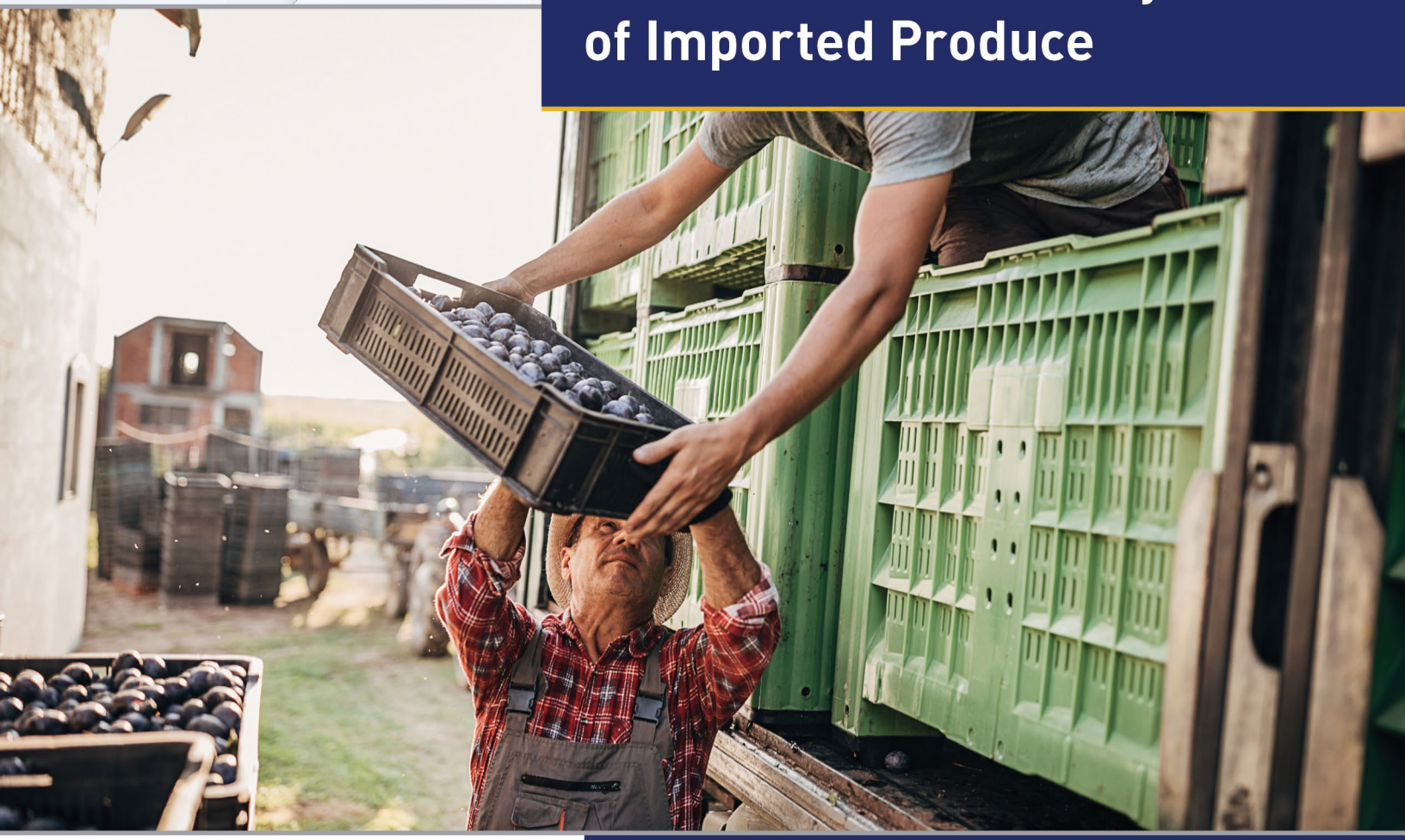
# Activities for the Safety of Imported Produce



U.S. FOOD & DRUG ADMINISTRATION

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## Introduction

This document details how the U.S. Food and Drug Administration's 2019 strategy for safeguarding imported food applies specifically to imported produce. It further describes how the work to enhance the safety of imported produce will advance in FDA's New Era of Smarter Food Safety as the agency leverages new technologies, tools and approaches to keep pace with an ever evolving food system.

FDA's efforts to enhance the safety of imported produce were advanced in 2011 when the FDA Food Safety Modernization Act (FSMA) was signed into law, shifting the focus of federal regulators from responding to contamination to preventing it. Since then, the FDA has developed prevention-based standards applicable to foreign and domestic food growers, manufacturers, processors, packers, and holders.

FSMA provided FDA with new tools and authorities to control the food safety risks associated with imported foods. In February 2019, the FDA released the *Strategy for the Safety of Imported Food* (Strategy or Import Strategy), which describes how FDA is integrating these new import oversight tools with existing tools as part of a comprehensive approach to imported food safety. It addresses the challenges to keeping food safe posed by complex global supply chains and varying food safety systems and differing regulatory oversight among the more than 200 countries and territories exporting food to the United States.

Soon after the release of the Strategy, FDA announced its New Era of Smarter Food Safety initiative that focuses on creating a more digital, traceable and safer food system to build on FSMA's successes. The New Era blueprint creates a 10-year roadmap for reaching this goal through tech-enabled traceability, smarter tools and approaches for prevention and outbreak response, new business models and retail modernization, and establishing a culture of food safety.

The safety of imported foods and the safety of produce are among the priorities outlined in the New Era blueprint. The success of FDA's imported food safety efforts relies in large part on the safety of produce since fresh fruit and vegetables represent a significant volume of imported food. About 15% of the U.S. food supply is imported, including nearly 55% of fresh fruit and 32% of fresh vegetables. This latest document, *Activities for the Safety of Imported Produce*, describes how the work to help ensure the safety of these commodities is a critical component of the New Era of Smarter Food Safety in building on the preventive standards established by FSMA.

