

FDA's International Food Safety Capacity-Building Plan



**Food Safety Modernization Act
Section 305**

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U.S. Department of Health
and Human Services



U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition

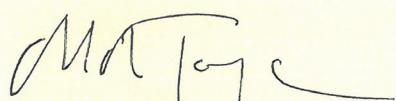
Letter from the Deputy Commissioner

I am pleased to present the U.S. Food and Drug Administration's (FDA) International Food Safety Capacity-Building Plan. While this Plan is mandated by the FDA Food Safety Modernization Act (FSMA), we have long recognized how important international capacity building is to meeting our food safety objectives. Capacity building provides us with an opportunity to enhance the safety of the multitude of food products coming into the United States from other countries each year. About 15 percent of the U.S. food supply is imported, including 50 percent of fresh fruits, 20 percent of fresh vegetables and 80 percent of seafood.

That is why FDA has long been involved on many fronts, working with various organizations and other government agencies, to help build the food safety capacity of countries that export food to the United States. The inclusion of international capacity building in FSMA reinforces its importance and provides us with an opportunity to move us even further on our path. At the same time, we recognize that capacity building is important domestically as well and have initiatives underway within the United States.

Capacity building is one tool in a larger toolbox FSMA has provided for FDA to hold imported foods to the same standards as domestic foods. FSMA requires every food importer to establish a risk-based Foreign Supplier Verification Program to provide documented assurances to FDA that importers are managing their supply chains. Congress also recognized the important role already being played in the international arena by private third-party audits and has given FDA a mandate to recognize accreditation bodies that accredit third-party auditors to, among other things, issue import certifications. Third-party certification does not substitute for inspection, so FSMA also mandates more foreign inspections. These and other elements of FSMA work in a complementary way to address the safety of imported foods.

As FDA moves forward to implement our capacity-building plan as well as other FSMA mandates, we recognize that ensuring food safety takes partnership—government, industry, academia, and consumers working together. That is why we held a public meeting on international capacity building in June of 2012, and we will continue to involve stakeholders now and in the future. We look forward to working with you to build a modern, global food safety system.



Michael R. Taylor

Deputy Commissioner for Foods and Veterinary Medicine

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Acronyms

AOAC	Association of Analytical Communities
APEC	Asia-Pacific Economic Cooperation
EPA	U.S. Environmental Protection Agency
FAO	Food and Agriculture Organization of the United Nations
FAS	Foreign Agricultural Service
FDA	U.S. Food and Drug Administration
FERN	Food Emergency Response Network
FSCF	Food Safety Cooperation Forum
FSIS	Food Safety and Inspection Service
FSMA	Food Safety Modernization Act
FSVP	Foreign Supplier Verification Program
FVM	Foods and Veterinary Medicine Program
GFSP	Global Food Safety Partnership
HACCP	Hazard Analysis and Critical Control Point
IFSTL	International Food Safety Training Laboratory
IICA	Inter-American Institute for Cooperation on Agriculture
INFOSAN	International Food Safety Authorities Network
JIFSAN	The Joint Institute for Food Safety and Applied Nutrition
NGO	Non-Governmental Organization
OECD	Organization for Economic Cooperation and Development
PMP	Performance Monitoring Plan
PTIN	Partnership Training Institute Network
PVS	Performance, Vision, and Strategy tool
SPS	Sanitary and Phytosanitary
STDF	Standards and Trade Development Facility
USAID	U.S. Agency for International Development
USDA	U.S. Department of Agriculture
VQIP	Voluntary Qualified Import Program
WHO	World Health Organization
WTO	World Trade Organization

Executive Summary

In 2011, Congress enacted the U.S. Food and Drug Administration's (FDA) Food Safety Modernization Act (FSMA), recognizing the unique challenges faced by FDA in the area of food safety in the 21st century. FSMA gives the agency new tools for meeting these challenges, shifting the focus from responding to contamination to preventing it. More specifically, FSMA directs FDA to build a new food safety system based on the public health principle of comprehensive prevention, an enhanced focus on risk-based resource allocation, and partnership across the public and private sectors to minimize hazards from farm-to-table. In addition, Section 305 of FSMA calls on FDA to develop a comprehensive plan to expand the technical, scientific, and regulatory capacity of foreign governments and their respective food industries in countries that export foods to the United States (the "Plan"). This Plan meets the Section 305 requirement, and does so by incorporating FSMA's principles of comprehensive prevention, risk-based resource allocation, and partnering.

This Plan provides a strategic framework for FDA's international food safety capacity-building activities. It provides examples of how FDA can expand the technical, scientific, and regulatory capacity of foreign governments and their food industries, and it describes capacity-building activities that the agency is already engaged in. This Plan will also enable all stakeholders to see the breadth of food safety capacity-building efforts that FDA is pursuing. It charts a direction for how FDA will prioritize its capacity-building efforts based on risk, and how the agency will work in partnership with counterpart authorities, industry, and other organizations in order to achieve lasting food safety results. FDA's capacity-building programs will aim to support efficient and sustainable improvements to countries' food safety systems. To increase the efficiency of these new programs, FDA will be strategic in how it allocates its scarce resources.

As described in this Plan, the agency will use enhanced intelligence of food safety risks on a country-by-country, commodity-by-commodity basis to determine the best candidates for technical assistance and capacity-building programs. FDA will coordinate with partners to avoid duplication of efforts and to broaden the reach of technical assistance and capacity-building efforts. FDA will use data to develop strategies, allowing the agency to make decisions about capacity building based on identifiable needs, while also allowing the agency to measure the impact of its efforts.



As explained in more detail below, this Plan addresses the six elements required by Section 305¹ by incorporating them into four key goals and objectives, as supplemented by additional themes. The Plan's key goals and objectives are:

Key Goals & Objectives

Goal 1: Ensure efficiency across the Foods and Veterinary Medicine (FVM) Program

- Objective 1.1** Ensure collaboration across the FVM Program
- Objective 1.2** Maximize coordination within FDA

Goal 2: Increase effectiveness through evidence-based decision making

- Objective 2.1** Enhance intelligence regarding food safety risks
- Objective 2.2** Utilize food safety assessments
- Objective 2.3** Design for effectiveness

Goal 3: Support the exchange of information between FDA and foreign government agencies or other entities

- Objective 3.1** Support bilateral and multilateral arrangements and agreements with foreign governments, including provisions to provide for responsibility of exporting countries to ensure food safety (*Element 1 of FSMA's Section 305*)
- Objective 3.2** Establish new or identify existing mechanisms to support secure electronic data sharing with foreign governments or other entities (*Element 2 of FSMA's Section 305*)
- Objective 3.3** Explore appropriateness of relying on mutual recognition of inspection reports (*Element 3 of FSMA's Section 305*)

Goal 4: Enhance technical assistance and capacity building in food safety

- Objective 4.1** Work with partners to develop/deliver food safety training programs focused on best practices and global food safety principles
- Objective 4.2** Train foreign governments and food producers on U.S. requirements for safe food (*Element 4 of FSMA's Section 305*)
- Objective 4.3** Develop recommendations on whether and how to harmonize requirements under the Codex Alimentarius (*Element 5 of FSMA's Section 305*)
- Objective 4.4** Support provisions for the multilateral acceptance of laboratory methods and testing and detection techniques (*Element 6 of FSMA's Section 305*)

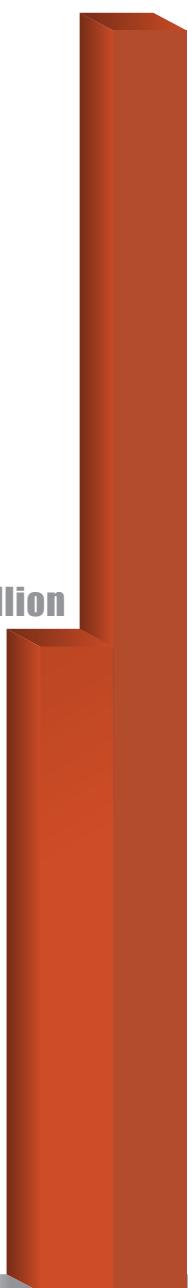
See Appendix A for a summary of FDA's key actions for achieving these goals and objectives.

¹ Under Section 305, the capacity-building plan must include, as appropriate: (1) Recommendations for bilateral and multilateral arrangements and agreements, including providing for responsibilities of exporting countries to ensure food safety; (2) Provisions for secure electronic data sharing; (3) Provisions for mutual recognition of inspection reports; (4) Training of foreign governments and food producers on U.S. requirements for safe food; (5) Recommendations on whether and how to harmonize requirements under the Codex Alimentarius; and (6) Provisions for multilateral acceptance of laboratory methods and testing and detection techniques.

Introduction

The U.S. Food and Drug Administration (FDA) is responsible for protecting the safety of much of the food supply reaching U.S. consumers, regardless of whether such food is produced domestically or imported. FDA's food safety responsibilities have become more challenging as the United States steadily increases the amount of food it imports. During the period between 2002 and 2010, the number of instances (entry lines) of imported food nearly doubled, climbing from 4.4 million to 8.6 million import lines. As of 2011, about 15 percent of all food products consumed in the U.S. were imported. For certain food products, the proportion of imports is greater: approximately 20 percent of fresh vegetables, 50 percent of fresh fruit, and 80 percent of seafood consumed in this country are imported.

**2010
8.6 Million**



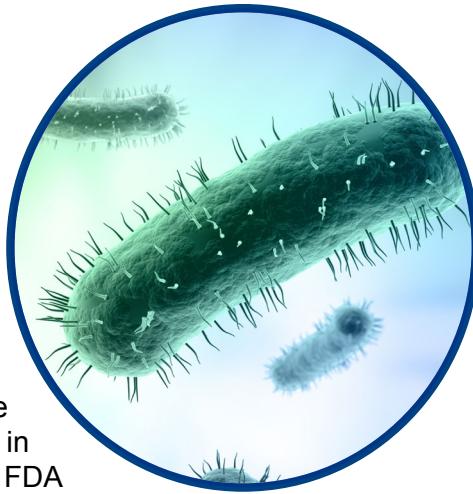
As food sources become more global, supply chains have become increasingly complex. Traditionally, FDA has primarily relied on inspections at ports of entry to ensure the safety of the commodities regulated by the agency. To respond to increasing globalization, however, FDA must extend its reach beyond U.S. borders. The responsibility for safe food must move upstream in the supply chain, closer to the source of the food. Consequently, there must be responsibility at each step of the food supply chain. FDA is modernizing the way it fulfills its mission to promote and protect public health and to help secure the benefits of global trade, while at the same time ensuring the safety of products prior to arrival at the border. To respond to increasing globalization and fulfill its mission, FDA must engage with its overseas regulatory counterparts, with overseas food industries, and with regional and international organizations to ensure the safety of food products in the global supply chain.

