the companies went out of business). During that time there was the development of technology “solutions” for “problems” that had not actually been specifically identified. The computer science sometimes expanded for technology sake, not for an actual market need. There was a saying that it “was a solution in search of a problem.” In the information technology field, there is often a strategy from the venture capitalists to invest in many start-up companies to hedge their bets that one will be a low-probability/ high-return investment. It was seemingly lucky if a technology innovation efficiently met a market need or “problem.” Some of those “lucky” products received big financial gains during their exit strategy of selling to a bigger company while some even stayed in business and succeeded.

A “solution looking for a problem” is the process to first create a unique, patentable, defensible technology and then try to sell it by identifying problems where it might fit. The opposite approach is to clearly identify and research a problem and then consider theoretically the perfect response. After clearly identifying the problem, then a targeted solution is sought or developed.

In the discipline of Criminology, when addressing a new “problem,” there is a focus on “environmental criminology” or the physical space of crime (for more, see Criminology chapter) (Beirne and Messerschmidt 2005). The focus is also on the human adversaries through concepts such as “rational choice theory” and “routine activities theory” (Cohen and Felson 1979; Felson and Clarke 1998; Clarke and Eck 2005). The criminologists focus on the root cause of the problem. An example is the influential publication

(continued)

“Crime Prevention in 60-Easy Steps” (Clarke and Eck 2005). This essentially explores the details of the “crime opportunity” and then considers countermeasures and control systems. Essentially this focuses from the “problem outwards” to only then consider countermeasures or “solutions.”

Food fraud prevention research began with that focus on the center or the “fraud opportunity.” Once that was understood, then it became clearer on how to prevent food fraud.

Without a focus on the overall fraud opportunity—or a vulnerability assessment for the entire system—then picking countermeasures and control systems is a guess at best. Without that enterprise-wide assessment, then stakeholders often hear of a new technology (solution) and try to apply it to the problem (“a solution looking for a problem”).

The application to food fraud prevention is that it is most efficient—critical—to focus on the fraud opportunity and then apply that insight to understanding what might contribute to detect, deter, and prevent.

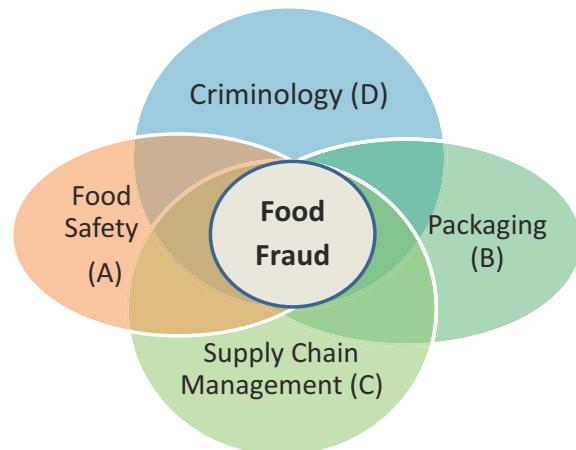
Personal Insight: The Positioning of Food Fraud Prevention

After reviewing the challenge of considering and selecting countermeasures and control system, a more basic question is about what is the science and sciences of food fraud prevention?

For our MSU research, the first academic home was in food safety where there was engagement in graduate course development, teaching, and research (see point A in the figure below) (Fig. 2.4). Next, the packaging science familiarity led to a natural consideration of packaging countermeasures and control systems such as traceability and anti-counterfeit security features (see point B, in Fig. 2.4). When including these two disciplines, the activity was still reactive—catching fraudsters by authenticity tests or counterfeit packaging or labels. The next innovation was including Supply Chain Management (SCM) (see point C). Supply Chain Management focus is on optimizing the transit of genuine products, so there was no a clear academic resources yet. The next important step was digging deeper to the root cause which was the human adversary which led us to Criminology (see point D). The first person to bring Criminology theory of Situational Crime Prevention to food fraud research the MSU School of Criminal Justice colleague Dr. Robyn Mace. Later, another MSU School of Criminal Justice colleague Dr. Justin Heinonen helped refine that focus into the SARA method and from a Victimology perspective. Our first immersion in Criminology was through the book *Crime in Everyday Life* by Felson (Felson 2002). This book introduced the crime triangle which has been a—or the—foundation of food fraud prevention.

Since the fraud prevention research was “from the problem outward”—rather than trying to apply one academic discipline to the new problem—there were constantly new disciplines that provided incredibly efficient contributions to prevention (next Fig. 1.1).

Fig. 2.4 The first disciplines considered to address Food Fraud Prevention: single or dual discipline “interdisciplinary research” then evolving to “multidisciplinary” researchers, education, and outreach. (Copyright Permission Granted) (Spink 2009)



Every time we gave a presentation we seemed to identify another discipline that adds to the science. As recently as late 2017, we were researching news media responses to suspected food fraud activity. This led—obvious in hindsight—to seek out journalism scholars. Michigan State University has a top Journalism Department in our College of Communications Arts and Sciences. Eventually, we found a scholar colleague Dr. Eric Freedman (Knight Chair in Environmental Journalism, director of the Knight Center for Environmental Journalism and a professor in the School of Journalism), who had research expertise in a similar area of science journalism. This collaboration led to a research project and journal article submission on investigating food fraud suspicious activity.

Earlier, when the political science and social anthropology were presented, first, the basic concepts were identified as critical but foreign to the current researchers. To step back, when hearing “social anthropology,” the thought came to mind of the movie character Indiana Jones digging up ancient artifacts. That is “archeology” the study of humans through their artifacts where “social anthropology” is the study of how and why humans interact in their culture. When this concept was presented to several senior anti-counterfeiting industry leaders, they were very interested. The encouragement led to even more of the research study of the motivation of the fraudsters. Not considering social anthropology is inefficient or even dangerous if the researchers or practitioners do not understand how and why people interact with each other and outsiders they cannot understand how to influence them.

These are all examples of the interdisciplinary nature of food fraud prevention. These disciplines have been considered in the development of food fraud prevention (Spink 2009).

The Disciplines of Food Fraud Prevention

Beyond the core disciplines of food safety, packaging science, supply chain management, and criminology, there are many others that contribute to understanding and controlling the problem (Fig. 2.5).

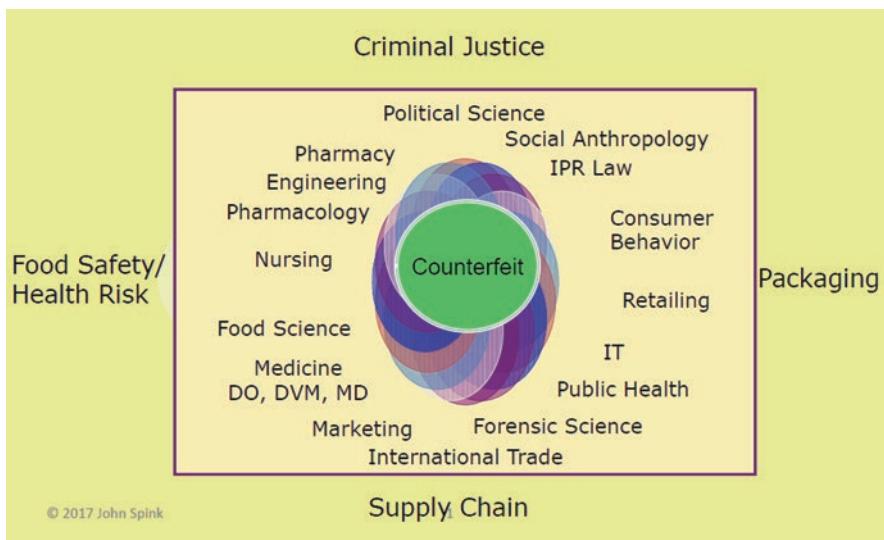


Fig. 2.5 Presentation of the extremely interdisciplinary nature of product fraud prevention. (Copyright Permission Granted) (FDA 2009; Spink 2009)

It became evident that almost any and every discipline has a contribution to helping understand the fraud opportunity, the role of the bad guy or consumer, or even the overall concept of prevention. This growing list of disciplines led to a focus on “food fraud” as a separate discipline.

Later, the science and sciences of food fraud prevention was organized in a honeycomb network of interrelated activities (Fig. 2.6) (Spink 2017).

Research Approach: Interdisciplinary Versus Multidisciplinary

Food fraud prevention is so challenging because it requires an *interdisciplinary approach* (Gray 2011). Traditionally an event that had a food safety hazard was assigned to a food safety group, and—logically—food safety countermeasures and control systems were applied. The problem is that “if the biological organism in question was a micro then we would use the discipline of microbiology; since the biological organism in question is a human we obviously must use the discipline of social science and criminology” (Wu et al. 2017). When the starting point is in one discipline, it is a challenge to expand to interdisciplinary—especially with such a leap such as from microbiology to criminology...let alone adding social anthropology, public policy, or political science. What is required is to step back and consider the root cause and only then consider the ultimate objective and then seek out the disciplines that help. The root cause is a human adversary perceiving a fraud opportunity and then having the opportunity and motivation to act. The ultimate objective is to put countermeasures and control systems in place that dissuade the human adversary from acting. Finally, the disciplines that most directly apply are



Fig. 2.6 The science and sciences of food fraud prevention. (Copyright Permission Granted (Spink 2017)

criminology, supply chain management, business (including considering the criminal enterprise having business characteristics) decision-making, and then science and technology to detect the fraud act.

Multidisciplinary Versus Interdisciplinary Approach

Beyond just the interdisciplinary group, there is a need for multidisciplinary researchers. The food fraud problem is very complex, and the fraud opportunity is created due to many complex supply chain networks combined with a patchwork of laws, regulations, standards, and certifications. Food fraud has not been defined as a specific area of study or as a particular responsibility of one group. The complexity of addressing food fraud is based in part on the need for an interdisciplinary or multidisciplinary understanding of the problem. In 2011, Dr. J. Ian Gray, MSU Vice President of Research and Graduate Studies, presented some insights ((Gray 2011) referring to (Pain 2003)). He stated that: “Multi-(or plural-) and interdisciplinary research – often used interchangeably, but originally referred to different approaches.”

- **Interdisciplinary:** “When experts from different fields work together on a common subject within the boundaries of their own disciplines, they are said to adopt a multidisciplinary approach. [...] If the experts stick to these boundaries of their own discipline, they may reach a point where the project cannot progress any further. They will then have to bring themselves to the fringes of their own fields to form new concepts and ideas – and create a whole new, interdisciplinary field.”
- **Multidisciplinary:** “A transdisciplinary team is an interdisciplinary team whose members have developed sufficient trust and mutual confidence to transcend disciplinary boundaries and adopt a more holistic approach.”

As food fraud is researched, it becomes clear that many disciplines contribute to the understanding and holistic perspective on the “fraud opportunity.” Food fraud is not only a problem of crime, food, business, food authenticity, packaging, traceability, supply chain management, social anthropology, political science, enhanced traceability transaction security, a customer problem, or a legal problem.

Dr. Gray also discuss *The Third Revolution* which is the convergence of the life sciences, physical sciences, and engineering (Sharp et al. 2011):

- “Convergence is a new paradigm that can yield critical advances in a broad array of sectors, from health care to energy, food, climate, and water.”
- “Convergence is the result of true intellectual cross-pollination.”

Not to get too philosophical, but the Science Fiction writer Isaac Asimov identified some of the future problems regarding researcher over-specialization (Asimov 1989):

1. “Could someone be a truly great mathematician if math was all they knew?”
2. “Specialists doing to their specialty to avoid thinking about anything else.”
3. “Over-specialization … it cuts knowledge, and it leaves it bleeding.”

While this multidisciplinary and third revolution convergence may be the future, there is usually little funding or resources for this new type of research. While there is an effort to support the interdisciplinary research activities of bringing experts in disciplines together, University Departments are organized by unique disciplines, judged on funding, publications, and thought leadership in their specific field. The multidisciplinary researchers are often some of the most productive on campus (e.g., at one University the fixed-term versus tenured faculty-led more of the \$1 million+ funded projects); they are often considered extension, practitioners, or outreach functions. So, while food fraud prevention is developing based on a marketplace need, due to the slow new funding, the research and multidisciplinary teams are slowly organically growing.

Management Structure: “Who ‘Owns’” It?

The multidisciplinary conundrum is also present in corporate accountability or governance with the question “who owns it?”

Another complexity to addressing food fraud prevention is even within a company and the role of assigning accountability. Before reviewing how to assess the problem, there is an important question of “who owns it” or basically what job function should address food fraud.

There is a complexity to food fraud that has led to inefficient strategies. A challenge is that the problem and controls are spread across the functions of a company. Using Michael Porter’s Categories of Tangible Interrelationships (defines a company’s job functions as primary and support activities) (Porter 1985), the concepts are plotted for identifying what function “creates” the problem, who “cleans” the problem, and finally who best can manage to “deter” the problem (Fig. 2.7).

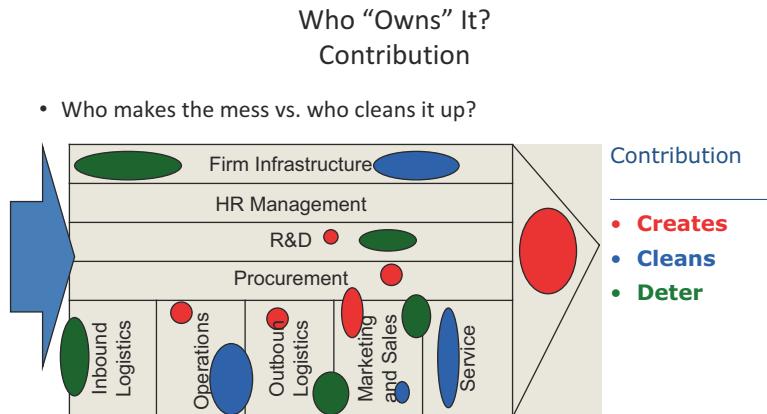


Fig. 2.7 Adaptation of Porter's corporate structure to show where product fraud problems are created, who responds, and where is the most efficient and effective deterrence or prevention. (Copyright Permission Granted) (Spink 2011)

An old story helps present insight into the complexity of the problem of implementing countermeasures and control systems. Product counterfeiting was a problem for a company. Corporate security conducted a major investigation and raid that resulted in the prosecution of a counterfeiter and the seizure of millions of dollars in counterfeit parts. These were “deceptive” counterfeits sold as “genuine,” so each part seized directly added to sales. The “ROI” on the seizure was very clear and realized by the Sales Department in the next sales cycle (Fig. 2.8). The Packaging Department was tasked with identifying and proposing new anti-counterfeit packaging components. When the packaging group sent the decision to the Purchasing Department the question was “ok, we’ll purchase the new packaging components but whose budget do we charge?” In this case, the Operations Department didn’t yet know they would have an additional operations cost!

At this point, the Purchasing Department was not provided additional budget dollars to cover the new products. The Sales Department wasn’t interested in volunteering the transfer of budget funds because the revenue was the avoidance of loss or future gains.

The application to food fraud prevention is that this was a case study the helped define the need for an overarching corporate policy as well as engaging enterprise risk management to more clearly define what the risk was outside the “risk tolerance.” A clearly defined corporate policy cannot be ignored. A risk that is clearly defined as outside the “risk tolerance” must be addressed or now disclosed—corporations don’t want to provide new disclosures of risks...especially inherent risks that have been present but unknown...what other risks might be unknown?

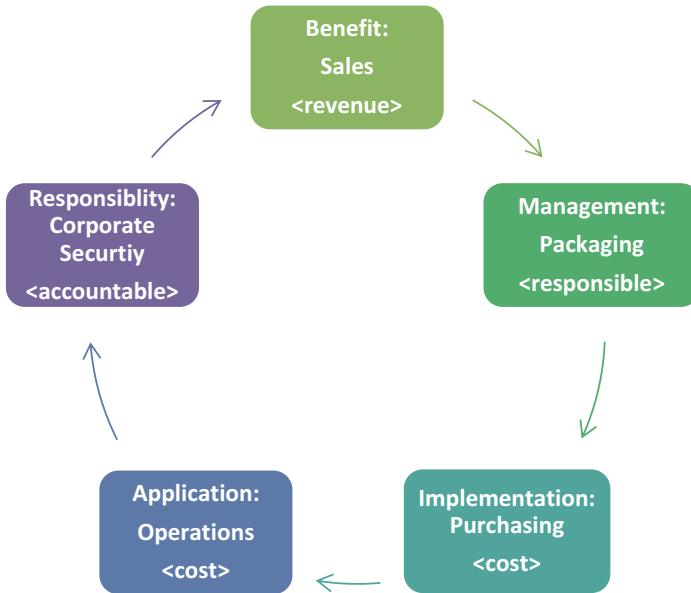


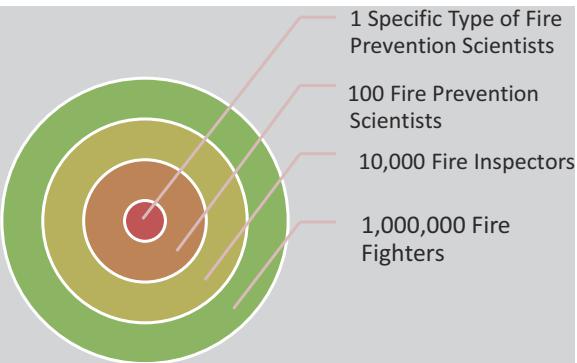
Fig. 2.8 Relationship cycle within an enterprise of benefit, management, implementation, application, corporate benefits and then back to the start. (Adapted from (Porter 1985))

Sidebar: Fire Prevention and Ben Franklin

Food fraud prevention is not exciting, and if done right, then it is intentionally monotonous and boring. It is exciting and newsworthy when a fireman runs out of a burning building rescuing a baby. On the other end of the spectrum, watching a fire inspector makes sure that the smoke detectors are working and the fire exits are well marked is about as exciting as “watching paint dry” (which is not very exciting). Listening to a building code review of fire resistance structural features is literally reading an engineering textbook (also, even less exciting than watching paint dry). *But* the most efficient and effective way to reduce the “fraud opportunity” is the prevention details. It may be exciting to purchase new and faster fire engines to put out fires faster, but it’s much more efficient to try to prevent the fires from starting in the first place (Fig. 2.9):

- For every 1000 firefighters who are trained in fire intervention, there might need to be 1 fire inspector.
- For every 1000 fire inspectors who are trained in the detection of vulnerabilities of fires, there might need to be 1 fire prevention engineer.
- For every 1000 fire prevention engineers who are trained in prevention science, there may need to be 1 engineer studying fire incidents for new root causes.
- *And* each person and job is critical to protecting society from injury from fires. Some of the actors are focused and trained on a different topic.

Fig. 2.9 Fire prevention human resource allocation example of fire fighters, fire inspectors, fire prevention scientists, and specific type of fire prevention scientist



- A complex and complicated follow-up assessment is how much is invested in each type of job.

Questions to start addressing the question could include the following: Are the firemen equipped or trained to conduct fire inspections? Are they educated on civil engineering theories about how to reduce the spread of chemical fires? No. Should they? No. *But* the people “accountable” for protecting public safety *are* “accountable” for addressing this root cause or vulnerability.

The famous Ben Franklin quote of “an ounce of prevention is worth a pound of cure” was reportedly based on his work during the creation of the Philadelphia Fire Department (Franklin 1735). When addressing fire prevention, he is reported to actually have said: “an ounce of prevention is worth *ten* pounds of cure.”

The application to food fraud prevention is that the same holds true for food fraud prevention. There is a need to step back and consider the root cause as well as the most efficient and effective ways to address the prevention actions... regardless of your current experience or education. This is consistent with many other concepts that will be covered later including ISO 31000 Risk Management that begins with “establishing the context.” For every 1000,000 food investigators, there only need to be a handful of food fraud prevention scientists.

Conclusion

This second Introduction chapter expanded on the definitions and scope of food fraud to the critical foundational or organizational subjects such as the food risks, the types of harm including why there is a fraud opportunity. In combination these two Introduction chapters present that for efficiently and effectively reduce the fraud opportunity—the goal is not to catch bad product but to prevent the food fraud act from occurring in the first place—addressing all types of fraud is critical as is a primary and holistic focus on reducing the fraud opportunity through prevention. The nature of the fraudsters is to attack any and all vulnerabilities, so an equally interdisciplinary approach is needed to understand and respond to that fraud

opportunity. ***The first conclusion is*** that there are a wide range of food fraud attributes that expand the vulnerability beyond public health harm and traditional detection and enforcement responses. ***The second conclusion is*** that the nature of the fraud act and the fraudster leads to vulnerabilities that are outside the usual focus areas of the proprietary, authorized, and legitimate supply chain. This recognized to also be outside the traditional HACCP programs or scope. ***The final conclusion is*** that there are many reasons why there has not been a coordinated, strategic, and interdisciplinary focus on the fraud opportunity. As with historical innovations such as the implementation of quality management or environmental sustainability programs, there is an unmet need that becomes so extreme that a paradigm shift is necessary and then the methods are developed. For food fraud prevention, that paradigm shift is underway which includes broadening the focus to all types of fraud, to all products wherever they are in the supply chain, and then a shift from response to prevention through criminology and business management focused efforts to reduce the vulnerability or fraud opportunity. If there's no fraud opportunity, then there's no fraud opportunity. There is a saying:

If there is no fraud opportunity, then you could be buying from the famous criminal Al Capone, and he wouldn't commit a crime against you... if there is no fraud opportunity, then he would not find a crime to commit (Of course you'd rather not buy from a known criminal).

Appendix: WIIFM Chapter on Introduction to the Concepts

This “What’s In It For Me” (WIIFM) section explains why this chapter is important to you.

Business Functional Group	Application of This Chapter
WIIFM all	Due to the complex nature of the risk, expand the focus from just addressing a problem or corrective action to the calibration of the overall vulnerabilities of the enterprise.
Quality Team	Food fraud is very different non-traditional food safety hazard that requires a unique shift to prevention, and that has a focus on new and unique vulnerabilities.
Auditors	The assessments and strategies you see will be very different from health hazard assessment and based more on business decision risk assessment.
Management	There is a solid foundation of scholarly literature, and there may be a need for additional training and education— but your implementation does not need to be costly since there are many synthesized and refined resources.
Corp. Decision-Makers	While this may seem like a very odd and abstract risk, there are work processes that are very strategically based and integrated with all other enterprise-wide risks.

Appendix: Study Questions

This section includes study questions based on the Key Learning Objectives in this chapter:

1. Discussion Question

- (a) Why does FF require a fundamentally different approach than addressing other types of food risks?
- (b) What are the most dangerous aspects of a FF incident (define “dangerous”)?
- (c) Does the type of food fraud change the concern for potential health harms?

2. Key Learning Objective1

- (a) What is “Product Fraud” and the relationship to “Food Fraud”?
- (b) What are the “Product Fraud” attributes?
- (c) What is the different enterprise risk of a product in a “Primary” or “Secondary” market?

3. Key Learning Objective2

- (a) What is a Food Fraud “Indirect Risk”?
- (b) What is the difference between “Detect” and “Deter”?
- (c) Is Food Fraud a non-deceptive counterfeit product?

4. Key Learning Objective3

- (a) What is “Smuggling” and in relation to “Diversion”?
- (b) Is “Port Shopping” a type of Food Fraud and if so, then why—or why not?
- (c) Explain why all types of Food Fraud are a compliance requirement of FSMA 21CFR117?

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Chapter 3

Food Fraud Prevention Overview

(Part 1 of 3): Basics



Summary

This chapter presents the overall food fraud prevention concept and introduces the fundamental theory of prevention, the relation of food fraud to all other food risks (e.g., food quality, food safety, and food defense), why the core focus is prevention, and finally the Food Fraud Prevention Strategy (FFPS). There is a specific focus on how these activities interact and also how new information enters the cycle. The next chapter will expand to include the application of the Food Fraud Prevention Cycle (FFPC).

The Key Learning Objectives of this chapter are

- (1) **The Interdisciplinary Prevention Approach:** This section will start with prevention versus reaction and then present the wide range of disciplines that cover the entire food fraud problem.
- (2) **The Interdisciplinary Nature of Prevention:** This section will review the interdisciplinary nature of prevention by considering how the fraud opportunity is created and the many academic disciplines that help risk assessors understand the identification of optimal countermeasures and control systems.
- (3) **Understand the Prevention Strategies:** This section presents several concepts that are important for shaping the prevention strategies. There are fundamental or principal theories that support the need to focus on vulnerability and the fraud opportunity.

On the Food Fraud Prevention Cycle (FFPC), this chapter addresses the overall fundamental prevention concepts of “connecting everything to everything” (Fig. 3.1).

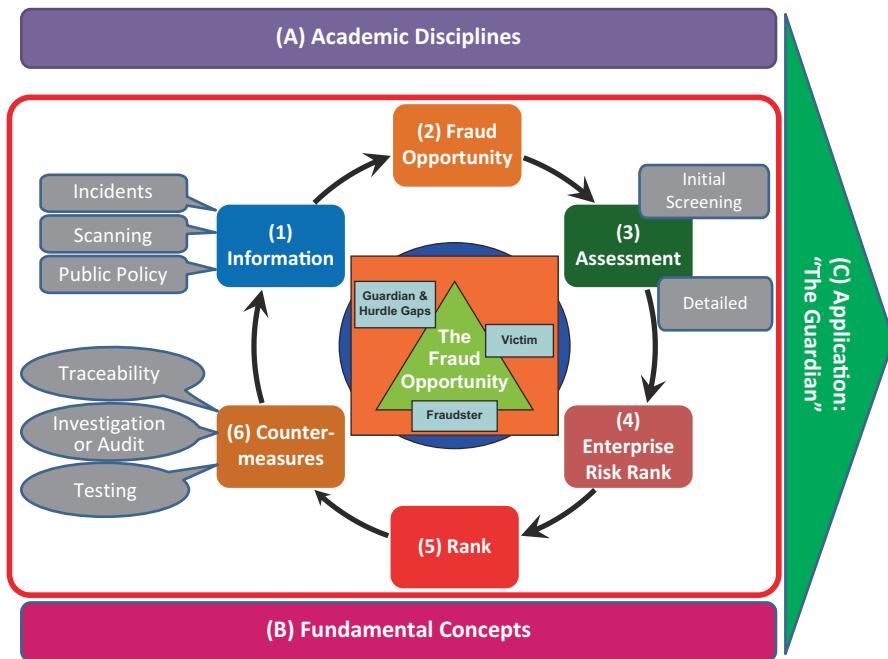


Fig. 3.1 Food Fraud Prevention Cycle—where this chapter applies to the overall concept: The entire Cycle 1, 2, 3, 4, 5, and 6 and the fraud opportunity. (Copyright Permission Granted) (Spink 2014; Spink et al. 2019)

Introduction

Food fraud is a fundamentally unique food risk since the root cause is an intelligent human adversary who is actively seeking to avoid detection. The human fraudster has the potential for a large economic gain, so they have the incentive and can justify financial spending to attempt to circumvent the countermeasures and control systems. The core goal of the prevention strategy is to reduce that fraud opportunity to the point that the fraudsters are dissuaded.

Key Learning Objective 1: The Interdisciplinary Prevention Approach

This section reviews the complex food fraud problem by considering the interdisciplinary approach combined with a practical and pragmatic consideration that prevention is the most effective approach.

The key Learning Objectives of this section are:

- (1) Interdisciplinary approach
- (2) “Why can’t we just arrest all the fraudsters?”
- (3) The methodical and efficient focus of the prevention approach

Overview of the Prevention Approach

While many disciplines are required to efficiently and effectively reduce the “fraud opportunity.” Each approach to the process, and their value and efficiency, must be judged in relation to their contribution to the overall prevention. A single-discipline approach is limited in effectiveness. For example, a pure *criminology* approach to food fraud prevention would prioritize crime-fighting activities such as investigation and enforcement—seizures of products and arrests. A pure *legal* or prosecution approach would prioritize punishment—judged explicitly by successful court cases and long-term incarceration. A pure *food science* or food authenticity approach would prioritize validated detection test methods—catching food fraud. A pure *supply chain management* focus would prioritize monitoring for anomalies in the movement of product and quickly replenish suspicious product—identifying when contraband is found. A pure *consumer behavior science* focus would prioritize educating buyers and consumers about the dangers of counterfeits and persuading them not to take purchasing risks or not to purchase the illegal product. A pure *forensic accounting* focus would prioritize finding financial anomalies that indicate fraud has occurred. A pure *packaging science* focus would prioritize on-package authentication or security features—such as traceability codes printed on the package or labels. Each single-discipline focus has limitations since they can be circumvented. An *interdisciplinary approach* can consider many often complex but straightforward countermeasures and control systems such as adding complex taggants to a simple packaging feature (Fig. 3.2). This interdisciplinary approach focuses on reducing the fraud opportunity which can vastly increase the challenge for the fraudster to commit the act successfully. This focused effort would reduce the “fraud opportunity.” The “fraud opportunity” is reduced by (1) increasing the risk of getting caught or (2) increasing the cost of conducting the crime with the most crucial step to (3) make sure the fraudsters know of the increased risks of detection. The efficiency of resource allocation and reducing the fraud opportunity is rooted in the best of many academic disciplines.

While there are core concepts that apply—e.g., criminology, supply chain management, packaging science, food authenticity testing, consumer behavior, and others—there is a need to provide an example of the application. The Food Fraud Prevention Cycle (FFPC) combines many basic concepts from a wide range of disciplines. This *interdisciplinary* approach is needed to combat the complex threat. Traditional research starts with one discipline and then focuses on the complex problem. Occasionally there are interdisciplinary teams that gather two or several

Fig. 3.2 Interdisciplinary considerations to address food fraud prevention: a range of academic disciplines that help to understand the fraud opportunity and implement a holistic and all-encompassing prevention strategy



single-discipline researchers. This research method would be to focus on the problem from the perspective of those disciplines. Counter to that “solution to the problem” focus, the MSU-FFI research started with “the problem outward.” A *multidisciplinary team* (experts from different disciplines) is different from an *interdisciplinary team* (colleagues whom each had expertise and experience in a broad range of fields including as corporate business managers) (Gray 2011).

The multidisciplinary team has a natural inclination to start with a specific type of technology and seeks possibly applications—“a solution looking for a problem.” The result of this research was to develop the Food Fraud Prevention Cycle which will be reviewed here. Later, another chapter will review the functionality and application of the cycle. The intent of this chapter is to provide background on the overall concepts and not to delve into the specific components of the cycle.

Sidebar: Can't We Just Arrest All the Fraudsters? No. (MSU-FFI 2018)

Title: Can't We Just Detect and Arrest Fraudsters? Sorry, But No.

By John Spink • October 3, 2013 • Blog (MSU-FFI 2018)

If we cannot arrest our way to food safety, can we rely only on authenticity testing and detection? Forget enforcement? Ignore investigation? Of course not... however, you cannot increase the safety of the food supply if you're only running around chasing “bad guys” or just “trying to catch bad product.” Prevention is by far the most efficient policy. To focus on prevention before developing detection methods will provide insight into the precise technical detection needs. A focus on prevention can help Food Science and Food Authenticity research to be more efficient.

I recently guest-lectured for MSU Food Science and Human Nutrition professor Dr. Gale Strasburg's course FSC 455 FOOD AND NUTRITION. This is a class for mostly undergraduate seniors. Even though my guest lecture material covered content that isn't usually included on their tests, I usually find a pretty engaged audience. If the only thing accomplished is introducing food fraud prevention to the next wave of future industry leaders then it was time well spent. I'm even starting to get calls from the alumni as a result of my past guest lectures. The ideas are sticking and becoming part of the formal or informal curriculum.

When I presented to those MSU students – the food scientists and chemists – I went through my usual “detect, deter, and prevent” concepts. Our discussion led me to really focus on the connection between “detect” and “prevent,” skipping over “deter.”

To review, “detect” is like a security alarm sounding in your house, alerting you that there is a burglar inside. “Deter” is like the police arresting the burglar as he is breaking in (in Situational Crime Prevention and the Crime Triangle this is the “guardian” factor), or like bars on the inside of your windows (barriers or hurdles). Moreover, “prevent” is like having lights on, doors and windows locked, an alarm on, and a dog barking – the burglar now has no interest in breaking into your house. Clearly, you’d rather have the “bad guy” pass right by rather than break your window or be in your house!

For protecting food, we need to focus on the “detect” function – and we need to keep developing more precise and targeted tests and equipment. As we’ve covered before, there are a seemingly near-infinite number of types of fraud, and they keep evolving, so we need to keep evolving. The specification of the “detect” innovations must be determined by the ability to support the ultimate goal, which is the “prevent” function. After an incident is under control, the focus must first be on “prevent” before we take any other steps.

The “deter” component is also critical, however, I’d rather leave that dangerous function of engaging burglars to the brave and committed law enforcement professionals. Facing potentially dangerous or violent situations is way out of the scope of the curriculum for food science, packaging, supply chain management, or public health. Hopefully, with the increase in the “prevent” and “detect” efficiency, we decrease the need – and cost – of the “deter” function.

Whether you are a big or small company, a manufacturer or retailer, industry or government, just understanding the “detect” and “prevent” functions can help increase the efficiency of time and money.

Sidebar: Boring Ole' Prevention (MSU-FFI 2018)

Food Fraud Prevention – Not Exciting or Urgent, But Critical

By John Spink • May 8, 2013 • Blog

No one gets a trophy for implementing a preventative program. Acts of heroism are defined in crisis moments, not in a strategic, methodical development of a prevention plan. While that is understood, the adage “an ounce of prevention is worth a pound of cure” still holds true here. Combating food fraud is an effort that requires prevention. That prevention is most efficient within a coordinated, global public-private partnership.

The concept of governments and industry working together was a recurring topic during the Food Safety Summit held last week in Baltimore (2013 which as after the 2011 passing of the FSMA law and the 2016 implementation of the FSMA-PC final rule). As in previous events, this attracted a wide range of important regulators and the usual influential food safety members of the industry. Those leaders kept mentioning the goal of public-private partnership and the efficiency of a coordinated collaboration. “Collaboration” was a common theme from a wide range of regulators including in the town hall meeting by Michael Taylor (Deputy Commissioner for Foods, FDA) and Elisabeth Hagen (Undersecretary for Food Safety, USDA) and to the employees at the FDA Center for Food Safety and Applied Nutrition (CFSAN) booth.

The FDA speakers in the food fraud Session defined the overall agency objectives and the alignment with the Food Safety Modernization Act (FSMA). They stated, “The FDA’s goal is not to just identify violations but to help provide safe food.” They also discussed some of the shifting regulatory landscape in the US and abroad such as:

- National to Global
- Component View to System Perspective
- Adversarial to Collaborative
- Reactive to Proactive
- Compliance to Oversight

These all underscore the prevention focus and the partnerships with industry.

Industry echoed these themes, including in the Keynote Address by Will Daniels (SVP of Earthbound Farms... a rousing presentation as expected) and by Yves Rey (General Manager of Corporate Quality for Danone and the Chair of the Global Food Safety Initiative – GFSI). Regarding food fraud prevention, Yves stated that it’s the perfect time to take a prevention approach because the science is still under development. The fundamental concepts and work processes can be influenced and shaped here at the start of the development of the core concepts. As groups start implementing programs or setting

standards, it will be more difficult to change the industry-wide direction. A lack of leadership could end up with a disconnected, confusing, inefficient, and non-harmonized set of actions.

With the growing list of high profile food fraud incidents – melamine to horse meat to rat meat – others in governments and industry WILL have to get going. The governments and industry will be quickly implementing programs and countermeasures and control systems. As I mentioned in a previous blog post, the GFSI is addressing food fraud and is receiving insight from a Food Fraud Think Tank it created (I am one of the five core members). Yves also stated “GFSI decided to tackle the issue head-on,” and “food fraud has been defined by the [GFSI board] as a food safety issue.” (GFSI is an important stakeholder since most of the world’s food safety management systems that are implemented by industry are GFSI compliant.)

While responding to a food fraud incident requires a team of crisis managers, stakeholders are starting to focus on prevention. How to expand the focus from detection to deterrence to prevention, and the roles of each player in the public-private partnership, are still to be defined... well, to correct that, we *are* all defining it now. This is an unprecedented opportunity for you to participate in shaping public policy and industry best practices. Join with your industry groups, make sure to submit your comments to the FDA request for comments on Economically Motivated Adulteration, and become educated. MSU-FFI.

Key Learning Objective 2: Interdisciplinary Nature of Prevention

This section reviews the interdisciplinary nature of prevention by considering how the fraud opportunity is created and the many academic disciplines that help provide an understanding of the optimal countermeasures and control systems.

The key Learning Objectives of this section are:

- (1) Applying social science and criminology
- (2) Considering business and supply chain management and traceability
- (3) Exploring ways to engage packaging science in increasing the “hassle factor” for the fraudster and thus reducing the “fraud opportunity”

There is a saying:

Repeat after me – “Social Science is a real science.”

In a room of food scientists, there is often a chuckle and then the start of a lot of discussion about the scientific method, validating hypotheses with tests and measures, and general emphasis on the clear nature of testing for the presence or absence of a chemical. A follow-up statement of “if the biological organism in question were

a microbe we would go to the field of microbiology; now the biological organism in question is a human so we must go to Social Science and specifically Criminology.” The main focus is on crime prevention and Situational Crime Prevention. This is a well-research field. A recent Google Scholar search from 2000 to the present for the keyword “Situational Crime Prevention” resulted in over 10,000 results. This specific topic has been researched since the mid-1970s. When dealing with human adversaries, it is critical to engage social sciences.

Social Science and Criminology

“Social Science is a real science.” “Behavioral Science and Consumer Behavior are sciences.” These are hard for food scientists or analytical chemists to believe or understand. When confronted with a food fraud incident such as melamine in milk powder or horsemeat in beef, the food scientist response is to apply food science tools such as authenticity testing. While this is critical when intervening during a human health hazard outbreak where the culprit is an adulterant-substance, this is a reactionary approach that tangentially contributes to prevention. Of course, detection and authenticity testing will help prevent—catching fraudulent product is essential—but without a prevention strategy, the countermeasures and control systems will only *catch* bad product not *prevent* food fraud from occurring in the first place.

Sociopaths When dealing with fraudsters and criminals, “it is most efficient to remove morals and ethics from the equation.” It is inefficient to try to “shame” the fraudsters into not acting. First, to deal with “morals” is to focus from the human fraudster outward to prevent the criminal activity. When focusing on the fraudster, an important concept to review is the nature of sociopaths. Second, ethics are often defined by local custom or tradition. In addition, “ethics” can be situational where “stretching the rules” may be more acceptable or practiced in one situation versus another. It is most efficient to remove appealing to the ethics of the fraudster and to shift to reducing the opportunity to commit the fraud act successfully.

To consider situational ethics, for example, if a parent needs \$100,000 for a cancer treatment for their child, they may consider stretching a trusted relationship or even break the law. If a company is on the verge of bankruptcy that would lead to 100 employees to lose their jobs with no social safety net, the decision-makers may “relax” their “risk tolerance.” They may save money by not paying for preventive controls such as supplier verification or expensive food safety testing. While this may be illegal or unethical, there may be a situation where someone rationalizes and justifies their activity due to prioritizing a “higher morality.”

You Are A Habitual Law Breaker To approach the question from a different direction, how much over the speed limit do you drive on the highway? A response is sometimes “but I’ve never been pulled over,” “I’ve never been in an accident,” or “if the road is icy, then I slow down.” So, where does the actual speed limit fit into

the consideration? If you drive over the speed limit, you are breaking the law. Period. You justify your activity possibly because you've never been penalized. What are the decision-making criteria? Is it the risk of getting caught (by the police) or the cost of conducting the crime (of wrecking your car from reckless driving in dangerous conditions)? If you drive over the posted legal speed limit—especially if you do it on a regular basis or basically “constantly”—do you consider yourself unethical or immoral?

The most relevant social science discipline that applies to food fraud prevention is criminology which is the studies of crime and criminals. The core of food fraud prevention is to understand and address the “fraud opportunity.” Since the mid-1970s, there has been an expanded research effort to shift focus from punishment to prevention. Concepts that will be covered more in another chapter are the study of the “space” of crime to adjust the physical environment to reduce the opportunity for crime.

Sidebar: Considering Sociopaths Are Everywhere (Everywhere!)

It is important to study the behavioral sciences to understand the motivation. The general criminal traits will be reviewed later, and this section will explore the more general concept of sociopaths. From an article on the challenges of intellectual property enforcement in agricultural products (Spink 2011):

When dealing with responsible parties, the [legal and regulatory] process works. The system breaks down when dealing with fraudsters and counterfeiters who are, in the worst but unfortunately the very common case, criminals not concerned with breaking the law, sociopaths not concerned with cheating or demoralizing others, or uninformed and ignorant of risks inherent in the actions. Specifically, counterfeiters are often “irresponsible defendants” who hide or flee from prosecution and have laundered their assets out of reach of the courts. ‘Those [counterfeitors and diverters] who evade the laws do so with the expectation that they can reap substantial profits and the risk of incarceration—or even detection—is minimal. (Spink 2011)

A typical fraudster exhibits sociopathic tendencies by not being concerned about the feelings of others and does not worry about cheating society (APA 2000; Stout 2005). “*Sociopaths* exhibit asocial or antisocial behavior while a psychopath is characterized by the antisocial behaviors that manifest in aggressive behaviors” (APA 2000). The potential for harm—even physical harm—is not a concern or consideration. The American Psychological Association estimates that 1 out of 25 humans would be classified as having an “anti-social personality disorder” or labeled as a “sociopath.” Consider that statistic for a moment. While different social or professional organizations may attract different types of people, consider that of the 25 people around you that statistically, 1 has a full-blown “anti-social personality disorder” and could be psychologically labeled as a “sociopath.” (Actually upon further review this may not be surprising, and maybe some of the vulnerability reducing strategies may work in your personal life!)

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A sociopath is defined as someone who exhibits a “high level” of three of seven key traits:

1. Failure to conform to social norms
2. Deceitful, manipulativeness
3. Impulsivity, failure to plan ahead
4. Irritability, aggressiveness
5. Reckless disregard for the safety of others
6. Consistent irresponsibility
7. Lack of remorse after having hurt, mistreated, or stolen from another person

There is a saying:

“Your best defense [against sociopaths] is to understand the nature of human predators” (Stout 2005).

The sociopaths are “satisfied” with their lives and are generally not concerned or cognizant of the feelings of others, so they do not seek and are not usually influenced by psychological treatment or messages. Sociopaths will not be shamed into compliance.

The focus on the fraud opportunity is to reduce the vulnerabilities, so this would change the target and thus be effective in changing the behavior of sociopaths. “To create a better world, we need to understand the nature of people who routinely act against the common good, and who do so with emotional impunity.” The sociopaths typically look for easy opportunities or targets, so creating barriers or “increasing the hassle factor” is a fundamental response—such as reducing the fraud opportunity. While all sociopaths are not the same, the physical space around the victim can be addressed systematically and universally. This target hardening and vulnerability reducing systems have been studied in the criminology theory of Situational Crime Prevention.

The next discipline to consider is the business function of supply chain management.

Key Management Disciplines

Supply Chain Management (SCM)

Another interdisciplinary consideration is supply chain transparency and traceability. The academic research field of supply chain management is covered more in another chapter—with over 100 global universities with Supply Chain Departments and many offering—traditionally focuses on controlling and optimizing legitimate product moving within an authorized network. Supply chain management includes

massive systems and networks that track and manage billions of global transactions almost simultaneously. The amount of “Big Data” is absolutely overwhelming unless it is managed by using statistical methods and data analytics.

That said, the food safety traceability systems are built upon trust and mutual need for quick and efficient product tracking and product recalls. The human fraudster *cannot* be trusted and may even use the traceability systems to comeingle fraudulent product in the supply chain. For example, fraudulent, hacked, or cloned codes could be used to mask (e.g., to cover-up or hide the detection of) the fraudulent product. If hackers uploaded fraudulent codes, then legal databases would identify the hacked codes as genuine. Once the legal and illegal codes are comingled, it may be difficult or impossible to un-comingle the data set—since there would be no way to identify which code was genuine and which as fraudulent, every code could become considered “adulterated” and “unfit for commerce” per the Adulterated Foods Section of the Food, Drug, and Cosmetics Act (FDCA).

Understanding how the supply chain management and transparency activities could be vulnerable is important during the shift to focus on how to identify countermeasures and control systems that reduce the “fraud opportunity.” The supply chain management systems are already in place and functioning, so they have a critical and primary role in the Food Fraud Prevention Cycle.

Managerial Accounting and Enterprise Risk Management (ERM/COSO)

The concepts of managerial accounting and enterprise risk management are so important that they will be covered in specific chapters on Business Decision-Making, Risk Analysis Fundamentals, and Risk Analysis Application. Managerial accounting is the academic discipline of how entities such as companies or countries are managed and operate. Financial accounting is the discipline of how they report to investors such as stockholders, the Board of Directors, or financial investment institutions. The Enterprise Risk Management concept was a system developed to meet laws and regulations to serve both managerial and financial accounting.

Packaging Science

To leverage another discipline, it is also important to consider packaging components. Whether an authentication features such as a hologram or a traceability code on a label, these are important parts of the overall system (Spink 2012a, b). The academic research field of packaging science—includes approximately 10-degree-granting universities worldwide, specialties in other disciplines such as polymer science and food science, and a \$500 billion global industry—traditionally focuses on protecting the product from damage and supporting the on-package consumer communication. Part of that damage protection includes tamper-resistance/tamper-evidence (do not refer to “tamper-proof”—you don’t want to insinuate something

cannot be defeated), anti-theft, and anti-counterfeiting. Again, the fraudsters may use the packaging-related countermeasures and control systems as a way to infiltrate the legitimate supply chain. For example, used packages—including the security features or authentication codes—can be reused and refilled with the fraudulent product. This is the type of fraud defined as unauthorized refill or tampering.

Regarding the consideration of a countermeasure, if one aspirin is good then is five better? Is one hologram (or any packaging security product) good then is five better? It depends on the contribution of this countermeasure or control system for reducing the “fraud opportunity.” Many product security or anti-counterfeit strategies begin and end with packaging components. This is logical and initially efficient since the external package is what is seen in the marketplace. Regardless of the impact on reducing the “fraud opportunity,” a resource-allocation decision can externally show and demonstrate an immediately visible and “aesthetic” result. Adding the anti-counterfeit features is overt and visible. These are very valuable countermeasures and control systems as long as they are considered in relation to the overall fraud opportunity and prevention.

A brand owner or manufacturer may focus on protecting their finished goods or consumer packaging, but there are also opportunities for incoming goods or raw materials. By reviewing the overall fraud opportunity, for all types of fraud, there may be a risk of tampering or unauthorized refill of bulk packaging. By taking a holistic approach, all these vulnerabilities are considered in relation to all possible countermeasures and control systems. By considering the overall fraud opportunity, innovative and synergistic benefits can be achieved such as a packaging component could be combined with a supply chain tracking feature then make sure to include a criminology focus to understand how fraudsters perceive the changing fraud opportunity. This interdisciplinary approach can provide an innovative countermeasure and control system that is very simple and yet very effective at reducing the “fraud opportunity.”

Sidebar: Packaging Countermeasures—Multipurpose Components

Expanding on the idea of multipurpose activities, when the holistic fraud opportunity is considered, often incremental adjustments can have a significant impact. For example, the holistic fraud opportunity may define additional countermeasures and control systems that support resource-allocation decision-making. For example, a shrink band between a cap and bottle provides a tamper-evident and tamper-resistant value. The materials and operations costs of applying the feature have been already justified and implemented. If diversion or counterfeiting is a concern, then a microtaggant or security printing can be added to the shrink band. The additional countermeasure does not require a new packaging component since it is added to the current shrink band and there are no additional operations needed to apply the component. The band could be preprinted, so no additional manufacturing operations step. This is an example of the value of considering all types of fraud within the scope of the Food Fraud Prevention Strategy.

From ISO 12931, specific types of anti-counterfeiting countermeasures apply to authentication and traceability which are overt, covert, and forensic:

- **Overt:** “authentication element which is detectable and verifiable by one or more of the human senses without resource to a tool (other than everyday tools which correct imperfect human senses, such as spectacles or hearing aids” (ISO 2011).
- **Covert:** “authentication element which is hidden from the human senses, utilizes the use of a tool by an informed person, reveals it to their senses or else allows automated interpretation of the element” (ISO 2011).
- **Forensic:** “scientific methodology for authenticating material goods by confirming an authentication element or an intrinsic attribute through the use of specialised equipment by a skilled expert with special knowledge” (ISO 2011).

Sidebar: Package Uplabeling—Using a Unique Lid Stock or Unique Cap

Unauthorized or illegal labeling of a packaged product is a unique fraud opportunity, and an example provides insight into the risk and possible countermeasures. An example of considering the overall fraud opportunity is to combat labeling fraud. A single package style (e.g., 8 ounce, polyethylene bottle, polypropylene cap, with paper label and inner seal over the opening) may be used for several types of products such as a medicine with 10%, 50%, and 80% strengths. A fraud opportunity exists where the fraudster could purchase the less expensive 10% strength product then creates a counterfeit label stating the 80% strength. If that counterfeit label is applied to the lower strength and lower priced genuine product, that is called labeling. The fraudster could buy the lower priced product, label it, and then sell it for the higher price of the 80% strength product.

For that uplabeled product, there will be a lower fraudulent business opportunity—ability to sell fewer products at the highest price—if they cannot infiltrate into the legitimate supply chain. That does not mean an individual fraudster is not motivated and that they will not seek other opportunities. If the low strength product has a retail price of \$1 per bottle and the 80% strength is \$5 per bottle then—combined with the potentially low threat of detection and prosecution—this could be a profitable enterprise. The number of fraudulent transactions could be increased if the product is sold online on a peer-to-peer website or auction website. There are examples of individual fraudsters conducting hundreds or thousands of transactions. The \$5 per unit fraud turns into \$500 or \$5000.

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A way to reduce the fraud opportunity is to add another countermeasure that differentiates the product strengths. For example, different colors of inner lid stock or the color of the cap could be changed for the different strength products. Also, to further reduce the fraud opportunity for the fraudster would be to use a “proprietary cap” that is harder to replicate (a “proprietary” packaging component would be produced for just the one company whereas a stock cap would be sold publically). If the cap is transparent, then the inner lid stock could be visible to an investigator or consumer and even if a buyer just asks for a photo of the package before making a sale. Presumably, the outer cap would be easier to dupe than the inner seal.

An interdisciplinary approach would consider how the consumer is deceived which is the criminology concept of victimization. When looking for a product online, the websites often use stock photos of the branded product. Also, a fraudster could take one picture of the genuine product and post that single image hundreds of times when representing the counterfeit product. At this point, it may seem there is no hope to reduce the fraud opportunity, but stress inspires innovation. “Necessity is the mother of invention.” This extra challenge can lead to a rational, practical, and pragmatic approach that builds upon all these “givens” and deals with reducing the overall “fraud opportunity.”

A key need that can be addressed by packaging components is to help an investigator identify counterfeit products. If the investigator can physically assess the product—such as at retail—then the lid and cap can be assessed. This does not seem possible online. However, the investigator could ask the online seller to provide a picture of the product next to a current newspaper. The investigator can now visually inspect that product and also compare that to what would be received in a “buy.” There is an incremental cost of the investigator interacting with the online seller, and the reduced fraud opportunity is potentially significant. This is an example of considering many disciplines to reduce the fraud opportunity.

Packaging Component Shortcomings: A Complex Scenario

From the article “Fade to Black” by Liang (2006) (emphasis added) (Liang 2006):

“In almost every case, the technology, be it a hologram, tamper proof labels, embossing, thermo-reactive ink, RFID tags, DNA markers, and the like, enable companies to track cardboard, not product. In the United States and in the European Union, the two largest pharmaceutical markets in the world, repackaging is legal; thus, without violation of any law, packaging, with all types of expensive, state of the art secure devices, can end up in the trash or worse, in the hands of a counterfeiter, while genuine product is legally distributed in packaging with no security features.”

“Counterfeitors generally deal, not only with the counterfeit product, but with diverted, expired, and stolen product as well. Envision the scenario where:

- A counterfeiter steals the product,
- Removes genuine product from the "secure packages," and then
- Puts the counterfeit product in these packages, and then reinserts the counterfeit product back into the system.

The counterfeit product would pass through all the readers successfully. What then happens to the genuine product? The irony is that the genuine product would most likely be repackaged in counterfeit packaging with unreadable tags and entered into the distribution system. *If the RFID system works correctly, the genuine product would be kicked out of the system, but later determined to be genuine, undermining any confidence in the system*” (Liang 2006).

Sidebar: Parallel Trade and Importation

Continuing from the “Fade to Black” article, Liang expands to address parallel trade and importation (Liang 2006):

“Parallel Trade Enablers and Risks:

“Although counterfeit/gray market problems are not well known in the United States, they are throughout the rest of the world. International drug counterfeiting difficulties are due in part to problems with parallel trade, i.e., international drug importation in Europe and other countries around the world. Through parallel trade, drugs may pass through many different countries and scrupulous and unscrupulous sellers' hands before ending up in a pharmacy. The incentive to engage in this practice is attributable in part to differences in medicine pricing amongst European countries and is permitted in the EU under Article 28 of the European Commission Treaty for the Free Movement of Goods and Services within the Internal Market of the EU countries. This principle of free movement mandates that no country within the EU may place legal, legislative, or other barriers preventing trade between members, *nor may an owner of a trademark use its rights to prevent repackaging* of the medicinal product if the repackaging will not adversely affect the original condition of the product” (Liang 2006).

“There have been significant issues of counterfeits in Europe both domestically and across international lines relating to parallel trade. Unfortunately, examples abound. *The UK recently uncovered one of the largest counterfeiting operations ever discovered, which was churning out 500,000 tablets of counterfeit drugs daily, and which disseminated those products through parallel trade means across Europe.* It is interesting to note that in the UK, like the US and Latin America, penalties are light. Allen Valentine, the mastermind of the UK counterfeit ring, who had been *convicted on 14 previous occasions on charges of medication fraud, only received 5.5 years imprisonment and the sentence was due to his copyright infringement, not his threat to public health.* He is eligible for release in two years.”

Usually, parallel trade, diversion, and the gray market product is a legitimate product that is safely traded across borders. As was demonstrated in this section, diversion demonstrates a system weakness or vulnerability that could be—and is—exploited by counterfeitors and fraudsters.

Food Science and Food Authenticity Testing

Food authenticity testing will probably always be the most complex and scientifically challenging aspect of food fraud prevention. A food product is not a synthetic chemical that is sold in a homogeneous state such as 99.99% pure. Food is subject to so many variables during the processes of growing, harvesting, processing, packaging, storing, distribution, and then during the final consumption and even disposal (farm to fork or farm to flush). There are so many variables in the food ingredient, and the final chemical composition is even impacted by fluctuations in humidity, temperature, amount of sunshine, or rain. An example of this variation is that orange juice has very different general product profiles depending on if the product is grown in Florida, California, or Brazil. All are genuine orange juice. They are not all genuine Florida orange juice. Another factor is whether the product is not-from-concentrate or concentrated. Then there is the more common fraud opportunity of adding synthetic flavors or diluting with added sugar.

A critical *detect* role is that, of course during an active incident, there is an urgent and immediate need to identify the root cause of the problem especially if there is acute public health harm. The medical sciences work with public health sciences to identify the root cause and then food science, and food authenticity testing is engaged to find a way to detect the problem. For example, during the melamine incident, after melamine was identified as the problem, there was an urgent need to identify a detection test and appropriate test method and then enough testing capacity to meet the need. For the melamine incident, there was even a basic medical and public health question of an acceptable threshold for melamine—in reality, there is not a “zero tolerance” but an Appropriate Level of Protection (ALOP) that is based on a threshold of detection (TOD), a threshold of regulation (TOR), and threshold of concern (TOC—or threshold of toxicological concern TTC or TTOC) (ILSI 2000; CFSAN 2005; EFSA 2015; HC 2016). Per Codex “This concept may otherwise be referred to as the ‘acceptable level of risk’” (CODEX 2003). Also, “An importing country has the right to set a level of sanitary protection it deems appropriate in relation to the protection of human life and health. The ALOP may be expressed in qualitative or quantitative terms” (CODEX 2003).

A critical *deter* role is to put a testing plan in place that identifies further problems from that specific incident.

The most important *prevent* role is to build upon the understanding of the root cause that is used in evaluating the vulnerability assessment that defines the key problems and unacceptable risks in a Food Fraud Prevention Strategy. That strategy would identify the countermeasures and control systems that would most efficiently and effectively address first the problems that were above the risk tolerance. Considering criminology and crime prevention, such as using Hot Product/Hot Spot Analysis, a very precise and specific test and testing plan can be identified, developed if needed, implemented, and then monitored (Lam and Spink 2018; Spink 2019).

Other Important Fields: Law, Accounting, Information Technology, and Others

There are many concepts that are critical and addressed below later in the Food Fraud Prevention Strategy.

- Laws and Regulations: The laws, themselves, are critical to establishing what is illegal and the details of compliance.
- Laws and Courts: The law system and the judiciary are critical to providing a criminal, civil, and regulatory penalty that is both a general deterrence but also in place to confront the most brazen and bold criminals.
- Accounting—financial accounting (expanding on managerial accounting): The communication to the investors and regulators is critical to both support confident investment but also establish common auditable practices.
- Accounting—forensic accounting and forensic audit: Beyond the concepts of managing a company or presenting information for external investors, there are separate functions of forensics accounting that includes systems to continually monitor for problems as well as a forensic audit that addresses the investigation of specific questions.
- Information Technology (IT): This is a very broad field that includes the internal communications and reporting as well as all external transactions.
- Consumer behavior: The focus on the full range of consumer to first understand why they act, to understand why they often inadvertently make dangerous decisions, and to finally be able to change their behaviors.
- Psychology/Business Anthropology (of buyers, brand protection managers, investigators, and others): Beyond consumer behavior, the psychology of stakeholders is important to understand the underlying principles or habits that shape behaviors.
- Risk Analysis and Risk Management: This is the application of managerial and financial accounting needs and includes decisions sciences before providing a methodical and systematic approach to evaluating and managing the problems of an enterprise.
- Decision Sciences: This is an applied focus on how decisions are made beyond statistics or analytical analysis to the support, feedback, and reinforcement of behaviors.
- Political Science: The world operates within government and agency control mechanisms both for the basic rules for a civil society but also for a geopolitical balance of resources and power.
- Public Policy: The study of how government policies are developed and changed over time.
- Public Administration: The management of the government and agencies is based on legal statutory guidelines and boundaries while based on common basic practices.

- Public Health: While healthcare focuses on the individual, this focuses on the population-wide issues and programs.
- Medical/Veterinary/Nursing: When considering the health of individuals, the medical professionals are the front line in detection and response to public health harms.
- *And others...*

While the list of disciplines could go on, the important point is that there are many disciplines that play a critical role in food fraud prevention. To implement the most efficient and effective, holistic, and all-encompassing strategy, it is important to start with a broad base foundation.

Key Learning Objective 3: Understand the Prevention Concept

This section reviews several concepts that are important to shape the prevention strategies. These are underlying theories that support the value of focusing on vulnerability and the fraud opportunity.

The key Learning Objectives of this section are:

- (1) The Food Protection Plan is a cycle of prevention, intervention, and response.
- (2) Strategies and tactics are two key types of responses.
- (3) The overall system is considered to implement countermeasures and control systems.

Food Protection Plan: Prevention, Intervention, and Response

When confronted with a new challenge, it is human nature to try to classify the unknown in previously known terms and then to apply familiar and currently applied risk treatments.

For food scientists or analytical chemists, the application is that if there is a problem, it should be solved with testing and detection. When melamine was found to be the source of the food safety outbreak, traditional food safety systems led to the intervention.

A saying is that:

If you are a hammer (food scientist) everything looks like a nail (food science problem).

Following the FDA Food Protection Plan concept, the first crisis step was “intervention”—to identify the hazard and find a detection method (Fig. 3.3) (FDA 2007, 2008). Focusing on an immediate, direct, and tactical response to “intervention” is absolutely critical and proper during a crisis. The next step was “response”—to find ways to remove the hazard from the supply chain quickly. The food safety system would be the key stakeholder to respond to a food safety hazard including analysis

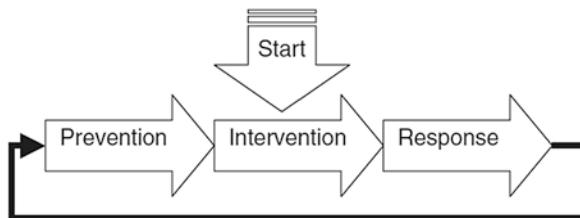


Fig. 3.3 Food Protection Plan series of activities: prevention-intervention-response (PIR) with the starting point after an incident at intervention. (Copyright Permission Granted) (Spink and Moyer 2011)

of the seriousness of the hazard, finding the product, and removing it from the supply chain. A key to reducing the acute health hazard was a quick response and to be reactive. Once the crisis is passed, then there is a cycle back to prevention.

Consider Strategies First and then Review Tactics

If there is a known incident, then there is an urgent need to act immediately—to do something. If not then don't start by just acting. Have a plan, a diagnosis of the problem, an understanding of the root cause, and a consideration of the resource-allocation decision-making options and limitations, and then consider the countermeasures. This set of steps is based on having a strategy before selecting tactics.

If food safety prevention concepts were implemented before the development of a Food Fraud Prevention Strategy (e.g., after finding melamine in the product to then only implement melamine testing of incoming raw materials), the countermeasures activities would still be “tactical” not “strategic” and possibly not reduce the vulnerability (the system weakness may not be for incoming raw materials). The management of the activities is “operational.” The focus would naturally *not* be on the fraud opportunity or the overall VACCP plan (see below for more on strategic, tactical, and operational).

- ***Strategic action:*** addressing an overall problem and then to prevention. Webster's Dictionary includes one definition as: “of great importance within an integrated whole or to a planned effect” (Merriam-Webster 2004).
- ***Tactical action:*** after “detection” then a specific countermeasure for a specific problem which would be “deterrence.” Webster's Dictionary includes one definition as: “made or carried out with only a limited or immediate end in view” (Merriam-Webster 2004).
- ***Operational action:*** the effort to apply the strategic or tactical plan.

To review the strategic and tactical concepts in more detail, there are specific definitions of the terms and standards for their adoption. These concepts are not defined directly in the quality management standards (e.g., ISO 9000 Quality Management) but have been codified elsewhere (such as ISO/IEC TR 33014:2013 deals with process improvement on three levels) (ISO 2013).

- **Strategic:** what goals to achieve, the motivation and direction.
- **Tactical:** how to achieve the goals of process improvement.
- **Operational:** how to perform the process improvement.

Also, from ISO 24516: 2017 (ISO 2016):

- **Strategic plan:** “plan containing the long-term goals and strategies of an organization; Note 1 to entry: Strategic plans have a strong external focus, cover major portions of the organization and identify major targets, actions and resource allocations relating to the long-term survival, value and adoption to ongoing changes of an organization.”
- **Tactical plan:** “prioritization in the medium term on the basis of influencing factors/indicators on performance, costs, risk and failure probability and scale of failure, including general determination; EXAMPLE 1: Indicators of damage probability can be age, usage, and damage; EXAMPLE 2: Indicators for the magnitude of failures can be hydraulic importance and vulnerable infrastructures; EXAMPLE 3: General determinations can be technology of rehabilitation and material.”
- **Operational plan:** “implementation of rehabilitation measures (short-term planning).”

Tactics are, by nature, reactive and can be very efficient if they are selected to support a strategy. For example, a food safety “Early Warning System” is usually a “tactic” to support the food safety “strategy” of rapid detection and response to known hazards (for more detail, see later review of Early Warning Systems). Other Food Safety Management System actions focus on prevention of the hazard in the first place. Thus, a traditional food safety “Early Warning System” by itself is not food fraud prevention but rather “rapid, rapid detection.”

To develop tactics (e.g., “just start doing something” or “we need some data” or “it must be good to improve the test method for this adulterant-substance”) before understanding the overall strategy is usually inefficient at best and dangerous at worst. If the typical fraud occurs at 1%, then a detection test at 10 parts per million is not needed. If there are a seemingly near an infinite number of fraudsters, then arresting 100 or 1000 bad guys probably do not reduce the fraud opportunity. Without considering the overall needs and the entire system, there may be gaps in the tactics that produce a new critical flaw that may lead to an even bigger fraud opportunity.

It is critical to consider how all the concepts connect together in the Food Fraud Prevention Cycle (FFPC)—and applying the concepts to a specific situation or system—to understand everything that needs to be covered and how much data or intelligence is needed to make resource-allocation decisions, and to consider how the system will be sustainable. Everything should be connected and calibrated to everything else. To consider the holistic and all-encompassing strategy *before* implementing programs provides an opportunity to identify unmet needs or gaps. If everything is *not* connected to everything, then the process and assessment are static and not dynamic—it does not actually re-calibrate and becomes out of date almost immediately.

Sidebar: Shift to a Prevention Focus

Food fraud prevention is similar to other food safety management concepts such as Hazard Analysis and Critical Control Point plan (HACCP) and the broader business quality management concepts such as Total Quality Management (TQM) or Six Sigma (“6S”). While both HACCP and quality management faced resistance when first implemented, they are widely accepted and understood. Quality is not only part of the corporate culture but even is often now a core company value.

Considering the quality management commitment, the core philosophies of the control systems are fundamentally similar to other food safety programs. The same concepts are the idea of identifying hazards, determining critical control points that should be monitored, and then a process to make sure the countermeasures and control systems are implemented. When developing and then implementing a new system, for getting buy-in and speed understanding, it is effective to start with a known concept to explain the value to the resource-allocation decision-makers. Food fraud starts with the highly regarded and familiar HACCP concepts and then refines the process to apply to the vulnerability uniquely. For food fraud prevention, the concept has been a “Vulnerability Assessment and Critical Control Point plan” or “VACCP” (GFSI FFTT 2013; GFSI 2016; FSSC 2018). Addressing food fraud in VACCP is identified as different as addressing food safety (HACCP) but yet utilizing very similar methods and systems. Food defense—an intentional act with the intent to inflict a health hazard, economic or psychological terror—often is considered a “threat” so the concept is “Threat Assessments and Critical Control Point plan” or “TACCP.” This philosophy creates an overarching set of concepts, but that identifies very different control and management activities.

When considering food fraud prevention—not just identifying human health hazards and implementing critical control points to monitor for an adulterant-substance like melamine or horsemeat—the countermeasures and control systems are fundamentally different than for addressing food quality, food safety, or food defense.

An Early Warning System as Prevention for Melamine Fraud? ...or Rapid, Rapid Detection of an Illness?

After the original melamine food fraud incident in milk powder and then in pet food, there was a sense that the food safety system “worked” and was proactive. These were intervention and response. After thinking about this, the trigger for the “Early Warning System” to look for melamine was the illness and death. So, there was a *rapid alert* that there was a problem which was an *early warning* of a food safety incident not a warning of a new vulnerability that rose to the level of now being a *hazard that requires a preventive control*.

To be fair to the food safety legacy systems, it is essential to define the scope and fit for purpose of the “Early Warning System.” Many systems were implemented to detect a chemical contaminant or pathogen that naturally occurs in the product. These systems were not originally designed or intended to monitor other activities such as food fraud or food defense attacks. The great opportunity is that an Early Warning System tracking and response system is already in place and functioning. There is an efficiency in integrating food fraud prevention activities into the current functional system.

An Early Warning System is critical to the rapid detection of all health hazard or fraudulent activity. To be efficient, a Food Fraud Prevention Strategy should inform the Early Warning System to know what to look for. Moreover, to actually lead to prevention of the fraud act, the fraudsters must know the prevention system is in place. Fraudsters just need to know that the supply chain monitoring is in place for “melamine”—and whatever else might be a concern—to dissuade the fraudulent act.

In Fig. 3.4, there are separate determinations or threshold of “unacceptable risks” for food quality, food safety, food fraud, and food defense. If a single threshold and general response were defined—such as a reported illness in a government product recall alert—the model would be an “ill-fitting tool.” For example, the US FDA CARVER+Shock food defense assessment system has a factor that prioritizes the “shock” of an incident. While addressing package tampering is critical, based on this assessment system, the 1986 Tylenol tampering incident that changed the entire US packaging laws would not have been prioritized. The “shock” would have been a low rank of 1 or 2 out of 10 points on the CARVER+Shock scale, and thus other higher ranking threats would have been clearly prioritized. Even after the incident occurred, the statistics and data on the Tylenol incident would still be prioritized in the CARVER+Shock scale as very low.

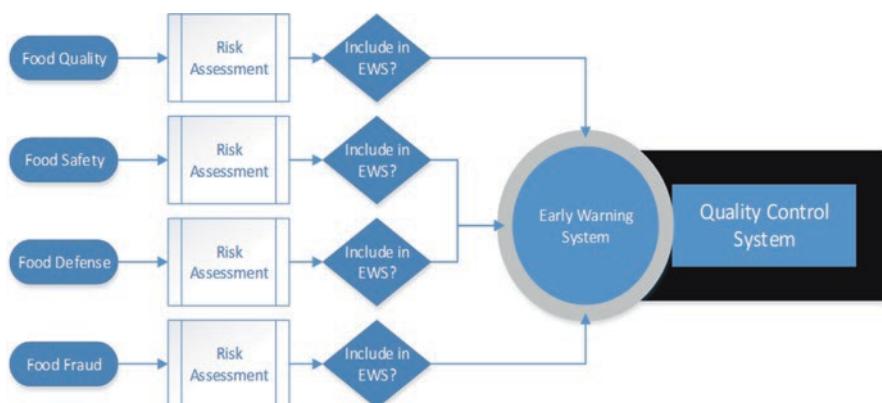


Fig. 3.4 Contaminant Early Warning System structure of multiple types of risks and implementation in a quality control system

With this organizational structure, the food safety Early Warning System methods and procedures can be utilized to address multiple types of risks. The food safety Early Warning System then broadens to really becoming a food quality Early Warning System.

Optimize the Countermeasure and Control System

Once the Food Fraud Prevention Strategy is in place and countermeasures and control systems are selected, it is crucial first to create a vision of the goal. At the very start of the process, it is important to consider “what are we really trying to do?” There are many ways to dissuade the fraudsters from acting. Before jumping to complex or expensive risk treatments, consider all your options. Review the countermeasure and control strategies in relation to your Food Fraud Vulnerability Assessment and on your corporate risk map. There are some situations where you may become aware of more incidents, but they don’t fundamentally shift your fraud opportunity. For example, the increased fraud opportunity does not shift the result above the “risk appetite.”

Also, before selecting new countermeasures and control systems—and after reviewing “what are we really trying to do?”—it is wise to review other testing, audits, or monitoring conducted by your company. There may already be subscriptions or processes in place that you can leverage and use.

Once you have identified a vulnerability that is above the “risk appetite” (unacceptable), you can use the Food Fraud Prevention Strategy Cycle (FFPC) to consider countermeasures and control systems. The range of countermeasures and control systems should be evaluated on a corporate risk map.

The Food Fraud Prevention Strategy (FFPS) is a self-correcting process that dynamically calibrates the fraud opportunity in relation to the goal to at least stay just within the risk appetite. As the fraud opportunity rises or lowers, it is compared to the evolving risk appetite. If the fraud opportunity drops, then there is a methodical recommendation that countermeasures and control systems could be reduced. Without a lot of evidence and enterprise support, a manager moving into a new position would never reduce the countermeasures that are already in place—if after that countermeasure was eliminated an incident did occur, that new manager could be held accountable for weakening the position of the corporation.

The most important part of the process here is that there are analytical, resource-allocation decision-maker-based assessments. Decreasing the countermeasures and control systems can be judged without bias or opinion. The process provides a rational justification for the decisions.

Engaging the corporate risk map places the risk appetite threshold decision where it should be which is at the CEO/CFO. The CEO/CFO is held accountable by the Board of Directors to keep the business operating below that risk appetite. The Board of Directors is the proxy for the owners and shareholders. All of these leaders

must report the risk management process in financial securities regulatory documents such as a “10-k form” that is part of the annual report. Not addressing these risks—or not reporting them—can lead to personal criminal liability.

Sidebar: A Supplier Credit Rating as a Proxy for Financial Duress

This may seem completely obvious, but credit ratings that are already monitored by every company’s credit department are an excellent way to gain insight on *every* supplier continually and very accurately. Potential fraudster companies—or owners and managers—do not all of a sudden shift from being financially secure to under duress. Unless there is an extenuating circumstance or a specific incident, for most situations, the company slips gradually.

During a project, there was a question about evaluating the fraud opportunity by conducting a judgment of the supplier “being under financial duress” or the owner “living beyond their means.” These are important root causes for someone to be tempted to commit fraud. From a practical perspective, how would you, your headquarter-based purchasing managers, your auditors, or supplier relationship managers evaluate this factor? Would you investigate your suppliers? What would trigger an investigation? How much would it cost to conduct an effective lifestyle evaluation across town or halfway around the world? What is “living above your means?” In one country is having two cows considered wealthy? What about owning a race car? If a fraudster is smart, they would not drive a Ferrari to their manufacturing plant but would pretend to be personally fiscally responsible and drive an old car.

Thus, the goal is to have some type of automated, data, and fact-based system to watch for triggers that might suggest an increasing vulnerability. Ideally, to tip you off of potential problems, this would be a currently produced streaming data that you can have automatically monitored. As we said, companies do not usually have an immediate shift in identifying new financial duress. Thus it would be an excellent countermeasure and control system to monitor something.

A company’s credit department already has the systems in place to monitor the credit rating of customers (accounts receivables) and maybe also already suppliers (accounts payable). So, an alert could be created to signal some type of countermeasure when a supplier slips. For example, if they slip from the Dun & Bradstreet creditworthiness rating of AAA rating to AA (of the range from a high of AAAA to a low of HH (Dunn and Bradstreet 2018), there could be an automated request to confirm some aspect of their supply chain. As long as there is a follow-up to confirm their response, “they know you’re looking.” If the supplier slips, again and again, there could be another more detailed request such as requiring that the supplier send copies of food safety tests or audits. If the supplier passes below a threshold, they could trigger routine on-site food safety audit. This is an audit you would be doing anyway, but this could just speed up that cycle.

If this credit monitoring system were to be put in place—even if the control system was just an automatically produced email request for some response—then the fraud opportunity is reduced since, if that supplier feels pressure and is tempted to commit fraud, they will perceive you are a lower fraud opportunity than other companies who are not asking. They will remember that you've been very diligent, engaged, and monitoring many aspects of the business. The fraud opportunity will be reduced since they will perceive they may get caught if they attack your company.

A burglar who is carousing your neighborhood to scout crime opportunities (a “motivated attacker” seeking a “crime opportunity”) is not usually trying to specifically break into your house. If your house has all the lights on and your neighbor’s house is dark... the fraud opportunity is at your neighbor’s house.

Personal Insight: Example of Starting a New Strategic Initiative—Sustainability, Quality... Food Fraud?

When a corporation takes on a new initiative, there is often little awareness by the general employees of why this effort was chosen and why this one and not another focus area. There is often an acceptance that “this makes sense” (or the contrary that it is “flavor of the month”) but little insight on the enterprise-wide motivations. There cannot be ten “top-3” initiatives. In reality, a Board of Directors and C-Suite review enterprise-wide risks for the short- and long-term. They then consider how their enterprise may reduce the negative impact. Along the way, creating a benefit is also the goal. The start of the Wal-mart sustainability effort provides an interesting case study (Note: I was fortunate to be the Michigan State University School of Packaging representative to the Wal-mart Packaging Sustainable Value Network (PKG-SVN) for the second to the fifteenth meeting).

Wal-mart was an early adopter of corporate sustainability initiatives. In 2005, their CEO Lee Scott presented his “21st Century Leadership” speech (Scott 2005). This was the proclamation that Wal-mart would fully embrace and engage in environmental sustainability. He mentioned the main reasons were:

- (1) Merchandising: have the products on the shelves that customers want
- (2) Control costs: predicting that raw materials such as electricity or truck fuel prices would increase, so the efficient use of energy would be important
- (3) Attract and retain employees: corporations faced hiring challenges, and there had been efforts to put in place, and support, innovative programs

None of these were a change or contrary to the Wal-mart Value Statement or culture of taking care of the customer under a motto of “everyday value.”

Fast forward to 2018 and “sustainability” is a common and accepted—even critical or mandatory—corporate initiative to the point of being core to a culture. The original response of suppliers to Wal-mart initiatives was to embrace sustainability

just to sustain or grow sales. Along the way, companies refined their programs to support good business growth for new “green” products that customers were seeking, controlling costs, or positioning their corporations to look good for the investment community.

Environmental sustainability initiatives were not always a “no-brainer.” At the very start, a Board of Directors—such as possibly Wal-mart—would have reviewed long-term threats to their enterprise. Futurists help envision what could be, what might be, and how to position for reducing risk and increasing the chance of success. For the 100s of possible initiatives, Wal-mart picked sustainability. The Wal-mart senior decision-makers decided where and how to direct and financially support their employees to strongly position the company in the short- and long-term. This type of awareness of typical Board-level review and decision-making is not well understood even by those who work at a company. Many employees just believe that “no-brainer” initiatives such as sustainability—or others such as quality, safety, food safety, and others—just “make sense,” so they just naturally become part of the culture.

Before sustainability, in the late 1980s and early 1990s, there was an earlier trend to implement quality management programs. While an employee for almost 12 years at Chevron Corporation, I experienced a wave of initiatives that had ended up being core to the Chevron culture and success such as quality (e.g., before Six Sigma there was Deming and then Crosby), safety, diversity, and sustainability. Over time these “new” initiatives became ingrained in the everyday practices or “culture.” When we had positive experiences—or the business kept growing—the efforts became even more valued.

While there are frontline compliance requirements such as by GFSI, the concept of food fraud prevention is at the very start of the corporate-level implementation process as well. There are many competing enterprise-wide priorities, and there is a need to conduct this very high-level assessment to help the enterprise consider how to best address this vulnerability. Over time there will be a calibration of “how much is enough” based on risk and reward. The Food Fraud Prevention Strategy helps connect the vulnerability to the corporate risk map to provide that high-level perspective. Using ERM/COSO, a food fraud incident can be effectively and efficiently compared to all other risks, vulnerabilities, or threats. In this integrated system, all risks can be compared to all other risks. There can be a real assessment of this new problem above the “risk tolerance” and of what countermeasure specification reduces the problem to within that threshold.

Sidebar: Food Fraud Strategy—Managing Diabetes Not Fixing a Broken Leg

An important concept is that addressing food fraud is not like fixing a broken leg where one intervention can “solve” the problem. Food fraud must be “managed.” It is essential to set the expectation or philosophy of managing food fraud which is more like managing diabetes than fixing a broken leg. For treating diabetes, the patient may look fine right now but without care could become very sick very quickly.

There has been feedback from anti-counterfeit or brand protection managers who have been gun-shy to approach their resource-allocation decision-makers to ask for more money since they are asked “We’ve been giving you millions of dollars each year... so why haven’t you solved this?” The problem here is that the countermeasures and control systems were positioned as “solutions” not “ongoing management”—a “solution” is expected to “solve” the problem. When you “solve” a problem, there is an expectation it no longer exists.

The vulnerability will continue to evolve, so the first step in the treatment is to create a methodical monitoring and continuous improvement process, program, or system. The second step is to assess risk treatments and implement effective countermeasures and control systems. Finally, there should be agreements on the success metrics. The goal is not to “catch” “more” bad product or to arrest “more” criminals; the goal is to “prevent” the incident from occurring in the first place. However, this is prevention, so success is not only measured by the “nonconformities,” which in these cases are food fraud incidents. As with a diabetes patient, we should be monitoring that the patient is still alive, but there are other indicators of success or well-being. For food, we would call this a product recall. The diabetes patient has other factors that indicate the process is under control such as blood glucose monitoring, exercise, a healthy diet, and other indicators.

In a food safety management system such as HACCP, this would be referred to as “Critical Control Points.” A proactive and sound patient treatment plan—as with a quality management system—identifies the root causes of the nonconformance, reduces out of control activities, and then monitors key aspects of that critical control point that are being addressed. For food safety, this would be a HACCP that monitors the temperature of a refrigerator (e.g., the temperature, that it has stayed even and that the monitoring system is stable). For food fraud prevention, this would be a Vulnerability Assessment and Critical Control Point plan (VACCP) that monitors the variation in non-targeted tests such as to see if there are any “unexpected” but not yet “suspicious” results.

The Food Fraud Prevention Cycle is an overall monitoring system to connect specific monitoring activities. The crucial point is that all systems are connected and calibrated to interact with all the other systems. The objective is to “connect everything to everything.” Without this integrated system, there really are no internal controls and no integrated framework to monitor, assess, and implement the strategy. Without the cycle then resource-allocation decisions are guesses. From the COSO report “Risk Assessment in Practice” (COSO 2012):

- “Without a standard of comparison, it’s simply not possible to compare and aggregate risks across the organization.
- “Risk aggregation models are extremely variable from one enterprise to another, even within the financial services industry.”

Sidebar: The Trophy Remains Elusive—How to Define Success? (MSU-FFI 2018)

By John Spink • August 22, 2013 • Blog

Melamine, horsemeat, rat meat, Sudan red carcinogen colorant... we understand food fraud is an issue, but how big of an impact does it make? How do we define the risk or vulnerability? Moreover, probably more importantly... how do we define progress or "success"? The presenters in the Economic Adulteration (Food Fraud/ Economically Motivated Adulteration) sessions at the IFT 2013 conference framed these questions... and set the direction to find the answers.

This year's IFT conference was held at McCormick Place in Chicago from July 11 to 17. It was reported that over 23,000 people attended. I presented three food fraud, packaging, and food defense sections in the HACCP certification pre-conference workshop. I was also a part of the MSU Online Master of Science in food safety exhibitor team and attended several educational sessions related to my research. Two sessions focused on Economically Motivated Adulteration (EMA), which included many mentions of food fraud (FF).

IFT is focused on food science and technology for ingredients, so it was logical for the conference to include a session on the adulterant-substances and the adulteration aspects of the food vulnerability. IFT and these presenters have been increasingly covering the economically motivated adulteration issues.

The first EMA session was on "Strategies and Technology to Prevent/Detect Economic Adulteration of Food." The presentations focused on test methods to detect EMA. The increased ability to detect product that has been adulterated will provide another, better weapon in the countermeasure arsenal. The presentations reviewed techniques to increase detection, not prevention. There were many excellent descriptions of fraud identification and authenticity testing.

The second EMA session was on "Risk Assessment for Economically Motivated Adulteration of Raw Materials and Ingredients: New Tools and Research Needs." This session started with a statement by Joseph Scimeca — a food safety VP at Cargill, speaking for the Grocery Manufacturer's Association workgroup on Economic Adulteration — stating, "Intentional adulteration is a game changer" since the potential impact is huge and the prevention countermeasures and control systems are from outside traditional food science. He continued to focus on the industry concerns of economic adulteration and, specifically, on the behavioral sciences and criminology aspects of prevention. He stated that there is a tremendous need for more research and that there is great industry concern on the topic. Next, Markus Lipp — a VP at U.S. Pharmacopeia and the Food Chemicals Codex — discussed some of the work of its food adulteration-related Expert Panels. Karen Everstine of the National Center for Food Protection and Defense (after the US Department of Defense funding ended it is now called the Food Protection and Defense

Institute – FPDI, who was an early funder of our MSU food fraud research) presentation included some of its complex and expansive data-gathering activities in the food fraud area. The NCFPD has a deep engagement with its U.S. agency funders in protecting our borders and food supply.

The session was moderated by Jonathon DeVries from General Mills/ Medallion Labs. He closed with an important concept about prevention – “we don’t have a way to claim success.” Later he stated, “If we prevent EMA no one knows for sure... we need to find a way to prove our success.”

The key takeaways for me were that food fraud is a critical food industry issue. Many great minds are collaborating at very high levels on the subject. As we found with our previous MSU-FFI efforts to quantify the economic impact or risk of counterfeiting, these fraud events defy our current methods and processes. We will need to continue to work together to develop the vulnerability and risk assessment systems. Finally, as Dr. DeVries stated, we need to find a way to “prove success” in prevention. We need to be able to define why food fraud prevention is important and to define how, and when, we reduce the vulnerability.

Update 2018: This concept of how to measure success was a key problem for quality management and crime prevention. While measuring an actual incident is important the more proactive measures are to reduce the actions that could lead to incidents. For quality management, this is identifying and addressing the root causes of an anomaly. Adapted to food in the HACCP plan this is identifying and managing critical control points. In crime prevention, this is identifying the crime “hot spots” and implementing countermeasures to reduce the opportunity. Adapted to food fraud, this is identifying and reducing the vulnerabilities. A critical control point or vulnerability can be identified, modified, and measured. Thus, the objectives shift to prevention and “success” can be defined by controlling those root causes of the problems. To assess food safety, we do count the number of incidents, but the greater focus is on monitoring and managing critical control points such as the consistent and calibrated temperature of a refrigerator. This shift from measuring only outcomes to focusing on addressing the root cause of anomalies is the founding principle of quality management. Measuring the end product is, of course, key, but the real focus and success measures focus on managing the critical control points.

Conclusion

Over the years, it has become clear that addressing food fraud incidents and implementing prevention strategies require a fundamentally different approach than for addressing food quality, food safety, or food defense problems. It has become clear that we will “not arrest our way to safety” and not “test our way to compliance.” The frustration and exasperation have led to deconstructing the root cause and shifting to disciplines such as social science and criminology with decision-making in

managerial accounting and enterprise risk management. There has been a simplicity in stepping back to consider the entire process and for all types of product fraud. *The first conclusion is* that there is an interdisciplinary approach to food fraud prevention. The basic idea of prevention requires a holistic, all-encompassing view of the problem and also awareness through to even the final resource-allocation decision-making process. This examination leads to a consideration beyond just tactics such as arresting bad guys or seizing product to taking a strategic approach to identify the fraud opportunity and then manage the vulnerabilities and root causes. *The second conclusion is* to start with an overall strategic approach and then select tactics. Finally, that strategic approach requires a system to consider all aspects of the vulnerabilities and the control systems. When there is a consideration of “everything,” then a systematic approach can be developed that “connects everything to everything.” This includes seeking new information, considering how that new information impacts our understanding of the fraud opportunity, then an assessment of whether this new or changing risk is above the risk tolerance, and then a method to select and monitor countermeasures. *The final conclusion is* to “connect everything to everything” in a Food Fraud Prevention Strategy.

There is a saying:

“If the biological organism in question was a microbe you would logically engage the field of microbiology; for Food fraud, the biological organism I question is a human to you would logically engage the field of Social Science and specifically Criminology.”
“Repeat after me – ‘Social Science is a real science.’”

Appendix: WIIFM Chapter on Prevention Basics

This “What’s In It For Me” (WIIFM) section explains why this chapter is important to you.

Business functional group	Application of this chapter
WIIFM all	Follow the process and start first <i>only</i> at a very high level with a quick, enterprise-wide assessment... <i>for now</i>
Quality team	This is not like any other food risk you are assigned to manage—step back, consider the root cause, and follow the process to start with a focus at the very high level, enterprise-wide assessment... and <i>then</i> drill down into the details
Auditors	The nature of the risk is that the controls are based on, and best assessed by, enterprise-wide assessments—a manufacturing site requirement may be <i>only to not</i> deviate from the corporate-wide plan
Management	Let your team follow the process and reinforce a quick, high-level, top-down assessment <i>before</i> getting into too much detail and <i>long</i> before conducting manufacturing plant-level vulnerability assessments
Corp. Ddecision-makers	Believe it or not, the process will provide you with a clear assessment that will be immediately applied in enterprise risk assessment type systems

Appendix: Study Questions

This section includes study questions based on the key Learning Objectives in this chapter:

1. Discussion Question
 - (a) Why was a FF interdisciplinary approach so hard to create and implement?
 - (b) How is the FF problem interdisciplinary?
 - (c) What are the strengths and weaknesses of a mono-discipline, interdisciplinary, or multidisciplinary approaches?
2. Key Learning Objective 1
 - (a) What is “interdisciplinary” versus “multidisciplinary”?
 - (b) What are the disciplines in the interdisciplinary approach?
 - (c) Are investigation and prosecution a preventive approach?
3. Key Learning Objective 2
 - (a) What is a “Sociopath”?
 - (b) What is the relationship between a “Sociopath” and a “Criminal”?
 - (c) Is a traceability code an overt or covert anti-fraud feature?
4. Key Learning Objective 3
 - (a) What is a supplier “Credit Rating”?
 - (b) How does the Food Protection Plan start?
 - (c) What is the difference between an action that is strategic, tactical, or operational?

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Chapter 4

Food Fraud Prevention Overview

(Part 2 of 3): The Approach



Summary

This chapter presents the application and utility of the overall Food Fraud Prevention Cycle (FFPC). Each component is connected to every other component. The decisions are calibrated and correlated to the formal enterprise-wide decision-making system. Essentially the FFPC “connects everything to everything” in a dynamic and self-correcting cycle. The FFPC components include (1) overall principles (e.g., A, B, and C) and steps that are the activities (e.g., 1, 2, 3, 5, and 5).

The Key Learning Objectives of this chapter are:

- (1) **Food Fraud Prevention Cycle (FFPC):** Presentation of a systematic approach to food fraud prevention
- (2) **Functionality:** The functionality and application of the Food Fraud Prevention Cycle
- (3) **Individuals Steps:** The process steps in the cycle

On the Food Fraud Prevention Cycle (FFPC), this chapter addresses the components and functionality of the entire cycle (Fig. 4.1). The next chapter will address each component of the FFPC.

Introduction

There were stories of that security products suppliers had challenges in getting brand owners to actually make a decision to implement the programs. There was an agreement that counterfeiting was “a problem” and that the brand owner must “do something.” There would be months and months of presentations and product reviews but usually a stall just before the final resource-allocation decision-making, the final sign-off from the CFO to purchase the anti-counterfeit component. Early on we saw the rate-limiting step was in the final decision. There was a lack of ability, willingness, confidence, or urgency to make the resource-allocation decision.

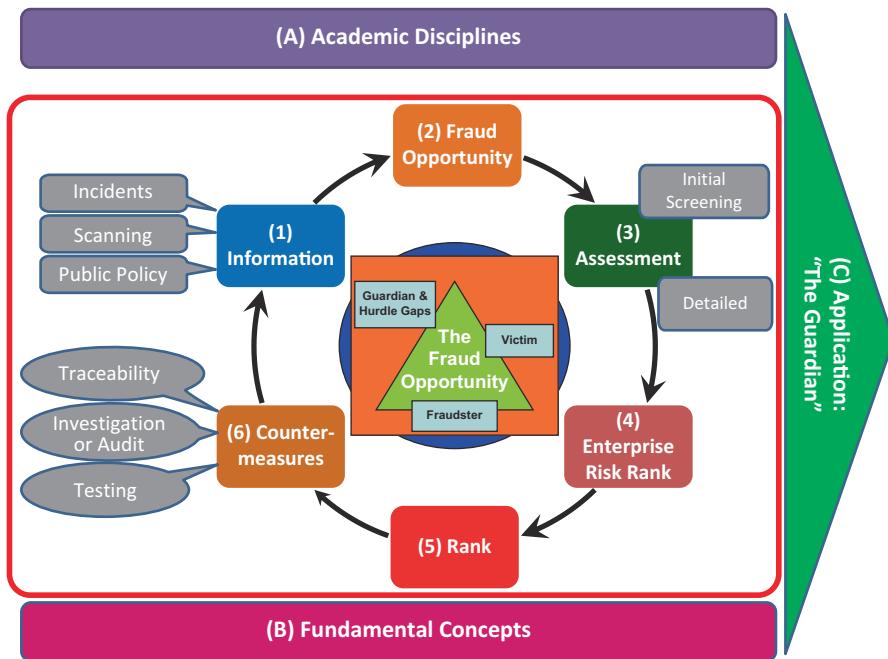


Fig. 4.1 Food Fraud Prevention Cycle: where this chapter applies to the overall concept—the entire cycle 1, 2, 3, 4, 5, 6 and the fraud opportunity (Copyright Permission Granted) (Spink 2014; Spink et al. 2019)

This led to a review of the entire system and then a focus on supporting that final resource-allocation decision-making. The result was the Food Fraud Prevention Cycle—a cycle that “connects everything to everything” including presenting the proposal in terms that the CEO/CFO needed.

The value of the Food Fraud Prevention Cycle (FFPC) is that all work functions or activities are included with methods to convert information into a useable form. If new functions or activities are identified, they will be added to the cycle or within current activities. The corporate-level risk assessor considers “I understand that there might be two deaths. I’m really concerned. I have no idea how I would assess this in relation to all other risks.” The resource allocation judgment was apart from other proposals. Unless there was a regulatory requirement (mandatory where inaction would be illegal)—or the influence of the General Counsel to “do something”—the other proposals were implemented.

The final, and transformational, step in the development of the FFPC was incorporating the food fraud vulnerability or risk into Enterprise Risk Management on a corporate risk map.¹ This is important because when the Board of Directors or the

¹ Note: COSO more often uses the term “risk map” or “heat map,” but “corporate risk map” is used here and throughout to clarify the intent review the formal and systematic assessment of enterprise-wide risk not a basic risk summary.

C-suite reviews a new risk, at first they are seeking just a broad and quick estimate of the issue. “How big is this problem?” “Will there be a big investment or many new resources needed?” “Should the CEO/CFO alert the Board of Directors immediately or is this really just another general risk?”

Beyond connecting every step or activity to each other, conceptually this is a cycle that is dynamic and self-correcting. The “fraud opportunity” and “risk appetite” fluctuate, and this cycle will provide a guide to increasing—or, key, decreasing—the ongoing investment in countermeasures and control systems. The value is that this is (1) a complete system that addresses all types of activities, (2) communicated in a format that supports decision-making, and that it is (3) self-correcting by encouraging a calibrated increase or decrease in countermeasures and control systems.

Key Learning Objective 1: Functionality and Application of the FFPC

This section reviews the functionality and application of the Food Fraud Prevention Cycle (FFPC). There are work processes for each function or steps that contribute to the bigger risk control strategy. The key is the overarching strategy that starts with a focus and understanding of the “fraud opportunity” rather than building upon or expanding other programs. The FFPC components include (1) overall principles (e.g., A, B, and C) and steps that are the activities (e.g., 1, 2, 3, 4, and 5).

The Key Learning Objectives of this section are:

- (1) Understand the process to coordinate and optimize countermeasures.
- (2) Continuous monitoring of the fraud opportunity and vulnerability assessment to optimize the risk treatment.
- (3) Consider the specific process steps in the Food Fraud Prevention Cycle.

Coordinating Countermeasures: Scouting Internally for Other Current Programs

It may seem either commonsense or utterly simplistic, but after the first review of the fraud opportunity, there is an efficiency of scouting across the enterprise for other countermeasures and control systems that could apply. Often, when there is a crisis, new programs or systems are implemented without extensive planning, coordination, or research. The work groups make the best decision they can under the time constraint and with the resources provided. There is usually a focus on one specific problem and with resources or insight from within one or a small group of experts. The urgency of the crisis does not lend itself to taking time to reflect too

much on the enterprise-wide perspective or to conduct a lot of additional data gathering. Also, there is often a “Crisis Management” or “Business Continuity” team who does not have a responsibility to review the incident over time or to conduct a more prevention-based assessment. Often there is a series of crises...often there is “fire after fire.”

Thus, when developing a Food Fraud Prevention Strategy, it is efficient to take the time to identify related programs or projects that could be helpful to reduce or control the fraud opportunity (Fig. 4.2).

Often holistic reviews of the programs or projects identify ways they could be connected for a more significant impact. In other instances, the food fraud prevention countermeasures and controls systems may already be in place (during the search, the mindset should be that there *are* other programs already addressing part of the problem, so keep searching). Those other projects, activities, or processes may be implemented but not *yet* considered in the Food Fraud Prevention Strategy.

Considering food fraud in the continuum of all food control programs, it is entirely possible that 99% of all audits, testing, oversight, inspections, traceability, transparency, and data collection are already implemented (Fig. 4.3). Those programs just need to be identified and coordinated within the Food Fraud Prevention Strategy. For example, the separate activities to address food quality, food safety, and food defense contribute insight to address food fraud. When utilizing the visibility to risks from those other areas, it is possible that only minor extra effort is needed to completely address food fraud.

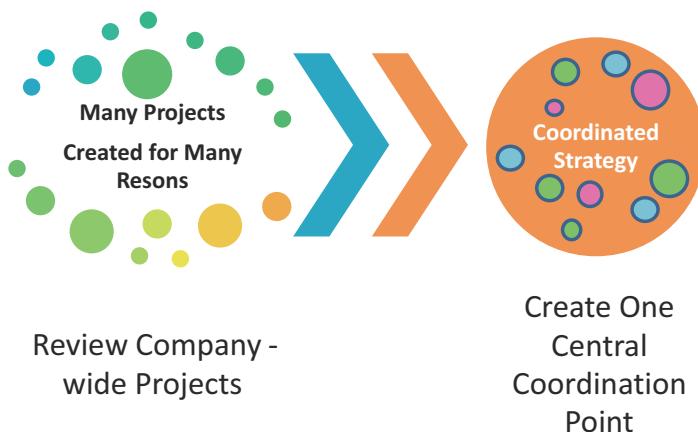


Fig. 4.2 Creating a coordinated plan that organizes and calibrates a seemingly unaffiliated set of activities (often projects are created as a response to one specific incident or required compliance requirements—the new project is not necessarily connected or calibrated with all other related projects)

Food Fraud in the Continuum

- Probably 99% of all audits, testing, oversight, inspections, traceability, transparency and data collection are already implemented...

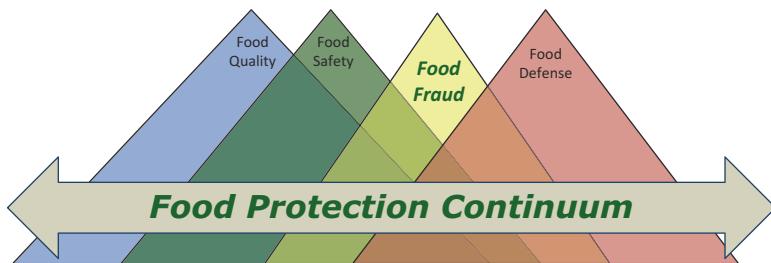


Fig. 4.3 Food fraud in the continuum—considering all food protection programs or projects and how they contribute to food fraud prevention (Copyright Permission Granted) (Spink 2015a, b)

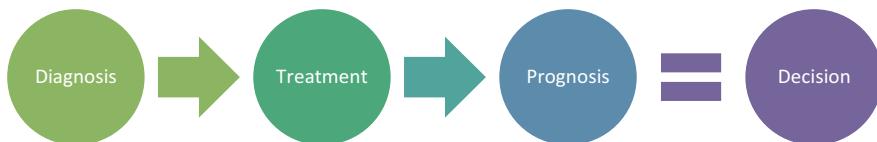


Fig. 4.4 Continuum of diagnosis, treatment, prognosis, and the decision (Copyright Permission Granted) (Spink 2019a, b)

Selecting Countermeasures and Control Systems

The component “(6) Countermeasures” includes the consideration of countermeasures and control systems. A **countermeasure** is an activity such as authenticity testing or including anti-counterfeit authentication features such as a serial number. A **control system** would be monitoring such as traceability or other supply chain transparency. The review of countermeasures is similar to a medical response of “diagnosis-treatment-prognosis = decision” (DTP).

Think about a sick person visiting a medical doctor. Overall there is a process for ‘diagnosis,’ then consider a series of possible ‘treatments,’ and each treatment considers a ‘prognosis’ (Fig. 4.4). The diagnosis is similar to considering vulnerabilities. The treatments are the countermeasures or control systems which do include ‘do nothing.’ Finally, each diagnosis-treatment option should consider a prognosis or result of the effort. For example, if fraud is occurring at 1 to 5% of the finished good, then there is no need for a treatment that reduces the sensitivity from 1 part per thousand to one part per million.

Sidebar: Review of the GMA Brand Protection and Supply Chain Integrity Report (MSU-FFI 2018):

Title: GMA Brand Protection and Supply Chain Integrity Report

By John Spink • March 13, 2014 • Blog

On February 20, 2014, the Grocery Manufacturers Association (GMA) released their new report on “Brand Protection and Supply Chain Integrity” (GMA 2014). With my MSU colleague Dr. Doug Moyer, we participated in the Brand Protection Working Group that provided guidance for the project. This report was commissioned by GMA and the Food Marketing Institute (FMI) based on a direct request from their 2012 CEO Leadership Forum—addressing counterfeit product was “among the highest priorities of the members.” The research was conducted pro bono—as are most GMA reports—by information technology/transaction management supplier Inmar and product authentication supplier Authentix. The report included expert insight by those authors, the best practices survey of GMA/FMI members, and was supplemented by a consumer survey previously conducted by Inmar.

The project was scoped to only include products with a human or animal public health threat (it did not seem to be the intent, but these were all FDA-regulated products.)

- “The scope of products covered in this guide includes CPG [consumer packaged goods] – food, over-the-counter medicines, pet and health, and beauty care products. The guide does not cover coupons, apparel, sporting goods, automotive, electronics or other non-food items found in mass merchandisers and specialty retail.”

The report used a broad—or macro—definition of counterfeiting, which expanded the focus beyond trademark, patent, or copyright infringement. It did zoom in on illegally manufactured or adulterated goods—specifically not including stolen goods or actions that do not violate the IP rights. In the USA, the “counterfeiting” laws focus on the intellectual property rights.

- “For the purposes of this guide, **counterfeit goods** are defined as illegitimately manufactured or adulterated goods. This guide does not address stolen goods or products such as ‘replica’ or ‘genuine imitation’ items that do not otherwise violate a brand owner’s rights.”

There was a focus—consistent with our previous MSU-FFI publications and research direction—on “detection, prevention, and deterrence.”

There was a broad range of best practices noted but few direct recommendations for countermeasures in the case study section of the report, except for the following regarding packaging:

- “[To address packaging anti-counterfeiting countermeasures] the manufacturer enlisted a third-party security company to develop a program that

was compatible with already existing programs. Four important steps were taken to combat the unauthorized product:

- Late stage customization to add security post-production
- Tamper-evident security labels with covert and forensic features
- Labels supplied from a secure, third-party print facility
- Labels printed with region-specific information to meet local regulations.”

Also, packaging technology expertise was identified as one of the key expert areas:

- “Create a dedicated group that has expertise in 4 key areas: law enforcement, supply chain, packaging technology and legal.”

A best practice directly addressed packaging countermeasures:

- “Build anti-counterfeit and brand protection elements into the product design process with the goal to employ in-product and on-package authentication technology.”

In summary, this report provides some interesting best practices and a base from which companies can start building a Brand Protection response. While our MSU-FFI is focused on food, none of us can ignore that the bad guys focus on all products. Expanding our perspective to understand the insights in reports like this is essential. There are best practices we can learn from by many adjacent industries.

Defining Food Fraud Prevention to Align Food Science and Technology Resources

Previously published blog post:

Title: Defining Food Fraud Prevention to Align Food Science and Technology Resources

By John Spink • December 16, 2013 • Blog (MSU-FFI 2018)

The EU food fraud resolution just advanced from task force committee to a full European Parliament vote in early 2014. Defining food fraud and a focus on preventative actions are no longer just academic exercises. That said, our new “Defining food fraud prevention to align food science and technology resources” is perfect timing, with very important insight for implementing regulations and industry best practices (Spink et al. 2013a).

Focus Research on Prevention

There have been incredible advances in food science and food integrity testing. A key to our success in preventing food fraud will be the balancing what we “can” do with what we “need” to do (e.g., “do I need to act?”). The effort to focus research on prevention will be critical to protecting the food

supply – our goal is not to just find adulterant-substances. Our goal is to create a system where they don't get in the food in the first place! From our article, “Whilst better means of detecting food fraud are required, ‘successes must be measured in terms of how the activities support prevention. We need a systems approach to optimize the roles of all food supply chain and research partners.”

Food Industry Leads the Efforts

In the article, a concept we emphasize and explain is that it is critical to have food experts leading—or at least involved in—every aspect of food fraud prevention efforts. “There are very unique aspects of the complex food production systems that are baffling to outsiders. There are complexities to authenticating food that are unlike any other sciences – the complexity of profiling a multi-component food product requires methodologies that are still far from routine or easy to use and interpret. There is an incredible amount of inherent variation in the same food product produced over the course of a year.”

Harmonization of Terms

We emphasize in the article that harmonization of terms and prevention efforts are both critical to a global, efficient, and effective effort. As I've published on and presented for years, Situational Crime Prevention and the use of the Crime Triangle are great way to deconstruct the fraud opportunity and really focus on prevention (we thank you Dr. Robyn Mace, MSU School of Criminal Justice, for introducing our food fraud prevention team to the topic back in 2006 and then Assistant Professor Justin Heinonen on the SARA model and victimology).

The Role of Science and Technology

Of course, traditional food science and the more recent focus area of food integrity (Food Authentication) both have critical roles in food fraud prevention. That said, there cannot be just a technology solution. Food fraud prevention requires a systems approach that includes Supply Chain management, criminology, and other fields, such as quality management. “For food fraud, the straightforward measure of the presence or absence of a contaminant is only part of ‘the puzzle,’ and in contrast to food safety hazards, there are a seemingly near an infinite number of adulterants. In the case of diversion, stolen goods, or production overruns, the fraud does not include an adulterant at all. Actually, the food fraud is conducted with genuine products.”

Acknowledging My Coauthors: Christopher Elliott and Kevin Swaffer

I'm very proud and honored to have worked with coauthors Professor Christopher Elliott and Kevin Swaffer on this article (Spink et al. 2013a). Chris is a world-renowned expert on foods and has conducted some incredible innovative research in food integrity and authenticity. He is the Director of the Institute for Global Food Security at Queen's University (Belfast, Northern Ireland, UK). He also is leading an independent UK review of the food

supplies network following the horsemeat scandal. Kevin Swoffer has been a constant colleague and supporter since we met at MSU back in 2007. He is the Director of KPS Resources. He has over 30 years of experience in the food manufacture and retail sectors. He was involved at the founding of the GFSI in 2000 and has been actively involved in its development. More recently, Kevin and I have been interacting with and discussing the Food Fraud Think Tank for the Global Food Safety Initiative. Collaborating on this article was a great opportunity to really harmonize our thinking.

Food fraud is not new, but the science is providing a framework within which we all work. By coordinating our activities—as theorists and scholars first—we can be much more efficient. Play your part and stay up on the latest thinking; link to the article to see the full discussion (MSU-FFI).

Key Learning Objective 2: Integrated Framework for “How Much Is Enough?”

This section reviews an integrated framework based on COSO Enterprise Risk Management to get to the most basic question resource-allocation decision of “how much is enough?” There are many methods and tools the address one part of the system, and the connection to the enterprise-wide management is a final integration step.

The Key Learning Objectives of this section are:

- (1) The most important and most overlooked step is to define the resource-allocation decision-making process.
- (2) The COSO Enterprise Risk Management compliance requirements are the overall system.
- (3) Then, these concepts are applied to the other food fraud prevention methods and tools into the internal controls and integrated frame to help determine “how much is enough?”

Monitoring for Efficiency: Review the Current Decision-Making Process

It seems redundant for a risk analysis process to include a review of the risk assessment, but this is the strength and value of the overall controls and provides more transparency and accountability. The process includes different levels of the organization reviewing the risk assessments of other levels. For example, the C-suite reviews the operation and vice versa (Fig. 4.5). Both have their risk assessments reviewed by the board. The Food Fraud Prevention Cycle incorporates these

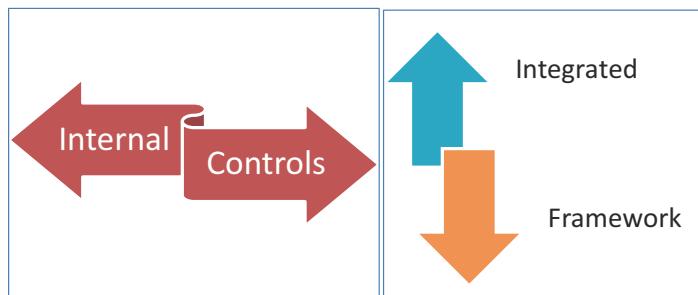


Fig. 4.5 Visual of the horizontal internal controls and the vertical integrated framework—together they “connect everything to everything”

ERM/COSO best practices and connects the ongoing updates of the “fraud opportunity” with the shifting “risk appetite.” Each level of these “internal control” steps includes an “integrated framework” reviews and calibrates to the other functions. Each new activity or information has a place to add to the cycle.

ERM/COSO is already a function and standardized method for monitoring the risks. Overall ERM is referred to as “internal controls and integrated framework.” The “integrated framework” includes assessments across and within the operations. An example of calibrating the actions within the organization includes correlating the assessments that are conducted. For example, “Principle 8” is “Assess Fraud Risk” and includes a method to root out fraud in fraud assessments (for more, see the Chapter on Business Decision-Making) (PWC 2014; COSO 2016).

Sidebar: ERM/COSO Five Concepts and 17 Principles

The ERM/COSO system explains how the activities are connected when they present the Five Components and 17 Internal Control Principles and this Guide’s Five Fraud Risk. This emphasizes that “a comprehensive fraud risk management program is not only the risk treatments or countermeasures but the organization and coordination of the entire process.”

“For organizations desiring to establish a more comprehensive approach to managing fraud risk, this [COSO Fraud Risk Management Guide] includes more than just the information needed to perform a fraud risk assessment. It also includes guidance on establishing an overall Fraud Risk Management Program including:

- Establishing fraud risk governance policies
- Performing a fraud risk assessment
- Designing and deploying fraud preventive and detective control activities
- Conducting investigations, and monitoring and evaluating the total fraud risk management program.”

The full details of the 5 concepts and 17 principles are presented here. To establish the frame, COSO defines the overall scope of the organization covers

the entire enterprise from the very highest board level throughout the operations to all products and services. From COSO:

- **The Organization:** “for purposes of the framework, the term ‘organization’ is used to collectively capture the board, management, and other personnel, as reflected in the definition of internal controls” (COSO 2013).
 - **Internal Control:** “is a process, effected by an entity’s board of directors, management, and other personnel, designed to provide reasonable assurance regarding the achievement of objectives related to operations, reporting, and compliance.”

Also, the classification of risk treatment of activities includes (COSO 2016):

- **Preventive Controls:** “designed to avoid a fraudulent event or transaction at the time of initial occurrence.”
- **Detective Controls:** “designed to discover a fraudulent event or transaction after the initial processing has occurred [and hopefully before the accounting transaction is complete].”

Fraud Risk Management Principles (ERM/COSO) (COSO 2016):

Principle 1: Control Environment—The organization establishes and communicates a Fraud Risk Management Program that demonstrates the expectations of the Board of Directors and senior management and their commitment to high-integrity control and ethical values regarding managing fraud risk.

1. The organization demonstrates a commitment to integrity and ethical values.
2. The Board of Directors demonstrate independence from management and exercises oversight of the development and performance of internal control.
3. Management establishes, with board oversight, structures, reporting lines, and appropriate authorities and responsibilities in the pursuit of objectives.
4. The organization demonstrates a commitment to attract, develop, and retain competent individuals in alignment with objectives.
5. The organization holds individuals accountable for their internal control responsibilities in the pursuit of objectives.

Principle 2: Risk Assessment—The organization performs comprehensive fraud risk assessments to identify specific fraud schemes and risks, assess their likelihood and significance, evaluate existing fraud control activities, and implement actions to mitigate residual fraud risks.

6. The organization specifies objectives with sufficient clarity to enable the identification and assessment of risks relating to objectives.

(continued)

7. The organization identifies risks to the achievement of its objectives across the entity and analyzes risks as a basis for determining how the risks should be managed.
 - (a) [Note: for food fraud prevention, this defines the requirement to conduct a holistic and all-encompassing assessment.]
8. The organization considers the potential for fraud in assessing risks to the achievement of objectives.
 - (a) [Note: for food fraud prevention, this considers that—beyond risk assessors who may not be well trained or expert on the task—there may be “fraud in fraud assessments.”]
9. The organization identifies and assesses changes that could significantly impact the system of internal control

Principle 3: Control Activities—The organization selects, develops, and deploys preventive and detective fraud control activities to mitigate the risk of fraud events occurring or not being detected in a timely manner.

10. The organization selects and develops control activities that contribute to the mitigation of risks to the achievement of objectives to acceptable levels.
11. The organization selects and develops general control activities over technology to support the achievement of objectives.
 - (a) [Note: for food fraud prevention, there should be a prevention strategy before tactical countermeasures or control systems are selected.]
12. The organization deploys control activities through policies that establish what is expected and procedures that put policies into action.

Principle 4: Information and Communication—The organization establishes a communication process to obtain information about potential fraud and deploys a coordinated approach to investigation and corrective action to address fraud appropriately and in a timely manner.

13. The organization obtains or generates and uses relevant, quality information to support the functioning of other components of internal control.
14. The organization internally communicates information, including objectives and responsibilities for internal control, necessary to support the functioning of internal control.
15. The organization communicates with external parties regarding matters affecting the functioning of other components of internal control.

Principle 5: Monitoring Activities—The organization selects, develops, and performs ongoing evaluations to ascertain whether each of the five

principles of fraud risk management is present and functioning and communicates Fraud Risk Management Program deficiencies in a timely manner to parties responsible for taking corrective action, including senior management and the Board of Directors.

16. The organization selects, develops, and performs ongoing and/or separate evaluations to ascertain whether the components of internal control are present and functioning.
17. The organization evaluates and communicates internal control deficiencies in a timely manner to those parties responsible for taking corrective action, including senior management and the Board of Directors, as appropriate.
 - (a) [Note: for food fraud prevention, it is clear that *not* having visibility or correlation into the ERM/COSO system would be a nonconformance.]

The “Internal Controls” are not just monitoring of activities across the business but also vertically. A corporate auditing firm may separately (and confidentially) audit the Board of Directors, the C-suite, and the business operations, and then audit up and down between those functions. This creates transparency (Fig. 4.6).



Fig. 4.6 Ongoing, comprehensive fraud risk management process (based on the 2013 COSO framework). (Adapted from (COSO 2012))

(continued)

For food fraud prevention, could you provide a documented report on examples and evidence that you competently address each concept and principle? Would you be comfortable presenting your document to an auditor, inspector, or investigator? A first step to providing an answer is to fully understand the details and expectation stated in the question. If you are a manager, you might start by asking your food fraud prevention manager or team to answer these questions.

COSO Principles in Detail: Fraud in Fraud Assessments

COSO is a very rigorous and thoroughly developed concept. There are main principles clustered in five groups (COSO 2013). Also, this process is conducted at different levels (board, c-suite, and then operations including comparing assessments across multiple businesses) and within levels (comparing assessments between levels). These “internal controls” and the “integrated framework” are critical to maintaining control of the risk tolerance across an enterprise. For a corporation—big or small—there may be one group or business unit that conducts business way above the risk tolerance of the enterprise thus putting the entire company at risk. In other instances, one group or business unit may be operating way below the risk tolerance and then theoretically reducing the financial return for the enterprise (assuming that taking on more risk provides an opportunity for more reward).

It is completely logical for there to be “fraud” in “fraud assessments.” Whenever anyone is subject to a positive or negative consequence, there is a potential for bias based on an inherent “fraud opportunity.” COSO/ERM considers this and has identified controls in several of their principles:

Principle 8: The organisation considers the potential for fraud in assessing risks to the achievement of objectives. (COSO 2016)

- “Fraud risk scenarios might include material bias in the development of complex accounting estimates, the overriding of controls in stuffing inventory into distribution channels to manipulate revenue recognition, and noncompliance with the Foreign Corrupt Practices Act.”
- “In identifying and evaluating those risks, management investigates incentives, pressures, opportunities, attitudes, and rationalization that might exist throughout the company in different departments and among various personnel. This undertaking equips management to determine the mitigating actions it should take to reduce to acceptable levels any risks of material misstatement due to fraud.”

So, “fraud” in “fraud assessments?” The concept of the related bias in business decision-making is a science that has been studied extensively by leaders such as Bazerman (Bazerman and Neale 1993; Bazerman et al. 2002, 2003; Bazerman and Chugh 2006). Here are several basic scenarios that apply to food fraud prevention:

- ***I want to grow my group:*** An up-and-coming manager who wants to increase their responsibility would have a bias toward finding *more* fraud and expanding

their budget and head count. People don’t get promoted for identifying there is “no need for change.”

- ***I want to reduce my work:*** Another manager may want to reduce their workload and thus would be predisposed to *under-estimate* the risks to *avoid* more responsibility or employees to supervise.
- ***I really do/don’t like this topic:*** Then there is a motivation to become—or avoid becoming—experienced in a new type of fraud or fraud prevention in general. Many times a manager is put into “cross-functional” positions for career growth. A “sales” track manager who is put in charge of “Brand Protection” may be biased to stay focused more on “sales.” (If they get “too good” at the new work functions, they may be forced to stay!) Growing experience in controlling a problem—rather than succeeding in a high growth or high impact area—may not be attractive.
- ***Contractor or supplier—I want more business:*** An external consultant who is hired to investigate or mitigate fraud risks would receive more business if there is more fraud. So a fraud investigator would have an inherent bias to find fraud to justify more future fraud investigations.

Overall, based on psychology theory and empirical business research, there is a potential for “fraud” in “fraud assessments” if the risk assessor has a vested interest or benefit from the outcome of the assessment. COSO/ERM considers this in their “Principle 8.”

Iterative Cycle: Review of the Process Itself

An important process step is to take the time to review the base method or process itself (MSU-FFI 2017; MSU FFI 2017). Food fraud prevention is an evolving vulnerability, and there are many new innovations in not only countermeasures and controls systems but also in implementing the process. For example, Enterprise Risk Management/COSO is not well known by food safety professionals and with even less actual application of the concepts. The Sarbanes-Oxley Act was unknown to those people developing or managing HACCP plans.

For food fraud prevention, there is an iterative cycle; meaning that when there is new information (e.g., a new incident, a changing fraud opportunity, or reduced enterprise-wide risk appetite), the entire system is reviewed and could re-calibrate. Usually, when resources (e.g., funding or employee time) is allocated, there is no mechanism to dial back down the investment. A new countermeasure or control is put in place to combat a concern or new issue, but there is no standard method to review “how much is enough?” and if systems should be reduced. It is fundamentally contradictory for a food safety professional to *increase* a risk. The key is not just “risk” but to clearly understand and address the level of “unacceptable risk.”

Without the method to reevaluate the current countermeasures and controls systems in relation to the shifting fraud opportunity, then costs will go up and up even if the business is well within the risk appetite. At the same time, there may be some risks that are unknown and where the business may be operating at an unacceptably high level of risk.

Sidebar: “How Much Testing Is Optimal?” It Depends

An example would be to test for horsemeat in beef. When there is a crisis, new countermeasures and control systems are put in place for detection and emergency response. There are many unknowns, so a broad testing plan is critical to getting a perspective on the entire supply chain. Also, there is concern that there is an illegal product in the current supply chain so thorough testing is critical. Once the new system is in place, usually one of two things happens:

1. After the crisis is over, the testing stops.
2. The high “crisis-level” testing never stops.

What is the “right” level of activity rests on “what is the right question?”

In the midst of a crisis where horsemeat is found in the marketplace, then massive and holistic “detection” programs should be implemented. This would be similar to traditional food safety monitoring tests. After the crisis, if there are still active perpetrators or product still trickling in, then a lesser but still random “deterrence” protocol is ideal. Once the incident has passed and the vulnerability is understood within the Food Fraud Prevention Strategy, then an extremely efficient yet very small “prevention” program can be implemented and defined.

To provide a more direct application, a hypothetical example is provided for the amount of testing to support the activity of “detect,” “deter,” and “prevent.” There are appropriate protocols for different objectives such as “detection test plan,” “deterrence test plan,” and “prevention test plan” (Fig. 4.7).

Detection test plan: The goal is to quickly and thoroughly “detect” the fraudulent activity and remove the product from the supply chain to reduce future product recalls or liability. The focus of the “detect” activity is for an intervention to find known (or confirmed suspicious) incidents. There would be a (1) clear identification of a single or few products and (2) particular fraud acts or adulterant-substances. During the “detect” focus, there could be (1) 100’s of food authenticity tests conducted on (2) possibly 100 supplier/product combinations which (3) could result in 10,000 tests per month throughout the year crisis. The 10,000 tests per month do attract a lot of attention for supplier research and development investment.

- Application: Using the horsemeat incident as an example, during and after the incident, there were massive-scale horsemeat species test plans put in place. There were also often species tests for related species depending on regions such as zebra, fox, pork, water buffalo, and others. The goal was to conduct a comprehensive and all-encompassing process to make sure there was no fraudulent horsemeat in the proprietary supply chain.

Deterrence test plan: The goal is to “deter” a specific fraudulent activity, so fraudsters are persuaded not to attack. The focus on the “deter” activity is to combat a specific fraud opportunity that is probably unique to an ingredient,

Product >	Detect					Deter					Prevent				
	A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
Amount of Testing															
1	■			■		■	■		■		■	■	■	■	
2						■			■						
3	■					■									
4															
5															
	Many tests for specific problems with specific product/ supplier groups.					Some tests for specific products or supply chains to combat specific problems.					A few tests but across the supply chain to reinforce that fraud could be detected.				
	100's of tests for each of the possibly 100 supplier/ product concerns (est. 10,000 per month).					100's of tests monthly for each of the possibly 5 product or supply chain problem (est 500 per month).					100's of tests across the entire product slate (est 100 per year).				

Fig. 4.7 Review of the optimal amount of food authenticity testing for specific objectives of detect, deter, or prevent (with hypothetical example)

product, or supplier/region combination. Although there is no active incident—or this would be in the “detect” category—there is a concern that there is a fraudulent product in the supply, and the goal is to find the fraudulent product but more to specifically lead the fraudsters to be concerned they may be caught. There would be a (1) broad set of target products and (2) particular fraud acts or known adulterant-substances. During the “deter” focus, there could be (1) 100 s of food authenticity tests conducted on (2) possibly 5 supplier/product combinations per *year* which could result in (3) 100 tests per *year*. The 100 tests per *year* is a lot less attractive market for a supplier than the 10,000 tests per month in the detect test plan.

- **Application:** Using the horsemeat incident as an example, after the company conducted the deter test plan, there was a frequent but lesser series of species tests conducted. For example, the company may have reduced the focus to the only test for horsemeat and also only for incoming goods.

Prevention test plan: The goal is to “prevent” food fraud across the entire product slate and to address “unknown-unknowns”—this is a real intelligence analysis science concept. The first “unknown” is that we don’t understand who the perpetrators are or even *if* they will attack (e.g., something that is

(continued)

completely a surprise and what is sometimes referred to as a “black swan event”—responses are often “why in the world did they try to do that?”). The second “unknown” is that if they do act, we don’t know when or where they will attack (e.g., it is known melamine is a type of food fraud, but we don’t know where they will attack). For melamine in infant formula, it is a known type of attack (the first “known”) but with an unknown exact time and place (the second “unknown”).

- Application: Using the horsemeat incident as an example, a company may move beyond horse to consider *all* types of protein fraud—other species, lower quality cuts of meat, spoiled meat, non-animal protein, alternate protein products such as powdered ground meal, country of origin, declared processing method, etc. The company would select a wide range of tests to be conducted on a wide range of products and on a very small scale.

To continue focusing on the “prevent” plan, these unknown-unknowns, a focus on reducing all vulnerabilities is efficient because the perpetrators are so creative that we may not yet be aware of how or where they may attack; we don’t know what to try to detect or deter. The focus on the “prevent” activity is to focus on “vulnerabilities” regardless of whether there is any known or even suspicious activity. This is partially just alerting fraudsters that they “could” get caught in a random test but also to conduct very broad and random information gathering.

- For a “detect” or “deter” focus on preventing food fraud, there would be a (1) broad set of target products to protect (a medium size company could have 1000 products) and (2) a broad set of fraud acts or adulterant-substances to test for (how many adulterant-substances could be used?).
- For a “prevent” focus, there could be (1) 100’s of food authenticity tests conducted on (2) possibly 5 supplier/product combinations, which could (3) result in 500 tests per month during the crisis.

Thus, an efficient and insightful Food Fraud Prevention Strategy could actually require a very small set of authenticity tests to effectively monitor the supply chain and holistically reduce the fraud opportunity.

Key Learning Objective 3: The Process Steps

This section reviews specific key process steps of (1) scanning, (2) Enterprise Risk Management-based corporate risk map, and (3) an iterative that is referred to here as the “corkscrew approach.” And once the theory is in place, then the overall management process can be implemented to support the defining the operation of these specific functions. This section brings together all the concepts and explains how the overall system operates in motion.

The Key Learning Objectives of this section are:

- (1) To understand scanning that gathers and processes new information or insight
- (2) Apply Enterprise Risk Management (ERM/COSO) for decision-making
- (3) The “corkscrew approach” that starts light and goes as deep as directed by the needs of the resource-allocation decision-maker

New Information: Monitoring for Changes

There are several functions that make up the scanning concept including (1) incident reviews (of known and internal incidents), (2) scanning (broader scouting of changes such as market supply fluctuations or external incidents), and (3) public policy changes. These three are interrelated, and the information is used to provide new insight to understand the “fraud opportunity.” For each of these functions, there are no current standard operating procedures *yet*. It is most efficient to adapt current or new work processes to the specific fraud opportunity and needs.

- ***Incident reviews*** are known incidents where there is some specific type of information. These provide the most detail and value.
- ***Scanning*** is both seeking broader changes such as market conditions or of external incidents.
- ***Public policy*** changes could be either new laws, statements of new priorities, or identification of new investigations.

Together these provide broad coverage of the types of new information that could influence the fraud opportunity.

Sidebar: Selection of Strategic Authentication and Tracing Programs

Previously published blog post (Fig. 4.8):

Title: Publication—Selection of Strategic Authentication and Tracing Programs

By John Spink • February 13, 2015 • Blog (MSU-FFI 2018)

Authentication is a key to food fraud prevention and a critical part of the “detect-deter-prevent” continuum. Selecting authentication countermeasures that contribute to prevention is often complex and challenging. This challenge was the subject of my 2012 chapter on “The Selection of Strategic Authentication and Tracing Programs” in the book Counterfeit Medicines Volume I: Policy, Economics, and Countermeasures (Spink 2012).

Beyond food products, authentication is a concept that has also been widely addressed in efforts to combat product counterfeiting. This chapter is based on research with the pharmaceutical industry and is also based on—and contributed to—the terminology standards in International Standards

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Fig. 4.8 Blog post image
(Copyright Permission Granted) (MSU-FFI 2018)

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Publication – Selection of Strategic Authentication and Tracing Programs

by John Spink • February 13, 2015 • [Blog](#) • 0 Comments

Authentication is a key to Food Fraud prevention and a critical part of the “detect-deter-prevent” continuum. Selecting authentication countermeasures that contribute to prevention is often complex and challenging. This challenge was the subject of my chapter on “[The Selection of Strategic Authentication and Tracing Programs](#)” in the book *Counterfeit Medicines: Volume 1, Policy, Economics, and Countermeasures*.

Beyond food products, authentication is a concept that has also been widely addressed in efforts to combat product counterfeiting. This chapter is based on research with the pharmaceutical industry and is also based on – and contributed to — the terminology standards in International Standards Organization Technical Committee 247 Fraud Countermeasures and Controls (ISO TC 247). The fight against Food Fraud can leverage this insight and experience.

IS Technical Advisory Group US TAG. Also, previous co-author authentication-and-tracing-programs/

Download Overview of the Selection of Strategic Authentication and Tracing Programmes

John Spink

Organization Technical Committee 247 Fraud Countermeasures and Controls (ISO TC 247). The fight against food fraud can leverage this insight and experience. (Note: I am the chair of the TC 247 US Technical Advisory Group US TAG. Also, previous coauthor and research colleague Dr. Hyeonho Park of Yong In University (Korea) is the Chair of the Korean TAG.)

The Goal of Authentication Countermeasures

The chapter discussed the pharmaceutical focus on all fraud versus only counterfeiting. This is similar to the food industry discussion of combating all fraud or adulteration. There is an emphasis on the goal of reducing crime, not just catching fraudulent product or the fraudsters. The goal is *not* to catch product but to prevent the attack in the first place. A couple of quotes from this chapter addressed these concepts.

- “The term ‘fraudster’ is used as a descriptive, formal term for this specific type of criminal and their activity.”
- “The goal is not to see how many infringers can be caught: the goal is to reduce the prevalence of counterfeit product in the first place – to reduce the vulnerability and determine which countermeasures also increase our probability of finding new or evolving threats. To be most efficient and effective, the countermeasures must be strategic, holistic, interdisciplinary, all-encompassing and proactive rather than single-discipline, narrow, reactive and tactical.”

Start with Intervention

Often the selection of countermeasures is a reaction to a single catastrophic incident. When horsemeat was found in beef, the logical, urgent, and necessary response was to immediately start conducting horse species authentication tests (Lam and Spink 2018; Spink 2019a, b). The supply chain had to be investigated *right now*. No discussion of strategy or prevention, the response had to be immediate. As we covered in our 2009 article titled “Defining the Public Health Threat of Food Fraud,” the starting point after an incident is intervention, then we move to response, and only after we have more information do we shift to prevention. Unfortunately, enterprises—companies and countries—often feel they cannot take the time to shift to prevention or that activity is the responsibility of “someone else.” There are good intentions to be proactive, but often a new crisis arises that takes the available resources. To break the reactive cycle, resources need to be assigned explicitly to prevention.

Intervention Shifting to Response Then to Prevention

To shift from response back to prevention, there must be a strategic priority and a systems approach. The Food Fraud Prevention Strategy does not have to be complex or big. The hardest part is taking the time to develop the corporate policy and establishing the strategy.

Picking a single countermeasure—such as immediately conducting horse species tests on all inventories—is a single tactical solution and not in and of itself strategic. It is a “product,” not a “program” or “strategy.” The countermeasure has a very specific and defined objective, which is detection.

- “Picking a single technology and hoping it is a magic solution is easy, but technology is only one of the many aspects of an anti-counterfeit strategy. The solutions are systems, not tools, and must include what is referred to as a layered approach. What is difficult is strategically explaining why and how it will help – including in comparison with all other countermeasures – and to not only expect but also anticipate how the bad guys will try to circumvent this system or countermeasure.”