The information in this document is organized according to the four goals that were introduced in the *Import Strategy*:

- **Goal 1:** Food Offered for Import Meets U.S. Food Safety Requirements
- **Goal 2:** FDA Border Surveillance Prevents Entry of Unsafe Foods
- **Goal 3:** Rapid and Effective Responses to Unsafe Imported Food
- **Goal 4:** Improving the Effectiveness and Efficiency of our Food Import Program

Following each goal is a description of activities specific to the FDA's work to enhance the safety of imported produce. This overview concludes with a discussion about how the activities supporting these goals interplay to protect produce imported into the United States

## Goal 1: Produce Offered for Import Meets U.S. Food Safety Requirements

One of the most effective ways to keep imported produce safe is for industry to comply with applicable U.S. food safety requirements. To ensure that produce offered for import into the United States meets U.S food safety standards the FDA engages in compliance verification activities such as inspections and testing; information sharing with foreign regulatory partners; and education and outreach activities to raise awareness and understanding of the requirements.

### 1.1: Optimize use of international inspections.

The Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Safety Rule or PSR) is one of the key regulations under the FDA Food Safety Modernization Act (FSMA) that applies to imported produce. The rule set science and risk-based minimum standards for domestic and international farms for the safe growing, harvesting, packing and holding of covered fruits and vegetables grown for human consumption. While the rule went into effect on January 26, 2016, the compliance date was rolled out over a series of years, depending on farm size. To assist international growers, the FDA issued materials and draft guidance and also translated the codified text of the PSR into Spanish, Portuguese, Chinese, Japanese and Korean.

The FDA began PSR inspections of international produce farms in April 2019. To prioritize produce farms for inspection the FDA uses a risk-based framework called the Produce Decision Analysis Tool (PDAT). The tool utilizes factors such as a farm's compliance history (i.e., inspections, audits, port of entry sampling, import alert status, etc.) and commodities handled to prioritize individual farms for inspections. PDAT's dynamic structure allows for new factors to be considered as additional farm-level data becomes available and as risk factors evolve over time. The same tool is used domestically to guide inspection prioritization by FDA and state inspection programs.

A specially trained group of investigators in the FDA's Office of Regulatory Affairs (ORA) takes the lead in conducting international produce farm inspections. These investigators are part of the Produce Safety Network (PSN), a network of produce safety experts and investigators from both the FDA's Center for Food Safety and Applied Nutrition (CFSAN) and ORA who are located regionally throughout the United States to support farmers, regulators and other key stakeholders with produce safety technical assistance. In addition to conducting international produce farm inspections, ORA PSN investigators perform domestic inspection and outbreak investigations, and support state produce programs. In addition to ORA PSN staff, FDA has at times been able to use investigators serving in its Latin American Office to conduct foreign produce safety inspections or to assist ORA in such inspections. These staff are trained in the same manner as the ORA PSN staff. FDA foreign offices also have staff available to assist ORA in conducting foreign inspections, especially in follow-up to farms associated with outbreaks.

### 1.2: Ensure importer use of verified foreign suppliers through effective implementation of the Foreign Supplier Verification Programs (FSVP) final rule

The Foreign Supplier Verification Programs (FSVP) regulation is a key FSMA requirement for importers of produce subject to the Produce Safety Rule. FSVP requires that an importer verify that the foods they bring into the United States have been produced in a manner that provides the same level of public health protection as certain applicable U.S. regulations— including the PSR. For the purpose of the FSVP, the importer is defined as the U.S. owner or consignee of a food offered for import into the United States. If there is no U.S. owner or consignee at the time of U.S. entry, the importer is the U.S. agent of the foreign owner or consignee at the time of entry. Specifically, FSVP requires importers to:

- Use a qualified individual to develop, maintain, and follow an FSVP
- Conduct and document a hazard analysis – based on experience, illness data, scientific reports and other information - of the known or reasonably foreseeable hazards for each type of food it imports to determine if there are any hazards requiring a control. Hazards include biological hazards, chemical hazards and physical hazards.
- Evaluate the risk posed by a food, based on the hazard analysis, and the foreign supplier's performance
- Use that evaluation of the risk posed by an imported food and the supplier's performance to approve suppliers and determine appropriate supplier verification activities (verification activities may include onsite audits, sampling and testing of the food, and review of foreign supplier food safety records).
- Take corrective actions as appropriate
- Maintain required FSVP records
- Ensure their importer identification information is provided at entry

FSVP adds a layer of oversight for imported food by holding importers accountable for the safety of products they are importing and provides the FDA with important data on foreign suppliers. The FDA has issued draft guidance and other materials to help importers comply with the FSVP regulation. During a routine FSVP inspection an investigator will review the importer's FSVP records that document the activities the importer conducted to verify that their suppliers were producing food in compliance with applicable U.S. food safety laws and the importer is meeting other FSVP requirements.

To align with the start of domestic and international inspections to verify compliance with the PSR in the Spring of 2019, specially trained FDA investigators began conducting FSVP inspections of produce importers in the fall of 2019. In addition, the New Era initiative challenged the agency to explore new ways of conducting inspections. In 2020, in response to the COVID-19 pandemic, the FDA began conducting remote FSVP inspections. The agency has been able to conduct more than 450 remote inspections of produce importers since October 2020. These inspections have provided us with more data and information that can inform our risk-based approach to preventing potentially unsafe imported food from reaching consumers.

To support importers' knowledge of the FSVP requirements, the Food Safety Preventive Controls Alliance (FSPCA) has developed training on the FSVP regulation for importers.

### 1.3: Take into account the public health assurances provided by reliable audits such as those conducted under FDA's Accredited Third-Party Certification Program or pursuant to other programs aligned with FDA produce safety requirements.

