



On-Farm Produce Safety Practices Assessment in Texas

ABSTRACT

This study aimed to evaluate data from on-farm assessments to identify patterns and challenges that resulted in noncompliance to the Produce Safety Rule (PSR). Sixty-nine large farms were assessed by field specialists from the Texas Department of Agriculture Office of Produce Safety by using PSR to determine non-compliance issues over a 16-month period. Large farms are defined as farms that have exceeded \$500,000 in average annual produce sales over the course of a 3-year period adjusted for inflation. The results showed a total of 164 non-compliance issues related to Subpart O-Record Keeping (78/164), Subpart L-Equipment, Tools and Buildings (37/164), and Subpart C-Personnel Qualifications and Training (26/164). The assessments of Subpart O demonstrated that growers or grower contractors may perform the activities without documenting records. Examples for Subpart L include growers not cleaning and sanitizing equipment for transporting produce, and some farms did not handle handwashing wastewater effectively. Study results

identified the need for training, education, or development of additional resources to specifically address underlying challenges related to non-compliance. This study is novel because the data analyzed demonstrate baseline compliance for large farms in the state of Texas.

INTRODUCTION

The Food Safety Modernization Act (FSMA) is a federal mandate that has shifted the focus from responding to foodborne illness to preventing it (30). The mandate has established seven final rules that include the preventative controls rules for human and animal food; foreign supplier verification program rule; accredited third-party certification; sanitary transportation rule; intentional adulteration rule; compliance with FSMA; and Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption regulation, commonly known as the Produce Safety Rule (PSR) (22). The Produce Safety Rule (PSR) establishes science-based minimum standards for the safe growing, harvesting, packing, and holding of vegetables for human consumption as part of FSMA (31). The goal of the

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U.S. Food and Drug Administration (FDA) is to collaborate with state partners across the country to minimize the risk of foodborne illness associated with the consumption of covered produce (34). Farms covered by the PSR will follow specific regulations for production practices in 12 component areas that then were generalized into 5 aspects: agricultural water quality, soil amendments of animal origin, worker health and hygiene, animal intrusion, and sanitary standards (7).

The Centers for Disease Control and Prevention estimate that each year 48 million people get sick, 128,000 are hospitalized, and 3,000 die from foodborne diseases in the United States (8). It is estimated that fresh produce commodities accounted for nearly half of all domestically acquired foodborne illnesses (46%) and were the second highest cause of death related to foodborne illnesses (23%) in the United States between 1998 and 2008 (20). Since then, foodborne illness outbreaks have been associated with fresh produce commodities such as leafy greens, peaches, onions, bagged salad mix, mushrooms, clover sprouts, pre-cut fruits, and whole fruits, to list a few, in just the past 3 years (9). Between 2015 and 2020, the state of Texas experienced 711 outbreaks, >15,000 illnesses, and 17 deaths associated with fresh produce (10); however, no documented outbreaks in this state have been traced back directly to a farm in Texas.

Food safety interventions such as large-scale trainings, educational extension courses, and suitable policymaking specifically supporting farmers will be crucial in Good Agricultural Practices (GAP)-related activities and FSMA compliance (23). GAP is casted by a guide that was released in 1998 by the FDA to reduce microbial hazards in the growing, harvesting, packing, and storing of fresh fruits and vegetables; instead of eliminating risks, it is focused on reducing risks that may occur during the growing process, including soil amendments, worker health and hygiene, animal intrusion, and post-harvest cleaning and sanitation practices (13). Produce growers, extension personnel, university researchers, and local and federal governments have been working in tandem for years to disseminate relevant information and educational materials to growers throughout the United States to increase compliance with GAP and now with PSR (27). Among them are programs such as the Produce Safety Alliance (PSA) that was established to provide food safety training for fresh produce growers to meet the regulatory requirements under FSMA through a collaboration between Cornell University, the U.S. Department of Agriculture, and the FDA (6, 13). As part of the national effort, during on-farm inspections, the aim is to “educate before and while we regulate” by identifying opportunities to educate farmers about the PSR, the supporting science, and the regulatory process before, during, and after assessments (32).

Before initial assessments, the growers were provided educational materials designed by the state department

of agriculture in conjunction with the FDA. Following this, state programs designed tools specific to each state focusing on state-specific challenges to include on-farm outreach programs. The rule only establishes the minimum requirements that are to be met and does not specify how the expectations are to be met. This provides for flexibility for covered farms regardless of type, size, geographical region, and commodities to meet these requirements with the resources available to them. Previous studies have sought to identify challenges that farming operations may encounter while working to become compliant with FSMA and the PSR; however, there is a paucity of literature regarding state-specific challenges with on-farm compliance under various subparts listed throughout the PSR. Adalja and Lichtenburg (1) conducted a national survey to determine the use of food safety practices among produce growers in the United States, but they highlight the need to focus on specific types of farming operations in limited geographic areas to fully grasp the issues that growers face in compliance with the PSR. Hence, the overarching goal of the current study was to determine areas where there were non-compliance issues with the PSR associated with large farms in the state of Texas. Specifically, the objectives of this study were to (1) analyze on-farm assessments of food safety practices, activities, and conditions specific to the PSR to identify non-compliance issues among large farm produce growers in the state of Texas; (2) identify patterns and underlying issues that may have resulted in non-compliance issues to the rule; and (3) determine the opportunity or need for training, education, or the development of additional resources to specifically address patterns and/or underlying issues of non-compliance.

