A Public-Private Partnership for Data Sharing on the Impact of Food Safety Capacity Building



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Harnessing Public-Private Partnerships to Improve Food Safety & Nutrition Outcomes



A Public-Private Partnership for Data Sharing on the Impact of Food Safety Capacity Building

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Abstract:

Under the U.S. Food Safety Modernization Act (FSMA), FDA for the first time was mandated by Congress to develop both an international food safety capacity building plan and a monitoring and evaluation (M&E) plan to aid in efforts to reduce foodborne diseases (FBDs) in the U.S. FDA is actively looking for ways to partner with the private sector to meet the goals of FSMA. The paper argues that this is the ideal time to have discussions and build a platform to share existing data to measure the impact of food safety capacity building efforts well as a partnership to collect additional agreed upon data not currently being collected. In the paper we propose an approach to measure the impact of food safety capacity building efforts, explain the rationale for forming a PPP to share data, and present a skeletal framework for a PPP. The proposed working version of a PPP to measure the collective impact of food safety capacity building is a doable and feasible way to move forward with this effort. Though the proposed PPP is focused initially on the impact to U.S. consumers, it has global dimensions from the start and is envisioned to develop a global focus over time. Our motivation for writing this is that we (a group of public and private stakeholders)³ are deeply involved in food safety capacity building efforts and want to be able to measure the impact of our investments to know if they are working.

Executive Summary:

FSMA set new terms for food safety, shifting some of the responsibility to the private sector. With the U.S. Food Safety Modernization Act in 2011 (FSMA), the U.S. Congress mandated FDA to develop both an international food safety capacity building plan and a monitoring and evaluation plan to help reduce FBDs in the U.S. FSMA also required FDA to set requirements for training and education programs for state, local, territorial, and tribal food safety officials, along with technical assistance. The goal was to develop prevention-oriented requirements for greater accountability of individuals and companies involved in the provision of food, so as to ensure high rates of compliance for both imported and domestic foods. FSMA created specific roles for manufacturers, importers, third-party standard setters, and foreign regulatory bodies. To make

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sure producers and processors would know what is expected, training became mandatory for all food products sold in the U.S.

With FSMA, the private sector has new obligations to train and new incentives to measure impact. The move from voluntary to mandatory training, a move with international reach, requires new ways of handling food supply chains for any actors contributing to food supply in the U.S. Companies not only have obligations to comply, but also incentives to collaborate, despite operating in a competitive space. A single FBD event by one company in one food sector can easily spill over to all companies in that food sector. Similarly, a redirection of aid to increase funding to improve training materials and techniques, can benefit all in the sector. In this way, although FSMA addresses impact on the U.S. market, its reach is global because of import requirements to comply with FSMA, making this an international exercise. Data collection has a cost, and some impacts take time to occur, but there is still a need to understand immediate and short-run impacts as soon as possible in case that points to a redirection of efforts. Measurements of these impacts are also important for substantiating why supply chain actors fund food safety capacity building efforts.

Food safety is a global public good. Food safety capacity building improves societal welfare. As the global food supply network grows, food safety affects everyone, , domestically and globally. Foodborne diseases (FBDs), caused by ingesting food contaminated with hazards is a significant source of morbidity and mortality around the world. Estimates put the global burden of FDBs at 33 million disability-adjusted life years (DALYs), comparable to malaria (37.3 million) and tuberculosis (51.6 million). Diarrhea, most commonly resulting from contaminated food, kills 2,195 children every day – more than AIDS, malaria, and measles combined. Low and middle income countries in South Asia, Southeast Asia, and Sub-Saharan Africa account for 53% of all FBDs and succumb to 75% of deaths from foodborne causes (WHO, 2016). The interests of food safety stakeholders lie in consumer health and welfare, development aid to people in need, and market access, but ultimately rest on an increasing recognition that food safety is a public good in an interconnected world.

Food safety capacity and FBDs risks are uneven across the world. Countries go through foodrelated transitions as they develop, according to a recent World Bank study ("The Safe Food Imperative – Accelerating Progress in Low- and Middle-Income Countries," 2019). To protect the food supply, regulatory systems need to keep up with the changing nature of food resources, food consumption culture, climate change and export markets. However, public capacity is often too weak to address these problems, which means the local ability to monitor and respond to problems and food safety risks may be missing. Without assistance, countries with poor food safety infrastructures have an increasingly hard time reducing FBDs. When average income increases, and customers demand higher value agriculture, this also increases the risk of FBDs, as the most nutritious foods (animal source food and fresh vegetables) are often the most implicated, especially in transitioning countries. This worsening situation has global implications for public health and food security. Low food safety capacity affects everyone; this is an international challenge. Existing technologies and methods to reduce food safety hazards are not in widespread use, particularly, but not only, in low and middle income countries (LMIC's). Producers and other supply chain actors in developed and LMICs alike, may not be aware of, understand, or be able to afford these technologies and methods. Poor infrastructure, like unreliable electricity, undermines the integrity of cold storage and testing labs. Smaller companies may not see the benefits or business case or lack capital for upgrading production or distribution methods. Returns on investment for private companies may not merit sole financing in risk reduction. Overall, this lack of capacity, infrastructure, and funding affects everyone's interests because of the globally-intertwined nature of food production and consumption.

Food safety activities engage the efforts of many different stakeholders across the food landscape. Food market actors on the supply side, who are responsible for food safety from farm to shelf, need awareness of the importance of food safety, knowledge and skills on how to improve food safety (including management strategies and frontline safety practices), and funds to invest in equipment and infrastructure to improve food safety. In a cyclical way, they also need access to markets, domestic or international, with safer products to generate sufficient returns to invest in food safety and sustain their ongoing businesses. The broad network of actors that support food safety includes many who do not directly participate in food market activities, but whose efforts are indispensable and synergistic, such as industry organizations, training organizations, regulatory and non-regulatory government agencies, research institutes, third-party certification programs, inspectors, auditors, testing laboratories, public-private partnerships, international organizations, and aid organizations.

Food safety capacity building depends on training and other support at all levels of the value chain. Food safety capacity building activities can be broken down into six primary functions: training/education/awareness raising, research, regulatory, benchmarking, monitoring, and funding infrastructure . The inability to perform any one of these activities will likely affect the availability or quality of what is taught or to effect food safety behavior change. If a government or other party is unable to provide any of these functions for producers and processors, it becomes difficult to achieve improved food safety outcomes.

Training and other food safety capacity building activities need to be monitored and evaluated for effectiveness. Stakeholders are interested in measuring the effectiveness of their efforts, so they can learn if money is being well-spent and if their efforts are achieving their goals. An efficient, systematic approach measures not only the training (including train the trainers), but also the impacts at four stages of the training impact chain: immediate (impacts on training capacity), short-run (impacts on knowledge, attitudes, and skills), medium-run (impacts on behavior and outputs), and long-run (impacts on welfare). There can be many reasons for lack of impact, including poor or inappropriate training materials, poor or unsuitable techniques, high turnover of participants, and system barriers. If the training outcomes are unsatisfactory, and stakeholders become aware of that, then stakeholders can take steps to alter the delivery method, identify another intervention approach, or possibly find alternative trainers. This feedback loop can improve training and enhance impacts over time.

Food Safety capacity building can be impacted by the current state of the regulatory and legal situation in a country. For some countries regulatory and legal reform for food safety modernization accompanied by enforcement with fines/penalties/closure, public/private consultative process and compulsory training and education are needed to have sustained impact associated with food safety capacity building efforts.

To measure the impact of food safety capacity building, data is needed. Early on, stakeholders need to come together and identify what types of indictors they are going to track and agree on what types of data they think are essential to collect. Because capacity building data collection can be costly, it is important to identify from the beginning what types of data already exist and what types of data might still be needed to measure impact. To understand what is needed, one needs to step back and understand what those who are investing in food safety capacity building are looking for. The same reasons for stakeholder investments in food safety capacity efforts (e.g., improve health, market access, effective enforcement/fines/penalties) also apply to the outcomes they are interested in and the types of data needed to measure outcomes.

Some data is already available, but more is needed, especially from the private sector. Currently public sector data to measure some impacts exists on a smattering of platforms, including U.S. Food and Drug Administration (FDA) refusal and inspection data, Department of Commerce trade data, and Center for Disease Control trace-back data. However, this data is limited, not comprehensive, and not well-targeted to measuring the different levels of food safety capacity building impact. The FDA inspects less than 2% of all imports into the U.S., providing only a limited snapshot of what is really occurring in the industry. The private sector – producers, manufacturers, suppliers, and sellers – also collects data, both for internal and external purposes. Some of that data is reported to the government and provided for government and third-party audits, but much of it pertains to internal compliance and control measures. This includes data around the number of test results within acceptable values, audit scores through internal or third-party audits, "risk" scores for industrial plants and suppliers, external certifications of facilities, frequency of required audits, and number of regulatory violations. If private sector data could be made available and aggregated, with trend information depicted over time, it could prove very useful for evaluating the impacts of food safety capacity building.

The convergence of public and private sector interests is a sweet spot for public-private collaboration. This convergence is a necessary and promising basis. Public and private partners may have different motivations and goals, but in the sweet spot, benefits meet expectations on both sides. Both sectors already share many principles, like orderly and predictable markets, rule of law and avenues of recourse, clarity and feasibility of regulations, fair competition and level playing fields, consumer awareness and empowerment, that can keep a partnership bridge across sectors robust. If partners start with a narrowly scoped sweet spot, where they feel

comfortable and confident, they can build from there as they address sensitive issues around confidentiality, competition, conflicts of interest, institutional integrity, public trust, and consumer confidence. With FSMA as the starting point for collaboration, a data sharing platform could facilitate efforts to understand the immediate, short-run, and medium-run impacts of food safety training and capacity building. By scaling efforts and sharing information, collaborative efforts can support M&E at a lower cost, with greater efficiency and immediacy.

This white paper promotes a PPP for data sharing on food safety capacity building and

training. PPPs (public-private partnerships) start with a solid foundational belief that all partners can better achieve their common goals by working together. The prospects of finding such support among food safety actors is substantiated by the recent experience of another successful PPP that developed a shared database. Taking on a topic that at first seemed intractable, these food-oriented partners devoted their efforts over several years to establishing a highly-appreciated and widely-utilized data sharing platform, the *Partnership for Public Health: Branded Food Products Database.* With this experience in mind, public and private sector partners can recognize that PPPs do not develop overnight, especially if they are being convened on an international scale to address global challenges. PPPs that are created in an inclusive process vetted among an extensive diversity of stakeholders are worth the effort. When creating a shared platform decisions need to be made upfront on about its open-source characteristics and ownership of a global database.

To this end, we present a blueprint of a PPP around a database for food safety capacity and training, based on the following proposed mission and objectives:

- Mission: To enhance global health by reducing the risk of FBDs through increased understanding of food safety and improved implementation of food safety capacity building measures along entire food production and distribution chains through the development of an international data sharing platform available to government, industry, the scientific community, and the general public.
- **Objectives:** To promote public health, food safety, and nutrition; to reduce the risk of FBDs by integrating industry data (blinded and protected to ensure proprietary data is not linked to individual companies or actors) and public data for a comprehensive view of operating practices and results.

The zero version PPP blueprint presented here takes inspiration from the well-considered precedent of the Branded Food Products Database and is a starting point for partners to engage. The proposal envisions a number of key structural components, including a data repository, a secretariat, a governing body, and multiple working groups (operations, criteria, IT, legal communications), all to be developed through ensuing discussions, coordination, and implementation. With enough support, this PPP, whatever form it takes, can be coordinated and catalyzed through a working group that reaches out to upcoming listening sessions and ultimately takes shape. With enough buy-in and support, this PPP can reach its goals of improving food safety capacity building and reducing FBDs in the U.S. and across the world.

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Introduction

Value chain actors, which include governments, and private partners along with consumers, are interested in ensuring the safety of food for four main reasons. First proper food safety practices result in improved health through the reduction of FBDs, which is a public good. Second, ensuring the safety of food produced in one's own country has global implications through trade. Improving food safety locally improves the welfare of consumers globally. Third, ensuring the production of safe food improves the welfare of people; people deserve safe food. Fourth improved food safety improves an individual' supply chain actors market access, brand recognition and profitability, thereby improving their rate of return on their investments. Capacity building is a non-regulatory tool to improve food safety. Both the public and private sectors are investing in food safety capacity building.

Drivers of change in food safety practices which would lead to capacity building can be:

- 1) Enlightened or progressive company or individual seeking certification for financial benefit or improvement
- 2) Regulatory/compliance/certification requirement
- 3) Buyer's demands from suppliers market access
- 4) Academic requirement

A key component of capacity building is measuring impacts to know if it is working. To measure impact, one needs data.

Historically there have been a number of different players in both the public and private sectors involved in food safety capacity building. One needs to measure the overall effort in global food safety capacity building over the past decades. **Measuring the impact of training and capacity building efforts on food safety can:**

- 1) document and examine past efforts so as to capture best practice
- 2) justify and galvanize future efforts to scale up best practices; and
- 3) identify new focus/improvements for future efforts.

As different groups have ongoing efforts to monitor the safety of food and related capacity building, sharing data will facilitate an improved understanding of the overall impact of this capacity building. We are interested in measuring the impact of food safety capacity building efforts as we believe such efforts benefit **everyone**: consumers, producers, distributors, processors, retailers and regulators. Improvement in food safety can result from **collective** attention to capacity building efforts by **public and private sectors globally**.

As a major global source of food safety capacity building, U.S. government-based, international training efforts historically were aimed at training lead trainers through lectures and exercises and sometimes augmented through field visits. These lead trainers then conducted multiplier trainings and rolled out the trainings in their respective countries. Such trainings were voluntary in terms of market access to the United States. However, under the 2011 FSMA, such training must now be undertaken with training materials from the Produce Safety Alliance and the Food Safety Preventive Control Alliance (or the equivalent) to obtain market access to the U.S.

FSMA additionally requires monitoring and evaluating (M&E) of the impact of food safety capacity building efforts to ensure effectiveness. However, this M&E requires data that is costly, proprietary, or simply unavailable. Meanwhile, several challenges have emerged as the Alliances (Produce Safety, Sprout Safety, and Preventive Controls) established by FDA to develop training material and lead trainers started to roll out the training material to growers on their own or through government-sponsored programs in the U.S. and abroad. It is important to understand if FSMA-driven capacity building efforts are having the intended effect on international producers and processors and, if not, how to best to deliver capacity building to international audiences. Recognizing the importance of measuring the impact of capacity building, many governments and organizations involved in capacity building are now including M&E as a requirement to receive further funding.

At the same time, it is important to recognize that some of the private sector is also investing in non FSMA food safety training for which they believe actions will improve the rate of return on their investment resulting in improved operational results or change in behavior. A comparison of the two approaches could shed valuable insight into whether the approaches and how actors see their own return on investment results in sustained behavioral change.

Under FSMA's mandate, private sector companies are responsible to ensure their suppliers are delivering safe food. Thus, they are likely involved in additional multiplier trainings that they deem necessary amongst their suppliers. Some of their buyers also require these companies to meet various bench marking schemes, such as SQF, BRC, FSS22000, Global GAP and PrimusGFS, which they recognize as necessary in ensuring the products they sell have certain safety, quality, or environmental sound productions/ processing attributes. Many of these companies use third-party auditors to certify their suppliers and processors meet the requirements of the bench marketing schemes. Some of these certification bodies also are affiliated with training organizations that provide specific trainings to suppliers so that they meet the requirements of the specific benchmarking scheme. Within FSMA, the Accreditation of Third-Party Certification Rule was established with the aim of facilitating FDA's recognition of third parties to conduct food safety audits and issue certifications of foreign entities so as to help the Agency in ensuring the competence and independence of the third parties participating in the program. If these same certification bodies were recognized under the Accreditation of Third Party Certification Rule and these schemes were willing to share select audit data aimed at measuring the impact of capacity building efforts in a central place, this monitoring data would be useful to measure the impact of combined training efforts. Also insight of these trainings and number of individuals who the pass certification process could lend insight into what is needed to support behavioral change.