The FDA Food Safety Modernization Act (FSMA), which was signed into law in January 2011, recognizes the importance of such partnerships. The law calls for numerous enhanced collaborations, as well as the development of this Plan for building international food safety capacity. Specifically, the legislation directs FDA "to develop a comprehensive plan to increase the technical, scientific, and regulatory food safety capacity of foreign governments and their respective food industries, from which foods are exported to the United States." As indicated throughout this Plan, building international food safety capacity contributes to FDA's efforts to ensure the safety of imported foods. This Plan sets forth a strategic framework for how FDA will develop international food safety capacity. Ultimately, FDA may develop a more specific, detailed operational document for implementing its capacity-building strategies. Additionally, FDA's ability to implement the actions laid out in this Plan is contingent upon the availability of funding and resources.

While the mandate to develop a capacity-building plan is new, FDA has successfully supported food safety capacity-building efforts and conducted training programs for many years. The agency has participated in global multilateral food safety programs, including through the World Health Organization (WHO), train-the-trainer programs (e.g., good agriculture practices), various seminars and web postings, and collaborations with other U.S. government agencies, among other efforts.

Background

Contamination incidents and outbreaks of foodborne illness have a substantial impact on public health – an estimated 48 million cases of foodborne illness occur every year in the United States, resulting in an estimated 128,000 hospitalizations and 3,000 deaths.² These outbreaks and incidents disrupt the food system at great economic cost and undermine public confidence in the food supply. Due to changes in the way food and feed products are produced and distributed, the increase in imported products, and the ongoing risk of emerging foodborne pathogens, FDA must undergo a paradigm shift in the way it safeguards America's food supply.



In response to various public health issues and the additional challenges posed by globalization, FDA recently released its “Global Engagement Report,” detailing the many activities and strategies FDA is using to transform itself from a domestically focused agency to a global public health agency.³ The report describes the steps the agency is taking to ensure that imported food, drugs, medical devices, and other regulated products meet the same rigorous standards for safety and quality as those manufactured domestically. Over the next 10 years, FDA will be working to transform itself from a predominantly domestically focused agency, operating in a globalized economy, to an internationally focused agency, fully prepared for a regulatory environment in which FDA-regulated products know no borders. Many of these themes were also echoed in a 2012 report by the Institute of Medicine entitled “Ensuring Safe Foods and Medical Products Through Stronger Regulatory Systems Abroad,”⁴ which was commissioned by FDA.

Collectively, the reports make clear that strengthening the safety and integrity of the global supply chain is and should be a key FDA priority. Strengthening the capacity of other countries’ food safety systems, including their regulatory systems, is critical in this regard and helps prevent problems in the foreign supply chain before they occur and before they reach U.S. borders.

FDA has taken many steps to work with countries around the globe to improve the safety of food placed in international commerce. In partnership with international organizations, FDA has supported global food safety efforts through activities such as trainings, technical exchanges, and assisting in the development of international food safety standards. In addition, FDA has expanded its global presence by establishing offices around the world. (More information on how FDA supports these efforts through its Foods and Veterinary Medicine [FVM] Program can be found in FDA’s FVM Strategy.⁵)

FDA has established:

- A China office, with posts in Beijing, Shanghai, and Guangzhou
- An India office, with posts in New Delhi and Mumbai
- A Latin America office, with posts in San Jose, Costa Rica; Santiago, Chile; and Mexico City, Mexico
- A Europe office, with posts in Brussels, Belgium; London, United Kingdom; and Parma, Italy
- A Sub-Saharan Africa post, in Pretoria, South Africa
- A Middle East and North Africa post, in Amman, Jordan
- An Asia-Pacific Office, in FDA headquarters

² Centers for Disease Control and Prevention (CDC). 2011 CDC Estimates of Foodborne Illness in the United States. (Available at: <http://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html>) Accessibility verified February 2013. A comparable analysis cannot be made between CDC’s 2011 estimates of foodborne illness and findings from earlier years due to a new methodology being used in 2011.

³ FDA. 2012. *Global Engagement Report*. (Available at: <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm298576.htm>) Accessibility verified February 2013.

⁴ National Research Council. 2012. *Ensuring Safe Foods and Medical Products Through Stronger Regulatory Systems Abroad*. Washington, D.C.: The National Academies Press. (Available at: http://www.nap.edu/catalog.php?record_id=13296) Accessibility verified February 2013.

⁵ FDA. 2012. *Foods and Veterinary Medicine Strategic Plan 2012 – 2016*. (Available at: <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/ucm273269.htm>) Accessibility verified February 2013.

FDA's international offices work with regulators, industry, scientific and academic communities, and other local government agencies. They build links with those communities and are the face of FDA overseas. They are developing regional and country-specific knowledge, monitoring events that affect the safety of food products that might enter the United States, seeking proactive means to mitigate emerging risks, providing information about FDA requirements for U.S.-bound products, and collaborating to strengthen regulatory science and evidenced-based approaches to product safety and quality.

In considering how to effectively enhance international food safety capacity, FDA has reviewed numerous global reports and studies. Just a few are described here.

- A report by the Food and Agriculture Organization (FAO)/WHO concluded that the development of an integrated regulatory system for food control needs to be founded on a transparent, risk-based approach. This report, titled "Assuring food safety and quality, Guidelines for strengthening national food control systems," also emphasized the importance of establishing strong relationships and mutual support among all stakeholders from farm to table, and provided valuable information on how to promote effective collaboration and assist in the development of national food control systems.⁶
- The World Bank has analyzed its own projects related to food safety.⁷ Similar to FAO/WHO, the World Bank stressed the importance of using a risk-based approach when determining what projects to support and deciding how to prioritize resources. The World Bank also emphasized the importance of increasing cooperation and participation among stakeholders, establishing public-private partnerships, and incorporating training and marketing activities. The report stressed the need for close connections between safety and quality management in practice, as well as small, but crucial, infrastructure investments or policy reforms in order to ensure project success. Lastly, the report emphasized the need for evaluations of public health outcomes from regulation. Such outcome evaluations will enhance countries' understanding of their own public health priorities and provide evidence-based guidelines for further developing food safety regulations.⁸
- The principles contained in a 2005 document published by the Organization for Economic Cooperation and Development (OECD), The Paris Declaration on Aid Effectiveness, stress the importance of ownership of the development of food safety priorities, mutual accountability, harmonization, alignment (with other donors and governments), and a focus on results.⁹ These five principles were developed based on decades of experience and were designed to improve the quality and impact of development. FDA is aligning its technical assistance and capacity-building efforts with these core principles to help ensure that the agency's efforts are effective, efficient, and sustainable.
- A report by the Standards and Trade Development Facility (STDF), titled "Establishing Priorities for SPS Capacity-building: A Guide to Multi-Criteria Decision-Making," provides a framework to help decision makers prioritize and make choices on where to allocate resources for sanitary and phytosanitary (SPS) capacity building. Specifically, the framework can be used to: (1) enhance the economic efficiency of SPS capacity building; (2) promote transparency and accountability in decision making; and (3) facilitate a more inclusive discussion surrounding the decision-making process. Application of the framework can help ensure resources are used in an efficient manner.¹⁰

⁶ FAO/WHO. 2003. *Assuring food safety and quality, Guidelines for strengthening national food control systems*. Food and Nutrition Paper No. 76. (Available at: <ftp://ftp.fao.org/docrep/fao/006/y8705e/y8705e0.pdf>). Accessibility verified February 2013.

⁷ The projects that were analyzed included 65 projects related to food safety, quality control, and/or animal health (i.e., Sustainable Coastal Resource Development Project, China, 1998; Agricultural Services and Institutional Development Project, Argentina, 1991; Animal & Plant Health Protection Project, Brazil, 1999; and Agricultural Services Project, Ghana, 2000).

⁸ Unnevehr, Laurian, and Hirschhorn, Nancy. 2002. Food Safety Issues in the Developing World. World Bank Technical Paper No. 469. World Bank: Washington, D.C.

⁹ OECD Development Co-operation Directorate. *The Paris Declaration on Aid Effectiveness and the Accra Agenda for Action*. (Available at: <http://www.oecd.org/dac/aideffectiveness/34428351.pdf>) Accessibility verified February 2013.

¹⁰ Henson, Spencer and Masakure, Oliver. 2012. *Establishing Priorities for SPS Capacity-building: A Guide to Multi-Criteria Decision-Making*. STDF. (Available at: http://www.standardsfacility.org/Files/EconAnalysis/MCDA_FrameworkGuide.pdf) Accessibility verified February 2013.

Provisions of FSMA

FSMA enables FDA to better protect the public health by strengthening the food safety system. The statute enables FDA to focus on preventing food safety problems, rather than merely reacting to problems after they occur. Specifically, the legislation provides significant enhancements to FDA's ability to achieve greater oversight of the millions of food products coming into the United States from other countries each year.

FSMA embodies the principle of prevention by requiring those who produce and import food ensure compliance with (or use of) adequate preventive controls. FSMA also provides FDA with new tools to require that imported food meets U.S. safety standards.

The law's major changes to the import system include:

Importer accountability: For the first time, importers have an explicit responsibility to verify that their foreign suppliers have adequate preventive controls in place to ensure that the food they produce is safe.

Third-party certification: FSMA directs FDA to establish a program through which qualified third parties can certify that foreign food facilities comply with U.S. food safety standards. This certification may be used to facilitate the entry of imports, as described below.

Certification for known food safety risks: FDA has the authority to require that imported foods with a known food safety risk be accompanied by a certification or other assurance of compliance as a condition of entry into the United States.

Voluntary qualified importer program: FDA must establish a voluntary program for importers that provides for expedited review and entry of foods from participating importers. Eligibility is limited to, among other things, importers offering food from certified facilities.

Authority to deny entry: FDA can refuse entry of food from a foreign facility into the United States if the facility or the country in which the facility is located refuses to permit entry of FDA inspectors to inspect the facility.

Capacity building of foreign governments with respect to food safety: FDA has been tasked to develop this comprehensive Plan to expand food safety capacity of foreign governments and their respective food industries that export foods to the United States.

In addition to these FSMA-mandated activities, FDA is also developing a process for conducting international systems recognition assessments to, among other things, assist the agency with setting its food safety regulatory priorities. FDA envisions such assessments¹¹ providing a process for determining whether a country's food safety system offers a system of protections similar, though not identical, to the U.S. food safety system, and the country's food safety authority provides similar oversight and monitoring activities for food produced under its jurisdiction. It is worth noting that food safety capacity building can support countries and their respective industries that are not able to meet the above-described FDA requirements or participate in the new FSMA importer programs.

