Chapter 14
Economic Rationale for US Involvement in Public-Private Partnerships in International Food Safety Capacity Building

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Abbreviations

APEC	Asia-Pacific Economic Cooperation
ARS	Agricultural Research Service
BPCS	Better Process Control School
CDC	Centers for Disease Control and Prevention
CSREES	Cooperative State Research, Education, and Extension Service
FAS	Foreign Agricultural Service
FDA	Food and Drug Administration
FSIS	Food Safety and Inspection Service
FSMA	Food Safety Modernization Act
FSPCA	Food Safety Preventive Controls Alliance
FSVP	Foreign Supplier Verification Program
GAP	Good agricultural practices
GFSI	Global Food Safety Initiative
GFSP	Global Food Safety Partnership
GMA	Grocery Manufacturers Association
GMP	Good manufacturing practices
HACCP	Hazard Analysis and Critical Control Points
HVA	High-value agricultural
IEC	International Electrotechnical Commission
IFT	Institute of Food Technologists
IICA	Inter-American Institute for Cooperation on Agriculture
IIT IFSH	Illinois Institute of Technology's Institute for Food Safety and Health
ILSI	International Life Sciences Institute
ISO	International Standard Organization
JIFSAN	Joint Institute for Food Safety and Applied Nutrition
M and E	Monitoring and evaluation

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MIS	Marketing information services
NASA	National Aeronautics and Space Administration
NASDA	National Association of State Departments of Agriculture
NOAA	National Oceanic and Atmospheric Administration
OASIS	Operational and Administrative System for Import Support
OECD	Organisation for Economic Co-operation and Development
PPP	Public-private partnership
SCM	Supply chain management
SPS	Sanitary and phytosanitary measures
SSA	Sprout Safety Alliance
UNIDO	United Nations Industrial Development Organization
USAID	US Agency for International Development
USDA	United States Department of Agriculture
WHO	World Health Organization

14.1 Introduction

Global agricultural trade has increased substantially during the past three decades, especially trade in high-value agricultural (HVA) products such as horticultural produce, dairy, fish, and meat products. Mike Taylor, the Deputy Commissioner of the Food and Drug Administration (FDA), reports in 2013 that "15 percent of U.S. food supply is imported, including 50% of fresh fruit, 20% of fresh vegetables, and 80% of seafood" (FDA 2013). In 2014 the United States imported a total value of $111 billion in agricultural food, which is nearly three times the 1990 value of $39 billion. Though Canada and Mexico remain the largest exporters to the United States in terms of value, the United States is increasingly sourcing from Asia, especially China, India, Indonesia, Vietnam, and Thailand. There are two reasons for this: firstly, there is year-round demand for seasonal foods (foods consumed as close to harvest as possible), which are usually in the HVA category and not domestically available. Secondly, there is a greater supply capacity, thanks to innovations in transportation and communication technology, enabling retailers to satisfy this growing demand through global sourcing (Fagotto 2010).

The World Health Organization (WHO) initiative to estimate the global burden of foodborne diseases (see Chap. 7) looked at 31 global foodborne hazards and estimated that they were responsible for 600 million (95% uncertainty interval [UI] 420–960) foodborne illnesses and 420,000 (95% UI 310,000–600,000) deaths in 2010 (World Health Organization 2016). With the increasing number of imported HVA foods being consumed in the United States, it is inevitable that some of these illnesses will be caused by imported food. The US Center for Disease Control and Prevention (CDC) estimates that each year foodborne diseases lead to roughly 48 million illnesses, 128,000 hospitalizations, and 3000 deaths in the United States (Scallan et al. 2011). To reduce the burden of foodborne illness, many countries, including the United States, are moving to strengthen their food safety systems by shifting the focus from responding to contamination to preventing it.

Food safety capacity building is a measure of preventive control. FDA has historically worked with the US land-grant system to roll out food safety training material to the states and territories. FDA has also worked with the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) to adapt that material to an international audience and roll it out. The Food Safety Modernization Act (FSMA), passed in 2011, formally shifted the focus from reaction to prevention and placed more responsibility on the private sector for preventing hazards from occurring. This move was in recognition that the private sector is in a better position to ensure that preventive control measures are in place by working with its suppliers.

Historically, regulatory tools, such as regulations and laws, have been used by governments to improve social welfare. These regulatory tools are used to correct market failures through requiring or incentivizing the private sector to change their behaviors. These actions may be costly to the private sector but are considered necessary by the public sector to ensure the safety of food the private sector is supplying to consumers. Capacity building, on the other hand, is a nonregulatory tool that the FDA has made available to help strengthen its efforts in preventing food safety problems in both domestically produced and imported food. Instead of telling the private sector what they should do, capacity building improves the private sector's ability take the required actions or achieve desirable outcomes. Prior to FSMA, FDA has been involved in capacity building abroad surrounding several voluntary measures such as good agricultural practices (GAP) and good aquaculture practices (GAqP). Through FSMA, FDA is required to develop an international capacity-building plan that addresses a wider range of stakeholders.

In 2011, the FSMA required FDA to promote food safety capacity building internationally and implement a complementary monitoring and evaluation plan. This plan allows for cost-benefit analyses and helps to make sure the benefits of the capacity-building efforts outweigh their costs. Data are essential to monitoring and evaluation. The public sector collects some data on imports and rejections, but these data are not sufficient. Both import and rejection data and production and compliance data are needed to measure the impact of food safety capacity building. Since the private sector collects production and compliance data to monitor their suppliers and operations, it is difficult to measure the impact of food safety capacity building without involving the private sector. The private sector may be reluctant to share data with a regulatory agency due to negative repercussions such as loosing proprietary data or facing a possible regulatory sanction. A plausible way forward would be to develop a voluntary data process that focuses on whether food producers are delivering safe food to consumers. The mechanism for measuring impact and data sharing still needs to be worked out. If the public and private sector were to work in a complementary manner, they would be in a better position to inform policy involving such efforts.

This chapter is organized as follows. Firstly, it provides some background on the various actors involved in international food safety capacity building. Secondly, it explains the economic rationale for the public sector to invest in food safety capacity building and to form partnerships with the private sector. Thirdly, it discusses capacity-building efforts that involve the public and private sectors and some

public-private partnerships (PPPs) that have already emerged. Fourthly, it discusses the importance of monitoring and evaluating the impact of these efforts so that adjustments can be made if goals are not being achieved. Lastly, it discusses the importance of PPPs not only in food safety capacity-building trainings but also in the monitoring and evaluation efforts associated with these trainings.

