Understanding Foreign Supplier Regulatory Oversight in the U.S. Fresh Produce Market

DISCLAIMER

This document provides an overview of the U.S. regulatory oversight system for imported fresh produce in comparison to domestic produce. It is intended for informational purposes. For this reason, it is recommended that readers periodically evaluate the applicability of any recommendations in light of particular situations and changing standards. The authors, contributors and reviewers make no claims or warranties about any specific actions contained herein. It is the responsibility of any purveyor of food to maintain strict compliance with all local, state and federal laws, rules and regulations. This document is designed to facilitate inquiries and develop information that must be independently evaluated by all parties with regard to compliance with legal and regulatory requirements. The providers of these documents do not certify compliance and do not endorse companies or products based upon their use of this document.

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ABSTRACT

This document addresses the growing importance of imported fresh produce in the U.S. food supply and the importance of effective oversight mechanisms. It evaluates key food safety and oversight considerations related to fresh produce imported into the United States, drawing on available public information such as USDA Economic Research Service production and import trends, U.S. Food and Drug Administration (FDA) inspection data, U.S Government Accountability Office reports, and current regulatory frameworks. It reviews the scope of the FDA authority, differences between domestic and foreign food safety inspections, surveillance activities, and the structure of the Foreign Supplier Verification Program (FSVP) rule, including third-party certification pathways and importer qualification requirements.

Because FSVP rule outcomes and comprehensive importer-specific performance metrics are limited, this document focuses on oversight information rather than compliance outcomes. This paper provides an overview of what is currently known through public data to identify significant gaps or opportunities. Further work should incorporate operational case studies and gather practical insights from importers, domestic and foreign operations, certifiers, regulators, and other stakeholders.

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IMPORTED PRODUCE LANDSCAPE

Prior to 2010, fresh produce imports supplied U.S. consumers primarily during the winter months when domestic production was limited. However, fresh produce imports have, more recently, begun to compete with U.S. growers during the heights of domestic production.[1] Strong consumer demand for fresh produce, less expensive labor and input costs in developing countries, and more favorable climates in other countries are some of the factors driving an exponential growth in U.S. imports for many fresh produce commodities.[2,3]

This trend has been occurring for an extended period of time. Since 1990, U.S. fresh produce production has been relatively stagnant, while imports have steadily increased (**Figure 1A**). Domestic fruit and vegetable production increased 13% and 11%, respectively, from 1990 to 2023/24. Relative to availability, the portion of fresh vegetable imports has increased from 9.7% in 1990 to 36.3% in 2024 and fresh fruit imports portion from 34.8% in 1990 to 58.5% in 2023 (**Figure 1B**).