FDA recognizes the utility of reliable third-party audits and their potential to support the agency's oversight activities. Audits are not a replacement for inspections, but they can contribute additional data that can be used to prioritize inspections and other regulatory work. There are a few different ways that the agency utilizes audits:

- FDA's Accredited Third-Party Certification Program (TPP): The FDA has established the TPP program in which recognized accreditation bodies accredit certification bodies which can then conduct food safety audits and issue certifications. These certifications can be used to establish eligibility for participation in the Voluntary Qualified Importer Program (VQIP) (discussed below in section 1.4) and, in certain circumstances, food or facility certifications issued under FDA's TPP may be used to satisfy an FDA requirement that an article of food be accompanied by an import certification attesting to its compliance with applicable requirements of the FD&C Act. Certification bodies conducting audits under this program provide additional oversight by immediately notifying the FDA when they encounter potential serious risks to public health.
- FSVP: Under the FSVP regulation, importers can choose to audit fresh produce farms to determine if they comply with the standards of the PSR. While these audits do not have to be conducted under FDA's TPP, they must be conducted by a "qualified auditor" and they must consider applicable food safety regulations (i.e., the PSR). FDA has provided templates that outline PSR standards and could be used by international farmers, importers, and other stakeholders to help ensure the audits being conducted in support of the FSVP program cover all elements of the PSR.
- The FDA also engages in audit alignment activities. Alignment of the auditing schemes is intended to help those being audited to assess their food safety practices and better understand how well they are meeting U.S food safety requirements. The following are two examples:
    - USDA Harmonized GAP Audits: The FDA and USDA worked jointly to align the USDA Harmonized Good Agricultural Practices Audit Program (USDA H-GAP) with the standards of the PSR. Alignment of the USDA program with the PSR requirements provides additional means for farms to assess their food safety practices while they comply with the Produce Safety Regulation.
    - New Era of Smarter Food Safety initiative: The FDA is exploring the increased use of third-party audits with enhanced reliability to help ensure safer food, recognizing the significant scale and reach of global food safety audits, including produce safety. FDA launched a voluntary pilot program to evaluate alignment of private third-party food safety audit standards with the food safety requirements in the Produce Safety Regulation and the Preventive Controls for Human Food regulation. Alignment

determinations would give confidence to those relying on audits conducted to those standards that they are meeting certain FDA requirements for supplier verification audits. In addition, information from the pilot will allow the agency to evaluate the resources and tools required to conduct alignment reviews.

### 1.4: Incentivize importers to use verified suppliers of safe food through the Voluntary Qualified Importer Program (VQIP)

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. Expedited entry incentivizes importers to adopt a robust system of supply chain management and further benefits public health by allowing FDA to focus its resources on food entries that pose a higher risk to public health. 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 for Human Food Rule and the Produce Safety Rule.

Participating importers are able to import their products to the U.S. with greater ease and predictability, avoiding unexpected delays at the point of import entry. Consumers benefit from the importer's robust management of the safety and security of their supply chains. Expedited review and import entry may be particularly helpful for those importing perishable products, such as produce, or using "just in time" processing, in which ingredients must be at a food facility at a certain time in the manufacturing process.

The agency has and will continue to monitor the qualifications of participants to protect the integrity of this importer incentive program via annual controls, the self-reporting of deviations that impact eligibility, and periodic audit examinations and sample collections. To maintain eligibility for importation under VQIP, annually participants must submit an online application and the foreign supplier(s) of a VQIP food must obtain re-certification. As outlined in the VQIP Guidance for Industry, participants are responsible for promptly reporting to FDA all deviations that may impact their eligibility to participate in VQIP and their plans for correcting the deviations. FDA may also periodically conduct audit examinations, which may include sampling, and a review of the labeling as it relates to the risk of the food, to verify compliance with FDA food safety requirements.

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

The FDA has long recognized the importance of leveraging the oversight that our trusted international partners have over foods produced under their jurisdiction. Two programs we have implemented with our international partners related to produce are systems recognition and international arrangements.

- *Systems Recognition:* is a partnership between FDA and a foreign regulatory counterpart (collectively referred to as "participating agencies"), in which the agencies have concluded that they operate comparable regulatory programs that yield similar food safety outcomes. Systems Recognition offers FDA an opportunity to foster stronger ties with food safety authorities in other countries, and to enhance data sharing and information exchange in support of food safety efforts, including produce safety efforts. The FDA has systems recognition arrangements with New Zealand, Canada, and Australia and is working with the European Union on a mutual assessment. Canada has the second largest export volume of produce to the U.S.; about 16% of imported produce is from Canada. All current Systems Recognition Arrangements include produce covered by the FSMA Produce Safety Rule, and these systems will be evaluated for comparability with the PSR when the systems come up for re-assessment.

- *International Arrangements:* FDA fosters international partnerships with foreign counterpart government agencies and international organizations. The tools that FDA uses to set up and memorialize these partnerships include two categories of International Arrangements: Confidentiality Commitments and Cooperative Arrangements.

- A **Confidentiality Commitment** is a document that allows FDA and international counterparts to exchange non-public information as part of cooperative law enforcement or regulatory activities. FDA currently has Confidentiality Commitments with counterpart agencies in over 40 different countries. FDA continues to develop information sharing arrangements with international partners to facilitate produce safety discussions. Confidentiality Commitments are especially important when investigating foodborne illness outbreaks, including outbreaks from produce, because they allow the US to exchange non-public information with the foreign regulatory counterpart to facilitate follow-up.
- A **Cooperative Arrangement** (which include Memoranda of Understanding and similar documents) is a written understanding that describes the intentions of FDA and international counterparts to engage in cooperative activities.

