



**U.S. FOOD & DRUG
ADMINISTRATION**

FDA Strategy for the Safety of Imported Food

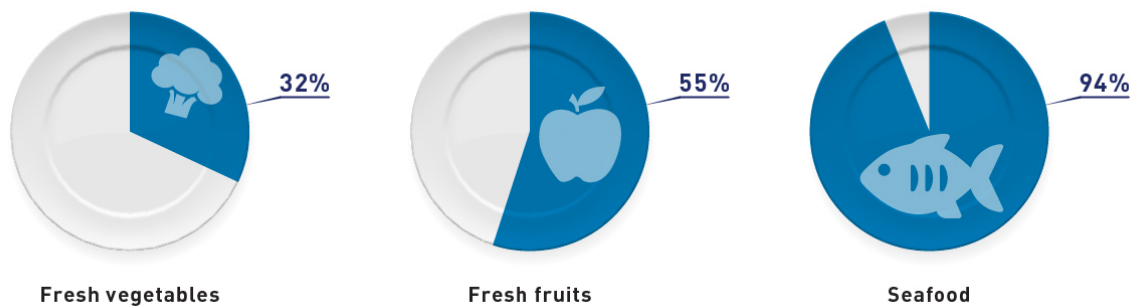


February 2019

INTRODUCTION

American consumers seek a diverse and abundant food supply that is simultaneously affordable and available throughout the year. To help meet these consumer demands, the United States imports about 15 percent of its overall food supply.¹ A 15-year trend of ever-rising import volume points to continuing increases, with other countries now supplying approximately 32 percent of the fresh vegetables, 55 percent of the fresh fruit, and 94 percent of the seafood that Americans consume annually (see Figure 1).²

Figure 1. Import share of U.S. food consumption (by volume)



Today, the nation imports food from more than 200 countries or territories and approximately 125,000 exporting food facilities plus farms. To meet consumers' growing demands, globalization of the food supply and adaptations of the food industry have resulted in more complex supply chains, varying business models, and increased specialization.

The Food and Drug Administration (FDA or "agency") oversees the safety of most of the human and animal food ("food") consumed in the United States. An important aim of the agency's strategy for the safety of imported food is to assure Americans that food imported from abroad is held to the same food safety requirements as food produced domestically. In the past, FDA's imported food safety system focused on intercepting unsafe food at the border and preventing its entrance into the U.S. marketplace. As the volume of imports increased, along with a diversity of products and countries of origin (see Figures 2 and 3) the traditional regulatory oversight model was challenged.³ In 2019, between 14 and 15 million shipments of imported food are expected to enter the United States.⁴

Figure 2. Number of imported food shipments by exporting country/region

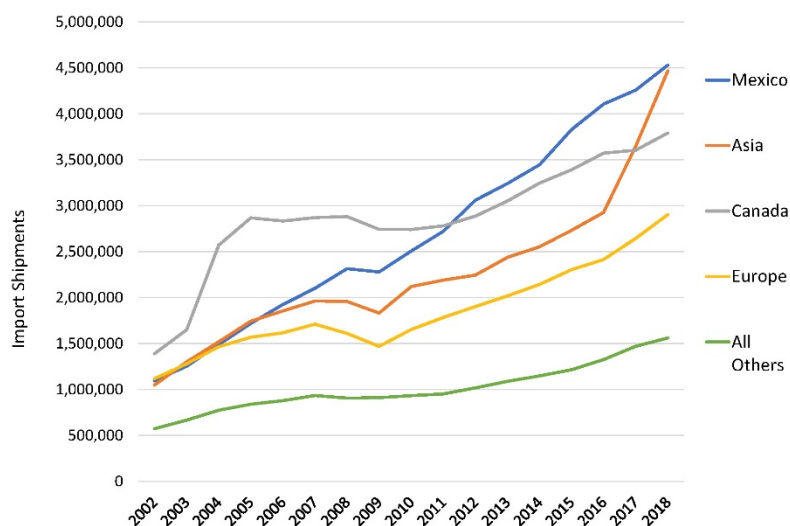
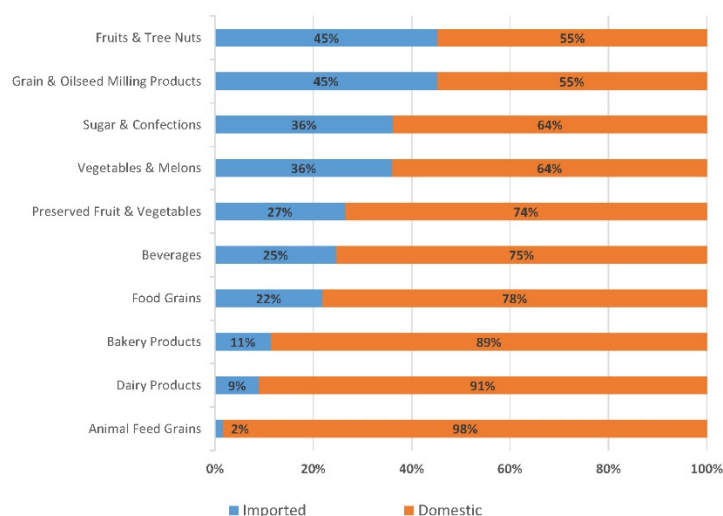


Figure 3. Imports vs domestic share of U.S. consumption (by value) selected food groups, 2016