In this paper, we propose a phased approach to data sharing around the impact of food safety capacity building efforts. We argue that a public private partnership (PPP) is needed to measure the impact of capacity building efforts internationally. We recommend that the group initially focus on measuring the improved safety of food products consumed in the U.S. We suggest starting with existing, FSMA-driven product safety data collected by the public and private sectors to capture some of the consumer benefits. As many actors are involved, this will require an inclusive partnership. Later we anticipate expanding the PPP to capture global efforts.

This paper has three parts:

- Part 1 introduces public and private sector actors and then discusses training and capacity building efforts for food safety. Taking the U.S. as a basis, it describes both the historical record and recent FSMA experience, as a globally-relevant example of how public sector efforts rely on private sector follow-through. It also positions food safety capacity building as a global public good with development challenges.
- 2. Part 2 discusses food safety stakeholders and capacity building stakeholders in great detail, followed by a look at the chain of training impacts, and the importance of M&E and data in measuring such impacts. It uses JIFSAN's experience, home of several of the authors, to highlight what can be done to measure impact. It includes a discussion of currently available data, missing data, and difficulties in data sharing. It underscores the need for combining public and private sector efforts.
- 3. Part 3 outlines basic elements needed to form and sustain a PPP. It discusses existing PPPs that have been formed to tackle difficult public health problems to improved social welfare. It concludes with a working version for discussion and catalytic purposes of a proposed PPP to measure the overall impact of food safety capacity building efforts and combine efforts to improve such efforts.

Part 1. Capacity Building Efforts for Improving Food Safety

A. Public and Private Sector Actors (detailed explanation in Part 2)

Food safety capacity building efforts can result in improved social welfare. Both public and private sector actors laid out in Table 1 have been and continue to invest in food safety capacity building activities to achieve this goal. In the U.S., domestic organizations that invest in food safety capacity building include U.S. health and agriculture agencies, land grant universities, as well as various Alliances formed as part of FSMA or earlier. Foreign public sector investors include foreign governments and non-government organizations. There are also international organizations such as the World Bank, the Inter-American Institute for Cooperation on Agriculture (IICA), the Standard Trade and Development Facility (STDF), the United Nations Industrial Development Organization (UNIDO), and the Food and Agriculture Organization (FAO). On the private side, there are domestic companies, industry organizations such as the Global Food Safety Initiative (GFSI) and the Grocery Manufacturing Association (GMA)/Consumers Brand Association, and a number of multinational companies.

		U.S. Stakeholders	Foreign Stakeholders	
Public Sector	Domestic Organizations	U.S. agencies: e.g., FDA, USDA, USAID; FSMA-related alliances, land grant universities, private universities, community colleges.	Foreign government and non-government agencies	
	International Organizations	World Bank, IICA, STDF, FAO, UNIDO		
	Domestic Companies	U.S. suppliers, distributors, importers, and exporters	Foreign suppliers, distributors, importers and exporters	
Private Sector	Industry Organizations	GFSI, trade/industry associations (GMA/CBA, United Fresh, AFFI, etc.), Food Safety Tech,		
	Multinational corporations	Cargill, Coca Cola, Kraft, Heinz, Mondelez, Unilever, etc.		

Table 1: Public / Private Sector Actors in Food Safety Capacity Buildin	Actors in Food Safety Capacity Building
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B. U.S. Food Safety Domestic and International Capacity Building Experience

The U.S. government has over the years developed training material, both directly and through contracted experts, on good practices for food safety and risk analysis for professionals in government ministries and industry. In addition, the U.S. government has developed guidance material for industry to ensure the safety of food. These guidance materials are updated as new insights associated with food borne hazards are gained and as regulations have evolved.

1) Pre-FSMA Training created through funding by FDA

In the early seventies, FDA responded to a case of botulism in the U.S. attributed to underprocessed, 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. With insight from that training program, FDA published the canned food regulations in 1973, Hazard Analysis and Critical Control Points (HACCP) regulations for seafood in 1995, and HACCP requirements for juice in 1998. In 2017, they came out with industry guidance material for both juice and seafood HACCP. This demonstrates early collaboration between the public sector and private companies. Though this activity was directed at specific sectors, it became a regular model for addressing emerging problems. Both the government and industry recognized that by partnering they could replicate the approach throughout the entire industry.

The Joint Institute for Food Safety and Applied Nutrition (JIFSAN) was created in 1996 as a public private partnership (PPP) between FDA, the University of Maryland, and the private sector. This collaboration was prompted by the relocation of FDA's Center for Food Safety and Applied Nutrition (CFSAN) to a spot adjacent to the University's College Park campus. At that time, FDA Commissioner and the University of Maryland President recognized potential opportunities for both institutions to cooperate on food safety research, training, and recruitment of new scientists to join FDA. Thus JIFSAN was formed.

In 1998, FDA published formal guidelines for the microbial safety of fresh produce, suggesting that good agricultural practices (GAP) and good manufacturing practices (GMP) for producers could help ensure the safety of produce. 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 FDA. Cornell was tasked with developing course material addressing the principles in the 1998 FDA guidelines and rolling out this material to the fresh produce industry through USDA land grant extension programs.

Although these domestic training programs were effective in the U.S., FDA recognized it would not address the needs of foreign produce suppliers. FDA thus tasked JIFSAN to alter the material to the needs of foreign producers and roll out a similar extension outreach system internationally. Most of the funding for the development of international training material came from FDA. Initial support for the development of Good Aquaculture Practices (GAqP) came from JohnsonDiversey Corporation. Initial support for Commercial Sterile Food Packaging (CSFP) came from Kraft Foods Group and Campbell Soup Company. Since then, JIFSAN programs have also been supported by USDA-Foreign Agriculture Service, USAID, and industry. Starting in 2002, all JIFSAN training programs funded through the cooperative agreement have been jointly supported by the government of the host country. Under cooperation agreements, JIFSAN supports all costs of training within national borders, while the host country provides (or finds other support for) local travel, housing, training venues, and logistical support. This shared funding policy is based on principles in the FDA International Capacity Building Plan, ⁴ which requires FDA to develop a comprehensive plan to expand technical, scientific, and regulatory food safety capacity of foreign governments and their respective food industries in countries from which foods are exported to the United States. In each case, the plan ensures the host country's commitment to the effort,

⁴ <u>https://www.fda.gov/food/food-safety-modernization-act-fsma/full-text-food-safety-modernization-act-fsma#305</u>

while simultaneously leveraging JIFSAN resources. Some countries that are not FDA priority countries for training come directly to JIFSAN for training. These countries either self-fund the travel or obtain funding through another party, such as the World Bank, Inter-American Development Bank, etc.

We want to note highlight here the FDA/JIFSAN pre-FSMA funded program as it is one of largest food

safety capacity building effort that we know of for which FDA has put over 47 million dollars to a as an example of a capacity building program that we are very familiar with. We recognize the importance of other food safety capacity building relying on non-FDA funds and want to be able to capture that impact also as different programs are designed to reach different value chain stakeholder and the combine impact is what is affecting the safety of food for consumers.

2) FSMA-related Training created through funding by FDA

With the Food Safety Modernization Act (FSMA) in 2011, there was a move from voluntary to mandatory training. The goal of the new Act was for FDA to develop a preventionoriented set of requirements to strengthen the accountability of individuals and companies involved in the provision of food and thus ensure high rates of compliance for both imported and

Three Phases of FSMA

1. Development of new requirements, regulations, and guidance documents

2. Designing strategies to promote and oversee industry compliance and developing a set of performance metrics

3. Designing an operational plan, implementing the plan, and setting up a monitoring and evaluation approach that focuses on public health impacts

domestic foods. The Act created specific roles for manufacturers, importers, third-party private standard setters, and foreign regulatory bodies. FSMA also formally required FDA to set the requirements for training, and education programs for state, local, territorial, and tribal food safety officials, and provide technical assistance. To make sure producers and processors would know what is expected, the training was made mandatory in order to market products in the U.S.

The **implementation of FSMA** in terms of both domestic and international capacity building was set up to be rolled out in **three phases**:

Phase 1 of FSMA focused on the development of new requirements and developed the regulations and guidance associated with the new rules. This was followed by FDA facilitating 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 partners and their roles are listed in Box A. These Alliances were responsible for developing a core curriculum for the training and outreach programs and providing certificates of completion demonstrating that participants had taken the official, FDA-recognized training course. The requirements for having the certificates and the optional charge for hard copies of the training material (online is free) was in part to help support the continual operation of the Alliances once the initial FDA funding was over.

Though the process of identifying and training lead trainers varies slightly by program, in general, individuals apply to be lead trainers and go through a training, certification, and vetting process. Once trained and recognized as lead trainers, they can deliver trainings by themselves to participants around the world. These trainers can charge whatever they like for the official training. As part of the new FSMA

rules, every produce center and processing center has to have at least one qualified person trained on the official, Alliance-developed material (or FDA-deemed equivalent, none of which currently exists) to have

Box A: Alliances that Developed Training Material Associated with New FSMA Rules

- Produce Safety Alliance (PSA) established in 2010 as a collaboration between Cornell University, FDA, USDA, and the private sector; trains on the Produce Safety Rule (PSR).
- Food Safety Preventive Controls Alliance (FSPCA) established in 2011 as a collaboration between Illinois Institute of Technology's Institute for Food Safety and Health (IIT IFSH), FDA, USDA, and the private sector; trains on food safety preventive controls for both human and animal food and on the Foreign Supplier Verification Programs Rule
- Sprout Safety Alliance (SSA) established in 2011 as a collaboration between Illinois Institute of Technology's Institute for Food Safety and Health (IIT IFSH), FDA, USDA, and the private sector; trains on sprout safety under the PSR.

market access to the U.S. The reason deemed equivalent is in the rules is that FSMA recognizes that one size doesn't fit all. To be effective FDA recognized that they needed an evolving strategy that included not only the Alliances but also regulatory counterparts in other countries, multinational organizations, and the private sector to promote training to the global community of food suppliers and have a positive outcome.

Phase 2 focused on designing strategies to promote and oversee industry compliance and developing a set of performance metrics. Working groups developed plans for larger outreach programs to provide the industry with commodity- and sector-specific guidance, education, and technical assistance. These working groups are currently coordinating efforts with the Alliances and working with FDA to provide guidance material to industry. In addition, FDA established the Technical Assistance Network (TAN) as a central source of information for questions related to FSMA rules, programs, and implementation strategies.

Phase 3, currently being undertaken, has FDA designing an operational plan, implementing the plan, and setting up a monitoring and evaluation approach that focuses on public health impacts. FDA is working to develop a set of performance metrics to measure the impact of the training efforts in both the short term and long term. However, resource limitations preclude the collection of all needed data. It is recognized that the private sector is collecting to monitor its suppliers and undergo audits extensively.

With FSMA putting more responsibility on the private sector to ensure the safety of the food they produce and distribute, the private sector may become more willing to share its data with the public sector or a third party to measure the impact of food safety capacity building efforts. This is discussed more fully in the section of the paper on impact measures. It is useful to note that In recent years AlchemySystems and their partners (Intertek Alchemy, Campden BRI, Safe Quality Food Institute, British Retail Consortium, Grocery Manufacturer's Association Science & Education Foundation, NSF Latin America, SGS, and TSI survey a number of food companies in terms of changes to their food safety culture, behavior changes and training challenges. The top three food safety training challenges reported for 2019 were scheduling time for trainings, verifying effective trainings, and organizing refresher trainings were

the key challenges leading food companies face. Linking to such data could prove very useful in the future as groups look to understand what might be limiting uptake of food safety trainings within a company.

The Produce International Partnership for Education and Outreach (PIP) was formed in 2018 as a joint effort between JIFSAN and the Produce Safety Alliance based at Cornell University (PSA) to provide food safety training to the international community that satisfies the training requirements in the Produce Safety Rule (PSR), which lays out what companies and producers must have in place for market access in the U.S. This includes working to ensure that educational materials are culturally sensitive and technologically sound. PIP is responsible for translating the existing PSA Train the Trainer (TtT) curriculum into other languages and offering training to international audiences. Additionally, PIP is building a network of qualified trainers and Collaborative Training Initiatives (CTI) that leverage food safety partners in countries that export produce to the U.S. They are also looking at ways to reach more growers which may not be able to afford the amount or time associated with the way the existing training as it is currently being delivered. See Appendix A for more details about the program and difficulties growers may experience in terms of being recognized as having the training.

It is anticipated that rolling out the **Preventive Controls Rule**, for food and for animals, to largescale processors will not have the same resource constraints, as these companies can afford the training fees and certification costs. It may, however, be **difficult to reach small and medium scale processors in developing countries**, as they may not have sufficient funds or the foreign exchange to pay for the cost of registration, training material, travel, and certification. In addition there may be a lack of awareness of the requirements under FSMA for market access amongst some value chain actors in some countries. **IICA**, **through funding from FDA/USDA**, **has subsidized trainings for small and medium processors in Latin America.** In addition, some FDA country offices, such as in India, are working with the relevant Ministry to roll out **Preventive Controls training**, which is also required for processors to have market access in the U.S. Private Sector Efforts Involving U.S. Companies

In addition to these public sector efforts in the U.S., a number of food companies have increased their involvement in food safety capacity building through social stewardship programs designed to improve environmental, economic, and social impacts of sustainable sourcing. For instance, Cargill, through its Rural Development Initiative partnership with CARE, provides training and skills development to improve market access for smallholder farmers in developing countries. Similarly, General Mills has developed a Supplier Engagement Program and works with suppliers to implement practices that improve yields, protect natural resources across the supply chain, as well as enhance livelihoods of farming communities.

Many **multinational food companies** have increased their involvement in international food safety capacity building. Many are members of the **Global Food Safety Initiative (GFSI)**, which created the **Global Markets Program** in 2008 to aid small and less-developed food companies in reducing food safety concerns. This includes improving market access in the areas of primary production and manufacturing through certification in one of several GFSI-recognized schemes. Even though market opportunities may exist for small-scale producers, GFSI recognized that these small businesses often lack access to the technical expertise and financial resources that would allow them to meet all necessary food safety requirements.

These companies also have worked with the U.S.-based **GMA** (**GMA**) through its **Science and Education Foundation**, which **offers international HACCP training and plant-specific training** tailored to the needs of different facilities using the **FDA-approved Better Processing Control Schools (BPCS).** GMA is also working with the Inter-American Institute for Cooperation on Agriculture (IICA) to build the capacity of sector professionals and private sector stakeholders to implement HACCP so as to increase trade opportunities in Caribbean countries.

3) PPP's Involving U.S. Stakeholders

In addition to these efforts, there are several public-private partnerships that have emerged to improve food safety capacity in which the U.S. government (FDA, Commerce, USAID, USDA-FAS, etc.) participates. Below we summarize some as examples, but recognize the list is not exhaustive. Examples include, the **Partnership Training Institute Network (PTIN)** was formed as part of the **Asian Pacific Economic Community (APEC) Food Safety Cooperation Forum (FSCF)** to improve food safety practices and technical processing expertise in the Asia-Pacific region. **PTIN includes government, industry, and academia from APEC member economies** and engages decision makers and experts from regulatory, agricultural, and trade agencies. PTIN helps prioritize and coordinate capacity building activities in APEC, taking into account the needs of developing member economies. Training has been offered on developing food laws, standards, enforcement systems, risk analysis, supply chain management, export certification, assessing food safety capacity building needs of food control systems, food safety incident management, including development of food recalls, and laboratory testing.