¹¹ In March 2011, FDA held a public hearing on comparability of food safety systems and import practices of foreign countries. The purpose of the meeting was to provide stakeholders the opportunity to discuss FDA's use of international comparability assessments as a mechanism to enhance the safety of imported foods and animal feed and lessons learned through equivalence determinations. (Details of the meeting are available at: <http://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/ucm243781.htm>) Accessibility verified February 2013.

Goal of Capacity-Building Plan

As discussed above, Section 305 of FSMA, titled “Building Capacity of Foreign Governments with Respect to Food Safety,” directs FDA to develop a comprehensive plan to expand the technical, scientific, and regulatory food safety capacity of foreign governments and their respective food industries, from which foods are exported to the United States.

Congress identified six elements (listed below) in Section 305 of the Act, and provided that the Plan must include, as appropriate:

1. Recommendations for bilateral and multilateral arrangements and agreements, including provisions to provide for responsibility of exporting countries to ensure the safety of food.
2. Provisions for secure electronic data sharing.
3. Provisions for mutual recognition of inspection reports.
4. Training of foreign governments and food producers on U.S. requirements for safe food.
5. Recommendations on whether and how to harmonize requirements under the Codex Alimentarius (“Codex”).
6. Provisions for the multilateral acceptance of laboratory methods and testing and detection techniques.

FDA interprets the phrase “as appropriate” to mean that the agency has flexibility in determining the extent to which each element should be stressed in this Plan. Therefore, FDA used its policy and subject matter expertise to determine the feasibility of, and emphasis given to, each of the six elements. Furthermore, Congress directed that the Plan be “comprehensive,” a charge that FDA interprets to mean that the Plan may go beyond the six elements listed in the legislation. Consequently, this Plan incorporates several additional themes. Specifically, the Plan incorporates themes associated with evidence-based decision making, partnerships, and assessment analysis.

FDA anticipates that this Plan will provide a strategic framework for the agency over the next five years, with periodic interim assessments and an in-depth evaluation after five years. Furthermore, the agency’s ability to implement the actions in this framework is dependent on the availability of funding and resources.

In developing this capacity-building Plan, FDA has kept in mind Article 9 of the World Trade Organization (WTO) Agreement on the Application of SPS Measures, which states that “Members agree to facilitate the provision of technical assistance to other Members, especially developing country Members.” FDA has also kept in mind six guiding principles for capacity building. These principles are described in the text box on page 6.

FDA's Guiding Principles for the Capacity-Building Plan

To provide food safety technical assistance and undertake capacity-building efforts in countries that export food to the United States, FDA is guided by the following overarching principles:

- Ownership:** Partnering countries will take active leadership over the development of their food safety strategies and policies. FDA will consult with the food safety authorities of partnering countries about the needs and approaches they identify so that partnering countries maintain a sense of ownership over the strategies and policies that are adopted.
- Alignment:** FDA will work in coordination with national development strategies, institutions, and food producers of potential partner countries. FDA will work with organizations in partner countries that have similar goals (such as public health and food safety).
- Leverage:** FDA will coordinate its efforts with other countries and organizations so duplication of work is reduced and resources will be used productively.
- Managing for Results:** As FDA designs and evaluates capacity-building programs, the agency will use a performance management approach to focus capacity-building efforts on results that are linked to public health outcomes.
- Mutual Accountability:** FDA and its partners are accountable for their respective efforts. In addition, mechanisms will be established to ensure work progresses according to the pre-determined plan. All parties will participate in setting goals and will work together toward accomplishing those goals.
- Sustainability:** To help ensure the sustainability of capacity-building programs developed pursuant to this Plan, FDA will seek the “buy in” and clear commitments from partnering countries. In addition, FDA will encourage and support partners in their efforts to create and maintain the structures necessary to sustain food safety programs.

The use of these principles will help FDA be more targeted in its planning.

Consultations

Congress directed that the Plan be developed in consultation with certain federal officials, including the Secretary of Agriculture, the Secretary of State, the Secretary of the Treasury, the Secretary of Homeland Security, the Secretary of Commerce, and the U.S. Trade Representative. Congress also directed that FDA consult with other stakeholders such as food industry representatives, foreign government officials, non-governmental organizations (NGO's) that represent interests of consumers, and other stakeholders. In addition to the congressionally-required consultations, FDA also consulted with the Environmental Protection Agency (EPA); the U.S. Agency for International Development (USAID); the Alcohol and Tobacco Tax and Trade Bureau; the U.S. Small Business Administration; academic institutions; participants in a FDA public meeting dedicated to international capacity building; trade associations; and small businesses.

FDA held several meetings to consult with various stakeholders:

- March 2011: Washington, D.C. (a panel at an FDA Public Hearing)
- July 2011: Washington, D.C. (FSMA meeting held at the Pew Charitable Trusts)
- March 2012: Washington, D.C. (meeting with U.S. government agencies)
- March 2012: Geneva, Switzerland (WTO/STDF work group meeting)
- April 2012: Panama City, Panama (meeting with food safety representatives of many Latin American countries)
- June 2012: Washington, D.C. (public meeting for this Plan)¹²
- July 2012: Rome, Italy (meeting on the margins of the Codex Commission meeting)
- October 2012: Washington, D.C. (consultation with U.S. government agencies)

FDA also established a docket to collect comments, data, and information relevant to the international capacity-building Plan (Docket No. FDA-2012-N-0437). In developing this Plan, FDA considered all comments it received, both oral and written. The following is a brief summary of the comments FDA received.

One of the most common themes in the comments centered on the need for FDA to ensure that the Plan is structured around The Paris Declaration on Aid Effectiveness. Recommendations included ensuring that the Plan is aligned and harmonized with existing food safety programs and strategies, such as WHO/FAO's "Guidelines for strengthening national food control systems."¹³ Several comments suggested that FDA coordinate with foreign governments, industry, academia, and consumer groups to help identify and implement capacity-building activities. For example, these comments suggested that FDA utilize existing food safety programs, networks, and initiatives, such as training institutions, lab networks, and global databases. Additionally, many of the comments suggested that the Plan support the development of public/private partnerships and clarify the roles and responsibilities of FDA and each partner. According to these comments, such approaches will improve information sharing, allow for better targeting of capacity-building activities, and support increased ownership and mutual accountability.

Multiple comments recommended that FDA prioritize its capacity-building efforts based on risk and need. Other comments suggested that FDA support global food safety (and not just meet U.S.-specific requirements). Additionally, comments requested that the Plan define the various terminologies used and provide a clear action plan that includes specific deliverables and goals, as well as information on exactly how FDA plans to prioritize and leverage its resources. Comments also stressed that FDA be transparent in its efforts and address how its activities will be sustainable. Other comments recommended strategies for ensuring the sustainability of FDA's capacity-building efforts, through approaches such as improved leveraging of existing resources and close collaboration with local institutions, experts, and universities.

In addition, a number of comments stated that the Plan should permit flexibility and avoid creating a "one-size fits all" approach to capacity building. Such comments stressed that needs vary across regions and countries, and recommended that capacity-building efforts take into consideration the distinct local conditions of developing countries. For example, comments noted that FDA should be mindful of the fact that arrangements and agreements should take into account countries' different legislative frameworks and food safety systems. Additional comments requested that FDA ensure that trainings are targeted and adapted appropriately to training needs, and tailored to specific regional and national contexts. A few comments also focused on the formats for training, noting the availability of web-based trainings and in-person trainings (e.g., classroom or hands-on) and suggesting that different formats should be explored when selecting the training methodology for a specific capacity-building activity. Some comments maintained that train-the-trainer approaches should be adopted where possible.

¹² For more information on FDA's International Capacity Building with Respect to Food Safety Public Meeting, held June 19, 2012, please visit: <http://www.fda.gov/Food/FoodSafety/FSMA/ucm303463.htm>. All comments submitted on the public meeting through the Federal Register Notice [Docket No. FDA-2012-N-0437] are publicly accessible through www.regulations.gov. Accessibility verified February 2013.

¹³ FAO/WHO. 2003. *Assuring food safety and quality, Guidelines for strengthening national food control systems*. Food and Nutrition Paper No. 76. (Available at: <ftp://ftp.fao.org/docrep/fao/006/y8705e/y8705e00.pdf>) Accessibility verified February 2013.

Comments also stressed that the Plan should recognize and acknowledge the possibility of assessing countries' food regulatory systems to determine whether such systems offer comparable levels of protection. According to other comments, FDA should consider the various audiences and stakeholders who have a role in developing and enforcing food safety standards, and should be cognizant of the different approaches that can be used to ensure the safety of food. Similarly, many comments stated that FDA should share its own training approaches. In addition, several comments recommended that FDA attempt to harmonize its own food safety requirements with Codex standards where appropriate, as well as identify the factors it will consider in determining the appropriateness of Codex standards. Furthermore, comments emphasized that Codex standards should be the basis of training programs and capacity-building activities. Additional comments maintained that focusing only on U.S. requirements and training methodologies is likely to have a limited effect on food safety outcomes.

To help promote laboratory capacity, a few comments recommended that FDA work with the private sector to establish a consensus about laboratory standards and testing methods, which, according to these comments, will in turn increase opportunities for countries to share information. Several comments maintained that FDA should also rely on internationally accepted laboratory methods when possible, and be transparent in sharing FDA's laboratory methods. Given that many labs have equipment limitations, especially those in developing countries, one comment recommended establishing a joint laboratory network at a regional level. According to that comment, this would leverage resources and develop a sustainable long-term approach. Several comments stressed the importance of FDA partnering with training institutions, domestic and international laboratory networks, and other parties to conduct outreach and education. According to these comments, this is an area where public-private partnerships can be very helpful, especially when the partnerships include assistance from academic organizations. A few comments also stated that "industry labs" should have the capability of becoming accredited and recognized in order to leverage resources.

With regards to mutual recognition of inspection reports, several comments maintained that FDA should develop a process to evaluate any potential conflicts of interest among the parties conducting inspections. These comments stated that such standards are needed before FDA provides for mutual recognition. Comments also requested that FDA recognize and acknowledge that other countries have inspection systems similar to that of the United States. Some comments suggested that where third-party certification/verification programs have proved effective in establishing quality and safety, such programs should be taken into consideration in deciding whether there is confidence in a product or regulatory regime. Additionally, some comments recommended that FDA consider the value of third-party certification/verification programs (including reports both by foreign governments and third-party auditors) in contexts beyond capacity building.

Some comments recommended that the Plan promote increased surveillance of foodborne illness and increased data sharing between all entities involved in food safety. Additional comments stressed that FDA should consider existing global initiatives related to surveillance and data sharing when developing the international capacity-building Plan. Comments also stated that FDA needs to consider appropriate ways to share data while being cognizant of intellectual property and trade secret protections, and that FDA should include recommendations in the Plan for ensuring that confidential information is protected. When FDA seeks to engage in data-driven decision making, commenters requested that the agency incorporate the use of available data already being captured by international organizations such as the WHO. According to these commenters, such use will support harmonization and sharing of information. Additionally, comments requested that the Plan be clear as to how FDA intends to use data it collects, and that the Plan explain the appropriate use of data.

