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# How Mexico's Horticultural Export Sector Responded to the Food Safety Modernization Act

Steven Zahniser, Belem Avendaño Ruíz, and Gregory Astill<sup>1</sup>







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# How Mexico's Horticultural Export Sector Responded to the Food Safety Modernization Act

Steven Zahniser, Belem Avendaño Ruíz, and Gregory Astill<sup>1</sup>

## Abstract

The Food Safety Modernization Act (FSMA) gave the U.S. Food and Drug Administration new powers to ensure that imported food meets U.S. standards. This case study used interviews with Mexican horticultural growers focused on the export market to explore how their industry responded to FSMA's new requirements. Half of the 26 companies interviewed identified training the head of the firm's food safety program as the main challenge. Medium-to-large companies (300–1,000 seasonal workers) were more likely to have modified their food safety activities and hold 3 or more food safety certifications—facilitating the sector's growing presence in the U.S. market.

**Keywords:** FSMA, Food Safety Modernization Act, Mexico, United States, trade, horticulture, tomatoes, strawberries, green onions, cantaloupe, outbreaks, food safety standards

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# How Mexico's Horticultural Export Sector Responded to the Food Safety Modernization Act

Steven Zahniser, Belem Avendaño Ruíz, and Gregory Astill<sup>1</sup>

## What Is the Issue?

The Food Safety Modernization Act (FSMA)—officially named the “FDA Food Safety Modernization Act”—was designed to improve the capacity to prevent food safety problems and detect and respond to such problems, as well as to improve the safety of imported food. Among its many provisions, FSMA gave the U.S. Food and Drug Administration (FDA) new powers to ensure that imported food meets U.S. standards and is safe to eat. Mexico's horticultural export sector is the largest source of U.S. horticultural imports (63.5 percent of U.S. vegetable imports and 46.1 percent of U.S. fruit and nut imports in 2021); as such, Mexican exporters had to comply with FSMA and its accompanying rules. Because most of Mexico's horticultural exports are destined for the United States, FSMA introduced an additional degree of risk into the sector since the extent to which the sector's firms would be able to comply with FSMA's new requirements was unknown. In general, government regulators associating a Mexican product with an outbreak of a foodborne illness in the United States can have a potentially harmful effect on a broad segment of Mexican horticultural exports, in part because it is difficult for government investigators to identify promptly and precisely which actors (e.g., producers, packers, shippers, retailers) in the agri-food system are responsible for a specific outbreak.

## What Did the Study Find?

FSMA does not appear to have had a major negative effect on Mexico's horticultural export sector. Since the act's implementation in 2011, the growth of Mexican horticultural exports to the United States has not slowed. Indeed, because FSMA provided a framework for the Mexican horticultural export sector to address food safety concerns, the act helped to secure Mexican access to the U.S. market for horticultural products.

In response to FSMA's new requirements, Mexican horticultural companies made changes to equipment, invested in new infrastructure, and implemented monitoring programs featuring improved sampling techniques—many of which were connected to ensuring a supply of clean water throughout the production process. The concentration of Mexico's horticultural exports in the U.S. market may have provided opportunities for economies of scale and



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scope when complying with FSMA. Costs of measures taken could be spread across all sales to the United States, and there were likely synergies across crops and even among the regulatory concerns of the United States and other markets for Mexico-grown produce, including Mexico itself.

To explore how Mexico's horticultural export sector responded to FSMA's new requirements, the researchers interviewed representatives of 26 companies in that sector. The main challenges in responding to FSMA related to training—half of the companies interviewed indicated that obtaining food safety training for the head of the firm's food safety program was their main challenge; nearly a third indicated that it was providing food safety training to seasonal farmworkers. Another challenge identified was the lack of accredited laboratories recognized by the FDA for the analysis of samples from water, soil, and surfaces of contact. To address this challenge, some companies set up their own laboratories and instituted relationships with entities recognized by the FDA.

Medium-to-large companies (300–1,000 seasonal farmworkers) seemed more adept at meeting FSMA's new requirements. Companies of this size were more likely to have modified their food safety activities in response to FSMA and more likely to hold three or more food safety certifications. These findings about Mexican horticultural growers generally align with findings about U.S. horticultural growers generated by past USDA, ERS research.

## **How Was the Study Conducted?**

A case study approach was used to examine how Mexican horticultural growers focused on the export market responded to the implementation of FSMA and why they were able to respond in that fashion. The researchers conducted a series of interviews from March 2018 to March 2020 with representatives of 26 produce firms that export 1 or more of 4 major produce commodities to the United States—tomatoes, strawberries, green onions, and cantaloupe. The researchers focused on these commodities because prior to FSMA, Mexican exports of each of these products had been associated with outbreaks of foodborne illness in the United States. The companies studied are in seven Mexican States that are among Mexico's main horticultural exporting States. Findings from these interviews are presented using summary statistics and qualitative assessments of interview data.

# How Mexico's Horticultural Export Sector Responded to the Food Safety Modernization Act

## Introduction

The global agri-food system may be thought of as the “totality of actors involved in the production, distribution, and consumption of food, the relations between them, and the regulatory apparatus governing these arrangements” (Castree et al., 2013). The historical evolution of this system has featured a general widening of the physical distance between the producer and the consumer (Steinfeld et al., 2019), rising levels of international trade (Beckman et al., 2017), greater management of production and consumption by transnational corporations, and a decline in the level of control that farmers and farm organizations have over food production (Castree et al., 2013). As part of this evolution, food safety issues now have an international dimension, as the actors in cross-border supply chains must work to satisfy the food safety concerns of regulatory authorities, regardless of whether they are in the exporting country, the importing country, or perhaps even a third country where an international standard-setting body is headquartered.

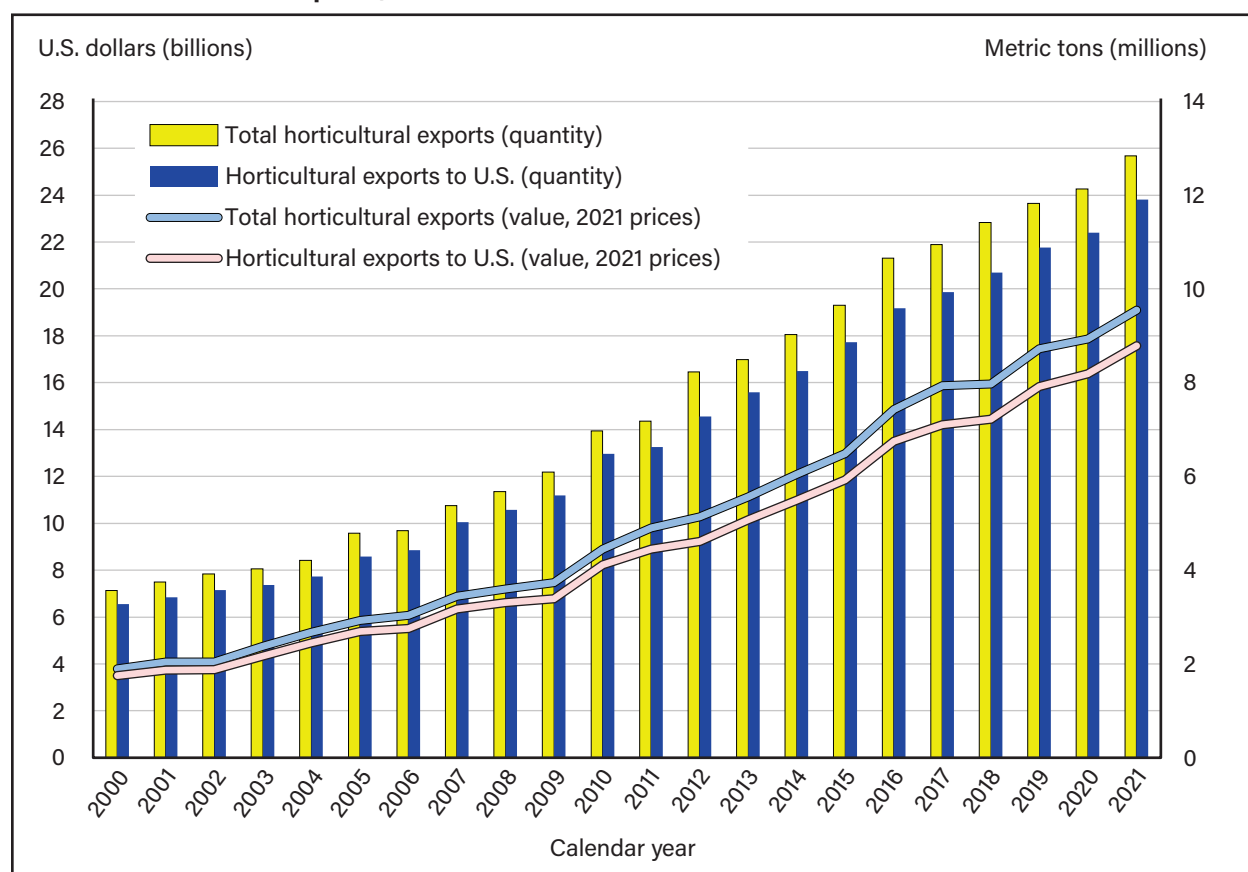
Mexico is not exempt from these global processes. The country has developed into a major producer and exporter of a broad range of fresh horticultural products—including tomatoes, avocados, raspberries, bell peppers, and strawberries.<sup>2</sup> Through more than a half century of participation in international trade, Mexico's horticultural sector has learned, assimilated, and improved upon productive technologies, including protected cultures such as greenhouses, screenhouses, and tunnels. The sector also implemented the food safety standards needed to access and maintain access to the international market. Other factors behind the sector's strength include its proximity to the lucrative U.S. market, duty-free access to the U.S. and Canadian markets as established by the North American Free Trade Agreement (NAFTA) and continued by the United States-Mexico-Canada Agreement (USMCA), and greater availability of farm labor relative to the United States and many other foreign markets. As a result of these factors, Mexican horticultural exports have quadrupled in real value since the turn of the 21st century (figure 1). In 2021, these exports reached \$19.1 billion, corresponding to about 12.8 million metric tons of product.

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<sup>2</sup> In this report, authors use the term “horticultural” to refer to those products in Chapters 7 (edible vegetables and certain roots and tubers) and 8 (edible fruit and nuts; peel of citrus fruit and melons) of the Harmonized System (World Customs Organization, 2021).



Figure 1  
**Mexican horticultural exports, 2000-21**



Note: The U.S. Government's trade statistics for U.S. imports from Mexico are used to represent Mexican exports to the United States. Total exports are calculated by adding U.S. imports from Mexico (as measured by the U.S. Government's trade statistics) and Mexican exports to countries other than the United States (as measured by the Mexican Government's trade statistics).

Source: USDA, Economic Research Service using data for Mexican exports to countries other than the United States from Instituto Nacional de Estadística y Geografía (INEGI) and Secretaría de Economía, as compiled by Trade Data Monitor (2022), and U.S. import data from the U.S. Department of Commerce, Bureau of the Census, as compiled by USDA, Foreign Agricultural Service (2022).

Most of Mexico's horticultural exports are destined for the United States. In 2021, 89 percent of Mexican fruit and tree nut exports went to the United States, as did 95 percent of Mexican vegetable exports (in terms of value based on data presented in figure 1). For some crops, the share of Mexican production exported to the United States is especially high. During the period 2016–18, for example, 40–50 percent of the tomatoes, lettuce, watermelons, avocados, and strawberries grown in Mexico and 60–75 percent of the asparagus, broccoli, and cucumbers were destined for the U.S. market (Zahniser, 2020).