MATERIALS AND METHODS

In total, 69 large farms in the state of Texas were assessed by field specialists from the Texas Department of Agriculture (TDA) over a 16-month period. Large farms are defined as farms that have exceeded \$500,000 in average annual produce sales over the course of a 3-year period adjusted for inflation (29). The on-farm assessments began in October 2019 and continued until February 2021. No assessments were conducted for 4 months between March 2020 and June 2020 because of the COVID-19 pandemic. All assessment activities resumed in July 2020. Commodities produced by these large farms included leafy greens, citrus, summer squash, watermelons, cantaloupe, mushrooms, and tomatoes. TDA field specialists conducted the on-farm assessments by using 21 CFR Part 112 to determine non-compliance issues by observations and then reported the data. The farm assessments were conducted by reviewing the farm inventory and identifying large farms that grew covered produce. The farms were contacted, and a date and time were scheduled for the field specialists to conduct assessments. During the assessments, the field specialists reviewed farm activity first

TABLE 1. Non-compliance issues observed during assessment of Texas large farms (N = 69)

Subpart variable	n	%
Subpart C-Personnel Qualifications and Training	26	16
Subpart D-Health and Hygiene	10	6
Subpart K-Growing, Harvesting, Packing, and Holding Activities	13	8
Subpart L-Equipment, Tools, Buildings, and Sanitation	37	22.5
Subpart O-Records	78	47.5
Total	164	100

to identify areas of compliance and non-compliance with the PSR in the areas of growing, harvesting, packing, and handling of covered produce to ensure that the minimum requirements of the PSR are being met by the farm. Activities were observed whether they were performed by the grower themselves or by grower hired third-party contractor. If non-compliance issues was observed during the assessment, it was recorded and the specialists worked with the growers to help them understand the non-compliance issues and areas of opportunity for compliance with the PSR. In Texas, the TDA documents and compiles all non-compliance issues as observations and in accordance with Texas Administrative Code 11.41, which requires growers to address the issues and propose corrective action plan to prevent reoccurrence (25). As part of these assessments, records required by the PSR were reviewed to ensure that records were maintained in compliance with the rule. The data of all non-compliance issues were tabulated using Excel (Microsoft, Redmond, WA) by subparts. All quantitative data were provided to the investigators anonymously. Qualitative or anecdotal data from each farm were documented without identifying farm information (anonymous). The qualitative data contain specific examples of non-compliance issues or activities with the PSR and were also tabulated and recorded as part of this study.

RESULTS AND DISCUSSION

In total, 164 non-compliance issues were identified among the 69 large farms that were assessed in this study. *Table 1* presents the non-compliance issues observed under Subpart C (Personnel Qualifications and Training), Subpart D (Health and Hygiene), Subpart K (Growing, Harvesting, Packing, and Holding Activities), Subpart L (Equipment, Tools, Buildings, and Sanitation), and Subpart O (Records). The non-compliance issues categorized into sections of the subparts is presented in *Table 2*. Among the reported non-compliance issues, Subpart O-Records had the highest number of non-compliance issues ($n = 78$), followed by Subpart L-Equipment, Tools, Buildings, and Sanitation ($n = 37$), Subpart C-Personnel Qualifications and Training

($n = 26$), Subpart D-Health and Hygiene ($n = 10$), and Subpart K-Growing, Harvesting, Packing, and Holding Activities ($n = 13$), respectively. *Table 3* shows the qualitative data and specific non-compliance challenges observed during on-farm assessments by sections of the subparts.

Evaluating on-farm produce safety practices

Although the focus of the FSMA is to take a proactive approach toward potential food safety issues, some studies have highlighted the challenges many produce growers have encountered as they face the need to become compliant with the federal mandate. Jayawardhana et al. (16) performed a systematic literature review to determine the relationship between environmental characteristics (such as the availability of physical resources such as handwashing materials) and risk management practices on produce farms. Although there was only one study that tested this relationship, specifically between the availability of handwashing materials and an increased frequency of handwashing by workers (21), the analysis of research in the literature review found that agricultural water use, the use of untreated biological soil amendments of animal origin, cleaning and sanitizing practices, and lack adequate animal control on farms provide numerous opportunities to contaminate produce during growing and harvesting activities. The following sections demonstrate the results of the current study and provide a discussion based on each subpart of the PSR for 69 large farms in the state of Texas over a 16-month period.