Despite advances in promoting food safety, millions of people still get sick each year from foodborne illness. The Centers for Disease Control and Prevention (CDC) estimates 48 million people get sick, 128,000 are

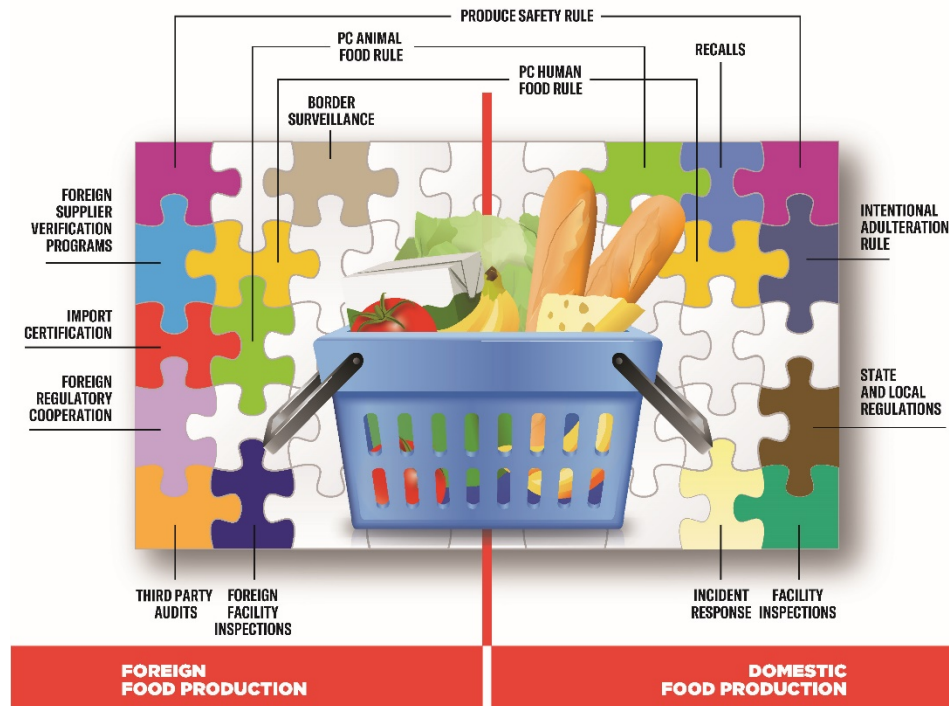
hospitalized, and 3,000 die from foodborne diseases each year in the United States.⁵ In addition, others are harmed by chemical and physical hazards associated with food intake. Animals, too, suffer illness and injury related to food. While these food safety problems can be traced to both domestic and imported foods, the volume and variety of imported products, coupled with the complexity of global supply chains, make food safety problems challenging to trace and address. In addition, globalization presents greater opportunity for economic fraud and food defense concerns (e.g., preventing health- and life-threatening adulterations). Moreover, many countries that export food to the United States may have different food safety systems, utilize different standards, and possess different regulatory capacities. Finally, during importation, FDA may find new hazards or known hazards in new places. This complex regulatory environment requires an adaptive and holistic approach to oversight.

The FDA Food Safety Modernization Act (FSMA) aims to ensure the U.S. food supply is safe by shifting the focus of federal regulators from responding to contamination to preventing it. This includes granting the agency expanded authority to mandate additional preventive controls designed to ensure a safe food supply in the United States. Over the last several years, the agency developed prevention-based standards applicable to foreign and domestic food growers, manufacturers, processors, packers, and holders. For example, the preventive control rules for human and animal food production require manufacturers, processors, packers, and holders of foods to broadly institute current good manufacturing practices and, as appropriate, to apply preventive controls, including supply chain controls as appropriate. The produce safety rule, which emerged from FSMA, requires foreign and domestic growers to implement minimum standards for the safe growing, harvesting, packing, and holding of produce.

In addition to establishing food safety standards, FSMA grants FDA new and supplementary oversight and enforcement authorities to ensure industry is meeting these standards. While inspectional oversight remains the primary tool for domestic food producers and is an important tool for foreign producers, the U.S. Congress determined that more was needed to control the food safety risks associated with imported foods. Thus, FSMA creates a multilayered safety net with respect to imported food, specifying distinct roles for manufacturers, importers, third-party auditors, foreign regulatory bodies, FDA, and other stakeholders. FSMA provides FDA significant new tools and, more fundamentally, it mandates an agency shift in perspective; FDA is charged with creating an oversight system designed primarily to prevent food safety problems from occurring, preferably before the food arrives at our border or reaches the plates of U.S. consumers.

Determining the best way to use the full range of available tools across the different segments of the international food-supply chain — in ways that decrease public health risks while maintaining a level playing field for domestic and foreign producers — requires both dexterity and pragmatism. This strategy document describes how FDA is integrating the new import oversight tools with existing tools as part of a comprehensive approach to imported food safety.

Figure 4. Foreign and Domestic Food Safety Oversight Activities



Guiding Principles

FDA applies the same U.S. food safety requirements to all food consumed in the United States, regardless of whether the facility or farm that produces the food is located within the United States or half way across the globe. Because FDA's enforcement tools abroad differ from the agency's tools domestically, Congress directed FDA to develop certain programs to ensure the safety of imported food. As with domestic oversight, FDA's strategy for overseeing the safety of imported food is to maximize agency public health impact by aligning resource allocation to risk level, tailoring the use of new and existing regulatory tools accordingly. FDA will work to optimize oversight of foreign firms and the portion of imported foods that receives FDA oversight, including leveraging the work of partners with strong regulatory systems or responsible parties in the food supply chain.