An important cooperative arrangement that the FDA has entered into is with our regulatory partners in Mexico. The FDA and the Mexican food safety authorities, specifically the National Service of Agro-Alimentary Health, Safety and Quality (SENASICA) and the Federal Commission for the Protection against Sanitary Risks (COFEPRIS), entered into the Produce Safety Partnership (a cooperative arrangement) in 2014 to work collaboratively on produce safety. In September 2020, FDA and its Mexican counterparts enhanced the arrangement, renamed the Food Safety Partnership (FSP). The FSP includes four work groups to focus on prevention of foodborne illness, laboratory collaboration, outbreak response, and food safety training. Through the FSP, FDA, SENASICA, and COFEPRIS collaborate on priority produce safety issues, such as training and outreach to industry, exchanging information on analytical methods, and increased data sharing to improve outbreak response. FDA also holds confidentiality commitments with both SENASICA and COFEPRIS.

### 1.6: Increase awareness of and training on produce safety requirements to strengthen the capacity of foreign suppliers to export safe produce.

Produce industry training is an essential component of successful implementation of the Produce Safety Rule. While members of the industry are ultimately responsible for receiving the training needed to comply with the FSMA regulations, the FDA recognizes the importance of its role in facilitating that training. FDA has worked with partners around the world, including academia, regulatory counterparts, industry, and multinational organizations, to address the diverse training needs of the global community of produce suppliers.

FDA offers a variety of educational opportunities, including programming to meet regionally-specific needs, to international growers to promote the safe production of unprocessed produce that is subsequently exported to the U.S. For example, FDA has:

- Worked with stakeholders to offer training on key produce safety topics. FDA collaborated with industry partners to arrange Produce Safety Summits in Ecuador (April 2019) and Mexico (September 2019). These summits provided opportunities for stakeholders to hear from FDA and other experts on key produce safety topics, recent rulemaking activities, and current produce safety research.
- Conducted webinars to international stakeholders in English, Spanish and Portuguese, in collaboration with USDA Foreign Agricultural Service, to increase awareness and provide content-specific presentations on the PSR.
- Delivered On-Farm Readiness Reviews (OFRR) to international growers. The OFRR is a voluntary, educational program delivered to growers by FDA PSN produce safety experts that helps growers to determine their Produce Safety Rule readiness or knowledge gaps through personalized discussions and on-farm learning experiences. The International–OFRR (I-OFRR) program builds upon the domestic platform for this educational tool that was developed under a cooperative agreement between the FDA and the National Association of State Departments of Agriculture (NASDA). The FDA conducted I-OFRRs in 2019 and 2020 for growers in Chile, Costa Rica, Ecuador, and Mexico. Additionally, the FDA also provided training to the competent authorities in Chile and Costa Rica to enable them to deliver I-OFRRs to their growers. FDA continues to assess, in collaboration with our international partners, the ability to offer this in-person education tool and training in light of COVID-19 conditions and travel restrictions.

- Participated in collaborative engagements with industry which have included at least 35 webinars, three virtual conferences, and one workshop focused on biological soil amendments of animal origin during 2021. The FDA will continue to provide support to international stakeholders through virtual and/or in-person webinars, workshops and conferences; and educational opportunities to support PSR implementation while taking into account regionally specific practices, conditions, commodities and challenges.

FDA also works closely with partners that offer a variety of educational programming to international growers to promote the safe production of produce that is subsequently exported to the United States. For example:

- The Produce Safety Alliance (PSA) Grower Training: The PSA, under a cooperative agreement with FDA and USDA, created a produce safety curriculum recognized by FDA as adequate as the standardized curriculum described in the PSR. This curriculum is used to prepare farms covered by the PSR to meet the regulatory requirements of the PSR, including the requirement for food safety training for a supervisor or responsible party. The training materials and grower courses are translated into several different languages to provide accessible resources for international audiences.

- Inter-American Institute for Cooperation on Agriculture (IICA): The FDA holds a cooperative agreement with IICA to support implementation of FSMA in Latin America and the Caribbean, by developing a cadre of professionals trained on the PSA curricula (trainers and Lead Trainers) to promote produce safety practices and food safety culture development in the Americas. IICA helps lead the PSA Train-the-Trainer initiative in Latin America. Through this cooperative agreement, IICA accomplished a bilingual webinar series on the Produce Safety Regulation providing FDA personnel a platform to offer outreach on the PSR and associated topics to industry, government, and academia affiliated persons from 21 different countries.

- Joint Institute for Food Safety and Applied Nutrition (JIFSAN) at the University of Maryland (JIFSAN): The FDA holds a cooperative agreement with JIFSAN through which JIFSAN coordinates the PSA Train-the-Trainer courses internationally and supports international produce safety capacity building. JIFSAN also collects and analyzes training metrics to inform and enhance future trainings. IICA and JIFSAN, in collaboration with the FDA, build trainer capacity in FDA priority countries so that these trainers can offer training to farmers in their countries, in a sustainable manner. These trainings are conducted in collaboration with local academic, governmental, and industry stakeholders. IICA and JIFSAN have also coordinated remote PSA Trainings so that stakeholders, during the COVID-19 pandemic, have been able to access training virtually.

## Goal 2: FDA Border Surveillance Helps to Prevent Entry of Unsafe Foods

The FDA conducts border surveillance activities at more than 300 active U.S. ports of entry. Generally, these activities include import entry screening, examination, sampling, and testing. To inform its border surveillance activities the FDA uses information such as compliance history and risks associated with the commodity to inform actions that can help us to interdict unsafe foods at the border.

### 2.1: Enhance and refine FDA's import screening and entry review processes.

FDA uses an automated import screening system called Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) to screen all regulated import shipments, including produce. PREDICT uses multiple factors to screen imported produce, such as the compliance history of the farm and associated hazards for the imported commodity. PREDICT is updated frequently as FDA introduces new import safety programs and collects compliance information from importers based upon FSVP requirements and other sources. Data from the FDA microbiological surveillance large scale sampling programs is also utilized in PREDICT. PREDICT assigns a risk score and recommends sampling or physical examination of higher-risk shipments while expediting the clearance of lower-risk shipments.

Under the New Era initiative, the FDA is exploring the preventive value of new data streams generated by modern food safety approaches while also harnessing new technologies such as artificial intelligence and machine learning to develop the next generation of import targeting tools that will screen imported produce in the future.

