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

J. W. Spink, *Food Fraud Prevention*, Food Microbiology and Food Safety,
https://doi.org/10.1007/978-1-4939-9621-6_12

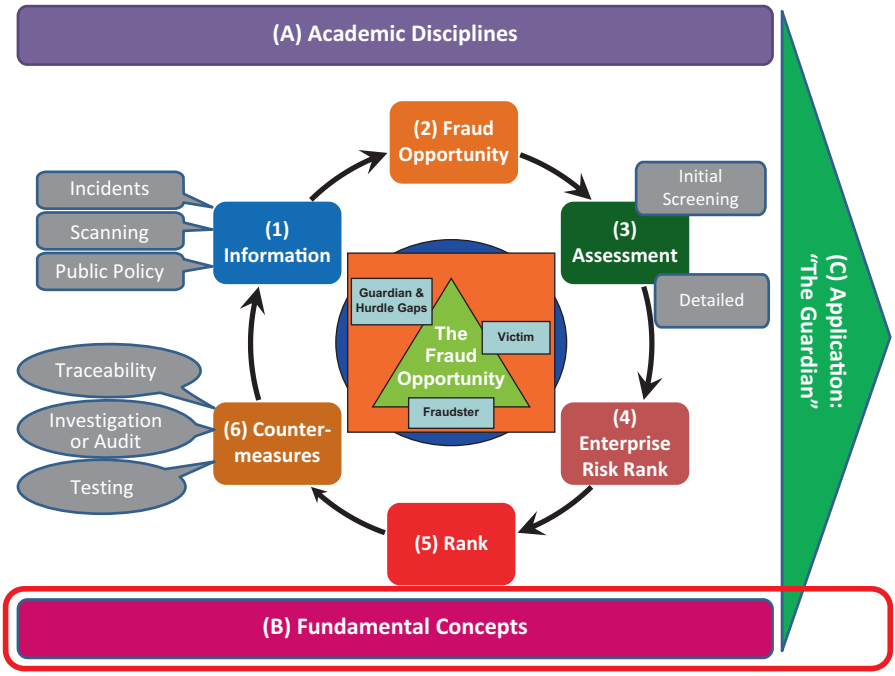

Fig. 12.1 Food Fraud Prevention Cycle—where this chapter applies to the overall concept: "(B) Fundamental Concepts" (Copyright Permission Granted) (Spink 2014, Spink et al. 2019)

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).

GSFI 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.

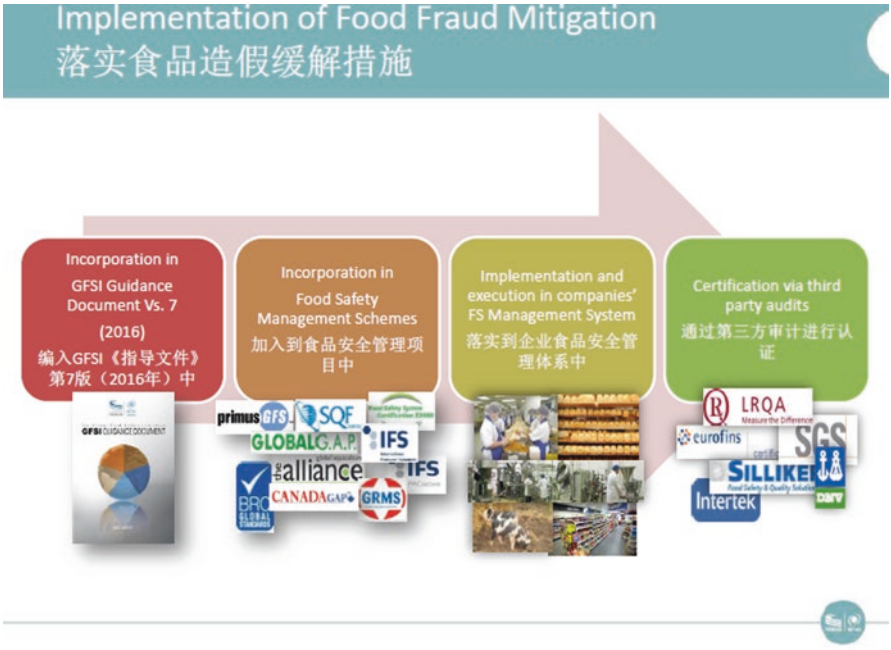

Fig. 12.2 GFSI system hierarchy including guidance document, standard, implementation, and certification (Copyright Permission Granted) (Spink 2013)

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

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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-FFTT) 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-FFTT 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

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"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:

- **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").

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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	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 Requirement: Assess and address "hazards that require a preventive control"—They do not specifically mention or address food fraud Consequence: Illegal product could be subject to product recall and financial penalties
Sarbanes-Oxley act	2002	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 Requirement: Address or disclose risks to revenue Consequence: Not an enforcement priority but noncompliance could be a felony crime
FSMA preventive controls	September 2016	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) Requirement and consequence: See FDCA above
GFSI version 7 (including certification programs such as FSSC, SQF, etc.)	January 2018	All types of food fraud must be assessed and prevention plans implemented for health hazards Requirement: Conduct and document annually a (1) food fraud vulnerability assessment and (2) food fraud prevention strategy and (3) address the GFSI scope. Note: FFVA—And food defense vulnerability assessment—Must be separate from the food safety assessment Consequence: Noncompliance will lead to being decertified
GFSI Certification Programs Organizations (CPOs)	January 2018	The core requirements are from GFSI, and each CPO has some additional requirements or details Requirement and consequence: See GFSI above

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/mg67m5c3lTE
- Food Fraud Update and Terminology Survey, Presented by John Spink, GMA Science Forum 2018,
- URL (21-minutes): https://youtu.be/lZNwilEz6fM

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)
BRC	Standard	BRC Global Standard Food Safety Issue 8 (Sect. 5.4 Product authenticity, claims, and chain of custody) + (BRC 2018)	August 2018
BRC	Guidance	BRC Global Standard for Food Safety Issue 7 Understanding Vulnerability Assessment (BRC 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
FSCC 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
BRC	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
BRC	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 ***product fraud***: 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.'2 ".
- "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."

BRC: 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" (WIFFM) 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 *require* addressing *all* types of fraud and for all products
Auditors	You, as the auditor, are required – *not optional* – to fully address the GFSI food fraud compliance requirements, and to conduct a competent audit, you *must* 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 *fully* addressing this enterprise-wide risk that you are accountable for whether you know it or not – this is *not* 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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