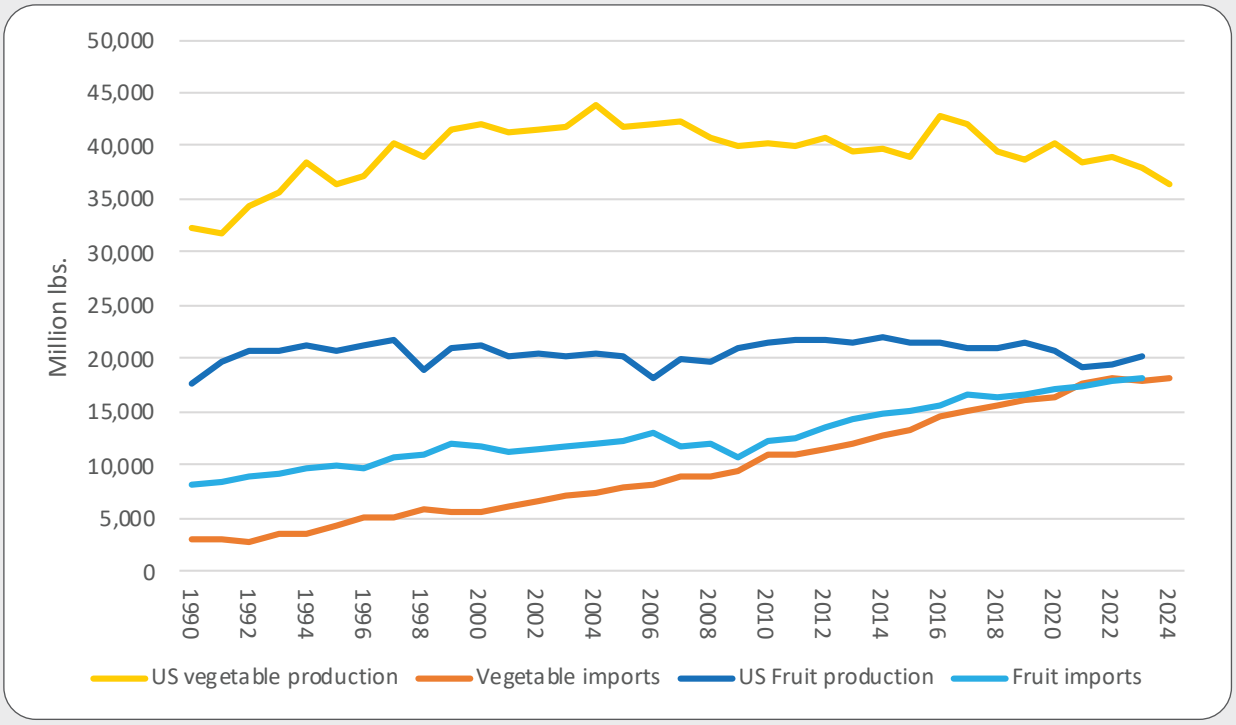

Figure 1A. Volume of U.S. fresh produce production and imports, 1990-2023/24

Source: USDA ERS

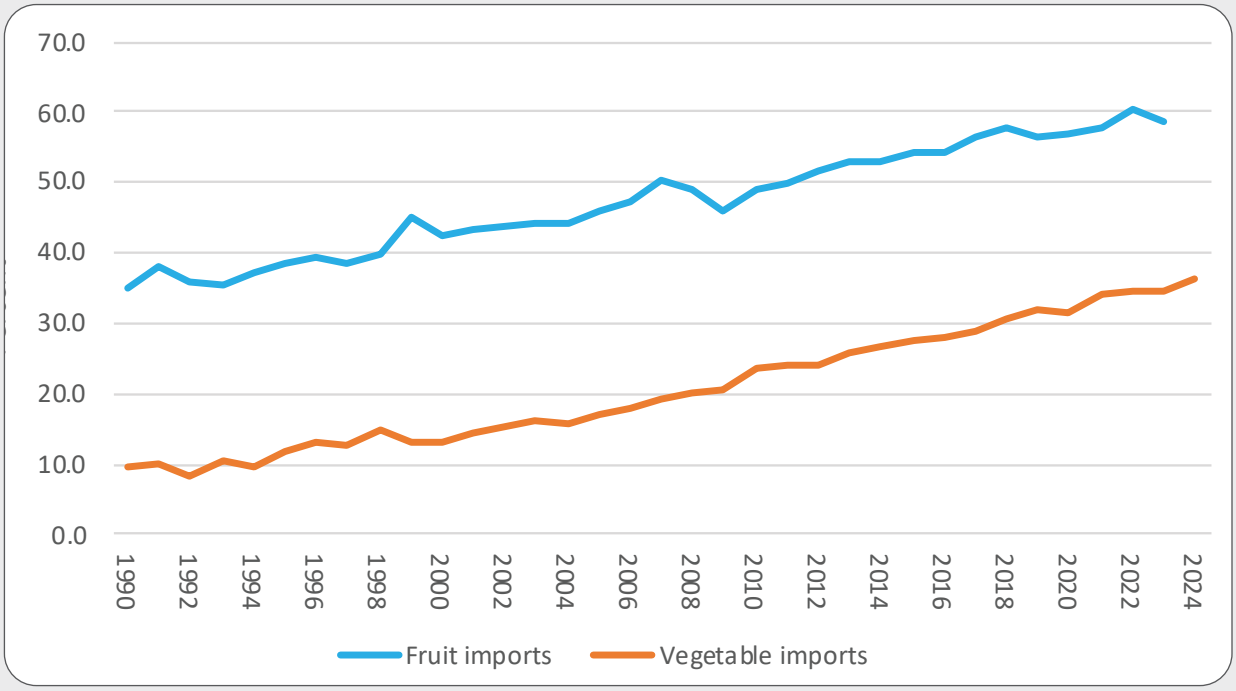

Figure 1B. Imports as a share of U.S. fresh fruit and vegetable availability, 1990-2023/24

Source: USDA ERS

Considering four major fresh produce commodities -- cucumbers, asparagus, tomatoes, and bell peppers, after hitting a peak of 7.1 billion lbs. in 2000, U.S. production fell to 3.3 billion lb. in 2024 while imports grew from 1.8 billion lb. to 10.6 billion lbs.

Taking a closer look at trends for imports of major commodities over the past decade (2014-2024), fresh asparagus imports have increased by 6% from 487 million lbs. to 515 million lbs., bell pepper imports have increased 50% from 1.97 billion lb. to 2.81 billion lbs., cucumber imports have increased 34% from 1.7 billion lbs. to 2.6 billion lbs., and tomato imports increased 27% from 3.4 billion lbs. to 4.7 billion lbs. During the same time period, production for all four commodities decreased substantially (**Figure 2A**).

[1] Khanal A, Poudel D, Munisamy G. 2024. Economic Impact of Fresh Fruit and Vegetable Imports on U.S. Producers. *Journal of Agricultural and Applied Economics*. 56:544-574.
[2] U.S. Fresh Vegetable Imports From Mexico and Canada Continue To Surge | Economic Research Service
[3] World Fruit Map: A changing basket of fruits and trade flows - Rabobank

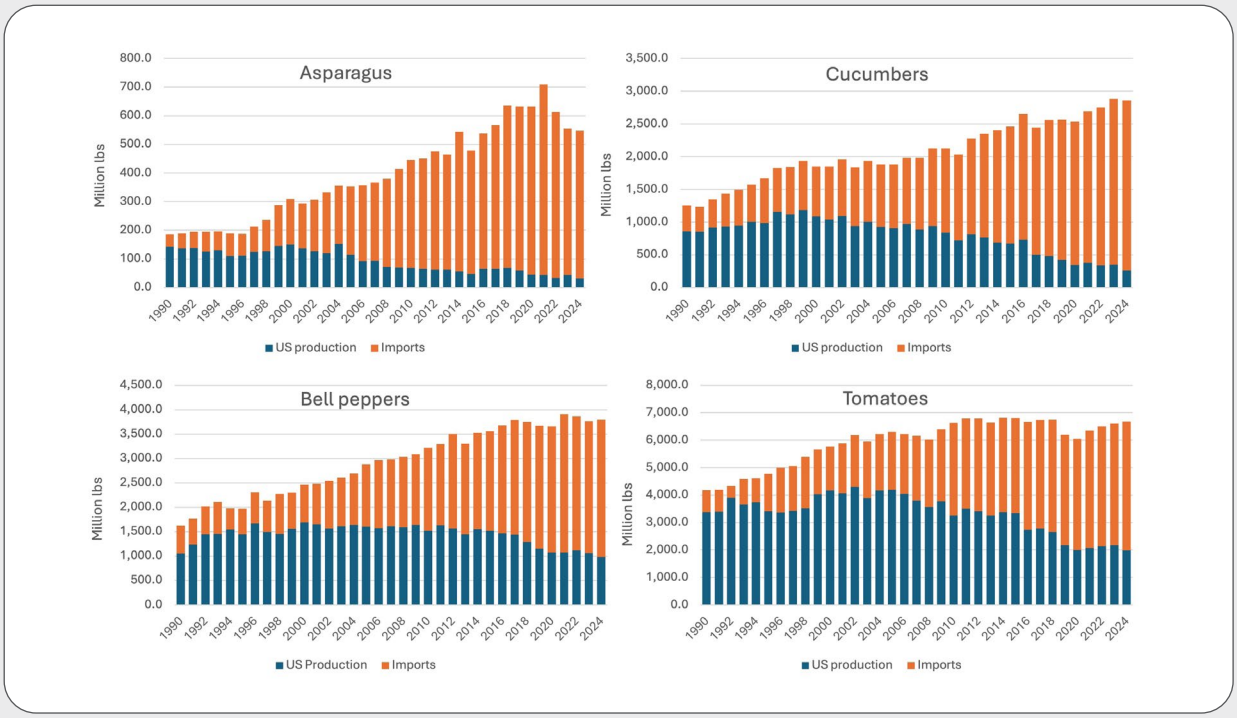

Figure 2A. Trends in U.S. production and imports for select fresh vegetable crops, 1990-2024