If there is a known hazard, it is logical and necessary to drop everything and address this problem which is probably considered a “reasonably foreseeable hazard.” If there are known incidents, then it is by definition “reasonably likely to occur.” Beyond what may be written or published in a law, regulation, or rulemaking, this is a legal and brand equity liability.

Systems Approach and Foundation

Without a shift to prevention, there will be *déjà vu* of reactionary emergency responses that are resource intensive and do not prevent future occurrences. Taking the time and effort to focus on a preventative systems approach is consistent with quality management principles such as Six Sigma or food HACCP programs.

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- “Understanding anti-counterfeit strategy is based on understanding the nature of the fraud and the fraudster. When this is achieved, there is a better chance of not only combating current risks but, by understanding the inherent vulnerability, predicting and anticipating the next moves as well. [The] counterfeit and substandard medicines ‘public health threat is similar to a disease that requires continual surveillance, monitoring and treatment (e.g., diabetic populations) rather than treating a single event (e.g., a broken bone).’” (Spink 2012)

Foundation: Harmonize Terminology

An important foundation is to establish agreement on definitions. Your company or country may have unique terminology, so, in that case, it would be even more important to define your terms in relation to the other common usage of the terms. Refer to standards or regulations whenever possible. From the International Standards Organization, International Standard ISO/DIS 12931: Performance criteria for authentication solutions for anti-counterfeiting in the field of material goods, counterfeiting of material goods, or physical product (Spink 2012):

- “**Counterfeit**: (verb) to simulate, reproduce, or modify a material good or its packaging without authorization” (ISO 2011).
- “**Counterfeit good**: material good imitating or copying an authentic material good.”

For combating food fraud, it would also be important to define food authenticity programs in relation to the ISO definition of authentication. The traditional food adulteration concept is similar but usually focused on testing the specification of the product; it does not really cover components that are authenticated to define that the product is genuine. Our ISO TC 247 felt that terminology was very important and it is the subject of a New Work Item Proposal (NWIP) and Work Group (WG).

- “As of January 2011 and led by Technical Committee 247 Fraud Countermeasures and Controls (ISO TC 247), ISO became involved in anti-counterfeiting. The current draft standard ISO/DIS 12931 [11] includes working definitions of:
 - ‘(a) **authentication** as the ‘act of establishing whether a material good is genuine or not.’
 - ‘(b) an **authentic good** as a ‘material good produced under the control of the legitimate manufacturer, the originator of the good or holder of intellectual property rights.’
 - ‘(c) an **authentication tool** as a ‘set of hardware and/or software system(s) that is part of an anti-counterfeiting solution and is used to control of the authentication element.’”

An ISO development that occurred after this chapter was published the definition of product fraud and fraud opportunity and the related food fraud topic of vulnerability (ISO/TC247 WG2 N0010 PWI). From that ISO draft:

- Scope of ISO TC 247: Standardization in the field of the detection, prevention, and control of identity, financial, product and other forms of social and economic fraud.
- “**Fraud:** ‘1) wrongful or criminal deception intended to result in a financial or personal gain
 - ‘2) A willful act of deception that creates human or economic harm.
 - Note 1 – types of fraud may include: product related such as counterfeiting, illicit diversion, alteration, intellectual property infringement; Identity fraud such as identity theft (imposter fraud, disguise, credential alteration) and document fraud such as cheque fraud, banknote fraud, certificate fraud
 - Note 2 – the consequences of ‘harm’ and ‘deception’ may vary between jurisdictions and cultures.”
 - “**Fraud opportunity:** The conditions which provide an attractive target for fraudsters, regardless of if a fraud has been perpetrated. This is similar to the criminology concept of the ‘crime opportunity’ in the ‘Crime Triangle.’
 - Note1 – A crime triangle means 3 elements; 1. Motivated offender, 2. Suitable crime target, 3. The absence of a capable guardian.”
 - “**Vulnerability:** area of exposure to fraudulent activities.”

Assessing the Situation

The first step in a proactive, systems approach to food fraud prevention is assessing the situation. There have been many risks or vulnerability assessments developed over the years. There are current activities specifically for food fraud prevention. Understanding and explaining the foundation is the first step—ISO 31000 refers to this as “Establishing the Context.”

- “This section provides an overview of an anti-counterfeit strategy to assist in risk assessment before choosing countermeasures. The first step is to conduct a risk assessment of the counterfeit product risk, which includes reviewing company and industry incidents. The second step is to seek to understand the nature of the fraud and fraudster, which includes understanding the criminology aspects of deterrence.”

Defining the needs of data or “intelligence analysis” is critical to the effectiveness of assessments. This is a key focus in our “Analysis of Food Supply Chains for Risks and Resilience for Food Fraud/ Food Crime” UK grant with Professor Christopher Elliott and Queen’s University Belfast. I am leading Work Package 3 “Incident data collection to assist in intelligence analysis” (note: results published in 2019 (Spink et al. 2019)).

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Also, my 2009 MSU Packaging Science doctoral dissertation was actually on this subject: “Analysis of counterfeit risks and development of a counterfeit product risk model” (Spink 2009).

To evaluate the situation, there are two parts to the preliminary assessment: incident review and the vulnerability assessment. A key point is to define exactly how the assessments will be used. Often the incident review is used to present the scope of a known vulnerability, as well as to conduct cluster analysis to identify key focus areas (see blog post on our article on a Product Counterfeiting Incident Clustering Tool). For evaluation by a company in an Enterprise Risk Management (ERM) system, the assessment must be in financial terms—public health may be the first priority, but it is because of the potentially catastrophic financial impact (see our previous blog post of our New Food article on decision-making).

The incident review is often very revealing, especially for managers who have not been familiar with the topic. Often the most significant threats are from within the legitimate supply chain which includes:

- “Rogue participants are not always autonomous and completely external to the supply chain, and can range from organizations outside the supply chain to companies in the legitimate supply chain that occasionally perpetrate fraud, to a single individual acting alone from within the supply chain.”
- “It is important to understand that, in the worst case, the counterfeiters are criminals not concerned with breaking the law, sociopaths not concerned with cheating others and not educated about the inherent public health or safety dangers.”
- “They are often ‘irresponsible defendants’ who flee, obfuscate ownership of their assets and effectively launder their money out of reach, who have networks that can re-form unnoticed, and who are often part of violent, criminal network.”

The Value (and Risk) of Preliminary Assessments

We are accustomed to conducting extremely data-driven food safety risk assessments. For food fraud prevention, as with many other risks and risk assessments—such as Military Standard 882D and Delphi method—expert opinion and preliminary qualitative assessments have a role. Even though it may seem rudimentary and straightforward, a preliminary, top-down, qualitative vulnerability assessment helps scope the overall situation. This simple method often helps reveal a previously unknown—or until now underappreciated—hazard. It is not uncommon for a full policy and strategy development process to get sidetracked to address an identified hazard. Even if this is a simplistic, preliminary exercise, the process may identify a severe hazard.

If the hazard is now known and occurring, it is by definition “reasonably likely to occur” and a “reasonably foreseeable hazard.” Countermeasures must be taken.

Selection of Countermeasures

The published chapter provides a thorough overview of the selection of product fraud countermeasures. The key point is:

- “For every countermeasure, there should be a precise description of exactly how it detects or deters specific types of fraud and fraudsters.”

The chapter also includes a comprehensive list of product authentication countermeasures (MSU-FFI).

End of the blog post.

Sidebar: Selecting Countermeasures—Specific Scoping Questions

There are specific scoping questions from the chapter on “The Selection of Strategic Authentication and Tracing Programs” in the book Counterfeit Medicines Volume I: Policy, Economics, and Countermeasures (Spink 2012).

“To turn attention to assessing anti-counterfeit countermeasures, several practical questions are necessary:

- **Overall Anti-counterfeit Goal – To Do What?**
- ‘(a) Where is the product being compromised?’
- ‘(b) Where will the product be verified?’
- ‘(c) Who will verify it, using what methods?’
- ‘(d) How will you use the results of the investigation?’’’

Then next, “To add to this set of questions, an optimal anti-counterfeit programme must include”:

- **Basic Understanding of the Fraud Opportunity—Why Will It Work?**
- ‘(a) an understanding of how the counterfeit product is entering the marketplace’
- ‘(b) the technical capabilities of the range of counterfeiters’
- ‘(c) the capabilities and willingness of supply chain stakeholders to partner in fighting the risk’
- ‘(d) the capabilities and willingness of governmental enforcement’
- ‘(e) consumers’ awareness of the problem’
- ‘(f) consumers’ willingness to participate in anti-counterfeit actions (e.g., consumer authentication)’

Sidebar: Product Counterfeiting Incident Clustering Tool—PCICT

There is often a significant challenge of organizing and assessing a wide range of food fraud incidents. To help this challenge, the Product Counterfeiting Incident Clustering Tool (PCICT) was developed and was published in a peer-reviewed, refereed, scholarly journal (Spink et al. 2014). The application of the PCICT was further formalized when it was codified in ISO 22380 Security and resilience—authenticity, integrity, and trust for products and documents—general principles for product fraud risk and countermeasures (ISO 2018). The tool is published in ISO as a recommended method for organizing and analyzing incident data.

The PCICT is based on basic criminology theory of incident clustering. Clustering is used to identify a group of crimes or criminals usually visually presented on a map or in a table. This can be used to inform the assessment of the “fraud opportunity” and to complete the Food Fraud Vulnerability Assessments.

An example of the PCICT is provided (Fig. 4.9). A product fraud data set was gathered and plotted based on the “type of counterfeiter,” “type of counterfeiting,” and “type of offender organization.” The example shows that the incidents were primarily conducted by “occupational” and “professional” counterfeiters and the “diversion” and “counterfeiting” types of fraud. The offenders were usually “individuals” or “small groups.” This assessment helps prioritize countermeasures and control systems. The findings from the incident clustering would lead to a focus on “diversion” and “counterfeiting.” The

		Type of Counterfeiter			
Type of counterfeiting		Recreational	Occasional	Occupational	Professional
Type of offense	Adulteration			x	
	Substitution				
	Tampering			x	x
	Over-run				
	Theft				x
	Diversion	x	xxx	xx	
	Simulation				
	Counterfeiting (IPR)		xxx	xxx	
Type of offender	Individual/Small groups		xxx		
	General criminal enterprise			x	
	Organized crime members				x

Fig. 4.9 Product counterfeiting incident clustering tool (PCICT) with examples of clustering (Copyright Permission Granted) (Spink et al. 2014; ISO 2018)

types of counterfeiters are “occupational” and “professional” so would seem to be informed adversaries who would respond to warnings of tighter supply chain controls. Also, the offender organization is identified as “individual/small groups” so possibly from within the supply chain. Knowing that the perpetrators are probably already operating within the legitimate and authorized supply chain leads to a realization that they can be directly communicated through messages sent to current suppliers. By using this tool and method, there is the opportunity to directly deter the “motivated offenders”—remember, the goal is not to catch food fraud but to prevent it from occurring in the first place.

The PCICT includes the type of offense which is similar to the types of fraud. The types of counterfeiter can also be presented as a type of fraudster. The types of counterfeiters or fraudsters include ((Spink et al. 2013b) which is also cited in (ISO 2018)):

- **Type of Counterfeitors/ Types of Fraudsters:**

- **Recreational:** for entertainment or amusement.
- **Occasional:** infrequent, opportunistic.
- **Occupational:** incidents at their place of employment either as an individual act, or in collaboration with the company.
- **Professional:** crime fully finances their lifestyle .
- Removed – **Ideological:** Domestic or international terrorist who commits this act to make an ideological statement or to economically harm an entity (note: later this type was removed since the goal of this perpetrator is “economic gain.” Later they would use their funds to conduct the ideologically motivated act.).
- Food fraudsters seem to be most likely “occupational” type; meaning that they conduct their operation within their business (their occupation) in the legitimate supply chain. This type of criminal can be patient and wait for a favorable *fraud opportunity*.

And the final factor is (Spink et al. 2013b):

- **Type of Offender Organization**

- **Individual/Small Groups:** “Although there are IPR cases involving solo or small groups of individuals who operate out of their homes, garages, or small storage facilities, there is little reporting and no actual analysis of the relative importance of such operators to the threat. … This lack of reporting and analysis may be a reflection of the fact that individuals and small operations are a less attractive target for law enforcement than larger enterprises engaging in a more significant infringing activity or also committing other more serious offenses.”

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- **General Criminal Enterprises (Members):** An example used to identify this group is “a criminal enterprise of 30 defendants charged with smuggling into the United States counterfeit cigarettes worth approximately \$40 million and other counterfeit goods, including pharmaceuticals worth several hundred thousand dollars.”
- **Organized Crime Members (Members):** “Organized crime groups are a specialized subset of criminal enterprises that maintain their position through the use of actual or threatened violence, corrupt public officials, graft, or extortion. For example, members of an organized crime group in New York trafficked in counterfeit goods and were charged with attempted murder and conspiracy to commit murder.” A challenge of deterring this group is their use of violence and the risk of retaliation to a company or investigators (e.g., violence or sabotage). ”
- **Terrorist Organizations (Supporters):** “Terrorist supporters have used intellectual property crime as one method to raise funds. Central to this judgment is the distinction between terrorist supporters who merely provide funding and resources to a terrorist organization versus terrorist organization members who engage in the actual terrorist activities of violence. ... It is widely reported terrorist supporters may use IPR crimes to provide indirect financial support to terrorist organizations, but little current evidence suggests terrorists are engaging directly in IPR crimes to fund their activities.” There are many confirmed cases of product counterfeiting for funding terrorist acts” (for more on this see (Spink 2015a, b)).
- **Gangs (Supporters):** “According to the National Gang Intelligence Center (NGIC), there are three subtypes of gangs: street gangs, prison gangs, and outlaw motorcycle gangs. Of these three groups, street gangs most often engage in and profit from IP theft, therefore this analysis focuses exclusively on this subtype.”
- **Foreign Government Offenders:** “The primary motivation in this offender group is the theft of sensitive United States information including trade secrets and economic espionage. There are examples of state-sponsored counterfeits of branded products.”
- **Warez Groups:** “[A] less common motivation for committing IPR [infringement] is personal fame and notoriety. These individuals are often members of Warez groups, sophisticated and hierarchical criminal groups operating in the United States and abroad that specialize in distributing infringing movies, music, and software via the Internet.”

In the types of offender list, there is an additional differentiator defined by the FBI as “member” or “supporter” (FBI 2012) in (US National Intellectual Property Rights Center [IPR Center] 2011).

- **Member:** “may have known ties to a larger criminal organization but is acting separately for the operation of the fraud. (For example, a member of a gang may be producing and selling counterfeit products with or without this being a formal activity of the gang.)”

- **Supporter:** “may agree with the ideology of a group, but does not participate in their group activities, and provides some type of product or service such as funding. (For example, a supporter of a terrorist organization may be producing and selling counterfeit products and then donating some of the proceeds to that terrorist organization.”

In the PCICT figure, there is a particular emphasis on “Organized Crime Members.” While this may be considered by many as “just another group of offenders” a company’s Corporate Security team usually takes a special interest in this group. Organized Crime—not just “crime that is organized” but the organized and structured large-scale criminal enterprises—is an especially concerning adversary since they may pose a wider range of threats including sabotage, violence, and unfair competitor practices, and depending on their infiltration into the local government could create regulatory or criminal threats (e.g., corruption or integration into the local government could lead to the use of government regulators to retaliate).

The PCICT was included and codified in the 2018 publication of the ISO 22380 standard (ISO 2018). When using the PCICT, above referencing a peer-reviewed, scholarly journal article, an additional level of credibility or authority can be used by reference to ISO 22380.

Sidebar: Analysis of Product Fraud by Using the Counterfeit Product Risk Model (CPRM)

There are many reasons to assess the product fraud risk information, and they each require a different type of methods or tools. A hierarchy of goals is provided with an explanation of the need and then examples of methods, tools, or processes (Table 4.1).

This section will review the “Counterfeit Product Risk Model (CPRM)” which was the subject of a 2009 Ph.D. Dissertation (Spink 2009).

From the report abstract:

Product counterfeiting is growing in both scope and scale. There is a need to take a holistic, all-encompassing approach to the anti-counterfeit strategy, including the development of a Counterfeit Product Risk Model (CPRM) to support the need for an assessment. This research process collaborated and leveraged a wide variety of academic and industry expertise utilizing a literature review and interdisciplinary peer consultation to develop the Counterfeit Product Risk Model for consumer products. The range of disciplines for the research included: Packaging, Food Safety, Criminal Justice, Supply Chain/Logistics, Risk Analysis/Risk Assessment, Food Law, Food Safety, food defense, Intellectual Property Rights Law, Political Science, and Social Science. For example, the Criminal Justice concepts include ‘the chemistry of a crime’ and ‘the crime triangle.’ The Counterfeit Product Risk Model focuses on the probability portion of a traditional probability versus severity matrix, uses qualitative ranking, and due to the nature of the risk and the data, emphasizes extensive use of expert panels.

(continued)

Table 4.1 Hierarchy of risk assessment goal, explanation, and examples of methods or tools from this book

Goal	Explanation	Examples from this book include:
To rank all risks in relation to the enterprise-wide risk tolerance	Gather information and insight to conduct a Food Fraud Vulnerability Assessment. To be complete, this will compare this new suspicious activity or problem with all other risks within the organization	e.g., FFIS/ FFVA
Sort incidents and vulnerabilities to understand the type of counterfeiting, counterfeiters, and offender organizations	After gathering a wide range of incident information or after action reports, there is a need to sort and categorize the findings to identify root causes. The output would be general insight such as a cluster of incidents in a specific type of fraud conducted by a specific type of fraudster and offender organization	e.g., PCICT
Monitor market commodity price fluctuations	Review the changes in supply and demand based on fluctuating current and futures product prices. An increase in price, which could be signaled by a projected short supply of product, is new information to consider in a Food Fraud Vulnerability Assessment	e.g., Bloomberg commodity news feed, etc.
Monitor public information for new incidents or trends	This is a scanning function to gather new information and insight on suspicious activity or potential problems. The processed information would feed into the FFVA	e.g., open source monitoring such as Internet keyword searches, keyword news alerts, or social media monitoring
Review suspicious activity to understand the problem in detail such as if it is an illegal act	This is a method to process suspicious activity concerns to evaluate if there is a fraud opportunity or incident and also the likelihood and severity. The information would be fed into the FFVA	e.g., FF-SAR
Use available information to identify the root cause of the system weakness	This is a variation of the other new information or insight gathering that expands to gather enough information on how the fraud act was conducted. The analysis would provide support for selecting countermeasures and control systems	e.g., open-source searches for vulnerabilities in hot spot analysis, pinch-point review
Review the overall counterfeit product risk	Review known information and expert insight to assess the overall fraud opportunity of the enterprise. This provides insight into the general system weaknesses	e.g., CPRM

This research defines five factors related to counterfeiting: Counterfeit-History, Counterfeit-Attractiveness, Counterfeit-Ability, Counterfeit-Hurdles, and Market Profile. The Model defines the derivation and integration of sub-factors, which 'roll-up' to determine the rank of the factors.

The model was then validated using a survey of 33 industry and agency experts. The survey included 17 ratings by people at a Corporate- or Vice-Presidential level, and included six \$1–\$5 billion revenue companies and sixteen over \$5 billion revenue companies. A broad and representative balance of industries was included: food, beverage, healthcare, pharmaceutical, medical device, law, finance, insurance, risk, consumer electronics, software, industrial original equipment manufacturers, and consumer packaged goods.

Assessing Agreement analysis was conducted on the surveys, and the interpretation of the result was an ‘almost perfect agreement’ with the model. Fleiss’ Kappa analysis was conducted to assess agreement over random chances, and this result was also an ‘almost perfect agreement.’ The research included a Case Study to demonstrate the use of the Model.

This research provides a valuable analysis of anti-counterfeit strategy, including an extensive look into the historical information. It provides a theoretically supported Counterfeit Product Risk Model that will assist in disrupting the ‘chemistry of the crime.

The overall CPRM hierarchy of risk factors and sub-factors builds to the overall risk rank (Fig. 4.10) (Spink 2009). The first step is to develop a *draft* of what seem to be the most important factors and sub-factors—the details are expected to adjust and change as more information is gathered and as the risk assessor becomes more familiar with the model and problem.

Once the factors and sub-factors have been identified, then the ranks can begin to be assessed. The CPRM emphasizes a start beginning with a very simple set of information which could be only subject matter expert insight. As the “low certainty” and “low robustness” assessment is concluded, there can be a process check to identify if or exactly what additional information is needed.

It is highly recommended to start the application of the CPRM with a very low-intensity prefilter or initial screen (as is consistent with ISO 31000, COSO/ ERM, and others).

The Overall Counterfeit Rank is comprised of five factors which, themselves, are comprised of several sub-factors. For example:

- Overall risk rank
 - Factor 5.0: Market profile
 - Sub-factors:
 - 5.1 Contract Manufacturing
 - 5.2 Single Distributors Per Country
 - 5.2 Refurbished or Remanufacturing market

An example of the sub-factor assessment is included (Fig. 4.11). This figure presented three sub-factors that feed into one factor that eventually is considered for the overall risk rank.

(continued)

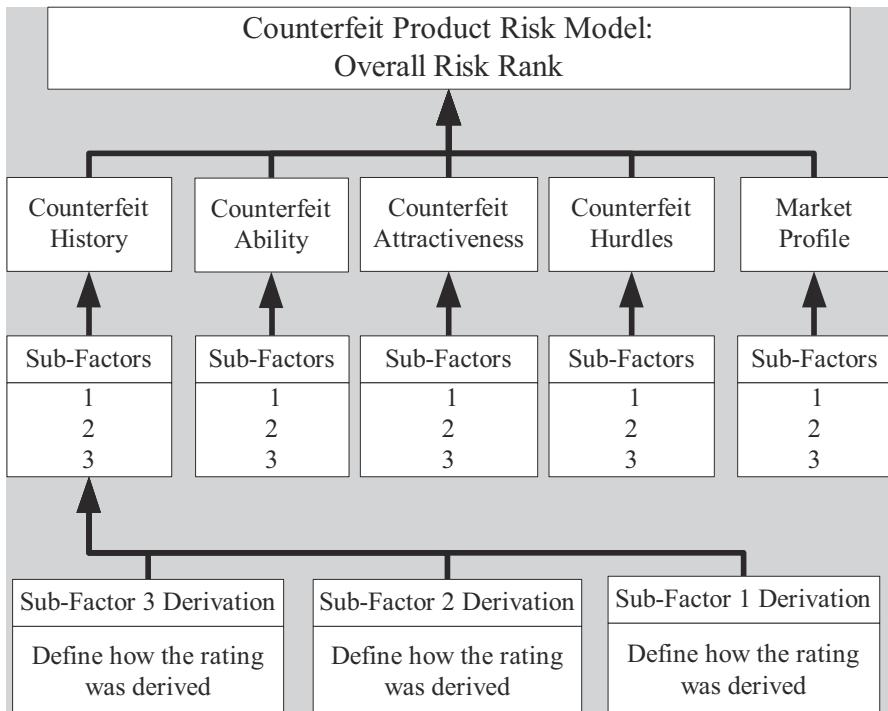


Fig. 4.10 Counterfeit product risk model overview (Copyright Permission Granted)

Factor 5. Market Profile

This would be entered in the table one level higher for "Factor 5.0 Market Profile", see next.

	Very High	High	Medium	Low	Very Low
Total Rank			X		
<i>Summary Function (for example)</i>					A+B+C=D
5.1 Contract Manufacturing		X			
5.2 Single Distributors per Country				X	
5.3 Re-Furbished Market		X			
(Sub-factors list for example)					

Fig. 4.11 Example of the sub-factor derivation of the market profile factor (Copyright Permission Granted)

The assessment of the five factors is combined in a summary report which is provided with information from a case study (Fig. 4.12). The summary report provides a simple way to present the findings while also including much deeper insight into the factors and sub-factors. Also, the summary report includes comments so a risk assessor can understand some of the reasons for the conclusion.

Overall Counterfeit Risk						
	Probability					
	Very High	High	Medium	Low	Very Low	
Total Rank				X		(1) 95+% of the product is manufactured at one proprietary location, (2) The company has comparably low volume combined with advanced packaging and product features that are somewhat complex to duplicate, (3) the company monitors product in the marketplace including online C2C
Factors						
<i>Summary Function: A+B+C+D+E=F</i>						All equal, manual derivation
1. Counterfeit-History	0	0	0	X	0	No known counterfeits, little diversion, but related lower premium product are faked
2. Counterfeit-Ability	0	0	X	0	0	The product and from are frequently counterfeited, but unique feature reduce risk
3. Counterfeit-Attractiveness	0	0	0	X	0	This is a premium product with \$2-5x generic pricing, but tight supply chain controls
4. Counterfeit-Hurdles	0	0	0	X	0	High hurdles for counterfeiters, in terms of packaging features, tight supply chain, and monitoring
5. Market Profile	0	0	0	X	0	Brand loyal consumers, price insensitive, pursue reputable sources, and in-house production

Fig. 4.12 Case study overall counterfeit risk (Copyright Permission Granted)

(continued)

From the report conclusion (emphasis added):

Companies and agencies constantly struggle to quantify the magnitude of the counterfeit threat from both a global and a specific product perspective. Although there are many examples of the dangers of product counterfeiting, the nature of the counterfeiters and counterfeiting makes it difficult or even impossible to determine the quantitative, hard data on the risk. Specifically, analysis of the risk, risk model literature review, in combination with peer-consultation, established a foundation for the Counterfeit Product Risk Model (CPRM) and for the supporting non-quantitative analysis. It is not practical to conduct quantitative or classical statistical tool-based risk assessments for the counterfeit threat because the results cannot be theoretically validated. This research set out to break new ground by presenting an overview of the product counterfeiting threat as a starting point for the development of a practical, useful and publically available, Counterfeit Product Risk Model.

This research used a very broad, very interdisciplinary perspective that led to important theoretical justifications, such as using a probability versus a severity matrix, qualitative ranking, and the language of enterprise risk management. Many current anti-counterfeit research projects are extensions of existing research (with a narrow focus that is not all-encompassing) or are so theoretical in nature that they are not applicable (e.g., very complex models that are not all-encompassing). This analysis and the development of the model provides a unique and practical approach in the implementation of anti-counterfeit strategies.

This type of research analysis and model has not been presented previously by other researchers for several reasons:

- the extremely interdisciplinary nature of the strategy;
- the fact that the hard data is elusive or non-existent—current industry actions are usually confidential, and agency actions are usually classified;
- broad, all-hazards risk assessment is still evolving; and
- a risk-based approach to regulation and legislation is only beginning to be applied to risks that are very real but very qualitative and hard to evaluate.

Since addressing product counterfeiting is probably no more than 10% of any one academic discipline, it is not surprising that there is a lack of research focus and leadership in the area of anti-counterfeit strategy. Packaging is a logical starting point for this anti-counterfeit research since the most efficient anti-counterfeit actions are packaging components, but there are many other disciplines that are equally important in an anti-counterfeit strategy. Critical disciplines which should be considered in an all-encompassing, strategic perspective on deterring counterfeiting include criminal justice, supply chain, risk management, social anthropology, consumer behavior, health risk communication, retailing, intellectual property rights law, food law, healthcare (medicine, nursing, etc.), public health, political science, international trade relations, and many more.

From the further research section:

The very nature of developing propositions for this research established a base for future research and model refinement. The logical next step is to use the model to gain insights, refine usability, and to present procedures for practical implementation.

As the model is used in practice, more detailed risk-based and classical statistical tools could be used to better support anti-counterfeit strategy decisions. Valuable insights could be gained from running the model for various industries and by conducting reviews of inter-industry best practices.

This next table builds upon the future research section with additional comments from 2019 (Table 4.2).

The early assessments considered one part of the overall question or focused only on specific product groups. Over the 10 years since the publication of the CPRM, there has been an implementation of compliance requirements that dictate an overall, holistic, and all-encompassing approach. Once the overall assessments are conducted, there is an identification of further, more detailed assessments which could expand to include the CPRM and others.

Table 4.2 Future research recommendation and result 10 years later

Commentary on the 2009 future research recommendations and the application over 10 years	
1. The logical next step is to use the model to gain insights, to refine usability, and to present procedures for practical implementation	<i>Yes.</i> This was a resource for new works such as the Food Fraud Initial Screening Tool and others
2. As the model is used in practice, more detailed risk-based and classical statistical tools could be used to better support anti-counterfeit strategy decisions	Somewhat. In 2017–2019 the Food Fraud Vulnerability Assessments are just beginning to be conducted and currently with a prefilter/initial screening approach. Also, the available data has not been through enough for high-level statistical analysis
3. Valuable insights could be gained from running the model for various industries and by conducting reviews of inter-industry best practices	<i>Yes.</i> The modification to the needs of the food industry compliance requirements has led to model development and a common approach that enables the sharing of best practices
4. Any future research should be combined with the evolving Enterprise Risk Management practice and with case studies to both understand and support how financial anti-counterfeit strategic decisions are being made within companies and agencies	<i>Yes.</i> There have been numerous food industry research projects and publications that expand to consider the enterprise-wide resource-allocation decision and specifically the COSO/ERM resources
5. Another important – probably the epicenter of all future anti-counterfeit strategy research – is exploring the behavioral aspects of ‘the chemistry of the crime’ and ‘the chemistry of consumer consumption’	<i>Yes.</i> Criminology—and specifically Situational Crime Prevention—has become a common topic in food fraud research and in the application
6. Finally, there should be an ongoing review of both the basic propositions and the model, itself, with refinements implemented as necessary	No. There has <i>not</i> been any further review or application of the CPRM. In 2012, part of the MSU research shifted from an all-products intellectual property rights infringement enforcement to food fraud and prevention. As the compliance requirements define a simple, basic starting point, further methods are now needed which could include the CPRM

Role of ERM in Decision-Making: Corporate Risk Map

The two critical parts of the FFPC is the “fraud opportunity” and the “risk appetite.” The current or projected vulnerability is presented on a “corporate risk map” (Fig. 4.13) and then two examples in Figs. 4.14 and 4.15. The application of ERM is that when there is new information, the fraud opportunity is reassessed, and then the new vulnerability is plotted on the corporate risk map. A very quick review of “acceptable/unacceptable” can be conducted by plotting the new vulnerability.

While the first incidents will need to have a case-by-case review by the entire food fraud team, over time, there will be standard operating procedures and thresholds. Consider how other incidents are managed. If there is a transportation problem and regular customer deliveries may miss deadlines, then in some cases, expedited more expensive transportation may be approved. The first time this would need to

Fig. 4.13 Corporate risk map plotting food fraud initial screening risk assessments (Copyright Permission Granted) (Spink et al. 2016)

		Likelihood				
		Very High	High	Medium	Low	Very Low
Consequence	Very High	A1		B3		
	High		C4			A3
	Medium		A2	D5		
	Low					D2
	Very Low					

Fig. 4.14 Example of a risk map with a range of risks or vulnerabilities above and below the risk threshold (this could be a raw material and product categories or specific stock keeping units) (Copyright Permission Granted) (MSU-FFI 2017)

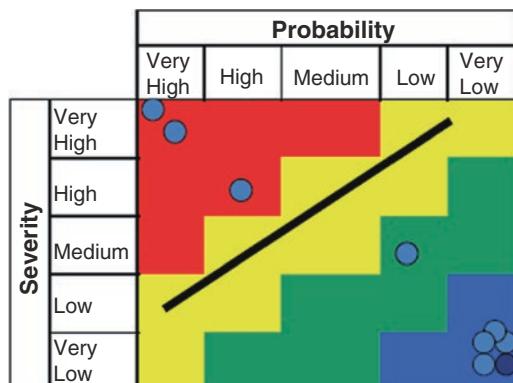


Fig. 4.15 Example of a risk map with a range of risks or vulnerabilities managed to just below the risk threshold (Copyright Permission Granted) (MSU-FFI 2017)

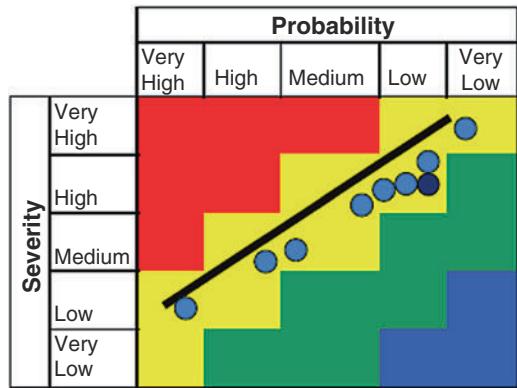
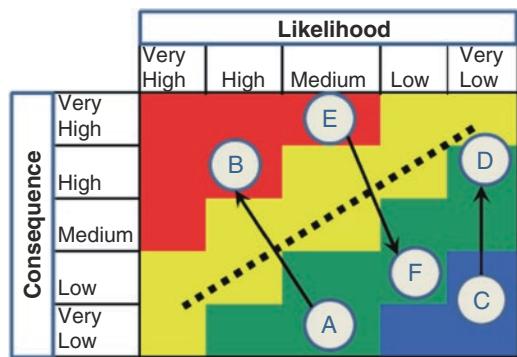


Table 4.3 Details of shifting vulnerabilities that are plotted on the corporate risk map example

Actions	Detail	Decision	Result
A to B	Reduce Food Fraud Prevention budget by \$1 M	No	The change is defined to be an unacceptable option since the enterprise-wide vulnerability shift to an unacceptable situation above the risk tolerance
C to D	A lot less of “Action 1”	Yes	Even though there is a reduction in activity, the resulting situation is still within the risk tolerance
E to F	More of “Test 3”	Yes	Conducting more of this activity reduces the vulnerability to below the risk threshold

Fig. 4.16 Risk map presenting the shifting vulnerabilities from the examples



be discussed and debated with the resource-allocation decision-maker. Over time it might become clear that every time customer “X” missed a shipping or receiving deadline due to bad weather that the CFO approves rush delivery up to \$1000.

To further demonstrate the use of an ERM/COSO risk map for resource-allocation decision-making, several other scenarios are presented here (Table 4.3 and Fig. 4.16).

The scenarios are plotted on a corporate risk map to provide a visual of all the shifting vulnerabilities and clear presentation of which are above the risk tolerance.

These scenarios included a very challenging question of basic financial allocation applied to a group such as a food fraud team or a food safety department. The corporate risk map can be used to at least start this type of discussion of “how much is enough” which is based on exactly what is—or then isn’t—being done. The “we need ‘more’” and “the business will be too risky” are subjective statements that cannot be compared to other vulnerabilities or risks. Once the reduction of funding is presented on a chart like this (the current financial allocation is at “Point A” which keeps the business under the risk tolerance, while reducing the budget by \$1 million will raise the company to “Point B” and above the risk tolerance). Someone has to tell you “no, we don’t believe the business will be in a too risky position.” If there is an incident, there will be documentation of who reduced that budget. It won’t be you.

The use of ERM/COSO and the corporate risk map synthesizes all—literally *all*—risks across an enterprise. The corporate risk map provides clarity on the risk. Full integration of the vulnerability into ERM and the corporate risk map correlates and automates the process.

“How to Start” and “How Much Is Enough”?: “The Corkscrew Approach”

Now that the system has been presented and the sections reviewed in detail, there is a need to discuss how to start. While the very detailed implementation methods will be covered in a later chapter, at this point, it is important to present the overall concepts. The “corkscrew approach” is to start very high level but to make sure to fully complete the process. The first step is a very high-level review of the entire system including a brief recommendation of next steps. In some instances, the resource-allocation decision-maker will have enough information for the decision at hand. If not then the resource-allocation decision-maker will be able to explain exactly what they need in the way of more information. If a full system review is conducted, there can be “management by exception”; meaning they can define exactly what they like, don’t like, and what is needed next.

The next turn of the corkscrew will be more in depth. The process will advance only as far as the resource-allocation decision-maker defines value. The question of “How much is enough?” is defined by this process.

Conclusion

This second food fraud prevention chapter expanded on the interdisciplinary approach and began to frame the question as the needs for a vulnerability assessment, and prevention strategy was being envisioned. ***The first conclusion is*** that

there are already a wide range of activities conducted by an industry or company that already contributes to reducing the fraud opportunity. It is important to search across a wide range of business activities to find information and data that is already being gathered. ***The second conclusion is*** that there should be an assumption that there *are* very competent and thorough current standard operating procedures that could immediately apply. Also, while understanding there are thorough and robust systems, they probably will not completely apply to food fraud prevention. ***The final conclusion is*** that while a food fraud is a food issue that is usually managed by food agencies that often require food authenticity tests, the selection of countermeasures and control systems may focus on many disciplines *except* the food sciences. The most important activity is often the most foreign or abstract which is plotting the food fraud risk on a risk map that compares this incident to all other incidents across the enterprise. There is a saying:

When addressing food fraud prevention, assume it is twice as complex as you think it is and you know half as much as you think you know...and you'll usually be just about right.

Appendix: WIIFM Chapter on Prevention Approach

This “What’s In It For Me” (WIIFM) section explains why this chapter is important to you.

Business functional group	Application of this chapter
WIIFM all	Enterprise Risk Management insights can be adopted into frontline processes and which will create dynamic methods that will address “how much is enough?”
Quality team	This food fraud prevention approach is an enterprise risk assessment linked process that will help you assess a new risk in relation to all other corporate-wide risks which will enable direct, methodical resource-allocation decision-making for “how much is enough.”
Auditors	This is more of an introduction to the strategically sound fundamentals behind the process.
Management	While this may seem very theoretical, it will end up being a very practical and directly applicable process to support very logical and obvious resource-allocation decision-making.
Corp. decision-makers	This may seem like an impossible task, but it works and allows frontline employees to use the enterprise-wide risk tolerance insight for decision-making (without revealing any commercially sensitive or expose and confidential risk assessments).

Appendix: Study Questions

This section includes study questions based on the Key Learning Objectives in this chapter.

1. Discussion Question:

- (a) What is the foundation of the FFFPC?
- (b) What are academic disciplines that are utilized by the FFPC?
- (c) For FF prevention, “how much is enough?”

2. Key Learning Objective1

- (a) What is the “Food Fraud Prevention Cycle (FFPC)”?
- (b) What is the central focus or driver of the FFPC?
- (c) How is a new countermeasure or control system technology reviewed in the FFPC?

3. Key Learning Objective2:

- (a) What is an “Integrated Framework”?
- (b) What is the authority and origin of the “Internal Controls/Integrated Framework” concept?
- (c) How are the Integrated Framework and Internal Controls connected and calibrated?

4. Key Learning Objective3:

- (a) What are the process steps in the FFPC?
- (b) Where does “New Information” (such as the awareness of a new industry incident) enter the FFPC?
- (c) Where does the FFPC start?

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Chapter 5

Food Fraud Prevention Overview

(Part 3 of 3): The Implementation



Summary

This chapter presents an expanded review of food fraud prevention to consider a systematic approach, the focus on vulnerabilities and then beginning to prepare for decision-making and “how much is enough?” The activities are presented in the Food Fraud Prevention Cycle (FFPC) (Spink 2014; Spink et al. 2019).

The Key Learning Objectives of the chapter are

- (1) **Introduction to the Food Fraud Prevention Cycle (FFPC)**—“a system of systems”
- (2) **The focus on vulnerability before risks or hazards**
- (3) **Then the decision-making criteria for “how much is enough?”**

On the Food Fraud Prevention Cycle (FFPC), this chapter addresses the overall fundamental prevention concepts of “connecting everything to everything” (Fig. 5.1).

Introduction

After understanding the basics and the approach, there is a pragmatic and practical need to actually implement the concepts and get to a point where there can actually be resource-allocation decision-making.

¹Note: COSO more often uses the term “risk map,” but “corporate risk map” is used here and throughout to clarify the intent review the formal and systematic assessment of enterprise-wide risk not a basic risk summary.

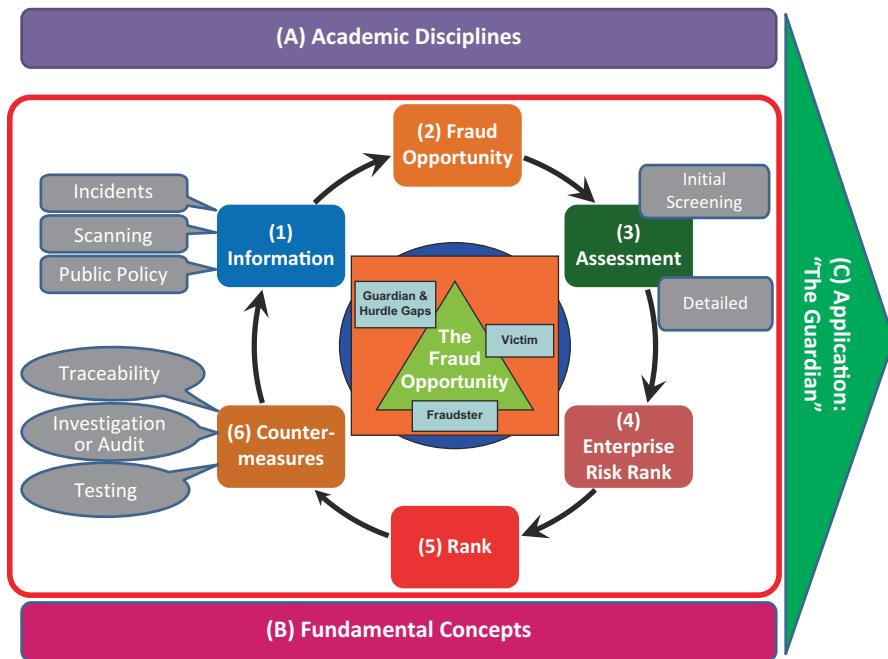


Fig. 5.1 Food fraud prevention cycle: where this chapter applies to the overall concept—the entire cycle 1, 2, 3, 4, 5, and 6 and the fraud opportunity. (Copyright Permission Granted) (Spink 2014; Spink et al. 2019)

Key Learning Objective 1: Systematic Prevention—A “System of Systems”

This section reviews the process for a systematic prevention strategy that is presented in a “system of systems” that is the Food Fraud Prevention Cycle (FFPC) (Spink 2014; Spink et al. 2019). This cycle is comprised of several key components that are presented here.

The Key Learning Objectives of this section are

- (1) Awareness that is comprised of the incident review and fraud opportunity
- (2) Introduction to the fraud opportunity based on the Crime Triangle
- (3) Consideration of how to seek and process new information.

Introduction to the Problem

The Food Fraud Prevention Cycle (FFPC) grew out of the effort to connect each of the separate activities into one complete cycle (Spink 2014). The FFPC is a “system of sub-systems.” Each sub-system cycles within the overall system. Everything is

connected. Each assessment feeds the other assessments in a dynamic process. This dynamic process is self-correcting; meaning that as the fraud opportunity fluctuates up and down, the countermeasures and controls systems are calibrated with the changing risk appetite.

Considering assessments, it is important to review that risk is not necessarily a negative. The owners of a company (which includes individual investors who own stocks, mutual funds or have a pension) expect a specific and ratable level of risk that equates to a financial return—some specific activities are too risky for that threshold. A business that is not risky enough will create lower financial returns. The financial security regulations create a standardized process for public companies to report the inherent risk. The Committee of Sponsoring Organizations of the Treadway Commission (COSO) created Enterprise Risk Management (ERM/COSO) accounting practices which were created in response to the US Sarbanes-Oxley Act and later the Frank-Dodd Act (Public Law 107-204 2002; 15 USC 7201 2006; Public Law 111-203 2010; 12 USC 5301 2018) (for more on US securities law, see (SEC 2013)). The Food Fraud Prevention Strategy can be directly integrated into the ERM resource-allocation decision-making system. The terminology used to address food fraud is the same terms that are used in ERM/COSO.

For this section, a simple previous version of the Food Fraud Prevention Cycle is used. The components and linkages are the same but in a less refined form (Fig. 5.2):

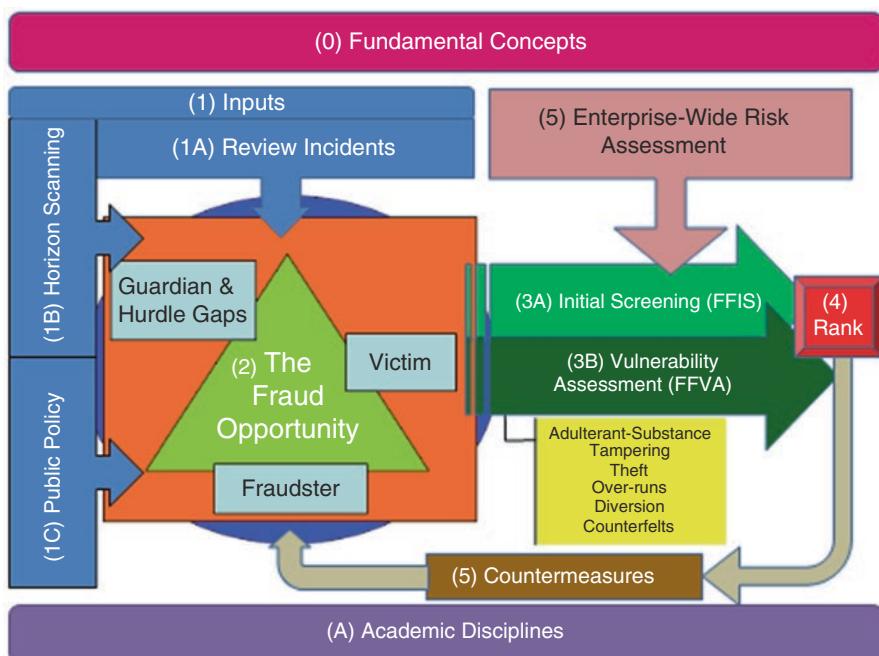


Fig. 5.2 Simple previous version of the food fraud prevention cycle (FFPC). (Copyright Permission Granted)

Criminology: Situational Crime Prevention

- Focus on motivation
- Factors that lead to system weakness
- Detect> Deter> Prevent

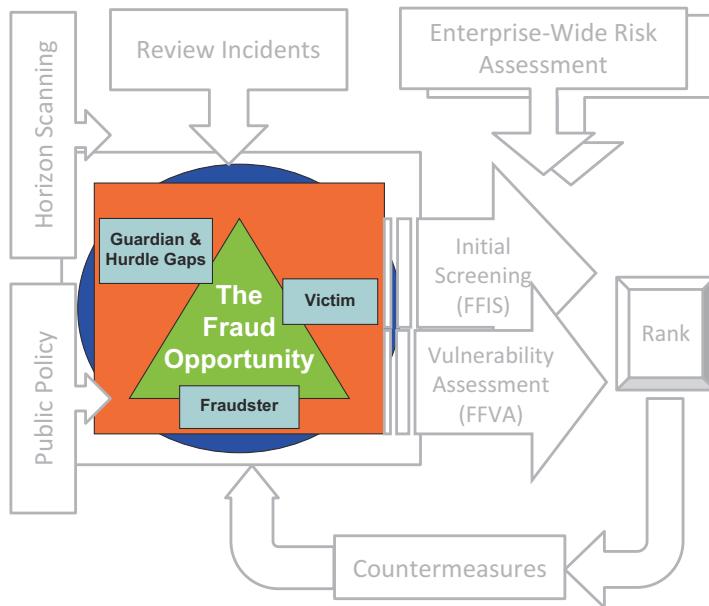


Fig. 5.3 The main influence on the fraud opportunity which is understood by criminology and specifically situational crime prevention. (Copyright Permission Granted) (Spink 2017)

The Engine: The Fraud Opportunity

A saying is that “It’s all about the fraud opportunity.” This means that the root cause of the entire food fraud problem is based on a weakness or vulnerability. The Crime Triangle concept is based on Situational Crime Prevention which includes on a fraudster human adversary identifying a target or victim, in relation to a guardian or hurdle gap (for more, see the chapters on Criminology) (Fig. 5.3). To reduce the fraud opportunity, the goal is to focus on the criminal motivation, identify factors that lead to system weaknesses, and then consider countermeasures to detect, deter, and prevent (Spink 2017).

Sidebar: How the Fraud Opportunity Engine Works—Illicit, The Dark Trade

In 2005, Moises Naim wrote, “Illicit: The Dark Trade” (Naim 2005). This is built upon his previous article “The Five Wars of Globalization” which are illicit trade (1) drugs, (2) arms, (3) intellectual property, (4) people, and (5) money (Naim 2003). Product counterfeiting, product fraud, and food fraud are in the intellectual property category.

Two insights are especially valuable: (1) governments, intragovernmental, and nongovernmental organizations have their hands full with a range of very complex and very bad problems, and (2) for food fraud prevention, there are lessons to be learned from those other problems.

Naim provides some shocking insights on the fraud opportunity including that (Illicit, Naim 2005):

[Product counterfeiting] is... more profitable than trafficking heroin... easier than photocopying... and with penalties like jay-walking.

A more detailed example is:

- “A batch of 1800 cartons of drugs made in China but labeled as manufactured in India and Pakistan under license from multinational companies...”
- Turned out to involve ten copycat manufacturers...
- In five provinces,...
- Using five different suppliers for packaging...
- Manufacturing sites range from small household workshops to legitimate factories: a firm that produces a drug under license need only run an extra shift with substandard inputs.
- Workers on the line may never know they were doing anything wrong.”

For all the five wars of globalization, there are reasons he says “Why Governments Can’t Win”:

- “Technology will continue to spread widely; criminal networks will be able to exploit these technologies more quickly than governments that must cope with tight budgets, bureaucracies, media scrutiny, and electorates.”
- “Those criminal networks:
 - They are not bound by geography.
 - They defy traditional notions of sovereignty.
 - They pit governments against market forces.
 - They pit bureaucracies against networks.”

Prior to any strategic review of product counterfeiting, it is important to establish some key concepts (Naim 2005):

- **“Illicit trade is driven by high profits, not low morals”**
- **“Illicit trade is a political phenomenon** – illicit traders cannot prosper without help from governments or accomplices in key public offices.

(continued)

- **Illicit trade is more about transactions than products** – we are so accustomed to parsing the illicit trades into separate product lines
- **Illicit trade cannot exist without licit trade** – all illicit businesses are deeply intertwined with licit ones. Indeed, traffickers have strong incentives to combine their illicit operations with legitimate business ventures.
- **Illicit trade involves everyone** – someone is buying...
- **Governments can't do it alone.”**

Ultimately, the insight from Naim may be disturbing or disgusting, but it is the reality. Once the underlying concepts are clearly understood and embraced, then there can be a rational and pragmatic path forward. The works by Naim were fundamental in the development of the food fraud prevention concepts.

Awareness: Incident Review and Fraud Opportunity

The first function or step in the FFPC is awareness which builds upon the information. Information could be from “incident reviews” which are known events, scanning, or “horizon scanning” that could be a wide range of “signals” such as price changes or commodity shortages and “public policy” which includes increased risk of detection or enforcement due to new priority setting (Fig. 5.4) (Spink 2017). This awareness building is based on the criminology-based science of intelligence analysis. To provide the right type of information or intelligence to assess the fraud opportunity or problem, there is a systematic gathering and analysis of raw data, a process to monitor changes, and then a step to filter and process this into actionable intelligence.

Sidebar: Does a Good Food Defense Program Help Prevent EMA?

Maybe (MSU-FFI 2018)

Title: Does a Good Food Defense Program Help Prevent EMA? Maybe.

By John Spink • November 13, 2013 • Blog

This is an excerpt of an email from a food industry leader. If this person has this question, then I’m sure many of you do as well. The original question was: “Would a good food defense program help prevent ‘intentional adulteration’?” Answer: Maybe, but probably not yet.

The “maybe” is based on questions of scope and scale of the food defense program. Let me begin by noting that food fraud is beyond an “adulterant-substance” or “economically motivated adulteration” (EMA), for example, you may also have problems or product recalls if you have a country of origin fraud, mislabeling, or even unauthorized repackaging that compromises traceability.

In most cases, food defense is defined as combating intentional attacks to harm another. The harm could be a terror, economic, or public health. The attackers often want to get publicity or want to really hurt people, so we often find out quickly about the act. With food fraud, they definitely do *not* want to get caught...they'll be sneaky, actively try to evade our tests and systems, and they'll be both persistent and keep evolving to stay stealthy.

As for addressing with other types of crime problems, prevention is not only infinitely more cost and time effective, but it is the only thing that often actually works. Using Situational Crime Prevention, we go look for the vulnerabilities...then decide how we can reduce that threat.

At that point, when we understand the vulnerability—e.g., species swapping of animal protein—we know what and where we should test. We know what we should be testing for, that is, to “detect.” If the frusterator is operating within in the legitimate supply chain, then the countermeasure can “deter” against that specific attacker. If it is known that the customer does “some” species tests when receiving products, and new bad guys can find out that the company is testing, then the species tests lead to prevention. Also, you’re looking for the right test at the right spot at the right frequency. For example, a company was running species tests 24 hours a day for 7 days a week during an incident and then completely stopped testing after the food fraud incident had passed. They said “Why test? The incident is over.” Click—that was the door of their fraud opportunity reopening. They don’t need to test a lot, but they should be testing at least some product if only to counter an accusation of “willful negligence” for this “reasonably foreseeable hazard.”

In a company, there are often two defined concepts of unintentional acts such as food safety and also of intentional acts defined as food defense. If this is the case, it is structurally efficient for a company to put food fraud under food defense but to understand that the countermeasures and control systems and processes are very different. Think of combating shoplifters compared to ferreting out suppliers diluting product. What about combating employee theft versus country of origin labeling fraud? No one—me included—will ever be able to be an expert on all food fraud concepts and threats. We’re trying to create an educational foundation of knowledge, moreover, and then a group of colleagues. (I consider myself as a food fraud librarian who is gathering, categorizing, and writing about all the information in the books we find.) We will need to help train and support those people who will take the reins of food fraud prevention. We will need to start by defining the scope and scale of a good food defense plan.

Overall, it is most efficient if food fraud prevention is a separate, stand-alone, interdisciplinary, enterprise-wide team or task force function. This is similar to anti-counterfeiting and brand protection programs that are coordinated at the corporate level, and then individual responsibilities are distributed into the operations and the business units.

(continued)

I ended my email to the food industry leader by stating “Actually, this would be a great blog post, maybe I’ll post it.” So I am. Consider if your food defense plan really does address food fraud prevention. Don’t wait for FSMA or GFSI; companies have food fraud risks every day (MSU-FFI).

Intelligence Analysis

- Systematic gathering and analysis of raw data.
- Monitor changes
- Filter and process into actionable intelligence

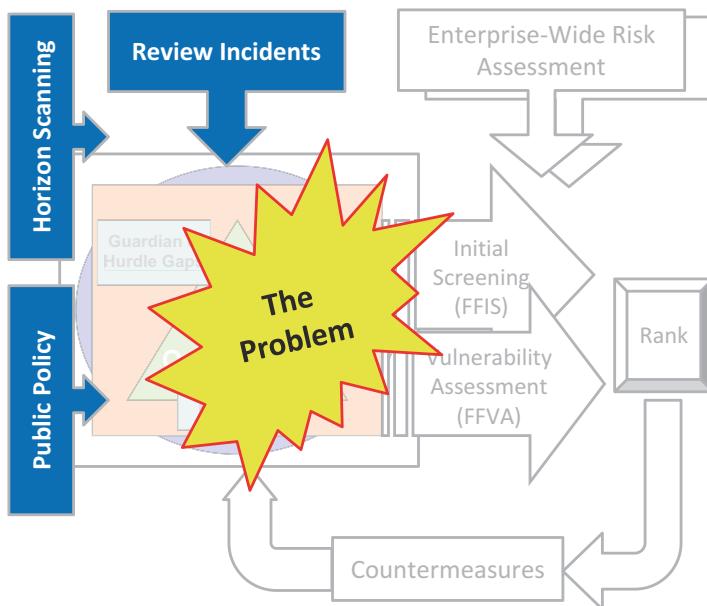


Fig. 5.4 The intelligence analysis that provides information and data to understand the food fraud problem. (Copyright Permission Granted) (Spink 2017)

Key Learning Objective 2: The Vulnerabilities and Countermeasures

This section reviews the next steps which are assessing the vulnerabilities and the final actions of judging or selecting countermeasures and control systems. These two steps are between other key activities such as understanding the fraud opportunity and conducting the risk rank which supports resource-allocation decision-making. Building on theories such as criminology, total quality management, and enterprise risk management, it is most efficient and effective to start by understanding the system weaknesses and the root cause of the problem.

The Key Learning Objectives of this section are

- (1) Review the process of vulnerability assessment: initial screen and detailed assessment
- (2) Consideration of what assessment or predictive models are even possible
- (3) Then the system to review and select optimal countermeasures and control systems

Vulnerabilities: Understood by Risk Assessment and Decision Sciences

Another function or step is the focus on vulnerabilities rather than risks. The core concepts of risk and vulnerability will be covered in more detail in the Business Risk chapter and the Vulnerability Assessment chapter. The key components are building upon an understanding of the fraud opportunity to then conduct assessments which would start with an initial screen before determining if there is a need for a more detailed assessment. The Food Fraud Prevention Cycle sub-system of vulnerability assessment is a two-stage process that includes an initial screen and then a detailed assessment that is conducted as required (Fig. 5.5). To support decision-making to reduce the fraud opportunity, the assessment should consider the following: is the issue an actual problem, how much of a problem, and then how to provide first a quick review before a more detailed assessment.

The Food Fraud Prevention Cycle (FFPC) is based on an objective to focus on the cause *and* effect—both. The food safety systems address the effect or result. Once a hazard is found in the food supply chain, it is usually classified as either a traditional hazard (e.g., food safety, an unintentional act with naturally occurring problems) or nontraditional (e.g., food defense, intentional act with non-naturally occurring food safety hazards). The traditional food safety management systems are refined to evaluate an acceptable or unacceptable hazard threshold clearly (e.g., product recalls are defined as Class I, II, or III (for more see (Fortin 2009)) and the industry and regulatory product recall procedures are refined and honed. These hazards are usually well known, researched, addressed by regulations with defined thresholds, and defined as biological, chemical, and physical.

On the other hand, the nontraditional hazards – if they don't fit into the more traditional food safety product recall activity – are often addressed by an ad hoc process by necessity. There occasionally incidents that don't seem to fit into general categories or response plans, so the responders do the best they can to figure some way to address the crisis. An intentional act to harm could be a single disgruntled employee or a coordinated, global terrorist network, or anything in between. When conducting a suspicious activity review “intervention,” the worst case should be assumed in for every incident.

These unknowns related to intentional acts to harm define the efficiency of creating a separate Food Fraud Vulnerability Assessment and Prevention Strategy. Also, the variability of the nontraditional hazards emphasizes the importance of focusing

Risk Assessment & Decision Sciences

- Is it a problem?
- How much of a Problem?
- First a quick review then detailed

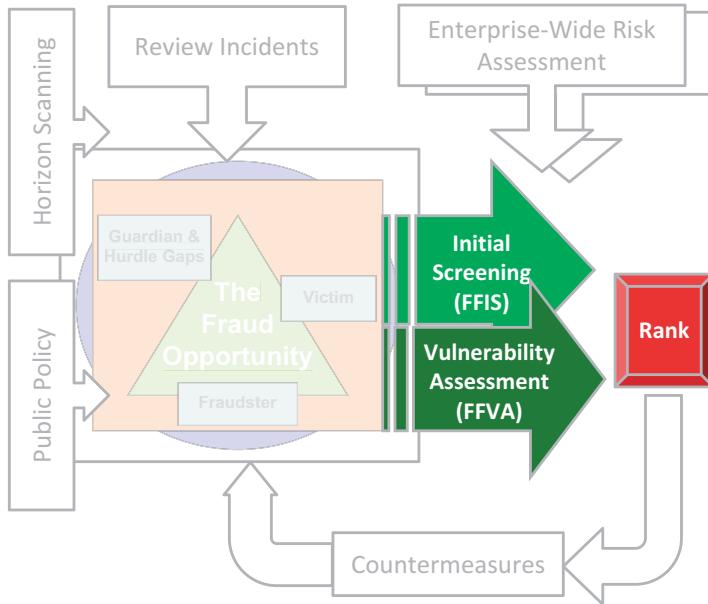


Fig. 5.5 The decisions sciences that provide a structured method to conduct the assessment and support the selection and implementation of countermeasures and control systems. (Copyright Permission Granted) (Spink 2017)

on prevention and thus vulnerabilities. When focusing on reducing the vulnerabilities—and reducing the fraud opportunity—it is most efficient to remove consideration of the human fraudster from the equation. It is easier to respond to the physical components of the vulnerability rather than to try to confront a specific fraudster or type of fraud act.

These concepts are included in the Food Fraud Vulnerability Assessment. These methods and processes are in their infancy and continue to evolve and mature as they are used. The GFSI Food Fraud Position paper was published in July 2014, the SSAFE/PWC Food Fraud Vulnerability Assessment was published in January 2015, and the Food Fraud Initial Screening Tool (FFIS) was published in November 2016 (GFSI 2014; SSAFE 2015; PWC 2016; Spink et al. 2016).

Essentially “if there is a fraud opportunity then there is a fraud opportunity.” If you did purchase from criminals, they might not commit a crime because they don’t perceive an opportunity...though you’d prefer not to purchase from criminals. “Where there is fraud opportunity there is a fraud opportunity; regardless of the morals, ethics, or honesty of the supplier.”

Sidebar: “It Is Simply Not Possible to Validate Predictive Models of Rare Events That Have Not Occurred”

At the 2008 Society for Risk Analysis annual meeting, Robert G Ross of the US Department of Homeland Security presented “Observations on the Importance of Risk Communication in Managing Homeland Security Risk”((Ross 2009) also (Ross 2006a, b, 2007)). He discussed “models for insight versus models to predict.” He recommended using a range of risk models to provide a wide range of insight on these unique vulnerabilities. Regarding probabilistic risk assessment and more advanced quantitative risk assessments, he made several important key points that apply to food fraud prevention (JASON 2009):

- “[It] is simply not possible to validate (evaluate) predictive models of rare events that have not occurred, and unvalidated models cannot be relied upon.”
- There is a “...distinction between models for probabilistic risk assessment on long timescales... versus specific point production of individual rare events.”
- “It is not a realistic goal to anticipate and prevent all rare events, but it may be possible to make rare events rarer, and to reduce their effect.”
- “A rare event is preceded by a chain of individually more likely developments that create intent, capability, and opportunity. Intervention may be possible at many points in that chain.”
- “There are two principal problems in applying quantitative models to the anticipation of rare events. One problem is that rare events are rare. There will necessarily be little or no previous data from which to extrapolate future expectations in any quantitatively reliable sense, or to evaluate any model.”
- “In the extreme, how can the probability of an event that has never been seen or may never even have been imagined be predicted?”
- “An additional difficulty is that rare event assessment is largely a question of human behavior, in the domain of the social sciences, and predictive social sciences models pose even greater challenges than predictive models in the physical sciences. Reliable models for ameliorating rare events will need to address smaller, well-defined, testable pieces of the larger problem.”

This insight provides a foundation regarding rare events for what *cannot* be expected from traditional probabilistic risk assessment. This insight encourages a shift in focus from predicting the exact incident that will occur to consider the wide range of factors, variables, or vulnerabilities that are known. Ross’s presentation encouraged the use of many different types of assessments and to focus on “models for insight” rather than “models for prediction”—risk-informed versus risk-based decision-making.

Recalls: Background and Definitions

The FDA website explains the “Types of FDA Enforcement Actions.” Overall, the FDA regulatory goal is to “assure compliance with the Federal Food, Drug, and Cosmetic Act (the Act).” While the Act covers a wide range of issues, efficient resource allocation is directed by a risk-based approach for a priority on the worst public health harms.

The first goal of the logical risk-based approach is to do whatever it takes to reduce the current or immediate public health harms. Sometimes this leads to a priority for a product recall over a possible extended criminal investigation. An immediate product recall reduces the success of a criminal investigation because the perpetrators are alerted that the officials know of the problem. It is important to take immediate activity since a perpetrator can destroy evidence, modify records, or even flee the country (Spink 2011).

“Specific enforcement activities include actions to correct and prevent violations, remove violative products or goods from the market, and punish offenders. The type of enforcement activity FDA uses will depend on the nature of the violation. The range of enforcement activities includes issuing a letter notifying the individual or firm of a violation and requesting correction, to criminal prosecution of the individual or firm.”

There are a range of actions or responses available for a regulator such as the US Food and Drug Administration (FDA). Recalls are actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm’s own initiative, by FDA request or by FDA order under 21CFR7.3 statutory authority (21CFR7.3 2014).

There are three types of product recalls:

- **“Class I recall:** a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.
- **Class II recall:** a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- **Class III recall:** a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.”

There are other potential actions including:

- **“Warning Letters** – are sent to the individuals or firms, advising them of specific noted violations; These letters request a written response as to the steps which will be taken to correct the violation. These letters constitute one form of warning that can be issued under current Agency policy.”
- **“Seizure** – An action brought against an FDA-regulated product because it is adulterated and/or misbranded within the meaning of the Act. The purpose of such an action is to remove specific violative goods from commerce.”
- **“Injunction** – An order by a court that requires an individual or corporation to do or refrain from doing a specific act. FDA may seek injunctions against individuals and/or corporations to prevent them from violating or causing violations of the Act.”

- “**Criminal prosecution** – may be recommended in appropriate cases for violation of Section 301 of the Act; Misdemeanor convictions, which do not require proof of intent to violate the Act, can result in fines and/or imprisonment up to 1 year. Felony convictions, which apply in the case of a second violation or intent to defraud or mislead, can result in fines and/or imprisonment up to 3 years.”
- “**Criminal Fines** for Food Drug and Cosmetic Act Violations – Misdemeanor fines under the Act may reach \$500,000 under some circumstances. The Criminal Fine Enforcement Act of 1994 (Public Law 98-596) provides for fines for violations of Federal law. Although it is not part of the Act, the Criminal Fine Enforcement Act of 1994 applies to all fines levied under the Act, as well as other statutes that contain provisions enforced by FDA.”

When responding to a regulatory or enforcement action, it is important to clearly understand the exact scope of each term. Several key terms are provided here (emphasis added):

- “(b) **Citation or cite** means a document and any attachments thereto that provide notice to a person against whom criminal prosecution is contemplated of the opportunity to present views to the agency regarding an alleged violation.”
- “(c) **Respondent** means a person named in a notice who presents views concerning an alleged violation either in person, by designated representative, or in writing.”
- “(d) **Responsible individual** includes those in positions of power or authority to detect, prevent, or correct violations of the Federal Food, Drug, and Cosmetic Act.”
- “(g) **Recall** means a firm’s removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure. Recall does not include a market withdrawal or a stock recovery.”
- “(h) **Correction** means repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location.”

Countermeasures and Decision-Making

Once the vulnerability assessment is in place and operating, this next component includes a review of countermeasures and decision-making in the corporate risk map (Fig. 5.6) (Spink 2017). The consideration of countermeasures is a vital separate sub-system, so there is a formal way to seek, consider, and reinforce resource-allocation decision-making. To connect the functions or steps, this sub-system would support the detect-deter-prevent steps and consider currently implemented and possibly new technologies which include the popular interoperable enhanced traceability innovations and also more tactical responses such as enforcement and prosecution. Countermeasures and control systems are the risk treatments that should be selected first on the confirmation of a need to address this vulnerability and then the direct contribution to reducing the fraud opportunity.

Countermeasures and Control Systems

- Support: Detect> Deter> Prevent
- Current and new technologies
- “Interoperable Enhanced Traceability”
- Enforcement and prosecution

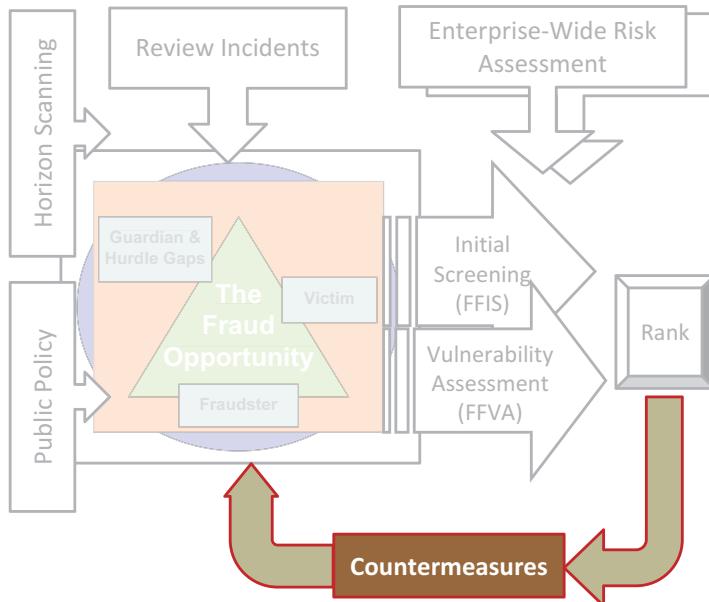


Fig. 5.6 The countermeasures and control system linkage that supports the reduction of the fraud opportunity. (Copyright Permission Granted) (Spink 2017)

The Determination of “How Much Is Enough” by Enterprise Risk Management (ERM/COSO)

At this point, there is a realization that there is usually no structured, analytical, methodical decision-making process for “how much is enough?” There are two critical benefits of applying ERM into the operations (covered in more detail in the Business Decisions chapter) which include that holistic countermeasures and control systems are considered efficiently when vulnerabilities are being assessed, and the frontline decision-making includes those overarching, corporate decision-making insights (Fig. 5.7) (Spink 2017). At first, the proposals will need to be evaluated on a case-by-case basis, but over time the risk assessors will become more familiar with what types of hazard levels and countermeasure are (or are not)

How much is enough? Enterprise Risk Management

- ROI is only project decision
- Is the current situation unacceptable...
 - compared to all other risks?
- Industry: Enterprise Risk Management, COSO Managerial Accounting Practices (regulatory compliance)

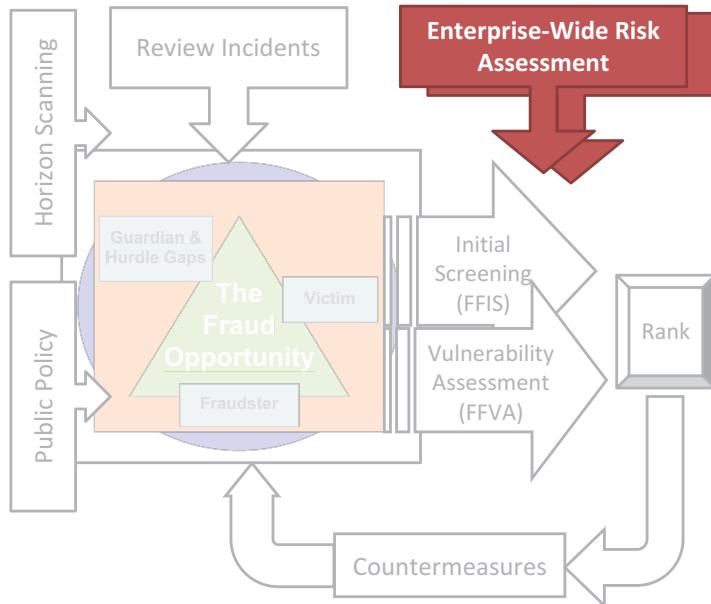


Fig. 5.7 The linkage to an enterprise-wide risk assessment that provides guidance resource-allocation decision-making and “how much is enough?”. (Copyright Permission Granted) (Spink 2017)

implemented. This sub-system is the resource-allocation decision-making step. By calibrating the FFPC to the ERM system, return on investment is only a project decision and not a consideration against all other possible allocations; this provides a way to review if the current situation is unacceptable as compared to all other risks across the enterprise and also correlate with the implemented ERM systems based on COSO managerial accounting practices. These sub-systems create a holistic and all-encompassing system to manage the Food Fraud Prevention Strategy.

Sidebar: Understanding a Generic or Specific Risk Tolerance

The calibration of the vulnerability assessment to the corporate risk tolerance is a separate and unique function in the Food Fraud Prevention Cycle. Without this calibration, the use of a generic assessment tool creates a generic risk rank. What is “high” for one industry, company, or product may not be “high” for your company—this could be for many reasons include some countermeasure or control system that is not considered in the vulnerability assessment or the general nature of your operations or supply chain.

The food fraud assessments and strategies build upon ERM/COSO which, itself, builds upon risk appetite or risk tolerance. These are terms that are defined in other total quality management systems and specifically in Six Sigma and also in a range of ISO standards from ISO 22000 Food Management and most importantly in ISO 31000 Risk Management.

- **Six Sigma:** this principle is based on a cycle of plan-do-check-act (PDCA) with a “specification limit.” A limit could be a type of variation or a resulting flaw. By design, the limit is “Six Sigma” or six times the standard of deviation. The method to determine the limit—or here, the variation or flaw—is undefined and refers to another decision-making system.
- **ISO 22000 Food Management Systems:** this standard is based on a “critical limit” that is a “measurable value which separates acceptability from unacceptability.” The method to determine of the limit—or here, critical limit—is undefined and refers to another decision-making system.
- **ISO 31000 Risk Management:** this standard has a process step to “establishing the context” which is “defining the external and internal parameters to be taken into account when managing risk, and setting the scope and risk criteria for the risk management policy.” The method to determine the maximum limit of tolerable risk—or here, the parameters—is undefined and refers to another decision-making system.
- **ERM/COSO:** this process is specifically focused on evaluating the maximum acceptable level of risk or uncertainty for an enterprise. An enterprise could be a company, a country, or any organization. Specifically, ERM is “designed to identify potential events that may affect the entity, and manage risk to be within its risk appetite, to provide reasonable assurance regarding the achievement of entity objectives.” Also, “an organization’s risk appetite should be articulated and communicated so that personnel understands that they need to pursue objectives within acceptable limits.” And, “ultimately, management and the board need an understanding of the entity’s portfolio of top risk exposures affecting entity objectives so that they can determine whether it is in line with the stakeholder’s appetite for risk.”

Sidebar: Chase the Problem or Try to Eliminate the Root Cause and Motivation?

To optimize the efforts, there is a need to shift the paradigm from addressing the problem to reducing the root cause of the anomaly. Henry David Thoreau was credited with saying “There are a thousand hacking at the branches of evil to one who is striking at the root.” Also, there is a question of “how fast do you need to run not to get caught by a bear?” The answer is “faster than the person you’re running with” (since it assumed that your colleague gets caught and eaten). Both of these analogies are considered when shifting the food fraud countermeasure and control system focus to prevention.

Continuing the analogy of the home burglary, if there start to be more home break-ins around your neighborhood what is the *first* thing you do? Call your politician to ask for more strict laws? Demand more investigation and prosecution by the county court? Do you ask for more police to patrol the neighborhood and investigate all suspicious characters? If you are concerned about those burglaries, maybe the first thing is to make sure you lock your doors and windows.

To think about this another way, to protect your house from a burglar: if you lock your doors, the criminal may climb in the window; if you lock your window, they might just break the glass; if you put bars on your windows, they may try to kick in your back door, on and on until the effort to break into your house is just too much of a hassle.

To review the selection of a food fraud prevention countermeasure, consider the cost of applying a unique serial code (a significant technological feat compared to lot number or manufacturing dates on a long production run) includes information technology infrastructure and management to control and confirm the application as well as the management through to the consumer. Depending on how much the system relies on the code to confirm authenticity, there is also a potentially high legal liability. For example, consider a medicine that is used to restart a heart after open-heart surgery. The legal liability for the manufacturer could be literally catastrophic if that “authenticated” product is really a counterfeit or substandard. The interoperable-enhanced traceability system value must be weighed against the loss.

These are examples of the “problem.” A more efficient focus is to consider reducing the “motivation” for the fraudsters to commit an act.

For any new countermeasure or control system, the question must be asked “*how will* the counterfeiter circumvent the system” or even “*how will* the counterfeitors *benefit* from the system.” This takes into consideration the counterfeitors will respond. This takes into consideration that counterfeitors research how to avoid detection both now and in response to future countermeasures and control systems. If these are all considered, then an efficient and effective countermeasure or control system can be selected and implemented. If not then the likelihood of success is a guess.

(continued)

The countermeasures and control systems don't have to be perfect or completely eliminate the "fraud opportunity." The response is calibrated to your unique fraud opportunity and reduces the vulnerability to within your specific risk tolerance. Often burglars are looking for a soft target. They are not trying specifically to break into your home. Usually, if your doors are locked, windows shut, lights on, no tempting bags of money in plain sight, dog barking, and the alarm is on, they will probably look for a softer target. That is the goal of food fraud prevention: run faster than the person you're running with and move on from raking leaves to hack at the roots of the tree.

Key Learning Objective 3: A Systemic Approach to Food Fraud Prevention

This section reviews the Food Fraud Prevention Cycle functionality—"how it actually works." The foundation is based first on the detailed framework of all industry or regulatory, domestic or international, compliance requirements and then integrates with other current systems. As is taught when addressing a geometry problem, first lay out all the "knowns" and "givens" and consider applicable "tools" *before* starting to gather more data or solving the problem. There is a need for a process or function that coordinates all the activities.

The Key Learning Objectives of this section are

- (1) Focus on the root cause which is the "fraud opportunity."
- (2) Conduct vulnerability assessments including a way to methodically seek and utilize new information. This should also consider this risk compared to all other enterprise-wide risks before determining a "rank."
- (3) Define a way to consider and select countermeasures and control systems including a feedback loop to dynamically monitor and recalibrate the entire cycle.

The Fraud Opportunity: The Root Cause

A fundamental idea is "It's all about the fraud opportunity"—every assessment or decision is defined in terms of how it contributes to the prevention and reduces the fraud opportunity. The engine of the cycle—the center of everything—is the "fraud opportunity." Everything revolves around understanding the characteristics and influencers of this Crime Triangle. When the fraud opportunity is understood, then there can be a more efficient selection of countermeasures and control systems as well as an explanation of how and why the interventions reduce the vulnerability. Without an understanding of the fraud opportunity, the risk treatments are guesses—granted they are educated guesses but still without a methodical approach.

Another fundamental idea is: “If one aspirin is good, then ten is better. Right?” “Traceability is good, so more is better. Right?” Then RFID, the blockchain, DNA, mass serialization, whole genome sequencing, and other things must be better, right? Maybe. The critical question is how these countermeasures and control systems contribute to the prevention and reducing the vulnerability. The Food Fraud Prevention Cycle (FFPC) is used to create and help decision-making in the strategy. The strategy is the action plan. The Food Fraud Prevention Cycle is a dynamic process since there is a constant fluctuation of the specific fraud opportunity and the unique risk appetite. The cycle is used to ramp up—or down—the countermeasure and controls systems.

The strength of the FFPC is that it covers all the activities including the resource-allocation decision-making and “connects everything to everything” and it is self-correcting to optimize the countermeasures and control systems. Without the feedback and recalibration step, the countermeasures and control systems usually keep adding up and up. With the calibration and review of all implemented programs, there is now a methodical approach to evaluate what countermeasures and controls systems should be scaled down or removed. This would include a corresponding addition or reduction in staffing.

The Components of the Food Fraud Prevention Cycle: How They Fit Together

At this point in the book, the Food Fraud Prevention Cycle (FFPC) is becoming familiar since it is the map for all the content. Once the overall Food Fraud Prevention Strategy (FFPS) is in place, it includes a dynamic Food Fraud Prevention Cycle (FFPC). Several vital systems help build awareness of the vulnerabilities and also for the entire cycle (see above in Fig. 5.1 from this chapter) (Spink 2014; Spink et al. 2019). The FFPC components include (1) overall principles (e.g., A, B, and C) and steps that are the activities (e.g., 1, 2, 3, 4, and 5).

Key components of the FFPC include these (the FFPC figure is included again here for convenience, Fig. 5.8):

- (A) Academic Disciplines: There is a range of academic disciplines that contribute to the understanding and management of the “fraud opportunity.” These are not specific systems in the FFPC but are important to provide insight on each factor.
- (B) Fundamentals: Some basic principles or fundamentals enable the actions and provide insight into the working of the cycle and the specific functions.
- (1) Inputs: This function considers new information to add to the review of the fraud opportunity.
 - (1A) Incident reviews and review of changing marketplace conditions such as commodity price changes.

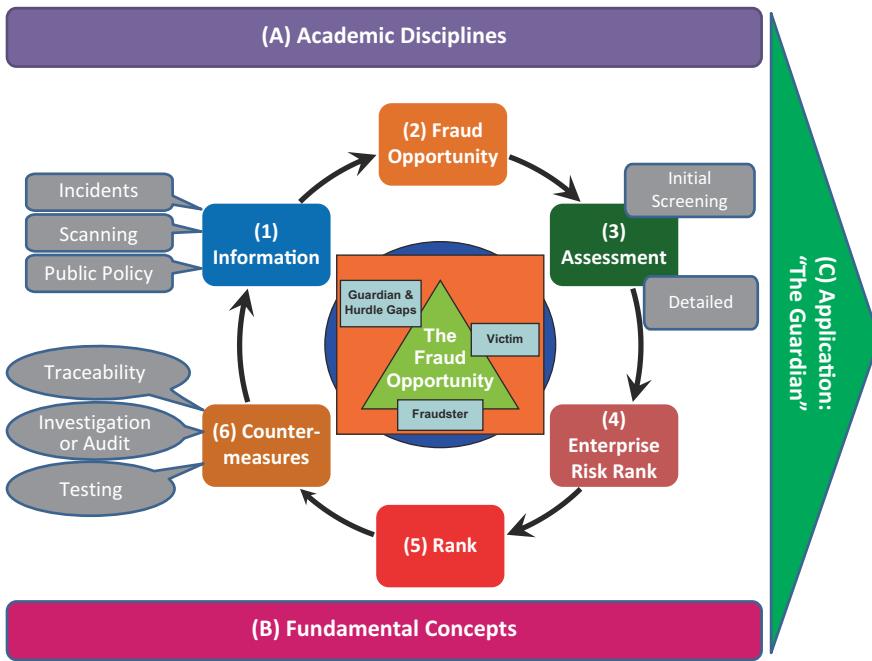


Fig. 5.8 This is the entire food fraud prevention cycle (FFPC). (Copyright Permission Granted) (Spink 2014; Spink et al. 2019)

- (1B) Scanning: this is an active review of what is happening externally such as market price changes, supply shortages, and other general intelligence about vulnerabilities or incidents.
- (1C) Public policy: changing public policy or regulatory focus.
- (2) Fraud Opportunity: This is based on the Criminology theory of Situational Crime Prevention. It is a separate assessment that feeds into the vulnerability assessment.
- (3) Vulnerability Assessment: The Enterprise Risk Management/COSO vulnerability assessment is a two-stage process starting with an “initial screening” and extends to a “detailed screening.” For food fraud prevention, this is demonstrated by the Food Fraud Initial Screening Tool (FFIS), the SSAFE/PWC Food Fraud Vulnerability Assessment Tool (FFVAT), and others (SSAFE 2015; Spink et al. 2016).
 - (3A) Initial screening or prefilter: Food Fraud Initial Screening (FFIS)
 - (3B) Detailed assessment or full review: Food Fraud Vulnerability Assessment (FFVA)
- (4) Risk Appetite: The ERM/COSO process extends to applying the vulnerabilities to the Corporate Risk Map. This map helps the corporation determine what

risks are within the risk appetite. Every new vulnerability or changing assessment does not lead to a risk that is an unacceptable hazard.

- (5) Enterprise-Wide Risk Assessment: Connection to the resource-allocation decision-making defined by the “risk tolerance.”
- (6) Countermeasures and Control Systems: These are a wide range of activities that either directly confronts specific types of attacks or that provide insight on when a product may be “out of control.”
- (C) Application—“The Guardians”: This includes combined external controls or programs that investigate, enforce, and prosecute the fraudulent activity.

This *system of systems* creates awareness that there is a cycle, and within that, there is an awareness of how all the emerging and current factors fit together.

Sidebar: Who in Their Right Mind Would Decommission an Anti-counterfeit Countermeasure?

Without a rigorous risk assessment system, no one in their right mind would reduce a redundant anti-counterfeit countermeasure. For example, a new packaging group manager could inherit a product with ten of the same anti-counterfeit features (e.g., holograms, micro-taggants, color shifting ink, etc.). If the decision is without a methodical approach or demand, and if there is a new counterfeit incident, the manager may be blamed. This would be like deciding that the lease on a second battery backup sump pump for your basement was not cost effective. That might be a logical decision, but if the basement floods, there will be huge consequences for the manager—possibly a career limiting move. Without a clear analytical assessment—not just the logic or common sense—the risk assessor could get fired. If a customer dies, this could lead to criminal prosecution! Thus, no one in their right mind would remove a legacy countermeasure or control system without a very thorough and analytical decision-making process.

By using the Food Fraud Prevention Cycle, including plotting the vulnerabilities on the Corporate Risk Map,¹ there is a clear, logical, methodical, and analytical assessment that the lease on the second sump pump is illogical. The FFPS and FFPC clearly define that removing the second sump pump is a wise and logical business decision. If there is an adverse event (e.g., the basement floods), the risk assessor can defend the decision to remove the second backup sump pump.

Sidebar: Food Fraud Criminal Cases – How to Keep your Boss Out of Handcuffs

While food industry managers are not thinking about criminal prosecution—at least not yet for food fraud prevention—one of the strongest motivators for action is a legal liability and the “court of public opinion.” Whether based on the EU-type food integrity laws or the US-type public health laws, a

suspicious product can be determined to be “unfit for commerce.” A product recall is quick and very economically harmful for a company. While additional liability for gross incompetence or willful blindness is impactful, a product recall achieves the most fundamental goal of removing the suspicious or dangerous product from commerce.

As for the “court of public opinion,” the impact of social media can be catastrophic for a brand or company. Often the risk of a possible product recall—or bad press about product integrity—has driven companies to change their operations. (MSU-FFI 2018):

Title: How to Keep your Boss Out of Handcuffs

By John Spink • May 22, 2013 • Blog

Are food fraud incidents being treated as criminal cases? In the first MSU-FFI Food Fraud Overview MOOC earlier this month, I briefly discussed this, and I want to follow up with examples and details here. It takes quite a bit for a US agency to pursue criminal charges when there are civil law options (Goldstone 2001). The burden of proof for a criminal case is much higher than for civil charges—and in many situations, even state-level civil cases can shut down a business and seize all assets, even when the business is not aware of the dangerous public health threat. For example, see the State of Alabama’s Deceptive Trade Practices Act (AL Code 8-19-1 2017). This Alabama act is focused on protecting public health and welfare but also on protecting the legitimate innovative businesses that are trying to provide healthy lifestyle products: “Legislative intent – The public health, welfare, and interest require a strong and effective consumer protection program to protect the interest of both the consuming public and the legitimate businessperson.” Several key definitions from the Alabama law include (emphasis added):

- **“GOODS:** Includes but is not limited to any property, tangible or intangible, real, personal, or any combination thereof, and any franchise, license, distributorship, or other similar right, privilege, or interest.”
- **“KNOW, KNOWING, KNOWINGLY, KNOWLEDGE, and KNEW:** Either actual awareness or such awareness as a reasonable person should have considering all the surrounding circumstances.”
- **“PERSON:** Includes but is not limited to natural persons, corporations, trusts, partnerships, incorporated or unincorporated associations and any other legal entity.”
- **“SALE, BUYING, and DISTRIBUTION:** In addition to their ordinary meanings, include but are not limited to the act of leasing, renting, or consigning.”
- **“SERVICES:** Work, labor, and other services, including but not limited to services furnished in connection with the sale or repair of goods.”
- **“TRADE or COMMERCE:** Includes but is not limited to the advertising, buying, offering for sale, sale or distribution or performance of any service or goods, and any other article, commodity or thing of value wherever situated and shall include any trade or commerce affecting the people of this state.”

In a Packaging World Magazine article, legal guru Eric Greenberg discussed the criminal charges levied against the Peanut Corporation of America (PCA). The criminal charges are outlined in an indictment that is based on intent to defraud. One of those people charged already pleaded guilty, so the prosecution will probably have a willing witness. One broader law, the US Park Doctrine, states that charges can be brought against corporate leaders even if they didn't know of the dangerous acts. In the PCA case, there is evidence that the leaders did know of the salmonella contamination, so other, more direct charges could be levied.

The PCA case highlights a concerning issue for food manufacturers and retailers where the fraudster actively seeks to avoid detection. Even in facilities that are audited by competent auditors—even in unannounced inspections—the bad guys can find ways to hide their fraudulent operations, which is what happened when PCA intentionally transferred product from a noncertified manufacturing plant to a certified one after inspections and then presented the goods as manufactured in a certified manufacturing plant.

Various types of criminal charges can apply. During the MOOC I mentioned what the US Customs has called “honey laundering.” This is where honey is transshipped from a country with a high tariff through a country with a lower tariff and labeled as coming from that low tariff country. The “origin laundering”—or “neutralization”—is the fraudulent and deceptive change of the country of origin on the label. The fraud opportunity for tax avoidance smuggling can be substantial. One honey case led to \$180 million in profit from the avoided taxes (DOJ 2009; ICE 2010).

There is a public health vulnerability in smuggling for two reasons. First, in a product recall, it is not possible to trace the fraudulent honey...or, worse, if the traceability codes are incorrect, the wrong product might be recalled while the dangerous product remains in the marketplace (CACP 2006; Liang 2006). Second, we lose transparency on the product itself (Roth et al. 2008). With the lack of transparency, there is an increased fraud opportunity to use unapproved or dangerous ingredients. At a minimum, the bad guys often get greedy and start adulterating the product to further increase their profits.

As was stated in the indictments, several of the food fraudsters did start adulterating the honey with sugar. In this instance, the perpetrators all knew they were committing a crime, so criminal charges were not a surprise—though criminals don't think they'll get caught.

Regarding food fraud prevention, the takeaway is that we need to reduce the fraud opportunity regardless of whether we trust our suppliers or don't think there is any logical reason for anyone to commit fraud. Regarding protecting your corporate leaders from being led out of your facility in handcuffs, be diligent in developing and supporting a Food Fraud Prevention Strategy. Address “reasonably foreseeable hazards,” and your actions will reduce the potential charge of “willful blindness.”

Risk Analysis of the FFIS and FFVA: “The Assessment”

There is a need to further expand on how and why “risk analysis” is incorporated in the Food Fraud Prevention Cycle. The fraud opportunity is covered in detail in the Criminology chapter, and risk analysis and vulnerability assessments were covered in other chapters. The application and use within the cycle are not really two distinct steps as indicated but a continuum. When starting to review food fraud for the first time, a CEO/CFO/CRO may ask “generally, what are we looking at here? Not so bad or really bad?” Considering an analogy of checking the weather outside, the scale needed could be as broad as “will tomorrow be deathly hot or deathly cold?” Their question is not about resource-allocation decision-making yet but more of a mental set on what is to come. Also, if this is perceived as a potentially very impactful activity, the C-suite may feel it is crucial to immediately update or warn the Board of Directors.

The most basic step is a very high-level prefilter or what Enterprise Risk Management refers to as an “initial screen”—for example, a Food Fraud Initial Screen (FFIS) (Spink et al. 2016). This is a review of all types of fraud and all products but at a very high level and with very quick assessments such as a small group of subject matter experts. At this point early in the process of reviewing the new risk, it is important to present a full and complete assessment—although possibly casual, uncertain, and un-robust—because the resource allocation decision-maker can define how much (if any) more detail is needed. There are examples where countermeasures and control systems were approved after just a broad discussion of the fraud opportunity and brainstorming of some countermeasures and control systems.

Through the use of the cycle and the continuous review, there can be an assessment of how much information—as well as the necessary level of accuracy, precision, and certainty—is needed. If the resource-allocation decision-maker has enough information, then that is the final specification. The resource-allocation decision-maker has the final say for how much information is enough to make a yes or no decision.

Countermeasures: The Risk Treatment

Consideration of countermeasures and control systems should be reviewed each and every time a vulnerability assessment is conducted. The best time for innovative and effective brainstorming is at that first point of awareness, but also it is the most dangerous time because an inefficient path and vision could be set. This also provides a great service to not only provide an updated vulnerability assessment but to already include ideas for countermeasures and control systems. When communicating problems to management, it is always best to present problems or a crisis alert accompanied by some possible responses. After a new incident, the updated

vulnerability can be presented as well as possible countermeasures and control systems that could get the situation within the risk tolerance.

To support this resource-allocation decision, the FFPC creates a method to review and explain countermeasures and control systems as well as utilizes the ERM and corporate risk map to explain “how much is enough?”

Case Study: Peanut Allergen Adulterant—Substances in Ground Cumin

This example uses the peanut in cumin food fraud incident of a company who does *not* have an immediate food safety incident. If a food fraud team did find a health hazard from the peanut allergen in cumin, the immediate response would be to contact the food safety or crisis management team. After confirming there is *no* immediate health hazard for this product, an effective food fraud prevention team use of the Food Fraud Prevention Cycle could include:

- The **information gathering** step of **scanning** identifies a new issue of “peanut in Cumin.” Specifically, the employee who is responsible for scanning receives an alert that identifies the new information. The responsible employee considers whether they should alert the “food fraud team leader” or wait to present this new information at the next regular team meeting. (The team will need to calibrate what leads to an emergency meeting or what can wait.)
- The **fraud opportunity** step considers the new information. The new incident is reviewed in terms of the impact on the three components of victim, fraudster, and guardian and hurdle gaps.
- Then the **vulnerability assessment** is updated to include the refined fraud opportunity details.
- The **Enterprise Risk Management** developed a **corporate risk map** that is updated including a consideration of the updated **risk rank**.
 - If the new incident is plotted in the “unacceptable” range of the corporate risk map, then countermeasures and control system responses are developed. At this point, only possible projects are researched, and they will be reviewed later for a final decision.
- It is always good to consider **countermeasures and control systems** so, if anything, the boss knows you’re already working on it and second to provide a very general idea of the effort for applying the risk treatment.
- The **risk communication** would be to review the new information that is provided to the resource-allocation decision-maker such as “A new food fraud incident of peanut in Cumin was identified. The [ways this could] impact on our company is”:
 - 1. “The incident does *not* fundamentally change how we understand our fraud opportunity, and the vulnerability is still in the “acceptable” range.”
 - 2. “The incident *does* fundamentally change the way we understand our fraud opportunity and the vulnerability is now in the “unacceptable range.”

Hopefully, to calm senior leaders, this should be followed with “the food fraud prevention team that is already meeting to consider and implement countermeasures and/or control systems within the policy and strategy that you have already approved. We will present more details as you require.””

Conclusion

The previous Food Fraud Prevention Overview chapters established the foundation and need for the proactive, holistic, and all-encompassing approach. This chapter built upon that and presented how the prevention strategy is managed in a cycle that “connects everything to everything.” The Food Fraud Prevention Cycle (FFPC) builds upon that prevention concept to demonstrate a systematic approach that builds upon the fraud opportunity and connects to a resource-allocation decision-making function that is Enterprise Risk Management (ERM/COSO). The emphasis is that “It’s all about the ‘fraud opportunity.’” ***The first conclusion is*** that there is a need for a system that connects all the essential components together with a focus on prevention. The basic workings of the cycle include broad concepts from the gathering of information, assessing the root cause (the fraud opportunity), conducting assessments that address all types of fraud for all products that then calibrate those assessments with all other enterprise-wide risks, and finally enabling decision-making for the selection of countermeasures and control systems *before* cycling deeper through the process again. ***The second conclusion is*** that it is possible to create a systematic way of assessing and managing the Food Fraud Prevention Strategy. A complex system cannot be efficiently or quickly implemented. There is a need to *not* build from the bottom up but to start with an approach that considers risks across the *entire* enterprise—all hazards approach for all types of fraud, all products, and all enterprise. The Food Fraud Prevention Strategy will then define—based on the specific fraud opportunity and the unique risk tolerance of the enterprise—“how much is enough.” This was referred to as the “corkscrew approach.” ***The final conclusion is*** that the Food Fraud Prevention Strategy is first implemented broadly but not deeply to then defines where to go deeper. The countermeasures and control systems will be drilled down such as the turning of a corkscrew. There is a saying:

Combating fraudsters is like a never-ending chess match of strategic moves and countermoves.

You can only trust as far back as you can trust (you may need to have the countermeasures and controls only focused on testing incoming good... but try to figure out how you can reduce the fraud opportunity by trying to dissuade the fraudster from actually attacking you).

Appendix: WIIFM Chapter on Prevention Implementation

This “What’s In It For Me” (WIIFM) section explains why this chapter is important to you.

Business functional group	Application of this chapter
WIIFM all	While it may seem overly complex at first, after review, the FFPC is a very simple “plan-do-check-act”-type method that “connects everything to everything”—and this starts at a high level and only goes as deep as you require.
Quality team	This presented the Food Fraud Prevention Cycle (FFPC) and provided methods and case studies.
Auditors	This provides more insight into the inner workings of the overall Food Fraud Prevention Strategy.
Management	This is a presentation of the FFPC which is a very thorough and methodical approach.
Corp. decision-makers	The FFPC is an information management and business process coordination that could actually be used for any decision—but for now fully implement for food fraud so you have a working example.

Appendix: Study Questions

This section includes study questions based on the Key Learning Objectives in this chapter.

1. Discussion Question:

- (a) What is a “system of systems”?
- (b) How is a “vulnerability” different from a “risk”?
- (c) Why is the focus on “prevention” versus “mitigation” important?

2. Key Learning Objective 1

- (a) What is the “fraud opportunity”?
- (b) Must the FFPC be following in the specific sequence?
- (c) Who—or what group—decides whether a Food Fraud Prevention Strategy (FFPS) is complete or compliant?

3. Key Learning Objective 2

- (a) Define “vulnerability”?
- (b) Is the goal to completely eliminate vulnerabilities?
- (c) How is a vulnerability assessed or defined?

4. Key Learning Objective 3

- (a) What are “risk tolerance” and “risk appetite”?
- (b) On the FFPC, where is the “risk treatment” applied?
- (c) What is the relationship between an initial screen/prefilter and a detailed assessment?

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Chapter 6

Business Decision-Making and ERM/ COSO



Summary

This chapter presents the details of the business decision-making that is based on the managerial accounting regulatory requirements laid out in Enterprise Risk Management (ERM). ERM is based on accounting principles developed by COSO (the Committee for the Sponsoring Organizations of the Treadway Commission that, itself, was created to add internal control requirements such as for the Sarbanes-Oxley Act of 2002). The overall resource-allocation decision-making is addressed under an enterprise-wide system such as the formal concept of “Enterprise Risk Management.”

The Key Learning Objectives of this chapter are:

- **‘(1) Introduction to Enterprise Risk Management:** Introduce the concept of an enterprise-wide risk assessment method that “compares everything to everything.” This allows an evaluation of this new risk in relation to all other risks and also to determine whether specifically above-defined “risk tolerance.”
- **‘(2) Applying ERM to Food Fraud Prevention:** Then there are steps to apply the enterprise-wide methods specifically to a Food Fraud Vulnerability Assessment and to incorporate in a Food Fraud Prevention Strategy.
- **‘(3) Implementing an Iterative Process:** Finally, there are methods and procedures to implement an iterative process that continually evolves and innovates to more efficiently and effectively balance the evolving fraud opportunity in relation to the enterprise-specific risk tolerance.

On the Food Fraud Prevention Cycle (FFPC), this chapter addresses the “(3) Vulnerability Assessments,” with “(4) Risk Rank” that is determined by the “(5) Enterprise-Wide Risk Assessment” (Fig. 6.1).

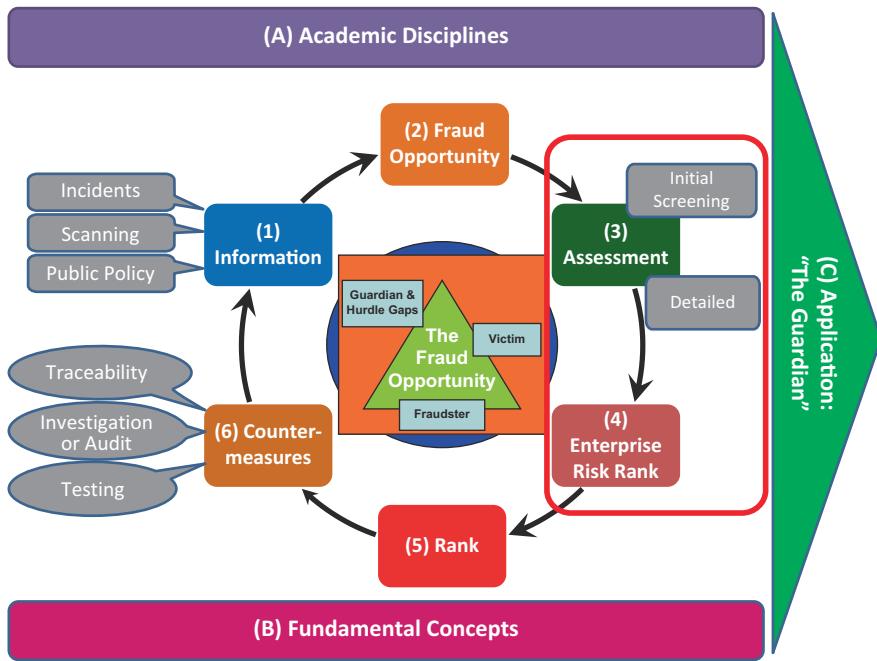


Fig. 6.1 Where this chapter applies Food Fraud Prevention Cycle—where this chapter applies to the overall concept: “(3) assessments” and “(4) enterprise risk rank.” (Copyright Permission Granted) (Spink 2014; Spink et al. 2019)

Introduction

Overall, businesses are financial entities judged by financial metrics. While the main focus of a food company is obviously on the food, ultimately they are a business. The first level of regulation and controls are on business functions. There are specific and unique requirements for financial reporting. One of those requirements is for internal controls to manage and report risks.

Companies produce a product and sell into the markets. Some additional regulations and controls focus on those details. Product-specific regulations would include the US Food Safety Modernization Act (FSMA) and the US Food, Drug, and Cosmetics Act (FDCA). Market- or trade-related specific regulations would include import and export laws such as from the World Trade Organization (WTO), the World Customs Organization (WCO), or the likes of the US Customs-Trade Partnership Against Terrorism (C-TPAT).

Without this calibration at best you are relying on “someone else” to figure it out—and no one probably knows the problem better than you. The basic concepts are not private or confidential. These are common business practices that are taught in undergraduate university courses.

Legal Requirements and “Opportunities”

Beyond the legal requirements, there are certifications or standards compliance to consider. For food safety, an example is the Food Safety Management System in the Global Food Safety Initiative (GFSI) Guidance Document. While there are specific regulatory requirements for financial reporting, there are programs managed by an organization such as COSO (Committee of the Sponsoring Organizations of the Treadway Commission) who created Enterprise Risk Management (ERM) to address US Sarbanes-Oxley Act requirements specifically.

Companies are instructed to implicitly or explicitly create these monitoring systems by their stakeholders (e.g., owners would include shareholders who put in place a Board of Directors to oversee the corporate-level officers). While finance and securities laws regulate public companies, even private owners (e.g., individuals, private equity firms, etc.) would also require some oversight and reporting mechanism. Investors don't just give a billion dollars to a company and hope for the best—"good luck and see you in a year." Ultimately all resource-allocation decision-making are accountable by the Board of Directors. Whether the frontline "business case" is in the same format or not, there is a central decision. Usually, there is a conversion of ERM concepts into everyday metrics—you might not be aware of your success measures integrated into the ERM system. There are two types of considerations to the decision with one being an increase in earnings (revenue) and the other is the cost of operation (operational costs and managing risk). From COSO [emphasis added]:

Opportunities: the possibility that an event will occur and positively affect the achievement of objectives, supporting *value creation* [increase sales or profit] or *preservation* [reduce risks]. (COSO 2013)

A central enterprise-wide system is the control mechanism. For many companies that system is a formal Enterprise Risk Management system. This chapter will introduce business resource-allocation decision-making and how food fraud (and all food risks) would fit into an ERM system (Fig. 6.2).

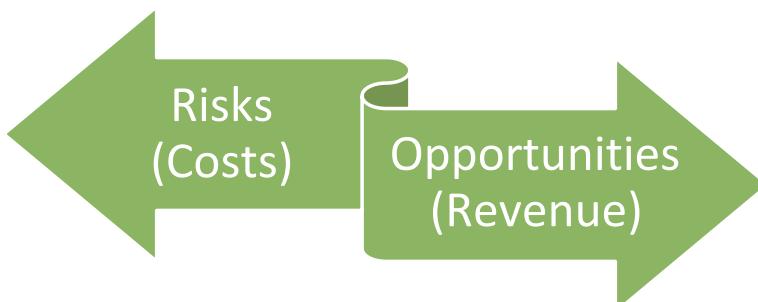


Fig. 6.2 Considerations for resource-allocation decision-making are a balance of increasing revenue and controlling costs

Key Learning Objective 1: Enterprise-Wide Risk Management System

This section reviews the enterprise-wide management systems that connect from the frontline tactical resource-allocation decisions to calibrate all the way up to the strategic assessment within the “risk appetite” of the owners of the company. Whether to meet regulatory compliance—or just competent business practices—these fully integrated mechanisms exist and are critical for a Food Fraud Prevention Strategy.

The section focuses on the basics of Enterprise Risk Management (ERM/COSO).

The Key Learning Objectives of this section are:

- (1) An overview of the legal, regulatory requirements for managerial accounting practices such as under the US Sarbanes-Oxley Act for Enterprise Risk Management (ERM/COSO).
- (2) Consider internal controls to harmonize the way separate business units assess, report, and manage risks.
- (3) Examine the integrated framework that connects and calibrates the separate internal control procedures.

COSO: Regulatory Compliance for Securities and Finance

Fortunately for Food Fraud Prevention, the enterprise-wide management structure concepts are already developed and include standards, training, certifications, and many case study examples. Whether formally published by COSO or in scholarly journals, there are many resources and examples. The key for Food Fraud Prevention is to leverage those processes to (1) use refined systems, (2) leverage current and already adopted regulatory training and certification, and (3) communicate clearly with financial group colleagues.

Regulatory compliance requires “a” process but not explicitly ERM/COSO. The requirement is an overall control system. It is important to explain the difference between “formal, full ERM regulatory compliance” and “ERM-like” systems. A full and formal ERM “compliance” can be extremely costly and resource intensive. This would cover all aspects of the corporation and all transactions. The system would include a comprehensive and formal audit of all internal controls and the integrated framework. An “ERM-like” system can apply the general principles. These general principles would integrate with any of the related systems.

From COSO (2013):

Enterprise risk management is a process, effected by an entity’s board of directors, management and other personnel, applied in strategy setting and across the enterprise, designed to identify potential events that may affect the entity, and manage risk to be within its risk appetite, to provide reasonable assurance regarding the achievement of entity objectives.

The definition reflects certain fundamental concepts. Enterprise risk management is:

- A process, ongoing and flowing through an entity
- Effect by people at every level of an organization
- Applied in [during] a strategy setting
- Applied across the enterprise, at every level and unit, and includes taking an entity level portfolio view of risk
- Designed to identify potential events that, if they occur, will affect the entity and to manage risk within its risk appetite
- Able to provide reasonable assurance to an entity's management and board of directors
- Geared to the achievement of objectives in one or more separate but overlapping categories.

This enterprise risk management framework is geared to achieving an entity's objectives, set forth in four categories:

- Strategic – high-level goals, aligned with and supporting its mission
- Operations – effective and efficient use of its resources
- Reporting – reliability of reporting
- Compliance – compliance with applicable laws and regulations.

There has been a benefit to assessing Food Fraud Vulnerability within an enterprise-wide framework even if there is currently no formal connection or calibration to the corporate-level system was developed or connected. The foundation in regulations and standards provides confidence that the Food Fraud Prevention Strategy is compatible with, and is compliant with, enterprise-wide regulatory financial and security compliance requirements. For example, the food fraud incidents can be reviewed within a Food Fraud Vulnerability Assessment; the results of that assessment can be plotted on an unofficial corporate risk map. What is meant by “unofficial” is that—even without contact with chief executive officer, chief financial officer, chief risk officer (CEO/CFO/CRO), or enterprise risk team—the food risk assessors create what is believed to be the risk appetite in terms of very high to very low likelihood and consequence. By using the same system as the CEO/CFO/CRO teams, they can use the assessment. Even if the risk ranks are not correlated between the food fraud assessment and the enterprise-wide system, this is a baseline or starting point that can be adapted. For example, the food fraud measures of likelihood and consequence can be adapted and then vulnerability assessment re-calibrated. If done correctly and thoroughly, the Food Fraud Vulnerability Assessment can be directly used in the ERM assessment.

While this may seem very formal and require additional steps, there is usually no need for a food safety or food fraud manager to be formally certified or trained in full ERM regulatory compliance.

The COSO/ERM concept and components are presented in “the COSO Cube” (Fig. 6.3) (COSO 2013).

The components of the COSO Cube include (COSO 2013):

1. Internal Environment
2. Objective Setting
3. Event Identification (re, awareness of a food fraud incident, suspicious activity, or identified fraud opportunity)
4. Risk Assessment (re, Food Fraud Vulnerability Assessment)
5. Risk Response (re, Food Fraud Prevention Strategy)

6. Control Activities (re, countermeasures and control systems),
7. Information & Communication
8. Monitoring (Re, a control system to continuously evaluate the evolving fraud opportunity)

The COSO Cube presents “components of enterprise risk management” in eight interrelated management components. This COSO Cube is an effective tool to explain this simplicity of connecting a new Food Fraud Vulnerability Assessment into the enterprise-wide decision-making system. A new food fraud incident—or the first full Food Fraud Vulnerability Assessment—would enter at the star on the front of the cube in the “Event Identification” component.

Event Identification: Internal and external events affecting achievement of an entity’s objectives must be identified, distinguishing between risks and opportunities. Opportunities are channeled back to management’s strategy or objective-setting processes. (COSO 2013)

Now that there is a specific component—or management function—to receive information on new “Event Identification,” there is now an “accountable” person and also a way to structure the information so it can actually be assessed in relation to all other enterprise-wide risks. After “Event Identification” the next step would be “risk assessment” and then a “risk response” decision that integrates information to and from the other sides of the cube including the four categories of objectives (e.g., strategic, operations, reporting, and compliance) and entity unit (e.g., entity-level (enterprise-wide), division (or operating company), business unit, and subsidiary).

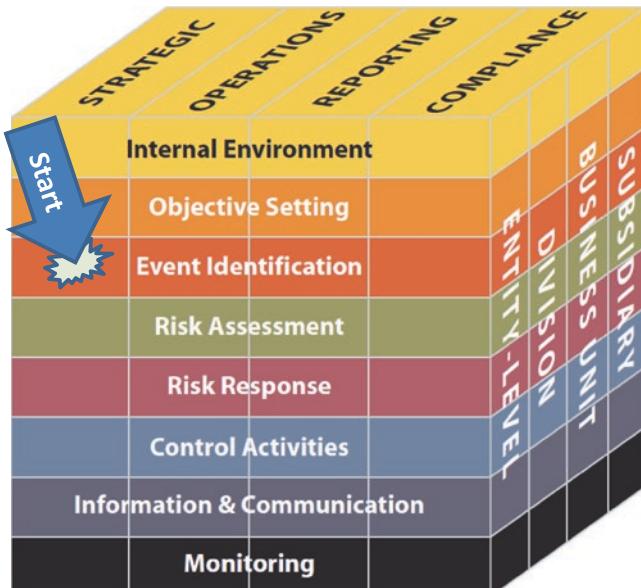


Fig. 6.3 “COSO Cube” representation of the organization of activities and work functions—the “start” point for a new concern at the “strategic” and “event identification” point. (Copyright Permission Pending) (COSO 2013)

Once the “enterprise-wide assessment” is added to the Food Fraud Prevention Cycle (FFPC), there is an actual decision-making system to evaluate “how much is enough.”

Internal Controls: ERM and ERM-Like

In the USA, the major push for additional regulations occurred after incidents at Enron, WorldCom, and Parmalat. In these examples, investors were defrauded which led to bankruptcy costing losses of \$62 billion (\$700 million of overstated profits), \$136 billion (\$3.8 billion misappropriated), and \$20 billion (\$17.6 billion in hidden losses) (Oppel and Sorkinnov 2001; Romero and Atlas 2002; Boland 2008). Each company conducted fraudulent operations that circumvented the then current audit and control practices. The failures of these companies—among others—contributed to the worldwide financial meltdown of 2001. Each of those three corporations went bankrupt, and the implications even extended to the corporate auditor companies such as Arthur Anderson.

The US securities and finance regulations expanded “internal controls” and an “integrated framework” to increase transparency of transactions and accountability of the individual leaders and managers. The regulations were successful in the sense that company employees have been prosecuted and sent to federal prison. Even if there is no prison sentence, most CEO/CFOs would rather not be convicted felons.

It is important to note that even though the regulatory requirement only applies to public companies, private and non-US companies usually have implemented similar controls.

- ***Internal control:*** “is a process effected by an entity’s board of directors, management, and other personnel, designed to provide reasonable assurance regarding the achievement of objectives relating to operations, reporting, and compliance” (COSO 2013).
- ***Integrated framework:*** “The original framework has gained broad acceptance and is widely used around the world. It is recognized as a leading framework for designing, implementing, and conducting internal control and assessing the effectiveness of internal control. [...] The Framework will enable organizations to effectively and efficiently develop and maintain systems of internal control that can enhance the likelihood of achieving the entity’s objectives and adapt to changes in the business and operating environments” (COSO 2013).

Other related COSO glossary terms are below (note the similarity and harmonization with ISO 31000 Risk Management):

- “***Inherent risk***—the risk to an entity in the absence of any action management might take to alter either the risk’s likelihood or impact.”
- “***Residual risk***—the remaining risk after management has taken action to alter the risk’s likelihood or impact.”

- “**Risk appetite**—the board-based amount of risk a company or another entity is willing to accept in pursuit of its mission (or a vision).”
- “**Risk tolerance**—the acceptable variation relative to the achievement of an objective.”

Other related COSO concepts that demonstrate the application to Food Fraud Prevention include (COSO 2013):

- **Enhancing risk response decisions:** Is a risk tolerable? How do you know? Who would dare to let a risk remain in a business operation? ERM provides a way to measure and calibrate new or changing risks.
- **Reducing operational surprises and losses:** By creating a system to look at all current risks and potential vulnerabilities—and monitor changes—the enterprise works to move quickly. An example is that before the subprime lending crisis of 2007, several financial firms such as Goldman Sachs shifted out of investments that eventually crashed (Taleb 2007). With an ERM-type system, the vulnerabilities were evaluated to have increased above their “risk appetite.”
- **Identifying and managing multiple and cross-enterprise risks:** Supporting the previous item, the enterprise-wide system helps evaluate a wide variety of risks and vulnerabilities within one system. For example, is it a better investment to hire two new salespeople or put in a metal detector at a plant? Without an enterprise-wide system, these two could not be quantitatively or analytically compared.
- **Seizing opportunities:** A company can become crippled if they feel they must address every risk. An ERM system helps evaluate the optimal amount of risk which frees up resources to pursue new or expanding revenue.
- **Improving deployment of capital:** Building on seizing opportunities, and outside the risk management, is creating a general mechanism to evaluate all financial and capital resource-allocation. New or different measures could be used such as value at risk (VaR) or return on capital employed (ROCE).

ERM/COSO is a critical part of Food Fraud Prevention Strategy since it provides a frame for assessing the risk, making decisions, integrating with other enterprise-wide systems, and organizing the activities.

ERM/COSO: Connect Everything to Everything

The ERM system provides internal controls and an integrated framework to increase transparency and accountability. The processes work to “connect everything to everything.” Each step in the process reviews the other steps—horizontally across a function or vertically from the front line to the board.

It is important to note that even if/when ERM systems are in place, they may not be evident to everyone across the enterprise. We have several instances where we have heard “we don’t do ERM.” Then later—and sometimes later in the same meeting—someone says “yes we do, we just don’t show you those charts!” The assess-

ment and judgment would be extremely commercially sensitive and actually not helpful for day-to-day decision-making for many organizations “as-is.” Also, the overall ERM assessment would include a very broad range of risks. For example, a food safety group would not provide data or analysis of employee kidnapping threats, but that doesn’t mean those risks are not real or important.

In reality, the board-level ERM assessments are comprised of a series of connected measures or activities. The overall ERM charts or questions are reduced to specific questions or data requirements from the specific operations or functions. Thus, the food safety group probably does provide quarterly statements about food safety risks, sometimes even with a requirement for the statement to be notarized. These statements feed upwards to a more formal ERM statement. The Sarbanes-Oxley Act requires a quarterly statement that is referred to as the 10-Q and an annual statement in 10-K.

The ERM system would include assessments and audits, and then the assessments and audits, themselves, would occasionally be audited.

The bottom line for the Board of Directors or CEO is that (1) a monitoring process is in place, and (2) the process is competently implemented adapted. A formal Food Fraud Prevention Strategy is becoming required to meet that compliance goal.

Sidebar: Fraud in Fraud Assessments—Intentionally Over- or Underestimation

Reportedly the guru investor Warren Buffett said “don’t ask a barber if you need a haircut.” The barber has a vested interest in the outcome of the analysis. The authors of the *Freakonomics* books would refer to this as the “influence of incentives” (Levitt and Dubner 2014). The same is understood to be for fraud assessments. This is often hard to even comprehend since most people think they make rational, fact-based decisions, without emotion or bias (see sidebar on “How (Un) Ethical Are you?”).

- **Overestimate Fraud Opportunity:** A manager who is trying to get promoted or grow their group has an incentive or personal benefit to overestimate the fraud opportunity. A higher fraud opportunity would lead to more high-profile projects, bigger budget, and more direct report employees to supervise.
- **Underestimate Fraud Opportunity:** A manager who is near retirement or not looking for more work may underestimate the fraud opportunity not to increase their work.

In both cases, the enterprise is at risk. In the first case, the enterprise over-invests in prevention and has fewer funds to pursue new markets or products—sacrificing revenue-generating opportunities. In the second case, the enterprise is exposed to strategic risks.

The internal framework concept includes an awareness of this inherent conflict and puts processes in place to calibrate the risk assessments. Essentially the internal controls look for fraud in fraud assessments.

Sidebar: Detail of an ERM/COSO Corporate Risk Map that Is Expanded to Include Both Risks and Opportunities

From COSO publications, the range of risks are presented on a “Combined Risk and Opportunity Map” where (Fig. 6.4) (COSO 2012). They state “This allows a direct comparison of the highest rated opportunities and risks for consideration and prioritization” (COSO 2012). Essentially, the costs of reducing risks are balanced with investments that increase revenue. It is important to note that the optimal risk level is not “zero risk.” There is an important balance between managing operational risk and investing in the business.

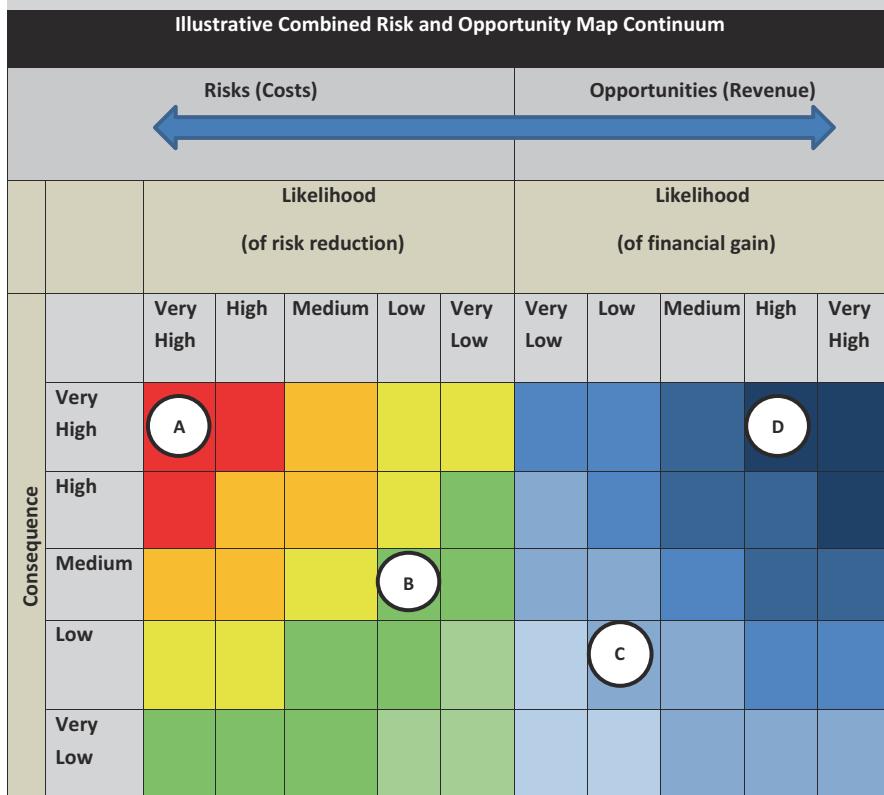


Fig. 6.4 ERM/COSO Combined Risk and Opportunity Map with examples. Note: The risks above the “risk tolerance” (the general range in red and orange such as point “A”) are either reduced or managed (to at least the point “B”). The investments that reduce the risks are balanced with the opportunities to increase revenue or profit margin. The revenue-generating opportunities include a range from low confidence/low benefit (“C”) to high confidence/high benefit (“D”). (Copyright Permission Granted from Committee of Sponsoring Organizations of the Treadway Commission (COSO). All rights reserved. Used with permission) (Base adapted from COSO (2012) and examples are new)

These ERM/COSO principles and practices help create a foundation for resource-allocation decision-making. Once these are understood and implemented, then the next Food Fraud Vulnerability Assessment results can be plotted and determine what are “acceptable” what are “unacceptable.” Without this type of method to “connect everything to everything,” then “how much is enough” is a guess and does not have a measure of success. The Combined Risk and Opportunity Map is important to understand the process for resource-allocation decision-making. When this is better understood by the risk assessors and risk managers, then more efficient and effective countermeasures and control systems can be proposed and selected.

Sidebar: “How Much Is Enough?” and Optimal Risk-Taking

“How much is enough” is often a type of threshold that is calculated within a managerial accounting standardized system such as by COSO in their Enterprise Risk Management (ERM/COSO) (COSO 2012). COSO explains that there is a “sweet spot” of “optimal risk-taking” (Fig. 6.5) (COSO 2012).

From COSO publications, the risks are plotted on a “risk map” or “heat map” (Fig. 6.6) (COSO 2012).

From COSO publications, the risks are plotted on a “risk map” or “heat map” (COSO 2012).

COSO then provides guidance on how to “assess risk”:

Risk Level - <expand title from COSO>

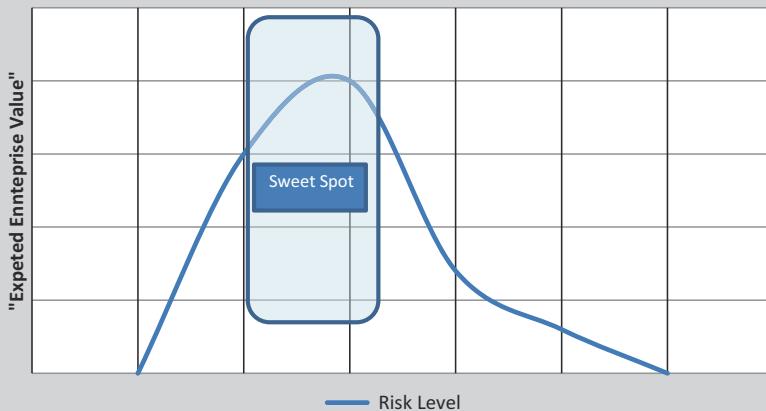
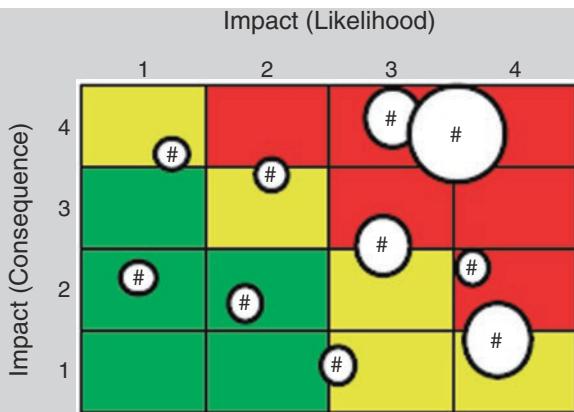


Fig. 6.5 An example of the “sweet spot” of the ideal risk tolerance for an enterprise—optimal risk-taking with the identification of the “sweet spot.” (Copyright Permission Granted, Committee of Sponsoring Organizations of the Treadway Commission (COSO). All rights reserved. Used with permission) (Adapted from COSO (2012))

(continued)

Fig. 6.6 Adapted from COSO, an “illustrative heat map” where the dots represent a risk and the size of the dots represent the speed of onset (Note: the term impact was adapted to the ISO 31000 terminology of consequence)



Assessing risks consists of assigning values to each risk and opportunity using the defined criteria. This may be accomplished in two stages where an initial screening of the risks is performed using qualitative techniques followed by a more quantitative analysis [detailed assessment] of the most important risks. (COSO 2012)

Thus, the decision of “how much is enough” of a risk treatment is supported by ERM/COSO identification of a “sweet spot” of “optimal risk-taking” and supported by a presentation on a corporate risk map.

Sidebar: The Influence of Michael Porter and Corporate Strategy

Michael Porter is considered the “father of corporate strategy.” His major work that summarized the overall “Competitive Strategy” was published in 1984 (this is covered in more detail in the other chapter on Market and Competitors) (Porter 1980). This work creates an overall theory to consider markets, how companies position products and services, as well as how companies manage or monitor the changing internal and external landscape. His follow-up book “Competitive Advantage” provides more focus on implementing the concept to achieve success (Porter 1985).

Key concepts from Porter that support the Food Fraud Prevention Strategy include:

- Identify the business functions.
- Measure and calibrate risks and rewards.
- Provide an overall perspective on optimizing decision-making.

Overall, there is an advantage—a strategic advantage as well as efficiency—of considering “fraudsters” or “counterfeitors” as a competitor. The fraudsters generally make business decisions based on macro (global-level trends) or micro (local or individual attributes) factors that are essentially corporate strategic decision-making. Essentially, the bad guys use the same decision-making theory as the good guys.

It is also a strategic decision to mention Porter’s theories since he was a guru from the mid-1980s to the end of 1990s. He influenced a lot of business

academic thinkers and students. The age of those students would now be in their mid-50s to mid-60s and who are probably leading your companies or agencies. Since those resource-allocation decision-makers will recognize the terminology and theories of Michael Porter, his concepts are an important anchor for explaining the food fraud problem.

Sidebar: Information Requirement of How Much Is Enough?

Regarding how much information to gather and how to present the assessment, an important question is “how much is enough”? The answer is as much—or little—as the resource-allocation decision-maker needs to make a decision. In some cases, they may have enough information to make a decision then; obviously, no further assessment is needed. Sometimes a simple review or story can lead to an instant decision. Since a resource-allocation decision often needs more information, to provide more structure to the process, there is usually a need for a more systematic review of the proposal.

There were two major theoretical new breakthroughs for Food Fraud Prevention that frame the question by examining (1) the root cause (2) the decision-making process, which will then define the (3) risk treatment needed.

To address this need and the first step in understanding the root cause, a first Food Fraud Prevention innovation was to expand from food science to apply the Criminology theory of Situational Crime Prevention. The second innovation was to apply managerial accounting and decision sciences to understand the process to determine “how much is enough.” Finally, after an understanding of the root cause and an awareness of the decision-making process, the countermeasure and control system risk treatments can be considered. To note, a countermeasure or control system could be food authenticity testing, market monitoring, enhanced traceability, stronger supplier agreements, expanded investigation and enforcement, and others.

For a wide range of industries, this “last” step of selecting countermeasures and control systems was informal, at best, and frequently a random process that was a reaction to a single incident. For example, after a counterfeit incident or lawsuit, a company might figure they need to do “something,” but they do not have a systematic way to identify “how much is enough?” Sometimes the decision might be made by the General Counsel to consider “how much do we need to do to not look bad?” In other instances, a certain budget amount may be allocated such as “spend no more than one million dollars.” In both cases, there would not be a systematic approach. There is no systematic way to judge what level of effort would be “enough to not look bad,” and there was also no real rationale as for why spending one million dollars (or whatever) was the optimal resource-allocation.

(continued)

When applying ERM, the problem is presented in a way that it can be systematically evaluated in relation to other enterprise-wide concerns. Basically, ERM helps assess this risk in relation to other risks.

In every—emphasis on “each and every time”—a new incident or problem is identified; it should be run through a systematic review that includes:

- ‘(1) A review of the suspicious activity (such as using the Food Fraud Suspicious Activity Report method—FFSAR (Spink et al. 2019)
- ‘(2) Conduct a vulnerability assessment.
- ‘(3) Then plot the problem on the corporate risk map.

Until this review is conducted, it is not defined as to whether the problems are unacceptable or shifts to outside the risk tolerance.

Key Learning Objective 2: Applying Enterprise Risk Management to Food Fraud Risk

This section reviews the ERM concepts of risk appetite and a corporate risk map which creates a theoretical leap for Food Fraud Prevention Strategy (FFPS). Before including these concepts, the assessments were stand-alone, not comparable to other risks, and that led to decisions that usually either stalled or were over- or underinvested.

The Key Learning Objectives of this section are:

- (1) Introduce the concept of risk appetite as a measure of a threshold.
- (2) Consider the two-stage process for the ERM assessment approach of first an initial screening and then a detailed assessment when needed.
- (3) Review these concepts in relation to business economic crimes.

Risk Appetite and Corporate Risk Map

An overarching objective of ERM/COSO is to create an internal framework to consider all risks across the entire enterprise. The goal is to seek and monitor even the most unlikely or unknown threats to the business. The overall ERM activity requires a center point to support decision-making to “connect everything to everything.” Each resource-allocation decision is evaluated with every other decision in relation to the financial goals—the financial goals include a “risk appetite” defined by the owners through their proxy, the Board of Directors. To note, the “owners” could be individuals who own mutual funds or individual stocks in their retirement accounts—those individuals expect a consistent rate of return and level of risk that they expect the Board of Directors to assure. The ERM system evaluates these risks on a “corporate risk map.”

While the exact single “corporate risk map” may not exist—or be so commercially sensitive that it is considered extremely confidential and made public or distributed widely—this is an effective way to present a novel risk such as food fraud.