In 2009, the United Nations Industrial Development Organization (UNIDO) started to partner with GFSI to roll out the **Global Markets Program** mentioned above with support of Metro, Aeon, Danone, Cargill, and Coca-Cola. The program provides free tools for voluntary development of supplier food safety management systems, supports operations in primary production and manufacturing that lack strong food safety systems, and provides guidance toward certification under GFSI-recognized certification programs. In 2016, UNIDO expanded its food safety partnership with GFSI using the UNIDO Sustainable Supplier Development Program and GFSI's Global Market Program to parts of Africa, China, the Middle East, and Southeast Asia (see Box B). GFSI is currently in discussion with regulators and governments (Canada, China, US, Mexico) to syndicate work already accomplished by the private sector and to promote the recognition of independent assessments.

The **Global Food Safety Partnership (GFSP)**, housed at the World Bank, grew out of the APEC forum and emerged in 2012 as a PPP aimed at improving the safety of food in middleand low-income countries through capacity building efforts. USAID and U.S. FDA were active in the initial phases of GFSP. Training supported by GFSP has included laboratory capacity building, HACCP food safety, and seafood disease management training.

Box B: GFSI and UNIDO Food Safety Capacity Building Road Map

- In China, the partnership aims to scale up food safety capacity building for local food enterprises throughout China in line with the Sustainable Supplier Development Program (SSDP) and establish the China Food Safety Initiative (CFSI).
- In South East Asia, the aim is to initiate a regional SSDP program, scaling up the UNIDO-AEON Malaysia SSDP program into a multi-country and multi-buyer initiative.
- In Africa, the project will benefit from a strong UNIDO presence to design and build a joint UNIDO-GFSI multicountry, multi-buyer project for Africa on capacity building.

The list provided here is illustrative and not meant to be exhaustive for instance GMA-SEF has also worked with Cargill to do food safety training on FSMA related rules and Better Process Control School in Indonesia (2017), Vietnam (2018) and India (2019).

C. Food Safety as a Global Public Good that Reduces FBDs

Globally, food safety is important as it affects everyone – both consumers and producers, both domestically and globally – as the global food supply network grows. Consumers and governments are interested in improving food safety so as to reduce foodborne diseases (FBDs). **FBDs results from the ingestion of foodstuffs contaminated with microorganisms or chemicals. FBDs are a significant source of morbidity and mortality throughout the world. They are closely linked to poverty and development.** In 2006, the Foodborne Epidemiology Reference Group (FERG) of the World Health Organization (WHO) conducted a study that provided estimates on the global burden of all relevant FBDs according to age, sex, and regions. Estimates from the study found the cost, measured in disability-adjusted life years (DALYs), of FBDs globally to be high. **At 33 million DALYs, the costs of FBDs are on a par with the cost of malaria (37.3 million DALYs) and tuberculosis (51.6 million DALYs).** (WHO estimates, 2016). Diarrheal diseases are the most common illnesses resulting from the consumption of contaminated food. Diarrhea kills 2,195 children every day—more than AIDS, malaria, and measles combined (ibid).

The global burden of FBDs is, however, unequally distributed around the world. Lower and middle income countries in South Asia, Southeast Asia, and Sub-Saharan Africa account for 53% of all foodborne illnesses and succumb to 75% of deaths from foodborne causes (WHO estimates, 2016). The food consumed in these regions is more likely to contribute to FBDs than food in richer regions. These countries also have relatively weaker health care systems to treat FBDs illness, which compounds the problem and increases the importance of prevention of FBDs in lower and middle income countries.

Though there are existing technologies and methods to reduce many food safety hazards, not all are in widespread use for a variety of reasons. For instance, producers and other supply chain actors may not understand, or lack sufficient knowledge or awareness, of how to properly use effective methods or technologies. They may also not be able to afford to procure and implement these technologies. Further, consumers in poorer countries may not be able to pay higher costs for foods being produced and processed using such methods.

Regulatory agencies tasked with ensuring the safety of food in many low and middle incomes countries are often working with very poor infrastructure, such as reliable sources of electricity to ensure the integrity of cold chains, functioning laboratories for testing, and monitoring the safety of food. This also affects the private sector. Without adequate infrastructure, it is difficult for the private sector by itself to invest in risk-reducing technologies, such as cold storage, as the return on investment cost may be too low. Understanding if the reasons producers and supply chain actors are not implementing such strategies is because of lack of infrastructure, lack of capacity, lack of funding, or some other reason is important, as these issues could potentially be addressed through developed country support of developing countries. The globally-intertwined nature of food production and consumption makes risk reduction in everyone's interest.

Clear evidence is emerging that the public capacity in many low and middle income countries is often too weak to address these problems. A recent World Bank study entitled "The Safe Food Imperative – Accelerating Progress in Low- and Middle-Income Countries" suggests that countries go through a number of food-related transitions as they develop. As depicted in Figure A, this includes changes in diet, consumer demand, growth in market opportunities, and changes in regulatory infrastructure until they have a well-functioning food safety regulatory system in place. To be effective at protecting the food supply, a regulatory system needs to keep up with the changing nature of food resources and food consumption culture. Systems that have historically been sufficient to ensure safe food may not be keeping up with rapid changes to food production and trade. Local health care and export markets require a well-functioning food safety regulatory system that fits existing food consumption and production. "Well-functioning" in this context means the capacity to monitor and respond to problems, as well as marshalling stakeholders to implement effective strategies to reduce food safety risks.

Without assistance, countries with poor food safety infrastructure will have an ever harder time reducing FBDs. As average income increases in these countries, customers in these countries increase their demand of high value agriculture, which is more prone to FBDs. The most nutritious foods are often the most implicated in FBDs (animal source food and fresh vegetables), especially in low income countries. Without stronger capacity to reduce foodborne hazards, the FBDs situation will get worse in these countries, with global implications.

Figure A: Food Safety Lifecycle from Page 16 of the Food Safety Imperative, World Bank, 2019



The Food Safety Lifecycle

D. Food Safety Affects Key 2030 SDGs

Food safety is linked to key UN Sustainable Development Goals (SDGs). Improvements in food safety and the reduction of FBDs are essential to meeting a number of the SDGs, including one that focus on improving human capital by reducing poverty and hunger and improving health by 2030 (see Box C). Many developed countries, including the U.S., have committed to supporting developing countries in meeting these goals, including through locally-targeted food safety capacity building efforts. A number of private sector companies, such as Cargill, Mars, Nestle, Coca Cola, and Unilever, have also agreed to help. Among other things, solutions can be found through key SDGs that work with industry to innovate and build infrastructure. Educating both consumers and producers can lead to responsible consumption and production. Leveraging SDG achievement can put pressure on regulators to meet consumer and private

Box C: S	DGs Impacted by Food
Safety C	apacity Building
	no novortv

SDG 1 – no poverty SDG 2 – zero hunger SDG 3 – good health and wellbeing SDG 9 – industry, innovation, and infrastructure SDG 12 – responsible consumption and production SDG 17 – partnership for the goals United Nations 2030 Agenda for Sustainable Development, https://sustainabledevelopment.un.

org/?menu=1300

sector demands in support of food safety. As a number of governments and companies have signed onto the SDGs, and many of the SDG's goals are related to improved food safety, there are increased commitments to improving food safety and ensuring the effectiveness of food safety capacity building.

Also recognized in the SDGs is the importance of partnership, specifically under SDG 17, but also more generally. The achievement of the SDGs by 2030 relies on extensive partnership efforts, including between developed and developing countries, between global and domestic actors, and between public and private sectors. It is in this spirit that this paper proposes a PPP for data sharing around food safety capacity building, as a key building block for reduced poverty, reduced hunger, and improved health.

Part 2. Capacity Building, Training Effects, and Measurements

A. Food Safety Stakeholders and Capacity Building Activities

Food safety stakeholders includes food market actors that take part in food market activities, such as farms and companies (see Figure B). They are directly responsible for food safety from farm to table. It also includes other stakeholders, such as industry organizations, government regulatory and nonregulatory agencies, research institutes, third party certification programs, laboratories and auditors, public-private partnerships, international organizations, and aid organizations, who do not directly participate in the agri-food market activities, but whose efforts are indispensable to improving food safety.

Food market actors include both the supply side and the demand side. The supply side is responsible for food safety from farm to retail shelf. The demand side is responsible for food safety from retail shelf to table. To produce and consume safe food, all food market actors need adequate capacities to act.

On the supply side, there are the value chain actors, including examples shown in Figure C. These actors need awareness of the importance of food safety, knowledge and skills on how to improve food

safety (including management strategies and frontline safety practices), and funds to invest in equipment and infrastructure. They also need access to markets, domestic or international, where safer products generate sufficient returns for their investments in food safety to sustain their business. This awareness, knowledge and skills, funds, and market access are all components of value chain actors' capacity to improve and maintain food safety.

On the demand side, consumers also need adequate capacity to practice and improve food safety from shelf to table. They need awareness of the importance of food safety, knowledge to select safe products and prepare them safely at home, resources to obtain information regarding food quality and choices, and access to local markets where they can buy but safe, healthy food products. Currently the greatest food safety risks and contamination are associated with food handling, preparation and hygiene in the kitchen. Consumers may have control over some of these components, but not all. Consumers rely on other actors and the government to enable their full capacity to consume safe food and avoid FBDs.

Food safety, nutrition and food security are inextricably linked. Unsafe food creates a vicious cycle of disease and malnutrition, particularly affecting infants, young children, elderly, and the sick. A reduction in FBDs in turn can improve their family's food security, nutrition, and livelihood. As suppliers, safer and greater quantity of output can increase farmers' income, in part because safe food can command reliable access in certain markets. Higher income, in turn, can contribute to better education, improved food security, better health, and improved livelihoods.

Other food safety stakeholders, including some of the examples listed in the Figure C, contribute to food safety through capacity building activities. These activities help improve food safety in two ways. First, by building awareness and knowledge, they incentivize and enable food market actors to improve the safety of their products. For example, research institutes provide practical food safety solutions for value chain actors and consumer challenges. Training organizations raise value chain actor awareness and help them adopt better practices. Government agencies provide food safety guidelines to and identify areas of importance for the general public. Aid agencies provide loans and subsidies to value chain actors for food safety investments. Second, food safety stakeholders improve food safety by supporting and facilitating activities for each other. For example, inspectors, auditors, and testing laboratories provide data that are used to monitor compliance with regulation and industry standards. Aid agencies fund training for value chain actors or provide funding for investments in laboratories. Food safety activities around capacity building are synergistic with the rest of the food safety landscape.

Food safety capacity building activities can be broken down into six primary functions, as shown in Figure B: training and education, research, regulating, benchmarking, monitoring, and aid and investment. These categories are covered in FSMA. With a focus on training / education and monitoring activities (highlighted with an asterisk in Figure B), Table 2 illustrates how these two capacity building activities are laid out in FSMA.

Figure B: Food Safety Stakeholders and Capacity Building Activities

Food Market	Ν	
Value Chain Actors (growers, packers, processors, transportation and storage, wholesalers and retailers, etc.)	Safe food	Consumers

Incentivize and enable food safety improvement

Food Safety Stakeholder Capacity Building Activities					
Training/Education/ Awareness Raising*	Research	Regulating	Benchmarking	Monitoring*	Aid and Investment in Infrastructure
 Training and knowledge transfer Educating the general public Demonstration plots Other information services (e.g. websites, newsletters, TV programs) 	 Inventing and adapting technology Designing production and consumption safety guidelines Analyzing monitoring data Develop risk management strategies Risk analysis to support policy design Evaluation and impact analysis 	 Assigning regulatory and non-regulatory food safety responsibilities Developing regulatory standards Developing trade and market access requirements Enforcing regulatory requirements Reforming regulations when needed 	 Developing 3rd party industry standards Harmonizing standards 	 Farm and manufacturer inspection and audit Product sampling and testing along the value chain Collecting data on product recall Collecting data on foodborne disease incidents and outbreaks Collecting data on capacity building progress Building food safety informatics platform 	 Financial aid Investment in infrastructure and other physical capital

Food Safety Stakeholders

e.g. farms and companies, industry organizations, government regulatory and non-regulatory agencies, research institutes, third party certification programs, laboratories and auditors, public-private partnerships, international organizations, and aid organizations

B. Other Capacity Building Activities

To substantiate impacts of training on societal welfare, we need a combination of capacity building activities from a variety of food safety stakeholders. Based on the experience of JIFSAN's International Train the Trainer (TtT) Program, which is described in more detail below, we can offer some examples of what activities are necessary, in addition to actual training. JIFSAN has been offering TtT programs for almost 20 years, with varying program designs. JIFSAN has accumulated experience from past successes and learnt from less successful stories.

International stakeholders need to collaborate in capacity building efforts through:

Incentives, Funds, Support

The purpose of TtT programs is not just to train, but to build training capacity. For the TtT program to have durable impacts on training capacity that in turn improves food safety, international stakeholders need to collaborate on capacity building. Key elements include:

- 1. *Incentives:* Importers like the U.S. can provide training incentives for exporting countries, such as FSMA's training requirements and FDA's identification of priority countries. Multinational wholesalers and retailers can incentivize countries by granting more market access to trained farmers.
- 2. **Funds:** Domestic agencies of exporting countries can either allocate funds to host TtT trainings or send participants abroad to training locations. Aid agencies and international organizations can provide funding assistance to developing countries.
- 3. **Support:** Exporting countries can also support TtT training in non-financial ways. For example, they can publicize training opportunities to attract more applicants and identify the most suitable candidates. They can provide support to Lead Trainers for proper translations of training materials. Training materials can be made more effective by including more examples from local production processes. In the case of the JIFSAN TtT program, countries are encouraged to develop and maintain long-term relationships with JIFSAN.

	Training and Education	Monitoring
FSMA Title I:	Capacity building with food market	Monitoring domestic value chain actor
Prevention	actors (Sec. 103, Sec. 112)	compliance (Sec. 101, Sec. 103);
		evaluating the progress of capacity
		building activities (Sec. 108)
FSMA Title II:	Capacity building with inspectors,	Tracking food and facilitating recalls
Detection and	auditors, and government officials	(Sec. 204, Sec. 206)
Reaction	at all levels (Sec. 209, Sec. 210)	
FSMA Title III:	Capacity building with foreign	Monitoring foreign value chain actor
Imported Food	producers and other food safety	compliance (Sec. 301, Sec. 306);
	personnel (Sec. 305, Sec. 207)	evaluating accredited third-party
		auditors (Sec. 307)

Table 2: How Food Safety Capacity Building Activities Align with FSMA Goals*

* Sections (Sec.) references are provided as examples.

To increase the pool of local farmers with more food safety capacity, stakeholders particularly need to focus on having more farmers participate in local trainings. This again has three primary elements:

What is needed to increase stakeholder participation:

Incentives, Financial Aid, Training

- Incentives: Domestic regulators need to provide training incentives directly to farmers. This
 also involves communication and awareness raising so that behavior change occurs. This
 could be in the form of training requirements set by the government. Farmers could also be
 incentivized through certification programs organized by wholesalers, retailers, or industry
 organizations.
- 2. *Financial Aid:* Trainings and certification programs can be expensive for farmers, especially in developing countries. Aid agencies and local governments can provide subsidies or loans to farmers for training purposes.
- **3.** *Training:* Local trainings should be designed and organized to reduce farmers' costs of participation. For example, Lead Trainers can choose locations that reduce farmers' travel cost. They can also offer more trainings during less busy seasons to accommodate farmers' schedules.