Source: USDA ERS

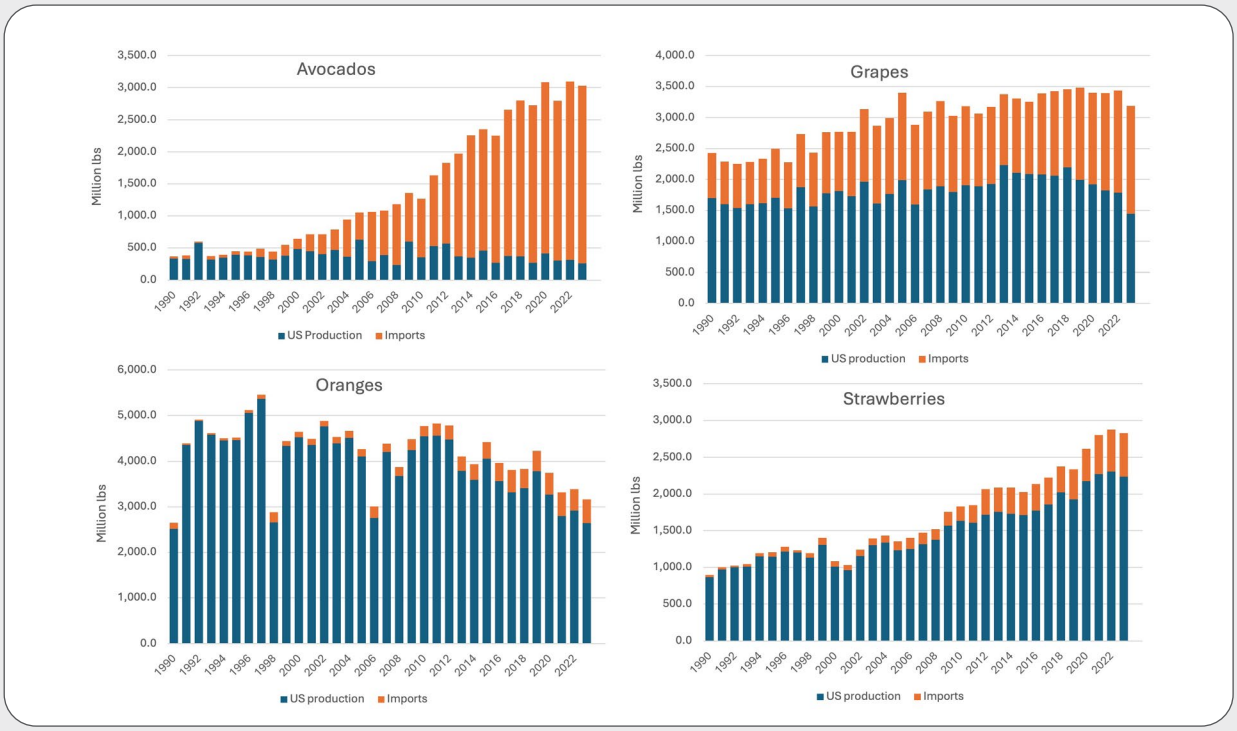

Figure 2B. Trends in U.S. production and imports for select fruits, 1990-2023

Source: USDA ERS

FDA AUTHORITY AND OVERSIGHT

The Food Safety Modernization Act (FSMA), the Federal Food, Drug and Cosmetic Act (FD&CA), and the Public Health Service Act (PHSA) established legal authority for the FDA to promulgate rules, such as *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption* (the Produce Safety Rule) and *Current Good Manufacturing Practices, Hazard Analysis, and Risk-based Preventive Controls for Human Food* (the Preventive Controls Rule), regulating food production. For imported food (when used in this document, "food" refers to fresh produce), the FDA has two goals: 1) to address potential food safety issues before the food reaches the U.S. and 2) to help ensure that imported food is produced in accordance with the same safety standards as food produced domestically.[4]

Compliance Standards

The first provision [§ 112.1(a)] in the Produce Safety Rule (PSR) states, "food that is produce within the meaning of this part and that is a raw agricultural commodity (RAC) is covered by this part. This includes a produce RAC that is grown domestically and a produce RAC that will be imported or offered for import in any State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico." Although both domestically produced and imported fresh produce is subject to the PSR (and in some case, the Preventive Controls Rule (PCR)), the regulatory approach used by the FDA to achieve its goals for imported food to be "produced in accordance with the same safety standards as food produced domestically" are substantially different than the regulatory approach it uses to ensure domestically produced food is produced in accordance with its food safety standards and is not adulterated. In addition, how domestic produce companies and foreign entities are held accountable for following the PSR and/or the PCR requirements are markedly different.

For U.S. produce grower-shipper operations, the FDA oversees and enforces PSR and PCR compliance, but for imported produce, the agency relies heavily on importers through the Foreign Supplier Verification Program (FSVP) and international regulatory agreements and collaborations to ensure foreign produce companies are following good agricultural and good manufacturing practices and are in compliance with the PSR and/or PCR.

Produce Safety Inspections: Domestic vs. Foreign Operations

Domestic grower-shippers and processors are subject to more frequent and thorough inspections. The FDA's ability to conduct inspections of foreign operations is limited by logistical constraints, inadequate funding, and reliance on foreign government authorization. The FDA has authority under FSMA to inspect domestic fresh produce operations and also has the State Produce Safety Implementation Cooperative Agreement Program (CAP) that enables other domestic parties to conduct domestic inspections for the agency.[5] Currently, 47 state entities (mostly state public health, food, and/or agricultural agencies) are participating in and receiving funding under this CAP.[6]

Under the Bioterrorism Act of 2002, domestic and foreign facilities that manufacture, process, pack, or hold food are required to register with the FDA. Based on this registration process, it is estimated that, as of March 2023, there are approximately 125,000 foreign food facilities and 75,000 domestic food facilities subject to FDA inspection.[7] Of the 125,000 foreign food facilities, fruit and vegetable products are number 2 and 3 behind seafood in type of products produced.[4]

For domestic food facilities, fruit and vegetable products are numbers 4 and 5 behind seafood, bakery products, and food warehouses.[4] Although domestic grower-shippers that fall under the PSR regulation are not required to register with the FDA, the 47 state governments that participate in the CAP must maintain inventories of farms in their state. The FDA does not have a comprehensive inventory of farms in foreign countries that export produce to the U.S. because foreign governments cannot participate in the CAP, and foreign grower-shippers are not required to register with the FDA, limiting the development of an inventory of foreign farms that would be useful for inspection purposes.

In May 2025, the FDA announced that it would begin unannounced inspections of foreign food manufacturing facilities.[8] Before this, the FDA conducted a pilot program of unannounced inspections in China and India, but in other countries, inspections have typically been announced, as communication with foreign embassies and pertinent government authorities is often required. Domestic grower-shippers and processors are routinely inspected and may be subject to unannounced inspections.[9] Under FSMA, the FDA is mandated to inspect U.S. domestic operations at least once every three years for high-risk facilities and at least once every five years for non-high-risk facilities.[10] A facility is designated "high risk" based on several factors, including compliance history with the FDA and the known safety risks associated with the food it produces (see **Table 1**).[11]

Table 1. Risk Factors and Supporting Data

KNOWN SAFETY RISK FACTORS (per section 421(a)(1) of the FD&C Act)	SUPPORTING DATA
Known safety risks of the food	Facilities manufacturing, processing, packing, or holding food in commodity categories associated with high incidences of: Class I recalls Outbreaks of foodborne illness Violative samples (laboratory class 3) Inspections classified as Official Action Indicator (OAI)
Compliance history of a facility	Facilities with a history of: Class I or II recalls Outbreaks of foodborne illness Violative samples (laboratory class 3) Inspections classified as OAI Compliance actions taken Inspections with no significant violations classified "No Action Indicated"(As opposed to an OAI inspection which can increase the risk-profile, an NAI classification could indicate less risk, which will be factored into our evaluation)

Table 1. Risk Factors and Supporting Data (continued)

KNOWN SAFETY RISK FACTORS (per section 421(a)(1) of the FD&C Act)	SUPPORTING DATA
Facility's hazard analysis and risk-based preventive controls	FDA has improved information technology systems that support FDA inspection reporting to monitor preventive controls inspection outcomes. FDA utilized the new information in FSMA performance measures and is further examining its use to support this FSMA risk factor.
Priority under section 801(h)(1) of the FD&C Act (inspections of food offered for import, especially to detect intentionally adulterated food)	The FDA is further examining the use of available data to support this risk factor for domestic human food facilities.
Certification per section 801(q) or section 806 of the FD&C Act (certification of certain imported foods and importers who participate in the voluntary qualified importer program (VQIP))	The FDA is further examining the use of available data to support this risk factor for domestic human food facilities.
Any other criteria deemed necessary	Type of Activity (establishment type).