The most important result of implementing enterprise-wide risk management is defining the “risk appetite” and presenting the risks on a “corporate risk map” (COSO 2013). Enterprise Risk Management (ERM) is a process to assist resource-allocation decision-making “...designed to identify potential events that may affect the entity, and manage risk to be within the risk appetite, to provide reasonable assurance regarding the achievement of entity objectives” (MSU-FFI 2017).

Traditional food safety risk assessors often do not realize that many of the “limits” are actually a qualitative judgment of a vulnerability-defined point. While there may be a quantitative measure, the determination of that limit may have been more arbitrary. There were defined limits for food safety such as (1) the legal 5-log reduction or (2) scientifically based appropriate level of protection (ALOP) or appropriate level of sanitary protection (ALOSP) (WTO 1995; CODEX 2003) or a defined food safety objective (FSO) (Buchanan 2007, 2016). For example, the US FDA Juice HACCP guidance requires a 5-log kill step (evidence that there is a manufacturing step that reduces the prevalence of pathogens by five orders of magnitudes). Why exactly is 5-log required? Is a 4.9-log reduction 100% lethal, and 5.1-log is 100% safe? Why not decide on a 4-log or 6-log requirement?

Sidebar: Introduction to Food Risk Assessments

This is an excerpt from the report “Applying Enterprise Risk Management to Food Fraud Prevention” (MSU-FFI 2017).

It is essential to review the concept of “risk” and an “optimal level” that is referred to as “risk tolerance” or “risk threshold.” Many Food Scientists and food safety managers use the term “risk” to define a point of the unacceptable or intolerable level. In Codex Alimentarius (CODEX) this is defined as an “Appropriate Level Of Protection” or ALOP. More broadly – including by statisticians, data scientists, and business decision-makers – risks are not all bad; it is usually inefficient or impractical to eliminate all risks. A company or agency that is operating with too-little risk is usually inefficient in meeting the overall objectives set by its stakeholders. There are situations of “insufficient risk-taking” that are the opposite of “excessive risk-taking.” To use US FDA terminology, there are “hazards,” and only some of those are “hazards that require a preventive control.” From COSO:

The Risk Assessment Process: Within the COSO ERM framework, risk assessment follows event identification and precedes risk response. Its purpose is to assess how big the risks are, both individually and collectively, in order to focus management’s attention on the most important threats and opportunities and to lay the groundwork for risk response. Risk assessment is all about measuring and prioritizing risks so that risk levels are managed within defined tolerance thresholds without being over-controlled or forgoing desirable opportunities. (COSO 2012)

(continued)

In this COSO report “risk” is used as a negative or positive uncertain outcome which is different from the traditional food safety concept of an “unacceptable risk” or a “hazard that requires a preventive control.” This ALOP threshold could be referred to as an “optimal” level of risk. Several important points are:

- Not all vulnerabilities are risks
 - Not all risks are hazards
 - Not all hazards are the FSMA type “hazards that require a preventive control.”

A risk is not always bad, or a negative result but uncontrolled risk-taking is unacceptable.

This excerpt provided insight on an introduction to risk assessments within the ERM/COSO principles.

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

**QUARTERLY REPORT UNDER SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934**

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934

For the quarterly period ended July 1, 2017

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934

For the transition period from _____ to _____
Commission file number 1-4171

KELLOGG COMPANY

State of Incorporation—Delaware

IRS Employer Identification No.38-0710690

One Kellogg Square, P.O. Box 3599, Battle Creek, MI 49016-3599

Registrant's telephone number: 269-981-2000

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the
Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required

Fig. 6.7 Example of a quarterly submission 10-Q form (Kellogg Company 2017)

Sidebar: The Sarbanes-Oxley Personal Statements by the CEO and CFO

The legal, regulatory document required by the US Securities and Exchange Commission referred to as an annual submission is referred to as a “10-K form” and a quarterly submission which is a “10-Q form” (see Fig. 6.7) (MSU-FFI 2017) citing (Kellogg Company 2017). The submission includes personal signed statements by the CEO and CFO for both the 10-Q form and Sarbanes-Oxley compliance (see Figs. 6.7 and 6.8). They are legal and formal statements publically available that are the base for the required corporate “annual report to shareholders.”

The Sarbanes-Oxley requirements are very explicit and, as the signed 10-K forms demonstrate, *very* personal. Your CEO and CFO are held accountable, and they, then, hold the businesses accountable. You might argue “that’s not my job” or “I thought someone else was doing that,” ... however, that’s not very convincing. If you are responsible for Food Fraud Prevention compliance, you are responsible for making sure your company addresses *all* types of fraud and for all products.

Exhibit

Page 1 of 1

EX-32.1 4 k-2017q2ex321.htm EXHIBIT 32.1

Exhibit 32.1

SECTION 1350 CERTIFICATION

I, John A. Bryant, hereby certify, on the date hereof, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that

- (1) the Quarterly Report on Form 10-Q of Kellogg Company for the quarter ended July 1, 2017 (the “Report”) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Kellogg Company.

/s/ John A. Bryant

Name: John A. Bryant

Title: Chairman and Chief Executive Officer

A signed copy of this original statement required by Section 906 has been provided to Kellogg Company and will be retained by Kellogg Company and furnished to the Securities and Exchange Commission or its staff on request.

Date: August 4, 2017

Fig. 6.8 Signed Sarbanes-Oxley compliance from the CEO (Kellogg Company 2017)

Assessments of ERM/COSO Initial Screening and Detailed Assessment

As mentioned, ERM is a thorough, precise, and formal method. The COSO principles are clearly defined and presented in many formal publications. These publications define a “two-stage process continuum from a quick, qualitative ‘initial screening’ which is ‘...followed by a more quantitative analysis of the most important risks’ (COSO 2012). The goal of the initial screen, or pre-filter, is to produce a quick and simple assessment before additional detailed requirements are defined by the resource-allocation decision-maker. In many cases the initial screening may be enough for a decision – for the specific decision at hand, the resource-allocation decision-maker (e.g., CFO, CRO, CEO, etc. or their proxy) defined the required level of accuracy, precision, and certainty.”

The continuum could be from one vulnerability assessment for the entire enterprise all the way to the other extreme of one for each supplier/product/manufacturing location (Fig. 6.9).

For even a moderately sized company, they could have 300 suppliers with an average of 10 products per supplier and possibly an average of 3 manufacturing plants for each product. The most detailed implementation in this company would result in conducting an impractical 9000 vulnerability assessments.

It is most efficient to address all types of food fraud at the same time and in the same system. The enterprise must address all of these risks. “All types of food fraud can result in enterprise-wide risks so an enterprise risk management system must cover all types of vulnerabilities. The model developed in this paper addresses the unmet need for the first stage referred to here as the Food Fraud Initial Screening (FFIS)” (Spink et al. 2016).

While the desired outcome for risk mitigation planning are detailed vulnerability assessments, broader initial screening can make the process much more manageable. Often a detailed, by-individual-product assessment is not practical due to the nature of the risk, the time allotted, or the detail needed for resource-allocation decision-making. (Spink et al. 2016)

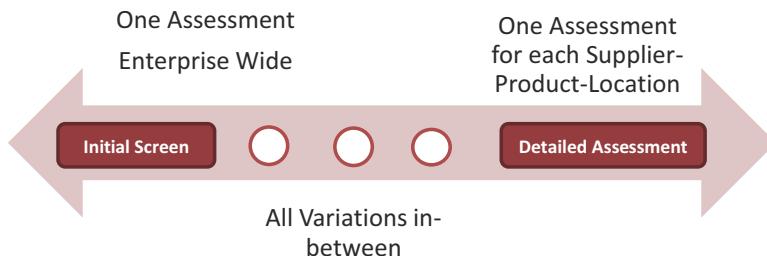


Fig. 6.9 Example of the continuum of the two-stage process for ERM risk assessment including from one initial screen for the entire enterprise through to one assessment for each supplier-product-manufacturing plant

Based on many factors—including the level of risk, cost of countermeasures and control systems, and certainty of the incident data, regulatory scrutiny, and vulnerability of the end consumer—different levels of assessments may be appropriate for different products. For example, “salt” may be able to be addressed with one overall initial screen for the entire corporation whereas due to many concerns “iodized salt for infant formula” may require a more detailed vulnerability assessment by source country, supplier, manufacturing plant, and transportation mode.

Overview of Business Economic Crimes Including Fraud

It is logical that food fraud, product fraud, and product counterfeiting have *not* been a primary focus of business economic crime or fraud investigations. The nature of the food fraud risk and root cause are so different from that of the other types of business fraud problems and that the current investigation or auditing fundamentals do not apply. A review of the types of business fraud often includes the likes of (PWC 2007, 2016):

1. ***Asset misappropriation*** including embezzlement and deception by employees
2. ***Accounting fraud*** either to benefit the enterprise or a specific business function
3. ***Corruption and bribery*** including racketeering and extortion
4. ***Money laundering*** of a wide range of revenues
5. ***IP infringement*** (a general category for Intellectual Property related issues) including trademarks, patents, counterfeit products and services, industrial espionage, etc.”

The first four would be investigated using forensic accounting and forensic audits. The investigation processes for these four are traditional accounting audits, whereas the fifth requires completely different activities, expertise, and skills. The fifth is a catch-all category for all intellectual property infringement beyond trademark and patent where the investigation would include market monitoring, field investigations, or other analysis.

The first four types of business fraud generally occur within the company or at least at their facilities. The audits would occur *inside* those proprietary known locations or on those known computer systems. The fifth category of incidents probably occurs *outside* the company facilities and proprietary computer systems.

Also, the first four occur on a relatively frequent basis, and the methods of responses are very similar. Known assessment methods or standard operating procedures could be used to investigate the incidents. For the fifth, there sometimes appears to be as many types of fraud incidents as there are fraudsters.

Finally, for the first four, there is a lot of research, data, and analysis of the quantitative, analytical assessment of how much occurs. There are specific methods to analyze the extent of the economic impact. For the fifth, the losses are often unknown and possibly unknowable. There is even debate on the confidence in estimates of the economic impact of counterfeiting and piracy, see OECD (2007). Also, there is

uncertainty as to how much an IP infringement actually costs the company. There is reduced legal liability if someone is injured—as long as the offending product can be confirmed a counterfeit. Also, even lost sales are hard to quantify since abnormally low prices attract some buyers (e.g., a bulk product “near expiration” and “selling at a deep discount”) or some consumers actually seek counterfeit products (e.g., fake luxury goods).

How (Un-)Ethical Are You?

What a question. This was the title of a 2003 Harvard Business Review article by Max Bazerman. The article essentially reviews and defines how we are not aware of our own sources of bias. This is an essential concept for Food Fraud Vulnerability Assessments. Our own “sources of bias” severely endanger our objectivity when conducting risk assessments.

Key biases that cloud our judgment include:

- **“The illusion of objectivity”:** we believe that what we know is right and objective. If you’ve been in “food safety” for a “long time,” then you think you’ve seen everything. Regarding food fraud, an example is an analytical chemist trying to conduct an authenticity test on stolen goods. Stolen goods are illegal, unfit for commerce, subject to a recall, could be mishandled, and become a health hazard, and they are a major concern for a company. That said, an authenticity test would only confirm the product is authentic but nothing about being stolen.
- **“Lack of awareness”:** Combining the previous concepts, we frequently find a lack of awareness of the business process from other operations or divisions. We frequently heard “we don’t do ERM” only to hear later—sometimes years—“oh, we have an ERM manager.”
- **“Narrow focus”:** “It’s not my problem.” Business is busy enough that we don’t need to go looking for work... or, we don’t *want to* go looking for more work. When new concepts are presented, there is often a belief that “someone else must be addressing this.” Or “if we don’t have a process, then it must not be important.”

Early in the development of Food Fraud Prevention as a separate research concept, there were repeated statements that the FDA 2009 definition of “economically motivated adulteration” already covered everything. Also, there was a belief that the Food, Drug, and Cosmetics Act already covered everything in the “Adulterated Foods” and the “Misbranded Foods” sections. There is a difference between all types of food fraud being illegal and the regulations promoting a preventive approach. There is a difference between addressing the food safety health hazards that result versus addressing all food fraud vulnerabilities.

When applying the FDA EMA working definition in relation to the FDCA definition of what was actually illegal, there were three revelations occurred:

- (1) Economically motivated “adulteration” (a “substance” only) was different from “adulterated” as defined in the FDCA Adulterated Foods section (any problem including spoilage of genuine product or stolen goods).

- (2) The food adulteration laws administered by FDA prioritized on health hazards and did not consider unique root causes that could be addressed with a preventive control.
- (3) The laws and regulations were focused on compliance and not prevention (of course, increased compliance or enforcement penalties had a secondary motivation to persuade companies to prevent).

Building on the Bazerman concepts are “confirmatory bias” and “trust-bias.”

- **“Confirmatory bias”**—We seek confirmation for our beliefs... then we often conduct no more additional research. Once we find one article or report that supports our view, then we feel we’ve “researched” it.

The application to food fraud is that when other researchers or risk assessors heard those statements that “everything is already covered,” they stopped looking and thinking... done and now move on to the next thing.

- **“Truth bias” or “Truthiness”**—We trust the people we know (Levine et al. 1999; Alba and Hutchinson 2000; Lapinski and Levine 2000; Park et al. 2002; Skurnik et al. 2005; Levine 2014; Levine et al. 2014; Van Swol et al. 2015). Or, to consider it from another perspective, when we’ve had a long history of experience with someone, then we feel we have no reason to mistrust the people we know. We trust people whom we know, are familiar with, and have interacted with for a long time. We can’t imagine we would cheat people we know, so we project that value system on other people who are around us. There is a comfort in the known. We aren’t aware of a problem so everything must be ok. Right? Also, there is a danger or risk of finding out that our present decisions have been sloppy, dangerous, or incompetent. We don’t seek problems especially when they could hurt us.

Thus, understanding how and why there is bias, we can present new risks such as food fraud into a frame that can be understood and directly addressed. It is important to understand not only how other people behave and abuse trust but also in how we are biased in our own assessments. This is extremely complex. To reduce the complexity, it is efficient to “take morals and ethics out of the equation” and only focus on the “fraud opportunity.” Regardless of the environment or the adversaries, “if there’s a fraud opportunity then there’s a fraud opportunity.” Considering this human nature and our biases can help shift focus to very effective and efficient risk treatments that are in control of the guardians (for more on guardians and guardianship, see the chapter on Criminology).

Key Learning Objective 3: Iterative Process or Mitigating Food Fraud Risk Using ERM

This section reviews the interdisciplinary nature of prevention by considering how the fraud opportunity is created and the many academic disciplines that help understand the selection of optimal countermeasures and control systems.

The Key Learning Objectives of this section are:

- (1) Detail of ERM by a further review of the COSO Cube
- (2) Integrating ERM concepts into quality assurance and food safety standard operating procedures
- (3) Examples of applying ERM to Food Fraud Prevention resource-allocation decisions

COSO Cube in Detail

COSO has presented the ERM concepts in what is referred to as the “COSO Cube” (above, see Fig. 6.3). This is a way to explain how all the control activities interrelate. This is also a visual representation of the process to explain how food fraud assessments and reporting is connected with the enterprise. This is a clear way to explain how the overall processes fit together.

For Food Fraud Prevention, the COSO Cube provides a visual identification of where and how the Food Fraud Vulnerability Assessment fits into the overall, enterprise-wide assessment. The “risk assessment” entry point is a place for the new assessment to be correlated and calibrated with other enterprise-wide risks. The ERM system can provide a structure and process for assessing the new risk in a way that it can be seamlessly integrated into the overall enterprise-wide decision-making system.

The original COSO Cube was 3×5 (and later expanded to 4×8) and included three sides: front, top, and side (COSO 2013):

- **Front:** The front consists of the control environment, risk assessment, control activities, information and communication, and monitoring activities. These are five separate processes that create an interconnected hierarchy. For Food Fraud Prevention, the entry point is at the risk assessment.
- **Top:** The top consists of operations, reporting, and compliance. These are three separate activities. For Food Fraud Prevention, this would remain in the risk assessment/reporting cell.
- **Side:** The side expands across the enterprise from an entity (corporation), division, operating unit, and function. For Food Fraud Prevention, until the overall Food Fraud Prevention Strategy is developed and implemented, the focus is on the strategic and entity-level. In many cases and unless there are some local anomalies, an entity-level Food Fraud Vulnerability Assessment (FFVA) is acceptable for each level of the entity.

When considering the overall concept of the COSO Cube, next there is a consideration of the relationship between *objectives* and *components*.

A direct relationship exists between *objectives*, *components*, and the organizational *structure* of the entity. Although they are not actually noted on the cube, these are fundamental concepts that explain the working of the cube.

- **Objectives:** The three categories of objectives—operations, reporting, and compliance—are represented by the columns. These are what an entity strives to achieve.
- **Components:** The rows represent the eight components: Control environment, risk assessment, control activities, information and communication, and monitoring activities. These represent what is required to achieve the objectives.
- **Structure:** The third dimension represents an entity's organizational structure: Entity level, division, operation, and function.

Sidebar: Integrated Framework Between the Organizational Structure

The “internal controls” are the process to review, manage, and communicate risks. The “integrated framework” is the process for each level of the organization to calibrate and coordinate the internal controls (Fig. 6.10).

How this report can be used depends on the roles of the interested parties (COSO 2013) (emphasis added for “accountable” and “responsible” persons):

- **The Board of Directors**—“The board should discuss with senior management the state of the entity’s system of internal control and provide oversight as needed. Senior management is accountable for internal control and to the board of directors, and the board needs to establish policies and expectations of how members should provide oversight of the entity’s

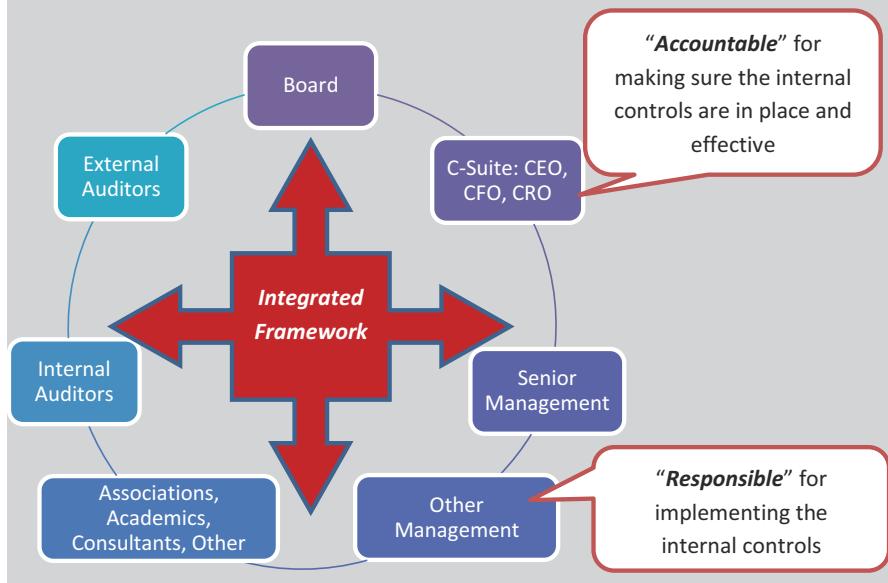


Fig. 6.10 Relationship between the internal controls (within business functions) and integrated framework (between functions)

(continued)

internal control.” Also, “The board should challenge management and ask the tough questions, as necessary, and seek input and support from internal auditors, external auditors, and others.”

- **Senior Management** (including C-suite of CEO, CFO, CRO, or their representatives or proxies): “Senior management should assess the entity’s system of Internal Controls in relation to the Integrated Framework, focusing on how the organisation applies the seventeen [ERM] principles in support of the components of internal control.”
- **Other Management and Personnel:** “Managers and other personnel... should consider how they are conducting their responsibilities in light of the Integrated Framework and discuss with [other] senior personnel ideas for strengthening Internal Controls. More specifically they should consider how existing controls affect the relevant principles within the components of Internal controls [presented in the COSO Cube]” (COSO 2013).
- **Internal Auditors [1st- or 2nd-party auditors]:** “Internal auditors should review their internal audit plans and how they applied the 1992 edition of the framework. Internal auditors also should review in detail the changes made to this version and consider possible implications of those changes on audit plans, evaluations, and any reporting on the entity’s system of internal control” (COSO 2013).
- **Independent Auditors [2nd- or 3rd-party auditors]:** “In some jurisdictions [such as for GFSI related certification], an independent auditor is engaged to audit or examine the effectiveness of the client’s Internal Controls over financial reporting in addition to auditing the entity’s financial statements. Auditors can assess the entity’s system of Internal Controls in relation to the Integrated Framework, focusing on how the organization has selected, developed, and deployed controls that affect the principles within the components of Internal Controls. Auditors, similar to management, may use the Illustrative Tools as part of this evaluation of the overall effectiveness of the entity’s system of internal control” (COSO 2013).
- **Other Professional Organizations and Educators/Academia:**
 - **Other Professional Organizations:** “Other professional organizations providing guidance on operations, reporting, and compliance may consider their standards and guidance in comparison to the Integrated Framework” (COSO 2013).
 - **Educators/Academia:** “With the presumption that the Integrated Framework attains broad acceptance, its concepts and terms should find their way into university curricula” (COSO 2013).

Each of the interested parties has a role in the further development of internal controls as well as the strengthening of the integrated framework. Each interested party has a role in holding the other parties accountable for their responsibilities.

Integration with Standard Operating Procedures and Terminology

When presenting a new concept or theory, it is most efficient to anchor or root the resource-allocation decision-maker to some known and accepted concept. For example, if Food Fraud Prevention is presented as:

- “HACCP but for Food Fraud Prevention called vulnerability and VACCP.”
- “This is just ERM but applied to Food Fraud Prevention.”
- “It’s basically total quality management or Six Sigma applied to Food Fraud Prevention.”
- “We identify CCPs (critical control points), but instead of measuring oven temperatures for HACCP, we’re verifying correct shipping documents for VACCP.”

Explain Food Fraud Prevention by comparing it with a procedure or example they already know, understand, and trust. Using these types of explanations, someone not familiar with food fraud can have a clear vision and mental anchor of understanding from a comparison to a familiar and successful standard operating procedure. There is a reduced concern because new systems are not being developed. There is a reduced concern about an organization’s adoption of new or different required procedures. At this point, the Food Fraud Prevention concepts have been presented in terms of common, implemented, widely accepted, and successful programs. Food Fraud Prevention research leveraged these concepts when forming the methods and processes.

It is just as important for a government agency to define their prevention actions in business terms since the concepts have been well researched, but also decision-makers or industry will be familiar with the methods. To note, many of the evaluators or critics of a government may be from the business world, so using business terms and methods is an efficient way to explain the functionality of the programs. A total quality management system or internal control framework is applicable to a government. The government agency does have a challenge that many of the final metrics are the social good (of course they must remain within budget, but success is ultimately a social measure such as “public health”) versus clearly financial (e.g., return on capital employed, dividend amount, share price, or net profit).

A first important standard operating procedure is a quality management system. Initially, this was developed by Deming, Crosby, Juran, and others through total quality management, to now a Six Sigma-type program. This creates a framework—while keeping an eye on final performance—to shift focus to processes and systems that are the root cause of anomalies that could lead to a nonconformance. A version of quality management tailored for the food industry is the hazard analysis and critical control point plan (HACCP). The application is focused on identifying a critical control point (CCP)—e.g., a refrigerator staying at an appropriate and constant temperature—rather than just “is there a dangerous pathogen in the finished product.” Expanding to focus on the controls, business adapted to create what ERM/COSO

defines as an “Internal Controls-Integrated Framework.” The application is checking—and cross-checking—that the right controls are in place and they are properly implemented.

The goal is to present Food Fraud Prevention in a way that the thought is “oh, this isn’t really anything new. This is just expanding our current program to address this new topic.”

Decision-Making Examples to Find the Ideal Scenario

There is a continuum of the types of risk assessments from *operational risk* (e.g., tactical, quantitative, and expressed in “return on investment”) and *enterprise-wide risk* (e.g., strategic, qualitative, and expressed as “vulnerability” and success is measured by reducing below the “risk tolerance”) (Fig. 6.11). The *operational risks* that are tactical usually impact a specific group, product, or manufacturing plant and could impact the operation, though probably not put the entire enterprise at risk—there is usually a finite sample size that could often be 100% inspected (see other content on strategic and tactical actions), for example, metal shavings found in a packaged food product at the end of a manufacturing package fill line. If needed, the entire production lot could be set aside and tested with metal detectors. 100% inspection could be conducted. The *enterprise-wide risks* are strategic in the sense that they could

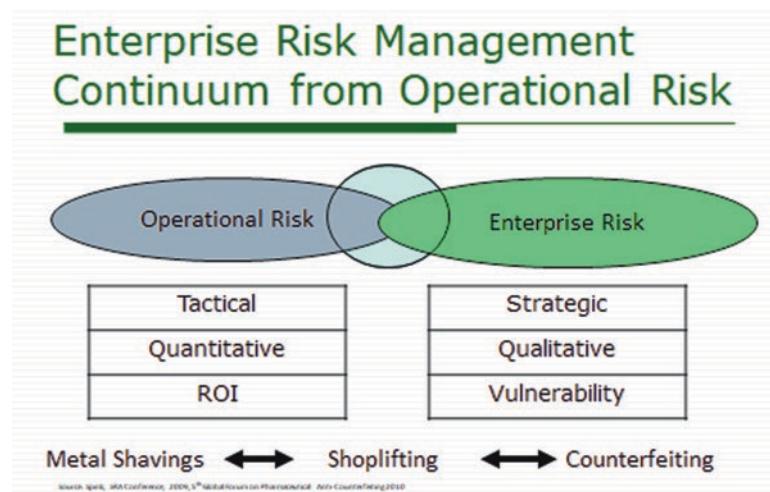


Fig. 6.11 Enterprise Risk Management Continuum from operational risk. (Copyright Permission Granted) (Spink 2009)

impact the entire enterprise and could be catastrophic could impact the entire company's brand, across the entire market, and could occur anywhere in the world, for example, the overall product counterfeiting threat. Assessing the risk or prevalence is extremely difficult because the sample population would be anywhere the product is sold anywhere in the world, including on the Internet and in illicit markets.

There is a continuum from the very specific and local event such as the metal shavings to the global event completely outside the legitimate supply chain. An example is assessing shoplifting losses in a retail store. Assessing the risk could include a physical inventory of the store, but it would not consider employee theft, incorrectly rung-up goods at the cash register, a damaged product that was destroyed but not recorded, or a product that was actually never received. This will be explained in more detail next in the example provided.

Example of Resource-Allocation Decision-Making with How to Measure Success

To provide an example of the different types of risks, several scenarios are presented. These examples span the continuum of operational/tactical to enterprise risk/strategic.

Metal Shavings

1. Incident: An incident is known with 100% certainty. If an incident occurs, then there is evidence there have been actual metal shavings in the finished products.
2. Scale: The inventory can be checked to approach 100% certainty. Each package could be tested.
3. Cost of nonconformance: This can be defined with certainty due to the cost of a recall, product disposal, and related costs, e.g., \$4 million.
4. Cost of risk treatment: This is a “known” based on what countermeasure is selected, e.g., \$1 million to purchase metal detectors.
5. How to measure success: Use the metal detectors. Create a process to calibrate, and make sure the metal detectors are used, e.g., high confidence if purchases quality equipment.
6. Confidence in the risk treatment: Create a process to calibrate, and make sure the metal detectors are used, e.g., high confidence if the operations are in control.
7. Financial assessment: In this case, an actual “return on investment” can be used. The very high-confidence savings (actually reducing in the loss of earnings—operations cannot be profit centers) of \$1.5 million investment compared to the cost of \$1 million will give an instant and—for a return of 1.5:1—a low rate of return but near 100% confidence in the return.
8. *Conclusion: Unless there are other pressing issues or business opportunities, this payback within 1 year would lead to a “yes” resource-allocation decision. This is a payback project within the year.*

Retail Shoplifting

1. Incident: There are probably reported and recorded incidents. The loss of inventory has many other root causes why a product may not be physically in the store. Other assessments or countermeasures and control systems may be needed for other issues such as employee theft. One assessment or countermeasure will not address the entire issue.
2. Scale: The inventory can be checked to approach 100% certainty but, again, not complete.
3. Cost of nonconformance: For the loss of inventory—though not only shoplifting—this can be defined with certainty due to the financial and inventory systems. Industry-wide, shoplifting—or “leakage”—is estimated to equate to 3% of corporate revenue, and so even industry-leading levels of shoplifting may be an additional 2% for a total of 5% of sales. For the last Fortune 500 company, with \$500 million in revenue, this could be \$10 million. Even if there are credits from the supplier or other offsets such as some type of insurance, every product that is stolen is lost revenue. That \$10 million loss would be much higher than the metal shavings loss.
4. Cost of risk treatment: This is a “known” based on what countermeasure is selected. A \$500 million retailer might have ten locations that each would be addressed, for example, \$3 million for additional electronic article surveillance system upgrade.
5. How to measure success: Monitor the shoplifting alert, or capture and continue to count the inventory. Both of these will be very certain.
6. Confidence in the risk treatment: For shoplifting, the measures will provide high certainty but not for all inventory losses (unless the losses are almost or completely eliminated). For example, there is high confidence that the loss is from shoplifting, but only time will tell if that is the actual root cause of the problem.
7. Financial assessment: This will only become high confidence *after* implementing the system and measuring over time. So for resource-allocation decision-making, this financial benefit is uncertain.
8. Conclusion: *There could be a 50% confidence in the risk treatment reducing the \$10 million loss by implementing the \$4 million system for a return of 10:4 with a 50% confidence.*

Product Counterfeiting

1. Incident: An incident is known with a near 100% certainty—if you find a counterfeit product, then you know it is occurring. The data collection could either be reactionary (what people send you) or proactive (which could expand to seeking counterfeit product even in markets where there have been no past known incidents).
2. Scale: The scale is unknown and probably unknowable (Spink and Fejes 2012). If the OECD economic impact of counterfeiting estimate is used, then 5–7% of global sales could be lost to counterfeiting. For the last Fortune 500 company, with revenue of \$500 million, that could be \$25–35 million. Different industries

differ, so the estimate could be higher or lower. There is also a variable of whether there are deceptive or non-deceptive counterfeits. A deceptive counterfeit would be a 100% loss of a genuine product sale *if* there would not be *any* other replacement product (e.g., not finding a \$50 pair of pants that usually retail for \$200 may not lead to the consumer purchase the \$200 genuine product; the consumer may opt for a \$60 pair of discount pants—for more see (USITC 1988)). The economic impact of counterfeiting could really be defined as a broad range of possible financial impacts with a very low certainty of the actual dollar cost. It is known that it is occurring and that the corporation is incurring some costs. The most certain costs are the cost of lawsuits or anti-counterfeit countermeasures and investigations.

3. Cost of nonconformance: One counterfeit incident can lead to a worldwide recall and massive loss of brand equity. The estimate of “5–7%” loss could be for just *one* incident if that incident was significant. Thus the loss could probably be from \$10 to \$250 million per year, but let’s use a very conservative \$50 million here.
4. Cost of risk treatment: This is a “known” based on what countermeasure is selected—actually probably multiple countermeasures and control systems. For example, let’s use a high \$20 million for various countermeasures and control systems.
5. How to measure success: This is more complex since a primary source of estimating the impact is by conducting in-market inspections... all around the world, including in illicit markets. Conducting market monitoring in dangerous countries or marketplaces increases the liability risk and danger to the investigators. Basic food safety inspectors are not trained—or have the liability insurance—to engage criminals in situations where there could be physical violence. To start, increased surveillance would add to the cost. The countermeasures and control systems need to be continually updated to stay ahead of the evolving counterfeiters, so there are additional management costs.
6. Confidence in the risk treatment: The counterfeiters continue to evolve—e.g., possibly shift their focus from counterfeiting to stolen goods—so the overall enterprise risk reduction is difficult if not impossible to assess. Market investigations can determine whether *some* counterfeiters have been deterred, e.g., there is a low confidence—high uncertainty, many unknowns, and difficulty in data collection—in the countermeasures and control systems.
7. Financial assessment: In this case, if an actual “return on investment” can be developed, the uncertainty would be so high that the resource-allocation decision-maker would run out of money by funding other projects before selecting this low certainty, high-cost project.
8. Conclusion: *There would be a very low confidence (30%?) in reducing the counterfeit product in half from \$100 to \$50 million in losses with a cost of \$20 million for a return of 50:20 with a maximum of a 30% certainty.*

When reviewing the details presented here, the CFO would instantly approve the metal shavings project, approve getting more detailed proposals for the shoplifting

countermeasures and control systems, and then possibly work with their General Counsel to determine “how little they can do” to address the counterfeit product. In all seriousness, the General Counsel and CFO then would assess the corporate risk appetite. These could use ERM/COSO type processes to define and defend “how much is enough.”

Conclusion

When there is a new or novel incident, the response and responsibility are naturally assigned to an “intervention” stage activity (referring to the prevention-intervention-response plan). For example, when a contaminant in a health hazard was found in pet food, the intervention was to detect the contaminant that was causing harm. The next effort would be to implement actions to remove the contaminated product from the marketplace. A final activity may be to implement incoming goods’ contaminant testing to try to prevent the additional fraudulent product from reentering the operations. This is a traditional food safety intervention, and often the proactive next step—of reducing the fraud opportunity—is not taken. The need to implement the last prevention step is often not done; for one, there is usually a regulatory definition of the “appropriate level of protection” or the scientifically measurable point of what is unacceptable. Waiting to respond *after* an incident is not proactive. Unlike for food safety and an adversary such as *E. coli*, for Food Fraud Prevention, the adversary is a human. This human behavior is studied within the field of social science and criminology. While studying the motivation of the adversary is the root cause, it does not include setting the limit. And in the absence of a regulatory or standards set unacceptable level, this is not a determination of the risk tolerance. *The first conclusion is* that business decision-making is a separate activity and discipline where systems are already usually in place including Enterprise Risk Management COSO. There are millions of theories or basic methods in the world, so the challenge is identifying what is applicable and adapting the response to a unique problem. Specific incidents are reviewed to refine and reassess the application continually. *The second conclusion is* that ERM-type systems can be adapted to create an efficient and straightforward application to Food Fraud Prevention. Once a general system is established, then there is a need for a standard operating procedure that both creates efficiency in the process and also continually monitor and evaluate the efficiency of the system. *The final conclusion is* that there is a need here based on ERM/COSO, for common internal controls paired with an evaluation system such as an integrated framework. There is a saying:

Connect everything to everything – evaluate this new risk or vulnerability in relation to all other enterprise-wide problems in relation to the overall risk tolerance.

“We need to do ‘more’” or “you should do ‘more’” is not a business case. “This is really bad” is also not an assessment that can be compared. At worst you are not being proactive or providing the resource-allocation decision-makers with the information they need.

Appendix: WIIFM Chapter on Business and ERM

This “What’s In It For Me” (WIIFM) section explains why this chapter is important to you.

Business functional group	Application of this chapter
WIIFM all	ERM/COSO is very logical and provides a common language for enterprise-wide, top-to-bottom risk communication, and decision-making
Quality team	This chapter presents the widely adopted and very thorough COSO-based, ERM-type process that will be a foundation for “how much is enough?”
Auditors	The overall concepts provided ERM awareness and how it is implemented within the auditee organization
Management	This ERM overview will help with communication upwards into the organization and to the C-suite—you may want to apply it to all your business risk and decisions
Corp. decision-makers	Expect the front line and managers to be able to speak the language of risk and ERM/COSOs

Appendix: Study Questions

This section includes study questions based on the Key Learning Objectives in this chapter:

1. Discussion Question

- (a) Who defines the “risk tolerance” in a properly or improperly managed system?
- (b) What is the regulatory foundation for business decision-making and determining an acceptable risk tolerance?
- (c) How does a food fraud versus a food safety incident impact the risk tolerance and ERM-based decision-making?

2. Key Learning Objective 1

- (a) What is “Sarbanes-Oxley”?
- (b) Who is required by law to comply with Sarbanes-Oxley?
- (c) When Sarbanes-Oxley may not be a legal requirement, what systems are in place to manage risk and risk tolerance for a company?

3. Key Learning Objective 2

- (a) What is a “corporate risk map” or “risk heat map”?
- (b) How does a CFO decide if a risk or vulnerability is so bad it must be reduced (or disclosed to investors)?
- (c) What is the most challenging aspect of applying ERM to FF?

4. Key Learning Objective 3

- (a) What is a “2nd”- and “3rd”-party auditor?
- (b) What is the COSO Cube?
- (c) Where does a food fraud incident enter the COSO Cube, and who does the review advance?

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Chapter 7

Criminology Theory (Part 1 of 2): Foundational Concepts



Summary

This chapter presents the criminology concepts that apply to not only catching bad guys but for preventing food fraud from occurring in the first place. Criminology addresses the root cause which is a human adversary who identifies a crime opportunity and is motivated to act. A key point for food fraud prevention is on guardianship which includes the monitoring the physical space of crime and putting hurdles in place that makes the act riskier or less profitable. Specifically, these crime prevention theories are based on Situational Crime Prevention, routine activities theory, and rational choice theory. The expansion to apply the social sciences and criminology theories is critical since the root cause is a human adversary.

The Key Learning Objectives for this chapter are:

- **(1) Introduction to Crime prevention theory overview:** Introduce the basic tenets of criminology and crime prevention.
- **(2) Examine the Crime Triangle and Situational Crime Prevention:** Several theories or applications are especially helpful when addressing food fraud prevention.
- **(3) Adapting the Criminology theory to Food Fraud prevention:** Finally, the theories are present in an application to food fraud prevention.

On the Food Fraud Prevention Cycle (FFPC), this chapter addresses the theoretical foundation concepts related to criminology and the fraudster “(A) Theoretical Foundation” (Fig. 7.1).

Introduction

The central and most important point is to understand the fraud opportunity before any countermeasure or control systems are evaluated. For food fraud prevention, the root cause is criminology theory and focused on the “fraud opportunity.” Without a

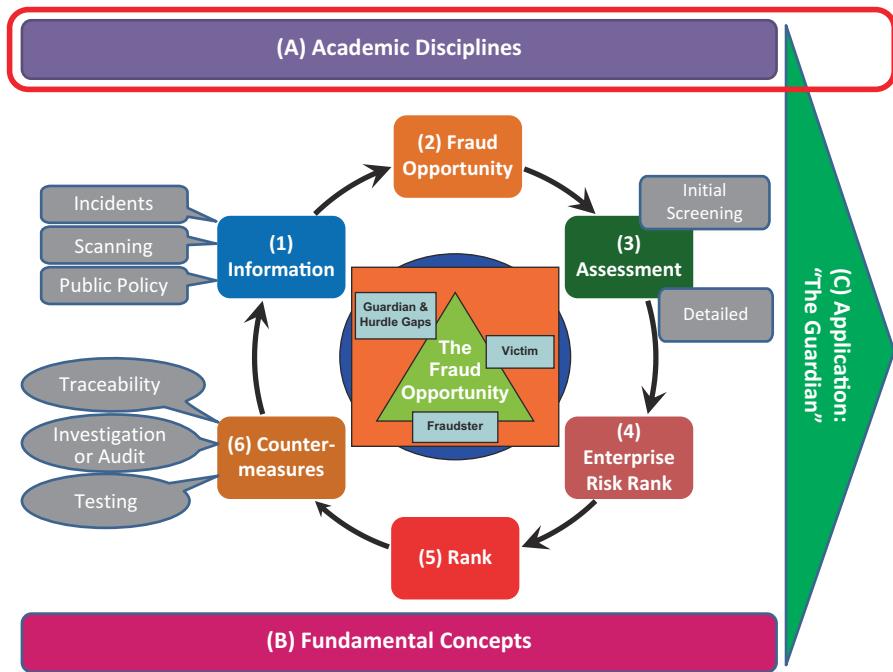


Fig. 7.1 Food Fraud Prevention Cycle—where this chapter applies to the overall concept: “(A) Academic Disciplines.” (Copyright Permission Granted) (Spink 2014; Spink et al. 2019)

clear understanding of the reason why a specific, individual, human adversary attacks the selection of a countermeasure or control system is a guess—an educated guess at best but still a guess. Fortunately the field of criminology—and specifically the crime prevention concepts including Situational Crime Prevention—provides a well-researched and developed theoretical foundation.

The general topic of “human situations and opportunities” was reported to be built upon a project led by Marcus Felson and Ron Clarke in 1973 during research on why some students ran away from reform schools and others did not. Later in 1976, “Crime as Opportunity” was published which expanded on the concepts. The core principles of Clarke, Felson, Eck, and others were based on the practical and pragmatic ideas (Clarke and Eck 2005):

- “Don’t get fancy.”
- “Don’t worry about academic theories. Just go out and gather facts about crime from nature itself (observation).”
- “Focus on very specific slices of crime, such as vandalism against telephones or soccer violence [or food fraud species swapping during transfer of ownership from supplier to the customer]. Even the crime ‘vandalism’ would be far too broad!”
- “Try to block [prevent] crime in as practical, natural, and simple way, at a low societal and economic cost.”

These concepts are the foundation for the study of “environmental criminology”—the physical space where a crime occurs not the environmental sustainability of the earth—started in the 1970s in part based on a foundation research paper “Social Change and Crime Rate Trends: A Routine Activity Approach” by Cohen and Felson (1979). The supporting literature and theories have been well researched with thousands of research projects. An August 2017 Google Scholar search resulted in over 10,000 documents with the phrase “Situational Crime Prevention.” The “environmental criminology” study of prevention and the space of crime concepts are a deviation from the “traditional criminology” which focuses on the criminal, courts, and the corrections system (Beirne and Messerschmidt 2005).

Situational Crime Prevention departs radically from most criminology in its orientation. Proceeding from an analysis of the circumstances giving rise to specific kinds of crime, it introduces discrete managerial and environmental [the physical space of crime] change to reduce the opportunities for those crimes to occur” (Clarke 1997a, b). The base theories and reports are often presented in very practical ways that can be easily and quickly implemented by practitioners. The underlying research is very scholarly, but the application is often referred to as practical or “down-to-earth. (Felson and Boba 2017)

Thus, [Situational Crime Prevention] is focused on [physical] settings for crime, rather than those committing those criminal acts. IT seeks to forestall the occurrence of crime, rather than to detect and sanction offenders. This seeks to eliminate the criminal or delinquent tendencies through improvement of society or its institutions and not merely to make the criminal activity less attractive to offenders. (Clarke 1997a, b)

These concepts are aligned with the objectives and needs of total quality management. These criminology theories are proactive and focused on what the enterprise can do and control rather than wait for outside entities to organize and respond.

Situational Crime Prevention focuses on the crime, not the criminal, and more specifically on “why crime occurs” (Clarke 1997a, b). Focusing on “why the crime occurs” is helpful for addressing food fraud since the focus of vulnerability shifts from “the suspect living beyond their means” to “identify a ‘fraud opportunity’.” For assessing a food fraud problem, a practical question is how would a risk assessor—probably a manufacturing quality control employee in a corporate office in a Western country—evaluate if a Bangladeshi farmer is living beyond their means? Would the supplier who owns two cows be equivalent to a Westerner owning a Ferrari? Also, if the fraudster were an intelligent adversary, they would not drive their Ferrari/second cow to the business where it could be viewed. Even if this was known, how would the risk assessor conduct an investigation into the lifestyle of the farmer?

If the fraud act is species swapping, then the vulnerability is a lack of specific tests conducted by the receiving company for the correct hot product and at the precise crime hot spot. There could be many species tests conducted but at the wrong spot and for the wrong product. That manufacturing quality control employee could recommend, and almost immediately implement, incoming goods testing for the correct hot product and at the hot spot. Regardless of whether the supplier is a criminal or not, the fraud opportunity would already be vastly reduced to the point that there may not be an opportunity to commit the act—that is, as long as the fraudster and all other suppliers know that new species tests are being conducted.

A focus on supply-side Situational Crime Prevention is very practical, can be quickly approved and implemented, and is easy to explain not just the features (what it does) but the benefits (how it specifically helps reduce the problem). The idea is so simple that it seems even intellectually offensive that “Reducing opportunities for crime can indeed bring a substantial net reduction in crime” (Clarke 1997a, b).

Key Learning Objective 1: Crime Prevention Theory

This section presents Key Learning Objective 1 which is to review crime prevention theory and specifically Situational Crime Prevention. The practical and applicable concepts are a natural fit to help implement food fraud prevention. The Crime Triangle is the start and center point for the Food Fraud Prevention Cycle (FFPC).

The Key Learning Objectives of this section are:

- (1) Fundamentals of Criminology and Crime Prevention
- (2) Review of Criminology, Crime Science, and Criminal Justice
- (3) Introduction to A range of Criminology Theories

Fundamentals of Criminology and Crime Prevention

Situational Crime Prevention is a structured and systematic approach to crime fighting. In the 1998 second edition of *Crime in Everyday Life*, the author Dr. Markus Felson stated that “[between 1994 and 1998] Criminology also changed in noteworthy fashion and more quickly than I would have dreamed in writing the first edition. We know much more about situational crime prevention. Also, those of us who study how everyday life produces or prevents crime have gathered more facts and ideas. We also are better able to tie together loose ends and to know what to study next.”

The “Crime Triangle” was presented in Felson and Clarke’s chapter “The Chemistry for Crime” in *Crime in Everyday Life* (Felson 2002). This built upon earlier work on Routine Activities Theory (Cohen and Felson 1979). The foundational concept is that “[Criminals] typically behave like criminals only in certain settings, that is, slices of time and space within which relevant people and things are assembled” (Felson 2002). The original Crime Triangle included:

1. “Suitable target”
2. “Likely offender”
3. “Capable guardian” (applied to food fraud this was later adjusted from Absence of a Capable Guardian (Felson 2002))

Before reviewing the Situational Crime Prevention application of the Crime Triangle, it is important to note that the use of a triangle to present a criminal or fraud opportunity is widely adopted for many different research questions. For example, “The Fraud Triangle Revisited” by Schuchter and Levi is based on earlier work by Cressey which focused on financial crimes such as embezzlement (Cressey 1950; Schuchter and Levi 2016). This has been a starting point and base for training for forensic accounting and fraud examiners. The “Fraud Triangle” considers motivation, opportunity, and rationalization which are similar to the suitable target, the absence of a capable guardian, and likely offender (Schuchter and Levi 2016). This “Fraud Triangle” was expanded to add the capability to a “Fraud Quadrangle” or “Fraud Diamond.” Schuster and Levi make the statement that:

We do not contest that all fire triangle elements are required for first (at least in the absence of severe rain) are sufficient to ignite. At this point, we strongly suggest that a distinction is made. Their conclusion by analogy misses the following point: the Fraud Triangle with its components can create a condition for fraud. As Romney, et al. (1980) note, all elements, even opportunity, are substitutable. (Schuchter and Levi 2016)

With this perspective, the Crime Triangle and the Fraud Opportunity is considered as a model that helps frame thinking, but it is not a rigid formula. As the food industry—and food authenticity and food science researchers—begin to consider food fraud as a unique and separate concept, the generalized Crime Triangle is helpful to understand the underlying elements that comprise a fraud opportunity (Lam and Spink 2018; Spink 2019).

An important aspect of crime prevention and Situational Crime Prevention is to provide a simple and obvious idea and method for practitioners rather a complex model for theorists. The focus is very practical and on implementation that considers a lack of time and competing for human resources to apply to the project. Also, there is an awareness and acceptance of a hierarchy of assessments that start with straightforward applications and then can become more complex and thorough (certainty, robustness, etc.) as needed or as is possible. Felson stated: “If anything, I have tried to get even more down-to-earth about crime as a tangible phenomenon” (Felson and Boba 2017).

The thought leaders of crime prevention have openness and drive to adapt their theories to new crime problems. This was an ideal starting point for food fraud prevention.

The original Situational Crime Prevention and Crime Triangle concepts were from the original publication by Cohen and Felson (1979). “In [Social Change and Crime Rate Trends: A Routine Activity Approach] we present a ‘routine activity approach’ for analyzing crime rate trends and cycles. Rather than emphasizing the characteristics of offenders, with this approach, we concentrate upon the circumstances in which they carry out predatory criminal acts. Most criminal acts require convergence in space and time of likely offenders, suitable targets and the absence of capable guardians against crime” (Cohen and Felson 1979).

This research was combined and presented the original Crime Triangle (Fig. 7.2) (Felson 2002).

Fig. 7.2 Original Crime Triangle. (Adapted from Felson (1998) or Cohen and Felson (1979))



Fig. 7.3 Adaptation of the Original Crime Triangle Components. (Adapted from Felson (1998) or Cohen and Felson (1979))



This was adapted from Food Fraud Crime Triangle (Fig. 7.3) (Spink and Moyer 2011).

The two were combined here to provide one visual (Fig. 7.4).

The three legs of the triangle must be present for a crime to occur. The important insight or contribution—which is direct, simple, logical, and immediately actionable—is that removing one of the three legs of the triangle removes the fraud opportunity. Reducing the length of a leg of the triangle reduces the “fraud opportunity.” They stated, “We further argue that the lack of any one of these elements is sufficient to prevent the successful completion of a direct-contact predatory crime...” (Cohen and Felson 1979).

Later a more sophisticated Crime Triangle was presented by Clarke and Eck (2005) and Felson (2002) (Fig. 7.5) (Felson 2002; Clarke and Eck 2005). This was adapted to consider that some of the factors actually apply all around the triangle rather than on a specific side. The original Crime Triangle has been efficient for the food fraud prevention needs and users.

Considering the emphasis and willingness to apply and adapt the core concepts to new problems, this was applied to food fraud prevention. Many different theories were evaluated and included in food fraud prevention.

While there have been further advances in a more complex criminology Crime Triangle, the adaptation of the original Crime Triangle has been efficient.

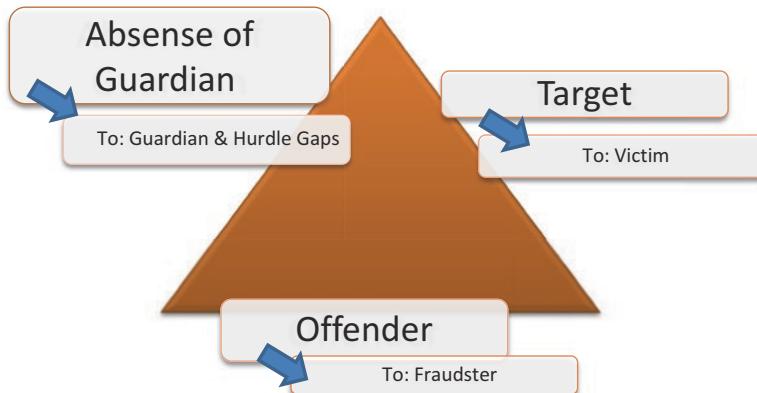


Fig. 7.4 Adaptation of the Crime Triangle to food fraud prevention. (Adapted from Cohen and Felson (1979) and Felson (2002) and published in Spink and Moyer (2011))

Fig. 7.5 Crime Triangle from Crime analysis for problem-solvers in 60 easy steps. (Copyright Permission Granted) (Clarke and Eck 2005)



Sidebar: Application—SSAFE Food Fraud Vulnerability Assessment Tool and Criminology

The Crime Triangle and the focus on the fraud vulnerability are crucial concepts in a Food Fraud Vulnerability Assessment (FFVA). One early presentation of this concept was by the GFSI Food Fraud Think Tank and published in the GFSI position paper on Food Fraud (Spink 2013; GFSI 2014). This was expanded upon by the SSAFE Organization-funded model developed with Wageningen University (Netherlands) which is as defined in van Ruth, Huisman, and Luning (2017). In “GFSI Position on Mitigating the Public Health Risk of Food Fraud,” the GFSI Board publically recognized and

(continued)

supported the SSAFE Food Fraud mitigation guidance that includes the FFVA (GFSI 2012). From the SSAFE report: “In accordance with the routine activity theory, food fraud vulnerability can be defined by the three elements: opportunities (suitable target), motivations (motivated offender) and control measures (guardianship) as presented in Fig. 1” (Fig. 7.6) (van Ruth et al. 2017). The three elements of the fraud opportunity are presented in a formula here and then later in a funnel and then spider diagram.

From the GFSI position paper on Food Fraud: “The GFSI Board will support SSAFE’s initiative which aims to develop and publish practical guidelines for companies on ‘how’ to assess and control food fraud vulnerabilities within their organizations and supply chains. SSAFE is worked to have these guidelines available before the release of Version 7 of the GFSI Guidance Document so that companies and Certification Program Organizations (CPOs, they create the actual standards, formerly referred to as scheme owners) can prepare their organizations before the new requirements are effective” (Fig. 7.7) (SSAFE 2015).

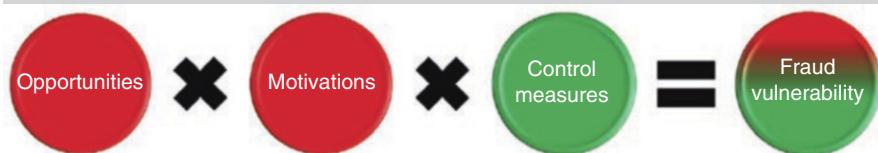


Fig. 7.6 Schematic presentation of the food fraud vulnerability concept based on the routine activity theory—SSAFE Main Body or Report noted in Figure 1. (Copyright Permission Granted) (SSAFE 2015)

Fig. 7.7 Fraud vulnerability: the three elements affecting criminal behavior—SSAFE Appendix. (Copyright Permission Granted) (SSAFE 2015)

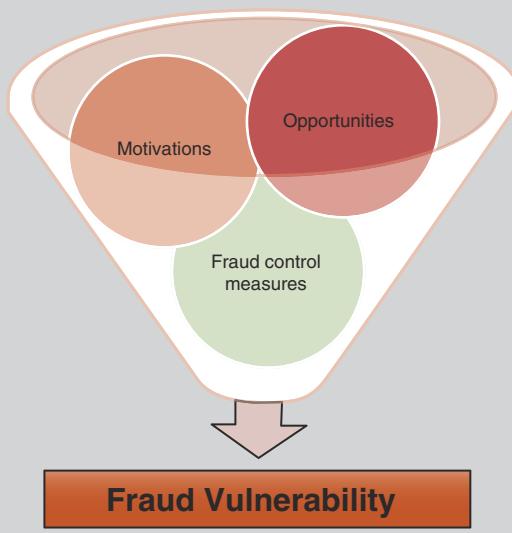




Fig. 7.8 The environment of the company and three elements of food fraud—SSAFE Appendix. (Copyright Permission Granted) (SSAFE 2015)

Then SSAFE presents the motivation, opportunities, and control measures on a spider diagram that is a variation of Crime Triangle factors (e.g., victim to opportunity, fraudster to motivations, and guardian and hurdle gaps to control measures) (Fig. 7.8). This figure presents the “company’s decreasing span of control” where there is more control within the company and then less and less control through the supply chain and into the open global market.

The core criminology theory that applies to food fraud prevention is Situational Crime Prevention. There is a simplicity, rationality, and pragmatism to focusing on the physical space of crime rather than concerns that include less direct control such as the mental state of potential fraudsters. Applying and adapting scholarly theories can be a delicate endeavor especially since there are many firmly held beliefs and sometimes a deep commitment to one theory or another.

Sidebar: The Incredible Value of the Peer Review Process—Peer Correction (MSU-FFI 2018):

Title: The Incredible Value of the Peer Review Process: Peer Correction
By John Spink • June 17, 2015 • Blog

To expand on the delicate nature of applying and adapting scholarly theories, a previous MSU FFI blog post presents some of the challenges and opportunities. This blog also provides insight into some of these activities.

From the blog post:

The peer review, scholarly journal process is long and tedious and absolutely critical to building a firm foundation for food fraud prevention. At least

(continued)

food fraud is now considered as a topic worthy for scholarly publication. There have now been more scholarly journal articles that include the words “food fraud” in the last 4 years than in the previous 100 years combined.

Sometimes – especially when dealing with interdisciplinary concepts – we focus so much on the process of writing that we do not step back to see how the foundational concepts have evolved. We recently had two key concepts clarified during the peer review process in our recently-submitted articles.

Article 1: Types of Counterfeiter – Remove “Ideological” Counterfeiter

A reviewer of our “Defining the Types of Counterfeiter, Counterfeiting, and Offender Organization” article questioned the inclusion of the “Ideological” type of counterfeiter in our list (published in Crime Science in 2014) (Spink et al. 2013). They argued that a terrorist would conduct a fraud act to make money. Making money is not an “ideological” act for the terrorist. The money they make could be used for a terrorist attack, which would be an “ideological” act. Considering the criminal motivation, the food fraud activity would probably fall under the “Opportunistic” type of counterfeiter.

The core research on defining the types of counterfeiting – or, more broadly, types of product fraud—for this article started during the several State of Michigan led food defense projects, so our initial focus was on terrorists. Through the evolution of the manuscript development, we shifted to economic crimes but did not entirely filter out the “Ideological” fraud motivation.

Removing the Ideological type was nuanced and not core to our hypothesis or discussion, but it was an excellent opportunity to get it right.

We are grateful to Editor Dr. Gloria Laycock (University College London) for organizing a reviewer team that is motivated and engaged enough to help us clarify this point.

Article 2: Situational Crime Prevention, Routine Activity Theory, or a Hybrid

We received comments from a reviewer for another article that was under review and is now published (Spink et al. 2014). The reviewer provided an incredibly thorough set of comments. The reviewer pointed out that we had not clearly explained our application of Situational Crime Prevention and Routine Activity Theory. These are two distinct theories but seem very similar to three core factors, often presented in a triangle, and often discussed together in the research.

- **Situational Crime Prevention:** This is a more overarching concept that includes “Environmental Criminology” (the space of crime not protecting nature), “Rational Choice Theory,” “Routine Activities Theory.” The theory is based on “victim,” “offender,” and “place” to create a “problem.”
- **Routine Activities Theory:** This is a more applied theory that focuses on everyday events in the life of criminals. The theory is based on a “suitable target,” “motivated offender,” and “absence of a capable guardian”

to create the “Criminal Event.” The entire system is often referred to as “The Chemistry for a Crime.”

Our research evolved while working with practitioners such as during our Executive Education/Short-Course programs. During that work, we move through the concepts of Situational Crime Prevention and then to Routine Activities Theory. We summarize the concepts into a single triangle figure that is fundamental to Routine Activities Theory titled “The Chemistry for a Crime.” Our first major article, “Defining the Public Health Threat of Food Fraud,” referred to this as “The Crime Triangle” and stated it was adapted from Felson’s Crime in Everyday Life (Spink and Moyer (2011) adapted from Felson (1998)). While there are many triangles applied to criminology theory, we utilize the Crime Triangle adapted from Felson’s model of the target (victim), offender (fraudster), and capable guardian (guardian and hurdle gaps). “These three elements produce the predatory crime triangle. [...] With a guardian present, the offender avoids attempting to carry out an offense in the first place. [...] Most offenders, however, have a pretty good idea of what they can get away with” (Felson 2002).

The clarification of Situational Crime Prevention and Routine Activities Theory was nuanced and not core to our hypothesis or discussion, but it was an excellent opportunity to help us clarify this point.

We are grateful for this editor for organizing a reviewer team that is motivated and engaged enough to help us clarify this point.

It is important that articles on food fraud be submitted, entered into the peer review process, and get such intense attention from reviewers. Food fraud is also becoming a topic for published articles.

Food fraud Topics are (Finally) Being Reviewed, Accepted, and Published

If a concept is not published in a scholarly journal, then academics seem to consider the concept does not exist. What is lost in the discussion in this blog post is a great accomplishment that food fraud articles are being reviewed, accepted, and published.

When we submitted our article “Defining the Public Health Threat of Food Fraud” – which was published in IFT’s ranked Journal of Food Science in 2011 – we had to persuade and defend that this was in the “aim and scope” of a food journal.

The Food Fraud Term in Scholarly Publication

A Google Scholar search on the topics:

Term	Google Scholar search results before 2011	Google Scholar search results from 2012 to 2017
Food fraud	247	394
Economically motivated adulteration	14	183

(continued)

To emphasize that point there have been more scholarly publications related to food fraud in the last 4 years as there had been in the previous history of publishing scholarly articles.

For emerging issues in food fraud and food safety, there has been an emphasis on a “science-based approach” that especially values the “peer reviewed” and “scholarly” publications. This emphasis is not to create a barrier to new ideas but to make sure the foundational concepts are well thought through and clear. This blog post provided two examples of the value of the peer review process. It is important for scholars and practitioners to pursue scholarly publications. Fortunately, food fraud is now defined as in the “aim and scope” of food journals. More articles are being submitted and published. With this success and momentum, more scholars will be more motivated to conduct food fraud research. Utilize these vast resources by reading these articles.

Personal Insight: Adapting Theories in New Disciplines: Discussion with Jay Albanese and Michael Levi

Further expanding on the challenges, there are also many examples of embracing the adaptations. I was fortunate to present on a panel at the 2015 American Society of Criminology (ASC) Annual Meeting in Washington, DC, with Nick Lord and Jon Spencer of the University of Manchester (UK) and Wim Huisman of the Vrije Universiteit Amsterdam (Netherlands). We presented a session on “Food Adulteration – The Organization of Food Crime.” After the session, we had the opportunity to talk with two highly published criminology thought leaders who are Jay Albanese and Michael Levi.

It was very encouraging to hear positive feedback on our approach and specifically how traditional criminology theories had been adapted for application to the food industry. Specifically, they were supportive of using the simplified Crime Triangle when introducing criminology theories to the food industry. They were supportive and cognizant of the challenges of introducing new theories to other non-criminology disciplines such as food science. Discussions like these have helped us be more creative when researching food fraud prevention.

Introduction to the Concepts of Crime Science, Criminology, and Criminal Justice

From the US Department of Justice/Office of Community Oriented Policing Services funded Problem-Oriented Policing Center (POP Center), “Most criminological theories focus on what makes people ‘criminal.’ They find causes in distant

factors, such as child-rearing practices, genetic makeup, and psychological or social processes. These theories are very difficult to test; are of varying and unknown scientific validity; and yield ambiguous policy implications that are mostly beyond the reach of police practice” (Clarke and Eck 2005).

Several key terms or concepts are criminology, crime science, criminal justice, traditional criminology, and environmental criminology.

Criminology (Traditional Criminology) “Most criminological theories [criminology] focus on what makes people ‘criminal.’ They find causes in distant factors, such as child-rearing practices, genetic makeup, and psychological or social processes. These theories are very difficult to test; are of varying and unknown scientific validity, and yield ambiguous policy implications that are mostly beyond the reach of police practice.”

- **Criminal Justice:** “Interdisciplinary academic study of the police, criminal courts, correctional institutions (e.g., prisons), and juvenile justice agencies, as well as of the agents who operate within these institutions. Criminal justice is distinct from criminal law, which defines the specific behaviors that are prohibited by and punishable under law, and from criminology, which is the scientific study of the non-legal aspects of crime and delinquency, including their causes, correction, and prevention. [...] The field of criminal justice emerged in the United States in the second half of the twentieth century. As the Supreme Court of the United States gradually expanded the rights of criminal defendants on the basis of the due process clause of the U.S. Constitution, the gap between the actual performance of criminal justice agencies and what was legally required and legitimately expected of them began to grow.”
- **Crime Science:** “takes a radically different approach. It focuses not on the reasons why criminals are born or made, but on the act of committing the crime. It seeks ways to reduce the opportunities and temptations for crime and increase the risks of detection. In doing so, it seeks contributions from a wide range of disciplines, including psychology, geography, medicine, to which it helps to reduce crime on our streets, and in our homes and businesses” (Romero and Atlas (2002) in Clarke and Eck (2005)).
- **Traditional Criminology:** “seeks to improve understanding of the psychological and social forces that cause people to become criminals in the hope of finding ways to change these causes” (Romero and Atlas (2002) in Clarke and Eck (2005)). “Traditional criminology seeks to improve understanding of the psychological and social forces that cause people to become criminals in the hope of finding ways to change these causes. [...] It seeks ways to reduce the opportunities and temptations for crime and increase the risks of detection.
- **Environmental Criminology:** “...The theories and concepts of environmental criminology (and of the new discipline of crime science) are very helpful in everyday police work. This is because they deal with the immediate situational causes of crime events, including temptations and opportunities and inadequate protection of targets. You will be a stronger member of the problem-oriented

team if you are familiar with these concepts. The problem analysis triangle (also known as the Crime Triangle) comes from one of the main theories of environmental criminology – routine activity theory. This theory, originally formulated by Lawrence Cohen and Marcus Felson, states that predatory crime occurs when a likely offender and suitable target come together in time and place, without a capable guardian present” (Clarke and Eck 2005).

Introduction to a Range of Criminology Theories

After considering the core concepts of Situational Crime Prevention and some of the challenges and opportunities of adapting theories, it is essential to provide a foundation that considers those other theories. Several basic criminology terms are the foundation of the discipline (Clarke 1997a, b).

- ***Situational Crime Prevention:*** Reviewed throughout this chapter is “opportunity-reducing measures that (1) are directed at specific forms of crimes, (2) involve management, design, or manipulation of the immediate environment in as systematic and permanent way as possible, (3) make crime more difficult or risky, or less rewarding and excusable as judged by a wide range of offenders.”
- ***Rational Choice Theory:*** Essentially those criminals believe they will not get caught and will benefit from an act.
- ***Routine Activities Theory:*** Essentially those crime opportunities are most prevalent when and where perpetrators have access to or awareness of the victim or target.
- ***Action Research Methodology:*** A model where “researchers and practitioners work together to analyze and define the problem, to identify and try out possible solutions, to evaluate the results, and, if necessary, repeat the cycle until it is achieved (Lewin 1947).”
- ***Problem-Oriented Policing:*** This is based on “...operational effectiveness for the police was not through improvements in organization and management but through detailed analysis of everyday problems they handle and the devising of tailor-made solutions.” This process required “identifying these problems in more precise terms, researching each problem, documenting the nature of the current police response, assessing its adequacy and the adequacy of existing authority and resources, engaging in a broad exploration of alternatives to present responses, weight the merits of these alternatives, and choosing among them.”

These core concepts are often adapted or evolved to address the specific needs of the practitioners. A system that has been adopted is the Criminology SARA approach (Eck and Spelman 1987). This is similar to the ISO 31000 Risk Management and Six Sigma quality management concepts of plan-do-check-act (PDCA).

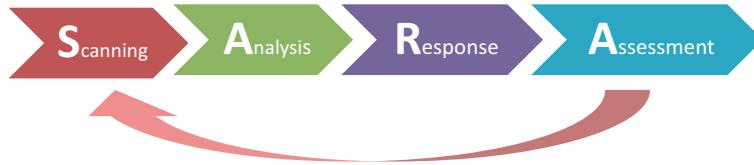


Fig. 7.9 Eck's SARA model for problem-oriented policing: scanning, analysis, response, assessment, and repeat. (Adapted from Eck and Spelman (1987))

Your work can help answer four fundamental questions. These questions correspond to the stages of the Scanning, Analysis, Response, Assessment (SARA) process (Fig. 7.9):

1. What is the nature of the problem? (Scanning)
2. What causes the problem? (Analysis)
3. What should be done about the problem? (Response)
4. Has the response brought about a reduction in the Problem? (Assessment)

The practical applications are relevant and apply to real-world needs and situations such as limited funding. The reality of limited and dwindling resources for law enforcement, investigation, and prosecution has been the subject of study. The insights from “Crime Analysis for Problem Solvers in 60 Small Steps” are so profound and applicable to food fraud prevention that many of the quotes are included here. From the report (Clarke and Eck 2005):

One of the primary concerns in policing in the United States today [published in 2005] – and for the foreseeable future – is the severe constraint on spending. The lion’s share of police budgets is consumed in personnel costs. As a result, many police agencies are already operating significantly below their authorized strength. Funds to hire new officers to meet growing needs are hard to obtain. And, of special relevance here, traditional forms of policing, because they are so heavily dependent on personnel, are being curtailed. Calls cannot be handled as completely and quickly as in the past. Personnel cannot be as freely assigned to increasing the police presence on the streets in labor-intensive tactics, such as crackdowns, sweeps, and special task forces. ...And [the constrained resources lends fresh impetus to meeting a long-standing, neglected need – the need to equip the police with an institutionalized capacity to examine its work product; to routinely ask, before committing to more of the same, what it is that the police are expected to accomplish and how they can more effectively accomplish it. ... This is the essence of problem-oriented policing. (Clarke and Eck 2005)

There are more criminology theories, but these are several that have been applied to food fraud prevention.

Article Review – Create Investigation Networks that Mirror the Criminal Network (MSU-FFI 2018):

Title: Article Review – Create Investigation Networks that Mirror the Criminal Network

By John Spink • November 13, 2017 • Blog

Our article focused on a recommendation for how the Public-Private-Partnership – that is, governments working together with industry and others – could be optimized to reduce the “fraud opportunity.” One co-author was Peter Whelan, who is the head of food fraud prevention for the country of Ireland (Irish Food Safety Authority – FSAI) and also a member of the European Union Food Fraud Network and INTERPOL Operation Opson (food crime).

One key concept in the article is the creation of investigation networks that mirror the criminal organization structure. A typical food safety incident investigation team may not have the expertise to address food fraud incidents. For example, food fraud is detected or deterred by focusing on cyber-crime, tax avoidance smuggling, or trade-based money-laundering.

Recommendations from the journal articles (Wheatley and Spink 2013; Heinonen et al. 2014; Spink et al. 2016a, b):

1. **Create a unique and specialized team:** Treat a food fraud incident and investigation with a fundamentally different approach than for traditional food safety or food quality problems. Consider the attributes of the unique food fraud network and then gather the specific experts.
2. **Be realistic about resource allocation and practical impact:**
 - (a) **Law enforcement priority setting (what can food investigators expect from other agencies, prosecutors, the judiciary, and the legislators):** The priority that consumers expect are: public safety (drugs, guns, violence), public health (major harms), large scale economic crimes that disrupt governments or markets (government bribery, sub-prime mortgage lending crisis), large economic crimes than impact many (billions across a market), and then smaller economic crimes and that impact one or a few stakeholders. **Conclusion:** Most food fraud incidents would fall into the last category and lowest priority.
 - (b) **Investigation and prosecution methods for results (the goal is not to catch bad guys and bad product but prevent food fraud from occurring in the first place):** Product fraud and counterfeiting is considered a “hybrid” crime with aspects of “white collar” crime and “traditional” crime (Heinonen et al. 2014). The planning and reward is a typical “white collar crime” while the violation is “traditional crime” where a victim has physical contact and impact of the act. A “traditional” law enforcement investigation would focus on where the crime

is conducted to either produce the illicit good or to work with the victim. For product fraud, it is very complex, difficult or often approaching impossible to even find the origin of the product or the fraudster (Spink and Moyer 2011). Also, when considering some simple types of tampering instead of major production locations, there could be thousands of home-based fraudsters (Wheatley and Spink 2013). **Conclusion:** Traditional food safety investigation methods may be impractical or inefficient.

From the “The role of the public-private-partnership in food fraud prevention—includes implementing the strategy” (Spink et al. 2016a, b):

Scope of the Public-Private Partnership

- “The [Public Private Partnership] may be a unique collaboration with a non-traditional focus. Government agencies have been traditionally created and focused on compliance and enforcement. This contributes to prevention but is often through dis-connected, reactive detection and prosecution. If there is a focus on an overall Food Fraud Prevention Strategy, then the resources could be defined in terms of exactly how they coordinate to reduce the overall fraud opportunity.”
- “More arrests or more seizures do not necessarily mean that a problem is actually decreasing. More seizures could be due to more efficient detection methods or a focus on a specific product. Fewer arrests could result from an actual decrease in fraud or the fraudsters evolving to new types of crime or the lack of attention to food fraud detection and prevention.”
- “It is also most efficient to align countermeasures to the structure of the crime and the criminal networks:”

Example of Investigation Task Force Mirroring the Criminal Network

- **Caribbean On-Line Species Substitution:** For example, if the fraud opportunity is within the Caribbean region and involves online market-places as well as species substitution, then the task force would ideally be staffed with a Caribbean team with cyber-crime and species identification expertise.
- **International Broker Network for Spice Dilution:** If the fraud opportunity is ground spices through a broker network from India to South America through free trade zones, then the task force would ideally be staffed with an international trade team familiar with brokers.
- **European Wine Trade-Based Money-Laundering:** If the fraud opportunity is a trade-based money-laundering of premium wines within Europe, then the task force would be ideally staffed with a European team with smuggling and wine experience.

(continued)

- “The most effective and efficient government countermeasures are the combination of controls where there is a regulated change of product ownership such as import tariffs or sales tax. Governments have the most control of the food supply chain at border crossings and in regulating the point of consumer purchase. Industry has the most control at the ownership exchange when receiving materials and at the sale to consumers. For these reasons, food fraud prevention is most efficiently achieved for the country, market, and world at these exchange points through a public-private-partnership.”

The most important conclusion is that there are a growing awareness and literature on food fraud prevention, including the investigation and enforcement. The most inspiring realization is that many global law enforcement agencies – e.g., UK National Food Crime Unit (Andy Morling and team), Dutch Food Crime Unit (Karen Gussow), Scottish Food Crime Unit (Ron Naughton), etc. – are taking this novel and broad approach. We look forward to continuing to learn from these thought leaders. MSU-FFI.

Sidebar: Review of Food Integrity Handbook (EC Food Integrity Project)

One of the deliverables of the European Commission-funded EU Food Integrity Project was the publication of this comprehensive food authenticity testing handbook. This is one of the most—if not the most—comprehensive and helpful guides to food authenticity testing. Most practitioners will not need to seek any other resources other than when searching for methodology details or actual test results,

From the Foreword from Professor Christopher Elliott: “A major element in the fight against fraud is the development, validation, and implementation of novel methodologies that can detect and often quantify the level of cheating that has occurred.”

Regarding the scope “The prime focus of this Handbook is, of course, food authenticity and the analytical solutions available to address existing concerns.” The target audience was industry quality control managers who are starting to review food authenticity response and also “young scientists starting their career in food science and to students and researchers with little prior knowledge of the area.”

Definitions

The definition of food fraud that is based on the CEN Workshop (agreed by the attendees but not reviewed by the entire CEN) is:

- **Food fraud:** An activity “intentionally causing a mismatch between food product claims and actual food product characteristics, either by deliberately making claims known to be false or by deliberately omitting to make claims that should have been made.”

For the types of food fraud, the report referenced the GFSI Food Fraud Think Tank and the CODEX Food Fraud draft discussion paper.

To review the exact statement in the handbook, the quoted the Codex EWG:

- **“Food fraud** is ‘any deliberate action of businesses or individuals to deceive others in regards to the integrity of food to gain undue advantage’.”
 - **For food fraud prevention:** Note—the action by the fraudster where the response would be food fraud prevention.
- “**Food authenticity**” and ‘food integrity’: Both are a status of a food product, but the former is the state of being ‘not altered or modified with respect to expected characteristics including, safety, quality, and nutrition,’ while the latter is the state of being ‘genuine and undisputed in its nature, origin, identity, and claims, and to meet expected properties’.”
 - **For food fraud prevention:** Note—a state of being or status of the product where the response would be to confirm the claims.

In the same way, the definition of an “Authentic food product” given by the CWA is very close to that of food fraud:

- **Authentic food product:** “A food product where there is a match between the actual food product characteristics and the corresponding food product claims; when the food product actually is what the claim says that it is.”

The handbook specifically focuses on adulteration, stating “One of the most common frauds is adulteration.”

- **Adulteration:** “A type of food fraud which includes the intentional addition of a foreign or inferior substance or element; especially to prepare for sale by replacing more valuable with less valuable or inert ingredients.” This practice is sometimes referred to as Economically Motivated Adulteration (EMA). This term is defined in the *Codex Alimentarius* position paper. It is recognized as “a subset of food fraud.”

The handbook notes other types of food fraud that are outside the scope of the FIP Handbook:

- **“Grey market:** this term includes production, theft, and diversion involving unauthorized sales channels for products. An example of this is the sale of the

excess unreported product when there are production agreements or quotas for the product and the product in question is deliberately produced in excess of these. A fish product originating from illegal, unreported, and unregulated (IUU) fishing is another example. This term also applies when there is a geographical restriction on the sale and distribution of the product, and the product in question is deliberately sold or distributed in other areas; this is often referred to as ‘grey market’ sales.”

- “**Counterfeit**: is a case when where Intellectual Property Rights (IPR) infringement is in effect. This could include any or all aspects of the other product or packaging being fully replicated, for instance, the process of copying the brand name, packaging concept or processing method for economic gain. Imitation wines and spirits with fake labels of a popular brand is a classical example (see the chapter on Spirits).”
- “**Mislabelling**: is a special case of food fraud. It concerns the process of putting false claims on packaging for economic gain. Selling farmed salmon as wild salmon, or conventional fresh produce as organic are examples of this fraud. Expiry date modifications fall under this category. However, mislabelling may apply to all forms of food fraud: to be efficient, a fraudulent product must indeed be ‘mislabeled’ to be purchased by a buyer. But the expression is mainly used to indicate distortion of the information provided on the label.”

Product Commodities Addressed

The handbook covers a wide range of product commodities that are generally understood to have a high fraud opportunity (Table 7.1). Each of the 20 product chapters includes a by-fraud-type review of the authenticity test methods. Examples of the sections from the milk and dairy chapter are authenticity issues, species substitution, geographical origin and rennet origin, technological processes (heat processing, freezing), and maturation. The types of authenticity issues for milk and dairy include undeclared addition of certain ingredients, adulteration with water, adulteration of nitrogen content, adulteration of the fat content, synthetic or reconstituted milk, and adulteration with preservatives. The handbook did include a mention of how this handbook contributed to the overall GFSI food fraud compliance requirements for all types of fraud and for all products.

Table 7.1 Product commodities covered in the *Food Integrity* Handbook

Milk and milk products	Eggs and egg products	Honey	Meat and meat products
Fish, seafood, and related products	Cereals and cereal-based products—wheat, rice	Species origin of gelatine in foods	Cocoa, cocoa preparation, chocolate, and chocolate-based confectionery
Spices	Saffron	Wine and must	Spirit drinks
Fruit juices	Vinegar	Coffee	Tea and flavored tea
Olive oil	Vegetable oils	Food flavorings	Nuts, nut products, and other seeds

Sidebar: Unique and Widely Adopted Concepts and Definitions—LEO or Gemini?

One challenge when conducting interdisciplinary research is understanding the general concepts, basic terminology, specific definitions, and “common sense.”

Leo or Gemini? Coming from a food science, food safety, and packaging background, originally there was little interaction with the law enforcement literature or community. Overheard while going through security screening into a US Government Building.

- Guest: “With the bad weather, did you have trouble commuting in here early to your security post?”
- Security Guard: “No, we got here before the snow started. Now, please put your bag on the conveyer belt and your keys in this bowl.”
- Guest: “Ok. I do not mind the snow since I just slow down and try to enjoy the trip. I guess I expect delays so if we get here quickly, then it is a nice surprise.”
- Security Guard: “Are you a Leo?”
- Guest: “No, I am a Gemini. So I am patient and didn’t mind the long commute.”
- Security Guard and a big group of colleagues: Outburst of laughter.
- They asked a security question of whether the guest was a “Law Enforcement Officer”—abbreviated “LEO”—they were not asking the guest’s astrological sign.

When addressing food fraud prevention, there should be an assumption that other disciplines have unique expertise and efficient practices and phrases.

Key Learning Objective 2: Situational Crime Prevention in Detail

This section reviews the criminology theory of Situational Crime Prevention in detail. Since the mid-1970s, there was an expansion of criminology theory to address questions such as the root causes related to the physical space and opportunities. The “environmental criminology” concepts provide an especially practical and pragmatic for food fraud prevention.

The Key Learning Objectives of this section are:

- (1) Review the Situational Crime Prevention fundamentals.
- (2) Apply the theory in relation to other crime-fighting objectives.
- (3) Then review application examples or case studies.

Situational Crime Prevention in Detail

The focus of Situational Crime Prevention is on “opportunity-reducing measures” (Clarke 1997a, b; Felson 2002). Situational Crime Prevention comprises opportunity-reducing measures that have a food fraud application (Clarke 1997a, b):

- “Situational crime prevention comprises opportunity-reducing measures that:
 - Are directed at highly specific forms of crime,
 - Involve management, design, or manipulation of the immediate environment in an as systematic and permanent way as possible,
 - Make crime more difficult or risky, or less rewarding and excusable as judged by a wide range of offenders.”

Four Components of Situational Crime Prevention are (Clarke 1997a, b):

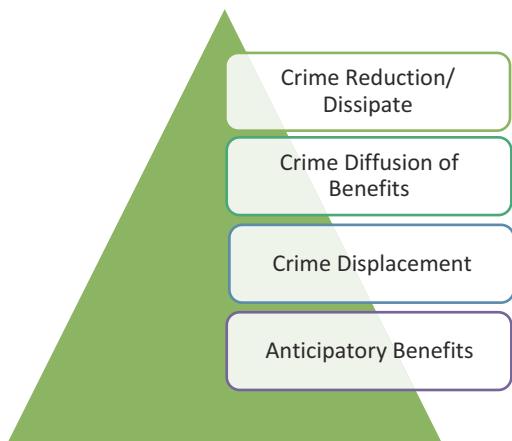
- “Four Components of Situational Crime Prevention
 - A theoretical foundation drawing principally upon routine activity and rational choice approaches,
 - A standard methodology based on the action research paradigm,
 - A set of opportunity-reducing techniques, and
 - A body of evaluated practice including studies of (crime) displacement.”

The criminology authors specifically and intentionally are general since “Situational crime prevention is assumed to apply to every kind of crime, not just to ‘opportunistic’ or acquisitive property offenses, but also to more calculated or deeply-motivated offenses” (Clarke 1997a, b). “This [value of the theory is that it] avoids speculation about the source of the offender’s motivation, which distinguishes it immediately from most other criminology theories” (Clarke 1997a, b). This is exactly why these vulnerability reducing crime prevention concepts simply and directly applied to food fraud prevention.

Review of Criminology Terms

The core criminology theories are the general models, and then there are specific terms used for aspects of the application. Regarding the goal of a crime prevention strategy, several fundamental concepts include anticipatory benefit, crime displacement (shift the target), diffusion of benefits (one activity will provide multiple benefits), and ultimate crime diffusion (there is no motivated offender), while the fourth goal of Situational Crime Prevention is “including studies of (crime) displacement” (Felson 1998). The ultimate goal here is to reduce the fraud opportunity to such a low level that the offenders are encouraged to attack elsewhere or give up on even trying to commit a crime—the ultimate goal is to reduce or eliminate the motivation to prevent the act from occurring in the first place (Fig. 7.10).

Fig. 7.10 Hierarchy of criminology terms



- ***Anticipatory Benefits, Crime:*** “Benefits from crime prevention that begin prior to initiation of crime prevention treatments” (Clarke and Eck 2014). Also, “... benefits were noted if a pre-initiative drop in a crime measure was observed” (Smith et al. 2002). The criminals reduce their activity in anticipation before the crime prevention countermeasures are implemented.
- ***Displacement (Crime):*** “is the relocation of crime from one place, time, target, offense, or tactic to another as a result of some crime prevention initiative” (Guerette 2009). Also, “Overall, displacement is viewed as a negative consequence of crime prevention efforts, but in some cases, it can still provide some benefit” (Guerette 2009):
 - “Temporal—offenders change the time at which they commit a crime
 - Spatial—offenders switch from targets in one location to targets in another location
 - Target—offenders change from one type of target to another
 - Tactical—offenders alter the methods used to carry out crime
 - Offense—offenders switch from one form of crime to another.”
- ***Diffusion of Benefits (Crime):*** “...entails the reduction of crime (or other improvements) in areas or ways that are related to the targeted crime prevention efforts, but not targeted by the response itself. Though less recognized than displacement, diffusion is recorded in many research evaluations of crime prevention responses. Diffusion effects are referred to in a variety of ways including the “bonus effect,” the “halo effect,” the “free-rider effect,” and the “multiplier effect.” “The opposite of crime displacement is diffusion of crime control benefits. Crime diffusion entails the reduction of crime (or other improvements) in areas or ways that are related to the targeted crime prevention efforts, but not targeted by the response itself (Guerette 2009)”. The criminals decrease a wide range of their activities even beyond where the crime prevention countermeasures are implemented.

- **Prevention (Crime):** “Crime prevention is about reducing the risk of occurrence, and the potential seriousness, of crime and disorder events by intervening in their causes. This definition is deliberately inclusive—centering on no particular kinds of causes or theories of crime, and favoring no kinds of intervention over others” (Ekblom 2013).
- **Reduction (Crime):** “is simply about decreasing the frequency and seriousness of criminal events, by whatever (legitimate) means. Crime prevention is intervention in the causes of criminal and disorderly events to reduce the risk of their occurrence [prevention] and/or the potential seriousness of their consequences [mitigation]. Most reduction is delivered through prevention, although some involve intervening directly in unfolding events” (Ekblom 2013).
 - **Designing Out Crime** (Newman 1972). This is a similar concept within crime reduction and applies to food fraud due to the focus on opportunity elimination.

While it is not a criminology term, for food fraud prevention the idea of crime reduction, designing out crime or even a hybrid with crime displacement would be to eliminate the fraud opportunity and could a to “dissipate.”

- **Dissipate** (applied to crime): “to cause to disappear; to cause (members of a group) to move widely apart” (Merriam-Webster 2004)

An extension on these criminology concepts, in relation to the food fraud prevention, could be **vulnerability elimination** or the removal of a system weaknesses or attributes necessary for a crime to occur. Remember, the three legs of the Crime Triangle are required—in the presence of a “motivated offender”—for a crime even to be able to occur.

To note, there is a resistance for criminology theorists to even refer to “eliminate crime.” There is a general understanding that crime cannot be completely eliminated. For a specific type of crime such as food fraud, the environmental criminology focus would be on understanding the root cause, displacement to less dangerous problems, and then to shape the space to that the frequency and seriousness are reduced to an optimal or acceptable level.

Sidebar: The Ecosystem of Organized Crime (and How to Disrupt Food Fraud Vulnerabilities) (MSU-FFI 2018):

Title: The Ecosystem of Organized Crime (and how to disrupt food fraud vulnerabilities)

This is a summary of Markus Felson’s 2006 report and presentation on ***The Ecosystem of Organized Crime*** (Felson 2006). As consistent with his other works and Situational Crime Prevention in general, the most efficient focus is on how and why a crime opportunity exists which is more than just catching bad guys or bad product.

Before getting into the details of this report, it is important to take a moment to consider the concept of “organized crime,” “crime that is organized” and “criminal cooperation.” Felson often addresses the public perception where “The televised version of organized crime depicts highly organized people in business suits sitting around a table for meetings, with intricate coordination across a vast field, and a certain brilliance of mind.” Felson emphasizes that “Scholars have long told us that the televised version of organized crime is substantially wrong – that most organized crime is much smaller in scale and coordination.” From a personal communication with Marcus Felson (2018):

Sometimes organized crime is very organized, such as in places where the state is very weak. Sometimes it is more a network. Sometimes it is more rudimentary.

Felson provided a footnote in the report regarding the organized crime term that “Note 4: I use the term ‘criminal cooperation and organization’ because of my allergic reaction to the term ‘organized crime.’ The latter conveys a specific image popularized by television, one not substantiated by scholarship and experience. However, this [ecosystem] paper does not include all criminal cooperation, much of which is too rudimentary to fit under the rubric of ‘organized crime,’ rightly understood.”

The ecosystem in this reference is not the components of the crime opportunity (see the Crime Triangle including the victim, criminal/fraudster, and guardian) but the attributes or activities that feed an entire criminal organism. For a very simplistic example from nature, bugs are eaten by birds that are eaten by mammals that then decompose to be nutrients for the bugs.

To address the problem of criminal cooperation, Felson provides insight into the environment. For our observation of the problem and consideration of the more effective and efficient countermeasures, there is a need to be aware of how much that can be actually observed:

Semipublic and semi-private settings: “These are very important for crime to occur. The following scale helps us understand how cooperative crime surfaces and where it is most exposed to interference:”

1. “Public Settings – Minimal supervision, easy contact with strangers
2. Semipublic Settings – Transition and transfer settings seen by many, but not all
3. Semi-private Settings – Transition and transfer settings seen by a few
4. Private Settings – Limited access.”

Consistent from feedback in other investigations, it is that often the product fraud events are conducted in secret, in private settings, and by actors from within the legitimate supply chain. For food fraud prevention, the consideration of the crime settings provides insight into why food fraud acts are difficult to see or find since they would seem to occur mostly in the semi-private and private settings.

(continued)

Next, Felson presents the ecosystem of how the smaller crimes feed into bigger operations:

“The Web of Crime Cooperation: The interplay of many crimes produces a web of interdependence. [...] This web of crime cooperation exposes each crime to a larger environment, without which it cannot thrive. ([Felson has] explained elsewhere the multitude of interdependencies between illegal and legal activities.”

- “Small time thefts lead to fencing stolen goods,
- Providing thieves money,
- For purchasing small amounts of illegal drugs,
- Contributing to small-time drug dealing,
- Feeding into large-scale drug dealing.”

For food fraud prevention, there should be a consideration of why and how the first “small-time theft” opportunity is identified and the potential for that fraudster to advance from diluting a food to selling illegal drugs. The occupational type of criminal usually grows their operation within their current infrastructure which would be related to the legal sales of food... and with the exception of extreme and desperate situations, this would *not* be deciding to switch from selling diluted beverages to selling illegal narcotics.

So, considering the concept that crime is difficult to observe and there is a symbiotic relationship between hierarchies of crime actors, Felson builds upon other Situational Crime Prevention theories to present some – where Felson admittedly refers to them as “unusual” – guidelines to efficiently address a crime problem. To consider each idea in relation to food fraud prevention further discussion is provided here. The incident used for the example is the UK 2012 incident where lower cost horsemeat was illegally and fraudulently blended into the product that was presented as 100% beef.

“These ideas lead me towards an unusual set of recommendations for understanding organized crime in society, as well as reducing it.”

1. “Focus on the *acts*, not the group engaging in it.”
 - (a) **For food fraud prevention**, focus on the vulnerability or system weakness, not the perpetrators. For horsemeat, this would be a focus on where and how the fraud was enabled to occur not on the specific fraudsters.
2. “Divide cooperative and organized crimes into *very* specific types.”
 - (a) **For food fraud prevention**, focus on very specific types of fraud acts with the bigger crime. For horsemeat, this would be narrowing the focus to the documentation vulnerability.
3. “Study the *vast variation* in criminal cooperation and organization.”
 - (a) **For food fraud prevention**, this would be to assess how the seemingly common fraud acts differ. For horsemeat, this would be to consider the specific relationships and capabilities that led to each fraud act, not the overall horsemeat vulnerability.
4. “Assume *minimal* levels of cooperative complexity, that such crime is seldom ingenious.”

- (a) **For food fraud prevention**, this is first to consider very simple vulnerabilities and straight-forward countermeasures. For horsemeat, this could be announcing to suppliers that species tests will be conducted. Remember, the goal is not to catch food fraud but to prevent it from occurring in the first place.
5. “Don’t follow the money; follow the *physical transactions*.”
- (a) **For food fraud prevention**, it is important to remember that the fraud acts are not the end objective but making money off the fraud is the goal. A disruption at the very end of the supply chain could vastly increase the risk of getting caught or the cost of conducting the crime. In Felon’s terms, the “Ecosystem” would be disrupted. For horsemeat, this could be an organization conducting even just a few, but routine, market species tests.
6. “Don’t look for deep secrets; look for the *obvious* and *almost obvious*.”
- (a) **For food fraud prevention**, building on item 4, it is efficient to start with the most basic and most obvious vulnerabilities. While there may be more clandestine and complex actions occurring, addressing the simplest crimes may create a ripple effect on all of the more complex crimes. If anything, there is a statement to the marketplace – and more importantly to any fraudster who may be lurking in the supply chain – that there is an increased focus and scrutiny. For horsemeat, this would build upon the discussion in item 4 to start with a focus on straightforward fraud acts.
7. “Find out how one crime *depends* on another.”
- (a) **For food fraud prevention**, this builds upon the previous items to consider the “Ecosystem” of the fraud act. Each criminal relies on another system to achieve specific goals. For horsemeat, a supplier of meat must have a group that enables the documentation to be forged, and the fraudulent company needs a customer who is not aware of the fraud act, doesn’t care, or is complicit. Compared to other types of crime, food fraud seems too often be very simple.
8. “Find out how crime *feeds off* legitimate and marginal activities.”
- (a) **For food fraud prevention**, the biggest opportunity is probably to co-mingle fraudulent and legitimate product. The fraudulent supplier needs a buyer for their product. The biggest opportunity is with buyers who are in the legitimate supply chain. After that, there are more opportunities in marginal activities that may have less oversight or controls. For horsemeat, this could be the series of digital brokers who consolidated and coordinated a series of bids that reduced transparency and highlighted the fraud opportunity.
9. “Tease out the *sequence* of events for ongoing criminal cooperation.”
- (a) **For food fraud prevention**, this is to consider the basic activities or components of the transactions including vulnerabilities or system weaknesses. It is critical to understand the specifics and nuance of specific fraud acts. This deeper focus helps define how a bad guy thought they were making a rational choice to conduct this act – the rational choice is that they can make a profit and get caught. For horsemeat, the understanding of the sequence of events could identify specific hotspots where even very simple counter-measure or control system could vastly reduce the fraud opportunity.
10. “*Interfere with that sequence*, access to the customer, or modus operandi.”
- (a) **For food fraud prevention**, this is to define and implement efficient and effective countermeasures or control systems that target very specific parts of the vulnerability and disrupt the ecosystem.

(continued)

Ultimately, while counterintuitive to many of the food fraud strategies, considering the crime ecosystem concept is very effective since it both identifies the overall system weaknesses and explains the simplest and most obvious first steps. If you are investigating or analyzing a food fraud incident, there are many resources to provide you with insight including this report by Felson on “*The Ecosystem of Organized Crime*.” Do not reinvent the wheel. First, seek out previous works by experts and then adapt to your problem. MSU-FFI.

Examples of Situational Crime Prevention for Other Crimes

Sidebar: Simple Example—Caller ID Reduces Obscene Phone Calls

An example of the hierarchy of criminology terms is considering how telephone caller identification reduces the frequency of obscene phone calls. Some of the best examples or case studies are very obvious. For this discussion, just the title explains the application telephone automatic caller identification (caller ID) of Situational Crime Prevention. The introduction of “caller ID”—telephones providing the phone number and name of the caller to the called—fundamentally changed the fraud opportunity where the perpetrator was no longer anonymous (Clarke 1997a, b). Over time, some perpetrators may no longer commit the act (*prevent crime*); they may change their methods (*displacement*), or they may act less (*diffuse crime*).

A broad focus on the fraud opportunity would identify that “obscene phone calls” are a function of the use of the “phone.” The underlying act is “obscene” contact with a victim. Applying Situational Crime Prevention—and for food, a Food Fraud Prevention Strategy—the general vulnerability changes and was not eliminated. It would have been understood and logical that the perpetrators would shift to other methods of attack based on the underlying perpetrator motivation. The crime would evolve. Cyberstalking is an example of the evolution.

Sidebar:

Case Study of Applying Situational Crime Prevention—Nigeria

To provide an example of the theories and terms of applying this case study of the Nigerian combating, counterfeit medicine initiative is presented (Fig. 7.11). A case study of applying Situational Crime Prevention is in the article “Addressing the Risk of Product Fraud: A Case Study of the Nigerian Combating Counterfeiting and Sub-Standard Medicines Initiatives” (Spink et al. 2016a, b). Here the Crime Triangle is used to present seven specific countermeasures and control systems and how they reduce the “fraud opportunity.”

Case Study - Details



Figure 4: Application of the Crime Triangle to the Nigeria Anti-Counterfeit Initiatives-Identifying the Influence of each Action on the Fraud Opportunity

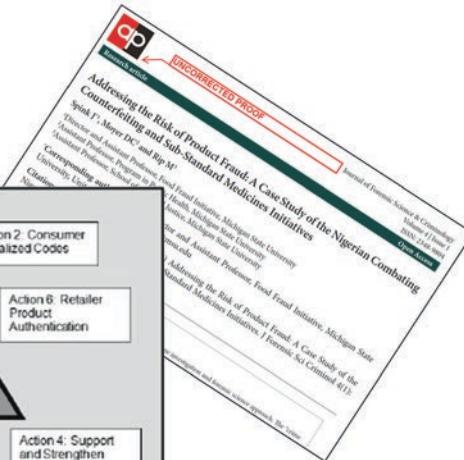


Fig. 7.11 Case study details of the review of the Nigerian fraud opportunity for *Counterfeit Medicines*. (Copyright Permission Granted) (Spink et al. 2016a, b)

The study is on counterfeit medicines in Nigeria, but the underlying concepts apply to all product fraud including food fraud. The Nigerian situation was a national public health crisis where in 2001 over 60% of their pharmaceutical market was counterfeit or substandard. The focused countermeasures and control systems led to a reduction identified in a World Health Organization survey and reported to 16% in 2004. Ongoing surveys found even further reductions in specific markets or sales channels.

From the article: “A methodology was developed to consider strategic countermeasures and control systems based on Situational Crime Prevention which includes the Routine Activities Theory and the Crime Triangle. The Nigerian SSFFC initiatives were used as a case study to apply this theory. The insights apply to reduce the public health risk of SSFFC in other countries. This article is a case study with an impact assessment that provides the foundation for application of a criminology theoretical perspective” (Spink et al. 2016a, b).

The holistic perspective on the entire countrywide fraud opportunity is important and effective when requesting—or defending—government resource allocation. “Each anti-counterfeiting countermeasure has a unique incremental benefit that, in combination, strengthens the entire system. The overall benefits include increased public health, a growing pharmaceutical manufacturing base, and reduced opportunity for crime. The development and

(continued)

presentation of the overall fraud opportunity—or a product fraud vulnerability assessment at the country-level—“...shifts the question from ‘which countermeasures to keep’ to a future review of ‘what additional countermeasures will further reduce the fraud opportunity’” (Spink et al. 2016a, b).”

For food fraud prevention, the insight is that a country-level assessment of the impact of the fraud opportunity *has* actually been completed and presented.

Key Learning Objective 3: Overview of the Crime Triangle

This section reviews the Crime Triangle and the related details from Situational Crime Prevention. The Crime Triangle has been one of the fundamental concepts to explain the food fraud “crime opportunity” or adapted to refer to the “fraud opportunity.”

The Key Learning Objectives of this section are:

- (1) From Crime Opportunity to Fraud Opportunity
- (2) Victims and Fraudsters
- (3) Guardians and Hurdle Gaps

From Crime Opportunity to Fraud Opportunity

Situational Crime Prevention is based on Routine Activities Theory which is presented visually in the “Crime Triangle.” Throughout the related research, there was a focus on “Action Research Method” being the engagement and interaction of the researcher with the practitioner. There are many reports and adaptations of the core concepts of new crime problems. Food fraud—and more broadly all product fraud—is a new crime problem where the crime prevention theories apply [...] with some innovations and adaptions.

For food fraud prevention, Situational Crime Prevention is a very effective and widely adopted process that has been adapted for use by the food industry for this new crime problem.

Sidebar: Is Product Fraud a Traditional or White-Collar Crime? Both

Food fraud is not a “traditional crime” or “white collar crime” so more of a “hybrid crime” (Heinonen et al. 2014).

We demonstrate that product counterfeiting incidents have properties both consistent and inconsistent with white-collar crime as traditionally defined, which sometimes occur concurrently. To advance criminal justice and security research and practice, we conclude that product counterfeiting defies broad classification and is

Table 7.2 Properties of White-Collar and Traditional Crime. (Adapted from Heinonen et al. (2014), #3816)

Offender status	Special social and occupational status	No special status
Offender technique	Trivial/nonphysical	Nontrivial/physical
Contact with victims	Separated	Not separated
Access to crime location	Specialized	Not specialized
Offender appearance	Superficially legitimate	Not legitimate

best considered a distinct crime event. Failure to embrace this broad classification can lead to ineffectively estimating its occurrence and its effects on the economy, public safety and health, and brand owners. (Heinonen et al. 2014)

There are several fundamental properties of “white-collar” crime that do not all always apply to product fraud incidents (Table 7.2).

The need to classify a crime into one category has been a challenge for getting priority for food fraud prevention research or enforcement.

Sidebar: Situational Crime Prevention—“Trends in Human Activity Patterns”

The concept of “**Trends in Human Activity Patterns**” by Cohen and Felson (1979) directly applies to the food industry and food fraud (Cohen and Felson 1979). Changes in the space of crime and global markets—“human activity patterns”—have changed the fraud opportunity and the public health and economic consequences of food fraud. Even before there was data empirically identifying the new crimes, the social anthropology insight would identify that there was an evolving vulnerability. An early understanding of the evolving vulnerability could lead to countermeasures and control systems that short-circuit the opportunity for new crimes to occur.

The discussion about the weaknesses in the criminal justice system “appeared so ineffective in exerting social control since 1960 [to the publication in 1979]” (Cohen and Felson 1979). “For example, it may be difficult for institutions seeking to increase the certainty, celerity [swiftness of movement] and severity of punishment to compete with structural changes resulting in vast increases in the certainty, celerity [swiftness of movement] and value of rewards to be gained from illegal predatory acts” (Cohen and Felson 1979). Essentially, in a traditional crime-fighting scenario, the fraudsters perceive such a high reward with such a low risk that they will accelerate their criminal activity. This is an essential theoretical foundation where a focus on new or evolving vulnerabilities can lead to proactive countermeasures and control systems even before an actual crime or incident is found.

The application for food fraud prevention is that being realistic about human and financial resource availability for crime fighting, the only way to get ahead is to focus on vulnerability and to reduce the “fraud opportunity.”

Victims and Fraudsters

The victim and fraudsters can be considered together because they are both human actors. The human actors have motivations and awareness and can be influenced.

A related concept is the “likely offender” compared to an “offender.” Many people are “likely offenders” but never actually get to the point that they decide to act or become “actual offenders” (Cornish and Clarke 1987). A focus on vulnerability allows for countermeasures and control systems that universally apply regardless of the mindset of the offenders.

Situational Crime Prevention theory identifies several victim related concepts (Felson 2002):

- ***Value of target to the likely offender:*** Some targets are preferred or many and sometimes complicated reasons. “For example, ATM robbers wait until after the victim takes out money.” The victim is a higher value target after they have money. For food fraud prevention, the value is when and what are the goods that are exchanged or sold.
- ***Inertia of target to the likely offender:*** There are some high-cost products that are actually not a frequent target for crimes (such as shoplifting of home appliances such as refrigerators). For food fraud prevention, inertia may be created by more very specific countermeasures and control systems.
- ***Visibility of target to the likely offender:*** There are situations where fraudsters clearly see the target and also a lack of guardianship. For food fraud prevention, the visibility is more focused on presenting countermeasures and control systems that could catch the fraud act.
- ***Access to the offender with a chance to exit easily:*** There are situations where fraudsters have easy access to, and exit from, the fraud act. For food fraud prevention, the access is conducting regular, legitimate business with the victim.

For the general “chemistry of the crime,” there are specific details that combine and react in the same ways. This is presented as “chemistry.” The chemistry concept is especially practical and useful for food fraud prevention since many in the food industry have a chemistry or related educational background (Felson 2002).

- “Figure out who and what must be present and absent for a crime to occur.”
- “Find out what slice of space and time (setting) makes this likely?”
- “Determine how many people move into and out of the setting when committing an offense.”

In the science of chemistry, “everything is connected to everything” with the equilibrium concept that “for every action, there is an equal and opposite reaction.” If you change different factors, the “chemistry” or “reaction” can be influenced—pressure, temperature, moisture amount of elements, new elements, or others. The same is true for crime and the fraud opportunity.

For food fraud prevention, a focus outward from the problem (the human adversary in relation to the attributes of the physical space of the crime) to the solution (the countermeasures and control systems or vulnerability reducing actions) can

create a simple and useable model. One model is the food fraud vulnerability assessment, Food Fraud Prevention Strategy, and that strategy as managed by the Food Fraud Prevention Cycle.

Guardian and Hurdle Gaps

One of the most important concepts is that “With a guardian present, the offender avoids attempting to carry out an offense in the first place” (Felson and Boba [2017](#)). Several concepts are “**Defensible Space**” and “**Crime Prevention through Environmental Design**” (Felson [2002](#)). The ideas are that intentional changes can reduce the fraud opportunity and crime.

The third leg of the triangle is the “guardian and hurdle gaps.” A “guardian” is someone monitoring the activity such as a forklift driver observing the incoming goods. A “hurdle” is an activity that makes the fraud act more difficult to conduct. This is similar to food industry “hurdle technology” that hinders the lifecycle of a pathogen. The guardian and hurdle gap leg is where a company or country can have the maximum impact on reducing the “fraud opportunity.”

The fraud opportunity is reduced by increasing the risk of getting caught or the cost of conducting a crime. Contrary to popular belief, the number 1 goal of a criminal is not to make money. The number 1 goal is not to get caught! This awareness leads to an efficient and primary food fraud prevention focus on “Guardian and Hurdle Gaps.”

There are 16 types of situational prevention attributes that consider the fraudster. Four general categories of TIGER are (Felson [2002](#)):

- “T – Target’s rewards, reducing
- I – Inducement, temptation
- G – Guilt
- E – Effort, increasing
- R – Risk on the spot, of getting caught.”

First, guilt or empathy is inconsistent and difficult to control category. To review, the worst case—which should be the base case—is that the fraudsters are sociopaths not concerned with cheating others and criminals not concerned with breaking the law. Any appeal to empathy or social justice would not change the fraud opportunity—actually it might identify new fraud opportunities (see the book *Freakonomics* and *Think Like a Freak* (Levitt and Dubner [2005, 2014](#)).

The other categories apply to both:

1. Increase the risk of getting caught.
2. Increase the cost of conducting the crime.

Increasing the risk of getting caught could be new detection and deterrent countermeasures and control systems. Increasing the cost of conducting the crime might be to force the fraudster to use higher cost or scarcer components or alternate distribution routes.

An aspect of Situational Crime Prevention that applies to guardianship is “How to Forecast Crime.” It is important to note that at this point the term “predict” is not used by the criminologists. The prediction has more complex actions that require more data, more complete data sets, many incidents, and further complex assessment. The focus of Situational Crime Prevention is on understanding how external factors influence the fraud opportunity or shifting vulnerabilities. “We must not let the offender stay two steps ahead. Not only do we now know much more about crime and its prevention, but we also know how to learn still more. We know what questions to ask about new products and settings” (Felson 2002).

This also shifts focus to the concept of “**Designing Out Crime**.” This “Defensive Space” concept is usually applied to spaces or locations such as banks, but a food supply chain is a discrete system and can be considered a “space” (Newman 1972).

The application to food fraud prevention is that there are three main factors that must be present for a crime to occur—whether a crime has or will occur these are factors that create a “fraud opportunity.” The most direct control is by the actions of increasing guardianship or increasing hurdles.

Conclusion

This criminology chapter addressed the foundational terms, concepts, and theories that apply to food fraud prevention. The next criminology chapter will expand to consider application both from the practitioner perspective but also as to how governments or agencies are addressing food fraud and related topics. ***The first conclusion is*** that criminology is a scholarly, academic field that has had an active focus on reducing the physical environment in a way that methodically reduces the fraud opportunity. The focus on pragmatic, practical, and often very low cost opportunity reducing actions can often be very quickly implemented, and the benefits immediately realized. If you lock the front door of your house, you have immediately reduced your vulnerability, *and* you can measure the success by just checking the door. ***The second conclusion is*** that the Social Sciences and Criminology theories are very simple and logical. After reviewing the root cause—the human adversary who perceives a system weakness—the Criminology focus is not only logical but completely obvious. The final conclusion is that although there are very detailed and complex research reports and systems, there is value in the beginning with simple concepts such as considering the fraud opportunity in tools such as the Crime Triangle. Crime prevention theory is not complex, but it is reinventing the wheel if you have never studied the field. An important lynchpin to all strategies or countermeasures and control systems is that the human adversary can and often will directly respond to our actions...if they can see that we are acting.

There is a saying:

Warning—Counterfeitors Attend Anti-Counterfeit Conferences. Complaint about it or use it to your advantage.

Appendix: WIIFM Chapter on Criminology Foundation

This “What’s In It For Me” (WIIFM) section explains why this chapter is important to you.

Business functional group	Application of this chapter
WIIFM all	The field of criminology—and specifically situational crime prevention—has many very sound theories that have had a tremendous amount of research and very simple concepts that can immediately help reduce the fraud opportunity
Quality team	This was an overview of crime prevention theory to provide basic insights to understand how to dissuade this intelligence human adversary
Auditors	This provided some insight into the types of prevention strategies that will be utilized and that the decision is based on a wide body of scholarly literature
Management	Repeat after me, <i>social science is a real science</i> —the foundation of the root cause is the human adversary that can only really be understood and addressed by criminology
Corp. Decision-makers	The root cause is a human adversary, and even though these will probably be very novel to you, there are many criminology concepts that will be efficiently applied

Appendix: Study Questions

This section includes study questions based on the Key Learning Objectives in this chapter:

1. Discussion Question

- (a) What is “traditional” and “environmental” criminology?
- (b) Which type of criminology applies to food fraud prevention? Why?
- (c) What is the role of criminology in food fraud prevention?

2. Key Learning Objective 1

- (a) What is “Crime Prevention”?
- (b) What is the difference between the original Crime Triangle and the updated version?
- (c) How do Routine Activities Theory and rational choice theory apply to food fraud prevention?

3. Key Learning Objective 2

- (a) What is Situational Crime Prevention?
- (b) What are the three components of the Crime Triangle and Situational Crime Prevention?
- (c) Where does food science and technology influence the fraud opportunity on the Crime Triangle?

4. Key Learning Objective 3

- (a) What is “designing out crime”?
- (b) Is Food Fraud a “white-collar” or “traditional” crime?
- (c) What are “guardian and hurdle gap”?

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Chapter 8

Criminology Theory (Part 2 of 2): Application Review



Summary

This chapter presents the criminology concepts that include how to visually present the fraud opportunity, how governments have addressed the broader product fraud problem, and then a review of lessons learned from other types of crimes that are related to food fraud. These all apply to not only catching bad guys but for preventing food fraud from occurring in the first place. The first criminology chapter presented the key terms, concepts, and theories. This third part builds upon that knowledge and presents applications such as how practitioners actually address the problem and also how governments or agencies assess the problem or aligns to coordinate responses.

The Key Learning Objectives of this chapter are

- (1) **The Crime Triangle**
- (2) **Review of governmental reports that address product fraud**
- (3) **Other crimes that are related to food fraud**

On the food fraud prevention cycle (FFPC), this chapter addresses the theoretical foundation concepts related to criminology and the fraudster “(A) Theoretical Foundation” (Fig. 8.1).

Introduction

After reviewing the foundational concepts of criminology, it is helpful to consider examples of the application to food fraud prevention. Beyond the main key learning objective, this chapter will include a series of examples or sidebar commentaries. Together, this book provides a foundation for understanding what and how the criminology theory applies as well as develops a “gut feel” for how and when to adopt formal theories to this specific application.

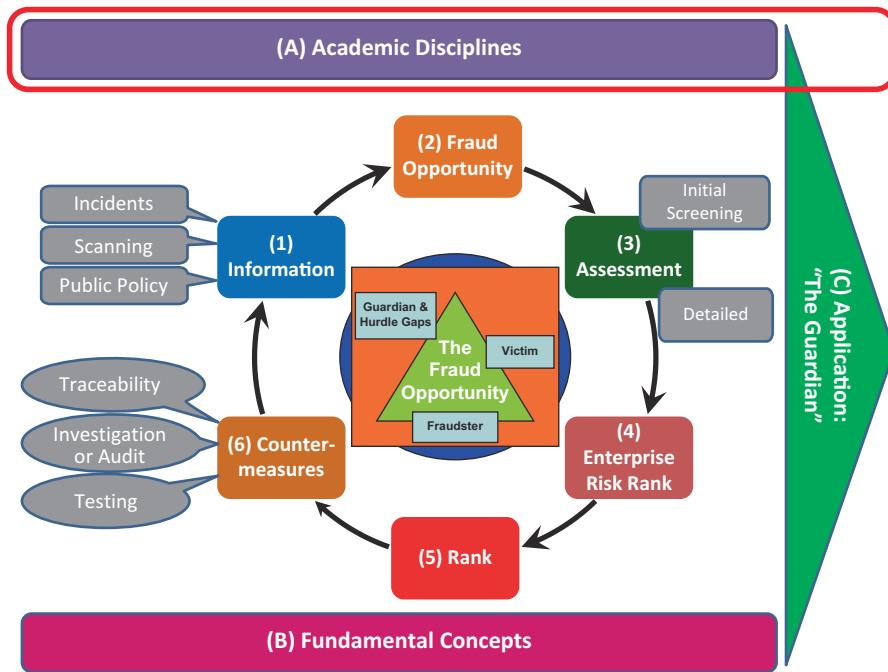


Fig. 8.1 Food Fraud Prevention Cycle—where this chapter applies to the overall concept: “(a) academic concepts”. (Copyright Permission Granted) (Spink 2014a, 2014b, Spink et al. 2019)

Key Learning Objective 1: Simplifying the Crime Triangle for the Food Industry

This section reviews the simplifying of the Crime Triangle for the food industry through examples that help select strategic countermeasure and control systems. The Crime Triangle provides a mental frame to consider how and why a fraudster perceives a fraud opportunity so efficient, and effective responses can be identified.

The Key Learning Objectives of this section are

- (1) The motivation that is macro—or micro—or both.
- (2) The motivation that is a “social scientific conception.”
- (3) Education is a weapon.

Motivation that Is Macro or Micro or Both

It is too simple just to consider that motivation for a food fraudster is “to make money.” That is actually the goal of all legitimate or illegal food businesses or operations. To focus on prevention, there is a need to deconstruct why and how a perpetrator perceived a fraud opportunity for a company protects itself or a government protecting their local consumers. It is also too simple to only focus on macroeconomic trends such as shifting commodity prices. It is too simple to only focus on the role of “organized crime” (i.e., capital “O” and capital “C,” formally defined and categorized organized crime not just a criminal organization or “crime that is organized”). Of course, in general, the macro-level global commodity price and availability fluctuation have an influence, but an individual criminal will decide to act based on their micro-level unique factors.

These micro-level factors are unique to the fraudster. By only considering the macro-economics, the fraud act may seem illogical or impossible. For example, a fraudster may have excess expensive beef product, while they are out of stock of lower-priced horsemeat. In some instances, substituting a **higher** priced product may be the “fraud opportunity.” For example, if an urgent order is received for horsemeat, the fraudster has a decision: (1) turn down the revenue from this order, (2) try to delay the order, (3) try to acquire more horsemeat quickly, or a fraud opportunity to (4) substitute the next best on-hand alternative which happens to be beef. If the order is very important—such as trying to win a new customer or not risk annoying a disgruntled customer—the microeconomic factors lead to the decision.

These microeconomic factors are similar to the criminology concepts of rational choice theory and routine activities theory. The problematic application is that the criminal may not share your idea of what is a “rational choice,” and you may not understand their “routine activity.”

Motivation as a “Social Scientific Conception”

To provide another example of the complexity of generalizing the fraud opportunity or the challenge of general prevention countermeasures and control systems is the “social scientific conception” outlined by Lord, Elizondo, and Spencer (Lord et al. 2017a). They present a “threefold typology of fraud” based on the work of Michael Levi (Levi 2007, 2008, 2016a, b). This theory helps to reinforce that there are many ways that fraudsters decide to commit the act. Lord et al. present three motivations (Levi 2008; Lord et al. 2017b):

1. ***Pre-planned fraud***, where a food fraud activity or scheme is set up from the start with the intent of defrauding victims (e.g., other businesses, individuals, the state);”

2. “**Intermediate fraud**, where people start out obeying the law but consciously turn to food fraud later (likely as a response to a particular event or state or condition);”
3. “**Slippery-slope fraud**, where deception spirals, often in the context of trying, whether absurdly or over-optimistically, to ensure that a business does not go bankrupt or cease trading.”

“The key argument to take from this typology is that ‘motivation to defraud can be heterogeneous [of many sources or reasons] rather than a single phenomenon’” (Lord et al. 2017a). While seeking to understand the many aspects of the motivation and the fraud opportunity, the countermeasures and control systems can be more completely judged. Most importantly, a broad view of the motivation usually shifts a focus to broad prevention and reducing vulnerabilities. When including insight on the “threefold typology,” the food fraud prevention can consider each unique fraud opportunity and assess specific countermeasures and control systems.

Sidebar: Expanding on the Types of Fraudsters Is a Concept by Scholar Michael Levi

Criminology scholar Michael Levi identifies three types of fraudsters being (1) pre-planned (business plan from the start), (2) intermediate frauds (a conscious move to illegal business), and then (3) slippery slope fraud (deception spirals often when trying to save a business) (Table 8.1) (Levi 2008):

- “In ‘The Phantom Capitalists’ (Levi 2016a, b), I suggested the utility of looking at bankruptcy and other frauds in terms of a threefold typology: (1) pre-planned frauds, in which the business scheme is set up from the start as a way of defrauding victims (businesses, public sector and/or individuals), (2) intermediate frauds, in which people started out obeying the law but consciously turned to fraud later; and (3) slippery-slope frauds, in which deceptions spiraled, often in the context of trying—however absurd and over-optimistic—to rescue an insolvent business or set of businesses that in reality had no hope of repaying its debts in the future.”
- For food fraud prevention this is helpful when considering the type of offender organization or how participants shift from legitimate activities to fraud. For all three, if there is no fraud opportunity, then there is no fraud opportunity. For the first two, the fraudsters are actively seeking targets or victims. The slippery slope root cause is a bit different because it is a business that does not really want to commit fraud but is tempted. For this third type, similar countermeasures or control systems apply but the lack of a vulnerability – or the awareness that they might get caught if they attack you – should be a lot more obvious. Investigations and reports of the criminal actions can be “easy to find” for those who are seeking fraud opportunities (Levi 2008).

Table 8.1 The process of fraud and other crimes for gain (Levi 2008)

Concept	Application to a current food industry stakeholder who may be tempted by potential offender
1. See a situation as a “financial crime opportunity”	A person is operating in the food industry and perceives an opportunity during their “routine activities”
2. Obtain whatever finance is needed for the crime	A person may already be working in the food operation or access to manufacturing so may <i>not</i> need new equipment
3. Find people willing and able to offend (if necessary for the crimes contemplated) and who are controllable and reliable	In addition to finding others, co-conspirators are willing to commit the offense; a person may be able to trick their employees or colleagues into inadvertently supporting and engage in the criminal enterprise
1. Obtain any equipment/data needed to offend	A person may already be working in the food industry and thus may already have insight or data from their current routine activities—they may become inadvertently aware of opportunities. This is within the “occasional” type of counterfeiter (Spink et al. 2013)
5. Carry out offences in domestic and/or overseas locations with or without a physical presence in the jurisdiction(s). This will usually involve manipulating—with varying degrees of complexity, technology, and interpersonal communication skills—victims’ perceptions of “what is happening”	For food fraud, there does need to be a direct transfer of the material good to the victim, but this can be accomplished without direct physical contact either through contracted delivery, through a courier including an e-commerce mail shipment or even pick up from a neutral location
6. Minimize immediate enforcement/operational risks. Especially if planning to repeat frauds, neutralize law enforcement by technical skill, by corruption, and/or by legal arbitrage, using legal obstacles to enforcement operations and prosecutions which vary between states	A person would be conducting the criminal activity in a “private setting” and also within a current trusted relationship that may not have intense oversight (see Felson and The Ecosystem of Organized Crime)
7. Convert, where necessary (e.g., where goods rather than money are obtained on credit), products of crime into money or other usable assets	A person needs to figure out how to mask their illegal gains, and sophisticated money laundering may not be in the expert area without expanding the operation to other co-conspirators
8. Find people and places willing to store proceeds (and perhaps transmit and conceal their origin)	Depending on the number of criminals involved and the scale of the criminal cooperation, a person may just be pocketing the extra cash, laundering it through the legitimate business, or creating a web of shell companies to receive the proceeds

(continued)

Table 8.1 (continued)

Concept	Application to a current food industry stakeholder who may be tempted by potential offender
9. Decide which jurisdiction(s) offers the optimal balance between social/physical comfort and the risk of asset forfeiture/criminal justice sanctions. Indifference in any one state or sub-state arena may suffice to neutralize an investigation, and staffing inadequacies, as well as corruption, may be the cause of official inaction	A person may already be operating within the food industry so already in the supply chain, so there are no necessary additional decisions

Expanding on the concept of how a person is tempted to conduct a fraud action is the development of a general type of crime scripts. The scripts are processes or required components that could create a “motivated offender.” There may be a misconception that this section is positioned to “blame the victim” since the countermeasures and control systems do not consider the fraudster. This section actually focuses on the guardianship or “guardian and hurdle gaps” since this is where the most direct controls can be implemented and controlled. In this scenario, the victim is often also in the role of guardian. This type of proactive, preventive approach is consistent with quality management efforts. For example, ISO quality management is based on “enhanced focus on root-cause investigation and determination, followed by prevention and corrective actions” in combination with “enhanced ability to anticipate and react to internal and external risks and opportunities” (ISO 2015).

Education as a Weapon

When starting to address food fraud, there is a frustration and concern that the criminals may research and try to circumvent or neutralize the countermeasures and control systems. Generally, product fraud prevention—and prevention of crimes that are complex or organized—is a chess match against very skilled and highly motivated adversaries. Once this is understood and accepted, many of the prevention actions are more transparent and more straightforward. While each and every action should not be made public instead of trying to keep the entire program confidential, there is some information that really *should* be shared publically. If the fraudsters do not know you are implementing new food fraud detection tests, then all you will do is “catch” fraudulent product and not actually prevent it!

Considering the worst-case situation is that fraudsters will conduct a thorough review, monitor, and test your countermeasures and control systems for weaknesses; this is just another consideration in the prevention strategy. Several important strategy considerations include:

- Constantly adjust or change the prevention system (so if they do not adjust their fraud act that they will eventually get caught).

- Find a way to delicately but effectively enable fraudsters to find that there are fraud detection and prevention actions (so they are dissuaded from attacking).
- Increase to the point where there are many other better opportunities for the fraudster (this is crime displacement that can be implemented to the point that there is an extremely low or no fraud opportunity).

It is highly recommended that a food fraud prevention strategy includes a team member from the corporate communications staff. This will establish an official and informed evaluation of the balance between the benefit of tipping off bad guys that you are a hard target while not coincidentally increasing the general liability or to inadvertently create consumer panic. For example, there is a possible increase in general liability from public statements or actions by employees that end up creating risks or costs for a company. For example, there may be responsibilities if *anyone* at a corporation conducts a formal Food Fraud Vulnerability Assessment that is public and identifies a “suspicious activity.” This risk awareness may become a requirement for the company to investigate the problem or possibly even be legally required to report this suspicious activity to the government—not reporting the known vulnerability may be, in and of itself, a crime. Also, regarding package labeling or information materials, a statement on a package of information materials such as “new anti-counterfeit features for your safety” sounds great, but consumers could interpret this as “our product is counterfeited so other products are safer.”

The goal is that if a fraudster is scouting for new targets that your product, brand, or company does not appear attractive. There are several ways that proactive and benign messages can be communicated that you are a hard target and have a competent food fraud prevention strategy. Examples of the communication weapons include:

1. Mentioning food fraud in supplier contracts noting requirements for a vulnerability assessment and strategy,
 - (a) To go a step further, whether the action can or would actually take place, to require suspicious activity to be reported by your employees to government law enforcement, food agency, and customs authorities. If possession and ownership do not transfer until the product is accepted and then if the government seized the product, the supplier would lose the cost of the entire shipment (and you would not be liable for paying that invoice).
2. Including a review of food fraud prevention activities during supplier audits or interviews.
3. Sharing food fraud information in supplier newsletters or news alerts.
4. Recommending food fraud prevention training or education resources such as webinars or online classes.

Finally, “education as a weapon” refers to strategically using training and education resources as a warning to suppliers, potential fraudsters, and fraudsters that you are aware of the vulnerability and taking action. Education is a weapon in your food fraud prevention arsenal since even just communicating the links to courses could

lead the fraudster to increase their concern for you as a target which would reduce the fraud opportunity.

Sidebar: Translating Courses—“MOOC to Mandarin”

From MSU press release: July 8, 2014

Mandarin Language MOOC

“We are pleased to have received a sponsorship from the Wal-mart Food Safety Team to translate our MOOC to the Mandarin language, focusing on our Chinese partners. Wal-mart issued a global press release:

Wal-mart to Sponsor Food Fraud Prevention Online Course In China, PR Newswire, Wal-mart China, June 29, 2014, <http://finance.yahoo.com/news/wal-mart-sponsor-food-fraud-prevention-020000444.html>

From the Wal-mart press release:

Frank Yiannas, Vice President of Food Safety for Wal-mart said, “At Wal-mart, we take the issue of food fraud very seriously. Because prevention of food fraud is a shared responsibility and education is a key to deterrence, Wal-mart is delighted to be able to help Michigan State University make the course more broadly available to regulatory officials, industry professionals, consumers and other stakeholders in China.”

Dr. Spink said, “We are grateful for forward-thinking companies like Wal-mart who are working, and investing in, improving the safety of the world’s foods.” He elaborated that, “When we rapidly expand the education and awareness-building at this early stage in the development of the science, we can more efficiently establish a starting point and trajectory of our actions.”

“Food fraud has been recognized as a common challenge not only for retailers but also the whole supply chain,” Wal-mart China Chief Compliance Office Paul Gallemore said. “As the largest retailer in the world, Wal-mart intends to leverage global food safety expertise and best practices to help our suppliers address the problem together in order to provide even greater assurance of food product quality, authenticity and safety to our customers.”

Please join us in creating a public forum and expanding awareness of the fraud vulnerability. By participating in the MOOC, you demonstrate that this concept is vital to your organization. By forwarding this information to your colleagues around the world, you help build harmonization of terms and the prevention focus.”

Sidebar: Publication—“Defining the Types of Fraudsters” and “Development of an Incident Clustering Tool”

Another example of adapting and applying the criminology theories is presented in this blog post that summarizes two articles. The first article

researched and published definitions of the types of counterfeits and types of counterfeiting and identification of the offender organizations. Previously, the definition of the concepts had not been the subject of a peer-reviewed, refereed, scholarly journal article. The second article applied those terms and introduced an incident clustering tool. This tool enables the organization of incident details to allow a focus on the most important and frequent types of problems.

The incident clustering tool was published in the ISO 22380 Security and resilience—authenticity, integrity, and trust for products and documents—general principles for product fraud risk and countermeasures under the Technical Committee 292 on Security Management and Resilience. This is an important step since the method is being codified by an international standard organization after an international, official government-entrusted partners' thorough, rigorous, consensus-based review process. The ISO standard—in addition to other standard activities such as Codex Alimentarius, GFSI, and others—will expand the use of the tool and support more harmonization and enable sharing of best practices. While the ISO process is not quick, it is thorough and builds a global consensus. This standard was conceived in an ad hoc product fraud terminology workgroup in 2014 (the work changed from Technical Committee 247 Fraud Countermeasures and Controls, WG2 ISO WD 19564 Product Fraud Countermeasures and control—General Principles—to TC 292 and the same content and title but now ISO 22380) (ISO 2018). The time and effort are important since it supports the harmonization of all terms, the focus on prevention, and now standardized processes that can be benchmarked and refined.

Start of the excerpt (MSU-FFI 2018):

Title: New Publications – ‘Defining the Types of Fraudsters’ and ‘Development of an Incident Clustering Tool’

By John Spink • April 30, 2014 • Blog

We just published two articles that are already contributing to advancing food fraud prevention. They are scholarly, peer-reviewed publications, which are especially helpful in supporting the development of government regulations and reports (scholarly journals meet the government need for “science-based” insight). These articles are already making an impact, as they are cited in a product fraud standard by the International Standards Organization (ISO). Both articles are published in an “open” journal so you can access them for free in the two links below.

The peer-review process is important not only for developing the theories but also because the rigorous process supports the articles as credible. We had some excellent and vital discussions and revelations during the intense review

(continued)

process. We would like to especially recognize Crime Science Journal editor Dr. Gloria Laycock, University College London, for her support and encouragement.

Beyond collaboration with the editors and reviewers, my co-authors and I are entrenched in the evolution of the research. By being directly involved with the theorists and practitioners, we can get a better feel for what exactly is needed. This series of articles and the implementation of standards and certifications is an example of the value of this research immersion.

The first article is a research project studying the fraudsters, the fraud act, and the fraudster organizational structures. The second article described a tool we developed to organize the often seemingly disconnected incident data. The first article helps establish the foundation, and the second helps us understand the data that will inform decision-making. Using these definitions and the incident clustering tool will help with the selection of efficient food fraud prevention countermeasures and control systems.

Regarding “Defining the Types of Counterfeitors, Counterfeiting and Offender Organizations” (Spink et al. 2013):

- We realized that before we presented the incident clustering tool, we needed to establish and define the core definitions. We were surprised to find that terms like “counterfeiting” and “counterfeiter” had not been the focus of an academic research article – many articles or reports just state definitions without any scholarly review. This article will help future researchers because instead of spending limited article space on justifying their interpretation of the definitions they can just cite this article. This actually helped us in our second article, where we could quickly review the terms but not go into the typical excruciating academic detail.

Regarding the “Development of a Product-Counterfeiting Incident Clustering Tool (PCICT)” (Spink et al. 2014):

- We had been trying to organize incident data and could not find a product fraud-related application directly addressed in a scholarly journal. We also didn’t find any standardized incident analysis model or tool. So we started with core crime science and Situational Crime Prevention (SCP) and adapted it to provide insight specifically for product fraud incidents. The tool has already been a great help, and we have used it many times.

An example of the impact of these articles is considering the use such as by the International Standards Organization (ISO) projects. Both articles are already being quoted and referenced in standards and certifications. I am the Chair of the US Technical Advisory Group ISO Technical Committee 247 on Fraud Countermeasures and Controls. Co-author Dr. Hyeyonho Park leads the Korean group. We have collaborated on many ISO projects, including a terminology standard and now a New Work Item Proposal (NWIP) based on these

two articles. It was during our ISO work that we realized the need for a standard and a scholarly article, so the articles were really driven by the practitioner need.