While there are seasonal patterns in Mexico's horticultural exports, the sector supplies some types of fresh fruit and vegetables to the United States year-round or almost year-round. For instance, at least 60 percent of fresh grape tomato shipments in the United States came from Mexico during every month in 2021. In contrast, seasonal patterns are much stronger in strawberry exports, with Mexico accounting for at least one-third of fresh strawberry shipments to the United States during just 5 months of 2021 (January, February, March, April, and December) (USDA, Agricultural Marketing Service, Specialty Crops Programs, Market News Division, 2022). In 2021, imports from Mexico comprised 63.5 percent of all U.S. vegetable imports



(Chapter 7 of the Harmonized System) and 46.1 percent of all U.S. fruit and nut imports (Chapter 8) in value terms (U.S. Department of Commerce, Bureau of the Census, as compiled by USDA, Foreign Agricultural Service (2022)).<sup>3</sup>

This high concentration of sales in a single foreign market presents an additional degree of risk to Mexico's horticultural export sector. Association of a particular product with an outbreak of a foodborne illness in the United States can initially have a detrimental effect on all suppliers of that product—foreign and domestic—partly because it is difficult for government investigators to identify promptly and precisely which actors in the agri-food system were responsible for the outbreak.

A common response of consumers to a government announcement that an outbreak of foodborne illness has been associated with a particular product is to purchase less of that product and more of a close substitute. For instance, Arnade et al. (2009) documented higher purchases of leafy greens other than spinach in response to the 2006 outbreak of *E. Coli* O157:H7 associated with U.S.-grown spinach, and Kuchler (2015) observed higher purchases of watermelon and honeydew melons in response to the 2011 outbreak of *Listeria monocytogenes* associated with U.S.-grown cantaloupe.<sup>4</sup> Such substitutions can occur without consumers considering if the remaining suppliers of the product associated with the outbreak are able to provide their product in a condition that is safe to eat. For many types of produce, Mexico is a major exporter of the substitute products as well. For instance, annual U.S. imports from Mexico exceeded \$50 million (nominal value, not inflation-adjusted) each year for watermelons since 2003 and for fresh lettuce since 2008 (USDA, Foreign Agricultural Service, 2022).

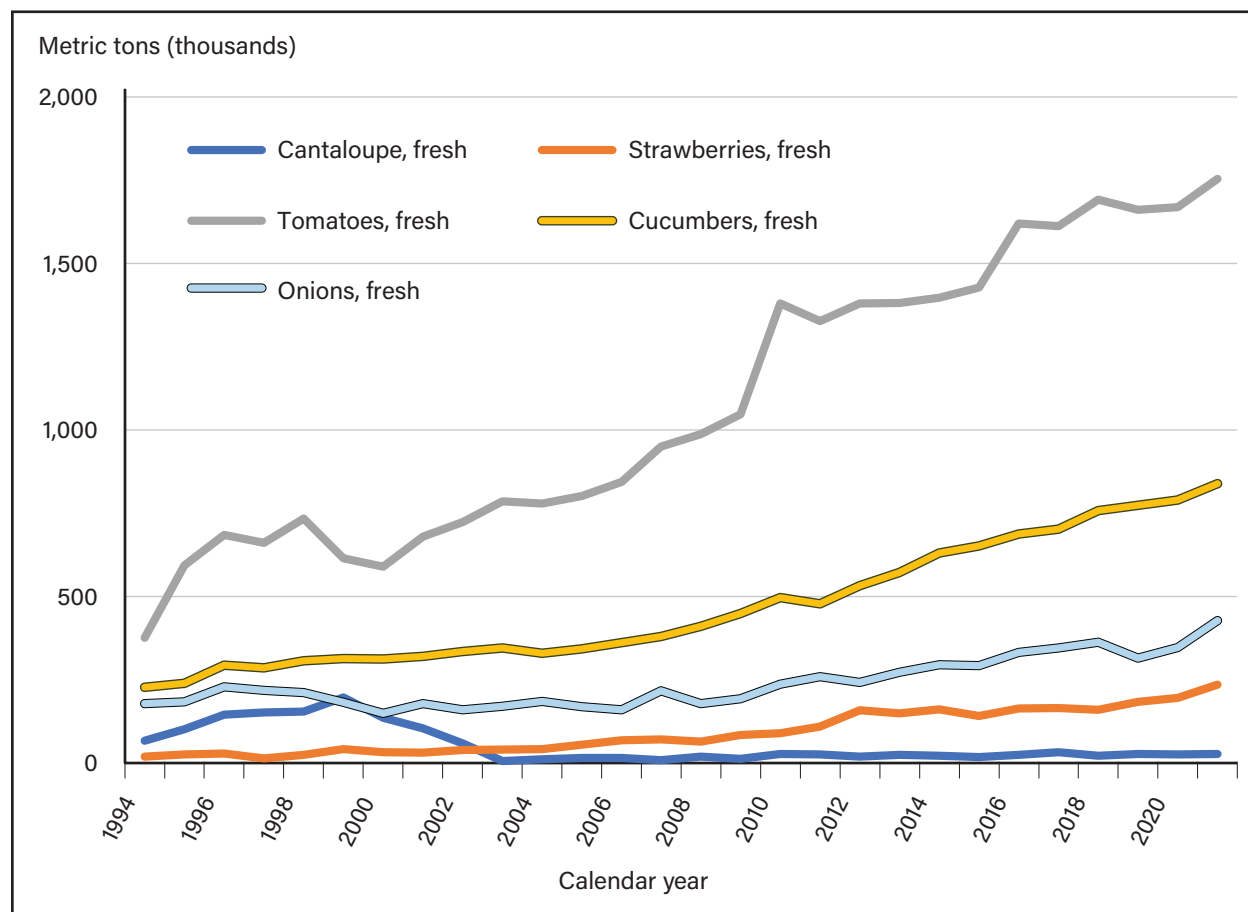
Substitutions in response to an outbreak of foodborne illness can also involve shifts from one supplying country to another without consumers necessarily evaluating the absolute and relative prevalence of safe practices in the horticultural sectors of each prospective supplying country. The history of the Mexican horticultural export sector includes many instances where outbreaks were linked to Mexican products—such as strawberries (1997), green onions (2003), tomatoes (2008), cucumbers (2013, 2015), and cantaloupe (1989, 1991, 1997, 1998, 2000, 2002, and 2006) (table 1). While the cases involving strawberries, green onions, tomatoes, and cucumbers did not seem to affect the long-term growth in Mexican exports of these products to the United States, the repeated cases involving cantaloupe eventually proved to be too much for some Mexican exporters of this product (figure 2).

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<sup>3</sup> For further analysis of recent increases in U.S. imports of fresh fruit and vegetables, see Kenner (2020) and Davis and Lucier (2021).

<sup>4</sup> Centers for Disease Control and Prevention (2006) provides an overview of the infections reported due to the outbreak associated with spinach.

Figure 2

**U.S. imports from Mexico of selected fruit and vegetables, 1994–2021**

Source: USDA, Economic Research Service using data from U.S. Department of Commerce, Bureau of the Census, as compiled by USDA, Foreign Agricultural Service (2022).

Following three successive springs (2000, 2001, and 2002) when food safety regulators in the United States, Mexico, and Canada traced outbreaks of *Salmonella* in the United States (and in Canada in 2001) to cantaloupe grown in specific locations in Mexico, the U.S. Food and Drug Administration (FDA) issued a countrywide import alert on Mexican cantaloupe in October 2002. The timing of the import alert was particularly inopportune for growers in the State of Sonora, whose harvest season was just beginning, and much lower quantities of Mexican cantaloupe were exported to the United States throughout 2003 (Green et al., 2005).

After several years of additional work to improve Mexican regulations and inspection systems for cantaloupe and to develop a Mexican certification program to identify growers who follow good agricultural practices (GAPs) and good manufacturing practices (GMPs), the FDA and Mexico's National Service of Agro-Alimentary Health, Safety, and Quality (SENASICA—Servicio Nacional de Sanidad, Inocuidad, y Calidad Agroalimentaria) signed a memorandum of understanding (MOU) in October 2005. The MOU provided a framework for Mexican cantaloupe growers identified by SENASICA as complying with the Produce Safety Rule of the Food Safety Modernization Act (FSMA) to gain access to the U.S. market (U.S. Food and Drug Administration, 2022d). Despite this framework, some Mexican cantaloupe growers shifted to other commodities, and some U.S. buyers shifted to other foreign suppliers, such as Guatemala and Honduras (Avendaño Ruíz et al., 2013; Avendaño Ruíz, 2019; Calvin, 2003; Green et al., 2005). (See box, "SENASICA's Role in the Mexican Horticultural Export Sector's Response to the Food Safety Modernization Act (FSMA)," on page 5.)

Table 1

**Foodborne illness outbreaks in the United States related to Mexican products, 1989–2022**

| Date | Product                    | Pathogen   |
|------|----------------------------|--|
| 1989 | Cantaloupe                 | <i>Salmonella</i> Chester  |
| 1991 | Cantaloupe                 | <i>Salmonella</i> Poona  |
| 1992 | Vegetables                 | <i>E. coli</i> 0157  |
| 1995 | Iceberg lettuce            | <i>E. coli</i> 0157  |
| 1997 | Strawberries               | Hepatitis A  |
| 1997 | Cantaloupe                 | <i>Salmonella</i> Saphra   |
| 1998 | Parsley, cilantro          | <i>Shigella sonnei</i>   |
| 1998 | Cantaloupe                 | <i>Salmonella</i> Oranienburg  |
| 2000 | Cantaloupe                 | <i>Salmonella</i> Poona  |
| 2002 | Cantaloupe                 | <i>Salmonella</i>  |
| 2003 | Green onions               | Hepatitis A  |
| 2006 | Cantaloupe                 | <i>Salmonella</i>  |
| 2008 | Tomatoes, chiles, cilantro | <i>Salmonella</i> St. Paul   |
| 2011 | Papaya                     | <i>Salmonella</i> Agona  |
| 2012 | Mangos                     | <i>Salmonella</i> Braenderup   |
| 2012 | Cilantro                   | <i>Cyclospora</i>  |
| 2013 | Cucumber                   | <i>Salmonella</i> St. Paul   |
| 2013 | Cilantro                   | <i>Cyclospora</i>  |
| 2013 | Salad mix                  | <i>Cyclospora</i>  |
| 2014 | Cilantro                   | <i>Cyclospora</i>  |
| 2015 | Cucumber                   | <i>Salmonella</i> Poona  |
| 2015 | Cilantro                   | <i>Cyclospora</i>  |
| 2017 | Papaya                     | <i>Salmonella</i> Thompson, Kiambu, Agona, Gaminara, and Senftenberg |
| 2017 | Papaya                     | <i>Salmonella</i> Anatum   |
| 2017 | Papaya                     | <i>Salmonella</i> Newport and Infantis                               |
| 2017 | Papaya                     | <i>Salmonella</i> Urbana   |
| 2019 | Papaya                     | <i>Salmonella</i> Uganda   |
| 2019 | Basil                      | <i>Cyclospora</i>  |
| 2021 | Whole onions               | <i>Salmonella</i> Oranienburg  |
| 2022 | Strawberries               | Hepatitis A  |

Source: USDA, Economic Research Service revision of table from Avendaño Ruíz (2019) using information from Centers for Disease Control and Prevention (2022).

### **SENASICA’s Role in the Mexican Horticultural Export Sector’s Response to the Food Safety Modernization Act (FSMA)**

The Mexican Government worked to provide training and conducted outreach to the Mexican horticultural export sector about the Food Safety Modernization Act (FSMA) and its accompanying rules, and it encouraged participation in the rulemaking process. The effort was implemented through the various governmental institutions and auxiliary bodies responsible for food safety in Mexico.