Source: Recreated from: https://www.fda.gov/food/inspections-protect-food-supply/how-does-fda-prioritize-domestic-human-food-facility-inspections

Of the 75,000 domestic food facilities, 17,000 or 23% are considered high-risk facilities. Figure 3, as reported by the U.S Government Accountability Office (GAO), shows: 1) the number of domestic high-risk and non-high-risk food facilities the FDA inspected from 2018 through 2023 according to the mandated schedule, 2) the number of attempts to inspect these facilities according to the mandated schedule, and 3) the number of facilities the FDA failed to inspect according to the mandated schedule.[3] The FSMA instructs the FDA to produce and publish annual reports with this information, which can be found on the FDA's website. Note, these reports are not required to include farm inspections, and thus, those numbers are not reflected in the reports. The FDA does not categorize foreign food facilities (*e.g., fresh produce processors*) as high-risk or non-high-risk but uses an undefined "risk-based approach to prioritize inspections at facilities determined to have a higher risk profile."[4] For both foreign and domestic food facilities, inspection outcomes are classified in one of three categories: no action indicated, official action indicated, or voluntary action indicated.

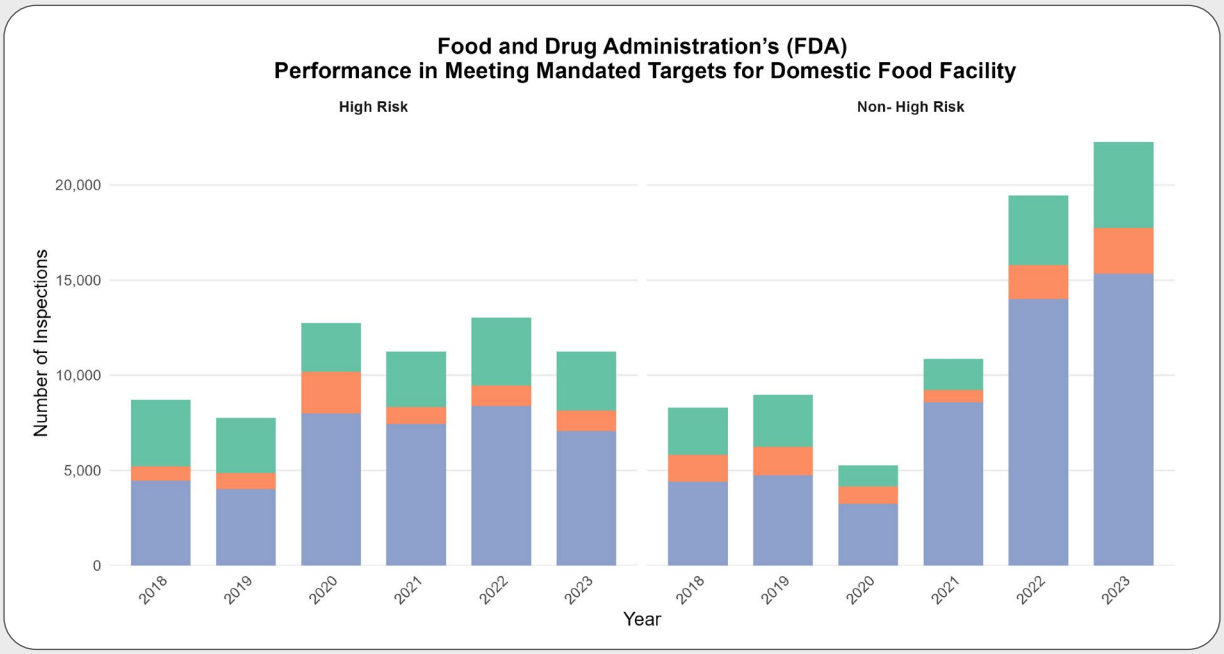

Figure 3. FDA's performance in meeting mandated targets for domestic food facility inspections according to FDA data, fiscal years 2018-2023.[12]

Image Recreated from GAO Report (FDA Should Strengthen Inspection Efforts to Protect the U.S. Food Supply) Using data from the FDA Data Dashboard for FSMA Report Measures

Unannounced inspections of domestic operations are typically conducted for routine compliance inspections, when repeated violations occur, to verify compliance and/or corrective actions for a previous violation, or to investigate a complaint, recall or foodborne illness outbreak. All farm inspections are documented in Form 4056, "Produce Farm Inspection Observations" and issued after each inspection. Facility inspections are only documented (in Form 483) when the inspector "observes conditions they deem to be objectionable".[6, 13, 14]

The agency also did not meet its quota of foreign facility inspections as mandated by FSMA. In the first year after the enactment of FSMA (2011), the FDA was to inspect at least 600 foreign facilities, and for each of the next five years, the agency was to inspect at least twice as many facilities as the previous year (*i.e., 1,200 in 2012; 2,400 in 2013; 4,800 in 2014; 9,600 in 2015; and 19,200 in 2016*).[15] Under this FSMA mandate, using the most recent registry information (March 2023), the FDA would be required to inspect 19,200 or 15.4% of the 125,000 registered foreign food facilities.

In their reports to members of Congress, the GAO reported FDA's shortfall on foreign facility inspections after the enactment of FSMA in 2011. FDA officials interviewed by GAO staff described the foreign inspection targets as "unrealistic and unachievable", questioned the usefulness of inspecting that number of facilities, and admitted that they did not plan to meet FSMA's mandate due to inadequate funding.[4, 16] The GAO recommended "that FDA complete an analysis to determine the annual number of foreign food inspections that is sufficient to ensure comparable safety of imported and domestic food." According to the GAO report, the FDA agreed with their recommendations; however, it is unclear whether the agency performed such an analysis.

In January 2025, the GAO released its second report to Congress describing the FDA's food facility inspection efforts.[4] One of the key takeaways for this report was that overall, the U.S. conducts significantly fewer foreign food safety inspections than it does domestically (see **Figure 4**). In 2023, 10,151 domestic inspections were conducted compared to close to 1,500 foreign inspections. From 2018 through 2023, the FDA conducted an average of 917 foreign facility inspections each year or about 5% of its annual target of 19,200 (see **Figure 5**).[4] As previously mentioned, FDA's mandate for domestic food facilities is to inspect high-risk facilities every three years and non-high-risk facilities every five years. According to a 2025 Office of Inspector General report, to meet its mandate, FDA would need to inspect approximately 7,000 (31.8%) of the 22,000 designated high-risk facilities each year.[17] Instead, domestic facility inspections have dropped from 6,942 facilities (18%) in 2017 to an average of 4,326 facilities (14%) in 2022 and 2023.[12]