14.2 Background on Public and Private Sector Actors Involved in International Food Safety Capacity Building

Various organizations, agencies, and industries form PPPs to support international capacity building in developing countries (Fig. 14.1). These parties are driven by mainly three types of interests: aid interests, trade interests, and food safety interests. International organizations (e.g., WTO, WHO, FAO, World Bank, IICA) and some government agencies (e.g., USAID, USDA/FAS) are driven by aid interests. Aid-driven agencies focus on agricultural capacity building in developing countries to increase agricultural output and food security as well as raise awareness of food safety and nutrition (Testimony on Food Aid and Capacity Building Programs 2015). Some government agencies emphasize the importance of technical assistance to developed countries and endeavor to remove inspection and testing technology barriers to trade. For example, the US Department of Agriculture and Foreign Agricultural Services are interested in building international trade capacity as a means to facilitate US agricultural export and to make sure US producers do not face trade obstacles due to poor testing facilities in the global market (USDA/FAS 2015). The public and private sectors in developed countries also choose to invest in international capacity building to further domestic food safety interests and for the private sector to ensure it is providing consumers globally a safe product. We will focus on the economic rationale supporting the behavior of these stakeholders and use the food market in the United States as an example to illustrate why both the public and private sectors in developed countries are needed in international food safety capacity building.

Fig. 14.1 Public-private partnership and international capacity building

14.2.1 Food Safety Interest and Public Sector Intervention

Figure 14.2 is a highly stylized model of how different players interact with each other in the import and domestic food markets. Domestic importers import food products from international suppliers and sell them to domestic consumers. To ensure the safety of their products, some importers choose to adopt third-party private standards, which help to monitor and ensure food safety practices among suppliers. The safety of imported food is also of interest to the domestic government, which relies on regulatory and nonregulatory tools to improve domestic food safety. Some international suppliers encounter technical difficulty in fulfilling the requirements by governments and importers in developed countries. In addition, some developing countries lack the regulatory capacity to manage their food supply chains. In both cases, international capacity building is an effective nonregulatory tool to ensure the safety of imported food.

Because of the nature of food consumption and structures of the food market, the private sector alone cannot achieve the socially optimal level of food safety and quantity of supply, and public sector involvement is required to correct market failures. In this section, we discuss three such market failures. Firstly, food consumption is food safety consumption in nature, which is considered a public good (Holmes et al. 2006; Roberts 2013; Unnevehr 2007). Food safety has public health benefits that cannot be captured by food prices in the free market. Foodborne illnesses, especially those caused by unsafe practices of suppliers and importers, can

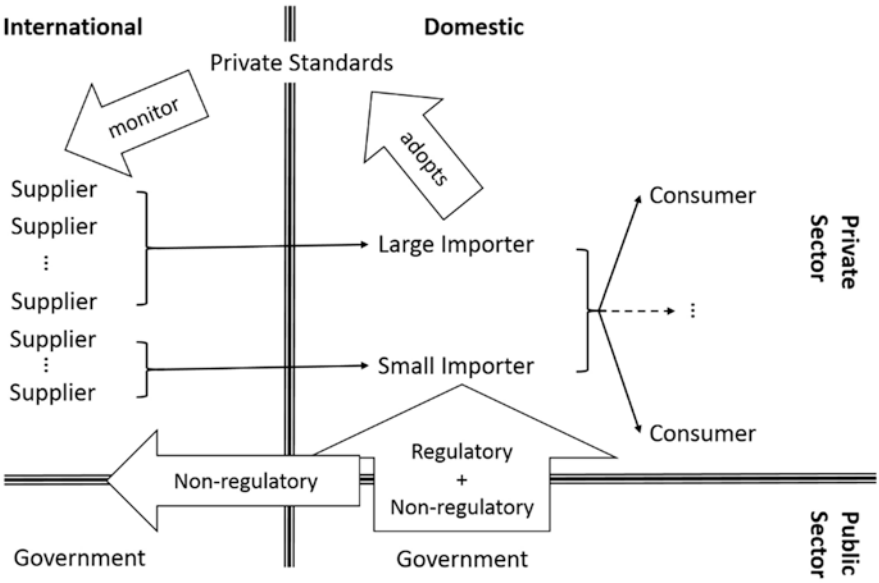

Fig. 14.2 Public and private sector players in food import market

affect large groups of consumers, lead to loss in both output and social welfare, put pressure on the public health system, and sometimes result in loss of lives. In addition, negligence by suppliers or importers can cause significant disruptions in food supply, undermine public confidence, and further reduce social welfare (FDA 2013).

Secondly, the food market suffers from imperfect information and, as a result, underinvestments in food safety. Information problems exist on every link along the food supply chain. For example, consumers are often processors of their own food. Without accurate information on the safety of the food they purchased, they may not take the required actions during preparation to reduce the risk of foodborne illnesses. But it is economically infeasible for the suppliers and importers to sufficiently raise the safety standards of their products because they lack information on consumer behavior (Elbasha and Riggs 2003). In addition, foodborne illnesses are often not recognized or diagnosed, since consumers do not always attribute episodes of illness to their food or seek medical attention. This is especially true when illnesses are caused by chronic exposure. This lack of recognition on the part of consumers leads to their undervaluation of food safety. Even when a food pathogen is identified, it is difficult to traceback to its point of origin due to the technology constraints and limited epidemiological data, especially when products from small-scale suppliers are comingled and sold collectively. The lack of firm-level traceability, then, entails another problem of collective reputation and underinvestment by suppliers in food safety practices (Winfree and McCluskey 2005).

Lastly but not the least, the private sector has limited ability to correct market failures, because each player acts to serve their own interests (Fagotto 2014). In the absence of public sector regulation, private governance did emerge to fill the regulatory gap (Fagotto 2014; Fulponi 2006; Lin 2014). Large importers such as Walmart, Costco, and McDonalds required their suppliers to be certified by private standards. However, the adoption of private standards is insufficient to guarantee a socially optimal level of safety and quantity of supply in the food market. Private standards are voluntary. Smaller importers and their suppliers may not be able to afford to adopt these standards. Moreover, the private standards historically have not been examined or recognized by government agencies to verify that they are sufficient to protect the health of consumers (in the United States, this may change for some of the private certification bodies under the accreditation of third-party certification rule under FSMA). From an efficiency point of view, suppliers certified by private standards are able to differentiate their product from the rest of the industry, implying a less competitive import market (McQuade et al. 2016).

14.2.2 Public Intervention in the Form of International Capacity Building

The market failures discussed above call for actions from the public sector to increase domestic food safety. Traditionally, for imported food, this goal is achieved by inspecting food products at the port of entry, rejecting any unsafe products.

However, this method is insufficient. There is a growing need for new policy tools, given the increasing amount of food being imported. There are three main reasons. Firstly, public resources are limited, while sampling and inspecting are costly. In order to be confident about food import safety, the inspection sample size needs to be large. However, in the United States, the FDA inspects less than 3% of FDA-regulated imports (FDA 2011). Secondly, reaction to foodborne illnesses is insufficient to protect public health and social welfare. Foodborne illness outbreaks are costly to society as they may spread quickly and reduce both public health and confidence in the domestic food system. What is worse is that it is often difficult to detect such outbreaks at their start because many foodborne illnesses are often not recognized or diagnosed. Thirdly, the global food supply chain, made possible by innovations in communication and transportation technologies, is increasingly complex (FDA 2011). The intricate supply chain makes it even harder to trace pathogens to suppliers and hold them accountable. The lack of firm-level traceability implies that it is impossible to deter unsafe suppliers by punishing them. The FDA recognized that it needed to reach beyond US borders and help to ensure the safety of products before they are imported (FDA 2011) and prevent outbreaks of foodborne illnesses arising from imported products.