Subpart C: Personnel Qualifications and Training

Subpart C of the PSR highlights the qualifications and training for personnel who handle covered produce or work with food-contact surfaces. It establishes minimum personnel qualifications and training requirements for personnel who handle covered produce or food-contact surfaces. It includes additional requirements for persons who conduct harvest activities for covered produce and explains that at least one supervisor or responsible party for the farm must

TABLE 2. Non-compliance issues by subpart observed during assessment of Texas large farms (N = 69)

Subpart variable	Sub-subpart	Sub-subpart brief description	Non-compliance observed	%
Subpart C-Personnel Qualifications and Training (n = 26)	112.21(a)	All personnel handling covered produce should be trained	5	19
	112.21(d)	Training must be repeated when personnel are observed as not meeting FDA standards	1	4
	112.22(a)	All personnel handling covered produce or supervising such activities must at least receive training that includes food hygiene and safety, personal hygiene, and FDA standards	1	4
	112.22(b)(1)	All personnel harvesting covered produce must receive training on recognizing covered produce that must not be harvested	1	4
	112.22(b)(2)	All personnel harvesting covered produce must receive training on inspecting harvest containers or equipment	1	4
	112.22(c)	At least one supervisor successfully completed food safety training	5	19
	112.30(b)	Records of training documents accessible	12	46
Subpart D-Health and Hygiene (n = 10)	112.32(a)	Personnel who work in an operation where covered produce are at risk of contamination must use hygienic practices to protect against such hazards	4	40
	112.32(b)(1)	The hygienic practices that personnel use when handling covered produce must include to maintain personal cleanliness	1	10
	112.32(b)(3)(iii)	The hygienic practices that personnel use when handling covered produce must include to wash hands and dry hands thoroughly after using the toilet	1	10
	112.32(b)(3)(iv)	The hygienic practices that personnel use when handling covered produce must include to wash hands and dry hands thoroughly upon return to the work station	1	10
	112.32(b)(4)	Personnel should maintain intact and sanitary gloves when handling covered produce, and replace gloves when it's not intact or sanitary	3	30
Subpart K-Growing, Harvesting, Packing, and Holding Activities (n = 13)	112.113	Personnel must handle covered produce in a manner that protects against contamination with known or reasonably foreseeable hazards	12	92
	112.114	Personnel must not distribute dropped covered produce	1	8
Subpart L-Equipment, Tools, Buildings and Sanitation (n = 37)	112.123(b)(2)	Equipment and tools must be stored and maintained to protect covered produce from contamination and to prevent from attracting and harboring pests	1	3
	112.123(d)(1)	Personnel must inspect, maintain, clean, and sanitize all food-contact surfaces of equipment and tools used in covered activities	4	11
	112.125(a)	Equipment that is used to transport covered produce must be adequately cleaned before usage	1	3
	112.129(a)	Operation must provide personnel with adequate, readily accessible toilet facilities	1	3

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TABLE 2. Non-compliance issues by subpart observed during assessment of Texas large farms (N = 69) (cont.)

Subpart variable	Sub-subpart	Sub-subpart brief description	Non-compliance observed	%
Subpart L-Equipment, Tools, Buildings and Sanitation (n = 37)	112.129(b)(1)	The toilet facilities must be designed, located, and maintained to prevent contamination of covered produce, surfaces, areas used for covered activities, and related water sources and systems	1	3
	112.130(a)	Operation must provide personnel with adequate, readily accessible handwashing facilities	1	3
	112.130(c)	Operation must provide for appropriate disposal of waste associated with a handwashing facility and prevent wastewater from contaminating covered produce, surfaces, areas used for covered activities, and related water sources and systems	9	24
	112.140(b)	Operation must establish and keep documentation of the date and method of cleaning and sanitizing of equipment	4	11
	112.140(b)(2)	Operation must establish and keep documentation of the date and method of cleaning and sanitizing of equipment that used in covered harvesting, packing, or holding activities	15	41
Subpart O-Records (n = 78)	112.161(a)(1)	Except otherwise specified, records are required under this part	1	1
	112.161(a)(1)(i)	All records required under this part must include the name and location of the farm	10	13
	112.161(a)(1)(ii)	All records required under this part must include the actual values and observations obtained during monitoring	3	4
	112.161(a)(1)(iii)	All records required under this part must include an adequate description of covered produce applicable to the record	1	1
	112.161(a)(1)(v)	All records required under this part must include the date and time of the activity documented	18	23
	112.161(a)(2)	All records required under this part must be created at the time an activity is performed and observed	1	1
	112.161(a)(4)	All records required under this part must be dated, and signed or initialed by the person who performed the activity documented	8	10
	112.161(b)	Records required under sub-subpart 112.7(b), 112.30(b), 112.50(b)(2), (4), and (6), 112.60(b)(2), 112.140(b)(1) and (2), and 112.150(b)(1), (4), and (6) must be reviewed, dated, and signed timely by a supervisor or responsible party	35	45
	112.166(a)	Operation must have all records readily available and accessible during the retention period for inspection and copying by FDA upon oral or written request	1	1

TABLE 3. Qualitative examples of non-compliance issues observed during Texas large farm assessments