To impact farmer behavior and farm outputs, we also need capacity building activities that go beyond training. Again, we can look at three aspects:

What is needed to have impact:

Incentives, Research, Resources

- Incentives: To provide correct incentives for food safety investments, regulators and benchmarking organizations need to set appropriate standards for farm food safety practices and safety of outputs. Inspectors and auditors need to monitor implementation of food safety practices. Laboratories needs to sample and test farm output. In turn, costly food safety investments and safe outputs needs to be rewarded with greater market access and higher selling prices.
- 2. *Research:* Some food safety practices may not be feasible for all regions or may be too costly for developing country farmers. Researchers can help by developing lower-cost food safety solutions.
- **3.** *Resources:* Food safety investments are costly. Farmers may need access to credit markets and financial aids to finance these investments.

Overall, to ensure safe products move along the value chain and reach consumers, many more capacity building activities are needed. Training needs to be provided to all the value chain actors. This training also needs support from other capacity building activities to ensure the arrival of safe food on the shelf. Consumers needs to be informed about the benefits of safe food and how to purchase and prepare it. Only when all conditions are met, can consumers be confident of consuming safe food and enjoying the nutritional and health benefits of safe food. As consumers become more willing to pay higher prices for safer foods, benefits from this greater value can be passed on to value chain actors, incentivizing them to be trained, adopt more food safety practices, and improve safety of outputs.

C. Interests of Food Safety Stakeholders Providing Capacity Building

Stakeholders providing funding for g food safety capacity building activities are driven by three broad types of interests: consumer health/societal welfare, development aid, and trade/market access/profit. Interests can be affected by incentives, including ones described in the prior section. However, regardless of all other motivations, both public and private sector actors (including producers, processors, and exporters) invest in capacity building to improve food safety as a public good.

In the U.S., the FDA invests in capacity building both domestically and abroad to ensure the delivery of safe food to U.S. consumers for both domestically-produced foods and imported products. The U.S. private sector is involved in training their suppliers worldwide to provide safe food, knowing this has direct ramifications for their businesses, including availability, branding, and public perception. Now under FSMA, the private sector is not only motivated to ensure the safety of food they are supplying, but also mandated to have systems in place that ensure their suppliers are providing safe food.

From a development perspective, public sector organizations invest in **food safety capacity building for societal welfare and aid reasons**. Aid-driven agencies focus on agricultural capacity building in developing countries mainly to increase agricultural output and food security, as well as raise awareness of food safety and nutrition. The private sector is also involved in food safety capacity building designed to provide aid to developing countries. For instance, Land O'Lakes International Development has worked with USAID and USDA in leveraging their experience working with farmer-owned cooperatives to improve livelihoods and enhance agriculture in both developed and developing countries by supporting new agricultural capacity building and food safety programs.

From a market perspective, both public and private sector stakeholders **invest in food safety capacity for trade/market ac**cess/profit reasons. The stakes have grown over the years. Unsafe product has costs associated with recalls, re-works, rejections, brand protection and compliance that companies need to consider. Further where food is grown and where it is consumed have become increasingly distant from each other. As food products travel long distances, food safety hazards coming from those products end up in distant, importing countries. As incomes increase, more consumers are demanding high value agriculture (HVA) year-round, which by its nature is highly perishable and susceptible to FBDs. Developing countries, which often lack effective regulatory infrastructure to ensure the safety of domestically produced products, are increasing HVA production and selling it in global markets.

Reliance on cross-country food safety capacity has also grown over the years. Because it is impossible for any regulatory system to inspect all the food crossing the border, consumers have to rely on the strength of other countries' regulatory processes and private sector capacity to ensure the safety of the food destined for consumption. Due to the global extent of food produced and traded, FBDs outbreaks in local areas can easily be linked to global outbreaks. Consequently, it is important to find ways to effectively reduce FBDs in countries where food is being produced, even in situations where local regulatory and monitoring capacity is weak. This includes reducing the rapid spread of FBDs in the event of an outbreak.

Understanding stakeholder motivations for investing in food safety capacity building is important when designing a monitoring and impact evaluation (M & E) program. Achievements that are measured in relation to investment interests can give credence to past efforts, while also justifying and galvanizing

future efforts. When problems arise, further analysis can identify new priorities and improvements needed for future efforts. In the next section, we turn our attention to the importance of measuring the impact of food safety training efforts as a feedback loop to improve food safety.

D. Food Safety Training Impacts and Measurements

Evaluation is needed to objectively demonstrate the effectiveness of food safety capacity building efforts. **Stakeholders are interested in measuring the effectiveness of their efforts, so they can learn if their money has been well-spent and is achieving their goals.** If a capacity building approach is not making an impact, or the right impact, providers need to determine how they should alter their approach. Lack of impact can be due to reasons other than the materials that individuals were trained on. It could be that the technique was not suitable for that specific stakeholder, which, if altered, might reach that stakeholder better. Training may also be targeting the wrong audience, or suffering from high turnover of participants in their work settings, or hindered by system barriers. Measuring the impact of training also holds trainers accountable. If the training outcomes are not satisfactory, and stakeholders become aware of that, then it becomes necessary to alter the delivery method, identify another intervention approach, or possibly find alternative trainers.

A common framework for assessing behavioral change in training evaluations is the Kirkpatrick "Hierarchical Model of Training Outcomes." The "hierarchy" has four levels. First, the trainer gauges the reaction of trainees in the training program. The idea is that trainees who are satisfied with a training program will get more out of it. Second, the trainer determines how much learning actually occurred. Learning can be quantified based on the knowledge or skills acquired, or changes in attitude. Third, 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, decreased FBDs and diarrhea). With this framework in mind, we can look at the training impact chain of an international Train-the-Trainer (TtT) program, the JIFSAN experience.

1) The Training Impact Chain

Using the JIFSAN TtT example, we can illustrate both the impact chain and the complexity of impact measurement. In general, a TtT program aims to increase other countries' training capacities by helping them develop trainers and adapt training materials. From a U.S. perspective, this approach allows the U.S. to leverage limited resources to reach a broader audience. The TtT program was developed before FSMA, but is also being used to fulfill FSMA's produce safety international training requirements. We can measure these effects of TtT in terms of immediate, short-run, medium-run, and long-run impacts.

Immediate: Completing a TtT training is one of the criteria to become a local Lead Trainer. In this TtT training, participants are trained on food safety materials by U.S. instructors. These are then the same materials Lead Trainers are expected to deliver to local farmers. When qualified TtT program participants become Lead Trainers in their own countries, these countries have greater capacities to train local farmers. These increases in training capacities are the immediate impacts of the TtT program.

Short-run: In local trainings, Lead Trainers explain the importance of food safety and the importance of good practices, such as hand-washing. They also teach skills, such as methods of waste

disposal and water treatment. Effective local trainings improve farmers' attitudes, knowledge, and skills on food safety. These improvements are short-run impacts of the TtT program.

Medium-run: By understanding the importance of food safety, farmers are more likely to improve their food safety practices. With improved knowledge and skills, they can know what practices to adopt and how to implement them. For example, farmers find access to clean water, install hand-washing facilities on their farms, and properly separate animals from food storage. After farmers make the necessary investments and improve their farming practices, they can improve the safety of their outputs. The behavioral changes and output improvements are medium-run impacts of the TtT program.

Long-run: Safer farm output provides a good starting point for food safety along the value chain, and the consumption of safer food. Safer food benefits consumers by improving their nutrition and health. It also benefits value chain actors through increased income and better livelihoods. In developing countries, improved food safety can also contribute to food security by reducing output loss and increasing farm income. These benefits on social welfare are long-run impacts of the TtT program.

2) Capturing Training Impacts

The four stages of the training impact chain – the immediate, short-run, medium-run, and longrun impacts – are more fully defined here based on training evaluation literature and JIFSAN's training experience. In each case, we consider what it takes to measures these different levels of impact.

Immediate impacts are the **reports from the training event**. They are measured as part of the reporting back of the training event. They include number of training sessions, number of participants trained, and number of countries benefiting from the program.

Short-run impacts are the *direct impacts from training farmers*. They are measured by considering the results of learning on farmers, such as improved attitudes toward and improved knowledge of food safety. Learning results can be collected through quizzes, training evaluations, retrospective surveys, and interviews. Quizzes are used to measure the immediate learning results and take place before and after the training event takes place. Assessments right after the training can also be used to measure the immediate learning impacts of the training on farmer attitudes and knowledge.

Medium-run impacts are *results of training knowledge transfer*. They capture whether farmers apply their learning and improve product safety. These impacts will lag behind (short-run) learning results, since it takes time for farmers to make food safety investments and employ safer practices in a new agricultural production cycle. Medium-term impacts can be measured in two ways. First, one can send out retrospective surveys and collect self-reported data by farmers. However, surveys that ensure the quality and quantity of self-reported data can be costly. Second, one can use existing records. Some of the records are aimed at prevention, which include capacity building activities, for which impact can be measured through existing monitoring efforts, such as inspection records (see FSMA Title I, Table 2). Other records are aimed at improving detection and response through capacity building of inspectors, auditors, and government officials, including activities that involve product testing and recall (see FSMA Title II). The latter measurements can leverage existing data collected by food safety stakeholders.

Long-run impacts are defined as the *effects of improved food safety on the society*. They include the impacts on consumers, such as improved nutrition and health. They also include the impacts on suppliers, such as improved income and livelihoods. In developing countries, farmers often play the dual role of consumers and suppliers. Long-run impacts are in line with the 2030 Sustainable Development Goals, such as improving food security (see earlier Box B). They can be captured by surveys and surveillance by governments or international organizations. Potential measurements include detailed survey records of consumers and farming households, as well as aggregated statistics on regional and national income level, poverty rate, food safety related nutrition and health records.

The difficulty of capturing training impacts varies along the impact chain. Some immediate measurements are easy to collect as part of the actual training activities. The earlier-stage impacts (e.g., the impacts on training capacity and impacts on farmer attitudes, knowledge and skills) are more direct results of the TtT program. They take fewer steps to reach and are conditioned on fewer other capacity building activities. The later-stage impacts (e.g., impacts on farmer behaviors and farm outputs and, eventually, impact on social welfare) are further removed from the TtT program. These impacts require more time to take place, are affected by many other dynamics, and involve more activities from different stakeholders.

This long chain of impacts makes it very difficult to attribute later-stage impacts to a specific training programs. There could be broken links along the chain, and training impacts may not reach consumers. Or they may take a long time to reach consumers. Even if we were to observe food safety improvement increases with respect to social welfare, it would be difficult to disentangle the impacts of any one training event from other dynamics and capacity building activities.

Instead of asking which part of the food safety benefit can be attributed to a particular training program, we can ask two alternate questions. The first question is whether food market actors are better off with the training program than without the training program (the counterfactual). To answer this question, one compares food safety, nutrition, health, and livelihood from two very similar groups of food market actors. The only difference is that one group is trained, and the other is not. However, to have these very similar groups of food market actors, one needs well-designed policy experiments and carefully sampled populations. This type of study is costly to implement.

The second question is whether one stage of the impact chain successfully reaches the next stage. To answer this question, one needs to trace the impact along the chain. In JIFSAN's TtT program example, we would examine the following questions one-by-one: (1) Did TtT trainees become local trainers and train farmers, how many and where? (2) Were farmers trained, and did they improve awareness and knowledge? (3) When farmers improved both awareness and knowledge, did they take actions and produce safer food? This second approach has several advantages. First, it allows us to leverage existing information and reduce the cost of the study. Second, by examining one stage at a time, we are more likely to identify the efforts made by each stakeholder. Third, if there is a broken link in the impact chain, we are more likely to find it and then figure out what other capacity building efforts are needed.

E. Activity Monitoring and Impact Measurements

We now turn our attention to the type of measurements that can be used at each impact stage and why impact evaluations of training need the collaboration of many different stakeholders, as illustrated in Figure C.

Training organizations should monitor their own activities. They should have a record of the number of trainings delivered, the number of people trained, the number of countries that benefited from the program, and so on. JIFSAN, as part of its training efforts, keeps these kinds of records. Increased training capacity in these countries is then measured as a direct impact of the TtT program.

Impacts on in-country training capacity are measured by the number of the TtT participants that become local trainers and by their training activities. The organization offering the TtT program may access basic information by collaborating with country agencies and international organizations. However, it is increasingly costly to maintain such access if the training organization has a broadening outreach. A data sharing platform could reduce the cost of individually aggregating data from disparate international sources.

The JIFSAN TtT programs are aimed at improving farmer's capacity (awareness, knowledge, and skills) to improve the safety of their produce. It starts by training lead trainers on the expectation that these lead trainers will train additional farmers through multiplier trainings. With these multiplier trainings, farmers will gain knowledge on how to implement better practices to ensure the safety of food and produce and lead to safer outputs. Safer farm output is the starting point for ensuring the safety of a food as it moves along the value chain. Safer food in turn benefits consumers by improving their health and nutrition. It also benefits value chain actors through increased income. This is especially true in developing countries, where improved food safety can entail improve food security and livelihoods.

Figure C: Chain of Food Safety Capacity Building Impacts



F. Data to Measure Impact

To measure impact of food safety capacity building, data is needed. Early on, stakeholders need to come together and identify what type of indictors they are going to track and agree what type of data they think is essential to collect. As capacity building data collection can be costly, it is important to identify from the beginning what type of data already exists and what type of data might still be needed to measure impact. To understand what is needed, one needs to step back and understand what those who are investing in food safety capacity building are looking for. The same three types of reasons for stakeholder investments in food safety capacity efforts (improve health, AID, and trade/market access) also apply to the outcomes they are interested in and the types of data needed: data that enables them to measure health, AID, and trade outcomes.

- Health measures might be reduced daily adjusted life years (DALYs).
- **AID measures** might be reduced global hunger, improved food security, improved health, and improved livelihoods amongst the poor.
- **Trade/market access/profit measures** might be improved trade of safe products and trade flows without increase FBDs outbreaks.

1) Existing Data Resources and Repositories

Currently all the data needed to measure food safety capacity building impact is either not collected or not in a central place where one can measure impact. We can start, however, by reviewing the existing data collected by the public and private sectors.

Data currently collected by the public sector. Currently there exists some public sector data to measure some impact, such as U.S. FDA refusal data, FDA inspection data, Department of Commerce trade data, and U.S. Center for Disease Control (CDC) trace-back data. This data may assist in determining if there has been any change associated with rejections of a product from a country in which related food safety capacity building training has occurred. Table 3 describes different sets of secondary data available to measure impact and limitations of that data.

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 publicly available. Predict (described below) will replace it.	The difficulty in using this is it provides data indicating that a product from a specific country, from a specific firm was refused. It does not provide data on amount of product refused. 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.

Table 3: Potentially Useful Secondary Data Sets

FDA Data dashboard - Compliance Dashboards on:	Only a small snapshot of what is happening
Inspections, Compliance, Actions, Recalls, Summary, Import	(see above)
FDA's Inspection Classification Database – Results of 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 FDA states that the database should not be used a source to compile official counts.
CDC National Outbreak Reporting System (NORS) contains trace back data on foreign sources of foodborne illness outbreaks in the U.S. exists.	Currently there are limited entries of actual trace backs, as many countries are in the process of still developing monitoring programs to conduct trackbacks.
European Union 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 amount, preventing the researcher from calculating real trade impact.
National Oceanic Atmospheric Administration (NOAA) data NOAA provides training programs seafood HACCP, they certify establishment as being capable of producing safe, wholesome products in accordance with specific quality regulations promulgated by the U.S. 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
PREDICT (Predictive Risk based Evaluation for Dynamic Import Compliance Targeting) is an electronic screening tool that 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 information can be gleaned.