Goal 1: Ensure efficiency across the Foods and Veterinary Medicine Program

Given the breadth and complexity of FSMA, FDA must develop mechanisms to promote effective collaboration within the agency and across agency components. Such collaboration should be executed with the goal of using FDA resources efficiently to develop risk-based strategies to address food safety issues. The goals and objectives described in this section focus on internal FDA management. They therefore differ from goals 2 - 4, as those goals address FDA's external strategies.

Objective 1.1 – Ensure collaboration across the FVM

FDA's FVM Program established a number of internal work groups responsible for implementing FSMA. These work groups were organized to focus on distinct FSMA provisions, and each such group draws expertise from across FDA and other U.S. government agencies. In developing this Plan, FDA benefitted greatly from the information and guidance generated by these work groups (especially the FSMA Imports Team). FDA will continue to draw from the work groups as the agency sets international capacity-building priorities.

Such collaboration makes sense. International food safety capacity building is closely linked to other FSMA provisions, namely Sections 303 and 308. Section 303, Authority to Require Import Certifications for Food, authorizes FDA, based on risk considerations, to require an article of food offered for import into the United States to be accompanied by certifications or other assurances that the food complies with relevant provisions of the Federal Food, Drug, and Cosmetic Act. In determining whether an article of food is required to have a certification, FDA shall consider a finding, supported by scientific, risk-based evidence, that the food safety programs, systems, and standards in the country, territory, or region of origin of the food are inadequate to ensure that the article of food is as safe as a similar article of food that is manufactured, processed, packed, or held in the United States in accordance with the requirements of the Federal Food, Drug, and Cosmetic Act. This scientific and risk-based assessment process can inform capacity-building efforts and priorities. Section 308, Foreign Offices of FDA, requires, inter alia, the establishment of FDA offices in foreign countries to provide assistance to the appropriate governmental entities with respect to measures to provide for the safety of articles of food and other products regulated by FDA exported by those countries to the United States, including by directly conducting risk-based inspections of such articles and supporting such inspections by such governmental entities. This Plan can assist the foreign offices in implementing Section 308.

Key Actions

- 1.1.1** Consult other agency work groups, as appropriate, and develop internal processes to ensure collaboration, communication, and timely decision making.
- 1.1.2** Ensure integrated planning across agency components involved in the implementation of relevant FSMA provisions through communication and leveraging experiences and work of FSMA work groups.

Objective 1.2 – Maximize coordination within FDA

In establishing a capacity-building program, it is imperative that FDA components work closely with each other and across organizational units. Improving program management and effectiveness is essential. In FDA's FVM Program, this will be accomplished through integrated operations and unified leadership, with a strong focus on strategic planning, risk-based priority setting and strategic allocations of resources.

Key Actions

- 1.2.1** Coordinate and implement key actions of this Plan within FDA efficiently and effectively by monitoring and evaluating outcomes.
- 1.2.2** Manage risk-based priority setting and resource allocation and other strategic management functions on an integrated, program-wide basis through the use of analytical tools.
- 1.2.3** Ensure integrated planning and policy development and efficient, timely decision making in the FVM Program through ongoing communications across FVM.

Goal 2: Increase effectiveness through evidence-based decision making

Objective 2.1 – Enhance intelligence regarding food safety risks

This capacity-building Plan recognizes the need for a change in agency strategy. Instead of focusing primarily on intercepting harmful products, FDA will attempt to prevent such goods from arriving at U.S. borders in the first place. In order to accomplish this change, FDA will acquire more information to inform its decision making, including information about risks that are specific to individual countries and commodities. Any given piece of information, however, may not be enough. FDA will seek to aggregate information from multiple sources, and will seek to use this aggregated information in carrying out capacity-building programs. Information sources will include, among others as available: (1) open source intelligence; (2) FDA foreign offices; (3) domestic and foreign inspections; and (4) FDA's import programs.

To inform the foreign inspection program, FDA is building a risk-based decision-making tool that will incorporate country-specific data to assist the agency in determining the specific facility, food products, processes, and hazards that merit inspection. This tool will mine validated publicly available information from the Internet and other open web sources. This tool, coupled with results from previous foreign inspections, will enhance FDA's ability to identify specific areas of concern in a foreign country's food safety system. With increased information, FDA can target its enforcement activities and capacity-building programs as appropriate.

FDA's foreign offices work closely with their foreign regulatory counterparts, as well as with foreign industries and in-country scientific and academic communities. The foreign offices also work with other U.S. government agencies that have offices abroad. These offices have a familiarity with the regulatory, public health, cultural, economic, security, and geopolitical dynamics in the countries in which they operate, and are uniquely able to serve as the face and voice of FDA in those countries – helping local stakeholders to understand the agency's policies and requirements for imported products. Their connections with foreign stakeholders will be particularly valuable in helping implement the capacity-building Plan and intelligence gathering.

FSMA requires two new programs focused on an importer's responsibility to ensure the safety of food brought into the United States. One program, the Foreign Supplier Verification Program (FSVP), requires importers to conduct risk-based foreign supplier verification activities to verify that imported food is not, among other things, adulterated and that it was produced in compliance with processes and procedures that provide the same level of public health protection as those required under FDA's preventive controls requirements and produce safety standards, where applicable. Under the other program, the Voluntary Qualified Import Program (VQIP), FDA must establish a voluntary, user-fee funded program for importers that provides for expedited entry into the United States of foods from eligible, qualified importers. To be eligible to participate in VQIP, an importer must offer food for importation from a facility that has a certification by an accredited third party. FDA will qualify eligible importers to participate in VQIP based on risk considerations.

FSMA also directs FDA to establish a system for the recognition of accreditation bodies that accredit third-party auditors to issue certifications for purposes of the import certification for food and VQIP provisions. FDA's new systems recognition program is also among the tools FDA can use to facilitate safe imports.

FDA recognizes that its programs can offer a great deal of information that will enable FDA to secure intelligence and track food safety trends over time.

Key Actions

- 2.1.1** Widely gather and obtain information that is country and product specific from a variety of sources (e.g., open source intelligence, domestic and foreign inspections, foreign offices, and import programs) by modifying IT systems and data reporting structures.
- 2.1.2** Utilize intelligence to inform risk-based decision making for setting capacity-building opportunities and priorities.

Objective 2.2 – Utilize food safety assessments

FDA believes it is important to place special emphasis on working with countries that have done their own food safety assessments to self-identify where targeted technical assistance and capacity-building efforts could lead to improvements in the country's food safety system or portions thereof. The international community has relied on this self-assessment approach in the past. In the development of this Plan, FDA reviewed a number of materials that provide guidance on assessing and evaluating capacity-building needs. WTO's STDF report on "SPS-Related Capacity Evaluation Tools,"¹⁴ for example, describes evaluation tools for food safety and animal and plant health developed by international organizations. One such tool is the Performance, Vision, and Strategy (PVS) tool developed by the Inter-American Institute for Cooperation on Agriculture (IICA) and the Pan American Health Organization. Currently, IICA is facilitating assessments in Latin and South American countries that have requested assistance through the "PVS for National Food Safety Services" program. In addition, FAO's "Guidelines and Quick Guide to Assess Food Safety Capacity Building Needs" assists governments in identifying capacity needs in their food control systems. Many of these tools are outlined in the STDF report on "SPS-Related Capacity Evaluation Tools, An Overview of Tools Developed by International Organizations."¹⁴ While the previous tools are well known, FDA is interested in any evaluation a country does to assess the effectiveness of its food safety system, either in whole or in part. In the U.S. context, FDA uses the Manufactured Food Regulatory Program Standards (MFRPS) to assess the capacity of U.S. state-level programs. Identifying self-assessment techniques used in other countries may be useful in determining those countries' capacity-building needs. Additionally, the Codex Committee on Food Import and Export Inspection and Certification Systems is developing *The Codex Principles and Guidelines for National Food Control Systems*, which will provide practical guidance to assist national governments in the development, operation, evaluation, and improvement of their national food control system.

¹⁴ Standards and Trade Development Facility. May 2011. *SPS-Related Capacity Evaluation Tools: An Overview of Tools Developed by International Organizations* (2nd ed.). WTO: Geneva, Switzerland. (Available at: http://www.standardsfacility.org/Files/Publications/STDF_Capacity_Evaluation_Tools_Eng.pdf) Accessibility verified February 2013.

Notably, FSMA Section 303 authorizes FDA to require, based on risk considerations, an article of food offered for import into the United States to be accompanied by certifications or other assurances that the food complies with relevant provisions of the Federal Food, Drug, and Cosmetic Act. As discussed above, in determining whether to require certification under Section 303, factors to consider include a finding, supported by scientific, risk-based evidence, that the food safety programs, systems, and standards in the country, territory, or region of origin of the food are inadequate to ensure that the article of food is as safe as a similar article of food that is manufactured, processed, packed, or held in the United States in accordance with the Federal Food, Drug, and Cosmetic Act, among other factors. This scientific and risk-based assessment process can inform capacity-building efforts and priorities. Additionally, FDA is piloting a new systems recognition process that will involve the assessment of countries' food safety systems. These activities may inform FDA's capacity-building undertakings, providing insight into how FDA should prioritize its efforts.

Key Actions

- 2.2.1** Use data from multiple types of food safety assessments to inform the planning process for international food safety capacity building.
- 2.2.2** When engaging in capacity-building efforts, seek assessment results from countries and encourage a discussion about the identified capabilities and needs of those countries' food safety systems. A lack of assessment information will impact FDA's ability to engage in capacity-building efforts.
- 2.2.3** Account for the interest of individual countries, their ownership of such undertakings, and their willingness to address the needs identified through assessment tools.
- 2.2.4** Collaborate on capacity building based on, among other factors, commitments from foreign country counterparts to address the needs identified through food safety assessments.

Objective 2.3 – Design for effectiveness

It is important to FDA to be able to answer questions about where it is investing its resources and how those investments are improving food safety and public health, thereby protecting consumers. Consequently, this Plan recognizes the need to ensure that FDA's efforts are data-driven and effective. Without a robust system in place to capture and analyze the public health data and outcomes associated with capacity-building activities, FDA will lack sufficient information to determine how to better invest resources to improve health and safety. Consistent with FDA's FVM Strategic Plan,¹⁵ FDA will use a comprehensive performance management system to track the performance and progress of its international capacity-building activities.¹⁶ This approach will focus on high priority countries with high-risk products.

Performance management systems promote effectiveness by establishing clear links between efforts and results. Without such links, it would be impossible to determine whether progress has been achieved, where additional efforts should be focused (or repurposed), and how future efforts could be improved. By changing what and how activities are measured, FDA will more effectively drive continuous improvements in public health.