FSMA recognizes the importance of aligning regulatory approaches with risk, and FDA is continuously improving its ability to identify areas of higher risk. As it implements FSMA and uses all available tools to monitor and ensure the safety of imported food, FDA has the opportunity to collect and analyze information from new data sources (e.g., foreign supplier verification programs, voluntary importer incentive programs, accredited third-party auditors, foreign regulatory authorities, and domestic supply chain activities) to form a more complete picture of the risk of imported food in a new era of smarter food safety. For example, information from the implementation of new oversight tools can help FDA identify which foreign facilities to inspect and which imported food shipments to test. By placing a greater emphasis on analyzing a larger pool of information, including implementing processes for investigators to relay the information back to the agency for incorporation into work planning and screening models, FDA can allocate resources in a

more targeted way. Likewise, data analysis will help the agency know where to supplement training or focus other outreach efforts by revealing areas of greater risk. FDA will be transparent by publishing non-confidential data about imported food, foreign suppliers of food, food importers, and FDA's related oversight activities. The agency also plans to develop performance measures and outcome indicators for imported food safety. To these ends, FDA developed this strategy according to several guiding principles:

Protecting public health is the first priority: All imported food safety activities are carried out with the end goal of protecting and promoting public health.

Partnering with others to build prevention-based systems is the key to success: FDA must partner with a variety of stakeholders to ensure that safety is built into food production and processing from farm to table, preventing foodborne illness and injury before they begin. Regulatory partners here in the United States and abroad play an important role in FDA identifying and rejecting unsafe food offered for import into the country as well as marshalling effective responses when foodborne illness or injury does occur.

Maintaining scientific expertise and innovation as the foundations of FDA's food safety work: Science drives FDA's imported food activities, from testing for compliance with food safety controls, to developing new testing methodologies for detecting pathogens or contaminants on foods offered for import, to establishing an expanded network of laboratories with the capability and capacity to ensure that imported foods meet U.S. safety requirements.

Sustaining a level playing field for domestic and foreign food producers: FDA must apply the full range of oversight tools to ensure that food imported from abroad is as safe as food produced domestically. Although the tools may differ in the foreign and domestic arenas, they ultimately create a multilayered food safety net strengthened with areas of overlap and interconnection.

Allocating resources according to risk is the most effective method for protecting public health, and data analytics is the key to prioritizing according to risk: FDA maximizes the public health benefit of its regulatory oversight by putting more resources toward riskier areas and fewer resources toward lower-risk areas. The agency understands where areas of greater risk are through effective collection and comprehensive consideration of intelligence from a range of sources regarding multiple risk factors. Supported by an improved facilities and farms inventory, FDA will strategically allocate resources across all foreign food facilities and farms and at the border.

Requiring measurement and ongoing refinement to ensure success: Development of performance measures and outcome indicators for imported food safety will improve and maximize the success of imported food safety activities.

Establishing transparency as the standard: FDA will publish non-confidential data related to inspections of foreign suppliers and importers, examination and sampling, or other imported food safety activities in support of our commitment to operate transparently.

GOALS AND OBJECTIVES

FDA's imported food safety goals fall into three categories: (1) preventing food safety problems in the foreign supply chain prior to entry into the United States, (2) effectively detecting and refusing entry of unsafe foods at the border, and (3) rapidly responding when FDA learns of unsafe imported foods. An overarching fourth goal is to create an effective and efficient food import program. This strategy outlines several methods the agency plans to use to accomplish these goals including strategies for each objective.

GOAL 1: Food Offered for Import Meets U.S. Food Safety Requirements

Objective 1.1: Optimize use of foreign inspections

Objective 1.2: Ensure importer use of verified foreign suppliers through effective implementation of the Foreign Supplier Verification Programs final rule

Objective 1.3: Take into account the public health assurances of reliable audits such as those issued under FDA's Accredited Third-Party Certification Program or pursuant to other assurance programs aligned with FDA food safety requirements

Objective 1.4: Incentivize importers to use verified suppliers of safe food through the Voluntary Qualified Importer Program

Objective 1.5: Leverage the oversight efforts of regulatory counterparts with strong food safety systems

Objective 1.6: Increase awareness of and training on food safety requirements and strengthen the capacity of foreign suppliers to produce safe food

GOAL 2: FDA Border Surveillance Prevents Entry of Unsafe Foods

Objective 2.1: Continue to enhance and refine FDA's import screening and entry review processes

Objective 2.2: Optimize use of physical examination and sampling of imported food

Objective 2.3: Strategically utilize import alerts and import certifications

Objective 2.4: Improve testing methodologies and tools used to determine admissibility of food offered for import

Objective 2.5: Maximize the benefit to border surveillance from state and other partnerships

GOAL 3: Rapid and Effective Response to Unsafe Imported Food

Objective 3.1: Maximize effectiveness of FDA response to an event involving an imported food

Objective 3.2: Enhance the efficiency and effectiveness of imported food safety recalls

Objective 3.3: Use information-sharing opportunities to prepare for and respond to the entry of unsafe imported food