FDA-TRACK program will be useful in the future. For instance FDA collects on the number of foreign inspections completed by investigators based in-country, 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. Recently released FDA-TRACK indicators include number and Percent of Foreign Preventive Controls inspections classified as no action needed, voluntary action needed, official action indicated, Number of Class I and Class II recall events attributed to imported human food, and Number of Class I and Class II recall events attributed to imported finished animal food that is not intended for further manufacturing or processing. Other indictors included number of recalls,	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), number of FSVO inspections and the voluntary qualified importer program (VQIP), and third party auditors. Increases in number of foreign laboratories accredited, increases in country system recognition or equivalence assessments of foreign food safety systems, increases number of foreign inspections and facilities registered.	The ability to measure impact based on this data will depend on what FDA makes publicly available.

Data currently collected by the private sector. The private sector already collects data on their suppliers and their suppliers' performance, both for their own purposes and for government and third-party audits. Potential private sector data sets are listed in Tables 4 and 5. In the context of FSMA, sharing such data with FDA could be very useful for FDA to measure impacts of food safety capacity building efforts. Under the right conditions they might be willing to share potential internal control measures for a company such as development of facility internal control measures, increased number of analytical test results within acceptable values, improved audit scores through internal or 3rd party audits, improved "risk" score amongst those companies who create risk scores for their plant and/or suppliers, external certification of the facility/operation, decreases in frequency of required audits, and reductions in regulatory violations.

Category of	Possible Measures	
Measures		
Measurements of production outcomes	 Number of products going through the "first pass" quality check without having to be reworked or diverted to a lesser value stream, Number of products on hold, Number of marketplace actions taken based on customer complaints or recalls, Ability to attract new customers and enter new markets that could be good measures of impact of capacity building efforts. 	
Internal control measures for a company	 Development of facility internal control measures, Increased number of analytical test results within acceptable values, Improved audit scores through internal or 3rd party audits, Improved "risk" score amongst those companies who create risk scores for their plant and/or suppliers, External certification of the facility/operation, Decreases in frequency of required audits, Reductions in regulatory violations 	
Geisert, Sarah,	former Sr. Director, Global Product Safety and Regulatory, General Mills. Personnel	
communication.	2014.	

Table 4: Potentially Useful Private Sector Data Sets

Missing data. Currently FDA inspects less than 2% of all imports into the U.S. Thus public sector data is a limited snapshot of what really is occurring in the industry. Access to industry data currently is missing from government and public view. If private sector data could be made available and aggregated, with trend information depicted over time, it could prove very useful for purposes of evaluating the impacts of food safety capacity building.

Returning to FSMA as our starting point for considering collaboration potential, a shared data platform could facilitate efforts to understand the immediate, short-run, and medium-run impacts of FSMA's efforts. Data collection has a cost, and some impacts take time to occur, but there is still a need to understand immediate and short-run impacts as soon as possible in case that points to a redirection of efforts. Measurements of these impacts are also important for substantiating why actors fund food safety capacity building efforts. Some data is already being collected, and combining that into a fuller set of shared data could provide valuable insights into the impacts of capacity building efforts in the era of FSMA. If a data sharing platform were formed, it would be one way to measure immediate, and possibly short-run and medium run, impacts at lower cost and with more efficiency and immediacy.

Table 5: Potentially Useful Data Sets by Sector

Sector	Category of Measures	Possible Measures
Public	Training	 Number of training sessions, number of participants trained,
Sector –		number of countries benefiting from training programs
training	Impacts of	Number of trainees becoming qualified lead trainers
providers	capacity	 Number of training material adapted and translate to local
	building	languages
		Number of trainings delivered
		Number of farmers or processors trained
		• Number of producer producers getting PSA or FSPCA certification
	Impacts on	• Surveys on producer's/processors knowledge, attitude and skills to
	knowledge, attitude skills	implement good practices before and after trainings
Public	Monitoring for	Rejection, Inspections, Compliance, Actions, Recalls, Summary,
Sector –	problems/progr	Import data
regulators	ess of efforts	Food safety incidents traced back to farms/processors
		Data on FBDs outbreaks
		Data on capacity building progress
		Data on food safety informatics program progress
	Monitoring of	Living standard statistics
	welfare	Health statistics of FBDs
	impacts	National statistics on poverty, income, nutrition
Private	Monitoring	Farm gate and manufacturer inspections, audit reports
Sector	measurements	• Product sampling and testing of products along the value chain,
	of production	trackbacks
	outcomes,	Number of products going through the "first pass" quality check
		without having to be reworked or diverted to a lesser value stream,
	As well as	Number of products on hold,
	impacts on behavior	 Number of marketplace actions taken based on customer complaints or recalls,
		• Ability to attract new customers and enter new markets that could
		be good measures of impact of capacity building efforts.
	Internal control	• Development of facility internal control measures,
	measures for a	• Increased number of analytical test results within acceptable values,
	company	 Improved audit scores through internal or 3rd party audits,
		Improved "risk" score amongst those companies who create risk
		scores for their plant and/or suppliers,
		External certification of the facility/operation,
		 Decreases in frequency of required audits,
		Reductions in regulatory violations
	Third-party	Companies passing audits to various certification schemes
	audit programs	

2) Data Sharing Challenges

While some or even most of the public sector data described above is likely already being collected, it is important to recognize that it belongs to different organizations or groups. There need to be justifications for these organizations or group to share data. In addition, public sector secondary data is collected for specific purposes and not solely or directly for measuring the impact of food safety capacity building. As a result, this data is often in a form that does not facilitate attributing changes to a specific food safety capacity building effort, or even more general efforts. For instance, the FDA refusal database does not provide data on the volume of product refused. It is therefore difficult to know to the full impact and cost of a rejection to the supplier. As another example, FDA's commodity codes do not match the trade data collected by Department of Commerce, which makes it difficult to understand the value of trade affected. Similarly, CDC's outbreak data has limited entries on actual trace-backs, as many countries are still developing their monitoring programs to conduct actual trace-backs.

As with public data, some or most of the private sector data described above is likely already being collected. However, here, too, it is important to recognize that this data belongs primarily to individual companies and is typically considered proprietary, sensitive business information. There need to be not only justifications, but also motivations for these companies to share their data. It is unclear whether the private sector would share such data with the public sector and more broadly, including with other companies, organizations, and academia, without some sort of novel PPP aimed at measuring the combined effect of capacity building efforts. Feedback from a product-tracing study in 2011 (IFT, 2012) raised two particular industry concerns: (1) data collection efforts would be costly; and (2) industry would likely resist sharing data unless it was through a voluntary approach.

We have several responses to these concerns:

- 1. In terms of cost, a data sharing platform could be structured around the receipt of existing data. If a number of organizations are requesting these types of data from the industry—the formation of a PPP data sharing platform could become the solution of "one and done. Industry could place their information in one place and everyone else who previously requested the information would get it directly form the data sharing platform. This could become the incentive for industry to participate. As indicated by Table 5, a significant amount of relevant data is already being collected by companies and organizations to facilitate their operations and advance their own business interests. The private sector would not need to incur significant new costs to participate in a data sharing PPP focused on food safety capacity building efforts.
- 2. Shared data does not need to be attributable to individual companies or organizations. PPP design could ensure that shared data is blinded or aggregated in ways that separate the identity of the provider from the data. That could include voluntary data sharing through trusted third parties. For example, an industry group could work with a university that blinds and aggregates the data received, it so it could be used to measure impact.
- If properly set up, a PPP could include measures that address data sharing challenges for the private sector. Concerns over confidentiality, in addition to reputational impacts and possible regulatory sanctions, could be addressed as part of the structure and design of a fit-forpurpose PPP.
- 4. Measuring the impact of food safety capacity building is mandated by FSMA. The U.S. regulatory framework provides a context in which the public and private sector together need to find ways to effectively fulfill the statutory requirement of impact measurement.
- 5. Finding a suitable method to share already-collected data amongst different actors is in the broader interest of both the public and private sectors. For industry, platform-shared data can have many useful business applications, including better understanding of business opportunities, deeper analysis of financial investments, reorganization of the agriculture sector, and development of improved infrastructure.

Establishing partnerships to share resources to improve public health outcomes is not new. Other major international partnerships have been formed to mobilize resources against disease and reduce public health problems through combined public and private sector involvement. Two prominent examples are worthy comparisons.⁵

GAVI, the Global Alliance for Vaccination and Immunization, was established in 2000. In the almost twenty years of its existence through July 2019, it received \$18 billion, averaging roughly \$1 billion a year. \$10 billion was contributed in cash by traditional bilateral donors, \$4 billion came from private sources, and another \$4 billion was contributed to back either capital market bonds or government vaccine purchases. The recently-launched GAVI replenishment effort for 2021-25 seeks \$7.4 billion.

The **Global Fund for AIDS, Tuberculosis and Malaria** originated in 2001. Since inception, it has received just under \$50 billion, averaging more than \$2 billion a year. Of that amount, roughly \$23 billion supported HIV/AIDs efforts, \$14 million funded malaria projects, \$8 billion addressed tuberculosis, and another \$4 billion went to tuberculosis and malaria efforts combined.

Disease	Cost in DALYs	Number of Deaths
	(millions)†	
Foodborne diseases	33	~420,000 *
Malaria	37.3	~435,000**
Tuberculosis	51.6	~1.6 million ** died from the disease (including 0.3 million
		among people with HIV)
HIV/AIDs	59.9	~770,000 *** people died from AIDS-related illnesses
		worldwide
Diarrhea	81.7	~230,000**
HBV	4.6	~887,000 ****
HPV		~266,000 *****
Cervical cancer	2.4	~311,000

Table 6: DALYs and Deaths Associated with Major Diseases

⁺ WHO estimates, 2016 ** WHO estimates 2017 *** WHO estimates 2018, Note HIV/AID's related deaths have decreased by 33% since 2010. **** WHO estimates 2015 ***** WHO estimates 2012

⁵ <u>https://www.kff.org/global-health-policy/fact-sheet/the-u-s-and-gavi-the-vaccine-alliance/</u> <u>https://www.kff.org/global-health-policy/fact-sheet/the-u-s-the-global-fund-to-fight-aids-tuberculosis-</u> <u>and-malaria/</u>

As a matter of scale, imagine what could be done if food safety, including capacity building efforts, were to benefit from similar resources. The development challenges are comparable in scope and social burden, particularly when measured in DALYs and deaths and considered in terms of globally interconnected impact. Table 6 compares DALY's to number of deaths. When one looks of the cost of FBDs, knowing that FBDs is the number one cause of diarrhea, one can argue there is just as much need to combat FBDs as some of these other diseases.

3) Data Sharing Example: The USDA Global Branded Food Products Database

PPPs do not develop overnight, especially if they are being convened on an international scale to address global challenges. They take considerable effort to be created in an inclusive process vetted among an extensive diversity of stakeholders. They start with a solid foundational belief that all partners can better achieve their common goal by working together.

The prospects of finding such support among food safety actors is substantiated by the recent experience of another successful endeavor to develop a shared database through a public-private partnership. Taking on a topic that at first seemed intractable, or at least impractical, these food-oriented partners devoted their efforts over [two years] to establishing a now highly-appreciated and widely-utilized data sharing platform: "A Public Partnership for Public Health: USDA Global Branded Food Products Database".

In 2013, the USDA Global Branded Food Products Database PPP was formed with the goal of enhancing public health and the sharing of open data by complementing the existing USDA Food Composition Databases with nutrient composition of branded foods and private label data provided by the food industry. The composition of the food supply and consumer dietary choices are key inputs for agricultural and food policy decisions. Comprehensive data can inform these decisions, but the volume and fluidity of branded food products in the U.S. marketplace are key challenges. At the time, the research community recognized that in order to facilitate better decision making, they needed to move into the era of big data and saw the benefit of gaining a much larger amount of computed data from food manufacturers on branded food products. Under prevailing sentiment, using existing data far outweighed the desire of having the public sector conduct analytical analyses on a far more limited number of branded food products. The move to embrace the use of such existing data was a huge paradigm shift for USDA.

To make this happen, six partners (USDA - Agricultural Research Service, International Life Sciences Institute (ILSI) North America, GS1 US, 1WorldSync, Label Insight, and University of Maryland, JIFSAN) came together with their shared goal. They recognized from the outset that this goal could not be accomplished by any single partner alone. For the partnership to work, the partners were selected carefully and had the necessary skills and expertise in data quality and management, data collection, supply chain standards, and research knowledge. As another key success factor, the partners chose to embed the USDA Global Branded Food Products Database in the USDA National Nutrient Database, which is recognized by the research community worldwide as the gold standard for food composition databases.

The partnership evolved over the years as challenges have presented themselves. The partnership was built using the set of principles from the work of ILSI North America and published in 2013 in *Nutrition Reviews;* "Principles for Building Public-Private Partnerships to Benefit Food Safety, Nutrition and Health Research". These principles provided the foundation for the success of the PPP. In the interest of

organization, coordination, and communication, six groups were formed: Steering Committee, Operations and Management Group, Criteria Group, Data Quality Subgroup, IT Infrastructure Group, and Communications Group.

The partnership started with gradual efforts and reached out to hear the needs and concerns of stakeholders. Initial concerns included a fear that competitors would be able to reverse engineer company recipes. That concern was overcome for at least one company when it realized it owned the patent to one of the major inputs into the recipe. Overall, the partnership held two listening sessions in 2013 to get input from stakeholders in the public, private, and academic sectors.

In 2014, the partnership undertook an initial, pilot data collection effort. For this beta test pilot, the platform had to identify which attributes need to be "Mandatory" vs. "Recommended" in the USDA Global Branded Food Products Database. Then GS1 and 1World Sync developed an Implementation Guide that was agreed upon by the partnership. The companies involved in the beta test had to learn how to publish nutritional data through the GS1 standards, since the submission of nutrient information to GS1 was a new process for some of these food manufacturers. In addition, quality control checks were established at the 1WorldSync level to ensure all mandatory attributes, as decided by the partnership, were provided.

For the second beta testing, the partnership recognized that not all companies wanted to submit their data through the GS1 process, but instead wanted to use another mechanism they were already using to scan food labels. Under the second beta testing process, two separate mechanisms for providing data were created. The first was the GS1 mechanism through 1WorldSync, and the second was food label scanning through Label Insight. Both mechanisms gave food companies control over their data, while relying on a third party environment outside of the University of Maryland and USDA. Both companies, 1WorldSync and Label Insight, voluntarily provided the University of Maryland access to test data for successfully completion of the 2nd beta test. The University of Maryland received product data directly from both data partners, aggregated it, and published the combined data. During the second beta test, over 1,000 foods were tested, which allowed a greater understanding of the data.

By 2016, the Partnership had 100,000 products uploaded to the database, and the Secretary of Agriculture launched the database at the GODAN initiative in New York City. By 2017, it had 215,000 products and by 2019 over 260,000 products. Currently, this database is the number one, most used application programming interface (API) offered by the U.S. government. In its inaugural year, the database had a combined 17 million page-views from 1.2 million users. The project came about with six partners, including several of the authors of this white paper, with combined expertise in data quality and management, data collection, supply chain standards, and research knowledge, all of which was essential for success in delivering their shared goal. Based on its success in a U.S. setting, this data sharing partnership is now being expanded to other countries. Discussions are being held with other organizations, like the United Nations Food and Agriculture Organization (FAO), that are recognizing the benefit of working together in this space and in this way.