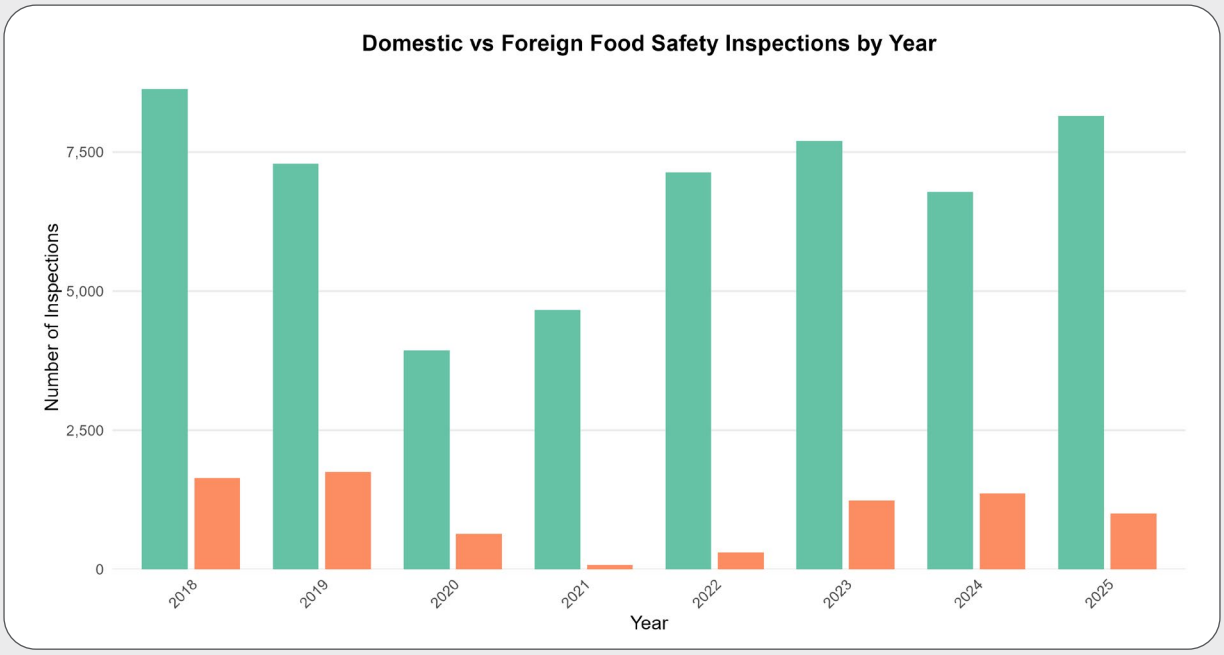

Figure 4. Number of FDA domestic and foreign food facility inspections conducted, fiscal year 2018-2023

Image Recreated from GAO Report (FDA Should Strengthen Inspection Efforts to Protect the U.S. Food Supply) Using data from the FDA Data Dashboard for Inspections

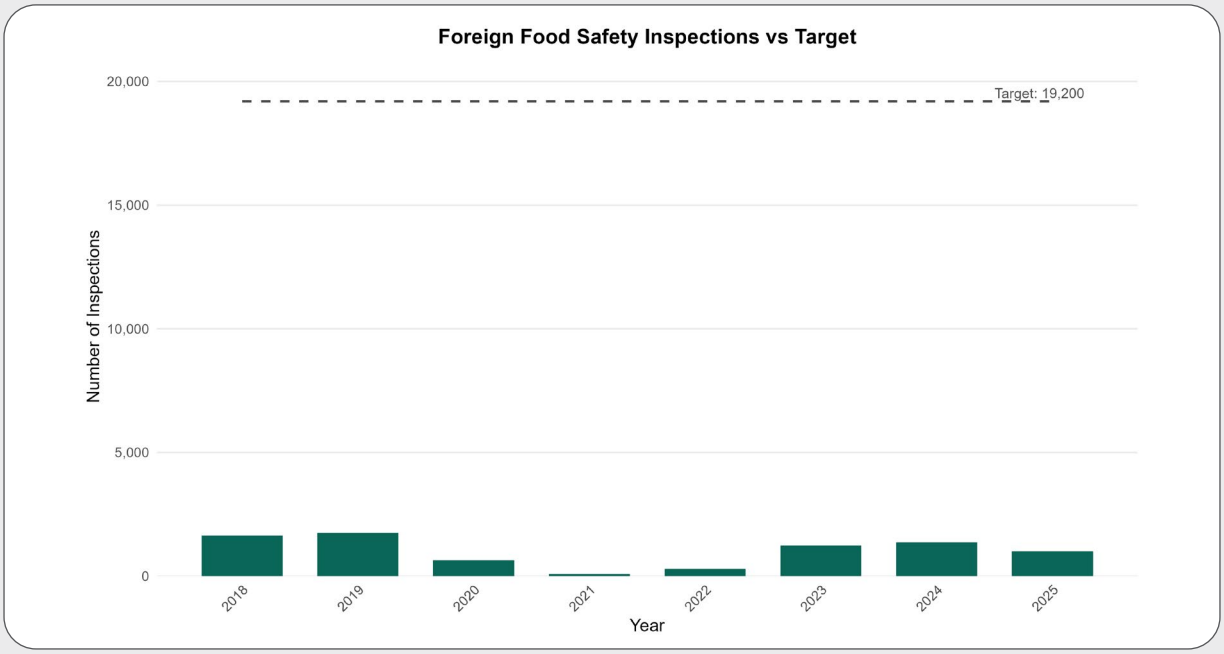

Figure 5. FDA's performance in meeting annual targets for foreign food facility inspections according to FDA data, fiscal year 2018-2023.

Image Recreated from GAO Report (FDA Should Strengthen Inspection Efforts to Protect the U.S. Food Supply) Using data from the FDA Data Dashboard for Inspections

The FDA reports some inspections electronically on the FDA Inspections Dashboard.[18] However, the dashboard does not include farm and food facility inspections that were reported on paper, conducted by states, or waiting for a final enforcement action. Because state agencies conduct a substantial portion of farm inspections, the FDA dashboard contains a markedly limited sampling of the total domestic produce farm inspections and underestimates domestic inspections for all types of food facilities. However, the numbers, although grossly underestimating inspections and citations for domestic facilities, are informative and worth considering (see **Table 2**).

Table 2. Inspections in domestic and foreign food facilities as reported on the FDA's Inspection Dashboard from January 2018 through December 2024

TIMEFRAME 2018-2024	DOMESTIC	FOREIGN
Inspections	14,861	3,133
Type of inspection		
Food and color additives petition review	19	1
Food composition, standards, labeling and economics	2,584	1,103
Foodborne biological hazards	12,175	2,028
Pesticides and chemical contaminants	82	1
Molecular biology and natural toxins	1	0
Violations of the PSR	895 (6.0%)*	135 (4.3%)*
Inspection/violation ratio	16.6	23.2

* Multiple violations are often cited during one inspection event.

Surveillance Sampling

The FDA uses surveillance sampling of fresh produce as part of its efforts to keep contaminated products from reaching consumers and to facilitate a greater understanding of hazards. The FDA's surveillance sampling assignments generally target commodities in domestic regions and are announced in advance to the commodity groups/industries affected. Surveillance includes collecting samples from farms, cooling facilities, distribution centers, and warehouses, often over several years (*e.g., leafy greens were sampled each year from 2019 through 2023*).[19]

Under the Sample Collection Operations Planning Efforts (SCOPE), the FDA conducts surveillance sampling of imported produce products (*e.g., fresh herbs surveillance sampling*).[20,21] Unlike domestic produce surveillance, under SCOPE, samples are collected at ports of entry, warehouses, and distribution centers; no samples are collected from farms.