Subpart	Subpart description	Subpart section	Sub-subpart description	Non-compliance issue observed in the field specific to subpart section subsection
<p>Subpart C-Personnel Qualifications and Training</p>	<p>Subpart C of the PSR highlights the qualifications and training for personnel who handle covered produce or work with food-contact surfaces. It establishes minimum personnel qualifications and training requirements for personnel who handle covered produce or food-contact surfaces. It includes additional requirements for persons who conduct harvest activities for covered produce and explains that at least one supervisor or other responsible party for the farm must have successfully completed produce safety training at least equivalent to that received under a standardized curriculum recognized as adequate by FDA.</p>	<p>112.21-The requirements apply regarding qualifications and training for personnel who handle (contact) covered produce or food-contact surfaces.</p> <p>112.22-The minimum requirements apply for training personnel who conduct a covered activity.</p> <p>112.30-The requirements apply regarding records.</p>	<p>112.21(a)-All personnel handling covered produce or food-contact surfaces (including temporary, part-time, seasonal, and contract personnel), or those who involved in supervision, must be hired with adequate training appropriate to their responsibilities and receive training periodically thereafter, at least once annually.</p> <p>112.22(c)-At least one supervisor or person in charge of the farm must have successfully completed food safety training at least equivalent to that received under a standard course approved by the FDA.</p> <p>112.30(b)-Records of training that document required personnel training, including training dates, topics covered, and who was trained, must be established, and kept.</p>	<p>Field personnel were working with covered produce, but were not trained.</p> <p>Supervisor or other responsible person for farm did not receive training of the standardized curriculum recognized as adequate by the FDA.</p> <p>Growers did not have documents of required training of personnel and specifics on dates and personnel trained were lacking.</p>
<p>Subpart D-Health and Hygiene</p>	<p>Subpart D of the PSR indicates the hygienic practices personnel must use to protect against contamination with known or foreseeable hazards, and the measures must be taken to prevent visitors and ill or infected persons from contaminating covered produce and food-contact surfaces with microorganisms of public health significance.</p>	<p>112.32-Hygienic practices that personnel must use.</p>	<p>112.32(b)(4)-If personnel choose to use gloves in handling covered produce or food-contact surfaces, keep the gloves intact and hygienic, and replace them when no longer able to do so.</p>	<p>It was observed that growers were wearing gloves with holes/tears during harvesting activities.</p>

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TABLE 3. Qualitative examples of non-compliance issues observed during Texas large farm assessments (cont.)

Subpart	Subpart description	Subpart section	Sub-subpart description	Non-compliance issue observed in the field specific to subpart section subsection
<p>Subpart K-Growing, Harvesting, Packing, and Holding Activities</p>	<p>Subpart K of the PSR highlights the requirements during growing, harvesting, packing, and holding activities. It explains measures that must be taken if personnel grow, harvest, pack, or hold both covered and excluded produce. It also states measures must be taken before and during harvest activities, how to handle harvested covered produce during covered activities, and requirements that apply to dropped covered produce. Measures that must be taken when packaging covered produce and the use of food packaging (including food packaging) material are also explained in this subpart.</p>	<p>112.113-How harvested covered produce must be handled during covered activities</p> <p>112.114-Requirements that apply to dropped covered produce.</p>	<p>112.113-Personnel must handle covered produce during covered activities in a manner that prevents contamination from known or reasonably foreseeable hazards, such as avoiding contact of the cutting surfaces of harvested produce with soil to the extent practicable.</p> <p>112.114-Personnel must not distribute dropped covered produce. Dropped covered produce is covered produce that falls to the ground before harvesting. Dropped covered produce does not include root crops that grow underground (such as carrots), crops that grow on the ground (such as cantaloupe), or produce that is intentionally dropped to the ground as part of harvesting (such as almonds).</p>	<p>Harvested product encountered soil or other non-food-contact surface.</p> <p>Growers were observed harvesting produce attached to tree or bush and produce that contacted the ground.</p>

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TABLE 3. Qualitative examples of non-compliance issues observed during Texas large farm assessments (cont.)

Subpart	Subpart description	Subpart section	Sub-subpart description	Non-compliance issue observed in the field specific to subpart section subsection
<p>Subpart L-Equipment, Tools, Buildings, and Sanitation</p>	<p>Subpart L of the PSR gives prominence to the requirements that apply to the equipment, tools, and buildings that are subject to this subpart, including the transport of covered produce, control of domesticated animals (and its excreta and litter) in and around covered buildings, and pest control. It explains the requirements that apply to the instruments and controls that are used to measure, regulate, and record. It also establishes requirements that apply to toilet facilities, handwashing facilities, plumbing, control and disposal of sewage, trash, litter, and waste in areas used for covered activities and records that are required under this subpart.</p>	<p>112.123-General requirements that apply regarding equipment and tools subject to this subpart.</p> <p>112.125-Requirements that apply to equipment that is subject to this subpart that is used in the transport of covered produce.</p> <p>112.129-Requirements that apply to toilet facilities.</p> <p>112.130-Requirements that apply to handwashing facilities.</p> <p>112.140-Requirements that apply regarding records under this subpart.</p>	<p>112.123(b)-Equipment and tools must be (1) installed and kept so as to facilitate cleaning of the equipment and of all adjacent spaces and (2) stored and kept to protect covered produce from being contaminated with known or reasonably foreseeable hazards and to prevent the equipment and tools from attracting and harboring pests.</p> <p>112.123(d)-(1) All food-contact surfaces of equipment and tools used in covered activities must be inspected, maintained, cleaned and, when necessary and appropriate, sanitized, as frequently as reasonably necessary to protect against contamination of covered produce. (2) All non-food-contact surfaces of equipment and tools subject to this subpart used during harvesting, packing, and holding, must be maintained, and cleaned as frequently as reasonably necessary to protect against contamination of covered produce.</p> <p>112.125(a)-Equipment that is subject to this subpart that are used to transport covered produce must be adequately cleaned before use in transporting covered produce.</p>	<p>112.123(b)-A farm was observed to grow covered and non-covered produce, but did not have two different schemes for covered and non-covered commodities. Farms were not able to demonstrate that they were meeting the requirements.</p> <p>112.125(a)-Growers were observed transporting covered produce in wheelbarrows contaminated with soil to trailer trucks.</p> <p>112.129(b)(1)-Portable restroom facilities were observed to be close to the fields with potential of spillage into growing area.</p> <p>112.130(c)-Observations showed that a catch bucket was not provided as part of handwashing facility, leading to wastewater entering the growing area and contaminating covered produce.</p> <p>112.140(b)(2)-It was observed that growers may be doing work, but not recording the information. Date and method of cleaning and sanitizing equipment were not documented.</p>