### 2.2: Optimize use of sampling of imported produce.

FDA implements sampling and testing through planned surveillance work and in response to notifications about potential produce safety risks. Sampling and testing can help us to discover and respond to food safety issues, inform and identify trends, and provide data that can aid in the agency's risk-based decision-making processes.

FDA establishes annual domestic and foreign sampling priorities through Sample Collection Operations Planning Efforts (SCOPE). SCOPE establishes annual sampling priorities utilizing a sampling request process, with input from various FDA experts as well as states and other partners. The sampling requests undergo a risk-informed prioritization process where requests are evaluated, selected, and included in the annual work plan. This process allows FDA to optimize resources to better protect the food supply. Focused risk-based sampling aids in ensuring FDA uses its resources in the best manner to support public health.

In addition to the priorities outlined in SCOPE, FDA conducts large scale, multi-year sampling programs to identify patterns of contamination by disease-causing pathogens, including bacteria and viruses. FDA samples imported and domestic food commodities aimed at gathering data to aid in decision-making and risk mitigation. Some examples of produce commodities sampled under this program include cucumbers, avocados, and hot peppers. FDA analyzes the data gathered through these sampling assignments to identify trends as well opportunities to enhance the food safety system. These results are summarized and shared with industry and consumers. Based on the results of the sampling assignments, FDA may take certain follow-up steps such as targeted sampling, inspections, working with domestic and international regulatory partners to improve food safety, developing new or enhanced information or guidance for industry, and/or conducting outreach to industry.

FDA also samples in response to food-safety events. For example, FDA may implement testing of imports at the border in response to a foodborne outbreak or other emerging food safety issues.

### 2.3: Strategically utilize import alerts and import certifications.

**Import Alerts**

Import alerts (IAs) inform the FDA's field staff and the public that the agency has enough evidence that the listed products may be refused admission, and that field staff may detain the products without physical examination (DWPE) because the products appear to be in violation of the FDA's laws and regulations. The use of IAs allows FDA to target risks, and information on import alerts may also be reviewed by importers and to regulatory partners in exporting countries. IAs can be firm/commodity specific or can cover a commodity in a region or country.

Each import alert describes the basis for the imported product being subject to DWPE. For a product or firm-specific IA, products and firms that appear violative may be added to the Red List of the alert. For a country or region-wide IA, firms in that country or region that have established that they have resolved the conditions that gave rise to the appearance of the violation may be added to the Green List of the alert.

FDA has issued several IAs that address apparent violations in produce, both on an individual firm/commodity basis and a region or country-wide basis. For example, IA # 99-35, "Detention without Physical Examination (DWPE) of Fresh Produce that Appears to have been Prepared, Packed, or Held Under Insanitary Conditions," outlines that, based on inspectional, analytical, epidemiological, and/or traceback evidence of insanitary conditions, FDA may detain, without physical examination, produce items from firms identified on the Red List of this IA. An example of a country-wide IA is IA #21-17, "Countrywide Detention Without Physical Examination (DWPE) of Papaya from Mexico." FDA issued the IA in part based on reoccurring outbreaks associated with papaya operations in Mexico. IA 21-17 was revised so that participation in SENASICA's SRRC program, which includes the Papaya Action Plan, may be considered as part of a firm's petition for addition to the Green List.

FDA has also issued IA #99-41, "Detention Without Physical Examination of Human and Animal Foods Imported from Foreign Suppliers by Importers Who Are Not in Compliance with the Requirements of the Foreign Supplier Verification Program (FSVP) Regulation," which provides that FDA may detain, without physical examination, food offered for import by importers identified on the Red List of the IA. An FSVP importer may be added to the Red List of this IA because it appears that the importer is not in compliance with FSVP requirements for one or more foods.

**Import Certifications**

The FDA also has the authority to require, based on the risk of the food, that an import certification accompany imported foods for entry into the U.S. The import certification may be provided in the form of shipment-specific certificates; a listing of certified facilities that manufacture, process, pack, or hold such food; or another form, as specified by FDA. An article of food that is imported without the required import certification is subject to refusal of admission into the U.S. The FDA has not yet used this authority for imported products, but this is another tool the agency may use to ensure the safety of imported produce. Import certification is supported by the FDA's Accredited Third-Party Certification Program (TPP).

### 2.4: Improve testing methodologies and tools used to determine admissibility of produce offered for import.

FDA scientists use hundreds of established, validated tests and screening methods to detect pathogens or contaminants in different types of food. For example, the FDA uses one method to test for the presence of pathogenic *E. coli* on fresh leafy green vegetables and another method to test for the presence of *Cyclospora cayetanensis*. 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 are also working to improve and expand our rapid screening analytical capabilities by developing methods and devices that deliver results more quickly and that can detect more than one kind of contaminant. Using sensitive 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 admissibility decisions, which is especially important given the highly perishable nature of produce. A few examples of ongoing work in this area include:

- The development of a real-time test to detect *Cyclospora cayetanensis* on fresh produce.
- Development of a method using dead-end ultrafiltration for detecting *Cyclospora cayetenansis* in agricultural water.
- Increased use of Whole Genome Sequencing (WGS), a technology that lets us see the complete DNA make-up of an organism. WGS allows us to differentiate, with precision, specific strains of pathogens. This can be particularly useful during a foodborne illness outbreak when comparing food or environmental pathogenic isolates with clinical isolates taken from ill patients. Having this information can help the FDA and other public health agencies identify where in the supply chain contamination may have occurred which can facilitate actions to protect public health. WGS provides greater accuracy than earlier subtyping technologies, such as Pulse Field Gel Electrophoresis, allowing FDA to identify and address affected produce more efficiently than in the past.
- The FDA has also published a final rule for Laboratory Accreditation for Analyses of Foods which will improve FDA's capacity to protect U.S. consumers from unsafe food. Although this program will be applicable to a number of food testing categories, it applies directly to importers in two ways:
    - owners and consignees of imported food will be required to use accredited laboratories for food testing to support the removal of a food from an import alert; and
    - they will also be required to use accredited laboratories for testing to support admission of an imported food that has been detained at the border.
- The FDA began implementing the laboratory accreditation program in 2022 as part of a stepwise approach to fully operationalizing this program.