For foodborne disease outbreak investigations, the FDA conducts targeted sampling of products, farms, or regions to identify the source of contamination. When relevant, these investigations may include sampling of the production area and product produced on a foreign farm.[22]

Limiting Supply and Legal Recourse

The FDA has broad authority to limit the supply of produce from domestic entities through enforcement actions, including recalls, detentions, injunctions, seizures, or administrative orders.[23,24] If the FDA determines there is a reasonable probability that a fresh produce item is adulterated or misbranded and that exposure to it poses a serious adverse health risk, the agency has the power to mandate its removal from the supply chain.[25] The FDA partners with state agencies and/or works directly with domestic farms to address non-compliance and has legal recourse to enforce compliance and ensure corrective measures are implemented. Non-compliance can result in warning letters, fines, and, in severe cases, shutdown of operations.

The FDA is not authorized under U.S. law to approve, certify, license, or otherwise sanction individual food importers, products, labels, or shipments.[26] Importers can import foods into the U.S. without prior sanction by the FDA, as long as the facilities that handle the foreign products are registered with the FDA, and prior notice of incoming shipments is provided to the FDA by one of the parties involved (e.g., the importer, exporter, or consignee).[18] If imported produce is found to violate U.S. standards, it can be detained at the border or refused entry.[27] For produce that has a history of known violations, the FDA can place an "import alert" on the product that allows the agency to detain shipments without having to test or physically examine them (*i.e., detention without physical examination*).[19] **Table 3** provides an overview of differences in food safety-related requirements for domestic and foreign producers.

Table 3. Differences in FSMA compliance, inspections and oversight between domestic and foreign entities

CATEGORY	US (DOMESTIC) ENTITIES	FOREIGN ENTITIES & IMPORTER
Produce Safety Rule	Covered farms are subject to the rule	Imported produce from covered entities is subject to the rule
Preventive Controls Rule	Covered facilities are subject to the rule	Imported produce from covered entities is subject to the rule
Sanitary Transportation	Domestic shippers must follow proper sanitary transport practices as mandated in subpart O of FSMA regulations (Sanitary Transportation of Human and Animal Food)	The Sanitary Transportation Rule only applies once the product is in the U.S.
Traceability standards	Traceability is mandated for specified foods in subpart S of FSMA regulations (also referenced as section 204 of the FSMA)	Detailed records for traceability from suppliers to the U.S. market. Traceability Rule requirements apply to foreign entities
Regulatory oversight	The FD&CA, as amended by FSMA and the PHSA, gives the FDA authority over fresh produce operations. The agency directly oversees domestic farms; the CAP allows other domestic state agencies to conduct inspections	As a practical matter, FDA primarily relies on importers (FSVP), non-government and international regulatory bodies
Inspections Mandate	Routine inspections for covered entities conducted by the FDA and state agencies under FSMA PSR & for foodborne illness outbreak investigations. No inspection frequency is prescribed	FSMA does not mandate foreign farm inspections; it only requires foreign facilities to be inspected, but limited inspections occur due to inadequate funding and jurisdiction constraints; inspections require coordination with foreign governments
Inspection frequency	High-risk facilities every 3 years, non-high risk every 5 years; unannounced inspections possible	No set frequency; frequency based on risk assessments and resource availability Fewer inspections: In 2024, 1,317 foreign inspections vs. 6,635 domestic ones

Table 3. Differences in FSMA compliance, inspections and oversight between domestic and foreign entities (continued)

CATEGORY	US (DOMESTIC) ENTITIES	FOREIGN ENTITIES & IMPORTER
Exemptions and modified requirements	Exemptions from PSR and PC rule for small farms based on size and local sales	Small importers and small suppliers may qualify for modified FSVP requirements
Sampling	FDA conducts targeted product and farm/facility environmental sampling (sampling assignments and surveillance activities)	FDA sampling mostly at ports of entry and warehouses; no routine farm-level sampling
Farm inventory	The CAP requires participating state agencies to maintain farm inventories.	No mandatory registration of foreign farms; no structured inventory similar to what is required under the CAP
Non-compliance violations	Non-compliance can result in warnings, injunctions, and recalls	FSVP warning letters and import alerts
Enforcement mechanisms	FDA can enforce compliance through recalls, administrative detentions, and administrative orders	FDA lacks direct enforcement authority over foreign farms; it relies on import controls, trade restrictions and the FSVP importer

[4] Accredited Third-Party Certification Program | FDA
[5] Produce Safety Inspections | FDA
[6] FDA-State Produce Safety Implementation Cooperative Agreement Program (PAR-21-174) - Factsheet August 2024
[7] Food Safety: FDA Should Strengthen Inspection Efforts to Protect the U.S. Food Supply | -.S. GAO
[8] FDA Announces Expanded Use of Unannounced Inspections at Foreign Manufacturing Facilities | FDA
[9] Foreign Food Facility Inspection Program Questions & Answers | FDA
[10] Inspections to Protect the Food Supply | FDA
[11] How Does FDA Prioritize Domestic Human Food Facility Inspections? | FDA
[12] FDA must inspect each high-risk domestic facility at least once every 3 years and each non-high-risk domestic facility at least once every 5 years. FDA uses "cover-by" dates for each facility to ensure it meets these mandated targets. For example, a high-risk domestic facility inspected on October 1, 2022, would have a cover-by date of October 1, 2025—exactly 3 years later. The figure depicts FDA's performance in meeting mandated targets for domestic food facilities with cover-by dates in a given fiscal year. Specifically, the fiscal year totals presented in the figure do not represent FDA's full inventory of approximately 75,000 domestic food facilities subject to FDA inspection. Instead, the fiscal year totals represent a subset of FDA's full inventory. This subset includes domestic facilities that are due for an inspection (i.e., have cover-by dates) in a given fiscal year as well as facilities that are past-due for an inspection (i.e., had cover-by dates in the prior fiscal year, but were not inspected). Therefore, domestic facilities that are not past-due or do not have a cover-by date in a given fiscal year are not included in the data for that fiscal year.
[13] FORM FDA 4056
[14] Inspection Observations | FDA
[15] Public law 111-353 FDA Food Safety Modernization Act – Title II, sec. 201(a)(2)(D)
[16] Food Safety: Additional Actions Needed to Help FDA's Foreign Offices Ensure Safety of Imported Food | U.S. GAO
[17] OIG 2025 Data Brief: FDA Food Safety Inspections of Domestic Food Facilities
[18] FDA Dashboards - Home
[19] Microbiological Surveillance Sampling | FDA
[20] CP 7303.050, Sampling for Foodborne Biological Hazards, and Filth - Domestic and Import
[21] Microbiological Surveillance Sampling: FY17-21 Fresh Herbs (Cilantro, Basil & Parsley) | FDA
[22] Guide to Produce Farm Investigations (11/05) | FDA
[23] Food Safety Issues: FDA Judicial Enforcement Actions
[24] USCODE-2023-title21-chap9-subchapIII-sec334.pdf
[25] Guidance for Industry and FDA Staff: Questions and Answers Regarding Mandatory Food Recalls | FDA
[26] Importing Food Products into the United States | FDA
[27] Import Alerts | FDA