GOAL 4: Effective and Efficient Food Import Program

Objective 4.1: Optimize resource allocation by developing a comprehensive global inventory of food facilities and farms and assessing the cumulative oversight applied to the global inventory

Objective 4.2: Ensure effectiveness of import activities through performance assessment and continuous improvement

GOAL 1: FOOD OFFERED FOR IMPORT MEETS U.S. FOOD SAFETY REQUIREMENTS

American consumers expect that the food they purchase at the marketplace is safe. With respect to food offered for import, the best way FDA can fulfill this expectation is to ensure that the foreign supply chain is compliant with U.S. food safety requirements. These include new prevention-based requirements that set the standards for safe food, whether imported or of domestic origin. To ensure the safety of the significant volume of food offered for import into the United States, FDA will pursue objectives related to verification, enhanced compliance, and increased data and information sharing. In particular, FDA will:

- Optimize the use of foreign facility inspections and allocate resources to other oversight activities based on risk
- Hold foreign suppliers to U.S. food safety standards and importers to foreign supplier verification requirements
- Consider information from reliable third-party audits and other assurance programs aligned with U.S. food safety requirements as appropriate
- Work cooperatively with our domestic and foreign regulatory counterparts to establish agreements designed to leverage each other's food and facility oversight through data and information sharing
- Provide training and outreach to a variety of stakeholders (e.g., foreign industry, importers, brokers, and regulatory counterparts) to increase compliance with U.S. food safety requirements

The public health outcome of these efforts is expected to be a reduction in the number and severity of food safety problems in the foreign supply chain.

Objective 1.1: Optimize use of foreign inspections

Overseeing food production in facilities and on farms located in foreign countries is challenging. Onsite inspections of foreign food facilities and farms yield strong first-hand evidence of compliance. However, foreign facility inspections are very resource-intensive. FDA is mindful of the need to balance the cost of agency action with the public health benefit. Optimizing and prioritizing agency use of the valuable but resource-intensive inspection tool abroad requires thoughtful work planning informed by an increasing amount of data and information from other oversight activities and partners, prioritized by risk to public health.

- **Strategy 1.1a:** *Incorporate more and better data into inspectional work planning and prioritization for foreign food facilities and farms*
- **Strategy 1.1b:** *Enhance the role of FDA foreign offices to perform and facilitate foreign inspections*
- **Strategy 1.1c:** *Optimize human resource allocation by using investigators who have specialized training in food safety to conduct the foreign food facility and farm inspections*

Objective 1.2: Ensure importer use of verified foreign suppliers through effective implementation of the Foreign Supplier Verification Programs final rule

FSMA provided FDA with a new tool to significantly enhance FDA's oversight of the inventory of foreign food facilities and farms. Under the Foreign Supplier Verification Programs (FSVP) regulation, a U.S.-based importer is now required, among other things, to conduct a hazard analysis – an evaluation of risk of the

food and foreign supplier – and to conduct verification activities based on the hazard analysis. FDA continues to develop and implement its robust outreach, training, and technical assistance plan for FSVP, to include partnerships and collaborations with regulatory counterparts, academia, and private industry. FDA is building its inventory of FSVP importers and increasing its understanding of their connections through the supply chain with FDA-regulated foreign food facilities and farms. This new authority augments the agency's authority in the seafood and juice hazard analysis and critical control point (HACCP) rules, which also require importers to verify their suppliers. In addition, the FSVP rule complements supply chain controls required as preventive controls for some foods. Through inspection of importers, domestic producers, and foreign suppliers, FDA will promote compliance with foreign supplier verification programs as well as supply chain requirements and will gather additional information to prevent unsafe food from entering the U.S. market.

- **Strategy 1.2a:** *Provide education and technical assistance to increase awareness of, and compliance with, foreign supplier verification programs*
- **Strategy 1.2b:** *Deepen importer and foreign food facilities and farms inventory knowledge base to enable FDA to evaluate the extent of agency oversight of the foreign inventory through FSVP and to inform work plan determinations as to type and frequency of inspection*
- **Strategy 1.2c:** *Deter noncompliance through strategic enforcement of foreign supplier verification programs and supply chain controls requirements*

Objective 1.3: Take into account the public health assurances of reliable audits such as those issued under FDA's Accredited Third-Party Certification Program or pursuant to other assurance programs aligned with FDA food safety requirements

FDA recognizes that audits can provide valuable public health assurances if they are reliable and aligned with relevant FDA food safety requirements. Examples of such audits include those under FDA's Accredited Third-Party Certification Program. FDA has established a voluntary program for the recognition of accreditation bodies to accredit third-party certification bodies, also known as third-party auditors, to conduct food safety audits and issue certifications of compliance regarding foreign facilities and the foods produced in them. The requirements of the Accredited Third-Party Certification Program will help ensure the independence of the accreditation bodies and the competence of the third-party certification bodies participating in the program.

FSMA specifies two main uses for third-party certifications from FDA's program. Importers will use third-party audits to help establish eligibility for FDA's expedited importation program, the Voluntary Qualified Importer Program (VQIP), based on safety assurances that the audits can provide. FSMA also specifies that an accredited third-party auditor's report may be used when the agency requires certification of a food before permitting entry into U.S. commerce. Also, third-party certification bodies must report to FDA when they discover conditions that could cause or contribute to a serious risk to the public health. These notifications also provide essential information that FDA can use to optimize allocation of border and facility inspection resources.