A third, related publication is “When Crime Defies Classification: The Case of Product Counterfeiting as White Collar Crime” (Heinonen et al. 2014). This project was led by Dr. Justin Heinonen while he was an Assistant Professor in the School of Criminal Justice at MSU. He has a very sound theoretical criminology foundation that was established during his Criminology Ph.D. work at the University of Cincinnati under the tutelage of committee members John Eck and Bonnie Fisher.:

- The connection to food fraud is that it defines how the crime exhibits white collar crime characteristics in the planning (and prevention), and traditional crime in the act (humans consuming the products). This is an important – critical – point when considering how the crime is classified, which influences the government’s focus on enforcement, prosecution, and preventative countermeasures and control systems. A key is that white collar crimes are often perceived as “victimless crimes.” This article lays a firm, theoretically sound foundation that food fraud and product counterfeiting are hybrid crimes. This article will contribute to ongoing reviews such as the UK Elliott Review of food fraud, the EU/DG-SANCO-led resolution on food fraud, and the China National Center for food safety Risk Assessment work in examining broad countermeasures and control systems. It will also contribute to the food fraud-related work of the Global food safety Initiative and possibly future reviews of food fraud by the US Congressional Research Service.

The food fraud and Product Fraud concepts are maturing. Peer-review articles are a key to the process. Beyond the journal being accessible through the most extensive scholarly databases, we felt these were such important topics that we sought publication in “open” journals that are free for anyone to access. The more people, who get full, free access to the articles, the more people who can use the concepts and the more significant impact of the work. These open educational resources (OER) are an important growing focus for academia. The goal is not to just fill our Curriculum Vitae/ Resume [...] why we should lock away great research where no one can find it? Please stay engaged and asking questions. We will continue to listen and try to support your needs.

Government and Law Enforcement Priority Setting

There are several key concepts to help to understand the government and law enforcement priority setting which is based on the direction set by resource allocation by the legislative branch.

Sidebar: Law Enforcement Priority Setting—“Who Cares?” (Where Is Food Fraud a Priority and Who Funds the Work and for How Long?)

After reviewing the fundamental theories, the key terms, and the analysis of the problems, there is a need to focus on the practical question of who is accountable and who will actually take action. After an incident, there are often outrage and public demands that the “government” “do something.” Law enforcement officers seek training and education on how to investigate and develop cases, so there is no lack of interest. As with business enterprise-wide assessments and priority setting, governments must also consider the scarce human and economic resources.

At the Food Fraud Conference in April 2017—and he reinforced in October 2017—the US FDA Deputy Commissioner of Foods, Dr. Steven Ostroff, posed the question of: “Government Priority Setting: “In circumstances where no regulatory agency has unlimited resources, where and how does EMA [Food Fraud] fit onto a list of priorities” (Ostroff 2017a, b; Newkirk 2018).

Dr. Ostroff responded that they consider the FDA mission as a public health agency and prioritized problems with—severe—health hazards. Considering this point, the commercial food fraud issues would be under the US Federal Bureau of Investigations (FBI) and the related economic issues possibly under the Department of Commerce (DOC) which would be pursued by FBI or others such as the US Marshals. From the FBI website in 2018, When considering “who cares” and “who has funding,” the publically stated agency priorities are a starting point (FBI 2018):

- **US FBI Priorities (2018)—in order:**
- (1) Protect the United States from terrorist attack.
- (2) Protect the United States against foreign intelligence operations and espionage.
- (3) Protect the United States against cyber-based attacks and high-technology crimes.
- (4) Combat public corruption at all levels.
- And others.

Also for reference, here are the FDA strategic priorities, 2014–2018, FDA (FDA 2018):

- **FDA’s core mission goals and objectives are:**

- Goal 1: Enhance oversight of FDA-regulated products.
- Goal 2: Improve and safeguard access to FDA-regulated products to benefit health.
- Goal 3: Promote better informed decisions about the use of FDA-regulated products.
- Goal 4: Strengthen organizational excellence and accountability.

Another way to consider the question is “importance vs. priority.” From the OECD report on The Economic Impact of Counterfeiting and Piracy (OECD 2007):

“Importance vs. priority – From an industry perspective, there is frequently a difference between the importance that governments attach to counterfeiting and piracy, and the priority is given to relevant authorities (such as police, customs, and prosecutors) when resources are allocated, and there seems to be some logic to explain their experiences. For example, it would be understandable that a greater proportion of resources are allocated to areas that deal with the more serious illicit activities, such as drugs, weapons, and people-smuggling, or even smuggled goods that avoid excise. As a serious, but “less serious” crime, counterfeiting and piracy could find itself towards the tail end of resource-allocation priority lists. Within the resources allocated to counterfeiting and piracy, there is also some logic for a pragmatic (if not intentional) hierarchy. For example, efforts to uncover pharmaceutical, food and drink, car parts and other items that have potential health and safety risks, may have greater access to resources than the more innocuous items, such as CDs, DVDs, and t-shirts. These priorities are matters for governments, and it is up to them to decide how to allocate their resources, but it is nevertheless worthwhile to at least note that in the experience of industry there is a clear difference between importance and priorities.” (OECD 2007)

Considering this hierarchy of priority, food fraud is not within the definition of “high technology” and not to the threshold of “public corruption.” Food fraud would not only *not* be a high priority; there is no category where it would be included.

To explore this challenge, over 2011–2012–2013, the MSU Food Fraud Initiative conducted surveys of the residents of the State of Michigan (USA) regarding several intellectual property rights topics including law enforcement priority setting. The findings were (Spink 2014a, b):

- “There was general support for increasing the investigating and prosecuting product-counterfeiting incidents (55% supported).”
- “There was little support for increasing funding or incarceration rates if it takes away from other types of law enforcement activity (2% supported).”
- “Of this, a minority (29% supported) supported increasing taxes to fund the anti-counterfeiting activities.”

Considering more detail from that report (Spink 2014a, b)

“Related Law Enforcement Priority Setting:

(continued)

- “While there is general support for investigating and prosecuting product-counterfeiting incidents, there is little support for increasing funding or incarceration rates if it takes away from other types of law enforcement activity. There is an opportunity for State and Local law enforcement to continue to try to pursue federal or industry-funded enforcement. In 2013 there was a drop in the respondents who thought the “government” should do “more” to combat counterfeiting (from 56 then 59% to 51% in 2013). There was also a drop in the percent for who tax support – 71% did not support more taxes to fund the anti-counterfeit activities.”

This research provides valuable insights into several aspects of product counterfeiting that are important for a holistic and all-encompassing perspective on public policy trends. These include:

- “While this assessment is concerning the lack of human or financial resources for law enforcement investigation and prosecution is a fact. Government funding is not growing as directed by the taxpayers instructing their elected officials. FDA, FBI, or other law enforcement has been willing to expand their operations and focus on product fraud, but there has been a lack of resources. Agencies are already capacity constrained and they – themselves – need to prioritize for their maximum impact. When the resident and lawmaker priority is “public safety (drugs, guns, violence including terrorism), public health (major public health incidents), and then large-scale economic crimes that disrupt governments or markets, and then de-escalating economic crimes” food fraud would be at the end of the list.”

To get to the question of “Who cares?” this ends up being based on who is harmed the most and who will be punished for not addressing the problem. A more important influence in the broad prevention or intervention activities is “Who pays?” This is a good question since as of June 2017 the total number of US-funded grants with the term “food fraud” or “economically motivated adulteration” was four (4). (To note, an ERM approach would help define if this was too little or too much government investment.)

The application to food fraud prevention is that the role of law enforcement is often minimal due to constrained resources and mandates a shift for victims to focus intensely on prevention. “New plans or expansion of scope should consider that there will probably be no—or little—additional resource allocation or funding for inspection, enforcement, and prosecution. For any expanding or new regulations it will be important to incorporate and leverage current activities” (Spink et al. 2016, 2019).

Sidebar: US DOJ Guidance on “Deciding Whether to Prosecute an IP Case”

When considering food fraud prevention, a key insight is the role of the prosecutors and courts including an understanding of their priorities. One type of food fraud is intellectual property rights counterfeiting. While this section only addresses counterfeiting, the insight is valuable when considering and government enforcement and prosecution priority setting.

Regarding criminal prosecution and conviction, there are many steps in the process including the Department of Justice setting priorities for the limited resources of the prosecutors, the judiciary, and the penal system. There are a wide range of illegal acts that—while still illegal and could lead to prosecution and incarceration—are not prioritized. One way to gain insight is to examine guidance for the prosecutors including the US Department of Justice (DOJ) published “Prosecuting Intellectual Property Crimes” (this fourth edition in 2013 is an update from 2006 earlier in 2001) (Goldstone 2001; DOJ 2006, 2013)).

The DOJ routinely publishes guidance for the US prosecuting attorneys. This document was published by the Computer Crime and Intellectual Property Section (CCIPS). While this document, not a law with “no regulatory effect, confers no rights or remedies and does not have the force of law,” it does provide “assistance not authority” in how these employees meet their key job responsibilities.

There is an awareness that civil or criminal liability may be “a cost of doing business” and the perpetrator may “and continue their infringement after civil sanctions, albeit with different products or under a different corporate guise.”

One key insight is “When Infringement Is Criminal” (emphasis added):

“Any instance of infringement will generally entitle a copyright owner to a civil remedy, such as damages or injunctive relief. But not every infringement is a criminal offense. Throughout the history of copyright in the United States, criminal copyright penalties have been the exception rather than the rule. Although criminal copyright law has greatly expanded the scope of the conduct it penalizes over the past century, criminal sanctions continue to apply only to certain types of infringement—generally when the infringer knows the infringement is wrong, and when the infringement is particularly serious, or the type of case renders civil enforcement by individual copyright owners especially difficult. As described in more detail below, a willful violation of any exclusive right for commercial advantage or private financial gain is a misdemeanor, whereas only a violation of the rights to reproduction and distribution under certain circumstances constitutes felony infringement.”

A challenge for prosecutors is to prove “beyond a reasonable doubt” that the accused “knows the infringement is wrong.” They emphasize that both the felony and misdemeanors require a “willful violation.”

Specifically of interest is the section on “Charging Decisions” or what and when cases should be prosecuted.

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“Broken down further, the relevant considerations include (emphasis added):

- The federal interest in intellectual property crimes.
- Federal law enforcement priorities.
- The nature and seriousness of the offense.
- The deterrent effect of prosecution.
- The individual’s culpability in connection with the offense.
- The individual’s criminal history.
- The individual’s willingness to cooperate in the investigation or prosecution of others.
- The probable sentence and other consequences of conviction [including the length of sentence].
- Whether the person is subject to prosecution in another jurisdiction.
- The adequacy of alternative non-criminal remedies.
- Special considerations for deciding whether to charge corporations.”

Next, special considerations of “the following factors in determining whether to commence prosecution” (emphasis added):

- ‘a) the scope of the criminal activity, including evidence of involvement by a foreign government, foreign agent or foreign instrumentality;
- ‘b) the degree of economic injury to the trade secret owner;
- ‘c) the type of trade secret misappropriated;
- ‘d) the effectiveness of available civil remedies; and
- ‘e) The potential deterrent value of the prosecution.”

Further on the “nature and seriousness of the offence”:

- “The offense’s nature and seriousness are indicated by the usual factors, with special importance placed on
 - threats to health or safety, ...
 - the volume of infringement as measured by the amount of revenue and profit, ...
 - the involvement of organized crime, ... and
 - Whether substantial harm was done to the reputation of the rights holder.”

The guidance provides additional priority setting considerations (emphasis added):

- Federal criminal prosecution is most appropriate in the most egregious cases. ... Even then, the government must prove its case beyond a reasonable doubt, including a high state of *mens rea*.
- Limited federal resources should not be diverted to prosecute an inconsequential case or a case in which the violation is only technical. Even some

branches of civil intellectual property law recognize the maxim, “*de minimis non curat lex* [Note: “The law does not care for, or take notice of, very small or trifling matters. The law does not concern itself about trifles” (Black’s 2014).].”

- Federal prosecution is most appropriate when the questions of intellectual property law are most settled [the violation of the law is clear, obvious, and has a history of case law].
- Victims have a broad range of civil remedies that include restitution, damages, punitive or quasi-punitive damages, injunctions, court costs, and attorneys’ fees.
- The more strongly an intellectual property owner acts to protect its rights, the stronger the interest in prosecution.
- Many intellectual property offenses include multiple victims, not only the owners of the intellectual property that was infringed but also customers who were defrauded. Both classes of victim deserve protection, and one class’s lack of interest in prosecution should not countervail prosecution when the other class’s interest is strong.
- The sources or manufacturers of infringing goods and services are generally more worthy of prosecution than distributors.
- Counterfeit goods or services that endanger the public’s health or safety deserve the highest consideration for prosecution.

Finally,

“The Adequacy of Alternative Non-Criminal Remedies”:

- “Department of Justice policy allows a prosecutor to decline criminal prosecution in a situation that could be adequately addressed by non-criminal remedies. Almost every federal intellectual property crime has an analog in civil law—be it state or federal—and those laws generally offer victims generous relief, such as injunctions, restitution, damages, punitive and quasi-punitive damages, court costs, attorneys’ fees, and even ex parte seizure of a defendant’s infringing products.”
- “The prosecutor should also consider whether existing civil remedies have been or are likely to deter a particular defendant. For those undeterred by civil suits and remedies, criminal prosecution may be more appropriate. When the defendant has violated an earlier civil order, however, civil or criminal penalties for contempt of court may be an acceptable alternative to prosecution for criminal intellectual property violations.”

For food fraud prevention, it is important to consider the role of the courts in the reduction of the fraud opportunity. This section provided an awareness of the resources, priorities, and information needed to pursue criminal prosecution. A key first step for protecting a company is to protect the product and reduce the fraud opportunity.

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Counterfeit Wine Food Fraud Part I: The Challenge of Enforcement and Prosecution with a Review of the Wine Spectator Article (MSU-FFI 2018)

Title: Counterfeit Wine Food Fraud

By John Spink • December 2, 2015 • Blog

“Counterfeit wine is almost as old as wine itself, a problem that [Roman Philosopher] ‘Pliny the Elder’ decried in first-century Rome.” A wine expert stated that “if someone is faking *Miraval*, a \$25 rose, I could be drinking counterfeit rarities.” This is a review of the November 30, 2015, Wine Spectator Magazine article of the investigation and prosecution of a major wine counterfeiting operation in the USA. The focus of the Wine Spectator story was on the collectible, rare wines (\$1000+/bottle) but there is also a discussion of more common wines.

The report on food fraud counterfeit wines provides insight into the very complex investigations and the priority-setting challenges for law enforcement.

Wine Spectator Article

Wine Spectator is a leading English-language magazine that covers wine. Its recent cover story was about the food fraud counterfeit wine case of Rudy Kurniawan who was arrested in Los Angeles in 2012 and who received a 10-year federal sentence in 2013 for wire and mail fraud. “The FBI believes Kurniawan made more than \$130 million in sales this way. These fakes were often well-crafted blends of old wines from poor vintages and young wines, designed to fool experts even when they opened and tasted.” (Note: the [DOJ.gov](#) press release states \$30 million.)

Also “No one knows exactly how large the [overall product] counterfeit problem is, but a report by the International Chamber of Commerce projected that more than \$1.77 trillion worth of counterfeit goods will be traded worldwide in 2015, up from \$550 billion in 2008” [Note: this estimate and report was the subject of a previous article reviewed in a previous blog post]. The wine spectator article did mention several wine food fraud incidents. There were no mentions of health hazards. The incidents mentioned were:

- \$2.8 million for 400 + bottles (\$7000 per bottle)
- \$60 million for 1.8 million bottles over 10 years (arrested for importing 1.4 million liters of table wine and bottling it as *Brunello* and *Chianti Classico*—60 shipping containers) (\$33 per bottle)
- \$4 million for 20,000 cases (\$16 per bottle)

Food fraud for a product like wine can fall into several categories, with a range of consequences, which lead to priority setting by law enforcement. To classify the investigation, rare wines were more categorized as “collectibles” and directed to the

FBI/ DOJ artwork forgery investigators. “They were collectible. Whether the collectible at issue is art or antique or wine.” As with many counterfeit cases, it is difficult to prosecute unless the seller knowingly sells a fake. For example, in a report by the US Chamber of Commerce/Coalition Against Counterfeiting and Piracy, the law firm Tory’s stated that “every” counterfeiter they prosecuted stated they were just diverting genuine product—so the counterfeiters say “prove it.” “[The DOJ’s] biggest question was whether Kurniawan was a counterfeiter or had been duped into selling fakes he’d purchased unknowingly.” If there was a health hazard (e.g., illnesses or deaths)—or even a vulnerability that violated FSMA or FD&C—this would have been a priority for FDA and even FBI.

A major base of evidence and insight for this investigation and prosecution was from a previous private investigation funded by “William Koch, the energy company billionaire, and avid wine collector who in 1985 purchases four bottles of wine he understood to be eighteenth-century Bordeaux once owned by Thomas Jefferson.” A 2003 Forbes article noted that a single Jefferson bottle was insured for \$225,000. In a 2011 California Court of Appeals document, Koch vs. Kurniawan identifies five bottles from 1934 to 1949 that cost a combined \$75,000. “‘Koch was a great resource,’ says Wynne. ‘He had been defrauded and had no problem saying. ‘I’m the victim.’”

The investigation and prosecution were helped by Kurniawan’s naiveté when a raid found his entire counterfeiting operation...in his house. All that evidence—and the case—was almost thrown out because the search of the house was conducted for a “protective” sweep looking for other dangerous criminals. The article noted that Rudy and his mother were the only people home. The situation did not seem to be very dangerous:

“Rudy Kurniawan [38 years old], a man of slight build, with piercing eyes under heavy brows, stands there in his silk pajamas.” He was standing in front of his house in “This leafy, suburban Los Angeles neighborhood just east of Pasadena, is the home to the Santa Anita horse track and the city’s botanical gardens.” “His mother, who owned the house and lived there with her son, was asked to stand beside him. To make sure the house was empty, [the FBI special agent] Wynne ordered some of his men to perform a protective sweep.”

The case and prosecution hinged on that critical “smoking gun” of the seizure of the “counterfeiting paraphernalia.”

Also, less than 10% of federal cases actually go to a trial, so this was a major resource commitment for the federal court and attorneys.

Law Enforcement Conundrum: Priority Setting

The Wine Spectator Magazine article covered the investigation and noted: “The case was a first [counterfeit wine] for federal law enforcement...” (note: a search of the DOJ.gov website resulted in only this case). The investigation took 21 months from the raid to the wire and mail fraud conviction. The court case took 8 months. Beyond the time and effort for this type of case, expertise is often a problem where

“The Justice Department did not have any wine specialists in its ranks.” The government expertise was lost since the FBI investigator retired, and the article stated he now worked for the bank HSBC. An internet search found the DOJ Assistant US Attorney now a shareholder at the law firm Stearns Weaver since 2014.

In general, there is a challenge to prioritize complex or nonviolent cases. If this had been classified an intellectual property rights counterfeiting case, rather than a collectibles/art case, it would be handled by the DOJ Computer Crime and Intellectual Property Section (CCIPS). A review of the 2015 DOJ press releases for Computer Crime and Intellectual Property Section (CCIPS) resulted in 70 entries comprised of 4 pornography cases, 28 intellectual property rights/counterfeiting, and 34 cybercrime/trade secret theft (we did not review for duplicate cases). The DOJ 2014 Annual Review stated that there were over 12,000 cases “favorably resolved” in FY 2014.

There is citizen interest for increased enforcement but a lack of support for diverting other law enforcement resource or for raising taxes. From one of our previous survey reports:

“Related Law Enforcement Priority-Setting. It was found that 55% of Michigan residents thought the “government” should do “more” to combat product-counterfeiting and 71% of the overall sample did not support increased taxes to cover the additional activity. Also, of the 55% that thought the government should do more, 82% of them did not support diverting resources from other crime-fighting activity and 76% of them did not support increased prison time if it meant other types of prisoners would be released.”

Additional insight on law enforcement priority setting can be gained from a November 2015 New York Times article on cyberstalking. “[The lead detective] knew that [the criminal] was causing real harm, but he didn’t seem to have good options. “The ordeal [of one incident] cost the taxpayers of Ontario [California, USA] \$6,500, yet it was sometimes difficult for the Ontario detective assigned the case to justify spending time on it. ‘I have felony cases sitting on my laptop,’ he says. ‘Why would I take this cyber case, tracking all these records, trying to find a guy who’s in another country?’” To note, the criminal pleaded guilty to 23 counts and sentenced to 16 months in youth jail and will be released in 8 months at age 18.

DOJ Priorities

To review all food fraud, product counterfeiting, and this collectibles case in more detail, it is important to consider the overall DOJ priorities set by Congress. The publicly stated—and US Congress approved—DOJ priorities for US law enforcement. For 2014 these were:

- Priority Goal 1, National Security: Protect Americans from terrorism and other threats to national security, including cybersecurity threats.
- Priority Goal 2, Violent Crime: Protect our communities by reducing gun violence using smart prevention and investigative strategies in order to prevent violent acts from occurring.
- Priority Goal 3, Financial and Healthcare Fraud: Reduce financial and healthcare fraud.

- Priority Goal 4, Vulnerable People: Protect vulnerable populations by increasing the number of investigations and litigation matters concerning child exploitation, human trafficking, and noncompliant sex offenders and by improving programs to prevent victimization, identify victims, and provide services. This includes goals to open investigations concerning noncompliant sex offenders, sexual exploitation of children, and human trafficking.

Collectables and rare wine, or even intellectual property rights counterfeiting, were not on this priority goal list. The victims did not fall under the definition of “vulnerable people.”

Overall Review

The future support for this type of problem (IP-related crimes for food such as collectible wines) investigation is challenging for many reasons:

- No health threat (and no public safety or violence threat).
- The crime classification was collectibles/art.
- There were few victims.
- Victims were not a “vulnerable people.”
- This was a complex case especially compared to a felony drug or weapon charge.
- The type of evidence was novel for the courts, complex to explain, and vulnerable to be dismissed.
- The nature of the evidence and case led to an actual trial and appeal—fewer than 10% of federal cases go to a trial, so this was an unusually and inefficiently high resource commitment for DOJ (to consider the BATNA and opportunity cost, what other case or cases could the prosecutor, investigator, and courts addressed?).
- There are already limited resources for collectibles/art or even for product counterfeiting cases. DOJ prosecuted 28 intellectual property cases nationwide in 2015.
- Not a “Priority Goal” area for DOJ.

It is always interesting to review details of food fraud cases that make it to court and that results in a criminal prosecution. It is important to review these details to understand how enforcement and prosecution can contribute to prevention. Law enforcement and the courts are under tremendous pressure, with constrained resources, and they need to be diligent in their focus on the priorities set by the Congress, which is national security, violent crime, financial and healthcare fraud, and vulnerable people—specifically, sexual exploitation and human trafficking. This is an important insight that underscores the importance of companies focusing on prevention. Law enforcement and prosecution play a critical role in combating food fraud, but the most efficient and effective countermeasures and control systems—for companies or countries—are prevention. MSU-FFI.

Key Learning Objective 2: Review of Governmental Reports that Address Product Fraud

This section reviews several US government reports that address product fraud or food fraud. These provide insight into the broad understanding of the problem and the governmental approaches. The official reports are important because they are often used as formal references or official resources by government agencies in both priority setting and by legislators for policy-making.

The Key Learning Objectives of this section are

- (1) Government Accountability Office reports are official government critiques of about the efficiency of government response to problems.
- (2) Congressional Research Reports are asked by the legislators and provide information or policy-making.
- (3) Other government-funded reports that will include “Crime Analysis for Problem-Solvers in 60 Easy Steps.

GAO Expanding from IPR and Economic Adulteration to Food Fraud

Before getting to the Food Safety Modernization Act (FSMA), several other important US Government reports will be reviewed. Since the food fraud/EMA laws and regulations are still in development, insight to Congressional thinking can be found in related reports. For example, the Government Accountability Office (GAO) and the Congressional Research Service (CRS) report on intellectual property rights or other food issues. The role of GAO is to review how agencies are responding to a specific law and to recommend changes. The role of CRS is to provide the US Congress with background information on hot topics that are presumably being considered for new legislation. Typically, agencies respond to GAO recommendations.

GAO-Intellectual Property (2007, 2010) In October 2007, the GAO published “Intellectual Property – Risk and Enforcement Challenges” and “Better Data Analysis and Integration Could Help U.S. Customs and Border Protection Improve Border Enforcement Efforts” (GAO 2007). This was followed in April 2010 by a significant deeper review in “Observations on Efforts to Quantify the Economic Effects of Counterfeit and Pirated Goods” (note: the acknowledgment includes “Individuals or organizations that we met with for these structured interviews are listed below: [...] John Spink, Michigan State University”) (GAO 2010). These were in a series of intellectual property rights themed of GAO reports (e.g., 2001, 2002, 2007, 2010, 2016, 2018, and others). The general conclusions are that there should be “more” coordination between agencies. One result from the formal questioning and recommendation for more coordination was the Prioritizing Resources

and Organization for Intellectual Property Act of 2008 (PRO-IP Act) established the US Intellectual Property Enforcement Coordinator (IPEC). It is important to note that IPEC is assigned to focus only on intellectual property rights counterfeiting and not focus on all types of fraud. Also, the focus is on enforcement and not broader prevention concepts. This group coordinates IP enforcement across all agencies. This added to the work on the National Intellectual Property Rights Center (IPR Center) that is working with 19+ US and international agencies.

GAO-Seafood Fraud (2009) In February 2009, the GAO published a “seafood fraud” report (GAO 2009). The report identified seafood fraud as a concern, an issue that agencies must deal with based on a law. Also, GAO identified the opportunity for more collaboration between agencies specifically, FDA, Customs, and National Maritime Fisheries Service (NMFS). There was a general emphasis on prevention but no guidance or vision for the holistic or all-encompassing theory or resource allocation. The comments included recommendations for more coordination and reduction of overlapping activities: “The federal agencies that share responsibility for detecting and preventing seafood fraud—CBP, NMFS, and FDA— … do not effectively collaborate with each other. Specifically, they have not identified a common goal, established joint strategies, or agreed on roles and responsibilities.” The phrase “detect and prevent” was mentioned throughout the report.

GAO-Fruit Juice Adulteration (1996) The GAO focus on this area goes back to 1996, and the publication of “Fruit Juice Adulteration – Detection Is Difficult, and Enchanted Efforts Would be Costly” (GAO 1995). The term “economic adulteration” was used, and there was an emphasis on “…they pose little threat to the public’s health and safety.” It is interesting to note that there was also such an emphasis on the resource requirement there was the reference to the high cost in the title.

CRS-Seafood Fraud (2010, 2013) In 2008, 2010, and 2015, the CRS published reports on seafood fraud (CRS 2007, 2010, 2015). There have been several efforts to bring forth legislation in this area. A key quote was “Congress is facing questions of whether the U.S. law applicable to fraudulent seafood sales and marketing is clear and enforceable, whether agency enforcement efforts targeting seafood fraud are adequate, and whether the penalties for seafood fraud are a deterrent.”

GAO-EMA (2011) In October 2011, the GAO published “Better Coordination Could Enhance Efforts to Address Economically Motivated Adulteration and Protect the Public Health” (GAO 2011). The key recommendations were to create a formal definition of EMA, create guidance, and coordinate activities between FDA centers. FDA did respond directly to these recommendations which included the creation of the Workgroup on Economically Motivated Adulteration. FDA did confirm they were using the EMA definition from the Federal Register notice of the Public Meeting on Economically Motivated Adulteration.”

CRS-Food Fraud and EMA (2014) In January 2014, the CRS published “Food Fraud and Economically Motivated Adulteration” (CRS 2014). CRS noted that congress has “not addressed food fraud in a comprehensive manner.” Also, this report noted that “no single federal agency or US law directly addresses food fraud.” This report noted many of the global activities such as the UK Elliott Review and the EU referendum on food fraud. To note, the FDA has solicited comments on EMA in the past and current draft rulemaking. FDA has stated that after the comments are received, they will formulate their plan on how and where EMA is addressed. FDA stated that EMA is addressed in the FSMA Preventive Controls Rule and is considered by the guidance based on the level of a health hazard. All types of food fraud have been illegal since at least since the Food Drug and Cosmetics Act of 1938.

It is important to review that there has been many past and current US government activities around food fraud and EMA. There are some common themes and frames for the activities including a broader focus on all fraud and a systems-based approach to prevention.

Sidebar: GAO Seafood Fraud Recommendations—“Coordinate More”

The US Government Accountability Office (GAO) is tasked with reviewing the US government activities related to a wide range of topics. In 2009, the GAO published “Seafood Fraud: FDA Program Changes and Better Collaboration among Key Federal Agencies Could Improve Detection and Prevention” (GAO 2009). The report states that seafood fraud is not a primary priority or responsibility for the agencies mentioned which were FDA, US Customs and Border Patrol (CBP), and Department of Commerce’s National Marine Fisheries Service (NMFS).

- **GAO Identified Agency Roles:**

- CBP—monitors imported product with a focus on “paying the appropriate customs duties as seafood products enter the USA.”
- NMFS—manages a “voluntary, fee-for-service inspection program” that focuses on proper weight and species identification.
- FDA—focuses on public health hazards and examines only about 2% of imported seafood annually, and the “primary seafood oversight program does not address economic fraud risks, which limits its ability to detect fraud.”

No one group has the “accountability” for prevention of seafood fraud. No one group has the authority or statutory requirement to address all seafood fraud. Thus, the GAO report identifies the gap. It is interesting to note that the Department of Justice (prosecution) and FBI (investigation) were not included in the study and not assigned any responsibility or activity.

The GAO report identified several types of seafood fraud that demonstrate the wide range of types of fraud (Table 8.2) (Spink and Moyer 2011). The wide range of types of fraud emphasizes the complexity of an integrated, central seafood fraud vulnerability assessment and seafood fraud prevention strategy.

Table 8.2 GAO seafood fraud report: types of food fraud and potential public health risk

GAO seafood fraud report detail (1)			New comment (2)
Fraud type	Description	Cause and motivation	Potential public health food risk
Transshipment	Transferring cargo among different transports and countries	Avoid tariffs or antidumping duties	Compromised storage, handling, and traceability (in the event of a product recall)
Overtreating	Adding more ice or water than allowed by regulation	Increase profits by including more weight for ice than fish	Water may include pathogens or chemicals (i.e., if ice was made from pond water)
Species substitution	Substituting less costly species and misrepresenting them as more expensive species	Increase profits due to the cost differential	Misrepresented species may be toxic or cause allergic reactions
Short weighting	Package labels state weights higher than packaged contents	Increase profits due to weight differential	None
Other mislabeling or misrepresentation	Misrepresenting country of origin, ingredients, etc.	Generally, avoid costs and maximize profits	Undeclared allergens, toxins from banned locals (e.g., ciguatoxin-prone reefs), weight increased added through other unknown materials, etc.

Adapted from GAO (2009) and Spink and Moyer (2011)

Note: In each case, fraudsters may not be following Good Manufacturing Practices (GMPs), Good Agricultural Practices (GAPs), or Good Hygiene Practices (GHPs)

(1) These columns are directly from the GAO seafood fraud report

(2) This column was not included in the GAO seafood report and was developed for this report

The GAO final recommendation was:

- **“What GAO Recommends” (from Highlights Cover Page)**
- “GAO is making recommendations to CBP, NMFS, and FDA that are intended to help reduce the prevalence of seafood fraud, increase interagency collaboration, improve information sharing, and reduce overlaps. In commenting on a draft of this report, CBP, NMFS, and FDA generally agreed with the recommendations.”

The longer recommendation is:

- “We are recommending that CBP, NMFS, and FDA collaborate to:
- ‘(1) develop goals, strategies, and mechanisms to efficiently and effectively share information and resources related to seafood fraud detection and prevention across agency boundaries and
- ‘(2) create a federal agency-wide library of seafood species standards. In commenting on a draft of this report, the Department of Commerce, representing NOAA; the Department of Health and Human Services, representing FDA; and the Department of Homeland Security, representing CBP, generally agreed with our recommendations. Appendixes II, III, and IV contain reprints of the departments’ letters, respectively.’”

and then:

Recommendations for Executive Action:

- “Propose amendments to FDA’s seafood HACCP regulations to include requirements that covered facilities include control points that can be used to identify and mitigate economic fraud risks”
 - “Provide the opportunity for stakeholder comments prior to formalizing any changes to the Seafood List not required by law or regulation and routinely update the public version of the list whenever FDA makes any changes.”
 - “Update the Fish and Fisheries Products Hazards and controls guidance to reflect the seafood labeling requirements of the Food Allergen Labeling and Consumer Protection Act of 2004.
- “To maximize the efficiency and effectiveness of each agency’s efforts to detect and prevent seafood fraud and to increase interagency collaboration, improve information sharing, and reduce overlaps, we recommend that the Commissioner of Customs and Border Protection, the Under Secretary of Commerce for Oceans and Atmosphere, and the Commissioner of the Food and Drug Administration take the following two actions:
 - “Develop goals, strategies, and mechanisms to share information and resources related to seafood fraud detection and prevention across agency boundaries and
 - “Create a federal agency-wide library of seafood species standards.”

Expanding on the resource allocation discussions above:

- Where should human and economic resources be reallocated?
- Since no additional allocations were recommended or offered, more collaboration and improved information sharing are useful for addressing seafood fraud and also for every activity.
- GAO did *not* provide recommendations for what collaboration should be increased or how the seafood fraud vulnerability would be reduced.

A question to consider, if a new “\$30 million” per year was donated to combat seafood fraud—so this is a new allocation not cannibalizing another budget or activity—what would be the specific recommendation? Specifically, hire more inspectors?

Where would you put them, what equipment would you purchase for them, what would you have them do, how would bad guys invest in circumventing those actions, and how would it all not only catch but prevent seafood fraud? Really, what do you recommend? This is a straightforward and practical question that is very difficult and complex to answer.

US CRS Report on Food Fraud and Economically Motivated Adulteration of Foods (MSU-FFI 2018)

Title: CRS Report on Food Fraud and Economically Motivated Adulteration of Food

By John Spink • January 19, 2014 • Blog

There has been an increased focus on food fraud, and now the US Congress is taking notice. On January 10 the Congressional Research Service (CRS) – a research provider to the US Congress – published this report on food fraud and Economically Motivated Adulteration of Food. As with many of the other recent related US and international reports, we are pleased that several of our research articles were referenced and contributed to the discussion. While we will continue to seek out research questions for review later, we will provide an overview below.

There were several fundamental concepts either in the report or regarding the CRS review of food fraud:

CRS and GAO

There have been reports regarding food fraud and Economically Motivated Adulteration (EMA) by both the CRS and GAO. CRS and GAO are two distinct organizations with different missions. The Congressional Research Service conducts research exclusively for the US Congress and is within the US Library of Congress. CRS provides policy and legal analysis for questions received directly from Congressional Committees or Members – there must have been a request for them to address food fraud. The CRS reports are overviews or briefs on topics, whereas the Government Accountability Office (GAO) focuses more on how the US Government is operating. GAO is under Congress and led by the Comptroller of the US. CRS and GAO are very different in their goals and objectives.

CRS food fraud Report

The report is a comprehensive and quite exhaustive overview of food fraud (FF) and economically motivated adulteration (EMA) of food. They defined the focus as “food fraud and ‘economically motivated adulteration’ or EMA, a category within food fraud.”

- They reinforce that there is no US statutory definition of FF and EMA. Also, that Congress has “not addressed food fraud in a comprehensive manner.” Also, that “no single federal agency or U.S. law directly addresses food fraud [or EMA].”

(continued)

- The food fraud risks are presented using our Food Protection Risk Matrix from our 2011 Journal of Food Science Article. The risks include food quality, food safety, food fraud, and food defense.
- They very clearly explain the content and value of the FF/EMA databases. The CRS report clearly defined the value of each of the databases and CRS – this is important for the Congress evaluating the scope and scale of the issue because the database results have frequently been misinterpreted. For example “This further reinforces the idea that a possible limitation of either database is that the available information may at times be more reflective of where research is being conducted or where resources have been dedicated to detecting fraud.” Whether for addressing food fraud, Product Fraud, or other related attacks by intelligent human adversaries, such as with intellectual property rights counterfeiting, there is an underlying challenge of quantifying or evaluating the probability of an incident. The CRS states, however, that most researchers acknowledge that the full scale of food fraud “may be unknown or even possibly unknowable” (which is a quote from our article with Lev Fejes on “A review of the economic impact of counterfeiting and piracy methodologies and assessment of currently utilized estimates.”).
- There was some international focus, mentioning the European Parliament, though it appears the UK Elliott Interim Report came out too late to be included here (see our previous blog post on the EU report, and we will soon publish a review of the UK report).
- The report begins to address marketing fraud (unsupported and often deceptive statements about products) versus product fraud (a physical act of deception that is clearly defined as illegal). We identified this as a research gap and have started working on this research question.

Potential Role of the Food Safety Modernization Act (FSMA): The FSMA law in the U.S. Code (USC) – not the Code of Federal Regulations (CFR)– directly addresses intentional acts in: “FSMA section 106 (Protection Against Intentional Adulteration).” This is an especially important CRS section to review since, on December 23, 2013, FDA just released their draft rulemaking on FSMA “Intentional Adulteration” (see our previous blog post on FSMA). The CRS report was published without including the new FDA FSMA insights.

- The CRS report recognizes that FDA did respond to the GAO report on FDA/EMA by creating the WEMA, and FDA did clarify the working definitions of EMA. Food fraud is not addressed yet by the FDA.
- There is an interesting and strong statement about food fraud countermeasures and control systems by industry and the role of FDA: “Having such controls in place would also allow companies to consider their responsibility regarding potentially adulterated foods involving the ‘absence,

substitution, or addition of constituents.’ … Since FDA could not possibly enforce every instance of food adulteration, such industry controls will be instrumental in helping to combat future adulteration before it ever reaches the marketplace.”

- As has been mentioned throughout FSMA and related reports or statements, the CRS report does clearly mention industry or commercial actions: “FSMA also recognizes ‘third party’ audits or certifications, and several such entities have already started to address food fraud both in terms of identifying terms or assessing implementation actions such as vulnerability assessments [104]” ((The citation is to one of our previous articles coauthored with Christopher Elliott of Queen’s University Belfast, and Kevin Swoffer, who is a frequent contributor to GFSI activities).

U.S. Congressional Actions regarding Food Fraud: This section of the CRS report is a summary of previous actions and the most direct statement was: “Congress has introduced a number of bills intended to address concerns about food fraud, mostly with respect to concerns about a particular food or food ingredient, but has not introduced legislation that would specifically address fraud in a comprehensive manner.”

Collaboration and Engagement: food fraud research has been odd in that the researchers have been collaborating on establishing a theoretical foundation and harmonized definitions before the laws and regulations are finished – actually, a range of global researchers have been quoted or referenced in most of the new laws and regulations. Beyond our MSU-authored scholarly journal articles, several of our non-scholarly, non-funded extra efforts have been valuable. Our Food Fraud Overview MOOC (free, massive open online course) and Food Fraud Initiative blog posts were each quoted and referenced several times. Several non-scholarly articles were also quoted and referenced to contribute unique points in the discussion. The CRS report also mentions our Food Fraud Initiative efforts in working with the National Center for Food Protection and Defense (NCFPD) and the US Pharmacopeia/ Food Chemicals Codex (USP/FCC). MSU-FFI

Review of “Crime Analysis for Problem-Solvers in 60 Small Steps”

One of the most influential and practical guides to crime prevention is “Crime Analysis for Problem- Solvers in 60 Small Steps” (Clarke and Eck 2005). This is an influential work since it is written by Ronald V. Clarke and John E. Eck who are two of the criminology science thought leaders, and it was published by the respected and widely adopted Problem-Oriented Policing Center (POP or POP Center). The POP is supported and reinforced by the US Department of Justice funded Office of Community Oriented Policing Services (COPS).

There are several of the “60 Small Steps” that are most applicable to food fraud prevention (Clarke and Eck 2005):

- **“Be very crime specific (#6):** “Your department will sometimes mount a crackdown on a particular crime such as auto crime or burglary, and you might be asked to map these offenses or provide other data to support the operation. But these categories are too broad for problem-oriented policing. They include too many different kinds of crimes, all of which need to be separately analyzed. [...] You can see these crimes are committed for a variety of motives, by different offenders, with varying degrees of organization, knowledge, and skills.”
- **“Use the CHEERS test when defining problems (#14):** “A *problem* is a recurring set of related harmful events in a community that members of the public expect the police to address. This definition draws attention to the six required elements of a problem: Community; Harm; Expectation; Events; Recurring; and Similarity. These elements are captured by the acronym CHEERS.”

Especially applicable to food fraud prevention from step #14 is:

“Similarity: The recurring events must have something in common. They may be committed by the same person, happen to the same type of victim, occur in the same types of locations, take place in similar circumstances, involve the same type of weapon, or have one or more other factors in common. Without common features, you have an arbitrary collection of events, not a problem. Common crime classifications - such as used by the Uniform Crime Reports - are not helpful. Vehicle theft, for example, includes joyriding, thefts for chop shops, thefts for export to other countries, thefts for use in other crimes, and a host of other dissimilar events. So a cluster of vehicle thefts may not be a single problem. More information is needed.”

The other CHEERS concepts are included here:

- **Community:** “Members of the public must experience the harmful events.” Note: “community” can be broadly interpreted to include food consumers, regulators, or others.
- **Harmful:** “People or institutions must suffer harm. The harm can involve property loss or damage, injury or death, serious mental anguish, or undermining the capacity of the police. Illegality is not a defining characteristic of problems.”
- **Expectation:** “Some members of the community must expect the police to address the causes of the harm. Expectation should never be presumed, but must be evident through processes such as citizen calls, community meetings, press reports, or other means.” Again, the “community” could be a few influential and amplified members.
- **Events:** “You must be able to describe the type of event that makes up the problem. Problems are made up of discrete events.”
- **Recurring:** “These events must recur. Recurrence may be symptomatic of acute troubles or a chronic problem. Acute troubles suddenly appear, as in the case of a neighborhood with few vehicle break-ins suddenly having many such break-ins. Some acute troubles dissipate quickly, even if nothing is done. Others can become chronic problems if not addressed. [...] Chronic problems persist for a long time, as in the case of a prostitution stroll that has been located along one

street for many years. Unless something is done, the events from chronic problems will continue to occur.”

- **Similarity:** (See above)”

For data collection or review of incidents, this concept of “similarity” is fundamental. The incidents—and use of the data—must be a consideration when evaluating the utility or value of a data set. That said, even an “arbitrary collection of events” has value.

- **“Know what kind of problem you have (#15):** Because local police have to deal with a wide range of problems that meet the CHEERS definition (Step 14 above), we have developed a classification for these problems. This classification scheme can help you precisely define the problem. It helps separate superficially similar problems that are really [actually different and] distinct. It also allows you to compare your problem to similar problems that have already been addressed, and it helps identify important features for examination. [...] The classification scheme is based on two criteria:

- **Classification Scheme:**

- The environments within which problems arise
 - The behaviors of the participants

Also, regarding the environment—or the place of the crime—there are 11 distinct types:

Distinctions for the place of the crime:

1. Residential: Locations where people dwell.
2. Recreational: Places where people go to have a good time.
3. Offices: Locations of white-collar work where there is little face-to-face interaction between the workers and the general public.
4. Retail: Places for walk-in or drive-up customer traffic involving monetary transactions.
5. Industrial: Locations for processing of goods.
6. Agricultural: Locations for growing crops and raising animals.
7. Education: Places of learning or study.
8. Human services: Places where people go when something is wrong.
9. Public ways: Routes connecting all other environments.
10. Transport: Locations for the mass movement of people.
11. Open/transitional: Areas without consistent or regular designated uses.

Regarding the behavior, there are six types:

Distinctions for Behavior of the Crime:

1. Predatory: The offender is clearly distinct from the victim, and the victim objects to the offender’s actions.
2. Consensual: The parties involved knowingly and willingly interact.
3. Conflicts: Violent interactions involving roughly coequal people who have some pre-existing relationship

4. Incivilities: Offenders are distinguishable from victims, but the victims are spread over a number of individuals, and the harms are not serious.
5. Endangerment: The offender and the victim are the same person, or the offender had no intent to harm the victim.
6. Misuse of police: A category reserved for unwarranted demands on the police service.

These classifications help to further understand and define the nature of the problem so optimal countermeasures or control systems can be selected.

- **“Know how Hot Spots Develop (#17):** “To expand from just considering the geographical location and place where crime occurs, there is more insight to gain when considering three kinds of hotspots:”
 1. **Crime generators:** “places to which large numbers of people are attracted for reasons unrelated to criminal motivation. Providing large numbers of opportunities for offenders and targets to come together in time and place produces crime or disorder.”
 2. **Crime attractors:** “places affording many criminal opportunities that are well known to offenders. People with criminal motivation are drawn to such locales.”
 3. **Crime enablers:** “occur when there is little regulation of behavior at places: rules of conduct are absent or are not enforced.”
- **“Learn if the 80-20 rule applies (#18):** “A very important principle of crime prevention is that crime is highly concentrated on particular people, places, and things. This suggests that focusing resources where crime is concentrated will yield the greatest preventive benefits. These concentrations (dealt with in more detail in later steps) have attracted labels that are becoming well known to most crime analysts:
 - ‘(1) Repeat Offenders
 - ‘(2) Repeat Victims: Note, “according to the British Crime Survey, repeat victims (just over 4 percent of all victims) endure 40 percent of the crimes reported in the survey (see Step 29).”
- **“Research your problem (#19):** “Other police agencies might already have dealt with the problem you are tackling, or researchers might have studied it. You could save a lot of time by finding out how they analyzed it and what they did, in particular, which responses seemed to be effective and which were not. Studying the efforts of others can provide you with useful hypotheses to test your problem (Step 20).” Two concepts are important:
 - Much of the Criminology literature may not be practical or applied enough to help with food fraud prevention: “Most criminologists are more interested in crime and delinquency in general than in specific forms of crime. They are also more interested in distant causes of crime, such as social disadvantage and dysfunctional families, than the near causes of a problem, such as poor security or lack of surveillance. So even when you find academic articles dealing with your

problem, you might find the causes they identify help little in developing an effective response.”

- While it is important to seek the lessons from others, do not be surprised if you *do not* find *any* applicable research: “Unless your problem is very common, do not expect to find many relevant police projects. Be skeptical about claims of success unless supported by evaluative data. [...] Be warned also that a response that worked in a particular town or neighborhood might not work in yours because of specific circumstances that make your situation different.”
- **“Be sure to answer the five “W” (and one “H”) questions (#36):** “When you have completed your analysis using the concepts discussed in the previous steps, you should ask whether it meets the test of a good newspaper story. Does it adequately answer the 5 W and one H questions: what, where, when, who, why, and how?”
 - What happened?
 - Where did it happen?
 - When did it happen?
 - Who was involved?
 - Why did they act as they did?
 - How did the offender carry out the crime?
- **“Find the owner of the problem (#44):** “First, for any problem, you need to answer three ownership questions:
 - Who owns the problem?
 - Why has the owner allowed the problem to develop?
 - What is required to get the owner to undertake prevention?
- **“Choose responses likely to be implemented (#55):** “Finding a suitable response can be a troublesome process. You may repeatedly be disappointed when promising interventions are vetoed because of expense or difficulty, or because of lack of cooperation. But there is more than one way to solve a problem. So, eventually your team will agree on a response that meets some basic requirements:
 - It is not too ambitious or costly.
 - It focuses on near, direct causes rather than on distant, more indirect ones, which gives it a good chance of making an immediate impact.
 - The mechanism through which each response should impact the problem has been clearly articulated.”
- **“Tell a clear story (#54):** “The purpose of your work is to help people make better decisions. To assist decision-makers, you must tell a clear story that leads to an important question to possible answers and then to effective actions.

This is the end of the review of the 60 Steps report. For food fraud prevention, note the constant criminology focus on reducing the opportunity for a crime to occur and also measuring success regarding the contribution to prevention.

Key Learning Objective 3: Additional Insights on Prevention

This section reviews additional insights on a wide range of criminology theories that apply to food fraud prevention. Law enforcement, of course, has a critical role, but it is only part of the overall strategy. These examples and discussions provide insight into the overall public-private-partnership approach.

The Key Learning Objectives of this section are

- (1) The role of enforcement in prevention
- (2) Food Science taking a back seat to social science
- (3) Special applications such as addressing Organized Retail Theft (ORT)

Can't We Just Arrest the Bad Guys? No. (MSU-FFI 2018):

Title: Can't We Just Detect and Arrest Fraudsters? Sorry, But No.

By John Spink • October 3, 2013 • Blog

We won't arrest our way to food safety, but eliminate research on authenticity testing and detection? Forget enforcement? Ignore investigation? Of course not... but you can't increase the safety of the food supply if you're only running around chasing "bad guys." Prevention is by far the most efficient policy. To focus on prevention before developing detection methods will provide insight into the precise technical detection needs. A focus on prevention can help Food Science and Food Authenticity research to be more efficient.

I recently guest-lectured for MSU Food Science and Human Nutrition professor Dr. Gale Strasburg's course FSC 455 FOOD AND NUTRITION. This is a class for mostly undergraduate seniors. Even though my guest lecture material covers content that isn't always included on the test... I usually find a pretty engaged audience. If the only thing accomplished is introducing food fraud prevention to the next wave of future industry leaders then it was time well spent. I'm even starting to get calls from the alumni as a result of my past guest lectures. The ideas are sticking and becoming part of the formal or informal curriculum.

The food fraud concepts were new to this group of students, so I used my typical Defining Food Fraud and the Role of Prevention presentation. Actually, to demonstrate the timeliness and impact of the concepts I used the exact deck that I presented the week before in Russia at the Moscow State University for Food Protection (MSUFP) and at the Association of Food and Drug Officials (AFDO). MSUFP is leading many Russian and regional initiatives in this

area. AFDO is the professional association for the US Federal, State, and Local regulators.

Even though this was the third time, I presented the same PowerPoint over the last few weeks... I keep finding new insights. The students and attendees in *every* case helped advance the science. The AFDO insights were covered in a previous post, and I'll have several following up from my trip to Russia. In presenting to the MSU students – the food scientists and chemists – I went through my usual “detect, deter, and prevent” concepts. Our discussion led me to really focus on the connection between “detect” and “prevent,” skipping over “deter.”

To review, “detect” is like an alarm sounding in your house, alerting you that there is a burglar inside. “Deter” is like the police arresting the burglar as he is breaking in (in Situational Crime Prevention and the Crime Triangle this is the “guardian” factor), or like bars on the inside of your windows (barriers or hurdles). And “prevent” is like having lights on, doors and windows locked, an alarm on, and a dog barking – the burglar now has no interest in breaking into your house. Clearly, you’d rather have the “bad guy” pass right by rather than break your window or be *in* your house!

For food, we need to focus on the “detect” function – and we need to keep developing more precise and targeted tests and equipment. As we’ve covered before, there are a near-infinite number of types of fraud, and they keep evolving, so we need to keep evolving. The specification of the “detect” innovations must be determined by the ability to support the ultimate goal, which is the “prevent” function. The focus must first be on “prevent” before we take any other steps.

The “deter” component is also critical... but I’d rather leave that dangerous function of tackling burglars to the brave and committed law enforcement professionals in that field. Facing potentially dangerous or violent situations is way out of the scope of the curriculum for food science, packaging, supply chain management, or public health. Hopefully, with the increase in the “prevent” and “detect” efficiency we decrease the need – and cost – of the “deter” function.

Whether you are a big or small company, a manufacturer or retailer, industry or government, just understanding the “detect” and “prevent” functions can help increase the efficiency of time and money.

Several Applied Examples Are Included Below

Sidebar: Food Fraud Prevention Is More Like Fighting Purse

Counterfeitors Than Controlling Microbes (MSU-FFI 2018)

Title: Food Fraud Prevention Is More Like Fighting Purse Counterfeitors Than Controlling Microbes

By John Spink • April 14, 2013 • Blog

“E. coli does not surf [FDA.gov](https://www.fda.gov) to find more efficient ways to get on products... counterfeitors do.” I frequently start my presentations with this statement, and it usually gets a chuckle...then a nervous laugh. All the research publications and sharing of best practices that help protect the food supply from food safety risks, if applied to food fraud, would actually give a roadmap to the bad guys. Combating food fraud requires a fundamentally different approach than the traditional expertise in food safety management systems.

There is a difference between “experience” and “expertise.” A bank manager who has been robbed a hundred times has “experience” in being robbed but, obviously, not “expertise” in avoiding being robbed. Food fraud prevention expertise requires an interdisciplinary approach from experts outside Food Safety, including Supply Chain and Logistics Science, Corporate Security, Intelligence Analysis, Packaging, and now Enterprise Risk Management.

There is a growing awareness not only of the public health (and economic) threat of food fraud but also that there will need to be new disciplines engaged to enable the shift to fraud prevention. Specifically, this was identified in two key US government reports. A 2011 GAO report specifically quoted an FDA official who stated that the FDA “does not have the range of expertise... with a background in intelligence gathering or law enforcement.” Also, the Food Safety Modernization Act (FSMA) draft rulemaking documents reiterate the complexity. The report stated, “FDA tentatively concludes that intentional hazards [Economically Motivated Adulteration and food fraud], which are not addressed in traditional HACCP or other food safety systems, likely will require different kinds of controls and would be best addressed in a separate rulemaking.”

Combating food fraud is different from food safety because the human fraudsters are clandestine, stealthy, intelligent, resilient, often well-funded, actively seek to avoid detection...and they are often very patient. I saw a need for a scholarly reference to define that the bad guys are very different from the traditional bad actors in the food supply chain, so I authored The Challenges of Intellectual Property Enforcement in Agriculture which was published in the Journal of Intellectual Property Rights in March 2011 (note: this is an open source article and free to download). This article includes five fascinating case studies that include a terrorist “weapons procurement officer,” \$40 million dollar tax-avoidance honey smuggling ring (referred to as Honey

Laundering), a \$500 + million product quality fraud scheme, a business person who bribed a Belizean judge to get released from jail then fled to the Mexican jungle, and a counterfeiter who is still openly operating due to a nuance in an extradition treaty. These will clearly define some of the challenges of trying to stop the bad guys or of even trying to conduct legal discovery in a court case.

Prevention and deterrence are more similar to forensic accounting than microbiology. You will not arrest (or sue) your way to safety. This discussion emphasizes the need to focus on reducing the fraud opportunity and the importance of a Food Fraud Prevention Strategy. By the way, in MSU's free Food Fraud Overview MOOC next month we will be introducing this concept. MSU-FFI.

Organized Retail Theft (ORT)– Sometimes We Cannot Test Our Way to Safety (MSU-FFI 2018):

Title: Organized Retail Theft (ORT) – Sometimes We Cannot Test Our Way to Safety

By John Spink • July 6, 2013 • Blog

Organized Retail Theft (ORT) is mass shoplifting and is a type of food fraud that results in a public health vulnerability that costs businesses billions and erodes consumer confidence. Since it involves authentic packaging and genuine product [...], we cannot test our way to safety. This is an immense fraud opportunity that requires a holistic, all-encompassing preventative approach.

Organized Retail Theft (ORT): For the lawyers, ORT is defined in Federal Law as shoplifting more product than for personal use. The broader Organized Retail Crime (ORC) includes cargo theft, warranty fraud and other forms of retail fraud-related activities. ORT is a primary concern for the industry since it costs billions in lost product and lost sales from a product not being on the shelves, and there is a public health vulnerability to the stolen goods. In 2011, the Government Accountability Office (GAO) report on Organized Retail Theft noted of the “billions” of dollars of genuine product stolen and reintroduced to commerce... though more precise estimates are hard to come by, as with other fraud and counterfeiting activities. ORT is perpetrated by professional shoplifters or boosters, and the act is referred to as boosting. The stolen goods are sold to a person referred to as a “fence,” and when sold online this is called **e-fencing**. In many cases, the fences provide a shopping list for the boosters to steal. The GAO report specifically identified infant formula as a primary target but any products that are high value – especially high value and

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small size – are targets. Think of small, reasonably expensive food or beverages you see at a corner gas station market. Food products are definitely ORT targets.

How it Works: The fences ask boosters to shoplift specific items. The boosters are paid pennies on the dollar for the product that they stole. The fences are connected to some retail outlet or scam that sells the product. In some cases, they sell this through traditional fencing venues such as flea markets, pawn shops, or privately owned stores (at 30% of market price). In other cases, they sell it through online sales sites (at 70% of market price). They can also conduct return fraud to the retailers (100% market value plus tax!). Generally, returned food products are not returned to store shelves by the retailers, so that product is either written off as a loss or, at best, counted against a return or damaged-goods allowance. In some sophisticated operations, the product is “cleaned” (retail markings removed, such as date codes, lot numbers, and store price tags – also referred to as de-coded) and the product is re-packaged to re-enter the wholesale market.

Why It's a Public Health Vulnerability: The GAO ORT report mentioned, “However, it is not currently known if the second-hand sale of these goods has actually resulted in a public health problem.” It also stated, “As a result [of the shoplifting], there is limited assurance that these products were lawfully acquired and are stored and handled according to the manufacturer's recommendations.” The key point is that we do not know how that product has been handled. The genuine product may have been swapped out with counterfeits. In many instances, the date and lot codes could have been changed, which would make traceability impossible. Even worse, fraudulent lot codes could be added, which could result in the recall of the wrong products! All this leads to a wide range of public health vulnerabilities and, if allowed to fester, can erode consumer confidence – and sales along with it.

The bottom line for a legitimate company is that this stolen product is a violation of the FDCA Adulterated Foods section – and probably also Misbranded Foods section – and thus, is illegal, unfit for commerce, and could be the subject of a product recall.

Consumer confidence is really a key to any countermeasure: Product protection needs to be conveyed in a way that enables that confidence. I am just returning from a trip where I presented at the GFSI China Focus Day. There has been a wide range of incidents in China related to infant formula that have eroded consumer confidence. I read about infant formula now being sold in pharmacies to benefit from the more regulated and secure supply chains there. Infant formula is still allowed to be sold in other retail outlets, but it will be interesting to watch how consumers in China respond to this drastic step. This effort is not only to increase the security of the supply chain but to increase consumer confidence.

Regardless of how ORT is legally classified or prosecuted by FDA, FBI, or others, ORT is a food fraud public health threat that requires a non-traditional food fraud prevention approach. Seek out insight from a wide range of disciplines that can provide best practices. Keep focused on reducing your overall fraud opportunity.

Additional definitions that apply to this section:

- **Boosting/ Booster/ Boost:** stealing an item to illegally re-sell
- **Shoplifting:** stealing a product from a store while acting as a legitimate customer
- **Fencing/ Fence:** someone who sells stolen goods
- **E-Fencing:** someone who sells stolen goods on an electronic commerce marketplace
- **Warranty fraud:** intentional deception to achieve an economic gain from misapplying guarantees such as replacement, repair, or refund of defective products.
- **Return fraud:** intentional deception to achieve economic gain from misapplying purchase privileges such as returning a product other than was purchased, returning stolen or counterfeit goods for credit, or using an old receipt to return a product from within the store.
- **Shrink/ Shrinkage:** the loss of inventory due to goods that are stolen, not actually received into inventory, accidentally not charged to a customer, or discarded but not recorded inventory.

Sidebar: Reflections on Food Fraud Prevention in Russia – Trip

Summary (MSU-FFI 2018):

Title: Reflections on Food Fraud Prevention in Russia – Trip Summary

By John Spink • September 25, 2013 • Blog (Fig. 8.2)

There is probably no better partner for our food fraud research than our Moscow State University for Food Production (MSUFP) colleagues. We engaged as scientists and worked together as friends. We are now collaborating on projects from a conventional perspective. We will build a firm foundation of education and harmonization to advance food fraud prevention. Reflecting on the trip, I am very encouraged by the growing working relationship between the US and Russia – including expanding to our mutual Korea colleagues.

I just returned from an incredible week in Russia at MSUFP. This partnership came about from a chance encounter while the University President (Dmitry Edelev) and Vice-Rector (Victor Fersht) were presenting at a conference in China last June. We immediately found that we had many similar research interests in food protection and food counterfeiting/ food fraud. We

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Fig. 8.2 September 2013, Moscow – John Spink with Russian Duma Member Anatoly Karpov (who is also a world chess champion) and Fulbright Russia Director Joel Ericson

also met with another Vice-Rector (Natalia Mayorova) the next day at the Global Food Safety Initiative meeting. I also had a great translator in MSUFP English Professor Marina Kosycheva, who really helped me with the interpretation of both their words and mine. Our discussions continued, and they invited me to their Food Safety Problems conference this last week in Moscow.

I am especially grateful to the Fulbright Foundation, the US Embassy Russia, and the International Institute for Education, which were the sponsors of last week's conference. An unexpected additional link was with our colleagues in Korea, as their representatives, who are connected with my research colleague from Yong In University, Dr. Hyeyonho Park, were also in attendance. Participating in the conference was an excellent way for MSUFP and our MSU Food Fraud Initiative (MSUFFI) to demonstrate international collaboration in action.

For any of you chess players, world champion Anatoly Karpov – and now a member of the Russian Duma/ Parliament – is the keynote speaker at the end of the clip. He is a leader at MSUFP, and on what we could call our Board of Trustees. He is the chair of a Duma Committee that covers issues including food fraud prevention.

The key points I presented were:

- Defining Food Fraud: There is a foundation of ideas that define the threat, aspects of the incidents, and the crime science theories of Situational Crime Prevention.

- A Public Health Focus: The focus on improved public health, not just catching “bad guys,” was well received. We must continue to shift the focus to public health first.
- Prevention is Efficient: I emphasized the efficiency (time and money) of focusing on prevention. For product fraud and related areas, the “bad guys” are so sneaky that herculean efforts are often required even just to find where they are hiding.
- Translate and Interpret: Defining the critical need to collaborate on terminology. That is, to go beyond the word (e.g., “adulteration”) to expand the definitions, and to then not only translate the word but to also interpret the meaning. We really need to study if there is a more useful word to use in other languages, such as Russian or Korean. This is a project that has already started and is based on the paper that I published in their conference proceedings publication.
- Exchange of Students and Scholars: I cannot even begin to explain how important it was for me to stay this long and spend so much time – professionally and personally – with my colleagues. Students and scholars need to spend time with each other and in the other’s environments. I can imagine how the science of food fraud prevention will advance when we bring more of our students together. Also, we realized that we had a very engaged and capable set of prospective researchers in the Fulbright scholars who attended the conference.

The rich experiences and insights of this trip are too many to list. We had already started collaborating, and this conference allowed us to create even more impactful projects. We will continue our discussions next month in Dublin, where I will be presenting with my Russian colleagues at Interpol’s 2013 International Law Enforcement IP Crime Conference. Stay tuned here for more insight on our expanding partnership. MSU-FFI.

The Role of Law Enforcement in Food Fraud Prevention (Fig. 8.3) (MSU-FFI 2018)

Title: The Impact of Prevention Defines the Value of Enforcement and Prosecution

By John Spink, October 17, 2013, Blog (Fig. 8.3)

Title: Reflections on My Week Here at the Interpol 2013 International Law Enforcement Intellectual Crime Conference, Dublin, Ireland.

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The Impact of Prevention Defines the Value of Enforcement and Prosecution

by John Spink · October 17, 2013 · [Blog](#) · 0 Comments

Reflections on my week here at the Interpol 2013 International Law Enforcement Intellectual Crime Conference, Dublin, Ireland

Food Fraud is a focus of Interpol, and the next big food crime [Operation Opson](#) already has 32 countries participating. The increasing impact on public health is being felt, which is providing a significant opportunity to further understand food crime.

The Interpol Trafficking in Illicit Goods and



Fig. 8.3 MSU FFI blog post: the impact of prevention defines the value of enforcement and prosecution – insert: interpol assistant director Michael Ellis, interpol inspector Simone DiMeo, underwriters laboratories VP of anti-counterfeiting Brian Monks, and Dr. John Spink. (Copyright Permission Granted) (MSU-FFI 2018)

Food fraud is a focus of Interpol (International Criminal Police Organization), and the next big food crime. Operation Opson already has 32 countries participating. The increasing impact on public health is being felt, which is providing a significant opportunity to understand food crime further.

The Interpol Trafficking in Illicit Goods and Counterfeit Sub-Directorate is leading the enforcement of food crime law with the third Operation Opson. The two lead investigators from INTERPOL (DiMeo) and Europol (Dreno) co-presented to us earlier this year at the Global Food Safety Initiative conference (GFSI). Their involvement with GFSI made a significant impression on the food industry and demonstrated the significance of the threat and risk – we couldn't remember a time previous to this when Interpol presented at a food conference.

For Interpol here in Dublin, Ireland, I was invited to present “Defining Food Fraud & the Role of Prevention,” where I discussed the deterrence effect of investigation and enforcement as a key part of reducing the fraud opportunity. The focus of the food-related sessions this week was on how enforcement and prosecution can more effectively contribute to prevention.

Another aspect of prevention is training and education. I am especially thankful for the encouragement and ideas from Mr. Michael Ellis, Mr. Silvio DiMeo, and Mr. Brian Monks. Specifically, Mr. Monks and Underwriters Laboratories have been a big supporter of the Interpol training programs and this IP Crime Conference series. We see the opportunity to create a range of products that can serve a variety of needs, including operational training through our free Food Fraud Overview MOOC programs, and through MSU’s Graduate Certificate in Food Fraud Prevention.

The role of universities is an important part of the bigger prevention picture, and Interpol has also been supportive of other outreach activities, such as with our colleagues from Moscow State University for Food Production. The Russian Federation had a large delegation here this week, which demonstrated their commitment to Interpol and food fraud prevention. Their commitment is so significant that Russian Duma member Mr. Anatoly Karpov presented a keynote address – he mentioned their interaction with our MSU Food Fraud Initiative as a demonstration of their focus on food fraud prevention.

These types of meetings are always an incredible opportunity to connect or reconnect with colleagues from around the world and across many functions. For example, I was surprised and pleased to see in attendance our researcher colleague Director Momodu-Segiru Momodu of the Nigerian National Agency for Food and Drug Administration and Control (NAFDAC). This meeting provided an opportunity for us to discuss the new topics and conceive our next research project.

While we had a good time visiting, there were many serious discussions about how to coordinate all our wide range of activities. The role and effectiveness of enforcement and prosecution must be judged by the impact on prevention. A question from my presentation that resonated was “are we disrupting the chemistry of the crime?” – do the bad guys wake up the next day and decide not to attack your product? For food crime, Interpol is leading the charge to answer this question. Follow INTERPOL-Europol and look for an opportunity to participate in Operation Opson. MSU-FFI.

Conclusion

The previous chapter on Business Decision-Making and ERM presented the resource-allocation decision-making method. That method is the final decision on “how much is enough” for countermeasures and control systems. This chapter Part 1 and Part 2 on criminology theories focused on the other end of the problem which is the root cause. ***The first conclusion*** is criminology theory is the key to understanding the root cause which is a human adversary that is conducting a criminal act. The academic discipline of criminology is based on applying the scientific method and an evidence-based approach to crime prevention. Without a focus on the social sciences and criminology, then any selection of countermeasure or control systems are nothing more than a guess. ***The second conclusion*** is that the most simple and directly applicable criminology theory is situational crime prevention. This theory focuses on the physical space of crime and includes practical concepts of where criminals spend their time (Routine Activities Theory) and how they perceive they can successfully commit the crime (Rational Choice Theory). These theories focus on controlling the physical space which helps a company to be a “hard target.” The fraud opportunity reduction is clear and also in direct control of the company which is the victim. ***The final conclusion*** is that while there are many considerations such as the nature of the criminals, the offender organizations, law-suits, and international law enforcement, the most important and efficient focus is on the “fraud opportunity.” “It is all about the fraud opportunity.” The overall criminology-based root-cause analysis is focused on understanding the root cause and reducing the risk of conducting the crime. Criminology theory is not new but has not been widely applied to food fraud prevention. It is novel to focus on the crime prevention theories that focus on the physical space of crime in relation to how fraudster perceives opportunities. With a holistic and all-encompassing criminology perspective, then the focus shifts from “catching bad guys or bad products” to “preventing fraud from occurring in the first place.” There is a saying:

It's all about the fraud opportunity.

Appendix: WIIFM Chapter on Criminology Application

This “What’s In It For Me” (WIIFM) section explains why this chapter is important to you.

Business functional group	Application of this chapter
WIIFM all	There are many examples of excellent and efficient fraud opportunity reducing criminology-based measures, and the recommendation is to start at the enterprise-wide level and with very simple initial approaches
Quality team	While the food safety risk assessments and authenticity detection tests are critical, the goal is <i>not</i> to catch bad guys but to prevent food fraud from occurring in the first place
Auditors	An efficient crime prevention strategy will have a significant focus on communicating to the criminal first through obvious and overt vulnerability reducing countermeasures and control systems
Management	A strong program will consider the science and technology long after there has been an understanding of the system weaknesses and how the human adversary can be dissuaded from attacking you
Corp. decision-makers	The root cause is a human adversary, and this process leverages the state-of-the-art criminology research and theories to reduce your vulnerabilities

Appendix: Study Questions

This section includes study questions based on the Key Learning Objectives in this chapter:

1. Discussion Question

- (a) If the goal is not to catch bad guys or bad products then what is the goal?
- (b) How does the Crime Triangle help understand and explain the fraud opportunity?
- (c) What is the role of law enforcement officer (and their organizations) in food fraud prevention?

2. Key Learning Objective1

- (a) What is a “macro” versus “micro” motivation?
- (b) Explain “Education is a Weapon.”
- (c) Why is prevention only activated when the criminals know of the countermeasures?

3. Key Learning Objective 2

- (a) What are the GAO and CRS?
- (b) What concrete prevention recommendations were in the GAO and CRS reports?
- (c) What is the role of FSMA in food fraud prevention?

4. Key Learning Objective 3

- (a) What is “Crime Analysis for Problem-Solvers in 60 Small Steps”?

- (b) How does “Know What Kind of Problem You Have” apply to FF prevention?
- (c) Why is “Food Fraud Prevention is More like Fighting Purse Counterfeitors than Controlling Microbes”?

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Chapter 9

Supply Chain Management (Part 1 of 2): Fundamentals



Summary

This chapter presents the discipline of Supply Chain Management—both the functions of product moving in the proprietary supply chain from manufacturing to the consumer and also the science of logistics, operations, and procurement supply chain management. This chapter will introduce the foundational concepts as well as general applications, review key issues such as globalization and an ever more digital supply chain (positives and negatives), and then the role in food fraud prevention.

The Key Learning Objectives of this chapter are

- (1) **Supply Chain Management Introduction:** Understand the science of supply chain management.
- (2) **Supply Chain Characteristics:** Review the application of supply chain management to food fraud prevention.
- (3) **Business Continuity Planning and Crisis Management:** Review of the management function with specific food fraud prevention examples.

On the Food Fraud Prevention Cycle (FFPC), this chapter addresses the theoretical foundation concepts related to supply chain management in “(A) Academic Disciplines” (Fig. 9.1).

Introduction

Supply chain management (SCM) is a crucial discipline in food fraud prevention because, naturally, the material goods must be delivered and managed through a supply chain to a customer and consumer (Voss et al. 2009; Speier et al. 2011). As commerce has become both more complex and complicated, supply chain management provides methods to manage the complexity as well as the associated risk and uncertainty. Product fraud and food fraud are problems that are escalating due to the emerging fraud opportunity created by more products moving farther and faster

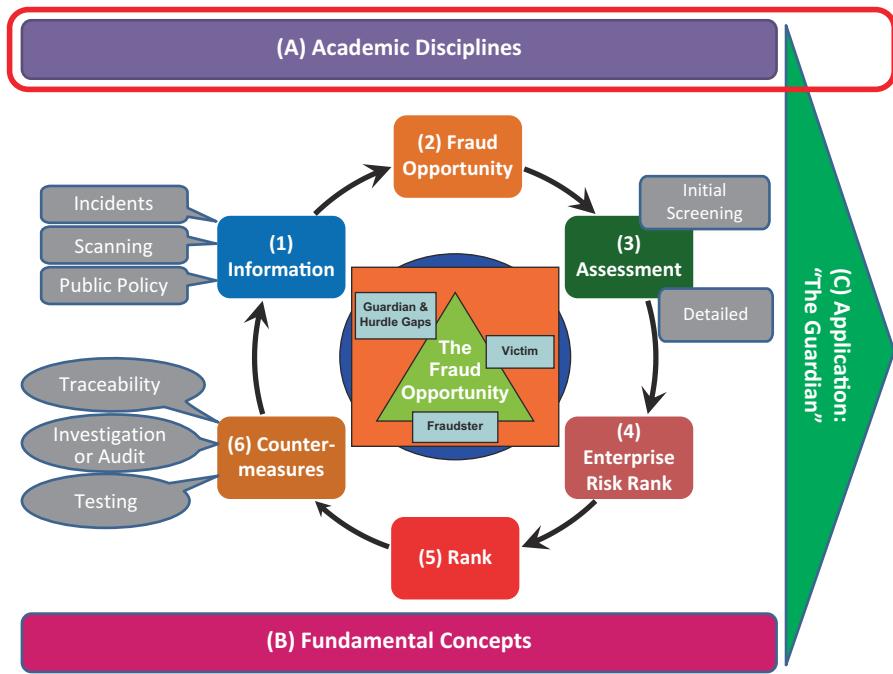


Fig. 9.1 Food Fraud Prevention Cycle—Where this chapter applies to the overall concept “(A) Academic Disciplines”. (Copyright Permission Granted) (Spink 2014; Spink et al. 2019)

around the world. The foundation of supply chain management is vital to understand both to find ways to leverage the systems but also to assist in a more productive supply chain.

In general, the discipline of supply chain management is essential for food fraud prevention because:

- Supply chains are vulnerable to food fraud, and the threat is currently misunderstood and often underestimated.
- Current internal controls and visibility of the product help reduce the fraud opportunity.
- Supply chain management is a separate business discipline, and a basic understanding is important to seek efficiencies.

This chapter will present the supply chain management concepts and then expand to consider the application to food fraud prevention.

Key Learning Objective 1: Supply Chain Management Introduction

This section will cover an overview of supply chain management (SCM) including that this is a specific area of academic research and study.

The Key Learning Objectives of this section are

- (1) Introduction to the academic discipline of supply chain management
- (2) Review of the complexity of supply chain management
- (3) The role of procurement in business management and vulnerability reduction

Theoretical Foundation

Supply chain management (SCM) is the science of “multiple firms collaborating to leverage strategic positioning and to improve operating efficiency” (Bowersox et al. 2002). It is also defined as “a network of organizations that are involved, through upstream and downstream linkages, in the different processes and activities that produce value in the form of products and services in the hands of the end user or consumers” (Christopher 2016). Generally, this is a collaboration and coordination of product flowing through from the manufacturing, distribution, storage, and presentation of the product to the customer (Bowersox et al. 2002). In the 1950s there was a specific focus on *logistics* which is the management and control within a company’s proprietary supply chain and essentially the “work required to move and geographically position inventory” (Bowersox et al. 2002). With growing computing power and globalization, there was a need to expand the focus from logistics to the overall supply chain. The modern science of Supply Chain Management has expanded to include Procurement (purchasing), Operations Management (quality control, inventory, and scheduling), and Logistics (transportation).

Since the 1970s, supply chain management has been an autonomous academic discipline. In the USA there are over 100 universities that offer a bachelor’s degree and over 30 that offer a Ph.D. in Supply chain management. This is often a separate department within a business school.

A foundational concept is the generalized supply chain model which is presented here (Fig. 9.2). Each step includes a complex web or network of participants and

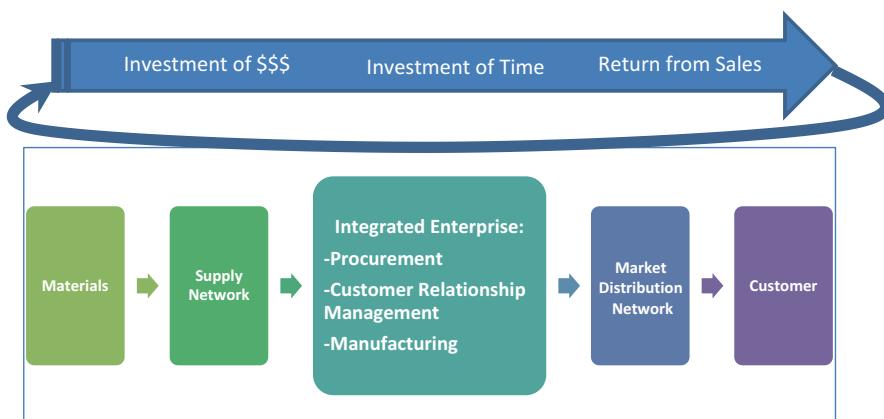


Fig. 9.2 Adaptation of the generalized supply chain model. (Adapted from (Bowersox et al. 2002))

processes. “The integrated supply chain perspective shifts traditional channel arrangements from loosely linked groups of independent businesses that buy and sell inventory to each other toward a managerially coordinated initiative to increase market impact, overall efficiency, continuous improvement, and competitiveness” (Bowersox et al. 2002).

For food fraud prevention, at each step in the supply chain fraud can occur and disrupt the system. As the supply chain becomes more complex and more automated, the fraud opportunity shifts and evolves. A lack of consideration of the fraud opportunity has been catastrophic for the supply chain of a product, company, or industry. Fortunately, the collaboration and coordination that is effective in supply chain management can evolve to consider and combat product fraud.

Supply Chain Complexity

The supply chains are getting more complicated and complex. They are complicated since more products are moving farther and faster around the world. They are more complicated because of the multiple hand-offs with more requirements for the transaction information. Three main factors reported have accelerated the development of supply chain management that includes (Black's 2014):

- “(1) Information and communication technology (ITC)
- (2) Global competition and expansion
- (3) Integration and interrelationships.”

The globalization is a great opportunity for the industry to expand markets and also for governments to expand their economies.

While globalization and electronic communication have increased the speed and efficiency of commerce, it also has some unintended side effects. With more products moving around the world farther and faster, the minimum economic scale of manufacturing has grown (Porter 1980). A manufacturing plant often produces a product that is used—literally—around the world. There are considerable economic and quality control efficiencies with bigger, fewer providers but also narrowing of supply through key nodes. With fewer and bigger suppliers, one quality control or production disruption can literally have global ramifications.

The expanding global supply chains also sometimes create uncertainty since there is often less transparency of the transactions, sometimes less control at each step, and generally more variables in the entire process. The uncertainty is in addition to usual risks—uncertainty is the inability to know in advance the exact likelihood of future events. Risk and uncertainty are two key variables that are a focus of the Enterprise Risk Management system implemented by COSO (2013):

- **Risk (ERM/COSO):** “The possibility that an event will occur and adversely affect the achievement of objectives” (COSO 2011).
- **Uncertainty (ERM/COSO):** “The inability to know in advance the exact likelihood of future events” (COSO 2011).

One complexity is that there is possibly a global network of direct suppliers (Tier 1) who also could be buying from a global network of suppliers (Tier 2) who then, in turn, could be buying from a global network of suppliers (Tier 3). There are usually strong relationships and oversight of the Tier 1 suppliers but less and less deep into the supply chain. A traditional tiered supplier structure is that one supplier buys from many, and there is the safety of many suppliers able to support the needs. The lack of supply chain transparency could inadvertently create a dangerous supply situation where many Tier 1 suppliers actually buy from few Tier 2 suppliers who, in turn, may actually be from only a handful or a single Tier 3 supplier. The danger is a lack of awareness that a company's supply chain—or even an industry-wide supply chain—could be impacted by supply variability at one, single supplier.

Tiered Supplier Structure—Traditional: Many-to-One While there can be visibility and management of Tier 1 suppliers (first supplier selling directly to a manufacturer), there is less transparency for Tier 2 (they sell to the first supplier who in turns sells to the manufacturer) and even less for Tier 3 (they sell to the Tier 2 suppliers) (Fig. 9.3). This is a concern for quality management but also for supply continuity. Usually, but not always, Tier 1 supplier buys from many Tier 2 suppliers who, in turn, buy from many Tier 3 suppliers. In practice, this is a dangerous assumption. In some cases, a key component could be produced by one company for wide-scale use across the entire supply chain.

Tiered Supplier Structure—Dangerous: One-to-Many: If there are only a few—or one—Tier 3 suppliers for the Tier 1 and Tier 2 suppliers, then a problem at the Tier 3 suppliers can cripple a supply chain and entire industries (Fig. 9.4).

The lack of risk awareness in *nontransparent*, multitiered supply chain could add an additional variable of a lack of communication of standards or food safety requirements. The Tier 2 or Tier 3 suppliers may not understand the end customer

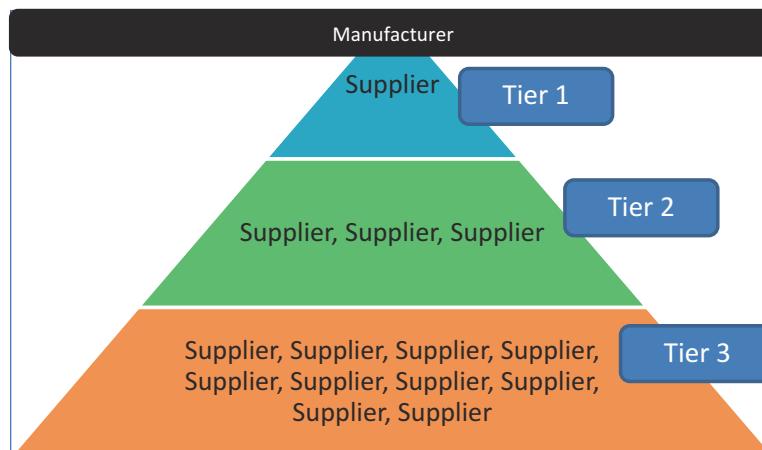


Fig. 9.3 Traditional tiered supply chain structure—traditional: many-to-one

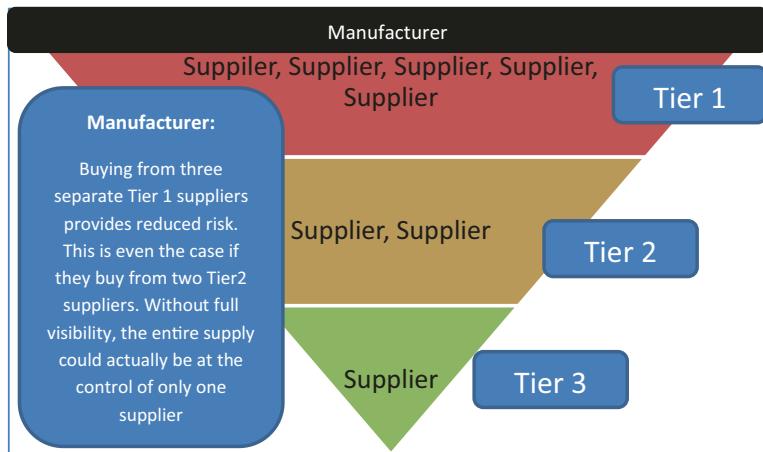


Fig. 9.4 Supply chain example of a dangerously tiered distribution network including Tier 1, Tier 2, and Tier 3

specifications or needs. The Tier 2 and Tier 3 suppliers may not even know who the manufacturer is. It is possible that the Tier 2 supplier does not correctly specify the product from the Tier 3 supplier, and the fraud opportunity is that the Tier 3 supplier can intentionally—but possibly not illegally—provide a different product than specified.

This is not only a plausible example; this is an actual incident where several automobile manufacturing plants were shut down due to the Japanese Fukushima Daiichi Tsunami incident. Several Tier 1 and Tier 2 suppliers all relied on the material from the Tier 3 supplier who was shut down during the tsunami (MacKenzie et al. 2012; Reuters 2016). For a specific example from this incident, the closure of one manufacturing plant that produced the material used to manufacture an 18" fuel tube for many auto manufacturers' led to worldwide automobile production shutdowns (Massey 2011). This is not a one-time anomaly since another time a fire at a local Michigan automobile parts supplier shut down several automobile manufacturing plants due to a lack of supply (Howard 2018).

Important Concepts and Focus Areas

To control for the uncertainty and risks inherent in business or government activities, there are many systems or programs that have been developed and refined such as quality management.

Total quality management (TQM) is a coordinated effort to identify and address the root causes of anomalies that negatively impact the final product or the operations (Boyer 1996; Jaycock et al. 1997). The overall focus shifted from Juran in 1951 focusing on controls in the *Quality Control Handbook* then Feigenbaum in

1956 shifted along the control spectrum to “total quality control” (TQC). In 1987 Gavin, among others such as Deming, Crosby, and Kaizen, further broadened the focus to “strategic quality management” or eventually the hybrid of TQM. The evolution was from controls and catching bad product to designing flaws or anomalies out of systems. For the food industry, quality assurance or quality management are familiar function titles.

There are eight dimensions of quality. These also possibly apply to the broader food concept of food integrity (Garvin 1987):

- Performance: how the product performs compared to expectations or specification
- Reliability: likelihood that the product will perform as intended
- Durability: likelihood that the product will perform over an expected period of time
- Conformance: meeting a specific description or attribute as designed
- Features: number of functions it is intended to perform
- Aesthetics: style, material, etc.
- Serviceability: ease of repairing or fixing compared to expectation
- Perceived quality: value judgment

One TQM program is Six Sigma—or a zero defects focus—program and processes that are widely adopted. For food fraud prevention, it is efficient to use TQM and Six Sigma concepts not only for the familiarity but due to the utility of the programs. The basic management of Six Sigma is five phases for of product or process development of define, measure, analyze, design, and verify (DMADV) or ongoing monitoring including stages of define, measure, analyze, improve, and control (DMAIC). These are basic concepts of plan-do-check-act (PDCA) that are the base for more general analysis management such as in ISO 31000 and applied assessments such as in the criminology scanning, analysis, response, and assessment method (SARA).

To prioritize the risk treatments, the basic quality management methods require an assessment of the overall problem (how can you say you’re addressing the most critical problem if you haven’t assessed the entire system) and also some factors that can be measured (define success metrics that can actually be measured and that realistically reduced the fraud opportunity).

The fraud opportunity can be deconstructed into measurable component root causes that are critical control points. While addressing food safety in a HACCP (hazard analysis) program is very different from addressing food defense in a VACCP program (vulnerability assessment)—or food defense in a TACCP program (threat assessment)—the underlying method applies (GFSI 2018). The underlying quality management principles are to identify the root cause, change operations to reduce the chance for the anomaly to occur, and then continually review the system remains in compliance.

“In the recent years, the Six Sigma program for quality and process improvement has been adopted by many of the larger firms in the United States and around the world” (Bowersox et al. 2002). The core of Six Sigma is based on the concept of a

statistical standard of deviation where the standard of deviation (one sigma) would result in 68% of the production meeting specification. To be a successful business, the Six Sigma system expands the goal to six standards of deviation (six sigma) or 99.99966% of the production meeting specification (3.4 defects per 1 million units produced) (NIST; ISO 2011a, b). As a raw percentage that may seem like an unrealistically low number but the errors can compound, the costs of just one nonconformance can be a global product recall costing hundreds of millions of dollars. A “defect” is something that is outside the customer specification—the customer specification should be clearly defined and expressed in a measurable factor.

There are four TQM types of costs (Jaycock et al. 1997):

- **Appraisal (audit):** the cost of inspections to assess quality levels
- **Internal failure:** costs of failures before the product is shipped
- **External failure:** costs of failure after shipped including recall, settlements, lost sales, rework, etc.
- **Preventive (countermeasures or control systems):** efforts to control quality or to mitigate failure costs

For food fraud prevention, without conducting a vulnerability assessment, the impact on the firm is not—and, thus, cannot be—evaluated. In most cases, the vulnerability is very low and does *not* lead to a risk that is so dangerous or costly that it must be mitigated. Often, when evaluating the vulnerability in relation to quality, there are many very simple, low-cost, efficient, and effective countermeasures and control systems.

Sidebar: HACCP as a Total Quality Management System

While the primary systems are based on quality management, food scientists often scoff at the idea that HACCP is a quality management system rather than a public health assessment. HACCP is focused on public health threats and the use of rigorous and methodical control systems to focus on and reduce the hazards. To review, the US FDA defines HACCP as:

- “**HACCP** is a management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement, and handling, to manufacturing, distribution, and consumption of the finished product”(FDA 2017).

HACCP is the application of a total quality management system to foods, and they both are aligned with international standards. One of the most widely adopted quality management systems is ISO 9000 Quality Management which was updated in 2015 and reportedly has over 1.1 million certificates issued worldwide (e.g., companies or locations that are certified to have met the requirements of the standard) (ISO 2015).

The International Standards Organization (ISO) with the most widely adopted and original quality system of **ISO 9000** series is “A quality

management system is a set of policies, processes, and procedures required for planning and execution (production/development/service) in the core business area of an organization" (ISO 2015). The ISO 9000 section "8.3 Control of Non-conforming Products" does state "customers seeking confidence in an organization's ability to consistently provide products and services conforming to their requirements." So considering the definitions of HACCP and quality management, HACCP is a quality management system that focuses on the management and control of a specific set of nonconformances that, if not controlled, could lead to public health hazards. The refinements in HACCP plan are a way to apply a specific method for the hazard identification and hazard analysis (the "HA" in "HACCP") then identifying the root causes of the nonconformances by identifying and managing critical control points (the "CCP" in "HACCP"). For HACCP, a CCP might be controlling and monitoring the temperature of a refrigerator. The HACCP principles are built upon basic quality management principles. It is logical to also base food fraud prevention concepts on a quality management system, to apply a specific method for the vulnerability assessment (the "VA" in VACCP), and then to identify the root causes of nonconformances by identifying and managing critical control points (the "CCP" in VACCP). A food fraud "CCP" might be to occasionally conduct and document a species test to confirm a supplier certificate of analysis.

Sidebar: ISO 9000 Key Terms

While reviewing quality management, it is good to review the key concepts and their definition. From ISO 9000 (with ISO 9000 section references) (ISO 2015):

Quality policy: policy (3.5.8) related to quality (3.6.2); Note 1 to entry: Generally the quality policy is consistent with the overall policy of the organization (3.2.1), can be aligned with the organization's vision (3.5.10) and mission (3.5.11), and provides a framework for the setting of quality objectives (3.7.2).

Quality objective: objective (3.7.1) related to quality (3.6.2); Note 1 to entry: Quality objectives are generally based on the organization's (3.2.1) quality policy (3.5.9); Note 2 to entry: Quality objectives are generally specified for relevant functions, levels, and processes (3.4.1) in the organization (3.2.1).

Quality planning: part of quality management (3.3.4) focused on setting quality objectives (3.7.2) and specifying necessary operational processes (3.4.1) and related resources to achieve the quality objectives; Note 1 to entry: Establishing quality plans (3.8.9) can be part of quality planning.

(continued)

Quality assurance: part of quality management (3.3.4) focused on providing confidence that quality requirements (3.6.5) will be fulfilled.

Quality control: part of quality management (3.3.4) focused on fulfilling quality requirements (3.6.5).

Quality improvement: part of quality management (3.3.4) focused on increasing the ability to fulfill quality requirements (3.6.5); Note 1 to entry: The quality requirements can be related to any aspect such as effectiveness (3.7.11), efficiency (3.7.10), or traceability (3.6.13).

Combining these quality management principles, there is an overall goal of product quality through management (Fig. 9.5).

There are several more terms in those definitions include:

Quality: degree to which a set of inherent characteristics (3.10.1) of an object (3.6.1) fulfills requirements (3.6.4); Note 1 to entry: The term “quality” can be used with adjectives such as poor, good, or excellent; Note 2 to entry: “Inherent,” as opposed to “assigned,” means existing in the object (3.6.1).

Management: coordinated activities to direct and control an organization (3.2.1); Note 1 to entry: Management can include establishing policies (3.5.8) and objectives (3.7.1) and processes (3.4.1) to achieve these objectives; Note 2 to entry: The word “management” sometimes refers to people, i.e., a person or group of people with authority and responsibility for the conduct and control of an organization. When “management” is used in this sense, it should always be used with some form of qualifier to avoid confusion with the concept of “management” as a set of activities defined above. For example, “management shall...” is deprecated, whereas “top



Fig. 9.5 ISO 9000 GOAL: Product quality through management

management (3.1.1) shall..." is acceptable. Otherwise different words should be adopted to convey the concept when related to people, e.g., managerial or managers.

Policy: (organization) intentions and direction of an organization (3.2.1) as formally expressed by its top management (3.1.1); Note 1 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1.

Strategy: plan to achieve a long-term or overall objective (3.7.1).

Objective: result to be achieved; Note 1 to entry: An objective can be strategic, tactical, or operational.

The concepts of "strategy" and "strategic" were not fully defined in ISO 9000, so other ISO standards were considered, specifically ISO/IEC TR 33014:2013 which addresses process improvement on three levels (ISO 2013).

Strategic: what goals to achieve, the motivation, and direction

Tactical: how to achieve the goals of process improvement

Operational: how to perform the process improvement

The Role and Responsibility of the Procurement Function

The procurement objectives are to purchase the specified product at the lowest cost and with high reliability of the quality of the product in conjunction with a continuous supply. It is too simplistic to vilify purchasing managers as only focusing on "lowest cost product." While "No one wants to pay a higher price than necessary," the focus is the "lowest total cost of ownership" (Bowersox et al. 2002). The firm must define the specifications for the procurement. The specifications include the "risk appetite" of the enterprise which manages all risks or vulnerabilities. That said, "What gets measured gets better" would have an opposite idea of "what doesn't get measured doesn't get better" or maybe "what doesn't get measured can kill a company."

Procurement objectives are (Bowersox et al. 2002):

- Continuous supply
- Minimize inventory investment (on-hand inventory)
- Quality improvement
- Supplier development
- Access technology and innovation
- Lowest total cost of ownership (low cost per unit plus all related costs)

For food fraud prevention, the vulnerabilities should be plotted on the corporate risk map to be able to consider and evaluate the fraud opportunity of the suppliers and supply chains. If a Food Fraud Prevention Strategy is implemented, then there can be a robust evaluation of the fraud opportunity and the benefits of purchasing

from a higher-quality supplier, conducting additional authenticity tests in-house, entirely avoiding a type of product such as by changing a recipe, discontinue producing a vulnerable product group, or to define what the current or commodity purchases are within the risk appetite.

Sidebar: Purchasing Higher-Priced Truck Engines for Lower Fuel Consumption Costs

At the start of the Wal-mart corporate environmental sustainability initiatives around 2007, their corporate leadership considered the changing market conditions and the uncertain financial impact on the business. The Wal-mart corporate environmental sustainability initiatives were conceived in then CEO Lee Scott's "21st Century Leadership Speech" (Scott 2005). Diesel fuel prices were projected to increase significantly over a number of years to a level that the overall profitability of the business could be threatened. The current purchasing specifications did not prioritize the higher-priced engines with higher fuel efficiency. It is not the purchasing department's role to increase the corporate spend.

Although it was never mentioned during the Wal-mart initiatives or since, when reviewing the decisions through an Enterprise Risk Management lens, the Wal-mart Board of Directors could have identified the increasing fuel costs as an enterprise-wide risk. If this risk was perceived to be above the risk tolerance, then risk treatments would be considered. One option would be to ignore the risk. Another option would be to seek longer-term fuel futures contracts. Then subsequently, an option that was selected was to implement a corporate-wide effort to reduce fuel consumption and related costs.

Wal-mart considered the total cost of ownership and then increased the specification of the truck engines they were procuring. The purchasing function received a bigger budget to pay for the higher-priced engines, and the fleet operations had their fuel budget reduced a similar amount. The costs were incurred in one operation (purchasing), and the benefits were incurred in a different business operation (fleet operations). Purchasing and fleet operations were connected in a joint operation where collaboration led to enterprise-wide success.

It is reported that over a multi-year period, diesel fuel prices did go up 25%, but due in part to the sustainability projects, the Wal-mart fuel consumption costs stayed the same or decreased. A key is that even at a break-even return on investment, Wal-mart benefited because it was estimated their competitors' fuel prices went up the full 25%. Wal-mart received other benefits of a reduced number of shipments needed to support the same amount of business. At a public meeting, a Wal-mart Supply Chain Logistics Senior Manager jokingly complained that the massive increase in efficiency caused a problem of them having to find a place to store all the empty and idle company-owned trailers.

For food fraud prevention, there may not be an as direct and quantifiable benefit in a traditional “ROI” sense, but total quality management analysis can be applied to focus on the critical control points that have a much lower “fraud opportunity.” Food fraud should be considered in an enterprise risk assessment and the vulnerability judged in relation to the risk tolerance. If food fraud is not a single identified problem above the risk tolerance, it probably contributes to other issues of concern such as food safety incidents, maintaining brand equity, and the ability to implement new products successfully.

Supply Chain Documentation

For food fraud prevention, there are several key supply chain documents and primary concepts.

- **Bill of lading or uniform bill of lading:** “is the basic document utilized in purchasing transport services. It serves as a receipt and documents the products and quantities shipped. [...] The information contained on the bill of lading determines all responsibilities related to timing and ownership [including when the invoice is to be paid]” (Bowersox et al. 2002).
- **Order notified export:** “It provides that delivery not is made unless the original bill of lading is surrendered to the carrier. ... Upon customer payment for the product, the credit institution [third party] releases the bill of lading [and ownership of the product]” (Bowersox et al. 2002).
- **Freight bill:** “is a carrier’s method of charging for transportation services performed [such as delivering a truckload of product]. ... The freight bill may be either prepaid [paid by sender] or collect [paid by receiver]” (Bowersox et al. 2002).
- **Shipment manifests:** “lists individual stops or consignees when multiple shipments are placed on a single vehicle” (Bowersox et al. 2002).

There are other documents which are specific to food or food safety (Fenoff and Spink 2016). A survey of food fraud industry experts found 35 different documents they deal with to conduct their operations. For food fraud prevention, these documents are statements of legal export/import, a statement about the product origin, a clarification of where ownership was transferred to the recipient, declaration of the specifications, declaration of the authenticity, and other tax or reporting requirements.

The five most common supply chain documents related to food fraud are listed below (Fenoff and Spink 2016):

- **Certificate of analysis:** A certificate of analysis is a statement of the test results for the product or sample provided, including the test results, methods used, testing lab, as well as the date of the test and in the identification of the original batch (WHO 2002).

- “The certificate lists the results and includes a final evaluation and the conclusions of the examination of one or more samples.” “In accordance with [Good Manufacturing Practice regulations], the certificate can be used in lieu of testing by the manufacturer (except for the identification tests as a minimum requirement), provided that the reliability of the supplier’s analysis is established by the periodic validation of the test results by appropriate means and, if feasible, by on-site audits of the supplier’s capabilities.”
- **Credence attribute statements or certifications:** A credence attribute statement is defined as confirmation or declaration of an attribute that a valuable aspect of the product that cannot be readily detected or evaluated such as organic, country of origin, fair trade, sustainably harvested, processing such as kosher or halal, or others.
- **Bill of lading:** These are described above.
- **Laboratory analysis test results:** These are the reports from specifically defined tests.
- **Import and export documents:** These are described above.
- **For food fraud prevention**, they are a statement of legal export/import, a statement about the product origin, a clarification of where ownership was transferred to the recipient, and other tax or reporting requirements.

Other related and essential concepts include:

- **Force majeure:** These are “circumstances beyond anyone’s control, such as natural disasters” (Bowersox et al. 2002).
- **For food fraud prevention**, supply agreements could be written to expand “force majeure” to a product that is determined to be illegal and seized by governments. In this case, the supply agreement could nullify the purchase and the requirement for the buyer to pay for the product. If the buyer corporate policy states suspected illegal product must be reported to the government, there might be a major reduction in the “fraud opportunity.” This is due to the situation that if the product must be reported to the government, then the fraudster risks losing the costs to produce the entire shipment after a seizure, the fraudster would become publically identified during court proceedings as criminals, and this could also lead all their global shipments to be suspicious and subject to additional government scrutiny.
- **Freight on board (FOB):** this can either be paid by the buyer (FOB origin) or paid by the seller (FOB destination).
- **For food fraud prevention**, there is a lower fraud opportunity if the purchaser takes possession of the product at FOB origin since there is more control of the supply movement and traceability.

There are other customs or financial documents that meet other details or needs.

For food fraud prevention, there should be an awareness of how and where fraudulent documents can allow fraudulent products to enter the supply chain.

Key Learning Objective 2: Supply Chain Characteristics

This section will cover the complexity of supply chain management and systems to organize, manage, and protect the flow of material goods.

The Key Learning Objectives of this section are

- (1) Understand the impact and risks of the globalization of commerce.
- (2) Explore traceability, electronic transactions, and e-commerce.
- (3) Implement food fraud prevention in the supply chain.

Globalization

The World Health Organization (WHO) defines ***globalization*** as “...the increased interconnectedness and interdependence of peoples and countries, is generally understood to include two inter-related elements: the opening of international borders to increasingly fast flows of goods, services, finance, people and ideas; and the changes in institutions and policies at national and international levels that facilitate or promote such flows. Globalization has the potential for both positive and negative effects on economic development and health” (WHO 2018).

To consider the supply chain management complexity, it is estimated that 90% of global demand for goods are *not* covered by local supply (Bowersox et al. 2002). There are many reasons for globalization including the enabling of more efficient production being shifted to areas with optimal natural and human resources. Globalization enables a bigger economic scale of manufacturing which also lowers costs due to being near raw materials supply, low-cost labor, and reduced manufacturing costs due to high-volume production. Production can be concentrated because the output can be moved farther and faster around the world. Each economy relies on the products being able to move quickly across borders. “In addition to the sales potential, involvement in global business is being driven by significant opportunities to increase operating efficiency.” The efficiencies include being able to strategically source raw materials, labor cost advantages in developing nations, and favorable tax laws for value-added operations (Bowersox et al. 2002).

From Bowersox, Closs, and Cooper (2013), the “logistics of internationalization” involve four considerations “plus one” (the term logistics is referring to challenges of organizing not the process of managing products through a supply chain) (Bowersox et al. 2002):

Logistics (Challenges) of Internationalization:

- (1) **Distance:** how far the product moves from production to user.
- (2) **Documentation:** more complex coordination of the record of the transactions.
- (3) **Diversity:** differences in the work practices, cultural norms, laws and regulations, and general operating environment.
- (4) **Demand:** differences in product preferences in different markets.

- (5) **Defense (“plus one”):** an additional consideration is defined as security and specifically here to address terrorism. This could expand to include all types of intentional acts including those such as terrorism that has intent to harm but expand to others such as disgruntled employees, malicious tampering, and sabotage. Another intentional act is product fraud conducted for economic gain—while there may not be an immediate incident, an entire supply chain could be infiltrated and compromised.

For each of the four plus one considerations, there is an increased “fraud opportunity” which has examples noted here.

- (1) **Distance fraud opportunity:** there are more transfers of products and less of a direct relationship from the manufacturer to the user.
- (2) **Documentation fraud opportunity:** there is more of a reliance on the statements about the product rather than direct control to the point that many transactions are only digital.
- (3) **Diversity fraud opportunity:** there are regional, industry, social, or socioeconomic norms that differ around the world—a practice that is commonplace and accepted in one market may not be understood or even be unknown in another. This difference in understanding of the norms can create confusion or problems.
- (4) **Demand fraud opportunity:** there are regional, industry, social, or socioeconomic norms that differ around the world—a practice that could lead to a misunderstanding of terms, specifications, or what makes “common sense.”
- (5) **Defense fraud opportunity:** this is a specific awareness and understanding of the range of security issues that could lead to a disrupted or compromised supply chain from intentional illegal acts.

Globalization is an essential driver of economic growth. The changing and expanding volume of the movement of goods also presents emerging and evolving risks such as product fraud. A key point is to understand how the supply chain is changing and consider the shifting fraud opportunity. When there is an understanding of the shifting vulnerabilities, then efficient and effective countermeasures and controls systems can be implemented.

E-Commerce

A new and rapidly evolving supply chain innovation is electronic commerce or e-commerce. *E-commerce* is the use of the Internet, or electronic methods, to conduct sales transactions. The number of mobile phone technology users is booming worldwide, which—when combined with the use of electronic currency (e-currency; e.g., PayPal, ApplePay, SamsungPay, WeChat, QQ, and Bitcoin) and mobile phone application software or “APPs”—leads consumers to benefit from the efficiency of

ordering online. Whether the APP is an online order from a physical retail store or a direct-to-consumer retailer, the consumer is getting more and more product delivered to them rather than picking up the product at a retailer. Depending on the product and the geographic location, the product can be delivered by traditional parcel delivery services (e.g., United Parcel Service UPS, government mail systems, or other rapid delivery such as FedEx or DHL) or local couriers (e.g., bicycle or motorcycle delivery or other more local options). In places like Beijing, China, companies like Amazon.com have their own fleet of delivery vehicles such as trucks, tuk-tuks, motorcycles, and bicycles. In places such as New York City, companies such as Peapod have their own truck fleets.

Once consumers get setup and familiar with an e-commerce company or system, the convenience is easy and can even be addicting. Online shopping for clothes or consumer products has boomed as “Black Friday” shopping sales have expanded to include “Cyber Monday.” Another example, why get up from your desk and walk to a coffee shop when one-click on an APP can have a latte delivered hot to your desk or your park bench. Also, the online ride-ordering services such as Uber and Lyft are providing many new mobile phone features such as being able to see a map of the drivers in your area and to see the wait time until pickup (which is easier than standing curbside waiting to hail a traditional taxi cab but not as easy as walking right up to a waiting taxi), there is a safety factor of your location and driver being monitored and recorded, and the transaction is cashless and even physical-interaction-less. So, consumers are becoming more and more confident and reliant on e-commerce. This has benefits but also significant drawbacks for food fraud prevention.

Some food fraud prevention concerns with e-commerce include (Spink 2016, 2017):

Food Fraud E-Commerce-Related Challenges:

- Not knowing exactly where the product is coming from (which could include a continuum from a national delivery service to a local courier).
- Not knowing how the product was handled or mishandled (such as a continuous cold chain or other contaminants).
- Not being able to sample or assess products before purchase.
- There is a lack of clarity on when the product—and legal responsibility—transfer to the end user (is the courier in contract with the end user or the seller? Is a trading platform such as Amazon.com, BestBuy.com when facilitating a nonproprietary marketplace transaction, or E-Bay, a participant in the transaction with legal responsibility?).
- There is a possible lack of supply chain and handling transparency across the different delivery options (you may order from one e-retailer, and the delivery may be conducted by multiple companies).

E-commerce is an immense opportunity for the marketplace, companies, and consumers, but there will need to be a tremendous amount of research to become aware of the evolving “fraud opportunity.”

Sidebar: “Do you Think that Is Why Those Brokers Stopped Bidding on Our Business?”

Consider a hypothetical—but realistic—example where a company’s purchasing volume required them to purchase through brokers, and during the implementation of their Food Fraud Prevention Strategy, the number of brokers bidding on their business decreased. While the exact reason could not be determined, it is possible that the increased awareness and discussion of food fraud—such as in the request for proposal RFP documentation and recommended training programs—scared fraudsters away. It is possible that the new food fraud prevention requirements led to fraudulent suppliers to decide not to bid on the proposal since they would risk getting caught.

For the company in this example, they bought a commodity ingredient and then adjusted their own operations to achieve a flavor profile. Whether they bought a fraudulent product or not, they were impacted by their cost of goods. On the other hand, if they labeled their product with details of the raw material (e.g., “Made in Michigan” when the ingredient was actually “Made in Illinois”), then not only would they be financially cheated but their finished good would be unintentional food fraud. Another misbranding problem would be if they made claims about the percentage or weight of honey in their product. Their finished goods would be illegal and subject to a product recall.

A primary concern by the company was that the procurement costs would increase due to fewer suppliers bidding on their business (Fig. 9.6). A statement from management was that “If we eliminate these suppliers then our costs will go up.” This took a while for us to think about. There were two issues with a first concern about limiting their procurement options but then second a lack of awareness that their own product may be a violation of the



Fig. 9.6 Example of the impact of reducing the fraud opportunity on the cost of goods

FDCA Adulterated Foods or the Misbranded Foods Sections. Later, when reviewing the process in detail, since they were buying the commodity for the attribute, not just the weight, their total cost of goods should usually be the *same* with a *reduced* fraud opportunity and reduced overall enterprise-wide risk. For example, if they previously paid \$1000 per 1000 pounds (\$1/pound) and the product was diluted by 10%, they were really paying \$1.11/pound of pure product. Also, they had an attribute quality specification in their own product (e.g., an amount of flavor), so purchasing the higher-priced pure product—which had a more intense flavor—also led them to use fewer pounds. While the previous operation may have needed to use 25 pounds of raw material per batch, to achieve the same flavor specification, they now only needed to use 22 pounds.

This example demonstrates the complicated and nontraditional thought process when dealing with food fraud. For most of the commerce, “laws are for the lawful,” and generally, companies are trying to do the right thing. For food fraud prevention, the fraudsters intend to deceive and actively seek to avoid detection.

Sidebar: Early Supplier Involvement (ESI)

A supply chain management concept is “early supplier involvement” (ESI) (Zsidsin 2007). “ESI is a form of collaboration in which purchasing firms involve suppliers at an early stage in the product development cycle, often during the need recognition and description phases of the [supplier development procurement] acquisition process” (Zsidsin 2007). The relationship deepens when “Involvement becomes more significant as the supplier takes an active part in development processes by activities such as executing detailed drawings based on rough sketches provided by the purchasing organization” (Zsidsin 2007). While the major enterprise benefit is efficient operations and reduced operating or handling costs and a proactive focus, there can be benefits for food fraud prevention. An early focus on “total quality” can include systems and processes to reduce food fraud throughout the entire supply chain.

During the longer and more in-depth relationship building during the ESI process, the supplier and entire upstream supply chain will come under more scrutiny, and more efficient processes will be identified, implemented, and then refined.

By reviewing the “managerial implications,” the additional benefits of ESI are identified (Zsidsin 2007):

- **Forming strong relationships:** This creates stronger relationships during the supplier selection process which increases the ability to “determine

(continued)

which suppliers will best be able to meet the specified outcomes in terms of quality, delivery, and cost and timeline goals.” The early engagement can encourage suppliers to adopt more rigorous or efficient quality management programs such as fraud prevention.

- **For food fraud prevention**, this could include sharing of Food Fraud Vulnerability Assessments and Food Fraud Prevention Strategy plans.
- **Avoiding adverse selection and moral hazard:** The longer and deeper involvement in the ESI process creates a more thorough vetting of suppliers. “Moral hazard is reduced by having suppliers that either cannot meet up-front or are not willing to put forth the required effort to meet demand requirements are eliminated from further consideration early within the process” (for more on moral hazard, see the section on Dr. Kenneth Arrow).
 - **For food fraud prevention**, an example is that suppliers who know—or suspect—their raw materials are fraudulent would most likely drop out of the program.
- **Transferring risk to suppliers:** Since the ESI process includes locking in agreements early, the buyer has some possible additional supply and price consistency. There is an increased benefit for the supplier to avoid budget overruns that often just get passed to the customer.
 - **For food fraud prevention**, the risk of sloppy purchasing practices, or the cost of procuring fraudulent product, would be transferring the risk to suppliers. This transfer of risk to the supplier would reduce the fraud opportunity.
- **Developing supply chains:** With the increased involvement, there is an increased long-term business engagement, so marginal companies may evolve into “world-class” suppliers. The longer-term agreements could increase the confidence of a supplier to invest in training, methods, or equipment. This is a benefit to both the purchaser and supplier.
 - **For food fraud prevention**, the longer and deeper relationship—combined with the thorough supply chain transparency—would reduce the willingness to commit fraud. An example would be suppliers who are encouraged and supported through higher-level standards and certifications such as the Global Food Safety Initiative. An example is the GFSI Global Markets Program which educates and trains small- and medium-sized enterprises.

In summary, adding fraud prevention to the early supplier involvement is efficient for the business and advances the overall benefits to both purchaser and supplier. The food fraud prevention tasks and benefits are secondary to the full relationship but can add value.

Key Learning Objective 3: Continuity Planning and Crisis Management

This section reviews the focus on keeping the operations going through continuity planning and crisis management.

The Key Learning Objectives of this section are

- (1) Overview of internal controls for SCM
- (2) Continuity planning and crisis management
- (3) The presentation of the Food Fraud Tabletop Exercise (FFTX)

Internal Controls for Supply Chain Management

With the more complicated and complex supply chains, there is a need for more robust internal controls and an integrated framework (MSU-FFI 2017; MSU FFI 2017). **Internal controls** are defined as standardized methods or systems to monitor and manage operations (COSO 2013).

It is important to emphasize that “Enterprise Risk Management” is not an informal or general term. ERM is a concept defined in financial or managerial accounting regulations. The statement that an assessment is “Enterprise Risk Management” or “ERM” could be inadvertently making a legal or regulatory statement (COSO 2011). An informal risk aggregation—or “gathering a bunch of food risks”—is not ERM.

From ERM/COSO, the specific definition and scope that apply to the SCM questions (COSO 2013):

- **Internal controls** are defined as “A process, effected by an entity’s board of directors, management, and other personnel, designed to provide reasonable assurance regarding the achievement of objectives in the following categories: effective and efficiency of operations, reliability in financial reporting, and compliance with applicable laws and regulations. An internal control system is a synonym for internal controls applied in an entity.” This is “An effective system of internal control reduces, to an acceptable level, the risk of not achieving an objective relating to one, two, or all three categories of objectives.”
- **Integrated frameworks** are defined as interconnectivity of internal controls to coordinate operations as well as provide an overall monitoring and calibrating system.

Supply chain management provides a vital role in the efficient management of a business. Information about supply, work-in-progress, sales, returns, and other inventory matters can be digital and can be automatically fed into an enterprise-wide system such as Enterprise Risk Management (ERM). The automatic, digital monitoring of the supply chain can be leveraged and also expanded to carry and analyze information about food fraud.

As food fraud prevention becomes a compliance requirement for food safety, such as for the Global Food Safety Initiative (GFSI) or the US Food Safety Modernization Act (FSMA), there is a more formal activity that will undoubtedly expand to ERM. Product fraud—including food fraud—is an enterprise-wide responsibility that can impact revenue and brand equity. Overall—including for the GFSI, related standards, and even regulation such as the US Food Drug and Cosmetics Act and the US Food Safety Modernization Act—addressing food fraud is *not* optional, so there will be more formalized analysis and reporting that can provide a clearer understanding of the extent of ERM/COSO compliance. This harmonized activity will also enable efficiency from the sharing of best practices and benchmark against conventional systems. Food fraud is being defined and researched as a specific type of enterprise risk. Food fraud prevention countermeasures and control systems are being analyzed in relation to ERM and presented on a corporate risk map.

Reviewing food fraud does *not* create a new risk. Food fraud is an ERM/COSO defined “inherent risk.”

- An ***inherent risk*** is defined as “An effective system of internal control that reduces, to an acceptable level, the risk of not achieving an objective relating to one, two, or all three categories of objectives” (COSO 2013).

From a previous MSU Food Fraud Initiative Report (MSU-FFI 2017):

The Options for Addressing Food Fraud:

- (1) Ignore the risk and “hope for the best.”
- (2) Implement Food Fraud Prevention Strategy.
- “*Not* being proactive can destroy a company and be a felony crime” (MSU-FFI 2017).

The Board of Directors—in addition to Sarbanes-Oxley Act reporting requirements—hold the C-suite accountable and responsible for addressing all risks whether they are currently known or not. The accountability and responsibility for inherent risk are one of the main drivers for implementing a food fraud prevention system that applies to all types of fraud, to all types of products, and that integrates into the enterprise-wide assessment system.

Business Continuity Planning and Incident Management

Business continuity planning (BCP) is a critical part of business controls including how to respond to an incident. BCP is a more positive term for “crisis management.” This can be reviewed or practiced in a mock incident review or tabletop exercise (Brindley 2017).

Business Continuity Planning (BCP) Components:

- (1) Create system awareness.
- (2) Prevent supply chain disruptions.

- (3) Remediate supply interruptions.
- (4) Manage knowledge.

In BCP, there is a focus on understanding and embracing the “uncertainty of supply,” especially with regard to events that could not have been foreseen. However, there may be circumstances where risk can be identified a priori [“theoretical deduction not from empirical evidence” (Black’s 2014)] (Brindley 2017). In food fraud prevention terms, this would be identifying and addressing vulnerabilities (that have not occurred... *yet*) in addition to risks (have occurred, known).

For food fraud prevention, one way to increase the awareness and concern regarding food fraud is to propose a BCP Mock Incident. There are several actual incidents that have a lot of public details about the event and the costs including legal or regulatory penalties. Several incidents should address different types of food fraud that had supply chain-stopping power, for example, horsemeat in beef (an adulterant substance of high quality and safety but illegal mislabeling), date-code tampering (initially a McDonald’s alleged incident in China but now also the widely publicized “2 Sisters” incident in the UK), stolen goods (either the stolen goods reentered into commerce or the remainder of the lot), or mislabeled product donated to a nonprofit but reentered into commerce (labeling error then the product philanthropic donation for export but some of the product reentered the US market).

Continuing the focus on BCP, food fraud is one type of “supply disruption.” “It is impossible to eliminate the risk of supply chain disruption totally; however, it is critical to have a plan in place to deal with the disruptions when they occur” (Brindley 2017). The most basic supply disaster recovery planning includes questions such as (Brindley 2017):

1. “Is there an emergency disaster/business recovery/business continuity plan established in the supplier company?” [Then, does it include food fraud?]
2. “Is the plan deployed according to all existing sites?”
3. “In the case of disaster are there procedures to restart minimum service levels and to organize transport to a backup site?”

The recovery plan is as important as the prevention focus since subsequent incidents or product recalls can occur from well-meaning individuals who creatively try to address the crisis. There should be clear standard operating procedures and approvals for any variation in the food production or handling.

Mock Exercise: Food Fraud Tabletop Exercise (FFTX)

There is often debate whether food fraud prevention and incident response are addressed in existing methods or programs. One way to test this is to conduct a mock incident response or mock product recall. If the methods and programs are

successful, then this is evidence of a working system. More times than not, addressing food fraud is very different from other incidents or product recalls, and the tabletop exercise defines the need to modify the management and business continuation plan (BCP).

Before conducting a tabletop exercise, it is essential to get an agreement on the scope of all food fraud which can be based on FSMA, GFSI, or other regulations or standards. After the scope is defined, it is recommended to start with previous, publicly known incidents such as melamine in skim milk powder, horsemeat in beef, and peanut allergen shells in cumin. In addition it is good to choose several incidents that do not have a public health threat, but that undoubtedly could lead to a product recall such as country of origin labeling fraud (e.g., incorrect country of origin on the label), credence attribute (e.g., kosher or organic), and stolen goods (e.g., that have been reintroduced into commerce by the criminals so without confirmation of following Good Manufacturing Practices).

An example of a Food Fraud Tabletop Exercise (FFTX) is the “Something’s Fishy” project that was funded by the US Food and Drug Administration to the Michigan Department of Agriculture and Rural Development (MDARD) in collaboration with the Michigan State University’s Food Fraud Initiative (MSU-FFI [2015](#)). The FDA FREE-B program provides training for food defense-focused themes (FDA [2015](#)). “The Food Related Emergency Exercise Bundle (FREE-B) is a compilation of scenarios based on both intentional and unintentional food contamination events (FDA [2015](#)). It is designed with the intention of assisting government regulatory and public health agencies in assessing existing food emergency response plans, protocols and procedures that may be in place, or that they are in the process of revising or even developing” (FDA [2015](#)). When originally funded by the FDA, the “intentional contamination” subject of economically motivated adulteration or food fraud was still within the scope. Later, the FSMA Intentional Adulteration Final Rule narrowed their focus to “wide-scale human health harm” ([21 CFR 121](#); FSMA [2016](#)). Thus, the current FREE-B website does *not* include the links to the “Something’s Fishy” exercise.

An example of the value of the mock exercise is that it is based on real incidents and then provides some unexpected insight. Questions include:

- Is there a threat of violence against inspectors?
- When should law enforcement officers be involved?
- What was learned from the series of suspicious activity reports?
- What is the best practice for gathering information on food fraud?

One of the biggest surprises for the participants was the question of “At what point is the food inspector risking physical violence? There was a realization that we’re not combating a microbe and the adversary is a human criminal.”

Sidebar: Blog—Food Fraud Tabletop Exercise (FFTX), “Something’s Fishy” (MSU-FFI 2018)

Title: Grant Deliverable for FDA’s Innovative Food Defense Program (IFDP)
By John Spink • March 1, 2018 • Blog

Attached you will find our “Something’s Fishy” free and public Food Fraud Tabletop Exercise (FFTX) that was the final deliverable for our 2013 FDA’s Innovative Food Defense Program (IFDP) grant. Feel free to use the content as you see fit. The grant deliverables included submitting materials ready to be posted online in the FDA FREE-B program Food Related Emergency Exercise Bundle (FREE-B).

Project Update Report:

- December 2015: The FFFTX grant project was completed in September 2013. In 2015 the USA Food Safety Modernization Act (FSMA) “Intentional Adulteration” draft rule (FSMA-IA) defined the scope only to “catastrophic events.” This covers terrorism and traditional FDA food defense scope as defined by HSPD-7 and -9. Specifically, FSMA-IA defined this section – and “food defense” – to cover only the very important and extremely complex concept of “catastrophic events” such as terrorism. FSMA-IA stated that “economically motivated adulteration,” and thus food fraud, would be covered under the FSMA Preventative Controls rule (FSMA-PC), which is the traditional “food safety” type of hazard. Thus, food fraud/EMA is no longer under “food defense” and thus outside the scope of the “Innovative Food Defense Program.” It is two years since we submitted the final report to FDA and we are not sure where – or if – it will be officially posted on FDA.gov. MSU and FDA are public institutions, and the FFFTX is subject to distribution via the Freedom of Information Act (FOIA). Thus we published the content on www.FoodFraudPrevention.com.

The Michigan Department of Agriculture and Rural Development (MDARD) and MSU partnered to propose and deliver this grant. The Principal Investigator was Brad Deacon from MDARD. Michigan State University was a subcontractor with Principal Investigator John Spink and Researcher Doug Moyer. The goal of the grant was to improve the understanding of food fraud and the roles and legal authorities of participants in a state’s food emergency management plan.

From the grant proposal:

- Development and Implementation of Food Defense Tabletop Workshop Exposing and Mitigating the Vulnerability of Economically Motivated Adulteration and food fraud Incidents (PAR-12-116)

(continued)

- The development of the content and the tabletop exercise project is relevant to public health and counterterrorism since increasing the awareness of economically motivated adulteration and food fraud, is, itself, a public health benefit, but also would reduce future opportunities for malicious attacks. This project leverages theory leadership and strong relationships between the Michigan Department of Agriculture (PI: Deacon) and Michigan State University (PI: Spink with co-PI: Moyer). Furthermore, this will leverage current relationships and credibility with a broad range of stakeholders including GMA, IFT, IAFP, AFDO, Great Lakes Border Health Initiative, Michigan State Police, FDA, FBI, US Customs, and the GCC/SCC. The project will include the development of a Free-B exercise.

Live Tabletop Exercise: Pilot Event, States of Michigan & Minnesota, 2013

The development of the research project culminated in a June 2013 live tabletop exercise held in East Lansing, Michigan. There was a wide range of participants from multiple federal, state, and local agencies representing agriculture, food, public health, and law enforcement, as well as industry representatives. In addition to the more than 65 participants in Michigan, the exercise created a multi-State scenario by connecting on the phone in real time to public health officials in the State of Minnesota.

To create a realistic complexity the scenario involved product that was produced and transported between Michigan and Minnesota. Participants from the Minnesota Department of Agriculture and the FDA Minneapolis District Office worked in tandem with the Michigan team to produce an incident plan. This work included reviews of how the incident would be addressed by FDA's Rapid Response Team program.

The scenario included:

- “Bad Fish” found at a convenience store in Michigan
- Product distributed from a warehouse nearby in Michigan
- The product was Whitefish packaged in Minnesota

From the research, the key questions addressed were:

- (1) Is there a threat of violence against inspectors?
- (2) When should law enforcement officers be involved?
- (3) What was learned from the series of suspicious activity reports?
- (4) What is the best practice for gathering information on food fraud?
- (5) For a food fraud suspicious activity or incident
- (6) What would happen?
- (7) What should happen?
- (8) How can that be enabled?

One of the biggest surprises for the participants was the question of:

- “At what point is the food inspector risking physical violence? There was a realization that we’re not combating a microbe and the adversary is a human criminal.

Live Tabletop Exercise: NEHA Convention, Nevada, 2014

Principal Investigator and MDARD Emergency Management Coordinator, Brad Deacon, received high praise when he conducted the FFTTX at the July 2014 National Environmental Health Association (NEHA) Convention. There were reportedly over 150 attendees.

This FFTTX scenario was intended to be a free and public document. Please feel free to use it as you see fit. Also, please let us know if you would like additional support or updated insight on food fraud. FFI

Course Materials with Links to Video Presentation Version:

Note: these are free, open, and available for anyone to use in any setting. The content is copyrighted which just means it does need to be correctly referenced.

Course Materials:

- Situation Manual (Instructor Guide): <http://foodfraud.msu.edu/wp-content/uploads/2018/03/FFtx-situation.pdf>
- Evaluator Form (Post Event Review): <http://foodfraud.msu.edu/wp-content/uploads/2018/03/fftx-evaluator.docx>
- Presentation PowerPoint: <http://foodfraud.msu.edu/wp-content/uploads/2018/03/FFTX2-basic.pdf>
- Videos (link to YouTube content – (contact us if your network does not allow access to YouTube.com):
 - Title (6 minutes): <https://youtu.be/0WDDOvyg-9A>
 - Grant Detail (12 minutes): <https://youtu.be/nmCSlunDUIU>
 - Food Fraud Overview (16 minutes): <https://youtu.be/JaU9DOaUgZk>
 - Law Overview (9 minutes): <https://youtu.be/woXbKrXfFOk>
 - Module1 Pre-Incident (5 minutes): <https://youtu.be/syibQHfLm1o>
 - Module2 Early-Incident (4 minutes): <https://youtu.be/8eqGA-2hbX0>
 - Module3 Late-Incident (4 minutes): <https://youtu.be/mGP8NXKygsM>
 - Module4 Aftermath (3 minutes): <https://youtu.be/baJjcxL6K8Y>
 - Closing Remarks and Next Steps (9 minutes): <https://youtu.be/3Uc0I976oYE>
 - Appendix: Industry Activities and Direction (12 minutes): <https://youtu.be/1acuPA1TJ9o>
 - Appendix: Marketing Notice Overview (8 minutes): https://youtu.be/lziUS9_FX3k

Conclusion

Addressing food fraud is based on the goal to reduce often unknown and unquantified—and possibly unquantifiable—possible future costs. Supply chain management has evolved to include data analytics that addresses these types of problems including to identify and quantify very minute nuances that result directly in millions of dollars of savings. ***The first conclusion is*** that Supply Chain Management is a thorough and robust field of study that provides vital tools and strategies to manage and reduce the fraud opportunity. The range of SCM topics expands from identifying the structure and the documentation, but also to the management of those systems. ***The second conclusion is*** that food fraud prevention is a unique and complex Supply Chain Management consideration. The emerging study of food fraud prevention—and more broadly on all product fraud—is consistent with the SCM principles of quality management, data organization, and the general business practices such as ERM/COSO. ***The final conclusion is*** that there is an opportunity for further collaboration or integration of food fraud prevention with concepts SCM. The further collaboration will increase the efficiency and effectiveness of reducing the fraud opportunity which will also increase the supply chain efficiency.

Appendix: WIIFM Chapter on Supply Chain Management Fundamentals

This “What’s In It For Me” (WIIFM) section explains why this chapter is important to you.

Business functional group	Application of this chapter
WIIFM all	SCM is a valuable and thorough science that provides critical insight and support of a robust Food Fraud Prevention Strategy
Quality team	SCM is a science that can be leveraged to increase the understanding and transparency for the supply chain, while both are utilizing current transactional relationships but also to coordinate a reduction of the fraud opportunity
Auditors	The SCM concepts provide indirect “supply chain controls” that can vastly reduce the fraud opportunity— — though once set up, the time and effort required should be very low
Management	To optimize enterprise-wide risk reduction efforts, it is critical to integrate SCM and quality management programs and activities. SCM and QA should be interacting both in the incident response activities but also highly integrated for strategic risk reduction and control
Corp. decision-makers	Project proposals should include insight and coordination between many business functions including SCM

Appendix: Study Questions

This section includes study questions based on the Key Learning Objectives in this chapter:

1. Discussion Question

- (a) Why is “supply chain management” a separate business area of study?
- (b) Why has it been a challenge for SCM to prioritize and address FF?
- (c) How does “business continuing planning” and “crisis management” address FF?

2. Key Learning Objective 1

- (a) What is “supply chain management” science?
- (b) How does supply chain management relate to all other business disciplines?
- (c) What are examples of strategic, tactical, and operational FF prevention?

3. Key Learning Objective 2

- (a) What is globalization?
- (b) What are the challenges for FF prevention presented by globalization?
- (c) How does ESI inherently reduce the fraud opportunity and how could it sometimes be dangerous?

4. Key Learning Objective 3

- (a) What is “business continuity planning”?
- (b) Why is food fraud an “inherent risk” and not just a “new risk”?
- (c) When addressing food fraud, at what point is there a threat of violence against auditors or inspectors?

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Chapter 10

Supply Chain Management (Part 2 of 2):

Application Applied to Food Fraud Prevention



Summary

This chapter presents the application of supply chain management practices to food fraud prevention. There are SCM systems that are created to address current concerns and also to comply with laws, regulations, certifications, standards, and common practices. This chapter will expand on the previous review of the SCM fundamentals and address several key application challenges as well as the presentation of some specific studies. Since food fraud prevention is currently being developed and implemented, it is opportune to review the broader business application as well as specific insight from other industries.

The Key Learning Objectives of this chapter are

- (1) **Supply chain management application to food fraud prevention:** How this discipline applies to food fraud prevention practices.
- (2) **Traceability and electronic transactions:** Explore key concepts and standards related to traceability, transparency, and the opportunity for new enhanced traceability technologies.
- (3) **Review of previous enhanced traceability efforts:** Then to review details of several supply chain traceability projects or initiatives.

On the Food Fraud Prevention Cycle (FFPC), this chapter addresses the theoretical foundation concepts related to supply chain management in “(A) Academic Disciplines” (Fig. 10.1).