FSVP PROGRAM

Because the FDA lacks direct enforcement authority over foreign farms, the agency relies on mechanisms such as import controls (e.g., the FSVP) and cooperation with foreign governments to ensure imported fresh produce meets U.S. standards or equivalent foreign standards. As previously stated, the FDA relies heavily on importers as the responsible party to ensure their foreign suppliers are following the appropriate U.S. food safety regulations. The FDA defines a "foreign supplier" as: "for an article of food, the establishment that manufactures/processes the food, raises the animal, or grows the food that is exported to the United States without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or any similar activity of a de minimis nature."[28] Each quarter, the FDA publishes a list of importers that are participating in the FSVP (company name and state). For the second quarter of 2025 (April 1st to June 30th, 2025), 26,660 companies were registered as importers in the U.S.[29] However, from the end of June 2017 to early May 2025, 4,203 companies were cited for not having an FSVP, and in 2024 alone, 443 companies were cited for not having an FSVP.

Under the FSVP regulation, key provisions that apply to importers of fresh produce are:[20, 30]

1. Develop and implement an FSVP plan by a qualified individual.
2. Perform a hazard analysis, determining the hazards reasonably likely to cause illness or injury with each food. Importers can conduct their own analysis of the potential hazards with a food or review and assess a hazard analysis conducted by another entity.
3. Evaluate the foreign supplier's performance and the risk posed by a food based on the hazard analysis, which entity or entities will be controlling the hazards, the foreign supplier's food safety practices, applicable FDA food safety regulations and the foreign supplier's compliance, the foreign supplier's food safety history, and any other relevant factors.
4. Evaluate the approval of foreign suppliers and determine appropriate supplier verification activities. An importer may rely on another entity to conduct this evaluation and to determine the appropriate supplier verification activities if the importer reviews and assesses the evaluation, determination, or both, as applicable. An importer must approve its own foreign suppliers.
5. Use approved foreign suppliers: In general, importers must establish and follow written procedures to ensure they only import foods from foreign suppliers they have approved. However, importers may import food from unapproved foreign suppliers, on a temporary basis when necessary and appropriate, if they subject the food from these suppliers to adequate verification activities before importing it.

6. Conduct supplier verification activities: The determination of appropriate supplier verification activities must be based on the evaluation of the food and foreign suppliers. Appropriate verification activities include:[20, 31]
    - On-site auditing[32]
    - Sampling and testing of a food
    - Review of the foreign supplier's relevant food safety records
    - Other activities that are appropriate based on the evaluation of the risk posed by the food and foreign supplier performance
7. Perform appropriate activities in other circumstances: The final rule also adds flexibility and recognizes the reality of modern distribution chains by not requiring an importer to conduct supplier verification (or evaluate the risk posed by a food and the foreign supplier's performance) when the hazard requiring a control in a food will be controlled by a subsequent entity in the distribution chain in the U.S.
8. Implement corrective actions: An importer must take appropriate corrective actions promptly if it determines that a foreign supplier of a food it imports does not produce the food in compliance with the processes and procedures that provide the same level of public health protection as those required under section 418 or 419 of the FD&C Act, if either is applicable, or produces food that is adulterated under section 402 or misbranded under section 403(w) (if applicable) of the FD&C Act.
9. Identify themselves as the importer of the food for each line of food product offered for importation into the U.S.
10. Retain records of FSVP activities.

Similar to the PSR, the FSVP has modified requirements for very small importers (*i.e., imported food averaging less than $1 million per year during the 3-year period preceding the applicable calendar year*) (summary comparison provided in **Table 3**). These importers are not required to conduct a hazard analysis and are able to verify their foreign suppliers by obtaining written assurance of their suppliers' compliance with the applicable food safety regulations. In addition, importers of food from foreign suppliers in countries with food safety systems, which the FDA officially recognizes as comparable or equivalent to the U.S. system, have modified requirements provided that: 1) The food is within the scope of the relevant official recognition or equivalency determination, 2) they determine that the foreign supplier is in good compliance standing with U.S. regulation or the equivalent country's relevant regulations, and 3) the food is not intended for further processing in the U.S. (e.g., packaged food products and RACs that will not be processed further before consumption).

International Agreements

The FDA works with regulatory partners in foreign governments to harmonize and align science-based food safety standards and best practices. The agency primarily uses two options by which it can structure these arrangements: 1) systems recognition (SR) is a reciprocal process whereby FDA and a foreign regulatory counterpart evaluate each other's food safety systems to determine whether their systems achieve comparable food safety outcomes, and 2) equivalence for foreign

food safety systems that achieve the same level of public health protection as measures required by U.S. law, even if they use different food safety controls.[33, 34, 35] Under the SR process, the FDA has officially recognized Australia's, Canada's, and New Zealand's food safety system as comparable to that of the United States.[25] The FDA lists both sharing data on inspections and reduced routine foreign inspections as benefits of SR arrangements. In contrast, equivalence was established by the World Trade Organization Agreement on Sanitary and Phytosanitary Measures as a trade-facilitating mechanism for countries seeking access to other countries' markets.

More U.S. food imports come from Mexico than from any other country, including, as of 2024, 48.4% of imported fresh produce. In September 2020, the FDA and Mexico's National Service of Agro-Alimentary Health, Safety and Quality (SENASICA) and the Federal Commission for Protection against Sanitary Risk (Cofepris) established a Food Safety Partnership (FSP). As stated on the FDA's website, "The goal of the FSP is to protect public health through the prevention of foodborne diseases in human foods, by using modern approaches and preventive practices based on technical and scientific evidence, health surveillance, and verification measures."[36]

Voluntary Qualified Importer Program (VQIP)

The FDA offers the VQIP, a fee-based program that extends quick and easier entry, limited examination and sampling, and faster laboratory test results for importers.[37] Eligibility criteria for this program is simple: importers must have a valid certification under the FDA's Accredited Third-Party Certification Program, comply with applicable food safety regulations, and maintain a clean compliance history for their operations and that of their foreign suppliers, among other requirements. Currently, only seven U.S. companies are listed as approved VQIP importers.[38]

Third Party-Certification

To help meet the need for auditing foreign food facilities, the FDA established a voluntary program, the Accredited Third-Party Certification Program (TPP) wherein the FDA recognizes "accreditation bodies" (ABs) that then have the authority to accredit third-party auditors or "certification bodies".[39,40] To become an AB, an entity must apply and pay an application fee, meet the requirements outlined in 21 CFR Part 1, subpart M, and, after receiving the FDA's recognition, meet routine requirements to maintain recognition such as conducting self-assessments and correcting any problems identified during the assessment.[41] The application fee is calculated each fiscal year based on the FDA's costs to evaluate and recognize applicants; the fee for fiscal year (FY) 2025 was $53,520.[42] FDA's recognition is for a maximum of five years after the initial recognition is granted and requires an annual fee of $2,505.[33] Within those five years, FDA is mandated to "evaluate the performance of each recognized accreditation body to determine its compliance with the applicable requirements of this subpart" (subpart M).[27] After five years, recognized ABs pay a renewal fee that is lower than the cost of the initial application fee ($32,802 in FY 2025).