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TABLE 3. Qualitative examples of non-compliance issues observed during Texas large farm assessments (cont.)

Subpart	Subpart description	Subpart section	Sub-subpart description	Non-compliance issue observed in the field specific to subpart section subsection
<p>Subpart L-Equipment, Tools, Buildings, and Sanitation</p>			<p>112.129(b)(1)-Toilet facilities must be designed, located, and maintained to prevent contamination of covered produce, food-contact surfaces, areas used for a covered activity, water sources, and water distribution systems with human waste.</p> <p>112.130(c)-Entities must provide for appropriate disposal of waste such as wastewater and used single-service towels that associated with a handwashing facility and take proper measures to prevent wastewater from a handwashing facility from contaminating covered produce, food-contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards.</p> <p>112.140(b)(2)-Personnel must establish and keep documentation of the date and method of cleaning and sanitizing of equipment subject to this subpart used in covered produce harvesting, packing, or holding activities.</p>	

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TABLE 3. Qualitative examples of non-compliance issues observed during Texas large farm assessments (cont.)

Subpart	Subpart description	Subpart section	Sub-subpart description	Non-compliance issue observed in the field specific to subpart section subsection
Subpart O-Records	Subpart O of the PSR focuses on requirements regarding records that are required by FDA. It demonstrates what should be included in the records required, requirements of the storage and time period of the records, the acceptable formats for the records, guidelines for using existing records to satisfy the requirements of this part, and requirements for providing records to FDA.	<p>112.161-General requirements that apply to the records required under this subpart.</p> <p>112.161 (a)(1)(ii)-All records required under this part must include, as applicable, actual values and observations obtained during monitoring, unless as otherwise specified.</p> <p>112.161(a)(1)(v)-All records required under this part must include, as applicable, the date and time of the activity documented, unless as otherwise specified.</p> <p>112.161(a)(4)-All records required under this part must be dated, and signed or initialed by the person who performed the activity documented, unless as otherwise specified.</p> <p>112.161(b)-Records required under 112.7(b), 112.30(b), 112.50(b)(2), (4), and (6), 112.60(b)(2), 112.140(b)(1) and (2), and 112.150(b)(1), (4), and (6) must be reviewed, dated, and signed, within a reasonable time after the records are made, by a supervisor or other responsible party.</p> <p>112.166-Requirements that apply for making records available and accessible to FDA.</p>	<p>112.161(a)(1)(i)-All records required under this part must include, as applicable, the name and location of the farm, unless as otherwise specified.</p> <p>112.166 (a)-Entities must have all records required under this part readily available and accessible during the retention period for inspection and copying by FDA upon oral or written request, except that you have 24 h to obtain records you keep offsite and make them available and accessible to FDA for inspection and copying.</p>	<p>112.161(a)(1)(i)-The records did not have the farm name and location included.</p> <p>112.161(a)(1)(ii)-Boxes were checked; however, a specific value was not included in the records (e.g., for the sanitizing agent, no actual PPM value was included).</p> <p>112.161(a)(1)(v)-Activities done, but not recorded in real time. Growers were recording the information during a future date and time.</p> <p>112.161(a)(4)-Records were not signed and/or initialed.</p> <p>112.161(b)-Records were not reviewed, dated, and signed by supervisor or other responsible person.</p> <p>112.166(a)-Documents specific to PSR were not shown to field specialists within 24 h.</p>

have successfully completed produce safety training at least equivalent to that received under a standardized curriculum recognized as adequate by the FDA.