Importers and manufacturers may request food safety assurance as part of contractual responsibilities of their suppliers. When these assurances are in alignment with U.S. food safety requirements, they are

valuable and contribute to a body of information that can be taken into account with respect to allocation of oversight resources. For FDA, there may be an opportunity to incorporate information from other assurance programs aligned with U.S food safety requirements into FDA's system of oversight.

- **Strategy 1.3a:** *Oversee effective implementation of FDA's Accredited Third-Party Certification Program*
- **Strategy 1.3b:** *Leverage third-party notifications to FDA, through the Accredited Third-Party Certification Program, of potential serious risks to public health*
- **Strategy 1.3c:** *Assess the alignment of audit programs with U.S. food safety requirements and consider how reliable audits can be taken into account in work planning and oversight of imported food*

Objective 1.4: Incentivize importers to use verified suppliers of safe food through the Voluntary Qualified Importer Program

The Voluntary Qualified Importer Program is a voluntary, fee-based program providing expedited review and importation of foods by importers who achieve and maintain a high level of control over their supply chains. Participants are eligible, if, among other criteria, they import food from suppliers certified by an accredited third-party auditor as producing the audited product in accordance with applicable FDA food safety requirements, including the preventive controls and produce safety rules. The agency will monitor continued qualification of participants to protect the integrity of this importer incentive program.

- **Strategy 1.4a:** *Promote the production of safe food through importer incentive programs*
- **Strategy 1.4b:** *Protect the integrity of VQIP through continued monitoring and transparency*

Objective 1.5: Leverage the oversight efforts of regulatory counterparts with strong food safety systems

To fulfill its mission to monitor and ensure the safety of the supply chain of imported food, FDA collaborates and partners with foreign governments, regulatory coalitions, standards development organizations, academic institutions, and others. These collaborations can take a variety of forms.

One such collaborative mechanism is food safety systems recognition, a regulatory cooperation tool between food safety authorities where we determine whether FDA can rely on other countries' food safety systems and oversight activities (and they on ours) to provide comparable levels of public health protection. FDA has made systems recognition arrangements with New Zealand, Canada, and Australia and is working with the European Union on a mutual assessment. Whereas systems recognition is a regulatory partnership intended to help us redirect limited resources to higher-risk areas, FDA may enter other types of arrangements that require assessments of foreign regulatory controls. For example, FDA may assess and decide to determine equivalence for a measure or set of measures. Equivalence determinations facilitate trade, while also providing confidence that the U.S. level of protection is being met.

In addition to systems recognition and equivalence arrangements, FDA may enter arrangements with foreign regulatory authorities to conduct specific oversight and offer certain verifications (e.g., pre-export testing) to provide assurances of the safety of certain exported products. Through reliance on the food

safety systems and information from regulatory counterparts with strong food safety systems, FDA can concentrate more resources on areas of higher risk.

- **Strategy 1.5a:** *Recognize countries with comparable food safety systems and reallocate oversight resources to areas of higher risk*
- **Strategy 1.5b:** *Conduct equivalence determinations to assess the safety of imported food and facilitate the export of safe food in accordance with our trade obligations*
- **Strategy 1.5c:** *In circumstances where neither systems recognition nor equivalence determinations apply, consider alternative international cooperative arrangements to leverage the inspectional, product, and export oversight activities of foreign regulators thereby providing supplementary public health assurances for imported food*

Objective 1.6: Increase awareness of and training on food safety requirements and strengthen the capacity of foreign suppliers to produce safe food

FDA uses various other methods to minimize the risk that unsafe imported food will make it into U.S. commerce, including by providing educational outreach to domestic and foreign industry on U.S. food safety requirements and food defense issues such as intentional adulteration. For example, the agency:

- Issues guidance to help food producers comply with U.S. safety regulations and requirements related to food defense and provides educational resources to individual firms during inspections.
 - Collaborates with educational institutions along with other government agencies to provide training and address scientific issues concerning human and animal food that may adversely affect the safety of imported food and health of U.S. consumers (e.g. the Sprout Safety Alliance, the Seafood HACCP Alliance, the Produce Safety Alliance, and the Food Safety Preventive Controls Alliance.)
 - Partners with federal agencies to develop training curricula for manufacturing processes, preventive controls, and best practices.
 - Collaborates with academic institutions to develop and deliver training and outreach to foreign suppliers, according to approved curricula, on practices that result in production of safe food prior to its reaching the U.S. border for importation.
 - Advances public-private research partnerships and research projects that support food safety and food defense efforts; FDA will comprehensively use results from these projects to inform a broad spectrum of risk-based decisions regarding imported food safety monitoring and enforcement of U.S. food safety requirements.
 - Conducts and participates in conferences, performs outreach to suppliers and regulatory officials, and works with other partners to disseminate information on U.S. food safety requirements.
- **Strategy 1.6a:** *Provide education, guidance, and technical assistance to facilitate foreign supplier and importer compliance with FDA food safety requirements*
 - **Strategy 1.6b:** *Advance public-private research partnerships and research projects in support of food safety and food defense efforts and comprehensively use results*

Public Health Outcome: Reduced food safety problems in the foreign supply chain

GOAL 2: FDA BORDER SURVEILLANCE PREVENTS ENTRY OF UNSAFE FOODS

FDA's surveillance effort at more than 300 active U.S. ports of entry, all points where shipments enter the U.S., remains an essential element of its strategy to ensure the safety of imported food. Generally, FDA's surveillance tools are screening, examination, sampling, and testing. The agency will maximize public health assurance by incorporating new sources of information into import screening and entry review processes. Strategic examination of shipments and sampling using refined testing methods will assist in the effort to find and prevent entry of unsafe foods into U.S. markets.