In addition to accrediting third-party auditors, an AB must monitor the performance of third-party auditors and submit monitoring reports to the FDA. An AB must allow the FDA to have access to records required by the program, but the FDA is not mandated to review their records. Three entities are recognized by FDA as ABs for the Produce Safety Rule, two of which are the

International Accreditation Services, Inc. and the ANSI National Accreditation Board (ANAB).[43] The third entity is the Jamaica National Agency for Accreditation (JANAAC), which is the only country to have an AB for the Produce Safety Rule.[27]

Certification bodies, otherwise known as third-party auditors, are entities that generally provide two services: conduct consultative and/or unannounced regulatory food safety audits and certify that eligible entities and the food they produce meet applicable FDA food safety standards.[44] Certifications of food importers serve two purposes: 1) They can be used to establish eligibility for companies applying to participate in the VQIP, and 2) under rare and limited circumstances, the FDA may require a potentially harmful imported product to meet specific, risk-based criteria and be certified as a condition for entry into the U.S. Certification bodies seeking direct accreditation from the FDA also pay an initial application fee based on the FDA's calculations of their costs for evaluation. In FY 2025, the FDA's costs were calculated to be the same as the evaluation of AB applicants ($53,520). Foreign governments and agencies and private third parties are eligible for accreditation as a third-party auditor. Ten entities have undergone the accreditation process and are registered as third-party auditors for the Produce Safety Rule. Of these entities, four are primarily based in the U.S., three are located in a single country, and three have international locations.[27]

As previously mentioned, third-party auditors conduct both consultative and regulatory audits. Consultative audits are intended to help foreign entities prepare for a regulatory audit. Auditors are not required to submit their consultative audit reports to the FDA, but are required to maintain records of these audits and make them available to the FDA upon request. A regulatory audit is conducted to determine whether a company complies with FDA's applicable food safety regulatory requirements.

[28]Federal Register: Foreign Supplier Verification Programs for Importers of Food for Humans and Animals
[29]Foreign Suppliers Verification Programs (FSVP) - List of Participants | FDA
[30]FSMA Final Rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals | FDA
[31]§1.506(d)(1)(ii)(A-D)
[32]When a hazard in a food will be controlled by the foreign supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, the default appropriate verification activity under the regulation is an annual onsite audit of the foreign supplier.
[33]Systems Recognition (Food) | FDA
[34]Equivalence and Food Safety | FDA
[35]International Cooperation on Food Safety | FDA
[36]FDA-SENASICA-COFEPRIS Food Safety Partnership | FDA
[37]Voluntary Qualified Importer Program (VQIP) | FDA
[38]Voluntary Qualified Importer Program (VQIP): Public List of Approved VQIP Importers | FDA
[39]Accredited Third-Party Certification Program | FDA
[40]Accredited Third-Party Certification Program: Public Registry of Recognized Accreditation Bodies | FDA
[41]eCFR: 21 CFR Part 1 Subpart M -- Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and To Issue Certifications
[42]Federal Register: Food Safety Modernization Act Third-Party Certification Program User Fee Rate for Fiscal Year 2025
[43]FDA Dashboards - Accredited Third-Party Certification Program
[44]Accredited Third-Party Certification Program: Public Registry of Accredited Third-Party Certification Bodies | FDA

ASSESSING FOODBORNE DISEASES ATTRIBUTED TO PRODUCE ORIGIN

Since 2014, there have been 38 produce-related foodborne disease outbreaks with an attributable origin. **Table 4** shows the distribution of these foodborne disease outbreaks. More produce-related foodborne disease outbreaks were attributed to domestically grown produce; however, when considering the number of illnesses, outbreaks from foreign origin account for a larger number of illnesses, and more importantly, higher numbers of illnesses per outbreak. A more in-depth assessment may be warranted to assess relative risk based on produce origin.

Table 4. Foodborne disease outbreaks attributed to produce

	DOMESTIC PRODUCTS	FOREIGN PRODUCTS	BOTH FOREIGN AND DOMESTIC PRODUCTS
Foodborne disease outbreaks	23 (60.5%)	13 (34.2%)	2 (5.2%)
Numbers of illnesses	3,122	4,361	NA
Numbers of illnesses per outbreak	135	336	NA

FSVP RULE BENEFITS AND CHALLENGES

The Foreign Supplier Verification Program (FSVP) regulation encourages importers to establish direct relationships with their suppliers and to actively evaluate them rather than rely on second-hand information. However, significant challenges remain. Congress mandated foreign food facility inspection targets under FSMA, but the FDA has not met these requirements and has stated that the inspection mandate is not achievable with current resources. In addition, compliance costs associated with FSMA are generally higher for domestic companies than they are for foreign suppliers, resulting in uneven regulatory and economic burdens across the supply chain.[45]

[45] Hamilton L, McCullough M. 2025. Two decades of change: Evolving costs of regulatory compliance in the produce industry (viewcontent.cgi)

CONCLUSIONS

This paper highlights the uneven landscape of imported fresh produce oversight and the significant limitations inherent in a regulatory system that relies heavily on importers and foreign governments. While domestic fresh produce operations are subject to clearly defined inspection requirements, routine oversight, and accessible enforcement pathways, the FDA's authority over foreign suppliers remains constrained by jurisdictional limits, resource shortages, lack of a comprehensive foreign farm inventory, and logistical barriers. Publicly available data reveal important gaps in foreign facility inspections, limited use of unannounced inspections overseas, and other regulatory tools and remedies.

Despite these structural limitations, the existing framework—FSVP, international agreements, and sampling programs—provides a foundation for aligning imported produce with U.S. safety expectations. However, the public data alone cannot illuminate the practical realities: how foreign supplier verification is actually carried out in diverse production regions, where verification breaks down, or how importers interpret and implement FSVP requirements. Additional insights from domestic and foreign producers, certification bodies, importers, and regulators are essential to understanding the true implementation challenges of regulatory requirements. These perspectives are critical to evaluating the performance of current programs beyond what regulations require or public reports describe.

Based on this paper, several recommendations emerge for future phases of work. First, systematic engagement with importers, foreign suppliers, certification bodies, and domestic producers is needed to identify operational challenges, resource gaps, and opportunities to strengthen foreign supplier verification at the field, facility, and distribution levels. Second, a deeper analysis of the FDA's enforcement tools, sampling strategies, and inspection prioritization, particularly in high-volume exporting regions, would help identify where risk-based oversight could be recalibrated. Third, improved transparency regarding foreign supplier inspections and compliance histories would support better risk assessment by importers and regulators. Finally, as imported produce continues to expand its share of the U.S. market, collaborative efforts between government, industry, and international partners will be essential to ensuring that foreign suppliers meet the same safety expectations as domestic producers, and that the U.S. fresh produce market remains both safe and competitive.