Food safety gained prominence as a public policy issue in Mexico in 2001 with the creation of the National Service of Agro-Alimentary Health, Quality, and Safety (SENASICA—Servicio Nacional de Sanidad, Inocuidad, y Calidad), a decentralized body within Mexico’s Secretariat of Agriculture and Rural Development (SADER—Secretaría de Agricultura y Desarrollo Rural) (SADER, SENASICA,

2017).<sup>5</sup> SENASICA’s mission is to “regulate, manage, and promote activities of agro-alimentary health, safety, and quality activities, reducing the inherent risks in agriculture, livestock, aquaculture, and fisheries, for the benefit of producers, consumers, and industry” (USDA, Economic Research Service translation of SADER, SENASICA, 2023). This set of responsibilities is broader than those of SENASICA’s predecessor—the National Commission of Agricultural Health (CONASAG—Comisión Nacional de Sanidad Agropecuaria), created in 1996. SENASICA’s activities are similar to those of the FDA, as well as USDA’s Animal and Plant Health Inspection Service (APHIS) and Food Safety and Inspection Service (FSIS).

In 2006, SENASICA’s internal regulations were modified to create within SENASICA the General Directorate of Agro-Alimentary, Aquaculture, and Fisheries Safety (DGIAAP—Dirección General de Inocuidad Agroalimentaria, Acuícola, y Pesquera) (SADER, SENASICA, 2017). The DGIAAP’s main purpose is “to propose and establish plans and strategies in matters related to food safety ... with the aim of achieving greater competitiveness in production and facilitating national and international trade” (authors’ translation of SADER, SENASICA, 2017).

One strategy employed by the DGIAAP is the Systems of Contamination Risk Reduction (SRRC—Sistemas de Reducción de Riesgos de Contaminación), a set of “methods and procedures to reduce contamination hazards and ensure optimal production and processing conditions” (SADER, SENASICA, 2021a). Examples of these methods and procedures include training, technical assistance, and support for the construction of infrastructure. As of June 2022, the DGIAPP had recognized 16,727 production units in the SRRC, 783 production units in the proper use and management of pesticides, 588 vegetable packaging units in the field, and 82 harvesting units (SADER, SENASICA, 2022a).

Many of the SRRC’s activities occur within the framework of State Plant Health Committees (CESVs—Comités Estatales de Sanidad Vegetal), a type of auxiliary organization where agricultural producers act as “assistants to prevent and fight pests that affect crops through collaboration with phytosanitary programs, development of strategies, procurement and application of economic resources, intervention in support of farmers to manage credit intended for crop protection, and promotion and dissemination of the programs” (SADER, SENASICA, 2022b).

Following FSMA’s implementation in 2011, the CESVs hosted a series of regional forums to disseminate information about FSMA and the act’s proposed regulations among producers, exporters, members of academia, and governmental bodies whose responsibilities are related to the act. At these forums, commissions were formed to discuss FSMA’s proposed rules, formulate comments about those proposed rules, and then submit the comments to the FDA.

Once a final rule was published, SENASICA helped to disseminate that information to growers of avocados, chiles, tomatoes, and mangos, among the main crops—underscoring the implications for and responsibilities of Mexican exporters. Special attention was devoted to FSMA’s Produce Safety Rule. In 2018, through a collaborative project between SENASICA, the FDA, and the Inter-American Institute for Cooperation on Agriculture (IICA), a total of 117 people from CESVs received training on the rule, of whom 29 people became recognized instructors in the project. As of 2019, SENASICA had conducted 37 training courses on the rule, following the guidelines of the Produce Safety Alliance. These courses attracted 972 participants, including producers, managers, and other individuals in charge of food safety at their respective companies. The courses were held in the main States in Mexico where fruit and vegetables are grown for fresh consumption, including the seven States where interviews were conducted for this study.<sup>6</sup>

<sup>5</sup> From 2000 to 2018, Mexico’s agricultural ministry was called the Secretariat of Agriculture, Livestock, Rural Development, Fishing, and Food (SAGARPA—Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca, y Alimentación).

<sup>6</sup> Information in this paragraph was provided directly by SENASICA.



The concentration of Mexican horticultural exports in the U.S. market may also provide opportunities for actors in the supply chain to achieve economies of scale and scope when complying with U.S. phytosanitary and food safety regulations. Costs of measures taken to satisfy U.S. food safety regulators may be spread across all sales to the United States, and there are likely synergies across crops, and even among the regulatory concerns of the United States and other markets for Mexico-grown fruit and vegetables, including Mexico itself.

This report examines how Mexico's horticultural export sector responded to one such major regulatory change: the new imperatives for food safety resulting from the FDA Food Safety Modernization Act (FSMA), signed into law on January 4, 2011. The authors employ a case study approach that concentrates on the effect of FSMA on Mexico's horticultural export sector.<sup>7</sup> The analysis is informed by a series of interviews with representatives of Mexican producers of horticultural exports and focuses on growers of four products: tomatoes, strawberries, green onions, and cantaloupe—all crops where Mexican product had been associated with U.S. outbreaks of foodborne illness prior to FSMA (table 1). In these interviews, FSMA and its rules were usually treated as a single entity without delving into the specifics of the law and its rules.

## The Food Safety Modernization Act

The Food Safety Modernization Act (FSMA, Public Law 111-353, with the official short title of “FDA Food Safety Modernization Act”) has been described as “the largest overhaul of the Nation’s food safety system since the Food, Drug, and Cosmetic Act of 1938” (Yiannas, 2021). FSMA represents a deliberate shift in emphasis from responding to foodborne illnesses to preventing them. The expressed aims of the act (as indicated in the names of its first three titles) are “improving capacity to prevent food safety problems,” “improving capacity to detect and respond to food safety problems,” and “improving the safety of imported food.”<sup>8</sup> Although FSMA was signed into law in 2011, its seven major rules (summarized in appendix A with relevant dates) were proposed and finalized over several years following multiple opportunities for public input and refinement. The final versions of these rules often contained staggered compliance dates, typically with 1-year and 2-year extensions for small and very small businesses, respectively. The first compliance dates for the largest firms were in 2016, while some compliance dates extend to 2025. Together, these rules gave rise for the first time to an obligation for companies to create a food defense plan by identifying, evaluating, and controlling safety-related hazards in production, using an approach similar to Hazard Analysis and Critical Control Points (HACCP), and identifying specific vulnerabilities in the process as well as corrective actions.<sup>9</sup> In the case of FSMA, the authors found at least four phases of activities where a food safety program incurs costs: implementation, monitoring, verification, and third-party authorization (table 2). The activities carried out in each phase will largely depend on the company's production structure and the standards in effect.

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<sup>7</sup> USDA, Economic Research Service (ERS) recognizes that more than 9 subjects were interviewed in 3 consecutive years. While the intent was to limit the interviews, more data were collected than originally planned. USDA, ERS established processes to prevent further noncompliance.

<sup>8</sup> For more background information on FSMA, see Collart (2016), Countryman (2016), Lupo (2021), Ribera (2016), and Ribera, et al. (2016).

<sup>9</sup> HACCP is a “management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement, and handling, to manufacturing, distribution, and consumption of the finished product.” For details, see U.S. Food and Drug Administration (2022c).

Table 2

**Classification of actions to implement FSMA**

| Implementation                          | Monitoring   | Verification   | Third-party authorization                         |
|---|--|--|---|
| Risk analysis and pollutant monitoring  | Maintenance and updating of records                    | Inspections by public or private organizations, annual or more frequent, based on risk | Qualified private or public personnel             |
| Generation of records                   | Review of risk analysis and monitoring of contaminants | Sampling and periodic analysis   | Focus on hazard assessment processes and controls |
| Training of personnel                   | Continuous checks                                      | Procedures and records, including providers  | Training for standardization of criteria          |
| Laboratory analysis under accreditation |  | Refusal of import  |   |
| Registration and control of suppliers   |  |  |   |

FSMA = Food Safety Modernization Act.

Source: USDA, Economic Research Service translation of table 4 from Avendaño Ruíz (2019).

The generation and maintenance of records is essential to demonstrate compliance, as is the constant training of personnel. Monitoring provides assurance that procedures are carried out according to established protocols, while verification activities—carried out by company personnel (internal audits) or external agents—inform areas of improvement. Finally, certification by a recognized third party indicates that the food safety program implemented by the company meets the previously established specifications (Pons and Sivardière, 2002) To understand the effect of FSMA on individual growers, it is necessary to understand what food safety practices they were already using (Astill et al., 2018).

## Methodology

This report relies on a case study approach like that used by Astill et al. (2019) and Minor et al. (2019), who examined the responses of U.S. produce growers to FSMA. In his text on the design and application of case study methods, Yin (2018) explained that a case study approach is appropriate when the following three conditions are met: (1) the research question is expressed in the form of “how” or “why;” (2) the researcher is unable to control the behavioral events being studied; and (3) the study examines contemporary events.

The present study addresses “how” and “why” questions: “How did Mexican horticultural export companies respond to FSMA?” and “Why were they able to respond in that fashion?” Given the subject matter, it was not feasible to assemble a sample that could be divided into experimental and control groups (with and without FSMA) and be large enough to be statistically representative.

While the Mexican horticultural sector has many farmers, the number of growers in particular segments of the industry is rather small. For instance, only 48 Mexican cantaloupe growers are on either the “Green List” or “Yellow List” of growers whose product is excluded from the FDA’s “Import Alert for Detention without Physical Examination of Cantaloupe from Mexico” dated June 24, 2022 (U.S. Food and Drug

Administration, 2022c).<sup>10</sup> This number means that one would need to interview at least 43 of these 48 growers to estimate statistically significant means for their population at the 95-percent confidence level.

Finally, FSMA and its accompanying rules were relatively new when the authors' interviews were conducted, and compliance was viewed as a challenge by many in the Mexican horticultural export sector.

To qualify as part of the case study's target population, companies needed to meet two criteria:

- The companies needed to produce and export one or more of four crops that had been involved in past outbreaks of foodborne illness in the United States—tomatoes, strawberries, onions, and cantaloupe; and,
- The companies needed to be in a region involved in a past outbreak of foodborne illness.

Prospective companies to be interviewed were identified using convenience sampling, a nonprobabilistic approach in which respondents are selected based on their proximity and/or accessibility to the researcher (Bornstein et al., 2013), and snowball sampling, a type of convenience sampling in which respondents help the researcher to recruit additional prospective respondents (Oregon State University, Research Office, Office of Research Integrity, Human Research Protection Board and Institutional Review Board, 2010). Several respondents in the States of Baja California, Baja California Sur, and Sonora were already known to the research team prior to the study. Snowball sampling was used to identify many of the respondents in the other States covered by the study.

Interviews with the companies' representatives usually started with a general conversation about the company and its origins and then delved into specific aspects about how the company modified its operations to comply with FSMA's new protocols and continue serving the U.S. market. These conversations were guided by a list of potential interview questions (appendix B) but loosely structured to allow ample time for elaboration and exploration of related topics, such as experiences with specific food safety certifications and testing laboratories. Some of these topics were unanticipated. Examples include the professional trajectories of individual food safety managers and the extent to which horizontal integration exists within the sector.

The fieldwork involved 26 companies and occurred between March 2018 and March 2020. The interviews were scheduled across 3 separate 12-month periods (March 2018–February 2019, March 2019–February 2020, and March 2020–February 2021) so that no more than 10 interviews occurred during any of these periods. With the onset of the Coronavirus (COVID-19) pandemic, the last 10 interviews were conducted by mail in March 2020, with the assistance of the Mexican Association of Protected Horticulture (AMHPAC—Asociación Mexicana de Horticultura Protegida). Handwritten notes were taken during the inperson interviews. Based on these notes and the survey instruments collected by AMHPAC, a database was constructed using the statistical software package SPSS version 25 (2017) to calculate frequency statistics and cross tabulations on specific topics. Since the conversations took place primarily in Spanish and were not recorded to allow people to speak more freely, quotations from those conversations in this report are approximate.