Implementation of a performance management system will enable FDA to assess and improve its capacity-building efforts by:

- Linking key activities to important public health outcomes;
- Providing the ability to measure and evaluate performance;
- Facilitating more effective communication and information sharing with internal and external stakeholders;
- Providing information to support evidence-based decision making; and
- Allowing for more focused prioritization of capacity-building activities and resources.

Key Actions

- 2.3.1** Develop a results-based approach to improve the management and effectiveness of FDA's efforts to prevent food safety problems in the global supply chain.
- 2.3.2** Develop and implement a comprehensive performance management system for high priority countries and high risk commodities, utilizing results frameworks to connect performance measures and outputs to public health outcomes.
- 2.3.3** Use the performance management system to inform decision making about strategic capacity-building programming.
- 2.3.4** Promote sharing and use of data (e.g., surveillance), as feasible, among all partners and stakeholders in food safety.

Appendix B provides additional information on FDA's efforts to ensure effectiveness, including information on its performance management pilot projects.

¹⁵ FDA. 2012. *Foods and Veterinary Medicine Strategic Plan 2012 – 2016*. (Available at: <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/ucm273269.htm>) Accessibility verified February 2013.

¹⁶ This approach is one of the key principles in The Paris Declaration for Aid Effectiveness (Managing for Developmental Results) and is a globally accepted best practice for ensuring effectiveness of programs and projects.

¹⁷ FDA is initially piloting this performance management system within two countries, and will potentially roll-out the program to additional select partner countries.

Goal 3: Support the exchange of information between FDA and foreign government agencies or other entities

Objective 3.1 – Support bilateral and multilateral arrangements and agreements with foreign governments, including provisions to provide for responsibility of exporting countries to ensure food safety (Element 1 of FSMA’s Section 305)

Agreements and other arrangements¹⁸ with other foreign regulatory authorities or other entities (e.g., multilateral or regional organizations) involved in food safety are extremely useful in ensuring the safety of food products and in avoiding duplication of efforts. At present, FDA has food-related cooperative arrangements and memoranda of understanding with approximately 20 different foreign governments. Some of these and other arrangements with other entities facilitate relationships and affirm participants' commitment to strengthening existing scientific and public health protection activities related to food safety. In these cases, the arrangements document the participants' general collaborative intentions. Other arrangements, however, are more technical; they address a narrowly defined problem or risk in a commodity exported from a specific country. Because these arrangements are highly specific in nature, subject matter experts are heavily involved in their drafting, negotiation, and implementation.

FDA's approach to arrangements and agreements is flexible. That is, FDA's approach is for each such arrangement and agreement to reflect the distinct needs and interests being addressed. Just how FDA achieves this depends on the objectives of FDA and its partners, ensuring mutual benefit to all parties.

Key Actions

- 3.1.1** In pursuing new arrangements and re-evaluating existing agreements, prioritize opportunities that optimize the leveraging of resources and have the greatest potential impact on U.S. public health.
- 3.1.2** Develop agreements and arrangements that are specific, goal-oriented, and offer a benefit for all parties.
- 3.1.3** Utilize arrangements and agreements to promote collaboration and technical exchange when possible.

¹⁸ FDA uses the term “international arrangements” to include all types of written documents between FDA and a foreign partner—whether the document contains binding commitments or non-binding aspirations. The term “international agreement” is reserved for arrangements that contain one or more binding commitments. When entering into “international arrangements,” FDA consults with the Department of State in accordance with established practices.

Objective 3.2 – Establish new or identify existing mechanisms to support secure electronic data sharing with foreign governments or other entities (Element 2 of FSMA’s Section 305)

FDA understands and recognizes that in order to advance the goal of becoming a global partner in food safety the agency will need to engage in open and regular dialogue with the regulatory authorities of other countries to identify data and information that would be mutually beneficial. Mechanisms – including agreements and the technology to transfer information – need to be developed, implemented or repurposed in order to facilitate such information sharing in a secure way. Developing these mechanisms will involve overcoming practical, legal, and technological limitations. In addition, and wherever possible, FDA should explore and leverage existing, successful information data sharing mechanisms established by other entities, such as WHO/FAO’s International Food Safety Authorities Network (INFOSAN)¹⁹ and the International Health Regulations.²⁰

As FDA implements the import-related provisions of FSMA, the agency will continue to analyze the capacity of current IT systems and determine whether any needs exist for system integration or the development of new systems to facilitate and enhance data sharing, where appropriate and where such systems will support the new FSMA import programs.

Key Actions

- 3.2.1** Explore opportunities to exchange scientific and technical information (e.g., outbreak data, audit reports, inspection findings), including the use of existing FDA data systems.
- 3.2.2** Establish IT infrastructure and mechanisms for secure information sharing that supports new import programs (e.g., FSVP) and provides information to inform regulatory decision making by providing a secure electronic system for information receipt, storage, dissemination, and authentication.
- 3.2.3** Support existing communication mechanisms that allow for the rapid exchange of information during an emergency (e.g., INFOSAN, International Health Regulations).
- 3.2.4** Ensure the protection of confidential information, industry trade secrets, and other sensitive information.
- 3.2.5** Be cognizant of technical infrastructure limitations and requirements of trading partners when evaluating or developing information-sharing mechanisms. Provide IT applications using current web technology through the Internet where such applications are conveniently accessible, secure, and easy to use from desktops or mobile devices.
- 3.2.6** Update FDA’s IT infrastructure to support data exchange and risk-based decision making. Such updates should align with technology advances and capitalize on evolving, agile technologies (e.g., cloud computing).
- 3.2.7** Engage in data exchange with counterpart public and private organizations to enhance risk-based decision making by providing a secure and easy-to-use capability that supports collaboration.

¹⁹ WHO/FAO. The International Food Safety Authorities Network (INFOSAN). (Available at: http://www.who.int/foodsafety/fs_management/infosan/en/) Accessibility verified February 2013.

²⁰ WHO. 2005. *The International Health Regulations*, 2nd Ed. (Available at: <http://www.who.int/ihr/en/>) Accessibility verified February 2013.

Objective 3.3 – Explore appropriateness of relying on mutual recognition of inspection reports (*Element 3 of FSMA’s Section 305*)

FSMA establishes a mandate for FDA to make foreign inspections a priority.²¹ With FDA now engaged in many more foreign inspections, and in light of Congress’s charge in Section 305 of FSMA for this Plan to include mutual recognition of inspection reports as appropriate, the agency has begun to explore its ability to rely on mutual recognition of inspection reports for foods. To do so, FDA will assess examples of existing global partnerships and harmonization efforts, albeit not food-specific, that provide potential models. This exercise will help FDA to consider a framework that may allow the agency to have confidence in another country’s inspection reports. There are many issues to consider. For example, in addition to identifying parties that might participate, the agency will need to identify the required manner of the inspection. For instance, FDA may need to work with countries to determine whether the inspections should be comprehensive or abbreviated inspections.²² FDA may also need to work with countries to determine the frequency of inspection, as well as the scope, format, and content.

In considering the feasibility of mutual recognition of inspection reports, new FSMA-related programs may also prove relevant. For instance, FSMA also directs FDA to establish a third-party accreditation program. Specifically, section 307 of FSMA directs FDA to establish a system for the recognition of accreditation bodies that accredit third-party auditors to, among other responsibilities, issue certifications for purposes of the import certification for food. Foreign cooperatives, government agencies and any other third parties are eligible to be considered for accreditation as third-party auditors. Once FDA has fully established this program, FDA could potentially consider recognizing the accreditation of other countries – and thus explore the possibility of mutually recognizing the results of the auditors accredited under the program.

Key Actions

- 3.3.1** Explore the issues surrounding mutual recognition of inspection reports, including the evaluation of similar programs in other FDA-regulated areas.
- 3.3.2** Develop a report analyzing the issues.

²¹ Indeed, under FSMA, FDA has been given specific inspection goals. FSMA establishes a mandated inspection frequency, based on risk, for food facilities and requires the frequency of inspections to increase. All high-risk domestic facilities must be inspected within five years of FSMA’s enactment and no less than every three years thereafter. Within one year of enactment, the law directed FDA to increase inspections of foreign facilities, and then increase that number every year for the next five years.

²² A comprehensive inspection directs coverage to everything in the firm subject to FDA jurisdiction to determine the firm’s compliance status (FDA’s Investigations Operations Manual: <http://www.fda.gov/ICECI/Inspections/iOM/ucm151267.htm#5.1.2.>). Accessibility verified February 2013. FDA’s FVM Program has historically not relied on abbreviated inspections, but such inspections could focus on a subset of the comprehensive inspection and generalize coverage of a facility’s operations for a more resource-efficient approach. FDA’s drug and device programs sometimes rely on drug and device-specific abbreviated inspections.

Goal 4: Enhance technical assistance and capacity building in food safety

While FDA is responsible for protecting much of the food supply marketed in the United States, it is important for FDA to coordinate its food safety capacity-building activities with all federal agencies involved (e.g., the U.S. Department of Agriculture [USDA] Food Safety Inspection Service [FSIS], EPA, and the National Oceanic and Atmospheric Administration, among others). It is also important to harness synergies with other countries that have common food safety requirements and offer or support similar trainings. This will help to minimize duplication of effort and inefficient use of resources.

FDA is also actively engaged in partnerships and alliances with other groups representing academia, industry, and other U.S. government agencies in providing stakeholders with food safety expertise. FDA will continue to partner with USAID and USDA's Foreign Agricultural Service (FAS) programs, the Asia-Pacific Economic Cooperation (APEC) Food Safety Cooperation Forum's Partnership Training Institute Network (PTIN), the newly developed Global Food Safety Partnership (GFSP) managed by the World Bank, the Joint Institute for Food Safety and Applied Nutrition (JIFSAN), the FAO, the WTO/STDF and Codex Alimentarius Commission, among others. These partnerships are focused on developing, delivering, and enabling training on food safety best practices and the science behind food safety requirements.

The goal of capacity building is not only to deliver training, but also to ensure that the training is effective and sustainable. These goals are best achieved when the objectives of capacity-building efforts are identified and used to guide the planning of the activities (see goal 2, objective 2.3).

There are many different methods and modalities for effective technical assistance and training on U.S. food safety requirements that can help build capacity. To be most effective, training should be geared toward the appropriate audiences throughout the farm to table supply chain continuum. Trainings should also be in the appropriate language and conducted in ways that are effective for each particular audience. A summary of considerations for developing and delivering training can be found in the text box below.