An important tool of prevention is international food safety capacity building, facilitating the ability of exporting countries to ensure that the food they produce for international markets is safe. Suppliers from developing countries often have difficulty meeting food safety requirements, and developing country governments sometimes lack the capacity to enforce these requirements. For instance, many lack regulatory frameworks to correct market failures, the laboratory infrastructure to identify risks, human capital to conduct risk analysis, and resources to educate and monitor the stakeholders along the food supply chain. Developed countries, with more experience, knowledge, and capacity in food safety, can support international food safety capacity building and secure a sufficient and safe supply of seasonal food domestically, which is mutually beneficial to importers and exporters.

All countries have the right to ensure that the food their consumers eat is safe and to prevent the spread of pests or diseases among animals and plants. Under the WTO Sanitary and Phytosanitary Agreement, countries are allowed to put in restrictions if they are supported by an objective risk assessment that is supported by accurate scientific data. Though many countries do use risk assessment in their regulatory process of reducing the risk of specific diseases, the SPS Agreement also encourages a wider use of risk assessment among all WTO members. Not all countries currently have the human capital to conduct risk assessment, thus the need for capacity building in risk analysis as articulated in the SPS Agreement. Countries under Article 9 of the WTO Sanitary and Phytosanitary Agreement have agreed to facilitate the provision of technical assistance to other members, especially developing country members, either bilaterally or through the appropriate international organization. As countries like the United States and the EU are increasingly reliant on imported HVA from developing countries, they have been providing capacity building to help improve the safety of their imported food.

In 2011, the US Congress passed the Food Safety Modernization Act (FSMA), mandating FDA's participation in international food safety capacity building and enhancing FDA's ability to engage in the global food market. International food safety capacity building is necessary to achieve the goals of FSMA. For example, after FSMA, all suppliers (except for very small farms) need to meet regulatory requirements by the United States, and importers are explicitly responsible for verifying that their suppliers comply (FDA 2013). This policy change requires supplier capacity building on implementing food safety practices and foreign government capacity building on regulating and training their suppliers. In addition, the FDA is tasked to assist the private sector players through the transition brought about by FSMA, which involves helping to develop guidance and training materials on the new requirements.

The scope of FDA's involvement in international food safety capacity building has also broadened over time. In the FDA Global Engagement report (FDA 2011), the FDA summarizes its past efforts in international capacity building as strengthening regulatory capacity building through information provision, training, and exchange programs. The FSMA Section 305 (FDA 2011) charges the FDA to "develop a comprehensive plan to expand the technical, scientific, and regulatory capacity of foreign governments and their respective food industries." In response, FDA's International Food Safety Capacity-Building Plan (FDA 2013) includes enhancing technical assistance as one of the main goals and plans to adapt training materials to "different players along the food supply chain."

A common interest between multiple US government agencies (e.g., the FDA, FSIS, and USDA/FAS) in international capacity building is to promote the use of recognized laboratory methods and testing and detection techniques. Agencies within the US government publish their recommended methods for testing for different food hazards (FDA 2016). There are also ISO documents that can be purchased on different methods. Countries and private suppliers need to test to the requirements of their buyers which may differ depending on which country a supplier is exporting to. If an exporter uses a method to validate the safety of the agricultural product that is different than the one the US government recommends, the exporter needs to show their method is equivalent to the recommended one. Thus, both FDA and USDA/FAS mention in various reports the need for technical assistance and working with local regulatory bodies and industries to develop multilaterally recognized requirements, standards, and methods.

14.2.3 Public-Private Partnership in International Capacity Building

As both the private sector and the public sector have similar interests in food safety capacity building, a PPP surrounding international food safety capacity building makes sense. Rich and Narrod (2010) lay out key processes linking farmers to markets for which PPPs in supply chain management may be optimal given the existence of market failures (see Table 14.1). They also suggest that PPPs have

Table 14.1 Institutional roles in the supply chain management of high-value agriculture: support processes

Supply chain support processes	Traditional institutional role		Needed roles for SCM	Market failures	Possible entry point for PPPs and NGOs
	Public sector	Private sector			
Extension services	Technical assistance to producers in farming practices	Provision of services to farmers and firms linked to private company	Knowledge of specialized techniques for high-value products	Variable smallholder access to public or private extension; limited public knowledge of new techniques; underfunding of services	Creation of partnerships to leverage public and private delivery of specific types of extension services (training, field schools, vaccinations, etc.)
Infrastructure development	Public infrastructure (roads, ports, storage facilities); public distribution of commodities	Private infrastructure (processing, storage); logistics and information services	Manage flows between chain links quickly and efficiently to meet rigid deadlines by buyers; reduce distribution costs to remain competitive with other supply chains	High transportation costs, low access to smallholder areas, poor infrastructure, erratic information flows, crowding out by public sector	Partnerships between public sector and producer groups/NGOs to jointly finance and maintain roads, storage facilities, etc.
Information services	Provision of public statistics on prices, production, etc.; provision of information on varieties through extension	The use of private marketing information services (MIS) and electronic data interchange (EDI)	Integrate information flows across supply chain actors	Imperfect information by smallholders on needs of buyers and customers in HVA	Development of MIS to integrate government statistics agencies with private producer associations, the use of IT to distribute market information

(continued)

Table 14.1 (continued)

Supply chain support processes	Traditional institutional role		Needed roles for SCM	Market failures	Possible entry point for PPPs and NGOs
	Public sector	Private sector			
Certification, grades, and standards	Public certification of seeds and varieties; development and enforcement of public standards and regulations; food safety inspection and monitoring	Private certification of seeds and varieties, development and enforcement of private standards; enforcement of ISO standards	Consistent, credible application of rigid standards on food safety and quality specifications to meet buyer and customer demands	Smallholders' ability to meet public or private standards limited; divergence between public and private standards; low capacity to enforce public standards	Creation of third-party certification agencies that manage quality and food safety in conjunction with government and producer groups
Coordination mechanisms	Creation and enforcement of regulations to ensure competition and market exchanges; mandatory cooperatives (centrally planned economies)	Development of contracts, alliances, and marketing agreements with suppliers	Mechanisms must ensure consistent delivery of high-quality products	Limited enforcement of contracts; divergence in market power between chain actors	Third-party PPP to underwrite and monitor contracts; development and promotion of producer associations to improve enforcement

Source: Rich and Narrod (2010)

advantages over pure public sector intervention in the free market in that, given the public sector's emphasis on social welfare and the private sector's control over its suppliers, PPPs bring forth the best aspects of both sectors (Rich and Narrod 2010).