## Overview of Companies

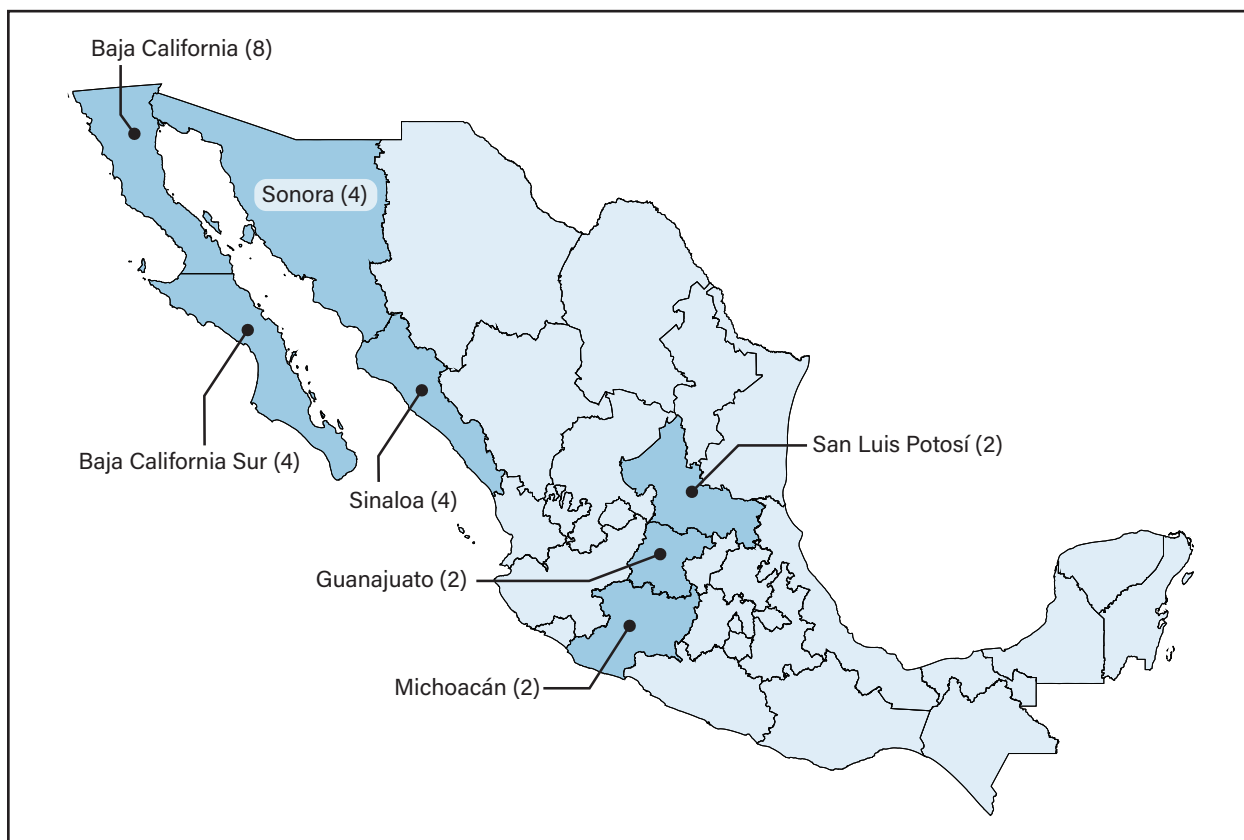
The 26 companies of this case study are in 7 Mexican States (figure 3) that are among Mexico's main horticultural exporting States (Sanchez-Gomez et al., 2019). Twelve companies are in the Baja California

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<sup>10</sup> The framework of Green, Yellow, and Red Lists is commonly used by the FDA in its Imports Alerts (U.S. Food and Drug Administration, 2019b). With respect to the Import Alert dated June 24, 2022, for cantaloupe from Mexico, 37 growers were on the Green List and thus excluded from the alert's criteria. An additional 11 growers were on the Yellow List, meaning that these "firms and their products [are] subject to intensified surveillance" or "further field examinations of individual entries and/or additional analyses." Once a firm on the Yellow List makes five shipments to the United States that are shown after laboratory tests to be free of Salmonella, the firm may submit a request to be moved to the Green List. Companies whose product is detained without physical examination must provide sufficient evidence to the FDA to overcome the appearance of the violation. Otherwise, the product is refused entry to the United States.

Peninsula, with eight firms (31 percent of the total) in the State of Baja California, and four firms (15 percent) in the State of Baja California Sur. Four companies (15 percent) are in Sinaloa—a State along Mexico’s Pacific coast that traditionally has been the heart of Mexico’s horticultural export sector. Four companies (15 percent) are in Sonora, a State in northwestern Mexico that borders the U.S. States of Arizona and New Mexico. The remaining six firms are in the States of Guanajuato, Michoacán, and San Luis Potosí.

Figure 3  
**Distribution of interviews by Mexican State**



Note: Total number of interviews = 26.

Source: USDA, Economic Research Service based on interview notes and map from Valle-Jones (2021).

Mexico’s horticultural export sector has a rich history and diverse origins. The companies studied in this report include large family farms that began as much smaller operations producing solely for the domestic market, multi-farm operations located across several Mexican States, and firms that have received direct foreign investment from the United States. Several of the companies have been in business long enough to have involved several generations of owner-operators, an observation that is consistent with published literature on the sector (Avendaño Ruíz and Schwentesius, 2005; González Chávez, 1991; Sánchez-Gomez et al., 2019).

The companies initiated their export operations at different times, and in most instances, well before FSMA’s enactment. Eight of the 26 companies (30.8 percent of the total) started to export during the period 2011–2019 (i.e., after FSMA’s enactment), while 18 companies did so earlier (table 3). The eight firms in Baja California have the longest experience in the sample as horticultural exporters—with one having export operations dating back to the 1970s, four starting in the 1980s, one beginning in the 1990s, and the remaining two launching their export activities in the first decade of the 21st century. In Baja California Sur, one company started export operations in the 1980s, two in the 1990s, and one during 2011–2019. In Sinaloa,



one firm initiated its export operations in the 1990s, two during 2001–2010, and another during 2011–2019. In Sonora, one company started to export in the 1990s, one during 2001–2010, and the other three during 2001–2019. The companies studied in Guanajuato and Michoacán all started their export operations after FSMA's enactment (2011–2019). Of the companies studied in San Luis Potosí, one started export operations during 2001–2010 and the other during 2011–2019.

Table 3

**Start of exports by selected period and Mexican State, 1971–2019**

| State               |                         | Export start year |         |           |           |           | Total |
|---------------------|-------------------------|-------------------|---------|-----------|-----------|-----------|-------|
|                     |                         | 1971–80           | 1981–90 | 1991–2000 | 2001–2010 | 2011–2019 |       |
| Baja California     | Number                  | 1                 | 4       | 1         | 2         | 0         | 8     |
|                     | Percentage within State | 12.5              | 50.0    | 12.5      | 25.0      | 0.0       | 100.0 |
| Baja California Sur | Number                  | 0                 | 1       | 2         | 0         | 1         | 4     |
|                     | Percentage within State | 0.0               | 25.0    | 50.0      | 0.0       | 25.0      | 100.0 |
| Guanajuato          | Number                  | 0                 | 0       | 0         | 0         | 2         | 2     |
|                     | Percentage within State | 0.0               | 0.0     | 0.0       | 0.0       | 100.0     | 100.0 |
| Michoacán           | Number                  | 0                 | 0       | 0         | 0         | 2         | 2     |
|                     | Percentage within State | 0.0               | 0.0     | 0.0       | 0.0       | 100.0     | 100.0 |
| San Luis Potosí     | Number                  | 0                 | 0       | 0         | 1         | 1         | 2     |
|                     | Percentage within State | 0.0               | 0.0     | 0.0       | 50.0      | 50.0      | 100.0 |
| Sinaloa             | Number                  | 0                 | 0       | 1         | 1         | 2         | 4     |
|                     | Percentage within State | 0.0               | 0.0     | 25.0      | 25.0      | 50.0      | 100.0 |
| Sonora              | Number                  | 0                 | 0       | 1         | 3         | 0         | 4     |
|                     | Percentage within State | 0.0               | 0.0     | 25.0      | 75.0      | 0.0       | 100.0 |
| Total               | Number                  | 1                 | 5       | 5         | 7         | 8         | 26    |
|                     | Percentage of total     | 3.8               | 19.2    | 19.2      | 26.9      | 30.8      | 100.0 |

Source: USDA, Economic Research Service tabulation of interview notes.

## Crops Produced

The companies examined in this study grow a diverse range of horticultural crops. In addition to the four crops that are the study's focus (strawberries, green onions, tomatoes, and cantaloupe), the companies grow cucumbers, chili peppers, asparagus, peas, cauliflower, leeks, table grapes, honeydew melons, watermelons, and raspberries, among others. Each company produces a different portfolio of crops. For instance, one company grows watermelon, table grapes, and cantaloupe, while another grows green onions, cauliflower, and asparagus. These portfolios reflect the experience and know-how of the growers, the agronomic resources at the growers' disposal, and the demands of buyers and consumers. Buyers of Mexican horticultural exports often establish contracts with their suppliers in advance of planting to obtain specified quantities of certain products grown under well-defined conditions, such as adherence to the standards of a specific food safety certification.

Each company in this case study relies on the export market for most of its earnings, with several reporting that they only supply the export market. One firm indicated that the domestic market was a stepping stone in the development of its export operations and described the domestic market as “not attractive” when compared with the export market. Another firm reported that it shunts products of lower quality (for instance, a product that does not meet the color or size standards of foreign buyers) to large metropolitan markets in Mexico, such as Mexico City and Guadalajara.

Based on the responses obtained, it was possible to identify the leading export crop (defined in terms of sales) for all but one of the firms. For nine of the companies studied (34.6 percent of the total), tomatoes were the main export. Strawberries were the main export of five companies (19.2 percent), and cantaloupe was the main export of another five. Green onions were the main export of four companies (15.4 percent), and cucumbers were the main export of two companies (7.7 percent). Three of these products ranked among the top six U.S. fruit and vegetable imports from Mexico in 2020 in terms of value: fresh tomatoes (first), fresh strawberries (fifth), and fresh cucumbers (sixth) (USDA, Foreign Agricultural Service, 2022).

Most of the companies studied (17 of the 26, or 65.4 percent) reported that they only export produce grown using conventional methods, a proportion that is broadly consistent with the available statistics on U.S. imports of organic produce from Mexico. U.S. trade statistics only contain details on organic imports for a subset of crops, and among the crops of interest in this case study (cantaloupe, green onions, strawberries, and tomatoes), this subset only includes strawberries. For the crops where such information is available, organics' share of U.S. fresh produce imports from Mexico ranged from 2.0 percent (raspberries) to 33.5 percent (bananas) in 2021 (table 4). Organics accounted for 3.0 percent of U.S. fresh strawberry imports from Mexico that year.