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

FSMA recognizes the benefit of leveraging relationships with partners in establishing a strong food safety system. State partners and other regulatory bodies often conduct sampling and analyses of foods including imported produce — once they have entered commerce in their jurisdictions — and they share findings with FDA that may indicate significant food safety problems. Below are a few examples of these information sharing partnerships:

- Food Emergency Response Network (FERN): FERN is a national network of food laboratories designed to integrate the nation's local, state, and federal food testing laboratories to detect, identify, respond to and recover from a bioterrorism or public health emergency/outbreak involving the food supply, FDA has initiated large sampling assignments through FERN laboratories for both domestic and imported produce.
- FDA Laboratory Flexible Funding Model (LFFM): The FDA funds numerous state laboratories through the LFFM to support and augment laboratory testing within the agency for domestic and imported food, including produce. For example, some laboratories are funded to build capability for detecting *Cyclospora cayetanensis* in produce, while other laboratories are funded to perform routine surveillance of food at the retail level, including produce samples. The LFFM is also funding laboratories to implement a new system of laboratory data exchange (National Food Safety Data Exchange; NSFDX) that will allow state laboratory data to be more easily exchanged with FDA.
- GenomeTrakr network: The FDA's GenomeTrakr consists of a network of laboratories throughout the world that utilize Whole Genome Sequencing (WGS) to identify pathogen isolate sequences that can be archived in the National Center for Biotechnology Information (NCBI) database. Inputs from food and environmental isolate sequences through GenomeTrakr can be used to: find potential contamination sources of current and future outbreaks, better understand the environmental conditions associated with the contamination of agricultural products, and help develop new, rapid testing methods. A recent study found that for each additional 1,000 WGS isolate sequences added to the database for a given pathogen, there is a reduction of approximately six illnesses per year associated with that pathogen. As part of the FDA's New Era initiative, the agency is working with international partners to increase the number of laboratories that can (and do) submit sequences from food samples via FDA's GenomeTrakr.

## Goal 3: Rapid and Effective Response to Unsafe Imported Produce

The 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 set 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 food-related outbreak of illness, including those associated with imported produce.

Produce has been identified as the vehicle, or likely vehicle, for a number of foodborne illness outbreaks, and some of these have been related to produce that was imported. For example, in 2017 and 2019, investigations of five outbreaks of multiple strains of *Salmonella* linked to whole, fresh Maradol papaya resulted in a total of 325 ill persons. Traceback, laboratory, and epidemiologic evidence indicated papayas as the likely source of each of these outbreaks. FDA's Coordinated Outbreak Response and Evaluation Network (CORE) provided a platform for federal, state, and local partners to rapidly share data and evidence. This information was used to protect public health through public guidance, recalls, and import alerts. The information also facilitated FDA collaboration with Mexican regulatory partners and industry, leading to increased food safety activities related to papayas imported from Mexico.

### 3.1: Maximize effectiveness of FDA response to an event involving imported produce.

#### Rapidly Responding to Outbreaks

- Coordinated Outbreak Response and Evaluation (CORE) Network: The FDA's CORE network manages foodborne illness outbreak surveillance, response, and post-response activities linked to FDA-regulated human food, including imported produce. If the evidence gathered during an outbreak identifies an imported product as the source of the outbreak, CORE works through FDA's international staff to inform foreign competent authorities and/or foreign firms of the outbreak investigation and findings as well as gather and share in-country information back with CORE. An International Food Safety Authorities Network (INFOSAN) Alert may be issued to inform international partners of the investigation. As mentioned earlier, international produce farm outbreak investigations are conducted by the specially-trained group of FDA investigators that are part of the Produce Safety Network and are supported by investigators from FDA international posts and subject matter experts from the FDA Center for Food Safety and Applied Nutrition (CFSAN).

- Promoting collaboration between FDA and counterparts in other countries is essential to strengthen attention on food safety issues, such as outbreaks. FDA's international offices play a key role in facilitating the agency's deeper understanding of international counterparts' food safety oversight systems, including produce safety systems. FDA's international offices also help establish and strengthen working relationships with international counterparts including during outbreaks investigations. The FDA international offices help facilitate engagement with corresponding counterparts in the exchange of information, communication, and collaborative efforts with counterparts during outbreaks investigations activities.
- The FDA is also undertaking rulemaking to establish additional traceability recordkeeping requirements (beyond what is already required in existing regulations) for persons who manufacture, process, pack, or hold foods the agency designates for inclusion on the Food Traceability List, the proposed version of which includes many produce commodities. The proposed rule, "Requirements for Additional Traceability Records for Certain Foods" (Food Traceability Proposed Rule), would apply to both domestic and international entities, and is a key component of both FSMA and the New Era initiative. When finalized, the rule will help FDA rapidly and effectively identify and remove contaminated food from the market to prevent or mitigate foodborne illness outbreaks and address credible threats of serious adverse health consequences or death.
- As part of the New Era of Smarter Food Safety, the FDA has recently published an outbreak response improvement plan. The plan is designed to help the FDA and our partners enhance the speed, effectiveness, coordination and communication of foodborne outbreak investigations. In an April 13, 2022, webinar about this plan, a stakeholder asked how it will impact imported produce. The answer: FDA will go where the evidence leads in investigating illnesses associated with food, whether the supplier is a U.S. company or another that exports to the U.S. The outbreak plan mentions regulatory counterparts in other nations as among the critical partners working with the FDA to strengthen outbreak response in this country.