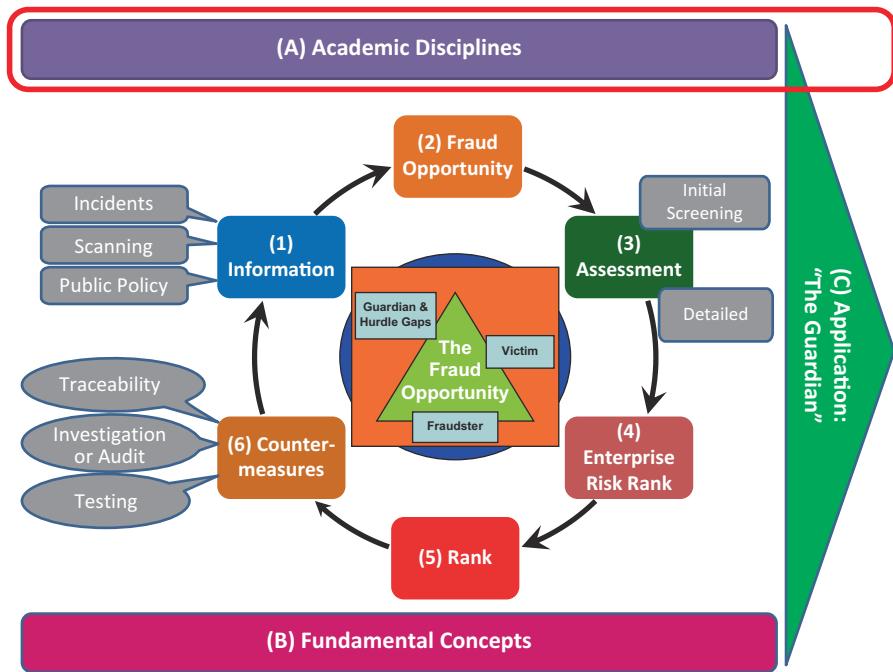


Fig. 10.1 Position on the Food Fraud Prevention Cycle: Where this chapter applies to the overall concept “(A) academic disciplines”. (Copyright Permission Granted) (Spink 2014; Spink et al. 2019)

Introduction

Supply chain management developed as a separate business school research discipline after there were examples of added value and explanation of an unmet need. As the terminology and value became clearer, the discipline kept evolving and rising in importance. Food fraud may be undergoing that type of evolution as a separate research discipline including with the direct application to supply chain management. Beyond the fundaments – of both food fraud and supply chain management – the value is explained through the application and synthesis of the academic disciplines. This chapter builds upon the previous food fraud prevention concepts and the preceding supply chain management fundamentals chapter to explain the application.

Key Learning Objective 1: Supply Chain Management Application to Food Fraud Prevention

This section reviews the food fraud prevention communication and integration into a supply chain management operation.

The Key Learning Objectives of this section are:

- (1) Understanding the current internal controls
- (2) Exploring the specific laws and regulations that apply to supply chain controls
- (3) Then reviewing the role and opportunity from enhanced traceability

Supply Chain Laws and Regulations

Laws or regulations are formal requirements, and they are supported by a range of programs or collaborations including standards.

The laws that govern the food supply chain are based on the food regulations (the production and consumption of the product) or supply chain-related regulations (the movement of the goods). The food laws in the USA include the Food, Drug, and Cosmetics Act (FDCA) and the Food Safety Modernization Act (FSMA). In addition, there are broader laws that cover smuggling, the safe transit of products, driver, and equipment requirements, as well as addressing stolen goods. For example, an FDA-administered law for drugs is the US Drug Supply Chain Security Act (DSCSA) which provides guidelines for compliance and consequences for the stolen product including considering the entire batch or lot unfit for commerce until the suspect product is identified and removed.

There are programs or collaborations from many governments, nongovernmental organizations (NGO), nonprofit organizations (NPO), nonprofit corporations (NPC), or industry initiatives (IRS 2018) (see Table 10.1). All programs provide additional transparency of the supply chain even though they often do not prioritize food or non-terrorism activities. In some cases, the focus on terrorism or public health issues shifts resources or focus from general activities and could actually create a new “fraud opportunity” for food fraud prevention.

- **For food fraud prevention**, an intense focus on pharmaceuticals, high-volume product counterfeiting, and weapons of mass destruction leads to fewer resources or prioritization of incidents such as nonpublic health-related food fraud.

There are a range of standards created and adopted including from industry organizations or international nongovernmental organizations (see Table 10.2) (for more, see chapter appendix).

Next, there is a range of ISO activities in security management and product fraud that apply to the Food Fraud Prevention Strategy (Table 10.3).

A key to all the laws and regulations is an expected level of supply chain traceability and the ability for transparency. Frequently there is even an assumption that traceability and transparency are a “given.”

Table 10.1 Review of US and global supply chain security programs

Title	Authority	Focus	Goal	Application to food fraud
Customs-Trade Partnership Against Terrorism (C-TPAT)	US Customs	Protecting the US market from terrorism and specific products imported to conduct the act	To increase the efficiency of identifying opportunities and to target inspection resources. Approved vendors can have more rapid border crossings	Additional transparency of the supply chain
Standards to Secure and Facilitate Global Trade (SAFE Framework)	World Customs Organization (WCO) (created within what would become the OECD)	Same as C-TPAT but global focus	To connect international trade communication to disrupt terrorist shipments	Same as C-TPAT. Note: the “SAFE framework” is different from the food-related “SSAFE Organization”
Partnership in Protection (PIP)	Canadian Border Services Agency	Combating terrorism but also organized crime, contraband, and other smuggling	Increase inspection effectiveness through voluntary collaboration. Similar requirements at C-TPAT	Food fraud would be one of the focus areas under smuggling, contraband, and counterfeiting
FAST (Free and Secure Trade)	US Customs (CBP) and Canada Border Services Agency (CBSA)	Facilitate US-Canada trade and inspections.	Increase inspection effectiveness through voluntary collaboration. Similar requirements as C-TPAT	Food fraud would be one of the focus areas under smuggling, contraband, and counterfeiting
AEO (Authorized Economic Operator)	European Community Customs Code (Regulation [EC] 648/2005)	Facilitate and streamline commerce across borders	Faster border crossings	Transparency of harmonized information exchange
CCSP (Certified Cargo Screening Program)	US Transportation Security Administration (TSA)	Explosives on airplanes	Protect against terrorist attacks	Some additional transparency. Resources could monitor for fraudulent activity
PCSC (Pharmaceutical Cargo Security Coalition)	NGO, similar membership as RX-360 and Pharmaceutical Security Institute (PSI)	Shared intelligence activity to secure products in the supply chain and especially large shipments such as container loads	Focus on pharmaceutical stolen goods, specifically full container (truckloads, shipping containers, etc.)	No direct application except insight on best practices

(continued)

Table 10.1 (continued)

Title	Authority	Focus	Goal	Application to food fraud
TAPA (Transportation Asset Protection Association)	An NGO organized by industry	Increase supply chain security of high-tech material and goods	A focus is on pharmaceuticals	Transparency of the entire supply chain. Resources could monitor fraudulent activity

Adapted in part from Arway (2016)

Table 10.2 Review of standards that apply to food fraud or related products

Title*	Authority*	Focus	Goal	Application to food fraud
ISO 9000 Quality Management	International Standards Organization (ISO), Technical Committee 76 Quality management and quality assurance, Sub-committee 1 Concepts and terminology (SO/TC 176/SC 1)	General business practices that streamline operations and reduce product specification anomalies. As ISO 22000 is the base for food safety management systems, ISO 9000 is the base for quality management systems	Increase the quality of the product produced and distributed	Food fraud is a component of product quality
ISO 28000 Supply Chain Security	International Standards Organization (ISO), Technical Committee (TC) 292 Security and resilience	Specifies security management of the products as they move through the supply chain, including control facilities and in route	“a) establish, implement, maintain and improve a security management system; b) assure conformance with stated security management policy; c) demonstrate such conformance to others; d) seek certification/registration of its security management system by an Accredited third-party Certification Body; or”	This supports control of the products as they move into, through, and out of the controlled legitimate supply chain. The ISO 28000 practices can reduce or increase the fraud opportunity

(continued)

Table 10.2 (continued)

Title*	Authority*	Focus	Goal	Application to food fraud
ISO 27000 Information Security	International Standards Organization (ISO), Joint Technical Committee JTC 1 Information technology, Sub-Committee 27 IT Security techniques (ISO/JTC1/WC27)	Protect information from attack or unauthorized access	Reduce risk from attacks and the potential illegal accidental disclosure of information	Protects the integrity of traceability and authenticity databases
ISO 22000 Food Safety Management	International Standards Organization, Technical Committee 34 Food products, Sub-Committee 34 Management systems for food safety (ISO/TC 34/SC 17)	Health hazards from food safety incidents	Reduce health hazards and increase the methodology to reduce the possibility of incidents	Focuses on health hazards, new food fraud requirements in 2018
ISO 22380: 2018 (previously ISO 19564) Product Fraud: Product fraud countermeasures and control – General principles	ISO TC292/WG4, focused on product fraud prevention management methods and systems.	Broadly addressing product fraud for all material goods and presenting basic principles and terminology	Enable harmonization and sharing of best practices by establishing a common terminology and basic prevention focused principles	Specifically addresses product fraud and food fraud. Includes methods to assess and address
ISO 12931:2012 Performance criteria for authentication solutions used to combat counterfeiting of material goods	International Standards Organization (ISO), Technical Committee (TC) 292 Security Management and Resilience (ISO TC 292/WG4)	Management of authentication features to detect or prevent fraud acts	Offer common and optimized countermeasures to provide holistic industry response	This provides insight and best practices from other material goods as well as provides a common terminology and methods for foods
ISO 22380: 2018, Section 4.5.1 Profiling product fraud	ISO 22380, section on the organization of incident information	Specifically, this adapts and synthesizes other best practices to present a simple and codified method for organizing incident information (see the PICT section)	Same as ISO 22380	

(continued)

Table 10.2 (continued)

Title*	Authority*	Focus	Goal	Application to food fraud
ISO 22380: 2018, Section 4.5.2 Risk assessment	ISO 22380, section presents a method to plot risks on a heat map (similar to ERM/COSO)	To enable calibrating a new product fraud risk with all enterprise-wide risks, this presents a method to create a single heat map	Same as ISO 22380	
GFSI (Global Food Safety Initiative)	Member organizations under the Consumer Goods Forum.	Defines expectations of a food safety management system	Reduce the opportunity for food safety issues including explicitly addressing the root cause of food fraud	There are direct requirements including a vulnerability assessment and prevention strategy
Business Alliance for Secure Commerce (BASIC)	An NGO organized by industry.	Create standards and common business practices	Increase the efficiency of transactions including information technology interoperability	Transparency of harmonized information exchange

Excluding the standards that are not supply chain specific such as the ISO product fraud and authentication noted above

Table 10.3 Review of ISO product fraud and related standards (ISO 2017)

Published	
ISO 12931:2012	Product fraud: Performance criteria for authentication solutions used to combat counterfeiting of material goods
ISO 16678:2014	Product fraud: Guidelines for interoperable object identification and related authentication systems to deter counterfeiting and illicit trade
ISO 22300: 2018	Security and resilience: Terminology (not to be confused with the ISO 22000 Food Safety Management series) (developed in parallel with other material goods product fraud standards ISO 22380, ISO 12931, and ISO 16678))
ISO 22380:2018 (formerly ISO/CD 19564)	Product fraud: Security and resilience (authenticity, integrity, and trust for products and documents)—general principles for product fraud risk and countermeasures
ISO 28001:2007	Security management systems for the supply chain: Best practices for implementing supply chain security, assessments, and plans—requirements and guidance
ISO 28002:2011	Security management systems for the supply chain: Development of resilience in the supply chain—requirements with guidance for use
ISO 28003:2007	Security management systems for the supply chain: Requirements for bodies providing audit and certification of supply chain security management systems
ISO 28004-1:2007	Security management systems for the supply chain: Guidelines for the implementation of ISO 28000 (Part 1: General principles)

(continued)

Table 10.3 (continued)

Published	
ISO 28004-3:2014	Security management systems for the supply chain: Guidelines for the implementation of ISO 28000 (Part 3: Additional specific guidance for adopting ISO 28000 for use by medium and small businesses) (other than marine ports)
ISO 28004-4:2014	Security management systems for the supply chain: Guidelines for the implementation of ISO 28000 (Part 4: Additional specific guidance on implementing ISO 28000 if compliance with ISO 28001 is a management objective)
Underdevelopment	
ISO/DIS 34001.4	Product fraud: Security management system for organizations assuring authenticity, integrity, and trust for products and documents
ISO/NP 22383	Product fraud: Security and resilience (authenticity, integrity, and trust for products and documents)—performance criteria for authentication solutions used to ensure genuineness and integrity of material goods
ISO/WD 22384	Product fraud: Security and resilience (authenticity, integrity, and trust for products and documents)—guidelines to establish and monitor a protection plan and its implementation
Not TC292 but related	
ISO/IEC 27000:2016	Information technology: Security techniques (information security management systems, overview, and vocabulary)
ISO/IEC 27001:2013	Information technology: Security techniques (information security management systems, requirements)
ISO/IEC 27002:2013	Information technology: Security techniques (code of practice for information security controls)

Sidebar: The Assumption of Traceability and Transparency as a “Given”

The assumption of supply chain traceability and transparency is a new and evolving concept that is challenging. It appears that the ability to monitor and identify the location of products is accepted as a “given.” The concept of monitoring for the rogue product—e.g., “and to prevent the introduction to the supply chain of unauthorized contraband” which is different than “*authorized* contraband”—is only mentioned as an odd or future consideration. (Product counterfeiting and other related activities are currently considered to be under the management of corporate security or brand protection.)

Sidebar: The Role of the “Brand Protection Manager” in Food Fraud Prevention

Expanding on the Brand Protection Manager concept and their role in food fraud prevention, an excerpt from (MSU FFI 2017):

Food fraud sounds like a responsibility for food scientists or purchasing agents. Brand Protection managers – usually focused on finished goods activities such as

diversion, illegal re-packaging, expired or sub-standard product, and counterfeiting – often are not responsible for ingredients or more operational problems. Due to the nature of fraud that does *not* include ingredients or adulterant-substance, in many cases, the Brand Protection manager may be the first one to identify the threat as product fraud. They will probably be the first to recognize preventative controls that *should* be applied by their accountable corporate CEO but probably not responsible in their own workgroup. Brand Protection managers have a unique skill set and experience that is critical to identifying, describing, and to help prevent or mitigate food fraud. Beyond FSMA, FDA has an expanding scope that covers cosmetics, personal care products, pet and animal food, tobacco, and alcohol so many “consumer products” Brand Protection managers are accountable for food fraud... whether they know it or like it.

Key Learning Objective 2: Traceability and Digital Transactions

This section reviews the traceability fundamentals and related electronic transaction products and services. A strategic approach considers the basic specification of the requirements in relation to what can be expected.

The Key Learning Objectives of this section are:

- (1) The role of traceability in food fraud prevention
- (2) The importance and benefits of supply chain transparency
- (3) Review of several application examples

Traceability and Electronic Transactions

Supply chain management has advanced as a discipline in part due to the ability to gather a tremendous amount of data, more real-time insight on buying and transportation of products, computing power such as global positioning, web and mobile communication, and the massive power of the computers themselves. With more information, there is more opportunity for more visibility of the entire supply chain including traceability, track and trace, and transparency.

- ***Traceability (ISO)*** is defined as where the product is, where it is going, and where it has been. A similar phrase ***track and trace*** is defined by ISO 12931 as a “means of identifying every individual material good or lot(s) or batch in order to know where it has been (***track***) and where it is (***trace***) in the supply chain” (Note: ISO 12931 states “Track and Trace technology when used alone is not considered to be an authentication solution” (ISO 2011)).
 - ***Track (ISO)***: where a product has been
 - ***Trace (ISO)***: where a product is going

The GS1 standards provide a similar but alternate set of definitions (GS1 2018a, b):

- **Trace/tracing (tracing back) (GS1):** “The ability to identify the origin, attributes, or history of a particular traceable item located within the supply chain by reference to records held” (GS1 2018a, b).
- **Track/tracking (tracking forward) (GS1):** “The ability to follow the path of a traceable item through the supply chain as it moves between parties” (GS1 2018a, b).
- **Traceability (GS1 references ISO 9001):** “is the ability to trace the history, application or location of that which is under consideration” (GS1 2018a, b).

When reviewing these concepts, there is a realization that there is a higher goal which is visibility of the entire set of all transactions:

- **Transparency (GS1)** is “defined as visibility of products and transactions throughout the supply chain” (GS1 2007). A similar concept *supply chain visibility* is defined as “location and status of supply chain inventory and resources” (Bowersox et al. 2002).

There are many ways that a company tracks or monitors products such as electronic invoices or interacts with consumers such as frequent shopper rewards. Any and all monitoring of the product increases the visibility of the flow as well as increases transparency. The electronic invoices already carry a lot of information about many aspects of the shipment and product as well as offering very high reliability and quickly accessible information. A receiving company monitors and confirms the physical shipment before accepting—and then paying—the invoice.

For food fraud prevention, the application is that two of the most intensely scrutinized supply chain handoffs are when there is a financial exchange (e.g., paying an invoice). This intense scrutiny is an opportunity for either inspecting or authenticating product as well as for electronically interacting with the pallet or case as well as the actual final consumer package. Barcode readers or scanners could provide additional functions such as to authenticate the product (actually this type of authentication confirms the label is correct, and it is assumed that the product inside the package is genuine).

The data security and information validity requirements are less stringent for supply chain management (trying to move product around to fill store shelves) than for food safety (stopping shipments before consumers ingest dangerous product) and for food fraud prevention management (providing assurance that the product is still genuine and has not been tampered with). For food fraud prevention, some criminals would benefit from hacking into the databases. Illegal and unauthorized access to databases could enable the uploading of fraudulent codes that would be then confirmed to be authentic, to the unauthorized release of products such as inventory, confirm that tax payments have been made, establishing that refunds should be paid, or confirming that shipments have already been inspected, or others.

The supply chain management focus is making sure the right product is in the right location to allow for a sale, while the food safety focus is finding the product to stop shipment or product recall. For food fraud prevention, there is an additional value or requirement to track the product once it enters the supply chain (assuming or checking authenticity at that entry point) and then monitoring the product through often many handoffs until delivering to the buyer or user.

Sidebar: Does Traceability Really Help Fight Fraudsters? (MSU FFI 2018)

Title: Does Traceability Really Help Fight Fraudsters?

By John Spink • May 29, 2013 • Blog

Traceability – finding where the product has been, where it is going, or where it is right now – is increasing in importance for the food industry for a number of reasons. Authentication – proving the product genuine or proving it fake – is also increasing in importance, especially when combined with traceability within the supply chain, which reduces the fraud opportunity. Together traceability and authentication provide transparency. When there is improved transparency, the Food Safety, Food Defense, and food fraud risks can be minimized.

Traceability initiatives have different benefits for different objectives:

- Food Safety – Minimizing Consumption of Suspicious Product. There have been calls from agencies and industry for improving traceability of the food supply chain. This is reiterated and defined further in the Food Safety Modernization Act (FSMA, the law itself) that was passed in January 2011 and is supported by draft rulemaking (how FDA will implement the law).
- Food Defense – Stolen Goods. The FDA has released a response to cargo theft that includes mandates for companies to be able to identify specific stock-keeping-units that have been stolen. If the company cannot identify the specific product that was stolen – and out of their control – then the company will need to recall all product in the smallest lot identifiable. For example, if three batches of products are in a load of stolen goods, then all of those lots will need to be recalled. To my knowledge this has not been implemented...but it could.
- Food Defense – Attack for Harm. The attack on the supply chain, specifically adulterating a food product with a contaminant that causes harm, is of particular interest to FDA. The FDA Food Defense directives leverage the transparency provided by the other food safety-related regulations.
- Food fraud – Identifying Suspicious Product. Food fraud is deceptive use of food for economic gain which is illegal in the US under the Adulterated Foods and Misbranded Foods sections in the Food, Drug & Cosmetics Act.

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The fraud opportunity is significantly reduced with increased transparency of ingredients moving through a long supply chain. As mentioned, the transparency is created by traceability and authentication.

These concepts are supported by the Institute of Food Technologists, the Global Food Safety Initiative, the Produce Marketing Association, and the International Association for Food Protection.

The concept of food traceability contributing to food fraud prevention is something that I included in the MSU-FFI public comments at an FDA public meeting in 2009. The MSU-FFI public comments were:

- Include food fraud considerations in the FDA traceability initiative as you include both food safety and food defense.
- Consider traceability programs integrated across all FDA regulated products including drug, medical device, food, cosmetics, and then all consumer products.
- It is my opinion that retailers and retail inventory management systems are a crucial supply chain node since this is the last transaction – scanning at checkout – before the product leaves the distribution system and is transferred to the consumer.

So, traceability is not a single magic bullet to stop fraud, but it is a critical part of the food fraud prevention system. Traceability and authentication provide transparency within the supply chain which reduces the fraud opportunity. If you review the MSU-FFI past blog posts, you'll see examples of how bad guys not only circumvent our protection systems but in some cases, even use them against us. Whether it is more active tracking of lot numbers, or expanding to unit-level serialization, traceability has a vital role in increasing transparency and in product protection. What you need to do is consider how a tactical program to track your products can become a strategic deterrence countermeasure. MSU-FFI.

Sidebar: Will Supply Chain Transparency Reduce Food Fraud? Sure, They Must, Don't They?

There is a saying:

General countermeasures generally help; specific countermeasures specifically help.

Unless there is a regulatory requirement, a specific proposal is required for financial or human resource expenditure. To review the value of a countermeasure or control system, a very specific question must be identified. Many supply chain transparency or anti-counterfeiting proposals stall because the final resource allocation decision-maker either can't prioritize or justify this specific

expenditure. A basic ROI would compare this allocation versus all other ROI proposals including examples such as hire a new sales representative, spend more on advertising, fix a piece of manufacturing equipment that is leaking, conduct discretionary maintenance, purchase a new piece of food safety testing equipment, or even address other risks. Even a specific ROI for a regulatory requirement—now only comparing proposals to address this risk—requires a level of confidence in the success of the proposal to meet the goals efficiently.

The Max Bazerman concept of “best alternative to a negotiated agreement” (BATNA) may be to “do nothing” (Bazerman 2001). For new technologies, it is often a better decision to be a “fast follower” than an “early adopter” (Porter 1985; Makadok 1998; Dietrich et al. 2006; BRIDGE 2007; Voss et al. 2009; Anthony 2012). “Manufacturers and distributors wanted to avoid being the early adopter, preferring to be a ‘fast follower’ with EPC/RFID [Electronic Product Code-based Radio Frequency Identification for brand protection and anti-counterfeiting]” (HDMA 2004).

To provide an example of the preference of being a “fast follower,” interoperable enhanced traceability has been a holy grail for solution providers. *Interoperable* refers to the ability for systems to interact and share information freely such as all supply chain partners using the same coding system such as the GS1 Global Trade Item Number (GTIN), universal product codes (UPC), or others (Bix et al. 2007; ISO 2017; GS1 2018a, b). “Enhanced” in this example refers to more standard and more capable systems. Finally, *traceability* is being able to track or trace product which could include where it is, where it has been, and where it is going, among others (ISO 2005). Together the interoperable enhanced traceability is a more robust product tracking system that includes a lot of information that is shared quickly and easily (we did not say “freely” because each activity usually includes fees such as for the use of the codes, storage, and retrieval of the data, analysis of the data, use of patented algorithms or computer programs, and the ongoing information technology computer support).

Sidebar: Enhanced Traceability Systems such as Barcodes, Mass Serialization, Pedigree, RFID, Transaction Security, Encryption, and Others

Whether the traceability enabler is one-dimensional barcoding (1-D), two-dimensional barcoding (2-D including QR codes), mass serialization, radio-frequency identification device (RFID) or automatic identification (Auto-ID), transaction security, and so on, there is a long list of magic bullet ideas. To consider the practical and pragmatic value of a new technology, there are some possible questions to consider:

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1. Is more traceability good? Sure.
2. Does more traceability improve transparency of the supply chain? Absolutely.
3. How soon will it be implemented to 95%—or even 50%—of a company’s entire supply chain? To be determined.
4. How much will it cost to implement? This could include preparing current IT systems to communicate with the new program, to enable the proprietary supply chain to interact, and to encourage and enable the upstream and downstream supply chain to interact any ongoing cost for the use of the codes, data storage, data retrieval, data analysis, and then ongoing management. To be determined. Millions? Tens of millions? Hundreds of millions?
5. How much will the interoperable enhanced traceability contribute to the bottom line? To be determined.
6. How does this interoperable enhanced traceability specifically reduce a unique type of fraud opportunity? Unknown.
7. “If one aspirin is good then ten is better? Right?” Not necessarily and usually “no.”
8. So far the interoperable enhanced traceability sounds promising, but there has not been a very compelling—or any—business case... *at least not yet.*

Often the recommendation or justification for adoption explains the “features” of the technology or system (e.g., the difficulty of a security product copied) with details of the severity of the overall problem (e.g., food safety product recalls create health hazards) but little on the exact “benefit” of how the specific fraud opportunity will be specifically reduced.

Sidebar: New Enhanced Traceability Technology and the Horsemeat Food Fraud Incident

The horsemeat food fraud incident has been reviewed and analyzed widely. Essentially the brand owner made their routine order to replenish packaged product from their manufacturer. A series of bids and proposals worked their way to a meat producer. The meat producer shipped the blocks of frozen raw meat to the manufacture, and the lasagna was made, packaged, shipped to the original customer, and then placed on the retail shelves in the UK. The meat was monitored for quality and food safety. Records were reviewed, kept, and all passed inspection. No one was assigned to check for the correct species.

This is a very specific food fraud incident that provides valuable insight into assessing and judging countermeasures and control systems. This is one type of food fraud, so it is an excellent case study to review the value of enhanced traceability technology.

The meat producer was a recognized and approved supplier, so they were considered a trusted and verified supply chain partner. The seller and purchaser are very formally and visibly connected through the invoice, inventory management, and accounts payable systems. The meat supplier in many cases has been audited by a certification body or even by the brand owner itself. This point of trust—human intervention—is where the fraud occurred.

So, considering that an approved, trusted, and verified supplier is a point of trust is actually a vulnerability, this is a specific point in the supply chain to consider that an additional specific countermeasure and control system can be considered. One type of risk treatment would be traceability or transparency. With enhanced traceability technology, the transactions and documents passed along are not able to be altered but only updated with a record of what was changed and by whom (assuming additional identity theft has not occurred—see your email spam folder for fraudulent emails from the URL of “your bank”). There would be less of a fraud opportunity to enter falsified claims if there is a check further down the supply chain. For example, the lasagna manufacturer or brand owner could occasionally conduct a species authenticity test and enter that into the traceability system. This would both identify the food fraud incident and reduce the fraud opportunity since the fraudster would know there is a higher chance their crime would be caught (assuming there is no fraud or bribery occurring at the brand owner itself).

When considering the overall countermeasures and control systems, it is logical that species authenticity tests should be conducted. If the new tests are publicized in a way that the fraudsters can be aware of the change, then there will be a decreased fraud opportunity. (If the fraudsters don’t know about your new test, then you will just catch more fraud and not achieve the real goal to prevent it from occurring in the first place.) It would be logical that the fraudsters will consider how to adapt their operations such as to change fraudulent methods, attack someone else, or stop conducting the crime (this is “crime displacement”). A question is whether the enhanced traceability technology system is—or how much more—valuable than the current tracking systems. To be determined. With this further review of a specific incident, there can be a specific assessment of enhanced traceability technology versus current or alternate systems.

Key Learning Objective 3: Reviews of Past Traceability Efforts Including the California Drug Pedigree and RFID

This section reviews several past traceability efforts related to radio-frequency identification devices (RFID) and drug pedigree laws. There are many best practices and lessons learned from many past effort that were successful... and maybe even more value from closely reviewing the efforts that did not.

The Key Learning Objectives of this section are:

- (1) Information database security and accuracy
- (2) Review of an RFID project
- (3) Review of drug pedigree and specifically the California efforts

Information and Database Security: Hackers Adding Fake Codes

Databases are only as good as the data in the system. There is a saying “garbage in, garbage out” which means that if the information being entered is not accurate, precise, or certain, then the results or conclusions will also be problematic. Another concept is that data systems have a tendency to gravitate toward chaos. A data set should be expected to develop problems or inconsistencies. An important concept is how to reconcile or correct errors, mistakes, or flaws. The idea that a data set could be imperfect is a point *not* understood when considering anti-counterfeiting systems such as validating the code on a medicine package in the surgical suite before (trying to) restart someone’s heart. In that setting, if reading the code to confirm authenticity, then the acceptable reliability of the data set is far *below* 1% or maybe probably below 0.1%. An important consideration is that most data sets are probably not accurate below 1% (if not much less accurate).

If a traceability or authentication system is used as the definitive method to recognize or approve products, then there is a tremendous fraud opportunity incentive for hackers to disrupt, corrupt, or co-opt the database. For example, if fake, duplicate, or nonsensical codes were entered, then the confidence in the entire database would be undermined. Also, there would be an incentive for hackers to upload counterfeit codes, so future authentication queries would confirm the counterfeit code and product to be “genuine.”

Another consideration is that fraudsters could flood the database with nonsensical codes, so the number of errors requiring correction would be so high (e.g., hundreds, thousands, more?) that reconciliation and correction would be impractical. The flooding of a database with nonsensical codes could undermine the value of the database, itself. Although not a database, there are examples of entire systems being undermined by errors. In 2005, the entire US supply of the very popular cholesterol drug Lipitor was recalled—sales were halted—since the unapproved product had been comingled and could not be immediately un-comingled. It would seem it was less risky for the supplier to recall the entire US supply of product rather than trying to sort which product was good or bad.

Also, during discussions about the US Prescription Drug Marketing Act of 1987 (PDMA)—still not fully implemented in 2017—and the California State Bill 1976 (SB-1476) California E-Pedigree Law, there were later discussions that possibly the credit card industry had database security that would apply (CSBP 2007, 2012, 2013). It was not mentioned that the credit card industry databases are frequently

hacked and there is an allowance for stolen or corrupt credit card numbers. (Note: Remember that credit card companies encourage consumers to review their credit card statements for fraudulent or incorrect transactions that are usually instantly credited.) While a 3% error or fraud rate for a credit card may be acceptable to the credit card industry or credit card users, a 3% uncertainty for medicine is far from the Six Sigma focus of accuracy levels of 99.99966%. There is an exponentially higher consequence of a fraudulent adrenaline injection restarting a heart after open heart surgery. While food fraud usually does not have a public health threat—and other than allergens, often never has an emergency, acute consequence—this is an example of data security considerations.

Review of Past Traceability Initiatives (RFID or Auto-identification): Cost \$282 Million Per Company

The philosopher Georgy Santayana reportedly said, “Those who cannot remember the past are condemned to repeat it.” For traceability the example may be a review of the RFID/Auto-ID initiatives from around the end of the dot-com rush in 2002; there were big statements of the benefits but few reports of the actual realized benefits. As with current interoperable enhanced traceability—essentially a more recent version of the same thing—the RFID/Auto-ID concepts were very promising.

- *RFID* is a *radio-frequency identification* which is a way that computers identify a package by sending radio waves to a label that has an antenna loaded with a code.
- *Auto-ID* is an *automatic identification* which is the ability to determine a product identity without an active process.
- *Non-line-of-sight* refers to the ability to identify a package or label without being able to actually physically “see” the label. For example, a label could be read on a package that is in the middle of a pallet, covered in an overwrap, or in a bag or shopping cart.

A consulting report that was published in the RFID Journal estimated “the theoretical retailer would gain approximately \$78 million from increased sales and labor savings across all 800 stores by implementing the Auto-ID Center’s technology for tracking cases. It could achieve benefits of nearly \$150 million from tracking individual units” (RFID Journal 2002). These were reportedly “used moderately to conservative numbers when assessing the benefits that could accrue from such a system” (RFID Journal 2002).

Those benefits would require an investment of

“\$465,000 to track cases at the first store and an average of \$62,000 per store for the entire system and \$827,000 for the first distribution center and \$353,000 per center for the entire system. That’s an investment of \$282 million for all 800 stores (RFID Journal 2002).”

The benefits were reported as “reduce labor costs, improve accuracy and boost throughput” (RFID Journal 2002).

That’s a lot of labor, a lot of capital invested for on-hand inventory, and an assumption of very high costs of inaccurate stock picking. There were no specific details on how the benefits would be received whether reduced carrying costs of inventory on hand, reduction of lost or stolen goods, fewer rush delivery charges, opportunity cost benefits of reducing lost sales due to stock-outs, or others.

The 2002 article ended with “When will that happen? We don’t know. The technology is still being worked through” (RFID Journal 2002). As of 2018, there did not seem to be any published specific results or case studies based on real projects.

Thus, while there was very high confidence the financial benefits when it came down to predicting how soon the benefits would be expected, the public statements were very cautious—the statements emphasized the technology was not ready for implementation and was still being developed.

Shifting to focus a bit on the underlying assumptions, from a basic ROI set of questions:

- **Cost:** A \$282 million initial investment and the annual upkeep are undefined but could be 5% or \$14 million per year. For the sake of argument, possibly use 1% or \$2.8 million.
- **Return on investment:** Not revenue but decreased costs. So the benefit is not increased sales or increased valuation but the reduction in losses of \$228 million (coincidence or not, this is very close to their estimated cost of implementation).
- **Time until return is realized:** Possibly 1 year after the system is fully functioning (the \$282 million cost offset by the \$228 million savings) and then at least 6 months for the benefits to be fully realized (e.g., actually experiencing the reduced costs of laid-off staff, losses avoided, inventory reduced, etc.). Note that the report stated that the system was still being developed so there was an undetermined time until return would start.
- **Confidence in the rate of return:** Undefined and not mentioned in the proposal.
- **Rate of return (at 2 years after investment):** 0.4 (\$228M-\$128M/\$228M) or about 2.5 years to break even on the investment. This is after the 2-year ramp-up.
- **Rate of return (at the start of full investment):** So add 2+ years to the 2.5 year ROI until the project value is realized.
- **BATNA (best alternative to a negotiated agreement), the value of spending the funds elsewhere:** Undefined. The value of this individual project is not judged in and of itself (e.g., spend the money or not) since there are other uses for the funds (e.g., what is the best return on the investment across the entire enterprise). Due to the lack of details or specificity, the systems were not ready for an actual financial investment, so the current BATNA is the investment of time and energy thinking about the project.

So, from the data provided here, the ideal situation seems to be to listen and be a “fast follower.”

Summary of CA-SB1476 (and then Why It Didn't Get Implemented)

Published by the California State Board of Pharmacy is a report on “Background and Summary of the California ePedigree Law.” From that report that appears to be published in December 2017, several key sections are presented:

- “Problem: there is an increasing prevalence of counterfeit prescription drugs showing up in the US, intermingled [co-mingled] with the legitimate drug supply. Counterfeit prescription drugs are a worldwide problem, reaching as high as 30 percent of the supply in some countries. The World Health Organization estimates that in developed countries, counterfeit drugs are less than 1 percent of the market.”
- “To put this in perspective: 3.4 billion prescriptions were dispensed in the US in 2006. If 1 percent of this supply is counterfeit, this would mean that perhaps 34 million of these US prescriptions were filled with counterfeit medicine. In California, we have roughly 9 percent of the US prescription drug market, so this would indicate that perhaps 3 million prescriptions were filled and dispensed with counterfeit medicine in 2006.”
- “In an attempt to prevent counterfeit medicine from entering the legitimate supply chain in California, in 2004 the state legislature passed anti-counterfeiting and anti-diversion legislation (SB 1307), including provisions pertaining to the licensure and qualifications of wholesalers, restrictions on furnishing, and the requirement of an electronic pedigree to accompany/validate drug distributions. Portions of the legislation were implemented in 2005 and 2006. In 2006, subsequent legislation (SB 1476) [or CA-SB-1476] sponsored by the board moved the implementation date for the electronic pedigree component until 2009; the same legislation also augmented and clarified portions of the electronic pedigree requirements.”
- “Under current law, as of 1/1/2009, no wholesaler or pharmacy may sell, trade or transfer a prescription drug at wholesale without providing, and no wholesaler or pharmacy may acquire any prescription drug without receiving, a pedigree. The **pedigree** is a record in electronic form containing information regarding each transaction resulting in a change of ownership of the given prescription drug, including returns. The law specifies the particular data elements pertaining to the drug and to each of the ownership links in the chain of distribution that must be included in this record and requires that the pedigree track each drug at the smallest package or immediate container (saleable unit). To implement this unit-level tracking requirement in an interoperable electronic system, requirements include a unique identifier (serialization number) placed on the smallest container saleable to a pharmacy, by the pharmaceutical manufacturer. Likewise, the manufacturer will also initiate the pedigree and pass that pedigree with the initial distribution; thereafter, the electronic pedigree will at all times accompany that particular container, appended by each successive owner to document each change of ownership of that particular container.”

- “Simply put, the goal is for any owner/possessor of a prescription drug located at a licensed wholesaler, repackager, reverse distributor, or pharmacy in California, upon request, to have and keep electronic records that show the lineage of the drug from the manufacturer through to the current point in the drug distribution channel (wholesaler, repackager, pharmacy). The electronic pedigree must contain specific information required by statute and must be made and passed in an ‘interoperable electronic system,’ an electronic track and trace system based on unique identification numbers (serialization) affixed at the point of manufacture.”
- “The unique identifier or unique serialized number on each saleable container of prescription drugs will most likely be carried either on a 2-D barcode or an RFID chip placed on the saleable unit by the manufacturer. The California Legislature has not mandated these specific technologies, but they are the two methods that have been identified that could meet the requirements of the legislation. The number on the serialized container could then be utilized to access the specific electronic pedigree for that individual container of a prescription drug.”
- “Industry participants have engaged in standards-setting work to develop industry standards necessary to interoperability and sharing of pedigree data and records. The primary standards-setting body for the industry that has been engaged in this work with industry participants has been EPCglobal, the same entity that developed the standards for the UPC barcode.”

Requirements:

- **Pedigree:** means a record, in electronic form containing information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer, through acquisition and sale by one or more wholesalers, manufacturers, or pharmacies, until final sale to a pharmacy or other person furnishing, administering or dispensing the dangerous drugs. The pedigree shall be created and maintained in an interoperable electronic system, ensuring compatibility throughout all stages of distribution. (California Business and Professions Code section 4034(a)).”
- **Interoperability:** this is one of the augmentations to the legislation in 2006. With input from industry, we determined for this pedigree concept to work effectively, all parties at all levels of the supply chain needed to be able to access the pedigree information without having to purchase numerous types of hardware, software, and middleware to be able to read whatever format a particular manufacturer chooses for their electronic pedigree. This will discourage companies from developing their own incompatible proprietary systems of electronic pedigrees, preventing the proliferation of systems and making it complex to read the pedigree by entities downstream (e.g., wholesalers and pharmacies). In January 2007, EPCglobal ratified a document-based pedigree messaging standard. Nearing finalization is a second EPCglobal standard, the EPCIS standard. The EPCIS standard would also allow the creation or appending of a pedigree, combined with a data storage and management system. This should be completed in several months.”

- **“Interoperable electronic system:** As used in this chapter means an electronic track and trace system for dangerous drugs that use a unique identification number, established at the point of manufacture, contained within a standardized nonproprietary data format and architecture, that is uniformly used by manufacturers, wholesalers, and pharmacies for the pedigree of a dangerous drug. (California Business and Professions Code section 4034(i)).”
- **“Serialization at the unit level:** this is the key to being able to enter, for instance, a pharmacy or wholesaler, to distinguish one container of prescription drugs from another, and to access the pedigree for each individual container. In addition, as long as the original container is available, the entire history of ownership for that specific container may be accessed. Specifically: “The pedigree shall track each dangerous drug at the smallest package or immediate container distributed by the manufacturer, received and distributed by the wholesaler and received by the pharmacy or another person furnishing administering or dispensing the dangerous drug” (California Business and Professions Code section 4034(d)).”
 - “With the California system, two containers of the same drug, same strength, same lot number, and same expiration date, can be differentiated from each other. They each may have traveled very different supply chain routes to arrive at the same location. Only with the California serialized product can you tell each change of ownership for each container. The California process allows regulators to determine the origin of a container and be much more likely to identify when or if a product has been tampered with or if a counterfeit product has entered the supply chain.”
- **“Repackaging:** This must be tracked on a single pedigree tracing back to the original manufacturer. Specifically: ‘a single pedigree shall include every change of ownership of a given dangerous drug from its initial manufacture through to its final transactions to a pharmacy or other person for furnishing, administering or dispensing the drug, regardless of repackaging or assignment of another National Drug Code (NDC) Directory number’ (California Business and Professions Code section 4034(c)).”
- **“Returns:** These must also be tracked on a single pedigree. ‘Any return of a dangerous drug to a wholesaler or manufacturer shall be documented on the same pedigree as the transaction that resulted in the receipt of the drug by the party returning it’ (California Business and Professions Code section 4034(e)).”

“The pedigree must contain (data elements):

- 1) The **source** of the dangerous drug, including the name, federal manufacturer’s registration number or a state license number as determined by the board, and principal address of the source.
- 2) The **trade or generic name** of the drug, the quantity of the dangerous drug, its dosage form, and strength, the date of the transaction, the sales invoice number, the container size, and the number of containers, the expiration dates, and the lot numbers.

- 3) The **business name**, address and the federal manufacturer's registration number or a state license number as determined by the board, of each owner of the dangerous drug, and the dangerous drug shipping information including the name and address of each person certifying delivery or receipt of the dangerous drug.
- 4) A **certification** under penalty of perjury from a responsible party of the source of the dangerous drug that the information contained in the pedigree is true and accurate.”

California law also requires that pharmacies may not act as wholesalers, and “A pharmacy may furnish dangerous drugs only to the following:

- 1) A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired.
- 2) The pharmaceutical manufacturer from whom the dangerous drug was acquired.
- 3) A licensed wholesaler is acting as a reverse distributor.
- 4) Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.
- 5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law.
- 6) A health care provider that is not a pharmacy, but that is authorized to purchase dangerous drugs
- 7) To another pharmacy under common control.” (California Business and Professions Code section 4126.5)

An important final set of considerations focuses on the compliance and implementation:

- **“Sanctions:** In addition to other possible sanctions for non-compliance with pedigree requirements up to and including civil or criminal prosecutions, the board may cite and fine \$5000 per occurrence (each saleable unit) or take formal discipline. Wholesalers must post a \$100,000 bond with the board as a condition of licensure, which provides a source to pay any fines assessed.”
- **“Reporting to the board:** a manufacturer, wholesaler or pharmacy with reasonable cause to believe a prescription medicine in or having been in its possession is counterfeit or subject of a fraudulent transaction shall notify the California Board of Pharmacy in writing within 72 hours of obtaining knowledge (only for drugs sold or distributed through California).”
- **“Implementation Delay:** the board can delay these requirements until 1/1/2011 if it determines, consistent with its public protection mandate, that manufacturers or wholesalers require additional time to implement electronic technologies to track the distribution of dangerous drugs within the state.”

In many previous anti-counterfeiting or enhanced traceability programs or efforts, there were key challenges that were either difficult to overcome or that were insurmountable. Often the same problems keep derailing projects since history

wasn't reviewed. For food fraud prevention, there are important lessons to be learned from previous related programs and efforts. These lessons can both provide insight on how challenges were overcome and if they were insurmountable then to figure out sooner rather than later of what *cannot* be done.

Sidebar: California's E-Pedigree Law Preempted by Federal Regulation

Due to concerns about the slow adoption of the US Prescription Drug Marketing Act of 1987 (PDMA), the State of California passed a drug electronic pedigree law (Public Law 100-293 [1988](#)). Before the California e-pedigree law could take effect, in November 2013, federal "Public Law 113-54" was signed (CA-SB-1476 [2006](#); Public Law 113-54 [2011](#); DCA [2013](#)). Details of the federal law include (DCA [2013](#)):

- "This law contains provisions for a national track and trace system for prescription medication. Included within this law are provisions that preempt California's e-pedigree requirements. These provisions are in addition to those in the California Business and Professions Code that also preempt California's provisions should federal legislation in this area be enacted."
- "The [California State Board of Pharmacy] board is required to post a message about the inactivation of California's e-pedigree provisions. This notice is provided below; it also will be published in the *California Regulatory Notice Register* and posted on our website. Also this year the board will sponsor legislation to repeal the e-pedigree provisions that are now inactive provisions in California law."
- "The board thanks to the many individuals from pharmaceutical supply chain companies, computer and technology firms, policymakers, the staff of the California delegation and the many others who worked with the board over the last 10 years to develop e-pedigree provisions and implement a system to strengthen the integrity of the US drug supply."
- "We especially thank the early adopters and those who worked on pilot projects to ensure California's provisions would be implemented by the coming deadlines. It was a large endeavor, and we trust that what was learned to 'get ready for California' will be transferable to the national system that is now under development. We are grateful to have played a role in this important area of public safety and health."
- "Public Notice: Pursuant to Business and Professions Code section 4034.1, which provides in pertinent part that '[upon] the effective date of the federal legislation... addressing pedigree or serialization measures for dangerous drugs, Sections 4034, 4163(c) – (g), 4163.1, 4163.2, 4163.4, and 4163.5 shall become inoperative,' and which requires that within

(continued)

90 days of the enactment of such legislation the board publish a notice regarding the invalidation of these statutes, the California State Board of Pharmacy is hereby publishing notice that federal legislation meeting the requirements of section 4034.1 has been enacted, and that Business and Professions Code sections 4034, 4163, 4163.1, 4163.2, 4163.4, and 4163.5 became inoperative as of November 27, 2013.”

Efficient application of supply chain management theories includes the consideration of laws and regulations as well as systems for traceability and transparency. As the supply chain management principles may be new for food scientists, the compliance and application requirements are even more novel. Food fraud prevention is a problem based on a complex fraud opportunity and efficient and effective countermeasures, and control systems must consider an interdisciplinary approach based on lessons learned from previous efforts.

Conclusion

This chapter covered a follow-up on the previous chapter on supply chain management fundamentals with applications such as laws, regulations, standards, and certifications as well as traceability and transparency. The fraud opportunity is complex and based on issues that are created by a web of interactions and gaps. *The first conclusion is* that there are wide ranges of applicable laws, regulations, standards, and certifications. Earlier food industry efforts can add value to understand the current needs as well as a range of activities by other industries. It should be expected that others—either within the food or in other industries—have pursued protecting the supply chain. It should also be assumed that there are many lessons learned by very smart people who worked very intelligently to try to address very similar questions. There is a saying, “fraud prevention activities are twice as complex and complicated as you think it is and you know half as much as you think you know.” *The second conclusion is* that traceability is complex and very specific needs should be the first focus of the project. “More” traceability is good, of course, but the exact value is undefined without an explanation of exactly how it addresses very specific problems. For example, regardless of the low-cost or easy, quick implementation, the new technology could be addressing a problem that is *not* above the risk tolerance. Also, it should be assumed that there are many very complex aspects of the system that could reduce the value of the result or even that could be a mission-critical issue that negates all value. *The final conclusion is* that the overall focus is on the transparency of the supply chain, transactions, and supply chain partners. With more transparency, there is a greater awareness of where the gaps or fraud opportunities occur and more specific insight on where and how suspicious product may be entering the supply chain. With more transparency, the fraud opportunity is reduced.

Appendix: WIIFM Chapter on Supply Chain Management Application

This “What’s In It For Me” (WIIFM) section explains why this chapter is important to you.

Business functional group	Application of this chapter
WIIFM	There are a range of SCM systems and processes that increase transparency and traceability which reduce the fraud opportunity
Quality team	This application will tighten the control of inbound products and ingredients with respect to the fraud opportunity
Auditors	There will be some SCM-focused activities related to proof of product and ingredient authenticity as well as general transparency
Management	Suppliers need additional scrutiny which may seem like a lot of new overhead and controls, but that will actually <i>increase</i> purchasing flexibility to buy from a <i>wider</i> range of low-price suppliers
Corp. decision-makers	The purchasing group needs to support SCM assessments and controls to <i>increase</i> the buyer flexibility while operating under your risk tolerance

Appendix: Study Questions

This section includes study questions based on the Key Learning Objectives in this chapter.

1. Discussion Question

- (a) What is the role of “supply chain management” in FF prevention?
- (b) How does traceability increase supply chain transparency and reduce the fraud opportunity?
- (c) What are the attributes of traceability systems that were inefficient or that did not realize their ultimate potential?

2. Key Learning Objective 1

- (a) What are ISO and ISO 9000?
- (b) Why is thorough and reliable traceability difficult to manage and expected to be a “given”?
- (c) What is the role of a brand protection manager in FF prevention?

3. Key Learning Objective 2

- (a) Regarding traceability, what is “pedigree”?
- (b) What is “track” versus “trace” and why is there a need for both?
- (c) What are “inherent risks” of enhanced traceability systems?

4. Key Learning Objective 3

- (a) What is the “PDMA”?
- (b) What challenges hindered industry-wide—or overarching regulatory—requirements for e-traceability efforts?
- (c) What are some lessons learned from RFID initiatives?

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Chapter 11

Standards and Certifications (Part 1 of 2): The Role of the Public-Private Partnership



Summary

This chapter presents an overview of the standards and certifications which are different from, but support, laws and regulations that apply to food fraud. This is not intended to be a deep dive into the exact specifications but to provide an overview of the organizations, their missions, their scopes, and the general concepts they address. There will be a deeper dive into the Global Food Safety Initiative (GFSI) requirements since they provide broad direction and foundation setting.

The Key Learning Objectives of this chapter are:

- (1) **NGOs:** The role of nongovernmental organizations in food fraud prevention.
- (2) **Public-Private Partnership:** The overall public-private partnership roles.
- (3) **International Collaboration:** This will review key international collaborator activities such as by INTERPOL, Europol, WHO, FAO, and others.

On the Food Fraud Prevention Cycle (FFPC), this chapter addresses the standards and certifications that are addressed on the figure a “(A) Theoretical Foundation” (Fig. 11.1).

Introduction

To support the definition and harmonized focus on prevention, there are key roles for laws, regulations, standards, and certifications. The optimal and most efficient situation is a combination of public-private partnership (PPP) activities including governments, nongovernmental organizations (NGOs, either aligned by trade groups or international or national activities), industry (actually implementing the compliance requirements), and academics. **Laws** state the intended objectives and provide statutory authority for agencies to implement regulations. **Regulations** are

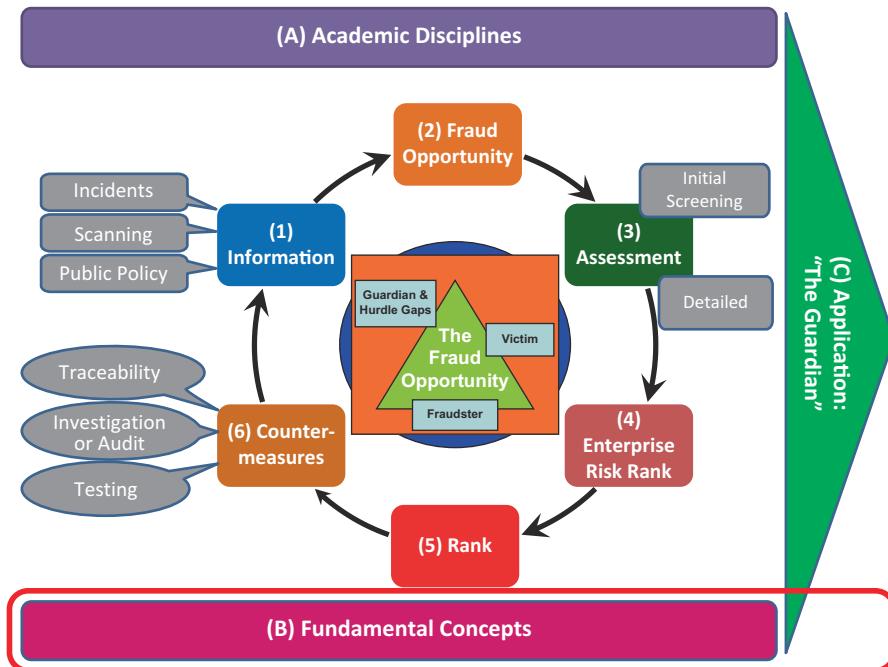


Fig. 11.1 Food Fraud Prevention Cycle—where this chapter applies to the overall concept: “(B) Fundamental Concepts”. (Copyright Permission Granted) (Spink 2014; Spink et al. 2019)

the application of laws where agencies explain the compliance requirements and explain the methods for:

- (1) **Inspection** (assessing that methods and processes businesses implement to meet the law)
- (2) **Investigation** (how nonconformances will be reviewed and the types of penalties to apply)

The concept of “inspection” versus “investigation” will be continually reviewed in this book. Laws and regulations are governed by—and within the scope—of governments.

Standards and certifications have a different function that operates in a beneficial relationship with **national laws** (creating efficiencies of best practices and common methods within a country) or **globally** (creating common practices that support multiple countries). **Standards** are a set of agreed-upon practices and objectives codified and shared. **Certifications** are a demonstration of meeting a set of agreed-upon standards.

It is most efficient if governments in the public sector and industry in the private sector work together. **Public-private partnerships (PPP)**—including the private certifications and food safety audits—have had officially recognized value by the governments including the FDA. For example, even before the publication of the

FSMA Accredited Third-Party Final Rule (FDA 2014), FDA stated “So, one of the most important questions we are grappling with at FDA is how we can enhance our role in verification and strengthen our ***public and private partnerships*** to better assure consumers that our food safety systems are working.” This was expanded to state “First, in our domestic inspection and compliance program, our focus will be on achieving and verifying that ***private food safety management systems*** are working effectively to prevent problems.” Then “Second, ***private verification and audit activities*** already play a central role in food safety systems” (FDA 2014).

Overview of Standards

Based on the European Committee for Standardization (CEN) (itself a group representing the standards-setting bodies of 34 European nations which also coordinates with ISO per the Vienna Agreement) summary, standards are categorized by four types (CEN 2018).

- **Fundamental standards:** which concern terminology, conventions, signs, symbols, etc.
- **Test methods and analysis standards:** which measure characteristics such as temperature and chemical composition.
- **Specification standards:** which define characteristics of a product (product standards) or a service (service activities standards) and their performance thresholds such as fitness for use, interface, and interoperability, health and safety, environmental protection, etc.
- **Organization standards:** which describe the functions and relationships of a company, as well as elements such as quality management and assurance, maintenance, value analysis, logistics, project, or system management, production management, etc.

Another summary is provided by ASTM which includes a statement that “Other categories of standards can be employed as necessary” (BSI 2018).

- **Test method:** A definitive procedure that produces a test result
- **Specification:** An explicit set of requirements to be satisfied by a material, product, system, or service
- **Classification:** A systematic arrangement or division of materials, products, systems, or services into groups based on similar characteristics such as origin, composition, properties, or use
- **Practice:** A definitive set of instructions for performing one or more specific operation that does not include a test result
- **Guide:** A compendium of information or a series of options that does not recommend a specific course of action
- **Terminology:** A document comprising definitions of terms, explanations of symbols, abbreviations, or acronyms

An expanded detail on “Categories of Standards” (BSI 2018):

- **Categories of standards:** “Most standards can be categorized according to the function they need to perform. The most common is the Specification, which is a highly prescriptive standard setting out detailed absolute requirements. It is commonly used for product safety purposes or for other applications, where a high degree of certainty and assurance is required by its user community.”

Types of standards include:

- **Codes of practice:** “recommend the sound good practice, as currently undertaken by competent and conscientious practitioners. They are drafted to incorporate a degree of flexibility in the application while offering reliable indicative benchmarks. They are commonly used in the construction and civil engineering industries.”
- **Methods:** “are also highly prescriptive, a setting out an agreed way of measuring, testing or specifying what is reliably repeatable in different circumstances and places, wherever it needs to be applied.”
- **Vocabulary:** “is a set of terms and definitions to help harmonize the use of language in a particular subject or discipline.”
- **Guides (standards):** “are published to give less prescriptive advice which reflects the current thinking and practice among experts in a particular subject.”

When most efficient, there is a commonality across the activities that both increase the protection of the food supply chain and also provide efficiency for government and agency activities. For food fraud prevention—and building upon very important and robust food safety activities—a very efficient system is envisioned and is currently being implemented.

It cannot be stressed enough that food fraud is in the very early stages of public-private partnership development since laws, regulations, standards, and certifications are just being developed (Spink et al. 2019b). Great care and coordination will be needed to implement an efficient and effective system. Since there is a holistic, all-encompassing, and theoretically sound focus on the broad prevention efforts—focusing on the root cause of the entire problem and on proactive prevention—there is a tremendous opportunity for every financially efficient and programmatically effective implementation. There are numerous examples of other risks where the scope was either defined to be too narrow (e.g., medicines focusing on intellectual property rights counterfeiting rather than all fraud) and too tactical (e.g., a single government agency focus on enforcement and prosecution not a government-wide focus on prevention).

The current international and public-private partnership collaborations are very promising. Also, the Food Fraud Prevention Cycle provides a broad and strategic theoretical foundation.

Key Learning Objective 1: Role of Key Nongovernmental Organizations (NGOs)

This section covers the role of the nongovernmental organizations—here this does not yet include industry or trade associations—in creating and managing standards and certifications. Each organization has a mission, vision, scope, and focus on products and services. Taking a holistic view of the organizations helps to refine the specific roles and also to identify gaps. For food fraud prevention, several key NGOs include Codex Alimentarius (CODEX) and parent organizations of World Health Organization (WHO) and the United Nations Food and Agriculture Organization (FAO), International Standards Organization (ISO), INTERPOL and Europol, Global Food Safety Initiative (GFSI), and other specification or quality management systems (e.g., US Pharmacopeia (USP), National Sanitation Foundation (NSF, not the National Science Foundation), American Organization of Analytical Chemists (AOAC), International Life Sciences Institute (ILSI), American Botanical Council (ABC), Natural Products Association (NPA)/Supplement Safety and Compliance Initiative (SSCI), International Aloe Science Council (IASC), and others).

The Key Learning Objectives of this section are:

- (1) The role of nongovernmental organizations in food fraud prevention
- (2) The NGO mission, actions, and method to develop and implement standards
- (3) The NGO challenge of addressing food fraud prevention

NGOs: How and Whom They Help—ISO, ISO, GFSI, and Others

The nongovernmental organizations (NGOs) have different members, stakeholders, and contribution to the general food fraud prevention activities.

ISO: Two main activities within ISO apply to food fraud prevention:

- (1) **ISO TC292 Security Management and Resilience/WG04** Product Fraud Countermeasures and Controls
- (2) **ISO TC34/SC17 Food Management/WG04** Food Safety Management (ISO 2017a, d)

Other ISO management systems standards provide a foundation such as **ISO 31000 Risk Management** and **ISO 28000 Specification for security management systems** for the supply chain. TC292 includes several approved ISO standards that provide a framework for addressing all product fraud including **ISO 22380:2018** Product Fraud: Product fraud countermeasures and control—General principles; **ISO 12931:2012** Product Fraud: Performance criteria for authentication solutions used to combat counterfeiting of material goods; and **ISO 16678:2014** Product

Fraud: Guidelines for interoperable object identification and related authentication systems to deter counterfeiting and illicit trade. TC34 has published ISO 22000 which is a foundation for GFSI and general food safety practices. As of June 2017, ISO 22000 is being updated to include food fraud and also food defense specifically.

ISO has provided clear statements regarding product fraud prevention, focusing on vulnerabilities, and addressing fraudsters. The ***ISO 22380:2018*** standard includes a table on “Types of Product Fraud” including counterfeiting, IP rights infringement, adulterant substance, tampering, substitution, simulation, diversion, theft, and overrun (ISO 2018b).

Understanding product fraud opportunities from ISO 22380 Section 4.1.1

- “The organization should base its fraud control strategies on proper understanding of the intentions, motives, nature, and types of the fraud and the fraudster. The organization should consider all the three elements (Fraudster, Victim/target, and poor Guardian) essential in crime occurrence for its basis of applied crime prevention. Crime occurs when a motivated fraudster and suitable target come together in time and place, without a capable guardian present. Product fraudsters commit fraud crime when perceiving that a specific fraud target is vulnerable, and there is sufficient rewards from the fraud attacks, and there is no or weak guardianship and countermeasures by deterring, delaying, hindering, stopping their attacks. The vulnerability is referred to as a fraud opportunity. Particularly this should be based upon criminological theory ‘rational choice’ that people commit a crime when the risk of offending is low, and the rewards are high from their point of view.”
 - **Organization:** “person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives; Note 1 to entry: The concept of organization includes, but is not limited to sole-trader, company, corporation, firm, enterprise, authority, partnership, charity or institution, or part or combination thereof, whether incorporated or not, public or private” (ISO 2017d).

There are two key TCs that address the underlying risk management and quality management system standards which are based on ISO 31000 and ISO 9000.

- **ISO/TC 262 Risk management:** The scope is standardization in the field of risk management (ISO 2017c). The major contribution is the management series based on ISO 31000 Risk Management.
- **ISO/TC 176 Quality management and quality assurance:** The scope is “Standardization in the field of quality management (generic quality management systems and supporting technologies), as well as quality management standardization in specific sectors at the request of the affected sector and the ISO Technical Management Board” (ISO 2017b). The major contribution is the management series based on ISO 9000:2015 Quality management systems—Fundamentals and vocabulary.

For food fraud prevention, the application is that ISO TC292 Security Management has many standards, though with limited adoption, which addresses the broad scope of product fraud and focus on prevention. ISO TC34 manages the widely adopted ISO 22000 Food Safety Management principles which expanded scope in 2018 to include food fraud and food defense. It would be logical for ISO 22000 to align with the broad food fraud scope and focus on prevention from TC292 and GFSI.

CODEX: CODEX has addressed specific authenticity specifications for products such as honey and olive oil (CODEX 2001, 2015). In May 2017 the CCFICS (Codex Alimentarius Committee on Food Import and Export Inspection and Certification Systems) reviewed a Discussion Paper on Food Integrity and Food Authenticity (food fraud) and approved the creation of an Electronic Work Group (EWG). To note, MSU's Food Fraud Initiative responded to a public request for comments from the US CODEX delegation that recommended the creation of an EWG. MSU-FFI had continued to support the US CODEX delegation and the overall CCFICS (CODEX CCFICS 2017). The direction of the CCFICS was for the EWG to present definitions of key terms (including agreement that food fraud and EMA are not the same and that food fraud is the preferred term), conduct a gap analysis of other CODEX standards, and to focus holistically on prevention rather than detection (see MSU-FFI meeting summary blog report).

For food fraud prevention, the application is that CODEX has defined their direction addressing the broad scope of food fraud and to focus on prevention which is in a development process that would lead to a global CODEX standard in 2022–2025. This may seem a long way off—which it is—but is an indication of future CODEX alignment with current definitions, scopes, and focus on prevention activities.

GFSI: The food fraud incidents were usually addressed within the Food Safety Management System and public health responses. It was logical for Food Safety Management Systems to review food fraud. GFSI—and essentially HACCP, itself—is an adaptation of quality management principles to the unique problem and countermeasure of food safety. Thus, after GFSI defined food fraud prevention to be within their mission—not responding to incidents but preventing root causes that could lead to food safety incidents—they followed the advice of their GFSI Food Fraud Think Tank and published their direction in the “GFSI Position on Mitigating the Public Health Risk of Food Fraud” (GFSI position paper on food fraud) (GFSI 2014) (Note: Dr. Spink represented MSU as one of six members of the GFSI Food Fraud Think Tank.) Compliance was required on January 1, 2018. GFSI updated their Guidance Document in February 2017 to include food fraud requirements of:

- (1) Conduct and document a Food Fraud Vulnerability Assessment
- (2) Implement and document a Food Fraud Prevention Strategy
- (3) Cover the “relevant GFSI scope” which includes all types of fraud (e.g., not just adulteration substances) and all products (e.g., raw materials and finished goods in the marketplace).

For food fraud prevention, the application is that GFSI has provided specific guidance on addressing the broad scope of food fraud and focusing on prevention which will be required by January 2018.

Each NGO has a different mission, focus, and membership needs. For food fraud prevention, there is an important task of reviewing, coordinating, and optimizing activities. Each has the opportunity to play a significant role in food fraud prevention.

Missions, Actions, and Resources

There impetus and motivations of the key NGOs provide insight into their role and future contribution to food fraud prevention. Key topics addressed will be mission, actions, deliverables, resources, and projects.

ISO: Their **mission** is similar to CODEX but focused on all products, all industries, and all processes. The actions are an extensive technical committee and sub-committee work by volunteers who create standards (e.g., ISO 22000 Food Safety Management). The **deliverable** is the published ISO standard. The standard is available for purchase.

ISO has limited **resources** and a varying degree of commitment from the member states and the individuals on the country-level Technical Advisory Group (TAG). The **actions** are to advance topics or activities that arise from the TAG and TC activity. The projects move forward as there are interest and support by the committees or work groups which is often a small group of individuals who have very specific interest areas.

GFSI: Their **mission** is to strengthen the Food Safety Management System for companies and the entire industry. The harmonized Guidance Document helps create one central document or system that meets multiple compliance requirements such as for different countries. The **actions** focus on harmonizing and strengthening Food Safety Management practices. Volunteer member companies provide the resources from manufacturing, retail, as well as suppliers, academics, and consultants. The **deliverable** is the Food Safety Management System Guidance Document and approving compliance by standards development companies known as scheme owners or Certification Program Organizations (CPOs). The GFSI Guidance Document is available free on their website, and the standards are accessed through separate standards companies such as FSSC 22000, BRC, IFS, and others. The standards are audited and certified by Certification Bodies (CBs) that are approved and recognized by the CPOs.

GFSI has limited **resources** which include an active volunteer Board of Directors, volunteer Technical Working Groups that refine the Guidance Document, and a small paid administrative staff. GFSI relies on research funded by other NGOs (such as the SSAFE organization, the Grocery Manufacturers Association (GMA),

the MSU Food Fraud Initiative, and others) or the member companies. The **actions** are to continue to refine the base expectations in the Guidance Document and to facilitate the adoption or acceptance. Acceptance outreach included meeting with the US FDA (which led to the update of Version 7 to Version 7.1 within 2 months and then 7.2 in December) and recognized “equivalence” by China FDA (meaning that GFSI compliance meets the Chinese food safety laws). The **projects** move forward with approval from the Board of Directors.

CODEX: Their **mission** is similar to ISO but focused on a harmonized and holistic food code or standard that can be widely adopted by countries. The process is very thorough, intense, detailed, and can typically take 5–8 years. The **actions** are publishing guidelines or standards published in the Codex Alimentarius procedural manual and separate standards. The **deliverable** is the food code that can be referenced or the source of a country food law. Codex is not a food law but is sometimes adopted by countries as their law. The publications are available free on their website.

CODEX has limited **resources**, itself, but significant commitment from their member states. CODEX provides standard setting and food code guidance for a wide range of related topics. CODEX does have a paid staff that facilitates and advances the activities. The **actions** include updating and expanding the standards as directed by the member states. The CCFICS activity on food fraud is an example (CODEX 2017). The **projects** move forward as recommended by the widely attended and supported committees (e.g., the May 2017 CCFICS committee meeting was typical with over 300 attendees from over 70 countries).

A summary table is provided of the organizations, governance, mission, and product or service (Table 11.1).

Table 11.1 Review of key NGOs that contribute standards and certifications to food fraud prevention

Organization	Governance	Mission	Product or service
Global Food Safety Initiative (GFSI) Note: including endorsed standards	Industry producer, manufacturer, and retailer managed to stakeholders including suppliers, academics, and governments	To harmonize and refine a central Food Safety Management System that is widely adopted and benchmarked	Membership and conference registration fees lead to publishing a “Guidance Document” that is used by others to develop standards
Codex Alimentarius (CODEX)	Member countries managed by WHO and FAO	To increase the health of global citizens through safer food while maintaining equitable trade practices	Creates the “world food code” of common practices which is often adopted as national laws
International Standards Organization (ISO)	Member countries managed by national standards bodies	To increase the harmonized practices and methods of conducting activities	Provides fee for access to the standards

Review: CODEX CCFICS23 Meeting Summary—Action to Define Food Fraud and Related Terms (MSU-FFI 2018):

Title: Review – CODEX CCFICS23 Meeting Summary

By John Spink • May 5, 2017 • Blog

Friday, May 5, 2017 -- Earlier today, Codex Alimentarius (CODEX, the world food code) took a major food fraud commitment by proposing an Electronic Working Group (EWG) to review other CODEX texts and to create a definition and scope for Food Fraud/Food Integrity/food authenticity/related terms. The recommendations of CCFICS will be submitted upwards to the Codex Alimentarius Commission (CAC) for final approval. The Draft Discussion paper was widely supported at this conference during the formal open discussion by the member countries. The Islamic Republic of Iran is leading the EWG with co-Chairs from Canada and the European Union. We were pleased to have attended the Codex Alimentarius Committee on Food Import and Export Inspection and Certification Systems (CCFICS) meeting as part of the US Delegation.

- **CCFICS – Codex Alimentarius Committee on Food Import and Export Inspection and Certification Systems:** This “...was created to address a range of emerging issues related to exports, inspection, and certification (CODEX CCFICS 2017). The main focus is “(a) to develop principles and guidelines for food import and export inspection and certification systems with a view to harmonizing methods and procedures which protect the health of consumers, ensure fair trading practices and facilitate international trade in foodstuffs;....”

The first step of the EWG will be to review and present definitions. For example, what are food integrity, food authenticity, and Food Fraud? There are other unanswered possible questions such as: What is an ‘adulterant’ and how is it different from a CODEX defined ‘contaminant’? Does Food Fraud only cover adulterant-substances? Are intellectual property rights counterfeiting included? Does counterfeiting include trademark, patent, copyright and trade secrets? Is Food Fraud the same thing as food integrity or food authenticity? Is it only a CODEX matter if there is a public health threat? Where else in CODEX are some aspects of Food Fraud covered? Is it completely covered? How much or how little?

The CCFICS -approved final report presents the direction for the Food Fraud EWG:

- “Support and agreement to create an Electronic Working Group (EWG).
- Review CODEX definitions of similar or related terms such as contaminant, etc.
- Consider gap analysis of where Food Fraud is or isn’t covered in other parts of CODEX.
- Define Food Fraud/food integrity/food authenticity/and others.”

CODEX intentionally follows a very formal and methodical process since this essentially, and literally, will change the way forward for the world. Creating the EWG is a very formal activity for CODEX that will start the review of it – and then how – Food Fraud will be incorporated into the formal Codex Alimentarius (world food code). If agreed to and it progresses forward, it will be a four to six-year process until Food Fraud would be in the formal CODEX texts. Once a topic is fully implemented in CODEX, it is widely adopted and becomes a requirement for conducting business in many countries essentially. CODEX is often the reference for food laws in many countries.

The Committee discussion was based on a Discussion Draft led by Iran and co-chaired by Canada and The Netherlands. That Discussion Paper included a working definition of Food Fraud (that will be reviewed by the EWG):

From the CODEX EWG document: “Food fraud, it is an emerging international issue that includes adulteration, deliberate and intentional substitution, dilution, simulation, tampering, counterfeiting, or misrepresentation of food, food ingredients, or food packaging; or false or misleading statements made about a product for economic gain.⁴” (Note 4: This quote cites the Elliott Review which includes citation “4” which is Spink and Moyer, Journal of Food Science, 2011)

The Discussion Draft authors specifically thanked four resources:

- “US Pharmacopeia and the (USP) Food Fraud Database” (USP is based in Rockville, Maryland, USA)
- “MSU and Dr. John Spink” (MSU is based in East Lansing, Michigan, USA; Dr. Spink attended the event as part of the US delegation)
- “The Food Fraud Network (FFN) administered by the European Commission (EC)”
- “The Elliott Review of Food Crime and Food Fraud” (the UK, DEFRA led by Dr. Christopher Elliott, Queen’s University Belfast, Northern Ireland, UK)

Comments from the CCFICS Open Discussion are included here, and the details are especially significant since they do not necessarily become part of the full published meeting summary:

Australia

- “[Creating a definition] is an important first step to understanding what we’re talking about.”
- “[The activity is useful] so that we’re clear on the definition of food fraud.”

China

- “Regarding usage of EMA and FF terms – the Discussion Draft flips back and forth... [it is recommended to] replace EMA with FF.”

(continued)

SSAFE (an NGO with CODEX Observer Status)

- “Does agree that it is a complex problem but should not dissuade CCFICS or Codex from addressing.”
- “We believe it is necessary because the authenticity of food is critical.”
- “SSAFE believes the scope will be determined on the definition of the terms that CCFICS [future work or project] provides.”
- “EMA is not exactly equivalent to FF”

European Union (EU)

- “This FF is of increasing importance and certainly an issue that we should not avoid discussing. It is certainly complex, but it should not prevent CCFICS from working on it.”
- “We can agree on the proposed way forward. This is really the very first step. It is such a complex matter it cannot be solved in one activity.”

United States (USA)

- The USA did not comment.

The CCFICS Chair then concluded, and summary statements are:

- “Start with defining FF/FI/FA/EMA – everything in that bucket – and then the EWG can reduce the scope if needed.
- This would create a foundation for CODEX and for global food regulation.
- This effort would help provide clarity for everyone.
- If we don’t address this properly now, then we’ll continue to get more proposals because we’ve missed something.”

From the CCFICS final report:

- “Conclusion – 29.” “The Committee agreed to establish an [Electronic Working Group], chaired by the Islamic Republic of Iran and co-chaired by Canada and European Union, working in English only, with the following terms of reference:

- “a.” clarify the definitions of food integrity, food authenticity, food fraud and [economically motivated adulteration] and delineate the scope for the preliminary assessment of CCFICS texts;
- “b.” based on those definitions, undertake a preliminary assessment of existing CCFICS texts to identify possible gaps and the impact, whether positive or negative, of those texts in mitigating potential problems; and
- “c.” prepare a discussion paper presenting the findings of that assessment and any need for potential new work.”

In many different forums, managed my many different stakeholders, there has been a debate about whether Food Fraud should be included in CODEX

or even in other international food safety programs. The CCFICS committee and attendees clearly feel Food Fraud should be included. Comments from the final report include:

- “Underscoring the complex implications of this area and the crosscutting nature of concerns involved, the Committee agreed that, while CCFICS undoubtedly had a role to play given the international trade-related implications, an integrated approach was required across all Codex.”

This is a significant point that emphasizes that efforts should be across CODEX and the response was not in individual commodity standards. From later in the final report:

- “CCFICS may be better positioned to provide general higher-level guidance, it would be difficult for any single committee to address such diverse concerns through a single document, and measures should not be limited to fraud detection but also seek to achieve mitigation.”

This is an important statement since it recognizes the effort should be on interdisciplinary prevention and not just detection or analytical test methods.

The CODEX CCFICS next steps are aligned with our previous MSU-FFI recommendations in the requirement for CODEX public comments. Our recommendations were consistent with the CCFICS conclusion: Food Fraud is now a ‘thing,’ so CODEX should address or at least provide a definition of ‘Food Fraud’ and ‘adulterant.’ The next step is just to develop a definition and scope and NOT yet the role of CODEX. When considering the recommendations and the way forward, it is important to remember that the scope of CODEX is public health AND trade. Throughout the discussions at this meeting, there is a growing consensus that Food Fraud is “too big” of a problem for CODEX to ignore. Engage through your country or trade organizations to continue to shape the direction of laws, regulations, standards, and certifications.

Key Learning Objective 2: Public-Private Partnerships Considering NGOs and NPOs

This section reviews the public-private partnerships specifically for nongovernmental organizations (NGOs) that are identified as a not-for-profit, nonprofit, or tax-exempt. The NGOs play a key role in supporting food fraud prevention including: US Pharmacopeia (USP), National Sanitation Foundation (NSF), American Organization of Analytical Chemists (AOAC), International Life Sciences Institute (ILSI), Global Standards One (GS1), and others. Specific stakeholders have different capabilities and capacities that are invaluable for protecting the food supply chain. This section will review the structure of the organizations, the roles different stakeholders play, and an overview of some of the organizations.

The Key Learning Objectives of this section are:

- (1) Identify and introduce the various public-private partners including NGO (nongovernmental organizations) and NPO (nonprofit organizations).
- (2) Review the overall public-private partnership and key interrelationships.
- (3) Examine the stages of public policy development.

Summary of Nongovernmental Organizations (NGOs) and Nonprofit Organization/Not-for-Profit Organization (NPOs)

All nongovernmental organizations (NGOs) are not the same. A nonprofit organization (NPO)—often referred to as a “501C3” based on US law code section—can be very competitive and operate as a for-profit company; while a corporation may be nonprofit, it does not necessarily “operate at a loss,” and many of the employees could be highly compensated or rewarded. A “nonprofit” organization can be defined as that the “residual revenue” is distributed at the end of the year before it is classified as “profit”—thus “nonprofit” or “not-for-profit.” Also, NGOs that are not purely volunteer organizations must find operating revenue through member fees, grants, or gifts or through user fees such as certifications or access to documents. In this case then, the more products and services, the more fees and the more revenue. Some NGOs can be multimillion-dollar enterprises.

From Title 26 of the US Code (USC), exemption from tax on corporations, certain trusts, etc., then section “c” is “list of exempt organizations, and finally part “3” is a list of exempt organizations. The US Internal Revenue Service defines a tax-exempt (nonprofit) as a “501(c)(3)” company (emphasis added): (26 USC 501 2012):

“To be tax-exempt under section 501(c)(3) of the Internal Revenue Code, an organization must be organized and operated exclusively for exempt purposes set forth in section 501(c) (3), and none of its earnings may inure [become an advantage] to any private shareholder or individual. In addition, it may not be an action organization, i.e., it may not attempt to influence legislation as a substantial part of its activities, and it may not participate in any campaign activity for or against political candidates. [...] The organization must not be organized or operated for the benefit of private interests, and no part of a section 501(c)(3) organization's net earnings may inure to the benefit of any private shareholder or individual” (IRS 2018).

Also, from the US Internal Revenue Service, “Nonprofits are organizations designed to forward ideas, beliefs, and initiatives as opposed to one individual, or a group of individuals. This is in stark contrast to corporations or many business entities, which transfer a percentage of profits to shareholders or private ownership. [...] Section 501(c) of the IRS Tax Code outlines the requirements for non-profits, regulating how they interact with the IRS. Each subsection guides a non-profit type. [...] 501(c)(3) serves as a reference for charitable organizations, including religious, educational, and medical organizations.”

According to the IRS Publication 557, in the Organization Reference Chart section, the following is an exact list of 501(c) organization types and their corresponding descriptions.[1][a]

- 501(c)(1)—Corporations Organized Under Act of Congress (including Federal Credit Unions)
- 501(c)(2)—Title-holding Corporations for Exempt Organizations
- 501(c)(3)—Religious, Educational, Charitable, Scientific, Literary, Testing for Public Safety, to Foster National or International Amateur Sports Competition, or Prevention of Cruelty to Children or Animals Organizations
- 501(c)(4)—Civic Leagues, Social Welfare Organizations, and Local Associations of Employees
- 501(c)(5)—Labor, Agricultural and Horticultural Organizations
- 501(c)(6)—Business Leagues, Chambers of Commerce, Real Estate Boards, etc.
- 501(c)(7)—Social and Recreational Clubs
- And others...

Some NPOs play an essential role in food fraud prevention, and to better understand their contribution—if there is any bias—these details such as the management structure and compensation motivation are essential to understanding (see the Bazerman section on “How (un-)Biased Are You?”).

The Challenge for NGOs and Nonprofit Organizations (NPOs) Addressing Food Fraud

Food fraud is an emerging topic, and many nongovernmental organizations (NGOs) or nonprofit organizations (NPOs) see an opportunity to expand or to capitalize on unmet needs. Some “food” groups or “fraud” groups see an opportunity and build upon their current capacity and capabilities. What has been missing is an overarching leadership position that considers the entire fraud opportunity and a priority on prevention. This is a scope to consider all types of fraud and for all products. Without the overarching prevention strategy, then it is difficult, if not impossible, to identify exactly what is the unmet need. Also, it is logical for science and technology-focused research to continue down the path of faster and deeper.

Specifically, an NGO or NPO builds upon their current activities and do not usually expand to consider the entire “fraud opportunity” and to “connect everything to everything.” As an example, a team of senior-level analytical chemists will naturally focus on their area of analytical chemistry. While this can be excellent for developing new and more robust food authenticity species tests, the actions do not help to combat stolen goods tax-avoidance smuggling or label country of origin fraud claims.

These challenges emphasize the efficiency and need of considering the whole fraud opportunity and the overarching Food Fraud Prevention Strategy before defining what is exactly needed to meet what specific unmet need. “If one aspirin is good then is ten better?” The role of science and technology—as well as investigation and prosecution—should be judged by the contribution to prevention. If there is not a

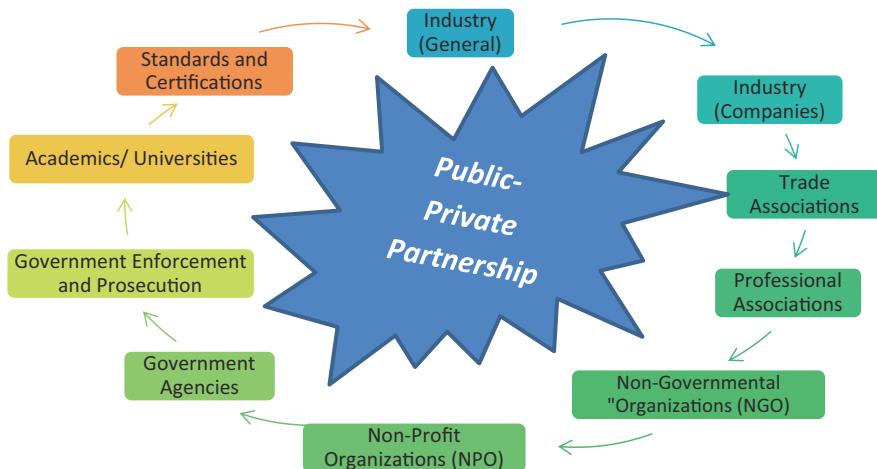


Fig. 11.2 Public-private partnership (PPP) for food fraud prevention

defined fraud opportunity or an overall vulnerability assessment, then the counter-measures and controls systems are no more than a guess. This would be an educated, intellectual best guess but a guess nonetheless.

The NGOs Supporting Role to and from Laws, Regulations, Standards, and Certifications

It is important to review the entire set of stakeholders to understand the optimal roles and the contribution to the public-private partnership. Different stakeholders have unique capabilities and capacity. The entire public-private partnership should be considered as well as the specific contribution to food fraud prevention. A broad focus will help create efficiencies for the overall group as well as help individual stakeholders identify their unique and optimal contribution.

There is an important relationship between different entities (Fig. 11.2):

Sidebar: The NGOs in the Optimal Activity for a Government—Require “a” Process Not Prescribe Compliance

In addition, other NGOs such as GFSI create a foundation that enables governments—through regulations, enforcement, and prosecution—to position for an optimal role. The optimal role of a government is to require “a process” for specifically addressing food fraud but do not include too many prescribed requirements. The figure below incorporates the role of regulations and a government requirement in the industry standards cycle (Fig. 11.3). The first efforts started with expanded regulations which led to the food industry creating GFSI

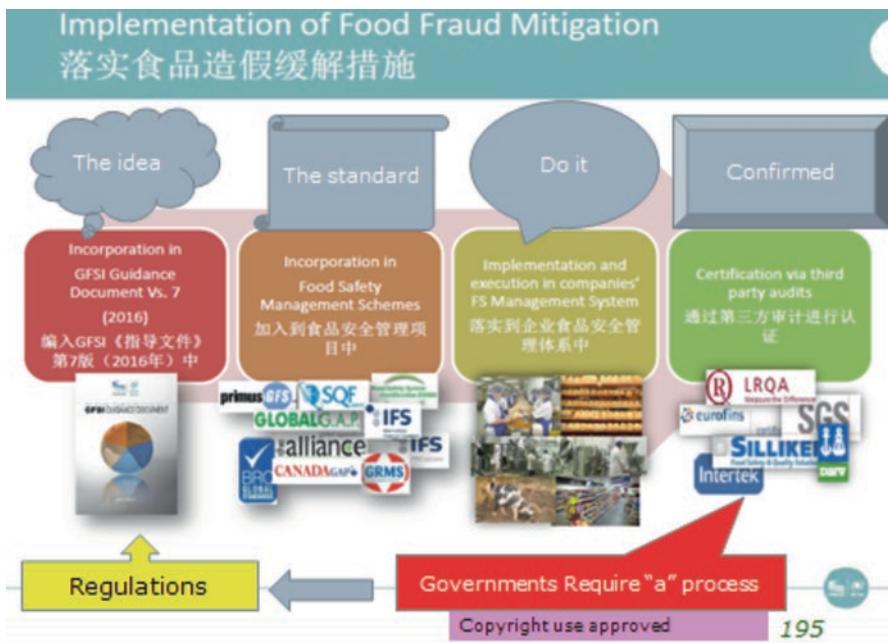


Fig. 11.3 GFSI Implementation hierarchy including the role of governments. (Copyright Use Approved) (Copyright Permission Granted) (GFSI FFTT 2013)

to harmonize practices, which was followed by the creation of standards, the implementation, and certification, which can then be reinforced by the government regulation. The government regulation meets the original goal to protect the food supply chain. The emphasis on requiring “a process” will lead the industry to collaborate and develop harmonized programs and benchmarking. The encouragement of the collaboration will meet the government goal of efficiently and effectively—and economically—protecting the food supply chain. Occasionally governments will identify when “not enough” is being done and then follow with enforcement and prosecution. That new government focus would be new incidents or information that is identified in the Food Fraud Prevention Cycle as “new information” for “public policy” or “incident review.” If there is a strong public-private partnership, then that level of what is “acceptable” or “unacceptable” will be identified and met early in the process. When considering the overall system, it is interesting to note that laws, regulations, investigations, and prosecutions have a critical but generally reactionary role in prevention—they are important but most efficient when encouraging crime prevention activities by the stakeholders rather than catching the bad guys. As long as the goal is to reduce the overall fraud opportunity—and not to just catch more bad guys or more ad product—then the public-private partnership can speed effective, efficient, and optimal food fraud prevention.

Stages of Policy Development: The Need for Clear and Formal Definitions

Food fraud is emerging and evolving as an area of study and for standardized methods of complying with or addressing prevention. To more clearly understand what will help food fraud prevention become more thoroughly and efficiently implemented, it is important to understand the current status and based on a routine method of public policy development (Cadieux et al. 2019). This research aim utilized a widely adopted and implemented Dye's process model (Dye 2012) and more generally Dye's insights (Dye 1976; Dye 2001; MacManus and Dye 2002; Dye and Gaddie 2013).

In the research project “Application of Public Policy Theory to the Emerging Food Fraud Risk: Next Steps,” a summary from the working paper is included here (Spink et al. 2019b):

“Scope and Approach: There is a need to assess the food fraud public policy development to understand the current state and to identify additional research to assist the efficient and successful implementation. A way to systematically review the food fraud concept was conducted using a public policy development “Process Model.” Process Model steps reviewed include: Problem Identification (Foundation Setting and Definition & Formation), Agenda Setting, Alternate Approaches, Legitimation, Implementation, and Evaluation.”

“Key Findings and Conclusions: The global food fraud policy-making is advancing through Agenda Setting, Alternate Approaches, and Legitimation. The key steps for a harmonized global food fraud public-policy are:

- ‘(1) Establish the definition and scope,
- ‘(2) Define food fraud as a “food” agency issue,
- ‘(3) Publish an official government statement focused on prevention (e.g., law, regulation, rule, guidance, etc.),
- ‘(4) Support and fund the policy, and
- ‘(5) Continue to evaluate and adjust the response.”

“There is a unique opportunity to take a holistic and all-encompassing approach to food fraud prevention that will be efficient and effective in protecting the food supply” (Spink et al. 2019b).

Dye's process model was applied to the food fraud issue including identifying the state of development for guardians including the USA, the UK, the European Commission, China, and then GSFI (Spink et al. 2019b) (Fig. 11.4).

By conducting a methodical review of the stages of policy development, the key activities or milestones needed for food fraud can be identified. It was evident that a fundamental concept was still critical which was just establishing common and formal definitions and scope of work.

Key Learning Objective 3: International Collaboration

This section reviews the international collaboration that has occurred as well as what should lead to a coordination-based decrease in the global food “fraud opportunity.” Severity and frequency are leading to responses. Prevention is an integrated

Stage	Description	Explanation	USA	UK	EC	China	GFSI
1A	Foundation Setting	This is a definition of the subject including the awareness level.					
1B	Definitions & Formation	This is the actual definition and dissemination of the concept that is presented in such a way governments must address the issue. This includes formal adoption of the concept and reports of the problem.					
2	Agenda Setting (At this stage:	This is the concept becoming formally addressed by governments such as in resolutions or formal reports.					
3	Alternate Approaches	This is the further development and adoption of new proposals or recommendations.					
4	Legitimation	This is the development of formal practices such as laws, regulations, practices, and guidance.					
5	Implementation	This is the actual application of the policy that changes standard operating procedures.					
6	Evaluation	This is a review of the impact of the public policy.					
Note: Some countries have more fully addressed specific types of fraud such as adulterant-substances. In other cases countries have defined the countermeasures or controls to be only required where there is a public health threat. In most cases, all types of food fraud is illegal under one law or another but not in a single law, regulation, rule, or guidance.							

Fig. 11.4 Application For food fraud prevention of the process model of public policy-making stages as of October 2017. (Copyright Permission Granted) (Spink et al. 2019b)

and proactive approach that requires harmonization of terms and actions. The countermeasures and control systems are often very simple, and with coordination, they can be low-cost and low-effort.

The Key Learning Objectives of this section are:

- (1) WHO and FAO activity through Codex Alimentarius and INFOSAN, then ISO in Food Safety Management, and also Security Management
- (2) Law enforcement efforts led by INTERPOL and Europol
- (3) Industry standards and certification specifically led by GFSI

WHO, FAO (UN), and ISO

There are several major international organizations that oversee the food fraud topics including the Codex Alimentarius (CODEX, overseen by the World Health Organization [WHO] and the Food and Agriculture Organization of the United Nations [FAO]) and the International Standards Organization (ISO). Other related groups include the WHO/FAO-led “International Food Safety Authorities Network (INFOSAN)” (INFOSAN 2017; CODEX 2018).

Codex Alimentarius (Codex) and INFOSAN (WHO/FAO)

CODEX: Codex is the world food code, and although not a law or regulation through CODEX states, “In many countries, most food legislation is already consistent with Codex” (CODEX 2014). There are 187 CODEX member countries. The CODEX mission is: “The Codex Alimentarius international food standards, guidelines, and codes of practice contribute to the safety, quality, and fairness of this international food trade. Consumers can trust the safety and quality of the food products they purchase and importers can trust that the food they ordered will be in accordance with their specifications.” The emphasis is on a balance of food safety, food security (the supply of food), and a balance with equitable trade practice (unfair trade practices) (CODEX 2014).

There are 24 CODEX committees that cover topics such as general subject, commodity, and coordinating activities. Some cover technical specifications, while others (“Methods and Analysis”) such as a specification for honey and others cover process or activities such as “Food Import and Export Inspection and Certification (CCFICS)” which includes food fraud (CODEX 2017; CODEX CCFICS 2017).

CODEX has an excellent, thorough, and clear definition of “contaminant” that clearly does NOT apply to food fraud:

- **Contaminant (CODEX):** “Any substance not intentionally added to food, which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or as a result of environmental contamination. The term does not include insect fragments, rodent hairs, and other extraneous matter” (CODEX 2014).
- **Adulterant:** Not defined by Codex.

During the 2017 CCFICS meeting, a “DISCUSSION PAPER ON FOOD INTEGRITY AND FOOD AUTHENTICITY [Food Fraud]” was presented, and it was recommended to advance for further work to an Electronic Working Group (EWG) (CODEX 2017). The working definition of food fraud is:

“[The working definition of food fraud] it is an emerging international issue that includes adulteration, deliberate and intentional substitution, dilution, simulation, tampering, counterfeiting, or misrepresentation of food, food ingredients, or food packaging; or false or misleading statements made about a product for economic gain.⁴” (Note 4: Citing the Elliott Review which directly quotes Spink and Moyer, Journal of Food Science, 2011 (DEFRA 2014), Ref. (Spink and Moyer 2011)).

The CCFICS-approved final report presents the direction for the Food Fraud EWG (CODEX CCFICS 2017):

1. Support and agreement to create an electronic working group (EWG).
2. Review CODEX definitions of similar or related terms such as contaminant, etc.
3. Consider gap analysis of where food fraud is or isn’t covered in other parts of CODEX.
4. Define food fraud/food integrity/food authenticity.

It appears the CCFICS activity will address this unmet need for CODEX guidance on food fraud and to publish definitions of food fraud, food integrity, food authenticity, food adulteration, adulteration, or adulterant. While there are still 5–8 years from the start of an EWG to a final adopted CODEX standard, it is significant that the process has started and that the scope is on all types of fraud and the focus is on prevention.

WHO/FAO Activity by INFOSAN

The Codex Alimentarius addresses the world food code, and WHO and FAO have other more direct support activities such as the International Food Safety Authorities Network (INFOSAN): INFOSAN is a global group of national food safety authorities, managed jointly by FAO and WHO with the secretariat in WHO. National authorities of 186 member states are part of the network. The INFOSAN goal is to address the idea that “Increasing globalization of food trade increases the risk of contaminated food spreading quickly around the globe” (INFOSAN 2017). And in a primary activity, they “...assist Member States in managing food safety risks, ensuring rapid sharing of information during food safety emergencies to stop the spread of contaminated food from one country to another. INFOSAN also facilitates the sharing experiences and tested solutions in and between countries in order to optimize future interventions to protect the health of consumers.” Their 2016 annual conference included food fraud as one of the four topics (INFOSAN 2016).

From an INFOSAN Food Fraud Survey, it is clear that INFOSAN members are concerned with food fraud and looking for support in understanding the topic and managing incidents. A 2017 survey led by INFOSAN and MSU-FFI revealed that food fraud was a major concern for member states and there was a need for leadership support and coordination (Spink et al. 2019a).

Some of the key points from the published peer-reviewed article (Spink et al. 2019a):

- “As a deliverable from the (INFOSAN 2016) Singapore meeting, a survey on food fraud was developed and presented to more than 450 INFOSAN members around the world. The development of this online, anonymous food fraud survey was led by the INFOSAN Secretariat at WHO and was administered and analyzed by the Michigan State University Food Fraud Initiative (MSU-FFI). There were 175 respondents upon distribution to 453 INFOSAN members from 166 WHO the Member States, six areas/territories of WHO the Member States and two associate members.”
- “The survey found that many INFOSAN members engage in food fraud prevention (70%) or are responsible for food fraud incident response (74%). The scope of food fraud covered in the survey comprised the full range of fraudulent activities, including the addition of adulterant-substances, tampering (including

mislabeling), theft, smuggling, gray market or diversion, and counterfeiting. The respondents do not generally conduct vulnerability assessments (84% replied “No” or “Don’t know”).”

- “Authority to manage fraud related events is often not designated within a food safety agency (55% say “No” or “Don’t know”) despite food fraud being overwhelmingly considered a food safety issue by respondents (93%).”
- “Most respondents indicate that INFOSAN plays an important role with respect to food fraud (75% “Yes” to 14% “No”) and suggest that they would share information through the network on fraud-related events (69% “Yes” to 4% “No” with more ambiguity of 20% “Don’t know”).”
- “Nearly all respondents acknowledged a desire for more guidance and information on best practices in managing “food safety events involving food fraud” (97%), but also for prevention of such events (97%), indicating a need to provide technical support beyond acute incident response.”
- “Key needs identified from respondents’ comments included:
 - 1) Capacity-building/education,
 - 2) A platform for information sharing, and
 - 3) Utilization of INFOSAN as an interagency/intergovernmental collaboration point.”
- “Potential next steps may include:
 - 1) Development of a food fraud fact sheet and subsequent dissemination to INFOSAN members;
 - 2) Presentation of food fraud resources for education and capacity-building to INFOSAN members; and
 - 3) Development and administration of a more detailed and targeted survey to better understand the issue at the individual country level.”

An important step is that INFOSAN is seeking feedback directly from their member states on very specific food fraud definition, scope, and resource needs.

There are important WHO/FAO activities due to the Codex work on definitions, the INFOSAN statement of addressing food fraud, and the outcomes from the INFOSAN survey.

Review: FAO’s Overview of Food Fraud in the Fisheries Sector Report (MSU-FFI 2018):

Title: Review – FAO’s Overview of Food Fraud in the Fisheries Sector Report
By John Spink, May 28, 2018 • Blog

A new 2018 FAO report, “Overview of Food Fraud in the Fisheries Sector,” presents a foundation and direction for the prevention of this type of food fraud. The report acknowledges the public health threat, negative impact on consumer confidence, and the enforcement challenge for governments. Key recommendations begin with a food fraud vulnerability assessment at the

product/country/industry level to create a foundation for selecting mitigation plans. This assessment will help identify gaps in laws and regulations. Also, this will help focus countermeasures and control systems that include authenticity testing, identity standards, traceability, and codifying the requirements such as in Codex Alimentarius.

This new report focuses on food fraud, which is also a focus of several missions by The Food and Agricultural Organization of the United Nations (FAO), World Health Organization (WHO), INFOSAN (a WHO/FAO group Food Safety Information Sharing Network), and Codex Alimentarius (CODEX – co-led by FAO and WHO). FAO has a core mission to focus on “international efforts to defeat hunger.” A specific aim of FAO is “Developing Inclusive and Efficient Value Chains” which focuses on “increasing demand for high-value products in international and domestic food markets that is an opportunity for developing countries to generate economic growth and gainful employment.” It was noted that this new FAO Fish Fraud report also supports “The FAO Agreement on Port State Measures to Prevent, Deter and Eliminate Illegal, Unreported and Unregulated Fishing (2016).”

The new FAO Fish Fraud report presents several key references:

- Definition: “**Food fraud**: is committed when food is illegally placed on the market with the intention of deceiving the customer, usually for financial gain.”
- Scope – General: “This involves criminal activity that can include food mislabeling, substitution, counterfeiting, misbranding, dilution, and adulteration.”
- Scope – Detail: “Some of the most common forms of fish fraud involve:
 - “Species substitution...;
 - Mislabeling of fish to conceal the geographical origin of illegally harvested species [including stolen or smuggled goods];
 - Marketing of counterfeit products...;
 - Undeclared use of food additives...;
 - Illegal use of food additives...;
 - Addition of glaze water to frozen products to increase weight; [and] mislabeling of ingredients....”

The “Overview of Food Fraud in the Fisheries Sector” report includes the following observations regarding food fraud:

- A real Public Health threat: While the primary goal is an economic gain, there is often also a public health threat to both the consumer and those producing the food [such as employees being exposed to toxins].
- A Negative impact on Consumer Confidence: There is potential for loss of consumer confidence both in the local market and also for exported goods.

(continued)

This lack of confidence can even impact the effectiveness of food control aid programs.

- Increase Product Authenticity and Traceability: To both identify species and also assess the source, expanded application of technology means that “...the possibility exists for far greater transparency in the fish marketing chain.”
- Harmonize Common Names: There are many practices in the marketing of seafood.
- “One of the principal challenges in tackling fish fraud is establishing an agreed list of common names that are linked to scientific nomenclature. This is an essential first step for national governments in introducing official fish fraud control programmes.”
- Coordinate Government Activity: There is a complex web of food laws or regulations that are often the responsibility of several agencies, which creates an opportunity for better coordination.
- “Greater cooperation between food control authorities and law enforcement agencies is required in order to combat the criminal activities involved in fish fraud.”
 - FFI Comment: This is a frequent conclusion of reviews where the idea is simple, but the implementation is very complex. In some instances, there are constraints on what information an agency can share with the public or even within the government. In other instances, the greater cooperation could lead to one agency taking on or giving up a specific responsibility. With changing responsibilities, there are additional approvals for shifting budgets or human resources. Regardless of the challenges of the changing or shifting activities, the most efficient first step is for the government to conduct a country-wide food fraud vulnerability assessment.
- “Food regulations need to be strengthened and penalties made proportionate to criminal infringements.”
 - FFI Comment: There are three points here, with one being strengthened food regulations and then proportionate penalties.

First, all types of food fraud are usually already illegal but under a wide range of laws. Often there isn’t a need for new regulations but really an effort to clarify what regulations do apply and then which agencies are accountable for enforcement.

Second, there is an ongoing challenge considering the level of penalties and the actual deterrent effect. To start, a challenge is implementing deterrent penalties where the “act” is usually a commercial violation with the lower types of penalties. Thus, while the unintentional result could be a death, the penalties for the commercial activities may be considered legally “proportionate.”

Third, the consideration of a “deterrent penalty” for an act where criminals think they won’t get caught and where there is a very high potential economic benefit. This has been a challenging question even back to 1994 and the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement. TRIPS includes Section 5: criminal procedures, Article 61, “Remedies available shall include imprisonment and/or monetary fines sufficient to provide a deterrent, consistently with the level of penalties applied for crimes of a corresponding gravity.”

Define New Regulations and Expanded Government Activities: Addressing food fraud includes a new or different government response.

“There is a need to strengthen official national food control programmes by:

- Developing new regulations to combat fish fraud;
- Enhancing enforcement activities prohibiting landings and market access for products from illegal, unreported, and unregulated fishing; introducing monitoring and surveillance programmes for assessing the degree of compliance with fish labeling regulations; and,
- Upgrading laboratory detection methods based on DNA barcoding.”

Food Fraud Vulnerability Assessments that are harmonized, standardized, and codified: There is a need to first assess the vulnerability before selecting countermeasures and control systems.

“Food safety management systems need to be expanded to include vulnerability and threat assessments to analyse risks and to put control and prevention strategies in place.”

Food Fraud Control Measures (Prevention Strategies) that are harmonized standardized and codified: Following the assessment should be a coordinated prevention plan.

“The industry needs to develop and implement systems … to prioritize control measures to minimize the risk of receiving fraudulent or adulterated raw materials or ingredients.”

CODEX as an International Harmonization Point: A logical coordinating body is CODEX.

“The Codex Alimentarius Commission, in association with its member countries, should develop international principles and guidelines designed to identify, manage and mitigate fraudulent practices in food trade and to develop guidelines to standardize food safety management systems for fish fraud vulnerability assessment.”

It is interesting and important to consider new research and recommendations that address food fraud prevention. There is a refined focus on basic concepts such as: the general definition and scope of food fraud, that food fraud is a public health threat, and that efficient and effective control plans

(continued)

start with a product/ country/ industry-level vulnerability assessment. This starting point will help refine and optimize the control plans, which include product authenticity testing, identify standards, traceability, coordinated government activity, and focus on consumer confidence. It is logical that CODEX is identified as an international harmonization point which would support other activity by industry or other standards bodies such as ISO. A key is that food fraud research and recommendations are continuing to include a focus on definitions, scope, and prevention.

International Standards Organization (ISO)

The International Standards Organization (ISO) “...is an independent, non-governmental international organization with a membership of 163 national standards bodies” (ISO 2008). Through authority from the US Department of Commerce, the USA is represented by the American National Standards Institute (ANSI) (ANSI 2018). ANSI manages the US activities including forming and overseeing the US delegations to the ISO Technical Committees (TCs). Through an open, consensus-based process, ISO developed internationally recognized standards for “[ISO creates] documents that provide requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes, and services are fit for their purpose” (ISO 2008). Several ISO TCs that apply to food fraud are:

- **ISO/TC292 Security management and resiliency:** The scope is “Standardization in the field of security to enhance the safety and resilience of society” (ISO 2018c). A major contribution to food fraud prevention is Work Group 4 (WG 04) Authenticity, integrity, and trust for products and documents. An applicable standard is ISO 12931:2012 Performance criteria for authentication solutions used to combat counterfeiting of material goods. This was followed with ISO 16678:2014 Product Fraud: Guidelines for interoperable object identification and related authentication systems to deter counterfeiting and illicit trade. Next was ISO 22380:2018 Security and resilience—Authenticity, integrity, and trust for products and documents—General principles for product fraud risk and countermeasures (ISO 2018b). This includes definitions of product fraud, definitions of types of fraud, authenticity, and others. This standard codifies the Product-Counterfeiting Incident Clustering Tool (PCICT) which is from a previous MSU-FFI published journal article (Spink et al. 2014).
- **ISO/TC 34 Food products:** The scope is “Standardization in the field of human and animal foodstuffs, covering the food chain from primary production to consumption, as well as animal and vegetable propagation materials, in particular, but not limited to, terminology, sampling, methods of test and analysis, product specifications, food and feed safety and quality management and requirements for packaging, storage and transportation.” A major contribution is Sub-committee 17 (SC17) Management systems for food safety (ISO 2017a). An applicable

standard is ISO 22000:2005 Food Safety Management Systems—Requirements for any organization in the food chain. The new ISO 22000:2018 revision was published in June 2018 (ISO 2005). (See appendix for the full list of all working groups and food products directly addressed.)

- **ISO/TC 262 Risk management (product fraud was formerly in TC 247):** The scope is “Standardization in the field of risk management” (ISO 2017c). The major contribution in this standard is the management series based on ISO 31000 Risk Management. Key points include definitions of risk and vulnerability as well as a method for risk analysis. (For more on ISO 31000 regarding the management system, see the chapter on food fraud prevention, and for the fundamental concepts, see the chapter on Risk Analysis.)
- **ISO/TC 176 Quality management and quality assurance:** The scope is “Standardization in the field of quality management (generic quality management systems and supporting technologies), as well as quality management standardization in specific sectors at the request of the affected sector and the ISO Technical Management Board” (ISO 2017b). The major contribution is the management series based on ISO 9000:2015 Quality management systems—Fundamentals and vocabulary.

Several ISO activities will be reviewed in more detail.

ISO/TC 292/WG 4 Authenticity, integrity, and trust for products and documents: This WG was originally created as TC247 Fraud Countermeasures and Controls before being merged into TC292. Several key definitions in ISO12931:2012 “Performance criteria for authentication solutions used to combat counterfeiting of material goods” are: (ISO 2011)

- “3.2” **Authentic material good:** material good produced under the control of the legitimate manufacturer, the originator of the good, or holder of intellectual property rights.
- “3.3” **Authentication:** act of establishing whether a material good is genuine or not
- “3.3.1” **Authentication element:** tangible object, visual feature, or information associated with a material good that is used as part of an authentication solution.
- “4.2” **Authentication process:** The typical authentication solution is shown in Fig. 11.1 and reveals the interrelationship between the material good to be authenticated and typical components of the authentication solution. They together yield a true or false verdict or provide information that will enable to detect the authenticity of the material good.

The TC292 has continued to evolve from application steps to the broader management system. These provide value and support for the Food Safety Management Systems.

ISO/TC34/SC17/WG8—Management Systems for Food Safety (ISO 22000): Specifically the main focus is ISO 22000 which was published in 2005 and updated in 2018 (ISO 2005, 2018a). New topics include food fraud and separately food defense. The revised standard is still based on Total Quality Management principles

such as Plan-Do-Check-Act (PDCA), the HACCP-type actions, and directs a Food Safety Management System (FSMS). The standard clearly includes food fraud where it is stated [emphasis added] “Understanding the context can be facilitated by considering external and internal issues including but not limited to legal, technological, competitive, market, cultural, social, economic environments, cybersecurity, and food fraud, food defence and intentional contamination, knowledge, and performance of the organization, whether international, national, regional or local....” (ISO 2005). (See chapter appendix for more ISO defined food safety terms that apply to food fraud.)

While ISO is not required but often is a starting, harmonization center point. If and when there can be ISO consensus on terms and focus, then many innovations can be developed and implemented more quickly.

Conclusion

The role of standards and certifications are vital to creating a harmonized and common starting point for any activity. This is especially important—and opportune—for food fraud prevention because it is at the start of the awareness building and of the development of requirements. It is essential since creating a common starting point will support harmonized terminology and efficient sharing of best practices. It is opportune since the first reviews are being conducted which are leading to the first holistic, all-encompassing requirements. From the UK Elliott Review to the Trinidad and Tobago Parliamentary Review of food fraud, there is a growing governmental awareness and formal statement of the problem. From ISO and Codex to GFSI, there is an emerging body of compliance requirements. ***The first conclusion is*** for standards and certification development and implementation, that there is a definite role in the public-private partnership for international nongovernmental organizations (NGOs) supported by nonprofit organizations (NPOs). The NGO groups such as ISO, CODEX, and GFSI provide a key overarching coordination role building both consensuses based and common codes of practice. There is a great benefit if the NGOs only create common definitions and management system goals that focus on overall prevention. ***The second conclusion is*** that it is critical to gather a wide range of interdisciplinary experts to provide insight and practical recommendations for starting the process but also considering the challenges through to implementation. While it is easy to identify the current state (“point A”) and the ultimate goal (“point B”), the most challenging part is to “just get started” and then completing the journey (“getting from point A to point B”). ***The final conclusion is*** that it is efficient first to consider what activities are already being conducted and to build upon standard operating procedures. Key and active systems for food fraud prevention are being implemented by industry to address GFSI compliance. The overall food fraud prevention strategy standards and certifications help support laws and regulations since the industry is working to protect the supply chain. There is a saying:

If laws and regulations require “a” process – rather than very specific, prescribed actions – then the result will be further momentum for the standards and certifications.

Appendix: Glossary of Addition Terms and Definition

Selected key ISO definitions related to audits and certifications:

- ***Audit:*** systematic, independent, and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled; SOURCE: ISO 22300:2018.
- ***Audit, first party:*** internal audit; Note 3 to entry: An *internal audit* is conducted by the organization or by an external party on its behalf. Internal audit can be for management review and other internal purposes and can form the basis for an organization’s declaration of conformity. Independence can be demonstrated by the freedom from responsibility for the activity being audited; [ISO BCP]
- ***Audit, second party, or third party:*** external audit; Note 4 to entry: *External audits* include those generally called second- and third-party audits. *Second-party audits* are conducted by parties having an interest in the organization, such as customers, or by other persons on their behalf. *Third-party audits* are conducted by external, independent auditing organizations such as those providing certification/registration of conformity or government agencies; [ISO BCP]
- ***Documented information (documentation, documented):*** information required to be controlled and maintained by an organization and the medium on which it is contained; Note 1 to entry: Documented information can be in any format and on any media from any source. [ISO BCP]
- ***Interested party:*** stakeholder, person, or organization that can affect, be affected by, or perceive themselves to be affected by a decision or activity; SOURCE: ISO 22300:2018, 3.124.
- ***Management:*** coordinated activities to direct and control an organization, SOURCE: ISO 9000:2015, 3.3.
- ***Management system:*** set of interrelated or interacting elements of an organization to establish policies and objectives and processes to achieve those objectives; Note 1 to entry: A management system can address a single discipline or several disciplines, e.g., quality management, financial management, or environmental management. The scope of a management system can include the whole of the organization, specific and identified functions of the organization, specific and identified sections of the organization, or one or more functions across a group of organizations; SOURCE: ISO 9000:2015, 3.5.3.
- ***Organization:*** person or group of people that has its own functions with responsibilities, authorities, and relationships to achieve its objectives; for organizations with more than one operating unit, a single operating unit can be defined as an organization; SOURCE: ISO 9000:2015, 3.2.1.

- **Policy:** intentions and direction of an organization as formally expressed by its top management [ISO BCP]
- **Prioritized activity:** activity to which priority is given to mitigate impacts following a disruptive incident [or a new awareness of a vulnerability]; terms commonly used to describe these activities include critical, essential, vital, urgent, and key; SOURCE: ISO 22300:2018, 3.176.
- **Top management:** person or group of people who directs and controls an organization at the highest level; Note 1 to entry: Top management has the power to delegate authority and provide resources within the organization; SOURCE: ISO 9000.
- **Verification:** confirmation, through the provision of evidence, that specified requirements have been fulfilled; SOURCE: ISO 9000:2015, 3.8.12.

Appendix: ISO 22000 Food Safety Terms Applicable to Food Fraud

The overall scope of ISO 22000:2018 is presented in the “4.1 Understanding the organization and its context” where it is stated (ISO 2005):

“The organization shall determine external and internal issues that are relevant to its purpose and that affect its ability to achieve the intended results of its food safety management system. The organization shall identify, review and update information related to these external and internal issues.”

Then Section 4.1, Note 1 clearly defines food fraud within the scope of the standard:

“Understanding the context can be facilitated by considering external and internal issues including but not limited to legal, technological, competitive, market, cultural, social, economic environments, cybersecurity, ***and food fraud***, food defence and intentional contamination, knowledge, and performance of the organization, whether international, national, regional or local.”

From ISO 22000:2018, selected definitions of terms that apply to food fraud prevention:

- **3.1 Acceptable level**—level of a **food safety hazard** (3.22) not to be exceeded in the **end product** (3.15) provided by the **organization** (3.31)
- **3.2 Action criterion**—measurable or observable specification for the **monitoring** (3.27) of an **OPRP** (3.30)
 - Note 1 to entry: An action criterion is established to determine whether an OPRP remains in control and distinguishes between what is acceptable (criterion met or achieved means the OPRP is operating as intended) and unacceptable (criterion not met nor achieved means the OPRP is not operating as intended).

- **3.6 Contamination**—introduction or occurrence of a contaminant including a **food safety hazard** (3.22) in a **product** (3.37) or processing environment
- **3.7 Continual improvement**—recurring activity to enhance **performance** (3.33)
- **3.8 Control measure**—action or activity that is essential to prevent a significant **food safety hazard** (3.22) or reduce it to an **acceptable level** (3.1)
 - Note 1 to entry: See also **significant food safety hazard** (3.40).
 - Note 2 to entry: Control measure(s) is (are) identified by hazard analysis.
- **3.11 Critical control point (CCP)**—step in the **process** (3.36) at which **control measure(s)** (3.8) is (are) applied to prevent or reduce a **significant food safety hazard** (3.40) to an acceptable level, and defined **critical limit(s)** (3.12) and **measurement** (3.26) enable the application of **corrections** (3.9)
- **3.12 Critical limit**—measurable value which separates acceptability from unacceptability
 - Note 1: Critical limits are established to determine whether a **CCP** (3.11) remains in control. If a critical limit is exceeded or not met, the products affected are to be handled as potentially unsafe products. [SOURCE: CAC/RCP 1-1969, modified—The definition has been modified, and Note 1 to entry has been added.]
- **3.14 Effectiveness**—extent to which planned activities are realized, and planned results achieved
- **3.15 End product**—**product** (3.37) that will undergo no further processing or transformation by the **organization** (3.31)
 - Note 1 to entry: A product that undergoes further processing or transformation by another organization is an end product in the context of the first organization and a raw material or an ingredient in the context of the second organization.
- **3.21 Food safety**—assurance that food will not cause an adverse health effect for the consumer when it is prepared and/or consumed in accordance with its intended use
 - Note 1 to entry: Food safety is related to the occurrence of **food safety hazards** (3.22) in **end products** (3.15) and does not include other health aspects related to, for example, malnutrition.
 - Note 2 to entry: It is not to be confused with the availability of, and access to, food (“food security”).
 - Note 3 to entry: This includes feed and animal food. [SOURCE: CAC/RCP 1-1969, modified—The word “harm” has been changed to “adverse health effect,” and notes to entry have been added.]
- **3.22 Food safety hazard**—biological, chemical, or physical agent in **food** (3.18) with the potential to cause an adverse health effect

- Note 1 to entry: The term “hazard” is not to be confused with the term “risk” (3.39) which, in the context of food safety, means a function of the probability of an adverse health effect (e.g., becoming diseased) and the severity of that effect (e.g., death, hospitalization) when exposed to a specified hazard.
 - Note 2 to entry: Food safety hazards include allergens and radiological substances.
 - Note 3 to entry: In the context of feed and feed ingredients, relevant food safety hazards are those that can be present in and/or on feed and feed ingredients and that can through animal consumption of feed be transferred to food and can thus have the potential to cause an adverse health effect for the animal or the human consumer. In the context of operations other than those directly handling feed and food (e.g., producers of packaging materials, disinfectants), relevant food safety hazards are those hazards that can be directly or indirectly transferred to food when used as intended (see 8.5.1.4).
 - Note 4 to entry: In the context of animal food, relevant food safety hazards are those that are hazardous to the animal species for which the food is intended. [SOURCE: CAC/RCP 1–1969, modified—The phrase “or condition of” has been deleted from the definition, and notes to entry have been added.]
- **3.27 Monitoring**—Determining the status of a system, a **process** (3.36), or an activity
 - Note 1 to entry: To determine the status, there may be a need to check, supervise, or critically observe.
 - Note 2 to entry: In the context of food safety, monitoring is conducting a planned sequence of observations or measurements to assess whether a process is operating as intended.
 - Note 3 to entry: Distinctions are made in this document between the terms **validation** (3.44), **monitoring** (3.27), and **verification** (3.45):
 - Validation is applied prior to an activity and provides information about the capability to deliver intended results.
 - Monitoring is applied during an activity and provides information for action within a specified time frame.
 - Verification is applied after an activity and provides information for confirmation of conformity.
 - **3.37 Product**—output that is a result of a **process** (3.36)
 - Note 1 to entry: A product can be a service.
 - **3.40 Significant food safety hazard**—**food safety hazard** (3.22), identified through the hazard assessment, which needs to be controlled by **control measures** (3.8)
 - **3.42 Traceability**—ability to follow the history, application, movement, and location of an object through specified stage(s) of production, processing, and distribution
 - Note 1 to entry: Movement can relate to the origin of the materials, processing history, or distribution of the **food** (3.18).

- Note 2 to entry: An object can be a **product** (3.37), a material, a unit, equipment, a service, etc. [SOURCE: CAC/GL 60–2006, modified—Notes to entry have been added.]
- **3.44 Validation**—(food safety) obtaining evidence that a **control measure** (3.8) (or combination of control measures) will be capable of effectively controlling the **significant food safety hazard** (3.40)
 - Note 1 to entry: Validation is performed at the time a control measure combination is designed or whenever changes are made to the implemented control measures.
 - Note 2 to entry: Distinctions are made in this document between the terms **validation** (3.44), **monitoring** (3.27), and **verification** (3.45):
 - Validation is applied prior to an activity and provides information about the capability to deliver intended results.
 - Monitoring is applied during an activity and provides information for action within a specified time frame.
 - Verification is applied after an activity and provides information for confirmation of conformity.
- **3.45 Verification**—confirmation, through the provision of objective evidence, that specified **requirements** (3.38) have been fulfilled
 - Note 1 to entry: Distinctions are made in this document between the terms **validation** (3.44), **monitoring** (3.27), and **verification** (3.45):
 - Validation is applied prior to an activity and provides information about the capability to deliver intended results.
 - Monitoring is applied during an activity and provides information for action within a specified time frame.
 - Verification is applied after an activity and provides information for confirmation of conformity.

Appendix: ISO 22000 Family of Standards

“The ISO 22000 family contains a number of standards each focusing on different aspects of food safety management.

- ISO 22000:2005 contains the overall guidelines for food safety management.
- ISO 22004:2014 provides generic advice on the application of ISO 22000
- ISO 22005:2007 focuses on traceability in the feed and food chain
- ISO/TS 22002–1:2009 contains specific prerequisites for food manufacturing
- ISO/TS 22002–2:2013 contains specific prerequisites for catering
- ISO/TS 22002–3:2011 contains specific prerequisites for farming
- ISO/TS 22002–4:2013 contains specific prerequisites for food packaging manufacturing
- ISO/TS 22003:2013 provide guidelines for audit and certification bodies.”

Subcommittee/Working Group structure:

ISO/TC 34/CAG Chairmen Advisory group	ISO/TC 34/WG 13 Royal jelly	ISO/TC 34/WG 14 Vitamins, carotenoids, and other nutrients
ISO/TC 34/WG 16 Animal welfare	ISO/TC 34/WG 17 Water activity	ISO/TC 34/WG 18 Natural food ingredients
ISO/TC 34/WG 20 Aflatoxins	ISO/TC 34/WG 21 Social responsibility/sustainability	ISO/TC 34/SC 2 Oleaginous seeds and fruits and oilseed meals
ISO/TC 34/SC 3 Fruits and vegetables and their derived products	ISO/TC 34/SC 4 Cereals and pulses	ISO/TC 34/SC 5 Milk and milk products
ISO/TC 34/SC 6 Meat, poultry, fish, eggs, and their products	ISO/TC 34/SC 7 Spices, culinary herbs, and condiments	ISO/TC 34/SC 8 Tea
ISO/TC 34/SC 9 Microbiology	ISO/TC 34/SC 10 Animal feeding stuffs	ISO/TC 34/SC 11 Animal and vegetable fats and oils
ISO/TC 34/SC 12 Sensory analysis	ISO/TC 34/SC 15 Coffee	ISO/TC 34/SC 16 Horizontal methods for molecular biomarker analysis
ISO/TC 34/SC 17 Management systems for food safety	ISO/TC 34/SC 18 Cocoa	

Appendix: WIIFM Chapter on Standards and Certification Overview

This “What’s In It For Me” (WIIFM) section explains why this chapter is important to you.

Business functional group	Application of this chapter
WIIFM all	There are many groups working in and around food fraud, and there will be many opportunities to learn and expand best practices
Quality team	There are many NGOs, NPOs, and other groups that can help in the public-private partnership as colleagues and collaborators—but define <i>your</i> needs and don’t just join every group or committee
Auditors	The FFPS may refer to organizations that you have not seen before
Management	While there should not be a high-resource requirement, there will probably be a need to connect your team to new resources, support groups, and international organizations
Corp. decision-makers	The team may seem to be wildly expanding into new and irrelevant disciplines, but the connections should not be too resource-intensive and will actually increase the efficiency from an interdisciplinary and international approach

Appendix: Study Questions

This section includes study questions based on the Key Learning Objectives in this chapter:

1. Discussion Question
 - (a) What is the relationship between laws, regulations, standards, and certifications?
 - (b) What are examples of PPPs in the food sector?
 - (c) What is the optimal role of the PPP in FF prevention?
2. Key Learning Objective 1
 - (a) What is the difference between “inspection” and “investigation”?
 - (b) How does ISO 22380 Product Authenticity apply to FF prevention?
 - (c) What is the impact of CODEX on food laws?
3. Key Learning Objective 2
 - (a) What is an “NGO”?
 - (b) What are the differences between NGO, NPO, and NPC?
 - (c) Why is it recommended that governments require “a” process not prescribe in a specific approach?
4. Key Learning Objective 3
 - (a) What is PDCA?
 - (b) What is authentic versus authentication?
 - (c) What is the relationship between CODEX, ISO, GFSI, and FAO/WHO?

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Chapter 12

Standards and Certifications (Part 2 of 2): Global Food Safety Initiative (GFSI)



Summary

This chapter presents the GFSI food fraud compliance requirements that build on the basics presented in other chapters. This more detailed chapter includes the assessments, prevention strategies, and the overall scope of the certification. The GFSI requirements build ISO 22000 Food Safety Management and require a Food Safety Management System (FSMS). GFSI is a benchmark that is endorsed by food safety standards such as FSSC 22000, SQF, BRC, and IFS, and others. As of January 2018, the GFSI requirement now includes specific and separate activities to address food safety, food defense, and food fraud. These requirements are an essential consideration for food fraud prevention.

The Key Learning Objectives of this chapter are

- (1) **The Overall Food Safety Management System (FSMS)**
- (2) **HACCP and TACCP:** The specific concepts addressing food safety in a hazard analysis or HACCP plan and food defense in a threat assessment or TACCP plan
- (3) **VACCP:** Finally, addressing food fraud in a vulnerability assessment or VACCP plan

On the Food Fraud Prevention Cycle (FFPC), this chapter addresses the theoretical foundation concepts related to criminology and the fraudster “(B) Fundamental Concepts” (Fig. 12.1).

Introduction

GFSI has been identified as a key stakeholder since they were the first industry group or NGO to holistically address the broad scope of food fraud and focus on prevention. GFSI is a unique NGO since they are comprised of the stakeholders who have the most influence in implementation and whom both have the financial

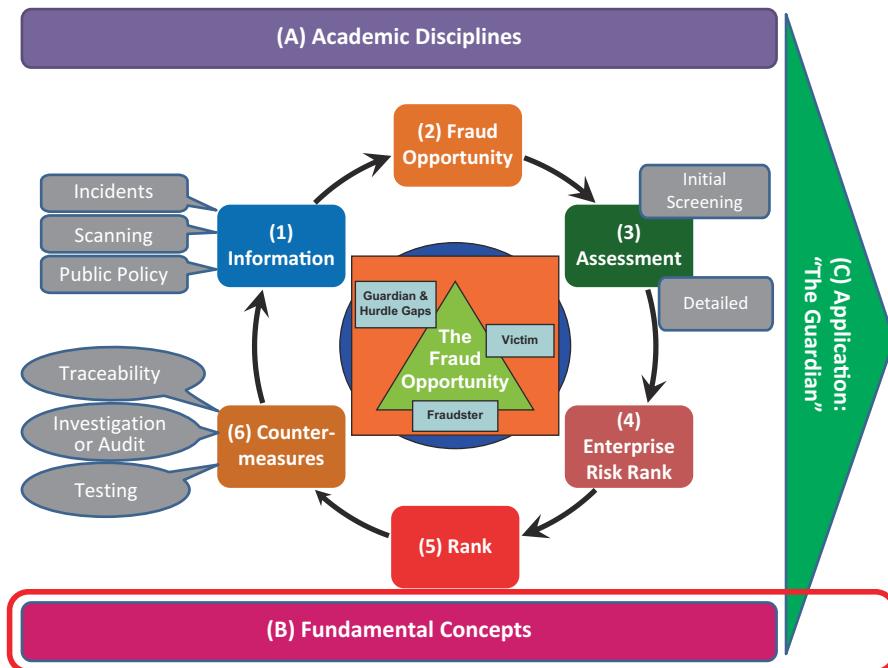


Fig. 12.1 Food Fraud Prevention Cycle—where this chapter applies to the overall concept: “(B) Fundamental Concepts” (Copyright Permission Granted) (Spink 2014, Spink et al. 2019)

and human resource capacity but can make compliance a requirement to do business. Thus, a deeper dive into the standards and certification of GFSI is provided.

Key Learning Objective 1: The GFSI Food Safety Management System

This section reviews the Global Food Safety Initiative (GFSI) and specifically the Food Safety Management System (FSMS—not to be confused with FSMA which is the US Food Safety Modernization Act).

The Key Learning Objectives of this section are

- (1) International industry collaboration
- (2) Food industry priority setting
- (3) Introduction to the GFSI and the Food Safety Management System (FSMS)

International Industry Collaboration Including GFSI

There are many global activities conducted by industry. For example, the American Spice Trading Association (ASTA) represents the spice industry, and the National Honey Board (NHB) is managed by the USDA to support the honey industry in the USA (ASTA 2018; NHB 2018). The Global Food Safety Initiative (GFSI) is an organization focused across the food industry and focuses on the overall concept of food safety (GFSI 2017).

GFSI has members from across the food industry and was created and is administered by the Consumer Goods Forum (CGF) (CGF 2017). CGF is an association led by the chief executive officers of companies across the product scope including food, consumer-packaged goods, consumer electronics, apparel, etc. (CGF 2018).

In 2002 GFSI was created to try to consolidate and harmonize a Food Safety Management System to meet a dizzying array of country codes of practice and laws (Fig. 12.2). GFSI creates a “benchmark” or expectation of a food safety standard. Standards are developed by Certification Program Organizations (CPOs or previously referred to as scheme owners). The companies then implement the standards which are confirmed by certification bodies (CBs). The goal is that the system and certification support government regulatory compliance.

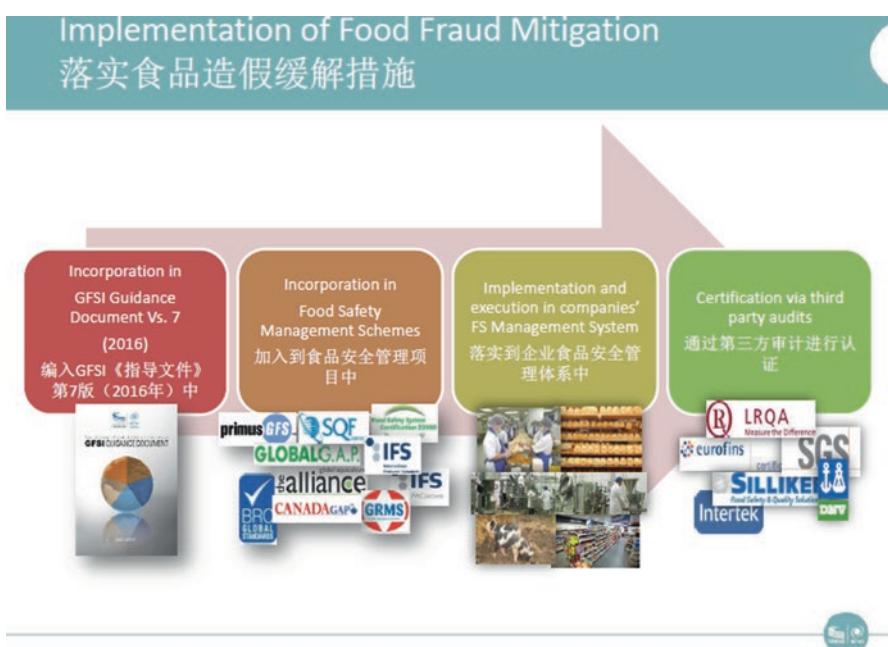


Fig. 12.2 GFSI system hierarchy including guidance document, standard, implementation, and certification (Copyright Permission Granted) (Spink 2013)

The GFSI food fraud-related requirements will be covered in more detail later written requirements are provided here (emphasis added) (GFSI 2017):

- **FSM AI 21 Food Fraud Vulnerability Assessment**
 - The standard shall require that **the organization** has a **documented** Food Fraud **Vulnerability Assessment** procedure in place to identify potential **vulnerability** and prioritize food fraud mitigation measures.
- **FSM AI 22.1 Food Fraud Mitigation Plan**
 - The standard shall require that **the organization** has a **documented** plan in place that specifies the measures the organization has implemented to **mitigate** the public health risks from the identified food fraud vulnerabilities.
- **FSM AI 22.2 Food Fraud Mitigation Plan**
 - The standard shall require that **the organization's** food fraud mitigation plan **shall cover the relevant GFSI scope** [as defined in the GFSI position paper] and shall be supported by the organization's Food Safety Management System.