The on-farm assessments indicated that the majority (46%) of non-compliance issues fell under subsection 112.30(b), which requires that farming operations establish and keep training records to ensure compliance with Subpart O (record keeping) of the PSR. Although farming operations did cover some of the necessary trainings required to safely handle covered produce, observations in 12 separate instances showed that specifics on dates and personnel trained were lacking. The second most frequent (19%) non-compliance issues were under subsection 112.21(a) that requires that all personnel who handle covered produce receive adequate training appropriate for their specific duties and continued training periodically thereafter. During on-farm assessments, observations in five independent instances showed that field personnel were working with covered produce, but were not trained. The remaining non-compliance issues focus on the specifics of the training that are required under the PSR. Under section 112.22, data from the assessment suggests that farms may need to focus training efforts on the principles of food hygiene and food safety and personal hygiene for all personnel and visitors, and have supervisors or other responsible personnel adequately trained under a standardized curriculum that is recognized by the FDA. In five instances, it was observed that a farm supervisor or responsible party of the farm had not received training based on the standardized curriculum.

The inherent assumption and design of training tools are that practices will be improved because of enhanced knowledge of the subject matter (17, 18). According to the PSR, at a minimum, all personnel who handle covered produce must receive training that includes (1) principles of food hygiene and safety; (2) the importance of health and personal hygiene for all personnel and visitors; (3) standards established by the FDA in Subparts C–O of this part that are applicable to the employees job responsibilities; (4) training that covers harvesting activities such as recognizing produce that must not be harvested, inspecting harvest containers to ensure that they do not become a source of contamination for covered produce, and correcting or reporting problems with harvest containers; and (5) at least one supervisor or responsible party must have completed a safety training recognized as adequate by the FDA (29).

Subpart D: Health and Hygiene

Subpart D of the PSR addresses adequate measures that are required to prevent ill or infected persons from contaminating covered produce, hygienic practices, and preventing visitors from contaminating covered produce. In addition, it establishes minimum measures and practices that farms must implement for personnel, supervisors, and visitors to prevent contamination of covered produce and

food-contact surfaces. General non-compliance issues under this subsection highlight the need to use hygienic practices used by the personnel conducting covered activities to the extent necessary to prevent possible contamination of covered produce and food-contact surfaces. The non-compliance issues reported by field specialists all fell under section 112.32, hygienic practices ($n = 10$). Specifically, non-compliance issues were centered around maintaining personal cleanliness to prevent the contamination of covered produce. An example of a specific non-compliance issue observed in the field was that farm workers were wearing defective vinyl or latex gloves (torn) during post-harvest activities. Under 112.32(b)(4), if personnel choose to use gloves in handling covered produce or food-contact surfaces, the gloves must be intact, clean, or replaced as necessary.

The lack of handwashing after using the restroom and before returning to work was reported among the non-compliance issues under Subpart D. The Centers for Disease Control and Prevention identify hand washing as an important prevention method for limiting the transmission of foodborne pathogens from hands to food and food-contact surfaces and vice versa (11). Moreover, handwashing after visiting the restroom is crucial because feces is a source of pathogens such as *Salmonella*, *Escherichia coli* O157:H7, and norovirus and could be transferred to food and food-contact surfaces upon returning to work (11). Independent studies suggested that hands are a storage of microorganisms and are important carriers for transferring them to fresh produce during manual production, harvesting, and packing (3, 14). For example, a previous empirical study showed that when *E. coli* was present on hands, the handled produce was up to 9 times more likely to be contaminated with the *E. coli* (3). The results of the current study showed that the provision of adequate handwashing facilities and proper waste disposal were among the non-compliance issues reported under Subpart L. A study by Bovay et al. (7) estimated that farms with annual produce sales of between \$500,000 and \$700,000 will incur an annual cost of compliance of 4.2% of their produce sales. Based on the statistics retrieved from the Regulatory Impact Analysis of Food and Drug Administration, a large proportion of costs to comply with the PSR are incurred by personnel qualifications and training, health and hygiene, and equipment, tools, buildings, and sanitation, with \$68.44 million (29%), \$69.74 million (29.6%), and \$63.33 million (26.9%), respectively (35).

Bovay et al. (7) also indicated that enhancements to practices in areas include agricultural water quality, worker health, and hygiene, and sanitary standards are anticipated to be helpful to reduce microbial contamination by restricting the exposure of produce to pathogens at the farm level. Worker health and hygiene practices were the most understood topic by produce growers; however, the frequency of reported hygiene practices was inconsistent.

Subpart K: Growing, Harvesting, Packing, and Holding Activities

Subpart K establishes standards for growing, harvesting, packing, and holding activities. Topics covered in Subpart K include the following:

- Measures to take for farms that grow, harvest, pack, or hold both covered produce and produce that is not covered, including the transition points between those produce items and separation of covered and not covered produce;
- Identifying and not harvesting contaminated covered produce;
- Handling harvested covered produce;
- Dropped covered produce;
- Packaging covered produce; and
- Food packaging material.

Generally, Subpart K had low numbers of non-compliance issues ($n = 13$) based on the data collected from 69 farms. Non-compliance issues under this subpart pertained to section 112.113 that requires covered produce be handled in a manner that protects from contamination against known or foreseeable hazards. Qualitative data showed that harvested covered produce encountered soil and non-food-contact surfaces. In addition, there was at least one non-compliance issue under section 112.114 that requires produce growers not to harvest dropped covered produce. Qualitative observational data from the assessment showed the harvesting of covered produce that made contact with the ground before harvesting activity.

