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

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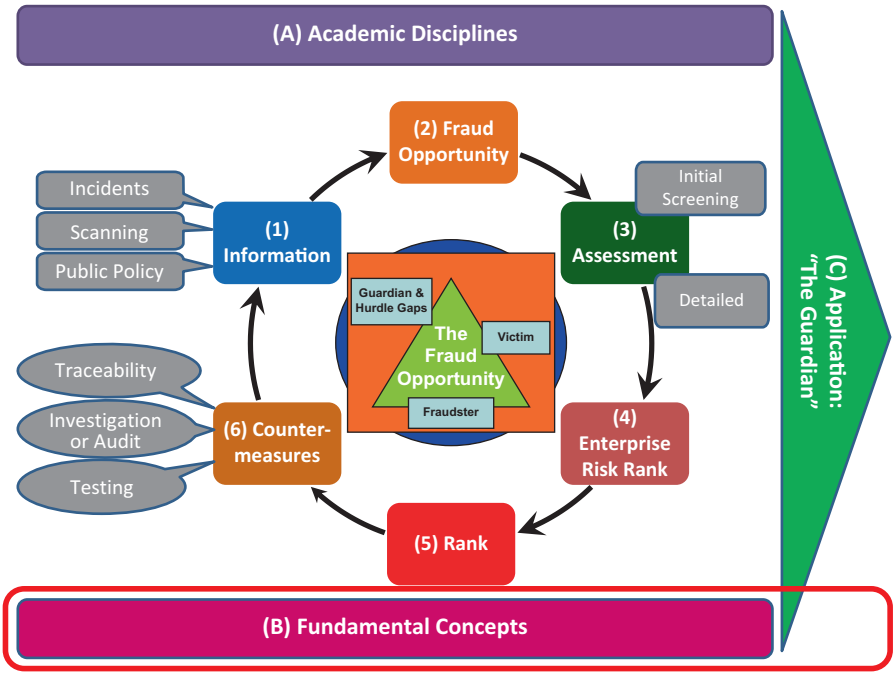

Fig. 11.1 Food Fraud Prevention Cycle—where this chapter applies to the overall concept: "(B) Fundamental Concepts". (Copyright Permission Granted) (Spink 2014; Spink et al. 2019)

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 subcommittee 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

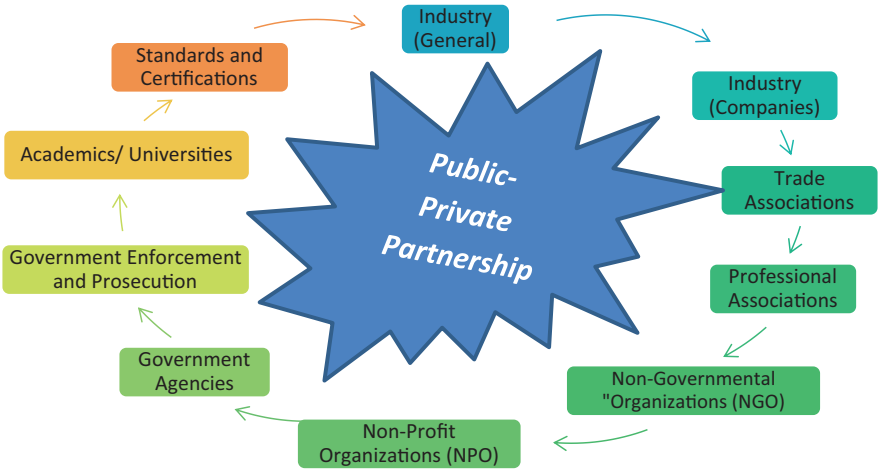

Fig. 11.2 Public-private partnership (PPP) for food fraud prevention

defined fraud opportunity or an overall vulnerability assessment, then the countermeasures 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

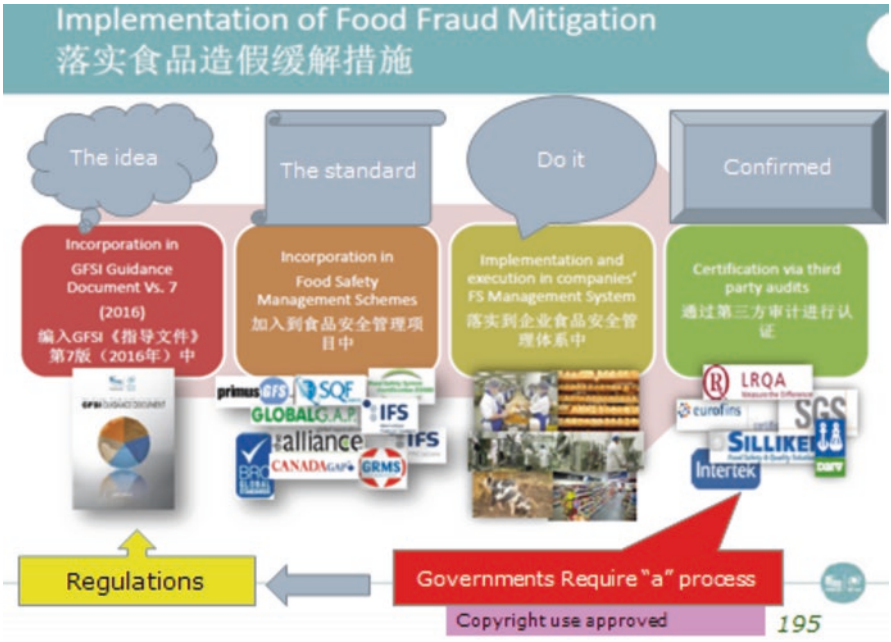

Fig. 11.3 GFSI Implementation hierarchy including the role of governments. (Copyright Use Approved) (Copyright Permission Granted) (GFSI FFTT 2013)

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 full 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" (WIFFM) 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 *your* 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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