#### Preventing Future Outbreaks

One way that the FDA responds to outbreaks of foodborne illness is by investigating the circumstances that led to the outbreak and developing and applying lessons learned to help prevent future outbreaks. At times, this work has warranted the development of comprehensive strategies to advance the safety of food produced both domestically and internationally through stakeholder engagement, research, and the implementation of prevention and response activities. Some examples of these strategies include:

- The Cyclospora Prevention, Response and Research Action Plan developed by the FDA's Cyclospora Task Force as a strategic guide to reducing the public health burden of foodborne illness caused by *C. cayetanensis* through three priority areas: improving prevention, enhancing response activities, and filling knowledge gaps. We will be developing future strategies as appropriate.
- A "Call to Action" to the papaya industry following reoccurring outbreaks associated with papaya operations in Mexico. As a result of FDA's letter, efforts have been made to improve industry practices through industry's development of a Papaya Best Practices Guide and SENASICA's publication of their Papaya Action Plan. FDA, produce industry, and SENASICA collaborated to conduct joint PSA Grower Trainings/Papaya Best Practices trainings to the Mexican papaya growing operations and created a joint work group to facilitate communication.
- The Leafy Greens STEC Action Plan (LGAP) that was developed to foster a more urgent, collaborative, and action-oriented approach to enhancing the safety of leafy greens.
- The development and implementation of a prevention strategy to address recurring incidences of enoki mushroom contamination with *Listeria monocytogenes*, following the 2020 listeriosis outbreak linked to enoki mushrooms from the Republic of Korea.
- The development and implementation of a prevention strategy to address incidences of onion contamination with *Salmonella* following two years of unprecedented outbreaks associated with onions produced domestically and produced in Mexico.

### 3.2: Enhance the efficiency and effectiveness of imported produce safety recalls.

FDA looks to responsible parties, such as an importer, distributor, or farm, to voluntarily recall their produce when they discover an associated violation or potential health hazard. FDA makes sure that firm issued press releases regarding recalls are posted to our website, and FDA issues public notices to inform consumers and retailers, when appropriate.

Moving rapidly to address public health issues is critical to public health protection. One tool the agency has available to speed recalls in certain situations is the Strategic Coordinated Oversight of Recall Execution (SCORE) team. SCORE is a team of key senior leaders who are tasked with speeding the agency's response when there are foods on the market that present a real or potential danger to consumers' health. SCORE gets involved with the most challenging recall situations, such as those that are complicated by such issues as the nature of the product, the scope of available evidence, and the company's response. The team can leverage data from inspections, sampling, and laboratory testing, and other sources to gain additional information. ORA publishes all recalls in the Enforcement Report.

### 3.3: Use information-sharing opportunities to prepare for and respond to the entry of unsafe imported produce.

Domestic partnerships are critical to responding to potentially unsafe imported produce. State and local laboratories and public health agencies are often our first line of defense – identifying, containing, and preventing outbreaks of foodborne illness, including those that may result from imported produce.

As such, the FDA enters into cooperative agreements that allow the agency to coordinate with state and local partners to investigate and communicate about produce that is potentially contaminated. Below are various domestic entities with which FDA partners.

- The Reportable Food Registry (RFR or the Registry) is an electronic portal to which both domestic and international FDA-regulated food facilities alert the FDA to potential safety issues involving food they have manufactured, processed, packed, or held. Farms are not required to register with the FDA; however, facilities that receive contaminated fresh produce for further processing would be required to submit a report. Early detection enables the FDA to investigate existing or emerging issues and then implement focused regulatory strategies to mitigate or eliminate the concern before it becomes a major problem or a foodborne illness outbreak.

- Rapid Response Teams (RRTs): The FDA also provides multi-year cooperative agreements to states to form and maintain Rapid Response Teams (RRTs). RRTs are multi-agency, multi-disciplinary teams that operate using Incident Command System (ICS)/National Incident Management System (NIMS) principles and a Unified Command structure to respond to human and animal food emergencies. The state RRTs coordinate with the FDA response team to follow-up to incidents of imported products that result in public health issues.

- Domestic Mutual Reliance: As part of the New Era initiative, the FDA entered into domestic mutual reliance partnership agreements with the states of California, Florida, Utah, Wisconsin, Iowa and Minnesota. These partnership agreements are intended to facilitate a coordinated effort between the FDA and individual states with the goals to reduce human foodborne illness outbreaks, reduce duplication of regulatory oversight and increase public health protection by focusing on areas of higher risk. As part of these agreements, these states of will coordinate with FDA, with the intent of leveraging one another's work, data, and actions to achieve a safer national food supply.

- Laboratory Association Cooperative Agreement Program: State and local laboratories play a critical role in the identification, containment, and prevention of foodborne illness, including illnesses that may result from imported produce. Therefore, the FDA has entered into the Laboratory Association Cooperative Agreement Program. The intended outcome of this program is to support and enhance food testing laboratory activities, specifically through the activities of an association that will offer trainings, workshops, meetings, and other educational resources; conduct research on national testing capability and capacity; prepare best practices and other guidance manuals; support ISO/IEC 17025 laboratory accreditation for non-accredited laboratories; and other activities, such as the GenomeTrakr network, to support human and animal food testing laboratories.

- FoodSHIELD: The FDA holds a cooperative agreement with the Food Protection and Defense Institute (FPDI), a Homeland Security Center of Excellence led by the University of Minnesota, to defend the safety of the food system from pre-farm inputs through consumption by establishing best practices, developing new tools, and attracting new researchers to prevent, manage, and respond to food contamination events. One result of this agreement is FoodSHIELD, a web-based system for communication, coordination, education, and training within the nation's food and agriculture sectors. FoodSHIELD offers a secure system for local, state, and federal public health and food regulatory officials to join and share with international partners and other government agencies.