The GFSI requirements are significant because they will require “some” action. The first steps will be just to create a Food Fraud Vulnerability Assessment and then publish a holistic, all-encompassing Food Fraud Prevention Strategy. The program requirements and audit breadth will continue to expand over time as there are process improvement and sharing of best practices.

GFSI and Industry Priority Setting

The Global Food Safety Initiative (GFSI) is uniquely positioned in the food fraud landscape since it is a Food Safety Management System that is broadly required and includes a certification system. The impact is significant and efficient for governments to leverage or at least consider since the supply chain participants can create essentially mandatory requirements. Many retailers have a requirement that their new suppliers are GFSI certified or are on the way to the certification. The retailers—either directly or through groups of companies such as the MSU Food Fraud Think Tank or the SSAFE Organization—provide training, education, and support for suppliers of all sizes.

GFSI first addressed food fraud when their Board of Directors requested in 2012 that at “Food Fraud Think Tank” review what is food fraud, how should it be addressed, and what—if any—is the role of GFSI. Food fraud was a key topic in the keynote presentation at several of the GFSI annual conferences.

A Summary of the 2013 Conference Is Included Here (MSU-FFI 2018)

Title: GFSI Update #2 – Food Fraud a Hot Topic

By John Spink • March 13, 2013 • Blog

This is the second post regarding the GFSI conference. This includes insight from the pre-conference GFSI stakeholder meetings on Wednesday and also from the conference closing remarks on Friday.

Pre-Conference GFSI Meeting

GFSI Vice-Chair Frank Yiannas (VP Food Safety, Wal-mart) led the meeting that included a set of electronic survey questions that solicited live responses from the 300+ session attendees. Two survey questions, in particular, addressed “Food Fraud/ Economically Motivated Adulteration” concerns:

1. “What critical area should GFSI focus on over the next 3 years?”

- Auditor competence: 18%.
- Driving common acceptance of GFSI recognition: 21%.
- Support for small suppliers: 18%.
- Regulatory acceptance of private schemes: 21%.
- Food safety culture: 15%.
- **Economically Motivated Adulteration/ Food Fraud: 7%.**

2. “What is the top food safety issue within your business?”

- Ingredient suppliers: 34%.
- Pathogens: 15%.
- Auditor competence: 10%.
- Training and education: 26%.
- Product labeling: 7%.
- **Economically Motivated Adulteration/ Food Fraud: 8%.**

I agree that food fraud is a very important topic and a critical emerging risk. Considering the traditional food safety challenges facing the food industry, I am surprised food fraud has risen to such importance in such a short period of time. Two years ago food fraud wasn’t even on the GFSI conference agenda.

Throughout the conference, food fraud was a topic of conversation. In the food fraud session, GFSI Chair Yves Rey said: “the prevention of adulteration is a clear goal of GFSI and of Interpol.” The role of GFSI in the bigger global setting was reiterated by the FDA. Michael Taylor, FDA Deputy Commissioner for Foods, Office of Foods stated: “public-private partnership [such as with GFSI] is utterly critical to the implementation of the Food Safety Modernization Act.”

Conference Closing Remarks

In the closing session presentation on “Beyond Benchmarking – The Future of GFSI,” Board Member Hugo Byrnes (VP Product Integrity, Royal

Ahold) identified food fraud as one of six top challenges for GFSI, along with the likes of globalization, complex supply chains, transparency in supply chains, increased technology to detect low levels of contamination, and gene typing that identifies sources of outbreaks. He stated that to prevent food safety incidents the industry must focus on new, broad concepts such as food fraud. He expressed the need to look beyond the usual concepts of “product risk” and “supplier risk” to broader “vulnerabilities.” GFSI strategic thinkers are making a statement that they are broadening their vision. (A risk is something that has occurred and will unfortunately probably occur again. The objective is to reduce risks. A vulnerability may never have, and might not ever, occur, but it could. A vulnerability can be eliminated.)

Mr. Byrnes made a very important statement about food fraud that I had not explicitly considered:

“Fortunately it is not [the food industry] responsibility to define what is illegal.”

Of course, the food industry and regulators will be dealing with this emerging risk no matter who defines whether or not an incident is technically “illegal.” MSU-FFI.

Appendix: Further China Insights – Wal-mart and the Chinese Shopper.

Paul Gallemore, Chief Compliance Officer for Wal-mart China, discussed a range of their Food Safety initiatives including Food Fraud. Their Food Safety Team addresses related concepts along the continuum of Food Safety, Food Fraud, and Food Defense. While this is a continuum, each concept is addressed with a unique focus. When addressing Food Fraud prevention, he stated: “We’re concerned with more than just adulteration.” Commenting on the complexity of the issue, he stated “That’s the reason why we need to work together. We need to work together to figure out how to reduce the fraud opportunity as an entire industry.” As part of that collaborative approach, we were pleased he had a slide that mentioned their sponsorship of our Mandarin language MSU Food Fraud MOOC. The focus on Food Fraud prevention is so intense because it is so important to consumers. He presented the top 5 most important shopping experience factors for Chinese shoppers:

1. No Fake Products = 81.4%.
2. Has Product Safety Guarantee = 79.4%.
3. Fresh Foods Smell Fresh = 78.3%.
4. Honest Pricing = 78.2%.
5. Has Product Quality Guarantee = 77.4%.



Fig. 12.3 GFSI Food Fraud Think Tank Presentation of the Food Safety Management System umbrella including the concepts of HACCP, TACCP, and VACCP assigned? (Copyright Permission Granted) (Spink 2013, GFSI 2014a, b)

The GFSI Food Safety Management System (FSMS)

The Global Food Safety Initiative (GFSI) defined that a Food Safety Management System (FSMS)—presented in their Guidance Document—includes requirements to specifically and separately address food safety, food fraud, and food defense. Food safety is addressed in hazard analysis and critical control point plans (HACCP). When the GFSI Food Fraud Think Tank was reviewing the food fraud topic, a hierarchy was developed to address food fraud in a Vulnerability Assessment and Critical Control Point plan (VACCP) and food defense in a Threat Assessment and Critical Control Point plan (TACCP). The GFSI umbrella is presented below (Fig. 12.3).

The GFSI position paper on food fraud was their first formal review of the topic (GFSI 2014a, b). Later more details were available in the SSAFE Organization Food Fraud Vulnerability Assessment guidance and tool where it was stated that “The GFSI Board of Directors endorses the SSAFE activities related to food fraud [referring to the SSAFE Food Fraud Mitigation Guide and Food Fraud Vulnerability Assessment Tool]” (SSAFE 2015). Finally, the requirements were published in the GFSI Guidance Document (GFSI 2017). More compliance details about the standards are presented by the Certification Program Organizations (CPOs).

Conducting three separate assessments—one for HACCP, another for TACCP, and then one for VACCP—is actually more efficient than expanding HACCP into one complex, interdisciplinary method. The root causes that apply to TACCP and VACCP are fundamentally different than for HACCP. Conducting three assessments does not triple the work; it actually is easier and more efficient. Further, it could actually also be efficient to conduct separate more focused assessments for each specific types of fraud. It might be simpler to conduct more specific assessments since the root cause for different types of theft is (e.g., cargo theft, employee theft, shoplifting, return fraud, warranty fraud, etc.) so different.

Next, the separate concepts will be reviewed in more detail including HACCP, VACCP, and TACCP (Spink 2013).

Sidebar: Background GFSI First Addressing Food Fraud

In July 2012 the GFSI Board of Directors created a Food Fraud Think Tank (GFSI-FFT) to review if—and possibly how—they should address food fraud. The project was spearheaded and championed by then GFSI Chair Yves Rey (Danone) and also co-GFSI Board Member sponsor Frank Yiannas (Wal-mart). The group was originally called the “Economic Adulteration” Think Tank. After considering the full range of risks, and specifically basing decisions on the previous work by ISO product fraud, the group changed the title and focus to food fraud. Early on the focus was clearly on “what” food fraud is and “if” it was something that should be addressed by GFSI.

During the early GFSI-FFT work, the horsemeat incident occurred in September 2012. This new incident increased the sense of urgency and importance of the group. Food fraud evolved from a unique and rare event to something that could have a catastrophic impact on a product, brand, or even a company. In July 2014 the final recommendation was published by the GFSI Board of Directors in the “GFSI Position on Mitigating the Public Health Risk of Food Fraud” (GFSI 2014a, b).

Early on the GFSI Food Fraud Think Tank identified that prevention of food fraud required a fundamentally different approach than for food safety or food defense. The GFSI scope was to focus on prevention based on root cause analysis. While detecting fraud is important, the total quality management-based perspective is to change or modify the environmental characteristics that allow the anomaly, nonconformance, or defect to occur. This insight identified a necessary shift from HACCP and TACCP type approaches to focus on the “fraud opportunity” or “vulnerability.” Thus, this identified the need for a separate assessment that is referred to as VACCP.

Sidebar: GFSI Releases Food Fraud Position Paper and GFSI Food Fraud Think Tank (MSU-FFI 2018)

Title: GFSI Releases Food Fraud Position Paper & GFSI Food Fraud Think Tank

By John Spink • July 15, 2014 • Blog

Earlier tonight the Global Food Safety Initiative (GFSI) Board released its position paper on food fraud prevention. The GFSI Food Fraud Think Tank (GFSI-FFTT), created in 2012, was identified as a key contributor to the development of their position. The GFSI-FFTT members included our MSU Food Fraud initiative, Danone, Eurofins, Inscatech, Royal Ahold, and Wal-mart. We are proud that our work was helpful, and they recognized us stating "...the Food Fraud Initiative at Michigan State University, leading the academic field of criminology with a special focus on food fraud." Our MSU work is focused on a very rational approach to prevention.

The goal of our blog series is to review and address some of the timely and important food fraud concepts. The clear GFSI position in the position paper is extremely important because it formally states the official position of the GFSI Board and GFSI. This is a statement of what the GFSI Board expects to find in a thorough and competent Food Safety Management System. We will review some of the key points below.

GFSI Position on Mitigating the Public Health Risk of Food Fraud.

Broad Definition of Food Fraud: GFSI formally defined their broad definition of food fraud to include adulteration, but also all fraud – explicitly including misbranding and stolen goods. Stolen goods present an especially complex challenge because authenticity testing would, of course, identify the product correctly as genuine. Stolen goods can present a public health threat since they may have been mishandled. Also, their date or lot codes could have been tampered.

- “Food fraud, including the subcategory of economically motivated adulteration, is of growing concern. It is deception of consumers using food products, ingredients and packaging for economic gain and includes substitution, unapproved enhancements, misbranding, counterfeiting, stolen goods or others” (GFSI 2014a, b).
- “The GFSI Board recognizes that the driver of a food fraud incident might be an economic gain, but if a public health threat arises from the effects of an adulterated product, this will lead to a food safety incident” (GFSI 2014a, b).

It should be emphasized that a holistic food fraud prevention plan addresses more than adulteration and expands beyond ingredients. These ingredients may be the most significant risk, but others can still lead to food safety incidents. (A future blog post will address the confusing concept that the US Food, Drug and Cosmetics Act could be used to determine a product to be

(continued)

“Adulterated Foods” – unfit for commerce – but there doesn’t need to be an “adulterant.” A stolen good would be classified by the FDCA as “Adulterated Foods.”). The broad definition of food fraud is a key concept to help increase transparency in the supply chain.

Requires a Unique Prevention Approach – Food Fraud Vulnerability Assessment and a Food Fraud Control Plan: The paper frequently cites the work of the Food Fraud Think Tank specifically in the development of the foundational concepts. Those base concepts include emphasizing that a different skill set is required than is used for mitigating food safety or food defense threats. The mitigation plan concepts are similar to HACCP or basic quality management systems: identify the vulnerabilities and have a control plan in place.

- “The GFSI Think Tank recommends that two fundamental steps be taken by the food industry to aid in the mitigation of food fraud:
 - “Firstly, to carry out a “food fraud vulnerability assessment” in which information is collected at the appropriate points along the supply chain (including raw materials, ingredients, [finished] products, packaging) and evaluated to identify and prioritize significant vulnerabilities for food fraud.”
 - “Secondly, ‘appropriate control measures shall be put in place to reduce the risks’ from these vulnerabilities. These control measures can include monitoring strategy, a testing strategy, origin verification, specification management, supplier audits, and anti-counterfeit technologies. A clearly documented control plan outlines when, where and how to mitigate fraudulent activities.”

Auditor Competence – Audit the Plan Does *Not* Find Bad Guys: GFSI is clear that the expectations are for the auditors to check for the presence of the assessment and the plan. They note this is similar to HACCP audits. Follow-up engagements may include consulting to help the company improve the control of their facility, but that is not specifically part of the HACCP “audit.” We included similar statements in our submission to the US FDA’s request for comments on the FSMA Intentional Adulteration (FSMA-IA) draft rule.

Implementation – Guidance Document Version 7 in 2016: This is a clear statement that food fraud prevention will be required for your company to be “GFSI Compliant.” Version 7 will be published in 2016, and there will also be an additional time period after that during which the GFSI-recognized schemes and audit strategies will be developed. However, there is no doubt that food fraud prevention requirements are coming. GFSI Compliance is required to sell the product to many companies. No GFSI certificate, no sale.

Global Laws and Regulations – Beyond GFSI: It is important to emphasize that while this is a GFSI position paper, governments around the world are

working to address food fraud. Addressing food fraud will eventually be required for regulatory compliance.

While some people may think today's press release will have huge rippled effects, it really wasn't earth-shattering. It's not a surprise to those who have been paying attention. Companies and countries have been rising to meet food fraud head-on. Regardless of the compliance requirements, every single day there are food fraud vulnerabilities that threaten the safety of the supply chain. Be proactive. Don't just start going crazy trying to implement programs or countermeasures and control systems. Take the first step of getting familiar with reports like the GFSI Food Fraud position paper. Also, reach out to the many training and educational opportunities. For example, see our website for a range of educational programs. MSU-FFI.

[Note 2018: GFSI shifted from the term Scheme Owner and schemes to Certification Program Owner and standards. Regarding the term "scheme," GFSI uses a more European definition of this term meaning a "plan for doing something" rather than the more American insinuation of "a crafty plot." A "crafty plot" implies trickery, deception, or some type of cheating. Reference: Webster's Dictionary (Merriam-Webster 2004).]

Key Learning Objective 2: GFSI HACCP (Food Safety) and TACCP (Food Defense)

This section reviews the GFSI Food Safety Management System (FSMS) topics of food safety addressed through HACCP and food defense addressed through TACCP.

The Key Learning Objectives of this section are

- (1) Food safety and HACCP
- (2) Food defense and TACCP
- (3) Other non-GFSI related to food safety and food defense requirements

HACCP (Food Safety)

In addition to GFSI food fraud requirements that are addressed in VACCP, the two other pillars of the Food Safety Management System are for food safety in HACCP and for food defense in TACCP.

HACCP is a ***Hazard Analysis and Critical Control Point*** plan. It is a widely adopted system for addressing and preventing food safety incidents (FDA 2017).

From [FDA.gov](https://www.fda.gov):

- **HACCP:** "A systematic approach to the identification, evaluation, and control of food safety" hazards.

- **HACCP Plan:** “The written document which is based upon the principles of HACCP and which delineates the procedures to be followed.”
- **HACCP System:** “The result of the implementation of the HACCP Plan.”
- **Hazard Analysis:** “The process of collecting and evaluating information on hazards associated with the food under consideration to decide which are significant and must be addressed in the HACCP plan.”
- **Prerequisite Programs:** “Procedures, including Good Manufacturing Practices, that address operational conditions providing the foundation for the HACCP system.”

The FDA “HACCP Principles & Application Guidelines” clearly separates prerequisite programs and HACCP:

“Prerequisite programs are established and managed separately from the HACCP plan.”

This separation of the prerequisite program and HACCP system seems trivial, but it is imperative for compliance. An important differentiation is where controls can be implemented and can be monitored to assure it does actually control or reduce the hazard. For food fraud prevention, many controls in a HACCP plan would only identify the problem and—other than removing the bad product, even if it is the entire inventory which would stop the production line—not provide a preventive measure or true corrective action. Consider the FDA HACCP definitions:

- **Control:** (a) To manage the conditions of an operation to maintain compliance with established criteria. (b) The state where correct procedures are being followed and criteria are being met.
- **Control Measure:** Any action or activity that can be used to prevent, eliminate, or reduce a significant hazard.
- **Control Point:** Any step at which biological, chemical, or physical factors can be controlled.
- **Corrective Action:** Procedures followed when a deviation occurs.
- **Critical Control Point (CCP):** A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

To compare definitions, from ISO 9000 Quality Management:

- **Preventive action:** “action to eliminate the cause of a potential nonconformity (3.6.9) or other potential undesirable situation; Note 1 to entry: There can be more than one cause for a potential nonconformity; Note 2 to entry: Preventive action is taken to prevent occurrence whereas corrective action (3.12.2) is taken to prevent recurrence.”
- **Corrective action:** “action to eliminate the cause of a nonconformity (3.6.9) and to prevent recurrence; Note 1 to entry: There can be more than one cause for a nonconformity; Note 2 to entry: Corrective action is taken to prevent recurrence whereas preventive action (3.12.1) is taken to prevent occurrence; Note 3 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO

Supplement to the ISO/IEC Directives, Part 1. The original definition has been modified by adding Notes 1 and 2 to entry.”

- **Correction:** “action to eliminate a detected nonconformity; Note 1 to entry: A correction can be made in advance of, in conjunction with or after a corrective action; Note 2 to entry: A correction can be, for example, rework or regrade.”

From the GMA HACCP Manual, there are specific differences between a prerequisite program and the HACCP program (GMA 2006):

- “Prerequisite programs deal only indirectly with food safety issues, HACCP plans deals solely and directly with food safety issues.”
- “Prerequisite programs are more general and may be applicable throughout the plant, crossing multiple product lines, while HACCP plans are based on hazard analyses that are product and line-specific.”
- “Failures to meet a prerequisite program requirement seldom result in a food safety hazard or concern, while deviations from a HACCP plan critical limit typically result in action to prevent product from entering commercial distribution, at least until its safety has been evaluated.”

The application to the type of countermeasures and control systems for food fraud prevention consider “Prerequisite programs include objectives other than food safety and it may be difficult to associate performance of a prerequisite program element with specific production lots or batches. Thus, usually, it is more effective to manage prerequisite programs within a quality system rather than as part of a HACCP plan” (GMA 2006).

Finally, the GMA HACCP Manual states:

“In the US, however, both the Food and Drug Administration (FDA) and the US Department of Agriculture (USDA/FSIS) have acknowledged that HACCP should focus only on food safety hazards. Thus, quality and economic issues (not involving safety) should be excluded [from the HACCP scope].” And “Only those hazards that pose significant risk to the health of consumers are included in a HACCP plan.”

To summarize, a HACCP plan covers:

1. An identified imminent food safety hazard that if not addressed will cause harm.
2. Where countermeasures and control systems can be implemented within the facility to effectively reduce the hazard—if they cannot be controlled or prevented during these operations, then they should be addressed before the HACCP system in a prerequisite program.

Food fraud is usually not in the scope of a HACCP plan for many reasons including that the incident almost always does not have a health hazard and that the control measures are outside the facility operations. Considering that, even authenticity tests on incoming goods would be conducted by the facility laboratory which is technically a “prerequisite program” (PRP). The laboratory and incoming goods quality testing is not technically the manufacturing operation. There are so many high-priority food safety hazards that it is not efficient or wise to divert the HACCP attention to other issues such as food fraud or food defense. That said, standard

operating procedures can be added to regular facility tasks, but the focus and direction would formally be from outside the HACCP plan.

TACCP (Food Defense)

TACCP is Threat Assessment and Critical Control Plan activities (Note: TACCP uses the term assessment, and HACCP uses analysis). When the GFSI Food Fraud Think Tank was conducting research in 2012, the UK Public Available Standard 96 Food Defence (PAS 96:2010) had compliance requirements for the TACCP term, and the scope was initially been the traditional food defense (intentional acts with the goal of terror, economic, or public health harm) (PAS 96 2014). Later the PAS96 scope expanded to include some aspects of “economically motivated adulteration” (PAS 96 2017).

The general definition of food defense is the intentional acts that have the intent to harm including health hazards, economic harm, or terror. It is confusing that after the publication of the FSMA Intentional Adulteration Final Rule, the FDA essentially changed their definition of food defense only to cover “wide-scale human health harm” (FDA 2016). To note, “food terrorism” is defined by the WHO in 2002, but is a term not usually used with only four results on their website. A challenge is that, in part, there is often a particular requirement that this act is conducted by someone classified as a “terrorist” or by a recognized “terrorist organization.”

Since there are various programs that address one type of an “intentional act with the intent to harm,” it is important to reiterate the GFSI definition and scope of food defense which is all types of acts which is broader than, but inclusive of, the FSMA-IA scope of “wide-scale human health harms”:

Food Defense (GFSI): “The process to ensure the security of food and drink and their supply chains from all forms of intentional malicious attack including ideologically motivated attack leading to contamination or supply failure” (GFSI 2012, 2017).

For GFSI compliance there must be three separate assessments and also that they are combined in the overall Food Safety Management System (FSMS)—the assessments do not function as stand-alone, so there is efficient overall management. Thus the concepts of HACCP and TACCP are separate, and the Food Safety Management System is complete only when including a separate VACCP.

Sidebar: Review—Final Rule for FSMA Intentional Adulteration (Food Defense) Regarding Food Fraud and EMA (MSU-FFI 2018)

Title: Review – Final Rule for FSMA Intentional Adulteration (Food Defense) Regarding Food Fraud and EMA

By John Spink • June 22, 2016 • Blog

Continuing the review of the definition and scope of “intentional with the intent to harm” is a review of the US Food Safety Modernization Act (FSMA) Intentional Adulteration Final Rule (FSMA-IA):

This is a detailed, 22-page review of the food fraud aspects or requirements of the recently published Food Safety Modernization Act Intentional Adulteration (food defense) Final Rule (FSMA-IA). In addition to regular contributors Spink & Moyer, we are pleased to add MSU's Dr. Andrew Huff (College of Veterinary Medicine, MSU) and University of Auckland's (NZ) Bradley Evans (Business School, Department of Management). While there are no new food fraud requirements, there are tremendous insights into related FSMA compliance.

This Intentional Adulteration Final Rule is the seventh and last that will be published by the FDA.

Yesterday FDA conducted their second public meeting (May 26, 2016, and June 21, 2016) to present and clarify the FSMA-IA requirements. The Appendix of our full report includes a summary of both of those meetings.

Overall:

- For food fraud prevention compliance (required in September 2017):
 - It appears that the current broad Food Fraud Vulnerability Assessment and Food Fraud Prevention Plan activities will lead to compliance with FSMA-PC.
- For food defense compliance (required in at least 3 years in May 2019):
 - assess how (and if) the FDA requirements will change from current programs, wait for more details on what is a 'significant vulnerability' that must be mitigated, also seek clarity on what is a 'credible threat' that would trigger a re-evaluation of the food defense plan.

From our report, Final Rule for FSMA Intentional Adulteration (food defense) regarding food fraud and EMA:

- The Food Safety Modernization Act (FSMA) Intentional Adulteration Rule (FSMA-IA) draft was published in December 2013, public meetings started in February 2014, and the final rule was published May 27, 2016. The effective date is in 60 days but "[FDA] are providing for a longer timeline for facilities to come into compliance" in at least 3 years, or May 2019.
- Economically Motivated Adulteration (EMA) – and food fraud (FF) – is in the FSMA law due to the text "...intentional adulteration, including acts of terrorism." FDA announced their scope narrowed to "wide-scale [human] public health harms" and removed from this rule the concepts of EMA, disgruntled employees, tampering, etc. The FSMA compliance requirements for FF & EMA are in the Preventive Controls Rule (FSMA-PC).
- FSMA-IA also continually confirms many times that the Food, Drug & Cosmetics Act (FDCA) is still in effect, which includes all types of food fraud, even without a health hazard ("Adulterated Foods" and "Misbranded Foods").

(continued)

Even though food fraud (FF) and Economically Motivated Adulteration (EMA) is not a compliance requirement for FSMA-IA, this final rule provides essential insight into FSMA and assessments:

- Addressing all types of food fraud is a requirement – and subject to a product recall – under the Food, Drug & Cosmetics Act (FDCA).
- FDA specifically reiterated the FDCA compliance requirement in sections on “Adulterated Foods” and “Misbranded Foods.”
- FSMA-IA stated that stolen goods (various types of theft) that lead to a public health hazard are clearly defined and expected to be covered under FSMA-PC.
 - Note: FDA has stated that “theft” is an act for economic gain where quoted in FSMA-IA: “With respect to the prevalence of theft of food during transport, such theft is economically motivated; the scope of this rule is limited to acts of intentional adulteration where the intent is to cause wide-scale public health harm” (FDA [2016](#)).
- There were no more clarifications of key terms such as reasonably foreseeable hazard, significant vulnerability, a rare occurrence, credible threat, or the threshold of acceptable or unacceptable.

The compliance requirement for food fraud prevention is addressed in FSMA-PC and *not* in this FSMA-IA. Other FSMA final rules provide some insight on FDA’s thinking regarding assessments, thresholds of acceptable / unacceptable, and the compliance priorities (see appendix of the full report regarding the May 26, 2016, FDA public call).

Reviewing FSMA compliance is exhausting. There are seven long Final Rules that impact *all* aspects of a food company. There are minute details that can lead to a product recall or regulatory penalties. We have focused on the food fraud aspects – and tried to provide as brief and concise insight as possible – so hopefully this one part of FSMA you can quickly address. We have been continually adjusting our research focus to provide academic theory, in the form of scholarly publications, to support your countermeasures and control systems. Many resources are available for assisting your FSMA compliance. Find trusted resources and rely on them. MSU-FFI.

Sidebar: GFSI Compliance Requirements in Relation to US Laws and Regulations

Compliance timing for the various food fraud laws, regulations, industry standards, and certifications are complex and not necessarily aligned with each other. The following summarizes the compliance timing requirements (Table 12.1).

Table 12.1 Summary of compliance requirements regarding food fraud

Requirement	Effective date	Scope
Food, Drug, and Cosmetics Act—Section on “Adulterated Foods” and “Misbranded Foods”	1938	<p>All type of food fraud is illegal and unfit for commerce, and regardless of the investigation or enforcement priority, they are subject to a product recall. Not addressing food fraud could be literally a criminal act</p> <p><u>Requirement:</u> Assess and address “hazards that require a preventive control”—They do not specifically mention or address food fraud</p> <p><u>Consequence:</u> Illegal product could be subject to product recall and financial penalties</p>
Sarbanes-Oxley act	2002	<p>All types of business fraud that could lead to a negative economic impact on revenue or equity; the annual report states that all risks are with the risk tolerance or reported; not reporting is a federal crime</p> <p><u>Requirement:</u> Address or disclose risks to revenue</p> <p><u>Consequence:</u> Not an enforcement priority but noncompliance could be a felony crime</p>
FSMA preventive controls	September 2016	<p>All types of food fraud that lead to a “hazard that requires a preventive control” (to determine this requirement, all food fraud types must be assessed)</p> <p><u>Requirement and consequence:</u> See FDCA above</p>
GFSI version 7 (including certification programs such as FSSC, SQF, etc.)	January 2018	<p>All types of food fraud must be assessed and prevention plans implemented for health hazards</p> <p><u>Requirement:</u> Conduct and document annually a (1) food fraud vulnerability assessment and (2) food fraud prevention strategy and (3) address the GFSI scope.</p> <p>Note: FFVA—And food defense vulnerability assessment—Must be separate from the food safety assessment</p> <p><u>Consequence:</u> Noncompliance will lead to being decertified</p>
GFSI Certification Programs Organizations (CPOs)	January 2018	<p>The core requirements are from GFSI, and each CPO has some additional requirements or details</p> <p><u>Requirement and consequence:</u> See GFSI above</p>

Key Learning Objective 3: GFSI VACCP (Food Fraud) and Auditing

This section reviews the GFSI FSMA topics of food fraud addressed through VACCP defined in 2014. The 2018 GFSI food fraud requirements should have been no surprise to anyone since the specification and scope were clearly defined in 2014. That said, there were many misunderstandings or misinterpretations when practitioners were addressing the definition, scope, or exact requirements. VACCP is the Food Fraud Vulnerability Assessment and also the plan to select, implement, and manage the critical control points in the Food Fraud Prevention Strategy.

The Key Learning Objectives of this section are

- (1) The overall food fraud and VACCP concept
- (2) Review of the GFSI-endorsed Certified Program Organizations (food safety standards)
- (3) The role of accredited third-party auditors in food fraud prevention.

VACCP (Food Fraud)

VACCP is Vulnerability Assessment and Critical Control Point plan activities. (It is important to note that the term “vulnerability” is used on other contexts such as in FSMA where addressing a “food defense vulnerability” (FDA 2016)—it is a best practice to provide definitions of the terms you are addressing.) The VACCP concept includes a vulnerability assessment (the “VA” in VACCP) through to identifying system weaknesses that are critical control points (the “CCP” in VACCP) and then developing, implementing, and managing a plan or strategy.

The GFSI-FFTT focus on vulnerability was based on a realization that the underlying root cause was fundamentally different than for food safety (HACCP) or food defense (TACCP). The GFSI-FFTT recommendations were incorporated in the GSFSI position paper on food fraud which then was directly included in the GFSI Guidance Document.

From the GFSI Version 7.2 Guidance Document glossary (GFSI 2017):

- **“Food Fraud (GFSI Glossary 7.2):** A collective term encompassing the deliberate and intentional substitution, addition, tampering or misrepresentation of food, food ingredients or food packaging, labeling, product information or false or misleading statements made about a product for economic gain that could impact consumer health.”
- **“Food Fraud Vulnerability assessment (GFSI Glossary 7.2):** Susceptibility or exposure to a food fraud risk, which is regarded as a gap or deficiency that could place consumer health at risk if not addressed.”

The GFSI Food Fraud Technical Document reiterates these requirements and further explains that the scope addresses all fraud and for all products:

- “Both definitions [GFSI 2014 and GFSI 2017] cover all types of fraud and all products and highlight that the motivation behind food fraud is intentional and economically driven, i.e., potentially linked to criminal activities and at least aiming to avoid detection” (GFSI 2014a, b, 2017).

Earlier, in December 2014, the GFSI position paper gave clear direction on the expectations. The recommendation was almost exactly the same as in the February 2017 GFSI Guidance Document Version 7 requirements.

- “The below key elements were prepared by the Guidance Document Technical Working Group based on the recommendations of the Food Fraud Think Tank. The consultation will continue during the development of Version 7 of the Guidance Document.”
- “‘Food fraud vulnerability assessment’ requirements: The standard shall require that the organization have a documented food fraud vulnerability assessment in place to identify potential vulnerability and prioritize food fraud vulnerability control measures.”
- “‘Food fraud vulnerability control plan’ requirements: The standard shall require that the organization have a documented plan in place that specifies the control measures the organization has implemented to minimize the public health risks from the identified food fraud vulnerabilities.”
- “This plan shall cover the relevant GFSI scope and shall be supported by the organization’s Food Safety Management System.”

Later in the GFSI Food Fraud Technical Document, “the Organization” was defined in more detail:

- “The requirements refer to the “The Organization”: While the traditional HACCP-type food safety approach is applied at manufacturing facilities, these operate within the overall organization. The food fraud vulnerabilities are company-wide, and thus the food fraud scope is company-wide” (GFSI 2018a, b).
- “This implies that any plans and activities to mitigate, prevent or even understand the risks associated with food fraud should consider an entire company’s activities, including some that may not be within the traditional food safety or even HACCP scope, applying methods closer to criminal investigation” (GFSI 2018a, b).

The “relevant GFSI scope” was defined in the position paper and then in the Guidance Document (GFSI 2017).

The definition from the GFSI position paper is (GFSI 2014a, b):

- “Food fraud, including the subcategory of economically motivated adulteration, is of growing concern. It is deception of consumers using food products, ingredients and packaging for economic gain and includes substitution, unapproved

enhancements, misbranding, counterfeiting, stolen goods or others" (GFSI 2014a, b).

GFSI presents two crucial points which are:

- Economically motivated adulteration is *not* the same as food fraud.
- The scope of food fraud includes *all* types of fraud (from adulterant-substances to stolen goods and counterfeits) and for *all* products (raw ingredients through finished packaged goods in the marketplace).

The GFSI requirements did come with some guidance or insight on how to meet compliance (GFSI 2014a, b):

- "The GFSI Board will support SSAFE's initiative which aims to develop and publish practical guidelines for companies on 'how' to assess and control food fraud vulnerabilities within their organizations and supply chains."

Sidebar: GFSI Food Fraud Technical Document, May 2018 (MSU-FFI 2018)

Title: Review of GFSI Food Fraud Technical Document

By John Spink, • May 17, 2018 • Blog

Last week on May 9, 2018, the Global Food Safety Initiative (GFSI) published a Food Fraud Technical Document titled "Tackling Food Fraud Through Food Safety Management Systems," which outlines the new compliance requirements (GFSI 2018a, b). Some requirements may be surprising or lead to audit non-conformances, but the basic principles are not new. In addition to this new document, there are many training and education resources, including a few listed below. This new document is a key resource for confirming the definition, scope, starting point, and the expectation for these first compliance requirements.

Excerpt from the MSU FFI Report:

Title: Review of GFSI Food Fraud Technical Document: Tackling Food Fraud through Food Safety Management Systems, MSU Food Fraud Initiative Report FFIR, May 16, 2018.

Summary

The Global Food Safety Initiative (GFSI) published the GFSI Food Fraud Technical Document titled "Tackling Food Fraud through Food Safety Management Systems" (GFSI 2018a, b). This publication supports the previous reports on the GFSI food fraud position paper (2014) and GFSI Benchmarking Document (2017) (Fig. 12.4) (GFSI 2012, 2017). This new document reinforces the previous GFSI statements and supports the efforts to "just get started." This new document is a key for confirming the definition, scope, starting point, and the expectation for the first compliance requirements. While HACCP is 20+ years in development, the GFSI food fraud requirements have only been in effect for 20 weeks. The new food fraud



Fig. 12.4 GFSI series of documents that address Food Fraud: Position Paper 2014, Benchmarking Document 2017, and Technical Report 2018 (Copyright Permission Granted) (MSU-FFI 2018)

requirements help move the risk assessors from “point A” to just “point B” and not all the way to a full HACCP-type plan which would be “point Z.” While “Point Z” is the ultimate goal, we must get to “Point B” before moving to “Point C,” “Point D” and on. This new technical document reviews the previous statements and clarifies the near path forward.

Conclusion

The critical conclusion points from the GFSI Food Fraud Technical Document include:

- Holistic scope – all fraud and all products: The scope is all types of fraud (from adulterant-substances to counterfeits and stolen goods) and all products (from incoming goods through to product in the marketplace including counterfeits.) All types of fraud and all products can cause health hazards and lead to economic harm.
- Just get started: There is continued emphasis on starting the process that will be supported by continuous improvement and sharing of best practices.
- Auditors are to confirm the process, not judge the plans: To begin the compliance, the scope is to confirm the process is started.

GFSI emphasized several key points, and our FFI Insight is included here (selected sections):

- ‘(2) “While a Food Fraud Manager is “accountable” for the full compliance, they may not be “responsible” for each of the individual tasks. For example, managing and monitoring stolen goods may already be conducted by a supply chain logistics or corporate security staff.”

(continued)

- FFI Insight: The GFSI document provides more detailed insight into compliance by explaining some details of the implementation. A concern by industry has been that a new food fraud task force would require many new staff members. This GFSI statement emphasizes that all the topics must be covered, but they could possibly be implemented by other current staff.
 - FFI Insight: It is significant that GFSI uses a non-traditional food safety example such as stolen goods that are not usually under the accountability of a food quality assurance team.
- ‘(3) “The requirements refer to “The Organization:” While the traditional HACCP-type food safety approach is applied at manufacturing facilities, these operate within the overall organization. The food fraud vulnerabilities are company-wide, and thus the food fraud scope is company-wide.”
 - FFI Insight: GFSI is clear that the food fraud vulnerability assessment and prevention strategy is intended to cover the entire organization, not just the facility that may be the location of an audit. A traditional food safety audit focuses on HACCP so would focus on the operations of a facility or manufacturing location. For food fraud, the overall vulnerability and control plans may be completely and competently addressed at the enterprise-wide level. Thus, a manufacturing site audit could rely on a company-wide assessment. Unless there is a unique operational activity, each manufacturing facility would usually not be required to conduct a separate review.
- ‘(8) “(B) Understand the difference between hazard (a potential source of harm), risk (the probability of loss or injury from a hazard) and vulnerability (susceptibility to a risk): many hazards will have a low or very low likelihood and therefore not represent a risk; likewise, the susceptibility of a company or system to a risk is not only linked to the severity of this risk but more to the company’s awareness of their weakness and how they manage it.” ... While an “all hazards” assessment approach is important, all vulnerabilities are not risks, all risks are *not* hazards, and all hazards are *not* hazards that require a preventive control. The final mitigation plan must focus on those vulnerabilities that require a preventive control as identified through a carefully and documented analysis of the risks, likelihood and fraud opportunities.”
 - FFI Insight: GFSI calms an industry concern that each and every identified vulnerability would require a control plan. Thus, this all-hazards approach allows for a broad lens to monitor the possible root cause while including a clear method to narrow the focus to only the worst problems. The GFSI requirements are for “a” method to conduct this assessment with no prescribed or required approaches.

- ‘(12) “With this in mind, there is an awareness that addressing food fraud is new and different for those being audited as well as for the auditors: “The auditor is not expected to detect fraud or affirm that an anti-fraud program is capable of “preventing fraud.” This approach is very much in line with the verification of a HACCP plan during the food safety audit.”
- FFI Insight: GFSI includes a practical and pragmatic approach that emphasizes the auditors be “not expected to detect fraud or affirm the anti-fraud program.” The audit is intended to confirm that a food fraud vulnerability assessment is in place and that there is a food fraud prevention strategy, and that it covers the relevant GFSI scope. Industry-wide compliance with these first efforts will be a key advancement from “point A” to “point B.” As time goes on, there will be more advanced programs that will provide insight into more advanced audit requirements.
- FFI Insight: To reinforce this point, the key and optimal first role of the auditor – especially now only 20 weeks into the food fraud requirements – not 20 months or 20 years – is to confirm the requirements are being addressed, documented, and cover the relevant GFSI scope.

The new GFSI Food Fraud Technical Document reinforces the previous statements and supports the efforts to “just get started.” Next will be “how to start,” then “how much is enough.” The new GFSI Food Fraud Technical Document is very important since we now have a firm and clear starting point to address food fraud prevention. Use this as a spark for you to start or refine your food fraud prevention strategies. See the link to the GFSI document, our review, or the resources below. MSU-FFI.

Also, the GFSI Food Fraud Technical Document included:

- References
 - GFSI Position Paper (2014).
 - GFSI Benchmarking Document, V7.0 (2017).
 - GFSI Benchmarking Documents, V7.2 (2018).
 - GFSI, Global Food Safety Initiative (2014b). Food Fraud – Threats & Impact – an Industry Perspective, Presented by Neil Marshall for GFSI, EU Food Integrity Project -Food Authenticity Technology Conference, UK Department for Environment, Food and Rural Development (DEFRA), York, England.
- Other Resources
 - Food Fraud Overview and History [includes the history of the GFSI Food Fraud Think Tank, Position Paper, and inclusion in the GFSI Benchmarking Document], Presented by John Spink, Food Fraud Session, GFSI Annual Conference, Tokyo, 2018,

(continued)

- URL (5-minutes): <https://youtu.be/mg67m5c3ITE>
- Food Fraud Update and Terminology Survey, Presented by John Spink, GMA Science Forum 2018,
- URL (21-minutes): <https://youtu.be/lZNwiEz6fM>

Comparison of GFSI Standards Related to Food Fraud

A comparison of GFSI standards presented the similarities in the standards and confirmed that all GFSI standards DO require addressing food fraud, and there are seven basic common requirements that will be presented below.

“Food fraud regulations and requirements are relatively new to food manufacturers and often are not consistent and clear. This was created to provide clarity around Certified Program Organizations’ expectations and to provide recommendations on harmonization of these standards. This report will be useful to food manufacturers seeking to create one food fraud plan that can satisfy multiple CPO’s requirements.”

The GFSI Guidance Document (the overall expectations but not actually written standards) that first included food fraud requirements was published on February 26, 2017. The Certification Program Organizations (the actual written standards) are updated on a rolling schedule every few years that includes new GFSI requirements. GFSI does state when the new requirements are expected to be adopted which was 1 year after publishing so January 1, 2018 (Table 12.2).

Each of the standards includes separate documentation that is varied in the definition and scope of food fraud. Each standard broadly covered food fraud under general quality and label claim controls. To maintain their “GFSI Endorsement” over time, each standard has expanded or formalized how they address food fraud prevention (Table 12.3). The Certification Program Organizations is required to:

Summary of Food Fraud CPO Requirement to Attain and Maintain GFSI Endorsement

- (1) Address the full GFSI food fraud requirements for audits starting in January 2017.
- (2) Auditors have been trained on food fraud.
- (3) Also have had an assessment on the concept.

To review the GFSI requirements of the CPO to the CBs (emphasis added):

- **Competence** is “The demonstrated ability to apply knowledge and skills to achieve intended results.”

Table 12.2 From the source, documents noting the organization, document title, and document publication date (Dickenson et al. 2019)

Organization	Document type	Document title (fees are noted)	Document publication date
GFSI	Benchmarking	GFSI Guidance Document v7.0 and 7.1 (GFSI 2017)	February 2017 (updated April 2017 and December 2017)
BCR	Standard	BCR Global Standard Food Safety Issue 8 (Sect. 5.4 Product authenticity, claims, and chain of custody) + (BCR 2018)	August 2018
BCR	Guidance	BCR Global Standard for Food Safety Issue 7 Understanding Vulnerability Assessment (BCR 2015)	January 2015
IFS	Standard	IFS Food: Standard for auditing quality and food safety of food products V6.1 (4.21 Food Fraud) (IFS 2017)	November 2017
IFS	Guidance	IFS Product Fraud Guideline (IFS 2018)	May 2018
SQF	Standard	SQF Code, eighth edition (Part B, section 2.7) (Institute 2017)	October 2016
SQF	Guidance	Food Fraud Guidance for Sites and Auditors (SQF Institute 2018)	August 2018
FSSC 22000	Standard	V 4.1 July 2017 (FSSC 2016)	July 2017
FSSC 22000	Guidance	Guidance on Food Fraud Mitigation (FSSC 2018)	April 2018

- “The GFSI Auditor Exam: “Version 7.2 introduces the requirements for any auditors of GFSI-recognised certification programmes to have passed an exam based on the content of the GFSI Benchmarking Requirements” (GFSI 2018a, b).

Also, it is important to note that GFSI also requires training and demonstration of competence by the brand owners and manufacturers:

“GMP D 16, EL 17 Training: The standard shall require that a system be in place to ensure that all employees are adequately trained, instructed and supervised in food safety principles and practices, commensurate with their activity.”

The CPO standards are based on or seeking to maintain GFSI endorsement, so they are consistent in their core starting point in addressing food fraud. Each standard has additional requirements that are unique which build upon the base Guidance Document content.

An underlying principle of the GFSI Food Safety Management System is to create a single, common, standardized scope that can meet a wide range of compliance requirements. The harmonized system will lead to efficiency using one system but also benefits from the sharing of best practices and benchmarking.

Table 12.3 Summary of the source documents for definitions of food fraud and noted as from a glossary or from in-text (Dickenson et al. 2019)

Group	Document type	Definitions—food fraud [1]	Definitions—Food Fraud Vulnerability Assessment [1]
GFSI	Benchmark	A collective term encompassing the deliberate and intentional substitution, addition, tampering, or misrepresentation of food, food ingredients, or food packaging, labeling, product information, or false or misleading statements made about a product for economic gain that could impact consumer health	Susceptibility or exposure to a food fraud risk, which is regarded as a gap or deficiency that could place consumer health at risk if not addressed
BRCA	Standard	[Note 2]: Fraudulent and intentional substitution, dilution or addition to a product or raw material, or misrepresentation of the product or material, for the purpose of financial gain, by increasing the apparent value of the product or reducing the cost of its production	Vulnerability assessment (implied FFVA): A risk assessment designed to examine processes and supply chains for potential food fraud
BRCA	Guidance	Same as standard	(In the text, no glossary): A vulnerability assessment is a search for potential weaknesses in the supply chain in order to prevent food fraud (i.e., to prevent the adulteration or substitution of raw materials before they arrive at the site). It is, therefore, a specialized form of risk assessment. It is important to note that the aim of the assessment is not to assess the potential for fraud at the site, but to examine the supply chain for potential concerns or weaknesses and therefore to identify those raw materials that are of particular risk of adulteration or substitution, so that appropriate controls can be put in place

(continued)

Table 12.3 (continued)

Group	Document type	Definitions—food fraud [1]	Definitions—Food Fraud Vulnerability Assessment [1]
IFS	Standard	[Note 2]: The deliberate and intentional substitution, mislabeling, adulteration, or counterfeiting of food, raw materials, ingredients, or packaging placed upon the market for economic gain. This definition also applies to outsourced processes	A systematic documented form of risk assessment to identify the risk of possible food fraud activity within the supply chain (including all raw materials, ingredients, food, packaging, and outsourced processes). The method of risk assessment may vary from company to company; however, the systematic methodology for food fraud vulnerability assessment shall include as a minimum (details)
IFS	Guidance	Technically no definition [2]. The document does provide a definition of <i>product fraud</i> : The deliberate and intentional substitution, mislabeling, adulteration, or counterfeiting of food, raw materials, ingredients, or packaging placed upon the market for economic gain. This definition also applies to outsourced processes. (note: The only product fraud scope only covers foods)	Technically no definition. The Food Fraud Guidance Document does provide a definition of Product Fraud Vulnerability Assessment which differs slightly from the FFVA definition in the IFS standard: A systematic documented form of risk assessment to identify the risk of possible product fraud activity within the supply chain (including all raw materials, ingredients, food, and packaging) until delivery to the customer. The method of risk assessment may vary from company to company; however, the systematic methodology for product fraud vulnerability assessment shall include as a minimum (details)
SQF	Standard	As defined by Michigan State University, a collective term used to encompass 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	No definition

(continued)

Table 12.3 (continued)

Group	Document type	Definitions—food fraud [1]	Definitions—Food Fraud Vulnerability Assessment [1]
SQF	Guidance	(in the text, no glossary): Food fraud is often described as EMA, economically motivated adulteration. However, it is more than that. As well as adulteration, food fraud includes substitution, dilution, addition, misrepresentation, or tampering of food ingredients or food products. It is, in fact, illegal deception for economic gain	(In the text, no glossary): The food fraud strategy is similar to the HACCP methodology that the manufacturing sites are familiar with. In general terms, it is (1) identify the risks (vulnerabilities), (2) determine corrective and preventative actions (mitigation strategies), (3) review and verify, and (4) maintain records. The food fraud requirements talk about “vulnerabilities” rather than “risk.” A risk (ISO 31000 Risk Management) is something that has occurred frequently before and will occur again, and there is enough data to conduct a statistical assessment. The vulnerability is more a condition that could lead to an incident (Dr. John Spink, MSU). GFSI considers an “incident” to be a “consumer health risk if not addressed”
FSCC 22,000	Standard	Collective term encompassing the intentional substitution, addition, tampering, or misrepresentation of food/feed, food/feed ingredients, or food/feed packaging, labeling, product information, or false or misleading statements made about a product for economic gain that could impact consumer health (with a reference noted to GFSI BRv7:2017)	Technically no definition but a glossary entry for vulnerability: Susceptibility or exposure to all types of food fraud, which is regarded as a gap or deficiency that could impact consumer health if not addressed (GFSI BRv7:2017)
FSSC 22,000	Guidance	The definition that FSSC uses is based on the GFSI position paper issued in 2014 (same as in the standard). Includes appendix 1. Types of food fraud—Definition and examples	No specific definition but additional details such as the following: When conducting the FFVA, it is allowed to group materials to start with (e.g., similar raw materials or similar finished products). When significant risks are identified within a group, a more in-depth analysis may be required

[Note 1] note: In a glossary unless noted otherwise

[Note 2] note: This includes a deviation from the GFSI definition of food fraud

GFSI Food Fraud Auditor Expectations: Not to Be a Counter-Fraud Expert

The GFSI Food Fraud Think Tank—and later GFSI in the 2014 GFSI Food Fraud Position Paper and the 2018 GFSI Food Fraud Technical Document—recognized the challenges addressing a fundamentally different issue including expertise in criminology (GFSI FFTT 2013; GFSI 2014a, b). There was an awareness of the challenges for food safety or food quality teams being assigned the responsibility for assessing and managing food fraud prevention. Also, a critical component of the GFSI system is auditors that can assess compliance with the requirements. These were considered in the recommendations and later in the implementation including training materials.

The expectation was that the initial audits would confirm that the requirements are addressed including the full scope of the types of fraud.

- “During a food safety certification audit, conducted against GFSI recognized schemes, the auditor will review the documentation related to the vulnerability assessment process and confirm that a comprehensive control plan, as outlined in the Appendix [of the GFSI position paper], has been developed and implemented by the company (GFSI 2014a, b).”

Also, the position paper stated that “The auditor is not expected to detect fraud or affirm that an anti-fraud program is capable of ‘preventing fraud’ (GFSI 2014a, b).” From the GFSI Food Fraud Technical Document (GFSI 2018a, b):

- ““During a food safety certification audit, conducted against GFSI recognised schemes, the auditor will review the documentation related to the vulnerability assessment process and confirm that a comprehensive control plan, as outlined in the [position paper] Appendix, has been developed and implemented by the company.””
- ““With this in mind, there is awareness that addressing food fraud is new and different for those being audited as well as the auditors:””
- ““The auditor is not expected to detect fraud or affirm that an anti-fraud program is capable of “preventing fraud.” This approach is very much in line with the verification of a HACCP plan during the food safety audit.””
- ““GFSI is aware that the harmonization and best practices are just now being developed and refined. A new system that is less than a year old in implementation cannot be expected to be as robust, thorough, or detailed as a system such as HACCP that has been implemented for more than 25 years. The most important step for the food industry is to start addressing food fraud, and for auditors to start asking the basic questions on how vulnerabilities were assessed and identified, and a strong mitigation plan thought through.””

The critical first step for an auditor is to confirm that an assessment and plan are in place. Over time the specific audit requirement will evolve as there is more clear insight on best practices and benchmarking.

Sidebar: The Optimal Role of GFSI Requirements and Auditors— “Push from Point A to Point B”

The accredited third-party auditors from the certification bodies (CBs) have a critical albeit seemingly very simplistic role in food fraud prevention. Their optimal role is to just help make sure the process starts. GFSI has been very clear—originally in their 2014 position paper and then in their 2018 Food Fraud Technical Document—that the first goal is to just get the process started of holistically addressing food fraud. GFSI clearly stated, repeatedly, that the first and most important role of the auditor is to just make sure a plan is in place, it covers the “relevant GFSI scope” (all fraud and for all products), and then it is implemented and followed. There is a saying: **“We’re trying to get from point A to point B and not all the way to point Z... at least not yet.”**

Thus, the most important role of the auditor is (1) confirm that the full scope of food fraud will be addressed in an audit, (2) audit against those requirements, and (3) clearly state exactly where a Food Fraud Prevention Strategy may fall short.

The audit is optimal even if the auditor only asks “yes or no” questions to each of the CPO food safety standard requirements. There is often a criticism that some audits are just a checkbox—did it, check. While this is true, the implication for the company being audited goes beyond just stating “yes or no.” Usually, the company preparing for an audit will create documents and notes that are approved up through the corporation and possibly to the Chief Compliance Officer and General Counsel. This is a new, formal, audited document, and usually, internal controls and integrated framework policy requires an executive to approve.

Thus, the auditor just asking simple “yes or no” questions is a critical spark to move the entire series of cogs in the machine forward (Fig. 12.5).

Fig. 12.5 Food fraud audit hierarchy of chain of events



Conclusion

The previous chapter presented standards and certification which helped frame these GFSI Food Safety Management System standards and related topics. ***The first conclusion is*** that the already implemented and widely adopted GFSI system is an adaptation and implementation of a wide range of best practices that have been adapted to meet global food safety requirements. These efforts are coordinated across the food industry and with close connection and calibration with governments, nongovernmental organizations, suppliers, researchers, and academics. ***The second conclusion is*** that there is often a lack of awareness of the breadth and depth of the GFSI system and the global GFSI adoption impact. The implementation of a Food Safety Management System is essentially a requirement to do business, and the benefits are for the very large multinational corporations to micro-sized businesses. ***The final conclusion is*** that while the food fraud requirements may seem very light and an afterthought for a holistic food safety program, these are requirements and *not optional*. The GFSI requirements are moving the entire industry to understand and value that addressing food fraud is *not optional* and *is a key component* of a robust and thorough Food Safety Management System.

There is a saying:

We're trying to get from point A to point B and not all the way to point Z... at least not yet. (Point A is the current state, and Point B is everyone at least implementing a common and basic holistic and all-encompassing VACCP - Food Fraud Vulnerability Assessment and a Food Fraud Prevention Strategy. Point Z is an ultimate future state.)

Appendix: Side by Side FF GFSI Standards Requirements

This appendix provides a review of the food fraud sections of key Food Fraud Management System standards including FSSC 22000, SQF, BRC, and IFS:

FSSC 22000: Food Safety System Certification for ISO 22000

From the FSSC 22000 standard:

“Part II – Requirements for certification v4.1

2.1.4.4 Food Fraud prevention

2.1.4.4.1 Vulnerability assessment

1) The organization shall have a documented and implemented vulnerability assessment procedure in place that:

a) Identifies potential vulnerabilities,

b) Develops control measures, and c) prioritizes them against the identified vulnerabilities.

2) To identify the vulnerabilities, the organization shall assess the susceptibility of its products to potential food fraud acts.

2.1.4.4.2 Control measures: The organization shall put in place appropriate control measures to reduce or eliminate the identified vulnerabilities.”

2.1.4.4.3 Plan

- 1) All policies, procedures, and records are included in a food fraud prevention plan supported by the organization's Food Safety Management System for all its products.
- 2) The plan shall comply with applicable legislation.

SQF: Safe Quality Food (SQF) Institute

From the SQF standard:

“2.7.2 Food Fraud: What the SQF Code says

2.7.2.1 The methods, responsibility, and criteria for identifying the site's vulnerability to food fraud shall be documented, implemented and maintained. The food fraud vulnerability assessment shall include the site's susceptibility to product substitution, mislabeling, dilution, counterfeiting or stolen goods which may adversely impact food safety.

2.7.2.2 A food fraud mitigation plan shall be developed and implemented which specifies the methods by which the identified food fraud vulnerabilities shall be controlled.

2.7.2.3 The food fraud vulnerability assessment and mitigation plan shall be reviewed and verified at least annually.

2.7.2.4 Records of reviews of the food fraud vulnerability assessment and mitigation plan shall be maintained.”

Also,

“2.4.4 Approved Supplier Program (Mandatory)

2.4.4.1 Raw materials and services that impact finished product safety shall meet the agreed specification (2.3.2) and be supplied by an approved supplier.

2.4.4.2 The receipt of raw materials received from non-approved suppliers shall be acceptable only in an emergency situation and provided they are inspected or analyzed before use.

2.4.4.3 The responsibility and procedure for selecting, evaluating, approving and monitoring an approved supplier shall be documented and implemented.

2.4.4.4 The site's food defense plan (refer to 2.7.1.1) shall include measures to secure incoming materials and protect them from deliberate act of sabotage or terrorist-like incidents.

2.4.4.5 The site's food fraud vulnerability assessment (refer to 2.7.2.1) shall include the site's susceptibility to raw material substitution, mislabeling, and counterfeiting which may adversely impact food packaging safety.

2.4.4.6 The food fraud mitigation plan (refer to 2.7.2.2) shall include methods by which the identified food packaging safety vulnerabilities from materials shall be controlled.”

And later,

“2.7.2 Food Fraud

2.7.2.1 The methods, responsibility, and criteria for identifying the site's vulnerability to food fraud shall be documented, implemented and maintained. The food fraud vulnerability assessment shall include the site's susceptibility to product substitution, mislabeling and counterfeiting which may adversely impact the food safety of packaging product.

2.7.2.2 A food fraud mitigation plan shall be developed and implemented which specifies the methods by which the identified food fraud vulnerabilities shall be controlled.

2.7.2.3 The food fraud vulnerability assessment and mitigation plan shall be reviewed and verified at least annually.

2.7.2.4 Records of reviews of the food fraud vulnerability assessment and mitigation plan shall be maintained.”

BRCA: BRC Global Standards

From the BRC standard:

Overall summary of key points:

1.1.6 The company must have a system for identifying new risks to the authenticity of raw materials.

3.5.1.1 The risk assessment of each raw material or group of raw materials must consider the potential for substitution or fraud.

5.4 The company must have systems in place to minimize the risk of purchasing fraudulent or adulterated food raw materials.

5.4.1 The company must have access to information on historical and developing threats relating to the risk of adulteration or substitution of raw materials.

5.4.2 The company must have a documented vulnerability assessment of all food raw materials

5.4.3 Where a raw material is at risk of adulteration or substitution, appropriate assurance systems and/or testing must be in place to reduce the risk.

The later from several other sections:

3.4 Internal Audits

“3.4.1 There shall be a scheduled programme of internal audits.

At a minimum, the programme shall include at least four different audit dates spread throughout the year. The frequency at which each activity is audited shall be established in relation to the risk associated with the activity and previous audit performance. All activities shall be covered at least once each year. At a minimum, the scope of the internal audit programme shall include the:

- HACCP or food safety plan, including the activities to implement
- Prerequisite programmes
- Food defense and food fraud prevention plans
- Procedures to achieve the standard”

3.5 Supplier and Raw Material Approval and Performance Monitoring

“3.5.1.1 The company shall undertake a documented risk assessment of each raw material or group of raw materials including primary packaging to identify potential risks to product safety, legality and quality. This shall take into account the potential for:

- Allergen contamination
- Foreign-body risks
- Microbiological contamination
- Chemical contamination
- Variety or species cross-contamination
- Substitution or fraud (see clause 5.4.2)
- Any risks associated with raw materials which are subject to legislative control”

5.4 Product Authenticity, Claims, and Chain of Custody

“5.4.1 The company shall have processes in place to access information on historical and developing threats to the supply chain which may present a risk of adulteration or substitution of raw materials (i.e., fraudulent raw materials). Such information may come from, for example: trade associations, government sources, private resource centers.”

“5.4.2 A documented vulnerability assessment shall be carried out on all food raw materials or groups of raw materials to assess the potential risk of adulteration or substitution. This shall take into account:

- Historical evidence of substitution or adulteration.
- Economic factors which may make adulteration or substitution more attractive.

- Ease of access to raw materials through the supply chain.
- Sophistication of routine testing to identify adulterant.
- The nature of the raw material.”

“5.4.3 Where the raw materials are identified as being at particular risk of adulteration or substitution, the vulnerability assessment plan shall include appropriate assurance and/or testing processes to mitigate the identified risks.”

“5.4.4 Where products are labeled, or claims are made on finished packs which are dependent on the status of a raw material, the status of each batch of the raw material shall be verified. These claims include:

- Specific provenance or origin.
- Breed/ varietal claims.
- Assured status (e.g., GlobalG.A.P.)
- Genetically modified organism (GMO) status.
- Identity preserved.
- Named specific trademarked ingredients.

The facility shall maintain purchasing records, traceability of raw material usage and final product packing records to substantiate claims. The site shall undertake documented mass balance tests at a frequency to meet the particular scheme requirements or at least every 6 months in the absence of a scheme-specific requirement.”

“5.4.5 Where claims are made about the methods of production (e.g., organic, halal, kosher) the site shall maintain the necessary certification status in order to make such a claim.”

“5.4.6 The process flow for the production of products where claims are made shall be documented and potential areas for contamination or loss of identity identified. Appropriate controls shall be established to ensure the integrity of the product claims.”

IFS: International Featured Standards

From the IFS standard:

“4.21 Food Fraud

4.21.1 A documented food fraud vulnerability assessment shall be undertaken on all raw materials, ingredients, packaging and outsourced processes, to determine the risk of fraudulent activity in relation to substitution, mislabelling, adulteration or counterfeiting. The criteria considered within the vulnerability assessment shall be defined.

4.21.2 A documented food fraud mitigation plan shall be developed, with reference to the vulnerability assessment, and implemented to control any identified risk. The methods of control and monitoring shall be defined and implemented.

4.21.3 In the event of increased risk, food fraud vulnerability assessment shall be reviewed.

Otherwise, all vulnerability assessments shall be reviewed at least annually.

Control and monitoring requirements of the food fraud mitigation plan shall be reviewed and amended when applicable.”

Then in “ANNEX 2: Compulsory fields to be completed by the auditor”

“Food Fraud- for Section 4.21.1 – The auditor shall provide the following information: – Has the company identified fraud-susceptible raw material groups / product groups in the vulnerability assessment? – If yes, which main fraud-susceptible raw material groups / product groups have been identified and for what reason?”

Appendix: WIIFM Chapter on Standards and Certification with GFSI

This “What’s In It For Me” (WIIFM) section explains why this chapter is important to you.

Business functional group	Application of this chapter
WIIFM all	The GFSI requirements are holistic and all-encompassing – be sure to review the entire set of requirements
Quality team	The GFSI requirements for a food safety management system <i>require</i> addressing <i>all</i> types of fraud and for all products
Auditors	You, as the auditor, are required – <i>not optional</i> – to fully address the GFSI food fraud compliance requirements, and to conduct a competent audit, you <i>must</i> ask the full set of questions that address all types of fraud, for all products, and across the entire organization
Management	Closely review the GFSI FF requirements, and you can thoroughly conduct a gap analysis with the seven simple “yes or no” questions presented in the back matter chapter
Corp. decision-makers	Provide information to internal auditors to reinforce <i>fully</i> addressing this enterprise-wide risk that you are accountable for whether you know it or not – this is <i>not</i> a new risk; it is an inherent risk

Appendix: Study Questions

This section includes study questions based on the key learning objectives in this chapter:

1. Discussion Question.

- (a) Who created GFSI and why is GFSI such an impactful food sector partner?
- (b) How is GFSI related to Food Safety Management standards such as BRC, IFS, SQF, and FSSC?
- (c) How does a Food Safety Management System integrate HACCP, VACCP, and TACCP?

2. Key Learning Objective 1.

- (a) What is a “Food Safety Management System”?
- (b) Why does GFSI consider food *fraud* to be critical in a Food *Safety* Management System?
- (c) Why is GFSI not that well known?

3. Key Learning Objective 2.

- (a) What is TACCP?
- (b) What is the full scope of TACCP beyond just an assessment?
- (c) How does TACCP differ from the US FDA/FSMA Intentional Adulteration Scope?

4. Key Learning Objective 3.

- (a) What is VACCP?
- (b) What is the CCP in VACCP?
- (c) How does the “risk tolerance” compare for HACCP, VACCP, and TACCP?

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Chapter 13

International Public and Private Response



Summary

This chapter addresses the international responses of both the public (governments and nongovernmental organizations) and private (industry or trade associations) activities related to understanding and managing food fraud prevention. To review this scope, there is a very brief overview of incidents to understand the severity of the issue; this is followed by a summary of foundational and more applied activities and then some of the collaboration interactions. The focus includes the UK, EU, China, and the international entities such as WHO, FAO, INFOSAN, Codex Alimentarius, ISO, INTERPOL-Europol, GFSI, and others.

The Key Learning Objectives of this chapter are:

- (1) **Review of International Incidents:** a review of key incidents and details that created the motivation for the activity
- (2) **Severity and Frequency Leading to Responses:** a review of more of the actions such as country-level reports or impact statements
- (3) **Intragovernmental Collaboration:** a review of efforts for harmonization of terms, scope, focus on prevention, or standards

On the Food Fraud Prevention Cycle (FFPC), this chapter addresses the theoretical foundation related to the overall application and implementation noted in “(Z) Application and Implementation: The Guardians” (Fig. 13.1).

Introduction

This chapter will cover the global public and private responses to the food fraud problem. This chapter will start with a review of issues by region of the world and then examine those government or agency priority setting (Table 13.1). These new incidents did not always lead to new laws, new regulations, or the allocation to enforce and prosecute.

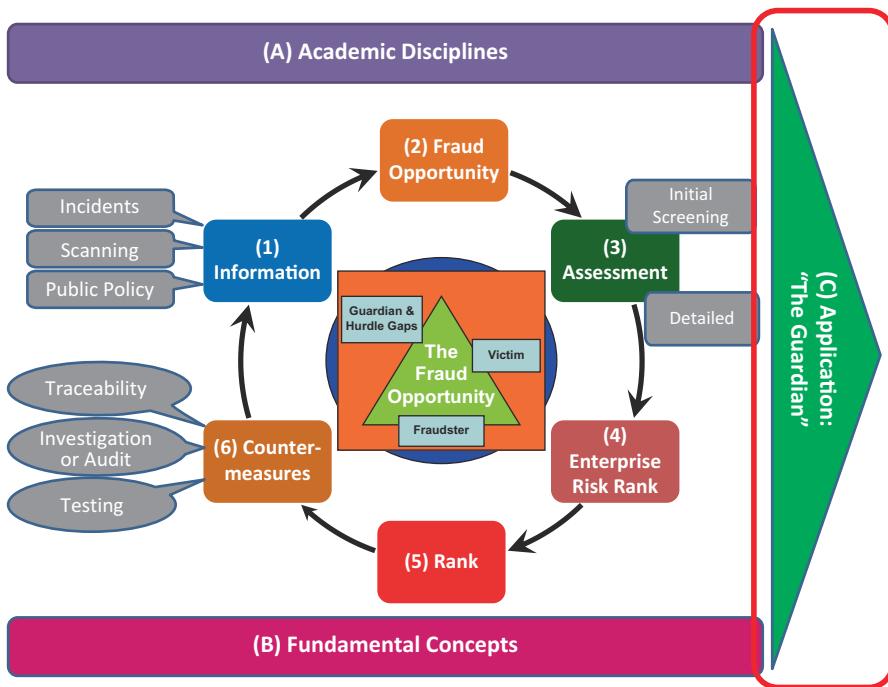


Fig. 13.1 Food Fraud Prevention Cycle: where this chapter applies to the overall concept—“(C) Application, ‘The Guardian’ ”. (Copyright Permission Granted) (Spink 2014; Spink et al. 2019)

For example, in the USA the FDA takes a public health risk-based approach, so their priority of response is set by incidents that involve deaths or illnesses. The melamine pet food fraud was one of the most impactful incidents in the USA. The range of other food fraud incidents seems to pale in comparison because—although there was an economic impact and a substantial vulnerability—food fraud incidents usually have very few public health threats. For another US example, the US Customs has focused on the tax avoidance smuggling of honey food fraud referred to as “honey laundering,” and the US FBI focuses on larger-scale crime (DOJ 2009; FBI 2018).

In the European Union, there is a focus on “food authenticity” or “food integrity” which is a broader impact than just public health to focus expanding to declarations about the product (previously presented in Figures 1–5). For example, the EU focus includes “protected designated origin” (PDO) such as Parmesan Cheese to be confirmed from the Parma region in Italy. To note, in the USA, the USDA specification for Parmesan Cheese is a “process method” not the “geographic origin.” In the USA a legal label is “Parmesan Cheese ‘Made in the USA’ with Wisconsin milk.” That label would be illegal in the EU.

Another example of an additional, nonpublic health threat impact of food fraud incidents is the UK countrywide horsemeat in the beef incident. The only product

Table 13.1 Incidents that led to activity or key events that significantly raised the awareness and actions by countries or NGOs. (With adapted from Ref. (DEFRA 2014))

Country/ region	Trigger incident	Years	Notes
China	Melamine infant formula	2007	“Nontraditional food safety incidents” now in the national “5-year plan” created Center for Food Safety Risk Assessment—CFSR, etc.
Codex Alimentarius	Grew from a country Focus to global	2017	Created Electronic Working Group (EWG) in 2017 to review definitions and gaps in Codex code and recommend the path forward generally focusing on prevention
Denmark	Fraudulent meat scandal in 2005–2006	2006	The Flying Squad has a team that bases activity on investigations and tips as well as intelligence-led operations. High visibility results of sensitive consumer products have reinforced the authority and support of the activities
EU	Ongoing protected designated origin but sparked by the horsemeat incident	2012	Allocated funding to the Food Integrity Project approved a resolution on food fraud and others
GFSI	Melamine and then horsemeat and ongoing incidents	2007, 2012, 2017+	Created GFSI Food Fraud Think Tank in 2012 to review; published food fraud position paper in 2014; and a commercial standard requirement in 2018
ISO	Anti-counterfeiting coordination for material goods expanding to food; food safety expanding to all root causes including fraud	2009; 2017	ISO TC 247 Product Fraud Countermeasures and Controls was formed in 2009 and then moved under TC 292 Security Management in 2016. In 2018, TC 34 Food products expanded ISO 22000 Food Safety Management added a statement that expanded the application “to include food fraud and food defense” ISO/TC34/SC17/WG8—Management Systems for food safety expanded to confirm all root causes were covered including food fraud and food defense
Netherlands	Ongoing focus on dairy then the 2017 Fipronil in eggs	2007, 2012, 2017+	Active in the EU Food Integrity Project (FIP), creation and expansion of the Food Crime Unit, etc.
UK	Ongoing but then horsemeat	2012	Active in the FIP; DEFRA funded “The Elliott Review” for food fraud; created the National Food Crime Unit

(continued)

Table 13.1 (continued)

Country/ region	Trigger incident	Years	Notes
USA	Melamine and other meds	2007	Public meeting on Economically Motivated Adulteration in 2009, created Work Group on Economically Motivated Adulteration (WEMA), not mentioned in FSMA, covered under general food safety “preventive controls.” (See other sections on priority setting of FDA for high public health harms, FBI for violence or large-scale economic crimes, and DOJ for prosecution and incarceration resource constraints.)

that was adulterated was beef—so only impacted the beef industry—but all food-related businesses experienced lost consumer confidence and a drop in sales. Furthermore, this incident even undermined the trust in the UK government.

In China, there is a need to keep consumer confidence high to support the massive economic growth which includes longer food supply chains. The growth is driven, in part, by consumers moving from rural to urban settings. Reportedly the urbanization of China is the largest migration of humans in history (Zwingle and Franklin 2002; Kirkby 2018). The 13th Five-Year Plan states “we will step up the pace of new urbanization,” and to provide a scale of magnitude, the plan is to “Make progress in granting urban residency to approximately 100 million former rural residents and other permanent urban residents without urban household registration” (this is equivalent to 1/3 of the entire US population) (CN-CPC 2016). The growth of the economy, combined with 50% of the population moving from near the agriculture production in rural, to long food supply chains in urban settings is occurring while there is an increase in consumer demand for premium proteins such as dairy and meat, has led to more complex food safety logistics challenges as well as a new and emerging “fraud opportunity.” In China, there is an intense focus on consumer confidence and supporting “social harmony” (Spink et al. 2015, 2016; Wu et al. 2016, 2017).

The initial spark for governments or entities to act is usually a specific incident or an event that triggers an activity or instigates significant new efforts.

Sidebar: Review of Trigger Incidents by Country and Year

There are trigger incidents that seem to be the spark to a country implementing food fraud-related regulations or significant initiatives (Table 13.1).

A review of these trigger events helps explain the foundation for actions. After the incidents, there is often a project or report that further reviews the problem, examines root causes, considers recommended actions, and then explores possible countermeasures and control systems.

Key Learning Objective 1: Review of International Incidents

This section reviews the international incidents that reveal a global problem both regarding the source and impact of the incidents. Food fraud incidents are created in, and impact, *every* country. Events in the USA or Western Europe are often just as dangerous as incidents from elsewhere. Every country has a negative consequence on their domestic food consumption, and also that negatively impacts the value of exports.

This section reviews some of the key incidents that created the start of many of the efforts and also reviewed some specific country-level reports or summaries.

The Key Learning Objectives of this section are:

- (1) The Elliott Review of food fraud (UK)
- (2) Incident reports at country-level (EU, China)
- (3) Then more general global incidents

Sidebar: Review of the UK DEFRA Elliott Review of Food Fraud (MSU-FFI 2018):

Title: Review of the UK Elliott Interim Report on Food Fraud

By John Spink • January 30, 2014 • Blog

The UK is taking a serious look at food fraud laws and regulations. It's encouraging that many of the global agency and industry reports are focusing on the same broad concepts as well as having a distinct focus on prevention – from the start, we are harmonizing the terminology and approaches. This UK report was led by our colleague Professor Christopher Elliott of Queen's University Belfast (QUB), and was funded by the UK's Secretary of State for Health, and the UK Department for the Environment, Food, and Rural Development (DEFRA) to carry out an independent review of Britain's food system regarding food fraud. This is a review of Professor Elliott's December 2013 Interim report. The final report is due spring 2014.

The UK Elliott Review – Interim Report

This report was conducted to provide guidance and actionable recommendations to the UK government on combating food fraud. The report was sparked by the horsemeat food fraud scandal but expands to all branches of government and all types of food crimes. "The aim of the [UK Elliott] review is to advise the Secretary of State for the Environment, Food and Rural Affairs, the Secretary of State for Health, and also industry on issues which impact upon consumer confidence in the authenticity of food products."

Summary. This is probably the most comprehensive report written on a country's food fraud threat in that it includes over 50 interviews from across agencies and industries. There are in-depth insights as well as case studies that provide extensive detail on the food fraud threat.

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There are forty-eight recommendations from across the food management system. Major recommendations reviewed below include: Customers First, Zero Tolerance, Intelligence Gathering, Laboratory Services, Audit, Government Support, Leadership, and Crisis Management. While many of the recommendations are already wholly or partially implemented by agencies or industry, it is critical to reinforce that these activities do matter. There is also an important emphasis on how all the recommendations should work together. The report states that there is an efficiency gained by gathering food fraud intelligence and data that has already been gathered from food quality, food fraud, or food defense initiatives. The report reiterates the constant challenge experienced by agencies from around the world — of receiving and sustaining resources for enforcement and prosecution of financial fraud, product fraud including intellectual property rights violations, and other food crimes. The report started with a focus on adulteration and detection and quickly broadened to food fraud and prevention. “The systems approach [that the report] have recommended is intended to provide a framework to allow the development of a national food crime prevention strategy.” Also, “Some of [The Elliott Review report recommendations] will require a change of culture within the industry and the UK Food Standards Agency so that they can work better together to protect consumers.”

Consumers First / Zero Tolerance. These sections stressed the importance of prioritizing the focus on public health, as well as confirming that the incidents should be prosecuted (Note: a review of “zero tolerance” concept will be addressed in the Criminology chapter). The report included an emphasis on:

- The importance of a systems approach and preventative measures – which is consistent with the EU draft resolution on food fraud, the USA FDA and the USA Congressional Research Service report.
- Shared investment between industry and government.
- A need for a “culture change.” There is an industry shift to embrace and engage with food fraud prevention, and reports such as this provide sustained pressure. The report encourages opportunities for agencies to collaborate with industry and non-governmental associations. Although not directly mentioned in the report, those partner entities could include the Global Food Safety Initiative (GFSI), the Grocery Manufacturers Association (GMA), the US Pharmacopeia/ Food Chemicals Codex, and the Institute of Food Technologists (IFT). There are other broader activities focused on combating product fraud such as by the International Standards Organization’s Technical Committee 292 Security Management and 247 on Fraud Countermeasures and Controls.
- Expanding the research focus from detection to collaborative prevention. There is an important research need in understanding the fraud opportunity

and beyond just gathering a list of incidents. This section emphasized expanding from the detection infrastructure of laboratories to deterrence and prevention, working with industry and law enforcement. The report states that “[The Elliott Review Interim Report] to date has identified a worrying lack of knowledge regarding the extent to which we are dealing with criminals infiltrating the food industry.”

Education. This section addressed the needs of educating a more extensive range of stakeholders from across the public-private spectrum. A key recommendation was to provide education programs ranging from basic concepts for general practitioners to in-depth courses to assist auditors and intelligence analysis.

Intelligence Gathering. This section of the report focused on data collection and intelligence gathering. The report included an emphasis on:

- The intelligence-gathering recommendations recognize the tremendous challenges when dealing with commercially sensitive information that could also have a public health threat. Often, when there is a public health threat, a criminal investigation is delayed until the suspect product can be removed from the marketplace. This quick public health response reduces the number of illnesses or deaths but also reduces the effectiveness of a criminal investigation. Once the criminals become aware their crime has been found out, they can destroy evidence or evade investigators.
- As is consistent with many reports from around the world and from research, the report reiterates that food fraud is a unique threat that requires specific attention, and although distinctly different, the countermeasures and control systems should be integrated with food safety, food defense, and large-scale organized crimes.

Audits. This section identifies an important role of food audits conducted by the government in conjunction with private/ industry/ third-parties, combined with a focus on engaging (and motivating) law enforcement. It mentions audit and certification “steps already being taken by industry.” Also, “I have found a great appetite within the industry to improve and expand upon the standard audits developed by organizations...” For example: “In July 2013, Asda announced plans to introduce unannounced BRC audits for all of its Asda brand suppliers starting 1st October 2013.”

Laboratory Services. There is a thorough discussion of the laboratory services and capacity-building.

Government Support/ Leadership. This section emphasized the critical role of government support and leadership in food fraud prevention:

- The report recommended clearer coordination and support from within the food agencies, as well as across law enforcement groups. An additional missing link that was not covered in the report is prosecution and the courts

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prioritizing these cases – or at least not discarding them out of hand before they are even considered. The education recommendation above should include information to the prosecutors and judges.

- The challenge for the government support and leadership is clarified when the report stated: “Food fraud is a complex issue and it is not always clear, particularly when first uncovered, whether or not a food fraud problem might also be a public health problem.”

Crisis Management. This section recommended specific crisis management actions, including to basically be aware of food fraud incidents. The report emphasized the important and unique collaboration between the food agencies and law enforcement.

This UK Elliott Review Interim Report is another example of food fraud rising on the legislative and regulatory agenda. It’s encouraging that many of the global agency and industry reports are focusing on the same broad concepts and that those initiatives have a distinct focus on prevention. From the start of food fraud becoming a global focus, the research and regulatory action we are taking are harmonizing the terminology, and the prevention approaches. With all these agencies and industry groups working – and working together – there is a great potential for a global, integrated, efficient, effective, food fraud prevention plan. Within your industry and within your country, stay aware of the activities and engage in the discussion. Be part of the solution. We will keep searching for and reviewing the latest food fraud reports and activities.

Incidents in China

Over the centuries, China has shifted focus from “food security” (producing enough food) to “food safety” (food that is safe to eat) to now a combination of food safety and food fraud (confidence in the food they consume.) Now, most Chinese reviews of food safety have a focus on food fraud (Wu et al. 2016, 2017). International Chinese presentations on the 2014 Chinese Food Safety Laws included “addressing food fraud” in the title, and books include a frequent mention of the issues (CFSAN 2015a, b). The Chinese government and agencies take a holistic approach to all food risks that include food quality, food safety, food fraud, and to a lesser extent food defense.

This section will review incidents in China including current issues and the history of incidents, and a later section will address the resulting focus by the food agencies.

Melamine, 2007

The major food fraud incident was the melamine incidents that started in 2007. This impacted a wide range of products consumed by the Chinese in China and for export. The major focus was melamine in infant formula and milk powder (Wu et al. 2016, 2017). Due to the massive “minimum economic scale” of the manufacturing

facilities and global distribution of the goods, the incidents can have a massive and rapid impact (Porter 1980). “For example, according to a report by the Ministry of Health (MOH), the 2008 melamine-tainted infant formula incident in China caused 294,000 infants and young children to be diagnosed with urinary tract stones, and 6 deaths” (Wu et al. 2017).

Food Fraud from 1000 BCE to 1000 CE

There are more early historical references of food fraud in China in part because they were a developed civilization earlier and also had earlier recorded history. The *Book of Rites* was published during the Zhou Dynasty which lasted from 1046 to 256 BCE and included a passage “Grains not in-season, immature fruit, cannot be vended” (Wu et al. 2017). Later in the Song Dynasty which lasted from 960 to 1279 CE, the author Yuan Shi Fa described incidents such as “Chickens with sand in the body, inflated geese and sheep, salt mixed with ash, silk products with glue paste, rice and wheat with increased moisture, meat with irrigation water, medical herbs substituted by something else” (Wu et al. 2017). And there are others through the Ming Dynasty which lasted from 1368 to 1644 CE.

New Incidents, 2017+

As has happened around the world, the consumers continue to be alerted to new incidents. Reports of food fraud incidents are especially impactful due to the history of fraud, the high growth rate, the massive urbanization (people moving from close to the food in rural settings to cities), and the very active social media. “These incidents may lead to public health or population-wide emergencies and can also cause social harmony issues (e.g., lowering consumer confidence in the food supply and the government” (Wu et al. 2017).

The food fraud incidents are widely reported publically and in social media, which increases the awareness and need for a direct response. “According to a report by the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ), the media reported that 266 of 694 typical food safety incidents from 2007 to 2013 were ‘non-food adulterant substances’ [a type of food fraud], and 128 of them were ‘tampering’ [another type of food fraud]” (Wu et al. 2017).

The food fraud incidents in China have occurred over a long period of time, have been dangerous, and have impacted the Chinese consumer confidence. This concern has led the Chinese government to invest in people and resources to not only focus on detection but also shift focus on adjusting the regulations and then on to more holistic prevention.

Sidebar: Food Supply Chain Interdependence—Melamine and a Review of Sowing the Seeds Report (MSU-FFI 2018):

Title: Food Supply Chain Interdependence—A Review of the “Sowing The Seeds” Report

By John Spink • June 10, 2013 • Blog

Food moves around the world faster than ever – an orange can travel from halfway around the world and be in a US retailer in a single day. For some

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highly integrated food manufacturing operations, such as seafood, the product can be harvested, processed, shipped, and retailed in two days. This is phenomenal for improved product quality and to accelerate the global economy... but it creates tremendous burdens and gaps for the food regulatory system. These regulatory and market dynamics contribute to the fraud opportunity for food. The burdens and gaps emphasize the need for global collaboration and an expanding public-private partnership.

A report that emphasizes this global collaboration is “Sowing The Seeds – Opportunities for U.S.-China Cooperation on Food Safety” by the US-based Woodrow Wilson Institute. This report provides incredible insight on food safety in China from both a food science and social science perspective. This interdisciplinary, holistic perspective is important because there are so many factors beyond just technological capabilities to assure food safety and food security – the safe, continuous, nutritious, and economically accessible supply of food.

Reports like Sowing the Seeds are important for us as researchers, if we look at them with a broad lens, to see future trends. While I found the amount of information that applied to food fraud and counterfeiting absolutely overwhelming, in looking back over the four years since I first read the report, I realize that it helped shape my thinking. Some insights that predicted changes that did occur included:

- The Chinese version of the CDC emphasized a need for collaboration in the areas of risk assessment and data collection. Now Chinese government officials are participating in Expert Panels for the U.S. Pharmacopeia (USP)/ Food Chemicals Codex, Chinese companies are members of the Global Food Safety Initiative (GFSI), and others.
- The role of the media was discussed by another Chinese government official who emphasized: “...the need to strengthen communication with the news media to prevent unscientific information from reaching the public, and to use the media as an integral part of emergency response.” They discussed reporters being “one of three pillars ensuring food safety at the local level.” Here in 2013, we just saw a food fraud-focused scientific and enforcement report published first to the media – the scientific information and data were reported openly, quickly, and with a lot of detail. You don’t have to consume too much media in the US to see that we still struggle with unscientific information (a carry-over trace contaminant versus a harmful level of an adulterant) or misinformation about what is actually fraudulent (some technologies, like irradiation, vastly improve product quality and safety (there has been a trend to refer to “electronic pasteurization”). A sensational article here in the US regarding unfounded food safety issues has crippled industries and led to the economic collapse of companies.

- The report continually emphasized the proactive steps that were started in China – as well as the economic and social drivers that indicated the programs would continue to be supported, as they were.
- One of the most impactful insights, which I frequently quote, is that there are over 450,000 food manufacturing facilities in China, 350,000 of which are on less than 2 acres of land each, with less than 10 employees (Wu et al. 2017). Their products are consolidated before getting into commerce, so those farmers have no brand to protect... and they probably don't even have traceability systems, let alone electricity to run computers. This is an amazing and *huge* number that defines the challenge of inspection and even traceability.
- As with the rest of the world, including the US, the “greatest food safety threat in China is still microbial contamination.”

Reports like Sowing the Seeds support what we think we know in traditional areas and they also open our eyes to other vulnerabilities. This report presented details in well-known areas such as general food safety, but we were also made aware of some very important issues in disciplines such as Veterinary Medicine. The animal populations are large, and include small animals as well as aquaculture such as fish – China is a huge exporter of fish to the US. The report details animal issues with drug residues or contamination including chloramphenicol, malachite green, furazolidone, nitrofuran, gentian violet, fluoroquinolones. Beyond optimal application practices of medicines, issues were highlighted including the impact of illegal or counterfeit veterinary medicines and feed. These food safety and Veterinary Medicine dangers are not always clearly understood, and the report stated that this information often does not make it to the regional or local level – highlighting an educational opportunity that would result in a great increase in public health and food security.

Reports like Sowing the Seeds emphasize that an integrated approach is critical across food security, food quality, food safety, food fraud, and food defense. If we approach “food” from all angles, we can reduce the overall risks and increase the production of the products we all need. Reports like Sowing the Seeds also emphasize that food protection responsibility is global and interdisciplinary in nature... emphasizing the efficiency and effectiveness of public-private partnerships. Prevention starts with education. Your education should begin with a broad range of information sources that provide insight on broad policy implications, but then continue all the way down to the application in the field. Start by reading reports like Sowing the Seeds. (MSU-FFI).

Incidents in the European Union (Including the UK)

The European Union (EU) still has a primary focus on food safety (food that is safe to eat) and has intensified activity related to consumer concerns of food fraud (specialty characteristics of the food integrity and food authenticity such as organics or specialty origins). Also, the EU focus on food authenticity is critical to the economies that are elevated due to premium-priced specialty products such as Parmesan Cheese and Champagne. These both will be reviewed in more detail.

General Intellectual Property Concerns (IPR) Throughout history there has been an ongoing concern with Protected Geographic Origin (PDO) such as Champagne from the Champagne region of France (in the USA this type product is “sparkling wine” or “Champagne-method”) or Parmesan Cheese that is only from the Parma region of Italy. Even though the US product has a label identification as “sparkling wine” or “Champagne method” (Methode Champenoise), it may cannibalize from the “French” “Champagne”—regardless of the official title, many Americans still consider the entire product category as “Champagne.” Also, an abundance of basic quality “Parmesan Cheese” “Made in the USA” may reduce the premium price of the Italian product. The EU has limited food production capacity, so they will never outproduce global competitors and, thus, must protect their premium designation.

Horsemeat in Beef The impact of the horsemeat in the beef incident cannot be underestimated. The intense consumer feeling of violation was extremely impactful on consumer confidence, the price of premium products, and the confidence not only in the food supply chain and food agencies but of all government. Soon after the incident, the EU conducted special inquiries, published the “EU Food Crisis Report on Food Fraud,” and quickly proposed EU-wide programs. The incident occurred when a rogue meat manufacturer substituted lower-priced 50-pound bags of frozen horsemeat for higher-priced pallets of frozen beef. The product slipped through inspections since the product was “safe” (no food safety issues), passed quality tests (actually reportedly in some cases, the illegal horsemeat blend was higher-“quality” cuts of meat than the beef that was ordered), and also passed taste specifications. The fraud opportunity was created by the lack of species tests being conducted. There was also another disconnect between the many procurement bidding transactions (often an anonymous digital bidding process) and the shipment through a separate channel for the physical product.

A heightened awareness—combined with more direct food authenticity testing—has led to a seemingly endless string of incidents. Consumer awareness is still very high, the government is still very focused on the issue, and the stakeholders are evolving to more preventative approaches.

Sidebar: Horsemeat Through the Ages—Book Review of “Taste of War”

There are incidents that can shape the intensity with which a region or country is concerned with food and the food supply. In Europe, there is both a broader, more general focus on food as a celebration and yet possibly an underlying extreme concern with basic supply needs. In the USA there is confidence—or lack of awareness of the vulnerability—of the consistent supply of food.

The book *Taste of War* reviewed the role of food and food supply in the expansion goals and needs of countries throughout history. Some countries have limited agricultural production due to severe weather or limited land that is suitable for agriculture (Collingham 2012). There are many examples throughout history that include the Vikings raiding the UK, Japan expanding to nearby countries, Germany expanding its border, and to Russia expanding eastward.

In the book, some specific examples of public policy shaped by food shortages included that of the 30 million Russians who died in World War II and 20 million died of starvation. The memories and trauma would still be remembered by the citizens now since the children who grew up during WWII who could remember that famine would be in their early 1980s in 2017.

Different countries experienced different levels of food shortages which, naturally, have impacted the short-term and long-term public policy-making. The US population—even during the Great Depression—has not experienced a total loss of food supply or mass starvations.

Other Significant Global Incidents

There are a range of incidents that have had a major impact on the public health or economic state of many countries to the point of creating economic and social instability, as well as national security concerns. When there is a public health threat, before the exact cause can be identified, blanket import bans can be implemented. These additional global impacts are important since they help emphasize the incredibly high impact incidents and the need to focus on vulnerabilities and prevention.

- ***Beef Mislabeling from Brazil (2017):*** A massive Brazilian food fraud incident includes widespread bribes to place “adulterated products” in the marketplace which included fake sanitary permits and loosened quality measurement oversight. The investigation was led by more than 1000 (!!!) officers in 194 raids covering 38 detention orders (Fonseca and Parra-Bernal 2017). This was reported as the Brazilian Federal Police’s largest search-and-raid operation ever. The incident led to an almost global block of all Brazilian beef imports.
- ***Cumin-Peanut Allergen Filler (2015):*** An incident of peanut shell filler that included the allergen in cumin was presented as “even more serious than the horsemeat crisis” (Bawden 2015; Sarda 2017). Reportedly a cumin harvest in India (and reportedly three-quarters of the world’s supply from just the state of

Gujarat) that was half the typical harvest led to drastically increased global prices. The very high fraud opportunity, combined with the widespread incidents and suspicious ground spice fraud, leads this to be at least in part an intentional act. Since this included an extremely dangerous allergen—that is a very severe public health threat to a large population in very small doses—the product recalls were swift and broad. The blocking of imports increased the economic impact on the producing nations including Iran and others primarily in the Middle East.

- ***Milk/Milk Powder Food Safety Incident of WPC in New Zealand (2013):*** While not food fraud, this incident demonstrates the impact of import bans. A food safety concern with Whey Protein Concentrate (WPC) led to an almost instant block of all New Zealand milk and dairy products imported to their biggest market of China. This food safety incident led to the swift and broad response possibly because it was just a few years after the 2008 melamine in milk incident. After a range of incidents, governments are encouraged to move quickly when a public health threat is suspected regardless of the source (Tajitsu 2013).
- ***Sunflower Oil Diluted with Mineral Oil from Ukraine (2008):*** A sunflower oil fraud incident in Ukraine included a product that was contaminated or adulterated with more than 10% mineral oil. “The EC said it was no longer receiving any sunflower oil from Ukraine which had stopped the exports prior to the contamination becoming public” (Patton 2008). The entire Ukrainian sunflower oil industry—and of some other edible oils—was halted, while the incident was sorted out. The minimum impact was a loss of cash flow from the immediate sales, and the worst impact would be missing the harvesting window or destroying the spoiled product.

At first, a food fraud incident can lead to an increased awareness and concern by a government’s customs import body. If a government or agency responds quickly and aggressively to a food fraud incident, the citizen support and positive reinforcement may increase the amount and intensity of future actions. When there is another incident—or suspicious activity—there may be an increased speed and breadth of future product recalls or block of imports for products, brands, companies, or even for wide ranges of products coming from an entire country. This continued citizen support could lead to the motivation to support and create a new directive, new regulations, or even a new law. While food fraud incidents are few and rarely a health hazard, they are a major consumer concern which leads to an intense focus by governments.

Key Learning Objective 2: Severity and Frequency Leading to Responses

This section reviews the severity and frequency leading to responses. The emphasis is on why food fraud is so important to so many groups. This will present the responses as well as direction for a more harmonized, efficient, and coordinated

focus on prevention. This includes the interdisciplinary nature of prevention by considering how the fraud opportunity is created and the many academic disciplines that help understand the optimal countermeasures and control systems.

The Key Learning Objectives of this section are:

- (1) China building capacity and capability base on their national Five-Year plans
- (2) EU (excluding the UK) starting with the resolution on food fraud
- (3) UK focusing on the National Food Crime Unit (UK NFCU)

Chinese Response and Direction

This section will review the Chinese government food fraud prevention response and direction. China has probably the most complex set of challenges which has led to an acute awareness that food fraud must be addressed and prevented. China has been probably the most proactive and innovative food fraud prevention-focused government in the world. China has also been one of the most open for international collaboration and scholarly engagement. The motivation is driven by necessity.

The unique and massive complexity of the Chinese food fraud issue includes many factors such as the rapidly growing economy, long-term transformations and modernization of the business processes, a need to produce more food increasing population who also are seeking different foods (9% of the world farmland is in China to feed their citizens who are 21% of the world's population), a transportation infrastructure that is also rapidly adapting to keep pace, longer supply chains as they experience massive migrations for urbanization, and rapidly innovating food packaging and supply. All this complexity is combined with a highly stratified regulatory and law enforcement system of national, state, county, and local agencies. Oh, also, the population is over 1.3 billion compared to 0.3 billion in the USA. The growing Chinese middle class who is seeking safer and higher-quality food products is more than 0.5 billion or approaches *twice* the *entire* US population.

- **Thirteenth, 5-Year Plan (2017):** The Chinese government and economy are centrally managed by a “5-Year Plan” process where the twelfth created a food safety infrastructure and the food safety/food fraud aspects of the thirteenth are still fully reported (CN-CPC 2016). These are more like a business plan than a traditional Western government set of goals. The plans are pragmatic, practical, and unlike some Western laws or regulations that are fully funded. The Chinese delivery on the plan—they fully support the goals, and they hold people accountable for failure. One key activity in the 2012 plan was the creation of the Chinese National Center for Food Safety Risk Assessment (CFSR—pronounced “siff-suh”) (CFSR 2018). CFSR was fully funded and has continued to grow in activity and impact. One activity in the 5-year plan is the collaboration with international scholars such as coauthoring publications (see translated articles such as (Spink et al. 2015)).

- **Twelfth, 5-year Plan (2012):** This five-year plan included the creation of the Chinese National Center for Food Safety Risk Assessment which includes a scope of work that includes food fraud and food authenticity testing (CN-CPC 2011).
- **New Food Safety Law 2009 and Updated 2013:** A new Food Safety Law was implemented in 2009 and updated in 2013. The law increased the focus on all aspects of food safety with a focus on food fraud.

A major activity of CFSAN was creating a food fraud “Negative List” (or “Black List”). This is a group of adulterant-substances that are considered the most dangerous for China, and there is a massive testing program. This program coordinates with the China CDC to evaluate and track public health outbreaks.

The Food Safety Laws are continually updated, and recently China FDA has been publishing a public request for comments on food fraud enforcement and prosecution. The overall focus has a firm foundation in investigation and prosecution (building upon detection) and is shifting focus to prevention.

E-commerce is a unique problem for China because of the even more complex distribution network. There is a new focus on this based on process control and traceability but also the regulatory requirements on all the supply chain partners. Beyond the sales or auction e-commerce companies, the delivery companies are also included and held accountable for the safety of the product through to consumption.

European Union Response and Direction

This section will review incidents in the European Union—still including the UK—including current issues, the history of incidents, and the resulting focus by the food agencies. It is widely published that some of the very first Western laws were created to address “food adulteration” which more broadly is food fraud.

When considering the history of the origin of European food laws, the book *Swindled*¹ (Wilson 2008) references two stages with one being before the 1820 publication of Frederick Accum’s *A Treatise on Adulterations of Food and Culinary Poisons* and before. During that time, Wilson refers to “Reading British newspapers from this period, you often come across the view that, while adulteration was regrettable, it was a natural consequence of the free trade that was necessary to power Britain’s commercial success” (Wilson 2008). Also, “To introduce new regulatory

¹Author Bee Wilson’s other publications include: *The Hive: The Story of the Honeybee and Us*, John Murray, 2004; *Swindled: From Poison Sweets to Counterfeit Coffee*, John Murray and Princeton University Press, 2008; *Sandwich: A Global History*, Reaktion Books, 2010; *Consider the Fork: A History of How We Cook and Eat*, Basic Books, 2012 (history of kitchen technology, from fire to the AeroPress); and *First Bite: How We Learn to Eat*, Basic Books and Fourth Estate[18] comer, Turner, 2016.

measures would have the undesirable effect of stifling the market. It was there for better to do nothing" (Wilson 2008).

Examples of Europe's several of the first food fraud-related laws are:

- Enquiry Into Plants, Theophrastus (370–285 BCE)
- Natural History, Pliny the Elder (23–79 AD)
- Assize [a judicial edict] of Bread and Ale, King Henry III of England, 1266
- Beer purity law (Reinheitsgebot), Duke Wilhelm IV of Bavaria, 1516
- Adulteration of Tea and Coffee Act, 1724 (England)
- Adulteration of Tea Acts, 1730 (England)

More recently, the EU has a specific focus on consumer confidence both within Europe and also for exports to Europe.

In 2014 the EU adopted their resolution "on the food crisis, fraud in the food chain and the control thereof" (EC 2014). This included a "five-point plan to restore consumer confidence." This stated that there was currently no commonly held European definition but included:

According to Spink and Moyer (1) 'Food fraud is a collective term used to encompass 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.' Drawing on from this definition the key characteristics of food fraud are: (1) non-compliance with food law and/or misleading the consumer, (2) which is done intentionally and (3) for reasons of financial gain. (EC 2014)

Later the EU report provided a definition that stated "Food fraud: There is currently no EU definition of the term, but it is generally accepted that food fraud is an intentional action carried out for financial gain. Different types of food fraud include adulteration [adulterant-substances], counterfeiting [intellectual property rights violations], substitution and deliberate mislabeling of goods" (EC 2014).

In support of these efforts, the European Union began looking closer at food fraud and specifically food authenticity or food integrity. The EU funded a 12 million euro (\$14.5 million) Food Integrity Project led by the UK Food and Environment Research Agency (FERA) (EU FIP 2017). The Food Integrity Project defines *food integrity* as "the state of being whole, entire, or undiminished or in perfect condition" (FERA 2018). This assumes food safety and quality to include meeting the entire consumer expectation including correct labeling of the processing and origin. They further state "Providing assurance to consumers and other stakeholders about the safety, authenticity, and quality of European food (integrity) is of prime importance in adding value to the European Agri-food economy." An emphasis has been on the economic contribution of the value-added European food products. Another outcome is the creation of a Food Fraud Network that includes key contacts from 28 national contact points in the member states and includes representatives from Switzerland, Norway, and Iceland (EC 2018).

An important first step is that the EU officially addressed food fraud in a formal resolution. The next public policy development step will be to get agreement from the member states and then for the proposals or activities to start adding value. The real value will be a holistic and all-encompassing perspective on the problem and a

collective shift to prevention. A next step is to monitor the progress of the definition of food fraud expanding from the EU resolution to then be defined in EU regulations and then through national laws or regulations.

Sidebar: Review of EU Draft Resolution to Adopt a Definition of Food Fraud (MSU-FFI 2018):

Title: Review of EU Draft Resolution to Adopt a Definition of Food Fraud
By John Spink • November 8, 2013 • Blog

Get ready for government regulations addressing food fraud prevention. The EU is defining Food Fraud, with a focus on prevention. This is a broad, holistic frame that covers all types of fraud conducted using food. This focus on food fraud and on prevention is consistent with other groups such as ISO, Interpol, and the Global Food Safety Initiative. It's fantastic that we're honing in on a harmonized set of terms and concepts before we all finish writing laws or implementing industry best practices.

The European Parliament created a Draft Resolution outlining a five-point plan following the “horsemeat fraud” scandal: European Parliament (2013). Draft Report – on the food crisis, fraud in the food chain and the control thereof, Rapporteur (Chair): Esther de Lange, Committee on the Environment, Public Health and Food Safety, (2013/2091(INI), October 10, 2013.

In this Draft Resolution, there is a very interesting, broad focus beyond adulteration and beyond just human food. They identify a wide range of activities including food and feed law, animal health, and plant health. They also discuss the specific roles of the disciplines of Food Safety and Food Law.

“...having regard to the proposal for a regulation on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health, plant reproductive material [and] plant protection products.”

One of their recommendations is that the EU and the Member States adopt a common definition of food fraud.

“Notes that EU law does not currently provide a definition of food fraud and that the Member States adopt different approaches; considers a uniform definition to be essential for developing a European approach to combating food fraud; stresses the need rapidly to adopt a harmonized definition at EU level, including elements such as (1) non-compliance with food law and/or misleading the consumer, (2) intent and (3) financial gain;”

When they proposed a definition of food fraud they quote one of our peer-reviewed, academic articles:

“According to Spink and Moyer (1), ‘Food fraud is a collective term used to encompass 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.’ [Note: “(1)” refers to the 2011 article Defining the Public Health Threat of Food Fraud.]

The food fraud and prevention concepts are taking root around the world and in proposed laws. To increase public health – and not just assure compliance — it is logical to take a holistic, all-encompassing approach to prevention. It looks like food fraud laws and industry best practices are coming sooner rather than later. Fortunately, there is a harmonization of terms and focus. Also, fortunately, there are a wide range of resources available before organizations begin developing their strategies.

Sidebar: Update—European Parliament Activity Final Report, Food Fraud Defined (MSU-FFI 2018):

Title: Update—European Parliament Activity Final Report, Food Fraud Defined

By John Spink • June 27, 2014 • Blog

The European Commission final report on food fraud was adopted back in January 2014. A 58-0 committee vote supported the broad definition of food fraud and an emphasis on prevention. The member states are beginning to implement countermeasures and control systems.

The report “On the food crisis, fraud in the food chain and the control thereof” provides excellent insight as to how the EU arrived at their position and established their next steps. I will review some of the key sections and quotes below.

Since food fraud was not previously defined in EU laws, there was, logically, not much previous focus.

“...whereas no statistics exist on the incidence of food fraud in the EU, and whereas the Commission has only recently identified food fraud as a new area of action;”

Later the report stated the need to gather data specifically on food fraud. This will help in understanding the extent of the problem and also support the ability to identify incidents. The final report:

“Underlines the need to gain further insight into the scale, incidence, and elements of cases of food fraud in the EU; calls on the Commission and the Member States to collect data systematically on fraud cases and to exchange best practices for identifying and combating food fraud;”

“Notes that EU law does not currently provide a definition of food fraud and that the Member States adopt different methodologies in the definition thereof; considers a uniform definition to be essential for the development of a European approach to combating food fraud; stresses the need to adopt swiftly a harmonised definition at EU level, based on discussions with Member States, relevant stakeholders and experts, including elements such as non-compliance with food law and/or misleading the consumer (including the omission of product information), intent and potential financial gain and/or competitive advantage;”

(continued)

There was a proactive emphasis on prevention:

“Considers that official controls should focus not only on food safety issues but also on preventing fraud and the risk of consumers being misled;”

The report specifically mentions collaboration with global activities, such as with our MSU Food Fraud Initiative. We have made a lot of effort aligned with MSU’s Extension and Outreach Mission, and it is rewarding to see that we are adding value:

“Considers it valuable that, in addition to and not replacing the system of official controls for the food sector, the sector itself proactively develops and uses private-sector anti-fraud initiatives such as product integrity checks, self-monitoring, analysis, product-tracing plans, audits and certification, and welcomes current initiatives such as the Global Food Safety Initiative and the Food Fraud Initiative at Michigan State University;”

As in the draft, they adopted the broad definition we presented in our Journal of Food Science article. Early in our research, we identified the value of establishing a theoretically sound definition. The potential to contribute to reports like this were exactly why we took the time and effort to publish that scholarly article (see above).

They establish the critical first step in coordinating activities... harmonizing the terminology and establishing common prevention-focused goals:

“Firstly it is necessary to define what constitutes food fraud: a clear and harmonised definition is essential as a basis for an effective national and EU approach.”

The additional “Opinion of the Committee on the Internal Market and Consumer Protection” included:

“Considers that the reference to fraudulent practices in the General Food Law is inadequate and that it leaves out frauds that do not pose a food safety or a public health risk; calls on the Commission to provide a definition of fraud which includes the financial gain and the intention of fraudulent practices;”

The additional “Opinion of the Committee on the Agriculture and Rural Development” included:

“Points out that a clear, legally valid EU-wide definition of food fraud is essential in order to facilitate the effective combating of fraud in the food chain;”

So the EU and the Member States have established a common foundation for combating food fraud – a definition and stated focus on prevention. Now other activities such as the UK Elliott Review of food fraud/Food Crime will help define how the Member States will be implementing countermeasures and control systems. As the EC reported noted, organizations such as GFSI will also be a key to the Food Fraud Network.

Horsemeat: One Year Review

In February 2014 the EC released the summary of their activities to combat specifically the horsemeat scandal but more broadly food fraud. They delivered a five-point plan that is on target, and almost all of the deliverables are completed. Specifically For food fraud prevention:

“1. Food fraud

- “To map existing tools and mechanisms to fight food fraud, with a view of developing synergies and contacts amongst competent authorities.” [Note June 2014: completed]
- “To promote the involvement of Europol in food fraud investigations where and as appropriate.” [Note June 2014: completed.]
- “To ensure a procedure for the rapid exchange of information and alerts in cases of violations which may constitute a fraud (similar to what the RASFF [EU wide Rapid Alert System for Food and Feed] does for serious risks).” [Note June 2014: ONGOING]

Since they've defined food fraud as a “thing,” they're now able to focus and coordinate their countermeasures and control systems. Also, now that food fraud is defined, they include it as a “thing” in databases. More clearly recording incidents will improve their ability to estimate the impact and improve rapid response. This is being managed by an “EU Food Fraud Network” which is national contact points – this is the start of an international task-force type network.

EU Research Grants

Now that food fraud is defined, the term is showing up in more reports such as EU grant solicitations. For example, a recent 500 k Euro (\$680 k) grant on “Sustainable Food Security” includes a specific topic of “Authentication of Food Products.” Not only is food fraud mentioned, but there is also a focus on prevention: “Beyond improving fraud detection, activities should aim at better anticipating and preventing frauds.”

Many countries in the EU have had a long-term focus on food integrity. The vulnerability of the food supply chain was heightened after the BSE scare in the UK in 2009. The horsemeat scandal further exposed the vulnerability and led to consumer outrage. The horsemeat scandal – and the increased awareness that led to more fraud incidents being publicized — brought food fraud to the forefront. The EU and the Member States have taken a very proactive approach to establishing a common starting point and coordinating activities. There will always be resource limitations and challenges for every government activity but the firm foundation and focus on prevention is the start of a very efficient and effective system.

The UK

The UK has been one of the European Union leaders in addressing food fraud. The impact of leaving the European Union (Briton exit or “Brexit”) is still to be determined, so this section will review previous and current activities.

Some of the very first Western food laws were developed in the UK and specifically addressed food fraud or “food adulteration.” These issues have been a concern but—as happens around the world—there is always a challenge of changing priorities once the incident passes and the reality of implementing the extremely interdisciplinary nature of shifting from detection to prevention. The traditional food safety and food adulteration focus rely on process improvement of diligent parties as well as testing of microbial perpetrators that are not intelligent and do not evolve to evade detection. The UK is currently applying criminology resources and—as the UK Home Office led the world in shifting from crime catching to crime prevention (UK Home Office 2015)—will logically shift from “intervention and response” to “prevention.” A main priority for the Home Office Crime Prevention is to decentralize priority setting from the central government (Whitehall) to the municipalities (Note: The UK National Food Crime Unit NFCU is with the Food Standards Agency which is an independent government department.).

The UK work was sparked by the horsemeat incident which led to several major funded project reviews including 2014 “The Elliott Review Elliott review into the integrity and assurance of food supply networks” (DEFRA 2014). This was funded by the UK Department for the Environment Food and Rural Affairs (DEFRA). A series of eight major recommendations were presented including the recommendation of a dedicated UK National Food Crime Unit (NFCU).

- **National Food Crime Unit (NFCU):** The NFCU was created after the publication of the Elliott Review and is “a criminal intelligence function within the [UK Food Standards Agency]” (NFCU 2017). This is a coordination point for the UK food crime activities, and they have investigation authority and some funding. The concept of a single coordinating group for food fraud prevention is efficient and logical. It will be interesting to monitor the evolution of the group, the UK FSA activity, the support from the broader crime-fighting resources, and—the ultimate barometer of the impact and importance defined by the government—the focus by prosecutors, judges, and the often very complex court cases. In a public presentation, the NFCU stated: “The way the NFCU operates at the moment is to develop an intelligence package that is then delivered to local authorities which can then pursue a prosecution.”

The NFCU is a stand-alone group with its own funding. That said, they operate with a bigger network that leverages resources and staffing from the UK Food Standards Agency and more generally from countrywide law enforcement under the UK Home Office. The UK, “the Home Office” is the lead government department for immigration and passports, drugs policy, crime, fire, counter-terrorism, and

police. It is useful to understand how food fraud fits into the priorities of partner agencies. Their publically stated goals for 2018 include (UK Home Office 2018):

UK Home Office Law Enforcement Priorities for 2018: Our Goals

- (a) “Cut crime and the harm it causes, including cyber-crime and serious and organised crime
- (b) Manage civil emergencies within the remit of the Home Office
- (c) Protect vulnerable people and communities
- (d) Reduce terrorism
- (e) Control migration: ‘Secure the border against threats from people and goods’ and others. [Note: other countries may use the term ‘immigration’ rather than ‘migration.’]
- (f) Provide world-class public services and contribute to the prosperity
- (g) Maximise the benefits of the United Kingdom leaving the European Union.”

Through several reports or guidances, the UK has reinforced a focus on food fraud prevention that is developing and evolving to the complex problem faced with the challenge of limited funding. The challenge, opportunity, and necessity for the UK will be to optimize the resources to achieve the greatest impact on prevention—optimizing all resource to reduce the “fraud opportunity.”

Sidebar: FDA Office of Criminal Investigation Priority and Examples

Within the FDA there is the Office of Criminal Investigations (OCI). OCI is a criminal law enforcement part of the FDA and has powers to criminally investigate and arrest perpetrators and bring cases to the Department of Justice for prosecution. “They have the authority to obtain and execute arrest and search warrants, carry firearms, and gather evidence to enforce U.S. criminal law.” The ability to arrest is a differentiator between a criminal and regulatory agency.

The OCI website stated priorities are [emphasis added]:

- **FDA-OCI Priorities:**
- “Breaches in the legitimate medical supply chain by individuals and organizations dealing in unapproved, counterfeit, and substandard medical products.”
- “Criminal violations in situations where the normal regulatory process has been unable to remedy the problem.”
- “Criminal violations where the risk of harm to the public health is particularly significant and the only remedy appears to be through the criminal process.”

(continued)

- “Criminal conduct that prevents the FDA from being able to properly regulate. This includes false statements to the FDA during the regulatory process and obstruction of justice.”

The food and dietary supplement cases were presented by FDA-OCI:

- “Peanut Corporation of America: Two former officials of the Peanut Corporation of America (PCA) are sentenced to prison for their roles in a conspiracy to defraud their customers by shipping salmonella-positive peanut products. They also confess to falsifying microbiological test results. The tainted peanut butter leads to an outbreak with more than 700 cases of salmonella poisoning in 46 states and nine deaths. PCA’s former president receives a sentence of 28 years in prison, the largest criminal sentence ever given in a food safety case.”
- “5-Hour Energy Drink: A federal jury convicts eight defendants for attempting to increase profits by selling mislabeled and counterfeit 5-Hour Energy drinks. The defendants remove the legitimate labels from more than 350,000 bottles of 5-Hour Energy and replace them with false labels. Eventually, they begin to produce counterfeit energy drinks. They sell the product for less than the standard market price. This case represents one of the largest domestic food counterfeiting cases prosecuted by the U.S. Department of Justice. The owner was sentenced to 86 months in Federal prison; his wife was sentenced to 26 months’ prison.”
- “Raw Deal, Incorporated: The owner of a company that makes and markets dietary supplements tells his employees to add ‘fillers,’ including cocoa replacer and rice flours, to the company’s products and to certify that some of the company’s products are kosher or organic, even though they are not. During an earlier FDA inspection, he instructs employees to alter documents and not to let the FDA inspectors see ‘fillers’ being added to customers’ orders.” For selling diluted and adulterated dietary ingredients and supplements, he is sentenced to 40 months in prison.
- “Jensen Farms: Two cantaloupe farm owners plead guilty to charges of shipping their cantaloupe knowing that it is contaminated by a poisonous bacteria, *Listeria monocytogenes* (*L. mono*). The cantaloupes go to 28 states, resulting in at least 147 hospitalizations and 33 deaths. One woman, pregnant at the time of her outbreak-related illness, has a miscarriage. Each of the two owners is sentenced to five years’ probation and is together required to pay a total of \$150,000 in restitution.”

Key Learning Objective 3: Intragovernmental Efforts Including INTERPOL, Europol, and OECD

This section reviews the intragovernmental efforts including INTERPOL, Europol, and the OECD.

The Key Learning Objectives of this section are:

- (1) Review of the OECD report on the *Economic Impact of Counterfeiting and Piracy*
- (2) The deeper OECD review the food supply chain
- (3) Then, INTERPOL-Europol operation Opson

OECD-Economic Impact of Counterfeiting and Piracy Report

The Organization for Economic Co-operation and Development (OECD) is a group funded by 35 member countries including the USA since 1961 (OECD 2018). They expanded their 1997 report in 2008 on *The Economic Impact of Counterfeiting and Piracy* (OECD 1998, 2007, 2008b). Their research found counterfeit product produced and consumed in virtually all countries. The scope of the report is crystal clear to only apply to violations of a trademark. In addition, it does not include other types of fraud including origin labeling, etc.

While the main body of the report did not provide an actual estimate of the economic impact, it did state:

- **Limitations on Estimates of the Economic Impact of Counterfeiting and Piracy.**
- “The overall degree to which products are being counterfeited and pirated is unknown, and there do not appear to be any methodologies which could be employed to develop an acceptable overall estimate.”
- “The conclusions reached can therefore only be viewed as a crude indicator of the role of counterfeit and pirated products in international trade.”
- “Carrying out assessments of the factors (or drivers), even on a qualitative, non-empirical basis, can generate insights into the counterfeiting and piracy situation in different products and in different economies.”

One major variable in their assessment was that the report did provide a rough estimate of counterfeiting and piracy based on a seizure rate of 0.5% (based on anecdotal evidence and expert opinion) (OECD 2007). On the \$3.7 trillion in world trade at the time of the report, 0.1% effort would result in a \$3.7 billion swing in the estimate. Nevertheless, they did provide an appendix with estimates. The authors did admit this limitation: “Taking a number of known biases into account, this information is then used to estimate a set of relative counterfeiting/ piracy propensities. This provides the foundation on which a ceiling of the phenomenon’s magnitude is

approximated" (OECD 2007). The report estimated a \$200 billion in cross-border counterfeiting and piracy trade.

The application of the global estimate and country "propensity for counterfeiting" was limited:

From the OECD graphs, with a 95% confidence interval, the propensity of importing a counterfeit product from the United States is from <1% to 40% with a baseline point estimate of 12%, implying there is a 12% chance of any product from the United States being counterfeit. The propensity of importing a counterfeit product from China is between 60% and 99% with a baseline point estimate of 97%. (Spink and Levente Fejes 2012)

The food and drink sectors were covered in their Chap. 12. Regarding food, they state:

In the experience of the industry, products most subject to counterfeit action are those that are the simplest to replace with passable substitutes, and whose substitutes would not be readily detected by the consumer (and sometimes the wholesalers and retailers). Tea, rice and vodka were examples of such items provided by respondents to the OECD survey.

Further,

Several respondents noted that counterfeiting and infringement of trademarks in food are relatively low compared to other products, due to generally low-profit margins and the significant logistical challenges associated with the production, handling, transport, and distribution of food products. These characteristics would be further magnified for perishable products, which require even more sophisticated handling and distribution chains capable of handling these products efficiently.

OECD and the Food Supply Chain

The OECD report then moved on to review food products and the supply chain. They reviewed factors that drive counterfeiting production and consumption. Their summary was:

Perhaps surprisingly, there seems to be a view within the food and drink sectors (although the actual extent of this is not clear) that the level of sophistication required to produce certain products, the difficulties associated with the handling and transport of food and drink products (especially those that are perishable), and the low-profit margins involved, would discourage many would be counterfeiters, and that therefore the levels of counterfeiting experienced in the sector are comparatively low [compared to counterfeiting of other products].

Also,

Based on the appraisal of drivers in Table 11.1 (referred below as

Table 13.2), it is suggested that the relative ease of deception, as well as the size of the market for well-known brand products, provide strong incentives for the counterfeiting of those goods. However, the generally low-profit margins, the challenges associated with transporting and distributing products and the potentially serious consequences of prosecution are also limiting factors.

Table 13.2 OECD report table on: Propensity to produce or consume counterfeited food and drink goods (referred to as Table 11.1 in the original text). (Adapted from Ref. (OECD 2008a))

Propensity to produce or consume counterfeited food and drink goods [Compared to all products including luxury goods, consumer electronics, pharmaceuticals, automobile parts, etc.]

For producers effect on propensities to produce

Unit profitability: **Generally low-profit margins**

Market size: **Large, mass market**

Genuine brand power: **High**

Production, distribution, and technology

Production investment: **Moderate investment required**

Technology: **Not a barrier**

Logistics: **Are problematic**

Marketing and sale: **Could be difficult**

Ability to deceive consumers: **Easy to deceive consumers**

Institutional characteristics

Risk of detection: **Low, but closely watched**

Enforcement: **If detected, risk of prosecution probably high**

Penalties: **Likely to be high**

For consumers effect on propensities to consume non-deceptive items**Product characteristics**

Price: **Cost savings relatively low**

Quality and nature of product: **Outwardly close in appearance to originals**

Ability to conceal status: **Image not a factor**

Consumer characteristics

Health concerns: **Could be high and dangerous**

Safety risks: **Not a significant factor**

Personal values: **Not a factor**

Risk of detection: **Low**

Risk of prosecution: **Low**

Penalties: **Low**

Regarding magnitude and scope estimates, the food industry seemed more concerned with broader food safety or contamination issues rather than trademark violation. The OECD researchers were frustrated with so few incidents, but maybe they did not realize that the priority for investigation and enforcement is first on public health and then later on other violations. A key is that the OECD survey did not provide much insight into the food IPR violations where they stated:

Unfortunately, the survey has shed very little light on the actual magnitude and scope of [intellectual property rights trademark violation] counterfeiting in the food and drink sector. Part of the reason for this is that there seems to be genuine and widespread misunderstanding in this sector of what is actually covered by counterfeiting.

The OECD report did review government resources applied to the problem of possibly that IPR resources are applied more readily to other product groups:

An observation made by most respondents to the survey, and one which has been reflected in all other sectors covered by the OECD survey, is that government resources (police, investigators, prosecutors, court facilities, etc.) allocated to deal with counterfeiting are generally inadequate [undefined and possibly human resources or the challenge of the marketplace], and reflect the relatively low priority (if not necessarily low importance) attributed to counterfeiting when compared to other breaches of the law, such as drugs or the smuggling of weapons and people. The industry noted that this has been especially troublesome in cases when well-defined underlying laws apply, yet effective implementation has been difficult to achieve.

An extremely important insight is the limited effect of enforcement and prosecution on deterrence or prevention:

Associated with the above, is another point made by many respondents (in all sectors surveyed): from their perspective, prosecution and other legal action against counterfeiting is difficult and expensive to carry out, and penalties and punishments are rarely sufficient to deter counterfeiters. This reflects a general view (that appears in virtually all industry responses to the OECD survey) that until the seriousness of the problems associated with counterfeiting are recognised, efforts to combat this growing phenomenon will always be inadequate ultimately.

The OECD concepts were summarized in tables that identified the propensity [“an inclination or natural tendency to behave in a particular way” (Merriam-Webster 2004)] to produce or counterfeit consumer products (Table 13.2).

While the OECD report did not identify the novel application of methods or processes, it did provide a very thorough and insightful review of “food counterfeiting” in relation to other types of “product-counterfeiting.” The enforcement and prosecution are important, but due to the complex nature of the investigations, there is a further emphasis on prevention... on trying to prevent food fraud from occurring in the first place.

INTERPOL and Europol

INTERPOL (International Criminal Police Organization) and Europol (The European Union Agency for Law Enforcement Cooperation) presented a food fraud prevention interaction between NGOs at the first interaction with GFSI at the 2013 GFSI annual conference. Once the prevention plan and processes are implemented, there is a significant additional role of INTERPOL to further enhance the linkages around the world, in Europe through Europol, and also to the US agencies. INTERPOL was aware of their optimal role as a communicator and connector (Figs. 13.2 and 13.3). It was understood that INTERPOL is an international law enforcement coordinating body, and it was interesting to see the stakeholders beyond prosecutors and judicial system, policy-makers, and law enforcement to add industry and academia.

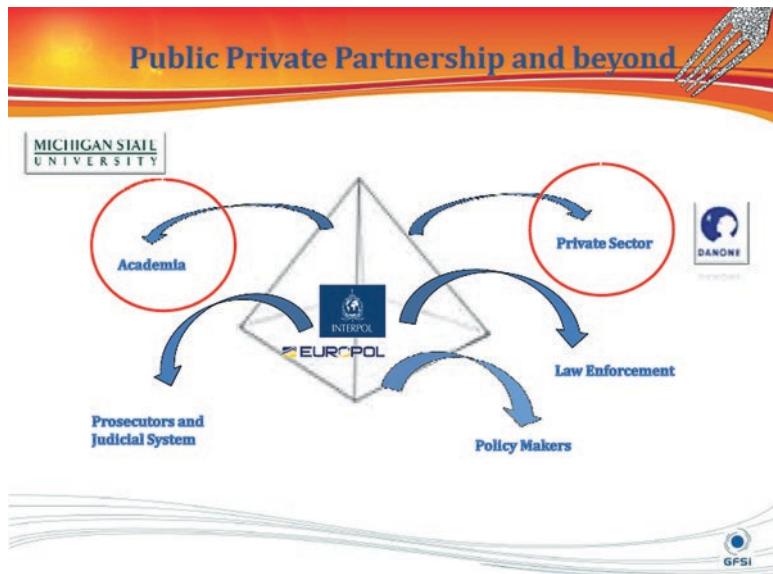


Fig. 13.2 INTERPOL-Europol presentation of their role in food fraud prevention connecting other stakeholders. (INTERPOL 2013)

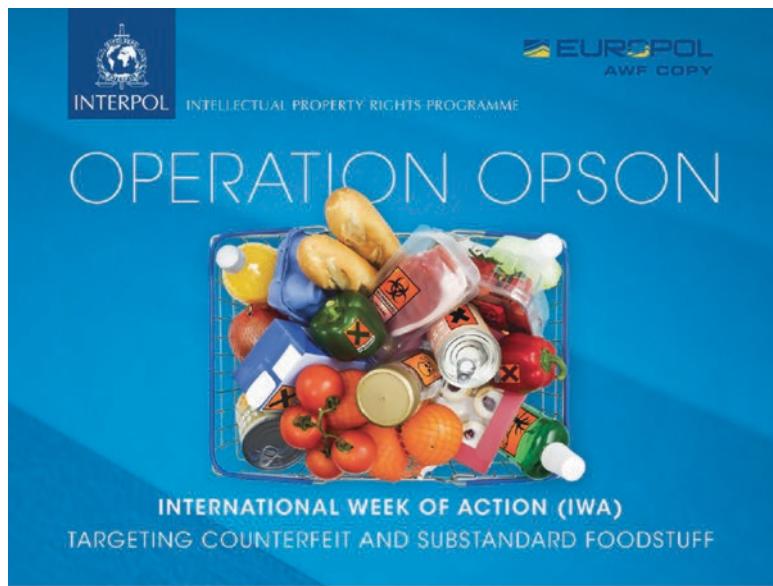


Fig. 13.3 Cover page of the INTERPOL-Europol operation OPSON program 2013. (INTERPOL 2013)

From The Economist (Economist 2018):

It is not a police force in the traditional sense—its agents are not able to arrest criminals. Instead, it is more of an information-sharing network, providing a way for national police forces to co-operate effectively and tackle international crime ranging from human trafficking and terrorism to money laundering and illegal art dealing. The organisation, based in France, operates centralised criminal databases that contain fingerprint records, DNA samples, and stolen documents: a treasure trove so valuable that police consulted it 146 times every second in 2017. Interpol's other main function is to issue notices: alerts to member states for missing or wanted persons. The best-known of these is the “Red Notice,” a notification that a member state would like someone arrested. States are not obliged to follow these notices, but will often treat them as a warrant for someone's arrest and extradition. “Diffusions,” which can be issued with less bureaucracy, are another popular way of seeking arrests through Interpol.

The role and resources of INTERPOL are often misunderstood since their actual mission and activities are different than portrayed in movies. INTERPOL is a law enforcement information sharing and coordinating body. Their budget is really very small and relies on the countries or other agencies for human resources. INTERPOL has no agents who are able to make arrests, but they help coordinate activities across national boundaries. EUROPOL is similar to INTERPOL-Europol but focuses within Europe (Europol 2018). One major joint engagement is Operation Opson that focuses on general food crimes and more specifically food fraud (INTERPOL 2011, 2012, 2013).

Operation Opson “...seeks to evaluate the threat regarding food fraud on the basis of the results reported by the participating countries. It also elaborates recommendations for the future of the initiative” (Note: the term economically motivated adulteration is not used). The sixth Operation Opson was concluded in 2016 which coordinated 61 countries and resulted in seizures of 9800 tonnes, over 26 million liters and 13 million items (INTERPOL 2017).

Operation Opson focuses on counterfeit food and beverages and substandard food and beverages:

- **“Food products [INTERPOL]:** are defined as any item or substance intended to be, or reasonably expected to be, ingested by humans or animals.”
- **“Beverages [INTERPOL]:** are defined as drinkable liquids, that is to say, liquids intended to be, or reasonably expected to be ingested by humans or animals.”
- **“A counterfeit food product [INTERPOL]:** is defined as a food product infringing an Intellectual Property Right. All intellectual property rights defined under the national and European law are included.”
- **“A substandard food product [INTERPOL]:** is defined as a product which does not meet the criteria required by European and national laws regarding its production, packaging, storage, and distribution. Generally speaking, it is a product of a quality inferior to that which is legally required under European and national standards.”

The Operation Opson team has worked with the GFSI organization including the GFSI Food Fraud Think Tank. At the 2013 GFSI conference in Barcelona, the Operation Opson team presented their role in food fraud prevention. Specifically, they identified an optimal role as a facilitator between many stakeholders.

Operation Opson meets the INTERPOL-Europol mission of coordinating law enforcement activities across international boundaries. As with the rest of the INTERPOL activities, there is an additional step of reaching beyond investigation and prosecution to prevention. There is an opportunity for a transnational focus on understanding the overall fraud opportunity to begin defining prevention policies and strategies. The goal is not to catch food fraud but to prevent it from occurring in the first place.

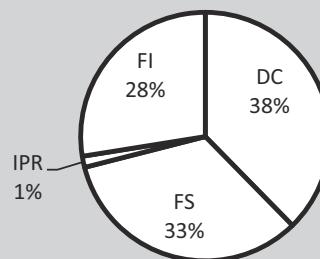
Sidebar: INTERPOL Opson—Shift from IP Counterfeit Emphasis to Food Fraud

For the food industry, IPR counterfeits are a concern and important to address, but the major focus of prevention and intervention is in other areas. The most important output or result from INTERPOL Operation Opson is the hard data and analysis of actual seizures. Over the years Opson has a shift from intellectual property rights counterfeit violations to an emphasis more on the maximum economic impact while prioritizing severe public health threats. The public health focus is demonstrated by the member countries that have sent representatives from the public health or food safety agencies rather than law enforcement or customs.

Table 13.3 INTERPOL Operation opson seizure results from 2017: table of results

Crime		
Deceiving consumer (DC), e.g., falsely labeled extra virgin olive oil	DC	26%
Food safety (FS), e.g., infringement related to storage conditions of the goods	FS	22%
Fiscal infringement (FI), e.g., alcohol duties	FI	19%
Intellectual property rights (counterfeiting) (IPRI), e.g., all IPR, including appellations of origins	IPR	1%

Fig. 13.4 INTERPOL Operation Opson seizure results from 2017: Pie chart of results



A food agency would prioritize a focus on “food laws” (e.g., UK Food Safety Act), while a “law enforcement agency” may focus more on “laws that apply to food” (e.g., money laundering, smuggling, counterfeiting). Many

(continued)

countries—and organizations including Europol and INTERPOL—have other operations that specifically focus only on intellectual property rights infringement. For example, Europol has operation “In Our Sites” (Europol 2018). INTERPOL has a range of activities including an annual “IP Crime Investigators College (IIPCIC)” (INTERPOL 2007).

This public health focus is evidenced in that less than 1% of the total operation seizures were categorized at IPR counterfeiting (Table 13.3 and Fig. 13.4).