Considerations regarding development and delivery of training on food safety principles

- Assessment of training needs should be done to ensure that established or new training programs meet identified needs.
- Training materials should be based on international food safety standards, best practices and requirements where available.
- Training materials should be developed in collaboration with regional experts from industry, government, and academia to increase the quality, accessibility, and use of training materials.
- Training materials should be adapted to meet local needs, and be delivered in the local language or dialect, using local case examples.
- Training materials should be adapted to target various audiences within the food supply chain (e.g., farmers, manufacturers, food handlers, and regulators).
- Delivery of training materials should include a variety of modalities including: face-to-face; hands-on laboratory training; webinars; on-line modules.
- Delivery of training materials through “train-the-trainer” programs should be encouraged to broaden dissemination of information.
- Delivery of training materials through local academic institutions (e.g., part of the academic curriculum or establishing an “extension-like” system) should be encouraged to broaden dissemination of information.
- Sustainability of training programs should be pursued through partnership with donor organizations to ensure adequate funding of training programs.

Objective 4.1 – Work with partners to develop/deliver food safety training programs focused on best practices and global food safety principles

With the globalization of the food supply, the responsibility for food safety has also become global. No single entity can alone assure the safety of the food supply. Given this reality, it is important to be aware of the roles and responsibilities of each player in the food supply chain. FDA's role as a regulator is to advance the public health of the United States. In pursuing that role, FDA has developed subject matter expertise about different food products, as well as expertise on building effective food safety systems. Consequently, FDA's expertise lies in both commodity and food safety systems perspectives. While FDA embraces its role in building food safety capacity, it recognizes that many other types of entities – including food safety experts, donors, development leaders, food processors, manufacturers, researchers, and trainers – can all contribute in building food safety capacity. FDA also realizes that it must partner with such entities to provide a comprehensive, coherent solution to food safety issues.

Similarly, as FDA seeks synergies with other countries that have common food safety requirements, such countries can support similar capacity-building undertakings. By partnering with other countries, FDA can help minimize duplication and strategically leverage these countries' expertise and resources.

Key Actions

- 4.1.1** Seek greater coordination within the global food safety community in pursuing global and regional food safety capacity-building efforts. FDA can achieve this by coordinating with other U.S. agencies involved in food safety and by participating in international fora, such as WHO and FAO, Codex, WTO/STDF, GFSP, and APEC (i.e., Food Safety Cooperation Forum [FSCF] and PTIN).
- 4.1.2** Support the development, refinement, and delivery of training materials focused on global food safety best practices and the science underpinning these practices in partnership with other food safety entities, such as the Produce Safety Alliance and JIFSAN.
- 4.1.3** Prioritize training and capacity-building activities according to risk assessments and needs assessments of identified countries, as appropriate.
- 4.1.4** Continue to encourage development agencies to invest in effective food safety systems as part of agricultural and economic development efforts (e.g., the newly established GFSP managed by the World Bank).

Objective 4.2 – Train foreign governments and food producers on U.S. requirements for safe food (*Element 4 of FSMA’s Section 305*)

Ensuring that foods are safely delivered to the American consumer requires FDA to cooperate with foreign counterparts, including by providing information about applicable U.S. food safety laws and regulations and the scientific basis for such requirements.

As discussed previously, FDA recently opened foreign offices in strategic locations around the globe. This Plan will assist the offices, as they put Section 308 of FSMA into practice, by providing assistance regarding FDA requirements to countries that export food to the United States.²³

Key Actions

- 4.2.1** Coordinate with other U.S. agencies involved in food safety to develop, refine, and translate open access materials (e.g., web-based materials) that provide information and guidance about U.S. food safety requirements, including requirements under FSMA.
- 4.2.2** Continue developing training materials through established Alliances (i.e., food safety preventive controls, seafood Hazard Analysis and Critical Control Point [HACCP], produce safety, and sprout safety).
- 4.2.3** Prioritize training and capacity-building activities according to risk assessments and needs assessments of identified countries, as appropriate.
- 4.2.4** Support FDA's foreign offices on technical assistance activities.

²³ As discussed above, Section 308 requires, *inter alia*, the establishment of FDA offices in foreign countries to provide assistance to the appropriate governmental entities with respect to measures to provide for the safety of articles of food and other products regulated by FDA exported by those countries to the United States, including by directly conducting risk-based inspections of such articles and supporting inspections by such governmental entities.

Objective 4.3 – Develop recommendations on whether and how to harmonize requirements under the Codex Alimentarius (Element 5 of FSMA’s Section 305)

The Codex Alimentarius Commission (“Codex”) is an intergovernmental body with over 170 members within the framework of the Joint Food Standards Programme established by FAO/WHO. The Commission’s purpose is to protect the health of consumers and to ensure fair practices in food trade. The Codex Alimentarius is a collection of internationally adopted food standards, guidelines, codes of practice, and other recommendations to ensure fair practices in food trade and protect the health of consumers.

FDA has been engaged in the work of the Codex Alimentarius Commission since its formation in 1963. FDA participates in all 19 currently active Codex committees and task forces, and in the Commission meeting. FDA currently provides the U.S. Delegate or the U.S. Alternate Delegate to 13 of these committees and task forces.²⁴ The objective of FDA’s participation is to encourage the development of science-based international food safety standards, labeling standards, and other standards that provide a level of consumer protection, labeling information, and prevention of economic fraud and deception. Furthermore, FDA believes that the use of Codex standards helps assure a safe global food supply. FDA also supports the Codex Project and Trust Fund for Participation in the work of Codex (Codex Trust Fund) to facilitate the participation of developing country members in Codex work. As part of the U.S.’s participation in Codex, FDA works closely with Codex and maintains its strong support of the science-based standard-setting process.

Under FDA’s regulations,²⁵ food standards adopted by the Codex Alimentarius Commission will be reviewed by FDA (and either will be accepted, with or without change, or will not be accepted).

Key Actions

- 4.3.1** Actively engage in assessing FDA’s current food safety requirements for consistency with Codex where appropriate. Recognize this assessment will be a long-term process and will involve engagement with stakeholders.
- 4.3.2** Continue active involvement and leadership in Codex, assist in developing science-based standards and explore options for reviewing and adopting new standards as appropriate.
- 4.3.3** Provide continued support to the U.S. Codex Office and support the development and implementation of Codex-based capacity-building programs.
- 4.3.4** Support the Codex Trust Fund and encourage active participation by all countries.

²⁴ Title 21 of the Code of Federal Regulations part 130.6 (21 CFR 130.6).

²⁵ This includes basic analytical technologies ranging from thin layer chromatography to instrument intensive technologies such as liquid chromatography with mass spectrometric detection.

Objective 4.4 – Support provisions for the multilateral acceptance of laboratory methods and testing and detection techniques

(Element 6 of FSMA’s Section 305)

FDA currently participates in a host of domestic and international laboratory networks (e.g., the Food Emergency Response Network [FERN]). These networks recognize the need to harmonize analytical methods so that surveillance data from different laboratories can be compared.

FDA recognizes that fit-for-purpose methods (i.e., methods based on performance criteria for a given outcome) need to include a range of appropriate technologies²⁶ to address the specific needs within the domestic and international food safety testing laboratories. FDA recognizes that being trained to use fit-for-purpose methods is not, by itself, sufficient for the analysts or their laboratories. Trained personnel must return to their laboratories and demonstrate that they can perform the method by developing validation protocols and participating in proficiency testing programs. Laboratory accreditation attests to the competency and technical capability of a laboratory to perform specific tasks.

To promote transparency, FDA makes publicly available its laboratory methods, including microbiological methods used for compliance purposes for foods and cosmetics. (These methods are contained in the Bacteriological Analytical Manual, which FDA posts on its website.²⁷) FDA has also made available its methods validation guidelines²⁸ for the validation of analytical methods to detect chemicals and microbial pathogens in foods.

FDA is partnering with training institutions and domestic and international laboratory networks to conduct outreach and education about fit-for-purpose laboratory methods, with a goal of increasing the multilateral acceptance and use of fit-for-purpose methods and acceptable current best practices by the international community. One partner that FDA actively engages is the University of Maryland’s JIFSAN’s International Food Safety Training Laboratory (IFSTL). IFSTL is a dedicated teaching facility located in College Park, Maryland, next door to FDA’s Center for Food Safety and Applied Nutrition. It was developed through a public-private partnership. The mission of the IFSTL is to deliver hands-on training to foreign and domestic scientists in the application of fit-for-purpose analytical methods for monitoring compliance with the broadest possible range of food safety standards. IFSTL’s work includes training modules related to method validation. IFSTL is the first of a global network of training laboratories dedicated to training of analytical methods to detect food contamination. The second facility in the network is located at the United Kingdom’s Food and Environment Research Agency. The training facilities within the network will coordinate and share expertise.

FDA intends to foster the development of a comprehensive preventive control food safety system by working with its global food safety partners, including foreign governments, industry, academia, and consumer groups. Its efforts related to building international food safety laboratory capacity are intended to assist in the effective implementation of FDA’s import-related authorities. FDA’s efforts are also designed to foster FDA acceptance of laboratory test results from competent authorities and third-party contract laboratories for regulatory purposes, thus reducing the burden on the agency’s own laboratories.

²⁶ Title 21 of the Code of Federal Regulations part 130.6 (21 CFR 130.6).

²⁷ This includes basic analytical technologies ranging from thin layer chromatography to instrument intensive technologies such as liquid chromatography with mass spectrometric detection.

²⁸ FDA. Bacteriological Analytical Manual. (Available at: <http://www.fda.gov/Food/ScienceResearch/LaboratoryMethods/BacteriologicalAnalyticalManualBAM/default.htm>) Accessibility verified February 2013.

Key Actions

- 4.4.1** Encourage the adoption/development of laboratory methods using a range of appropriate technologies based on performance criteria for a given outcome (such as for screening purposes or regulatory action) and validated appropriately for its intended use. Work towards this result through participation in international fora such as the AOAC International, as well as established laboratory networks such as FERN.
- 4.4.2** Partner with training institutions, domestic and international laboratory networks, multilateral organizations and other U.S. government agencies (e.g., USDA's FAS and FSIS) to conduct outreach and education about fit-for-purpose laboratory methods for food and animal feeds.
- 4.4.3** Continue to be transparent and, where appropriate, make available FDA methods that the agency uses for compliance purposes.
- 4.4.4** Build on existing platforms (e.g., scientific meetings, APEC/PTIN events, Codex meetings) and explore other platforms (e.g., web-based) to enhance information exchange on current and new testing methodologies, needs for proficiency testing, validation protocols, and other topics as needed.

Conclusion

FDA's International Food Safety Capacity-Building Plan outlines goals, objectives, and key actions that will provide a framework for FDA in setting priorities and managing international food safety capacity building—both within FDA's FVM Program, and throughout other areas of FDA (e.g., Office of International Programs, Office of Planning, Office of Information Management). Ultimately, FDA may develop a more specific, detailed framework for implementing its capacity-building plans. In the meantime, this Plan illustrates how FDA can expand the technical, scientific, and regulatory capacity of foreign governments and their food industries. This Plan also enables stakeholders to see the breadth of food safety capacity-building actions that FDA is pursuing and the purposes for which the agency is pursuing them.