According to the FDA, microbial contamination of fresh produce during pre-harvest and harvest activities may result from contact with soils, fertilizers, water, workers, and harvesting equipment (33). Foodborne pathogens may persist on the uninjured surface of fresh produce, but growth is not common because of the protective outer barriers found on most produce; however, once the protective epidermal barrier has been broken by physical damage, the nutrients and moisture released by the produce significantly enhance the survival of foodborne pathogens (15). This is an important factor to consider when assessing the risks associated with reusing soiled tools and equipment because punctures and bruising of fresh produce are common occurrences during various stages of harvesting (15). Furthermore, the guidance document identifies tables, baskets, and containers as fomites that can easily spread microorganisms through cross-contamination to fresh produce and recommends that they be cleaned and sanitized before hauling fresh produce and reuse (33). A previous study demonstrated the persistence of key foodborne pathogens (*E. coli* O157:H7, *Listeria monocytogenes*, *Salmonella*, *Staphylococcus aureus*, and MS2 bacteriophage) on cardboard, plastic, tablecloth, molded pulp fiber, and wicker baskets commonly used on the farm and for transporting produce (5). The results of this previous study

showed that molded pulp fiber, plastic, and wicker surface materials supported the persistence of *Salmonella* and *S. aureus* for up to 59 days (5); hence, it is critical to limit the potential of containers as a vector for cross-contamination.

Subpart L: Equipment, Tools, Buildings, and Sanitation

Subpart L establishes requirements for preventing equipment, tools, buildings, and inadequate sanitation from contaminating covered produce. This part includes requirements for toilet and handwashing facilities, as well as the appropriate storage, maintenance, and cleaning of equipment and tools. Subpart L had the second highest non-compliance issues ($n = 37$) from the data collected in this study. This subpart of the PSR targets various equipment and tools that are likely to come in contact with covered produce, building structures and functionality, and sanitation requirements for all items covered under this subpart. The most frequent non-compliance issue reported was section 112.140 ($n = 19$) that requires that records be maintained that satisfy Subpart O of the PSR, record keeping. The most prominent non-compliance issues stem from the documentation of the date and method used to clean and sanitize equipment; specifically, regarding covered harvesting, packing, or holding activities. Another noteworthy non-compliance area under this subpart is section 112.130, handwashing facilities where a total of 10 non-compliance issues were observed across 69 farms. The data collected identify the provision of handwashing facilities, and significantly, proper waste disposal for these facilities as areas that require attention by farming operations. Other areas where non-compliance issues occurred relate to the inspection, maintenance, and cleaning of food-contact surfaces; the storage of equipment and tools to prevent contamination; equipment used to transport covered produce; and the provision of toilet facilities and measures to prevent toilet facilities from becoming a possible source of contamination on the farm. Qualitative data showed that a handwashing facility close to the fields did not contain a catch bucket for wastewater leading to the field and possibly contributing to the contamination of covered produce.

One of the non-compliance issues of this subpart observed was under 112.130(a), the failure to provide adequate and readily accessible handwashing facilities during growing, harvesting, packing, and holding activities. According to several studies, lack of properly equipped handwashing facilities and tools addressing proper handwashing practices are the two main reasons for employees' contravention of handwashing as well as the two most common obstacles to public health, because poor handwashing by personnel who work in the food industry has been a crucial risk factor associated with foodborne illnesses (2, 4, 19, 24). From this perspective, a key to improving handwashing practices is to ensure the installation, inspection, and maintenance of adequate physical sanitary facilities.

The most frequent non-compliance issue observed under this subpart was 112.140, the establishment and possession of records that include the date and method of cleaning and sanitizing of equipment used for growing sprouts and harvesting, packing, or holding activities; and this subsection is in relation to Subpart O as well. Nineteen (51%) of 37 non-compliance issues under this were related to growers doing the work without documenting the information as per the PSR. Specifically, not recording the date and method of cleaning and sanitizing equipment used for covered activities. Keeping records and documentation of information needed including practices and corrective actions are significant for regulatory agencies to determine whether proper procedures were being followed and to take necessary actions if traced back to a troublesome point (12).

Subpart O: Records

Subpart O specifies the general requirements for records, including those required for training, agricultural water, exemptions, cleaning, and sanitizing. This subpart also includes requirements describing how records must be established and maintained, including record retention, storage, and verification, as well as official review and public disclosure. Record keeping was a non-compliance issue that appeared in other subparts in the current study's dataset. The focal point of the records section is to document and monitor tasks in the farming operation that reduce food safety risks and to provide evidence of these tasks that satisfy the PSR. Subpart O had the greatest number of non-compliance issues observed ($n = 78$; 47.5%).