Conclusion

This chapter covered the application of industry standards with a focus on the Global Food Safety Initiative (GFSI). The previous chapter on standards and certifications regarding the public-private-partnership provided a foundation regarding the current industry activities to address food fraud prevention. The actions are the new setting of standard operating procedures and are both influenced by and influence government and international responses. This chapter was built upon the previous concepts to explore the “why” and “how” these responses lead—or are leading—to action. ***The first conclusion*** is that there are often food fraud incidents that create the call to action for the governments or nongovernmental organizations. These trigger incidents do not follow a standard scope or impact but somehow create a response. For example, sometimes there is an underlying concern about food fraud, and as the focus grows to the point of major focus, an incident that may have previously gone unnoticed becomes the proverbial straw that broke the camel’s back. ***The second conclusion*** is that the growing focus on the food fraud problem has led to more rigorous and science-based reviews which will probably lead to a country—possibly a developing country—to create the most holistic, all-encompassing, integrated, efficient, and effective countrywide Food Fraud Prevention Strategy. That country could create a case study that becomes the template for the rest of the world. A developing country has more at risk so can less afford to wait. Also, a developing country has more immediate and direct benefits from reducing the fraud opportunity in both increased consumer satisfaction and economic growth from the confidence of citizens that their extra effort will be rewarded. ***The final conclusion*** is that collaboration and integration of concepts have occurred and will continue to evolve the focus from reactionary intervention and response to proactive prevention that reduces the fraud opportunity. Naturally, the initial response is within an individual scholarly discipline or a single agency. For example, in the USA, melamine in foods was a food safety incident, treated as a routine contaminant, and the FDA-focused response was to intervention and response. These types of efforts do not naturally expand from one discipline to another from the “bottom up.” Without an interdisciplinary focus on prevention, an

incident occurs over and over again. The international public and private response are continuing to mature and evolve to an interdisciplinary, collaborative focus on reducing the fraud opportunity.

Appendix: WIIFM Chapter on International Response

This “What’s In It For Me” (WIIFM) section explains why this chapter is important to you.

Business functional group	
WIIFM all	Foreign suppliers have same issue concerns, and the activities are based on some key issues that were presented—countries have had specific incidents that have led them to implement a wide variety of actions, and the specific problems help explain their priorities and sensitivities
Quality team	Same
Auditors	The FFPS may consider very global and very high-level issues and that is the most efficient and effective way to start—starting local is usually <i>not</i> the way to start
Management	This is just background on how laws and regulations have become a focus for individual countries
Corp. decision-makers	Same

Appendix: Study Questions

This section includes study questions based on the Key Learning Objectives in this chapter:

1. Discussion Question:

- (a) What are the characteristics of FF incidents that led governments to act (or not)?
- (b) What was the most significant global FF incident that sparked FF prevention efforts?
- (c) What is the level of international country-level collaboration on FF prevention strategy?

2. Key Learning Objective1

- (a) What is “the Elliott Review”?

- (b) What were the key FF incidents that impacted the European Parliament action?
 - (c) Explain “zero tolerance” and the challenges in the application?
3. Key Learning Objective2:
- (a) What is the Chinese “Negative List”?
 - (b) Explain if the PCA recall was a food fraud or food safety incident?
 - (c) What agencies have a high government set priority for FF enforcement and prosecution?
4. Key Learning Objective3:
- (a) What is Operation Opson?
 - (b) What are the enforcement and prosecution powers of INTERPOL?
 - (c) What are the key findings and results of Operation Opson?

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Chapter 14

Marketing, Competitive Strategy, and Competitive Intelligence



Summary

This chapter presents an overview of the marketing, competitive strategy, and competitive intelligence concepts that apply to food fraud prevention. The fraudster should be considered a competitor alongside the traditional marketplace adversaries. The fraudster is a business which makes business decisions, so they can be influenced or “dissuaded” from attacking a company, brand, or product. This chapter will provide a review of marketing and corporate strategy concepts before laying the foundation for selecting food fraud prevention countermeasures and control systems.

The Key Learning Objectives of the chapter are

- (1) **Competitor Analysis Overview:** This is an introduction to the basics, terminology, and the key theories. This is primarily based on Michael Porter’s work on corporate strategy.
- (2) **The Basic Factors in the Marketplace:** To begin to analyze the market and create a method for decision-making, this considers the attributes of the marketplace, consumers, and competitors.
- (3) **Scenarios that Help Define Countermeasures:** Reviews of the marketplace and consumer behavior can be understood by developing models of specific product and supply chain characteristics.

Introduction

Marketing as a science has rapidly developed as brands become more recognized and preferred by consumers in all four corners of the world. Social media and the spread of mobile technology are accelerating the popularity of brands. The increase

in brand awareness and brand demand has also increased the “fraud opportunity.” The expanding marketing through digital media combined with e-commerce sales and distribution is rapidly evolving and morphing the “fraud opportunity.”

The foundations of marketing theory are essential to cover before considering:

- (1) The fraudster as a competitor
- (2) The application to competitor analysis
- (3) Competitor intelligence gathering for targeted countermeasures.

One of the most basic and holistic concepts is Kotler’s “5 Ps of Marketing” which include Product, Price, Place, and Promotion, and then he considered People to be the underlying foundation (Kotler 2012). A key to his theory is “control” which means understanding, preparing for, and responding to market conditions. The four Ps combine to consider the overall objective of product “positioning”—especially if there is an evolving fraud opportunity or awareness of counterfeits in the marketplace—then this would be a potential threat to success. CFOs, general managers, and brand managers frequently understand “counterfeiting is bad” and “we should do something,” but the concern is usually not put into an immediately actionable form. In essence, the raw information (“we have a counterfeit problem”) is not processed into “actionable intelligence” (e.g., implement task “a” with test sensitivity “b” at point “c” to reduce the vulnerability to within the Enterprise Risk Management risk tolerance). So then the questions are:

- (1) How to understand the dynamics or factors of the fraudsters?
- (2) How to communicate in “marketing terms”?
- (3) Then how to evaluate “how much is enough”?

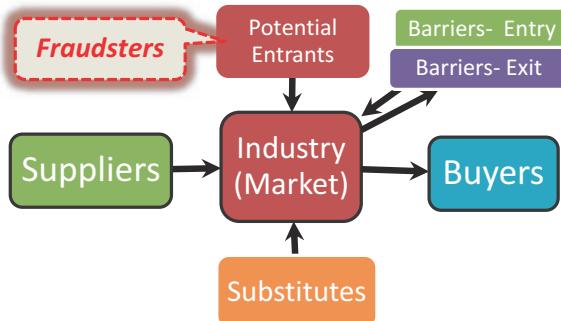
Key Learning Objective 1: Competitor Analysis Overview

This section reviews an overview of *Competitor Analysis* based primarily on the books of Michael Porter including *Competitive Strategy* and *Competitive Advantage* (Porter 1980; Porter 1985). These are basic principles to understand the dynamics of how businesses compete to find ways to influence the marketplace which also applies to the “fraud opportunity.”

The Key Learning Objectives of this section are:

- (1) Porter’s five forces analysis
- (2) The basic factors that drive the marketplace
- (3) The “decisional scope” for countermeasures or control systems

Fig. 14.1 Adaptation of Michael Porter's five forces analysis (expanded upon and adapted from Porter (1980))



Five Forces Model Applied to Food Fraud Prevention

While it may seem counterintuitive to consider fraudsters as a competitor and to assess their threat within a competitor analysis, it is logical and very efficient in strategy development.

Michael Porter is considered the godfather of corporate strategy after publishing the “five forces analysis” in his book *Competitive Strategy* (Fig. 14.1) (Porter 1980). The five forces define the rivalry or aggressive marketing within the industry. The greater the rivalry or competition in the market, the lower the profit margins. Porter states “The goal of competitive strategy for a business unit in an industry is to find a position in the industry where the company can best defend itself against these competitive forces or can influence them in its favor.” So, understanding the market—including the goal and role of fraudsters—is a fundamental component of the competitive strategy.

The five forces model includes the items below. These apply to a “competitor” whether it is another brand or a counterfeiter.

1. **Industry or market** (“rivalry among existing firms”): For food fraud, this is the brand owner who is the producer, manufacturer, and retailer.
2. **Suppliers** (“the bargaining power of suppliers”): For food fraud, these are the providers of incoming goods and outgoing goods.
3. **Buyers** (“bargaining power of buyers”): For food fraud, these would be downstream manufacturers or retailers who would then sell to the end consumer.
4. **Potential entrants** (“threat of new entrants”—new competitors): For food fraud, these are not only other legitimate company who produce similar products but also the fraudsters or counterfeiters who compete with genuine product sales. (Note: the “deceptive” and “non-deceptive” counterfeits are discussed in detail elsewhere in this book.)
 - (a) **Barrier to Entry:** For food fraud, these would be challenges to produce products, such as (1) procuring the funding to begin the entire operation; (2) procure the acceptable raw materials; (3) development of a recipe or formulation; (4) manufacturing and distribution; (5) insertion into the legitimate

supply chain; and (6) supporting the continuing criminal enterprise. Generally, Porter refers to major barriers including (1) economies of scale, (2) product differentiation, (3) capital requirements, (4) switching costs, (5) access to distribution channels, (6) cost disadvantages independent of scale, and (7) government policy. A counterfeiter who is already in a similar or identical industry would have fewer challenges with these barriers.

- (i) **For food fraud prevention:** Sophisticated or unique product or process attributes may decrease the “counterfeit ability” or “counterfeit profitability.” This is especially true of a product or process that is especially inexpensive for the brand owner to include. This is a key competitive intelligence insight that to add specific process steps that are easy or inexpensive for the brand owner may be a “countermeasure or control system” that decreases the business case for conducting fraud or attacking your company.
 - (b) **Barrier to Exit:** For food fraud, this would be the resistance to dismantle the probably capital-intensive fraudulent operation, which could include shifting to genuine products (“going legit”).
 - (i) **For food fraud prevention,** this is a key competitive intelligence insight into how to “dissuade” the fraudster from producing an illegal product and “encourage” them to “go legit.”
 - (c) **Competitors-Fraudsters:** It is efficient to expand the same competitor analysis from the legitimate competitors to the fraudsters. The basic market considerations are similar, though the countermeasures and control systems are often very different. Following another of Porter’s concepts is “Signal Your Intent” which is traditionally providing advance notice of expanding operations or manufacturing capacity, so other competitors do not also decide to add more capacity. When applied to fraudsters is a warning that they may get caught (reduced sales) and that there are better controls in place (increase their cost of producing the fraudulent product).
 - (i) **For food fraud prevention,** as with legitimate competitors, fraudsters will respond to a shifting market. Specific countermeasures and control systems change the business opportunity for the fraudster. With effective communication, the fraudsters can be “dissuaded” from attacking your product.
5. **Substitutes** (“threat of substitute products or services”): For food fraud, these are not only direct competitors of similar products but also alternatives. For transportation, a trucking company competitor would be another truck company and a substitute would be rail transportation.

Sidebar: “Learning by Buyers” to Reduce the Fraud Opportunity

In *Competitive Strategy* Porter discusses “Learning by Buyers” in terms of a tendency of products to evolve from unique or differentiated to become commodities (Porter 1985). Over time, the buyers learn to adapt their specifications and purchasing goals. “A buyer’s learning tends to progress at different rates for different products, depending on how important the purchase is and the buyer’s technical expertise. Smart or interested buyers (because it is an important product) tend to learn faster.”

Porter identifies a weakness where differentiation (with a premium price) gives way to commoditization (with a lower price). For food fraud, if the overall vulnerability is communicated so that a buyer becomes aware of the value of a reduced “fraud opportunity,” then food fraud prevention may help shift a commodity to a differentiated product. In certain situations, an informed buyer may determine that a differentiated, higher-priced product is actually less costly than a commodity product when considering Enterprise Risk Management and total cost of ownership. For example, if a higher-priced flavor is more intense or stable, this could result in fewer ounces of the ingredient being required in the recipe or for use in the manufacturing (see the Wal-mart sustainability examples).

Sidebar: Fraudster Decisions—Entry into New Businesses

Continuing with concepts from *Competitive Strategy* by Michael Porter, a fraudster is a business and subject to the business decision-making process. The fact that an action may be illegal is only one of many considerations for the fraudster. It is most efficient to consider the worst case that the fraudster is a criminal not concerned with breaking the law and a sociopath not concerned about cheating or possibly endangering consumers (if they intended harm, they would be a psychopath). Also, many fraudsters rationalize their actions with ideas such as “the consumers don’t notice anyway,” “the brands make some much money they’ll never miss this sale,” “our counterfeit product is just as good as theirs,” “our product has been and inspected, and “we’ve never been caught,” “they don’t look for counterfeits so they must not be concerned,” or others. The fact that the fraud is illegal is often just a minor consideration for the fraudster.

For food fraud, understanding these dynamics and decisions can help “dissuade” fraudsters from attacking a product or for even trying to attack an industry. “Some crucial economic principles identify businesses that are attractive targets for entry and help determine what company assets and skills will make an entry profitable” (note: this is an interesting opposite perspective but complementary prevention strategy to the criminology theories on hot products and hot spots that seek to reduce the attractiveness of a target) (Porter

(continued)

1985). Though the macroeconomic factors are significant, the final decision will be made on microeconomic factors unique to the fraudster. The fraudster operation is often exponentially smaller than the target brand or even the brand operating in a region.

With a focused strategy that considers the economic decisions made by the fraudster, there may be simple changes to the product, distribution, or consumer sales that increase the risk of getting caught or the cost of conducting the crime. The fraudster may be able to be “hassled” out of the market.

The two key concerns are:

1. Structural entry barrier.
2. Expected retaliation of incumbent firms.

For food fraud prevention, the “structural entry barrier” would be the ability to produce a high-enough-quality product to deceive consumers and access to markets to sell the product. The “expected retaliation of incumbent firms” is more than just lawsuits and government enforcement. The “expected retaliation” includes proactive changes that increase the chance of getting caught and the cost of producing the product. The response includes changing products that are hard to duplicate, tightening markets controls, and shifting buyer or consumer concern. The entire product and sales life cycle should be reviewed for a defensive strategy to identify efficient and effective countermeasures and control systems (e.g., consider the entire beef supply chain with a concern of horsemeat). For example, there may be one key new step that undermines the ability of the fraudster to succeed (e.g., build a lab and outfit with new equipment to implement a highly effective horse species test). Also, if this type of highly effective countermeasure is found, then it might be proactive to go ahead and implement this across all products (e.g., use contract labs to conduct random tests on incoming beef products).

For food fraud prevention, there is a unique balance of factors. Generally, the food industry is very concerned with “contaminants” (defined by Codex as unintentional ingredients at an unacceptable level) and “adulterants” (intentional unauthorized ingredients), especially those that lead to health hazards or product recalls. Also, the threat of retaliation by the brand owners should be considered “very high.” Then, generally, it appears that many food fraudsters are already producing food, so they have low entry costs, access to markets, and expertise in identifying fraud opportunities. The threat to the fraudster of detection for certain and specific fraud acts could be “very low.” By conducting a methodical and holistic market analysis—including on the decisions for entering a new business—there are often low-cost and straightforward countermeasures and controls systems that can significantly reduce the “fraud opportunity.”

With an active and efficient Food Fraud Prevention Strategy, the fraudsters may be “hassled” out of the market—trying to counterfeit this product may just be “too much trouble” at least compared to other products.

Competitor Analysis Factors

Competitor Analysis is a formal process or method to review other marketplace participants who challenge either the sales or margins of the product you sell. *Competitor Intelligence* is developing the analysis into actionable steps. Later, a corporate strategy is the system or cycle to review and manage the actions. Considering the “Food Fraud Prevention Cycle,” competitor analysis applies to the “scanning” step, and *Competitor Intelligence* applies in the “countermeasures” step. A competitor analysis—and there is no reason why it would not apply to a fraudster—includes (Hussey and Jenster 1999):

- **Marketplace Competitor Analysis Factors Applied to Food Fraud Prevention:**
- **Market share:** For food fraud, the question is: is the counterfeit product “deceptive,” taking direct sales from the brand (the consumer intends to buy the genuine product)?
 - **For food fraud prevention,** some fraudulent product is “non-deceptive” and is sold to consumers who are actually seeking counterfeit products, e.g., counterfeit luxury goods. These “non-deceptive” products would not offset a genuine product sale and do not lower the market price of the genuine good.
- **Price:** For food fraud, is the product undercutting the market price (with a lower price) or cannibalizing sales (taking sales at the same price)?
- **Brand positioning:** For food fraud, is the fraudulent product of high quality (a desirable product) or positioned as lower grade “substandard” or “non-deceptive” counterfeits? A problem could be if “deceptive” counterfeits were of lower quality and reduced the consumer satisfaction.
- **Advertising expenditure/customer acquisition:** For food fraud, is the fraudster either selling direct to buyers or comingling counterfeits in the legitimate supply chain? The direct sales advertising spend would be in terms of online spam emails, selling through online e-commerce auction sites.
- **Distribution coverage:** For food fraud, this would generally be where the fraudulent product is found in the marketplace.
- **Product line breadth:** For food fraud, whether fraud is occurring in only specific products or across the manufacturing steps.
- **Organizational structure:** For food fraud, are there large-scale fraudsters making similar products or many small operations making a wide range of products? There also may be a web of small suppliers making separate components that are combined later into larger operations.

- **For food fraud prevention,** the countermeasures are very different for different types of fraudsters and different types of fraud acts in different markets and supply chains. General global testing of the counterfeit product in a market will remove that product from the market and generally, incrementally, reduce the “fraud opportunity.” Specific testing on your receiving dock for a specific adulterant-substance—with a corporate policy to immediately report suspicious activity to US FDA, US FBI, and US Customs—will have a specific effect on your direct suppliers. General countermeasures generally help while specific countermeasures specifically help.
- **For food fraud prevention,** to note, if the product is determined to be illegal and seized by the government, then it would be logical that the invoice is null-and-void... you are not liable for paying the invoice, and the fraudster loses the of the entire shipment.
- **Manufacturing capacity and capability:** For food fraud, is there enough volume and quality of the production? Often, the counterfeit product is manufactured on legitimate manufacturing operations during a “fourth shift” or “ghost shift.” In other instances, a contract manufacturer may routinely cycle through the production of a wide range of brands so the local operations may not be aware the production is actually illegal.
- **Quality and customer satisfaction:** For food fraud, is the perception of quality and customer satisfaction lower for the fraudulent product? In some cases, the fraudulent product is of high quality—or at least at a quality level that does not lead to a reduction in customer satisfaction... *for now*.
- **For food fraud prevention,** if a counterfeit branded product was recalled would it impact the entire brand or just one product line or sales in one region?
- **For food fraud prevention,** to note, even though you did not make the counterfeit product, never touched it, never had a chance to authenticate it, and probably would have very limited legal liability... still, *your* product is recalled. *Your* product is withdrawn from the market.

Competitive Analysis: Scope of Response Decisions

Based on the urgency, there is a hierarchy of decision-making. These concepts can be integrated into a COSO-based Enterprise Risk Management (ERM/COSO) system. The analyses are defined by the urgency of a countermeasure and the breadth of the impact. Different levels in an organization address the specific analysis.

When a Food Fraud Prevention Strategy (FFPS) is in place, the different analyses provide valuable input across the Food Fraud Prevention Cycle (FFPC).

For food fraud, an incident or suspicious activity could quickly result in a product recall, so the analysis may often be much more urgent than for a typical competitor analysis. The “competitor analysis” could also be the same as an “incident review.”

The types of competitor analysis are included here, and readers will recognize similarities to the terms or concepts from Enterprise Risk Management (ERM/COSO) (Hussey and Jenster 1999):

- **Modes of Competitor Analysis Factors Applied to Food Fraud Prevention:**
- **Operational Competitor Analysis:** For marketing, this is an immediate issue and impacts functional details such as manufacturing more products or rushing deliveries to meet a customer order. The response is within the control of the firm, and the impact is operational. For food fraud, this could be testing inventory and in-process products for an adulterant-substance that is reported to be in the marketplace, e.g., testing for nut allergens in cumin after an FDA alert.
- **Tactical Competitor Analysis:** For marketing, this is an emerging issue of a competitor lowering prices, increasing production, or changing their supply chain. The response does not need to be immediate but may have a longer-term negative impact if not addressed. The response requires a more detailed analysis of the competitor or the market, and the internal response is usually tactical. For food fraud, this could be an awareness of a shifting fraud opportunity that could become a suspicious activity, e.g., changing garlic market prices that could lead to more food fraud. A countermeasure may be to review how garlic is used in manufacturing, how it is authenticated or certified, reviewing the supplier networks, and considering new or expanded garlic authenticity tests or traceability.
- **Strategic Competitor Analysis:** For marketing, this could be an awareness that a new competitor may enter the market, a product innovation could be under-development, or a regulation could significantly impact the supply of a raw material or finished good. The response would be a major corporate decision such as capital expenditure, and not responding could have a significant impact on the overall brand equity or even the viability of the firm. For food fraud, this could be conducting ongoing updates of the counterfeiter operations and products produced.
 - ***For food fraud prevention,*** for food fraud, it is important to address the urgent crisis but then to have a process for continuing to review the underlying root cause or system vulnerabilities. When there is new information, the first question should be “does this new information fundamentally change the way we understand our fraud opportunity?” The second question is then whether the changing fraud opportunity changes the vulnerability assessment and the position of this issue on the corporate risk map—specifically if the new information and updated vulnerability assessment shift the position of the issue to above with “risk tolerance.”

Key Learning Objective 2: The Basic Factors of the Marketplace

This section reviews the basic factors in the marketplace. These are factors that define the actions of the different players and how their influence is connected.

The Key Learning Objectives of this section are

- (1) A review of the competitor analysis theories
- (2) The potential responses to marketplace changes
- (3) Then a specific focus on defensive strategies that apply to food fraud prevention

Competitor Intelligence Foundation: Review of Theories

As summarized in the book *Competitor Intelligence*, several key theories form the foundation of competitor analysis (Hussey and Jenster 1999). The previous section on *Competitor Analysis* focused on the marketplace and modes action, whereas *Competitor Intelligence* is focused on how to understand the adversaries that could include fraudsters. The researchers focus on “individual/micro view” versus “societal/macro view” and “natural selection” versus “managerial choice.” The micro/macro view is consistent with food fraud prevention theory, where the fraudsters are impacted by macroeconomic factors, such as shifting market prices, but their final decision is based on microeconomic factors, such as their own access to adulterant-substances.

- **Resource view:** Hamel and Prahalad (1990) focused on how a company’s assets and capabilities provide gaps that competitors will attack (Hamel and Prahalad 1990). For food fraud, a fraudster’s resources cannot be judged very accurately and are often not a global factor since their value is individually very low—the resources of one fraudster are very small in relation to the entire global market. Also, the fraudster’s resource value is judged by the very unique and individual fraud opportunity. The global price of cocoa is a factor but nowhere near “the” deciding factor for an individual fraudster.
- **Positional view:** Porter (1985) and Day (1997) take a more proactive approach to build upon the “resource view” to support changes that create a more solid position for the brand in the market (Porter 1985; Day 1997). For food fraud, this may be to create relationships and supply chain security to reduce the fraud opportunity. This may also include implementing business efficiency tools that increase the transparency of each transaction as well as the product itself and the supply chain partners.
- **Game theory:** Teck and Weigelt 1997 examine “moves and countermoves of competitors” (Ho and Weigelt 1997). The competitors are rational and calculating. The underlying focus is on two competitors competing for the same prize.

For food fraud, this is inefficient to apply since it is not clear what game the fraudster is playing (e.g., adulterant-substance or stolen goods or tax avoidance smuggling) or even if the fraudster is now playing! Unless there is other intelligence, we don't know if the fraudster is attacking now. Furthermore, when we put countermeasures or control plans in place, the fraudster will usually be tipped off and then logically modify their attack... essentially not just changing how they are playing but would completely change the game they are playing.

- **Behavioral theory:** Meyer and Banks 1997 shift focus to how and why “cognitive and behavioral” factors, “including psychological biases and motivational forces,” impact decision-making (Hussey and Jenster 1999). For food fraud, this is challenging since there are so many variables for each fraudster. There is no one detailed specific type of fraudster. In criminology this would be focusing on the specific criminal (traditional criminology) and not the space of crime (crime prevention or Situational Crime Prevention).
- **Public policy view:** Areeda 1986 focuses on “what is legal/illegal” to help corporate strategy avoid concerns such as anti-trust issues (Hussey and Jenster 1999). For food fraud, this provides macro-level considerations of the source economy (where the fraudulent product is produced) and the market factors. The most important point is beyond what is “illegal” but on what is actually enforced and prosecuted. There are many countries with very strong intellectual property rights laws, but they only apply resources to enforce imported product, not products being exported. For example, the customs agencies for most countries have a much more thorough focus on monitoring and inspecting imported products rather than exports. Also, many countries are going through civil wars or other types of crises where the legislature or society could not justify a shift in resources from public health to intellectual property rights. The point is that the laws should be considered in relation to the level and efficiency of enforcement and prosecution to reduce the fraud opportunity.

Porter's work applies to food fraud prevention since the concepts are a balance of macro- and micro-factors with the managerial choice focus but also trying to change the underlying marketplace to influence natural selection. Porter's works combine these business theories with criminology theories (e.g., Situational Crime Prevention, routine activities theory, and rational choice theory).

The underlying theories are broadly researched, published in journals, and fundamentally sound. The Food Fraud Prevention Cycle (FFPC) and Food Fraud Prevention Strategy (FFPS) are an adaptation and application of many theories.

Competitive Analysis: Responses

There are a range of food fraud prevention responses that include offense, defense, or collaborate (Porter 1980, 1985; Hussey and Jenster 1999). The full Food Fraud Prevention Cycle (FFPC) should be considered when selecting risk treatments which would include the cost and potential for success.

- **Responses from Competitor Analysis**
- *Offense* would be attacking the competitor, such as by flooding the market with product. For food fraud, this could be investigating and prosecuting the fraudsters or otherwise disrupting their operations.
- *Defense* would be a deterrent to reduce the competitor benefit of attacking your product. For food fraud, this could be implementing countermeasures or control systems that increase the risk of getting caught or the cost of conducting the crime. For food fraud prevention, deterrence is combating a specific type of attacker and attack, e.g., actions that target the melamine adulterant-substance at bulk milk collection sites. Of course, detection is a crucial part of a deterrent but only if it is applied to a specific question. For example, testing for the melamine adulterant-substance across the market is helpful but is not a targeted approach.
- *Collaborate* would be to merge or form a partnership with the competitor. For food fraud, this may not seem like an option, but there are stories of brand owners who sought new contract manufacturers who were suspected to be the provider of high-quality counterfeits.

While going on the “offense” may feel like the most rewarding and impactful response, the nature of the fraudsters and the fraud is such that the actual reduction in the fraud opportunity is negligible compared to prevention efforts. While it is essential—*critical*—to pursue enforcement and prosecution, it plays only a minimal role in prevention. Fraudsters don’t think they will get caught.

For example, suing and prosecuting a fraudster is important but could be extremely costly (e.g., international courts, a long case, complex discovery process, expensive and long-term evidence storage costs, etc.) and provide little financial return (e.g., the criminal may have spent all the money or already laundered it in a secure location as well as a traditionally low repayment), and another criminal could quickly replace the gap left by the fraudster (see US Guidance for US Attorneys for prosecuting IP cases).

The “collaboration” is often not a direct option when addressing product fraud since the partners are criminal organizations.

The response that is most efficient and effective is “defense” or prevention. While the competitive analysis will start with understanding the fraudsters as a competitor, the countermeasures and control systems should shift to leverage criminology and specifically Situational Crime Prevention. Crime prevention has been adequately developed, implemented, and studied. With an ongoing competitor analysis, the criminology theories can be instrumental in reducing the “fraud opportunity.”

The goal is to change the operations and market, so the fraudsters do not find an attractive “fraud opportunity.” The countermeasures and control systems do not need to be perfect and cannot be impenetrable, but they need to be just enough of a hassle or danger to “dissuade” the skittish fraudsters from acting. There are plenty of fraud opportunities in the world, and an effective Food Fraud Prevention Strategy can be light as long as it is very focused.

Competitor Analysis: More on Defensive Strategies

In *Competitive Advantage* Michael Porter reviewed “defensive strategies” that are adapted to combat the fraudsters (Porter 1985). He stated “Every firm is vulnerable to attack by competitors. Attacks come from two types of competitors – new entrants to the industry and established competitors seeking to reposition themselves” (Porter 1985).

An incredibly important point that applies to strategy but also to financial decision-making and return on investment (ROI) is that reducing a risk or vulnerability is not seen as “strategic” or a main function of the business. “Instead of increasing competitive advantage *per se*, the defensive strategy makes a firm’s competitive advantage more sustainable.” So to be realistic, presenting fraud reduction projects are essential but will be less understood and be less exciting than other options (Fig. 14.2). This is a significant reason why it is best to focus the justification on the ERM problems that are above the risk tolerance rather than increased benefits such as reducing counterfeits to increase sales.

The fraudster’s goal is to make money, so the financial factors should be the prime focus of the defensive strategies. The defensive strategies apply to food fraud prevention when the goals are to:

- **Lower the probability of attack:** For food fraud, this could be increasing the fraudsters’ risk of getting caught or the cost of conducting the crime. This is classic crime “prevention” or “reduction.” Examples could be to increase the complexity of the recipe, authentication technologies, or packaging that is required by the fraudster to deceive the buyer or consumer. Other options could be channel blocking by strengthening the connection with buyers such as direct shipments, stronger distribution relationships, or more robust traceability systems. In addition, using formulations or manufacturing that requires massive “minimum economic scale” can both challenge the required capital expenditures and also increase the production volume needed for the fraudster to compete.
- **Divert attackers to less threatening avenues:** For food fraud, there is more of a goal “dissipate” or eliminate fraud opportunity of the crime rather than “displacement” to another time, place, or target. That said, countermeasures and control systems could focus on the highest and most impactful fraud opportunity so fraudsters “don’t even try” to attack specific products or markets.

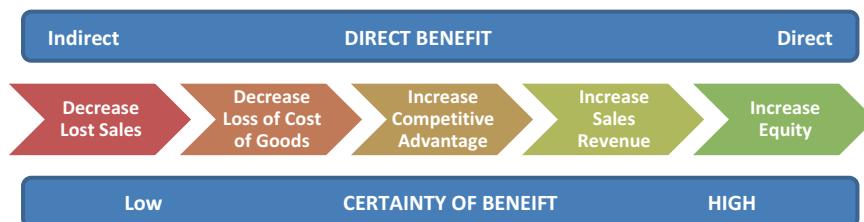


Fig. 14.2 Relationship of benefits and certainty of business losses

- **Lessen the intensity or impact of the attack:** For food fraud, this could be increased rapid detection or to shift the criminals to lower volume or less risky products. This is classic risk mitigation—reducing the impact of an event when it does occur.

A key focus should be on increasing the fraudsters' awareness that there are countermeasures and control systems in place and that there is an increased risk of getting caught and the increased cost of conducting the crime. Porter refers to this a “Signal Commitment to Defend” which is:

- **“Announce intentions by management to defend marketshare in the industry”:** For food fraud, this could be subtle mentions of food fraud prevention in supplier agreements or contracts that announce or allow authenticity testing.
- **“Corporate pronouncement of the importance of a business unit to a firm”:** For food fraud, this could be statements of the commitment to food fraud prevention including actions, countermeasures, prosecution, etc.
- **“Announcement of intention to build adequate capacity ahead of demand”:** For food fraud, this would be statements that demonstrate long-term, future, sustained commitment to implementing and evolving the Food Fraud Prevention Strategy.

While it may seem that a lot of complex and resource-intensive proposals have been presented here, in reality, after the vulnerability assessment and strategy have been developed, the first and most impactful countermeasures and controls systems are usually minimal. Elsewhere it has been noted that probably 99% of the necessary audits, information, inspections, programs, and processes are already in place but just not organized within the Food Fraud Prevention Strategy (FFPS). A systems approach and perspective can lead to a straightforward yet effective reduction of the “fraud opportunity.”

If the competent detection programs are put in place with no consideration of communication to the bad guys, then you will catch bad product but not prevent it from getting into the supply chain. There is a saying:

“Remember, the goal is not to catch food fraud but to prevent it in the first place.”

Sidebar: ERM for Defensive Strategy Decisions—What Must Be Done and How Much Is Enough

The fraud vulnerability is framed in Enterprise Risk Management (ERM) terms, where if a “lost sales” situation is above the “risk tolerance” of the enterprise, and then the ROI of other projects is irrelevant. If the new incident is above the “risk tolerance,” then the resource allocation decision-making is the “ROI” of only reducing the current situation back to within control.

Without first establishing the vulnerability on the corporate risk map, there is no tangible, measurable argument that this is a problem that needs to be addressed (e.g., no consequence for *not* acting) or “how much is enough”

(e.g., a bottomless pit of “how little do you dare to do” or “what’s the minimum to make it look good”). In some cases, the ERM system will allow more risk-taking, but the real result is that there is a logical and process-based method to determining “what must be done” and “how much is enough.”

Competitor Analysis: Tests for Evaluating Defensive Tactics

Porter provides a series of tests for evaluating the effectiveness of defensive tactics (Porter 1985):

- **“Value to Buyers”:** While the main focus of food fraud prevention is reducing your own fraud opportunity, Porter makes a good point that “A tactic directed toward buyers will not be effective for defensive purposes unless the buyer values it.” For maximum value, the prevention strategy should be clear, and the buyers should be educated on why this is important. For maximum impact, buyers should be made aware of and educated to value the countermeasures and control systems. Also, the new, expanded, or new resource requirements need to be included in the buyer key job responsibilities and success metrics (see Wal-mart Sustainability section).
- **“Cost Asymmetry”:** Countermeasures and control systems should be selected that create the “greatest relative cost disadvantage” for the competitor. For food fraud, this could be including a complex technology or process that is already implemented in other parts of the firm but are very different from usual fraudster manufacturer operations.
- **“Sustainability of Effect”:** To be most efficient, tactics should be selected that have a longer-term effect. For food fraud, the fraudster response should be considered. The fraudsters *will* respond and adapt. There is a saying: “The chess match of food fraud prevention should consider ‘how *will* the fraudsters circumvent this system and when *will* it occur.’” That said, in some cases, there can be so many efficient and costly countermeasures and control systems that increase the fraud opportunity so much that the fraudster shifts to another target company.
 - From criminology, while considering the first move to address the fraud, there should be an awareness that the food fraudsters may be operating within the legitimate supply chain so their temptation—or routine activities—may lead their fraud to adapt. **Adaptation** (criminology): “refers to a longer-term process whereby the offender population as a whole discovers new crime vulnerabilities after preventive measures have been in place for a while. Paul Ekblom, Ken Pease and other researchers often use the analogy of an ‘arms race’ between preventers and offenders when discussing this process. So, in time, we can expect many crimes that have been reduced by preventive measures to reappear as criminals discover new ways to commit them.” (For more see Ekblom (2013) and Clarke and Newman (2005).)

- **“Clarity of Message”**: “A firm should select defensive tactics it is confident that potential challengers will detect and will understand the implications.” The bad guys need to understand they have in an increased chance of getting caught. The bad guys need to be “dissuaded” from attacking you. If they don’t understand—or don’t believe—your threat of action, they will keep attacking.
- **“Credibility”**: From Criminology, there is an “anticipatory benefit” where criminals will reduce their crime when there is an announcement of additional investigation or scrutiny (Smith et al. 2002; Clarke and Eck 2014). The benefit will last for a short while before the criminals will check the actions. For defensive strategies the tactics should be believable and actually increase the risk of getting caught, the implementation should be demonstrated, and the bad guys should view them to be permanent or long-lasting.
- **“Impact on Competitors’ Goals”**: The countermeasure and control systems should be as measurable as possible. This is very difficult for vulnerability reduction activities, but leverage quality management principles could be a foundation. For example, a quality management system does measure the final output (e.g., number of fraud incidents) but really focuses on the precursor root causes of nonconformance (e.g., a wire connection is weak, so the link is redesigned and checked during manufacturing). For food safety and HACCP, this is identifying critical control points and monitoring compliance (e.g., a refrigerator is kept at a constant temperature). For food fraud, there could be other critical control points that are monitored (e.g., every spot buy, emergency raw material ingredient purchase passes a full-spectrum, nontargeted, authenticity test).
- **“Matching by Other Incumbents”**: If more market participants include similar countermeasures and control systems, the entire supply chain should become more secure and reduce the “fraud opportunity.” If best practices are shared, and resources are combined, then innovations could further reduce the vulnerabilities. A fraud incident hurts the entire market.
- **“Other Structural Effects”**: This is not just an “other” category but is a focus on leveraging—or at least supporting—other business operations and countermeasures. For example, a supply chain logistics program could include tamper-evident tags to secure truck trailers. The record of the feature being secured is valuable to reduce the fraud opportunity, and maybe an incremental action of tracking the time between close and open could provide benefit for both the security and the fraud reduction.

After reviewing the interdisciplinary strategies from marketing, criminology, food science, and others, it becomes more clear that defensive tactics are the most efficient and effective countermeasures and control systems. Also, once the basic business factors are considered, there is an important insight that the “fraudster” is just another “competitor.”

Key Learning Objective 3: Scenario Development that Helps Evaluate Countermeasures and Control Systems

This section reviews the scenario development that will help to understand the interaction of the factors and dynamics to help identify the most efficient and effective countermeasures and control systems.

The Key Learning Objectives for this section are

- (1) Understand scenario development
- (2) Review food fraud prevention scenarios
- (3) Consider the development of unique scenarios.

Industry Scenarios: Response

In *Competitive Advantage*, Michael Porter emphasizes the value of creating a series of “industry scenarios” to address uncertainty. The process identifies the concerns, assumptions, variables, and then to gauge the estimated financial impact. Porter provides guidance on the range of scenarios that provide a full insight on the problem which includes worst case, best case, then the most likely case, or, more appropriately, several most likely cases that are based on several fundamental assumptions or variables.

For food fraud, the scenario planning would consider a range of issues such as:

- Increased government scrutiny.
- Major incidents that create consumer concern for a specific product.
- Increased testing technology that identifies an unknown fraud act.
- Changes in the legal liability from lawsuits.
- Changing supply that creates new or emerging vulnerabilities.
- Changing consumer preference for a product with a higher fraud opportunity.
- And many others.

These industry scenarios are helpful when formulating the forward-looking “corporate strategy.” To benefit from opportunities and avoid losses, there should be a dynamic link between the industry scenarios (e.g., the underlying shifting assumptions, variables, etc.) and the corporate strategy. The corporate strategy would direct actions that optimize the outcomes for each of the scenarios or as many as practical. There may be a scenario where the future is too risky, and a quick exit may be the best strategy.

Porter presents five basic scenario responses for dealing with the uncertainties (Porter 1985):

1. **Bet on the most probable scenario:** This is predicted to be the most likely future state so the corporate strategy would focus on this scenario but with a balance and consideration of other futures. The level of confidence in this scenario will

dictate how much focus is allowed here. It is dangerous to focus *only* on this scenario.

2. **Bet on the “best” scenario:** This scenario has the highest return so—if this does occur—the firm should be prepared to excel. Of course, in an ideal world, the “most probable” and “best” are the same. Longer-term corporate strategy can help the firm evolve their market position to this ideal spot.
3. **Hedge:** A more significant focus here is on satisfactory results under all of the scenarios. This is an ideal option when there is considerable uncertainty in the marketplace, society, consumer preferences, or regulations. This is sometimes referred to as “minimax,” where “a player makes the move that minimizes his maximum loss” (Porter 1985).
4. **Preserve flexibility:** Here final decisions are held off as long as possible to wait until uncertainties are more apparent or variables have revealed themselves. This is sometimes referred to as a “fast follower.” “A firm preserving flexibility often pays the price in their strategic position because of first-mover advantages gained by firms that commit early.” Sometimes the “fast follower” requires a very fast, costly, and haphazard response. Conversely, early movers can put processes in place that increase the barriers to entry for the fast follower.
5. **Influence:** Here the firm uses the longer-term vision to try to encourage or change the future direction. This may include collaboration in industry associations, supporting technological changes, channel policies, government regulation, and other influence of causal factors. “Since a causal factor in casual user demand for chainsaws is wood burning stove installations, a firm might try to influence stove demand. This might involve coalitions with wood burning stove manufacturers, or advertising that stressed the value of wood-burning stoves at the same time that it advertised chainsaws.” This strategy can be very costly and time-consuming and take focus from other more direct actions, and the final influence is hard to measure.

Two primary considerations in setting corporate strategy—or how much to focus on each scenario—are (1) degree of inconsistency of strategies for alternate scenarios and (2) relative probability of the scenarios. If there isn’t much difference between the worst and best scenarios, then there is less benefit to influencing factors. Also, if there is a scenario that has a high probability—or if they all exhibit great uncertainty—then there may also be less benefit to hedging or influencing.

Methods of Competitor Analysis

The best model to use for competitor analysis is one that is fully implemented and already used at your company. It is recommended that you find the method and review the content. Use the method for your own assessments and analysis in developing the Food Fraud Prevention Strategy. After refining the analysis and applying it in your company’s system, only then is it recommended to engage the marketing

team. Adding fraudsters or counterfeiters to the formal and official competitor analysis will sound absolutely crazy until they see an example, completed, and implemented.

The process for conducting and updating a competitor analysis is similar to the updates for the FFPC steps of Incident Review, Scanning, and Public Policy.

1. Define the question, the process, and how the result will be used
2. Consider if there is enough of the right information to address the specific question
3. Assign an accountable party or person
4. Identify the sources of information
5. Assign a function to monitor sources of information
 - (a) External
 - (b) Internal
 - (c) Market research
6. Review the new information in relation to the fraud opportunity, to vulnerability assessment, and to plot on the corporate risk map.

Whether your company formally includes fraudsters as competitors or not, this is an effective resource for your Food Fraud Prevention Strategy (FFPS).

Case Study: Market Share of Fraudsters in the Food Flavor Industry

The book *Competitor Intelligence* included a chapter on “The World Flavor Industry” (Hussey and Jenster 1999). One section reviewed the market shares (Hussey and Jenster 1999). The specific companies and names are not important, so only abbreviations are included. There is a common estimate that the general worldwide counterfeiting is “5 to 7%.” If that estimate is applied to the market and then the total of counterfeits, then counterfeiters, as a whole, could be the sixth to the 11th largest competitor (Table 14.1).

While this general estimate of “5 to 7%” is easy to apply to a table like this, the real fraud opportunity is harder to assess. First, the approximately \$130 million sales at the 5% market share level are probably not from one company and actually could be from literally thousands. Second, the same type of fraud is probably not occurring at each company, so there is probably no single countermeasure or control system that will address all fraud. Finally, this global, general estimate does not consider the nuance of unique supply chains or specific supplier-buyer countermeasures and control systems.

So, it is efficient to compete against your total vulnerability rather than against each individual fraudster while realizing that each fraudster is not influenced in the same way by the macro- and micro-factors. The most efficient and effective activity

Table 14.1 Example of market share of product fraudsters in the food flavor industry—all fraudsters are combined into one estimate

Company	Sales (\$ millions)	Percent
A	328	12%
B	298	11%
C	221	8%
D	206	8%
==fraudsters if 7%	188	
E	163	6%
F	150	6%
G	145	5%
==fraudsters if 5%	130	
H	125	5%
I	120	4%
J	119	4%
K	100	4%

Adapted from Hussey and Jenster (1999)

is to try to understand common influences or motivations. The fraud opportunity is the attractiveness of your company for an attack. The one area where you have the most clarity and control is your company as a target. “Target hardening” is under your control.

This case study is an example of why the individual fraud opportunity should be considered not only for selecting countermeasures but also for even making the first, high-level, “10,000 foot” estimates of the problem.

Conclusion

The product and food fraud problem is very complex and based on a wide range of problems from across the legitimate and illegitimate supply chain, and thus the response is interdisciplinary. A subset of marketing is competitive strategy including competitor analysis. *The first conclusion is* that for business people who study business activities—including product and food fraud—it is logical to conduct specific studies of the patterns and responses by the adversary. For criminologists studying crime, it is logical to understand routine activity theory and rational choice theory. The logical expansion is to consider the counterfeiter as a competitor. *The second conclusion is* that a critical aspect of competitive strategy is to understand inherent vulnerabilities. While attacking and growing in the market, it is also essential to consider vulnerabilities and defend current positions. The logical expansion is to not only protect the products and prosecute the criminals but also to consider actions that reduce the fraud opportunity—increase the risk of getting caught or the cost of conducting the crime. *The final conclusion is* that the theory is put into

action by first considering overall strategy scenarios and also of building model scenarios to review specific incidents. It is efficient to consider the counterfeiter as a marketing competitor.

There is a saying:

“Why not just consider the fraudster as another competitor? The logical and methodical step would be to include fraud business ‘barriers to entry’?”

Appendix: WIIFM Chapter on Marketing

This “What’s In It For Me” (WIIFM) section explains why this chapter is important to you.

Business functional group	Application of this chapter
WIIFM all	Overall, this chapter provides an introduction and insight on the part of the food fraud prevention strategy that may not have been considered which is classifying the fraudster as a business competitor
Quality team	This chapter provides a structure to review and evaluate the fraud opportunity as well in terms of market position and of the fraudster as a business competitor
Auditors	This chapter mainly provides an overview of how companies must position and then create their food fraud prevention strategies to address fraudsters as business competitors
Management	This provides an explanation of why and how marketing should consider the counterfeitors as a competitor
Corp. Decision-makers	Generally, this provides a Michael Porter-based— <i>Competitive Strategy</i> and <i>Competitive Advantage</i> —Overview of how competitors are assessed

Appendix: Study Questions

This section includes study questions based on the key learning objectives in this chapter:

1. Discussion Question.
 - (a) Why does marketing science provide valuable insight for FF prevention?
 - (b) How does FF prevention benefit from competitor strategy and competitive analysis?
 - (c) Why is it efficient to consider the fraudster as just another business competitor?

2. Key Learning Objective 1.

- (a) What is a “Five Forces Analysis”?
- (b) Why does a “Five Forces Analysis” apply to FF prevention?
- (c) How is the “Five Forces Analysis” a vital resource for selecting countermeasures and control systems?

3. Key Learning Objective 2.

- (a) What is “Competitive Analysis”?
- (b) How do “Competitive Analysis” defensive strategies apply to FF prevention?
- (c) Why does “Certainty Of Benefit” hinder resource allocation for addressing FF prevention?

4. Key Learning Objective 3.

- (a) What are “Industry Scenarios” in a business strategy?
- (b) How is a “Competitive Analysis” method approach applicable for FF prevention?
- (c) How do each of Porter’s “Five Basic Scenario Responses” apply to FF prevention?

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Chapter 15

Risk Analysis (Part 1 of 3): Basic Fundamentals



Summary

This chapter presents risk assessment and the broader concept of risk analysis. This chapter will introduce the foundational concepts as well as general applications, review key issues such as hazard identification, risk assessment, risk management, and risk communication. In addition this will include the information used to conduct the assessments such as data analytics (“Big Data”) as it relates to decision-making and the role in food fraud prevention.

The Key Learning Objectives of this chapter are

- (1) **Fundamentals:** Understand the fundamentals of risk analysis that apply to food fraud.
- (2) **Adaptation to Food Fraud:** Understand how those fundamentals are adapted to the unique attributes of the variables.
- (3) **Tools and Models:** Finally, understand current tools or models.

On the Food Fraud Prevention Cycle (FFPC), this chapter addresses the “(0) Fundamental Concepts” beyond what is risk analysis to the details of risk assessment as applied to food fraud prevention (Fig. 15.1).

Introduction

Risk assessment is a specific function within the concept of risk analysis. The entire process includes gathering information and processing it into a useful and reliable form. The fraud opportunity for food—and more generally to all product fraud—is unique and adds multiple layers of complexity. That is, there are multiple systems that interact to increase the complexity of the problem and sophistication needed to put efficient and effective countermeasures and control systems in place. For example, food safety risk assessment deals with a specific set of hazards and variables. Traditional supply chain management looks within finite systems and deals with a

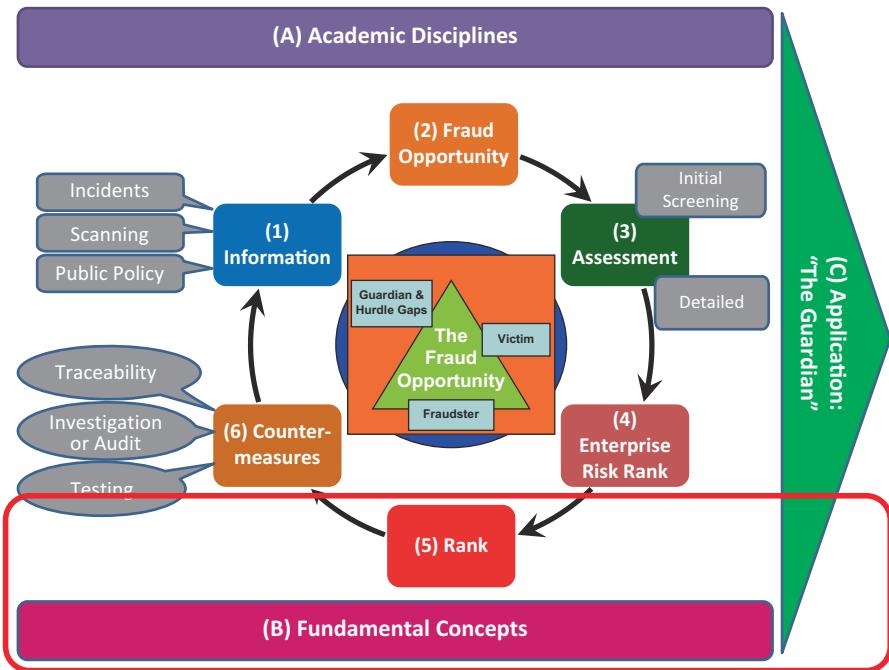


Fig. 15.1 Food Fraud Prevention Cycle—where this chapter applies to the overall concept: “(B) Fundamental Concepts” and “(5) Risk”. (Copyright Permission Granted) (Spink 2014; Spink et al. 2019)

different set of variables. To consider the root cause—the human adversaries—this adds a new set of variables from criminology. Then, when decision sciences apply all the variables, the complexity expands again.

In general, the risk analysis and basic assessment concepts are essential for food fraud prevention because:

- Foundation: There needs to be an underlying foundation to understand and evaluate the vulnerability.
- Value of Information: Without a deeper understanding of the usefulness of the information, subsequent assessments could be misleading or false.
- Unique Considerations: There are unique considerations that must be defined before even considering modeling. These include risk versus vulnerability and mitigation versus prevention.
- Share Best Practices: Finally, rather than starting with a novel approach, it is best to adapt other currently implemented systems to food fraud prevention.

This chapter is a key component in the theoretical foundation of food fraud prevention.

Key Learning Objective 1: Introduction to Risk

This section reviews the fundamentals of risk analysis, the concepts such as risk versus vulnerability, and then the founding discipline of decision sciences.

The Key Learning Objectives of this section are

- (1) Risk analysis
- (2) Review of terminology
- (3) Review of the many types of risks

Introduction to Risk Analysis

The overall risk analysis is not a quantitative analytical number or value—through a specific tool could present a ranking for a specific question—but judgement of “what could happen, how likely it is to happen, and what the consequences are if it does happen” (Kaplan 1997; CFSAN 2002, 2003; FDA 2003; CFSAN 2005; CBER 2006; CFSAN/FDA 2007). Risk analysis consists of four concepts including hazard identification, risk assessment, risk management, and risk communication (Figs. 15.2 and 15.3). This is a cycle that is constantly in motion and continually adjusted.

A significant challenge for starting risk analysis for a new type of risk such as food fraud is breaking from a current paradigm and standard scope and method (e.g., a traditional food safety risk assessment or a traditional crime assessment). New risks are initially attempted to be addressed, logically, by currently implemented

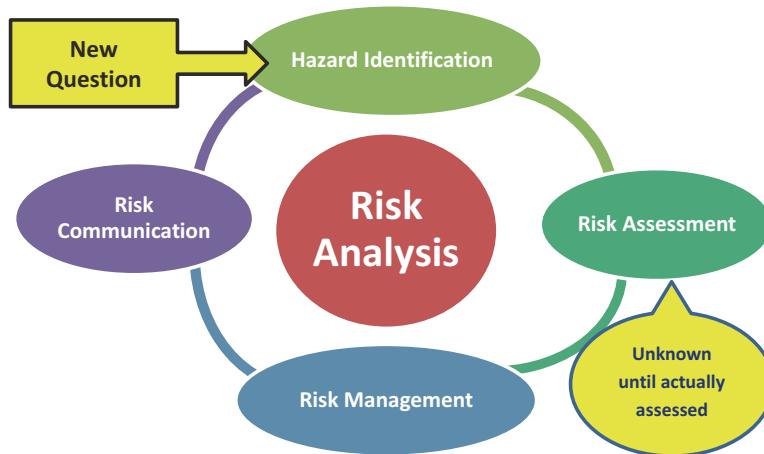


Fig. 15.2 Risk analysis cycle including hazard identification, risk assessment, risk management, and risk communication



Fig. 15.3 Hierarchy of information and response: suspicious activity/question, problem, vulnerability, risk, and hazard

systems. These previous systems address them until it is proven a new paradigm is needed.

As there is more awareness of novel or evolving risks, the old methods may become ill-fitting tools. When a new topic is addressed, there is often a lack of historical data or even a lack of knowledge of how the information will be used (Cruz 2002; Van Der Fels-Klerx et al. 2002). “A common challenge faced in risk assessment is a lack of appropriate historical data, a basic lack of knowledge important in decision-making and data that is not yet available” (Spink 2009). Also, “One common method used for taking the first step is peer consultation or expert panels” (Spink 2009). Peer consultation has been standardized in the “Delphi Method” which was originally developed by the RAND Corporation after World War II (RAND 2018).

A danger when dealing with new or emerging risks is that the previous methods—and even the assumptions about the availability of the “right” data—no longer apply. Underlying issues include understanding the nature of risk, uncertainty, and vulnerability.

For *food fraud prevention*, the entire cycle should be understood as well as the challenge of including a new hazard as well as new needs for data collection.

Introduction to Risk and Vulnerability: Foundational Terms

While it seems very simplistic to provide definitions for the most basic concepts, it has been determined by experience as a critical first step when addressing food fraud. Often there are different definitions—often unknowingly—applied. There is an expectation that “everyone” knows what that word means. While you may not agree with the exact definition provided, you at least can clearly see how the term is being used.

A first consideration is how do we refer to new information or concerns. Criminology has a logical starting point with a consideration that it applies to all responses not just the actions or responsibilities of the police (Clarke and Eck 2005):

- **Problem:** “...the basic unit of police works rather than a crime, a case, calls, or incidents. A problem is something that concerns or causes harm to citizens, not just the police. [...] Addressing problems means more than quick fixes: it means dealing with conditions that create problems” (Goldstein 1990).

These next definitions are from a previous research project was conducted on the definition and scope of several key terms (see that article for full citation details that are within the quoted sections) (Spink et al. 2017):

- **Event:** “An event is essentially something that occurs (summarizing: ISO31000; CNSSI 2010; Merriam-Webster 2004). There is no evaluation yet of the change in the consequence.”
- **Incident:** “A type of event is an incident that has occurred and evaluated, and that could have a negative consequence (DHS 2008; ANSI 2009; CNSSI 2010).”
- **Vulnerability:** “[A] weakness or flaw that creates opportunities for undesirable events related to the system (“system design”) (ISO 2007a; ISO 2002, 2012; DHS 2013; NIST 2011; CNSSI 2010; NRC 2009; COSO 2014; Merriam-Webster 2004). The result of a vulnerability assessment is usually a qualitative statement of the susceptibility of the system e this influence the likelihood (NRC 2009).”
- **Risk:** “Risk is an uncertainty of an outcome that is assessed in terms of likelihood and consequence (ISO 2007a; NIST 2002; CNSSI 2010; DHS 2013). Often the consequence is sub-divided to other factors such as onset, severity, or other. Risk is a based on factors of the probability of the threat and the susceptibility from vulnerability (NRC 2009). In other applications, it is an unwanted outcome (DHS 2008; Codex 2014, 21 CFR 50 (A) (.3)(k), Merriam-Webster 2004).”
- **Hazard:** “Also, a hazard is an event that has not occurred and could cause harm if not addressed (ISO 2007b; PAS 96 2014; NRC 1996; 21 CFR, Merriam-Webster 2004) -- this includes damaging potential (ISO 2007b). For food, this is often applied to unintentional events that have potential to harm. A new note to add is that the US FDA further defines an unacceptable level of protection as a “hazard that requires a preventive control” (FDA 2015) (for more on the appropriate level of protection see (WTO 1995; CODEX 2003)).
- **Threat:** “...is the cause of an unwanted event that includes generally known variables or attributes of the source of the negative consequence (“threat source”) (ISO 2012; ISO 2002; 21 CFR 121, ANSI 2009; PAS 96 2014; FSMA 2016; NIST 2002; CNSSI 2010; UNODC 2010; DHS 2013) – this includes incident, hazard, damaging potential, etc. In crime and security science, this is often a person(s) who have the intent and capability to cause harm. This is often applied to intentional acts with the intent to harm. The result of a threat assessment is usually a quantitative probability that the event to occur – but not an assessment of the consequence.”

- **Mitigation:** “...is intended to reduce the consequence of the event (ISO 2007a, b; ISO 2007; DHS 2013; Merriam-Webster 2004). This assumes the hazard event will occur, so the goal is to mitigate or reduce the negative consequence. This focuses on reducing the risk that cannot be eliminated.”
- **Prevention:** “...is intended to reduce or eliminate the likelihood of the event occurring (ISO 2007; ISO 2007a, b; ISO 2008; Merriam-Webster 2004). This focuses on identifying and eliminating or reducing vulnerability.”

Building on these definitions and applying to food fraud (Spink et al. 2017):

- **Food fraud vulnerability:** “...is the susceptibility of a system to food fraud (e.g., milk is not tested for adulterants such as water).
- **Food fraud threat:** “...is the cause of a food fraud event; e.g., a criminal could dilute milk with water and then sell to a deceived customer.”
- **Food fraud risk:** “...is the combined likelihood and consequence e that considers the threat and vulnerability e of food fraud. This is a function of the vulnerability and threat; e.g., an estimate of the likelihood and vulnerability and threat; e.g., an estimate of the likelihood and consequence of milk diluted with water, sold to a deceived customer.”

From this review of definitions, there is more clarity on the current activities (focus on risk and mitigation) and the ideal future state (focus on vulnerability and prevention).

Other related terms defined in ISO 31000 include (ISO 2009):

- **Control:** “measure that is modifying.”
 - “Note 1 to entry: Controls include any process, policy, device, practice, or other actions which modify risk.”
 - “Note 2 to entry: Controls may not always exert the intended or assumed modifying effect.”
- **Probability:** “measure of the chance of occurrence expressed as a number between 0 and 1, where 0 is impossibility and 1 is absolute certainty.”
- **Frequency:** “number of events or outcomes per defined unit of time.”
 - “Note 1 to entry: Frequency can be applied to past events or to potential future events, where it can be used as a measure of likelihood/probability.”

When focusing on how to address risks and determine “how much is enough” for countermeasures and control systems, ISO 31000 Risk Management presents several key concepts (ISO 2018):

Addressing risk perception (ISO 2018):

- **Residual risk:** risk (2.1) remaining after risk treatment (2.25) [SOURCE: ISO Guide 73:2009, definition 3.8.1.6]
- **Risk acceptance:** informed decision to take a particular risk (1.1) [ISO Guide 73]; Note 1 to entry: Risk acceptance can occur without risk treatment (3.8.1) or

during the process of risk treatment; Note 2 to entry: Accepted risks are subject to monitoring (3.8.2.1) and review (3.8.2.2).

- **Risk aggregation:** a combination of a number of risks into one risk (1.1) to develop a more complete understanding of the overall risk [ISO Guide 73] [Note: also referred to as risk summing or risk overview.]
- **Risk appetite:** amount and type of risk (1.1) that an organization is willing to pursue or retain [ISO Guide 73]
- **Risk attitude:** organization's approach to assess and eventually pursue, retain, take or turn away from risk (1.1) [ISO Guide 73]
- **Risk aversion:** attitude to turn away from risk (1.1) [ISO Guide 73]
- **Risk perception:** stakeholder's (3.2.1.1) view on a risk (1.1) [ISO Guide 73]; Note 1 to entry: Risk perception reflects the stakeholder's needs, issues, knowledge, belief, and values.
- **Risk review:** activity undertaken to determine the suitability, adequacy, and effectiveness of the subject matter to achieve established objectives *Note* Review can be applied to a risk management framework (2.3), risk management process (2.8), risk (2.1) or control (2.26)." [ISO Guide 73:2009, definition 3.8.2.2]
- **Risk tolerance:** organization's or stakeholder's (3.2.1.1) readiness to bear the risk (1.1) after risk treatment (3.8.1) in order to achieve its objectives [ISO Guide 73]; Note 1 to entry: Risk tolerance can be influenced by legal or regulatory requirements.

While the definitions of many terms seem to be "common sense," it is still relevant to research terms and consider formal references.

Types of Risks

Excerpts from "Analysis of Counterfeit Risks and Development of a Counterfeit Product Risk Model" (Spink 2009)

There are general risk analysis guides that are important to consider when developing food fraud prevention theories. One such resource is the types of risks identified by many authors. This type of general list provides insight into the challenge of classifying or categorizing product fraud or counterfeit products – they could fall into several or many categories.

- **"Catastrophic risk (Nader):** This affects industries and firms whose financial assets are exposed to catastrophic natural perils, such as earthquakes, hurricanes, volcanic eruption, and so on.... Although catastrophic risk is usually considered as an outcome of natural perils, one nonnatural peril, terrorism, has emerged in recent years as a source of risk whose conse-

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quences for the insurance industry appear increasingly capable of attaining the same dimensions as those of catastrophic risk.”

- “**Foreseeable risk (Nader):** This is primarily a legal definition derived from the concept of “foreseeability.” Accordingly, the *foreseeable risk* is any risk whose consequences can reasonably be expected to occur, by a person of ordinary prudence.”
- “**Fraud risk (Nader)** [also categorized by Nader as *security risk*]: This may be defined as the entity’s total exposure to the probable misconduct, dishonesty, and deceit by internal as well as external parties.... What is peculiar about *fraud risk* is that it can never generate any returns to the party at risk. Therefore, no business entity acting rationally should ever voluntarily bear or expose itself to any type or amount of *fraud risk*. However, we live in an imperfect world, and it is unrealistic to expect that total elimination of *fraud risk* can be achieved.”
- “**Fundamental risks (Nader):** This is impersonal in nature, and any person affected by such risks is exposed to losses that do not arise from that person’s own individual choice or behavior, but from events beyond his or her control. Examples of such events include natural disasters, political and social developments, economy-wide phenomena, industry-wide phenomena, and so on.”
- “**Legal risk (Nader):** This is one of the risks of doing international business. It arises from the weaknesses, incompleteness, nonenforceability, and other similar problems with a foreign country’s laws and its legal-judiciary machinery.... Such problems increase the probability that the legal system will fail to provide adequate protection of physical and intellectual property rights or remedies against breaches of contracts and other violations of contractual rights.”
- “**Liability risk (Nader):** This is applied to a very broad category of *pure risks*, many of which are *insurable*.... Liability risk arises whenever one party is exposed to possible loss of present or future assets or income as a result of causing one or more of the following events to another party or to assets owned by another party, whether those events (torts) are caused by the first party willfully or through negligence.”
- “**Marketing risk (Nader):** This is used to describe the uncertainty that surrounds the future demand for a firm’s products as a result of numerous variables which affect this demand, but may be unpredictable or not entirely under the firm’s control. Marketing Risks arise from unanticipated or uncontrollable shift in any of the factors which affect the firm’s marketing mix (which are product, price, place, and promotion.”
- “**Particular risks (Nadar):** These are those types of risk whose consequences affect individuals separately, and are not so pervasive (as in the case of *fundamental risks*) as to affect an entire group of individuals. *Particular risks* arise from personal actions or events that are under an

- individual's control, and are therefore considered to be the responsibility of the individual, rather than the responsibility of society as a whole.”
- “**Property risks (Nadar):** These encompass all events which carry a possibility of loss, to a property owner, of one or more of the following: the value of property (direct loss), the use of property (indirect loss), and the future income generated by property (indirect loss).”
 - “**Pure risk (Nadar):** This is defined as any risk which can only result in a loss or no loss, but can never generate any gains to the party at risk. In other words, a pure risk consists entirely of downside risk and does not contain any upside risk component.... The designation of some risks as *pure risks* is useful for setting apart those risks that are normally *insurable risks* from *speculative risks*, which are normally *uninsurable risks*.”
 - “**Speculative risk (Nadar):** As distinguished from pure risk, is a term applied to describe all risky situations that, in addition to carrying the possibility of loss, also carry the possibility of gain to the party at risk. In other words, speculative risks incorporate not only a downside risk component but an upside risk component.”

When the specific threat or response is hard to classify – such as from product fraud or product counterfeiting – there could be a problem if there is a debate about who “owns” the problem. The application to food fraud prevention is that it really doesn’t matter how the risk or vulnerability is categorized. There is a process to review new or changing enterprise-wide risks or vulnerabilities. When connected to enterprise-risk management this enables in the Food Fraud Prevention Cycle.”

Sidebar: Meeting Dr. Kenneth Arrow—The Godfather of Uncertainty Assessment

In 2009 I was fortunate to meet with Dr. Kenneth J. Arrow at a Society for Risk Analysis meeting. We had a chance to discuss how he saw the uncertainty principles applying to a wide range of risks and vulnerabilities. To step back, Dr. Kenneth Arrow is a Nobel Prize-winning economist—and five of his students were also a Nobel award winner—who is regarded as one of the greatest economists. He was the researcher who developed one of the fundamental concepts of business and economics of “moral hazard” as it relates to risk, uncertainty, and decision-making.

To review, a **moral hazard** is a situation where an actor may take greater risks if they receive rewards from the activity but do not personally suffer the consequence of a related loss—it is insinuated that it is immoral to take more risk with someone else’s money than you would with your own (Arrow 1951, 1963, 1966, 1968). Applied to food fraud prevention, a buyer may receive a

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bonus for purchasing the inexpensive product but not be penalized for the cost of a product recall or other re-work expenses. It is argued that the term “moral” is ill-fitting since, unless the activity is illegal or there is some other fraudulent deception, the actor is maximizing the set parameters or specifications, so their activity is not “immoral.”

His most significant impact is the “general equilibrium theory.” Basically, the idea is that many other factors throughout the economy influence a single decision. The decision to purchase a product (or commit a fraud act) is not only based on if you have money in your wallet (or have other fraud opportunities including do nothing). This was a core to the food fraud strategy goal to “connect everything to everything.” Of course, there are direct and indirect variables as well as a wide range of the impact of those variables. He not only developed the idea, but he proved the existence of the equilibrium in the form of a mathematical proof (a mathematical formula that demonstrates and confirms the theory).

An especially interesting and important idea that is applied to food fraud prevention—and defines how it is different from food safety or even food defense—is “social choice theory.” This concept is not to be confused with criminology theories such as “rational choice theory,” but they are similar. Arrow modeled individuals (a person) as “rational in a narrow sense.” The individual has a unique set of decision criteria (e.g., the person sells beef and horsemeat), but it is influenced by society-wide (the entire population) criteria (e.g., the beef commodity price increases). So, if “A” is preferred to “B” and “B” is preferred to “C,” then does everyone prefer “A” to C”? Maybe but not necessarily.

In later publications, Dr. Arrow expanded the social choice theory and general equilibrium to “risk” and “uncertainty.” The same product in a different “state of the world” or changing market condition is really a different product. He saw that there were more variables involved or “contingent commodities”—commodities that are influenced by when and where they are in the world. Horsemeat within a national border—and not subject to customs inspections—is a different commodity than horsemeat outside the country which would be required to cross a border that would include different laws and face possible inspection. Horsemeat to a company that sells a wide range of meat is a different commodity than for someone who sells wrist watches.

To summarize Dr. Arrow’s theories, there is a consideration of several concepts. To apply to food fraud prevention, then consider the “commodity” as a “fraud opportunity”:

- Commodity as it relates to the *entire world*.
- Commodity as it is a value to an *individual*.
- Commodity as it is a value to an *individual in a specific situation*.

- Moreover, information that influences that specific situation [“fraud opportunity”] including risk and uncertainty that could be a fraudster concern they might get caught. This is an especially critical contribution to the food fraud prevention theories.

The application to food fraud prevention is that while the fraud opportunity is influenced by macroeconomic factors such as pricing, the real decision is by an individual who is in a specific situation.

That seems like “well, duh, of course,” but until that was mathematically proven, it was not considered a real theory. It is important to note that Dr. Arrow applied his theories to market and economic decisions and not to public policy. “He laughed when we asked him how he applied sophisticated mathematical modeling to public policy. His answer was that he did not” (Greenberg and Lowrie 2010). In general, Dr. Arrow considered his theories as a foundation and starting point that could be applied to a wide range of new and emerging risks. Meeting with him encouraged our quest to continue to adapt current models or tools to the unique needs of food fraud prevention.

I am personally grateful for the patience and willingness of someone such as Dr. Arrow to spend a few minutes with a “grad student” talking about some crazy topic such as anti-counterfeiting. He said, “Well, my research would seem to apply.” Yes, Dr. Arrow, it does.

Key Learning Objective 2: Fundamentals of Risk Analysis and Risk Communication

This section reviews the academic discipline of decision sciences as a structured way to review the basic risk analysis concepts used to conduct assessments and define the strength of the data and then the recommendations for presenting the findings.

The Key Learning Objectives of this section are

- (1) Introduction to decision sciences
- (2) Fundamental risk analysis concepts such as likelihood, consequence, and risk tolerance
- (3) Fundamental dataset characteristics such as accuracy, precision, certainty, and robustness

Introduction to Decision Sciences

As there is a closer review of food fraud prevention and the foundation, more core concepts are identified. One specific area is the decision sciences. The Decisions Sciences Institute publishes the peer-reviewed, refereed scholarly Decision Sciences Journal (Decision Sciences 2018). Beyond risk and vulnerability assessment or enterprise-wide management, decision-making is the underlying process of the science of decision-making. INSEAD University states (INSEAD 2018):

- “The area of Decision Sciences includes:
- Risk management,
- Decision making under uncertainty,
- Statistics and forecasting,
- Operations research,
- Negotiation and
- Auction analysis, and
- Behavioral decision theory.”

Thus, beyond the behavioral science of how people make decisions, this focuses on the methods and processes to organize and assess information to support the exact question that is posed. A primary focus is on defining the specific and detailed question that is being addressed, so there can be an assessment of the right data to support the decision-making (Fig. 15.4).

Research is supported by agencies such as the US National Science Foundation (NSF) within their Division of Social and Economic Sciences which has a section on Decision, Risk, and Management Sciences (DRMS). Their funding focuses “in the areas of judgment and decision making; decision analysis and decision aids; risk analysis, perception, and communication; societal and public policy decision making; management science and organizational design” (NSF 2018).

There are four main goals for decision sciences study:

- (1) “Enrich the diverse disciplines of the decision sciences” meaning to connect and integrate multiple information exchange systems.
- (2) “Integrate these disciplines into bodies of knowledge that are effectively utilized for decision making” which is interoperability and basically to “connect everything to everything.”
- (3) “Develop theoretical bases for such fundamental processes as implementation, planning, and design of decision systems” which is studying and refining the process or method to create harmonization and enable sharing of best practices.
- (4) “Improve educational programs and instruction in the decision sciences” which is sharing information through publications and also educating new scientists?

The application to food fraud prevention is that decision sciences emphasizes:

- (1) The need to be very specific in defining the question that is being asked

Fig. 15.4 The hierarchy of decision-making:
enterprise risk management
to risk analysis to decision
sciences



- (2) To focus on the process or method of gathering information and supporting that final decision

The core focus is on what exact decision is being made, such as to put the product on hold and conduct authenticity tests, implement a product recall, cancel a supplier contract, report a suspicious activity to a government agency, etc. Moreover, another consideration is what specific information would change a decision, such as “parmesan cheese has had incidents of this type of cheese fraud” versus “the US FDA just issued a warning letter to one of our suppliers regarding swapping types of cheese fraud.” These questions “Establishing the context” of the question to be asked to help identify what and how much data is needed.

Risk, Risk Attitude, Likelihood, and Consequence: ISO 31000—Clarity and Conflict

ISO 31000 Risk Management was published in 2009 after years of a consensus-driven process involving national standards organizations. Even though this was a comprehensive and interdisciplinary approach, it was not without critics. There was support with seemingly simultaneous criticism such as “The consequence of this is that certain ideas about risk and its management have got a boost in credibility and prominence while others have lost out” (Leitch 2010). The meaning is that while the field of risk management received credibility from an ISO standard and future research that was more harmonized, there were also some fields that would have to change their current terminology to be compliant. In some cases this is easy, but

often they are very formalized and in-depth research using one or another of the terms. An example may be the early research on food fraud and economically motivated adulteration. Some research was published using economically motivated adulteration, but the later research shifted to food fraud—there could be confusion or a lack of prestige from those who changed their terminology. This was true for some of the risk assessments and use of terms such as probability versus likelihood, severity versus consequence, and prevention versus mitigation.

Other than the common terminology, the two major steps were to (1) identify that risk could lead to a benefit (consider a financial investment in a high-risk product that results in a higher rate of return) and (2) a standardized methodology for assessing and managing risks.

From ISO 31000 there are some key definitions (including a few terms that have been presented and defined earlier in this book) (ISO 2009):

- “**Risk**: effect of uncertainty on objectives;
 - NOTE 1: An effect is a deviation from the expected — positive and/or negative.
 - NOTE 2 Objectives can have different aspects (such as financial, health and safety, and environmental goals) and can apply at different levels (such as strategic, organization-wide, project, product and process).
 - NOTE 3 Risk is often characterized by reference to potential events (2.17) and consequences (2.18), or a combination of these.
 - NOTE 4 Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated likelihood (2.19) of occurrence. ISO 31000:2009(E)”
- “**Risk attitude** (referred to in later ISO documents or COSO as ‘risk tolerance’ or ‘risk appetite’): organization’s approach to assess and eventually pursue, retain, take or turn away from risk [ISO Guide 73:2009, definition 3.7.1.1]”
- “**Consequence**: outcome of an event affecting objectives
 - NOTE 1: An event can lead to a range of consequences.
 - NOTE 2: A consequence can be certain or uncertain and can have positive or negative effects on objectives.
 - NOTE 3: Consequences can be expressed qualitatively or quantitatively.
 - NOTE 4: Initial consequences can escalate through knock-on effects. [ISO Guide 73:2009, definition 3.6.1.3]”
- “**Likelihood**: chance of something happening
 - NOTE 1: In risk management terminology, the word ‘likelihood’ is used to refer to the chance of something happening, whether defined, measured or determined objectively or subjectively, qualitatively or quantitatively and described using general terms or mathematically (such as a probability or a frequency over a given time period).
 - NOTE 2: The English term ‘likelihood’ does not have a direct equivalent in some languages; instead, the equivalent of the term ‘probability’ is often used.

However, in English, ‘probability’ is often narrowly interpreted as a mathematical term. Therefore, in risk management terminology, ‘likelihood’ is used with the intent that it should have the same broad interpretation as the term ‘probability’ has in many languages other than English. [ISO Guide 73:2009, definition 3.6.1.1]”

This is published in coordination with other ISO standards including:

- ISO Guide 73:2009, Risk management—Vocabulary: A thorough glossary of terms with detailed definitions.
- ISO/IEC 31010:2009, Risk management—Risk assessment techniques: A further review of the process of analyzing and managing risks.

ISO 31000 has a focus on the sources of risks or broadly how they are generated, root cause analysis and then an integrated focus on how best to implement and manage a risk treatment.

- “**Risk source:** element which alone or in combination has the intrinsic potential to give rise to risk, NOTE: A risk source can be tangible or intangible. [ISO Guide 73:2009, definition 3.5.1.2]”

For food fraud prevention, the focus on root cause analysis supports the focus on social science and criminology. While these are new disciplines for a food safety group to consider, this is the most efficient method to reduce or address the root cause—the human adversary. Also, some risks such as stolen goods may seem to have countermeasures and control systems far outside the normal scope of a Food Safety Management System, but the simplest way to reduce the food safety risk is to focus on the risk source which is that the product is stolen. Again, the concept of “accountable” versus “responsible” is important where a Food Fraud Vulnerability Assessment would naturally include stolen goods and the actual controls of securing the inventory would be the “responsibility” of corporate security or plant management.

When the Food Fraud Vulnerability Assessment guidances were being completed, one company estimated it would take 5 years to complete the process. That is interesting, but the GFSI compliance requirements were due in 12 months. “[There are often] disconnects between the available scientific data and the information needs of decision makers also hinder the use of risk assessment as a decision-making tool” (NRC 2009).

Also, “The depth, extent, and detail of the uncertainty and variability analyses should be commensurate with the importance and nature of the decision to be informed by the risk assessment and with what is valued in a decision. This may best be achieved by early engagement of assessors, managers, and stakeholders in the nature and objectives of the risk assessment and terms of reference (which must be clearly defined).” (NRC 2009).

ISO 31000 includes a consideration for the preliminary or general assessments that may not require data that is very detailed, accurate, precise, certain, or robust decisions. What is often important is that “a” risk assessment is conducted as long

as the specification of the low certainty and low robustness is clearly defined. For food fraud prevention decisions, there may not be a lot of detail needed for a decision, or there may not be details provided (at least not yet).

It is very important and a great value that ISO 31000 Risk Management provides a common set of terms and methods so risk assessors across many industries can share insight and expertise. The bottom line is that ISO 31000 is an implemented and standardized system, so it is inefficient and illogical *not* to follow the guidance or definitions.

Quantitative or Qualitative Analysis: Both Are Supported in ISO 31000

ISO 31000 repeatedly emphasizes to conduct the assessment that is most logical and efficient for the question being asked. This can be very formal and quantitative or more informal and qualitative (Purdy 2010). “Analysis can be qualitative, semi-quantitative or quantitative, or a combination of these, depending on the circumstances” (ISO 2009).

This is reiterated in the ISO 31000 standard:

- “The way in which consequences and likelihood are expressed and the way in which they are combined to determine a level of risk should reflect the type of risk, the information available, and the purpose for which the risk assessment output is to be used. These should all be consistent with the risk criteria.”
- “The confidence in determination of the level of risk and its sensitivity to preconditions and assumptions should be considered in the analysis, and communicated effectively to decision makers and, as appropriate, other stakeholders.”
- “Risk analysis can be undertaken with varying degrees of detail, depending on the risk, the purpose of the analysis, and the information, data, and resources available. Analysis can be qualitative, semi-quantitative, quantitative, or a combination of these, depending on the circumstances.”

The bottom-line summary is to select a system and specification that meets *your* needs. Occasionally levels of detail or methods are defined in standards; however, often they are not. For food fraud prevention, the FSMA, GFSI, COSO, or other standards are not very specific.

The general “risk treatments” are presented with flexibility for the risk assessor (ISO 2009):

“Risk treatment options are not necessarily mutually exclusive or appropriate in all circumstances. The options can include the following:

- a) Avoiding the risk by deciding not to start or continue with the activity that gives rise to the risk;
- b) Taking or increasing the risk in order to pursue an opportunity;
- c) Removing the risk source;
- d) Changing the likelihood;
- e) Changing the consequences;

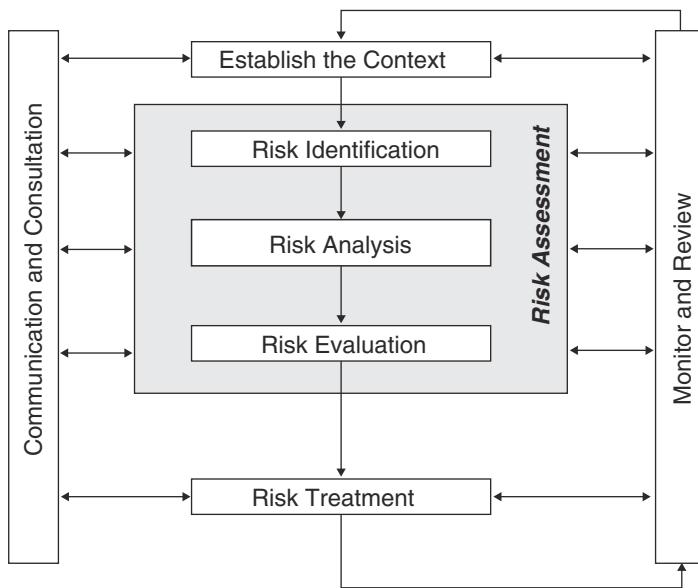


Fig. 15.5 Relationships between the risk management principles, framework, and process, Clause 5 Process. (Copyright Permission Granted) (ISO 2009)

- f) Sharing the risk with another party or parties (including contracts and risk financing); and
- g) Retaining the risk by informed decision.”

For risk assessors in the security or food safety area, the thought of “retaining the risk” seems terrible, irresponsible, and absolutely illogical. In reality, there is no “zero risk” or “zero tolerance” situation, and actually approaching “zero risk” would be inefficient.

ISO 31000 also provides a basic framework that is a logical starting point (Fig. 15.5):

“Establishing the context” is one of the most important steps and is so basic that it is often overlooked by traditional food science risk assessors. Often an incident such as melamine is identified, and the risk assessors quickly use currently available and understood control measures to select and implement risk treatments. The incident is melamine in the product (risk identification), this is a product recall, so it is a problem (risk analysis and risk evaluation), and so applying traditional food safety controls would be to implement a melamine detection test (risk treatment). “Experts” who believe they are already familiar with the incident almost automatically jump to conclusions.

The key concepts for food fraud prevention include these adapted ISO 31000 steps including:

1. **“Establishing the context.”** defining the external and internal parameters [context] to be taken into account when managing risk, and setting the scope and risk

criteria (2.22) for the risk management policy (2.4) [SOURCE: ISO Guide 73:2009, definition 3.3.1].

a. ***For food fraud prevention:*** this would be defining the scope. For example, FSMA would focus only on health hazards. Also, GFSI would focus on vulnerabilities for all types of fraud and for all products.

2. **“Risk Identification”:** in HACCP terms this would be hazard identification.

a. ***For food fraud prevention:*** this would be an incident review and suspicious activity report.

3. **“Risk Analysis”:** in HACCP terms this would be a combined step of hazard identification and hazard assessment.

a. ***For food fraud prevention:*** Vulnerability assessment—review the hazards that were identified and conduct an assessment to define what requires further review.

4. **“Risk Evaluation”:**

a. ***For food fraud prevention:*** Risk assessment—conduct a more detailed review that includes likelihood and consequence.

5. **“Risk Treatment”:** managing the system to reduce to within the risk tolerance.

a. ***For food fraud prevention:*** this would be documented and managed within the Food Fraud Prevention Strategy and by using the Food Fraud Prevention Cycle.

This section provided insight into ISO 31000 Risk Management, presented the terms and concepts, and then presented the application to food fraud prevention. This is a valuable exercise to present the underlying consensus-based standards base and also to explain the logic of the process.

The ERM/COSO system is most efficient and effective for a company to utilize when calibrating the enterprise-wide risks and assessing the vulnerability in relation to the risk tolerance.

Those conclusions are logical if they consider past incidents and a food safety, public health risk-based approach. However, the “Establishing the context” may not be “detect melamine in the product that is being received.” The best overall goal could be to “reduce the fraud opportunity of a range of adulterant-substances to be sent to the company.”

Several related ISO risk terms include:

- **“Risk assessment:** overall process of risk identification (2.15), risk analysis (2.21) and risk evaluation (2.24) [ISO Guide 73:2009, definition 3.4.1.]”
- **“Risk criteria:** terms of reference against which the significance of a risk (2.1) is evaluated [SOURCE: ISO Guide 73:2009, definition 3.3.1.3]
 - Note 1 to entry: Risk criteria are based on organizational objectives, and external (2.10) and internal context (2.11).

- Note 2 to entry: Risk criteria can be derived from standards, laws, policies and other requirements.”
- “**Risk management policy:** statement of the overall intentions and direction of an organization related to risk management (2.2) [SOURCE: ISO Guide 73:2009, definition 2.1.2.]”
- “**External context:** external environment in which the organization seeks to achieve its objectives [SOURCE: ISO Guide 73:2009, definition 3.3.1.1]
 - Note 1 to entry: External context can include:
 - the cultural, social, political, legal, regulatory, financial, technological, economic, natural and competitive environment, whether international, national, regional or local;
 - key drivers and trends having impact on the objectives of the organization; and
 - relationships with, and perceptions and values of external **stakeholders** (2.13).”
- “**Internal context:** internal environment in which the organization seeks to achieve its objectives [SOURCE: ISO Guide 73:2009, definition 3.3.1.2]
 - Note 1 to entry: Internal context can include:
 - governance, organizational structure, roles, and accountabilities;
 - policies, objectives, and the strategies that are in place to achieve them;
 - the capabilities, understood in terms of resources and knowledge (e.g., capital, time, people, processes, systems, and technologies);
 - information systems, information flows and decision-making processes (both formal and informal);
 - relationships with, and perceptions and values of, internal stakeholders;
 - the organization’s culture;
 - standards, guidelines, and models adopted by the organization; and
 - form and extent of contractual relationships.”

Foundational Definitions: Accuracy, Precision, Certainty, and Robustness

Regarding this section, there is an applicable anecdote: “To be wrong with infinite precision”—Taleb. There is a tendency to very thoroughly analyze the information on-hand... often beyond what is appropriate. A very complex and intricate statistical assessment will insinuate that the underlying information is accurate, precise, and certain.

Several foundational definitions should be reviewed before going into more detail. While there are many possible references for these definitions, since the

research question here is focused on “food,” then when possible the US FDA definitions are presented:

- **Accuracy:** “how close the measured result is to the actual result” (Capra and Canale 1998). In addition: “The accuracy of an analytical procedure expresses the closeness of agreement between the value which, is accepted either as a conventional true value or an accepted reference value and the value found. This is sometimes termed **trueness**” (Teasdale et al. 2017).
- **Precision:** “how two measurements agree with each other regardless of the ‘accuracy’” (Capra and Canale 1998). The quote is: “The precision of an analytical procedure expresses the closeness of agreement (degree of scatter) between a series of measurements obtained from multiple sampling of the same homogeneous sample under the prescribed conditions. Precision may be considered at three levels: **repeatability, intermediate precision, and reproducibility**. Precision should be investigated using homogeneous, authentic samples. However, if it is not possible to obtain a homogeneous sample, it may be investigated using artificially prepared samples or a sample solution. The precision of an analytical procedure is usually expressed as the **variance, standard deviation or coefficient of variation** of a series of measurements” (ICH 2005).
- **Bias (also referred to as Inaccuracy):** “is defined as systematic deviation from the truth” (Capra and Canale 1998). In this context, it is very different from a more general dictionary definition such as “an attitude that always favors one way of feeling or acting especially without considering any other possibilities” (Merriam-Webster 2004). This term creates confusion due to the difference in scientific and popular definition.
- **Uncertainty (Imprecision):** “on the other hand, refers to the magnitude of the scatter” (see Certainty) (Capra and Canale 1998).
- **Certainty:** “[A] parameter, associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributed to the [thing being measured]” (JCGM/WG1 2008). Is generally a statement of the confidence in a measurement. Further from that definition “The parameter may be, for example, a standard deviation (or a given multiple of it), or the half-width of an interval having a stated level of confidence” (NIST 2018). A general dictionary definition is “1. fixed, settled, 2. of a specific but unspecified character, quantity, or degree, 3. dependable, reliable, indisputable, etc.” (Merriam-Webster 2004).
 - **Robustness:** “The robustness of an analytical procedure is a measure of its capacity to remain unaffected by small, but deliberate variations in method parameters and provides an indication of its reliability during normal usage” (ICH 2005).

It is usually helpful to provide a case study to explain concepts, definitions, and most importantly how the terms relate to each other. Of course, without a methodi-

cal and thorough review, the accuracy and precision cannot be judged. What can be judged is the method and process to gather data (Re., seeking many, varied sources and considering insight and patterns) in relation to what is known about the overall data set (Re., all types of food fraud).

First, consider measuring the speed of a person jumping out of an airplane (emphasis added) (Capra and Canale 1998):

Errors sometimes enter into an analysis because of uncertainty in the physical data upon which a model is based. For instance, suppose we wanted to test the falling parachutist model by having an individual make repeated jumps and then measuring his or her velocity after a specified time interval. Uncertainty would undoubtedly be associated with these measurements since the parachutist would fall faster during some jumps than during others. These errors can exhibit both inaccuracy and imprecision. If our instruments consistently underestimate or overestimate the velocity, we are dealing with an inaccurate, or biased, device. On the other hand, if the measurements are randomly high and low, we are dealing with a question of precision. (Capra and Canale 1998)

The accuracy and precision concepts are applied to a food fraud example in Table 15.1.

A visualization of the accuracy/inaccuracy and precision/imprecision is provided (Fig. 15.6):

For food fraud prevention, it is important that *you* know what accuracy and precision *you* need before *you* can judge the value of a data set. If the provider of a data set cannot define their accuracy and precision—as well as the 7 Vs of data analytics—then they may be “Just gathering whatever data you can find” (example “a” above).

Fig. 15.6 Visual example.
(Adapted from Capra and Canale (1998))

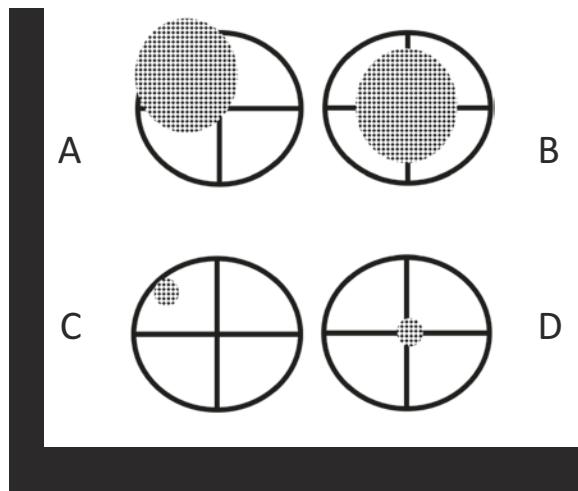


Table 15.1 Explanation and examples of accurate, inaccurate, precise, and imprecise with results and a food fraud example

Accuracy	Precision	Result	Food fraud example
Inaccurate	Imprecise	A <i>random</i> pattern that does <i>not</i> cluster around the center	Example (see figure position “a”): “Just gathering whatever data you can find.” This could be a 5-minute internet search of the phrase “food fraud incident.” Possibly one type of incident—or multiple mentions of the same incident—skews the focus away from the actual target
Accurate	Imprecise	A <i>random</i> pattern that <i>is</i> clustered around the center	Example (see figure position “b”): This could be gathering information from a source that covers a broader range of issues than the topic of concern. This could be using a database that records many incidents that are outside the specific scope of food fraud such as including fraud acts that are intentional and unintentional
Inaccurate	Precise	A <i>tight</i> pattern <i>not</i> around the center	Example (see figure position “c”): This could be analysis from only one type of test or only from one market. This could be referred to as being “uncertain with great precision.” This could be a detailed assessment of one type of fraud and possibly one incident. This could be many tests of meat but from one grocery store or city
Accurate	Precise	A <i>tight</i> pattern <i>is</i> around the center	Example (see figure position “d”): A thorough method to consider all types of incidents and then extensive development of the data set to provide insight from many incidents. This could be testing many products from many types of retail locations from a wide region and with a sampling plan that is designed to be holistic and all-encompassing

(Adapted from Capra and Canale (1998))

Key Learning Objective 3: Review Who Is of “Accountable” and “Responsible”

This section reviews the most important question of “who is accountable” which is quickly followed by “who is responsible.” Once those questions are clear, then there can be more direct agreement what are the exact tasks that define competent “accountability” and “responsibility.”

The Key Learning Objectives of this section are

- (1) Who is accountable and who is responsible?
- (2) What are the exact tasks for those who are accountable and who is responsible?
- (3) What are the metrics to define competence?

Who Is “Accountable” Versus Who Is “Responsible”

The concept of “accountable” and “responsible”—including explicit or de facto assignment—was fundamental to the concepts behind the Food Risk Matrix. The four cells represent the food risks that a company is “accountable” to manage regardless of their knowledge of the risk. Following ISO 31000, each new problem or incident *must* be put into one of the cells. Some must be identified as “accountable” for that cell and cannot give up their role until someone else acknowledges and agrees to take over the problem or incident. This also identifies that someone is “accountable” but delegates a task to someone “responsible” for implementation (emphasis added).

- ***Risk Owner:*** “person or entity with the accountability and authority to manage a risk [ISO Guide 73:2009]”
- ***Accountability:*** “The organization should ensure that there is accountability, authority and appropriate competence for managing risk, including implementing and maintaining the risk management process and ensuring the adequacy, effectiveness, and efficiency of any controls. This can be facilitated by:
 - Identifying risk owners that have the accountability and authority to manage risks;
 - Identifying who is accountable for the development, implementation, and maintenance of the framework for managing risk;
 - Identifying other responsibilities of people at all levels in the organization for the risk management process;
 - Establishing performance measurement and external and/or internal reporting and escalation processes; and
 - Ensuring appropriate levels of recognition.”
- ***Stakeholder:*** “person or organization that can affect be affected by, or perceive themselves to be affected by a decision or activity; *note* a decision maker can be a stakeholder [ISO Guide 73:2009, definition 3.2.1.1]”
- ***Interested party:*** “person or organization (3.32) that can affect, be affected by, or perceive itself to be affected by a decision or activity” (ISO 2005).

Also from “Establishing Risk Management Policy” clearly identifies different individuals who are “accountable” and “responsible”:

- “Commitment to make the necessary resources available to assist those accountable and responsible for managing risk;”

Moreover, “Preparing and Implementing Risk Treatment Plans” stated:

- “The information provided in treatment plans should include: ... those who are accountable for approving the plan and those responsible for implementing the plan;”

At the end of the day, after an incident, you do not want to find out that you were the “accountable” person! If you know about food fraud, then you are now aware and may be legally liable for being “accountable” until you transfer this to another “risk owner.”

Conclusion

The foundational risk analysis and risk assessment concepts in this chapter are very general and broad so as to add value during food fraud prevention. Building on the foundation and fundamentals identified in the previous chapters, there are specific methods—and adaptations of even more broad theories—that are effective and efficient. ***The first conclusion is*** that there are some basic, standardized, and codified terms and methods that are efficient and effective to utilize. There are also some commonly used risk analysis and risk assessment concepts and theories that absolutely do *not* apply. The use of a common definition and scope helps both the risk communication of food fraud as well as enables the application of expertise and insight from other fields. ***The second conclusion is*** that it is most efficient to build upon other currently implemented risk analysis systems but to adapt the methods based on the unique food fraud prevention needs and nature of the dataset. For the new topic of assessing and managing food fraud, it is most efficient to build upon previously understood and trusted systems to provide a mental anchor. For example, a Food Fraud Vulnerability Assessment can be described as “like HACCP but for food fraud vulnerabilities in VACCP.” Another example is to state that “food fraud prevention strategy is just a specific application of the total quality management Six Sigma concepts of root-cause-analysis and plan-do-check-act.” HACCP and Six Sigma are well known and trusted by a wide range of interested parties including the C-suite of companies and internal auditors who might be accountants by education and to financial analysts at investment firms. ***The final conclusion is*** that the risk assessment methods and analysis that applies to other food problems do *not* necessarily apply to food fraud. When food scientists or food safety professionals first address the food fraud problem, there is an assumption that there is “enough” of similar food safety data. The nature of the data generator is very different since it is a human, not a microbe. The human is an intelligent adversary that rapidly evolves to shifting fraud opportunities. Also, compared to food safety, there are many fewer incidents and few incidents that occur in the same way. This chapter provided a risk assessment foundation specific to food fraud prevention. There is a saying:

VACCP is like HACCP but for food fraud prevention.

Appendix: WIIFM Chapter on Risk Basics

This “What’s In It For Me” (WIIFM) section explains why this chapter is important to you.

Business functional group	Application of this chapter
WIIFM all	This is an introduction to the basic risk analysis and risk assessment concepts to provide a thorough understanding of the basics as well as a common terminology and approach
Quality team auditors	This provides insight on how auditees conduct an FFIS and ongoing RAs
Management	Same
Corp. decision-makers	The risk analysis terms may be new to you, but they are universally used and will reduce confusion

Appendix: Study Questions

This section includes study questions based on the key learning objectives in this chapter:

1. Discussion Question

- (a) Is “risk” tolerable when addressing a food safety?
- (b) Discuss the relationship between vulnerability, threat, and risk.
- (c) What are the challenges of data collection and assessment for food fraud?

2. Key Learning Objective 1

- (a) What is “moral hazard”?
- (b) Why is it more efficient to focus on “vulnerability” rather than “risk”?
- (c) Is “suspicious activity” a “risk”?

3. Key Learning Objective 2

- (a) What is “decision sciences”?
- (b) Why is ISO 31000 considered the definitive source for risk management?
- (c) What is the “impression of excessive precision”?

4. Key Learning Objective 3

- (a) What is “accountable” and “responsible”?

- (b) Why is it important to define and assign “accountable” and “responsible” parties?
- (c) What job function and position should be “accountable” for FF prevention?

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Chapter 16

Risk Analysis (Part 2 of 3): Application to Food Fraud



Summary *This chapter presents* the risk analysis application to food fraud prevention. The risk analysis concepts and theories are well known and widely researched but not often adapted to the unique fraud opportunity and resource-allocation decision-making needs for food fraud prevention.

The Key Learning Objectives of this chapter are

- (1) **Risk Analysis:** Application of risk analysis to food fraud prevention
- (2) **Data Analytics and Big Data:** Introduction to data analytics and Big Data
- (3) **Extreme Events:** A review of extreme events, the highly improbable, and Black Swan events

On the Food Fraud Prevention Cycle (FFPC), this chapter addresses the “(0) fundamental concepts” beyond what is risk analysis to the details of risk assessment as applied to food fraud prevention (Fig. 16.1).

Introduction

This chapter continues the risk analysis topic on the application to food fraud. While the basic concept (risk is bad and something that should be controlled) and a method to judge the seriousness of a problem (likelihood and consequence) is clear, there is often little direction on actually applying the findings to a resource-allocation decision. To define a need to do “more,” without a calibration with all other risks or resource-allocation options, is not usually helpful. There is value in considering the application to a specific problem which here is food fraud. When the project moves toward an actual decision, there are often questions about the data and data set. While risk theories are often not fully applied to a specific problem, the specification of the data and data sets is often not defined until questioned near the end of the process. It is helpful to understand the attributes of the data you have for your

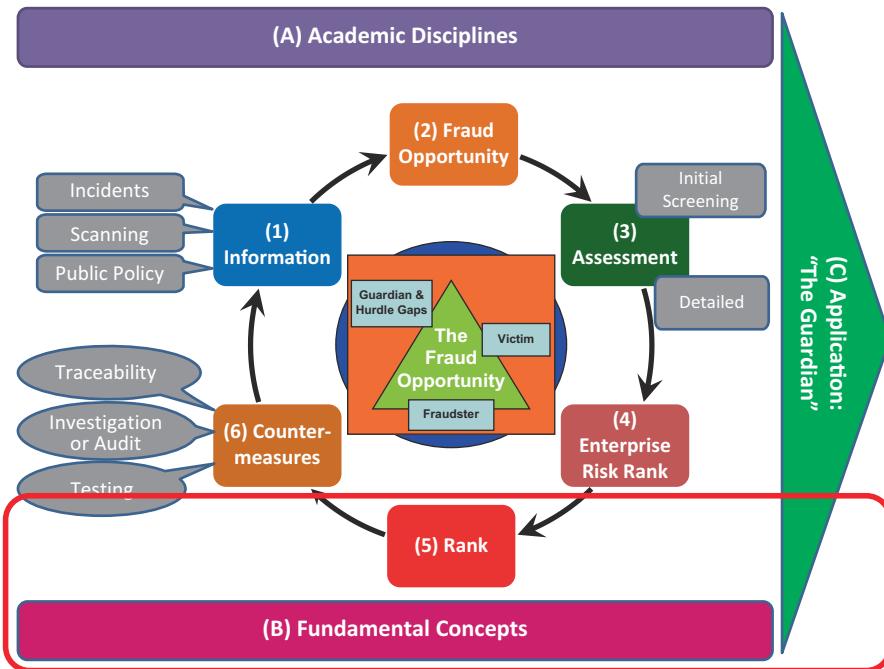


Fig. 16.1 Food Fraud Prevention Cycle—where this chapter applies to the overall concept: “(B) fundamental concepts” and “(5) risk” (Copyright Permission Granted) (Spink 2014; Spink et al. 2019)

review. When the analysis of a risk moves through an assessment and consideration of countermeasures and control systems, there is sometimes an awareness that all of this formality is based on some very extreme and improbable events...and can they even be predicted or prevented? These are sometimes referred to as Black Swan events. Fortunately, as with other parts of food fraud prevention, there is already a well thought through and thoroughly researched body of scholarship to draw upon.

Key Learning Objective 1: Application to Food Fraud Prevention

This section reviews the application of food fraud prevention in terms of how the assessment is presented. The presentation focus here is on the format of the finding.

The Key Learning Objectives of this section are

- (1) Review the insinuations made from an assessment including accuracy, precision, and certainty.

- (2) An overview of the definitions of the types of risks from across many disciplines to make sure to be clear in risk communication.
- (3) Then consider the nature of the data set and risk management needs to understand the most efficient format for presentation of the data and recommendation. The presentation format questions include qualitative or quantitative, also words or numbers, the amount of analysis required for the decision at hand, and others.

Appropriate Precision, Accuracy, Certainty, and Presentation of Findings

Albert Einstein is reported to have said: “everything can be counted, but not everything counts.” This applies to food fraud prevention both in the evaluation of the underlying data sets and the subsequent assessments. Judgments of the source and type of information (e.g., raw data, information, and then more advanced and formally defined intelligence) are covered in more detail in the Criminology chapter. A series of incidents are provided that contribute to very important insights into the fraud opportunity, and the final reports should take into consideration the nature of the underlying data. For example, a wide range of statements of the economic impact of counterfeiting and piracy are presented with high-level statistical analysis but based on an underlying assumption of all counterfeiting and piracy in the range of “5 to 7 percent of world trade” (Spink and Levente Fejes 2012). The high-level statistics were conducted on a data set with a very informal and qualitative foundation. This could be considered “excessive precision.”

“Analysis of Counterfeit Risks and Development of a Counterfeit Product Risk Model” (Spink 2009)

“Basics of Risk Assessment – Appropriate Precision”

An expert or group of experts can provide quick insights, as well as identify potential influences that may not show up until much later using data-intensive statistical methods. A limitation of using an expert’s judgment is the role assumptions play in the judgment. Techniques that simplify an analysis can compound into greater uncertainty in the final output of the model (Claycamp 2006; CODEX 2014). Usually, these heuristically-derived assumptions (e.g., using expert judgment rather than hard, unchanging data) are not clearly defined in the statistical review, and yet reports presenting the results as very precise.

In the report “Understanding Risk,” the National Research Center (NRC) at the National Academies of Science discussed related analysis that is conducted to reduce the complexity of the model, and the danger that is

(continued)

oversimplifying complex, multidimensional problems can lead to results that are “highly contentious” to the decision-making process (NRC 1996).

Additional insight includes (Hassenzahl 2006):

Risk analysts are often asked to generate precise numerical calculations. The expectation serves an essential role in risk evaluations by forcing discipline on the analysts. At the same time, however, the act of generating such precise numerical calculations permits the unfortunate possibility that the resulting estimates will be interpreted as sufficient and accurate depictions of the risk. Alternatively, analysts may feel compelled to present estimates that are more precise than they feel is warranted. Stripped of quantitative and qualitative information about uncertainty, these precise estimates may become repeatedly mentioned and thereafter be interpreted as the “true” or “actual” value of the risk.

The concern is that the analysis may reach a point of “excessive precision” or a “false sense of precision and it is an important point to remember in making preliminary risk assessments or in reviewing emerging risks (Pittenger et al. 2003; Jablonowski 2005; Hassenzahl 2006).

Sidebar: Perceived Risk, Trust and Confidence, Source Credibility, and Dread and Outrage

Several key definitions and concepts from “What Role Can We Count on Consumer to Pay in Product Authentication” (MSU-FFI 2018):

Perceived Risks. The types of consumers and ways consumers respond are important base concepts, especially when dealing with perceived risk.

Perceived risk is a specific consumer behavior concern which is “expected negative consequences of performing an activity such as purchasing a product” (Peter and Olsen 2005). There is a large body of research on perceived risk from a consumer behavior and a risk assessment perspective (Green et al. 1972; Gorn 1982; Haley 1995; Green et al. 2000; Haimes 2009; Lewis and Tyshenko 2009; Lindell et al. 2009; Terpstra et al. 2009; Venables et al. 2009). The intensity of the risk is influenced by the severity and the probability of the negative event (Kearny 2009; Cox 2009; Meijnders et al. 2009). “Risk depends on more than frequency and severity of consequences” (Cox 2009).

Trust and Confidence. There is research on the trust or confidence in a product or provider of products (Gotlieb and Sarel 1991; Tyler and Degoeij 1996; Andrew et al. 1999; Kramer 1999; Cvetkovich et al. 2002; White et al. 2003; Chen 2008; Eitzinger and Wiedemann 2008; Sanquist et al. 2008; Earle 2009; Malka et al. 2009; Meijnders et al. 2009). Trust is

usually associated with companies or agencies whereas confidence associated with an evaluation or technical assessment (Earle 2009). Trust and confidence are heavily correlated to a consumer's world view or personal experiences (Schoell and Binder 2009). In high-counterfeit markets or products, increased communication of the risks can increase consumer confidence. Consumers have a higher confidence in science confirming a risk rather than science confirming the absence of a risk (Siegrist and Cvetkovich 2001; Schoell and Binder 2009). It is easier to confirm a risk than confirm a lack of a risk (Keller et al. 2009).

Source Credibility. Source credibility, or source dynamism, is an important concept when communicating to consumers (Berlo et al. 1969; Chaiken and Maheswaran 1994; Van Kleef et al. 2007; Malka et al. 2009; Meijnders et al. 2009). Here, again, a consumer's perception could be swayed by world view or personal experiences (Burgoon et al. 1990; Gotlieb and Sarel 1991; Gotlieb et al. 1992; Stern 1994; Magee and Kalyanaraman 2007). There has been specific research on how corporations are, or are not, trusted (Kopalle and Assuncao 2000; Lafferty et al. 2002). A Harris poll identified low trust of the message of some agencies and of messages from companies (Harris Interactive 2008). In the high counterfeit markets or products, government messages about counterfeits or authentication are perceived as trusted public health promotion. "Prevention campaigns should systematically incorporate and respond to at-risk population's existing beliefs, emotions, and perceived barriers in the message design process to effectively promote behavior change" (Cho and Witte 2005).

Dread and Outrage. There is a specific study of hazard and outrage, which is also referred to as dread. Specifically, Sandman (2004a, b) developed the formula that for consumer "risk = hazard + outrage" (Sandman 1988; Sandman et al. 1993; Sandman 2004a, b; Cho and Witte 2005). The emotional concept of "dread" leads consumers to underreact to a high hazard/low outrage, such as snowboarding (Sandman 2004a, b). Consumers overreact to a low hazard/high outrage, such as terrorism (Sandman 2004a, b). Risks out of the control of the consumer, involuntary, are more of an outrage (Levitt and Dubner 2005). Generally, counterfeits in low probability markets appear to be in the low hazard/high outrage category, which would lead to a consumer overreaction.

Fear Appeals. There is a wide range of research on *fear appeals*, also called *fear arousal*, which use fear as a marketing tool (Tanner Jr. et al. 1991; Witte 1992; Hale and Lemieux 1995; Witte and Morrison 2000; Cho and Witte 2005; Levitt and Dubner 2005; Green and Witte 2006; Nielsen and Shapiro 2007; Lapinski and Nwulu 2008; Backer-Grøndahl et al. 2009; Furukawa et al. 2009). Examples are to either stop a dangerous behavior such as smoking or to reinforce avoiding danger such as using sunscreen. Fear appeals engage two processes: danger control and fear control (Ray

and Wilkie 1970; Witte 1992). Different consumers could respond to the same message with either the danger or fear response. The danger is more cognition and fear is more effect. For counterfeits in markets with a low probability and severity, a quantitative thinking consumer may not perceive danger. Remember that the WHO report on counterfeit medicines reported that worldwide, ~70% of counterfeits are a placebo at worst (WHO 2007) and <0.2% of the US drug market is estimated to be counterfeit (Kearny 2009).

These wide ranges of perceived risk details demonstrate the importance of engaging the discipline of consumer behavior before implementing any new warning messages.

Qualitative vs. Quantitative Assessments and Words Versus Numbers

“Analysis of Counterfeit Risks and Development of a Counterfeit Product Risk Model,” a 2009 Ph.D. Dissertation by John Spink (Spink 2009):

Risk assessments do not need to strive for quantitative output (numerical data). In fact, there is a body of literature which supports qualitative (high/medium/low) output, when there is qualitative (high/medium/low) input, including agencies such as the FDA, US Office of Management and Budget (OMB), US Department of Defense (DOD), international standards organizations, and industry associations (Broder 2000; Jablonowski 1994). For example, in a CFSAN/FDA presentation, “Tools for Prioritizing Food Safety Concerns: An FDA Perspective” (Note: author Dr. Robert Buchanan was the FDA/CFSAN Senior Science adviser and Director of Science) either qualitative and quantitative tools or models for risk ranking or assessment were validated, noting that each can have their strengths and drawbacks (Buchanan 2007). This is supported by other authors, as well (Claycamp and Hooberman 2004; Shepherd et al. 2006; Etherton et al. 2008).

In a *Risk Management* Journal study by Jablonowski (1994), a survey of risk managers found that “words” communicated the risks better than “numbers” (Jablonowski 1994). For example, it was more descriptive and helpful to call something “rare” than to refer to a “0.05” percent chance of occurrence.

The security industry also echoes the lack of detailed history. For example, the book “Risk Analysis and the Security Survey,” which is recommended reading for the American Society for Industrial Security ASIS Certified Protection Professional certification, specifically addresses

security-related risks that apply directly to the anti-counterfeit strategy situation (Broder 2000):

“Threat occurrence rates and probabilities are best developed from reports of occurrences or incident reports, whenever this historical data exist. Where information does not exist, it may be necessary to reconstruct it. This can be accomplished by conducting interviews with knowledgeable persons or by projecting data based upon educated guesses, supported by studies in like industries and locations.”

The review of the literature and other reports did reveal a way to specify how to separate the categories (e.g., high/medium/low) beyond stating that the categories should be spaced far enough apart to be meaningful. The categories should not be set to parts-per-trillion if the test equipment can only measure to parts-per-million (the data would be impractical to measure). Likewise, the categories should not be set, so all the responses fall into the same rank (if all are “medium” there is no differentiation).

This focus on the presentation of the data should consider the final use of the results. Presenting the data on a broad scale or bell-shaped curve can be helpful except where the results are plotted in relation to the overall risk tolerance. When plotting versus the risk tolerance then it is possible that all food fraud vulnerabilities could cluster all above or all below that threshold.

Sidebar: Risk Assessment Numerical Methods

“Analysis of Counterfeit Risks and Development of a Counterfeit Product Risk Model” (Spink 2009):

Basics of Risk Assessment – Numerical Methods

Traditional numerical models, formulated to be solved with arithmetic operations, are the focus of engineering textbooks (Capra and Canale 1998). Unlike engineering problems (e.g., will a bridge withstand a certain load?), the counterfeit risk has human factors, and there may be no physical laws in the root cause. Due to the nature of the data, even traditional “fundamental laws” (e.g., energy cannot be created or destroyed) cannot be derived from empirical tests (e.g., observation or experiment) (Capra and Canale 1998). The Counterfeit Product Risk Model [CPRM] is not a physical system or process that is easily defined for future threats [Note: the CPRM is a general model presented in the Ph.D. Dissertation and is similar to a food fraud initial screen or pre-filter assessment].

Since engineering problem-solving concepts are familiar to many of the risk assessors assigned with counterfeit risk prediction, these concepts will be reviewed for their relevance to the model:

- **Flowcharting:** While *flowcharting* of the processes can work in a very general sense for counterfeit risk, the lack of large, historical data sets reduces the effectiveness of developing numerical models.

(continued)

- **Analytical versus numerical methods:** *Analytical methods* are considered exact, approximated by linear functions, and are of limited value since most “real” problems are more complex (Capra and Canale 1998). *Numerical methods* are based on “equations, non-linearity, and complicated geometries” and are very common in engineering problem-solving (Capra and Canale 1998). Even though the numerical solutions can be quite complex, they are still an approximation. “Although perfection is a laudable goal, it is rarely, if ever, attained” (Capra and Canale 1998). Neither applies to the Counterfeit Product Risk Model due to the underlying lack of historical data and the ever-changing nature of the risk.
- **Truncation versus round-off errors:** *Truncation error* is a different concept that measures the variation in the approximation of a number and the actual number (e.g., a measured number 4.859 but truncated to 4.9) (Capra and Canale 1998). *Round-off error* is due to method or computers simplifying the data to a finite number (e.g., Pi is 3.141592653589... but rounded off to 3.14) (Capra and Canale 1998). These concepts both assume there are a large historical data sets and some accurate measure of the system. The only historical data about counterfeiting is whether the product is known to be counterfeited and how many occurrences of the fake product were identified. Thus, neither concept applies to the Counterfeit Product Risk Model [or current food fraud risk assessments].
- **Significant figures, accuracy, and precision:** *Significant figures* refer to the number of digits that can be used to represent the data point (Capra and Canale 1998). Since the actual number for a counterfeit risk calculation cannot be known, these concepts do not apply to the Counterfeit Product Risk Model.
- **Blunders,” formulation errors, and data uncertainty:** Engineering problem-solving assumes that the model and assumptions are sound, but in the real world that should not be assumed.
 - **Blunders (in risk modeling):** are considered to be gross errors in the data gathered or models that are not fundamentally sound relative to the data collection or measurement methods (Capra and Canale 1998).
 - **Formulation errors, or model errors:** are from “incomplete mathematical models” (Capra and Canale 1998). If a counterfeit risk model is based on the analysis of past data, then a mathematically representative model can be developed, but in trying to predict future risks the model developed would be fundamentally incomplete. With these fundamentally incomplete models, uncertainty (bias) would be associated with the results. When the counterfeit risk is to consider future risk, the uncertainty could magnify, detracting from the value of the prediction.
 - **Data uncertainty** is the error from the physical data that was used to build the model (Capra and Canale 1998). The physical data used to

build an analytical counterfeit or product fraud assessment could be both inherently uncertain and imprecise.

Quantitative methods are not always the most efficient or most appropriate prediction models. Also, classical statistical methods are based on the fundamental concepts outlined above and are not practical to apply to the Counterfeit Product Risk Model. The use of classical statistical tools such as mean, standard deviation, or variance could give an impression of excessive precision.

If the Counterfeit Product Risk Model used a traditional analytical or numerical model, the associated error would lead the output to be impractical in practice. This review supports using a more general, qualitative model for counterfeit risk assessment [and also, later, for product fraud including food fraud].

Key Learning Objective 2: Introduction to Data Analytics and Big Data

This section reviews the concept of data analytics and Big Data. The terms are often used casually referring to “gathering a bunch of information.” Data analytics is a specific scientific field of study that includes universities that offer master’s degrees and Ph.D.s on the topic. The study of data analytics includes very specific definitions and evaluations that will be presented in this section. Data analytics is a specific discipline with unique terminology and methods. The science is not to “just gather a bunch of data” and run some spreadsheet averages. The science of data analytics is critical to understand before making any decisions regarding food fraud prevention.

The Key Learning Objectives of this section are

- (1) A review of the types of assessments or, more precisely, analytics.
- (2) Then an understanding of the ways to classify the nature of the data in the “7 Vs of Big Data.”
- (3) Finally, building upon the types of analytics and nature of the data an evaluation survey is presented.

Types of Analytics

It is critical not to overstate utility of the results of an assessment such as an “impression of excessive precision” (an overview summary is provided in (Spink et al. 2019)). Descriptive analytics are very valuable but not if a customer is expecting a prediction. There are three types of analysis or analytics (Schniederjans et al. 2015):

- **Descriptive Analytics:** This is beyond a list of events or historical past probabilities. This is defined as: “A simple statistical technique that describes what is contained in a data set or database.” “To identify possible trends in large data sets or databases” (Schniederjans et al. 2015), e.g., descriptive statistics such as averages or standard of deviation, charts, graphs, sorting methods, or lists.
- **Predictive Analytics:** Apply statistical modeling to not only interpolate the history from the past but consider dependent and independent variables to predict future occurrences. This is defined as: “Advanced statistical, information software, or operations research methods to identify predictive variables and build predictive models to identify trends and relationships not readily observed in a descriptive analysis” (Schniederjans et al. 2015). “To build predictive models designed to identify and predict future trends” [e.g., ANOVA and multiple regression analysis].
- **Prescriptive Analytics:** Build upon predictive analytics assessment of future events to decide and apply resources that mitigate consequences, e.g., linear programming and decision theory (Schniederjans et al. 2015).

These are the types of conclusions and recommendations that can be drawn from large data sets. The more data—and the more accurate, precise, and certain the data—the higher-level analytics can be conducted.

Describing the Nature of the Data

Further, to describe the data and analytics in more detail, there are the “5 Vs of Big Data”—or sometimes these range from 4 to 7 and are summarized here (McAfee and Brynjolfsson 2012; Schniederjans et al. 2015; Haan et al. 2015; Meehan 2016; Sivarajah et al. 2017):

The 5 Vs of Big Data

1. **Volume:** the amount of data. “Big Data” is judged in terabytes or above.
 - For example, how much information is in the data set such as the number of food fraud incidents?
2. **Velocity:** the speed of data collection with Big Data defined in real-time or near real-time.
 - For example, how recently is information collected and how they would include recent incidents? For example, is the entire data set reviewed and updated at least monthly, weekly, daily, hourly, etc.)?
3. **Variety:** a range of forms including pictures, text messages, GPS signals, sensor readings, etc.

- For example, how many different data sources are used including in how many languages?
4. **Veracity:** the trust in the accuracy, precision, and certainty as well as if the data set is representative of the entire event.
- For example, how complete is the data set in covering all problems in the real world and not just “everything we could find”?
5. **Value:** this is a rough judgment of the actual usefulness of the data set to address the specific question or the thoroughness recommendation based on this data set.
- For example, how much more or other information would need to be collected to make a final decision such as recalling a product, putting a product on hold to conduct authenticity tests, canceling a supply contract, or contacting a government agency to report suspicious activity?

For another perspective on “data analytics” and the “Vs of Big Data,” consider the US National Institute for Standards and Testing (NIST) report on “Big Data Interoperability Framework”(NIST 2015). The NIST reference is especially important due to the formal and authoritative role of the influence on US laws and integration to international standards such as ISO.

The NIST report expands the “Vs” list and provides more detail on the veracity term:

1. **Value** refers to the inherent wealth, economic and social, embedded in any data set (i.e., the value of the analytics to the organization, also sometimes referred to as **validity** [i.e., appropriateness of the data for its intended use]).
2. **Variability** refers to the change in other data characteristics.
3. **Variety** refers to data from multiple repositories, domains, or types.
4. **Velocity** refers to the rate of data flow.
5. **Veracity** refers to the accuracy of the data.
6. **Volatility** refers to the tendency for data structures to change over time (i.e., the tendency for data structures to change over time).
7. **Volume** refers to the size of the data set.

One of the most important concepts for the food fraud prevention application is veracity, so more detail is provided here:

“**Veracity** refers to the completeness and accuracy of the data and relates to the vernacular ‘garbage-in, garbage-out’ description for data quality issues in existence for a long time. If the analytics are causal, then the quality of every data element is extremely important. If the analytics are correlations or trending over massive volume datasets, then individual bad elements could be lost in the overall counts, and the trend will still be accurate. As mentioned in Section 2.2, many people debate whether “more data is superior to better algorithms,” but that is a topic better discussed elsewhere.” (NIST 2015)

The “Vs of Big Data” provides a framework for explaining the nature of a data set.

Table 16.1 Evaluation of the value of data regarding data analytics: types of analytics and Vs of Big Data

Product and suspicious activity: assessment of the data and “fit for purpose”	
Research question:	
Current data set (source, information, etc.):	
Type of analytics possible (descriptive, predictive, or prescriptive):	
Details of Data—5 Vs:	Concept and then judge confidence in the current data set meeting the immediate need without further processing
Confidence:	1 (low) to 5 (high)
1. Value: this is a rough judgment of the actual usefulness of the data set to address the specific question or the thoroughness recommendation based on this data set	
2. Variability: this is the change in other data characteristics	
3. Volume: the amount of data. “Big Data” is judged in terabytes or above	
4. Velocity: the speed of data collection with Big Data defined in real-time or near real-time	
5. Variety: a range of forms including pictures, text messages, GPS signals, sensor readings, etc.	
6. Veracity: the trust in the accuracy, precision, and certainty as well as if the data set is representative of the entire event	
7. Volatility: refers to the tendency for data structures to change over time	
Total =	

Assessing the Value or Utility of a Data Set

If you are going for a walk outside then, you might check the weather to examine what you might expect. First, you may look outside your window. Is it raining, snowing, windy, or calm? Should you bring an umbrella with you? How long will you be away? Will you be near a shelter? Will the consequence of getting wet be bad? Would the consequence of getting wet be catastrophic? You only can assess what you can see out your window; it would be so much wiser to look at the clouds in all directions and then check a weather report.

The application to food fraud prevention is that once the specific decision is identified, then the available data can be evaluated and assess the “fit for purpose” (Table 16.1). A data set could be judged by the type of analytics possible and then a Likert scale for the Vs of Big Data.

This table is an example of how to possibly explain and present the nature of a data set regarding the appropriate application of Big Data and data analytics.

Sidebar: Review of FMEA Application to Food Fraud

There are many risk assessment models or tools that are very successfully implemented. Some provide more value in addressing food fraud prevention than others.

Excerpt from Ph.D. (Spink 2009):

Failure Modes and Effects Analysis (FMEA)

Failure Modes and Effects Analysis (FMEA) is a quality control and risk analysis system with underlying risk assessment and management concepts that are very sound and insightful, although not necessarily suited to the all-encompassing counterfeit threat [and for food fraud prevention]. FMEA is a widely used, pro-active quality tool that focuses on design improvements and physical failures (Kmenta and Ishii 2000). The FMEA failure mode is defined here:

Failure Mode and Effect Analysis (FMEA): the manner in which a component, sub-system, or system could potentially fail to meet the design intent. The potential failure mode could also be the cause of a potential failure mode in a higher level subsystem, or system, or the effect of a lower level effect (Kmenta and Ishii 2000).

FMEA focuses on system performance by analyzing reliability, maintainability, and safety (Onodera 1997). FMEAs are most frequently used in early product development and then again in manufacturing (Onodera 1997). The FMEA system is based on data gained from known recorded failures—in the lab and in the field—which leads to the efficient use of a probabilistic approach (probabilities based on historical data) (Kara-Zaitri et al. 1991). Other reports specifically identified FMEA in manufacturing operations, focusing on “the ways equipment can fail or be improperly operated,” with an emphasis on identifying the specific single component that failed (Graver 2001). FMEA is used to analyze “risk by identifying hazards and suggesting process design modifications” (Zambrano et al. 2007). The FMEA emphasis on monitoring recurring actions within a specific system is demonstrated in the abstract of the FMEA Reference manual, published by the Society of Automotive Engineers (SAE). Its focus is on “potential failure of a product/process” and identifying actions that could reduce or eliminate the failure (Society of Automotive Engineers (SAE) 2002).

The key component of FMEA is the Risk Priority Number (RPN), which is used to assess the risk using the three criteria of occurrence, severity, and detection. Detection focuses on identifying the failure before the customer receives the product.

Detection considers the physical product’s development, manufacturing, and operations. FMEA is a widely used quality and risk assessment process that is event and data intense. It focuses on specific products and systems, so it does not directly apply to the Food Fraud Prevention Strategy.

To consider the challenges of the direct application of FMEA for food fraud prevention:

- While there are known “failures” (known food fraud incidents) there are actually relatively few known “recorded failures” (100’s in the world not 100’s per manufacturing plant)

(continued)

- There are not enough incidents to conduct a statistically significant probabilistic risk assessment
- Food fraud incident cannot be created “in the lab.”
- There can be an assessment of “the ways systems fail” based on the incident reviews
- There can be monitoring on controlling the “potential failure of a product or process.”
- An adaptation of the RPN can be used in terms of assessing vulnerability assessments, but there is a key concern that a numerical assessment may “imply excessive precision” – on a scale of 1 to 5 (versus very low, low, medium, high, and very high) is a 3.5 actually significantly different from 3.7? Also, by presenting an assessment of “3.7” implies the assessment is accurate to two significant digits. Even “3” – not “3.0” since “3.0” insinuates that there is confidence in stating it is not “2.9” or “3.1” – implies accuracy to one significant digit. If the assessment is qualitative, it is clear to state that two assessments are both “Medium” rather than “3.5 and 3.7.”

Thus, the *general* FMEA principles can *generally* be applied to food fraud prevention. That said there should be great care of unintentionally presenting more accuracy, precision, or certainty than intended by the risk assessor.

Key Learning Objective 3: Extreme Events, the Highly Improbable, and Black Swans

This section reviews the study of extreme events and the highly improbable that are sometimes referred to as Black Swan events.

The Key Learning Objectives of this section are

- (1) Review of extreme events and the highly improbable results
- (2) Black Swan events
- (3) The GermanWings suicidal pilot airplane crash as a Black Swan event?

Black Swan Events: The Impact of the Highly Improbable (Fig. 16.2) (MSU-FFI 2018)

Title: The Black Swans of Food Fraud

By John Spink, May 15, 2013, Blog

No, Black Swans are not the next food fraud incident. Black Swan events are extreme events that are not foreseen, but if they occur could have catastrophic results, and in hindsight could have been seen coming (see “*The Black Swan*” book by Nassim Taleb). Black Swan events are the types of threats that led to the creation of Enterprise Risk Management (ERM).

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Beware the Black Swans of Food Fraud!
by John Spink - May 15, 2013 - [Blog](#) [0 Comments](#)

No, Black Swans are not the next Food Fraud incident. Black Swan events are extreme events that are not foreseen, but if they occur could have catastrophic results, and in hindsight could have been seen coming (see *The Black Swan* by Nicholas Taleb). Black Swan events are the types of threats that led to the creation of Enterprise Risk Management (ERM).

Using ERM concepts to conduct Food Fraud vulnerability assessments is not only efficient but has been recognized as progressive by higher level managers. Stepping back to consider this broader corporate strategy can seem foreign since we are scientists and want to jump into taking action and testing products. But to be competent corporate leaders with an enterprise-wide risk such as Food Fraud we need to speak the language of finance and of the Board of Directors.

ERM is a concept and system that monitors all risks across an entire enterprise. ERM is filtering down from the Board Rooms through the organizations and will soon be an everyday practice in



Fig. 16.2 Image of the blog post on the subject (Copyright Permission Granted)

Using ERM concepts to conduct Food Fraud Vulnerability Assessments are not only efficient but has been recognized as progressive by higher-level managers. Stepping back to consider this broader corporate strategy can seem foreign since we are scientists and want to jump into taking action and conducting tests of the environment. However, to be competent corporate leaders with an enterprise-wide risk such as food fraud we need to speak the language of finance and of the Board of Directors.

ERM is a concept and system that monitors all risks across an entire enterprise. ERM is filtering down from the Board Rooms through the organizations and will soon be an everyday practice in Business Units and also further down in Operations. Specifically, these enterprise-wide risks – as opposed to the more traditional operational risks – are more “vulnerabilities” than “recurring events.” Their impact is more strategic than operational. An extreme event may be very unlikely but, if it occurs, could be catastrophic to the entity. For example, consider the impact on your business of the sub-prime lending crisis (economic collapse), the Japanese Tsunami and nuclear meltdown (radioactive migrating tuna), another avian influenza scare (shut down of some trade routes), or food fraud (the horsemeat scandal and the global suspicion of a food staple). The growing awareness of these types of complex risks that are distributed across an enterprise led to the creation of the ERM system and of

(continued)

a Chief Risk Officer (CRO) position. The CRO is responsible for all risks across the entire enterprise regardless of the frequency, impact, or if they have actually occurred.

It is important to emphasize that each business function is usually competently addressing risks that are clearly defined as within its roles and responsibilities. In each of the ERM examples above the food safety or Food Defense group would be competently focusing on the objective of reducing foodborne illnesses or attacks that can create public health threats – but within their boundaries what could they do about mitigating the risk of the sub-prime lending crisis?

What is unique about enterprise-wide risks is that they are often distributed across many business functions. In addition, the specific incidents are so improbable or uncontrollable that it would be inefficient for any single business function to address that vulnerability alone. That being said, the combined risk to the enterprise could be catastrophic.

What is also different about these types of strategic risks is that they are governed at the Board of Directors level (where the risk appetite and defining accountability are determined), at the Company level (where CEO and CFO evaluate the risks across the entire enterprise), and at the business unit level (where they are responsible for implementing and managing countermeasures and control systems in line with the Board of Directors and Company requirements).

Food safety professionals will find that ERM principles are similar to the International Standards Organization (ISO) standards such as ISO 31000 Risk Management and ISO 22000 Food Safety. We can also rely on best practices from ISO 27000 Information Technology Security, ISO 28000 Supply Chain Security, and the work of Technical Committee 247 on Fraud Countermeasures and Controls. All these standards also provide a framework to address the “written risk assessment” mandate in the Food Safety Modernization Act.

This is not just another version of HACCP or CARVER+Shock. Are you ready for a Black Swan event? Are you speaking the language of Enterprise Risk Management?

Sidebar: The Black Swan—“To Be Wrong with Infinite Precision”

This is a review of an idea presented by Nassim Taleb in his book *The Black Swan—The Impact of the Highly Improbable* (Taleb 2007). The analogy of a “Black Swan” is that until a swan that was black in color—rather than white—was found by explorers in Australia, the Western belief was that all swans were white. In one incident, everything changed.

One of the concepts Taleb presents is “The narrative fallacy addresses our limited ability to look at sequences of facts without weaving an explanation into them, or, equivalently, forcing a logical link, an arrow of relationship, upon them. ... Where this propensity can go wrong is when it increases our impression of understanding” (Taleb 2007). This review starts with reviewing what insight is outside and inside our information set.