The public sector's advantage is in its extensive connections with foreign government counterparts and authority to negotiate with other countries, human resources in the agencies and USDA land-grant universities, knowledge on food safety regulatory framework, information on US food safety policy changes and the development of various laboratory methods, and information on agricultural development in foreign countries. It is in the best position to develop guidance and training materials, deploy experts as trainers, and reach out to a wide range of stakeholders. It is also in the best position to identify priorities in international capacity building.

However, public sector involvement alone is not sufficient. Firstly, public sector resources are limited. The budget constraint affects the public sector's capacity in three ways: the number of trainings supported, the number of inspections conducted overseas, and the ability to connect with international suppliers. Secondly, traditionally, extension efforts and research tended to focus less on HVA and more on low value stable products (Rich and Narrod 2010). In addition, though the public sector

has historically provided technical assistance in farming practices to producers, public sector extension services have often been criticized as being unresponsive to the diverse needs of farmers. Contracting with private extension service providers could increase responsiveness (Anderson et al. 2007).

The private sector complements the public sector with its existing experience, resources, and infrastructure on monitoring international suppliers. The FSMA, by shifting the responsibility of ensuring international suppliers' compliance with the US food safety regulatory requirements to importers, motivates the importers' participation in international capacity building. Extension service roles that were traditionally played by the public sector can benefit from being transferred to or shared with the private sector providing services to their suppliers. The private sector is able to connect with the private sector players in foreign countries and help to meet FDA's new goals of adapting technical assistance and capacity building to different players along the food supply chain and local needs in different countries. In addition, the private sector has firm-level data that, if made available, could help to evaluate the effectiveness of capacity building, which is essential to prioritizing capacity-building effort and making adjustments as the global food market continues to evolve. The data problem will be discussed in greater detail in Sect. 14.4.

14.3 To Effectively Build International Food Safety Capacity, PPPs Are Needed

The idea of PPP in ensuring food safety is not new. The FDA, under the Federal Food, Drug, and Cosmetic Act of 1938, became responsible for ensuring that foods were unadulterated and truthfully labeled. The FDA built its enforcement activities around pre-market and post-market activities involving the private sector. The FDA also is governed by the Public Health Service Act of 1944 which provides broad authority to protect public health by establishing certain "public-private" cooperative programs, providing authority for emergency authority to prevent the spread of communicable diseases and establishing the role of CDC in public health surveillance.

Hazard Analysis Critical Control Points (HACCP) was the first food safety system to involve training programs. It has its origins with the National Aeronautics and Space Administration (NASA), who had mandated the use of critical control points to ensure the safety of food in flight, and Pillsbury Company, the NASA contractor since the late 1950s(Sperber and Stier 2009). In the early 1970s, the FDA responded to a case of botulism attributed to under-processed, low-acid canned food by reaching out to Pillsbury. Pillsbury organized and conducted a training program for FDA inspectors on how to use critical control points to regulate the production of canned foods (ibid.). With insight from that training program, the FDA published the canned food regulations in 1973, HACCP regulations for seafood in 1995, and subsequently juice HACCP requirements.

In 1998, the FDA published formal guidelines for the microbial safety of fresh produce, suggesting that good agricultural practices (GAP) and good manufacturing practices (GMP) for producers are ways public and private sector entities can ensure the safety of produce (Rushing and Walsh 2006). Later in 1999, the National GAP training program was established at Cornell University through a grant from the USDA Cooperative State Research, Education, and Extension Service (CSREES) and the FDA. The goal of the National GAP program was for Cornell to develop a course material addressing the principles in the 1998 FDA guidelines and to roll out this information through the USDA land-grant extension programs to the fresh produce industry. Although these domestic training programs were effective in the United States, the FDA recognized that they did not address the needs of foreign produce suppliers without a similar extension outreach system abroad. The FDA thus tasked the JIFSAN, one of FDA's Centers of Excellence, to alter the material to the needs of foreign producers and roll out the training internationally.

The JIFSAN, created in 1996, is a PPP between the FDA, the University of Maryland, and the private sector. Its mission is to advance sound strategies that improve public health, food safety, and applied nutrition using risk analysis principles through cooperative research, education, and outreach programs. A major component of its mission is to develop food safety capacity abroad. Initial efforts focused on improving human capital through train-the-trainer programs in good agricultural practices, good aquacultural practices, good fishing vessel practices, food inspection trainings, and commercially sterile packaged food. Much of the JIFSAN's capacity building is funded through an FDA cooperative agreement with a support for specific country programs from the private sector, FDA, USDA-Foreign Agricultural Service (USDA/FAS) and the Food Safety and Inspection Service (USDA/FSIS), and the US Agency for International Development (USAID). JIFSAN trainers are from the industry, are FDA scientist (if an FDA priority country), are retired FDA or USDA scientists, or are the faculty from the University of Maryland or other academic institutions. Starting in 2002, the host countries have cost-sharing agreements supporting JIFSAN International training programs funded through the cooperative agreement. The JIFSAN funds programs up to the port of entry into the host country. The host country and any other partners then provide funding for training activities inside the country. Some governments have also reached out directly to the JIFSAN to request trainings for their food safety specialists; and they either fund themselves or find funding from a donor agency like the World Bank, IDB, and USDA/FAS. Figure 14.3 shows how the effort in capacity building funded through the FDA cooperative agreement with the JIFSAN has increased with increased amounts of imports into the United States. Though the shared funding policy was implemented well before FSMA, it aligns with several of the principles with the FDA International Food Safety Capacity-Building Plan such as ensuring the host country's commitment to the effort while also leveraging JIFSAN resources. Figure 14.4 shows the global reach of all the JIFSAN's training programs.

In 2010 the JIFSAN recognized that one-off training in a country may not be sufficient to reach all the needed stakeholders, which led to the establishment of

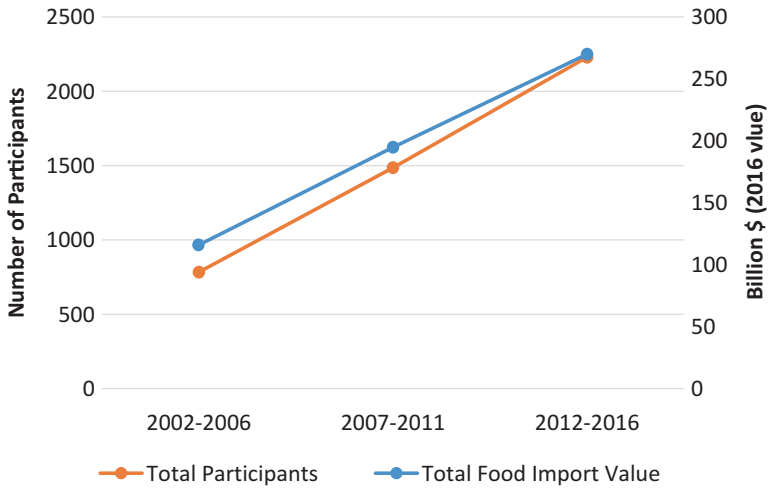

Fig. 14.3 FDA-funded international training and food import values from hosting countries