Table 4

**U.S. imports of selected fresh produce from Mexico and the share that were organic, 2021**

| Crop                         | Total imports from Mexico      | Imports from Mexico identified as organic in U.S. trade statistics | Organics' share of total |
|------------------------------|--------------------------------|--|--------------------------|
|                              | <i>Metric tons (thousands)</i> |  | <i>Percent</i>           |
| Avocados, Hass and Hass-like | 1,085.0                        | 58.0   | 5.3                      |
| Bananas                      | 412.9                          | 138.4  | 33.5                     |
| Blueberries                  | 63.5                           | 10.4   | 16.3                     |
| Blackberries                 | 120.2                          | 5.6  | 4.7                      |
| Bell peppers                 | 566.7                          | 39.3   | 6.9                      |
| Garlic                       | 19.2                           | 0.4  | 2.2                      |
| Lemons                       | 48.6                           | 9.2  | 19.0                     |
| Mangos                       | 337.7                          | 46.2   | 13.7                     |
| Raspberries                  | 108.1                          | 2.2  | 2.0                      |
| Squash                       | 475.9                          | 23.1   | 4.8                      |
| Strawberries                 | 236.3                          | 7.1  | 3.0                      |

Source: USDA, Economic Research Service based on data from the U.S. Department of Commerce, Bureau of the Census, as compiled by USDA, Foreign Agricultural Service (2022).

Organically produced fruit and vegetables often command a premium retail price when compared with conventionally grown produce (Carlson and Jaenicke, 2016). Organic production in Mexico requires specific practices, such as the establishment of a rock perimeter to separate organic from conventional production, the systematic monitoring and testing of soils to ensure that they do not contain prohibited chemicals, and obtaining one of the organic certifications approved by SENASICA.<sup>11</sup> In addition, organic products imported from Mexico to the United States must be certified to the organic regulations of the U.S. Department of Agriculture (USDA) by a USDA-accredited organic certifying agent. While only about 20 such agents are in Mexico, more than 2,500 organic operations in Mexico have been certified by these agents (USDA,

<sup>11</sup> A list of certifications for organic production approved by SENASICA is at SADER, SENASICA (2021b).

Agricultural Marketing Service, 2022).<sup>12</sup> Meeting the entire set of standards required for organic certification can be difficult. For instance, one company reported that it had intended to produce organically grown cantaloupe but ended up marketing its cantaloupe as conventionally grown because the company was uncertain that all the organic standards had been met.

## Research Findings

### Implementation of Food Safety Programs

Efforts by the Mexican horticultural export sector to ensure the safety of its fruit and vegetables did not begin with FSMA. In a survey of vegetable exporters in northwestern Mexico conducted in 2002 (nearly a decade prior to FSMA’s enactment), Avendaño Ruiz et al. (2006) found that 29 percent of the companies had already implemented GAPs and 51 percent were in the process of doing so, while the remaining 20 percent had shown no progress in that direction.

Table 5 shows when the 26 companies in this case study initiated their food safety programs. Two firms started their programs before 1997, the year when then President William J. Clinton announced the National Initiative for Food Safety. This initiative aimed “to upgrade domestic food safety standards and to ensure that fruits and vegetables coming from overseas are as safe as those produced in the United States” (White House, 1997)—objectives like those of FSMA. While the initiative resulted in published guidelines for reducing the risk of microbiological contamination, these guidelines were not mandatory, thereby limiting the initiative’s impact on food safety (Collart, 2016).<sup>13</sup>

Table 5  
**Start of Mexican company’s food safety activities prior to 1997–2019**

| Starting period       | Number of companies | Percentage | Cumulative percentage |
|-----------------------|---------------------|------------|-----------------------|
| Before 1997           | 2                   | 7.7        | 7.7                   |
| Between 1997 and 2005 | 7                   | 26.9       | 34.6                  |
| From 2006 to 2010     | 5                   | 19.2       | 53.8                  |
| From 2011 to 2015     | 5                   | 19.2       | 73.1                  |
| From 2016 to 2019     | 7                   | 26.9       | 100.0                 |
| Total                 | 26                  | 100.0      |                       |

Note: Totals of the percentages do not add to 100 due to rounding.

Source: USDA, Economic Research Service tabulations based on interview notes.

Between 1997 and 2010, several developments in the United States—ranging from concerns that the attacks on September 11, 2001, could be followed by acts of bioterrorism, to new outbreaks of foodborne illness associated with domestically produced spinach (2006), peanut butter (2008–09), pistachios (2009), and cookie dough (2009)—prompted the U.S. Congress to develop legislative proposals that eventually took the form of FSMA. Aware of these developments, horticultural growers in Mexico continued their efforts to implement food safety programs.

<sup>12</sup> Organic products imported from the United States to Mexico must be certified to the organic regulations of Mexico’s Law of Organic Products (LPO—Ley de Productos Orgánicos) or standards recognized as equivalent. At the time of writing, the Mexican Government did not recognize USDA’s organic standards as being equivalent to Mexico’s. Certifiers are accredited by SENASICA (USDA, Agricultural Marketing Service, 2022).

<sup>13</sup> See Binder et al. (1998) for more information about the National Initiative for Food Safety.

As table 5 shows, by 2010, the year immediately before FSMA was signed into law, 14 of the 26 companies in the case study had already launched food safety programs, and the remaining 12 firms did so during FSMA's first 9 years of existence (2011–2019).

The demands of actors throughout the supply chain bolstered the adoption of food safety programs by the Mexican horticultural export sector. When asked to identify the main actor motivating the adoption of a food safety program, 17 of the companies indicated that they did so at the request of the importer, 8 companies reported that they did so under their own initiative, and 1 company said that it did so at the request of the retailer. Thus, the expectation that Mexican growers of horticultural exports should have effective, well-functioning food safety programs was shared by multiple actors in the supply chain. For example, one company's representative described food safety as part of a firm's broader set of social responsibilities for which the private sector and not the government was responsible. As part of the private sector, however, these growers had their ultimate focus on the bottom line of the balance sheet. As one company representative said, "Food safety begins with the responsibility of the producer, but in reality, there has been the interest in not losing customers."

These trends closely resemble those observed among U.S. horticultural firms by Astill et al. (2019). In that study, U.S. horticultural firms reported that commercial buyers were the major drivers for the adoption of food safety practices. Some of the earliest adopters in the U.S. horticultural sector did so during the late 1990s and early 2000s because they were exporting to high-value markets in Europe or Japan or were selling to large foodservice or processing buyers in the United States. In contrast, small and medium U.S. firms that typically sold to nonretail channels were among the least prepared to meet FSMA's new standards. This difference in preparedness across U.S. horticultural firms marketing to different channels highlights the interplay between the food safety standards of government and those of industry—an interplay that also exists among Mexican horticultural firms. Most Mexican exporters that maintained commercial relationships with large U.S.-based foodservice, processing, or retail buyers did so by meeting their buyers' quality standards, including food safety standards, well before those standards were required by U.S. law.

## Certifications

Food safety certifications are an important tool used by Mexican horticultural growers to show that they meet food safety standards, particularly standards set by the Mexican and U.S. Governments. A food safety certification may be defined as "a third-party verification that products, processes, or systems in the food supply chain meet accepted food standards. It is distinct from other systems of proof of conformity such as supplier declarations, laboratory test reports, or inspection body reports. Food safety certification is based on the results of tests, inspections, and audits and gives confidence to the consumer because an organization's products and/or system are being thoroughly evaluated against national and international industry standards by a competent third body" (Global Food Safety Resource, 2021).

The Mexican horticultural export sector's use of food safety certifications predates FSMA. In their study of food safety in the U.S. and Mexican green onion industry, Calvin et al. (2004) found that many growers were already relying on third-party certification programs for GAPs and GMPs well before the 2003 outbreaks of Hepatitis A in the U.S. green onion sector.

Many Mexican growers of horticultural exports use more than one food safety certification. Among the 26 companies in this case study, only 3 firms have a single food safety certification, 10 firms have 2 certifications, and 13 companies have 3 or more. Companies with organic production also certify their practices with respect to organic standards, and some companies count corporate social responsibility among their standards. Indeed, one respondent indicated that a certification in corporate social responsibility was a requirement of several major retailers supplied by the firm, and another company in this study operates a foundation to meet the needs of agricultural workers.



PrimusGFS is the food safety certification most used by the companies studied. Eleven out of the 26 companies (42.3 percent) indicated that their buyers require this certification. PrimusGFS is an audit certification program owned and managed by Azzule Systems that covers both growing operations and producers of fresh-cut products. According to the PrimusGFS website (Azzule Systems, 2021b), audits are tailored to the type of operation and can potentially cover four areas of activity: Food Safety Management Systems, GAPS, GMPs, and HACCP. The program's current version is represented as having "simultaneously incorporated all FSMA requirements, including those of the Produce Safety Rule, Preventive Controls for Human Food, and the Sanitary Transportation Rule." Use of this version is now mandatory for those seeking the PrimusGFS certification (Azzule Systems, 2021a). The relatively wide use of PrimusGFS may reflect its benchmarking with the Global Food Safety Initiative (GFSI), a private sector coalition that "bring[s] together 38 retailers and manufacturers ... and an extended food safety community to oversee food safety standards for businesses and help provide access to safe food for people everywhere" (Global Food Safety Initiative, 2021).

Four of the 26 companies (15.4 percent) use a food safety certification provided by SENASICA. Through its Systems of Contamination Risk Reduction (SRRC—Sistemas de Reducción de Riesgos de Contaminación), SENASICA offers certificates in four areas: Best Agricultural Practices; Proper Use and Handling of Pesticides; Best Field Vegetable Packing Practices; and Best Harvesting Activities Practices. The SRRC's certification process involves a compliance assessment by a registered authorized external specialist (SADER, SENASICA, 2021c).

SENASICA has entered into agreements with two private sector associations in the Mexican agri-food sector, in part to bolster the commercial impact of the SRRC and extend its reach to more buyers and sellers. In December 2020, SENASICA and Mexico's National Agricultural Council (CNA—Consejo Nacional Agropecuario) established an accord to exchange scientific and technical information and form working groups in several areas, including food safety including food safety (SADER, SENASICA, 2020).<sup>14</sup> In May 2021, SENASICA formalized an existing agreement started in September 2020 with the National Association of Self-Service and Department Stores (ANTAD—Asociación Nacional de Tiendas de Autoservicio y Departamentales) (Hernández López, 2021; SADER, SENASICA, 2021d). One aim of this second collaboration is to connect Mexican retailers with SRRC-certified suppliers of selected fresh fruit and vegetables using a digital business platform called Antad.biz. In October 2021, the CNA, SENASICA, and ANTAD conducted a 3-day webinar on the SRRC and these two collaborations (CNA, SADER, SENASICA, and ANTAD, 2021).

Two of the 26 companies (7.7 percent) use GLOBALG.A.P. to satisfy the food safety concerns of their U.S. buyers. Advertised as "Your Ticket to the Global Market," GLOBALG.A.P. is a voluntary certification program that encompasses more than 40 standards and is available for crops, livestock, or aquaculture (GLOBALG.A.P., 2021a). The certification covers several subject areas: food safety and traceability; the environment (including biodiversity); workers' health, safety, and welfare; animal welfare; Integrated Crop Management (ICM); Integrated Pest Control (IPC); Quality Management System (QMS), and HACCP (GLOBALG.A.P., 2021b). In addition, the program offers several "add-on" modules, including one focused on FSMA's Produce Safety Rule that is intended to be accompanied by GLOBALG.A.P.'s Integrated Farm Assurance Standard for Fruit and Vegetables (IFA FV) (GLOBALG.A.P., 2021c). The remaining nine companies (34.6 percent) indicated that they relied on a food safety certification other than PrimusGFS, SENASICA, and GLOBALG.A.P. to access the U.S. market.

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<sup>14</sup> The Consejo Nacional Agropecuario (CNA) plays a similar role in Mexico as the American Farm Bureau Federation does in the United States. The CNA's stated objectives are "to unite in a single front the agricultural producers, producers of inputs and services to the field, and agroindustrial producers; to represent the private agricultural sector of the country before the public, private, and social sectors and defend free enterprise in agriculture; and to promote Mexican agriculture and its producers through the achievement of favorable conditions for organization, investment, transformation, added value, commercialization, and productivity" (USDA, Economic Research Service's translation of information from Consejo Nacional Agropecuario (2021)).