Appendices

Appendix A: Summary of Key Goals, Objectives & Actions

Key Goals, Objectives & Actions

Goal 1: Ensure efficiency across the Foods and Veterinary Medicine Program

Objective 1.1 Ensure collaboration across the FVM Program

Actions

- 1.1.1 Consult other agency work groups, as appropriate, and develop internal processes to ensure collaboration, communication, and timely decision making.
- 1.1.2 Ensure integrated planning across agency components involved in the implementation of relevant FSMA provisions through communication and leveraging experiences and work of FSMA work groups.

Objective 1.2 Maximize coordination within FDA

Actions

- 1.2.1 Coordinate and implement key actions of this Plan within FDA efficiently and effectively by monitoring and evaluating outcomes.
- 1.2.2 Manage risk-based priority setting and resource allocation and other strategic management functions on an integrated, program-wide basis through the use of analytical tools.
- 1.2.3 Ensure integrated planning and policy development and efficient, timely decision making in the FVM Program through ongoing communications across FVM.

Goal 2: Increase effectiveness through evidence-based decision making

Objective 2.1 Enhance intelligence regarding food safety risks

Actions

- 2.1.1 Widely gather and obtain information that is country and product specific from a variety of sources (e.g., open source intelligence, domestic and foreign inspections, foreign offices, and import programs) by modifying IT systems and data reporting structures.
- 2.1.2 Utilize intelligence to inform risk-based decision making for setting capacity-building opportunities and priorities.

Key Goals, Objectives & Actions

Objective 2.2 Utilize food safety assessments

Actions

- 2.2.1** Use data from multiple types of food safety assessments to inform the planning process for international food safety capacity building.
- 2.2.2** When engaging in capacity-building efforts, seek assessment results from countries and encourage a discussion about the identified capabilities and needs of those countries' food safety systems. A lack of assessment information will impact FDA's ability to engage in capacity-building efforts.
- 2.2.3** Account for the interest of individual countries, their ownership of such undertakings, and their willingness to address the needs identified through assessment tools.
- 2.2.4** Collaborate on capacity building based on, among other factors, commitments from foreign country counterparts to address the needs identified through food safety assessments.

Objective 2.3 Design for effectiveness

Actions

- 2.3.1** Develop a results-based approach to improve the management and effectiveness of FDA's efforts to prevent food safety problems in the global supply chain.
- 2.3.2** Develop and implement a comprehensive performance management system for high priority countries and high risk commodities, utilizing results frameworks to connect performance measures and outputs to public health outcomes.
- 2.3.3** Use the performance management system to inform decision making about strategic capacity-building programming.
- 2.3.4** Promote sharing and use of data (e.g., surveillance), as feasible, among all partners and stakeholders in food safety.

Goal 3: Support the exchange of information between FDA and foreign government agencies or other entities

Objective 3.1 Support bilateral and multilateral arrangements and agreements with foreign governments, including provisions to provide for responsibility of exporting countries to ensure food safety (*Element 1 of FSMA's Section 305*)

Actions

- 3.1.1** In pursuing new arrangements and re-evaluating existing agreements, prioritize opportunities that optimize the leveraging of resources and have the greatest potential impact on U.S. public health.

Key Goals, Objectives & Actions

3.1.2 Develop agreements and arrangements that are specific, goal-oriented, and offer a benefit for all parties.

3.1.3 Utilize arrangements and agreements to promote collaboration and technical exchange when possible.

Objective 3.2 **Establish new or identify existing mechanisms to support secure electronic data sharing with foreign governments or other entities**
(Element 2 of FSMA's Section 305)

Actions

3.2.1 Explore opportunities to exchange scientific and technical information (e.g., outbreak data, audit reports, inspection findings), including the use of existing FDA data systems.

3.2.2 Establish IT infrastructure and mechanisms for secure information sharing that supports new import programs (e.g., FSVP) and provides information to inform regulatory decision making by providing a secure electronic system for information receipt, storage, dissemination, and authentication.

3.2.3 Support existing communication mechanisms that allow for the rapid exchange of information during an emergency (e.g., INFOSAN, International Health Regulations).

3.2.4 Ensure the protection of confidential information, industry trade secrets, and other sensitive information.

3.2.5 Be cognizant of technical infrastructure limitations and requirements of trading partners when evaluating or developing information-sharing mechanisms. Provide IT applications using current web technology through the Internet where such applications are conveniently accessible, secure, and easy to use from desktops or mobile devices.

3.2.6 Update FDA's IT infrastructure to support data exchange and risk-based decision making. Such updates should align with technology advances and capitalize on evolving, agile technologies (e.g., cloud computing).

3.2.7 Engage in data exchange with counterpart public and private organizations to enhance risk-based decision making by providing a secure and easy-to-use capability that supports collaboration.

Objective 3.3 **Explore appropriateness of relying on mutual recognition of inspection reports**
(Element 3 of FSMA's Section 305)

Actions

3.3.1 Explore the issues surrounding mutual recognition of inspection reports, including the evaluation of similar programs in other FDA-regulated areas.

3.3.2 Develop a report analyzing the issues.

Key Goals, Objectives & Actions

Goal 4: Enhance technical assistance and capacity building in food safety

Objective 4.1 Work with partners to develop/deliver food safety training programs focused on best practices and global food safety principles

Actions

- 4.1.1** Seek greater coordination within the global food safety community in pursuing global and regional food safety capacity-building efforts. FDA can achieve this by coordinating with other U.S. agencies involved in food safety and by participating in international fora, such as WHO and FAO, Codex, WTO/STDF, GFSP, and APEC (i.e., FSCF and PTIN).
- 4.1.2** Support the development, refinement, and delivery of training materials focused on global food safety best practices and the science underpinning these practices in partnership with other food safety entities, such as the Produce Safety Alliance and JIFSAN.
- 4.1.3** Prioritize training and capacity-building activities according to risk assessments and needs assessments of identified countries, as appropriate.
- 4.1.4** Continue to encourage development agencies to invest in effective food safety systems as part of agricultural and economic development efforts (e.g., the newly established GFSP managed by the World Bank).

Objective 4.2 Train foreign governments and food producers on U.S. requirements for safe food (*Element 4 of FSMA's Section 305*)

Actions

- 4.2.1** Coordinate with other U.S. agencies involved in food safety to develop, refine, and translate open access materials (e.g., web-based materials) that provide information and guidance about U.S. food safety requirements, including requirements under FSMA.
- 4.2.2** Continue developing training materials through established Alliances (i.e., food safety preventive controls, seafood HACCP, produce safety, and sprout safety).
- 4.2.3** Prioritize training and capacity-building activities according to risk assessments and needs assessments of identified countries, as appropriate.
- 4.2.4** Support FDA's foreign offices on technical assistance activities.

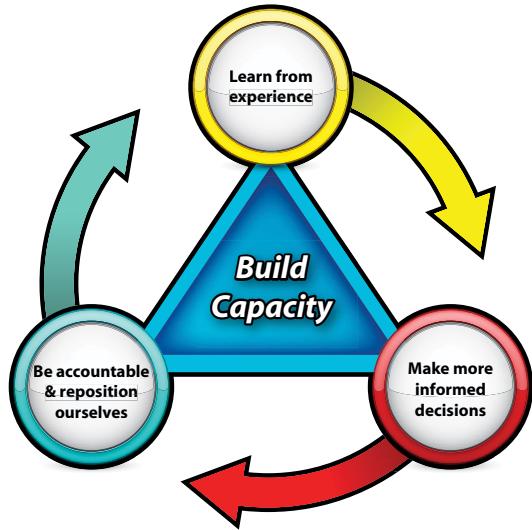
Key Goals, Objectives & Actions

Objective 4.3	Develop recommendations on whether and how to harmonize requirements under the Codex Alimentarius (Element 5 of FSMA's Section 305)
Actions	
4.3.1	Actively engage in assessing FDA's current food safety requirements for consistency with Codex where appropriate. Recognize this assessment will be a long-term process and will involve engagement with stakeholders.
4.3.2	Continue active involvement and leadership in Codex, assist in developing science-based standards and explore options for reviewing and adopting new standards as appropriate.
4.3.3	Provide continued support to the U.S. Codex Office and support the development and implementation of Codex-based capacity-building programs.
4.3.4	Support the Codex Trust Fund and encourage active participation by other countries.
Objective 4.4	Support provisions for the multilateral acceptance of laboratory methods and testing and detection techniques (Element 6 of FSMA's Section 305)
Actions	
4.4.1	Encourage the adoption/development of laboratory methods using a range of appropriate technologies based on performance criteria for a given outcome (such as for screening purposes or regulatory action) and validated appropriately for its intended use. Work towards this result through participation in international fora such as AOAC International, as well as established laboratory networks such as FERN.
4.4.2	Partner with training institutions, domestic and international laboratory networks, and other U.S. government agencies (e.g., USDA's FAS and FSIS) to conduct outreach and education about fit-for-purpose laboratory methods for food and animal feeds.
4.4.3	Continue to be transparent and, where appropriate, make available FDA methods that the agency uses for compliance purposes.
4.4.4	Build on existing platforms (e.g., scientific meetings, APEC/PTIN events, Codex meetings) and explore other platforms (e.g., web-based) to enhance information exchange on current and new testing methodologies, needs for proficiency testing, validation protocols, and other topics as needed.

Appendix B: FDA's Performance Management System for International Capacity Building

A performance management system is a systematic process of collecting, analyzing, and reporting data and information. It aims to help managers and stakeholders learn from their experiences, make more informed decisions, increase accountability, and reposition activities, if needed (Figure 1).

Figure 1: A performance management system helps staff to...



Source: Adapted from UNDP's Handbook on Monitoring & Evaluation for Results, 2002

It is comprised of a number of tools that assist managers in instituting a results-based approach, such as:

- A results framework: A graphical representation of a strategy, directly linking activities to the achievement of specific results and goals (see Appendix C for an example).²⁹
- Performance indicator: A metric that supports the results framework and enables measurement of the magnitude of change for the results identified. More specifically, while results identify what we hope to achieve (that is, desired results), performance indicators tell us by what standards the results will be measured.³⁰
- Performance monitoring plan (PMP): A plan that organizes performance management tasks and data over the life of the program. It contains information such as the indicators (including definition of, unit of measurement, data source, and method collection) and the plan for analysis, use, and reporting.³¹

To initiate the development of the results-based approach, FDA hired a consultant to help guide the agency. Working with the consultant, FDA created an Imports Safety Results Framework (Figure 2) highlighting FDA's efforts to achieve the overall goal that we identified of protecting the public from unsafe imported foods (see "Protecting the Public from Unsafe Imported Foods" in Figure 2).