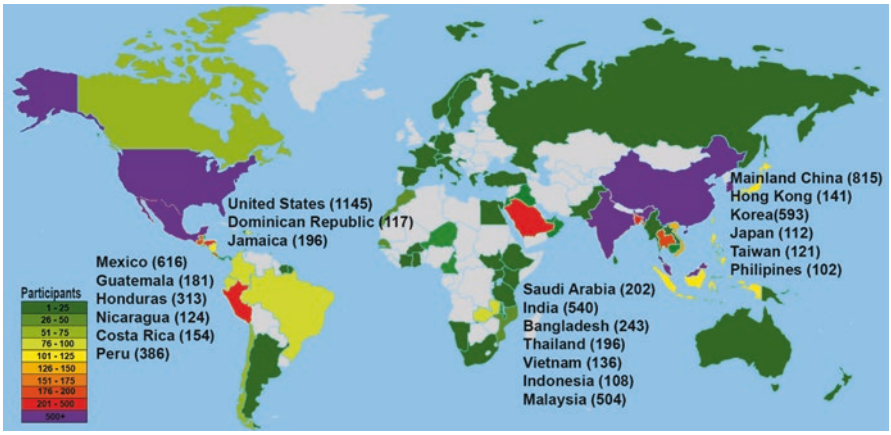

Fig. 14.4 Historical global coverage of JIFSAN's programs

JIFSAN's Global Collaborative Training Center Initiative. The primary goal of the centers is to work with in-country partners to build capacity of both regulators and industry in the use of international best practices in food safety management, enhancing the safety of the food supply in a country or region. The Aquatic and Aquaculture Food Safety Center (AAFSC), in collaboration with the Bangladesh Shrimp and Fish Federation, was established in 2010. The establishment of AAFSC was based on discussions between JIFSAN, the CFSAN's Division of Seafood, and Bangladesh Shrimp and Fish Federation about continuous training needs on good aquacultural practices (GAqP) after an initial training in 2009. Since then, lead

trainers have been trained; and the Center has conducted a number of multiplier trainings and has been instrumental in integrating GAqP into university curricula in Bangladesh.

In 2012, the JIFSAN worked with the CFSAN, the FDA's India Office, the Spices Board of India, and the Confederation of India Industry Food and Agriculture Center of Excellence (CII-FACE) to establish the Centre for Supply Chain Management for Spices and Botanical Ingredients in India. Following the same approach as in Bangladesh, lead trainers were identified, trained, and have rolled out multiplier training programs to producers and marketers throughout much of India. In 2013, the JIFSAN, Delta Professional Consultancy, and the Malaysia's Ministry of Health initiated the International Food Safety Training Centre Malaysia, focusing on building laboratory testing capacity, risk analysis capabilities, increasing the skills of the ministry's food inspection staff, and increasing their understanding of global food laws and regulations. Several other initiatives are in the process but have not progressed as much as these three to date.

The JIFSAN, in recognition that the SPS Agreement placed an increased emphasis on risk-based decision-making in facilitating global trade, also established a risk analysis training program in 2002. Though initially the training material was developed with funds from the cooperative agreement, training participation is largely supported through program fees paid for directly by a country's ministry, competitive grants, and funds from the private sector. In 2011, an extended risk analysis fellowship in partnership with International Life Sciences Institute (ILSI) was established. The program is a 3-month program involving 1 month of classroom training followed by a 2-month guided research period. In the guided research period, fellows develop quantitative risk assessments and populated them with data from their countries (or data from nearby regions if country-specific data is currently unavailable). Additionally, the fellows are introduced to various agencies in the US food safety system and participate in several field trips to food companies and retail establishments. Since 2011, 27 fellows from developing countries were trained through this program; and funding came from the ILSI fellowship, USDA-FAS, USDA Borlaug programs, and national governments. In August 2017, a modified extended risk analysis training program began at the MARs Training Center in China.

The laboratory program was established in 2010 as a partnership between the JIFSAN and the Waters Corporation, where it offers hands-on laboratory training in chemical and microbiological food safety analysis. The training courses are "fit for purpose" in that they are designed to teach participants instrument-independent analytical techniques ranging from the most sophisticated to the simplest approach, thereby allowing effective analysis regardless of the facilities available. The focus of the program is on both FDA-recommended methods for sample preparation and analysis required to meet US import standards and the harmonization of methods to ensure food safety worldwide. Participation in this program currently is largely supported through program fees by a country's ministry, competitive grants, and funds from the private sector.

14.3.1 New Era Under FSMA

The abovementioned history illustrates that at each point, the private sector was involved. The FDA is now in a new era under FSMA, the first major change since 1938 in how food is protected in the United States. The goal of the new law is for the FDA to develop a prevention-oriented set of requirements to strengthen accountability of individuals involved in the provision of food and thus ensure high rates of compliance for both imported and domestic foods. The new law created roles for the manufacturers, importers, third-party private standards, foreign regulatory bodies, and the FDA at both the federal and state levels. In 2011, the FSMA formally required the FDA to set requirements; administer training and education programs for the state, local, territorial, and tribal food safety officials; and provide technical assistance so producers and processors know what is expected.

Section 305 of FSMA also charged the FDA to "develop a comprehensive plan to expand the technical, scientific, and regulatory food safety-capacity of foreign governments, and their respective industries, from which foods are exported to the United States." The purpose of the plan is for FDA to be transparent to their stakeholders about FDA's interests and priorities with respect to food safety capacity-building efforts. This was the first time Congress charged the FDA with comprehensively addressing international food safety capacity building. The key principles including ownership, alignment, leverage, managing for results, mutual accountability, and sustainability are articulated in the FDA's International Food Safety Capacity-Building Plan (FDA 2013).

The goals of the international capacity-building plan were to ensure a high level of compliance with the new rules under FSMA; and the FDA recognized that to do this effectively they needed an evidence-based decision-making process. They also needed to coordinate with other US agencies and international organizations and work with partners in the public and private sectors in developing training materials. They needed to prioritize their training and capacity-building efforts based on risk assessments and needs assessment and support the FDA's foreign offices on technical assistance. They also needed to develop a monitoring and impact assessment process.

Under FSMA, the FDA will continue to roll out the Produce Safety Rule internationally through Produce International Partnership (PIP) training program involving the JIFSAN and the Produce Safety Alliance. This is largely in recognition that it will be difficult to get producers trained in these areas without continual support from the public sector. This, however, is not the case with some of the other rules such as the Preventive Controls Rule where there is a large number of lead trainers emerging in both the public and private sectors who can help disseminate the materials internationally and bring all firms up to speed in time to meet the implementation deadlines for the new rule.