Food safety standards in the certification programs change over time because of the implementation or modification of the rules and regulations governing food safety such as FSMA, the evolving expectations of large food retailers, and scientific advances in understanding how horticultural companies can effectively enhance the safety of their products. Respondents were asked whether they had observed any changes in the certified food safety standards required for the U.S. market. Fifteen indicated that they had noticed such changes (table 6). The main changes detected related to internal control in companies (reported by 4 of the 15 firms), an increase in audits (reported by 2 of the 15 firms), and the necessity to obtain related certifications (reported by 2 of the 15 firms).

Table 6

**Recently observed changes in guides of certified food safety standards required for U.S. market**

|                             | Number of companies | Percentage of subcategory | Percentage of total |
|-----------------------------|---------------------|---------------------------|---------------------|
| <b>Changes observed</b>     | <u>15</u>           | <u>100.0</u>              | <u>57.7</u>         |
| Greater internal control    | 4                   | 26.7                      | 15.4                |
| Increased number of audits  | 2                   | 13.3                      | 7.7                 |
| More related certifications | 2                   | 13.3                      | 7.7                 |
| Other                       | 7                   | 46.7                      | 26.9                |
| <b>No changes observed</b>  | <u>11</u>           |                           | <u>42.3</u>         |
| <b>Total</b>                | <u>26</u>           |                           | <u>100.0</u>        |

Source: USDA, Economic Research Service tabulations based on interview notes.

By 2019, all growers in this case study had at least one food safety certification. By comparison, Astill et al. (2019) found that by 2016, most smaller U.S. horticultural firms and firms selling directly to U.S. consumers had not obtained certification from a third-party audit, unlike most larger firms and those selling to commercial buyers. In the United States, as in Mexico, horticultural firms use GFSI-benchmarked certifications such as PrimusGFS and GLOBALG.A.P. Moreover, like the certification provided to Mexican firms by SENASICA, USDA operates a Harmonized Good Agricultural Practices (GAP) and Harmonized GAP Plus+ auditing program through the USDA, Agricultural Marketing Service (2021). Like some Mexican firms in this study, some U.S. firms saw that certain markets required an increasing number of audits and certifications in the new food safety environment created by FSMA, while others observed only minor changes to food safety practices.

## Changes Made by Companies to Their Food Safety Programs After FSMA's Implementation

To comply with the protocols associated with FSMA, 19 of the 26 companies changed their food safety programs, while 7 companies stated either that it was not necessary to do so or that changes had been planned but not been carried out (table 7). The changes made by the companies to adapt their operations to FSMA mainly related to equipment, infrastructure, and water sampling. Several companies offered more specific descriptions of their investments, including completely enclosing packing sheds, installing walls in coolers that can be easily sanitized, and establishing their own on-site testing laboratories. Note that the number of companies that made changes to their food safety programs (19 in table 7) is greater than the number that observed a recent change in the guides of certified food safety standards required for the U.S. market (15 in table 6). This suggests that some firms made improvements to their food safety programs within the existing frameworks of their certifications.

Table 7

**Main change made by company to comply with FSMA**

| Type of change         | Number of companies | Percent |
|------------------------|---------------------|---------|
| Equipment              | 3                   | 11.5    |
| Infrastructure         | 4                   | 15.4    |
| Water sampling program | 2                   | 7.7     |
| Other                  | 10                  | 38.5    |
| Did not make a change  | 7                   | 26.9    |
| Total                  | 26                  | 100.0   |

FSMA = Food Safety Modernization Act.

Source: USDA, Economic Research Service tabulations based on interview notes.

A company's adaptation to FSMA often required the increased use of clean water. Produce needed to be washed more thoroughly, and surfaces in packing facilities needed to be cleaned more frequently. Water used for these purposes must be discarded into wastewater systems or treated before reuse. For workers, potable water needed to be available for drinking and for washing hands before entering the field, after using bathroom facilities, and after exiting the field, reflecting both the company's social responsibilities to the health and safety of its employees and the production of safe food.

Suitable water also was needed for irrigation, given the dry climates of the production regions in this study. Several respondents described the testing of irrigation water for unacceptable levels of heavy metals, agrichemicals, and microorganisms as a common business practice that predated FSMA. Two respondents indicated that water monitoring was the main area in which they made changes in response to FSMA, such as a modified sampling approach or additional training for staff, as insisted by their certification companies. For all types of testing (e.g., water, soil, surfaces in facilities, and the final product), the emphasis of respondents was generally placed on better sampling frames—the list of items from which the sample is drawn—and larger and more frequent samples. Several respondents indicated that having on their properties one or more deep wells with ample supplies of clean water was key to their companies' success. Maintaining the quality of well water was crucial to these operations and was described as the responsibility of the producer and not the government. Overall, the respondents emphasized that access to sufficient suitable water is necessary for a successful horticultural export operation that complies with established food safety standards. One respondent said, "Access to water is a privilege."

Like the Mexican firms in this study, the U.S. horticultural firms examined in Astill et al. (2019) discussed issues of capital investment and issues related to agricultural water. U.S. growers described the high cost of capital upgrades that improved food safety alongside other operational features, such as completely enclosed packing buildings, modern coolers with interior walls that can be sanitized, and sorting and packing equipment with surfaces that can be sanitized. U.S. growers noted that the owners of some neighboring firms opted to retire rather than invest in upgrades, while other firms had made these investments well before FSMA. In many parts of the United States, as is the case in many parts of Mexico, horticultural crops are unable to grow without irrigation. Water standards were a major focus of U.S. firms after the enactment of FSMA, especially given the uncertainty on the final rules (see appendix A, footnote 17). Many U.S. firms had already tested the agricultural water used in the field before the publication of the final rules, but the challenge of absorbing water testing costs for smaller firms was a concern.

## Main Challenges Presented by FSMA

Twenty-one of the 26 companies identified food safety training—of either the company’s food safety manager or its hired farmworkers—as the main challenge presented by FSMA (table 8). Specifically, 13 companies indicated that training the company’s food safety manager was the main challenge, while 8 companies identified training hired farmworkers as the main challenge. While firms in the Mexican horticultural export sector started to provide food safety training well before FSMA, one respondent recalled that such training was once viewed in the industry as far less important, with sentiments such as, “I don’t have time to train people” and “That’s one of the tasks that my son does—why should I invest in that?” being prevalent. With the arrival of FSMA, food safety training took on greater importance in the sector, given the objective of maintaining access to the U.S. market. One firm reported that after FSMA, it was directed by its food safety certifier to expand its training activities, particularly among farmworkers.

Table 8  
**The main challenge identified by Mexican companies as they worked to comply with FSMA**

| Main challenge                                     | Number of companies | Percentage |
|--|---------------------|------------|
| Training for the head of the company's food safety | 13                  | 50.0       |
| Training of workers                                | 8                   | 30.8       |
| Attention to a greater number of audits            | 1                   | 3.8        |
| Accredited laboratory services                     | 2                   | 7.7        |
| Increases in (financial) costs                     | 1                   | 3.8        |

FSMA = Food Safety Modernization Act.

Note: Total of percentages does not add to 100 due to rounding.

Source: USDA, Economic Research Service tabulations based on interview notes.

Half of the 26 companies indicated that training their food safety managers was the main challenge. An important resource in this task was the Produce Safety Alliance (PSA), a collaborative project established between Cornell University, FDA, and USDA in 2010 with the objective of providing “the produce industry and associated groups with training and educational opportunities related to current best practices and guidance, and future regulatory requirements” (Produce Safety Alliance, 2021a). One of the PSA’s main activities is a training course on FSMA’s Produce Safety Rule. Initially, this training was only provided in English, which limited the participation and attendance of food safety managers from Mexico. Over the past several years, the PSA has improved the effectiveness of its communication strategy to Spanish-language growers and trainers (Produce Safety Alliance, 2021b). Since 2019, the alliance has employed several Spanish-language extension associates, translated its curriculum into Spanish, and created a Spanish-language website. In addition, the PSA translated its curriculum into Portuguese and Chinese (Rodger, 2021).

Some members of management responsible for food safety at the companies studied worked previously for other horticultural firms in junior positions, while others were the sons or daughters of the owner-operator. During the interviews, it was observed that most of the food safety supervisors were relatively young and at early points in their careers, although the ages of the respondents were not recorded as part of the interviews. The relative youth of this next generation of food safety managers raises the question whether these individuals are fully aware of the opportunities to broaden their knowledge of food safety practices, including activities supported by the Mexican Government at the Federal and State levels. In addition, several of the larger operations had food safety teams whose members had additional management responsibilities. The interviews did not explore the implications of such multiple assignments, which could indicate that the food safety

activities of a Mexican grower focused on the export market do not normally require the complete work time of an upper-level manager or that such companies have a possible vulnerability if the manager responsible for food safety is unable to devote sufficient attention to that aspect of the company's activities.

Eight of the 26 companies viewed providing food safety training to farmworkers as the main challenge. Such training is critical to assuring that the farmworkers do not inadvertently contaminate the crops and thus is crucial to the company's livelihood. As one company's representative said, "One bad practice at the level of the producer could be the result of one bad practice of a single worker."

Several attributes of hired farm labor in Mexico complicate the task of training farmworkers. First, turnover is relatively high. One firm indicated that its average farmworker is employed for a year and a half, and many workers are employed only seasonally. Second, the size of the company's workforce is large relative to the size of the management team responsible for food safety. In the companies studied, the number of seasonal farmworkers ranged from fewer than 100 to as many as 5,000 at one of the larger companies with multiple production sites. Third, the workforce's command of Spanish varies greatly from one worker to another, with some workers speaking one of Mexico's indigenous languages as their first language. For this reason, one company reported that it keeps interpreters on hand during food safety training sessions in case farmworkers require that the materials be provided in a language other than Spanish.<sup>15</sup> Many farmworkers in Mexico have not obtained more than a middle school education, which may also complicate training. Analysis of Mexico's 2015 Intercensal Survey reveals that the average educational level of a Mexican farmworker, aged 15 or more, was 6.2 years at the time of the survey (Valdivia Correa and Sánchez Peña, 2017).

The issue of training food safety supervisors and agricultural workers is the most significant distinction between the concerns expressed by Mexican horticultural growers in this study and the concerns expressed by U.S. horticultural growers in Astill et al. (2019). A key finding in the latter study is that the firms most confident in their ability to meet industry and legal food safety standards had strong communication channels with peer firms, buyers, regional commodity organizations, agricultural extension, and State departments of agriculture. As a result, the members of management responsible for food safety at U.S. firms had a high level of knowledge about food safety standards and likely had a head start over many of their Mexican counterparts in receiving and disseminating information on best practices in food safety, especially as they related to FSMA. However, U.S. firms also identified a need for Spanish-language training materials for their agricultural workers.

Two of the 26 companies reported that working with an accredited laboratory service was the main challenge. One respondent described how their company elected to hire an outside consultant to design a strategy for testing and trend analysis following an outbreak of Salmonella. Another company commented that accredited laboratories were not located nearby and expressed concern that the FDA might view tests performed by a Mexican laboratory as being less reliable.