FDA identified three major streams (i.e., areas of focus) for achieving the goal:

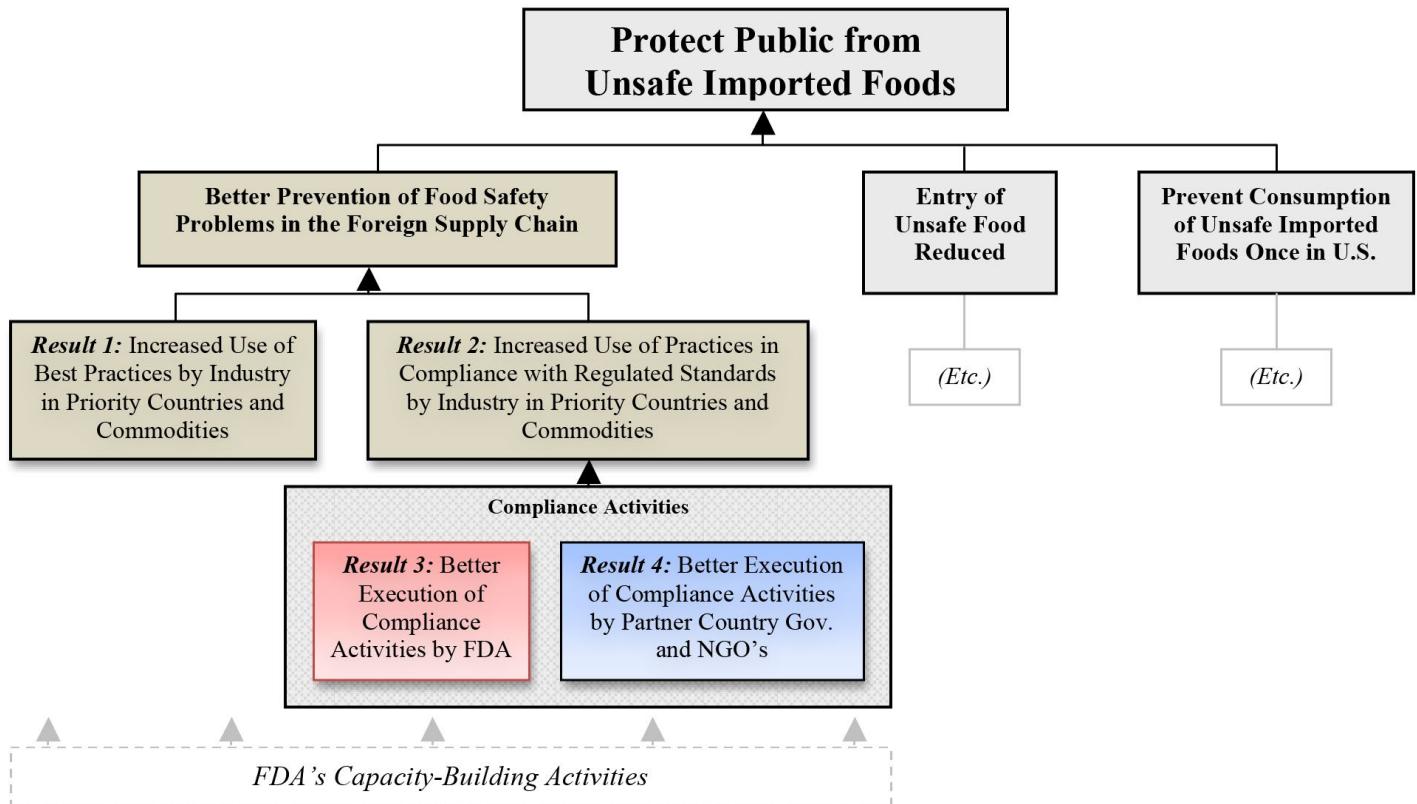
1. Better prevention of food safety problems in the foreign supply chain;
2. Entry of unsafe food reduced (if the above effort fails); and
3. Prevent consumption of unsafe imported foods once in the United States.

²⁹ USAID. 2010. *Performance Monitoring Tips: Building a Results Framework*, 2nd ed. Number 13.

³⁰ USAID. 2010. *Performance Monitoring Tips: Selecting Performance Indicators*, 2nd ed. Number 6.

³¹ USAID. 2010. *Performance Monitoring Tips: Preparing a Performance Monitoring Plan*, 2nd ed. Number 7.

Figure 2: Import Safety Results Framework³²



FDA framed the international capacity-building activities within the broader imports framework. The capacity-building efforts aim to improve the safety of the foreign supply chain and provide the foundation for the ‘Imports Prevention Results Framework’ (see Appendix C). The following four results were identified as being both necessary and sufficient to achieve “Better Prevention of Food Safety Problems in the Foreign Supply Chain.”

- Result 1** Increased use of best practices by industry in priority countries and commodities
- Result 2** Increased use of practices in compliance with regulated standards by industry in priority countries and commodities
- Result 3** Better execution of compliance activities by FDA
- Result 4** Better execution of compliance activities by the partner country government and non-governmental organizations (NGO’s)

These four results represent the understanding that in order to achieve the higher level result of “Better Prevention of Food Safety Problems in the Foreign Supply Chain,” partner countries and FDA need to make their compliance activities more effective. In addition, all actors in the supply chain need to adopt best practices. Although these steps are critical, achieving these four results requires also achieving all other supporting sub-results as well. These sub-results are shown in the draft Imports Prevention Results Framework (see Appendix C).

³² Figure 2 shows only the top level of the framework and specifically highlights the results related to the international capacity-building activities. Imported foods refer to those regulated by FDA. The results identified for the right side of the framework (i.e., ones not applicable to capacity building) have been excluded from this figure for simplicity sake. This results framework is current as of February 2013.

FDA also identified a set of foundational results that are vital to the Framework. The achievement of these foundational results is essential for achieving many, if not all, of the results in the results framework. The following four foundational results (shown at the very bottom of the Framework in Appendix C) support all three streams of the framework:

More Effective Cooperation & Information Sharing with Partner Country Regulatory

and Enforcement Agencies: Fostering more effective cooperation and information sharing between partner countries and the U.S. food safety community on possible or existing sources of contamination will be foundational to achieving results in each of the three streams and ultimately to preventing unsafe foods from being exported to the United States.

Improved Policy and Regulatory Framework for Food Safety in Partner Country: Updating and strengthening the policies, regulations, and standards for food safety in the partner country will support all three streams in the framework by encouraging or requiring the use of good practices and giving regulators more authority to carry out more effective compliance activities. This result covers improvements to the enforcement of the regulatory framework.

Improved Capability of Partner Country Food Safety Regulatory Organizations & Industry

Groups: This result seeks to build the skills and knowledge of partner country government regulatory organizations and industry that pertain to their ability to understand and identify food safety issues and apply appropriate preventive practices.

Increased Understanding of Problems & Risks in Global Supply Chain: This result addresses the importance of having awareness and understanding of the potential risks and causes of contamination at different points in the global supply chain, such as at the farm level, in packing, processing, shipping, or other areas. The ability to identify these trends feeds into many of the results above. This is a key result for being able to address the challenges of prevention.

Lastly, several factors were identified that were deemed to be critical to the achievement of the results captured in the framework, but that FDA is not able to directly control or substantially influence. These are called critical assumptions. In order for the results to be achieved, these critical assumptions must hold true. One such critical assumption is that FDA has the budget and staff necessary to implement the strategy.

Draft performance indicators have been identified to support the Import Prevention Results Framework. Simply, a performance indicator is a data element that provides a numerical value that can be collected and analyzed over time. The use of performance indicators allows for the measurement of the magnitude of change over time for each of the results identified, thus providing insight into how well an activity, program, or organization is achieving its objective. Examples of some draft indicators under consideration are presented in the Table below. It is important to note that the performance indicators will be further defined for each specific commodity and country participating in this results-based approach.

Table: Example Indicators for the Import Prevention Results Framework

Results

Prime (Top) Result

Better Prevention of Food Safety Problems in the Foreign Supply Chain

- Number of reported incidences of contamination or outbreaks in foreign supply chain reduced
- Volume of imported products rejected at the U.S. border reduced

Result 1

Increased use of best practices by industry in priority countries and commodities

- Number of growers and processors for which third-party audit confirms use of best practices
- Percentage of those trained by FDA or its partners who can identify three or more best practices, 2 months after training was received

Result 2

Increased use of practices in compliance with regulated standards by industry in priority countries and commodities

- Number (percentage) of firms that come off of import alert
- Number (percentage) of re-inspections that find corrective action was taken

Result 3

Better execution of compliance activities by FDA

- Number (percentage) of inspections targeting the highest risk products, processes, and/or procedures during investigation
- Number (percentage) of FDA food inspectors and investigators that have passed general Good Manufacturing Practice certification assessment within a 5-year period

Result 4

Better execution of compliance activities by the partner country government and NGO's

- Number (percentage) of inspections that meet accepted standards
- Percentage of inspections and investigations conducted that were targeted

FDA is piloting this results-based approach in high-priority countries and with high-risk commodities. Specifically, FDA will implement the program in two countries, with two different commodities – produce and seafood. FDA will focus on tailoring the Imports Prevention Results Framework and related performance indicators to the needs and realities of each country and commodity. These pilots will serve to: (1) initiate a results-based approach to food safety technical assistance and capacity building within the pilot country's food safety system; (2) inform FDA of the framework's effectiveness; and (3) aid in implementing similar performance management systems for additional countries and commodities.

Rather than imposing cumbersome requirements on partner countries or duplicating existing systems, FDA intends to utilize, where possible, countries' existing data and data processes. FDA will consult with

relevant stakeholders (e.g., governments, industry, and academia), and will consider those consultations in developing the results framework, performance indicators, and PMP.

Developing tailored-result frameworks and performance indicators will enable FDA to monitor and evaluate the performance and progress of preventing problems in a foreign supply chain to ensure the safety of priority commodities entering the United States from exporting countries. It will also provide information on where additional capacity-building efforts should be placed. Similarly, partner countries that choose to participate in this effort will also directly benefit. Partner countries will have an opportunity to: (1) build partnerships with FDA; (2) gain insights into FDA's priorities and strategy for improving food safety; (3) collaborate and provide input on FDA decision making; (4) network with FDA scientists and regulatory experts; (5) deepen their capabilities and experience with regards to results-based management; (6) strengthen the management of their food safety systems; (7) work more effectively with other governments and multilateral institutions who are also applying this approach, as this approach becomes increasingly widespread; and (8) identify and communicate the technical assistance and capacity building areas they believe would be most useful for their food safety system.

Appendix C: Imports Prevention Results Framework