FDA is committed to working with domestic and international food safety regulatory and public health partners to increase the effectiveness of identification of food safety issues at the border. FDA will develop feedback loops for the intelligence gathered from multiple sources and use that information to maximize the effectiveness of its border oversight. Data analytics inform FDA decisions about how and where to use border surveillance resources to deploy available border tools more strategically. The public health outcome of these measures is more effective interdiction of unsafe food at ports of entry.

Objective 2.1: Continue to enhance and refine FDA's import screening and entry review processes

FDA electronically screens every one of the millions of shipments of food offered for import into the United States every year. Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) is FDA's automated import screening tool. FDA uses PREDICT to identify higher-risk shipments of food offered for import. PREDICT screens all regulated shipments, taking into account multiple factors about each import shipment – everything from compliance history of the facility that produced the imported product to the level of risk associated with that product. With that current intelligence, PREDICT assigns a risk score¹ to every imported food shipment, identifying higher-risk shipments for potential examination and expediting the clearance of lower-risk cargo.

FDA continues to assess opportunities to optimize import screening by incorporating new sources of intelligence with its current data. By optimizing import screening in this fashion, FDA is better able to identify and hold food offered for import when food poses a risk to public health.

- **Strategy 2.1a:** *Optimize import screening by incorporating new sources of intelligence with current data*
- **Strategy 2.1b:** *Use import screening to prevent entry of food shipments by importers lacking adequate foreign supplier verification programs*

¹ The PREDICT risk score is a percentile ranking compared to similar commodity.

Objective 2.2: Optimize use of physical examination and sampling of imported food

Reviewing entry documents and conducting physical examination of the contents of food shipments offered for import is valuable, but resource-intensive. Sampling and testing food before admitting it into the country can be an effective method for detecting contamination; however, it is labor-intensive and costly to industry as well as to the agency. FDA will use an approach to examination and sampling that targets the highest-risk products, allows regular monitoring and surveillance of imported products, facilitates targeted assignments to collect data that informs oversight activities, and assists with verification of other related programs. Smart work planning — using all available intelligence — is essential, as is the ability to adjust work plans when information supports reallocation of resources.

- **Strategy 2.2a:** *Develop and execute strategic and targeted physical examination and sampling based on advanced analyses of data from multiple sources*

Objective 2.3: Strategically utilize import alerts and import certifications

Import alerts (IAs) are used to provide information to field staff when the agency has reason to believe that future shipments of a product offered for entry may appear to violate FDA laws or regulations. The agency uses a variety of data to determine if future shipments are likely to appear violative. IAs are incorporated into the electronic system that screens food shipments being offered for import, and this helps FDA communicate with field staff across all ports of entry.

After FDA detains a shipment that is listed on an IA, the importer has the opportunity to prove that the product it wants to import into the U.S. is safe. This helps FDA efficiently allocate oversight resources toward products warranting increased monitoring. IAs are usually specific to a manufacturer, importer, product, facility, or farm, and, if there is sufficient evidence, they may apply world-wide, country-wide, or area-wide. FDA may also list an entity on an IA when a foreign facility refuses inspection or when an importer is in violation of FSVP requirements.

FDA has the authority to make a risk-based determination to require, as a condition of admissibility, that a food imported or offered for import into the United States be accompanied by a certification or other assurance that the food meets the applicable requirements of the FD&C Act. The authority to mandate import certification for food, based on risk, is one of the tools we can use to help prevent potentially harmful food from reaching U.S. consumers. When FDA has determined that a food import is subject to such certification, FDA will require, as a condition of entry, a certification issued either by an accredited third-party certification body or by an agency or representative of the government of the country from which the food at issue originated, as designated by FDA.

- **Strategy 2.3a:** *Utilize data and information from oversight activities, regulatory cooperation, and other reliable sources to enhance the effectiveness and efficiency of import alerts*
- **Strategy 2.3b:** *Detain and refuse admission of food from a foreign facility, if FDA is refused inspection*
- **Strategy 2.3c:** *Address known safety risks of food by requiring import certification as a condition of admission, where appropriate*

Objective 2.4: Improve testing methodologies and tools used to determine admissibility of food offered for import

FDA scientists use hundreds of established, validated tests and screening methods to detect pathogens or contaminants in different types of food and food presentations. For example, FDA uses one method to test for the presence of *E. coli* on fresh leafy green vegetables and another method to test for the presence of drug residues in seafood. In cases where there is no satisfactory method to test for a pathogen or contaminant in a type of human food offered for import, FDA scientists are working to develop and validate new methods.

Scientists also are working to improve and expand our rapid screening analytical capabilities by developing methods and devices that produce results more quickly and that detect more than one kind of contaminant. Using rapid screening methods and devices when examining shipments of food offered for import makes FDA border operations more efficient and allows the agency to make quicker admission decisions. FDA will also establish a laboratory accreditation program, designed, in part, to ensure that accredited laboratories that test imported foods produce accurate and reliable results.