For many companies in this study, however, the use of laboratory services seemed routine, with testing of irrigation water, soil, surfaces of contact in facilities, and the final product occurring in many instances on a daily, weekly, biweekly, or monthly basis. Several respondents underscored that their companies' use of laboratory tests predated FSMA, was not done to satisfy some requirement of FSMA, and reflected their general commitment to food safety instead. The project's fieldwork included a visit to a grower-supported testing laboratory that was a legacy of past cooperative efforts within the Mexican horticultural export sector. While this older laboratory was still in operation, the head of the laboratory indicated that it had been eclipsed

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<sup>15</sup> At least 68 indigenous languages are still spoken in Mexico, including Náhuatl, Mayan, Tsotsil, Mixtec, Tsotsil, Zapotec, Otomoi, Totonac, Choi, and Mazatecan (Notimex, 2019). According to Mexico's 2020 decennial census, about 7.5 million Mexicans, age 3 or older, speak one or more indigenous languages, and of this group, 866,000 people do not speak Spanish (Instituto Nacional de Estadística y Geografía, 2021a).



by private sector laboratories that are better positioned to provide a much larger battery of tests. Moreover, several respondents indicated that their companies conduct some testing using their own laboratories, a practice that was reported to be common in the Mexican horticultural export sector.

One respondent described how his company worked with multiple laboratories, including some associated with a particular certification program, and was well acquainted with the prices of specific tests at different laboratories. Overall, he expressed confidence in the tests and sampling strategies of these laboratories, noting that they offered the possibility of “sleeping without problems,” and described the additional cost of laboratory tests (roughly several pennies per box of produce) as “one of the best investments that we could make.”

## Complying with FSMA: Mexico Versus the United States

An important facet of FSMA is that it applies to both domestic and foreign growers who supply produce to the U.S. market. Some participants in the Mexican horticultural export sector welcomed this aspect of FSMA. For instance, one respondent indicated that in 1994, when NAFTA was implemented and began to phase out tariff and quota restrictions on U.S.-Mexico agricultural trade, there were doubts within the U.S. and Mexican horticultural sectors about who was committed to food safety and who was not:

“With respect to food safety, producers would always say that they didn’t know. Perhaps they didn’t want to comply with the requirements. And if the Americans didn’t want to comply, why should we? ... With FSMA, there is a better attitude. How good it is that FSMA appears to apply to everyone. For the producers, it gives us the opportunity to increase compliance to 100 percent—large company or small. FSMA is the possibility that the consumer is guaranteed food safety. One plan, one set of rules.”

Still, some members of the Mexican horticultural export sector continue to be concerned that FSMA might be applied less stringently to U.S. growers than to Mexican growers. When asked if the programs for complying with FSMA differed between Mexico and the United States, 8 of the 26 companies in the case study answered affirmatively, while 18 gave a negative response. This question of equivalence in the application of the law within and outside the United States is highlighted by the structure of FSMA’s rules and by the verification processes established in each rule.

For example, the FDA conducts periodic inspections of a subset of domestic and foreign registered food facilities to verify compliance with the Preventive Controls for Human Foods Rule, prioritizing inspections based on risk. Additionally, under the Foreign Supplier Verification Program, all importers of record are legally responsible for verifying that imported food was grown, manufactured, and transported in accordance with FSMA. In the case of foreign farms growing fresh produce to be exported to the United States, the FDA conducts periodic inspections, but the importer of record is legally responsible for verifying that this produce meets the standards in the Produce Safety Rule. In contrast, to verify that farms in the United States grow fresh produce in accordance with these standards, most State departments of agriculture have entered into agreements with the FDA to conduct routine inspections. For States without agreements, routine on-farm inspections are conducted by the FDA. The FDA may also conduct unannounced inspections on U.S. farms based on risk. Given the multitude of independent importers of record, dozens of State departments of agriculture, and the FDA itself performing verification activities, for a minority of the Mexican horticultural growers in our sample, the question remains of how consistently the standards are applied to the firms supplying fresh produce to U.S. consumers.

## The Effect of Company Size on the Response to FSMA

When FSMA was being developed by the U.S. Congress, a commonly expressed concern by supporters of exemptions for small farms was that the act would be “too expensive, too burdensome, and unnecessary for small producers” (Damewood, 2013). To address this, most rules in FSMA contain staggered compliance dates and qualified exemptions for firms selling below certain thresholds or firms also predominantly selling directly to consumers. Most Mexican horticultural exporting firms, however, are unlikely to qualify for these provisions, such as the qualified exemption provision in the Produce Safety Rule for firms with less than \$500,000 in total sales and more than half of their food sales being sold directly to consumers, restaurants, or retail food establishments within 275 miles of the farm. Among the firms that do not qualify for these provisions, concerns persist about the differential effects of FSMA across firms of different sizes (Bovay and Sumner, 2018).

To contemplate the possible relationship between a company’s size and its response to FSMA, the companies in this case study were assigned to size categories based on the number of seasonal farmworkers employed by the firm:

- Very small (100 seasonal workers or fewer);
- Small (101–300 seasonal workers);
- Medium (301–500 seasonal workers);
- Large (501–1,000 seasonal workers); and
- Very large (1,001 seasonal workers or more).

These categorizations of a small company and very small company differ from FSMA’s definitions of a “small business” and a “very small business.” For instance, in FSMA’s Preventive Controls for Human Food Rule, a “small business” is defined as “a business, including any affiliates and subsidiaries, employing fewer than 500 full-time equivalent employees,” while a “very small business” is defined as “a business (including any subsidiaries or affiliates) that averages less than \$1,000,000 (adjusted for inflation) in sales of human food plus the market value of human food that is manufactured, processed, packed, or held without sale (for example, held for a fee), per year during the previous 3-year period” (U.S. Food and Drug Administration, 2022e). For 2019–21, the baseline value for the cutoff was \$1,169,816 (U.S. Food and Drug Administration, 2022b). Because the authors did not collect information on the number of employees in full-time equivalents and the value of total food sales during the discussions, it is not possible to determine how many companies in the case study are small or very small businesses using FSMA’s definitions.

Nineteen of the 26 firms changed their food safety programs in response to FSMA (table 9). Medium-to-large firms (using the case study’s categories) tended to be the ones that made such changes. By size category, 8 out of 10 of the medium-sized companies and 4 out of 5 of the large companies modified their food safety programs, compared with only 6 out of 9 of the small or very small companies and 1 out of 2 of the very large companies.

Table 9

**Changes made to company's food safety program by company size**

|  |     |            | Very small<br>(fewer than<br>101 seasonal<br>workers) | Small (101<br>to 300<br>seasonal<br>workers) | Medium<br>(301 to 500<br>seasonal<br>workers) | Large (501<br>to 1,000<br>seasonal<br>workers) | Very large<br>(more than<br>1,000 seasonal<br>workers) | Total |
|--|-----|------------|---|--|---|--|--|-------|
| Did the company<br>make changes<br>to its food safety<br>program to com-<br>ply with FSMA? | Yes | Number     | 2   | 4  | 8   | 4  | 1  | 19    |
|  |     | Percentage | 10.5  | 21.1   | 42.1  | 21.1   | 5.3  | 100   |
|  | No  | Number     | 1   | 2  | 2   | 1  | 1  | 7     |
|  |     | Percentage | 14.3  | 28.6   | 28.6  | 14.3   | 14.3   | 100   |
| Total  |     | Number     | 3   | 6  | 10  | 5  | 2  | 26    |
|  |     | Percentage | 11.5  | 23.1   | 38.5  | 19.2   | 7.7  | 100   |

FSMA = Food Safety Modernization Act.

Note: Totals of percentages may not add to 100 due to rounding.

Source: USDA, Economic Research Service tabulations based on interview notes.

The vast majority of firms (23 of the 26) had at least 2 food safety certifications, and medium and large companies tended to have 3 or more. Among the 15 companies in either the medium or large categories, 9 indicated having 3 or more certifications, 4 had 2, and 2 companies had just 1 certification (table 10). These size relationships in Mexican firms are somewhat like the U.S. firms studied by Astill et al. (2019). In that case study, larger U.S. firms had more experience meeting food safety standards, were more ready to meet FSMA requirements, and had more audits compared with smaller U.S. firms.

Table 10

**Number of food safety certifications by company size**

| Number of certifications |            | Very small<br>(fewer than<br>101 seasonal<br>workers) | Small (101 to<br>300 seasonal<br>workers) | Medium (301 to<br>500 seasonal<br>workers) | Large (501 to<br>1,000 seasonal<br>workers) | Very large<br>(more than<br>1,000 seasonal<br>workers) | Total |       |
|--------------------------|------------|---|---|--|---|--|-------|-------|
| Only one                 | Number     | 1   | 0   | 1  | 1   | 0  | 3     |       |
|                          | Percentage | 33.3  | 0.0                                       | 33.3                                       | 33.3  | 0.0  | 100.0 |       |
| Two                      | Number     | 2   | 3   | 3  | 1   | 1  | 10    |       |
|                          | Percentage | 20.0  | 30.0                                      | 30.0                                       | 10.0  | 10.0   | 100.0 |       |
| Three or more            | Number     | 0   | 3   | 6  | 3   | 1  | 13    |       |
|                          | Percentage | 0.0   | 23.1                                      | 46.2                                       | 23.1  | 7.7  | 100.0 |       |
| Total                    |            | Number  | 3   | 6  | 10  | 5  | 2     | 26    |
|                          |            | Percentage  | 11.5                                      | 23.1                                       | 38.5  | 19.2   | 7.7   | 100.0 |

Note: Totals of percentages may not add to 100 due to rounding.

Source: USDA, Economic Research Service tabulations based on interview notes.

## Policy Implications

This case study offers several policy implications. First, the Mexican horticultural export sector's experience with FSMA demonstrates that it is possible for horticultural suppliers outside the United States to comply with U.S. legislation in food safety. At the micro level, no respondents in this study reported that FSMA or its accompanying rules disrupted their companies' sales to the United States. Instead, the respondents generally related how their firms adapted to FSMA and its new imperatives for food safety, thereby maintaining—and perhaps

even expanding—their presence in the U.S. market. At the macro level, there have been few, if any, major interruptions in Mexican horticultural exports to the United States since FSMA’s implementation in 2011, even with the onset of the Coronavirus (COVID-19) pandemic in North America. Indeed, these exports more than doubled in volume between 2010 and 2021, although the pace at which these exports grew slowed during the 11 years after FSMA’s implementation. Between 2010 and 2021, the volume of Mexican horticultural exports to the United States grew at a compound annual growth rate (CAGR) of 5.7 percent, compared with 7.0 percent during 2000–10, the decade just prior to FSMA’s enactment (rates calculated using data presented in figure 1). This slowing in export growth is not surprising, however, given that the period 2000–10 overlaps with NAFTA’s 14-year transition (1994–2008) when tariffs and quotas governing intraregional trade in agricultural and nonagricultural products were gradually eliminated (Zahniser et al., 2015).

Second, the case study provides some idea of the characteristics that may have helped companies in the Mexican horticultural export sector to adapt better to FSMA, even though the authors were unable to conduct a statistically significant analysis of this topic. Medium-to-large companies, companies with well-trained food safety management and workers, and companies with multiple food safety certifications were among those that stood out in this study as possibly being more able to adapt. Interestingly, roughly a fourth of the companies studied indicated that it was not necessary to change their operations in response to FSMA—a sign of the existing experience of the Mexican horticultural sector with food safety. These companies tended to fall in the category of very large firms.

Third, the case study illuminates the important role played in the regulation and promotion of food safety under FSMA by food safety certification programs and the large retailers and distributors that purchase imported food. Since these private sector entities are not governmental bodies, they are not regulatory authorities in the traditional sense of the word, but they carry out similar activities that can be seen as advancing the public interest in food safety. Certification programs provide guidance to meet standards and are not subject to direct supervision from the U.S. or Mexican Governments.

The reliance on certifications reveals the contours of current governmental approaches to food safety in the United States and Mexico. The costs of these certifications are paid directly by horticultural growers and then shifted partially to other actors in the food supply chain through market transactions, with some of the costs ultimately borne by consumers. It is unlikely government regulators in either country would be able to perform a large portion of the audits, inspections, and tests now performed by certification companies or in conjunction with certifications in the absence of much greater budgetary allocations.