What facilitated the success of the partnership and having the private sector voluntarily share data was the following:

- Development of a transparent, actionable framework for the creation of public-private partnerships for food and nutrition research;
- Having a clearly defined and achievable goal to benefit the public;
- Articulating a governance structure, which included a clear statement of work, rules, and partner roles, responsibilities, and accountability, that facilitates the building of trust, transparency, and mutual respect as core operating principles;
- Acknowledging upfront if there were "deal breakers" precluding the formation of an effective partnership; and
- Ensuring that objectives will meet stakeholder partners' public and private needs, with a clearly defined baseline to monitor progress and measure success.

What facilitated the merging and sharing of data from different sources was first understanding and defining the data elements upfront and communicating the data limitations. In addition, stakeholders had to collaborate on agreeing to a shared set of terminology. Second, there were discussions around the use of the data so the partners had an understanding of the importance of standardization for comparison, how nutrient values are presented, and how the data would be archived. Third, as food labels are complex, the developers of the database enabled the data to tell the story, rather than have the developers dictating what they thought should be presented. Lastly, the partnership created a roadmap and met regularly with the partnership and stakeholders on what future features needed to be captured and communicated and how to maximize collaboration.

Building on the success of USDA Global Branded Food Products database, we believe there is ample potential and stakeholder interest to develop a data sharing platform for the promotion and improvement of food safety capacity building. We believe a PPP for this purpose can similarly start from a U.S. context, in response to FSMA's emphasis on public-private cooperation. We recognize that this engages an international scope through the global dynamics of food safety and the development challenge of in-country capacity building. We encourage the public and private sectors to find the common ground and safe spaces needed to make this new PPP a sustained success.

Part 3. Basic Elements Needed to Form and Sustain a PPP⁶

A. PPP Basics and Baseline

Excellent work has been done by many stakeholders that are firm believers in the catalytic and synergistic possibilities of coming together in partnership. Some salient, relevant examples have been cited, including the recent and remarkably successful USDA Global Branded Food Products PPP. Stakeholders have also convened to consider lessons learned and brainstorm about what makes PPPs work best, especially in international contexts. We tip our hat in particular to ILSI North America, with its published "Principles for Building PPPs to Benefit Food Safety, Nutrition and Health Research" (see Annex 1).⁷

Before presenting a zero version of the proposed PPP in the next section – a working blueprint for discussion and deliberation – we can consider some basics about the process of engaging in public-private collaborations. What follows may appear rudimentary, but a focused look at the building blocks of structure and design can provide a useful framework within which to develop a PPP designed to promote and improve food safety capacity building through robust and meaningful data sharing.

1) About Joining, Engaging, and Sustaining

Partnerships are voluntary. They have to work for everyone that participates. To put it another way:

- a) Only partners who have **motivations** to partner will become partners.
- b) Only partners who have **incentives** to participate will engage as partners.
- c) Only partners who realize **benefits** of partnering will stay on as partners.

Each of these factors has its place, and one leads to another. Partnership interest starts with motivations, is galvanized by incentives, and becomes sustained over time through actual benefits.

⁶ A resource of note is the workshop summary entitled "Building Public-Private Partnerships in Food and Nutrition Workshop Summary" published by the Institute of Medicine of the National Academies in 2012, with Leslie Pray and Laura Pillsbury as rapporteurs, and conducted at the Food Forum of the Food and Nutrition Board on November 1-2, 2011 (the IOM Workshop); FBDs was cited as a public health problem that could benefit from PPPs (page 14). Other resources of note include materials from the Agriculture for Nutritional Health (A4NH) event on October 31, 2017 on "Public-Private Partnerships and the Nutrition Agenda: Challenges and Opportunities"; "The Role of Public-Private Collaborations in Global Food Safety" by R.E. Brackett, in Food Safety Magazine on January 12, 2018; "A Commitment to Consumers to Ensure the Safety of Imported Foods: Four Pillars of Public-Private Partnerships" from the GMA in 2007; and "Designing International Partnership Programs – A Primer for Partners: How to Structure for Sustainability, Efficiency, and Development Impact," published in 2019 by one of the authors.

⁷ Principles for Building Public-Private Partnerships to Benefit Food Safety, Nutrition and Health Research, Rowe, S. et.al, Nutrition Reviews 2013; 71(10):682-691.

JOINING	ENGAGING		
<i>motivations</i> have to match	incentives have to work	SUSTAINING	
		benefits have to happen	

a) Motivations: Motivations have to match for partners to join.

To start, partners have to be motivated to partner. Even though partnering means finding common ground, motivations are not something everyone has to agree on. Each partner brings its own set of drivers, along with its own skill sets and comparative advantages. The diversity of partners reflects the diversity of their contexts.

In PPPs, this diversity is built in. While many partnerships rely on like-minded and like-situated partners, the value of bringing public and private sectors together lies in their differing profiles. The value lies in the combination, even if the match-up is harder.

Fortunately, those differing contexts remain, and differing drivers can stay different, even as the partnership comes together. Even better, partners can be respected and appreciated for their differences – and that appreciation can result in stronger motivations to partner.

For example, as to accountability, the public/private contexts and related motivations are quite distinct:

- Public sector partners are accountable to the public. Public sector partners are called "public" because that is their legitimizing base and purpose to serve the public first and foremost. Civil servants are beholden to their specific employers, like government agencies. However, from a big picture perspective, they have a larger raison d'etre and calling. They are put in place and funded by the public as voters and taxpayers, and are in turn expected to serve the public as citizens and members of the community.
- **Private sector partners are accountable to their corporate, for-profit entities.** Private sector, for-profit partners may want to do good, but their interest in serving the public always loops back to their corporate bottom lines. The litmus test is whether the engagement is beneficial or harmful to their business interests. This is not optional; it is part of the statutory set-up. Companies that actively or intentionally undermine their own businesses can even face legal claims by their shareholders or owners, who expect for-profit entities to make a profit. Like taxpayers more broadly, investors expect something in return for the funds they provide, only more specifically and directly as returns for themselves.

Despite these divergent starting points, public and private sector players can find common ground on any number of issues, while still, on the one hand, meeting public sector interests in serving the public and, on the other hand, meeting private sector interests in serving their individual businesses. Case after case shows that these disparate profiles can support each other and converge in common goals. **Transparency** in PPPs starts with transparent acknowledgement and appreciation of these different starting points. This forms the basis of **mutual respect** among partners. If the public sector does not recognize and leave room for private sector considerations, it is difficult to sustain public-private partnering. Likewise, if the private sector does not embrace public sector ambitions in promoting public goods, the partnership rests on a shaky foundation. But there are limits. Each sector can acknowledge and accommodate the interests of the other sector only as long as this does not undermine its own interests.



This intersection of interests is the *sweet spot* that every partnership needs – and one that is especially vital to PPPs. It is worth confirming from the start that the sweet spot is broad enough and deep enough to firmly ground the partnering effort over time.

b) Incentives: Incentives have to work for partners to engage.

If motivations bring partners to the table, incentives get them to pull up a chair and stay. Partners think about where they want to end up and then create processes and structures – including incentives – that harness individual motivations to reach collective goals.

Partnership incentives are built into the design and structure of the partnership, mostly in the form of if-then relationships: "if" being the action, and "then" being the desired result. Linked this way, each desired result becomes a reason to act. For example:

- If I contribute financially, I can be part of the decision making I have an incentive to contribute.
- If I contribute more, I can stimulate more activities I have an incentive to contribute more.
- If I contribute my time and effort, I can help develop lessons learned that create a better knowledge base, improve implementation and get more effective results – I have an incentive to be more engaged.



Partners can choose to set up incentives

that bring partners into the fold (matching their motivations) and keep them on board (sustaining their participation). The crucial place for a partnership to engineer incentives is around the "collectives" – those convergence points that create efficiencies and synergies. Typical collectives of partnership programs include a governing body (collective decision making), secretariats (centralized support), and trust funds (pooled funding). Some useful incentives to bolster these collectivized elements could include:

- Governing Body: Giving the governing body a substantive decision making role that is high level (strategic direction) or project level (funding allocations), or even a meaningful advisory role, can incentivize governing body participation. A governing body with little bearing on partnership operations may not hold partner interest for long.
- Secretariat: Having the secretariat leverage partnership visibility and sharing, like running a website or knowledge platform, can incentivize partners to provide enough core support for dedicated staff. Because partners tend to focus on projects and results on the ground, getting partners to appreciate and pay for core support often needs deliberate incentivizing.
- Trust Fund: Making participation on a governing body contingent on trust fund contributions, at any amount or above minimum thresholds, can incentivize participation in a commingled fund. This in turn allows partners to be more strategic and flexible in what they finance using unrestricted instead of earmarked funding with a resulting, impactful portfolio that reflects well on every contributor. Having such a portfolio is an incentive in its own right.

i. Disincentives

Incentives are as important to create as disincentives are to avoid. Incentives can steer good partner behavior by fortifying collectives, while disincentives can result in the opposite. Aspects that undermine partnership collectives may not be very visible. They may corrode over time and become visible only after it is too late. Their cumulative effect can rob partnerships of the center that holds it all together until it falls apart – when the whole no longer adds up to more than the sum of the parts.

Examples of disincentives include the flip side of incentives. For example, if partners are all allowed to restrict their funding to specific projects with no expectation that they contribute generally to core support, will anyone be left to pay for the secretariat, meeting logistics, annual reports, website and more? Similarly, if partners are allowed to participate in governing body decision making without any skin in the game – no cash in the trust fund, no in-kind support, no value-add through valuable expertise, no essential role or responsibility like implementation – then those who do pony up may become less inclined to contribute over time. Too little engagement by some, too many exceptions for others, and the partnership may lose its solid footing and balance.

ii. Free Riders

This raises the prospect of free riders that dilute the partnership core. Free riders may at first appear neutral or irrelevant, but can become disincentives for other partners. They can use up partnership resources, create distractions, tilt the playing field and otherwise deter other partners from being as engaged or effective as they would otherwise be.

It may be good practice, especially in the beginning, to start every governing body meeting by acknowledging what respective partners have contributed since the last meeting, whether in cash, inkind, through staff, expertise, or otherwise. Visibility generates accountability. By taking note of the positive, partners may also notice the negative – and those not contributing may be encouraged to find ways to contribute. In a culture of contribution, free riders may prefer not to stand out.

iii. Positive Feedback Loop

It is up to the partners to match inputs with outputs. In the same way that partners strive for mission impact – the very reason they come together – they also need to look at partnership impact on

themselves. They can start at the front end and think about what kind of participation they want to cultivate and how to make it worthwhile for each partner. They can come at it from the back end, focusing first on goals and working backwards to create conducive conditions to reach those goals.

Incentivizing means recognizing and rewarding. It links partner contributions and behavior with results that reinforce a positive feedback loop. Incentivizing works both through deliberate measures to strengthen the partnership core and vigilance against aspects that weaken the partnership core.

Unlike motivations, which are unique to each partner, incentives are part of the collective. Partners individually bring their own motivations and pursue their own interests, but collectively agree on incentive structures as part of the partnership design. Partners together decide how to incentivize behavior that fortifies their partnership and resist behavior that erodes the partnership. In deciding where to put the emphasis, it all depends on how partners want their partnership to function and what they seek to achieve.

c) Benefits: Benefits have to happen for partners to stay.

The main purpose of PPPs is to effect change for the common good. That much is widely understood. But in choosing a PPP structure, partners are also expecting to be direct beneficiaries themselves, each with respect to its own interests. To put it another way, if PPP partners do not realize the benefit and see the impact and the value of the PPP they will not continue itnue to engage.

i. Benefits that Benefit All

PPPs start with an idea, a goal, vision or mission that galvanizes both sectors – a space where public government and private corporate interests converge. This end point is invariably articulated in terms of results that shared efforts can achieve and that partners can share as achievements. Partners typically establish results frameworks to position their intended benefits, which are then measured for actual outputs, outcomes and impacts.

Clearly, these benefits belong to the beneficiaries, the parts of society that are intended to be benefited, and they may also have positive ripple effects for other parts of society. Less acknowledged is that these benefits also accrue to the partners. In fact, benefits to the public that emerge from partnership endeavors belong to the whole partnership, to every partner. This is not inconsequential from three perspectives:

- Benefits achieved by the partnership reflect on all partners, no matter their contributions.
- Results that achieve intended benefits sustain partner engagement.
- Failure to achieve intended benefits also reflects on all partners and affects sustainability.

The nature of partnerships, including PPPs, is one for all and all for one. This means every partner has a vested interest in how the partnership fares. Associating with others in the PPP usually involves broad brush exposure, especially reputationally, to the full scope of the partnership. Partners accordingly care about the scope of the partnership, i.e., what all fits under the brand. Sometimes they may also try limit or modulate their exposure. While partners happily associate themselves with all the good that a partnership achieves – yes, I'm part of that! – the reverse is also true. When something goes awry, unless

a partnership is very good at delineating and separating roles and responsibilities, it may carry over to all partners.

In the best of circumstances, partnership success comes from the ability of partners to benefit others with impact on the ground, while in turn also benefiting themselves by getting credit for such beneficial impact. This becomes a virtuous cycle where benefit begets benefit. Partnerships help themselves by helping others, which in turn lets them do more to help others. This dynamic matters to the public sector, which is under pressure to demonstrate that it is using public funds wisely and widely, caring for the citizens under its charge and adding to the greater good. This also matters to the private sector, which is under pressure to build good reputations among consumers, manage good relations and good standing with the public sector and – not to be cynical – often truly cares about its impact on the world. There is also an element of time in realizing benefits. Public partners may be prepared to look for benefits on a longer timeline, while private partners may be interested in seeing benefits in a shorter time frame, but in the sweet spot, benefits meet expectations, whatever they are.

Ultimately, a virtuous partnership cycle depends on **positive, perceptible, presentable results**. Partners may be thinking about SMART (smart, measurable, achievable, relevant, and time-bound) results, but they also want to be thinking about PPP results. Capturing, cataloguing, and conveying results is in the interests of (i) each partner for its sustained participation, (ii) the partnership overall for its continued ability to function, and (iii) ultimately for all intended beneficiaries who can be further benefited if the partnership is successful.



ii. Benefits of PPP Combinations

Benefits also come from the choice of structure and design. Combining public and private sectors, and adding other sectors like academia, non-profit organizations, and NGOs/CSOs, is done with partnering benefits in mind. Some NGOs have public sector mandates, such as requiring all activities to have a public health benefit, although they are funded largely by the private sector. Typically, these organizations cannot lobby and are distinct from trade associations, but create an interesting nexus to both public and private sectors, which lends itself to PPP partnering.