Under our Confidentiality Commitments (CC), FDA can share certain non-public information with our international regulatory partners to help increase our response capabilities. . For example, FDA has a CC in place with SENASICA and COFEPRIS which allows the FDA to exchange information more rapidly on epidemiological surveillance, samples analysis, and traceback activities. Sharing information during the early stages of an outbreak investigation would allow more rapid response.

Additionally, the FDA provides alerts, advisories, and safety information on the agency website for consumer awareness, including information on unsafe produce or imported goods.

## Goal 4: Improving the Effectiveness and Efficiency of our Food Import Program

Advancing FDA's public health mission as it pertains to imported food includes 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, the FDA will implement an adaptive, risk-informed, and cost-effective management system and infrastructure to support organizational excellence, performance, and accountability.

### 4.1: Develop an improved understanding of the global inventory of produce facilities and farms that distribute food in the U.S. in order to utilize this information across produce import programs.

Having a global inventory of produce farms and facilities will help increase the FDA's ability to target its foreign inspection and sampling strategies and identify those countries with which to partner to increase imported food safety outreach. Developing an international and domestic inventory of produce farms is challenging, largely because most international and domestic farms are exempt from food facility registration with the FDA. States that participate in the state produce Cooperative Agreement Program (CAP) are responsible for inventory development of farms in their state. The FDA is responsible for farm inventory development for international farms and inventory development for several U.S. states where states are not participating in the CAP.

For international produce farms, the FDA has created a new process to use existing data supplied to the FDA through prior notice, import entries, FSVP importer data, international inspections, and other sources to develop an estimated international farm inventory. Building and improving this inventory will allow help to better inform risk prioritization to enhance oversight activities.

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

When the FDA set up its FSMA implementation program, it identified monitoring and continuous improvement as a key component. Collecting and maintaining measurement data allows the FDA to monitor the agency's progress toward our goals over time and reevaluate the program, when necessary. The development and publication of metrics, describing how we applied our oversight tools, and what the results were, can provide the basis for an assessment of each tool.

The FDA has developed a Data Dashboard where the agency publishes data related to the FDA's oversight of imported foods, including inspections of foreign suppliers and FSVP importers; examinations and sample collections; as well as import refusals and importers approved to participate in the VQIP. The Data Dashboard provides data to help demonstrate how the FDA provides oversight of international and domestic producers.

In developing the FSMA Implementation Plan, the FDA committed to developing metrics to measure the impact of the FSMA programs. The FDA has developed and will continue to develop performance measures and outcome indicators for the agency's imported food safety programs and will continue to refine them, as necessary, to meet the overall food safety objectives. The FDA-TRACK (Transparency, Results, Accountability, Credibility and Knowledge) is the FDA's agency-wide performance management program that monitors, analyzes and reports key performance data and projects for the agency's program offices and cross-cutting initiatives. The FDA-TRACK Food Safety Dashboard module on Imported Food Safety Measures monitors progress and performance of outcomes including the implementation of the FSVP regulation. This module is in its early stages, and it may take several years to establish baselines and identify meaningful

trends in FSVP implementation and the imported foods program generally. As the agency gathers additional data on the effectiveness of the imported foods program, objectives and operations may be adjusted.

The FDA is also developing measures specific to implementation of the Produce Safety Regulation. When published, these measures will provide information for the FDA and stakeholders about the farming industry's success in meeting the Produce Safety Regulation for both domestic and international farms.

## Produce Safety Research

The FDA also conducts research that can be used to support the agency's produce safety efforts. For that reason, we discuss it separately here, rather than as part of any of the goals listed in this document. Below are a few examples of research that the FDA is engaging in related to produce grown outside the U.S.

- The FDA, in partnership with the JIFSAN, is studying water samples in Latin America. As part of this study, the FDA is working with several academic researchers in Mexico, Chile, and Brazil to analyze *Salmonella enterica* in surface waters using Whole Genome Sequencing (WGS). The study began in 2019 and has already begun to provide preliminary data about *Salmonella* persistence as well as both genetic and geographic diversity in the environment. The data will aid in the expansion of the global WGS database, further validate environmental sampling and analysis methods, assess the distribution and subtypes of Salmonella in these waters and how they compare to similar environment studies in the United States and globally, analyze the relationship of *Salmonella* in Latin American surface waters associated with produce production and provide insight into the proficiencies and barriers faced by other nations in these efforts.
- Similarly, the FDA is partnering with the Food and Agriculture Organization (FAO) to raise awareness about how the improvement of water and soil quality can decrease the number of foodborne pathogens that could contaminate the food supply. A summary of scientific methods, related to understanding the geospatial link between foodborne pathogens in environmental water sources and food safety, will be explored. This portfolio of work relates to FDA's goal of better understanding the geographical genomic diversity of foodborne pathogens in the environment (e.g., water) and how that information can shape policies related to the use of water within food production systems. Ultimately, an increase in sampling and sequencing foodborne isolates in the environment can help improve food safety initiatives through preventive controls and reducing contamination events. The FDA's intent with this grant is to increase the sampling, sequencing, and sharing of foodborne pathogen data in the environment, thus providing the international community with a valuable resource that can ultimately help improve global public health.

## Conclusion

The FDA has long recognized the need to ensure the safety of both imported and domestic produce to meet the agency's public health mission. As demonstrated in this document, the FDA employs a multi-layered approach to its oversight of imported produce. While this includes inspections, we also have many other tools that we utilize to help ensure that the imported produce that reaches U.S. consumers is safe, including:

- Border surveillance
- Multiple regulatory approaches including Produce Safety Rule and FSVP compliance
- Strategic utilization of sampling and testing
- Partnerships with domestic and foreign competent food safety authorities

These activities along with enhancements to data and information have allowed the FDA to implement oversight regardless of whether produce is grown domestically or elsewhere. The FDA will continue to incorporate FSMA and New Era approaches while implementing the *Strategy for the Safety of Imported Food* for all food, including produce.

## Appendix Guiding Principles from the Strategy for the Safety of Imported Food

- **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.


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