Insight from *outside* Our Information Set

A key point—and incredibly important challenge for food fraud prevention incident databases—is “what could be inferred from outside our information set.” Often there is a lack of awareness of what is *not* included. Now, these next few thoughts seem like gibberish but follow the logic closely:

- We know what we know (also, “known-knowns”).
- We don’t know what we don’t know (also, “unknown-knowns” or “known-unknowns”).
- Wisdom comes from knowing—and to the point of assuming—we do *not* know everything.
- Further wisdom is knowing how much we do *not* know (also, “unknown-unknowns”).

In that order, this seems entirely logical. That said think about some decisions made about food fraud prevention for countermeasures and control systems. There is often an unsupported assumption or stated confidence and presentation that the information set is complete. This creates Black Swan event opportunities.

Insight from *Inside* Our Information Set

A first concept is a “post hoc rationalization” where humans have a need for “sense-making” and seek logic or patterns even where there are none. An example from Taleb is first to read this statement:

A BIRD IN THE
THE HAND IS WORTH
TWO IN THE BUSH

Did you catch something wrong? In a busy world, the human brain tries to make sense of and focus on the important things. Brain scientists have found that some people have a lower rate of error in assessments based on if they are more “right brained” or “left brained.” There are other interpretations and decision-making mechanisms and habits that add to the complexity. Applied to food fraud prevention, this presents interpretation bias – you might miss something obvious.

Overcausation

The world is busy, and massive amounts of information are presented. Humans need to make a lot of assumptions just to be able to walk down a hallway. Taleb stated “We [humans] harbor a crippling dislike for the abstract.

(continued)

Humans have a need to identify a root-cause to explain an event. Scientists, the public, media, and others go to great lengths to process the problem and root-cause. This is a “confirmatory bias,” “overcausation,” or “It is as if they wanted to be wrong with infinite precisions [this is sarcasm by Taleb or a statement that some risk assessors intend to deceive the reviewer].”

When there are many unknowns and uncertainty, rigorous assessments or probabilities become less and less precise and thus less valuable when selecting countermeasures and control systems. Applied to food fraud prevention, this would be trying to predict “the next melamine incident” or “which imported shipping container should we inspect.” One way to address this is to accept the uncertainty and lack of precise data. When considering what information is available there is an ability to create models that identify vulnerabilities but not necessarily probabilities. Countermeasures and control plans can be implemented that reduce *all* vulnerabilities regardless of the market dynamics or stakeholders.

The Black Swan: Experience Versus Expertise

When a new food fraud article or interview is published, there often many people who say “oh, I’ve been studying this topic for years.” Do they have “experience” or “expertise”? If they’re such experts and been working on this for so many years, then why is food fraud still a problem?

If you were leading a project to protect a bank, would you rather hire a bank manager who has “experience” being robbed or someone with “expertise” *not* being robbed? From “The Black Swan,” author Taleb would define this as two terms that which will be defined below which are the “empty-suit problem” and “epistemic arrogance” (Taleb 2007). Some key definitions help provide insight on this question (the food fraud prevention application is added for several of the key terms) (Taleb 2007):

Black Swan blindness: The underestimation of the role of the Black Swan and occasional overestimation of a specific one.

- For food fraud prevention, this would be focusing on preventing a recent incident such as melamine or horsemeat and basically ignoring trends that may identify a new “fraud opportunity.”

Black Swan ethical problem: Owing to the nonrepeatable aspect of the Black Swan, there is an asymmetry between the rewards of those who prevent and those who cure.

- For food fraud prevention, this would be the post-incident focus on detection of the specific incident rather than focusing on the root cause and general vulnerability reducing control systems.

Confirmation error (or *platonic confirmation* or *confirmatory bias*): You look for instances that confirm your beliefs, your construction (or model)—and find them.

- For food fraud prevention, this could be relying heavily on a published data set to be representative of all vulnerabilities.

Empty-suit problem (or “expert problem”): Some professionals have no differential abilities from the rest of the populations but for some reason, and against their empirical records, are believe to be experts.

- For food fraud prevention, some professionals rely on their previous experience as an expert and have not reviewed new insight or methods. (It is amazing to hear absolutely positively incorrect statements made by industry experts—but the statements are made with high confidence.)

Epistemic arrogance: Measure the difference between what someone actually knows and how much they think they know. An excess will imply arrogance and a deficit of humility. An epistrocrat is someone of epistemic humility, who holds their own knowledge in greatest suspicion.

- For food fraud prevention, this could be a professional who has worked in food adulterant detection, and there is a belief that the food fraud prevention, opportunity reducing countermeasures, and control systems are from within their area of expertise (e.g., a food scientist who applies food safety microbiological prevention techniques to the human criminal adversary).

Gray Swan (Mandelbrotian): Black Swans that we can somewhat take into account—earthquakes, blockbuster books, and stock market crashes—but for which it is not possible to completely figure out the properties and produce precise calculations or probabilities.

- For food fraud prevention, the reality is that almost every single incident is a “Gray Swans” with an inevitability or warning signs. The incidents may even be “White Swans” if we assume they will eventually occur. Earthquakes do occur. Depending on the geographic location of your building, you will take more or fewer precautions.

Ludic fallacy (or uncertainty of the nerd): The manifestation of the Platonic fallacy in the study of uncertainty, basing studies of chance on the narrow world of games and dice. A-Platonic randomness has an additional layer of uncertainty concerning the rules of the game in real life. The bell curve (Gaussian), or GIF (Great Intellectual Fraud), is the application of the ludic fallacy to randomness.

- For food fraud prevention, this could be when a food safety or risk scientist applies statistical methods to a data set that is not appropriate or that is incomplete. For example, the most complex statistical analysis is usually based on the underlying assumptions of “5 to 7 percent of world trade” (Spink and Levente Fejes 2012).

Narrative fallacy: Our need to fit a story or pattern to a series of connected or disconnected facts. The statistical application is data mining.

- For food fraud prevention, this could be addressing the food fraud problem with current data sets or within current countermeasures systems. This could include food fraud being addressed in food safety early warning systems.

Reverse-engineering problem: It is easier to predict how an ice cube would melt into a puddle than, looking at a puddle, to guess the shape of the ice cube that may have caused it (“the melting ice cube”). The “inverse problem” makes narrative disciplines and accounts (such as histories) suspicious.

- For food fraud prevention, there are sometimes data sets that use themselves to validate the model (in sometimes unintentional or ignorance of circular references). For example, predicting the type of food fraud once fraud has been identified—the primary challenge is not really what type of fraud is occurring but to figure, first, if fraud is occurring. Another example is to use a known data set to create a model and then demonstrate the accuracy and precision by running examples from that data set.

Others include:

Frequency vs. probability: “Overconfidence is less significant when the problem is expressed in frequencies as opposed to probabilities.” This also applies to vulnerabilities rather than risks or a probabilistic risk assessment.

Lack of awareness of ignorance: “In short, the same knowledge that underlies the ability to produce correct judgment is also the knowledge that underlies the ability to recognize correct judgment. To lack the former is to be deficient in the latter”.

Overconfidence: “Overconfidence can be influenced by item difficulty; it typically diminishes and turns into under-confidence in easy items.”

Randomness as incomplete information: Simply, what I cannot guess is random because my knowledge about the causes is incomplete, not necessarily because the process has truly predictable properties.

Retrospective distortion: Examining past events without adjusting for the forward passage of time. It leads to the illusion of posterior predictability.

Uncertainty of the deluded: People who tunnel on sources of uncertainty by producing precise sources like the great uncertainty principle, or similar, less consequential matters, to real life; worrying about subatomic particles while forgetting that we can’t predict tomorrow’s crises.

The Problem of Induction: “Things cannot be known with perfect certainty because their causes are infinite.”

A new appreciation for our assumptions or bias is helped when stepping back and reviewing broader risk assessment concept such as the Black Swan definitions.

Sidebar: The Black Swan—“The Melting Ice Cube”

This is a review of the concept presented by Taleb in “The Black Swan” (Taleb 2007). This is one of the most effective and simple explanations to reinforce the focus on vulnerability reduction rather than specific event detection. The analogy explains a “forward process” and “backward process.” He states “The backward process is much more complicated. The forward process is generally used in physics and engineering; the backward process in nonrepeatable, nonexperimental historical approaches. In a way, the limitations that prevent us from un-laying an egg also prevents us from reverse engineering history” (Taleb 2007).

Option 1 “The Melting Ice Cube”: place an ice cube on a table and imagine the puddle that will result.

- For food fraud prevention we know there will—or could—be a puddle in the future. A focus could be keeping the ice cube in the freezer or to contain the puddle once it is formed. The melting ice cube and the damage from the puddle are vulnerabilities. Crime prevention theory would identify characteristics of the situation or environment that lead to the ice cube being removed and left to melt. The focus can be on reducing those root causes for a range of problems related to the access to the freezer.

Option 2 “Where did the water come from”: try to reconstruct the shape of the ice cube by analyzing the puddle. This assumes the puddle is from the ice cube.

- For food fraud prevention, if there was an ice cube, there are infinite possibilities for the shape if there was, in fact, an ice cube, to begin with. Authentication would tell us that there is a puddle and that the liquid is water that is similar to what was used to make ice cubes. Control systems could tell us that an ice cube was removed from a freezer. The focus would be on alerting us when an ice cube has been attacked.

To be proactive and focus on prevention is to take the “forward process.” To detect and to deter is, of course, important, but the real focus is on prevention.

A Black Swan Event?: Review of the Germanwings Airplane Crash (MSU-FFI 2018)

Title: Germanwings Airplane Crash: Was it a Black Swan Event? Was it a “Reasonably Foreseeable Hazard” or “Reasonably Likely to Occur”?

By John Spink • March 31, 2015 • Blog

(continued)

Was last week's Germanwings intentional airplane crash by a rogue pilot a "reasonably foreseeable hazard"? Was it "reasonably likely to occur"? What is the regulatory or jury-determined legal liability expectation of what is "reasonably" and "likely"? For food fraud prevention: To-be-determined.

The Germanwings plane crash from last week is a horrible tragedy on many fronts. The cause points to an intentional act by the co-pilot. The result was the crash and death of all 150 people on board. The co-pilot had a medical condition (still undefined but there is speculation) that he did not reveal to the employer. Investigators stated they found a torn-up doctor's note stating the co-pilot was "... too ill to work, including on the day of the crash."

It was reported that "Some international airlines responded to the crash by introducing new rules requiring that two crew members always be present in the cockpit. The airlines that said they were instituting a two-person rule in the cockpit included Air Canada, EasyJet, and Norwegian Air Shuttle." "The European Aviation Safety Agency [EASA], based in Cologne, Germany, also advised airlines across the region to adopt a two-person rule. The agency said the recommendation was temporary, pending the outcome of the French investigation into the Germanwings crash."

This article reviewed seemingly related suspicious airplane crashes which were:

- 2013: Mozambique Airlines, Dead: 33, "When the flight's co-pilot left to use the lavatory, the captain locked him out of the cockpit and manually steered the plane downward."
- 1999: EgyptAir, Dead: 217, "Investigators conclude that the most likely explanation was that that co-pilot, ... deliberately brought down the plane... The flight data recorder showed that he waited for the captain to leave the cockpit and then disengaged the autopilot."
- 1997: Dead: 104, "[The plane] was cruising at 35,000 feet when it suddenly dove... [The pilot] had recently been demoted and disciplined by the airline and had large gambling debts."
- 1994: Air Morocco, Dead: 44, "The pilot... intentionally disconnected the plane's automatic navigation system... and crashed the plane... shortly after takeoff..."
- 1992: Japan Air Lines, Dead: 24 of 166 passengers, "...the pilot... sent the plane into Tokyo Bay moments before it was to land... He had a history of 'psychosomatic disorders' in the late 1980s, but airline doctors said he was fit for duty."

So, after considering this new information, is the suicidal pilot risk a Reasonably Foreseeable Hazard or Reasonably Likely to Occur?

This incident raises some interesting questions about the definition of what is a "reasonably foreseeable hazard" and what is "reasonably likely to occur." This incident also provides an example of the difference between: (1) the need

or expectation to address a hazard and (2) knowledge that an incident could occur. The data is that there were five (5) related suspicious airplane crashes in the last 23 years. Though it could be argued that a Probabilistic Risk Assessment would be an inappropriate assessment for this type of “vulnerability” there would have been an infinitesimal probability of this incident occurring. That said, the intentional airplane crashes are not unheard of.

FDA Food Protection Plan: Intervention, Response, and to Prevention

For food fraud prevention we have discussed the process of prevention to intervention to response. We note that after a new incident the process starts at Intervention, then to Response, and finally back up to Prevention. By definition, the new incident either defines a previously unheard-of risk (e.g., a “Black Swan” event) or provides new information on a previously known risk (e.g., a “Gray Swan” event). (Note: see the previous blog post on “Beware the Black Swans of Food Fraud.”)

Intervention

- This Incident: The plane has already crashed. The incident has passed. There is no “Intervention” for this incident.
- Future Incidents: This would focus on how to intervene in future situations where a pilot may try to take over the cockpit. Actually, expand this to anyone with access to the cockpit including other staff or a passenger. There are times during a flight when the cockpit door does open. The health of the pilot would also be a consideration, but that is more “traditional criminology” focusing on the perpetrator, not “environmental criminology” focusing on managing the “space” of the crime – Situational Crime Prevention. The company has more control over the physical space of the crime rather than of the perpetrators.

Response

- This Incident: This incident has passed so no “Response.”
- Future Incidents – Immediate: Airlines and the EASA have implemented a temporary mandatory requirement that two pilots be in the cockpit at all times even if this means a third pilot is required on a flight. (This will be interesting on flights where there are only two seats in the cockpit.)
- Future Incidents – Future: This would technically be addressed under the Prevention category.
- In General: It appears that the Response for this and other incidents is related to the catastrophic nature of the risk and the clarity of the immediate effect of a countermeasure. Requiring two pilots to be in an airplane cockpit can be implemented immediately, and there is logic to how this reduces the “crime opportunity.”

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Prevention

- Future Incidents: It appears longer-term research into Prevention is already underway. The “two-pilot” rule may become – or may just have become – a standard industry practice.

The Germanwings airplane crash provides a case study to define the nuance of “reasonably foreseeable hazard” and “reasonably likely to occur.” For food fraud prevention this incident emphasizes the importance of taking the time and effort to thoroughly and precisely define the fundamental concepts. While this will require a lot more consideration and research, this incident seems to emphasize a focus on prevention and reducing vulnerabilities. For food fraud prevention these are already core, fundamental concepts. MSU-FFI

Conclusion

This second risk analysis chapter expanded on the basic fundamentals to an application to food fraud prevention. Through a series of basic concepts, and application examples, consistent and revealing practical and pragmatic insights can be found. ***The first conclusion is*** that food fraud is a new and different type of food risk so the “it” in “do it right the first time” is to *only* conduct a PRELIMINARY review...at least for now. There is an expectation that the insights will probably reveal very different types of best practices. This leads to an insight that at different stages in the implementation there are very different needs from the data (e.g., accuracy, precision, certainty, and robustness). Also, due to the nature of the data sets and the assessments, seemingly simplistic qualitative assessments and presentations may be optimal. ***The second conclusion is*** that all data analysis should include basic data analytics/Big Data review. Often, due to the nature of food fraud and the fraud act compared to other problems, there is a massively smaller data set with exponentially less thorough information. It is critical to characterize the nature of the data to explain the level of output that can be expected. Often for food fraud, there is so little data that there is almost never enough for a “prescriptive analytics” or “predictive analytics” and often not even enough to state a statistical significance meaningful “descriptive analytics.” There is absolutely enough information and data to conduct incident reviews that explain the system weaknesses such as in the Product Counterfeiting Incident Clustering Tool (PCICT) or Hot Product and Hot Spot analysis. ***The final conclusion is*** that there are great insights to be gained from the study of extreme events and the research on the highly improbable. Many food fraud incidents fall into the realm of Black Swan events. Once there is a realization of being in “Extremistan,” there is a new perspective, theories, and models to apply. With the right perspective and vulnerability assessment, there is shift from being surprised by Black Swan events to seeking Gray Swans—a shift from mitigation (a quick response to minimize the negative consequences of an event after it has

occurred) to prevention (reducing system weaknesses to try to prevent the event from even being able to occur). There is a saying:

Avoid presenting the “impression of excessive precision” and the temptation “to be wrong with infinite precision.”

Appendix: WIIFM Chapter on Risk Application

This “What’s In It For Me” (WIIFM) section explains why this chapter is important to you.

Business functional group	Application of this chapter
WIIFM all	There are very different work processes, but they are key to addressing these highly improbable but often catastrophic Black Swan-type events
Quality team	There are very specific risk analysis and risk assessment methods that apply and do <i>not</i> get overly complex until you conduct high-level, prefilter information gathering projects
Auditors	Due to the nature of the risk—and the current GFSI requirements—the assessments will seem extremely simple and light compared to other HACCP-type assessments
Management	Support the continuous review of the process with a series of lighter activities and deliverables—“do it right the first time” is to conduct enterprise-wide assessment that is not very certain or robust, yet
Corp. decision-makers	The first assessments will be light but effective, for now

Appendix: Study Questions

This section includes study questions based on the key learning objectives in this chapter:

1. Discussion Question

- When considering data needs, what is the relationship between accuracy, precision, and certainty?
- When presenting FF vulnerabilities, what are the strengths and weaknesses of “qualitative versus quantitate” and “words versus number”?
- How do the concepts of Black Swans, Gray Swans, and White Swans apply to FF prevention?

2. Key Learning Objective 1

- (a) What is “data uncertainty”?
- (b) How does “dread and outrage” impact the responses to a FF incident?
- (c) How do “blunders” impact the effectiveness of addressing FF prevention?

3. Key Learning Objective 2

- (a) What is “data veracity”?
- (b) What are the “7 Vs of data analytics”?
- (c) Are most FF vulnerability assessments “descriptive,” “predictive,” or “prescriptive” analytics or none of the above?

4. Key Learning Objective 3

- (a) How did the “Black Swan event” get its name?
- (b) What is “experience vs. expertise”?
- (c) What does mean to be “wrong with infinite precision”?

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Chapter 17

Risk Analysis (Part 3 of 3): Implementation



Summary

This chapter presents a shift from the general risk analysis theory to the application and implementation of the Food Fraud Prevention Strategy. The following chapter on Risk Assessment Application provides more detailed examples and case studies. This chapter will focus more specifically on the vulnerability assessments including preparing to address the problem, conducting a quick initial screening, expanding to a more detailed assessment where and when warranted, and finally connecting the assessment to all other enterprise-wide problems.

The Three Key Learning objectives are:

- **(1) Framing the Problem and Scope:** Define what question you are asking and exactly what information is needed to change a specific decision.
- **(2) Conducting a Prefilter or Initial Screening to Start:** At minimum, review the entire fraud opportunity to document an assessment. This will demonstrate a method to identify the most important problems.
- **(3) Conducting a Detailed Food Fraud Vulnerability Assessment (FFVA) Including Presentation in an Enterprise-Wide Assessment:** This final step will allow a detailed—and often spirited—debate of the conclusions and very specific discussions about countermeasure and control systems.

On the Food Fraud Prevention Cycle (FFPC), this chapter addresses the “(0) fundamental concepts” beyond what is risk analysis to the details of risk assessment as applied to food fraud prevention (Fig. 17.1).

Introduction

This chapter will expand on risk analysis to specific vulnerability assessment concepts. It is important to build upon a theoretically sound foundation to establish the overall principles and finally to make sure the concepts are coordinated and

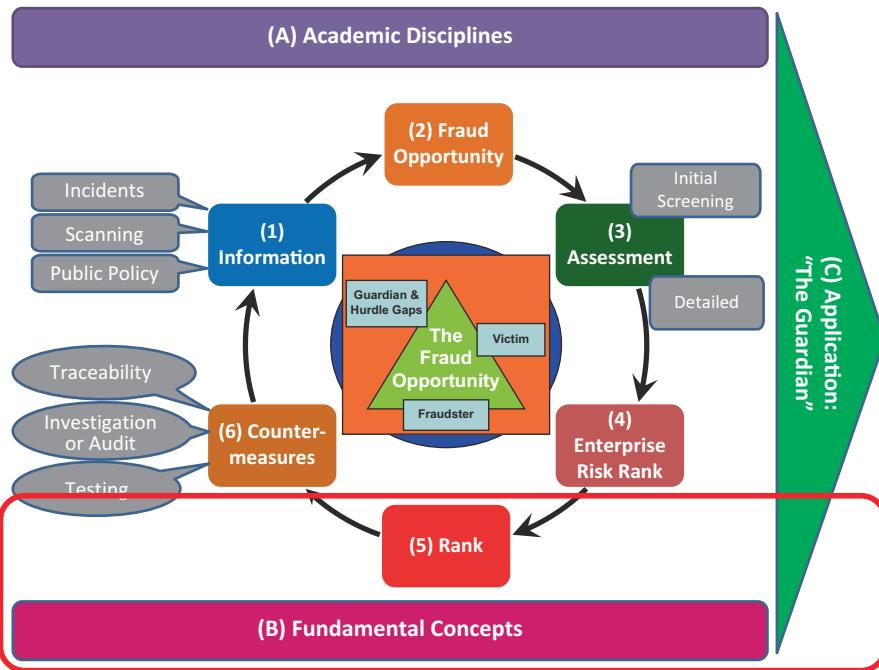


Fig. 17.1 Food Fraud Prevention Cycle—where this chapter applies to the overall concept: “(B) fundamental concepts” and “(5) risk”. (Copyright Permission Granted) (Spink 2014; Spink et al. 2019)

calibrated all the way to actual implementation (Fig. 17.2). Too many times academics study one part of a process—ad infinitum to way beyond the point of diminishing return—but leave the integration to some anonymous “others.” There is often an empty and unsupported claim that “can be used by decision-makers” or “is valuable to support decision-making.” The “decision” is never clearly defined, and the “decision-makers” are often generic “risk assessors.” *General* recommendations *generally* help while *specific* recommendations *specifically* help. This general approach to answering non-correlated research questions is similar to creating separate links in a chain but never checking that the entire chain actually connects and can support the weight of the lift. Without framing the problem and scope of the application or value of the new research cannot be judged... *at all*.

To consider more details of the Food Fraud Vulnerability Assessment and decision-making, there is a flow from the beginning with a consideration of the issue through decision-making (Fig. 17.3). There are specific steps required to advance from an assessment through processing to supporting an actual resource-allocation decision.

As is presented in the Business Decision-Making chapter, the COSO managerial accounting practice of Enterprise Risk Management is based on an assessment in a

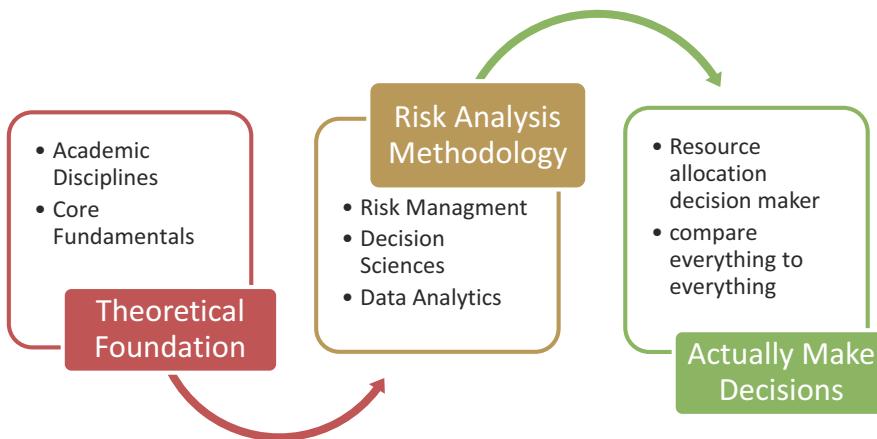


Fig. 17.2 Process from theoretical foundation through risk analysis methodology to actual decision-making

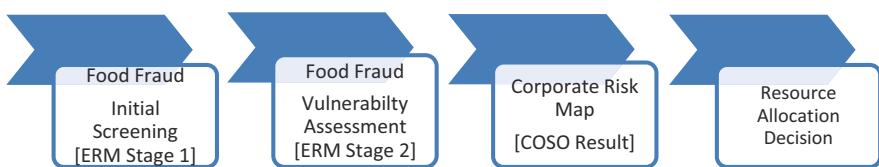


Fig. 17.3 The role of the Food Fraud Initial Screening (FFIS) in the Food Fraud Risk Continuum. (Copyright Permission Granted) (Spink et al. 2016)

two-stage process. The first is a qualitative, prefilter, or quick “initial screening” following more detailed assessments only as required for the specific question and resource-allocation decision. In many cases, more assessment is not needed. The third step is to include the assessment in some sort of enterprise-wide calibration system. This new problem must be compared to other enterprise-wide problems. Finally, the assessments and analysis have a definitive role in supporting resource-allocation decision-making. The entire system is refined to both increase the efficiency of the assessments and also support the final decision-making.

Key Learning Objective 1: Framing the Problem and Scope

This section reviews framing the problem and scope which is referred to in ISO 31000 as “Establishing the context” (ISO 2009). Specifically, the preparation is critical to consider what really needs to be completed and how the resource-allocation decision-making can best be conducted.

The Key Learning Objectives are:

- (1) Prepare and review scope which is not just to authenticate but to prevent.
- (2) Internal and external resources such as to spend 10-minutes on Google Scholar can save 2 weeks of laboratory research or project work.
- (3) Needs of the boss and many decisions are based on very little data.

Prepare and Review

If you do not identify the specific question in detail, then there is really no way to judge the efficiency of countermeasures and control systems. Aspirin is good, taking an aspirin must be good, then taking ten aspirins would seem to be better, right? If $A = B$ and $B = C$, then $A = C$? However, for a broken leg or acne, that is not a very efficient risk treatment. If you clearly identify the problem (broken leg or facial acne), then the urgency of response can be defined and defended. Also, the most efficient and effective risk treatment can be identified and explained. For the broken leg, immediately call an ambulance to go to an emergency room to set the broken leg. For acne, maybe begin to try using acne soap and face cream for a month. Aspirin is good but never considered as a recommended treatment for either problem.

An example of defining the problem in detail is presented here (Spink 2017):

- **Problem:** Counterfeit or substandard vodka poisoning consumers, undermining consumer confidence, and possibly reducing the demand and price for local vodkas.
- **Market:** An entire country.
- **Goal:** There is a hierarchy of needs that get synthesized for specific agencies or countermeasures and control systems.
 - What is the problem?
 - Stop e-commerce? No.
 - Detect fraud? Yes.
 - Deter fraudsters? Yes.
 - Stop consumers getting cheated? Yes, and now getting more specific.
 - Stop consumers getting hurt? Yes, and now getting even more specific.
 - Reduce public health harm from fraudsters? Yes, getting yet even more specific.
 - Reduce consumer victimization? Yes, a final key focus.
 - “Prevent it all violations?”—Ok, this is more of an aspiration and is good as a vision, but what is “it” again?
 - Prevent all health harms from all e-commerce? No.
 - Address illegal e-commerce alcohol and specifically vodka? Yes.
 - Review the updated project scope: The problem statement is to address counterfeit or substandard vodka poisoning dangers which undermine consumer confidence and possibly reducing the demand and price for locally produced vodkas.

Thus, a first step is to conduct a risk assessment to identify the root causes of the vulnerabilities so that a prioritized focus can be concluded.

After following this detailed process, the research question is clearly and precisely defined. If this is written, then it can be shared, edited, discussed, debated, and refined. Now that there is a very specific research question, a response can be identified and evaluated. This type of detail is helpful to identify success metrics and then also support a resource-allocation decision.

Sidebar: Detail on Starting to Address the Problem (Starting from a Blank Page)

Of course, if there is an actual, live incident, then addressing that problem is the priority. If there is a known or suspected public health threat that gets the immediate focus. If there is no specific incident or suspected public health threat, the first step is *not* to “respond to risks” or to select countermeasures and control systems. Before selecting countermeasures and control systems, there is a methodical approach to frame the question.

Overall, there will appear to be similar theoretical concepts that keep presenting themselves between the ISO (e.g., ISO 9000, ISO 22380, and ISO 22000), criminology (e.g., SARA method and Situational Crime Prevention), and the business management (e.g., COSO, Total Quality Management (TQM), and Generally Accepted Accounting Principles (GAAP)).

Risk assessment process based on the COSO managerial accounting practices state that “The ERM risk assessment process is outlined here” (COSO 2011):

“1. Identify risks. These might impact the enterprise (external or internal).”

“2. Develop assessment criteria. Assessment criteria are often difficult to develop as it is very difficult to compare and aggregate risk across the enterprise. Such criteria often focus on the relative likelihood of an enterprise experiencing a specific risk as well as the impacted financials and all other negative consequences that might occur. Since risks might have negative consequences across functions/business units/etc., it is important these different constituencies within the enterprise have an understanding of the breadth of risks and their impact and such that consistent interpretations of risk/consequences can be developed.”

“3. Assess risk. This is accomplished in two stages that include:

- ‘(1) A qualitative initial screening is driven by categories of likelihood/impact (e.g., this risk as a high likelihood and a moderate impact).
- ‘(2) A more detailed quantitative assessment of those risks that were deemed most consequential in the initial screening.”

“4. Assess risk interactions. This step focuses on understanding the enterprise risk portfolio in an integrated or holistic way by examining how iden-

tified risks positively or negatively are influenced by specific changes/processes that might occur within the enterprise. For example, efforts to reduce the potential for supply chain disruption might involve bringing in new raw material suppliers. Such a change might increase the risk of food fraud within the firm (e.g., unadulterated product, more difficult to audit each supplier, etc.).”

- “**5. Prioritize risks.** This step includes evaluating risks against “predetermined target risk levels and tolerance thresholds [later referred to as risk appetite].” It is important in this step that the potential holistic impact of a given risk is included when prioritizing the importance of a given risk. For example, beyond the financial loss, other important criteria such as the health and safety, brand reputation, etc. should be carefully considered.”
- “**6. Respond to risks.** In this step, risk responses (accept, reduce, share, and avoid) are determined and implemented. These steps create the foundation for the assessment. The next step is creating the vulnerability scales.”

An example of the continuum from an initial screen to the detailed assessment is provided (Fig. 17.4).

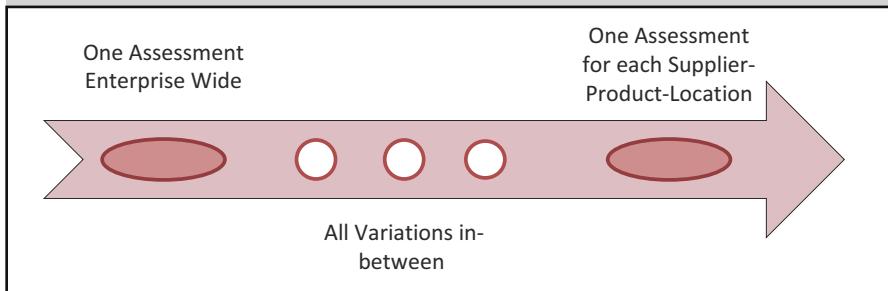


Fig. 17.4 Continuum of the ERM two-stage process of risk assessments from “initial screen” to “detailed assessment”

This is a detailed list that helps define the start of the risk assessment process which helps with the following step of “how to start.” It is important to emphasize that framing the question and identifying “how to start” creating a strategy are important before selecting or implementing countermeasures.

Risks of Conducting Risk Assessments

To continue to review “how to start,” there is a need to define the end goal but also other ways that the process could start, such as testing for the fraudulent product (Spink et al. 2013; Spink 2019). There is a saying “If you are a hammer everything looks like a nail.” That means that if a “hammer” is trying to complete a task, it will start by treating the problem like it is a “nail” and start banging. For food fraud

prevention, this could be a packaging manager recommending a packaging anti-counterfeiting component, a corporate security officer recommending investigating for suspicious activity, a law enforcement agency recommending investigation and prosecution, a customs officer recommending border inspections, a corporate lawyer recommending a lawsuit, or a food scientist recommending food authenticity tests. While each manager is trying to do the right thing and to make real progress on the problem, the most efficient way to start is with a risk assessor conducting an enterprise-wide assessment.

Next, it is important to understand the possible ramifications of any first action. While it may seem logical to “just start testing,” there may be no consideration of what you might find. It would be illogical *not* to find *any* suspicious activity regardless of their actual vulnerability, risk, or hazard. Early in the process, there may be no assessment calibration or decision-making criteria; any and all suspicious activity or innuendo may require a response. A response could be a global product recall of all products related to the suspicious activity. A more scientifically or methodologically based decision-making process could consider all the suspicious activities—or vulnerabilities—but include a filter that reduces the situations that require the most urgent and comprehensive responses.

If you find something suspicious, you may need to act—if you suspect a health hazard or illegal act, then not acting may be literally criminal—and criminal for *you*, individually, not just for your corporation. Most times, the issue is just peculiar or odd but not dangerous. If you “just start testing” or “just start investigating,” you may be inadvertently taking on new risks.

Another consideration is that there is even a risk of conducting risk assessments. At an early FFVA session that included senior food safety managers for food companies, there was a lack of awareness of the general liability in even just doing a prefilter assessment. The operations-focused personnel felt they were taking a science-based approach to more data gathering. They ignored and laughed off mentions of potential general legal liability. When the food scientists were asked “have you actually run this by your General Counsel,” they responded “yes, yes”—it seemed apparent that they hadn’t. In later sidebar discussion with a Deputy General Counsel, it was clear that the liability was a concern that was not fully understood by the food safety managers. The Deputy General Counsel was extremely concerned with the “risk of conducting risk assessments” and the liability of “just start testing product.” To be clear, if there were any incident or suspected health hazard, there would be immediate action.

For example,

- Action: Consider a packaging summer intern employee at your company uses a published Food Fraud Vulnerability Assessment without full information, and the automated system concludes your company has “high” food fraud vulnerability.
- Response: So, “yes or no” does your “company” have knowledge of a “high” food fraud vulnerability? “Yes, but...” The fact is “yes.”
- Consequence: This may be found during discovery during a lawsuit.

If you conduct an investigation and find *any—each and every*—suspicious activity, that concern *must* be further investigated. *Each and every* suspicious activity could be a public health threat or fraudulent product that would be illegal and unfit for commerce. Without a full system to assess the vulnerability, you may find a lot of “suspicious activity” that really is *not* a risk and actually within the risk tolerance. The suspicious activity may be just peculiar or odd but not dangerous or illegal.

Research Internal and External Resources

It is amazing how the little background research is often conducted before implementing big food fraud projects such as a lack of awareness of the value of criminology before addressing the human criminal adversary. Also, the general lack of risk analysis focuses on defining the problem and understanding the decision-making method. There is a mantra to “just get started.” There is an ignorance or lack of perspective that just because you have not heard of a problem before that, the vulnerability does not exist. Some companies and industries continuously create a completely new system from scratch or “reinvent the wheel.” Usually, they reinvent a poorer version of “the wheel.” The first inclination should be that:

- ‘(1) Someone else has been studying this.
- ‘(2) The available systems probably do not exactly apply to food fraud prevention.

The action to “just get started” could lead you down a long and winding path to a dead end. While “analysis paralysis” is the other end of the spectrum, for food fraud prevention there are guides and recommended paths forward.

In many (most) situations, there is new technology development that “is a solution looking for a problem.” This is backward. If you clearly understand your problem, then you can seek out or develop an optimal solution. If you don’t know your problem, then it is “dumb luck” if the technology or solution you select actually meets your needs (see section on Diagnosis, Treatment, Prognosis, and Decision).

There is a joke in academia that “two weeks in the laboratory can save you one day in the library”—yes, it is intended in that illogical order. With the Internet, the “1 day in the library” is probably about “10 minutes online.” A little background research could help you find previous work and both learn from the past and also start your work in an optimal direction.

After clearly defining and documenting the definition and scope of the research question, it is important to review currently available internal and external insight, methods, or resources. While fraud may be new to the food industry, product fraud prevention is not new to all of industry. There are 30+ years of experience addressing some aspects of fraud prevention-related work in many industries such as pharmaceuticals, personal care products, luxury goods, apparel, or even currency.

Because the question is new to you or your industry does not mean it is new for the world.

There are several examples of technology moving faster than the understanding of the root cause and the resource-allocation decision-making mechanism. For example, around 2006, radio-frequency identification (RFID) technologies were the hot technology that was perceived to be the magic bullet solution for traceability. As food safety traceability is a regulatory push in 2017 (re FSMA and previously the “one step forward and one step back” in the Bioterrorism Act of 2002), the US Prescription Drug Marketing Act of 1987 was that push due to mandated serial number-based traceability systems (as of 2018, the PDMA is still in limited stages of implementation not because of the package level capabilities but more straightforward challenges such as a single coding system, interoperability, data sharing concerns, and database security). Later in 2006, Wal-mart made a big push stating their “early adopter” intent to apply machine-readable automatic identification (Auto-ID) and RFID technologies. The number of Auto-ID or RFID vendors at the PackExpo packaging exposition boomed over about 2 years to the point there was an entire floor of the massive Chicago McCormick Place conference center dedicated to just the technology. While the frenzy has passed with little of the projected benefits, there is a wealth of experience and expertise in selecting, implementing, and managing new technology or solutions. The food industry can learn from the previous projects implementation successes and failures.

For food fraud prevention, systems and services are being developed to support a wide range of prevention needs. Some products or services provide insight on incidents while others help with assessments and then others support enhanced traceability.

To find case studies or successful implementation examples, an extensive literature and marketplace search is very efficient if you have your needs and scope clearly defined. You may find that the most efficient and effective resource is from outside your industry.

Product fraud is new to the food industry, but it is not new to all industry. Since at least the early 2000s, the pharmaceutical industry—including the drug side of the US Food and Drug Administration—has been conducting coordinated internal and external security activities. The drug industry has a long history of traceability, serialization of products, and end-to-end digital traceability. The US Prescription Drug Marketing Act of 1987 was the first effort to create this program. Additional US laws and regulations have further refined the focus and activities such as the Drug Supply Chain Security Act (DSCSA) of 2013 (Public Law 113-54 2011). The food industry—including the “food” side of agencies such as the EU DG-SANCO and US Food and Drug Administration—can learn a lot from their counterparts. By reviewing the past—the good and the less efficient—hopefully the food industry can both avoid pot-holes but also leapfrog to the next generation of prevention-focused activities.

Any proposal or project that does not begin with a thorough literature or research review is beginning as a guess and hoping for “dumb luck” to succeed.

Key Learning Objective 2: A Prefilter or Food Fraud Initial Screening (FFIS)

This section reviews the prefilter or Food Fraud Initial Screening tool (FFIS) which was created and published in response to an unmet research need (Spink et al. 2016). While there are many ways an assessment can be started, the FFIS began with understanding the need (e.g., compliance for GFSI, ISO 31000, FSMA, Sarbanes-Oxley, and others), acceptance of the very limited human and financial resource allocation (e.g., often a new assignment piled on top of other food quality or food safety job responsibilities), the limited and uncertain base incident data available or collected, and the other Food Fraud Vulnerability Assessment products, services, tools, and methods.

The Key Learning Objectives of this section are:

- (1) Review the foundational concepts of the FFIS.
- (2) Conduct a brief overview of the FFIS tool and method.
- (3) Consider the final presentation of the assessment and address the resource-allocation decision-making process.

The next sections will present the methods including the initial screening and detailed vulnerability assessment.

Introduction to the COSO Initial Screening: Food Fraud Initial Screening Tool (FFIS)

For vulnerability assessments, there is a range of actions from very casual and qualitative to the other extreme of very formal and quantitative. The COSO Enterprise Risk Management system describes a two-stage process of an initial screening and then a detailed assessment (COSO 2011). From COSO:

- “This [risk assessment following the event identification] may be accomplished in two stages where an initial screening of the risks is performed using qualitative techniques followed by a more quantitative analysis of the most important risks.”
- “Risk assessment is often performed as a two-stage process. An initial screening of the risks and opportunities is performed using qualitative techniques followed by a more quantitative treatment of the most important risks and opportunities lending themselves to quantification (not all risks are meaningfully quantifiable).”

This theory and terminology were used to create the Food Fraud Initial Screening Tool (FFIS) (Spink et al. 2016). The initial screen has also been referred to as a prefilter or first-step assessment. While the desired outcome for risk mitigation planning includes detailed vulnerability assessments, broader initial screening can

make the process much more manageable. Often a detailed, by-individual-product assessment is not practical due to the nature of the risk, the time allotted, or the detail needed for resource allocation and decision-making (Spink et al. 2016).

The FFIS is an efficient way to start with a review of the entire company. The important step is to complete the first assessment to identify where the more detailed investigation is necessary. Also, many compliance requirements already require “an” assessment but have no specification for the depth or breadth. For example, the basic GFSI requirements published in 2017 only require that an assessment is conducted and documented. A conversation was overheard at a conference where a company said: “our detailed vulnerability assessment will take five years”... the response was “that’s nice, but it was due two months ago.”

Introduction to the COSO Detailed Assessment: Food Fraud Vulnerability Assessment

The initial screening addresses the assessment from an overarching view of the entire operation, while the FFVA builds up from reviews of specific assessments by product/supplier/manufacturing location (Table 17.1).

Table 17.1 Attributes of the FFIS and FFVA

Food Fraud Initial Screening (FFIS)	Food Fraud Vulnerability Assessment (FFVA)
Initial screen/prefilter	Detailed assessment
Company level perspective downward	Supplier/product level perspective upward
Minimum acceptable activity as small as a group of subject matter experts	Maximum activity as detailed as an assessment for every supplier, product, package style, manufacturing location, and supply route
Qualitative	Quantitative (if each data point is generated from a test of some kind) though some are semiquantitative, but actually most would be still considered qualitative (since the individual questions may also be qualitative (Note 1))
Number of assessments: minimum one assessment matrix for raw materials and one for finished goods. The FFIS typically has a minimum of 25 cells per matrix. With a two-matrix process, this would be 50 assessments with a likelihood and consequence that equates to the overall, enterprise-wide risk assessment	Number of assessments: maximum could be for every supplier/product/manufacturing locations/supply logistics item. A medium-sized food company with 100 ingredients from 3 suppliers and 3 logistics methods could reach 900 assessments. If the FFVA has 30 questions each, then there could be 27,000 data points

Note 1: See Fejes and Spink, 2011, presented in the sidebar section “So, How Big Is the Food Fraud Problem? *Unknowable!*” That publication found that each of the quantitative estimates of the economic impact of counterfeiting and piracy was either without a citation or based on a core estimate of “5–7% of world trade.” Thus, the high-level statistical analysis conducted was based on a guess where a 1% error for the 2017 World Trade Organization estimate of world trade exports at \$15 trillion would be plus or minus \$150 billion

Once a holistic and all-encompassing FFIS assessment is conducted that covers the entire enterprise, then the specific additional data collection needs can be determined.

Sidebar: “Enterprise-Wide Assessment” or “COSO Enterprise Risk Management (ERM)”

Be careful when using new terms or phrases. The COSO/ERM concepts are new to many food safety risk assessors. COSO/ERM is a formal, regulatory, certification based concepts that often have legal ramifications. It is very important to be very careful with risk terminology.

A frequent conversation goes like this:

- Generalist: “Oh, I know all about enterprise-wide assessments.”
- Expert: “Wow, I’m impressed you’re experienced with managerial accounting regulations.”
- Generalist: “Oh, not that.”
- Expert: “(Silent but thinking) Ok, so you really do *not* know what you’re talking about.”

Yes, the idea of considering how risks are related to all the risks of an enterprise is a general concept, but it is not “Enterprise Risk Management (ERM).”

Another more dangerous conversation demonstrates an unintentional shift from general concepts to inadvertently offering legal, regulatory compliance advice is related to the Sarbanes-Oxley Act. A common statement could be “Now we will consider how the food fraud risk compares to other risks across the company. These impact the enterprise. Food fraud is an enterprise-wide risk. So we will now present Enterprise Risk Management.” This seems like a natural flow, but the word “Enterprise Risk Management” shifts this casual statement to a formal term that possibly has legal ramifications. Using the term incorrectly might be like telling an FDA inspector that you have a plan to analyze and manage risks, so you cook your product to 160F. “It’s a HACCP plan.” Wait, is it a formal official auditable “HACCP” plan or just something you decided to do? In reality, it is *not* a HACCP plan. Stating it as a HACCP plan could create legal or regulatory liability. Thus, it is important to state whether the assessment is really ERM or just a general broad assessment.

Before moving on, and continuing here to review ERM/COSO, a question is “Does your job require expertise?” Is there a critical aspect that comes from years of experience? ERM/COSO is a formal regulatory requirement. Don’t just assume your current expertise will suffice.

Sidebar: Developing Assessment Scales and Outputs

This section will build upon previous ISO and criminology discussion on qualitative and quantitative assessment to now review several basic aspects of model development.

Regarding the assessment scales, a quote from the FFIS research article is provided including “meaningful differentiation” and the recommended “five-point scales” (Spink et al. 2016):

“Applied to the research question in this paper, an important aspect of developing assessment criteria is defining the ranking scales. ‘Scales should allow meaningful differentiation for ranking and prioritization purposes. Five-point scales yield better dispersion than three-point scales. Ten point scale imply precision typically unwarranted in qualitative analysis, and assessors may waste time trying to differentiate between a rating of six or seven when the difference is inconsequential and indefensible’ (COSO 2011). This statement presents several key concepts. First, meaningful differentiation refers to fidelity in the data meaning that the result provides a clear and appropriate presentation of the risks. Unless all the risks are the same or very similar, which could be the case, the risks should be presented on a scale that can quickly and visually present the differences.” (Spink et al. 2016)

Regarding numbers versus words, a quote from the FFIS research article is provided (Spink et al. 2016):

“Another important COSO concept for developing assessment scales is implied precision. This is the rationale for defining scale attributes with words (e.g., “Low”) and not as number values (e.g., “3”) (also see [REF Cox, 2009; Hassenzahl, 2006; Jablonowski, 1994]). Often the core data input for assessing food fraud vulnerabilities is qualitative incident data. This enables the FFVA to apply the qualitative judgment of what constitutes “very high” or “very low” risk. Numbers could be used to aggregate and sort the risk ranks, but the final presentation should shift back to qualitative or word results. Presenting numerical results could “imply precision” that is unjustified.” (Spink et al. 2016)

Regarding “implied excessive precision,” a quote is provided (Spink 2009):

“Another key concept that is related to implied precision is indefensible values or positions. Managing enterprise risk can appropriately generate rigorous debate surrounding competing risks or countermeasures that often involve significant resource allocations. The decisions and the data must be defensible. As long as the foundation is clearly stated it is acceptable if such assessments are qualitative and have limited accuracy or precision. Data uncertainty is common in early stage assessments of risk, and thus evaluations should be considered qualitative, not quantitative.”

Regarding quantitative and qualitative assessments addressed in government documents, a quote from a research article is provided (Spink 2009):

“An example of this comes from the US Government Accountability Office (GAO). They reviewed the methods used to assess the economic impact of counterfeiting and piracy (GAO, 2010). The GAO report concluded that there were no quantitative, statistically supported methods to conduct such an assessment. The GAO report missed the opportunity to support qualitative assessments such as those espoused in COSO. The challenge for anti-counterfeiting research and assessment is that it con-

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tinues to be presented as analytical, quantitative data. The assessments have been indefensible in some situations such as testimony by the Director of the US Office of the Intellectual Property Enforcement Coordinator (IPEC) to a US Senate subcommittee (see discussion and transcript highlights below and in (Spink and Levente Fejes 2012)). The estimates would probably be defensible if they were presented as qualitative.” (Spink 2009)

Regarding an example of an actual challenge during an open Senate testimony (Spink and Levente Fejes 2012):

“This need was reiterated in U.S. Senate Testimony by Victoria Espinel, the Director of the U.S. Office of the Intellectual Property Enforcement Coordinator (IPEC), Office of Management and Budget (Espinel, 2011). When pressed by the Senators for quantification or even an order of magnitude [of the economic impact], her response aligned with that GAO report: “So I would say it is very difficult to quantify precisely the impact of infringement on our economy because infringement... is illicit activity and it is difficult to quantify”. (Senate Hearing 111-847, 2011)”

“When further pressed for even ‘Orders of magnitude, tens of millions of dollars, tens of billions of dollars, trillions of dollars?’ She responded in ‘It is not my nature or inclination to speculate without precise data.’ Ms. Espinel did refer to upcoming U.S. International Trade Administration analysis (though both reports eventually only reviewed China) (USITC 2011, USITC 2011). The string of questions concluded with ‘Well, let me jump in and ask that you conclude your answer on that in the form of a written response to a question for the record, to get back with whatever data you have.’ IPEC and the Senate Subcommittee have not published a public response. Neither IPEC nor others have published or referred any new initiatives on assessing the economic impact of counterfeiting.”

These examples consider the risk of presenting estimates as quantitative, analytical, or statistical where, when pressed, the underlying data set is often built on qualitative assessments or wild guesses. The application to food fraud prevention is that starting with a qualitative assessment—as long as the method and challenge of the underlying data set is explained—is an efficient and effective starting point. Once this starting point is achieved, the resource-allocation decision-makers can ask for more information if needed. Academics and scientists are more comfortable with precise analytical data sets, but often there is not enough time, the effort to gather “enough” data is too costly and requires a deep understanding of the underlying root cause. The FFIS combined with the resource-allocation decision-making method in ERM and presented in the Food Fraud Prevention Cycle provides a holistic and all-encompassing system.

It often seems that a prefilter or initial screening, a qualitative assessment, is way too simple, but it is a legitimate process and at least creates a manageable starting point.

Sidebar: Review of USITC 1988 Report on IPR Crime Impact on the US Economy (1541)

Title: Review of USITC's Foreign Protection of Intellectual Property Rights and the Effect on US Industry Trade Report of February 1988, by John Spink, Internal MSU Report, January 17, 2011

It appears that the earliest reference to quantifying the economic impact of counterfeiting and piracy is the US International Trade Commission (USITC) Foreign Protection of Intellectual Property Rights and the Effect on US Industry Trade Report of February 1998 (covering surveys for 1986). This does refer to previous Commission's study on The Effects of Foreign Product Counterfeiting on US Industry (USITC Pub. 1479, January 1984, "out of print" but hardcopy received through Freedom of Information Act request); however limitations were noting "the primary focus of that study was on foreign product counterfeiting; licensing revenues and service industries were not included in the study." The other early report is the Counterfeiting Intelligence Bureau report in 1997, which does not include mentions of other methods. As a reference for the time frame, the World Intellectual Property Organization (WIPO) defined counterfeiting in 1996 (CIB 1997). The World Trade Organization (WTO) first Trade-Related Aspects of Intellectual Property Agreement (TRIPs) definition was developed in 1993–1994. The CIB 1997 notes the earliest criminalization of counterfeiting in "the early 1980s," including the US Trademark Counterfeiting Act of 1984, and they refer to the future TRIPs agreement.

"The [USITC] was asked to develop, to the extent possible, quantitative estimates of the distortions in the US trade associated with deficiencies in the protection provided by foreign countries to US intellectual property rights, including trademarks, copyrights, patents, trade secrets, semiconductor chip designs [also defined as mask work, or the design of the chip architecture], proprietary technical data [e.g. included in regulatory paperwork or patent requests] and other types of intellectual property rights."

The report and estimates were developed from questionnaires sent to 736 US companies including all the largest 500 publicly traded companies. It is very interesting and important that the USITC stated:

- "The data, therefore, represent estimates from a percentage of an unknown universe; the losses suffered by the US industry as a whole may well be much larger."
- A third of the respondents stated IP was *not* important to their business.
- "Infringing product sales" were in \$9.5 billion, including copyright violations. The trademark violations were \$5 billion in lost sales and \$754.9 million in lost profit—it is a key point that they made the distinction of revenue versus profit. Later they state "counterfeit sales imply some loss of revenues."

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- The USITC continually emphasizes that the “discouragement of investment represents a social loss in that fewer new or improved products will be available in the future.” The damages were very broad and beyond the usual sales numbers included:
 - Fees or royalties not paid.
 - Reduced profit margins.
 - Damage to reputation or trade name.
 - Research costs not recovered.
 - Research or business foregone (opportunity cost).
 - Weakening of sales of other product lines.
 - Enforced reduction in plant efficiency.

Interesting for future reference, the annual 1986 loss for pharmaceuticals was \$1.9 billion, and loss for food and beverages was \$86 million.

The surveys identified a loss of 5374 US jobs, with half in the software industry, 478 in electronics, and 22 in the pharmaceutical industry.

Regarding the methodologies, “The Commission could identify no better means of developing estimates than asking a broad range of firms in the industry’s most probably affected for the core evidence on US losses from inadequate intellectual property protection – estimates that could admittedly be biased and self-serving.”

Appendix F was titled “Calculating the Effects of Counterfeiting Sales on Output, Total Revenue, and Profits of Legitimate Producers.” This Appendix included methodologies which focus on deceptive counterfeits (perfect substitutes of the genuine article) and that assumed the amount of counterfeits are known.

For a company to estimate their loss in revenue they would require the data inputs of:

- Sales in a defined market (usually known, includes diversion).
- Value of counterfeit sales in a market (usually not very well known, if at all able to quantify in any meaningful or statistically significant level).
- Profit per unit of sales (known).

Counterfeiting is described as to reduce demand by competing with the legitimate product. Further model development by other researchers (not the USITC researchers) often assumes counterfeits *are a perfect substitute* for the legitimate product, or what would be defined as deceptive versus non-deceptive counterfeits. This USITC model does not consider non-deceptive counterfeits since they are assumed not to reduce the sale of a genuine product.

“For example, if counterfeit blue jeans are sold from the back of a truck on a street corner, they are actually different goods from blue jeans of the identical material and

styling sold in a fashionable retail outlet.” The model appears to adapt supply and demand economics using the counterfeiter as the perfect substitute competitor.”

Both methodologies are only presented, for example, and no assessments are included or used.

Appendix H (Protection of Losses from Inadequate Intellectual Property Protection for all US Industries) clearly states that this assessment is only for US companies impacted from international counterfeiting:

- “Because the [survey] sample did not provide a statistically verifiable basis on which to project this loss estimate (based on a sizeable but still fractional sample of the US firms) to the total of susceptible transactions, we did not attempt to make such a projection has not [sic] been included in the body of this report.”[...]
- “The data collected by the Commission’s questionnaire cannot be projected to US industry as a whole with any statistical validity. This is due to two characteristics of the samples and universe involved:
 - (1) The universe of all US businesses is unknown;
 - (2) The sample of questionnaire recipients was not randomly-drawn; and
 - (3) Those companies responding to not represent a random sample (of either all companies or all those sent questionnaires).”[...]
- “However, one can illustrate a likely range of aggregate losses from inadequate foreign intellectual property protection by making a number of assumptions concerning properties of both responding and non-responding companies. [...] The range of possible estimates is wide. At the bottom end, to assume that companies not surveyed had no losses gives a \$24 billion loss estimate. [...] At the high end, to assume that firms not surveyed experienced the same ratio of losses to sales as those surveyed would give an estimate of \$102 billion. Neither is this a reasonable assumption because our sample concentrated on industries and firms known to have the greatest problems with intellectual property losses.”

From the extensive analysis, it was estimated that “For all [US company] respondents then, estimated losses would be 1.9% of worldwide sales.” And “Thus, it is estimated worldwide losses to US industry would range from inadequate foreign protection of intellectual property rights would range from \$43 billion to \$61 billion. It should be stressed that this figure may be ‘reasonable,’ but its limitations and lack of statistical validity should be kept in mind.” The Appendices and the report end on that statement.

The conclusion is that:

- There was a small response to the survey with 431 of 736 companies responding (58%).

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- Less than half of those who did report reported losses with 198 of the 431 companies (46%) reported the \$23.8 billion in losses, whereas 233 companies did not report or did not report losses (54%).
- Although companies reported under oath, and a meta-analysis was conducted to review the estimates, there was no methodology outlined or defined for providing responses.

For reference, here is the full USITC 1988 text regarding the counterfeit product as a substitute (emphasis added):

- “At first face, the above analysis does not appear well suited to many counterfeit cases, because counterfeit goods often sell at a price that is much lower than that of the genuine article. However, on closer examination, this objection does not appear to seriously detract from the analysis. The counterfeit units used in the analysis are perfect-substitute equivalents of the more expensive genuine article. For example, if counterfeit blue jeans are sold from the back of a truck on a street corner, they are actually different goods from blue jeans of the identical material and styling sold in a fashionable retail outlet. Jeans bought from the retail outlet can usually be tried on for fit, and the consumer may be able to return the jeans if he finds later that they are flawed or if he simply changes his mind. Also, the retail outlet is likely to have a more pleasant ambiance, regular hours, and a well-advertised location. Locating the counterfeit supply may impose some information costs on the consumer because a well-advertised, stable location for the counterfeiter would increase the likelihood that he would be detected and punished. If the consumer knows the product is counterfeit, he may also feel moral qualms about engaging in an illicit transaction. These are all attributes of a good that makeup part of its price. If counterfeitors are able to supply an entire market with goods that are perfect-substitute equivalents and lower priced than the genuine article, we should expect to see the legitimate producer forced out of that market entirely.”

Sidebar: Application of Qualitative, Quantitative, or Semiquantitative Assessments

At the start of research on food fraud, the assessments seemed to mirror quantitative, data-intense food safety risk assessments. As the food fraud assessments were first being considered, there seemed to be a belief or assumption that there was “enough” of the “right” data to conduct the detailed quantitative assessments (Spink et al. 2019). The food fraud assessments built upon food science methodologies that are not from the probably more appropriate crime assessments or business enterprise risk assessments.

For food fraud prevention there has been a focus on quantitative and by-individual-product assessments. These are valuable and are placed in the context of the stages of assessment. Some advantages and disadvantages of both qualitative and quantitative analyses are further described by COSO (COSO 2012):

- **Qualitative**
 - Is relatively quick and easy to implement
 - Is easily understood by a large number of employees who may not be trained in sophisticated financial modeling techniques
 - Results in limited differentiation amongst levels of risk (e.g., a macro assessment)
 - Is imprecise—risk events that plot within the same risk level can represent substantially different amounts of risk.
- **Quantitative**
 - Allows for financial aggregation taking into account risk interactions when using an at-risk measure such as Cash Flow at Risk.
 - Can be time-consuming and costly especially at first during model development.
 - Other qualitative impacts or factors may be overlooked when they cannot be meaningfully quantified.
 - Quantification (e.g., rankings of “7” vs. “8” compared to “medium” vs. “low”) may imply greater precision than the uncertainty of inputs justify.”

Application of the Assessment and Supporting Resource-Allocation Decision-Making

The basic FFIS steps are to develop assessment criteria (e.g., details of likelihood and consequence), identify risks, assessment of risk components, combine the risk assessment, and then risk aggregation and evaluation in relation to all other enterprise-wide risks.

Prework is conducted before starting the assessment. Reviewing these concepts before considering any likelihood or consequence of judgment is important. If the vulnerability or risk assessment is presented early in the process, the risk assessors usually cannot help leaping ahead to consider risk treatments. It is recommended to separately and specifically “develop assessment criteria” *before* reviewing incidents.

Develop Assessment Criteria: Several factors are critical to the FFIS process.

- **Likelihood details for very high to very low:** This includes details such as the number of lost sales, the public health hazard level, amount of market share lost, regulatory penalty level, legal liability lawsuit level, etc.

– **For incoming goods:**

- **Products:** identify five types of products with one category including “other.”
- **Markets or channels:** identify five types of markets or channels with one category including “other.” The market could be raw materials from a country or region (e.g., Canada, etc.) or a specific type of supplier (e.g., major food manufacturer, broker, etc.)

– **For outgoing goods:**

- **Products:** identify five types of products with one category including “other.”
- **Markets or channels:** identify five types of markets or channels with one category including “other.” The market could be in the end markets for a country or region (e.g., Canada, etc.) or a specific type of supplier (e.g., major food retailer, broker, etc.)

Identify Risks: Next would be to conduct a review of risks. The level of certainty and robustness does not—repeat *not*—need to be high at the start. Consistent with COSO guidance, many successful programs started with nothing more than experts in a single meeting. It is important to note that the report should clearly identify an estimated level of “certainty,” “robustness,” and the risk assessment team.

Beyond expert insight, the events could include:

- Known food fraud incidents at this entity.
- Known food fraud incidents in a similar company, same industry, or related product.
- Product fraud incidents in other industries but for the somehow related product (e.g., liquid chemicals and liquid food products).
- Then vulnerabilities identified through scanning which could include market price fluctuations, supply irregularities, etc.
- Another factor is public policy changes where a new focus could lead to more oversight or testing that could increase detection.

Assessment of Vulnerability or Risk: The assessment is conducted for incoming goods and a separate assessment for outgoing goods. One matrix is created for each of the two types of goods (Fig. 17.5). Of course, more than five categories can be used, but more categories increase the complexity. Also, more detailed matrixes can be created. For example, consider that cell “A2” in the final incoming goods matrix one cell could be “meat” from “Europe.” That could be expanded into another 5x5 matrix listing European countries versus different types of meat (e.g., beef/pork, poultry, seafood, ground meats, and processed meats/meal/powder/other).

Incoming						Outgoing					
Product/ Group	Market/ Region					Product/ Group	Market/ Region				
	A	B	C	D	E		A	B	C	D	E
Spices	1	VH									
x	2										
x	3										
x	4										
x	5										

Figure 2. Food Fraud Initial Screening Matrix for Assessment by Market or Region and Product or Group

Figure 2. Food Fraud Initial Screening Matrix for Assessment by Market or Region and Product or Group

Fig. 17.5 Example of the FFIS matrices for incoming and outgoing goods. (Copyright Permission Granted) (Spink et al. 2016)

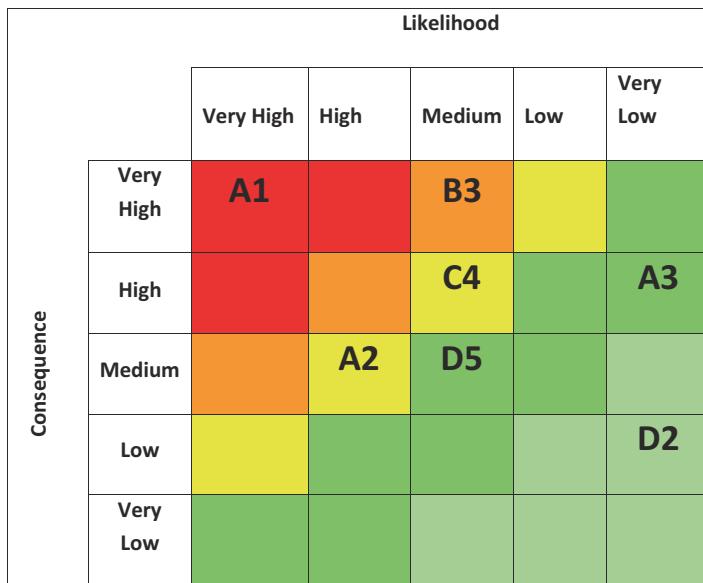


Fig. 17.6 Corporate risk map plotting Food Fraud Initial Screening risk assessments. (Copyright Permission Granted) (Spink et al. 2016)

Risk Assessment: Once the factors and categories are plotted on the matrix, then the risk assessment can occur. To start, a quick assessment of the entire matrix is efficient. Identifying the assessment certainty and robustness is important. For example, “Certainty: 1/10” and “Robustness: 1/10.” It is important to document how each cell rank was determined and also if/what additional information is needed. For example, maybe none of the experts has experience selling a product in the country of India. For each cell, the “likelihood” and “consequence” would be estimated.

Risk Aggregation and Evaluation: A specific risk assessment is a static estimate that is not compared to any other problem in the enterprise. While the risk ranks were identified, the overall conclusions had not been calibrated or tested. To “connect everything to everything,” it is recommended by COSO/ERM to plot the risks on an enterprise-wide assessment usually in a corporate risk map (or risk heat map) (Fig. 17.6) (COSO 2012). (Note: The corporate risk map originally included the

colors red/orange/green/blue but changed to red/orange/green/light green since a more complex COSO investment matrix uses the blue color for all positive return opportunities.)

The FFIS process is completed when the vulnerabilities or risks are plotted on the corporate risk map. The process is documented and the meeting attendees recorded (when considering an audit, it didn't occur if it wasn't documented"). For the full enterprise supply chain, this is a complete Food Fraud Vulnerability assessment, it is documented, it covers all types of products, and it addresses all types of fraud. Technically that meets the GFSI food fraud requirement.

Sidebar: ERM/COSO Examples and Definitions of the Likelihood and Consequence Details

An example of the likelihood details is provided from a COSO report (Table 17.2) (COSO 2012).

An example of the consequence details is provided from a COSO report (Table 17.3) (COSO 2012).

These are general examples of the likelihood and consequence provided by COSO and can be helpful in creating a starting point.

Table 17.2 Illustrative likelihood scale with definition from COSO (2012)

Likelihood	Detail
Very high	Up to once in 2 years or more
High	Once in 2 years up to once in 25 years
Medium	Once in 25 years up to once in 50 years
Low	Once in 50 years up to once in 100 years
Very low	Once in 100 years or more

Table 17.3 Illustrative impact scale with definition from COSO (2012)

Consequence	Detail
Very high	<p>Financial loss of \$X million or more</p> <p>International long-term negative media coverage; game-changing loss of market share</p> <p>Significant prosecution and fines, litigation including class actions, incarceration of leadership</p> <p>Significant injuries or fatalities to employees or third parties, such as customers or vendors</p> <p>Multiple senior leaders leave</p>
High	<p>Financial loss of \$X million up to \$X million</p> <p>National long-term negative media coverage; significant loss of market share</p> <p>Report to regulator requiring a major project for corrective action</p> <p>Limited in-patient care required for employees or third parties, such as customers or vendors</p> <p>Some senior managers leave, high turnover of experienced staff, not perceived as an employer of choice</p>

Table 17.3 (continued)

Consequence	Detail
Medium	Financial loss of \$X million up to \$X million National short-term negative media coverage Report of breach to the regulator with an immediate correction to be implemented Outpatient medical treatment required for employees or third parties, such as customers or vendors Widespread staff morale problems and high turnover
Low	Financial loss of \$X million up to \$X million Local reputational damage Reportable incident to the regulator, no follow-up No or minor injuries to employees or third parties, such as customers or vendors General staff morale problems and increase in turnover
Very low	Financial loss up to \$X million Local media attention quickly remedied Not reportable to the regulator No injuries to employees or third parties, such as customers or vendors Isolated staff dissatisfaction

Key Learning Objective 3: FFVA and Presentation of Results (5265)

This section reviews the preparation, management, and communication of the results of an assessment. This section is not intended to be a review or judgment of Food Fraud Vulnerability Assessment (FFVA) tools, methods, or systems since it would be inefficient to cover that detail here since the science and application are changing so quickly that the insight or recommendations would quickly be outdated. That said, there are some basic concepts or principles that will always apply.

Key Learning Objectives of this section are:

- (1) Review the Food Fraud Vulnerability Assessment and detailed assessment.
- (2) Consider sources of data and “how much is enough” for the current decision.
- (3) Corporate risk map summary and presentation.

Food Fraud Vulnerability Assessment (FFVA) Which Is a Detailed Assessment

Based on the ERM/COSO principles, there is a continuum for the two stages of vulnerability assessments from the first stage which is an “initial screen” and then a “detailed assessment” that is presented here as a Food Fraud Vulnerability

Assessment (FFVA). The full continuum spans from one vulnerability assessment for an entire enterprise to the other extreme which could be one assessment for each product/supplier/manufacturing location. A top 100 multinational food manufacturer could have 1000 suppliers and purchase an average of 10 products from each supplier. In turn, each supplier could have an average of three manufacturing facilities for each product. To address the detailed end of the spectrum, a food company would be required to conduct 30,000 individual and separate vulnerability assessments. It is estimated that just saying the name of each of those manufacturing facilities could take 25 hours (e.g., based on 30,000 names that take 3 seconds each to pronounce). This would be a realistically impossible task; alternatively, the human and financial resource justification would need to be very well defined and supported. There may be unique vulnerabilities, but there is probably a logical balance of specificity and reality. That said, there is a documented method to define why the level of detail decided was practical and logical.

Databases and Sources of Information

To review databases and sources of information, this section will focus on the overall specifications and utility rather than individual available databases. These food fraud products and services are not reviewed in detail since they are changing so fast that as soon as a book is published, the insight will be obsolete (actually, during the writing of this book, several of the commercially available food fraud incident databases underwent significant changes, reductions, expansions, or consolidations). The underlying needs and specifications of the user will be consistent.

As has been emphasized throughout this chapter and this book, the “right” data set is defined by assessment needs. The scope of the research question defines the assessment needs (e.g., adulterant substances or all types of food fraud), the decisions (e.g., presenting trends for discussion or initiative for a recall of products from around the world), or the needs of the resource-allocation decision-maker (e.g., some managers, or for some decisions, require more or less information).

In general, there are many sources of information that are logical even if they seem very casual or informal: subject matter insight, known incidents with the company, databases, and Internet searches (Table 17.4) (Spink et al. 2016).

While analysis of the specific databases is outside the scope of this work, it is essential to review the sources of information and types of data gathering methods (Table 17.5).

It is efficient to identify the research question and then start assessing the available data sources. There may be no single data set that includes all products or that is updated on a frequent enough basis (for more, see the section on Introduction to Data Analytics).

Table 17.4 Sources of data for the Food Fraud Initial Screening (FFIS) and Food Fraud Vulnerability Assessment (FFVA) (Spink et al. 2016)

Information source and detail
Subject matter expert insight
Known incidents within the company (i.e., internal sources)
List incidents
List details and costs if known
Databases (i.e., static external sources)
Review product recall information (i.e., company, product group, industry, etc.)
Review food fraud or related databases
Internet searches (i.e., dynamic external sources)
General Internet searches (i.e., by individual products, etc.)
Set up automated Internet keyword alerts (e.g., ongoing Google Alerts, etc.)

Note: This content would usually be described by regulators such as FDA as “science-based” since it is published in a peer-reviewed, refereed, scholarly journal. “Science-based” is not just “a group of scientists” who made a decision

Table 17.5 Review of FFIS information gathering details such as databases and sources of information

Databases and sources of information
Recall and incident information: These are public government statements, or their summaries consolidated by-product supplies.
Incident databases: These are reviews of information summarized and presented. The incidents could be from many sources and also include a wide range of detail. A key is to understand whether the database includes:
1. Your specific supplier/product/country item
2. The robustness of the data search
3. Frequency of assessment. For an urgent incident review, this could be a starting point that is supported by a review of current product recall information or an immediate internet search
Market monitoring: These are reviews of changes in the marketplace such as price changes, product shortages, or consumer concern on social media. These provide insight that possibly influences the macro-level “fraud opportunity.”
Internet searches: An internet specific keyword search can evaluate a wide range of sources and identify if “anything” is publically known. This can be an excellent resource during an urgent incident review or research on suspicious activity.
Internet keyword alerts: An automated process can be to set up keyword alerts to be passively made aware of possible concerns.

Sidebar: Estimates of Product Counterfeiting—Same Challenges for Food Fraud

There is an Aesop’s Fable “Belling the Cat” that proposes impossible solutions. In the fable, a group of mice proposes to put a bell on the pestering cat. The problem is that no one offered a solution as to how to get the bell around the cat’s neck. The idea is excellent and effective, but there was no consideration of the implementation. Estimating the economic impact of counterfeiting and piracy sometimes seems like belling the cat.

(continued)

Before developing an assessment model, it is wise to consider the available data. A proposed utopian model may require a mythological data set that does not exist. A frequent misperception—regardless of what may be stated publicly—is that most companies do *not* have the ability to quantify their product fraud risks or costs accurately. They know what has been reported to them, but they face the same challenges as their predecessors of gathering useful data. Over time, and based on identifying unmet needs, they can refine their process to understand their vulnerabilities better.

In many situations, this type of assessment is trying to quantify the “unquantifiable” or to try to “know” the “unknowable.” Ok, it may be technically possible to gather enough data, but in reality, it would be cost prohibitive. A key consideration is “cost prohibitive” in comparison to “how much is enough” for the current resource-allocation decision-making.

Compared to other risk or threat assessments—such as food safety, food defense, or also terrorism—the fraudster does not “need” to act, so there is an undefined threat of the incident; there are a wide range of types of attacks, so the consequence is also usually undefined; and finally this combines to make the consequence very uncertain. However, this has not been an insurmountable hurdle because the shift from economic impact to vulnerability is a common factor already in place in a company under a CSO/ERM system.

Finally, the most important fallacy is that there is an assessment that already integrates into the resource-allocation decision-making system (“There must be? Right?”). There is a belief that “someone else” does that integration. Well, I would challenge to ask “who?” Do you “know or think” that someone does that integration? What is their name? Have you have confirmation that their key job responsibilities include meeting your exact question or the specific compliance requirement? Also, does your current risk assessment actually help them?

Any proposed model that does not include an application case study—including the final and actual resource-allocation decision-making—is not really that helpful. Hypothetical examples are often incomplete and cause either dangerous assumptions that it is already being conducted or frustration when the risk assessor cannot figure out how to answer the question.

Sidebar: Inconsistent Sources of Data

When researching the methods to assess the economic impact of counterfeiting and piracy, details of the inconsistent sources of data were determined (Spink and Levente Fejes 2012). Several examples are presented:

“Seizure data and interdiction rate: ‘Seizure data reports are not considered as core documents because they only represent what has been caught and not an estimate

of the entire counterfeit product marketplace.’ A quote is from the US GAO ‘We wouldn’t consider the seizure rate to be a random sample of the extent of counterfeit goods coming in [to a country].’ Moreover, then, the USITC stated ‘The data, therefore, represent estimates from a percentage of an unknown universe.’ ”

Challenges of Using Seizure Data: Regarding seizure data and published reports, there are often even challenges of getting *any* data. While the most basic customs data such as seizure amounts and rates may seem like “just a fact,” even sharing what seems like the most basic and sterile information or data is a challenge. For example, the customs survey used in the OECD counterfeiting and piracy survey was sent to 169 World Customs Organization members with 70 responses (OECD 2007). For the general country survey sent to the 30 OECD member countries, there were 20 responses. From the OECD report (OECD 2007):

- “Caution must, of course, be exercised in interpreting the results of surveys, as participants may not necessarily report fully or truthfully on their activities, particularly if these activities involve unlawful deeds. While these limitations need to be kept in mind, the value of surveys in suggesting patterns and changes over time should not be underestimated” (OECD 2007).
- “The general lack of data with respect to counterfeiting and piracy activities necessitates that more information on the phenomenon be developed. One of the most promising sources of information in this regard currently concerns seizure statistics as registered by customs authorities around the globe. Apart from being collected on a systematic basis, in most cases, these data also constitute the only official data that exist on infringement activities. Hence, despite their apparent shortcomings, they currently constitute the best foundation for measurement analyses as far as counterfeiting and piracy issues in a global context are concerned” (OECD 2007).
- “Answers to the survey ranged from being limited in their usefulness for developing information on infringement activities to being very detailed and thus of great value with respect to the analysis. Of the 70 responses received, only 45 economies [countries], provided information detailed enough to allow a more elaborate assessment of the counterfeiting and piracy activity. The number of data records submitted varied largely across economies” (OECD 2007).

The report noted analysis based on 19 reporting countries including “Andorra, Angola, Australia, Cyprus, Denmark, Estonia, France, Germany, Japan, Latvia, Mauritius, Netherlands, New Zealand, Portugal, Korea, Romania, Spain, the UK, and the USA.” Notably missing some of the biggest economies in the world including China, Hong Kong, Brazil, Russia, India, as well as EU-15 countries of Austria, Belgium, Finland, Greece, Ireland, Italy, Luxembourg, Portugal, and Sweden.

(continued)

Data Representative of the Marketplace: Another consideration is if the data received is representative of the marketplace. From the World Customs Organization report on capacity building (2007) “An increase in seizures of counterfeit goods might mean that it has become more of a problem; or, more likely, it could mean that IPR enforcement has become more aggressive and thus successful”(WCO 2007). Essentially, more counterfeits are found after there is more effort to find counterfeits. Conversely, an increase in one type of counterfeit product does not necessarily mean that a specific problem is increasing. Often law enforcement or regulatory inspectors shift focus from one product to the next. If counterfeit electric cords were a priority in 1 year and then counterfeit watches in the next, it would be expected that the number of seized counterfeit electric cords would decrease and counterfeit watches would increase. This data of the change in seizures does *not* necessarily indicate a change in the rate of counterfeiting.

From a 2012 article that “A Review of the Economic Impact of Counterfeiting and Piracy Methodologies and Assessment of Currently Utilized Estimates” (Spink and Levente Fejes 2012):

- “Lack of historical data: ‘The first challenge is that, compared to many other crimes or quality control defect assessments, there are a very few identified incidents.’ Moreover, ‘If there are limited or incomplete historical data, any model development would include formulation- or model-errors.’ And then ‘Furthermore, the counterfeiters evolve their operations quickly, and so there is a question of time-sensitive data perishability where an assessment at one time is not applicable or useful at a future time.’”
- “Data uncertainty: ‘The second challenge is that for product counterfeiting, uncertainty refers to estimates that are not necessarily agreed upon as being accurate.’ Also, ‘These errors are caused by the physical data used to build the models or conduct the assessments that do not represent what is actually occurring.’ And finally ‘What is seized is not technically a statistically representative random sample of what was actually counterfeited, so there is probably no test of the marketplace that could provide a representative sample of the prevalence of actually counterfeit product.’”
- “Data input and uncertainty: ‘The third challenge is that although some products or brands are counterfeited repeatedly, the details of how the infringement occurs can be nearly infinite.’”
- “Model uncertainty: ‘A fourth challenge is that due to the evolving nature of the marketplace and the fraudsters, a model constructed from known types of infringements cannot possibly predict every risk.’ Then ‘Counterterrorism addresses this challenge by focusing on vulnerabilities in addition to assessment and mitigation of known risks.’ However, then ‘Although the data are uncertain and inaccurate, this is often not a

hindrance to governments and companies taking action in situations where the data are framed as uncertain.””

In combination, these inconsistent sources of data undermine the ability to conduct advanced statistical analysis or analytics. The nature of the data supports a less formal review method such as a vulnerability assessment rather than something more advanced such as a probabilistic risk assessment.

Sidebar: A Review of the Economic Impact of Counterfeiting and Piracy Methodologies and Assessment (MSU-FFI 2018):

Title: So, How Big Is the Food Fraud Problem? *Unknowable!*

By John Spink • April 3, 2013 • Blog

Quantitative estimates of product fraud are elusive if not impossible to determine. The bad guys don’t submit annual reports and don’t share estimates of their activities – at least not outside their criminal organizations. We know what we caught, but we have no idea what we didn’t catch. Did we only catch the sloppy or the unlucky? There are even legal and cultural debates on “what is fraud?”

This interest in the research question about the estimate of the economic impact of counterfeiting and piracy was sparked during an interview with the US Government Accountability Office (GAO) when they were developing its 2010 report on “Observations on Efforts to Quantify the Economic Effects of Counterfeit and Pirated Goods.” That report found that no quantitative methodology is in use and that the government agencies relied upon industry estimates of counterfeiting. It stated, “it is difficult, if not impossible, to quantify the economy-wide impacts.” This report is an important starting point for estimating food fraud and demonstrates the need for additional research, which we have begun through the MSU Food Fraud Initiative.

There is definitely a perception implied by many authors that the product fraud or counterfeiting estimates are quantitative and based on precise, accurate, and certain data. To review this, we conducted a research project on the estimates. The assessments all kept coming back to just three core sources [see Spink and Fejes (2011) *A Review of the Economic Impact of Counterfeiting and Piracy Methodologies and Assessment of Currently Utilized Estimates*, International Journal of Comparative and Applied Criminology]. In most cases these estimates are often considered quantitative their authors were very clear that their findings were “educated guesses” and one even stated that there were “no methods known to develop an overall estimate.” While this research was for intellectual property rights violations of trademark, patent, or copyright, the findings also apply to food fraud.

(continued)

It cannot be emphasized enough that any seizure data is based only on what we caught and that there is probably no way to correlate this with the actual incidents in the marketplace. That is a bold and important statement. In our article, we stated: “The models being used to estimate the impact are being generated from extremely low-frequency events, or if the exact process and method of the counterfeiters is considered, events that have never occurred before.” We went on to point out that the data uncertainty was based on:

- “(1) The lack of historical data;
- (2) The incomplete and often inaccurate nature of available data;
- (3) The seemingly arbitrary infringements by the counterfeiters (data uncertainty created by the data generator which in this case is a human); and
- (4) The model uncertainty which is also referenced as formulation errors.”

Thus, a survey of the marketplace can be valuable as a snapshot of activity in a known, infiltrated, high-counterfeit activity setting... however, a random sampling of the globe would require millions of samples to even approach being considered anywhere near statistically significant.

Even though the quantitative, statistically significant estimates are unknown or unknowable... we do know the vulnerabilities. We can assess how counterfeit or diverted product did get into a marketplace. Although that exact type of fraud incident may not occur again, we can assess whether the system is still vulnerable.

Although the estimates of product counterfeiting and product fraud lack accuracy and precision, this should not be an impossible hindrance to governments or companies taking action. It is important to note that governments do require more quantitative rigor when deciding which projects to fund, but this lack of data hasn’t hindered resource commitment in areas such as homeland security or human trafficking.

It is critical that the estimates be framed as based on “uncertain” data and be viewed more as an evaluation of the vulnerability rather than an exact estimate of the threat. Once we evaluate the vulnerabilities, we can begin protecting the supply chain gaps. A first step in determining the appropriate, strategic, and efficient food fraud prevention program – beyond what is technically required by law – is to evaluate the vulnerabilities that allowed past incidents to occur.

Incident Reviews

To consider the incident reviews, insight from a research article is provided (Spink et al. 2016):

“In [the data gathering], incidents or suspicious activity is reviewed. There are many acceptable sources for the information including subject matter expert insight. This is a very efficient starting point that can quickly identify whether there is a lack of information or

where the enterprise decision-makers will need more data. For example, an enterprise considering the start of a food fraud strategy needs fewer details than a situation where competing and costly risk tactics are being evaluated. This is the process to gather and assess historical or emerging threats. Currently, there are no explicit or detailed process steps for gathering and sorting data. Government regulation and industry standards refer to experts, or a qualified person, to assess hazards and assign risk ranks. Also, many key terms are not defined such as the FSMA concept of a ‘known or reasonably foreseeable hazard’.” (Spink et al. 2016).

There are many ways to sort or organize known incidents. Encoding data, establishing a typology, or using a data cluster tool are all acceptable methods to organize and analyze incident data. One method developed for product fraud is the “Product-Counterfeiting Incident Clustering Tool” (PCICT) that is codified in an ISO standard (see the section on “Product-Counterfeiting Incident Clustering Tool”) (Spink et al. 2014; ISO 2018).

“After conducting the incident review step, there can be information relating to a realization of an inherent risk requiring an immediate redefinition of the overall project (i.e., not simply performing an FFIS). This is a natural opportunity to review the overall Food Fraud Prevention Plan and development process.”

Presentation: Corporate Risk Map

COSO/ERM recommends the presentation of the assessment results on a corporate risk map or also referred to as a risk map or heat map. The single figure is well recognized by a Board of Directors, Risk Audit Team, or Internal Audit Team. It is efficient and important to present the assessment in the terminology and format of those enterprise leaders. The subject is introduced previously in this chapter and in the chapter on Business Decision-Making. Several case studies are provided including a hypothetical county level FFIS and a product-specific FFIS.

Sidebar: Case Study—FFIS for an Entire Country Including All Products and All Fraud (Yes, It Can Be Done)

This exercise was to refine the process and to demonstrate the utility of a final assessment. This assessment covered the entire market for all products and all types of fraud (Fig. 17.7). The creation of the countrywide completed assessment enables a review of specific issues rather than the more conceptually difficult first step in conducting the broad assessment. Also, once issues are identified as “high” or “very high,” there is often an intense engagement and questioning of the assessment. Presenting the assessment usually creates motivation from other stakeholders or interested parties to engage in the process. (Note: refer to ISO definitions of key terms such as interested parties, organization, management, management system, and other.)

(continued)

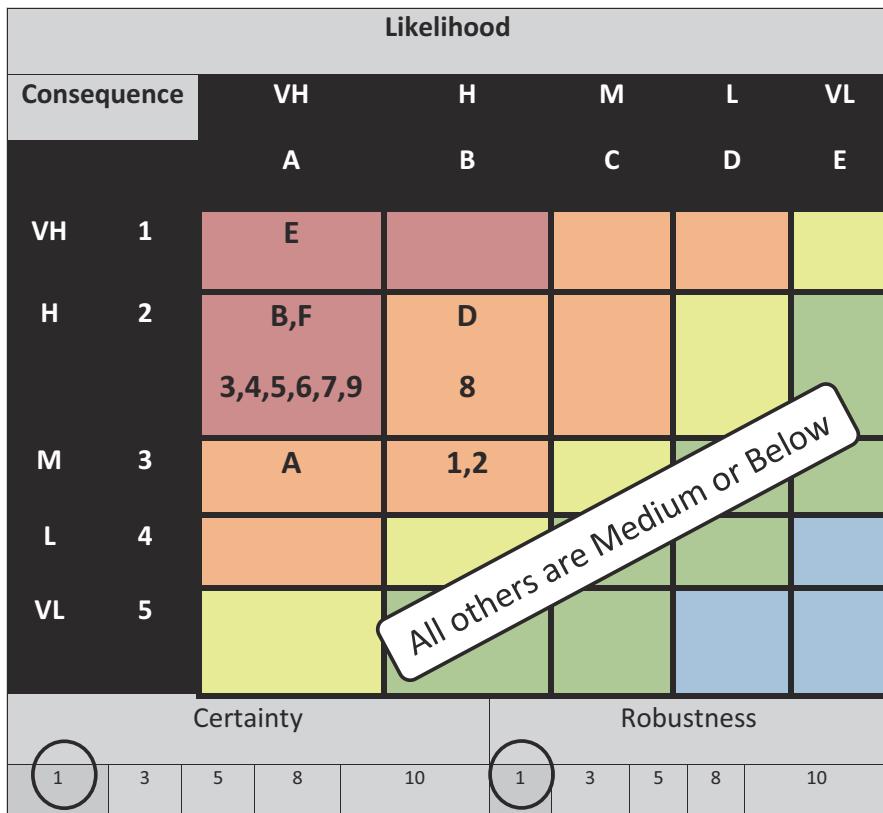


Fig. 17.7 FFIS summary matrix that for this assessment includes only outgoing goods

- Since this is a prefilter, preliminary assessment with low pre-research, the matrix was identified to be very low on “certainty” and very low on “robustness.”
- The assessment found 14 items that were a “very high” or “high” food fraud vulnerability based on an estimate of the country-level risk tolerance.
- Of the 14 issues, 11 were in 2 products which were “spirits, alcohol, etc.” and “meat, seafood, dairy.”
- Also seven of nine “incoming goods/raw materials” were imports from developing countries (Eastern Europe, China, and others).
- The imported product was both at a port and smuggled into the marketplace.
- For “outgoing goods/finished goods,” four of six were for “private/kiosk/bazaar/trolley” and “e-commerce/online shipping.”

This country-level assessment provided a review of all vulnerabilities. The next step is to conduct further edits to the conclusions. After final agreement

on the rankings, there is now a clear method to identify the focus topic which would be the item highest risk that is item “E.” Also, the presentation of the conclusions raises a question about the urgency of addressing the other risks that are above the risk tolerance (in the red and orange zones).

Sidebar: Case Study—European Country, Food, Alcohol, Spirits, Vodka

Included here is an example of a quick but complete FFIS that includes plotting the vulnerabilities on the corporate risk map and then a quick review of possible countermeasures and control systems. Each of the “very high” risks seems to have risk treatments that could be implemented almost immediately—and for all three problems, the equipment or process may already be in place so they could be implemented with only a slight adjustment in the screening target or message. In all three problems, the countermeasures and control systems were not the usual food authenticity tests or anti-counterfeiting components.

From the report:

Title: Prefilter Food Fraud Initial Screening (FFIS) Using Open-Source Information

For: *Country/Vodka*

Date: October 6, 2017

Summary: An open-source search was conducted to review the food fraud vulnerability for *Country/Vodka*. The goal was to provide an example of the FFIS tool for a specific problem. The review assessment is ranked as certainty 1/10 and robustness 1/10, and the team was the MSU Food Fraud Initiative members. The assessment identified three specific “very high” and four specific “high” vulnerabilities. The likelihood was an estimate based on base awareness and local discussions. The consequence was a combination of the health hazard incidents, the loss of economic contribution from lost sales, and then a social factor of concern raised by an incident/illness/death by the specific retail location. For example, it is more concerning for consumers if there is a slight problem at a trusted supplier rather than an incident at an informal or illicit market. The “market” main concerns appeared to be (1) online marketplaces and (2) “white van” deliveries (e.g., an unofficial seller of product “out of the back of a ‘white van.’” The “product” for an online sale is the delivery, and the main concerns were (1) local courier or person-to-person delivery and (2) private or contract couriers. Together, three “very high” problems were identified. Possible countermeasures and control systems were suggested for each:

1. For high incident geographic areas (such as a specific postal code), possibly utilize an X-ray/computer system to identify >0.5 L glass or plastic bottles.

(continued)

Markets/ Products	Major retailer/ Specialty	Minor retailer/ Independent	Bazaar/ Kiosk/ Flea Market	Online	“White Van” – individual & Other	
	A	B	C	D	E	
Pick-up	1	VL	VL	M	NA	NA
Local Inventory – Direct Delivery	2	VL	VL	M	H	H
Domestic Ship – Mail	3	L	L	NA	VH	NA
International Ship – Mail	4	NA	NA	NA	VH	NA
Local Inventory – “Courier” Delivery, P2P Handoff & Other	5	VL	M	H	VH	H

Fig. 17.8 FFIS assessment detail of the specific fraud opportunity problems. (Copyright Permission Granted) (Spink 2017)

2. Add or adapt current mail X-ray/computer scanner for >0.5 L liquid in glass or plastic.
3. Review warning communication to this target group of consumers (e.g., social media of Snapchat, Instagram, specific information brokers).
4. Note: All three countermeasures and control systems may already be implemented by other agencies.

The next step would be to review if the resource-allocation decision-maker requires an increase in the certainty and robustness to a level necessary to decide on countermeasures and control systems.

Method: The prefilter Food Fraud Initial Screening Tool (FFIS) is the first of the two-stage process for Enterprise Risk Management (ERM). The initial screening is conducted both as a Food Fraud Vulnerability Assessment starting point and to understand public information that could lead to litigation. The limits for likelihood, consequence, and corporate risk appetite were estimated.

Assessment Detail: This conclusion was based on an assessment. The nature of the product and specific research question enabled one matrix to be used (Fig. 17.8).

Next, although it was very easy to see the cluster of “very high” concerns, the results were plotted on a risk map (Fig. 17.9).

Process Check—These “very high” food fraud problems versus all countrywide “very high” problems: Plotting the problems on this corporate risk map is helpful for the resource-allocation decision-maker since these findings can be calibrated against all of the enterprise-wide risks. For example, while it may be clear, these are by far the most concerning three problems; they may actually be lower compared to enterprise-wide problems. For example, a countrywide *Salmonella* outbreak would seem to be higher than all three of these food fraud problems. This brings up a question of whether the likelihood and consequence were properly calibrated.

Process Check—Recalibration: The corporate risk map and enterprise-wide ranking include a built-in recalibration feature. The original likelihood

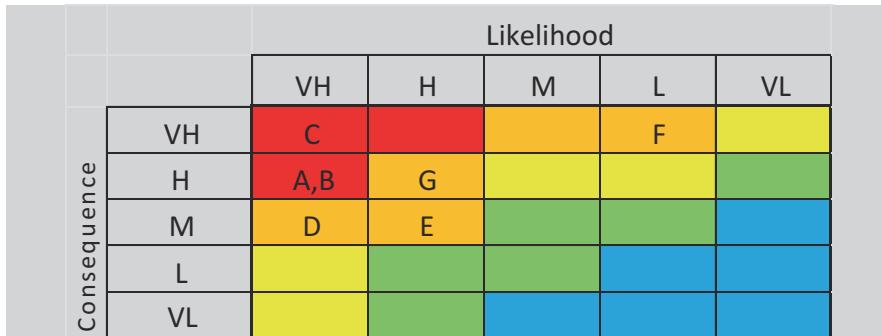


Fig. 17.9 FFIS heat map summary of the fraud opportunity problems. (Copyright Permission Granted) (Spink 2017)

Total # (Likelihood * Consequence)		Group/ Product
<u>Incoming Goods-TOTAL (Econoimc + Hazard + Social)</u>		
1	<<NOT REVIEWED	
2		
3		
<u>Outgoing Goods-TOTAL (Econoimc + Hazard + Social)</u>		
A	VH = VH * H	Online company, domestic mail delivery
B	VH = VH * H	Online company, international mail delivery
C	VH = VH * VH	Online company, courier or P2P handoff delivery
D	H = VH * M	Online company, local inventory direct delivery
E	H = H * M	Online company, courier or P2P handoff delivery
F	H = L * VH	White Van, direct delivery
G	H = H * H	White Van, courier or P2P handoff

Fig. 17.10 FFIS detail of the heat map fraud opportunity problems including the total, likelihood, consequence as well as the details of each problem. (Note: the incoming and outgoing goods detail is included to clarify that only the local impacts were assessed) (Copyright Permission Granted) (Spink 2017)

and consequence estimates can be recalibrated. Each of the 25 cells can be reassessed based on the newly defined likelihood and consequence factors. The recalibration is not bad—it is actually good or even *great*. If there is a need for a recalibration, then it indicates that the resource-allocation decision-maker has reviewed the process in detail and provided more refinement. The next FFIS/FFVA will be more finely tuned.

A legend for the risk map was created (Fig. 17.10). This allows a quick presentation of the findings.

(continued)

Table 17.6 FFIS detail of each cell with reference number, rank, problem, and countermeasures (Spink 2017)

Ref #	Rank	Problem	Countermeasure
D3	VH	Vodka bottles shipped through the domestic mail	For high incident, areas utilize X-ray/computer scanner to identify >0.5 L glass or plastic bottles (Q: are these already in use?)
D4	VH	Vodka bottles shipped through the international mail	Add or adapt current mail X-ray/computer scanner for >0.5 L liquid in glass or plastic (Q: are they already in place?)
D5	VH	Late night young people buying vodka from pedestrians	Review warning communication to this target group (social media of snapchat, Instagram, specific information brokers) (Q: what other public health information distribution or programs exist?)

Next, since there was such a tight cluster of “very high” incidents in terms of the markets and products, there could be a simple consideration of countermeasures and control systems (Table 17.6).

While this is a quick assessment that is low in certainty and low in robustness, it does add value to provide a case study but also for the country to begin to address this specific research question.

Conclusion

Before conducting assessments, it is important to thoroughly review the theoretical foundation and then adapt the use case to the specific application. The previous chapter covered risk analysis and basic assessment which provide a foundation that was built upon here to provide an expanded review of the application and assessment. This chapter provided a series of examples and reviews that led to key conclusions. ***The first conclusion is*** to clearly define the research question and the specification of the resource-allocation decision-making. The research question is exactly what problem you are addressing such as reducing the fraud opportunity and not a tactical middle step such as which test to choose. This effort to not just review the incidents but consider the decisions that will be made will help refine the specification of “how much is enough” for an assessment. ***The second conclusion is*** to conduct a case study or a use case (description of the method of how a goal is achieved) to be able to refine the assessment to meet the specific need. Since this is often the first time a food fraud assessment is conducted, a quick exercise will help both to provide insight but also to refine the process. This preliminary step seems contrary to the “do it right the first time” mantra. In this situation, it is probably impossible or at least impractical to try to decide on the method that would be used forever. For the first time addressing food fraud prevention the “do it right the first time,” the “it” is a pilot or preliminary study. The key outcome is the lessons learned

Sidebar: Bell-Shaped Distribution of Your Risks Versus an ERM Heat Map

The presentation of an assessment has several forms. There is no right or wrong method.

That said, be *very clear* about your goal *before* plotting the data or even before gathering any data. If the goal is to review food fraud in relation to all other enterprise-wide risks (the most applicable goal), then the method would *not* be to create a bell-shaped, even distribution of all food fraud incidents.

- First, there may be a need for an even distribution of the findings.
 - This spreads the results evenly across a spectrum such as very low to very high.
 - The calibration is the specific data set against itself.
 - This spreads the results evenly across the scale. This is similar to grading students on a bell-shaped curve. Even if all the students were brilliant, the bell-shaped curve would require the top 10% of students to be categorized as “excellent” and the bottom 10% to be categorized as “failing.”
 - As risk treatments are applied, and as individual vulnerabilities are reduced, the plot is recalibrated to spread the data over that span.
- Second, there may be the use of a standardized heat map that plots the assessment on a matrix such as bound by likelihood and consequence pre-defined in a method or standard.
 - This spreads the results as determined by the definition of very low to very high.
 - The calibration is the assessment of the general definition of very low to very high.
 - This spreads the results as determined by the general definition of likelihood and consequence.
 - As risk treatments are applied, and the individual vulnerabilities are applied, the entire data set could shift below the risk tolerance—actually, that is the goal. The risk threshold is set by the method.
- Finally, a variation of the standardized heat map is a corporate risk map that plots the likelihood and consequence determined by the entity’s unique and specific risk tolerance.
 - This spreads the results as determined by the definition of very low to very high.
 - The calibration is the assessment of the entity’s unique and specific definition of very low to very high.

(continued)

- This spreads the results as determined by the entity’s definition of likelihood and consequence.
- The risk threshold is set by your own company’s risk managers based on a formal system such as ERM/COSO (which is actually set by your owners through their proxies, the Board of Directors).

As discussed elsewhere, the likelihood and consequence are presented in qualitative terms (e.g., words: very high, high, medium, low, very low) or quantitative terms (e.g., numbers: 5, 4, 3, 2, 1). The plot can include only the points or include a statement of the standard of deviation or confidence intervals. Presenting two dimension figures with the point estimate and confidence intervals is very complex, and the charts are often confusing. Thus, just the point plot is usually used.

It is important to note here that the use of numbers may imply precision where a “3” is presented as defined by an analytical method to be significantly different than “2”. Further, a “3.7” versus a “3.8” implies accuracy and precision to two significant digits. For initial screening, prefilter, or early stage assessments, it is strongly recommended to use words not numbers.

Appendix: WIIFM Chapter on Risk Implementation

This “What’s In It For Me” (WIIFM) section explains why this chapter is important to you.

Business functional group	Application of this chapter
WIIFM all	This provided insight and methods for the overall starting point of vulnerability assessments which is the Food Fraud Initial Screening (FFIS) within the Food Fraud Prevention Cycle (FFPC)
Quality team	This chapter presented the prefilter and Food Fraud Initial Screening (FFIS) method—with case studies
Auditors	This chapter will provide insight on the type of assessments you might recognize that are effective risk communication and that it is based on sound methods
Management	The output should be a very simple one-page summary that presents <i>all</i> enterprise-wide risks under your control—with as much background detail as <i>you</i> need
Corp. decision-makers	The process will provide <i>you</i> with a high-level, one-page summary which the Food Fraud Prevention Strategy will seamlessly integrate into your COSO/ERM type system with just with as much detail as <i>you</i> need

Appendix: Study Questions

This section includes study questions based on the Key Learning Objectives in this chapter:

1. Discussion question
 - (a) What is the COSO/ERM source of credibility or authority?
 - (b) Why is it so difficult to obtain even a simple estimate of the economic impact of food fraud or product counterfeiting?
 - (c) What are the biggest hindrances of conducting a countrywide or company-wide assessment?
2. Key learning objective 1
 - (a) What is a COSO defined “initial screen”?
 - (b) What is the first step in a COSO assessment?
 - (c) What is the “risk of conducting a risk assessment”?
3. Key learning objective 2
 - (a) What is an FFIS?
 - (b) What is an enterprise-wide assessment per COSO/ERM?
 - (c) What are the COSO defined strengths and weaknesses of a qualitative vs. quantitative assessment?
4. Key learning objective 3
 - (a) What is “seizure data”?
 - (b) What are the “challenges of using seizure data” in a FF assessment?
 - (c) Why does FF prevention—and many types of crime such as IPR counterfeiting—inherently include “inconsistent sources of data”?

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Chapter 18

Conclusion



Summary

This book addresses the food fraud prevention concepts cover a wide range of academic disciplines and include a breadth of applications. *This chapter addresses* the conclusions of the other chapters in a structured approach that presents the specific insights and then a summary of how they fit into the overall concept. This Conclusion Chapter will review each of the chapter conclusions and then provide an overall perspective. This is intended as a review of all the chapters but also a holistic and all-encompassing consideration of their application to the overall food fraud prevention goal. There are so many specific concepts or processes that it is easy to be distracted from the focus on the fraud opportunity to completing the individual tasks.

The Key Learning Objectives of this book are

1. Clearly understand and define the fraud opportunity by focusing on criminology—understand why there are system weaknesses or vulnerabilities and how and why criminals perceive an opportunity.
2. Conduct a pre-filter or initial screen for all types of fraud, for all products, and for the entire organization—if you can't identify the most important problems, then you're just guessing at the most urgent problems.
3. Create an overall strategy that is broad enough to address compliance and business management requirements—build upon the Enterprise Risk Management COSO concepts.

Conclusion

There is a broad and deep body of work to draw upon for food fraud prevention. There is no shortage of insight from other disciplines, and the difficult part is to both narrow the content to consider and the application in a logical way. Considering the food fraud prevention concept and this book, *The first conclusion is* that addressing

food fraud is fundamentally different from management of the other food risks of food quality, food safety, and food defense. *The second conclusion is* that the only real way to implement a holistic and all-encompassing system is to focus on vulnerabilities and prevention. *The final conclusion is* that a systems approach is necessary that starts at a very light level and gets deeper as defined by the unique fraud opportunity and the company-specific, fluctuating risk tolerance. Finally, through all the work, continue to focus on the fraud opportunity. The Food Fraud Prevention Cycle is an efficient way to “connect everything to everything” and manage the process. Remember, “It’s all about the fraud opportunity.”

Afterword

If this book is successful, then at this point, the path forward is completely logical... common sense... and so obvious that it is ridiculous that a book was even published on the topic.

A note to other professors and instructors: We are very happy to collaborate on projects or course development. Please contact us through social media.

Afterword: Food Fraud Compliance—A Roadmap Summary (Fig. 1) (MSU-FFI 2018):

Title: Review—Trade Journal Articles on Food Fraud Compliance Requirements for GFSI, FSMA, and Sarbanes-Oxley

By John Spink • February 23, 2017 • Blog

Are you compliant with the current and pending regulatory and standards requirements to address “all” types of food fraud and “all” products? Probably not... but there are fairly simple steps to get started. Our MSU FFI team just published two trade journal articles that summarize numerous peer-reviewed, refereed scholarly journal articles. MSU’s Dr. Doug Moyer is a co-author on both articles.

Overview

Food Fraud is beginning to be understood as a unique food risk. Industry is shifting focus to Food Fraud Vulnerability Assessments requirements and creating a Food Fraud Prevention Strategy. Full compliance requires addressing all types of Food Fraud (e.g., stolen goods and counterfeits) as well as all products, (e.g., incoming goods and outgoing or finished goods.) Also, the vulnerability assessment must cover all of your products, but not necessarily an individual assessment for “each” product.

It is important to realize that implementing separate plans for food safety, Food Fraud, and Food Defense plan does not triple the work—splitting up the tasks into three steps reduces the overall complexity.

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FEATURED POSTS

 **The Ecosystem for Organized Crime and how to disrupt Food Fraud vulnerabilities**
by John Spink - February 23, 2017 [Blog](#) [0 Comments](#)
December 14, 2018
This is a summary of Markus Felson's 2006 report and presentation on The Ecosystem...

 **Presentation - Food Fraud Prevention Research Strategy at the National Academy of...**

Review – Trade Journal Articles on Food Fraud Compliance Requirements for GFSI, FSMA, and Sarbanes-Oxley
by John Spink - February 23, 2017 [Blog](#) [0 Comments](#)

Are you compliant with the current and pending regulatory and standards requirements to address “all” types of food fraud and “all” products? Probably not... but there are fairly simple steps to get started. Our MSU FFI team just published two trade journal articles that summarize numerous peer-reviewed, refereed scholarly journal articles. MSU's Dr. Doug Moyer is co-author on both articles.

 **Food Fraud Vulnerability Assessment and Prevention Strategy**

Food Fraud is beginning to be understood as a unique food risk. Industry is shifting focus to Food Fraud Vulnerability Assessments requirements and creating a Food Fraud Prevention Strategy. Full compliance requires addressing all types of Food Fraud (e.g., stolen goods and counterfeits) as well as all products, (e.g., incoming goods and outgoing or finished goods.) Also, the vulnerability assessment must cover all of your products, but

Fig. 1 Blog post image. (Copyright Permission Granted)

Combining the key points from the series of articles:

- **7 Questions:** “Food Fraud Compliance Requirements — The general compliance requirements for Food Fraud prevention are:
 1. Conduct a Food Fraud Vulnerability Assessment
 2. Confirm it is written
 3. Implement a written Food Fraud Prevention Strategy
 4. Confirm it is written
 5. Minimally conduct an annual Food Fraud Incident Review
 6. Address all types of Food Fraud
 7. Address all products from both incoming goods (e.g., ingredients) and outgoing goods (e.g., finished goods) through to the consumer.”
 8. Plus: Who is “accountable” for Food Fraud compliance (or blamed if there is a fail)? Do they know they are accountable?
 9. Plus: Who is “responsible” for managing the Food Fraud strategy? Do they know they are responsible?”
- **2 Concepts:** “The first steps include:
 1. Convene a Food Fraud Task Force—this is the group to start the review and others may take over the ongoing management

2. Create an Enterprise-wide Food Fraud Policy/Mission Statement—also begin drafting a Food Fraud Prevention Strategy—the key is to “start,” not necessarily finish or wait for the final approval of the corporate level policy/mission”
- **7 Steps:** “for a Food Fraud Task Force project—developing the proposal for a strategy
 1. Convene a Food Fraud Task Force
 2. Create an Enterprise-wide Food Fraud Policy/Mission Statement and begin drafting a Food Fraud Prevention Strategy/ Plan
 3. Conduct the pre-filter Food Fraud Initial Screening (FFIS)
 4. Review additional needs including additional information or a more detailed Food Fraud Vulnerability Assessment (FFVA)
 5. Review specific Food Fraud vulnerabilities in an enterprise risk map (Enterprise Risk Management)
 6. Consider countermeasures and control systems to address the ‘very high’ and ‘high’ vulnerabilities
 7. Propose a Food Fraud Prevention Strategy including the calibration of the Food Fraud risks on the enterprise risk map”
- **1 Decision: Decision, Approval, and Implementation:** The Food Fraud Task Force project proposal is intended to be a full and formal recommendation of the optimal Food Fraud Prevention Strategy for your enterprise:
 1. Formal Project request from an Executive sponsor
 2. Review by the Executive sponsor
 3. Decision by the Executive sponsor

At the end of this process, if there is either (1) no request for a formal proposal or (2) no approval of a new project or strategy, then the decision is to maintain the status quo. No decision is a decision.

Upon deeper review, the requirements are clear for the scope and timing of a Food Fraud Vulnerability Assessment and a Food Fraud Prevention Strategy. That said, there is a steep adoption curve that most companies are just now approaching. This may seem like a daunting and complex task, but fortunately, there are guidelines, summaries, research, and best practices to help the industry to navigate the various requirements and expectations in order to fully realize an effective Food Fraud Prevention Strategy.

Reference

MSU-FFI, Food Fraud Initiative. (2018). *Blog series, food fraud initiative*. Michigan State University, developed and presented by John Spink. URL: www.FoodFraud.msu.edu/Blog/

Glossary

- A detailed glossary of terms is constantly changing. It is recommended to see the last Food Fraud Terminology Glossary on the Michigan State University Food Fraud Initiative Website at (MSU-FFI 2018): www.FoodFraudPrevention.com

Further Reading

This section provides recommendations for further reading that are not by the author of this book. These are also not focused on specifically food fraud or food authenticity.

Ten Recommended Readings: Reports by Government or Association

There are several key reports by governments or associations that provide foundational insight or shaped the early FF research:

1. OECD, organisation for Economic Co-operation and Development, *Estimating the magnitude of counterfeiting and piracy*, in *OECD, The Economic Impact of Counterfeiting and Piracy*, OECD Publishing, Paris, URL (full text): <http://dx.doi.org.proxy2.cl.msu.edu/10.1787/9789264045521-5-en>. 2007: OECD Publishing. (OECD 2007)
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Ten Recommended Readings: Books Related to Product Fraud

There are several books that were key to shaping the thinking and direction in this book. The key books are listed here:

1. Naim, Moises, *Illicit: How Smugglers, Traffickers, and Copycats are Hijacking the Global Economy*. 2005, NY, NY: Doubleday. (Naim 2005)
2. Felson, M, *Crime and Everyday Life (3rd Edition)*. 2002: Thousand Oaks, CA: Sage Publications. (Felson 2002)
3. deKieffer, Donald, *Underground Economies and Illegal Imports: Business and Legal Strategies to Address Illegitimate Commerce*. 2010: Oxford University Press. (deKieffer 2010)
4. Hopkins, David M., Lewis T. Kontnik, and Mark T. Turnage, *Counterfeiting Exposed: How to Protect Your Brand and Market Share* 2003, Hoboken, New Jersey: John Wiley & Sons. 304. (Hopkins et al. 2003)
5. Phillips, Tim, *Knockoff: the deadly trade in counterfeit goods: the true story of the world's fastest growing crime wave*. 2005, London: Kogan Page. (Phillips 2005)
6. Fortin, Neal D., *Food regulation: law, science, policy, and practice*. 2009, Hoboken, NJ: Wiley. (Fortin 2009)
7. Wu, Yongning, Hong Miao, Bing Shao, Jing Zhang, J. Spink, and DC Moyer, *Food Fraud [Chinese Version]*, in *Food Safety in China - Past, Present, and Future: Science, Technology, Management and Regulation*, Joseph Jwu-shan Jen and Junshi Chen, Editors. 2016: Beijing. p. E. & Wu, Yongning, Miao Hong, Bing Shao, Jing Zhang, John Spink, and DC Moyer, *Chapter 15: Food Fraud [English Language]*, in *Food Safety in China - Past, Present, and Future:*,

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Ten Recommended Readings: Books Related to Business and Management

1. Porter, Michael E, *Competitive strategy: Techniques of industry and competitor analysis*. 1980, Free Press. (Porter 1980)
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5. Dye, Thomas R, *Understanding public policy (14th Edition)*. 2012: Prentice Hall Englewood Cliffs, NJ. (Dye 2012)
6. Stout, Martha, The sociopath next door: the ruthless versus the rest of us. 2005, New York: Broadway Books. (Stout 2005)
7. van Schendel, Willem and Itty Abraham, *Illicit Flows and Criminal Things: States, Borders, and the Other Side of Globalization*. 2005, Bloomington, IN.: Indiana University. (van Schendel and Abraham 2005)
8. Saviano, Roberto, *Gomorrah: A Personal Journey into the Violent International Empire of Naples' Organized Crime System*, trans. Virginia Jewiss, New York: Farrar, Straus and Giroux, 2007. (Saviano 2007)
9. Friedman, Thomas, *The world is flat*. New York: Farrar, Straus and Giroux, 2005. 488. (Friedman 2005)
10. Peters, Tom, *Thriving on chaos*. Vol. 7. 1987: Alfred A. Knopf New York. (Peters 1987).

Recommended Readings: Key Journals Articles

1. Liang, Bryan A., *Fade to black: Importation and counterfeit drugs*. American Journal of Law & Medicine, 2006. **32**(2–3): p. 279–323. (Liang 2006)
2. deKieffer, Donald, *Trojan drugs: counterfeit and mislabeled pharmaceuticals in the legitimate market*. American Journal of Law and Medicine, 2006. **32**(2–3): p. 325–49. (deKieffer 2006)

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10. Huisman, Wim, *Compliance and Corporate Crime Control*. Encyclopedia of Criminology and Criminal Justice, 2014: p. 488–496. (Huisman 2014)

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Appendix

Appendix: Public Policy History and Status

Excerpt from food fraud public policy development article (Spink et al. 2019): This appendix is an expanded review of the key agenda setting activities or events that advanced the public policy-making. This is an expansion of the topics noted in the text above (for detailed citations of the quoted text, see the original publication (Spink et al. 2019)).

2009—USA—Defining Economically Motivated Adulteration: As mentioned earlier, in May 2009, the US Food and Drug Administration (FDA) conducted a Public Meeting on Economically Motivated Adulteration (EMA) that applied to all products they regulate including medicines, food, food ingredients, dietary supplements, medical devices, and others. Due to this broad scope, the FDA defined EMA addresses more than just food. At the same time, FDA's EMA scope was narrowed to only a “substance” for “economic gain” and not the broader “Adulterated Foods” concept in the Food, Drug, and Cosmetics Act (21 USC §331 2008; FDA, 2009). The FDA meeting emphasized that beyond an adulterant-substance, the FD&C defines “Adulterated Foods” to include goods that are stolen, smuggled, genuine but expired, genuine but spoiled, or others. To note, the FDCA defines “Misbranded Foods” as a separate concept (21 U.S.C. 362 2011). Thus, there is confusion where an “Adulterated Food” may not include an *adulterant-substance* or may not be food fraud in the case of *genuine spoiled* goods. Other FDA groups, such as medicines, have had a more precise focus on product counterfeiting or stolen goods. The formal regulatory “Adulterated Products” definition is not common across all FDA products, so the concept could not be implemented uniformly across FDA. There were also other confusing points such as EMA being a common abbreviation in medicines regulation referring to the EU

European Medicines Agency. Using EMA for all products would be as confusing as the food industry using “FDA” as an abbreviation for an entity other than a food and drug administration. Regardless of the debates, EMA of food was explicitly defined by the GAO and CRS to be on the FDA public policy agenda.

2009—ISO—ISO Technical Committee 247 Fraud Countermeasures and Controls: Expanding from US standards that focused on anti-counterfeiting, the American National Standards Institute (ANSI) proposed and led the International Standards Organization (ISO) Technical Committee 247 Fraud Countermeasures and Controls (TC247). This focused on a range of counterfeiting for fraud including currency, tax stamps, identify documents, and product fraud including product counterfeiting. In 2015 TC247 was moved into the Technical Committee 292 Security Management and Resilience. The standards that have been adopted—or are in final approval stages—include interoperability of authentication features, analysis of product fraud incidents, and definitions.

2011—USA—Food Safety Modernization Act (FSMA) Law: This new statute has over 70 mentions of “prevent” or “prevention” and 11 mentions of “intentional adulteration” (FDA 2011). EMA was shifted from the FSMA Intentional Adulteration rule to the FSMA Preventive Controls rule (FSMA-PC, or PC). The Intentional Adulteration section (FSMA-IA or IA) was later defined to be only essentially “catastrophic events” such as terrorist attacks. This shift of the rule is consistent with the text of the original law published in the US Code. Regardless of the EMA or food fraud terms not specifically mentioned in FSMA, the law clearly states that FDA is expected to lead a prevention effort for all types of hazards even those that are “economically motivated.”

2012—USA—Food Safety Modernization Act, Intentional Adulteration Rule (IA): During rulemaking, the FDA interpreted the Congressional lawmakers’ intent of the IA section scope to only be “catastrophic events” such as terrorism. The text of “intentional adulteration, including acts of terrorism” (note the comma) to really mean “intentional adulteration acts of terrorism” (no comma). Considering a related concept, the IA section was also refined to not cover “disgruntled employees” or “malicious tampering.” Those two actions are illegal under FSMA but not addressed in a rule. The final IA rule stated that EMA would be addressed in the *Preventive Controls* section of FSMA. This rule was finalized in 2016.

2012—GFSI—Global Food Safety Initiative (GFSI) Addressing Food Fraud: The GFSI created a Food Fraud Think Tank to provide insight and guidance to the GFSI Board of Directors. The original title was Economic Adulteration Think Tank but shifted to food fraud. The goal was to review the food fraud issue, how it might be addressed under the GFSI type Food Safety Management

System principles, and if it was within the scope and mission of GFSI. GFSI solicited feedback from their broad membership, including in many public workshops and presentations. Thus, this activity raised the awareness that food fraud was *going to be* addressed. This became a requirement in February 2017 to be required in January 2018.

2013—UK—DEFRA Elliott Review of Food Crime: The UK Department for Environment, Food and Rural Affairs (DEFRA) and Department of Health co-funded the Elliott Review (led by Professor Christopher Elliott of Queen's University, Belfast) on food fraud which reviewed the issue and proposed countrywide countermeasures and programs. The very clear directives are being broadly implemented in what can be considered as world-leading efforts.

2012—Scotland—Food Standards Agency, Arrangements to secure food standards and safety in Scotland (The Scudamore Report): Scotland created a report that reviewed the options for managing all food standards and food safety (FSAS 2012). Scotland clearly defines food fraud (“Food fraud is committed when food is deliberately placed on the market, for financial gain, with the intention of deceiving the consumer.”). They also clearly define food fraud as a food agency issue (“The Food Standards Agency takes the issue of food fraud very seriously and... the Agency has a responsibility to protect the consumer.”). They also clearly assign responsibility for enforcement but not explicitly a countrywide prevention strategy (“In Scotland, the Incidents Team within the Enforcement Branch manages and co-ordinates the response to food fraud”).

2013—EC—European Commission Resolution on Food Fraud: The European Commission (EC)—the administrative branch of the European Union—published a draft resolution that defined food fraud and the focus on prevention in 2013 that was passed in 2014. The EC has proposed and is supporting that the European Member States also adopt this broad definition of food fraud and the focus on prevention.

2013—Ireland—Review of Food Standards Agency response to the incident of contamination of beef products with horse and pork meat and DNA, An Independent Report: Ireland conducted a review of the horsemeat incident that included recommendations for managing future related incidents (Food Safety Authority of Ireland 2013). The report stated, “The FSA should take the lead in building capability, but a collaborative approach will be essential.” It also recommended that “The arrangements for authenticity and in particular the management of incidents need to be clarified and placed on the FSA website.”

2014—EP—European Parliament Prioritizing Food Fraud: The European Parliament—the legislative branch of the European Union—food fraud was identified as a *top-5* policy issue, not just a top-5 food issue but at top-5 for all issues.

2014—GFSI—GFSI Food Fraud Position on Food Fraud Published: GFSI published their *Position Paper on Food Fraud* that defined food fraud would be included—and required—for companies to achieve future GFSI Certification. In 2014, GFSI even identified implementing food fraud to be a *top-5* priority for 2015. This certification is often a prerequisite to conduct business.

2014—UK—National Food Crime Unit (NFCU): In response to the recommendations in The Elliott Review, the UK government created the National Food Crime Unit (NFCU). Housed within in the UK Food Standards Agency, the NFCU is headed by a law enforcement director and operates across all agencies. The NFCU has been established as a coordinating body similar to INTERPOL but has more direct intelligence gathering powers. The initial funding was “minimal as the Unit initially evolved from a small but similar capability within the FSA.” The annual running cost was £580,000 (US\$725,000), and the final allocation is agreed to £1.2 million (US\$1,500,000) (Parliament 2016).

2015—USA—Food Safety Modernization Act, Preventive Controls, EMA: While not too many details are provided in the FSMA-PC Final Rule, it appears it covers an “agent” that causes a “hazard” that must be mitigated from an “economically motivated” act (MSU FFI 2018). FSMA-IA specifically mentions “stolen” goods to FSMA do cover all types of fraud or the traditional definition of “food fraud.” The prevention focus shifts the burden to the manufacturer. As with other FDA regulations such as for medicines and tampering, the responsibility shifts from a prescriptive approach (what you need to do) to performance (demonstrate a control measure is effective). A question becomes “why did you decide this was NOT a ‘hazard that required a preventive control?’” Many of the seven FSMA Final Rules reiterate that the Food, Drug, and Cosmetics Act is still in effect. For food fraud, the sections that are most applicable are “Adulterated Foods” and “Misbranded Foods.” This rule was finalized in 2015 and is a legal requirement starting in September 2016.

2015—BRC—Food Safety Management System Food Fraud Requirements Being Audited: In April 2015, the British Retail Consortium (BRC) Issue 7, a GFSI compliance standard, required a food fraud vulnerability assessment and mitigation plan. It was announced that BRC would be auditing against the food fraud concepts meaning that addressing food fraud would be a requirement to receive the certification. While the depth and breadth of implementation are currently undefined, there is a current, industry-wide, food fraud strategy in place.

2015—China—Chinese Food Law Addressing Nontraditional Food Threats: Public presentations by Chinese government food officials have revealed a root in criminal law and not just a regulation. Also, while the laws build upon *adulteration* and *counterfeiting*, the concepts are presented in a hierarchy or

continuum that emphasizes addressing all the risk together. The food fraud term has been explicitly defined as holistic, all-encompassing, and harmonized with the global government and industry scope.

2016—CODEX—Codex Alimentarius Draft Discussion Document on Food Authenticity and Food Integrity: CODEX included a food fraud agenda item in 2015 and 2016 until the draft documents were created.

2017—GFSI—GFSI Guidance Document Version 7: In February 2017, the new GFSI Guidance Document was published which defined the requirement for a (1) food fraud vulnerability assessment and (2) food fraud prevention strategy (GFSI 2017). The definition and scope of food fraud is “A collective term encompassing the deliberate and intentional substitution, addition, tampering or misrepresentation of food, food ingredients or food packaging, labeling, product information or false or misleading statements made about a product for economic gain that could impact consumer health.” To be compliant with GFSI, a company, standard, or auditor company must address all types of fraud (including stolen goods, tampering, and mislabeling) and all products (including raw materials through packaged goods in the marketplace). It is important to note that not every vulnerability is a hazard that would be identified as a risk—every vulnerability must be assessed, but a countermeasure is not always required. The formal compliance requirement is 1 year after publication.

2017—China—China FDA Request for Comments on “Fraud in Food Safety”: In March 2017, the China Food and Drug Administration (CFDA) published a public request for comments on addressing “Fraud in Food Safety.” This is in support of the Chinese Food Safety Law that was enacted in 2014 and is being updated (Wu et al. 2017a, b). The questions included a focus on investigation and prosecution with an emphasis on efficiency and prevention.

2017—CODEX—CCFICS EWG: Codex Alimentarius Committee on Food Import and Export Inspection and Certification Systems (CCFICS) reviewed a food fraud discussion draft paper at the May 2017 meeting. An Electronic Working Group (EWG) was formed to review the definitions of food fraud, food integrity, and food adulteration, as well as gaps in the current CODEX standards, with a focus on broad food fraud incidents and on prevention (MSU FFI 2017). While there are no final conclusions, the EWG is a first formal step in the development of a standard.

2017—ISO—ISO 22000 Update: In June 2017, the ISO 22000 standard is being reviewed for an update. There are specific sections that are proposed to deal separately with food fraud and also with food defense (ISO 2017b).

2019—Canada—Food Fraud Work Group (FFWG): Creating in December 2018, the Canadian government has undertaken a project to review the Food Fraud problem, the current state, and then to consider gaps and best practices for an optimal public-private partnership approach (Cadieux et al. 2019).

Appendix: Scholarly Works by the Author

Review of scholarly works by the author per Google Scholar as of January 10, COFS2:

	Title	Cited by	Year
1	<i>Development and application of a database of food ingredient fraud and economically motivated adulteration from 1980 to 2010</i> JC Moore, J Spink, M Lipp Journal of Food Science 77 (4), R118-R126	376	2012
2	<i>Defining the public health threat of food fraud</i> J Spink, DC Moyer Journal of Food Science 76 (9), R157-R163	315	2011
3	<i>Economically motivated adulteration (EMA) of food: Common characteristics of EMA incidents</i> K Everstine, J Spink, S Kennedy Journal of Food Protection 76 (4), 723–735	150	2013
4	<i>Understanding and combating food fraud</i> J Spink, DC Moyer Food technology 67 (1)	45	2013
5	<i>The economics of a food fraud incident—Case studies and examples including melamine in wheat gluten</i> DC Moyer, JW DeVries, J Spink Food Control 71, 358–364	41	2017
6	<i>Defining the public health threat of dietary supplement fraud</i> VM Wheatley, J Spink Comprehensive Reviews in Food Science and Food Safety 12 (6), 599–613	36	2013
7	<i>Defining the types of counterfeiters, counterfeiting, and offender organizations</i> J Spink, DC Moyer, H Park, JA Heinonen Crime Science 2 (1), 8	35	2013
8	<i>Review of package warning labels and their effect on consumer behaviour with insights to future anti-counterfeit strategy of label and communication systems</i> J Spink, J Singh, SP Singh Packaging Technology and Science 24 (8), 469–484	39	2011
9	<i>The challenge of intellectual property enforcement for agriculture technology transfers, additives, raw materials, and finished goods against product fraud and counterfeiters</i> J Spink NISCAIR-CSIR, India	27	2011
10	<i>Backgrounder: Defining the public health threat of food fraud</i> J Spink, DC Moyer Research Grants. National Center for Food Protection and Defense (NCFPD) ...	26	2011

	Title	Cited by	Year
11	<i>Introducing the food fraud initial screening model (FFIS)</i> J Spink, DC Moyer, C Speier-Pero Food Control 69, 306–314	34	2016
12	<i>Introducing Food Fraud including translation and interpretation to Russian, Korean, and Chinese languages</i> J Spink, DC Moyer, H Park, Y Wu, V Fersht, B Shao, M Hong, SY Paek, ... Food chemistry 189, 102–107	21	2015
13	<i>A review of the economic impact of counterfeiting and piracy methodologies and assessment of currently utilized estimates</i> J Spink, Z Levente Fejes International Journal of Comparative and Applied Criminal Justice 36 (4 ...)	20	2012
14	<i>Defining food fraud and the chemistry of the crime</i> J Spink Improving Import Food Safety, 195–216	16	2012
15	<i>Food fraud prevention shifts the food risk focus to vulnerability</i> J Spink, DL Ortega, C Chen, F Wu Trends in Food Science & Technology 62, 215–220	15	2017
16	<i>Combating the impact of product counterfeiting</i> J Spink, OK Helferich, JE Griggs Distribution Business Management journal 10 (6)	14	2010
17	<i>Food fraud prevention: Policy, strategy, and decision-making—implementation steps for a government agency or industry</i> J Spink, ND Fortin, DC Moyer, H Miao, Y Wu CHIMIA International Journal for Chemistry 70 (5), 320–328	12	2016
18	<i>Overview of the selection of strategic authentication and tracing programmes</i> J Spink Counterfeit Medicines: Policy, Economics and Countermeasures 1, 111	11	2012
19	<i>When crime events defy classification: The case of product counterfeiting as white-collar crime</i> JA Heinonen, J Spink, JM Wilson Security Journal 30 (2), 621–639	9	2017
20	<i>Development of a product-counterfeiting incident cluster tool</i> J Spink, DC Moyer, H Park, JA Heinonen Crime Science 3 (1), 3	9	2014
21	<i>The role of the public-private partnership in Food Fraud prevention—Includes implementing the strategy</i> J Spink, DC Moyer, P Whelan Current Opinion in Food Science 10, 68–75	8	2016
22	<i>Addressing the risk of product fraud: a case study of the Nigerian combating counterfeiting and sub-standard medicines initiatives</i> J Spink, DC Moyer, MR Rip Journal of Forensic Science & Criminology 4 (2), 1–13	5	2016

	Title	Cited by	Year
23	<i>The case for global standards</i> L Bix, R Clarke, H Lockhart, D Twede, J Spink The GS1 Global Healthcare Users Group	5	2007
24	<i>Global counterfeit food and beverage packaging: Impacts on food safety</i> J Spink Association of Food and Drug Officials (AFDO), Annual Conference. Available ...	5	2007
25	<i>Product counterfeiting in Michigan and the expectations and priorities for state and local law enforcement: Assessing the awareness of and response to the problem</i> J Spink, J Heinonen Anti-Counterfeiting and Product Protection Program Backgrounder Series. East ...	4	2012
26	<i>Food fraud</i> Y Wu, H Miao, B Shao, J Zhang, JW Spink, DC Moyer Food Safety in China: Science, Technology, Management and Regulation, 253–270	3	2017
27	<i>Food fraud and food fraud detection technologies</i> R Fenoff, J Spink The Routledge Handbook of Technology, Crime and Justice, 295	2	2017
28	<i>Safety of food and beverages: Risks of food adulteration</i> J Spink	2	2014
29	<i>Product fraud and product counterfeiting as a source of terrorist financing</i> J Spink Security Journal 30 (2), 640–645	1	2017
30	<i>Food fraud prevention</i> J Spink The International Union of Food Science and Technology (IUFoST) Scientific ...	1	2016
31	<i>Counterfeiting</i> R Fenoff, J Spink The Encyclopedia of Criminology and Criminal Justice, 1–3	1	2014
32	<i>Analysis of counterfeit risks and development of a counterfeit product risk model</i> JW Spink Michigan State University, Ph.D. Dissertation	1	2009
33	Food Counterfeiting: A Growing Concern J Spink Academic Press, Encyclopedia of Food Chemistry	0	2019
34	Food Fraud and Adulteration: Where We Stand Today J Spink Academic Press, Encyclopedia of Food Chemistry	0	2019

	Title	Cited by	Year
35	The application of public policy theory to the emerging food fraud risk: Next steps J Spink, PV Hegarty, ND Fortin, CT Elliott, & DC Moyer Trends in food science & Technology - Elsevier	0	2019
36	Introducing the Food Fraud Prevention Cycle (FFPC): A Dynamic Information Management and Strategic Roadmap J Spink, W Chen, G Zhang, C Speier-Pero Food Control, 2019 - Elsevier	0	2019
37	Gap analysis of the Canadian food fraud regulatory oversight and recommendations for improvement B Cadieux, LD Goodridge, J Spink Food control, 2019 - Elsevier	0	2019
38	Food fraud data collection needs survey J Spink, C Elliott, M Dean, C Speier-Pero npj Science of Food, nature.com	0	2019
39	The Current State of Food Fraud Prevention: Overview and Requirements to Address “How to Start?” and “How Much is Enough?” J Spink - Current Opinion in Food Science, 2019 - Elsevier	0	2019
40	Global perspectives on food fraud: results from a WHO survey of members of the International Food Safety Authorities Network (INFOSAN) J Spink, P Ben Embarek, CJ Savelli & A Bradshaw npj Science of Food, nature.com	0	2019

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