A well-designed PPP can leverage key benefits from its multi-sectoral approach. The IOM workshop summary on Building Public-Private Partnerships in Food and Nutrition listed quite a few:

- Greater variety of expertise and perspectives, with fewer blind spots
- Capacity to leverage multiple resources
- Team spirit and enthusiasm fostered by a concerted effort
- Sense of ownership among participants
- Enhanced credibility from broadened involvement and buy-in
- Consistency in messaging and action that helps the public make good choices

- Ability of the public sector to get resources and expertise from the private sector
- Ability of the public and private sectors to influence each other's activities
- Opportunity for the private sector to generate goodwill and burnish its reputation

Whether these benefits are realized in a particular case depends on many factors, but not all partners in a PPP have to benefit the same way, and no partner should be selectively disadvantaged. The starting point is usually a public-sector-prescribed regulatory context that frames private sector behavior. With corporate power and reach increasing internationally, most [many] regulatory contexts already anticipate or encourage public-private cooperation. A hallmark of the United States' FSMA is its extension of public welfare responsibilities to the private sector. Especially in these contexts, a PPP gives private sector partners an opportunity to be more interactive – and hopefully more constructive – about the interplay of market conditions and regulatory requirements, all working together for the public good.

iii. Inappropriate Benefits

It is good practice for partners to agree on their partnership's intended benefits and beneficiaries. This should be a transparent, explicit element of the partnership's common foundation, so partners can stay oriented to their goals. In PPPs, it matters in part because neither the public nor private sector should become a pawn or instrument of the other sector. Skewed "benefits" like these should be avoided:

- Private sector using the public sector: If a PPP confers benefits on certain companies but not
 others, or even performs at the cost of others, this can undermine the competitive landscape
 and affect the PPP's credibility. PPPs should not be used, or perceive to be used, to give
 selective advantages to only certain companies. Of course, companies cannot be forced to
 participate in partnerships, but those that wish to participate should be able to do so if their
 competitors can. This calls for "open access" approaches to partnering vis-à-vis the private
 sector (including participation through non-profit organizations supported by the private
 sector, trade associations) that maintain a level playing field. Partners should exhibit
 sensitivity when inviting or including private sector participants so as not to exclude others
 that may have wanted to participate.
- Public sector using the private sector: If a PPP targets beneficiaries from only certain parts of the population for political gain, or if it is perceived to be acting politically, this can compromise the integrity of the endeavor. (Selectively inviting only certain private sector players into the partnership for political purposes would have a similar effect – see above.) This makes the clear articulation of the PPP's mission a crucial stepping stone for participating

partners. There is room to prioritize targeted beneficiaries, for example if resources are scarce or pilot efforts precede larger scale-ups, but the framing is best positioned for the broader good of the public, rather than playing into the political purposes of any public sector players or particular governing party.



d) Risks: Benefits in Light of Risks

This brings us to the subject of risk, as the counterpoint of benefits. Risks can deter partners from joining, keep them from engaging, and cause them to leave. No matter how strong the benefits, a partnership can be undone by risks to reputation, credibility, and, in the case of PPPs, private sector bottom lines. Some may think risks are especially endemic to PPPs, with an inherent bias of avoidance. However, the main message here is that many, if not most, PPP risks can be mitigated and managed.

i. PPP Risks

Government and industry are not necessarily natural bed fellows, and each sector partners with the other with caution. There are pitfalls for the public sector when bringing the private sector on board, as there are barriers for the private sector when trying to bring the public sector on board. However, for most concerns that are raised, there are countervailing perspectives that reflect the value of PPPs. The upshot is a recognition that it is all in the balance. A PPP that considers these issues head on can usually find an appropriate, productive scope of engagement that leverages sensitivities into synergies. We can start with a closer look at typical public sector concerns, by way of example in Table 7:

Public Sector Concerns	Countervailing Perspective
Corporate influence over public policy	Corporate perspectives can be a valued part of determining what works best.
Distraction from important issues	Partners can together determine what critical issues to address.
Cooptation by commercial interests	Commercial interests can include the promotion of public goods.
Funding-driven shifts in priorities	Partners can first determine priorities together and then stick to the goals.
Inappropriate sharing of information	Partners can start from a culture of transparency when addressing competitive concerns.
Tacit endorsement of company or product	The overall goal of strengthening industry for consumer benefit can prevail.
Partners with spurious motives	All partners have an interest in knowing that all others are there for shared purposes.

Table 7: Examples of Public Sector Concerns

Private sector participants may add their own list of concerns, and a similar balancing of perspectives and interests can be deployed to address them. All partners can benefit from a willingness to be clear about common goals, candid about concerns, transparent about risks, and articulate about processes for addressing them. Risk profiles of partnerships are more co-owned than partners may realize. A partnership's exposure to risk affects all partners. This may not amount to legal liability, but it can readily have reputational and other consequences.

Segregating roles and responsibilities is one way to manage PPP risk. This could, for example, rest on an acknowledgement that the private sector does not participate in developing policy, but provides information to those who do. Who makes decisions on what and how involves design choices that can mitigate risks if partners stay mindful of both risks to themselves and their partnership.

ii. Portfolio Risks

PPPs also face programmatic risks, meaning risks in relation to downstream activities and with respect to beneficiaries. Partnerships collectively have to decide where they want to be on the risk spectrum and whether, for example, they want to try new approaches that may fail or go into low capacity areas with limited financial management. Partners need not be risk averse, and partnerships need not be low risk. But they should be risk aware and work toward a common perspective on risks – or riskiness – of the partnership's portfolio.

All for one, one for all among partners translates into a shared approach to risk management relative to roles, responsibilities, and results, as designed or structured within a partnership. A partnership that deliberately chooses to be high risk and ends up realizing some setbacks is ultimately less risky – or less at risk – than a partnership that stumbles into them.

iii. Shared Risks and Shared Benefits

Taking a collective view on risk – or a collective view of anything for that matter – points to the direct value of partnering as a result in and of itself. The benefit of a partnership often lies in the very act of coordinating, cooperating or collaborating. Even if the partnership exists only to gather experiences and perspectives, while partners do their own implementing outside of the partnership, there may still be great benefit in convening. Or in cases where partnerships do both, coordinating *and* implementing under the partnership umbrella, the convening part may be vital to the rest.

To reflect this, partners can articulate their partnership objectives by identifying partnering benefits in addition to programmatic / portfolio benefits. Reducing carbon emissions or improving education with new schools *and* serving as a coordination platform is an entirely plausible set of laudable objectives.

In coming together with different drivers and interests, partners expect the beneficial results of the partnership to go beyond what each of them individually can achieve. In that sense, it is perfectly legitimate for public sector engagement to benefit private companies, although the primary beneficiary is intended to be the public, and vice versa for private sector engagement to benefit the public and the government, although their corporate duties are to benefit themselves. Indeed, both spillovers have to occur for a PPP to respond to both sets of motivations and further the interests of both public and private partners.

PPP Core Values Complementarity Trust Transparency Mutuality Stability Flexibility Incrementalism Sustainability

2) About Foundational Elements

To harness motivations, fortify incentives and increase impact, PPPs do well to embed core values into their structure and design. These are bedrock elements that allow partners to find and foster their sweet spot. We can consider the following in more detail here: complementarity, trust, transparency, mutuality, stability and flexibility, incrementalism and sustainability.

a) **Complementarity – Partners need to want to partner.**

It is best to test partnership fit prior to establishment. As a voluntary endeavor, PPPs are dependent on good will and good connections among partners. Partnering with organizations that have proven track records of engagement on public goods builds from a comfort zone. However, it may also be important to reach out to other, less traditional, less established actors where compatibility may be less evident and less tested. Open access structures that avoid giving selective advantage to some but not others can also pose challenges when compatibility is not subject to selectivity. Inclusive PPPs can be as messy as democracies, which makes the use of structure, processes and other design features important management tools to maximize complementarity.

An early indicator of compatibility is whether partners can rally around a common statement of purpose. A subsequent indicator is the ability to allocate roles and responsibilities around the respective interests and comparative advantages of the partners involved. Incentives for compatible participation can turn on the benefits of participation versus the risks of not participating. And a litmus test for compatibility is public reaction, whether the PPP will engender public trust and appreciation.

Compatibility has both institutional and individual dimensions. On the one hand, partners need enough common ground to enable productive partnering. On the other hand, representatives of the partners, the individuals sitting on governing bodies or participating in partnership activities, also have to get along and interact constructively in partnership settings. The goals of the PPP should always be front and center to avoid detours into interpersonal / interinstitutional politics or other detracting dynamics.

b) Trust – Trust is an activity more than a state of mind.

Complementarity by itself is not enough in PPPs. Trust is a necessary element, one that takes ongoing nurturing. The IOM workshop referred to "authentic trust" as opposed to blind trust (which includes self-deception) and cordial hypocrisy (which works off a façade). Authentic trust recognizes that trust is not a given. It is earned through continuous cultivation.

Trust that holds PPPs together and makes them effective happens at both institutional and individual levels. Both organizational and personal levels of trust matter. Building trust is a deliberate dynamic that has to work especially hard across sectors and even harder within sectors. In particular, the private sector has to overcome competition to find common ground through trust. This works if partners are able to elevate their common goals above competitive interests, which also means accepting that everyone, including competitors, will derive overall benefit from the PPP. Other barriers to trust in PPPs include self-interest and fear, stereotypes, misrepresentations, manipulation of information, systems, organizational or individual rigidity, and competing world views – all impediments to PPP success.

Trust has to function consistently to be sustained. The erosion of trust can be corrosive over time or suddenly divisive. But where there is trust, there is also greater capacity to address complexity and enable cooperation. It can be a significant factor in risk management and mitigation. Trust in public institutions can be key to securing public trust.

Recommended trust builders, including some from the IOM workshop, are: upfront planning, inclusive participation, impartial moderation, promoting intersectoral perspectives, developing upfront intellectual property (IP) and confidentiality understandings, creating safe space for conversation, ringfencing issues outside the PPP, and testing new collaborations before going public. Partners who understand the value of trust will take other steps to fortify trust along the way. Trust within the PPP, and one voice to the outside, can then engender public trust in what the PPP is able to accomplish.

c) Transparency – Transparency builds trust.

Trust relies on transparency. Partners can interact more effectively if they are upfront with each other and their constituents. A willingness to share candid views within the partnership and disclose appropriately framed minutes of meetings and other documents outside of the partnership signals a robust and confident partnership. Partners can strike a balance that still leaves room for internal deliberations (a safe space to trust) and institutional interests (like proprietary information).

PPPs, in particular, need to navigate between information to be shared and information to be protected. It would be inappropriate to expect private companies to divulge their trade secrets or share data that make them vulnerable. It is similarly inappropriate for the public sector to tilt the competitive playing field by exacting or leveraging transparency.

A healthy PPP can harbor a culture of transparency while still recognizing partner interests in confidentiality for proprietary or sensitive information. As before, the common goal of the PPP can be the leitmotiv for guiding partnership decisions about what gets shared within the PPP and what gets disclosed to the public. All partners have an interest in finding mechanisms that maximize transparency and build trust, rather than invoking a blanket inability to share information.

In this sense, integrity also leans on transparency. Partners that promote transparency within and through the PPP can also bolster institutional, programmatic and scientific integrity in support of the PPP's common goals. This includes stocktaking on a regular, systematic, honest basis – of both the portfolio and the PPP itself – through progress reporting, midterm reporting, independent evaluating, and other ex post analysis that can be widely shared and absorbed. A PPP that uses transparency to build credibility with the public, as both citizens and consumers, is likely to benefit both public and private sector partners in the long run.

d) Mutuality – Partnerships are built on collectives.

Partners can collectivize more or less, depending on how much they want to partner, what they want to contribute, and what they want to achieve. Mutuality starts with a commonality of interests in the form of shared goals that bring partners together and sustain their endeavor. Mutuality can expand to include common ground for engaging. It can include sharing at various levels: governing body decision making, centralized administrative support, pooled funding, coordinated activities, and combined knowledge. Partners can collectively share a header under a branded partnership name.

In PPPs, mutuality spans across sectors. If the PPP objectives are framed with care – with precision and tailored to the sweet spot of overlapping interests – it may be less of a challenge. Many principles are, in principle, shared by public and private sectors. That includes orderly and predictable markets, rule of law and avenues of recourse, clarity and feasibility of regulations, fair competition and level playing fields, consumer awareness and empowerment, to name a few. If public and private partners use these and other basic precepts to operationalize specific partnership initiatives (see Box E), the bridge that spans the two sectors can stay robust.

Mutuality does not require the same motivations or even the same benefits. If government is working for the longterm public good, and industry is looking for short-term commercial solutions, and academia is pushing for more public Box D: The IOM workshop concluded that PPP success rested on a few key aspects:

- relatively narrow targets;
- common agendas that benefit all partners;
- complementary skills, contacts, perspectives that different partners bring;
- real incentives for industry partners to collaborate; and
- limited or no financial disincentives or competitive disadvantages.

information and knowledge, these disparate end points can still converge in shared objectives and principles that create the PPP. These varied ambitions can, for example, all embrace a scientific approach to solving a problem, or, to cite the specific case under consideration here, a neutral repository for storing and sharing data.

e) Stability and Flexibility – Like rock, like water.

All of the above contribute to keeping a PPP stable: complementarity breeds trust, which thrives on transparency, that fosters mutuality. Nothing, however, stays the same. As important as stability is flexibility, the ability of partners to adjust their PPP over time to reflect the changing environment and their own changing circumstances. Partnerships are not expected to be static, especially as they mature and grow through lessons learned and accretion over time. It behooves partners to build in flexibility from the start.

Collective decision making can be leveraged as an efficient tool for proposing and agreeing to change. Delegated roles and responsibilities let different elements of the partnership use their expert discretion to navigate operations in fluid environments. High level strategic purview within an articulated framework can effectively complement, guide and monitor on-the-ground implementation. And if partners feel mismatched over time, flexibility upfront can pave the way for exits as needed, so that no partner is stuck and disengagement can be smooth. These are the conditions that will, in fact, encourage partners to stay.

Too little foundational rock, and the PPP can collapse under its own weight, but too little flexible water, and the PPP will snap or tip over. PPPs need to stay fluid and attuned to changing landscapes: (i) on the consumer front, food preferences associated with rising incomes, raising awareness of the need for nutrients, increased urbanization, and generally consumer evolution from low to middle to high income countries; (ii) on the industry front, integration into regional and global markets, efficiency and reach of production systems, and value chains; and (iii) on the regulatory front, the need to respond to consumer and market conditions, expectations to recognize trends and foresee changes, and political winds. Rather than get caught in the gale, PPPs can establish themselves in ways that anticipate change.

f) Incrementalism and Sustainability – Let it grow slow.

Partnerships can follow the big bang theory and come into being all at once, or they can evolve over time. PPPs may well do both by taking time to solidify their foundations with ample common ground and common understandings before launching. Thereafter, they may expand their operations as their engagement is validated and reinforced.

PPPs can take time to develop, and some take years to pull into place. First building blocks include:

- Identifying leaders and champions within each included sector
- Establishing common ground and common goals
- Clarifying roles, responsibilities, and accountabilities
- Deciding what to collectivize, and what is under the PPP umbrella
- Projecting a time horizon and scope for contributions

As with other aspects of PPPs, how this plays out is a question of balance. Partners can embrace the ability to start with a narrowly scoped sweet spot, where they feel comfortable and confident, and then build from there. With sensitive issues around confidentiality, competition, conflicts of interest, institutional integrity, public trust, consumer confidence, and more, a prudent approach may be a solid approach, deliberate and accretive, with flexible room for growth. Sustainability may come from incremental steps more than initial scale.

B. Specifics of a Food Safety Capacity Building Data Sharing PPP

A zero version of a PPP structure is presented here in outline form for discussion purposes.

This zero version draws heavily from the successful experience of the public-private partnership "USDA Global Branded Food Products Database" for public health. (See the Development Phase Progress Report from the Steering Committee to the USDA dated January 2014, an internal document—reported to the USDA Under Secretary.)

Mission: To enhance global health by reducing the risk of *foodborne diseases* (FBDs) through increased understanding of food safety and improved implementation of food safety capacity building measures along entire food production and distribution chains through the development of an **international data sharing platform** available to government, industry, the scientific community, and the general public.