Subsection 112.161(a), for records required by the rule must include the name and location of the farm, actual values and observations obtained during monitoring, adequate descriptions of covered produce, the location of a growing area, and the date and time of the activity documented. In addition, documents must be created when the activity is performed and be accurate, legible, and indelible and be dated and signed by the person who recorded the activity. These activities represented the most frequent ($n = 42$) non-compliance issues reported by TDA field specialists under Subpart O. Notably, the date and time of the recorded activity were missing from farming records. In some instances, boxes were checked on cleaning and sanitizing; however, specific concentration values (parts per million) were not included. Field specialists also observed that activities were performed, but not recorded, in real time. Subsection 112.161(b) had the second most frequent number of non-compliance issues ($n = 35$) under Subpart O, the subpart that requires that supervisors or other responsible parties review, date, and sign records within a reasonable time after the records are made. These results indicate that although records are maintained by large farms, they are not reviewed by a supervisor in an adequate amount of time to allow for potential food safety risks to be addressed. There was only one reported non-

compliance issue with subsection 112.166(a), which requires that records of recorded activities be readily accessible during the retention period for inspection and copying by the FDA and within 24 h for records that are stored offsite. Overall, these results showed that record keeping had the highest number of non-compliance issues from the large farms assessed, which spanned across multiple subparts of the PSR. For example, the leading non-compliance issues reported under subparts C and L were related to maintaining adequate records that satisfy Subpart O of the PSR. Specifically, the inclusion of the date, name, location, and review and sign-off on documents by a supervisor was the major cause of non-compliance issues from the on-farm assessments. In addition, some subparts, such as Subpart C and Subpart L, maintained adequate records, but lacked some key components such as required trainings and specific information regarding the methods used to clean and sanitize equipment.

Records are an important part of on-farm food safety risk management because they keep track of measures directed at minimizing the risk of known or reasonably foreseeable hazards, identify a pattern of problems that increase the risk of such hazards, and facilitate verification and compliance with regulatory standards (29, 33). The struggle to adopt or maintain record keeping practices is not unique to produce farming operations and may stem from perception or behavior issues. A previous study investigated the record keeping behavior of small-scale poultry farmers in the Ga East Municipality in Ghana and found that 46% of surveyed farmers did not keep records because they did not find it beneficial to them; 22% could not give a reason as to why they did keep records; 14% complained of time constraints; and 8% mentioned that they did not keep records because of difficulty entering data due to stress, forgetfulness due to deferred entries, hired personnel did not maintain adequate records, and barriers related to lower levels of education (26). Tokede et al. (28) conducted a two-part study in the field of dentistry to determine (1) what information should be included in dental records and (2) practitioner attitudes and reasons why records are not accurately or completely executed. The study concluded that the study participants agreed on the importance of record keeping in general; however, there was variability among participants regarding the frequency they believed records should be maintained and updated based on individual institutions, practitioner preferences, and varying demands in patient care (28). Notably, the study suggested that challenges in record keeping may be attributed to a busy workplace setting in which workers must balance multiple information sources and competing tasks and suggest that the challenge may be in finding a way to make record keeping more efficient, complete and accurate and as least disruptive as possible to the overall workflow (28).

Although record keeping is a requirement for FSMA compliance, previous literature from various farming

operations suggests that there are other incentives for farms to keep and maintain adequate records that may be beneficial for produce farmers as well. A study to assess the effect of record keeping on dairy farm milk production and revenue in Thailand found that farms that kept records had a higher milk yield per farm and a higher monthly milk revenue per farm than those that did not (37). Furthermore, the study suggested that these records were used by farming operations for monitoring, planning, culling, and selection decisions and improving management efficiency, which had a positive impact on their outputs and bottomlines (37). Van Staaveren et al. (36) examined the relationship between record keeping of tail lesion scores from pig biting and farm performance parameters on pig farms and found that farms that recorded financial and performance-related records had a lower instance of moderate tail lesions, which is considered an indicator of good management practices and positively affected the health, welfare, and value of the pigs. Organizations such as the PSA and local, state, federal, and extension programs throughout the United States have created various training materials and record keeping templates for farming operations to assist with PSR compliance.

CONCLUSIONS AND RECOMMENDATIONS

The results of the farm assessments showed that there are several areas of opportunity to address compliance with the PSR. This section demonstrates the specific areas based on subsections that had the greatest number of challenges across the 69 farms included in this study in complying with the PSR. First, there is a need to address training needs of farm personnel and the supervisor or responsible person for the farm. In addition to the training component, it is crucial for farms to document the training and include information such as training dates and personnel trained. In 30% of assessments, it was observed that growers were

wearing torn gloves during harvesting activities. There were multiple instances (90%) where observations showed that harvested covered produce came in contact with soil or non-food-contact surfaces. In 41% of instances, observations were made that although personnel were performing the task, information was not recorded. For example, the farm personnel were cleaning and sanitizing equipment, but the date and method used were not documented. Last, 45% of instances showed that records were not signed and dated by the supervisor or responsible person. These non-compliance issues can be addressed by emphasizing the importance in addressing specific items in the PSR and how it aligns with produce safety in general. The farm assessments are conducted as part of the regulatory process; however, education is a crucial component of the process. Growers need to know what they will be held accountable to and why. This includes explaining components of the PSR and including scientific and empirical evidence of why following specific practices can reduce the risk of contamination.

The data in this study contains on-farm field data from the first batch of assessments conducted on Texas farms. The analysis of the data provided herein can serve as a baseline for future studies. In addition, the patterns of non-compliance observed can provide critical approaches to future training needs for farms of all sizes so that on-farm produce safety issues can be addressed preemptively.

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