The implementation of the FSMA in terms of both domestic and international capacity building is being done in three phases. Phase 1 sets the requirements and develops the regulations and guidance documents, when a series of new rules were

Box 14.1 New Rules Under FSMA

Preventive Controls Rule for food—requires a food facility to have and implement preventive controls to significantly minimize or prevent the occurrence of hazards that could affect food manufactured, processed, packed, or held by the facility.

Preventive Controls Rule for animals—establishes requirements for good manufacturing practices and requires that certain facilities establish and implement hazard analysis and risk-based preventive controls for animal food, including ingredients and mixed animal feed.

Produce safety rule—establishes the science-based minimum standards to reduce the risk of foodborne hazards associated with the production and harvesting of raw fruits and vegetables that are marketed as raw agricultural commodities.

Foreign Supplier Verification Programs rule—describes what a food importer must do to verify that its foreign suppliers produce food that is as safe as food produced in the United States.

Accreditation of third-party certification rule—establishes a voluntary program for the accreditation of third-party certification bodies to conduct food safety audits and issue certifications of foreign facilities and the foods they produce.

Sanitary Transportation of Human and Animal Food rule—establishes requirements for shippers, loaders, carriers by motor vehicle and rail vehicle, and receivers engaged in the transportation of food, including food for animals, to use sanitary transportation practices to ensure the safety of the food they transport.

Intentional adulteration rule—requires facilities to implement a food defense plan to prevent actions intended to cause large-scale public harm.

developed (see Box 14.1). Between 2010 and 2011, the FDA facilitated the creation of the alliances, which are public-private alliances composed of the food industry, academia, and representatives from federal, state, and local food protection agencies. The Produce Safety Alliance was established in 2010 as a collaboration between Cornell University, the FDA, and USDA. In 2011, the FDA provided a grant to Illinois Institute of Technology's Institute for Food Safety and Health (IIT IFSH) for the development of the Sprout Safety Alliance (SSA) and the development of the Food Safety Preventive Controls Alliance (FSPCA). These alliances are responsible for developing a core curriculum for the training and outreach programs. Lead trainers are selected and trained and are then responsible for the training delivery and issuance of certificates of completion to participants around the world.

Phase 2 of FSMA focuses on designing strategies to promote and oversee industry compliance and developing a set of performance metrics. Working groups are

developing plans for larger outreach programs to provide the industry with commodity- and sector-specific guidance, education, and technical assistance. These working groups are coordinating with the alliances to get the materials ready as a teaching guidance.

Phase 3 of FSMA focuses on designing an operational plan, implementing the plan, and setting up a monitoring and evaluation approach that focuses on public health impacts. Currently, the FDA is working to develop a set of performance metrics to measure the impact of the training efforts both in the short term and in the long term. A review of public sector data sources, discussed in the next section, indicates that there are limits to publicly available data and partnering with the private sector in the voluntary sharing of potential agreed-upon indicators may provide improved insight to the impact of capacity-building efforts.

14.3.2 Private Sector Involvement in the International Capacity-Building Efforts

In addition to these public sector capacity-building efforts, there are a number of complementary private-sector capacity-building efforts. Several public-private partnerships have emerged to further food safety capacity building globally. Some of the more prominent ones are summarized below.

The Global Food Safety Initiative (GFSI) was formed in 2000 by a group of global food companies that came together at the Consumer Goods Forum and agreed that the way to improve consumer trust in the private sector's efforts to maintain safe supply chains was for the private sector to harmonize their food safety standards and maintain the safety of food along the supply chains they worked in. The GFSI developed a benchmarking model that defined the key elements in food safety schemes for the production of safe food and feed, packaging process, and service provision. With these elements, the GFSI could recognize existing food safety schemes if they are equivalent to the benchmarking model. The recognition of equivalent schemes allowed for flexibility in the private standards marketplace. The GFSI encouraged companies to accept certificates issued during third-party audits against the GFSI-recognized schemes with the goal of enabling their suppliers to work more effectively through fewer audits. The standards currently recognized by the GSFI include requirements about incident management food defense and allergens that go beyond the general principles of food hygiene costs of practice laid out in *Codex Alimentarius* (Fagotto 2014).

The GFSI's Global Markets Program, a food safety capacity-building program created in 2008, established how small- and less-developed food companies can reduce food safety concerns and improve market access in the areas of primary production and manufacturing through certification to one of the GFSI-recognized schemes. This was done because it was recognized that market opportunities may exist for small-scale producers, but these small businesses often lacked access to the

expertise, technical, and financial resources that would allow them to meet all necessary food safety requirements (Rey 2016). The GFSI does not carry out training programs, nor does it develop training materials, but relies on a number of organizations which have already developed training manuals and courses for suppliers wishing to implement the Global Markets Program. In 2009 in a PPP with the United Nations Industrial Development Organization (UNIDO), several companies and groups of companies such as Metro, Aeon, Danone, Cargill, and Coca-Cola have rolled out the Global Markets Program. In 2016 UNIDO expanded its partnership with the GFSI to advance food safety using UNIDO Sustainable Supplier Development Program and GFSI's Global Market Program to parts of Africa, China, the Middle East, and Southeast Asia.

The Grocery Manufacturers Association (GMA) through their Science and Education Foundation offers international trainings in HACCP and plant-specific training in better processing controls (BPCS) tailored to the needs of different facilities using the FDA-approved BPCS text. Their mission in regard to training is to deliver training and education programs to the food industry and consumers. They are also working with the Inter-American Institute for Cooperation on Agriculture (IICA) to build the capacity of sector professionals and private sector stakeholders in HACCP to support implementation of SPS measures and increase trade opportunities in the Caribbean countries. This effort is a PPP in essence.

The Food Safety Cooperation Forum was formed in 2007 within the Asia-Pacific Economic Cooperation (APEC) with the goal of building robust food safety systems so as to accelerate progress toward harmonization of food standards internationally to improve public health and facilitate trade. The Partnership Training Institute Network (PTIN) was formed in 2008 to improve food safety practices and technical processing expertise in the Asia-Pacific region utilizing a network of decision-makers and experts from the regulatory, agriculture, and trade agencies. It also includes industry and academia from APEC member economies who help prioritize and coordinate capacity-building activities within in APEC, taking into account the needs of developing member economies and other capacity-building activities in the region. To date, trainings have taken place on developing food laws, standards, enforcement systems, risk analysis, supply chain management, and export certificates and assessing food safety capacity-building needs of food control systems and food safety incident management, including development of food recalls.

The Global Food Safety Partnership (GFSP) housed at the World Bank grew from the APEC forum and emerged in 2012 as a PPP aimed at improving the safety of food in middle-income and developing countries through capacity-building efforts. The program has struggled in its infancy and has undergone a major reorganization to implement sound monitoring and evaluation strategy without duplicating other efforts. To date the partnership has provided trainings in laboratory capacity building, HACCP food safety, and seafood disease management training.