This reliance on certifications poses a long-standing question: Who certifies the certifier? In some instances, the answer to this question is “another certifier.” Through its Accredited Third-Party Certification Program, the FDA provides a formal structure by which the certification bodies that audit and certify foreign food entities can be accredited by accreditation bodies recognized by the FDA. While this program is voluntary, certifications can establish the eligibility of a foreign food entity to participate in the Voluntary Qualified Importer Program (VQIP), with benefits including the expedited entry and review of all foods specified in an approved VQIP application (U.S. Food and Drug Administration, 2022g). In addition, under “rare and specific circumstances,” the FDA can require that an imported product comes from a certified entity in order “to prevent a potentially harmful food from entering the U.S.” (U.S. Food and Drug Administration, 2022a). In addition, nongovernmental bodies have offered their evaluation of food safety certifications, such as with fair trade certifications (Brown, 2016).

In the arena of environmental marketing, Heh (2015) outlined several approaches grounded in a legal evaluation of certification marks: creation of a national certification standard, raising the standards for registering a certification mark, institution of a Federally protected certification symbol, and giving citizens and competitors greater standing to contest existing certification marks. Environmental marketing specifies environmental conditions of production that the consumer desires but may not affect the quality of the final product, rather than the possibility that the product is unsafe to consume. In this case study, Mexican horticultural growers, as consumers of certifications, were observed to have their own opinions about the relative strengths and weaknesses of different certification programs. Importers and food retailers are likely to have their own opinions as well and often require the use of specific certifiers to provide the desired level of food safety certification. These assessments may translate into market pressures on the companies supplying those programs, which may then respond as they attempt to maintain and expand their base of customers. Contractual specifications often require specific certifiers to provide the level of food safety required by purchasers. Importers and end purchasers likely have their own food safety specifications.

## Conclusions

This case study offers insights into the Mexican horticultural export sector's response to the new requirements of the Food Safety Modernization Act (FSMA). The act directly affected the interests of Mexico's horticultural export sector due to its heavy reliance on the U.S. market as a destination for its product. Judging solely by the sector's trade performance, FSMA did not appear to have a major negative effect on the Mexican horticultural sector. In fact, Mexican horticultural exports to the United States have doubled in volume since FSMA's implementation in 2011. This outcome suggests that the implementation of FSMA and the subsequent response of the Mexican horticultural export sector to comply with FSMA and its accompanying rules helped secure, rather than jeopardize, Mexican access to the U.S. market for horticultural products.

The Mexican horticultural export sector modified its operations in response to FSMA's new requirements for food safety. Companies made changes to equipment, invested in new infrastructure, and implemented new testing programs featuring more sophisticated sampling techniques. Often, the increased commitment to food safety was a water-intensive activity—with ample supplies of clean water being indispensable for many steps during production. Challenges encountered by the Mexican horticultural export sector included food safety training for management and workers and working with accredited testing laboratories.

The medium-to-large companies in the case study (as measured by the number of seasonal workers employed) were more likely to have made changes to their operations in response to FSMA and possessed a larger number of food safety certifications. These findings generally resemble those of Astill et al. (2018), who concluded that larger U.S. growers were more likely than smaller growers to have adopted food safety practices that would comply with FSMA's Produce Safety Rule. The most significant distinction between Mexican and U.S. firms is the challenge faced by Mexican firms to meet the training needs of their food safety supervisors and seasonal farmworkers. This difference may be due to the lag in the translation of training materials into Spanish, and the likely head start that U.S. professional networks had in receiving and disseminating the information contained in FSMA training materials.

Finally, food safety in the Mexican horticultural export sector did not begin with FSMA. More than half the companies in this case study reported that their food safety programs predated FSMA's enactment in 2011. This long history with food safety may explain why about one-quarter of the companies studied stated that they did not make any changes to their food safety programs in response to FSMA. Overall, the activities of Mexican growers in food safety—before and after FSMA—appear to be one of several factors explaining the tremendous growth in Mexican horticultural exports to the United States seen so far during the 21st century.



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## Appendix A

### Seven Rules Under the Food Safety Modernization Act

#### *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Safety Rule)*

This final rule took effect on January 26, 2016. The rule included staggered compliance dates beginning on January 26, 2017, for the largest farms regarding “Subpart M – Sprouts” and, for most other requirements, beginning on January 26, 2018, for the largest farms; January 28, 2019, for small farms; and January 27, 2020, for very small farms.<sup>16</sup> The rule established scientific standards for the cultivation, harvesting, packaging, and handling of fresh fruit and vegetables. Requirements cover water quality, the health and hygiene of workers, domesticated and wild animals, compost and manure of animal origin, requirements for sprouts, and cleaning and sanitizing machinery and equipment, tools, and facilities. The rule does not affect foods that are generally not consumed raw, such as certain types of beans, beets, nuts, coffee, sweet corn, dates, figs, potatoes, and asparagus (U.S. Food and Drug Administration, 2015e, 2021a). Among the crops grown by the companies in this case study, the only crop that is generally not consumed raw is asparagus.

#### *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (Preventive Controls for Human Food)*

This final rule took effect on November 15, 2015, with staggered compliance dates beginning on September 19, 2016, for larger businesses; September 18, 2017, for small businesses; and September 17, 2018, for qualified facilities, including very small businesses.<sup>17</sup> The rule covers processed food products that do not fall under the Produce Safety Rule. The rule requires a written food safety plan based on hazard analysis and critical control points (HACCP), and it includes the development of risk-based preventive controls, supervision, monitoring, corrective actions, and verification—thereby launching a review of current good manufacturing practices (GMPs) (U.S. Food and Drug Administration, 2015c, 2020e).

#### *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals (Preventive Controls for Animal Food)*

This final rule established a similar framework as the Preventive Controls for Human Food but for animal feed rather than food for human consumption. The rule took effect on November 16, 2015, with staggered compliance dates beginning September 19, 2016, for larger businesses; September 18, 2017, for small busi-

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<sup>16</sup> Compliance dates for Subpart E - Agricultural Water were originally set to be 2 years beyond the compliance dates for other provisions (U.S. Food and Drug Administration, 2015f) and were extended 2 years in 2017 (U.S. Food and Drug Administration, 2017) to January 26, 2022, for the largest farms; January 26, 2023, for small farms; and January 26, 2024, for very small farms. After additional stakeholder feedback, the FDA published a proposed rule on December 2, 2021, to revise Subpart E for preharvest agricultural water (U.S. Food and Drug Administration, 2021c) and stated its intention to exercise enforcement discretion of agricultural water requirements for the largest farms after January 26, 2022. On July 18, 2022, the FDA issued proposed revisions to compliance dates, dividing agricultural water requirements into two portions: the unchanged harvest and postharvest requirements and the proposed preharvest requirements. For harvest and postharvest water requirements, compliance dates were as follows: January 26, 2023, for the largest farms; January 26, 2024, for small farms; and January 26, 2025, for very small farms. Compliance dates for preharvest agricultural water were yet to be determined at the time of writing but will be set to be 9 months after the effective date of the final revised agricultural water requirements for the largest farms, 1 year and 9 months after for small farms, and 2 years and 9 months after for very small farms (U.S. Food and Drug Administration, 2022f).

<sup>17</sup> One part of this rule was amended, taking effect on September 17, 2018, and the effective date of a particular paragraph has not yet been announced. For details, see U.S. Food and Drug Administration (2015c).

nesses; and September 17, 2018, for qualified facilities, including very small businesses (U.S. Food and Drug Administration, 2015b, 2020d).

### *Foreign Supplier Verification Programs for Importers of Food for Humans and Animals*

This final rule took effect on January 26, 2016, with staggered compliance dates beginning on May 30, 2017 (U.S. Food and Drug Administration, 2018a). The rule addresses the safety of imports and is related to the obligation of importers to verify that food imported into the United States was produced in accordance with the safety standards that apply to food produced in the United States (U.S. Food and Drug Administration, 2015d, 2021b, 2023).

### *Accredited Third-Party Certification*

This final rule took effect on January 26, 2016. It established a comprehensive oversight program based on external audits and the issuance of compliance certificates to foreign food facilities to assist in FDA's decision-making regarding the admissibility of imported food for human consumption or imported animal feed (U.S. Food and Drug Administration, 2015a, 2020b, 2023).

### *Mitigation Strategies to Protect Food Against Intentional Adulteration*

This final rule took effect on July 26, 2016, with staggered compliance dates beginning on July 26, 2019, for larger businesses; July 27, 2020, for small businesses; and July 26, 2021, for very small businesses (U.S. Food and Drug Administration, 2019a). The rule aims to prevent the intentional adulteration of food via actions aimed to cause large-scale harm to public health, including acts of terrorism. It is directed at larger food companies (more than \$10 million in total sales) with activities vulnerable to the intentional adulteration of food. Such companies are required to have a written food defense plan and to develop and implement mitigation-focused strategies to address vulnerabilities to the deliberate contamination of the food supply (U.S. Food and Drug Administration, 2016a, 2020c).

### *Sanitary Transportation of Human and Animal Food*

This final rule established requirements and resources regarding motor and rail vehicles and transportation equipment to protect food during transportation (e.g., temperature control, bulk food, packaged food), as well as the parties responsible for transport operations. It also covers training and technical assistance from the FDA and the management of records to demonstrate compliance with the rule. The final rule took effect on June 6, 2016, with staggered compliance dates beginning on April 6, 2017, for larger businesses and June 6, 2018, for small and very small businesses (U.S. Food and Drug Administration, 2016b, 2018b).

## Appendix B

### Spanish-to-English Translation of Interview Questions

1. In what year did your firm start its food safety programs?
2. How many food safety certifications does your company have and with whom are they?
3. Select the reason that led you to implement food safety programs:
  - a. Own initiative
  - b. Request of the importing company
  - c. Request of the retailer
  - d. Because one of the company's products was related to an outbreak of foodborne illness
  - e. Other
4. What fruits and/or vegetables do you produce?
5. In which of the products mentioned have food safety programs been implemented?
6. Indicate if the same food safety program is used in the products mentioned and why.
7. Did FSMA compliance lead you to make changes to what you used to implement?
8. Are you aware of differences between Mexican companies and their affiliates in the United States in the actions they carried out for FSMA?
9. What food safety standards does the North American market require?
10. What recent changes have you noticed in these standards?
11. How has the industry reacted to previous outbreaks of foodborne illness?
12. Regarding your company, which of the following actions have been challenging to comply with FSMA?
  - a. Training the person in charge of the company's food safety programs
  - b. Training workers for compliance with food safety programs
  - c. Greater number of audits
  - d. Accredited laboratory services
  - e. Increase in the sampling program
  - f. Financial actions regarding costs
  - g. Other



13. When it comes to FSMA compliance, does company size matter? If so, why?
14. Are the FSMA rules and programs issued by FDA clear and specific in detail, facilitating their implementation?
15. Regarding the implementation of food safety programs:
  - a. Did you notice changes in compliance between products?
  - b. Did you notice differences depending on location or environmental conditions?
16. Where is food safety compliance more affordable?
  - a. Mexico
  - b. United States
  - c. Equal
17. In what areas or aspects?
18. Regarding FSMA, do you think that some companies could leave the market? If so, why?
19. Regarding FSMA, do you think that some companies will have to change products or markets? If so, why?
20. Regarding FSMA, do you consider that some companies will lose competitiveness compared to other regions? If so, why?
21. Has your company received any specific requirements from its importer in the United States? If so, which ones?
22. Please indicate the characteristics of your company in terms of its staff (numbers and distribution):

Temporary workers (maximum number in season):

Administrative workers:
23. Generally speaking, how do you see the impact and challenges of complying with FSMA regulations across products, company sizes, regions, etc.?