Objectives: To promote public health, food safety, and nutrition; reduce the risk of FBDs by integrating industry data (blinded and protected to ensure proprietary data is not linked to individual companies or actors) and public data for a comprehensive view of operating practices.

Justifications: Food safety capacity building data is a linchpin for ongoing investments in activities to improve public health; improving food safety capacity building efforts and reducing FBDs needs a combined, international, public-private effort; a PPP provides increased value over what either public or private sectors can do and monitor themselves; public sector interest in creating a platform with trusted, quality-controlled data that is correct; private sector participation demonstrates corporate responsibility and supports continuous improvement of their efforts; U.S. FSMA pre-positions combined public-private effort.

Measures of Progress: Seeking to achieve a certain degree of robustness within the database (% market share participating, level of data quality achieved, etc.); getting to the point where companies see the value and want to include their data.

Incremental Approach: Start with focus on data sharing and database to avoid diluting efforts; keep open to adding related elements over time, including training and capacity building support.

1) Baseline Principles

- Act on a shared value system: impact / inquiry / innovation / inclusion
- Maintain impartiality, financial transparency, and scientific integrity
- Build trust in the PPP as an ethical, legitimate way to conduct business
- Leverage unique resources, expertise, and perspectives that each partner brings
- Promote mutual understanding about roles and issues
- Share resources, especially around resource gaps
- Establish win-win relationships

2) Establishment To-Do Items

- agree on what outcomes the PPP is interested in and the types of data needed to measure impact
- based on data needs, understand what types of data are already being collected and whether it can be used in its current form
- consider how to make data collection transparent and comprehensive
- agree on main topics where technical or other expertise is needed; leverage working groups
- assess and address greatest gaps, potential conflicts of interest, proprietary concerns, other barriers to participation for broad public and private sector engagement
- establish clearly defined progress measures and agree on results framework

3) Structural Components

- a) Core Partners (for establishment purposes) Around five founding partners with essential roles for purposes of convening the PPP, representing public and private sectors, food safety and capacity building expertise, technical systems expertise (data repository entity), FSMA and international reach
- b) Listening Sessions (for establishment purposes) several in diverse locations for public input and feedback
- c) **Data Repository** Neutral (non-public sector, non-private sector) partner with a proven track record for managing complex and diverse data streams
- d) **Secretariat** Potentially same entity as for the Data Repository with core responsibility for supporting the PPP
- e) **Governing Body** (for operating purposes) Transitioning from Core Partners and adding key stakeholders, a partnership body with strategic and oversight responsibility for the PPP
- f) **Working Groups** (for operating purposes) Governing Body subgroups with specific subject matter expertise that support the PPP's work:
 - i. Operations Group (Core Partners),
 - ii. Criteria Group,
 - iii. IT Group,
 - iv. Legal Group,
 - v. Communications Group, and
 - vi. Lessons Learned Group.

a) Core Partner Roles:

- Core Partners shepherd the partnership building process until ready to convene the Governing Body; thereafter Core Partners continue as (i) part of the Governing Body, and (ii) the Operations Subgroup in an executive coordination function
- 2. Develop an explicit shared value system stressing impact, inquiry, innovation and inclusiveness
- 3. Meet weekly from beginning to stay well-coordinated.

b) Listening Sessions:

- 1. Convened as an international series to engage a broader group of stakeholders
- 2. Core Partners share information and gather feedback about the PPP

- 3. Participants are both users and providers of data; piggyback on other events where feasible
- 4. Three individuals to run each session one to facilitate, one to synthesize, one to record (follow protocol for U.S. rulemaking public sessions)
- 5. Develop mechanism for public comments on website
- 6. Important for creating the PPP, but also throughout the life of the PPP

c) Data Repository:

- 1. Success of the PPP depends on success of the database
- 2. Check ability to leverage existing elements, including existing data sources
- 3. Check ability to receive and hold confidential information
- 4. Check ability to collect and display information real time
- 5. Develop submission Process focus on ease of data transfer (potentially use multiple tracks)
- Quality control build automated QC checklist into data submission process, including expected ranges, mechanism to flag out-of-bounds data, etc. (review use Nutrition Labeling and Education Act (NLEA) data quality system; major manufacturers have documented QC programs for NLEA compliance)
- 7. Develop confidence Building measures (e.g., potential FDA/USDA seal of approval)
- 8. Key recommendation capture the data acquisition and quality system in a white paper published by the PPP to demonstrate the rigor behind the system.
- 9. Undertake continual assessment of needs, monitoring and updating of data.

d) Secretariat Role:

- 1. Serve as general hub, coordinator, first point of contact, gatekeeper, etc. for PPP
- 2. Arrange Listening Sessions
- 3. Arrange and support Governing Body and subgroup meetings
- 4. Coordinate subgroup activities; serve as interface between subgroups and Governing Body
- 5. Run PPP website
- 6. Provide staff, hire consultants
- 7. Provide legal entity role for PPP business, as agreed
- 8. Coordinate closely with database repository
- 9. Support Governing Body resource mobilization efforts in coordination with Communications Group
- 10. Scope of Secretariat depends on funding available and other support provided by partners

e) Governing Body Role:

- 1. Balance inclusion and workable number of participants
- 2. Combine decision making and observer participation; use consensus decision making
- 3. Private sector participation based open access, no competitive advantage, work through associations; develop code of conduct
- 4. Potential composition:
 - a. Core Partners
 - b. 4 public sector representatives
 - c. 4 private sector representatives
 - d. 2 scientific community / academia representatives
 - e. 2 NGO / CSO representatives

- f. 2 developing country representatives
- 5. Decide on Chair or co-Chairs
- 6. Agree on and adopt a foundational partnership document (PPP Charter)
- 7. Report at each meeting who has contributed what to the PPP and on RASCI chart progress
- 8. Identify short-term achievable goals vs. stretch goals re Listening Session requests
- 9. Develop a value proposition document (with Communications Group) including:
 - a. PPP data reposition to become a one-source database; submit once and done
 - b. Data quality standards of PPP (FDA/USDA sanctioned, etc.)
 - c. Potential use of validated algorithms for missing inputs
 - d. Essential tool for developing research strategies
 - e. Essential tool for supporting development and evaluation of public policy
 - f. Serves as master data for to-be-developed apps
 - g. Responds to government required data under FSMA
 - h. improves customer service
 - i. Availability of historical data
- 10. Take responsibility for resource mobilization with Secretariat support
- 11. Monitor progress re PPP results framework; update results framework; potentially lead to inclusion of partnership work on training and capacity building

f) **Operations Group Role:**

- 1. Pragmatism rather than ideology; accountability and transparency
- 2. Need to include champion supporters from both public and private sectors
- 3. Develop an adopted **partnership document** (charter-type rather than MOU-type) with foundational terms for Governing Body approval / endorsement
- 4. Develop roles and responsibilities in **RASCI charts** for each workstream (responsible, accountable, supportive, consulted, informed); follow up on different workstreams with relevant subgroups
- 5. Develop a budget and funding plan
 - a. Goal is to make PPP self-sustaining over time
 - b. How to ensure sustainability is this a revenue generating or paying membership model; initially does this rely on champion donors, including nontraditional donors, philanthropy, private sector foundations?
 - c. Direct funding preferably not tied to seat at the table choose governing body participants on other grounds
 - d. Industry's primary contribution is to provide data already involves financial burden
 - e. Research comparison before and after the database to demonstrate the value to prospective funders / partners
 - f. Evaluate revenue generating potential in providing specific analysis on data
 - g. Coordinate with Communications Group on resource mobilization strategy and materials
- 6. Consider forming a finance committee to support Operations Group / Governing Body
- 7. Develop feedback loops around submitted data as a platform for knowledge generation and sharing
- 8. Submit recommendations, as applicable, to Governing Body

g) Criteria Group Role:

- 1. Focus is on scope and quality of data (the "what")
- 2. Tasked with proposing short-term / long-term scope of repository data for Governing Body approval
- 3. Develop data criteria (attributes) consistent with current laws for Governing Body approval
- 4. Develop clear **process for quality control** (together with IT Group), including system for different levels of data quality to build trust; Criteria Group has first-line responsibility for quality of data in the PPP
- 5. Develop system management for timely, up-to-date submission of data and data archiving
- 6. Goal is a one-source database with robust search engine, downloadable data, updated periodically containing comprehensive, high quality, current data
- 7. Inclusive membership for greater buy-in and expertise; 12-15 members
- 8. Work closely with IT Group, overlapping membership
- 9. Develop a **statement of work** that ensures a comprehensive record of food safety capacity building is made available to government, industry, scientific community and general public
- 10. Develop a **statement of ground rules** (code of conduct) on transparency, decision trail, etc.
- 11. Make recommendations to IT Group about storing and maintaining data for easy access and linkages to related databases
- 12. Incorporate views from Listening Sessions
- 13. Consider establishing a data quality subcommittee (with overlapping membership) to oversee data quality before inclusion in database
- 14. Submit recommendations, as applicable, to Governing Body

h) IT Group Role:

- 1. Focus is on the mechanism and modality of database operations (the "how")
- Responsible for identifying infrastructure options for the Data Repository that ensure future scalability; consider CFS3, University of MD (synergy with the USDA Global Branded Food Products database)
- 3. Identify and build on existing and potential data sources and technology using robust outreach effort
- 4. Work on solutions that are not burdensome to industry, favoring single push to one place in standard format
- 5. Include user-friendly, easy-to-access search function
- 6. Develop plans for periodic reassessment of data, archiving data, submitting additional or updated information, communications system for notifying additions and updates
- 7. Develop algorithms for imputing missing information
- 8. Develop beta-testing plan and identify beta candidates to participate
- 9. Work closely with Criteria Group, overlapping membership
- 10. Submit recommendations, as applicable, to Governing Body

i) Legal Group Role:

- 1. Resource for developing positions on legally sensitive issues for PPP
- 2. Membership primarily legal staff from cross-section of partners
- 3. Consider how to handle confidential information, limit legal liability, mitigate risks and exposure; degree of Data Repository entity responsibility for safeguarding confidential information; what protections are available (e.g., FOIA exclusion re "trade secrets and commercial or financial information")
- 4. Develop PPP positions on ownership/copyright/usage
- 5. Develop an upfront approach for managing proprietary data; consider USDA Global Branded Food Products database experience
- 6. Advise on agreement / charter terms from PPP perspective
- 7. Submit recommendations, as applicable, to Governing Body

j) Communications Group Role:

- 1. Importance of transparency to explain PPP and build trust
- 2. Support secretariat in setting up a PPP website with interactive features
- 3. Help develop **short value proposition document** for Governing Body approval
- 4. Develop an outreach plan and materials to build PPP support; invitation to engage
- 5. Develop fundraising materials
- 6. Develop FAQs that highlight mission and objectives
- 7. Develop format and materials for Listening Sessions
- 8. Work closely with Secretariat
- 9. Submit recommendations, as applicable, to Governing Body

k) Lessons Learned Group Role:

- 1. Place to develop feedback loops around submitted data
- 2. Platform for knowledge generation and sharing
- 3. Promote development of derivative information from available data
- 4. Not meant to reduce focus on data sharing platform
- 5. Potentially lead to inclusion of partnership work on training and capacity building
- 6. Monitor progress re results framework for PPP; updating results framework

ANNEX 1: Experience in rolling out the produce safety trainings to growers in LMIC's

In 2018 and 2019, PIP rolled out two intensive trainings to develop a cadre of Spanish-speaking lead trainers to roll out the PSR in Latin America. Individuals were prescreened by IICA and the FDA Latin America office. In 2018, individuals were selected from each of the 13 countries (total 60 trained) to become lead trainers to deliver the trainings to growers, and in 2019, were selected from 8 countries, with a total of 61 additional trainers trained. Once the lead trainer candidates complete the training and fill out the required paperwork, they can apply to become lead trainers, with the ability to train on their own. As part of their payback requirements, they are to train an additional 125 individuals before they start to roll out their own training. PIP has an active role in collaborating with international industry associations, universities, government organizations, and others in the development and delivery of training programs that address local and regional needs of foreign farms in complying with the PSR. For this first set of intensive trainings of country lead trainers, IICA is facilitating the payment of their certification fees through Cooperative Agreement funds with FDA. In the future, if individuals choose to become a PSA Lead Trainer, the PSA Lead Trainer Supplemental Application is \$325 for non-profit organizations and \$500 for for-profit organizations. This fee covers the cost of the PSA Lead Trainer Review Committee member's time reviewing and approving applications, as well as any time spent conducting follow-up interviews with applicants.

Although FDA is a U.S. agency, it works with LMIC's. LMIC's are increasingly suppliers of food consumed in the U.S. The U.S. is also a member of the WTO, and capacity building is an important part of developed country membership. However, the fees associated with the various Alliance training services, as mentioned above, were set up primarily with US producers and processors in mind, without considering foreign implications. As it turns out, many developing country producers are finding it cost prohibitive to pay for training materials, certificates, and travel to training sessions. For many of the developing country producers, the cost of the training material and certification at \$85 is prohibitive. Figure A (on the next page) shows how the same nominal cost can impose different levels of financial burden on international growers around the world. Using the daily per capita income or consumption (from the World Development Indicator), we calculated the ratio between certificate cost and daily per capita income of the country. Considering that farming households are often at the lower end of income distribution in developing countries, we used the bottom 40% average daily per capita income or consumption to represent the financial burden of certificate cost on farming households. The financial burden of certificate cost in exporting countries can be more than 10 times in Latin America and Asia and around 30 times in Africa, compared to the U.S. The contrast is even more drastic. Although an average low-income individual can afford a certificate with less than 4 days' daily income, it can take a low income individual up to a month in Latin America or Asia and over 4 months in Africa.

FDA's Office of International Programs recently entered into a cooperation agreement with IICA to determine if there are alternative delivery mechanisms for produce safety materials. The goal is to find something appropriate for produce producers in developing countries who do not have the financial

means to pay for training, the certification process in addition to taking a week off of work to attend lecture-based trainings.



Figure D: Produce Safety Grower Certificate Cost to Mean Daily per Capita Income (Bottom 40%)

ANNEX 2: Principles for Building PPPs to Benefit Food Safety, Nutrition and Health Research

1. Have a clearly defined and doable goal to improve the health of the public

2. Ensure that objectives will meet stakeholder partners' needs, with a clearly defined baseline to monitor progress and measure success

3. Select objective scientific measurements capable of providing common ground for both public and private-sector research goals

4. Articulate a clear statement of work, rules, and partner roles, responsibilities, and accountability, to build in trust, transparency, and mutual respect as core operating principles

5. Considering the importance of balance, ensure that all members possess appropriate levels of bargaining power

6. Minimize conflict of interest by recruiting a sufficient number of partners to mitigate influence by any single member and to broaden private-sector perspectives and expertise

7. Adopt research questions and methodologies established by partners with no vested financial interest in them, ideally in the precompetitive space

8. Engage partners who agree upon specific and fundable research question(s) to be addressed by the partnership

9. Enlist partners who are committed to the long term as well as the sharing of funding and research data

10. Along with government and the private sector, include academics and other members of civil society as partners

11. Be flexible and ensure ongoing transparent communications

12. Consider a third-party convener to ensure equality at the table, clarify rules, establish operational guidelines, and specify funding arrangements

Source: Principles for Building Public-Private Partnerships to Benefit Food Safety, Nutrition and Health Research, Rowe, S. et.al, Nutrition Reviews 2013; 71(10):682-691.