In addition to these collaborative efforts, a number of food companies have increased their involvement in food safety capacity building through social stewardship programs so as to improve environmental, economic, and social impacts of

sustainable sourcing. For instance, Cargill, through their Rural Development Initiative partnership with CARE, a humanitarian organization, works with Cargill's local teams to provide training and skills development to improve market access for smallholder farmers, enhance education and nutritional support for children, and provide access to social services for communities they are working with. Similarly, General Mills has developed a Supplier Engagement Program and works with their suppliers to implement these requirements so as to enhance the livelihoods of farming communities, improve yields, and protect natural resources across the supply chain. All these programs have discussed the difficulty in measuring the impact of their efforts.

14.4 The Importance of Monitoring and Evaluation Efforts Associated with International Capacity Building

Integral to FSMA is the need to develop a monitoring and evaluation approach to measure the impact of training efforts. In 2011, prior to the finalization of the new rules under FSMA and the publication of the FDA's International Food Safety Capacity-Building Plan, the FDA's International Program asked the JIFSAN to develop and pilot a set of evaluation/self-assessment tools to measure the effectiveness and impact of JIFSAN's international capacity-building training programs that were already in process. The approach uses a modification of Kirkpatrick's (Kirkpatrick 1959a, b, 1960a, b) "Hierarchical Model of Training Outcomes," one of the most popular methods for assessing behavioral change in training evaluation. The "hierarchy" has four levels. Firstly, the trainer gauges the reaction of trainees to the training program. The idea is that trainees who are satisfied with a training program will get more out of it. Secondly, the trainer determines how much learning actually occurred. Learning can be quantified based on the knowledge or skills acquired or changes in attitudes. Thirdly, the trainer assesses how this learning affects actual job performance. This step is a measure of how behavior on the job changes as a consequence of the training. Finally, the trainer measures the impact of the training on the ultimate outcomes of interest (e.g., increased sales or productivity, improved market access, etc.).

The program was piloted in 2012, and primary data were subsequently collected at each international training session for program evaluation (see Fig. 14.5). First, questionnaires were used to collect participant feedbacks. Secondly, pre- and post-training factual tests (pretests and posttests from here on) were administered to provide a quantitative measure on knowledge gain in the training. These data enabled the JIFSAN to evaluate the immediate training effects and improve future trainings (Kirkpatrick levels 1 and 2). Approximately a year after training, another survey instrument was disseminated to collect information on medium-term effect of the training (Kirkpatrick level 3). Several years after training has taken place, secondary data sources, including FDA refusal data, the FDA inspection data, trade data, and CDC traceback data, are used to determine if there has been any long-term changes

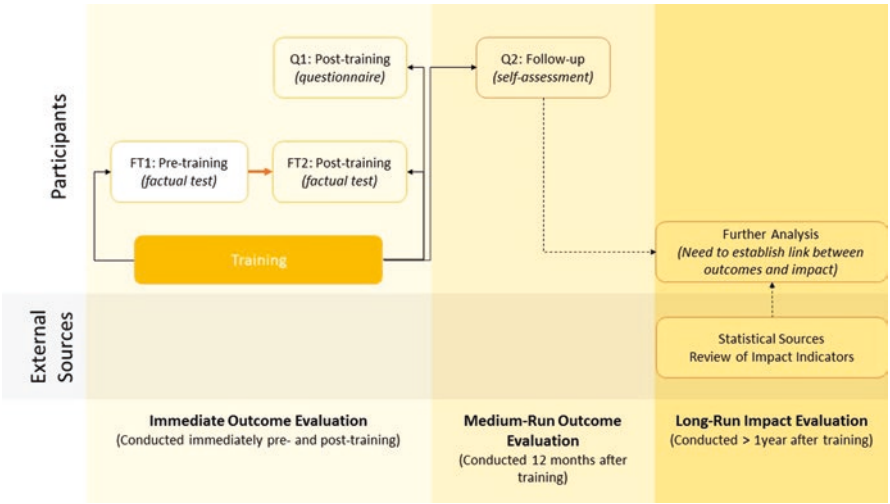

Fig. 14.5 JIFSAN's metrics approach

associated with rejections of a product or in trade patterns from a country in which training has occurred (Kirkpatrick level 4).

The approach was adopted by the GMA and IICA who used it in their recent trainings on HACCP in the CARIFORM countries. Maryland Extension programs have also used it in GAP trainings with local farmers. The GFSP laboratory capacity-building training in China also made use of the approach. Recently, it was also adopted as a way to measure the impact of international produce safety trainings that use alliance material to teach the Produce Safety Rule.

The JIFSAN still is in the early process of measuring impact. The goal is that several years after training has taken place, JIFSAN's monitoring and evaluation team will use secondary data sources, including the FDA refusal data, FDA inspection data, trade data, and CDC traceback data to determine if there has been any change associated with rejections of a product from a country in which training has occurred and to identify changes in trade patterns. All this secondary data was collected for specific purposes, which were not measuring the impact of food safety capacity building. So often it is in a form that does not really facilitate attributing changes to a specific training. For instance, the FDA refusal database does not provide data on the volume of product refused; thus it is difficult to know to the full cost of a rejection to the supplier. Further, the FDA's commodity codes do not match the trade data collected by the Department of Commerce, which makes it difficult to understand the value of trade affected. Similarly, CDC's outbreak data have limited entries on actual tracebacks, as many countries are still developing their monitoring programs to conduct actual tracebacks. Table 14.2 describes the different sets of secondary data available that might point to impact. As noted in the table under each potential secondary dataset, there are limitations to much of the publicly available data. This points to the need to engage the private sector in helping the FDA measure the impact of capacity-building efforts.

Table 14.2 Potential useful secondary datasets

Description of database	Possible limitations
FDA's Operational and Administrative System for Import Support (OASIS) database Information on product that FDA detained on regulated products that are out of compliance with the Food, Drug, and Cosmetic Act. Information of the products, country of origin, and reason for refusal are entered into and is publically available. Predict (described below) will replace it.	The difficulty in using this is it provides data indicating that a product from a specific country and from a specific firm was refused. It does not provide data on amount of product refused. The FDA commodity codes used in the refusal database and the codes of the trade data collected by Department of Commerce do not match, making it difficult to estimate the financial impact of that turned away or destroyed due to a food safety hazard
FDA's Inspection Classification Database—Results of the FDA's inspections of regulated facilities to determine if a firm's compliance with regulations and the Food, Drug, and Cosmetic Act. For this dataset, FDA is disclosing the final inspection classification for inspections conducted of clinical trial investigators, Institutional Review Boards (IRB), and facilities that manufacture, process, pack, or hold an FDA-regulated product that is currently marketed	Inspection classifications listed in this report reflect the compliance status when the report was generated and may not represent the final agency determination. The disclosure of the information is not intended to interfere with planned enforcement actions; therefore some information may be withheld from posting until such action is taken. The database does not represent a comprehensive listing of all conducted inspections, and the FDA states that the database should not be used as a source to compile official counts
CDC National Outbreak Reporting System (NORS) which contains traceback data on foreign sources of foodborne illness outbreaks in the United States exists	Currently there are limited entries of actual tracebacks, as many countries are in the process of still developing monitoring programs to conduct trackbacks
European Union's Rapid Alert System for Food and Feed contains monitoring reports on problems associated with imported foods	These are reported problems once the product has entered the EU and are not associated with the amount, preventing the researcher from calculating real trade impact
National Oceanic and Atmospheric Administration (NOAA) data. NOAA provides training programs on seafood HACCP; they certify establishment as being capable of producing safe, wholesome products in accordance with specific quality regulations promulgated by the US Department of Commerce. There may be some country data information that they collect associated with training	Currently we are unable to find publicly available data but expect that NOAA has such databases where they keep track of such information