- **Strategy 2.4a:** *Update and expand our analytical test method portfolio through identification and development of additional methods for testing food offered for import*
- **Strategy 2.4b:** *Deploy new analytical tools to augment imported food screening capability and capacity*
- **Strategy 2.4c:** *Establish a program for laboratory accreditation to ensure that laboratories that test imported foods produce accurate and reliable results*

Objective 2.5: Maximize the benefit to border surveillance from state and other partnerships

Under certain circumstances, states conduct sampling and analyses of higher-risk imported foods — once they have entered commerce in their jurisdictions — and they share findings with FDA that may indicate significant food safety problems. FDA will continue to support collaborations and shared communications with state regulatory partners. This is a foundational element of our nation's strategy for supporting and ensuring an effective and efficient Integrated Food Safety System by leveraging the work, expertise, resources, and authorities of partner agencies with food safety responsibilities. FDA also will continue to encourage participation in organizations and networks that support the speed and accuracy of signal detection and response by providing platforms for sharing scientific evidence of food safety problems internationally.

- **Strategy 2.5a:** *Collaborate with state and other regulatory authorities to ensure effective and efficient bilateral exchange of data on imported foods*
- **Strategy 2.5b:** *Develop clearly defined criteria for FDA's acceptance of state food regulatory laboratory results to support agency action, thereby maximizing FDA's ability to leverage states' work to advance public health*
- **Strategy 2.5c:** *With input from state regulatory partners, develop and distribute best practices to prepare human and animal food testing laboratories for accreditation*

- **Strategy 2.5d:** *Support speed and accuracy of signal detection and response by encouraging foreign regulatory counterparts to participate in organizations and networks, such as GenomeTrakr, that provide platforms for sharing scientific evidence of food safety problems internationally*

Public Health Outcome: More effective interdiction of unsafe food at ports of entry

GOAL 3: RAPID AND EFFECTIVE RESPONSE TO UNSAFE IMPORTED FOOD

FDA designs procedures and processes to ensure that in the event unsafe food enters the country, it is quickly identified and removed from the marketplace. Once a food is admitted through importation, FDA may use the same portfolio of tools it uses for domestically produced foods, including recall.

The agency works with regulatory partners that have public health missions related to food safety to maximize FDA's ability to facilitate quick response to outbreaks through collaboration and resource leveraging. The expected public health outcome of these measures is a reduction in the duration and public health impact of any imported food-related outbreak of illness.

Objective 3.1: Maximize effectiveness of FDA response to an event involving an imported food

FDA's Coordinated Outbreak Response and Evaluation (CORE) network analyzes internal and external information to identify human foodborne illness and injury trends and evaluates potential and emerging clusters of illnesses and injuries. CORE communicates regularly with CDC and the United States Department of Agriculture about emerging human food-related illness outbreaks and acts as the lead for FDA in coordinating response as well as related surveillance and post-response activities. CORE manages these incidents for all human food, regardless of whether it was imported or produced domestically. CORE also analyzes emerging information about human foodborne illness outbreaks overseas that may lead to contaminated food being exported to the United States. FDA's foreign posts in the Office of International Programs also highlight significant signals of public health risk that may impact food exported to the United States, which FDA can use to inform subsequent activities.

As applicable, registered food facilities are required to inform FDA if there is a reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals. FDA's *Reportable Food Registry* (RFR, or the "Registry") compiles these mandatory reports. Though not mandatory, local and foreign governments are encouraged to submit these reports to RFR, as well. The agency uses the RFR filings to track patterns, target inspections, and begin responding to risks posed by food intended for consumption in the United States. The sooner and more often that foreign and domestic partners and other stakeholders notify FDA of food safety problems, the sooner FDA can act to lower the risks posed to public health.

If unsafe human and animal foods do enter the U.S. marketplace, FDA may use a variety of tools to minimize the risk to consumers. The agency can recommend or request a voluntary recall by the responsible party. When the threat to public health rises to a certain level and a firm refuses to or does not voluntarily recall an unsafe food, FDA is authorized to mandate food recalls. We may also seize or administratively detain unsafe food. In addition, FDA can use the authority to suspend a facility registration and, thereby, prevent importation of foods determined to have a reasonable probability of causing serious adverse health consequences or death to humans or animals.

- **Strategy 3.1a:** *Enhance FDA decision making and coordination when responding to food safety problems caused by imported foods through greater access to information from foreign sources*
- **Strategy 3.1b:** *Enhance processes that allow foreign and domestic partners and stakeholders to notify FDA of food safety problems in a timely manner, for example, in accordance with requirements of the Reportable Food Registry, so FDA can act against products that have entered the United States*
- **Strategy 3.1c:** *Further develop and refine processes to enable use of agency authorities to prevent importation of unsafe food from facilities, including those with suspended registrations*

Objective 3.2: Enhance the efficiency and effectiveness of imported food safety recalls

Before FSMA was enacted, FDA primarily relied on responsible parties to voluntarily recall violative food products. While voluntary recalls are still the primary means to remove violative products from the U.S. food supply, FSMA granted FDA the authority to mandate a recall when FDA determines the food is adulterated or misbranded with respect to allergen labeling and that there is a reasonable probability that the food would cause serious adverse health consequences or death to humans or animals. When a marketed imported food presents a danger to consumers' health and the recall is complex or the importing firm(s) is reluctant to act, the agency will leverage the experience and expertise of its senior leaders through its Strategic Coordinated Oversight of Recall Execution (SCORE) team to help ensure that a human food recall or any other appropriate action is taken. Additionally, improved traceability will help to increase the effectiveness of an agency response. FDA will also oversee the adequacy of foreign facility recall plans when identified hazards require preventive controls. The requirement for recalling unsafe food is the same whether the food is produced domestically or abroad.