(continued)

Table 14.2 (continued)

Description of database	Possible limitations
PREDICT (Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting) is an electronic screening tool that the FDA uses to flag high-risk imports of food products for additional monitoring and inspection. PREDICT uses a variety of assessments including information on the product, information on weather conditions during shipment, country of origin, and manufacturer's safety record to rank and score shipments according to risk. Based on the risk score, inspectors will target higher-risk shipments for examination	Whether the public version of the tool will facilitate better understanding of changes in trade based on capacity-building efforts is yet to be seen, given the current limitation of the public version of the OASIS system, but we plan to also see what other information can be gleaned
FDA-TRACK program may prove useful in the future. For instance, the FDA collects on the number of inspections completed by investigators based on in country, the data on total number of inspections completed in the month, and number of verifications of foreign firm registrations with their China, India, and Latin America offices	Currently, the public version is in the aggregate, thus somewhat limiting. If more detailed data was available, it could help facilitate impact evaluations associated with food safety capacity-building efforts
Possible new data associated with new rules under FSMA—as FSMA is rolled out, one might be able to also look at increases in the numbers of participants in Foreign Supplier Verification Program (FVSP), the voluntary qualified importer program (VQIP), and third-party auditors. Increases in the number of foreign laboratories accredited, increases in country system recognition or equivalence assessments of foreign food safety systems, and increases in the number of foreign inspections and facilities registered	The ability to measure impact based on this data will depend on what the FDA makes publicly available

14.4.1 Engaging Private Sector in Monitoring and Evaluation Efforts

Stakeholders involved in food safety capacity building have different interests in improving public health, livelihoods, and financial measures. Their interests in measuring the effectiveness of capacity-building efforts also differ. Understanding the interests of these stakeholders is crucial when designing monitoring and evaluation programs. This is because different stakeholders may be better motivated to fund different capacity-building efforts. Here it would be helpful to refer back to Fig. 14.1 where we identified the stakeholders involved in international food safety capacity building. The FDA is a public health agency whose main goal in capacity building is to improve health outcomes (a health measure). There are limits to the capacity building and impact evaluation that the FDA can do based on their mission and the

fact that they are a regulatory agency. USAID's Feed the Future initiative on the other hand is focused on reducing global hunger and improving food security; thus the outcomes they would be interested in examining would include the health and livelihood improvements among the poor in Feed the Future countries. The private sector and industry organizations are interested in capacity-building efforts primarily for financial reasons such as preventing the production of defective products and the consumption of unsafe food products and improve economic and social outcomes through sustainable sourcing.

The private sectors may be interested in several potential measurements of production outcomes, for example, the changes in (1) the number of products going through the "first-pass" quality check without having to be reworked or diverted to a lesser value stream, (2) the number of products on hold, (3) the number of marketplace actions taken based on customer complaints or recalls, and (4) the ability to attract new customers and enter new markets. Potential internal control measures for a company include (a) the development of facility internal control measures, (b) increased number of analytical test results within acceptable values, (c) improved audit scores through internal or third-party audits, (d) improved "risk" score among those companies who create risk scores for their plant and/or suppliers, (e) external certification of the facility/operation, (f) decreases in frequency of required audits, and (g) reductions in regulatory violations (Geisert 2014). Whether the private sector would share such data with the public sector is unclear without some sort of novel PPP aimed at measuring the combined effect of capacity-building efforts.

Sharing such data can be difficult, due to confidentiality concerns and worries over possible regulatory sanctions. Feedback from a product-tracing study in 2011 suggested there was a concern from the industry that data collection efforts would be costly and it was unclear if all industry would share data unless it was through a voluntary approach (Institute of Food Technologists 2012). This does not have to be the case; a public-private partnership can be made that facilitates the sharing of data in a way that blinds or aggregates the data that some companies may voluntarily share through a third party, so that more fruitful impact analysis can be done. A mechanism might be for an industry group to work with a university who can blind the data received.

Partnering with the private sector and forming such partnerships for data sharing is not new and is increasingly looked upon as a positive way to achieve improved public health outcomes. The recently released USDA Branded Food Products Database is the result of a successful PPP with USDA/ARS, International Life Sciences Institute (ILSI), GS1 US., 1WorldSync, Label Insight, and University of Maryland's JIFSAN. Through this initiative, a number of private companies who work with ILSI voluntarily chose to submit data to the JIFSAN. The goal of the PPP is to enhance public health and the sharing of open data by complementing the USDA National Nutrient Database for Standard Reference with nutrient composition of branded foods and private label data provided by the food industry. This partnership and the development of the mechanisms for sharing data came out in the 2011 Presidential Memorandum from President Obama that directed agencies to develop public-private partnerships in areas of importance to the agency's mission (Kretsera et al. 2015).

14.5 Conclusion

This chapter examines the evolving rationale promoting PPPs in food safety capacity-building efforts. It discusses how the private sector developed both voluntary mechanisms to improve food safety and ways to audit such approaches among their suppliers. It discusses how the public sector has altered their regulatory mechanism to embrace private-sector efforts and how the public sector may want to focus their training efforts on those who were not aligned to these private mechanisms. It suggests that, in addition to PPPs in capacity-building efforts, PPPs in monitoring and evaluation efforts are needed to guide public and private actions and deliver capacity-building outcomes more effectively in the future. It is argued that in order for the FDA to achieve sustained public health outcomes, it will be necessary to work beyond traditional methods to deliver food safety capacity building. It will also be necessary to evaluate outcomes of interest to other stakeholders investing in international capacity-building efforts. This will include measuring outcomes that go beyond the FDA's mission and looking at some of the spillover effects such as improved livelihoods, which are of interest to the aid community, and production measures that are of interest to the private sector and industry organizations. If suppliers knew that behavioral changes had positive livelihood and health impacts, they would be more likely to sustain these changes. Currently, to our knowledge there are no studies measuring spillover effects, and this is worthy of research.

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