- **Strategy 3.2a:** *Exercise mandatory recall authority, when appropriate, to remove unsafe imported food from the U.S. market*
- **Strategy 3.2b:** *Continue SCORE team's oversight of complex recalls of imported human food, when necessary, to ensure they are carried out efficiently and effectively*

Objective 3.3: Use information-sharing opportunities to prepare for and respond to the entry of unsafe imported food

FDA regularly participates in information-sharing collaborations with domestic and international partners on projects involving preparation and response process development, intra-agency and interagency collaboration and communication, joint training of staffs, identification of preventive practices, and sharing

of best practices, including mechanisms that promote quick and coordinated responsive action to outbreaks and effective communication to consumers.

- **Strategy 3.3a:** *Use international arrangements to facilitate imported food safety investigations*
- **Strategy 3.3b:** *Share and expand use of state-of-the-art science to solve foodborne illness outbreaks occurring at the state, national, and international levels related to food imported to the United States*
- **Strategy 3.3c:** *Collaborate with state and other partners to develop and maintain a nationally integrated laboratory science system*
- **Strategy 3.3d:** *Develop and disseminate outreach, consumer education, and technical materials to consumers, industry, and state regulatory partners about imported food products that are potentially contaminated*

Public Health Outcome: More rapid and effective response to unsafe imported food

GOAL 4: EFFECTIVE AND EFFICIENT FOOD IMPORT PROGRAM

Advancing FDA's imported food public health mission depends on enabling smarter food safety, a world-class workforce, integrated and agile management systems, and meaningful engagement with stakeholders. It also requires responsible stewardship of resources, including both taxpayer dollars and user fees from industry. Faced with constrained resources and a rapidly evolving regulatory landscape, FDA will implement an adaptive, risk-informed, and cost-effective management system and infrastructure to support organizational excellence, performance, and accountability.

Objective 4.1: Optimize resource allocation by developing a comprehensive global inventory of food facilities and farms and assessing the cumulative oversight applied to the global inventory

As provided in FDA's statutory authority under the Food, Drug, and Cosmetic Act and as augmented by the import provisions of FSMA, FDA will employ the full range of oversight tools across a global inventory of food facilities and farms. To do this, we need to understand the cumulative value of oversight applied to foreign facilities and farms using all FDA's regulatory tools (e.g., inspection, third-party audits, examination, sampling). FDA will use the information collected from a variety of sources to optimize FDA resource allocation for imported food safety oversight to areas of higher risk.

- **Strategy 4.1a:** *Develop an improved global inventory of human and animal food facilities and farms that intend to distribute food in the United States*
- **Strategy 4.1b:** *Develop a modeling framework that supports risk-based resource allocation decisions related to the strategic global oversight of human and animal food facilities and farms*

Objective 4.2: Ensure effectiveness of import activities through performance assessment and continuous improvement

As a federal agency with a public health mission, FDA is obliged to measure success in meeting the objectives designed to accomplish this mission. FDA will develop performance measures and outcome indicators for imported food safety and will continue to hone these, as necessary. Accountability depends on transparency, and the agency therefore will publish FDA performance measures and outcome metrics as well as non-confidential data about imported food, foreign suppliers, and FSVP importers and other importers.

- **Strategy 4.2a:** *Develop performance measures and outcome indicators for imported food safety*
- **Strategy 4.2b:** *Publish meaningful data related to imported food, foreign food suppliers, and FSVP importers and other importers*

¹ Import Value Shares, 2016, USDA, ERS, International Markets, U.S. Agricultural Trade report, <https://www.ers.usda.gov/topics/international-markets-us-trade/us-agricultural-trade/data/>.

² Import share of fresh fruit consumption by volume: 55.1% in 2017, USDA-ERS Fruit and Tree Nuts Yearbook 2018, Table H-1 (<https://www.ers.usda.gov/data-products/fruit-and-tree-nut-data/fruit-and-tree-nut-yearbook-tables/>); Import share of vegetable consumption by volume: 31.6% in 2017, USDA-ERS Vegetables and Pulses Yearbook 2018, Table 12 (<https://www.ers.usda.gov/data-products/vegetables-and-pulses-data/vegetables-and-pulses-yearbook-tables/#Supply%20and%20Utilization:%20Fresh%20Market>); Import share of seafood consumption by volume: 94.1% in 2016, Fisheries of the United States, 2016 Report, (<https://www.fisheries.noaa.gov/resource/document/fisheries-united-states-2016-report>).

³ Figure 2: Import Value Shares, 2016, USDA, ERS, International Markets, U.S. Agricultural Trade report, <https://www.ers.usda.gov/topics/international-markets-us-trade/us-agricultural-trade/data/>; Figure 3: FDA's Operational and Administrative System for Import Support (OASIS), 2018.

⁴ Total imported human and animal food lines: 13.8 million (FY18), FDA's Operational and Administrative System for Import Support (OASIS). Fiscal year 2019 projected total imported human and animal food lines: 14.6 million, based on a five-year compound annual growth rate (CAGR).

⁵ <https://www.cdc.gov/foodborneburden/index.html>.